The following individuals/organizations submitted written comments for consideration by the Federal Coordinating Council for Comparative Effectiveness Research

Submitted by
Cynthia Crummey
American Board of Orthopaedic Surgery
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The American Board of Orthopaedic Surgery appreciates the opportunity to comment on the value of comparative effectiveness research. Founded in 1934, The American Board of Orthopaedic Surgery provides a 2 step process for initial certification of candidate orthopaedic surgeons and is responsible for the recertification process in orthopaedic surgery, and hand surgery and sports medicine subspecialties. As a part of our dual mission to serve the public and the medical profession we have ingrained specific elements of ethics, professionalism and evidence based practice in multiple areas of our process. To be eligible for the Board certification process, residents must satisfactorily complete an accredited 5 year training program in Orthopaedic surgery. For the initial certification process, we have developed a psychometrically valid examination that tests cognitive expertise in Orthopaedic Surgery (Part I). If successful in Part I, candidates may apply for an Oral Examination (Part 2) after approximately 2 years of independent practice. For the second part of the initial certification, candidates must successfully pass a 360 degree peer review evaluation process prior to sitting for the part II oral examination. Our peer review process employs a standard tool that represents the 6 core competencies, accrues input from multiple types of observers (colleagues, partners, administration and nursing), specifically assesses ethics and professionalism and is unique to our Orthopaedic surgery process. The part 2 examination is an oral examination for which the candidate must submit 6 months of operative cases in a standard format to our proprietary database. In the part 2 examinations, candidates present their own cases to 6 different Board certified volunteer examiners. Candidates are graded on a variety of skills including use of evidence based medicine, ethics and professionalism and systems based practice. Further, The ABOS owns and operates a recertification processes that includes a variety of recertification alternatives that are equally robust and are designed to both protect the public and meet the needs of busy practicing orthopaedic surgeons. Integral to the recertification process is the option of a recertification oral examination. Again for this examination, candidates that have been in practice for almost 10 years submit cases to our proprietary database providing another important evaluation of orthopaedic practice. We believe that this process developed by the American Board of Orthopaedic Surgery has high value to the diplomate and serves to protect the public good.

Though a small percentage of physicians, orthopaedic surgeons provide “cradle to grave” medical care to nearly 25% of the population. As such, orthopaedic care is a high priority to the public. The direct cost for musculoskeletal care and rehabilitation is on the order of 800 billion dollars. In 2004, HHS identified the care of arthritis and nontraumatic joint disorders as conditions as being of special significance and were among the first to be addressed by the Effective Health Care Program. The ABOS recognizes the need for effective health care programs in arthritis, nontraumatic joint disorders and also in the care of the injured patient. The

ABOS believes continued evaluation of practice patterns of practicing orthopaedic surgeons gives it the unique opportunity to report on and improve certain aspects of care.
The ABOS is strongly supportive of comparative effectiveness research as an important tool in the fabric of medical decision making and its accumulation of information on orthopaedic practice, including procedures and outcomes, through the certification process provides ABOS a unique opportunity to conduct such research. As part of our commitment to this research, the ABOS has partnered with the Dartmouth Institute of Health Policy and Clinical practice to design, execute and publish a number of articles that are based on observed orthopaedic practices using our proprietary database. We have published or will soon publish articles that describe geographic variation in various orthopaedic practices, trends in practice patterns for the treatment of various conditions, the differential effectiveness of certain procedures in the treatment of various conditions and the effectiveness of educational programs in Orthopaedic surgery. These manuscripts, published in rigorous peer review journals can improve orthopaedic practice and are, therefore, useful to both our colleagues and the public.

Because we have useful data in our proprietary database that has been systematically collected over a number of years, the ABOS is in a unique position to continue to report on issues of effectiveness, device utilization, geographic practice variation and other important issues in Orthopaedic Surgery. Constructively employed, works of this type should be reported to give both physicians and patients a better understanding of the ramifications of personalized medical decisions. Hopefully, works of this type will stimulate innovation, further research and not stymie progress. We will continue our independent work in this area for the benefit of the profession and for the value to the public. Such initiatives will also have translational benefit in related fields of surgery and musculoskeletal health. We are eager to work with the Department of HHS in furthering the work that will lead to improved, clinically useful evidence-based guidelines and new educational formats that provide safe, effective treatment, while conserving the resources available for healthcare.

Novel projects that partner with the individual Boards that control the certification process for their diplomates in the various specialties could yield the next generation of performance improvement in the specialty of orthopaedic surgery and other specialties.

Respectfully submitted,

John Gray Seiler, III MD, President, American Board of Orthopaedic Surgery
Harry Herkowitz, MD, President–Elect, American Board of Orthopaedic Surgery
Shep Hurwitz, MD, Executive Director, American Board of Orthopaedic Surgery

For further information on the American Board of Orthopaedic Surgery: abos.org

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Current ABOS Research Projects

1) Board Certified and Non Board Certified Orthopaedic Surgeons- differences in outcomes, cervical spine.
2) Arthroscopic shoulder surgery, changes in practice for subacromial decompression.
3) Shoulder surgery, changes in practice for rotator cuff conditions.

Submitted by
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Lakes Inter-Tribal Epidemiology Center
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I am responding to the invitation to provide comment to the Coordinating Council pertaining to CER (comparative effectiveness research). As the Director of the Great Lakes Inter-Tribal Epidemiology Center, one of twelve "epicenters" currently residing in Indian Health Service Areas, I would like to invite our involvement in the education and application of CER consistently when working in our Tribal communities. I am just now learning more about CER, and am understanding that CER may be (or has been) the standard process for clinical research and program evaluation as health care reform proceeds. The Tribal Epidemiology Centers began as a result of legislation in 1996 and have built trusting relationships with Tribal communities in order to increase data collection, analysis and use in health care decision making. We play a vital role in advocating for increasing representation of American Indians in data samples, data accuracy and translation of research in the community.

Actually, I would like to propose a conference call between the Coordinating Council and Directors of the 12 Tribal Epidemiology Centers (or face to face if possible) to explore how we can be involved and therefore, including the US indigenous population. I recommend that the

meeting also include members of HRAC. Currently, American Indians carry a high burden of disease and are underserved. Unless we increase American Indian research, data and representation, any health care system designed will continue to under serve this population. Please call me at your convenience and I will be pleased to coordinate a meeting.

Submitted by
[personal information redacted]

Comparative Effectiveness Research should comprise the following components:

1. A well thought out design to answer a specific, important question or questions. This design should include context, objective(s), populations to be studied, specific study design, expected and then actual results and conclusion(s).

2. Funding should be based on relative importance of the study to health of the public as compared to other proposed studies

3. A definite time line that can be completed realistically considering the population (numbers and types of individuals available) and other resources needed to complete the study.

4. Periodic reporting of results to determine the likelihood of completing the study. Scare funding should not be allocated to those studies that clearly cannot meet the time line indicated.

5. Peer review of the study results and publication with no further funding for that research if results do not meet expectations for that study

Submitted
Karen Lencoski, JD, MBA
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American Urological Association
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The American Urological Association (AUA), the pre-eminent professional association for over 16,000 urologists worldwide and almost 10,000 in the U.S., greatly appreciates the opportunity to present our suggestions for comparative effectiveness research priorities to the Federal Coordinating Council. The long-standing mission of the AUA is to promote the highest standards of clinical urologic care through education, research, development of clinical guidelines, and the formulation of healthcare policy. The public health burden of urologic disease in the U.S. is large and growing, with an estimated annual impact of over $11 billion. Urologists are the specialists who most often diagnose and treat prostate cancer, the second leading cause of cancer deaths among men in the U.S. Urologists treat many other conditions common to Medicare beneficiaries, including urinary tract infections, benign prostatic hyperplasia (BPH), and urinary incontinence. Over fifty percent of the patients who see urologists are Medicare beneficiaries. We heartily endorse the Administration's focus on comparative effectiveness research (CER) as an evidence-based, systematic way to identify the best treatments for specific patient populations

and to generate the critical information that will help guide both physicians and patients through the complex decision process to select the most appropriate treatment. Medical specialty societies are uniquely positioned to identify evidence gaps in care, and where CER should be focused.

The AUA nominates three areas that warrant further investigation in a CER framework.

I. *Prostate cancer treatment*.

In 2008, an estimated 200,000 men were newly diagnosed with prostate cancer in the U.S., and about 29,000 men died from the disease. Prostate cancer is one of the most common cancers in men, and a significant health problem. Significant prostate cancer disparities exist between rural and urban populations and across racial and ethnic groups. Several studies have demonstrated that patients with prostate cancer in rural areas are more likely to be disadvantaged due to being diagnosed at later stages, receiving different management, being uninsured or underinsured, and having less desirable outcomes than their urban counterparts. African American men have prostate cancer mortality rates that are more than twice the rates observed in other racial and ethnic groups, and compared to white men are less likely, across all age groups, to receive treatment for prostate cancer, especially when diagnosed with more advanced cancer. Because prostate cancer is the second-leading cause of cancer deaths in men, these disparities are particularly significant. Appropriate PSA testing has helped with early detection of prostate cancer, but PSA is not equally available to the above noted populations.

Moreover, depending on whether the cancer is aggressive or slow growing, the range of options can vary significantly, and patient preference regarding treatment side effects and quality of life plays a particularly prominent role in prostate cancer treatment choice. In addition, prostate cancer is a focus of the Medicare program: it has been identified as one of eight high cost conditions selected for the Physician Resource Utilization Report pilot program authorized by Congress in the Medicare Improvements for Patients and Providers Act of 2009 (MIPPA). Yet, despite its prevalence, cost and complexity, there is a distinct lack of evidence comparing the treatment options for localized prostate cancer, These options include:

- Active surveillance (watchful waiting);
- Radical prostatectomy, which includes both conventional and robotic surgeries; and
- Radiotherapy, which includes brachytherapy, proton beam, and Intensity-Modulated Radiation Therapy.

The benefits and risks (e.g., incontinence, impaired bowel function, reduced sexual function) of each of these options must be carefully weighed by the patient and his family in consultation with his physician. CER studies should compare long term treatment option outcomes such as overall survival, quality of life and patient satisfaction for different patient populations (e.g., age, race, tumor characteristics, genetic profile, etc).

II. *Sustained public/private support for a robust quality infrastructure*.

All healthcare reform proposals are predicated on the presumption that a robust and well-developed quality infrastructure exists. However, this is not uniformly the case. The infrastructure varies substantially by provider type (hospital, dialysis facility, specialist physicians) and condition (diabetes, cardiovascular disease, prostate cancer). There are several

building blocks fundamental to the creation and maintenance of this essential infrastructure. First, basic clinical research provides the evidence needed to formulate clinical guidelines. In turn, evidence-based clinical guidelines are a prerequisite for the development of quality performance measures, and clinical registries provide the data to revise guidelines, test measures, provide comparative performance information and benchmarks, identify areas for quality improvement and highlight areas that require additional research.

We ask for support for the development and maintenance of the quality infrastructure through creation of a public/private partnership, under the auspices of AHRQ or NIH, both of which are positioned to accept private funds. This venue could be used to pool the resources of those public and private stakeholders, including government, business, private insurers, research entities, and medical specialty societies, all of whom have a vested interest in quality measurement and improvement and evidence based medicine.

III. –*Comparison of Imaging Modalities for Major Urologic Conditions*. A number of analyses conducted for MedPAC have established that at least some portion of the rapid rate of increase in physician ordered imaging services is attributable to duplicative or inappropriate imaging. Under the Deficit Reduction Act of 2005 (DRA), Congress reduced reimbursement for some imaging studies to exert control over this area. The AUA is embarking upon a comparative effectiveness study of imaging modalities for ureteral stones, with the intent of producing evidence-based guidance on the most effective and efficient imaging for this condition to disseminate to urologists, primary care practitioners and others who may treat this condition. The AUA requests that the Council consider the comparative, evidence-based study of imaging modalities for urologic and other conditions as an important focus for comparative effectiveness research. Such guidance across a range of conditions could go a long way to help the medical profession order only those imaging studies that are most effective and appropriate for the condition in question.

Submitted by

[personal information redacted]

The comments below were submitted verbatim numerous time. Possibly initially sent to a large mass (for instance a list serv or other media) and encouraged interested parties to submit the written statement.

Comparative Effectiveness Research is essential to determine the etiologies of chronic illness and to determine those treatments that are effective versus those treatments that merely attempt to suppress symptoms while ignoring the underlying cause of the illness. In 2004, the Milken Institute (non-partisan, non-profit) issued its report, *An Unhealthy America: The Economic Burden of Chronic Disease* citing the most prevalent chronic illnesses in America as lung disease, heart disease, hype rtension, mental illness, cancer, diabetes, and stroke. ; Fifty percent of all Americans have at least one of these chronic illnesses. Each of these chronic illnesses has an environmental contribution in its etiology that rarely is identified or evaluated. Yet billions of dollars are spent---often wasted—by trying to suppress symptoms without identifying the cause of the illness. The healthcare costs and dollars of lost productivity can be found, state by state, on their website www.milkeninstitute.org.

For years, there has been a debate whether certain chronic illnesses are psycho-somatic, or illnesses emanating from the body with psychiatric sequelae. Those who insist these illnesses

are psychosomatic have never fully evaluated the patients to determine whether an underlying physical illness might be contributing to the psychological features. The phenomenon of a healthcare practitioner ascribing a psychiatric diagnosis to a real physical illness is eloquently penned by Harvard researcher Jerome Groopman , M. D. in his book *How Doctors Think*. Repeatedly, Dr. Groopman documents that serious and even life-threatening illnesses go undiagnosed by "well-trained" physicians who have=2 0a pre-conceived idea of what the patient should have, and are inexperienced in the patient's particular presenting diagnosis. Illnesses from celiac disease to Wilson's disease have been missed by physicians. In both of these cases, the patients would have died without the correct diagnosis which was later made by a more thorough and experienced doctor.

This issue of misdiagnosis due to inexperience raises grave questions about medical competency, medical training, patient outcome, and healthcare costs. In every instance of misdiagnosis, the patient is harmed and loses faith in a medical care system that should be wiser.
The Gold Standard research model in medicine which can clarify many issues of accurate diagnosis and effective treatment is the Environmental Control Unit (ECU). Consistent with President Obama's insistence on transparency and integrity in government, there is no area more important than healthcare where transparency and integrity are imperative. We need objective, accurate, non-lobbied data and outcome information if we are to reverse the downward spiral of chronic disease and its enormous financial burden on U. S. citizens, personally and financially. Each of the above seven chronic diseases is on the rise. We must stop this trend by identifying the causes, eliminating them, and provide treatments that restore the patient's health rather than merely medicate the symptoms. An Environmental Control Unit is the research tool that can accomplish our best medical goals with complex medical conditions.

An ECU is a set of patient care rooms either on a wing of a medical facility, or located in a free-standing building. The air on the ECU is filtered to be free of any chemicals and the ECU is constructed with low- or no toxicity building materials. No fragrances are allowed on the Unit, and temperature and humidity are controlled. The specially-trained medical staff is instructed in the protocols necessary to identify and monitor the patient's symptoms, obtain baseline data on each patient, and monitor each patient as modifications to the patient's environment (air, food, water) are made. The 24-hour medical staff is available to document the impact of each carefully determined change for each patient. The test results are then assessed by the medical staff, and specific courses of treatment are identified for not only each patient, but also for symptom clusters that were previously considered unrelated. Japan has several ECU's.
This scientific approach is crucial for illnesses thought to be "purely" psychological (mental illness, chronic fatigue, fibromyalgia, etc.) as well as for patients with illness primarily somatic (COPD, cardiac disease, etc.). The data collected through an ECU will demonstrate the etiologies and treatments that are accurate and effective and end the needless and unproductive controversy between psycho-somatic and somatic illness for some well-described disease states. Once delineated, psychological counseling and/or psychotropic medication may be required to stabilize the patient.
Of course there another, related perspective: Those patients with neurological illnesses which have an environmental component as a possible cause. *Harrison's Principles20of Internal Medicine* 16th Edition 2005 New York, McGraw Hill p 2408 , includes the following possible causes for Parkinson's Disease: Valproic acid, Fluoxetine, Lithium carbonate, alpha methyldopa,

typical antipsychotic medications, manganese, methanol, carbon disulfide, carbon monoxide, anti-emetics, and possibly n-hexane to name a few. Yet these etiologies often go unexplored in patients with Parkinson's Disease.

Another related area for research funding is evaluating the human health consequences of chronic exposure to low levels of toxic chemicals. Cigarette smoke is a paradigm for many environmentally-triggered illnesses. Once thought to be harmless, with package labeling dispelling any health concerns in the 1960's, through observation and research we have come to learn that cigarette smoke causes multi-system disease that can lead to death. Lung cancer, heart disease, stroke, asthma, vasculitis, and low birth weight are all consequences of exposure to cigarette smoke, whether one smokes or whether one is exposed to second-hand smoke. This is not surprising considering cigarettes contain more than two hundred chemicals that were applied in the growing of tobacco through the production of the final pr oduct.
Other chemicals cause human illness as well, and increased incidence of illness has also been established between environmental chemicals and asthma, prostate cancer, and many other illnesses. These findings have been published in a wide variety of medical journals, and research into the environmental causes of disease is spread among many research institutes, therefore, the vast amount of information regarding the environmental impact on health is poorly centralized. We already have an unfortunate baseline describing chronic disease as reported in the Milken report. Funding is needed to conduct research that will identify the cause of illness and describe the best treatments. Funding an ECU will accomplish this and spawn an improvement in medical education so physicians will be better trained to diagnose and treat complex medical conditions.

Dr. Adrienne Sprouse presented this statement at the Listening Session in Washington, D. C. on April 14, 2009. I support this plan and ask the FCC to recommend its funding.

Submitted by
Naomi Aronson, PhD
Executive Director, Technology Evaluation Center
Blue Cross Blue Shield Association

Blue Cross and Blue Shield Association's Statement to the Federal Coordinating Council on Comparative Effectiveness Research Listening Session (May 13, 2009)*
I am Naomi Aronson, Executive Director of the Technology Evaluation Center, speaking for the Blue Cross and Blue Shield Association (BCBSA). Collectively, BCBS Plans provide healthcare coverage for 1 in 3 Americans. BCBSA strongly supports advancing comparative effectiveness.

Our priority recommendations are based on the potentially large populations affected; recognized "gaps" in the evidence; known disparities in outcomes; need for evidence specific to affected subpopulations; and the need for evidence to inform patient preferences in selecting among treatment alternatives.

Our first priority is management of chronic stable angina. Coronary heart disease is the leading cause of death and a major cause of disability in the U.S.

Specifically, we call for research that compares:

- optimal medical management;
- percutaneous coronary interventions (including bare-metal versus drug-eluting stents); and
- coronary artery bypass grafting (including on-pump versus off-pump techniques).

We also want to know what works best in specific subpopulations: women; racial and ethnic patient groups; the elderly; diabetics; individuals with co-morbid conditions; and the exercise impaired.

Given the complexity of comparisons, the starting point should be a comprehensive systematic review. Identifying gaps in the evidence will set priorities for new studies.

Our second priority is treatment of localized prostate cancer.
One in 6 men in the U.S. will be diagnosed with prostate cancer. African-American men are disproportionately affected, having higher disease incidence and mortality; however, a recent Agency for Healthcare Research and Quality (AHRQ) report found no randomized, controlled trials that stratified patient outcomes by race.
Overall, there is a well-known lack of evidence comparing management strategies for localized prostate cancer, namely:

- active surveillance;
- radical prostatectomy (including the manner performed, i.e., robotic or conventional); or
- radiotherapy (conformal therapy, brachytherapy, proton beam, or intensity-modulated radiotherapy).

The outcomes should include overall survival, quality of life, adverse effects, and costs. Specific variables examined should include race, age and, of course, tumor characteristics. The recent AHRQ systematic review has demonstrated the dearth of comparative studies. Recognizing that launching randomized, controlled trials of this complexity would be a resource-intensive undertaking, we suggest that a thoughtfully designed observational study could be efficient and informative. Such an observational study could focus questions for subsequent trials.

Our third priority is cross cutting: how to translate knowledge of what works to care that will work.

What interventions can improve clinician and patient adoption and use of evidence-based care? When is it more effective to target change at the organizational level, the community level, or the individual level? What approaches and incentives to dissemination and adoption are most effective and under what circumstances? We must know how knowledge of what works can be translated to health care that will work.
The Blue Cross and Blue Shield Association appreciates the Council's efforts to set priorities for comparative effectiveness research. Thank you for the opportunity to present today.

Submitted by

Ron Manderscheid, PhD
Global Health and Civil Sector, SRA International, Inc.
and Department of Mental Health
Bloomberg School of Public Health, Johns Hopkins University
[personal information redacted]

Dr. Clancy and Other Council Members:
My name is Dr. Ron Manderscheid. I am the Director of Mental Health and Substance Use Programs at SRA International and Adjunct Professor in the Department of Mental Health at the Bloomberg School of Public Health at Johns Hopkins University. Previously, I held research and managerial appointments at the National Institute of Mental Health and at the Substance Abuse and Mental Health Services Administration.

I am here to speak on behalf of the 107 mental health and substance use prevention and treatment organizations that comprise the Whole Health Campaign. The Campaign seeks good universal health insurance coverage, good integrated care, and good prevention services for persons with mental or substance use conditions. We strongly support national health reform efforts and have prepared eight policy analyses that address key topics of reform.

I would like to make three very brief points today:

First, and most important, the federal comparative effectiveness research enterprise must be guided by consumer and family input. Consumers and families have the direct, lived experience of major health problems, as well as direct experience with successful and failed interventions. They can provide important and needed advice on priority setting and ongoing operations.

Second, the federal comparative effectiveness research enterprise must build infrastructure and train researchers. Currently, the mental health and substance use prevention and treatment fields lack the infrastructure and trained personnel to undertake comparative effectiveness research and bring needed innovation to the field. I know of only two comparative effectiveness studies done for either field. It is critical that the mental health and substance use fields not become backwaters in an ocean of progress: We do know that a person cannot have good health without also having good mental and addictive health. Hence, developing appropriate infrastructure will be important to the entire health enterprise.

Third, the federal comparative effectiveness research enterprise must be designed broadly. Specifically, it must span treatment, prevention, promotion, and health determinant interventions designed both for persons and for populations. To achieve better balance in expenditures on person and population interventions, we recommend that at least one-quarter of federal comparative effectiveness research expenditures be devoted to population interventions.
Also, comparative effectiveness research must span traditional research boundaries. For example, we need to be able to understand the joint effects of targeted depression and diabetes treatments, since these conditions very frequently co-occur together. Failure to consider such joint effects in the past has resulted in a situation where public mental health clients die 25 years prematurely.

In closing, the Whole Health Campaign looks forward to dramatic improvements in mental health and substance use interventions as a result of comparative effectiveness research. We want to support the Council in any way that we can because we recognize the vital importance of your work.

Thank you very much for the opportunity to testify today.

Submitted by
Grace-Marie Turner
President and founder
The Galen Institute – a nonprofit research organization dedicated to patient-centered health reform solutions
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To the members of the Federal Coordinating Council for Comparative Effectiveness Research:

Thank you for requesting comments and suggestions from the public about the role of comparative effectiveness research in American health care. It is widely agreed that doctors and patients need improved information about medicines and treatments to make the best decisions about patient care. As you know, many of us are concerned about how our country's program of comparative effectiveness research will be structured, what type of information will be gathered, and how it will be used. I would like to share some of our concerns with you now.

President Obama has repeatedly told us that we won't have to give up the health care we have if we're satisfied with it. In his Questions and Answers document during the campaign, he further stated that his **"plan will not tell you which doctors to see or what treatments to get. …No government bureaucrat will second-guess decisions about your care."**

Yet now the Federal Coordinating Council for Comparative Effectiveness Research, created through the economic stimulus bill, will have new and untested power over comparing medical treatments.

The real intent of the legislation came out in draft language from House Appropriations Chairman David Obey (D-Wis.), declaring that drugs and treatments "that are found to be less effective and in some cases, more expensive, will no longer be prescribed." This caused a political uproar, with some legislators urging that the council be strictly limited to "clinical" effectiveness studies and not allowed to embark on "cost-effectiveness" studies. We urge the council to focus exclusively on clinical effectiveness in directing research.

Many Americans are concerned about any federal policy that moves decisions away from patients and their doctors and puts them in the hands of federal authorities. I am concerned that the board could be susceptible to political influences and far removed from the unique medical needs of individual patients. Though the members of the council surely are well-intentioned, one body simply cannot judge what is best for all Americans.

The idea behind comparative effectiveness research is to make recommendations on the merits of competing medical treatments. While the idea of this “evidence-based medicine” sounds attractive – everyone wants to get better value for their health spending – giving a governmental or even quasi-governmental body authority over people’s health choices is more likely to interfere with quality care than to improve it.

Experts from Europe and Canada, where comparative effectiveness agencies already are established, warn that this is far from the glide path to saving money and improving the quality of care that many political leaders believe.

Professor Michael Schlander, a well-respected German physician, medical researcher and economist, found that decisions by the National Institute for Health and Clinical Excellence in the U.K. have actually led to higher spending for the National Health Service, not the savings that had been expected.

The complexities of the clinical decision-making process are enormous, including the necessity of taking into account the needs of patients who may fall outside norms. Individual differences in responses to drugs and treatments are shoved aside, especially disadvantaging patients who do not respond well to standard care.

The central problem lies in having the federal government serve as the ultimate decision-maker in comparative effectiveness reviews. CER certainly has a place in the health care system in which multiple entities are analyzing and reviewing research, but one centralized government decision-making body simply cannot take into consideration the individual needs of multiple payers and 300 million Americans.

It is imperative that America use CER to provide the highest quality of information, not to dictate how doctors and patients use that information.

A centralized system conceived to compile information about the relative effectiveness of medical treatments would quickly turn into a tool to reward doctors who follow recommendations and punish those who don't. Doctors and hospitals would be directed to follow the recommendations, and their reimbursement – and risk of lawsuits – likely would depend on compliance. Comparative effectiveness boards, not doctors, would be making decisions about which treatments would be available, and the system would become more and more rigid as doctors fear going against the rules.

It is also evident that comparative effectiveness could stifle innovation.

If allowed to dictate the preferred practice of medicine, comparative effectiveness essentially replaces the experience, wisdom and knowledge of physicians with bureaucracies that reduce decisions to formulas. In the name of protecting their bottom lines, public and private health care plans would likely refuse to cover treatments and procedures that didn't have the approval of this centralized agency.

Physicians and hospitals, fearing lawsuits, would also be much less likely to try treatments not

yet analyzed and approved by the comparative effectiveness body – even if early evidence suggests a treatment might work for a particular ailment or set of patients.

And medical companies would be less likely to pursue research on new and potentially life-saving drugs, biologics, and medical devices when faced with another major bureaucratic hurdle to introducing their products to market. Ultimately, funds for new research would shrivel.

We cannot allow bureaucracy to replace innovation.

A centralized process of CER decision-making would slow the adoption of new medicines and other innovations in medical practice, including surgeries. The health sector would become more rigid and less open to innovation in the process. Federal standards simply cannot be flexible enough to accommodate the ever-changing and evolving nature of any science, including or perhaps especially medicine.

Those with experience in CER abroad say it is almost impossible to integrate clinical findings and cost estimates because they use different methods of evaluation. As a result, many subjective decisions are made in what is believed to be an objective scientific process.

A new study from the Institut économique Molinari in France says that approval processes in Europe are increasingly "tough, heavy-handed and costly … Despite the best intentions, the inevitable consequence of these regulations is to push up the cost of innovation substantially, to undervalue its benefits and to reduce the number of new products by making certain projects unprofitable."

I urge you to put patients first in all you do and in your coordination with federal agencies and Congress. Comparative effectiveness reviews must focus on creating quality information about medical treatments and then allow doctors and patients to make decisions, without limiting their freedom.

Thank you again for receiving my comments.

Submitted by
[personal information redacted]

I am writing regarding the Federal Coordinating Council for Comparative Effectiveness Research, authorized by the ARRA. As a clinical effectiveness researcher with nearly 20 years of experience in pediatric emergency medicine, I have a strong interest in this extremely important initiative. I hope the Council will consider the following points as they proceed with their work:

-- Diagnostic and therapeutic interventions frequently differ in their effectiveness in children compared with adults. Moreover, the measures of effectiveness needed to evaluate services may be different. Any program of CER must account for those conditions and services that are relevant to children, and use methods (including outcome measures) that are appropriate to the population under study.

-- Emergency physicians, and emergency departments, have a unique role to play in CER for both adults and children. First, the ED is often the point of contact for many individuals with both acute and chronic conditions, especially among populations with limited access to regular sources of care. Second, the spectrum of illness and injury treated in the ED is broad. Acute illness and injury is the primary cause of morbidity and mortality for children. In addition, for many chronic conditions, such as asthma or diabetes mellitus, much of the morbidity is in the form of acute exacerbations requiring emergency care. Finally, the ED is frequently at the nexus of care, with interconnections across disciplines and settings.

-- Much comparative effectiveness research is conducted in single settings or systems of care, posing a threat in terms of power and generalizability. Indeed, many of the questions that remain unanswered relate to uncommon conditions or outcomes that have proven challenging to study. Multicenter research networks provide a promising means of addressing such pressing questions, and use of such networks is the best way to ensure that CER is adequately powered for important but uncommon conditions or outcomes. Examples of such problems include pediatric trauma, life-threatening medical illness in children (such as sepsis and severe asthma), and issues related to special populations (such as children with special health care needs).

Thank you for your consideration, and I look forward to seeing the work of the Council as it progresses.

Submitted by
[personal information redacted]

I presume that the approach going forward will include, in addition to new traditional controlled studies or meta-analyses of currently published studies focusing on specific clinical interventions—procedures, medications, diagnostic studies, etc—the utility of programs such as disease management or case management which are now highly touted, but to date have shown mixed results. The way we provide therapy may likely be as important as the specific therapy provided regarding outcomes. The reason I mention this is because it is through partnerships between patients and providers that best outcomes may be achieved. For example treating hypertension may be more effective when anti-hypertensive medications are provided as part of a comprehensive hypertension management program, not simply as stand alone interventions. Of course the null hypothesis is that comprehensive DM programs result in little improvement per se, but that is why the universe has given us Chi Square.

Submitted by
[personal information redacted]

Dear Members of the Council.

I have served as a public patient safety advocate for the past six years.

As a supporter of the President's healthcare agenda, I have been shocked repeatedly, when hearing the contents of this agenda, that the public issues surrounding the elimination of medical errors are missing.

Besides saving more that 200,000 lives annually, safer medical care could reduce the financial burden on American taxpayers by more than $4 Billion every year.

Let me encourage your support of the reinstatement of "Patient Safety" as a major item on the national agenda by your Council.

"In patient safety circles, I am also know as **"justapatient".**

Submitted by
[personal information redacted]

To the Council:

An appropriately large proportion of the discussion on comparative effectiveness research has regarded specific interventions for specific disease states.

However, knowledge translation research must not be overlooked. The emergency setting provides a unique environment wherein strategies to bring knowledge to the bedside that have been studied in other settings (e.g. in-patient setting) may not be applicable or effective.
I hope that the discussants will consider the importance of performing research that compares the effectiveness of different implementation strategies, such as decision support, on patient outcome for an array of diagnostic tests and therapeutic interventions in the ED setting.
We are behind other countries in knowledge translation research; now is an opportune time to catch up.

Submitted by
[Personal identification redacted]

As you know, the level of spending on health care in the US exceeds that of all other countries in the World. In 2007, health care expenditures in the US rose 6.1% to $2.2 trillion, or 16.2 percent of gross domestic product. By 2017, total expenditures are expected to reach $4.3 trillion.
While the US spends more on health care and prescription drugs then other countries, data are mixed as to the value it gets for the money spent. For example, with a life expectancy of 77.5 years, the US ranks twenty-second among 30 OCED counties, with the average for OCED countries being 78.3 years. The US also has the lowest kidney transplant survival rate, the third highest rate of deaths from medical errors, and the third highest infant mortality rate among OCED countries.
Part of the problem in the US is that we do not have good information to make decisions when selecting among treatments for a specific indication. In particular, there is increasing awareness of the limited information provided by traditional randomized clinical trials to inform decisions about therapeutic alternatives as applied in actual practice. The randomized controlled trial (RCT) has long been recognized as the “gold standard” for evidence on the efficacy of innovative medical care interventions, particularly drugs, and RCTs are required by the FDA to market a new drug product. The pivotal Phase III RCT sponsored by a pharmaceutical company

in the drug development process has a specific purpose – to establish the efficacy of the new drug (i.e., Can the drug work?). Yet it is now increasing understood that the traditional RCT does not provide the information necessary for practitioners to understand how the agent works in normal practice (Does the drug work?), and how it compares to existing agents.
These are the questions that CER answers. Thus, while traditional phase III RCTs have a clear purpose – that being to provide efficacy data to support market approval of a new drug, these trials do not typically provide the direct evidence required by decision-makers to make selections between therapeutic alternatives. Comparative effectiveness studies, on the other hand, are designed to generate such evidence and thus are more relevant to actual practice. Both types of studies are important and together complete the breadth of evidence needed for effectively evaluate therapeutic options.

I strongly support the work that AHRQ has conducted to-date in the area of comparative effectiveness research (CER). The Agency has developed a sound infrastructure that includes dozens of centers and hundreds of researchers from across the United States. These centers and researchers have produced important results and advanced the field of CER from a place of relative obscurity a few years ago to one that is now routinely discussed in the lay press. The EHC, which is comprised of the DEcIDE Centers, CERTS, and EPCs, among others, represent a wealth of experience and expertise; and these centers should remain the center point of the CER efforts going forward.

While the work that had been conducted under the EHC Program has been extremely successful, it is my opinion that more needs to be done to ensure that the findings of CER results in actual changes in practice. AHRQ should use funding provided under the ARRA legislation to ensure that physicians and other health care practitioners have access to results of CER and are able to translate the findings into their own practices. By doing so, AHRQ will better ensure that the American public is benefitting from the investments made in CER. I also believe that the Agency can expand the types of CER conducted, to include both retrospective observational studies and prospective clinical trials.

The ARRA funds present an unprecedented opportunity to both expand the important infrastructure already developed by AHRQ to conduct CER, but also to expand the scope of the work conducted.

Submitted by
Todd A. Lee, PharmD, PhD
Center for Pharmacoeconomic Research, University of Illinois at Chicago
toddlee@uic.edu

The following statement reflects the views of the University of Illinois at Chicago (UIC) Center for Pharmacoeconomic Research. The Center for Pharmacoeconomic Research is part of the UIC College of Pharmacy and is affiliated with the UIC Institute of Health Research and Policy through the Center for Health Services Research. Importantly, the UIC Center for Pharmacoeconomic Research is the coordinating center for the Chicago-Area DEcIDE Center, and has been actively involved in comparative effectiveness research (CER) for several years.

Researchers associated with the UIC Center for Pharmacoeconomic Research conduct studies evaluating the comparative effectiveness and cost effectiveness of medications and other medical technologies. Too often new drugs are approved and marketed in the United States (US) without sufficient evidence available to understand the relative benefits and risks compared to existing agents. Pharmaceutical companies rarely have incentives to compare their agents to reasonable therapeutic alternatives. Yet this is the type of study necessary for patients and healthcare providers to make informed treatment decisions when considering treatment alternatives. Given its unique position to facilitate research for the public good, it is imperative that the federal government take the leading role in supporting the generation of new evidence that directly compares relevant treatment alternatives – just as the Agency for Healthcare Research and Quality (AHRQ) has done through the Effective Health Care (EHC) Program.

While the work conducted by AHRQ to-date in the arena of comparative effectiveness has been noteworthy, we feel that there should be greater consideration of economic factors in future CER. Incorporation of costs is an integral part of informed decision-making, and as such understanding of the cost implications of therapies should be a central element of comparative effectiveness research. The relevance of costs highlighted by the current budget pressures faced by US healthcare payers and likely will have to become one of the explicit criterion by which policy is guided as US healthcare, as currently structured, becomes unsustainable. Information about costs allows us to understand not only the direct differences in terms of clinical outcomes but also the value of interventions and whether or not they represent an efficient use of resources.

We would note that AHRQ EHC Program is well conceptualized and executed, and provides an existing infrastructure on which to build for the conduct of CER. Further, the DEcIDE Centers, CERTS, and EPCs represent a wealth of experience and expertise. With appropriate funding, this resource has the capacity to do much more than it has in the past.

We also feel that CER should continue to use a variety of study designs to generate evidence about the comparative effectiveness, comparative safety, and cost effectiveness of medical interventions.

Observational studies, pragmatic clinical trials, and other study designs offer complementary information with varying resource requirements and we believe it is important to continue to take advantage of a broad array of study designs as well as to examine new ways to collect and organize the data and conduct these types of analyses.

Finally, we would support a broad agenda for future CER that focuses on the evaluation of important new medical technologies, interventions and programs. Not only do we need to understand comparative effectiveness of treatments for a particular disease, but we also need to understand the value and impact of preventative health care interventions, programs for medication therapy management, diagnostic technologies, and disease management programs. Not only is the generation of this evidence important, but its uptake into practice is critical, and new approaches for dissemination and translation of CER will be essential to inform and change practice in healthcare that balances the interests of all stakeholders.

The ARRA funds present an unprecedented opportunity to expand the important infrastructure already developed by AHRQ to conduct CER. In doing so, we can usher a new era of evidence-based decision making into the US healthcare system that will benefit all Americans. The UIC Center for Pharmacoeconomic Research stands ready to continue to assist in this endeavor.

Submitted by
Cliff Shannon
[personal information redacted]

The Pittsburgh Regional Health Initiative (PRHI – www.prhi.org) is among the country's first multi-stakeholder, regional healthcare improvement coalitions and was a founder, and now fiduciary agent, of the Network for Regional Healthcare Improvement (NRHI). PRHI's board of directors includes representatives from the region's hospitals, its physician community, major private and public healthcare purchasers, consumer advocates, and insurers. Our stakeholders believe strongly in the power of such regional collaborations to test and disseminate quality and efficiency improvements that will have the greatest effect on patients and cost.
We at PRHI associate ourselves with the recommendations you have received from NRHI. In addition, we want to bring to your attention unique PRHI projects that could define and shape comparative effectiveness research (CER) by building on experience from regional projects and demonstrating the value of a leadership role for regional quality coalitions like PRHI to advance CER.

While many regional healthcare coalitions concentrate on encouraging quality improvement through public reporting, PRHI has focused on initiating clinical quality improvement projects, and on measuring results on the basis of patient outcomes. Because PRHI has been able to tap into the singularly comprehensive clinical database of the Pennsylvania Health Care Cost Containment Council (www.phc4.org), most projects are measured in terms of unequivocal patient outcomes: e.g., risk-adjusted rates of in-hospital mortality, complications and 30-day readmissions; incidence of hospital-acquired infections.
When PCH4 data is not available, we work with our project partners to develop data and measures that track patient outcomes. For instance: (a) partnering with the Centers for Disease Control and Prevention and the region's hospitals on central line-associated bloodstream (CLAB) infection project that resulted in a 68% reduction in CLAB's; (b) a regional cardiac arterial bypass graft (CABG) improvement project that showed initial, highly variable outcomes among cardiac centers and individual surgeons, and then engaged the surgeons in creation of a regional cardiac registry that was followed by lower mortality and complication rates.
Current PRHI-sponsored quality improvement projects that we believe respond to CER priorities are described below very briefly. Please note that these projects are organized both to demonstrate effective quality improvement approaches and disseminate them within local (outpatient and inpatient) care networks and the entire region. We believe that further regional demonstrations could build on these projects to advance CE knowledge.

- Chronic Obstructive Pulmonary Disease (COPD)/Readmissions Project. This is an ongoing project that engages two local hospitals and several affiliated primary care practices that admit COPD patients to them. Readmission rates among chronically ill individuals are a significant problem, and the 30-day COPD readmission rates at the participating hospitals exceeded 25%. As a result of improved transitions of care from

hospital to community, and augmentation of primary care with deployment of a care manager (including home visits), significant reductions in readmissions are being achieved. Interim success is sufficiently dramatic and unequivocal that the region's largest commercial insurer has already made performance improvement payments to the participating hospitals. There is an excellent opportunity for implementing the COPD project model across the region and adapting it for other chronic diseases with high readmission rates. This could be designed and replicated by comparing hospital experiences when different hospitals with demographically similar service areas are designated for intervention/no intervention.

- Integrating Treatment in Primary Care Project. This is a recently initiated, privately-funded project that engages five community health centers. The goal is to demonstrate patient-level, practice-level and system-level outcomes through evidence-based practice for patients with chronic disease and co-morbid mental health/substance use conditions. Many chronically ill patients have co-morbid medical problems, which are often exacerbated by co-occurring behavioral health problems, including depression and hazardous or addictive use of legal and illegal substances. These problems correlate with high hospital admission and readmission rates, and much higher cost. The project goal is to demonstrate significant reductions in 30- and 90-day readmission rates through training of primary care staff in effective screening methods for depression (IMPACT depression intervention) and substance use (SBIRT - Screening, Brief Intervention, Referral and Treatment). If successful in proving better patient outcomes and return-on-investment, PRHI will seek to disseminate and reimburse for these interventions throughout the regional healthcare system. A meaningful project would compare FQHCs' patient outcomes when SBIRT and IMPACT are implemented, as contrasted with outcomes in non-participating FQHCs or outcomes within the experimental sites, pre- and post-interventions.

- Polypharmacy and Medication Reconciliation. This is a recently completed series of demonstrations, the results of which made such a compelling case for widespread action that a follow-up project is contemplated. Through its "Healthcare Champions" program, PRHI recruits teams of caregivers to conduct explorations of important patient care issues. The most recent iteration, organized as "Pharmacy Agents for Change," engaged 8 teams of clinical pharmacists in related studies of polypharmacy and chronically ill patients. The teams documented medication error frequency, lapses in care coordination and transitions of care, and patient falls among chronically ill patients. Design and implementation of specific interventions demonstrated the benefits of physicians, clinical pharmacists, and nurses collaborating on systematic medication documentation and reconciliation (med rec). The project also raised awareness of polypharmacy issues among providers and changed prescribing practices. Results point to the potential for reduced medication cost, lower utilization of high-risk polypharmacy combinations, and fewer adverse drug reactions and patient injuries, that could be proven through a rigorous RCT. Such research could demonstrate the ROI for med rec in reducing hospital admission and readmission rates and average length-of-stay, and improving patient quality of life and functionality.

- Improving Chronic Disease Care by Small Primary Care Practices and Safety Net Providers. This is a series of recently initiated and impending PRHI projects. PRHI's overarching goal is to prove the feasibility of developing formal or informal local accountable care networks, through which community hospitals and affiliated/aligned primary care practices would share electronic patient information, enable primary care provider direct access to hospital specialists, and coordinate care in both the inpatient and outpatient settings. The goal is show that through such local accountable care networks patient outcomes can be improved, particularly among high-risk patients. All three projects promise financial rewards for delivering more effective care, which could be measured by savings accrued through reduced hospitalizations.

  Our unifying premise is that trends in healthcare reimbursement and outcomes-based performance measurement will require that many/most community hospitals and primary care practices re-invent themselves and their relationships. Community hospitals are already under significant financial stress, and inevitable changes in healthcare payments make it untenable for most of them to rely financially on filling beds. The small practices that admit 90+% of patients to community hospitals are also under significant financial stress, lack resources to make needed changes, but will be penalized if they do not adopt EHR's, etc. These hospitals and the practices that admit to them, however, have an opportunity to transform themselves into high-quality, efficient networks for both primary care and acute episodes of care. We propose that any of the following projects be enhanced, tracked and standardized to prove the relative effectiveness of aligning payment with desired outcomes (reduced ER visits, hospitalizations and re-hospitalizations):

  1. CMS EHR Demonstration Project, for which southwestern Pennsylvania is one of four sites, and through which 140 small primary care practices will be able to earn substantial amounts for EHR implementation and attainment of CMS chronic care quality measures. Because EHR costs are only part of the challenge for small practices, PRHI and Highmark Blue Cross Blue Shield have formed a strategic partnership to provide $1 million in customized staff training, technical help and business management assistance for participating practices.
  2. Regional Chronic Care Demonstration Project, sponsored by the Pennsylvania Governor's Office of Health Care Reform, through which two dozen small primary care practices and safety net clinics will receive financial incentives for participating in PRHI-coordinated practice coaching, collaborative learning, and patient registries which will enable participants to implement the Chronic Care Model.
  3. Transforming Safety Net Clinics into Patient-Centered Medical Homes, a collaboration with the Commonwealth Fund, through which PRHI will work with 12 federally qualified health centers to transform them into Patient-Centered Medical Homes (PCMHs).

In conclusion, we believe that research and dissemination of research findings at the regional level is unequivocally essential to realizing the quality improvements and returns-on-investment that are integral to CER success. As described above, PRHI projects are continuing to bring about relevant, measurable advances at the regional, state, and national level. We hope that significant funds will be set aside for regional research and dissemination projects and look forward to working with you and others.

Submitted by
Cynthia Reilly, B.S. Pharm.
Director, Practice Development Division
American Society of Health-System Pharmacists
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Good afternoon. My name is Cynthia Reilly and I am the Director of the Practice Development Division at the American Society of Health-System Pharmacists. ASHP represents 35,000 pharmacists, pharmacy students, and pharmacy technicians who practice in hospitals and health systems. Pharmacists' expertise in medication use ensures that drug therapies are used safely, effectively, and in a cost-conscious manner. I appreciate the opportunity to present the Society's perspective on comparative effectiveness research, or CER, to the distinguished members of the Federal Coordinating Council for Comparative Effectiveness.

ASHP is a member of the Alliance for Better Health Care, which advocated for inclusion of comparative effectiveness research funding within the American Recovery and Reinvestment Act of 2009. The Society is also publisher of *AHFS DI*, a comprehensive, independent reference on the clinical use of medications, which is recognized through federal legislation under Medicare Part B, Medicaid, and Medicare Part D as an official compendium. For over 50 years, *AHFS DI* has followed sound and high-quality editorial processes to synthesize complex evidence for dissemination and use by a broad range of stakeholders, including prescribers, pharmacists, individuals who make health-policy and coverage decision, patients, and others. ASHP believes there is significant need to compare the effectiveness and safety of specific drug therapies within pharmacologic classes, drug therapies within different classes, and drug therapies with other treatment modalities. *AHFS DI* can serve as a foundation for medication information to support CER and ASHP looks forward to participating in this research.
Today, ASHP requests that the Council consider three CER recommendations related to health care delivery systems that represent critical information needs to improve patient outcomes:

- Optimal practice models for delivery of patient care,
- Strategies for using IT-enabled decision support for delivery of CER, and
- Best practices for disseminating and implementing CER.

As described by the Dartmouth Atlas, the quality and cost of care is inconsistent across geographic regions, with much of this inconsistency attributed to variation in the care setting and the health care professional that provides the service. Under Medicare Part D, pharmacists provide medication therapy management services that include formulating medication treatment plans; monitoring and evaluating patients' response to therapy; performing medication reviews

to identify, resolve, and prevent medication-related problems; and coordinating and integrating MTM services within the broader health care services provided to patients. Pharmacists also participate in chronic disease management and prevention activities under collaborative practice agreements with physicians. MTM programs and published research have demonstrated that pharmacist management of disease and drug therapy significantly improves patient outcomes, while reducing overall health care costs. However, there is limited research that directly compares this practice model to models in which care is provided by other health care professionals or interdisciplinary teams. ASHP believes such research would demonstrate best practices and strongly recommends models of care as a research priority for CER.

A critical element of CER is ensuring that research findings reach the point of care where clinicians, together with patients, can use the information to make informed treatment decisions. Electronic health records and other technologies are expected to provide point-of-care information; however use of these technologies is currently limited, as described in a recent *New England Journal of Medicine* study that found less than 2% of hospitals have fully implemented an electronic health record with clinical documentation, test and imaging results, CPOE, and decision support. Decision support technology has great potential to deliver CER findings, but strategies for creating and integrating these programs within other technologies, as well as barriers to implementation, are not well-studied. ASHP encourages the Council to support research that compares approaches for using clinical decision support and other technologies in the translation and implementation of CER.

In addition to technology, other effective dissemination and translation techniques are needed to ensure that CER findings are used to make informed decisions that improve patient outcomes. However, there are significant challenges in these activities. It has been estimated that there is a 17-year lag time between evidence generation and its widespread implementation. Many strategies have been used to enhance the rate and extent of adoption of evidence-based best practices, including clinical guidelines, continuing education for health care professionals, patient education tools, and most recently, academic detailing. However, these approaches are not well studied and results are variable. ASHP would encourage the Council to support research that compares the benefits and limitations of each approach in order to determine the strategy, or combination of strategies, that facilitates use of CER by each audience, including clinicians, patients, and payers.
Finally, based on ASHP experience as a drug information publisher, we encourage the Council to consider that, similar to drug information, CER research and dissemination efforts are not single events, but rather an ongoing process that requires sustainable and ongoing effort to ensure the currency and usefulness of the information as evidence evolves.

ASHP appreciates this opportunity to provide recommendations for CER. Along with our members, we look forward to collaborating with the Council and others to ensure that CER is not only useful, but also disseminated to clinicians, payers, and patients and subsequently translated into practice.

Submitted by
[personal information redacted]

Please support the building of a universal health information network (uhin). In order to benefit from medical and health experience we should have uhin to quickly and efficiently evaluate health threats and health interventions. The uhin may also be used for administering the financing of health care and cost/effectiveness evaluations in a global context. The Kaiser Family Foundation surveys now show the majority of the public acceptable to health information networks and the possible privacy risks.
http://www.npr.org/templates/story/story.php?storyId=103458129 .

To develop the uhin efficiently the Federal and State governments with International cooperation should develop a publicly endorsed monopoly or authority to direct vendors and health care providers in enforceable acceptable standards and pay vendors for use of their expertise. The uhin may also be used as a single virtual payor with all payors having access for an administrative fee.

Submitted by
[personal information redacted]

Dear Council Members,
Comparative effectiveness research should include estimates of population level effectiveness as well as patient-level effectiveness. A growing body of research offers evidence that the same biologically efficacious treatment may be associated with increased or decreased disparities and/or increased or decreased mortality rates in different geographic areas. From the older literature, there is evidence that introduction of Sabin vaccine transformed poliomyelitis from a disease that predominantly affected whites to one that predominantly affected blacks (1,2). A similar problem, not so clearly related to access to care, led to intra-city disparities upon release of measles immunization in the divided community of Texarcana. Because of structural community inadequacies, the Texas side of the city was unprepared to translate research on measles immunization into practice while the Arkansas side of the city was ready. If "effectiveness" studies had been done only on the Texas side (or in communities like the Texas side), there might have been concern that the vaccine, though efficacious, was not effective. In fact, this is one reason the Texarcana study was done. Landrigan's research showed that biological efficacy or even effectiveness did not predict public health effectiveness (3). More recently, it has become clear that Medicare's decision to reimburse providers for screening mammography (4) as well as the introduction of HAART for HIV (5) and surfactant for neonatal respiratory distress (6) were all associated with increased disparities in most, but not all communities. Preliminary studies on breast cancer using Medicare claims data suggests that communities that appear to be successful in delivering mammography to both black and white elderly cannot be characterized by county-level estimates of the availability of medical resources or socioeconomic status. In summary, comparative effectiveness research that ignores public health success or failure, and public health comparative effectiveness research that ignores variation in community capability for translating innovation into practice could both lead to alpha- and beta- errors in effectiveness estimates.

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Submitted by
[personal information redacted]

Dear Sirs,

The disease specific focus of much of the proposed Comparative Effectiveness health services research to date risks a serious deficiency in both the impact and generalizability of the resulting work. In particular, those of us doing research in patient care quality and safety are concerned that the proposed clinical domain/disease focus will hamper major advances in our efforts to reduce medical error, enhance the design and impact of healthcare information technology, and improve quality. Moreover, the targeting of specific clinical topics means that other domains/topics will be excluded from priority consideration yet some of these may be superior laboratories for the initial evaluation of quality/safety/informatics interventions that ultimately will have broad-reaching impact.

I implore you to consider adding comparative effectiveness priority research areas to include critical cross-cutting research questions (e.g., clinical decision making, human-technology partnership, team coordination and continuity of care) and evaluation of general intervention/improvement methodologies (e.g., simulation-based training and assessment, computer-based clinical decision support).

I would be happy to discuss these concerns with you further.

Submitted by
Herb Kohl, Chairman
Senate Special Committee on Aging
Independent Drug Education and Outreach
Nicole_Brown@aging.senate.gov

<u>The Problem</u>

Currently, pharmaceutical sales representatives are one of the most common ways doctors receive information about the latest drugs on the market. However, most of the information they provide is designed to market their company's products, rather than serve as an unbiased source of data about the range of pharmaceutical treatments available to patients. With evidence showing that interaction with pharmaceutical sales representatives can impact doctors' prescribing patterns, it is important to ensure that physicians have access to independent information that is well-researched, comprehensive, and objective.

The Solution

Academic detailing programs send trained pharmacists, nurses, and other health care professionals into doctors' offices to disseminate independent data about the benefits, risks, costs, and comparative effectiveness of the full array of pharmaceutical options for patient treatment, including low-cost generic alternatives.

- **Fund grants or contracts to develop educational materials.**
  - The grantee or contractor would develop educational materials showing the relative safety, effectiveness, and cost of prescription drugs, including generic and over the counter alternatives and non-drug treatments for selected conditions. These materials would include brochures, handouts, and electronic information accessible to both patients and doctors.
  - Entities that can demonstrate clinical expertise in pharmaceutical research, such as medical and pharmacy schools and academic medical centers, would be eligible to apply.
  - Applicants may not receive financial support from any manufacturer of the drugs being reviewed.
  - AHRQ will review and approve the accuracy and effectiveness of the materials on a bi-yearly basis.

- **Fund ten grants or contracts through AHRQ to dispatch trained medical professionals into physicians' offices to discuss and disseminate the unbiased educational materials.**
  - Public entities and nonprofit groups would be eligible to apply for the grant or contract, as would other entities that demonstrate the capacity to train and deploy the medical professionals to disseminate and discuss the materials.
  - Applicants may not receive financial support from any manufacturer of the products being discussed.
  - The grant or contract recipients would hire and train appropriate staff, identify health care providers to be the recipients of the outreach, and evaluate the effectiveness of the program on both cost and prescribing behavior.
  - Regulations would also be in place to ensure the accuracy and timeliness of the information being distributed, to prevent conflicts of interest, and to promote the effectiveness of the program.

The Cost

There is documented cost savings in the states that already have academic detailing programs in place. Analysis of a program in Pennsylvania found that drug expenditures for a single class of

drugs were reduced by roughly $120 per doctor per month for patients in the state program. Among the heaviest prescribers, the reduction was $378 per doctor per month for just one class of drugs. A study in the New England Journal of Medicine projected that for every dollar spent on academic detailing, two dollars can be saved in drug costs. This kind of academic detailing program would likely pay for itself and create additional cost savings for the federal government, private insurers, and patients. Most importantly, it will help ensure that patients receive the most appropriate, highest quality treatment.

Written statement of the Association of periOperative Nurses (AORN)
Patrick Voight RN BSN MSA CNOR; President
Linda Groah RN MSN CNOR FAAN; CEO

Thank you for giving AORN the opportunity to address the Council on the very timely and important issue of comparative effectiveness. We want to emphasize three points:

1. Data collection from **nursing sources** is a critical element to inform **effectiveness** decisions;

2. **Standardized data** available from the point of patient care is essential to inform **comparative** analysis.

3. **Syntegrity** creates an opportunity for a national surgical data repository that could be used to measure quality outcomes and potentially be used for comparative effectiveness studies to decrease cost and improve quality.

Since the 1980's the Association of periOperative Registered Nurses (AORN) has been a pioneer in developing and promoting the Perioperative Nursing Data Set (PNDS), a standardized language for documentation and evaluation of the care provided in the operating rooms of our nation's hospitals and ambulatory surgery centers. As a 501(c)(6) association based in Denver, AORN represents over 43,000 registered nurses and has a history of patient centered safety and quality activities.

The guiding premise of the PNDS effort was to assist perioperative nurses in documenting the care they gave before, during and after the surgical procedure, while providing a foundation for examining and evaluating the quality and effectiveness of that care.
While effectiveness within a hospital or surgery center was informed by this data, the ability for comparison between providers was rarely available because each facility customized the PNDS to their environment.
In early 2008, AORN initiated the development of an electronic and standardized perioperative framework referred to as Syntegrity.

This standardized perioperative framework is not intended to replace current information and documentation systems, but is designed to be incorporated into existing software. Most hospital surgical IT vendors already license AORN's PNDS but again, this is often customized for a specific facility. With the emphasis on electronic and standardized data collection coming from the federal government, the Syntegrity framework is poised to fill that emergent need.
AORN is acknowledged nationally as the association that establishes evidence based standards and recommendations for care of the surgical patient. Syntegrity incorporates these standards

and recommended practices into the database. Thus, Syntegrity creates an opportunity for a national surgical data repository that could be used to measure quality outcomes and potentially be used for comparative effectiveness studies to decrease cost and improve quality.

Here is a concrete example of how Syntegrity could be helpful for infection prevention: Syntegrity includes current CMS requirements for documentation on infection prevention processes. This "pop up box" requires the nurse to document from the choices in the electronic field or provide an explanation for any exception. This standardized, electronic data capture now becomes available for a repository from which specific analysis may be performed to measure the effectiveness of the CMS requirement. It is important to emphasize that the data collection by the nurse is already part of most surgical processes – what Syntegrity does is STANDARDIZE the data collected in an ELECTRONIC format . This creates an opportunity for a national surgical data repository that could be used to measure quality outcomes and potentially be used for comparative effectiveness studies to decrease cost and improve quality.

As further guidance to the Coordinating Council on the important priorities of health reform that AORN believes are impacted by the consideration of comparative effectiveness, we provide the following information and specific AORN resources that are meaningful to this discussion.
Quality improvement must play an essential role in health care reform efforts ensuring reform not only expands coverage, but also improves the care patients receive.

- AORN standards and recommended practices are a key resource. AORN is acknowledged nationally as the association that establishes evidence based standards and recommendations for care of the surgical patient. Syntegrity incorporates these standards and recommended practices into the database.
- AORN's Perioperative Nursing Data Set (PNDS) is a standardized language that facilitates the documentation and evaluation of the care provided by perioperative nurses.
- AORN has embarked on an initiative to create a standardized perioperative framework (Syntegrity) that will be integrated into hospital and surgery center electronic perioperative information systems.
- The essential role of the RN as Circulator and the value added of the registered nurse first assistant underscore the role of perioperative nurses in achieving quality and may be informed with comparative effectiveness analysis arising from data made available through Syntegrity data repository.

Performance measurement is a core building block to provide high quality affordable care. Information that is grounded in good evidence will support quality improvement, payment reform, and enable better clinical and consumer decision-making. This information can tell us which care is leading to better outcomes and which treatment options are more cost effective.

- AORN supports the National Priorities Partnership convened by NQF
- AORN supports Stand for Quality

Investment in **health information technology** should be linked to improving care. Health information technology (HIT) represents an important means of advancing quality measurement and improvement. But HIT can only help improve the quality of care if it is designed to more effectively collect performance information.

- AORN Syntegrity provides a standardized perioperative framework (SPF) that will be integrated into hospital and surgery center electronic perioperative information systems to provide evidence for quality improvement in the operating room.
- Syntegrity creates an opportunity for a national surgical data repository that could be used to measure quality outcomes and potentially be used for comparative effectiveness studies to decrease cost and improve quality.

Performance measurement must be dramatically expanded, but measurement is not enough. Expanded efforts on all fronts to foster greater use of **performance information to support clinical improvements** and the delivery of more cost effective care, expand public reporting, and expand the use of performance information to promote changes in payment to promote value.
In conclusion, we want to emphasize three points:

- Data collection from **nursing sources** is a critical element to inform **effectiveness** decisions.

- **Standardized data** available from the point of patient care is essential to inform **comparative** analysis.

- **Syntegrity** creates an opportunity for a national surgical data repository that could be used to measure quality outcomes and potentially be used for comparative effectiveness studies to decrease cost and improve quality.

For further information from AORN or to set up an information briefing, contact Craig Jeffries, AORN Public Policy Consultant at CJeffries@AORN.org.

Submitted by
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Since our founding in 1992, the work of the Center for Advancing Health (www.cfah.org) has been guided by three principles:

- That scientific **evidence**, while always evolving, offers the best guide for positive changes in the health of the individuals and the nation.
- That individuals, sick or well, will only benefit from the expertise of health professionals and available technologies if they have the knowledge, skills, judgment and willingness to **engage** in their health and health care over time.
- That minimizing the social and behavioral barriers to people's engagement in their health and health care will contribute to **equity** of opportunity for health for all.

Determining priorities for comparative effectiveness research (CER) comes at a time in our nation of great uncertainty, but also a time of enhanced scientific and political opportunity. At the CFAH, we acknowledge the complexity and significant challenges that this coordinating council faces at this critical time in our history.

Rather than nominating one condition over another (which is outside the core expertise of the CFAH), we simply offer that priorities for CER should be on high volume and/or high cost conditions for which there exist significant variations in practice AND multiple treatment or diagnostic options. Research priorities and methodology should also factor in any systematic variations in disease prevalence or treatment response across different populations, as well as consider known health disparities in treatment provision.

It is our belief that substantial efforts must be expended to build public interest in and support for CER. These efforts should be focused on communicating the value of and application of CER for everyone's health and health care. It is, therefore, our primary recommendation that your effort to advance public understanding of CER and even more critically, develop TRUST in the value and output of an institute(s)/body(ies) devoted to CER, be as important as a debate about "who's on first" with regard to selecting priority areas of study.

At the CFAH we recognize that as a society we have often been lulled into believing that new scientific discoveries, that "wonder pills" and technology are the keys to living well. And that more treatment and/or more costly treatments are frequently equated with quality. This expectation and preference for the latest, often "high-price" option means that apparent advances in the number and variety of treatment options creates both a solution AND a problem. However, we also know that advances in scientific knowledge can only increase health and quality of life IF people are able to make informed decisions about their health care. In addition, people must be willing to change life-long habits and manage complicated medical regimens. The success or failure of modern medicine is increasingly dependent on an individual's ability to engage more fully in their own health.

For example, here are some observations of our president and founder, Jessie Gruman, when she conducted over 200 interviews with patients and their families about their experience with health care for her book *AfterShock, What to do When the Doctor Gives You - or Someone You Love a Devastating Diagnosis*. She learned that the vast majority of them were <u>surprised</u> at what they were expected to know and do, and <u>overwhelmed</u> when they grasped (however dimly) that their actions and their choices could make the difference between receiving good care and bad and could even contribute substantially to the quality and even the length of their lives. She also learned that they often felt <u>abandoned</u> in their attempts to find the right care and administer it for themselves or their loved one. Surprised, overwhelmed and abandoned…not exactly criteria associated with making sound decisions. If CER is to meet its potential, we must address the realities and concerns of an already compromised patient.

So we would like to offer five potential strategies to engage the public:

1. Align early and often with trusted public advocacy groups and spokespersons to disseminate basic information about the need for and the value of CER.

2. Institutionalize the participation of consumers and patient advocates in the reviews and dissemination of findings.
3. Be fully transparent about the selection and study process for treatment reviews.
4. Make all findings directly available to the public in accessible formats.
5. Share potential outcomes and/or consequences of CER reports in various “real-life” scenarios for the average patient and physician (downside and upside from each perspective).

Lastly, it is of great concern to the CFAH that opponents of CER have grabbed rhetorical high ground with negatively framed language specifically designed to frighten people. Thoughtful perspectives from a variety of trusted sources are urgently needed to provide the public with a more balanced understanding.

Thank you again for this opportunity to add input to your important process.

Submitted by
[personal information redacted]

Our medical system has failed. This problem doesn't touch one person, or ten, or one hundred, this problem touches every citizen of The United States of America. This problem has probably touched all citizens in one way or another, either as a victim, or friend or family member of a victim. The hospitals and the doctors they employ have either killed or maimed someone the reader of this letter has known. That is how far the government, insurance companies, and "we" the citizens, including all employees of the medical system, have let this happen right in front of our eyes without any action, and with what little action already taken, not the best results.

I have had the same doctor who told me they are sorry I couldn't get justice also tell me that doctors won't testify against each other.

There are bills being passed in the "billions of dollars" range to help with our medical system. My broken left leg has already cost the government almost fifty thousand dollars and will continue to cost the government through my upcoming amputation. The amputation is due to an infected rod (pseudomonas aeruginosa, coagulase negative staphylococcus) that was placed into my lower left leg, tib-fib break that never broke the skin. The only time my skin was open was in the operating room at [information redacted]. The operation was done by Dr. [information redacted]. I filed several complaints with The TN Department of Health, [information redacted], with no action taken so far. The hospital has already been let off the hook by a "surprise attack investigation" which never included me, you're welcome to get a copy of that review at the [information redacted], the last two complaints mentioned have been handed over to another office, the Office of Health Care Facilities, for whatever action they deem appropriate. This means no action will be taken. If you multiply the fifty thousand dollars already spent on me times just one percent of our population on the same insurance I'm on (Medicare) the cost to the government is now around one hundred and fifty billion. Why can't these doctors be held accountable for that money? Why is the government gladly and generously paying for their mistakes?

If someone doesn't pay their child support the government threatens to take away their drivers license and put them in jail. If someone has a dog and it bites another person, the government arrests the dog owner. Where's the involuntary manslaughter or reckless endangerment charge for the medical field. The government of The United States of America has made "murder" a common word for the common people to have to deal with when it comes to the problems with hospitals or doctors. The government of The United States of America has made it legal for hospitals and doctors to get away with murder and reckless endangerment cases pertaining to their patients. Where's the justice in that? I'll answer that for the government, since they aren't brave enough to stand up and do the right thing. There is no justice in these situations, but you, the government, doesn't care. Do you think the Founding Fathers of this country would have stood for this? Remember, "No Taxation Without Representation". Do you think Abraham Lincoln would have stood by and let this happen? He thought to much of every citizen alike to let this happen to any of his people, but now, you answer these questions because you, the government of The United States of America, deep down in your heart and soul know the answer, whether you say it out loud or not. The lawyers of this great country are doing more right now for the rights of all citizens than the government. The lawyers know there can and should be no caps on pain, suffering, and death, and we appreciate that.

The Malpractice Laws are designed for monetary compensation from the hospitals and doctors to the patient for the services the patient received when something went wrong. It's to late for an apology and a set amount of money at this stage. We're tired of the way the government allows and the doctors and hospitals insurance companies having the power to control the "buy out system" the hospitals and doctors go through for their unprofesionalism. Where is the retribution in that system? There are enough doctors going to school that would be glad to take over the offices on Main Street of the unprofessional and unethical doctors running the medical field. Even politicians seem to get into more trouble than doctors. Why?

The doctors try to fix problems, but most of them really don't "help" anyone when a large percentage of patients are leaving sicker than when they came to the hospital. Then, most get a "second opinion doctor" who tells the patient what the other doctor did wrong and has to spend their valuable time fixing botched up work from another doctor. That's how it was worded in my case. Well, the United States citizens will no longer stand by and let this happen. Instead of caps and apologies, I think it would be better to assure the population as a whole that the hospitals and doctors WILL be held accountable for their mistakes, instead of patients dying or being maimed by our medical system. Also, it costs the common people (in my case, one thousand dollars for a medical review of my file from a specialist in a contingence state) money that a large percentage doesn't have. I had to get a loan to start a medical malpractice lawsuit. That is unfair, and the government knows this is true.

Justice is what the common people long for, the government of The United States of America stands for, and what the politicians on Capitol Hill are withholding. What went wrong? Maybe, no one in Washington D.C. is looking at this problem from the right angle. The solution to this problem is not to condemn the hospitals or doctors of this great country, the solution to this problem should give all citizens alike the confidence of their medical system and to give the medical system back its reputation in which it has strayed. I don't want our future generations to go through what we have HAD to go through. Should they "inherit" this problem?

This is corruption at its best. The insurance companies of the hospitals and doctors are controlling this situation, and you (the government) know it. Is that what they're talking about when they say "monopolize"? Well, if so, the government of The United States of America is allowing this to happen. Is it like this in other countries, let's say, with "socialism"?

Stand by me, as two warriors should, and help the hurt, infected, dying, and families of the dead, etc., citizens of The United States of America not be the only ones being held accountable for the infected rods, bad joint replacements, etc. We were just the ones putting our trust in hospitals and doctors who are fouling up, the patients were just innocent bystanders laying on the hospital beds while the doctors were performing the operations.

Thank you for your time and attention.

Submitted by
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Good afternoon. My name is Gary Persinger, Vice President for Health Services Research at the National Pharmaceutical Council (NPC). On behalf of NPC, I would like to thank you for providing this opportunity to comment on comparative effectiveness research (CER) and the activities of the Coordinating Council. This is a critical discussion focused on providing health care decision makers with timely, balanced, and high quality clinical evidence to help inform their decisions and improve patient health outcomes.

About the National Pharmaceutical Council
Briefly, the National Pharmaceutical Council sponsors and conducts scientific analyses on the appropriate use of pharmaceuticals and the clinical and economic value of improved health outcomes through pharmaceutical innovation. CER and its foundation of high quality scientific evidence are important areas of focus for NPC. It is our goal to ensure that sound evidence is recognized by independent experts, considered appropriately by private and public payers, reflected adequately in benefit designs, and incorporated into clinical practice. NPC was established in 1953 and is supported by the nation’s major research-based pharmaceutical companies.

Chronic Diseases Afford Greatest Impact
It is clear today that health care costs are rising at an unsustainable rate, making it reasonable for CER priorities to focus on medical conditions with the greatest impact on morbidity and cost. These include chronic conditions such as cardiovascular disease, chronic respiratory diseases, cancer, diabetes, arthritis, and serious mental health conditions. CER should not be limited to the drugs used to treat those conditions, but rather, it should be extended to all relevant health care services including medical and surgical procedures, diagnostics, and medical devices.
In addition, this research should include alternative health care delivery methods and insurance benefit designs. The proposed prioritization of research topics and studies in these areas of

medicine, their associated research time frames, final study outcomes, and related information should be made transparent to all stakeholders and should be disseminated in a timely manner.

Key Additional Factors for Consideration
It also will be important for the Federal Coordinating Council to consider several key questions as it assesses the CER-related research conducted by Federal agencies and departments and develops recommendations for selection of the highest priority research.

- First, what strategies can be employed to ensure the continuous evaluation of new evidence related to specific health care technologies – for example, how best to determine when a health technology assessment should be revised based on new clinical information?

- Second, how can CER be employed optimally in a manner that preserves incentives for the continuous innovation of health care technologies in areas of unmet need?

- Third, how can CER at a broad population level be balanced with the goals and rapid scientific advancements in the area of personalized and stratified medicine in order to encourage the development of targeted therapies for subpopulations?

- Fourth, what research should be conducted to define rigorous, high quality, and validated CER methodologies that are focused on providing timely, accurate and balanced information in order to assist clinical decision making?

    - This research should include, but not be limited to, defining how best to address the full range of health effects of a new technology, including quality of life, functionality, and productivity, as well as how best to appropriately characterize the strengths, weaknesses, and limitations of various underlying health technology assessment analytic techniques.

- Lastly, what support is required for the development of new CER methodologies, such as analysis of non-randomized studies of treatment effects using secondary databases, practice-based clinical practice improvement studies, more accurate modeling and simulation techniques, and methodologies that ensure optimal interpretation and application of CER in a variety of patient care settings?

The National Pharmaceutical Council welcomes the opportunity to be a part of this critical dialogue and stands ready to assist the Coordinating Council as it moves forward in developing recommendations to ensure coordination and best use of resources for CER.

Thank you.

Submitted by
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BACKGROUND

Consumers spend millions of health care dollars annually on Complementary and Alternative Medicine (CAM) practices and therapies that have limited or no solid medical evidence base and which may interact adversely with existing treatments or even exacerbate existing medical conditions. No widely-accepted systematic and rigorous process exists for collecting safety and efficacy data on these untested CAM practices. The Scientific Evaluation and Review of Claims in Healing (SEaRCH) program addresses this national need through a well-documented, transparent process for evaluating CAM practices and therapies. SEaRCH performs a systematic assessment of the methodologies, techniques, and outcomes reported for CAM practices and compares these to existing medical practices and methodologies. SEaRCH provides a rapid, cost-effective screening before time and money are spent on future research or evaluation of untested practices.

SEaRCH has grown through public and private partnerships over the last decade. The original SEaRCH concept began in 1996 with a mandate from Congress to document and evaluate CAM therapies and practices. In 1997, through collaboration with the Centers for Disease Control and Prevention (CDC), the Office of Alternative Medicine (OAM) at the National Institutes of Health (NIH) developed the Field Investigation and Practice Assessment (FIPA) program and conducted several large-scale evaluations of CAM practices. The FIPA program was extended in 2003 under the Congressionally-mandated CAM Research for Military Operations and Healthcare (MIL-CAM) program and was further developed as the Epidemiological Documentation Service (EDS) through a subcontract to the National Foundation of Alternative Medicine (NFAM). The EDS program was transferred to the Samueli Institute in 2008 where it was further developed and renamed SEaRCH.

The Samueli Institute is currently refining and expanding SEaRCH to enable more rapid throughput and assessment of CAM practices. SEaRCH fits well into the existing Samueli Institute research portfolio, which includes the Prospective Outcomes Documentation System (PODS) for conducting clinical observational studies, the Institute's Systematic Review program, and its capacity for conducting rigorous pre-clinical research through its network of laboratory partners.

GOALS AND OBJECTIVES

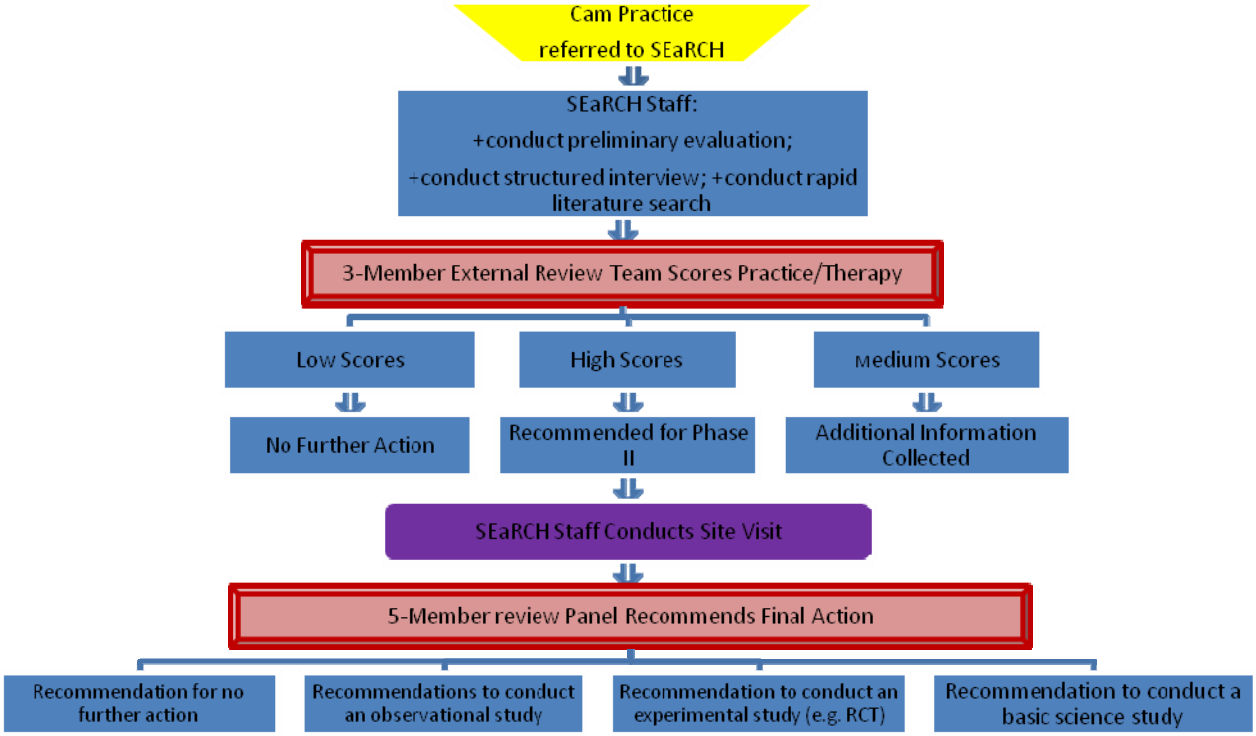
In the highly competitive and resource-limited world of medical research, many potentially valuable CAM therapies and practices are often left uninvestigated. The **goal** of the SEaRCH program is to systematically and rigorously evaluate CAM practices, therapies, and claims worldwide to determine if they warrant further scientific investigation and research. The **long-term is goal** is to identify safe, effective, and affordable CAM treatments that warrant the time and effort for further testing and comparison against existing therapies. The specific **objectives of the expansion** of SEaRCH are to: further develop the methodology and toolkit for evaluating

healing claims, build a team of scientific reviewers and partners, systematically identify candidate CAM practices, employ the methodology to prioritize and make recommendations to perform comparisons of CAM practices and therapies with existing therapies, and to communicate the initial findings from these evaluations to the public. SEaRCH methodology will be available for use for CAM therapy, practice and claims by CAM practitioners, the National Center for CAM (NCCAM), the office on Cancer CAM at the NCI, the CDC and the Department of Veterans Affairs - all of who have expressed a need for such a methodology and approach.

SEaRCH PROCESS

SEaRCH employs a rigorous two phase evaluation process: Phase I: Practice/Therapy data compilation and screening; Phase II: Therapy or Practice Site Visit and direct data collection and Final Review and Recommendations (See Exhibit).

When a therapy or practice is referred to SEaRCH for evaluation, Phase I begins with compilation of basic information and documentation. SEaRCH staff does a preliminary evaluation through contacting the principal investigator/therapist and identifies any missing data elements. SEaRCH staff then conducts a rapid literature search to amass data on comparison practices. The SEaRCH staff also conducts a structured interview with the principal investigator/therapist to obtain additional specific data on the history and current breadth of the practice reach. Phase I culminates with three external scientists/practitioners reviewing the amassed data using a rigorous scoring approach which supports the range of CAM therapies, practices, and procedures. Low scores in the Phase I screen lead to constructive reviews sent to the principal investigator/therapist and a recommendation of no further action. Mid-range scores lead to requests for additional information from the principal investigator/therapist and/or additional SEaRCH staff background research. Based on this new information, the practice/therapy may be reviewed again or recommended for no further action. High scores in screening are recommended for Phase II. In Phase II the SEaRCH staff performs a highly structured site visit. The data collected on the site visit is added to the practice/therapy file with the staff recommendation for action. The entire file is then evaluated by the same external team who conducted the screening review plus two new members. The review team is expected to reach consensus and write a comprehensive report to recommend a specific research protocol involving the practice/therapy or recommend no further action.



SUMMARY
SEaRCH is a systematic, rigorous methodology for evaluating unusual and novel claims for improving health. Through its iterative protocol driven process SEaRCH can critically evaluate and triage the multitude of claims for healing, and select the ones with the most capacity and promise to make a difference for community and global public health. The consumer medical and health services communities will benefit from SEaRCH because resources and efforts can be focused on the CAM practices with the greatest validity and most promise. An expanded rapid through put capacity will enable SEaRCH to widely serve the heath care community and become the standard approach for evaluation of CAM therapies.

Submitted by
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Vice President of Public Affairs,
Association of Clinical Research Organizations
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Members of the Council, thank you for the opportunity to speak with you today.
My name is John Lewis. I am Vice President of Public Affairs for the Association of Clinical Research Organizations, ACRO. Our members have more than 70,000 employees who are involved in research in more than 60 countries around the world. Working primarily for pharmaceutical and biotechnology companies that sponsor clinical trials, ACRO companies perform a wide range of activities, from providing assistance with study design through regulatory submission, across the spectrum of clinical trials, from phase I first-in-human studies through phase IV post-market evaluations. In addition to clinical trials, our members' expertise includes: health services research; patient registries; safety surveillance and other public health activities; data management, analysis and reporting, biostatistics; and the topic at hand today, comparative effectiveness research.

I would like to make three points:

First, to generate the maximum impact from the research dollars allocated by the American Recovery and Reinvestment Act (ARRA), we should use as much currently available data as possible as the basis for comparisons between alternative treatments. This includes Phase IIIb and Phase IV studies that use active comparators, and are reported to the FDA today, as well as a wide range of other data sources; from electronic health record systems to health care claims databases, and databases of various government health plans such as CMS and Veterans Affairs. Special attention should be paid to the methods and standards used to aggregate, analyze and report this data. In allocating ARRA funds to this endeavor, priority should be given to organizations with a successful and demonstrable track record of working with large of amounts of data from disparate sources.

Second, when meta-analysis of existing data is an insufficient method to reach the desired research endpoint, new clinical trial designs are needed. As research organizations that specialize in complex trial design, we would be pleased to participate in any effort to establish the

methodologies and standards by which these trials are conducted and to carry out these important and complex trials.

Third, because expertise on CER resides in both public and private entities, every effort should be made to encourage public-private collaboration in the design, conduct, analysis, and reporting of CER. We believe such collaboration should extend to include research sponsors, patients, providers and other stakeholders. We realize that the composition of this Council was established by legislation and did not provide for the inclusion of industry representation. Nevertheless we urge the Council to seek the required expertise to carry out this research whether in private, government or academic settings.

ACRO currently participates in the FDA's Clinical Trials Transformation Initiative, the NIH Biomarkers Consortium and several other similar collaborations and we could envision a similar collaborative process working in this regard. In the Biomarkers Consortium, for instance, one of our members, Quintiles Transnational, is playing a lead role in statistical and data analysis on a project involving the review of existing clinical trials data for a specific metabolic disorder.

As global leaders in clinical research, ACRO members are well suited to aid in the design, conduct and analysis of CER. We stand ready to work with all the stakeholders – pharmaceutical and biotechnology companies, academic and other researchers, patient groups, prescribers, payers, and government agencies – in shaping and executing a CER portfolio that will promote continued innovation in drug development rather than limit it.
Thank you.

About ACRO

The Association of Clinical Research Organizations (ACRO) is the professional organization of companies whose focus is clinical research. The association provides an active voice for the CRO industry, which provides specialized services that are integral to the development of drugs, biologics and medical devices. ACRO helps its members improve the quality, efficiency and safety of biomedical research. ACRO member companies employ more than 70,000 professionals worldwide. For more information, please visit www.acrohealth.org

Submitted by
James B. Couch, M.D., J.D., FACPE*
Managing Partner & Chief Medical Officer
Patient Safety Solutions, LLC
[personal information redacted]

I would like to thank all the members of the Council for providing me with the opportunity to address you today. As a physician-attorney who has devoted his career to improving patient safety and healthcare quality, I would like to discuss briefly the potential medical legal implications of the scientific findings deriving from comparative clinical effectiveness research.

The Potential Liability and Risk Management Implications Deriving from the Results of Comparative Clinical Effectiveness Research

Many physicians may find it controversial enough that the results of comparative clinical effectiveness research may impact their future reimbursement. This controversy could intensify if the results of these studies could be taken into account in liability actions, also.
What potential legal weight might the results of these studies have in liability actions? What would these studies need to have taken into account in arriving at their conclusions for a physician to be able to use adherence to them as a shield? What would need to be taken into account to permit the other side to use them as a sword against physicians for not following them (or even for following them resulting in a bad outcome)?
A close cousin to comparative clinical effectiveness research (controlled clinical trials) has carried varying degrees of weight in medical liability actions in the past. As the standard of care has slowly evolved from local determinations of "what would a reasonable physician have done under similar circumstances" to what is the recognized best evidence based practice(s) to employ, the results of these studies have acquired more heft in liability actions.
Comparative clinical effectiveness research will likely be somewhat similar in its evolution and probable applications in medical liability actions. What may well turn out to be different about comparative clinical effectiveness research are at least two things:

- Reimbursement (in whole or in part) may turn in the future upon proof of following the recommendations deriving from this research; and

- To get their results into the mainstream more quickly and cost effectively than the very expensive and time-consuming controlled clinical trials), comparative clinical effectiveness research may be conducted through the analysis of large electronic databases to link certain practice patterns with superior value clinical outcomes.

Especially in the case of studies whose results are produced by the analysis of large clinical databases (often derived from the use of electronic medical records), there would need to be certain safeguards built in to ensure fairness and accuracy in using the fact of adherence or non-adherence with best practices as a basis for liability or exoneration. Some of the factors that would need to be taken into account during these studies when applied to demonstrate potential negligence (or lack thereof) for not following their care recommendations would be:

- **Pre-treatment Severity of Illness**: Did the plaintiff in a particular action exhibit a comparable clinical condition and severity of illness to those in the study whose results are being introduced either as a sword by the plaintiff or a shield by the defense?

- **Statistically Significant Conclusions:** Were there enough patients in the samples comparing interventions to be able to conclude with an acceptable level of statistical significance that the variations in clinical outcomes were due to the differences in the interventions and not due to chance?

- **Impact of Other Clinical and Non-Clinical Factors:** Were there other countervailing factors occurring during the comparative effectiveness studies other than the interventions being evaluated (e.g. preventive measures, lifestyle changes, environmental influences, etc.) which were not sufficiently "teased out" of the analysis of the results so as to open to question the conclusions for recommending one specific intervention over another?*

As these comparative effectiveness studies begin to be conducted and their results disseminated, it will be important that physicians know the extent to which they may be able to rely upon them as an affirmative defense in medical liability actions. It will also be important for these studies to be carried out with the above considerations in mind to ensure that their results may be judged as fair and accurate to provide assurance that following their care recommendations will meet or exceed the standard of care.

I thank again all members of the Council for providing me the opportunity to make this statement to you on this historic day for those of us who have devoted our careers to improving the quality and safety of healthcare.

***The foregoing three bullet points have been excerpted from an upcoming online article to appear in the April, 2009 edition of "Risk Review" copyrighted by the Princeton Insurance Company (http://www.princetoninsurance.com)**

Submitted by

[personal information redacted]

Introduction and Summary

The primary message of this statement is the importance of including addiction and mental disorders in the scope of work supported by comparative effectiveness research. The basic comparative effectiveness question for these conditions is to understand the cost and quality implications to the overall health system of continuing to under treat both conditions in systems that are siloed and distinct from mainstream health and health care.

The role of comparative effectiveness research in reforming our health and health care systems depends in part on the scope of the research that is undertaken. This statement supports that the Council consider a broad scope of comparative effectiveness research. Specifically, the Council should consider the relative effectiveness of research on policy, the organization, financing and delivery as well as the prevention, treatment, and recovery of addiction and mental disorders. Including both addiction and mental illness in the scope of your consideration is essential to achieving the goals of health reform for two reasons. First, the prevalence of addiction and mental disorders suggests that other health conditions and illnesses coexist in large segments of the population. Experience as well as empirical evidence suggests that positive outcomes for general medical and other chronic illness requires in part simultaneous treatment of addictive disorders. Second, the cost of untreated addiction for our health care system is significantly more than the cost of extending treatment for addiction disorders and the same holds for mental disorders.

Policy Research

While there are many public policies that impact addiction disorders, most are not health policies but found in such areas as criminal justice, housing, transportation, etc. The basic policy question for comparative effectiveness research is the impact of recognizing addiction disorders as preventable and treatable health conditions. Can we weigh the relative cost and impact of extending treatment to the 90% of 23.6 million people affected who do not receive any treatment, but represent more than 70% of people incarcerated in correctional facilities at state and county levels? For the 6% of adults with serious mental illness, is community based comprehensive care a more efficient, humane, and effective form of care than warehousing in

county corrections facilities that result for example in Los Angeles County jail being the largest 'mental institution' in the US today. In this case, before we can look at the relative effectiveness of one treatment versus another it is essential to understand the relative effectiveness of investing in making treatment available through insurance and or public mechanism versus the effect and cost of leaving 90% of those with addiction disorders untreated.

Organization, Financing, and Delivery of Addiction Prevention, Treatment and Recovery Services

Others have noted the gap in health care that exists between what we know that works, and what is actually used to promote well being. Experience and some research suggests, that the latest evidence based interventions are underused, less often because of a lack of technical knowledge, and more often because the organization, delivery and financing of these interventions represent barriers to the adoption and use of proven practices. Understanding optimal designs for the organization, delivery and financing systems that promote the use of what science tells us works, is critical. For example, The Network for the Improvement of Addiction Treatment (NIATX) represents an empirically established approach to improving efficiency, eliminating redundancy, and streamlining systems that provide access to and delivery of effective interventions. The Council should consider the relative effectiveness of approaches to delivery system improvement and change as part of the scope of your work.

Preventing, Treating and Supporting Recovery

Empirical based interventions are available to prevent, treat, and support recovery from addiction disorders. These standards, backed by controlled and peer reviewed research, unfortunately compete with a wide range of practices, beliefs, traditions and philosophies used in many contexts to prevent, and treat addiction. The NQF standards should be a foundation from which analysis of addiction treatment interventions are examined. In addition, greater understanding is required for the relative prevalence and applicability of 'natural or self directed' recovery processes. Finally, while pharmacology and behavioral therapies together offer great promise for managing addiction disorders, their development and market use is hampered by perceptions of 'poor market potential' at this time. The comparative effect of accelerating the development of these and other new interventions is a critical area of investigation.

Submitted by
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President & CEO
National Hispanic Medical Association
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Chairman and Committee Members, I am Dr. Elena Rios, President & CEO, the National Hispanic Medical Association, a non profit association in Washington, DC representing Hispanic physicians. The NHMA mission is to improve the health of Hispanics and other underserved. The NHMA supports policies that will reform public health and medical services to decrease health care disparities and improve health status of Hispanics and other vulnerable groups.
The Unequal Treatment Report highlights the recommendations needed to decrease health care disparities – educate the leadership about health care disparities, diversify the health care workforce, expand cultural competence training, expand data collection with racial/ethnic and

language variables and support research on the system's responsiveness to minority populations – access, utilization patterns, performance measures, innovation, and "collecting data on race, ethnicity, and language of preference is a quality of care as well as a civil rights issue."
Evidenced-based public health and medicine strategies are necessary to decrease variation of service delivery that impacts and rations care to Latinos, especially in our poor neighborhoods. We know from the annual AHRQ National Health Care Disparities Reports that our community has the worst access and quality care compared to non-Hispanics in the nation.
The U.S. is facing a tremendous growth of the diversity in the population. According to the Census Bureau, by 2042, one out of four Americans will be of Hispanic origin. We support the Obama Administration deliberations to help shift health care delivery based on increased services for acute and chronic disease to a systemic approach with integrated care in a region that is responsive to its population and focuses on prevention first. Medical treatment should be based on comparative effectiveness value of treatment strategies that produce the greatest benefit for the Hispanic community at the lowest cost.
We recognize that comparative effectiveness research is about value in health care. According to the report, HHS in the 21st Century, "assessments of value should include measures of both individual and societal costs and benefits that result from research on prevention and treatment as well as methods of organizing, delivering and paying for services."
Yet, despite this research being supported by the federal government over the past several years, we recognize there have been alarms sounded - the Congressional Black Caucus says beware of producing information for ' a one size fits all' approach that could decrease access to treatments for minority patients; and Amgen and Johnson and Johnson in the HHS in the 21st Century report cautioned that cost comparisons could lead to increased costs and rationing care.
However, we believe that comparative effectiveness research will add to the body of knowledge for reducing health disparities for 1) physicians to use to improve quality care for patients; as well 2) for administrators to use to improve health systems of delivery in the following priority areas:

1. Cultural competence and health literacy research in order to ultimately change behaviors and improve lifestyle in our communities
2. Effective ways of communicating with Hispanic patients and their families
3. Knowledge about health disparities interventions between hospital systems and clinics that have longstanding experience with Hispanic physicians and their patients
4. Innovative research targeted to Hispanic patients and their families
5. Integrated care that is outcomes based – and with mental health and oral health as well as physical health

Besides supporting comparative effectiveness research studies, there is a need to develop the mechanisms to share the research results with our minority provider community. HHS could lead the development of public private partnerships with Hispanic health care professionals and community based leaders about rewarding caregivers or showcasing providers who deliver high value care to Hispanics and to increase Hispanic physicians and others to participate in focus groups to develop mechanisms for information dissemination to providers in our communities. HHS should take this opportunity to develop Hispanic health professional researchers by targeting the untapped pool of Hispanic health professional students and residents and graduate students interested in serving in their communities.

Lastly, given the growth of the Hispanic population, there is a need to create regional areas for Hispanic health research and follow the health care decision-making in the health systems.
For more information, contact NHMA – 202-628-5895

Submitted by
Eunice K. M. Ernst CNM, MPH, DNSc(hon)
Mary Breckinridge Chair of Midwifery
Frontier School of Midwifery and Family Nursing
[personal information redacted]

Who is proposing this research project?

The Frontier School of Midwifery and Family Nursing (FSMFN), American Association of Birth Centers (AABC), Duke Clinical Research Institute (DCRI) and Orases Consulting Corporation (OCC) have collaborated to develop a methodology for a study of optimal birth and an online registry of obstetrically uncomplicated pregnancy, labor, birth and postpartum/newborn care outcomes and the practices applied in achieving those outcomes. FSMFN is dedicated to educating nurse-midwives according to the best available evidence for collaborative practice in all birth settings. AABC is dedicated to developing a seamless experience for mothers within a system in which the institutions and care providers effectively collaborate to offer high quality, evidence-based maternity care. DCRI, consultants for the project, plan to establish the first registry on "normal" birth for comparative research by any researcher seeking such a data set. OCC, specialists in computer systems design, provide programming for the web-based data collection and reporting, system maintenance and technical support. The work to date has been conducted by volunteers with minimal funding from the AABC and FNS foundations for computer services.

Who will participate in this study?

All types of providers of maternity care services practicing in all settings are invited to participate in the proposal for a study of optimal birth. To date, 68 clinical sites that include midwife and physician collaboration in home, birth center and hospital sites have agreed to participate and over 22,000 childbearing women have been entered into the data base. When fully implemented, it is estimated that 200 sites will be participating.

The study instrument includes a profile of the practice and site, demographics of the mother, a description of the care that was provided, the outcomes of that care and the level of the mother's satisfaction with her care. It is available for review at www.birthcenter.org. Over the past four years the instrument has been developed and beta tested. A pilot study of five sites by a doctoral student at the FSMFN is currently under way to further test reliability and validity of the data. Funding for the full implementation of the project is being requested.

Why is this study important?

This study is needed to provide current information for policy decisions, removal of barriers to implementation of the midwifery model of care, and the importance of educating for collaboration within the professions and institutions providing that care. Although the outcomes

and cost benefits of nurse-midwifery care in a variety of settings have been reported over the years, a current, comprehensive, prospective study of comparative practices that led to improved outcomes is lacking. This study is designed to provide current information on what constitutes optimal birth and how it may be best achieved.

The hypothesis is that optimal birth is best achieved when the mother makes an informed choice based on the best available evidence about her birth environment, primary care provider and family or other support personnel; participates in the decisions made about her care and medical intervention; and when midwives, obstetricians and nurses work collaboratively to focus on the individual needs of each woman and family they serve.

Background

Eighty years ago the Frontier Nursing Service (FNS) demonstrated that nurse-midwives could provide a model of care in a remotely rural, underserved area that was safe, satisfying and cost effective. In fact the care provided by FNS nurses resulted in such a dramatic improvement in maternal and newborn outcomes that the Metropolitan Life Insurance Company on analysis of the data recommended that the FNS model of care be adopted nation-wide. For the past eight decades, nurse-midwives, as primary care providers referring to obstetrical specialists as medically indicated, have continued to document improved maternal newborn outcomes at lower cost but midwifery has not yet been fully integrated into our health care system.
Now, well into the first decade of the twenty-first century The Cochrane Review of reliable research on maternity care world-wide, has recently reported that all women should have access to, and be encouraged to use, midwifery led units. Midwifery is the gold standard of primary care in the 29 countries with better infant mortality rates than seen in the United States.

Therefore it is relevant in this time of change to ask – why, when there is so much evidence supporting the health and cost benefits of midwifery care do we continue to educate so many surgeons and minimally support midwifery education while expressing concerns about rising Cesarean Section rates that increase costs without any significant improvement in birth outcomes? Why alternative measures for pain relief are not available to all laboring women such as hydrotherapy, choice of positions, or self administered Nitrous Oxide which is a proven safe, affordable and effective method of pain relief in labor that is being used in all settings in other countries across the globe but only available in the United States in a few teaching centers? It could be said that we have marginalized the basic needs of the majority of healthy women anticipating an uncomplicated childbirth experience by exposing them to routines designed for women with complications of labor and birth who need acute care services.

Policy implications for activating change

Workforce development

To educate a nurse-midwifery workforce in the United States we have relied on an adequate supply of nurses. Although enrollment in these education programs is up, we would benefit from offering to our unemployed young people a program like the Cadet Nurse Corp that was introduced during WW II under “the Bolton Act”. It would serve to more rapidly prepare to meet projected demands not only for childbearing women for an aging population.

We should teach evidence based midwifery instead of obstetrics in all nursing and medical schools so that students receive an evidence-based orientation to the care of the majority of women rather than a disease and fear-based orientation to the minority of women experiencing this essentially normal life event. This is a better foundation for basic students making career choices for specialization.

It has become clear that nursing may not be the only pathway to midwifery education. To expand the midwifery workforce that this study will indicate is needed, education, certification and licensure for direct entry to the profession needs to evaluated, standardized and barriers removed.

Removal of existing barriers

We cannot produce midwives if we do not have access to clinical training sites. It is a strange paradox that we import foreign trained physicians to fill obstetric residency programs here to focus on the pathology and surgical intervention of child birth while midwifery students increasingly are sent to foreign lands for clinical experience. To bring the ratio of midwives to obstetricians in balance with the ratio of the estimated 80 percent of healthy women giving birth to the 20 percent needing medical or surgical intervention and to meet the staffing needs of clinical teaching sites, we must look at directing tax dollars to fund midwifery and obstetric residency programs to match the women served, residencies that include instructing these two very different professional groups to work together to bring their individual talents to the care of each woman served.

Autonomy in practice and payment for services

Autonomy in practice and equitable payment for services must be assured. To pay a midwife 65 percent of the payment afforded physicians for the time and education intensive care that improves maternal and newborn outcomes is discriminatory. Midwives must be paid as any other licensed primary care provider and birth centers must be paid like any other health care facility. Midwifery-led units like birth centers should be included in the formation of the “health care homes”. Midwifery and advanced practice nursing units established as a seamless part of a collaborative health care system would greatly improve access to quality care in both rural and urban underserved areas.

Conclusion

Although this represents a paradigm shift, there is no better place for beginning reform for efficient utilization of the health care system than providing midwifery time and education-intensive care to expecting mothers when they are most open to learning family health improvement measures. Mothers provide much of the primary health care to their families and are the major decision makers for when, where and to whom they will entrust their family’s medical care needs. The cost of birth continues to rise. The current gap between maternity care practices and the available evidence is widening. Evidence-based collaborative midwifery and obstetrical care is an important part of the solution for reducing costs, expanding access to quality care and improving the birth outcomes. It must continue to be evaluated as it develops. A normal birth registry and a study of optimal birth is a step in the right direction for achieving that

end. Without this paradigm shift, it is doubtful that the United States will ever reach its goal of optimal health outcomes for all mothers and babies.

Submitted by
Theresa Morgan, Legislative Assistant
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The Consortium for Citizens with Disabilities (CCD) believes that comparative effectiveness research is, and should continue to be, an important tool in helping patients and providers distinguish between the effectiveness of both existing and emerging treatment options. Having better evidence to support the clinical effectiveness of a wide range of health care interventions has the potential to lead to improvements in the quality of care and could potentially maximize the impact of the health care dollars spent in this country.

CCD, a coalition of national disability-related organizations, urges caution, however, to pursue comparative effectiveness research in a manner that does not lead to inappropriate restrictions in coverage of and access to assistive devices, therapies, treatments, medications, and long term services and supports for people with disabilities and chronic illnesses.

Many of the assistive devices, technologies, and therapies used by persons with disabilities to be functional and live independent and fulfilling lives have widespread application and are generally accepted by physicians and other health care professionals. Because many of these devices and technologies do not have to undergo the rigors of FDA review, the formal evidence base for such treatments may be less developed than other areas of health care.

With respect to all devices, therapies, and medications, it is important to recognize that disability conditions vary widely in severity and complexity. There are often multiple comorbid conditions in play and many disabilities are low prevalence, making specific and meaningful clinical effectiveness studies challenging to pursue. Ethical questions and other factors often make double-blind clinical trials in this area non-viable. Even well-grounded research on the general population can be easily misapplied to the disability and chronic illness populations, especially persons with intellectual, behavioral and cognitive disabilities.

In fact there are many potential applications of comparative effectiveness research to areas other than acute care medicine such as long term services and supports for these populations. It is critical that the outcomes of such research are not misapplied or used to broadly establish coverage rules that trump an individual's circumstances and specific needs.

For these reasons, the CCD believes that comparative effectiveness research is not a substitute for the clinical judgment of the physician or health care professional in consultation with the patient. In the absence of double-blind clinical studies, due consideration should be given to reliable observational studies and consensus medical opinion, along with the clinical judgment of the health care professional. This is particularly important for people with complex, disabling, or chronic conditions.

Comparative effectiveness research is very important and has the potential to bring down health care costs over time by improving the quality of care. CCD supports the pursuit of comparative effectiveness research as long as there are meaningful protections to prevent inappropriate restrictions in coverage of and access to health care and long term services and supports for people with disabilities and chronic conditions.

Submitted by
Richard W. Olson
Director, Federal Government Affairs
AstraZeneca Pharmaceuticals
Washington, DC
[personal information redacted]

AstraZeneca Pharmaceuticals LP (AstraZeneca) is pleased to submit the following comments on comparative effectiveness research priorities in the American Recovery and Reinvestment Act to the Federal Coordinating Council (FCC) for Comparative Effectiveness Research (CER) in advance of the public listening session on Tuesday, April 14, 2009.

AstraZeneca is a leading global healthcare company dedicated to the research and development of new medicines in therapeutic areas including cardiovascular, gastrointestinal, oncology, respiratory, and neuroscience. AstraZeneca is committed to the discovery of drugs that will allow patients to lead longer, healthier and more productive lives, and to supporting scientifically robust research that improves the delivery of effective, high-quality care to patients. AstraZeneca is also committed to patient health; including helping ensure that patients have access to the most appropriate therapies in the most appropriate setting.

Healthcare reform is a top priority for our nation's policy makers. AstraZeneca believes that today's discussions – whether about healthcare coverage or healthcare costs - are important steps toward enhancing patient health and improving the quality of healthcare in the United States.

AstraZeneca believes CER, the comparison of one diagnostic or treatment option to one or more others, is an important component of healthcare reform. The goal of CER is to conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk and benefits of two or more medical treatments and services that address a particular medical condition. CER offers the promise of improving healthcare quality and outcomes by making it easier for patients and their doctors to choose the best treatment or treatments through evidence-based decisions. Yet, given today's financial challenges and political dynamics, AstraZeneca is concerned that CER could be used to deny coverage or reduce payments for interventions, thus limiting patient access to treatment options.

At AstraZeneca, we are committed to ensuring that patients and their health care providers have the best information available to support their decisions regarding treatment. In support of that commitment, we have been, and continue to be, engaged in CER activities. To ensure patients and their health care providers receive the most value from CER, AstraZeneca is proud to share the principles that guide our discussions related to this issue:

Outcomes First

Focus on improving individual patient outcomes rather than short-term, population-based cost control.

Drive, Not Limit Innovation

Encourage the development of innovative healthcare interventions and not be utilized as the sole rationale for product approval, coverage, pricing, or reimbursement decisions.

Research Across All Interventions

Employ rigorous, transparent research methodologies applied across the range of healthcare interventions and treatment modalities.

In addition, AstraZeneca believes:

- The current decentralized approach to conducting CER in public and private settings has yielded highly useful information in an efficient manner. If CER is centralized, it should be a public/private partnership, funded from both public and private sources, focus on the patient, and be distinct from any organization making coverage and policy decisions.

- Funds applied to CER should focus on diseases where there is a significant burden to the patient and the health system. For example, the impact of providing better care to patients with chronic diseases such as diabetes, asthma and heart disease, could be profound if the breadth of research includes comparative benefit designs, prevention programs, delivery systems and medical and behavioral interventions.

- CER offers the promise of improving healthcare quality and outcomes by making it easier for patients and their doctors to choose the best treatments.

- CER, when focused on clinical-effectiveness and not short-term cost-effectiveness, will encourage the development of innovative interventions.

AstraZeneca thanks you for the opportunity to comment on CER. We look forward to continuing to engage in a thoughtful dialogue around this important component of the future of our healthcare delivery system in the US. If you have any questions, please do not hesitate to contact Christie Bloomquist at (202) 350-5545 or Christie.Bloomquist@astrazeneca.com or Brian Maloney at (202) 350-5542 or Brian.Maloney@astrazeneca.com.

Submitted by
Winifred S. Hayes, RN, MS, PhD
President and CEO
Hayes, Inc.

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Dear Sir or Madam:

The following is being submitted on behalf of Dr. Winifred S. Hayes, President and CEO of Hayes, Inc. Hayes, Inc. is a leading provider of evidence-based health technology assessments that serves health plans, government agencies, hospitals, health systems, and consumers. Hayes also provide consulting services to help these same constituents put our research into action to improve patient care and outcomes. Today, Hayes clients serve over 200 million consumers and patients.

Statement of Dr. Winifred S. Hayes:

To the Federal Council for Comparative Effectiveness Research:

You asked the American public to share potential solutions for our current healthcare crisis. Thank you for opening this dialog and your willingness to include all citizens to help improve America's healthcare system.

I have worked in health care for nearly 40 years, as a nurse, an educator, a researcher, and in the healthcare business sector. Twenty years ago, I founded Hayes, Inc., a health technology assessment company that provides evidence-based research reports on new, emerging, and controversial health technologies to health plans, government agencies, hospitals, health systems, and consumers. We also provide consulting services to help these same constituents put our research into action to improve patient care and outcomes. Today, our clients serve over 200 million consumers and patients. In the interest of transparency and disclosure, I have a vested interest in the synthesis, dissemination, and application of the expanded base of clinical evidence that would be created under Stimulus Act funding provisions. As such, I am fully committed to improving the safety and quality of healthcare through decisions grounded in evidence. This is my passion, this is my mission, and I believe this is the cornerstone of any meaningful healthcare reform efforts.

With my front-row seat in healthcare, I have thought a lot about why our health care system lags other developed nations. The factors that follow, I believe, are among the most important:

- Failure to effectively and efficiently integrate scientific evidence into healthcare decision-making, resulting in overuse, misuse, and even (in some instances) underuse of health technologies.
- Insufficient, and in many cases poorly designed and executed, comparative effectiveness and cost effectiveness research.
- Adoption of newly-approved technologies before evidence supports it, which contributes to spiraling healthcare costs without commensurate improvement in patient care.
- Perverse financial incentives that drive premature dissemination of new medical technologies even when they do not improve patient care or outcomes.
- Lack of efficient and effective methods to keep clinical practitioners up-to-date on "best evidence" and "best practice" at the time of need.

- A consumer population that is largely overwhelmed with navigating the health care system and finding the right evidence-based resources to make the best health care decisions.
- Uneven and untimely health care access and quality.
- Continued erosion in employer-sponsored health insurance.
- Insufficient focus and allocation of resources to health promotion and disease prevention.

I believe that the comparative effectiveness funding provided for in the Recovery Act (ARRA) will help to stem the tide of rising healthcare costs and will provide research that is sorely needed for payers, providers, and consumers to make better healthcare decisions. To maximize the impact of this funding, I believe the council must focus on primary comparative effectiveness research. There are a number of private sector entities, including Blue Cross Blue Shield Association's TEC Program, Federally-funded Evidence-based Practice Centers, and my firm, Hayes, Inc. that are already positioned to help payers, providers, and consumers synthesize existing and new evidence and integrate the resulting conclusions into the healthcare decision making process. If the Federal Government ultimately assumes the primary role for synthesis of evidence, it will short-circuit these private sector initiatives, add a layer of bureaucracy to the system, and politicize the process.

With this as a backdrop, the following are my recommendations to make best use of the new Federal funding for comparative effectiveness research and improve acceptance and buy-in from the healthcare community at large:

- Coordination and prioritization efforts of the Federal Coordinating Council for Comparative Effectiveness Research must include the private sector in setting the research agenda. Questions about which treatments, technologies, medicines, and procedures to compare are best posed by the hospitals, universities, manufacturers, consumers, providers, and private research organizations that are at the front lines of healthcare.
- Let the private sector determine how to put the resultant clinical evidence into practice. As noted above, the private sector has already made progress in accomplishing this and I encourage you to build on this base. Federal involvement in putting research results into practice will be seen as a form of rationing.
- Create an environment where providers and consumers have access to the best available clinical evidence. Federal support of the dissemination of comparative effectiveness and cost effectiveness research findings, including digital and user-friendly ways to do so, is needed.
- Allow the private sector to respond to the improved evidence base in making healthcare decisions and avoid an expanded federal policy role that determines coverage and reimbursement beyond the current CMS structure. This approach will allow for public dialogue and solutions and will be less politicized and ultimately better accepted in the healthcare community.
- Encourage all healthcare-accrediting organizations to create standards that require the consideration of scientific evidence in healthcare decision-making. If a technology is adopted in spite of weak evidence, the standards should address a mechanism to evaluate the technology's impact on patient safety, clinical outcomes and comparative value, specifying patient indications and contraindications.

- Fund the creation of patient registries by the private sector. Consider incentivizing industry participation. Universal industry participation is essential if patient registries are to be successful.
- Facilitate public discourse around the meaning, role and importance of clinical evidence, clinical significance, utility, comparative effectiveness and cost-effectiveness as these terms relate to healthcare services, costs, benefits and, ultimately, the choices we make.

Implemented in this manner, the additional funding for comparative effectiveness research provided in the Stimulus Act will eliminate many of the healthcare industry issues I articulated at the start of this letter. I would welcome an opportunity to discuss these and other ideas and recommendations further and to support our healthcare reform efforts.

Submitted by
Stephen A. McFadden, M.S.
Independent Scientific Research Advocates
Dallas, TX
[personal information redacted]

There is a wide variation in the human xenobiotic (foreign chemical) metabolism pathways that is conserved across most advanced life forms on earth. These polymorphous pathways include the Cytochrome P-450s and N-acetylation, but, at least in humans, also lesser known pathways such as glucuronidation, methylation, sulfoxidation, sulfation, glycination, and esterases such as paraoxonase and pseudocholinesterase.

This genetic diversity in the metabolism of xenobiotic chemicals would not exist if it was not evolutionarily advantageous to species or populations as a whole.

A key point is that some metabolism pathways will not only detoxify toxicants, but they can also activate carcinogens. Thus, while some individuals may have a slow xenobiotic metabolism pathway--and may be more prone to toxicity buildup rather than carcinogen activation, others individuals have a fast xenobiotic metabolism pathway, which may reduce toxicity buildup but may tend to activate carcinogens and thus increase their risk of cancer. This wide diversity in individual metabolism guarantees that no matter what the toxic exposure, some individual or another in the population is likely to survive in order to preserve the genome.

In fact, this diversity is so great that if on were to add up all the "sensitive" subpopulations, they would probably include the majority of the population. To quote a former director of the U.S. National Institutes of Health (NIH): "Everyone is sensitive to something".

In short, the genetic diversity in individual metabolism of toxics by humans and animals provides robust protection for species and populations in the face of the ever changing environment which has existed on earth over the course of billions of years.

Given these genomics, it is "contrary to nature" to adversely select against individuals who bear genetics which benefit the species.

To paraphrase Sheldon Samuels of the AFL-CIO, failure to protect sensitive subpopulations is social, as opposed to natural, selection against those individuals. But in the case of those polymorphous xenobiotic metabolism pathways with a very high frequency in the genome, such social selection is also contrary to long term species survivability.

In the near future, technology will allow the inexpensive determination of individualized detoxicogenomic profiles, such as by using gene-chips. The National Institute of Environmental Health Sciences (NIEHS) Environmental Genome Project (EGP) has been studying the genetics of the xenobiotic metabolism pathways since 1992 http://www.niehs.nih.gov/research/supported/programs/egp/ and comparative toxicogenomic databases are now being created. http://ctd.mdibl.org/ This may soon allow personal biochemical analysis and individualized medical treatment to be provided at low cost.

We implore the Federal Coordinating Council (FCC) for Comparative Effectiveness Research (CER) to not use simplistic models in designing their research studies, that may provide results on the purported effectiveness of simplistic treatments that under a single-payer or socialized medicine economy instituted under health care "reform" in the U.S. may be used to severely limit choice of treatment to only those previously deemed effective on large groups, including the treatment choice of those with chronic illness that consequently face medical indigency.

Examples of some of the economic and political forces presently at work to constrain treatment choice include:

We have seen complaints about the British National Institute for Health and Clinical Excellence (NICE) report on Chronic Fatigue Syndrome (CFS) and Myalgic Encephalomyelitis (ME) being used to limit the treatments for CFS/ME patients in Britain to Cognitive Behavioral Therapy (CBT), Graded Exercise Therapy (GET), and psychiatric drugs. CFS and ME are in fact symptomatic aggregates of conditions with a diversity of causes, and the few approved treatments in Britain either do not work or are counter-productive in many cases. When combined with a single-payer health care system, this effectly results in denial of individualized treatment for at least medical indigents.

Similarly, in the U.S., we have seen the American Psychiatric Association (APA) re-writing the DSM-V psychiatric manual to try to enlarge the category of purported "somatoform disorders" to include about 15% of primary care patients which they label as having "functional somatic syndromes" such as CFS/ME and Fibromyalgia (FM), and to impute a psychological mechanism of "somatization" to their genesis, in order to try to apply "psycho-social" and psycho-pharmaceutical treatments. Further, the DSM is intended to be "harmonized" with the World Health Organization (WHO) ICD-11 medical coding manual, so that this expansion into medicine by American psychiatry may be promulgated worldwide.

We believe that these regressive efforts to psychiatrize the patients of numerous medical specialties and those who use alternative medical treatments are counter-productive, and are contrary to the progressive possibilities of personalized genetic and biochemical analysis and individualized medical treatment which may soon become possible through modern technology.

We urge the FCC-CER to lead the future towards increasing medical knowledge and improving individualized medicine, rather than to allow its research to be used to regressively promote the rationing of treatment choices for the masses in the name of purported cost savings.

Thank you.

References:

McFadden SA: "A Xenobiotic Metabolism Research Initiative: A Vision of the Future of Pharmacology and Toxicology". Public comment to the Review of the National Toxicology Program held at U.S. Health and Human Services (HHS) on September 11, 1992.

McFadden SA: Phenotypic variation in xenobiotic metabolism and adverse environmental response: focus on sulfur-dependent detoxification pathways. Toxicology. 1996 Jul 17;111(1-3):43-65.

Submitted by
[personal information redacted]

My name is [personal information redacted]. I am unable to attend Tuesday's session on Effectiveness Research and would like to contribute a written request prior to the session.

I am a physician trained originally in Internal Medicine. I subsequently gained further training in Integrative Medicine and Homeopathy as a way to address my patient's chronic disease conditions and to practice more holistically with an eye towards safety and disease prevention.

I would like the Council to include homeopathic treatment for both acute and chronic disease states in their research considerations. There are many studies which validate the effectiveness of homeopathic treatment for a wide variety of acute and chronic ailments including otitis media, diarrhea, fibromyalgia, flu, allergic rhinitis, rheumatic disease, mild traumatic brain injury, respiratory conditions, etc...Recently the UK has conducted a large scale public health project looking at the cost effectiveness of homeopathic treatment in primary care, since in Europe homeopathic medicine is much more widely prescribed and accepted. This study reflected favorably on homeopathic treatment and also showed marked cost-savings. In countries where socialized medicine is practiced, it is important to show efficacy as well as cost savings. Our medical educational system focuses almost exclusively (excepting in cases where surgery is indicated) on pharmaceutical approaches to diseases to the exclusion of homeopathic or naturopathic medicine. It was my patients who initially shared with me their experiences using complementary/alternative approaches and for that I am extremely grateful. I subsequently took it upon myself to learn more about these therapies, since there was little to no CAM education in the world of conventional medicine. As a primary care practitioner I was eventually able to treat most diseases more effectively resulting in far less toxicity than when I practiced purely pharmaceutical medicine. It is my sincere hope that we will see well- designed and coordinated clinical outcomes research projects performed in the upcoming years which include homeopathic medicine. The public is more aware than their providers in many cases and wonder why it is that

their physicians are not more educated about complementary, alternative, and integrative approaches to disease.

In the last several years I have been trained as an Improvement Advisor by the IHI and am intimately involved in Quality Improvement at my organization. I would like someday to put these QI/Outcomes research skills to good use in conducting such clinical outcomes trials using practice-based research networks that include homeopathic medical treatment. I am hopeful that this administration will pave the way to finance high quality clinical and community outcomes research using a variety of non-pharmaceutical approaches to both acute and chronic disease. I would be happy to provide references to the research studies that I referred to at the beginning of my email.

Submitted by
Daniel B. Fisher,MD,PhD
Steering Committee
National Coalition of MH Consumer/Survivor Org.
[personal information redacted]

The National Coalition of MH Consumer/survivor Org. would like to see NIMH research funds available for:
1. determining the comparative effectiveness of peer-run and peer-assisted crisis respite services as an alternative to psychiatric hospitalization.
2. research into the degree to which psychosocial, recovery-oriented community supports can reduce the use and cost of of medication.
3. Degree to which peer-run warmlines can reduce the use of emergency room and hospitalization by psychiatric consumers
4. Major psychosocial, and peer related factors involved in persons recovery from mental illnesses when used with medication compared to medication to medication alone as is being practiced in most locales now

Submitted by
Barbara Goldsmith, PhD
President, American Association for Clinical Chemistry

The American Association for Clinical Chemistry appreciates the opportunity to provide comments to the Federal Coordinating Council for Comparative Effectiveness Research in regards to how the Department of Human Services should allocate the $400 million in comparative effectiveness research funding it received under the American Recovery and Reinvestment Act of 2009. We believe this research is critical to gathering the evidence-based data on the utility of health services needed by health care providers to improve the quality of patient care.

AACC strongly supports the purpose of this Council, namely to coordinate the comparative effectiveness research (CER) activities of the federal agencies and to assist the Department in

prioritizing future research projects. We believe this approach can reduce overlapping initiatives among the agencies and lead to a more cohesive research agenda. Further, AACC applauds the Council's efforts to engage the health care community and public in this deliberative process. We believe this is important to ensuring that the selected research studies meet the needs of caregivers and relevant best practices organizations.

Although there are many worthy areas for research, AACC recommends that the Coordinating Council include Acute Coronary Syndrome, Heart Failure, Diabetes Mellitus and Cancer, particularly as they as apply to laboratory medicine, among its national priority areas. We think cardiac care, diabetes and cancer need to be addressed given the prevalence of the diseases and their impact on patients, families and the health care delivery system. Also, we recommend that the scope of CER include the evaluation of approaches to health care delivery and care management that foster effective application of personalized medicine.

AACC strongly believes that the Council must maintain the focus of CER on gathering and disseminating knowledge for improving clinical decision-making and patient outcomes rather than emphasizing its cost effectiveness aspects. AACC believes CER must not be used to restrict medical decision-making, hinder technological innovation or, most importantly, limit patient access to effective treatment options. We appreciate the opportunity to provide this input to the Council and look forward to working with you as this process moves forward.

AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists--and is the leading laboratory association in the realm of evidence-based medicine. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (617) 879-0267, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Submitted by
Dominic Hodgkin, Ph.D.
Associate Professor
Institute for Behavioral Health
Heller School of Social Policy and Management Brandeis University, MS 035
Waltham MA

To: The Federal Coordinating Council for Comparative Effectiveness Research
From: The Workgroup on Comparative Effectiveness in Behavioral Health, Institute for Behavioral Health, Heller School for Social Policy and Management, Brandeis University
We welcome the new administration's initiative to expand funding for comparative effectiveness research. This initiative has particular relevance to behavioral health care, the area where our own research is focused. It is relevant because behavioral health care (which includes mental health and alcohol and drug abuse treatment) has been particularly prone to some of the problems that comparative effectiveness research is intended to address. These problems include:

- Rapid provider adoption of costly new psychotropic medications, often in the absence of any head-to-head trials demonstrating their superior effectiveness over existing, less costly medications.
- Slow dissemination of certain other effective medications that are mainly used in public sector settings, e.g. naltrexone for alcoholism.
- Under-utilization of approaches with a strong evidence base, such as cognitive behavioral therapies.
- Persistence of non-evidence based practices, such as sub-therapeutic dosing of methadone.

We therefore encourage the Coordinating Council to make sure that some of the new federal funding is directed toward comparative effectiveness research in behavioral health care.
At the same time, we note that these studies will need to go beyond merely measuring 'average' effectiveness of a medication or treatment across the whole population treated. Previous studies have found that a given medication can have widely different effects across patients, which might be masked by an average effect. We are pleased to note that the enabling legislation takes account of this and calls for studies of subpopulations.
Targeting federal funding for comparative effectiveness research also offers the chance to compare treatments that have been relatively less studied, for example some psychotherapies that are less easily standardized across providers. In some cases this might involve comparing different ways of delivering a given treatment, e.g. web-based treatment versus traditional treatment with counselors.

Many behavioral health care purchasers and providers are frustrated with the current lack of knowledge, and eager to learn more about what works to help patients. They would be likely to act upon the findings that would result from future comparative effectiveness research, for example by disseminating information, removing institutional barriers, and redesigning incentives. In conclusion, behavioral health care may be an especially fruitful area for finding results with policy implications.

Members of the Workgroup on Comparative Effectiveness in Behavioral Health:
Dominic Hodgkin, Associate Professor (chair),
Constance Horgan, Professor and Director, Institute for Behavioral Health
Elizabeth Merrick, Senior Scientist
Gail Strickler, Senior Research Associate
Eve Wittenberg, Senior Scientist

Submitted by
Tony Coelho
Chairman
Partnership to Improve Patient Care

Dear Federal Coordinating Council Members:
As you convene the first of three meetings this afternoon to hear from the public concerning their views on the implementation of comparative effectiveness research (CER) under the American

Reinvestment and Recovery Act of 2009 (ARRA), I would like to express support of CER that is transparent, patient-centered and considers the broader body of evidence, the patient's individual needs and preferences, and the physician's clinical expertise.

The Partnership to Improve Patient Care (PIPC) was formed in November 2008 to support new comparative effectiveness research proposals that are centered on patient and provider needs, raise awareness about the value of well-designed CER and promote the important role of continued medical innovation as part of the solution to cost and quality challenges in health care.

PIPC members, representing a diverse, broad-based group of health care stakeholders, are dedicated to working together to promote CER that protects patient access to innovative treatment options; supports the ability of patients, doctors and other health care professionals to choose the care that best meets the individual needs of the patient; and, fosters continued medical innovation. Comparative effectiveness research can be a valuable tool to "learn what works in health care" and support good clinical decision-making. At the same time, such research can be misapplied in ways that restrict patient access to optimal care, undermine physician/patient decision-making, and discourage continued medical progress. Below is a list of PIPC Supporting Principles that we believe must be met to ensure that patients and providers interests remain paramount:

- Define CER as a tool to improve patient care;
- Enhance information about treatment options and about how to close the gap between care known to be effective and the care patients receive;
- Focus on communicating research results to patients, providers and other decision-makers, not making centralized coverage and payment decisions or recommendations;
- Provide information on clinical value and patient health outcomes, not cost-effectiveness assessments;
- Design studies that reflect the diversity, including racial and ethnic diversity, of patient populations and communicate results in ways that reflect the differences in individual patient needs;
- Assure that studies are technically excellent and appropriate;
- Require open and transparent processes where all stakeholders have input into research priorities and design and have an equal voice in governance of a CER entity;
- Examine all aspects of health care including care management, medical interventions, benefit design, and processes of care for all patients;
- Support continued medical advances, including personalized medicine and other advances that can help improve patient care and control health care costs;
- Recognize the unique nature and value of targeted therapies that benefit specific groups of patients with rare and orphan diseases.

CER has the potential to transform healthcare and better inform patient and provider decision-making. Focusing on improved quality is the best way to achieve a more sustainable and affordable healthcare system, and comparative clinical research can help us reach this goal. It is important to distinguish comparative clinical effectiveness research which focuses on health outcomes from cost-effectiveness research, which can be misused in ways that deny individuals access to the medical care that is best for them based on arbitrary cost thresholds. Working with PIPC, I will strive to make sure CER is centered on patient needs and does not become a basis for denying patients access to the care they need.
On behalf of PIPC's member organizations, I look forward to working with you to advance CER that improves the lives of all Americans.
Thank you for your consideration.

Submitted by
Christopher J. Krueger
Manager, Government Relations
American Urogynecologic Society (AUGS)
Washington, DC
[personal information redacted]

The American Urogynecologic Society (AUGS) appreciates the opportunity to provide comment to the Federal Coordinating Council for Comparative Effectiveness. AUGS is a health care organization comprised of clinicians and scientists dedicated to advancing research, education and patient care in the area of female pelvic medicine and reconstructive surgery. AUGS believes significant investment from the $1.1 billion in funds for comparative effectiveness research provided by the American Recovery and Reinvestment Act of 2009 should be granted to areas focused on pelvic floor disorders. AUGS is committed to ensuring that these investments would be well spent and would yield better patient outcomes.

Although pelvic floor disorders (PFD), including disorders of urinary and/or bowel control, and pelvic organ prolapse are common and costly, these conditions are relatively understudied. Of these disorders, urinary incontinence is the most common.

A recent report from the Pelvic Floor Disorders Network, funded by NICHD, and published in the *Journal of the American Medical Association* (JAMA) reports that pelvic floor disorders are common and serious conditions impacting women in America. This report sited that of the women who reported any symptoms of a pelvic floor disorder, 16% experienced urinary incontinence, 9% reported fecal incontinence and almost 3% had symptoms of pelvic organ prolapse. These numbers increased with age with half of all women over 80 being affected. One out of 11 women will undergo surgical treatment for pelvic organ prolapse and urinary incontinence in her lifetime. In February another study was published in the *New England Journal of Medicine* that demonstrated that weight loss resulted in a 47% drop in weekly incontinence episodes. These findings confirm that weight loss can be considered a first-line treatment for women with incontinence. These two articles demonstrate that there are so many things we are still discovering about these conditions and additional research funds need to be allocated to encourage further investigation and education of these disorders that are associated with depression, isolation, and decreased quality of life.

There are three key areas where we believe comparative effectiveness research could identify treatments that would yield better outcomes and care for women who suffer from pelvic floor disorders.

Stress Urinary Incontinence

Improvements in surgical treatment of urinary incontinence will improve the quality of life for American women and reduce associated health care costs. Surgery for treatment of stress urinary incontinence (SUI) is common and increasing, with 135,000 surgical procedures done in the US, an approximately 45% increase from 1988[1]. Ongoing efforts to select the most appropriate initial surgery and comparative trials to compare surgical therapies to non-surgical treatments, including pelvic floor exercises are needed.

Approximately 10-40% of women have recurrent or persistent SUI after a continence procedure and therefore re-operation rates after surgery for urinary incontinence are high, with at least one third of women undergoing repeat surgery during her lifetime [2,3]. Few data are available to guide surgical treatment of recurrent or persistent SUI, although it is commonly accepted that repeat continence procedures are associated with higher failure rates and that failure rates increase over time[4-6]. Comparative effectiveness trials are urgently needed to guide the care of women with persistent or recurrent SUI.

The NIH has invested in comparative effectiveness trials for women with uncomplicated SUI. The NIDDK Urinary Incontinence Treatment Network recently reported in the SISTEr Trial that cure rates after continence surgery are considerably lower than previously reported[7]. Unfortunately, only a small minority of women in this trial had undergone a prior continence surgery: 13% in the sling group and 15% in the Burch group. A second comparative effectiveness trial has just completed enrollment, but given the similarity in inclusion/exclusion criteria, it is likely that the network will enroll a similar percentage of women with recurrent or persistent SUI after a prior continence procedure.

Therefore, despite the high incontinence prevalence rates and high re-operation rates, there are no adequately powered randomized trials investigating the optimal method for treating SUI in this population of women. Without advanced understanding of the consequences and optimal surgical strategies for SUI, treatment in this important area of women's health is advancing slowly.

Prolapse Surgery

Three to six percent of women will develop pelvic organ prolapse during their lifetime, with half reporting significant impact on her quality of life secondary to the prolapse[8]. Surgical therapy is the gold standard for the treatment of pelvic organ prolapse. Pelvic organ prolapse is the main indication for hysterectomy in women over the age of 50. In 1997, approximately 225,000 surgeries were performed for pelvic organ prolapse in the United States with a direct cost of $1.12 billion dollars[9].

While numerous surgical options are available, relatively few comparison studies have been performed. In a recent Cochrane review, only 22 studies of significant quality and follow-up could be included in the review. Astonishingly, these 22 studies included less than 3,000

patients to compare the effectiveness of different surgeries for pelvic organ prolapse[10]. Many more studies with adequate power are needed to determine the best surgical procedures. Randomized trials with long term follow-up to access cure, risks for failure, and complications are drastically needed. Without comparative effectiveness studies, women and their surgeons do not know the best procedures to perform to help relieve women of this common health problem.

Randomized Trials and Mesh Registry

In an attempt to improve surgical repairs of pelvic organ prolapse, many surgeons have begun the use of vaginally placed mesh to strengthen the native tissues. Currently very little data exists to support this treatment option, yet its use is growing in popularity. The use of mesh adds cost and potential complications to the procedure, with little data to support improvement in outcomes or reduction of surgical failures. We are very interested in accessing comparative effectiveness research dollars to support randomized surgical trials and/or for the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data.

The medical community would benefit greatly through the creation of a patient registry that tracks the use and effectiveness of surgical mesh for the treatment of pelvic organ prolapse and stress urinary incontinence. The collection of pre- and post-market data is key to understanding why mesh erosions occur and what can be done to eliminate the risk to patients.

Establishing a national registry is a large project and one which can not be done by one organization alone. AUGS would like to work with NIH and partner with the FDA and CMS to create a mesh registry that improves outcomes while saving patients from medical complications and the need to undergo multiple costly surgeries.

Conclusion

AUGS sincerely appreciates the support our members have received and the work we have been able to accomplish to date through government supported grants. Millions of women are impacted by pelvic floor disorders. Comparative effectiveness studies are needed to determine best practices and therapeutic options. Thank you for your attention to our requests and this important area of research in women's health.

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Submitted by
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Payment and Healthcare Delivery Policy
AdvaMed
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My name is Teresa Lee, and I am here on behalf of AdvaMed, the Advanced Medical Technology Association. AdvaMed represents the medical device and diagnostics products industry, and our members produce nearly 90 percent of the health care technology purchased annually in the United States.

We greatly appreciate the opportunity to comment today on HHS's implementation of comparative effectiveness research funds allocated to AHRQ, NIH and the Secretary in the American Recovery and Reinvestment Act of 2009. We have comments on three subjects today: (1) transparency and stakeholder input; (2) selection of the comparative effectiveness research priorities; and (3) content of the research topics.

Transparency and Stakeholder Input

First, regarding transparency and stakeholder input, we have been pleased to hear of the Obama Administration's strong commitment to "openness and transparency," particularly in relation to operations around comparative effectiveness research and that the Council "looks forward to hearing from all parties as it moves ahead." AdvaMed values the Council's conduct of this listening session today as a major first step in considering stakeholder input. In keeping with the Administration's emphasis on openness and transparency, we urge the Council to make public all of its meetings in order to keep the public informed of the priority-setting process, and to enable on-going input. Furthermore, we urge the Council to make its draft findings and recommendations available for public comment before they are finalized and submitted to the President and Congress. This approach will enhance the credibility of the Council's findings and recommendations by enabling fully informed decision-making with input from patients,

clinicians, health care providers, and scientific and clinical experts employed by manufacturers who have firsthand experience with how various topics would be relevant for clinical practice.

Selection of Comparative Effectiveness Research Priorities

Second, regarding comparative effectiveness research priorities, AdvaMed recommends that HHS first focus on efforts to improve the infrastructure for comparative effectiveness research. Using the Recovery Act funds to improve health services research workforce training would be one good way to lay the groundwork for any longer term efforts to bolster comparative effectiveness research. In particular, we think that sponsorship of interactive forums where comparative effectiveness grantees can work shoulder-to-shoulder with private sector researchers would be valuable so that these clinical and technical experts can learn from one another. Another priority area should be the development of improved pathways to translate research into practice. As you know, one study found that it takes 17 years on average for clinical research results to enter into mainstream practice. To ensure that comparative effectiveness research successfully advances practice, we should invest in developing better methods and tools to make sure that clinicians and patients understand and integrate research findings.

With respect to specific research subject areas, AdvaMed recommends that the comparative effectiveness research agenda be prioritized with a focus on areas that have major clinical significance and that will have the greatest impact on delivery of health care to patients in the United States. By way of example, chronic disease management and hospital-acquired infections and conditions represent significant comparative effectiveness research opportunities. Selecting comparative effectiveness research priorities along these lines would be consistent with the recommendations set forth by the IOM in its 2003 report "Priority Areas for National Action: Transforming Health Care Quality." From a public health standpoint, it makes sense to follow a broad-based approach that is not purely disease-based, but rather includes preventive care and behavioral health as means to improve quality.

We also recommend that the Council be inclusive in the research priority areas selected, so that the process of care, including the services involved, clinician capability, and other factors are taken into account in assessing comparative effectiveness. This is particularly important in assessment of medical devices.

Content of the Research Topics

Third, AdvaMed supports using comparative effectiveness research to inform medical decisions. The purpose of comparative effectiveness research should be to provide better evidence for physicians and patients to use in making individual clinical decisions. It should enhance, not hinder or preclude, a physician's ability to exercise independent professional medical judgment in providing care to patients, so that patients have access to the interventions that best meet their individual needs and circumstances. That is why it is essential that clear, comprehensible study results be disseminated to physicians and the patients whom they treat. It is why comparative effectiveness findings should not result in one-size-fits-all coverage recommendations.

Finally, we believe that the comparative effectiveness research pursued should focus on clinical effectiveness, not cost effectiveness. As stated in the Conference Report to the Recovery Act,

the purpose of the comparative effectiveness funding is for the conduct or support of research on "*clinical* outcomes, effectiveness, risk and benefits" (emphasis added). We note that on March 4th, NIH announced its new initiative called the "NIH Challenge Grants in Health and Science Research," which may use funding designated by the Recovery Act specifically for comparative effectiveness research. The NIH listed several topics that would include cost effectiveness analysis. To use the Recovery Act's comparative effectiveness funds in this manner would run contrary to the statement in the Conference Report language and for this reason, we recommend against this application of the funds. Moreover, using this research to deny access to appropriate treatments for individual patients with individual medical histories and individual needs should not be the objective. AdvaMed supports the conduct of clinical comparative effectiveness research and believes that such research will ultimately improve quality of care and have a favorable impact on overall efficiency in the health care system.
Thank you for your time today.

Submitted by
Dale Lupu, Ph.D.
Vice President for Professional Development
American Academy of Hospice and Palliative Medicine
[personal information redacted]

Dear Dr. Haddix and members of the Federal Coordinating Council,
We are writing to provide input into how to most effectively allocate the new CER resources.

Several reports from the National Institute on Health[1] and the Institute of Medicine[2] have called for substantial investments in palliative care research. While the growth of our field has been remarkable, the knowledge base to support basic elements of clinical practice still remains small. The need to evaluate efficient, patient-centered care delivery systems has grown even more critical. CER activities that address critical research questions in palliative care will help align CER with the critical areas identified by the National Quality Forum Priority Partners as fruitful areas to achieve systemic improvement in health care. [3]

The ***American Academy of Hospice and Palliative Medicine*** recommends the following strategies be integrated into the CER priorities:

1) Integrate palliative care outcomes into a broad range of CER.
Along with studying the comparative impact of interventions, pharmaceuticals and devices on the outcomes of survival and function, all CER in the seriously ill patient population should look at palliative care outcomes related to the burden of disease. These outcomes include:

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[1] National Institutes of Health, **National Institutes of Health State-of-the-Science Conference Statement on Improving End-of-Life Care** State-of-the-Science Conference Statement. December 6–8, 2004. http://consensus.nih.gov/2004/2004EndOfLifeCareSOS024html.htm

[2] Marilyn J. Field and Christine K. Cassel, Editors; Committee on Care at the End of Life, Institute of Medicine**.** **Approaching Death: Improving Care at the End of Life. 1997**
www.iom.edu/CMS/3809/12687.aspx

[3] Palliative and end-of-life care is one of six priority areas identified by the National Quality Forum as critical for improving our national health care delivery.
http://www.nationalprioritiespartnership.org/PriorityDetails.aspx?id=608

- Quality of life including disease-related burden of pain and other symptoms
- Patient and family experiences with care

When comparing program interventions, additional outcomes to be measured should also include:

- Quality of care including the quality of communication and alignment of care and its outcomes with patient preferences, and care transitions

2) Target CER efforts to develop the evidence base for the clinical interventions that best ameliorate pain and other symptoms.

Ample evidence demonstrates that patients with serious illness experience a multitude of profoundly distressing symptoms. A conservative estimate suggests that of the 1 million persons who died in a U.S. hospital in 2001, 324,000 had fatigue, 280,000 had loss of appetite, 244,000 had shortness of breath, 232,000 had dry mouth and oral ulcers, 208,000 had cough, 196,000 had pain, 148,000 had confusion, 148,000 had depression, 140,000 had nausea, 92,000 had difficulty sleeping, and 88,000 had vomiting. The reasons for this distressing state of affairs are many but almost all stem from an approach to medical research that has often viewed symptoms and suffering as interesting primarily insofar as they guide the physician to a correct diagnosis.[4] The prevailing philosophy dictates that once the diagnosis is made (e.g., cancer) and the disease is treated (e.g., chemotherapy), the symptoms will dissipate. What should be done to relieve suffering during treatment or when a disease can't be treated or cured is rarely discussed, and certainly has not been adequately researched. It is not surprising, therefore, that a recent NIH-supported comprehensive review of research revealed that data that should guide the treatment of late life symptoms are not only inadequate but in many instances completely absent. High quality evidence informing symptomatic management is glaringly lacking for even the most common, highest impact symptoms such as dyspnea. Concerted application of CER to routinely used clinical interventions could yield important advances in improving treatment of common, distressing symptoms.

3) Compare palliative care delivery models.

The last year of life consumes almost 30% of lifetime Medicare expenditures[5], and evidence for the positive impact of both hospice and palliative care programs on both quality of care and cost of care is accumulating.[6] However, the knowledge base is sorely lacking in methodologically rigorous studies that illuminate which processes of care and specific program interventions and models are the most effective. Although we understand that comparisons of service delivery models have not typically been an object of study via CER, we believe that applying CER to palliative care models would yield important and actionable information that is critical for informing efficient, higher quality late life care. In particular, the palliative care field needs studies to illuminate best care models for difficult populations, such as minorities and nursing

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home patients, and to reduce health outcome disparities and inform policy debates about shaping reimbursement policies.

4) Create the infrastructure needed to carry out CER in patient populations using palliative care.

The NIH State of the Science Consensus Panel noted that research in palliative care is hampered by an under-funded, under-resourced research sector specific to palliative care. The NIH panel recommended*:*

> *"Create a network of end-of-life investigators and well-defined cohorts of patients to facilitate coordinated interdisciplinary, multi-site studies. This should include establishing new networks of end-of-life investigators as well as expanding existing networks (such as the National Clinical Trials Cooperative Groups) so they have a critical mass of end-of-life investigators and appropriate study populations. These networks should enhance training of a new generation of interdisciplinary scientists (through funding mechanisms, such as K-awards, T32s, and R25s)."*

This directly supports an existing priority of the National Institute on Aging: 05-AG-101* Data Infrastructure for Post-Marketing Comparative Effectiveness Studies.

> "*The challenge is to create the data infrastructure that will enable comparisons of particular therapies, prescribing patterns, and benefit designs on health outcomes. Problems with currently available studies include omission of key patient groups (such as the elderly in nursing homes), lack of information on adherence and outcomes in polypharmacy, lack of information on outcomes across different insurance benefit designs, and lack of information on actual prescribing patterns and outcomes across regions and over time.* "

In summary, we believe that comparative effectiveness research in hospice and palliative medicine can yield many benefits for patients, providers, and our healthcare system. In the coming decades more Americans than ever will be facing their later years of life, and we must therefore ensure that these priorities are integrated within CER.

Thank you for this opportunity to participate in this inquiry. We would be happy to provide more information for clarification.

Submitted by

[personal information redacted]

Dear Federal Coordinating Council:

This statement is written with respect to the allocation of money (1.1 billion dollars) from the 2009 Recovery Act fund for the purpose of achieving Comparative Effectiveness Research.

Recommendation #1 Prioritize the End of Corporate Fraud

Research into the comparative effectiveness of medical treatments is a laudable goal, but only if it does not repeat the same errors of the past. When, in the early 1990s, medical journals,

medical schools, residency and postgraduate training curricula, and health care facilities came under the influence of Evidenced Based Medicine (or EBM), the favored treatments in American medicine came to reflect the following values and priorities:

1) symptom suppression (rather than elimination of root cause of illness)
2) short-term studies (e.g., Randomized, Placebo Controlled Trials)
3) fraudulent research designs (e.g., placebo washout/lead-in)
4) concealment of data unfavorable to the interests of the drug industry
5) academic censorship (e.g., non-disclosure and confidentiality agreements)
6) distortions in the medical literature (ghostwriting, file drawer effect)
7) treatment by consensus (rather than treatment based upon science)

Each of these developments contributed to the hegemony of sham standards of care.

Effectiveness Research will be meaningless if it repeats these errors of the past.

Recommendation #2 Focus Upon Basic Science and Biology

The current system for approving new medications and medical devices emphasizes proof of efficacy in principle, *rather than proof of effectiveness in fact*. This system has given rise to the introduction and widespread use of one, after another, copycat therapies based upon dubious definitions of benefit (e.g., checklists of subjective symptoms in psychiatry; measurements of "risk factors" and surrogate endpoints as substitutes for real progress in ameliorating the symptoms of chronic disease). Most critically, the past 20 years of American medicine have diverted attention away from the study of basic physiology and the mechanisms of disease.

Unless and until the treatment paradigm in American medicine returns to an emphasis upon root causes of illness and disease, and upon the eradication or amelioration of those causes, the system of healthcare will continue to reflect interventions which are largely futile for patients.

What might be done:

1) identify environmental sources of illness and map the epidemiology of risk factors and diseases related to same
[e.g., the U.S.A. needs a national equivalent of Green Cross International]

2) re-evaluate national healthcare policy with respect to HPDP
[Health Promotion / Disease Prevention]

-- verify or refute high cholesterol as the necessary and sufficient cause of heart disease

-- verify or refute the existence of cumulative safety thresholds for diagnostic radiology

-- verify or refute the long-term harmfulness of the current immunization schedule

(particularly, with respect to autoimmune dysfunction, diabetes, asthma, obesity, and neurobehavioral syndromes)

-- verify or refute the long-term harmfulness of fetal ultrasound

-- verify or refute the long-term hazards of fluoridation

-- verify or refute the validity of Gallo's work, positing HIV as the cause of AIDS

[see Nortin Hadler's books: *The Last Well Person* and Worried Sick]

Recommendation #3 Prevent and Mitigate Iatrogenic Harm

The allopathic model of medicine is failing America because authorities will not acknowledge the unnecessary harmfulness of synthetic chemicals. All of the existing training programs, textbooks, Board Certifications, and treatment algorithms emphasize the use of pharmaceuticals that are based upon short-term drug trials, and short-term studies in lab animals. Yet, human subjects (at least, in the U.S.A.) are increasingly encouraged to consume multiple medications for life. This philosophy of lifetime, prescription drug dependence ignores the scientific realities of what happens to patients under the influence of chronic medication.

Unless and until health care providers, policy makers, and regulators recognize the problems of *allostatic load* (the body's adaptations to therapy which ultimately result in diminishing benefits or worsening disease) and prioritize the avoidance, amelioration, and/or reversal of *target organ toxicity*, no amount of "effectiveness research" will be meaningful.

What might be done:

1) effectiveness research must involve considerations of treatment UTILITY (Benefits *and* Hazards)

2) effectiveness research must include considerations of **Target Organ Toxicity** [e.g., how various treatments harm the diseased organ] and **allostatic load** [e.g., how various treatments induce changes in gene expression which may result in delayed but potentially long-lasting effects]

3) effectiveness research must include considerations of treatment effects upon the **environment** (e.g., xenobiotic diffusion via sewage; air pollution from hospital incinerators) and environmental effects upon treatment (proximity of treatment facilities and patients to radon, radioactive waste, Superfund or other toxic waste sites, petrochemicals, etc)

Recommendation #4 Recruit the Best Treatments from Around the World

The federal government gives lip service to the importance of research in the areas of complementary and alternative systems of health care. However, the U.S.A. has become a pharmaceutical oligarchy which permits no challenge or rival to allopathic medicine. No amount of effectiveness research will be meaningful unless and until the yoke of pharmaceutical authoritianism is broken. Ideally, effectiveness research will incorporate the "best treatments" (herbs, diet and lifestyle modification, environmental modification) from around the world.

Recommendation #5 Protect the Privacy of Patients and Physicians

Given the pervasiveness of corporate fraud and the denigration of integrity within the American health care system – particularly, as these have progressed in the era of Evidence Based Medicine -- patients and physicians require protection from harmful practices. Treatment facilities, insurance companies, and State Medical Boards mandate compliance with corporately shaped, corporately biased Group Think.
Clinicians have lost the right to practice medicine by using their best clinical judgment, informed by an understanding of basic science, direct observation, and the consideration of the unique circumstances of each and every patient.

It is extremely unlikely that America's pharmaceutical oligarchy will ever be displaced or transformed into the kind of system which serves mankind, rather than profit and power. This being so, the ***results of effectiveness research must not be allowed to infringe or violate the privacy of patient***s, nor the rights of clinicians who desire the freedom to honor the ethical principles of patient autonomy, physician beneficence, and physician non-maleficence.

What might be done:

1) patients and providers must be allowed to opt out of electronic medical records system, health care registries, and other databases where biological and social information can -- and most likely will -- be used to ration health care, restrict employment or travel, or reduce entitlements

2) patients must be protected from medical tyranny (i.e., medical blackmail --- the allocation of therapies or benefits based upon compliance with dubious and potentially harmful treatments)

3) health care providers must be protected from medical tyranny (i.e., medical blackmail in the form of Pay-for-Performance programs, "Consensus" Statements, Sham Peer Review/Disruptive Physician proceedings, etc).

Summary

Effectiveness research is a laudable goal, but only if it is conducted in a way which avoids the tragic errors of the past (i.e., the corporate medical fraud which has gained traction under the influence of EBM, the Daubert decision of 1993, the Prescription Drug User Fee Act, the Bayh-

Dole Act, Direct-to-Consumer Advertising, etc), and only if it anticipates new challenges of the future.

Particularly in the context of emerging technologies (brain mapping, gene mapping, high-speed information exchange), there will be ever more opportunities for the leaders of allopathic medicine -- and for the leaders in government -- to enslave, rather than to serve, the providers and consumers of health care.

Ultimately, effective health care must also be ethical health care. This will require a return of integrity in the conduct of American medical research. It will also require a health care system which prioritizes the delivery of services that are consistent with fundamental human rights, and with the human species' duty to protect (rather than to plunder) the planet's biosphere.

Thank you for the opportunity to contribute these ideas and opinions.

Submitted by
[personal information redacted]

I write to day to express my concern about the impending termination of the Partnership Program of the Cancer Information Service as of January 2010. I am especially concerned given the current stimulus package opportunity to maintain the community infrastructure and employment of a cadre of highly trained cancer control specialists. The stimulus package provides a unique opportunity to maintain this effective and high quality program in the community during your planning process to determine the future initiatives to translate science into practice and address health disparities.

Given the historical mistrust of researchers and federal government by minority communities, and the fact that these same communities bear a disproportionate share of the cancer burden, we simply cannot afford to purposely cause a break in the relationship between community organizations and the National Cancer Institute. The current plan to "pause" and reconsider the paradigm is high on risk and has no reward when taken in the context of community partners.

The translation of science into practice is the logical end-point for bench science. It is also the beginning point for public health practice. Both researchers and practitioners must engage in this natural shared responsibility. Community partners – whether they are churches, clinics, health departments, or local cancer control coalitions – need the expert, unbiased guidance and support of the Partnership Program in order to target audiences, select or adapt programs, implement and evaluate evidence-based programs, and plan strategically for the future. This is difficult work, and work that cannot be done solely via electronic media or avatar.

I understand that other Partnership Program models could potentially be more effective or efficient but the truth now is that NCI is the current sole custodian today of the trust between minority communities and NCI. And although NCI supports a number of projects via grants, none provide ongoing, comprehensive coverage throughout the United States. As such, NCI needs to maintain an ongoing presence and some level of face-to-face, personal engagement with

minority and rural communities until a new paradigm can be designed, procured and implemented.

Specifically, I strongly urge you to implement these policy actions:

1. Implement a transition strategy where current Centers are funded through stimulus dollars at a level sufficient to maintain these core functions:
   a. link NCI to community organizations
   b. link communities to NCI
   c. build capacity of community organizations to interpret, adapt and implement evidence-based programs
   d. communicate future plans of NCI in such a way as to promote the community's acceptance and trust
   e. facilitate a smooth transition to new model(s)

2. Incorporate local community organization leaders into the redesign process, not just representatives from national organizations (e.g., community health workers, community development corporation leaders)

3. Accelerate the planning process as much as possible so a new procurement process can avoid missed opportunities to innovate in the field.

To be certain, community trust is the prime concern here. Yet, there is one other concern I believe to be important.

The current workforce of the Partnership Program is a unique and valuable part of our country's infrastructure. In these times when local and state health departments, as well as voluntary associations and other non-profit organizations, all across the country have hiring freezes or some combination of furloughs and lay-offs, we simply cannot and should not weaken our already fragile public health workforce. I believe my suggestion of funding Centers so that core functions may be maintained until the next iteration of the Partnership Program is in place will serve to minimize the short-range harmful impact on the workforce.

In addition to my practical, low-cost policy suggestions, I have several important questions:

(1) I would like to have a copy of the full evaluation results of the Partnership Program evaluation that was conducted about a year ago and included community collaborator feedback;

(2) I would like to have concrete action steps that demonstrate NCI's commitment to "community trust" that go beyond the study group

(3) I would like to know why NCI thinks a gap in service to community and the loss of 80-100 jobs is acceptable when one looks at the effort and investment in saving and creating jobs through the Recovery Act.

In closing, given the recent historic investment in Economic Recovery Act, NCI has the mandate to uphold its responsibility to community partners and make preservation of this part of the public health workforce a high priority. You can do this by taking the steps I have suggested in this correspondence.

This is an important leadership opportunity.

I look forward to your response and action to implement these recommendations.

Submitted by
Carl H. Rush, MRP
Community Resources, LLC
[personal information redacted]

Thank you for the opportunity to comment. I am Secretary of the Community Health Worker (CHW) interest group of the American Public Health Association. I was also a principal author of HRSA's CHW National Workforce Study (2007) and convened an invitational conference in 2007 to draft a national research agenda on CHWs.

I strongly recommend that your plans include significant studies of the cost-effectiveness of CHW interventions. Past studies suggest a great potential for CHWs to reduce total costs for programs such as Medicaid, Medicare and SCHIP but the data are limited. There has been increasing interest in CHWs but policy has been slow to respond due to an inconclusive evidence base, largely due to methodological weaknesses and inconsistencies in past research. A group of leading researchers is planning a follow-up conference to recommend common metrics for CHW effectiveness and cost-effectiveness early in 2010.

CMS is currently testing CHW approaches to interventions such as excessive Emergency Room utilization (Medicaid) and diabetes self-management (Medicare) but neither initiative is rigorously studying cost-effectiveness of CHW methods. Minnesota has recently (February 2008) authorized hourly reimbursement for CHW services under Medicaid, the first State to do so. Various reports such as the IoM's "Unequal Treatment" (2002) have recommended greater roles for CHWs. The 2009 SCHIP reauthorization specifically includes mention of CHW roles in outreach and education. The recent NIH Challenge Grants announcement includes three Topic Areas which specifically mention CHWs: 05-MD-102* (Prevention of Chronic Diseases in Disparity Populations), 05-MD-105* (Health Literacy) and 09-MD-101 (Creating Transformational Approaches to Address Rural Health Disparities).

It would be helpful to all these agencies to have a coherent, coordinated interagency approach to understanding the full potential of this workforce. HRSA's Maternal and Child Health Bureau obtained private commitments of some $2 million for a large scale CHW cost-effectiveness study in 2000-2001 but the project was cancelled by the incoming Administration. The present economic recovery appropriation is an ideal vehicle for such an investment.

I would be happy to provide further information and contacts.

Submitted by
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Good evening:
On behalf of Bayer HealthCare Pharmaceuticals Inc., we are writing to notify the Council and the Office of the Secretary that we intend to submit a written statement for consideration regarding comparative effectiveness research.

We understand from the Federal Register notice published on April 10, 2009, that interested persons registering for the public meeting on April 14th notify the Office of the Secretary of their intent to submit a written statement for consideration by the Council. Although we are not submitting our comments at this time, consistent with the information in the Federal Register notice, we write today to notify the Council and the Office of the Secretary of our intent to do so in the near future.

Please let us know if you have any questions in the interim.

Submitted by

David M. Carlisle, M.D., Ph.D.
Director
California Office of Statewide Health Planning and Development

Mark B. Horton, M.D., M.S.P.H.
Director
California Department of Public Health

States and local jurisdictions, with Medicaid, SCHIP, public health and a variety of other programs, will directly benefit from the results of Comparative Effectiveness Research.

Given these potential benefits, it is critical that the priorities of state and local jurisdictions be given consideration in evaluating various Comparative Effectiveness Research strategies. For example, many jurisdictions, such as California's Medi-Cal program, have on-going

investigative agendas designed to improve program effectiveness that can be considerably amplified by Federal support. Such efforts would extend beyond purely clinical protocols to include the evaluation of public health, community-based, and behavioral strategies that may enhance the effectiveness of public programs.

States and local jurisdictions also have strengths and advantages that compliment Federal Comparative Effectiveness Research programs. These strengths and advantages include functional relationships with academic partners, access to a variety of special demographic,

cultural, and linguistic populations, and a direct knowledge of how potential interventions may work in their local environments.

Submitted by
Susan Hodges, President
Citizens for Midwifery
[personal information redacted]

Maternity care, one of the largest sectors of the health care system, clearly needs the Council's attention and needs Comparative Effectiveness Research (CER) funds directed to it.

Over 4 million women give birth to over 4 million babies each year in the US. Research tells us that around 80% of those women go into labor relatively healthy, but nearly all are subjected to inappropriate practices and unnecessary medical interventions that result in high rates of complications and morbidity. Multiple organizations have compiled extensive systematic reviews of the research about many aspects of maternity care, and the evidence clearly demonstrates that much of what is done in US maternity care is unnecessary and often harmful, and very costly, resulting in poor outcomes.

We urge the Council to recognize the enormous importance of maternity care, both for the economy and for the lifelong outcomes for babies, mothers and families, and to make use of the large body of available research comparing outcomes of typical obstetric practices and protocols with the supportive care of midwives, in and out of the hospital.

The recently released report, *Evidence-Based Maternity-Care: What It Is and What It Can Do*, from Childbirth Connection in New York City (http://www.childbirthconnection.org/article.asp?ck=10575) , is the most recent and most complete analysis of the evidence relevant to birth practices. This report states that "Effective maternity care with least harm is optimal for childbearing women and newborns." It is also optimal for taxpayers, who directly pay for nearly 40% of births through Medicaid, but also for those who will need to pay for the harms that result from ineffective care, sometimes for a lifetime. The report also examines the many barriers to optimal care.

Despite spending far more on maternity care than any other country, the US has dismal outcomes relative to other developed countries high infant mortality rates, stagnant or rising maternal mortality rates, high maternal morbidity rates, high rates of preterm birth, high rates of low birth weight babies, and relatively low rates of breastfeeding success. The other industrialized countries, who spend less and get better outcomes, use midwives as primary health care providers for pregnant women, because midwives are trained to support normal (physiological, undisturbed) birth, and only refer to obstetricians those women who actually need their skills.

One example of a problem that needs attention is the record high rate of cesarean section, which cost us much more than normal vaginal births. Over 1 in 3 women now give birth by major abdominal surgery, although research shows that the benefits for mothers and babies break even at a rate of 10 to 15%. Overuse of cesarean section is having short and long term impacts on the health of mothers and babies and will likely impact the whole health care system for years to

come. Indeed, cesarean section and induction of labor are cited as factors in the continuing rise in late preterm birth, which greatly increases the risks for long term health and educational difficulties for the babies involved. Furthermore, more than 800 hospitals in the US now have policies to not allow women to attempt vaginal delivery for a pregnancy following a cesarean section, even though there is ample evidence that vaginal birth after cesarean (VBAC) is a healthier choice for the majority of such mothers and their babies.

Women can find out more about a used car than they can find out about their obstetrician or their local hospital, because only two states are required to publicly report birth outcomes and interventions for hospitals, and there is NO reporting for individual obstetricians. Combined with the lack of transparency and accountability, few women and their families are aware that most maternity care is not based on research evidence, or that where and with whom they choose to give birth are independent risk factors for whether they have induced labor, cesarean section, or episiotomy (another overused surgical procedure) and a myriad of other practices and interventions. This lack of transparency about how their providers practice and what happens in their local facilities makes finding appropriate care very difficult for women and families.

We hope CER will not only look at Comparative Effectiveness Research for maternity care, but also consider how government agencies can help the public understand the need for evidence-based practice that is so desperately needed in maternity care.

We are asking CER to look at the extensive existing evidence comparing the care practices used by midwives, who have excellent outcomes in and out of the hospital, with the care practices used by obstetricians in hospitals that result in abnormally high rates of interventions and complications. Obstetricians are extremely skilled specialists in the pathologies of pregnancy and childbirth. However, unlike nearly every other sector of health care, most pregnant and birthing women and their babies are healthy and do not need the skills these expensive specialists possess. In no other area of health care do we expect (and pay for) physicians to provide interventive and invasive “care” that is not medically indicated.

Midwives on the other hand are trained in the normal processes of pregnancy and childbirth, with an understanding about when greater intervention is needed. Most of the other developed countries with better outcomes and lower costs use midwives to attend most women and babies. Indeed, the Midwives Model of Care (see below), which provides respectful, individualized care that includes education, support, and appropriate use of technology, has been shown to not only improve outcomes overall, but to also help reduce disparities among women at risk for poor outcomes due to race, ethnicity, income-level, and other demographic factors, while reducing costs.

We urge the Council to examine the current research and work with all stakeholders, including consumer advocacy organizations and midwives, to direct CER funds toward maternity care. We also need to develop an appropriate national data set of criteria for optimal maternity care. This will allow providers, facilities, payers, and most importantly, women and their families to determine the appropriate facilities and providers that will offer them optimal care and give their babies the best start possible.

Thank you for your attention to these very important concerns and for your consideration of the need to use Comparative Effectiveness Research to bring about better and more cost-effective care and outcomes for all mothers and babies in the US.
Sincerely,

Citizens for Midwifery Board of Directors
Susan Hodges, President
Arielle Greenberg
Carolyn Keefe
Nasima Pfaffl
Willa Powell

The Midwives Model of Care
The Midwives Model of Care is based on the fact that pregnancy and birth are normal life processes.
The Midwives Model of Care includes:

- Monitoring the physical, psychological, and social well-being of the mother throughout the childbearing cycle
- Providing the mother with individualized education, counseling, and prenatal care, continuous hands-on assistance during labor and delivery, and postpartum support
- Minimizing technological interventions
- Identifying and referring women who require obstetrical attention

The application of this woman-centered model of care has been proven to reduce the incidence of birth injury, trauma, and cesarean section.

Submitted by
Hazel H. Moran
Senior Director of Healthcare Reform
Mental Health America
Alexandria, VA
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Members of the Federal Coordinating Council for Comparative Effectiveness Research, I would like to thank you for the opportunity to provide public comment on CER and the Council's activities.

My name is Hazel Moran, and I am from Mental Health America, America's oldest and largest advocacy organization concerned with all aspects of America's mental health. In fact we celebrate our Centennial this year. Given our longstanding interest in the public's health we are the founder of the National Working Group on Evidence-Based Health Care (The Working Group), which is a collaboration of approximately 40 patient and consumer organizations, professional societies, providers and other interested stakeholders that want to help shape the initiatives in evidence-based healthcare (EBH) in order to close the gap between our knowledge and ordinary practice. As such, I am pleased to speak on behalf of consumers and patients in support of comparative effectiveness research.

Since 2005, we have worked to broaden participation of patient groups in all aspects of EBH to improve the usefulness of this information for consumers and clinicians as well as to assure that the locus of decision making remain with the patient and his/her clinician. We focused principally on comparative effectiveness reviews and evidence dissemination as two key components of the EBH movement.

Through information exchange and engagement in public dialogue, the Working Group has emphasized the importance of balancing an understanding of scientific research with real-world clinician expertise, each individual patient's needs and history as well as their perspectives and preferences. The Working Group strives to empower patients and consumers by involving them in designing and prioritizing research, as well as reviewing evidence and contributing to its translation, dissemination and implementation. For example, Mental Health America participated in the review and dissemination of several publications including AHRQ's Summary Guides on the Off-Label Use of Atypical Antipsychotic medication and the treatment of Depression. Our involvement has been viewed as constructive and helpful we would like to continue to engage in the growing federal CER effort by helping to deepen patient involvement in CER. To generate the balanced and practical clinical evidence that the legislation envisions, it will be critical for the Council to ensure that all those conducting federal CER incorporate the patient and clinician perspective into the direction and design of CER.

The creation of new evidence and new decision support techniques to inform patient's treatment decisions offer great potential to improve care. To help realize this progress, patients and consumers can provide important support to federal CER research in three principal ways.

First, they can advise on topic selection. Second, by specifying the information they need to make decisions about their care, patients can help determine what data should be captured in CER. Third, patients can provide valuable public support for the CER dissemination and implementation.

In the Federal Register Notice for this meeting, you specifically asked for individuals making comments to respond to six questions. We would like to respond to those questions with three recommendations:

- **Create a national citizens' advisory board to help HHS** better understand the perspectives and values of the general public when designing and disseminating CER. This is critically important to make sure that the full continuum of issues are considered when making policy recommendations regarding the implementation of CER findings. A good model for this is the Citizens Council that the UK's NICE convenes.[2] NICE charges the Council with conveying the views of the public both to the Institute and to the groups that NICE commissions for appraisals and clinical guidelines.
- **Establish an explicit channel for patients to advise HHS on CER.** The FDA's Patient Representative Program is an excellent model for this kind of participation.[1] The program educates patients to be effective advisors, and then includes them on advisory boards that correspond to their particular medical experience. HHS could similarly inform patients on some basic scientific and methodological concerns of CER and then solicit their input. Additionally, these patients must be trained and supported to effectively engage in this

- **Sponsor research that is designed to improve clinical decision making by both clinicians and patients.** Research that considers the individuality of health conditions and factors such as family history, individual experience in treatment and patient values and preferences is needed. Designing CER trials that mine the heterogeneity of response for identifiable sub-groups and that include outcome variables that are aligned with patient preferences should improve the clinical applicability of the work. Patient involvement in trial design would assist in improving the relevance of their findings. Integration with the developing HIT architecture should ensure that decision support tools informed by CER and systematic reviews are included in this new technology – moving knowledge to the bedside in order to craft individual treatment plans for individual patients.

Greater roles for patient advocates are essential to advance medicine in collaboration with scientists and physicians to interpret the effectiveness of therapies. Understanding the experiences of patients and the public is important to helping organizations work more effectively to evaluate and improve services. People should have the opportunity to be actively involved in shaping the organization and the delivery of health and social care services for their communities. Changes that are made to the delivery of services should be based on their experiences and views.

The National Working Group on Evidence-Based Health Care appreciates the opportunity to provide the Federal Coordinating Council on Comparative Effectiveness Research with specific comments on its activities as it relates to comparative effectiveness research. The Working Group plans to submit formal comments to the Council with further detail on our recommendations.

Submitted by
Perry D Cohen, Ph.D.
Director, Parkinson Pipeline Project
[personal information redacted]

My diagnosis with Parkinson's disease 13 years ago directed my life toward developing new roles for patients in medical research and health care. Previously, my doctoral level business school education focused on systems analysis and organizational development and 20 years experience as a management consultant gave me wide exposure to health care and medical research at all levels and with many vantage points. What I did not already know about dynamic systems approaches to management of quality service systems, I learned from active participation in the IOM roundtable on evidenced based medicine, which has detailed the

concepts of “learning health systems.” These pathways to transform health care provide a context for CER priorities. In earlier priority setting comments I have focused on the role of the patient with serious chronic illness as distinct from the role of consumer with interests in public safety, and suggested that patients empowered by IT via information access and networking with peers are underutilized in our provider oriented delivery system.

My vision for future learning health care systems puts an emphasis on the role of disease oriented sub-specialists as leaders and educators to not only conduct rigorous randomized controlled studies for regulatory approval, but at the same time to provide the 'academic detailing' for community doctors in the context of clinical trials in continuous processes of introducing new therapies (medical innovation). The focal point for from medical research to health care is the community network of providers who treat chronic diseases like PD and provide the bridge to link innovation and quality in knowledge transfer both ways between the sub specialist academic knowledge leaders and the patients

Patients and their doctors will be involved in the system by aggregation and incorporation of electronic medical records (EMR) of physicians and personal heath records (PHR) of their patients into a data base or a distributed network of data elements that will enhance the available information for both doctors and patients through regular updates of data and downloading of research findings as they become available. Issues of privacy and identity will be addressed and ways to enhance communications between doctors and patients will be tested. Data generated will be available for tracking safety over the life cycle of a medical product, quality and utilization management, as well as observational research and other patient oriented activity. Problems of implementation of IT solutions and managing the change process can be addressed through demonstration projects.

In spite of the promised benefits to both cost and quality of medical care, US providers have been slow to adopt these information technologies. The ARRA recognizes the lack of incentives for participation and allocates major funding to buy cooperation from reluctant providers. Care must be taken in implementation of such an approach that we do not merely automate our sub-optimal system. The way to avoid this is to pay for creation of system improvements as well as incentives for providers.

Key among the system improvements, especially given the immediate scale-up of activity necessary to provide short-term economic stimulus through longer term investments in technology is to enhance the roles of patients and patient advocacy organizations to keep policy decisions focused on patient relevant goals, and enhance the capabilities of these organizations to evaluate and use these technologies. This human resource capacity development will be necessary to gain the trust of patients being asked to share their case history for the common good regarding maintenance of privacy and confidentiality of personal data that can be used against them. Disease specific patient advocacy organizations are among the few kinds of organizations that are trusted by patients to represent our interests faithfully in the execution of privacy and confidentiality standards. The establishment of trust of patient groups should be a major criterion for the designation as a gate keeper to control the collection and aggregation of patient data, whether the patient organization elects to take on this role itself or endorse a third party with greater technical capability. Our experience with implementation of advanced

telecommunications networks over the internet indicates that even large non-profit mission-driven advocacy organization generally lack the technical skills and IT capacity to perform the transactions necessary to maintain the data flows required to make optimal use of the data. These facts point to high priority investments in infrastructure development effort up front to enhance the capacity of patient organizations to understand the value and manage the powerful HIT tools expected. Existing coalitions of patient groups, such as the Working Group that have been set up to represent patient interests are ideal for this development activity

Experience from the unintended consequences HIPPA, designed to protect patient privacy, illustrate the difficulty to pre-specify all the special cases where the rules do not apply or have negative effects. Training and development of patient organization boards and executive staff about how to evaluate the HIT implementation plans, including case examples, for their decisions regarding endorsement to their members and their own role in as gatekeeper to represent interests of their constituents

Similar to the key role of patient organizations to make the on-going judgments about standards for data exchange and aggregation, trustworthy input from specialty professional organizations with expertise to define and update knowledge structures, and validate results from aggregate data is necessary to make this process credible and meaningful. Investments in human resources and expertise to manage processes for gaining consensus on technical issues among specialty doctors and patients are necessary to make the systems adaptable over time.

Submitted by
Karen E. Howard
Executive Director
American Association of Naturopathic Physicians (AANP)
Washington DC
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The American Association of Naturopathic Physicians (AANP) applauds the Obama administration for its commitment to outcomes research and determining best practices. We recommend that this perspective include the evaluation of alternative systems of healthcare. While conventional medicine's focus on treatment of disease has produced many benefits—especially in acute and life-threatening conditions, its effectiveness for the treatment of chronic disease or the promotion of health is limited. This failure has been a major cause of the out-of-control healthcare costs plaguing the nation.

We propose a project that tests a new model of primary care; one that incorporates the best of what both conventional and complementary and alternative medicine can offer and focuses on prevention, health promotion, and treatment of the whole person. This project involves taking advantage of health information technology and electronic medical records in a practice-based research network (PBRN) containing both conventional and naturopathic medical practice. This PBRN will provide a laboratory to compare "real world" effectiveness and cost-effectiveness, initially in the area of type 2 diabetes.

There is at present a severe shortage of primary care physicians. A number of proposals have been put forth as to how to fill that shortage and many of these are aimed at increasing the number of medical students going in to primary care. However, there are also a number of proposals to utilize the skills of other licensed healthcare practitioners and expand access to patient-centered primary care in both federally funded and private health care offerings—e.g., naturopathic doctors (NDs), nurse practitioners, physician assistants, and health coaches.

Naturopathic medicine is a system and philosophy of medicine that has been in use for over 100 years. The AANP represents licensed naturopathic physicians who are trained at fully accredited four-year residential medical programs. Graduates of our medical schools serve as primary care physicians and have the same training in the basic and clinical sciences as conventional medical doctors. In addition, NDs receive training in a variety of core treatment methods including nutrition, botanical medicine, homeopathy, pharmacology, physical therapy, and minor office surgical procedures. Some licensed naturopathic physicians are also trained in traditional Chinese medicine, acupuncture and Ayurvedic medicine as well as clinical specialties such as natural childbirth. Therefore, naturopathic medicine and NDs provide the ideal laboratory to test a complement to the present primary-care-deficient model of health care.

Researchers at naturopathic academic clinics initiated a practice-based research network (PBRN) and are proposing to expand this network in collaboration with Oregon Clinical and Translational Research Institute (OCTRI) at Oregon Health & Science University (OHSU), Kaiser Permanente, and the University of Washington School of Public Health. The PBRN will also include a number of naturopathic private practices. The data coordinating center will be the newly established center for clinical informatics at the Helfgott Research Institute, National College of Natural Medicine (NCNM). EMR systems compatible with the data in the OCTRI data warehouse will be implemented at participating naturopathic institutions and practices. The EMR system under consideration is EPIC, the same system as used by OHSU, Kaiser and University of Washington clinics. The Helfgott clinical informatics center will coordinate system and coding compatibility among the ND agencies and OCTRI. It will work with OCTRI to securely archive the growing database while making de-identified and customized datasets available to researchers. The proposal calls first for retrospective and pilot prospective studies to test the feasibility of protocols based on an informatics approach to naturopathic medicine outcomes research and to characterize the populations before going on to more definitive study. If there are positive results with comprehensive treatment, the treatment and the outcomes data can be examined for factors associated with improvement.

We propose as our initial disease focus to study type 2 diabetes (T2D). T2D is epidemic and often inadequately controlled (only 37% in adequate glycemic control) by approved treatments. Nearly half (47.9%) of US diabetes patients also use complementary and alternative medicine (Garrow & Egede 2006; Yeh, Eisenberg, Davis & Phillips, 2002). The Diabetes Prevention Program (DPP) conclusively demonstrated that diet and lifestyle changes could prevent diabetes more effectively in a susceptible population than metformin (58% reduction in incidence versus 31%). The DPP lifestyle intervention used lifestyle coaches and a focus on weight loss and exercise, and although it proved less expensive per case of diabetes prevented than pharmacological management alone, it still presents a substantial cost to implement. ND practices will be used to test modifications to this model that include a primary care setting

allowing diabetes prevention to be incorporated into patients' overall focus on health. It may be even more effective, e.g., through the inclusion of nutritional supplementation (Bartlett & Eperjesi, 2008; Farvid, Jalali, Siassi & Hosseini, 2005; Bonnefont-Rousselot, 2004)), and potentially, more cost-effective.

Diabetes is paradigmatic of endemic chronic diseases for which NDs have specified well rationalized treatment protocols of which the elements, individually, show promise but which have not been tested in combined practice. A pilot comparative effectiveness study of naturopathic medicine in T2D is currently underway in Seattle.

It is also important to stress that this PBRN can be used to test components of primary care that can also be incorporated into conventional practice. Diabetes is an important chronic condition but is only one of many conditions toward which the informatics-based research infrastructure that we propose can be targeted. Once the system is established for diabetes, it can be extended to any health condition. For prevention studies, long observation periods will be required and the informatics system developed under this proposal will be in place for such studies. The functions of the naturopathic PBRN and its data coordinating center will include recruitment of participating NDs, aiding in the selection and implementation of EMR systems, prioritizing research questions and developing research protocols, facilitating ethical approvals as well as the extraction, compilation, analysis and archiving of naturopathic clinical and economic data parallel to standard conventional medical data.

Summary

We propose the establishment and funding of a PBRN that includes both conventional and naturopathic primary care physicians to act as a laboratory to test components, approaches and models of primary care that can include the best of what conventional and complementary and alternative medicine have to offer. The PBRN will initially address Type 2 diabetes, but can also be used to determine the best approaches to general primary care/family practice, pain, and other chronic disease conditions.

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Submitted by
[personal information redacted]

Thank you for inviting me to speak today. My name is [personal information redacted]. I am a physician, who specializes in a field called [personal information redacted]. I make my living, by researching how the availability and presentation of information to patients, physicians,

nurses, and other members of the healthcare team can improve healthcare delivery with respect to its patient-centeredness, effectiveness and efficiency, timeliness, safety, and equity.

I work at Marshfield Clinic, the largest private group medical practice in Wisconsin, one of the largest in the United States, with 783 physicians representing more than 80 different medical specialties, 6,490 additional employees, and more than 45 locations spread across over 25,000 square miles. The reason that I left my position at [information redacted], three years ago, is that over the past 40 years, on its own, Marshfield Clinic developed and acquired sophisticated tools, technology, and other resources that complement and support the population health management mission and strategy of the Clinic. These include an electronic medical record, a data warehouse, an immunization registry, a telehealth network, and an epidemiological database that enable research studies of both the effectiveness and cost of healthcare interventions. All of these components together comprise our electronic health record (EHR).
Our electronic health records go back to 1960 and contain 9.1 million patient-years of data. In 2007 we closed the last of our paper chart rooms and are now essentially paperless.

The fact that we are essentially paperless was not our goal we have proved beyond a shadow of doubt that an effective electronic health care record partnered with the right clinical care systems allows us to achieve the “holy grail” of comparative effectiveness research: to improve our quality of care while simultaneously reducing costs. And if you have doubts, which you should, simply ask CMS about Marshfield clinic's performance in the Physician Group Practice Demonstration Project.

The reason I am speaking to you today is to strongly encourage you, as you look at comparative effectiveness research, to include the evaluation of the comparative effectiveness of different types of EHR-mediated interventions. I feel compelled to speak about this for two main reasons: (1), my concern about the narrowness of CBO's definition of comparative effectiveness; (2), my concern that people are considering the value of electronic health records without understanding the totality of what an effective system does for the healthcare delivery team, from patient to physician.

The CBO defines comparative effectiveness as "a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients." Practically, this is interpreted to mean drugs, devices and surgical procedures. I fully support the notion that this research requires rigorous evaluation. But we need to expand this definition to include electronic interventions that are only possible through an EHR.

Most of acute healthcare delivery today occurs at hospitals which serve as a nexus of multitudinous, complex, competing, reactively configured, poorly coordinated processes, directed toward a person, who in this context, represents a complex, physiologically unstable (acutely ill) organism. Furthermore, this care is delivered by a team whose membership not only changes by the hour and whose members are frequently unfamiliar with each other, and consequently who operate under wide ranging assumptions about the status of the patient and their role in at patient's care. In short, poorly informed patients are being treated with poorly informed processes administered by poorly informed nurses directed by poorly informed physicians, supported by poorly informed laboratory, diagnostic, and pharmacy services. Unless

we address this context in an energetic, direct, and rigorous manner the benefit of knowing the most effective treatment for a medical condition in a given set of patients will be severely limited.

The context of preventive and subacute healthcare delivery is not any better. This portion of healthcare delivery occurs in an ambulatory care environment that is characterized by competing provider organizations, who incompletely share information about patients. Information that requires expertise in using a highly specialized vocabulary and set of concepts that frequently intimidates patients and their families, without imparting much understanding, let alone the ability to communicate that information to multiple providers.

Healthcare delivery cries out for applied research, comparative effectiveness research that evaluates the impact of different options for providing timely, accurate, understandable and actionable information to all members of the healthcare team, from patient to provider. Hence, my concern that many who are evaluating the value of electronic health records in the context of healthcare delivery reform do not understand the totality of an effective electronic health record.

We are not talking about the importance of an electronic version of the written medical record. We are not talking about a bridge from the billing system to the clinical care system, which is where many of the commercial electronic health records started. We are not talking about an electronic tool that provides non--essential convenience to patients or providers. Quite frankly, the current national discourse on value of EHRs at the level of asking whether "EHRs improve quality and reduce cost." This is equivalent to asking whether "drugs" treat "disease." From comparative effectiveness research we know that optimal care is only achieved if we:

- Know what disease we are treating;
- Choose the right drug;
- In the right dose;
- Administered at the right time; and,
- Delivered through the right route.

We also know that if we get any of those factors wrong, we may not only fail to cure the patient, we might make them worse.

The same is true of EHRs. There are many different EHRs on the market. Each one can be configured in many different ways.

At this point, the literature on the impact of EHRs is largely anecdotal. It has been well demonstrated that some electronic interventions at some institutions improve quality. In other setting, seemingly similar interventions show no effect. There have also been widely publicized cases where the quality of care was negatively impacted. Unfortunately, the current state of our knowledge of the interaction between EHRs and quality is analogous to the days when most medical journal articles were single case reports or small series.

By using and integrating EHR tools into rationally designed care and care measurement processes, Marshfield clinic, through it's participation in the CMS PGP Demonstration Project saved CMS over $25 million in the first two years of this demonstration, while meeting or

exceeding 27 out of 27 possible quality metrics. We are just scratching the surface of what can be done.

Instead, the national discourse on EHRs and health care quality should be focused on what are the attributes and relative value of electronic systems and tools that effectively and efficiently capture clinical data; provide decision support at the point of care; help convey true understanding and meaning to patients about what they are experiencing; assists patients in making truly informed decisions about their health care; in a manner that engages its patients in a way that motivates advancement of healthy behaviors; and, the nation understanding the performance of our health care system in rightly caring, in an effective, efficient, and compassionate manner for its citizens.

Submitted by
Marcie Granahan
CEO
United States Psychiatric Rehabilitation Association
MGranahan@uspra.org

Dear Sir or Madam:

On behalf of the United States Psychiatric Rehabilitation Association, I would like to submit the following statement for consideration by the Federal Coordinating Council on Comparative Effectiveness Research.

Psychiatric rehabilitation principles and psychosocial supports have been successfully employed for more than 30 years to bring about recovery in individuals with mental illnesses. Psychiatric rehabilitation, including such modalities as supported employment, supported education, and assertive community treatment, have assisted individuals to live a meaningful and satisfying life in the community. Psychiatric rehabilitation promotes recovery, full community integration and improved quality of life for persons who have been diagnosed with any mental health condition that seriously impairs their ability to lead meaningful lives. Psychiatric rehabilitation services are collaborative, person directed and individualized. These services are an essential element of the health care and human services spectrum, and should be evidence-based. They focus on helping individuals develop skills and access resources needed to increase their capacity to be successful and satisfied in the living, working, learning, and social environments of their choice.

USPRA would like to see a portion of the $400 million in funding for the National Institutes of Mental Health allocated to comparative effectiveness research on crisis residential services as an effective alternative to psychiatric hospitalization. Current studies in this area suggest crisis residential services result in more successful outcomes and a quicker return to the community than traditional psychiatric hospitalization. In addition, USPRA recommends comparative research is developed to examine the degreed to which psychiatric rehabilitation services reduce the use and cost of hospitalization and medication.

Thank you for your consideration.

Submitted by
Alan Mertz
President
American Clinical Laboratory Association
Washington, DC

I am Alan Mertz, President of the American Clinical Laboratory Association. ACLA members develop and perform laboratory testing providing physicians with information that is central to the prevention, diagnosis, treatment, and management of virtually all disease. Laboratory testing provides critical information in 70% of health care decision making, yet spending on laboratory services accounts for less than 3 % of U.S. national health care expenditures.

Laboratory testing is one of the most cost-effective components of our health care delivery system. For example, consider that a *six dollar* glucose test is the primary screening tool for prevention and/or early diagnosis of diabetes – a disease left undetected and untreated that will cost tens of thousands of dollars and untold suffering. While more complex genetic and molecular tests cost more, they often have an immediate substantial benefit for prevention, targeted treatment and management of disease.

There is growing interest in better evidence to support relative benefits and risks of alternative interventions used to treat particular health problems, to drive more efficient use of limited health care resources. Proponents contend that such evidence can contribute to more efficient use of limited health care resources. Although the greater emphasis of CER by far has been on therapeutic modalities, laboratory testing is integral to CER. Laboratory values are essential in CER, including identifying patients to be studied in CER of therapeutic interventions (e.g., to be enrolled in clinical trials or for other prospective or retrospective studies) and for quantifying baseline characteristics, assessing intermediate outcomes, conducting subgroup analyses, and more. You cannot measure the comparative effectiveness of treatments & outcomes for the major chronic disease cost drivers (heart disease, diabetes, cancer, kidney, etc) without utilization of laboratory services. In fact, studies have shown that lab testing is underutilized for these diseases. Other key considerations for CER are the availability and use of laboratory testing data in registries, claims databases, electronic health records, and other sources. There is also increasing interest in CER of diagnostic technologies, with some attention to laboratory testing. Certainly, some of the new, genomic-based tests could become subject to CER themselves.

An important consideration of CER involving laboratory testing is the relationship between CER, which is typically a population-based form of inquiry, and personalized medicine. Based on growing knowledge about inter-individual genetic variation that influences drug selection, laboratory testing is helping to determine how specific patients are likely to respond to a given drug. It is of significant importance that as CER develops, it will not diminish or counteract progress in personalized medicine, but be able to integrate protocols and study technology that will accelerate this new frontier of medicine.

Another caution -- comparative effectiveness will be a failure if it looks at health care spending in individual silos and uses short time horizons. Comparing different laboratory tests without

looking comprehensively at the "costs" (in dollars, health, and quality of life) of failing to prevent or diagnose disease early is bound to be a disaster. If CE looks only at a 5-10 year horizon, the cost of the tests and resulting preventative treatments might look high. Early screening, prevention, early diagnosis, and effective early treatment using the best technology available sometimes costs a more in the shorter (or even medium) term than doing nothing. It will be an error if CE programs stifle these approaches by limiting options and care. Continued innovation requires adequate reimbursement of the current technologies to finance research on the new technologies.

I hope you agree it is important for the clinical laboratory industry to be part of the equation in CER programs. We stand ready to support your efforts in all ways possible.

Submitted by
John D. Shaw
President
Next Wave
Albany, NY
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Our major recommendation is to move beyond traditional approaches and define comparative effectiveness as the approaches that yield actual improvement of quality on the ground, not simply more standards that take 17 years to implement.

Next Wave is one of 165 Supporting Organizations for **Stand for Quality.** To paraphrase function 6 in its recently released report "Building a Foundation for High Quality, Affordable Health Care: Linking Performance Measurement to Health Reform" - Comparative Effectiveness Measurement should not an end unto itself. An appropriate role for the HSS Office of the Secretary is to support evaluation of how best to get the tools developed by NIH and AHRQ into routine use by practitioners in their daily practices.

Our current health care system does not do this well. Only slightly more than half of existing best practices are actually implemented. Simply creating additional best practices as we have done traditionally will give us more of the same. What is needed is innovation and increased focus on non-traditional approaches that have been overlooked in bringing standards into use:

- Evaluate better ways of engaging patients in their own chronic care.
- Evaluate which types of community grass roots efforts have achieved rapid and effective implementation for their types of communities (homogenous middle class, diverse immigrant populations, rural, inner city, etc.)
- Patient centered/cross agency (e.g. health, education, environment for children's environmental health issues)

Submitted by
John C. Ring, MD
Director, Office of Policy Research and Development
American Heart Association - National Center

Washington, DC
john.ring@heart.org

The American Heart Association (AHA) and its Division – the American Stroke Association – appreciate this opportunity to inform the work of the Council on comparative effectiveness research (CER). We share with other stakeholders – Congress, the Administration, healthcare professionals, policy-makers and, most importantly, patients – the conviction that this is a very important initiative.

The Association feels that our contribution to this key discussion is apropos for three reasons:

- The AHA has 'standing' in this matter, because we represent patients confronting medical problems of massive personal importance and public scope.
    - The Association is the oldest, largest voluntary health organization having as its sole Mission the "build(ing of) healthier lives, free of heart diseases and stroke".
    - Despite considerable progress, cardiovascular diseases and stroke remains the number one and number three killers of residents of the United States. Coronary heart disease alone accounts for one in five deaths. The total direct and indirect costs in 2009 are estimated to be $475.3 B.
- AHA professional volunteers are recognized leaders in research pertinent to this consideration. Last year, the Association invested $160 M, out of $642M in total revenue on research, second only to the Federal government as a funding source for cardiovascular diseases and stroke.
- That AHA is not conflicted. The Association does not accept government funding. Our relationships with industry are limited and fully disclosed on our websites. The primary source of our funding is the individual donations of millions of U.S. residents.

We commend the Administration and the Congress for taking an essential first step in creating an effective CER enterprise.

The Association has developed a document, scheduled for publication next month in *Circulation*, that articulates our principles for CER. They are twelve in number, organized into four broad categories.

1. CER should be conducted and interpreted according to <u>fundamental, established and accepted scientific principles</u>. Analyses need to be disseminated quickly, clearly and effectively to a wide variety of target audiences to have the desired impact. The determination of cost effectiveness requires the same scientific rigor as the determination of clinical effectiveness.

a. Randomized controlled clinical trials determine efficacy and safety, which forms the basis for CER; several – CASS, TIMI, NASCET, ACAS, WASID, BARI and WARSS – are all landmark clinical effectiveness trials that meet the definition of CER.

b. Some important questions, however, must be addressed in larger, more diverse patient populations. Different types of evidence are required to do this most effectively, e.g. evidence gathered from registries and other observational studies. This type of evidence may be a better representation of 'real world practice' and is often less expensive and time-consuming to perform, but it is also subject to important methodological concerns:

- the role of chance;
- the impact of selection, recall and protopathic bias; and
- uncertainty re: extent of exposure, including misclassification of data.

c. It is essential that all stakeholders understand the limits of every type of evidence considered and that that understanding in incorporated into decision-making at every level, from the individual clinical encounter to coverage decisions made by public and private insurers.

2. The goal of CER should be to determine the **value** of an intervention <u>for patients</u>.

a. Research should define the most important metric: value. Value is the change in key patient-centered variables – clinical outcomes, quality of life and patient satisfaction – per unit investment. Determination of cost-effectiveness alone is insufficient to define value and may lead to unintended consequences: adverse clinical outcomes; and limited innovation. It is necessary to compare both clinical and cost effectiveness to determine comparative value.

b. Both comparative clinical effectiveness and cost-effectiveness need to be considered in the long-term. A focus on short-term gains alone is likely to have a particularly untoward effect on the wellness and prevention agenda.

c. CER, with its focus on the application of drugs and devices already developed and approved, is compatible with innovative healthcare research. All stakeholders should support limiting the use of high-cost products that are shown to be of marginal benefit from the perspective of individual patients.

3. CER <u>should</u> be applied to the care of individual patients, but <u>should not</u> be a substitute for sophisticated clinical judgment. Priority should be given to evaluating interventions that pertain to high-volume, high-cost chronic conditions; reduction of healthcare disparities; and filling gaps in current evidence-based guidelines.

4. The CER process must be transparent, fair and accountable so that findings are credible and actionable.

   a. Structure – governance and funding – are key. It must be inclusive, comprehensive and resistant to inappropriate influence from the public or the private sector. Apparent conflicts of interest raise skepticism and concern about participation by industry, despite its constructive and necessary role in the care process. Experience with the National Center for Health Care Technology, the Office of Technology Assessment and the Agency for Health Care Policy and Research underscore that this is more than a theoretical concern. It must – knowledgably and candidly – advance and balance the concerns of the individual patient and the public's health.

   b. A larger investment in CER will be required to realize its full potential.

   c. CER should not be funded at the expense of traditional forms of research that are supported through the National Institutes of Health, other public agencies and the private sector.

The Association has applied that position statement to the six questions posed by the Council on 4-10-2009 (*Federal Register* 2009;74(68);16398-99).

1. The Council should invest in the development and application of electronic health records, scientifically sound research methodologies, and a research workforce with the necessary size and skill set. This will require consensus on balance between utility and privacy/security. The Council should quickly develop and implement a robust system of evaluation to accurately and completely evaluate the impact of this initial investment and to direct future investment.

2. Short-term gain is more likely to be achieved by focusing on identifying and leveraging existing resources. Long-term gain will result from a careful consideration of priorities, coupled with better ways of estimating savings over time. Investments – both short and long-term – should prioritize the following: high-volume, high-cost chronic conditions; health care disparities; and evidence gaps in current clinical guidelines. These are not mutually exclusive, but need to be balanced, especially in terms of managing stakeholder expectations.

3. The Federal Government has a central role to play in CER for two reasons: it provides many of the services that need to be studied; and it has both a statutory and a moral obligation to advance the public's health. Development of infrastructure and of a process for prioritization are a good place to start.

4. Efforts limited to the public sector may be easier to implement rapidly and have the scope to inform broader efforts if the process is structured as an active learning system.

    a. Particular attention should be paid to the development of unintended adverse consequences, such as increasing health care disparities or limiting innovative research.

    b. Coordination of activity within the Federal Government is crucial for maximum effectiveness, especially over the short-term; the DHHS seems well-suited to performing this coordinating function, especially given the distribution of ARRA ’09 funding.

5. A crucial step in advancing the CER enterprise is the establishment of a public-private partnership with transparency in governance and funding and conducted in a manner that is inclusive and fair.

6. Two actions would increase understanding and trust within the broader community: establishment of an utterly transparent process, with realistic opportunity for public response; and a clear statement of whether or not the Federal CER enterprise will inform coverage decisions made by the Government or make those decisions itself .

Thanks you for inviting the Association to participate in today’s discussion. We look forward to working closely and constructively with the Council on this important issue. These public meeting represent a good start in making use of the nation’s initial, though substantial, investment in CER.

Submitted by
Steven Yannicelli, PhD, RD
Vice President, Science and Education
Nutricia North America
[personal information redacted]

The purpose of this letter is two-fold. First on behalf of Nutricia North America (Nutricia) a leader in clinical nutrition, I would like to take this opportunity to commend all of you on being selected to serve on the Federal Coordinating Council on Comparative Research. The roles you play are paramount in helping our country’s ongoing efforts to improve the quality of care in a cost-effective manner.

A leader in clinical nutrition, Nutricia North America specializes in development and sale of “medical foods” and specialized orphan infant formulas for the nutrition therapy of rare genetic, metabolic, allergic gastrointestinal and neurological disorders. The term “medical food” as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which

distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation " [1].

“Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision and intended for the specific dietary management of a disease or condition. The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for the patient who is seriously ill or who requires the product as a major treatment modality.”

The use of food in the treatment of disease was recognized as early as the 4th century BC and was a key component of the classical Hippocratic Oath. In that version of the oath, physicians were sworn to apply dietetic measures for the benefit of the sick. More recently, the value of medical foods for the treatment of certain conditions like Phenylketonuria (PKU) has become widely accepted as a standard of care.

Over the past 20-30 years, medical foods have played an integral role as primary therapy in many genetic, gastrointestinal and neurologic disorders in infants, children and adults. For example, in individuals with PKU, newborn screening, early diagnosis and use of medical foods early in infancy has prevented permanent retardation and improved quality of life in thousands. With proper use of medical foods, individuals with PKU are now enjoying a normal high quality of living. In patients with seizures unresponsive to drugs, medical foods, as part of a special diet, have been shown to either eliminate seizures completely or significantly reduced the number of seizures per day. Regardless of these outstanding medical benefits, knowledge of the efficacy of medical foods, as a cost-effective treatment of various diseases and conditions remains minimal at best in the U.S.

While no one can deny the impact that pharmaceutical drugs like antibiotics have had on the eradication of many diseases and the overall quality of health in general, clinical nutrition (medical food) as treatment continues to wage an uphill battle against a “Pavlovian” conditioned medical philosophy of a “pill for every disease”. Medical foods, as either the primary or partial therapy in managing chronic diseases remain overshadowed by large pharmaceutical companies. In all cases where medical foods are used as therapy the cost is minimal when compared to medications. We agree that there is a important role for pharmaceuticals in treatment to many disorders, but where there is a role for medical foods, they should be considered as part of the therapy.

We strongly believe that there is room for both pharmaceuticals and medical food treatments in specific diseases where medical foods can play an integral role. More importantly, we believe patients should have choices in their treatments, as long as those treatments are found to be comparable.

As such, we welcome comparative effectiveness research studies that include comparisons of medical foods to pharmaceutical drugs especially in the treatment of pediatric epilepsy, pediatric food allergy, genetic metabolic diseases, adult diabetes, and Alzheimer's disease.

Thank you for your time and consideration in this important matter. Please feel free to contact me if you have any questions. We look forward to the progress made by your committee.

A leader in clinical nutrition, Nutricia International specializes in the manufacture, marketing and (mail-order) distribution of medical foods and infant formulas for the dietary management of rare genetic, metabolic, allergic gastrointestinal and neurological disorders.

Submitted by
Jennifer L. Reck, MA,
Policy Director, Prescription Policy Choices
Hallowell, ME
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Dear Council Members,

Comparative effectiveness research will realize its potential to improve the quality of health care in the United States only to the extent that it is effectively disseminated to health care providers. Even the best, most objective data needs to be actively championed in order to make sure it is heard. The relatively limited impact of the federally-funded hypertension trial known as ALLHAT is a sobering reminder of that fact.[i] A large investment in research is ultimately wasted if not matched with a proportionate investment in effectively communicating the results.

Prescription Policy Choices urges the Council to prioritize adequate funding for the dissemination of comparative effectiveness research, including determining the most effective means for educating adult professionals.

Prescription Policy Choices is a national, nonprofit, nonpartisan, educational and public policy organization which provides objective research and expertise on prescription drug policies. We have worked with many states establishing and administering prescriber education programs (also known as academic detailing). Our white paper on this topic is available at: www.policychoices.org.

Submitted by
Andrew Kessler
Consultant
Friends of SAMHSA
Annandale, VA
Andrew@friendsofsamhsa.org

Good afternoon, and thank you for the opportunity to speak this afternoon. On behalf of the Friends of SAMHSA, a non-profit organization dedicated to advancing SAMHSA's mission and

visibility, I will be addressing the importance of comparative effectiveness research in behavioral health.

We recognize that it is not the charge of this council to recommend clinical guidelines for health care payment, or coverage or treatment. Yet in considering the needs of populations served by federal programs and opportunities, this council will recommend how to build and expand on current investments and priorities.
We appear today to urge the members of this committee not to overlook comparative effectiveness research in the area of behavioral health. Treatments for mental illness and substance abuse disorders must be studied and evaluated. Tens of millions of people require treatment for behavioral health disorders, so therefore much is at stake when determining how best to treat this population.

The Department of Health and Human Services has rightfully received a substantial amount of funds from the 2009 Economic Stimulus legislation recently passed by Congress and signed by the President. We all know that a healthy populace is a productive one, and economic growth cannot be initiated or sustained if the workforce is not well cared for.

Unfortunately, there is much to be disappointed about as well. While many HHS agencies will benefit from the funds allocated by the stimulus bill, there has been a glaring omission. The Substance Abuse and Mental Health Services Administration (SAMHSA) is not slated to receive any funding. As a result of this oversight, it is critical that we address behavioral health when setting priorities for comparative effectiveness research. If our country is to achieve its goal of a healthier and more productive society, behavioral health issues must receive the same attention as other chronic and acute diseases.

Because the issue today is funds from the economic stimulus bill, and the monies to be spent on health in conjunction with economic growth, I wanted to place on the record the economic cost of behavioral health disorders. In lost productivity, in emergency room visits and other health costs, the price tag is hundreds of billions of dollars. Also, consider the critical education that our children are deprived of when behavioral health disorders go undiagnosed and untreated. Untreated children face the high probability of becoming uneducated. Uneducated children leads to a weaker workforce. The link between effective behavioral health treatment and economic prosperity is not, by any stretch, a tenuous connection.

There are countless numbers of health disorders and diseases that require the attention of our government. Each and every one should be addressed using only the most effective treatments and prevention strategies. Yet in setting priorities, difficult choices must be made. It is hard to ignore the sheer numbers of those that require treatment for behavioral health disorders, as it is hard to ignore the money that can be saved with effective prevention and screening strategies.

The landmark mental health and addiction parity legislation that became law late last year has shown that our government is finally willing to take the bold action needed when it comes to behavioral health. Yet more action is required. Please, do what must be done in order to ensure that comparative effectiveness research involves behavioral health. It is a tough decision, one that may be politically or socially unpopular. But the right one.

Submitted by
Charles Homer, MD, CEO
National Initiative for Children's Healthcare Quality
James M. Perrin, MD, Director,
MGH Center for Child and Adolescent Health Policy
Boston, MA
Stephen Berman, MD, Professor of Pediatrics and Chair in General Pediatrics
University of Colorado and Children's Hospital
Debbie Chang, Senior VP and Executive Director
Nemours Health and Prevention Services
Newark, DE
Charles Bruner, PhD, Executive Director
Child and Family Policy Center,
Des Moines, IA
Christina Bethell, PhD, Executive Director
Child and Adolescent Health Measurement Initiative
Oregon Health Sciences University
Robert Restuccia, Executive Director
Community Catalyst
Boston, MA

The National Initiative for Children's Healthcare Quality (NICHQ) is pleased to have the opportunity to provide input to the Federal Coordinating Council on Comparative Effectiveness agenda. NICHQ is an independent, not for profit organization committed to achieving a world in which all children receive the health care they need; our focus is to improve child health by improving the quality of children's heath care, a strategy well aligned with the purpose of comparative effectiveness research. We write today to urge you to include children's health care, broadly conceptualized, in your research agenda.

In order to develop our recommendations, we convened a policy advisory group consisting of both NICHQ senior staff and key external advisors from a broad set of organizations with deep expertise in children's heath care and public policy. The committee quickly came to a number of major recommendations for the Committee's consideration:

1) At least three compelling arguments call for including children's health care as a significant focus of the comparative effectiveness research agenda:
    a. children particularly depend on public sources of funds for their health care (Medicaid, SCHIP),
    b. the consequences of poor health and health behaviors in childhood have long term, costly implications, and
    c. the research base for child health has been historically under-funded.

2) The topics for emphasis for comparative effectiveness research in child health should reflect the unique characteristics of child health and children's health care, specifically, their

a. Dependency on others, leading to the importance of supporting parental capabilities,
b. Rapid pace of development, leading to the key role of developmental surveillance and preventive care,
c. Distinct epidemiology, i.e., the increasing prevalence of a few highly significant chronic conditions such as obesity and asthma and mental health, coupled with the cumulative significance of a large number of relative rare conditions, and
d. Relative economic disadvantage and cultural diversity

3) Relative economic disadvantage and cultural diversity Considering these characteristics, the scope of comparative effectiveness for children should extend beyond the medical system to include all areas where children live, learn and grow with a focus on assessing how they can best promote and maintain child health.

4) The comparative effectiveness agenda for children should build on the excellent work of previous Institute of Medicine Committees. We recommend the comparative effectiveness research agenda draw from the pediatric priorities articulated by the IOM Committee that established Priority Areas for National Action. Relevant child health topics on this list included:

- Care coordination (cross-cutting)
- Self-management/health literacy (cross-cutting)
- Medication management—preventing medication errors and overuse of antibiotics
- Children with special health care needs
- Asthma—appropriate treatment for persons with mild/moderate persistent asthma
- Immunization—children and adults
- Major depression—screening and treatment
- Nosocomial infections—prevention and surveillance
- Pregnancy and childbirth—appropriate prenatal and intrapartum care
- Obesity

The key points we would emphasize in considering this list are:

a) A focus on cross-cutting themes (care coordination, family and self management support).
b) Consideration of children with special health care needs as a whole, as many of the issues in management (role of family, organization of services) are cross-cutting, as are many clinical issues (e.g., appropriate use of g-tubes or muscle lengthening procedures).

c) Attention to improving birth outcomes—and, correspondingly, care in pre-conception, prenatal, intrapartum and newborn care—as these are the biggest drivers of infant and maternal mortality and responsible for substantial health care cost as well.
d) Attention to children's mental health, both preventive and therapeutic, especially given the apparent growth in prevalence and long-term implications of mental health conditions.
e) A continued focus on both prevention and treatment of childhood obesity as this is increasingly a major driver (with smoking) of poor health outcomes.
f) A particular focus on addressing conditions relevant to populations experiencing disparate health outcomes (e.g., sickle cell disease, obesity, asthma, mental health).

We also urge a broad conceptualization of comparative effectiveness research. Comparisons of clinical treatments are necessary and valuable; comparisons of models of practice, care financing, information systems, population-based strategies, and practice supports and the like are also crucially important to arrive at a more effective health care system for children and all Americans. Parents, patients and other consumers should be involved in the formulation, prioritization and communication of this research.

We, the undersigned (CEO of NICHQ and members of Policy Advisory Committee), are extremely supportive of a strong program of comparative effectiveness research and want to make sure that children can also benefit from this new and exciting endeavor. We are available to offer advice in prioritizing areas of children's health comparativeness effectiveness with you.

Submitted by
[personal information redacted]

I marked my 10th college reunion with a miscarriage. It was my first pregnancy, and although I was well past 30, I was not remotely prepared for the physical loss, let alone the emotional one.

I flew home to the East Coast that night. When I arrived at the registration desk of a highly regarded academic medical center for a D&C the next day, I was handed an "informed consent" document typical of the period. It included provisions to the effect that excess specimens (which otherwise might be discarded) and information about me and the care I received might be used for research and that as a patient at an institution of higher learning, I agreed to this disposition. My profound grief temporarily gave way to outrage, and I marked up the document – an occupational predilection of a young lawyer regardless of distressed mental state – to allow the hospital to bill my insurance company for my treatment but not much more. I handed it back to the receptionist, who curtly informed me that I could sign the form "as is" or be denied treatment. I had no energy to put up a fight and was in too much pain to walk away, so signed a fresh copy with some vague intention to take it up again later.

Many years (and three healthy kids) later, I understand the significance of that simple consent – or really notification – process in enabling the clinical trials, health services research, and related public health activities so critical to learning about disease, developing new prevention strategies and interventions, and improving health outcomes. I appreciate that our expectation of continuous advances in science and medicine requires some measure of sacrifice. And I now recognize that it is imperative to make the best use possible of existing data and human tissue that otherwise would be discarded, especially as health care costs soar, resources disappear, and consumers, payors, and government officials increasingly and loudly demand that health care delivery and payment systems become more efficient and effective. Barak Obama pointed to the importance of health services research during his 2008 presidential campaign in his *Plan for a Healthy America*:

> One of the keys to eliminating waste and missed opportunities is to increase our investment in comparative effectiveness reviews and research. Comparative effectiveness studies provide crucial information about which drugs, devices and procedures are the best diagnostic and treatment options for individual patients. This information is developed by reviewing existing literature, analyzing electronic health care data, and conducting simple, real world studies of new technologies.

Congress embraced this approach in the American Recovery and Reinvestment Act ("ARRA"), appropriating $1.1 *billion* to comparative effectiveness research and establishing a Federal Coordinating Council for Comparative Effectiveness Research to "foster optimum coordination" and avoid "duplicative efforts". The legislation requires the Council, whose members were named in mid-March, to submit its first report to Congress on June 30, 2009, and in it to describe current activities and recommendations for use of the appropriated funds.

Yet we are in real danger of squandering the tremendous opportunities those funds provide to advance scientific knowledge and translate that knowledge to medical practice. Why? Because single-issue privacy hawks have succeeded in recent years in focusing public attention and concern on individual privacy rights without regard to the consequences for society. The foundational conceptions of a civil society or the common good seem almost entirely absent – or at best an afterthought – in current academic and political discourse on the "ethics" of research with human biospecimens and personal health data.

For example, the federal HIPAA Privacy Rule, which recently has been integrated in significant part and expanded upon in federal legislation through a section of ARRA titled the Health Information Technology for Economic and Clinical Health ("HITECH") Act, do not recognize research or public health activities as integral to a functioning health care system. The Institute of Medicine is just the latest organization to investigate the challenges this rule imposes to the pursuit of research and public health activities and recommends several policy changes aimed at mitigation. I have opined elsewhere that the challenges are due largely to the failure of the HIPAA Privacy Rule to recognize research as equally integral to the delivery of health care as accreditation, peer review, quality improvement, and other activities without which there is no ultimate accountability in the health care system. This failure, in turn, results in over-valuing "autonomy," a core privacy right that the HIPAA Privacy Rule is designed to protect.

To my knowledge, the cost of this construct to advancing knowledge and discovery and informing public policy has not been systematically weighed against the questionable benefits the HIPAA Privacy Rule and similar efforts bestow on individual rights. Fred Cate's brief but cogent piece delivered to the 2007 Privacy Symposium in Cambridge, *The Autonomy Trap*, explains how our overwhelming concern with individual choice or control, reflected in laws and regulations mandating various procedural protections, does not actually do a very good job serving its intended purpose of protecting substantive privacy rights. He argues forcefully that we should permit the use of medical records for research without individual consent, by recognizing the distinction between "privacy of the body – the right to refuse treatment or to choose among medically appropriate treatments – and privacy *about* the body." Quoting from Helena Gail Rubinstein's article, "If I Am Only for Myself, What Am I? A Communitarian Look at the Privacy Stalemate," 25 *Am. J. Law & Med.* 203 (1999), Cate observes that "relying on consent refuses to recognize 'in exchange for the vast improvements in medical care, a correlative responsibility on the part of the individual, as a potential consumer of health care services, toward the community. As individuals rely on their right to be let alone, they shift the burden for providing the data needed to advance medical and health policy information. Their individualist vision threatens the entire community[.]'"

As the current Administration and responsible agencies work to develop regulations to implement the HITECH Act's (and GINA's) new privacy and security provisions, it will be incumbent on them to consider the impact the regulations will have on comparative effectiveness and other health services research, with the ultimate goal of reasonably balancing individual privacy rights against scientific discovery, biomedical innovation, and quality improvement. The stakes are far too high to continue pursuing the goals of scientific and medical advancement, on one hand, and protection of individual privacy rights, on the other, in separate silos. It is my hope that, pursued together, these initiatives will result in reasonable compromise, for example by enhancing education and transparency about research uses of secondary data (and excess biospecimens) while reducing unnecessary regulatory barriers to *bona fide* research uses of these invaluable resources.

The views expressed above are my own and are not necessarily those of my current or former employers or clients.

Submitted by
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Thank you for the opportunity to participate in this Listening Session. My name is Patricia Adkins and I am the Chief Operating Officer and the Director of Public Policy for the Home Safety Council, a national nonprofit in Washington, DC.

The mission of the Home Safety Council is to help prevent and reduce the deaths and injuries that happen in and around the home such as falls, poisoning, fires and burns, choking and suffocation, and drowning. The Home Safety Council is one of the leading public health and safety nonprofit organizations working in the injury and violence prevention and response community. Our primary goal is to improve the opportunity for all individuals to lead healthy, active, and fulfilling lives.

I believe it is imperative that the Federal Coordinating Council include public health as a priority, with a specific focus on injury and violence prevention and response, when it makes its recommendations to the President, the Congress and the Federal agencies.

Purpose and Goals of the Federal Coordinating Council

Under the American Recovery and Reinvestment Act of 2009, the purpose of the Council is to assist the Federal departments and agencies in reducing duplication and encouraging coordination of comparative effectiveness and related health services research, as well as advising the President and Congress on its progress through its initial report which is due on June 30, 2009.

By definition, comparative effectiveness research compares treatments and strategies to improve health. And by knowing what works best, clinicians and patients can decide on the best treatment. Ultimately, this research enables our nation to improve the health of communities and the performance of the health system.

The White House Forum on Health Reform

The White House Forum on Health Reform was held on March 5, 2009. The President invited a diverse group of people to participate in this event to begin the process of addressing what he called "one of the greatest threats not just to the well-being of our families and the prosperity of our businesses, but to the very foundation of our economy – and that is the exploding cost of health care in America today."

During Breakout Session One at the Forum, the Executive Summary of the discussions highlighted the following: "Nearly every participant stressed the importance of investing in public health prevention…The group agreed this that would both improve health and reduce costs."

In response to the question, "how can we contain rising health care costs," one Congressional Member observed, "the model of our system is sick care, not health care…" Other comments centered around "wellness programs that focus on managing and preventing illness…" and another "noted the importance of public health and prevention."

Why injury and violence prevention and response are important to the work of the Council?

In 1998, the National Academy of Science stated - "Injury is probably the most under-recognized public health threat facing the nation today."

Each year, injuries resulting from a wide variety of physical and emotional causes – motor vehicle crashes, sports trauma, violence, poisoning, fires and falls – keep millions of children and adults from achieving their goals and making the most of their talents and abilities.

This is some of what we know:

- Nationally and in every state in the United States, injuries are the leading cause of death in the first 44 years of a person's life.
- In a single year, more than 50 million injuries required medical attention, with an estimated total lifetime cost of $406 billion.
- This total lifetime cost includes $80 billion in medical care costs and $326 billion in productivity losses, including lost wages and benefits and the inability to perform normal household functions.

These three statistics clearly show the consequences of injuries and the major burden on the health care system.

Fortunately, because of scientific discoveries and injury research, there are steps that can be taken to stop injuries before they happen and increase the likelihood for full recovery when they do. By incorporating these strategies into the community and everyday activities, we can improve the opportunity for all individuals to lead active, useful, and fulfilling lives.

<u>An Injury Example – Protecting Older Adults</u>

We all want a society where people, including our older citizens, can live to their full potential. And we can help many older adults avoid injuries. There are a variety of actions we can take to prevent injuries and premature death to our parents, grandparents, and friends. Some of the most important include preventing older adults from falling or from being injured in fires or motor vehicle crashes.

Let's focus on one of the injuries that affect the quality of life for older adults – falls. Falls are the leading cause of fatal and nonfatal injuries for those 65 and older. Each year, 1.8 million older adults are treated in emergency departments. Every 35 minutes, an older adult dies from a fall-related injury and every day 5,000 adults 65 and older are hospitalized due to fall-related injuries.

The cost for treatment is enormous - over $19 billion annually; and most of these expenses are paid for by CMS through Medicare.

While falls are a threat to the health and independence of older adults and can significantly limit their ability to remain self-sufficient, the opportunity to reduce falls among older adults has never been better. Today there are proven interventions and strategies that can reduce falls and help older adults live better and longer. They include medication review and adjustment, vision correction, and physical exercise. These evidence-based interventions can help save health care costs and greatly improve the lives of older adults. The costs are small compared to the potential

for savings. For every $1 invested in a comprehensive falls prevention program, it returns a $9 benefit to society.

How the Council Can Help

The Council can be a catalyst for changing people's perceptions of the value of preventing and responding to injury and violence by helping to create the social and political will to more fully support this public health issue.

Whether it's the lack of knowledge that solutions exist to reduce the impact of injury and violence; or not understanding that injury and violence are public health issues; or believing that unintentional injury is unpredictable and not preventable, the Council can address these challenges and provide a common foundation for collaboration.

The American Recovery and Reinvestment Act provides for $400 million to be allocated at the discretion of the Secretary of Health and Human Services. Incorporating the public health prevention strategies and interventions into the comparative effectiveness research is critical to developing a comprehensive plan for health reform. I urge the Council to reinforce the adoption of these public health strategies within the injury and violence prevention and response field to ensure that Americans remain healthy and live their lives to the fullest potential.

Submitted by
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I appreciate the opportunity to provide comments on behalf of Virtual Radiologic Corporation, a provider of teleradiology services, headquartered in Minneapolis. vRad was founded by radiologists and is a leader in teleradiology, with more than 140 contracted U.S.-based radiologists, of which 70% are fellowship trained, serving 1,025 medical facilities nationwide and providing more than 2.2 million interpretations in 2008.

vRad and teleradiology provide a number of well-established healthcare system features including:

- Infrastructure for electronic and digital transmission, reading, interpretation, reporting and record-keeping for diagnostic imaging services
- Efficient and cost-effective 24/7 deployment of highly-skilled diagnostic resources
- Access by rural and small community-based facilities to specialized, subspecialty-trained radiologists
- A resource for supporting clinical registries, clinical data networks, and other forms of electronic health data that could be used to generate or obtain outcomes data.

We recognize the magnitude of the Council's task in recommending priorities for the Comparative Effectiveness funding provided by Congress. You have the opportunity to look broadly across many divergent and competing segments of the U.S. healthcare system and we urge you to select topics that will have broad cross-cutting impacts.

We urge the Council to consider the following issues and priorities for comparative effectiveness research:

- Existing teleradiology and telemedicine resources should be developed and utilized as part of the infrastructure to establish registries, networks and other e-health data to analyze comparative effectiveness on diagnostic and treatment pathways for targeted health conditions.
- Reimbursement policies and claims processing systems aimed at controlling costs are impeding rather than facilitating the development of teleradiology and other innovative systems that provide cost-effective health IT-based services. Conflicting quality, credentialing and state policies under Medicare and Medicaid also impede access to quality teleradiology. Comparative effectiveness studies involving diagnostic services must be cognizant of the impact of these forces and provide solutions to improve access.
- Coordinating, leveraging, and providing synergies with Recovery Act and ongoing projects in developing and implementing the infrastructure for health IT, digital image transmission, e-health records, telemedicine, and teleradiology.

vRad is extremely well-positioned and very interested in serving as a partner in these important efforts to improve the nation's healthcare system.

Submitted by
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The National Association of Children's Hospitals and Related Institutions (NACHRI) is a not-for-profit membership organization of more than 215 children's hospitals. NACHRI promotes the health and well-being of all children and their families through support of children's hospitals and health systems that are committed to excellence in providing health care to children. Children's hospitals work to ensure the health of all children through clinical care, research, training and advocacy.

NACHRI supports increased investment in comparative effectiveness research (CER) to improve the quality of patient care and to support patients, families, physicians and providers in making decisions about the "right care at the right time." We welcome and appreciate the opportunity to provide this statement at the first listening session of the Federal Coordinating Council for Comparative Effectiveness.

Widespread variability in care, such as that demonstrated by the Dartmouth Institute for Health Policy and Clinical Practice in the Medicare population, exists in care for children as well. A chart book on quality of health care for children and adolescents developed for The Commonwealth Fund suggested that "one-quarter to three quarters of children do not receive the health care that is scientifically proven and/or that experts recommend to prevent disease, reduce

disease complications, and achieve optimal health and development" and that "up to one in five pediatric patients receives inappropriate care" (Leatherman and McCarthy, 2004).
NACHRI offers the following considerations as the Federal Coordinating Council develops its recommendations.

- Children and adolescents should be specifically included in priorities identified for comparative effectiveness research with careful consideration for separate studies evaluating only pediatric populations. Because many diseases afflicting adults originate in childhood and, because many of these diseases can be prevented, investing in children's health care effectiveness research is both a moral imperative and cost effective as the "impact of investments in quality will be longer lasting" (AHRQ, accessed April 9, 2009). According to the Agency for Healthcare Research and Quality, improvement in just four quality and patient safety topics could save between 3,700 and 7,400 children's lives in a single year.

- Priorities identified by the National Priorities Partnership (*Aligning our Efforts to Transform America's Healthcare: National Priorities and Goals*, 2008) and the Institute of Medicine (*Priority Areas for National Action: Transforming Health Care Quality*, 2003) should help to guide CER priorities.

- Comparative effectiveness research should address systems issues such as care models that integrate primary and tertiary care, longitudinal management of chronic conditions and transitions from pediatric to adult health care and should not focus only on specific drugs, devices and conditions. The largest immediate impact on quality and cost may not come from trials of specific drugs and devices but from identification of effective models of care delivery and avoidance of medical errors. This is especially true for children. Except for a very few conditions, the numbers of children with a single condition are small, and children and youth with special health care needs (CYSHCN) often have multiple chronic conditions. These children represent approximately 15 percent of children but consume 40 to 60 percent of health care resources devoted to children.

  Similarly, patient safety and prevention of avoidable medical errors, including safety of children's health care, should be an important focus for comparative effectiveness. For example, healthcare-associated infections (HAIs) result in significant disease burden and cost, are of great public interest and are an IOM and National Priorities Partnership priority area. HAIs are among the top 10 causes of death in the U.S. (GAO, 2009). Interventions to prevent HAIs often require adaptation for pediatrics. For example, unlike in adults in whom central line insertion bundles can eliminate Catheter Associated Blood Stream Infections (CABSIs), the insertion bundle alone does not eliminate pediatric CABSIs. A multi-center collaborative on reducing CABSI in Pediatric ICU's found that, in contrast to adult-based efforts, reliable use of nursing-oriented standardized daily line maintenance practices is the most significant factor in reducing CABSI in children. To-date the collaborative effort has reduced CABSI over 50 percent with an estimated 80 lives saved and over $23 million in health care cost savings.

- Sufficient research to establish effective and proven treatments in pediatrics is needed. It cannot be assumed that treatments shown to be effective in adults will translate into effective treatments for children. Accordingly, consideration for how to facilitate inclusion of children in randomized control trials with specific subgroup analyses and other comparative effectiveness research is required.

- Data, as well as demonstration efforts, should not focus only on the Medicare population, but should include Medicaid and CHIP as well. Investment in information to enable identification of variability, similar to that available for the Medicare population, in children's health care is critical.

- Representatives from the pediatric community should be included in any body or committees overseeing and guiding comparative effectiveness research.

Submitted by
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Thank you on behalf of CIGNA and the 12 million individuals and the companies that we serve for the opportunity to speak before the Institute of Medicine on establishing national priorities for comparative effectiveness research. It is our belief that in developing national priorities for comparative effectiveness research, there should be three guiding principles.

First, focus research on high impact areas. Research priorities should first focus on high prevalent conditions, which account for significant healthcare spending, and which have competing diagnostic or treatment pathways. Cardiovascular diseases, cancer, obesity, and arthritic conditions all have competing diagnostic and treatment pathways, and they collectively have a major impact on healthcare costs in the US in the adult population.

Second, costs should not be considered as the initial goal of comparative effectiveness research. Costs should only be considered in limited circumstances after the comparative effectiveness research shows that two alternatives are clinically equivalent: For these high impact conditions, there are often competing diagnostic modalities and treatment pathways, the comparative effectiveness has not as yet been established with the available evidence for the typical patient, or selected subpopulations. We should first establish through comparative effectiveness research, if one diagnostic modality or treatment pathway is superior to another, in terms of its safety and clinical effectiveness. This will have the effect of focusing treatment and coverage decisions on the most effective treatments available ***without*** consideration of the cost. However, if comparative effectiveness research shows that the two treatments are essentially equivalent to each other in terms of safety and clinical effectiveness, ***then and only then***, is it appropriate to consider the total medical costs associated for each treatment because patient outcomes would be the same and it would be appropriate to ask which alternative is the better value for our healthcare dollar.

Finally, we should first fund "shovel ready" projects. It is important that national priorities for comparative effectiveness research should focus initially on those studies which can be quickly approved by the NIH, AHRQ or CMS, and which can be up and running in a relatively short period of time.

Thank you for the opportunity to speak before this committee on this important topic.

Submitted by
Tony Curry
Gundersen Lutheran Health System
[personal information redacted]

To the Federal Coordinating Council for Comparative Effectiveness,

Thank you for your work in guiding the direction of Comparative Effectiveness research as part of the American Recovery and Reinvestment Act. Thank you also for the opportunity to share our comments today.

We believe that comparative effectiveness studies should focus on medical delivery systems and operations, resulting in information that can be leveraged to foster better clinical and cost outcomes.

With a one hundred year history of treating patients, Gundersen Lutheran Health System in La Crosse, Wisconsin is not new to medicine, but studies suggest that if the nation's healthcare organizations and health insurers replicate the way that Gundersen delivers healthcare, we could see a greater than 30% decline in national healthcare costs and improve healthcare value in the United States (2008 Dartmouth Atlas Health Study).

The annual Dartmouth Atlas Study identified La Crosse, Wisconsin as the lowest cost-of-care city in the nation for Medicare patients during the last two years of life. Health care at Gundersen Lutheran in La Crosse costs 72% less than the leading medical center in New York, 71% less than in Florida, 68% less than in California, and even 42% less than the leading medical center in Minnesota.

Why is the cost of care at Gundersen so much lower while the quality of care remains as good or better? Gundersen's cost and quality success is driven by their integrated delivery system. Every Gundersen program, from advance care planning and care coordination to heart care and breast cancer care stems from their integrated delivery approach. And each program that achieves top-in-the-nation status also has a correlating reduction – significant reduction – in healthcare costs.

As one example, Gundersen Lutheran's breast cancer program has become the first and only in the nation to achieve the highest level of distinction from the National Quality Measures for Breast Centers™ (NQMBC) Program. Gundersen Lutheran is also one of only two organizations in the country with every available accreditation for the full scope of breast care, diagnosis and treatment from the American College of Radiology. Gundersen's interdisciplinary model of caring for breast cancer patients has the potential to save an estimated $4.15 billion dollars in healthcare costs if it is implemented on a national scale.

As a lean and medium-sized medical center, however, putting resources into researching their programs' results for wider dissemination or use as a national best practice are resources Gundersen Lutheran just hasn't had in the past. This comparative effectiveness funding represents a mechanism by which organizations like Gundersen Lutheran can share their results and best practices.

So, in addition to investing comparative effectiveness dollars into treatment approaches for specific conditions, comparative effectiveness funds should invest in comparing the most effective health system delivery approaches in the United States. Only then, can comprehensive, sustainable healthcare delivery and payor system reform take root.

Gundersen Lutheran is a living lab for applied comparative effectiveness research. Understanding how and why Gundersen's approaches work will help lower U.S. healthcare costs, improve quality and create a more sustainable payment system that incentives the outcomes it seeks to achieve. Gundersen Lutheran is willing to share further information and our program data to help move this work forward.

Thank you again for the opportunity to share our recommendations for comparative effectiveness research as part of the American Recovery and Reinvestment Act. We hope for the opportunity to contribute to this movement toward healthcare reform.

Headquartered in La Crosse, Wisconsin, Gundersen Lutheran Health System is a not-for-profit organization that provides quality health services to patients at its hospital and clinics throughout western Wisconsin, southeastern Minnesota and northeastern Iowa. Gundersen Lutheran is comprised of nearly 700 medical, dental and associate staff, and supported by a staff of more than 6,300. Gundersen has been consistently ranked in the top 5% of hospitals in the country.

For additional information, contact Gundersen Lutheran's Joan Curran, Chief of Government Relations and External Affairs, at (608) 775-1400, located at 1900 South Avenue, La Crosse, WI 54601. You may also contact our Washington-based associate Ladd Wiley, Akin Gump, at (202) 887-4083.

Submitted by
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My name is Meridith Mitchell and I am presenting on behalf of M2S, Inc. I thank you for the opportunity to comment today and appreciate the willingness of this committee to seek public input with regard to Comparative Effectiveness Research (CER.) The focus of this statement is on the utilization of a Clinical Technology Organization (CTO) to effectively facilitate CER.

M2S has significant and specific expertise in the development of patient registries, endovascular 3-D modeling, and medical imaging core lab service. M2S is a CTO with experience, flexibility

and efficiency, delivering the highest quality benchmarked reporting at the lowest total delivery cost.

As funds are allocated for CER and Health Services Research (HSR) it will be critical to utilize a CTO. A CTO is a clinical research company that focuses on clinical informatics and optimizes the use of technology to increase efficiency, reduce cost and maintain or enhance clinical quality. Equally important is to rely on a CTO that is knowledgeable in CER initiatives and capable of delivery today. A CTO is powerful when actively used in the clinical pathway as well as for research initiatives such as CER.

M2S recognized the need for CER as it relates to endovascular aneurysm repair beginning in 2001. M2S' Patient Evaluation and Management System (PEMS®) is the largest radiological/clinical footprint in the world relied upon by highly respected physician investigators. It is a database of 150,000 patient entries providing CER of FDA approved Aortic Stent Grafts. The service has been broadly adopted by health care advocates in both practice and industry having recognized the impact that this vast and valuable repository of data has on quality improvement.

In the past Comparative Effectiveness studies have evaluated a particular therapy only against itself. M2S evaluates the full scope of information including the patient health record, radiologic information with patient input. This model is unique, highly effective and patient centric and has direct impact on the quality of patient care.

M2S believes that simplifying the work flow facilitates summarization of comparative data and enhances a clinician's ability to make informed treatment decisions. An effective CTO collects data simultaneously as fields are populated by the institution or Electronic Medical Record (EMR) system. The flow of data provided for comparative analysis is aggregated, risk-adjusted, evaluated and reported on by an independent panel of physician thought leaders.

We all agree that the goal of CER is to enhance patient care; a web-based integrated clinical technology platform is a key component in the success of these projects. Health care organizations are striving to make better use of clinical informatics as an adjunct to Comparative Effectiveness. Involving a CTO early in the planning phase will streamline the process, reduce costs, and facilitate better data aggregation with one accessible portal for all relevant information.

Submitted by
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As an organization focused on information and education for physicians and other healthcare professionals, Medscape, LLC endorses the increased funding for comparative effectiveness research ("CER").

Results of the CER are highly relevant to all stakeholders, consumers, patients, physicians, nurses and healthcare professionals. Furthermore, it is extremely important that the latest results on effectiveness, safety and quality measures be incorporated into clinical practice as rapidly as possible. A multidisciplinary, multi-modal approach is essential to accomplish this result. Therefore, it is important that communications and education for both healthcare professionals and consumers/patients be incorporated into the overall strategy for CER.

In measuring significance of comparative effectiveness research on clinical practice, one must not overlook the importance of disseminating the results to as wide-spread a professional audience as possible.
It is particularly critical to include educational components and educational outcomes studies in order to determine the effect of this research on changes in clinician behavior and patient health.

An AHRQ Evidence Report on Continuing Medical Education (CME) published in 2007 concluded that, despite limited evidence, CME appears to be effective at the acquisition and retention of knowledge, attitudes, skills, behaviors and clinical outcomes. In addition, the study suggested the following:[1]

- Live media was more effective than print. In fact, print interventions were either not beneficial or very weak in their ability to improve attitudes.
- Multimedia was more effective than single media interventions.
- Multiple exposures were more effective than a single exposure.

Furthermore, evidence is increasingly demonstrating that on-line CME may have particularly large positive effects on outcomes.[2] According to a 2008 meta-analysis published in JAMA, 16 of the 17 studies analyzed revealed improved knowledge, behavioral outcomes, or both for participants using Web-based interventions.[3] In a recent randomized controlled trial of 113 primary care physicians, those who viewed an on-line diabetes seminar were 63% more likely to order an eye exam for diabetes patients than physicians in the control group (27%).[4]

MedscapeCME is currently a major provider of online CME/CE, reaching over 1.5 million physicians and nurses each month. In an analysis of outcomes studies on 97 Medscape on-line CME activities taken by 13,520 physicians, participants were 52% more likely than non-participants to make diagnostic and therapeutic choices based on clinical evidence. [5]

Specifically, over the past two years, Medscape has published CME activities based on several AHRQ Effectiveness Report Executive Summaries:

- Comparative Effectiveness of Treatments To Prevent Fractures in Men and Women With Low Bone Density or Osteoporosis: http://www.medscape.com/viewprogram/17304
- Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer: http://www.medscape.com/viewprogram/17364
- Comparative Effectiveness of Angiotensin-Converting Enzyme Inhibitors (ACEIs) and Angiotensin II Receptor Antagonists (ARBs) for Treating Essential Hypertension http://www.medscape.com/viewprogram/8669
- Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics http://www.medscape.com/viewprogram/7361

- Comparative Effectiveness of Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression: http://www.medscape.com/viewprogram/7793

These activities have been viewed by 5,000 to 18,000 nurses, physicians, and medical students and the CME participation rates for each AHRQ activities have ranged from 3,300 to over 8,500. In 2007, Medscape commissioned an educational outcomes study with a third party research group based on the CME activity for *Comparative Effectiveness of Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression.* Over 3,000 physicians participated in this on-line activity and the outcomes study results suggested that these participants are 68% more likely than non-participants to make evidence-based choices in the diagnosis and treatment of adult depression. It should be noted that these 3000 physicians are estimated to see at least 72,000 patients each week who have adult depression, suggesting the significant positive impact of online CME based on these Effectiveness Reports.

In conclusion, funding for a massive educational program is imperative for changing clinician behavior and effecting improved patient health and cost effective care. Both the evidence and Medscape's experience emphasize the benefits of a comprehensive online educational program. It is imperative not to neglect this component of the CER funding available in the Recovery Act. Finally, it should be strongly noted that educating the patient on the results of this research is critical to the effectiveness of these programs in improving health and reducing medical costs.

[1] Marinopoulos SS, Dorman T, Ratanawongsa N, Wilson LM, Ashar BH, Magaziner JL, Miller RG, Thomas PA, Prokopowicz GP, Qayyum R, Bass EB. Effectiveness of Continuing Medical Education. Evidence Report/Technology Assessment No. 149 (Prepared by the Johns Hopkins Evidence-based Practice Center, under Contract No. 290-02-0018.) AHRQ Publication No. 07-E006. Rockville, MD:Agency for Healthcare Research and Quality January 2007.

[2] Casebeer L, Engler S, Bennett N, Irvine M, Sulkes D, DesLauriers M, Zhang S.A controlled trial of the effectiveness of internet continuing medical education. BMC Med. 2008 Dec 4;6:37.

[3] Cook DA, Levinson AJ, Garside S, Dupras DM, Erwin PJ, Montori VM. Internet-based learning in the health professions: a meta-analysis. JAMA. 2008 Sep 10;300(10):1181-96. Links

[4] Weston CM, Sciamanna CN, Nash DB. Evaluating online continuing medical education seminars: evidence for improving clinical practices. Am J Med Qual. 2008 Nov-Dec;23(6):475-83.

[5] Poster Presentation at CME Congress 2008 in Vancouver, BC; C. Grimes, M. Irvine, DJ Sllkes, L Casebeer, M Abdolrasulnia, M DesLauriers, Medscape LLC, New York, NY, USA, Outcomes, Inc. Birmingham, AL, USA

Submitted by
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National Patient Advocate Foundation (NPAF) is a non-profit organization dedicated to improving access to healthcare services through policy reform. Our mission of creating avenues of patient access through improved access to, and reimbursement for, evolving therapies, therapeutic agents, and devices is influenced by the experience of patients who receive case management services from our companion organization, Patient Advocate Foundation (PAF). Last year, PAF received more than 9.5 million inquiries from patients throughout the United States seeking information and assistance for access to care issues resulting from diagnoses of a chronic, debilitating or life-threatening disease. Of those, 48,369 became full patient cases involving communications made by PAF staff on behalf of a patient in order to reach positive resolution.

The *"American Recovery and Reinvestment Act of 2009"* includes $1.1 billion in new funding for comparative effectiveness research. NPAF supports comparative effectiveness research and believes it should be used as a tool between providers and their patients to determine the best course of action in treatment. However, NPAF is concerned that the Federal Coordinating Council established in the stimulus bill does not include roles for patient representatives.

NPAF strongly believes that the Federal Coordinating Council should consist of all relevant stakeholders, including patient and consumer groups, government, providers, insurers and manufacturers of drugs and medical devices. These stakeholders should be involved in every step of the process, from setting the research agenda, and developing study methodology, to the translation and dissemination of findings.

While we appreciate the invitation to participate in today's public listening session, other health agencies, such as FDA and CMS routinely appoint patient representatives to their scientific research panels, and we encourage the council to seek to correct this situation.

In addition, NPAF is concerned that comparative effectiveness research may ultimately be used to make cost-effectiveness decisions. NPAF would like to emphasize our support for comparative effectiveness research for the purpose of improving the quality, safety and delivery of care; however, NPAF does not support using this research to limit access, deny treatment or reimbursement.

Many European countries have already developed a system for comparative effectiveness research but many of these countries impose cost-effectiveness analysis in ways which ultimately deny patients access to more expensive drugs. In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) conducts research and develops guidelines for the country's National Health System (NHS). In the last several years, NICE has instituted certain coverage decisions based on cost-effectiveness that severely impact patient access to appropriate care. As recent as

January 2009, Ministers in the Welsh Assembly overturned a NICE decision that prohibited kidney cancer patients from accessing drugs such as Sutent, Avastin, Nexavar and Torisel, all of which have been proven to treat kidney cancer effectively. In the United States, it is common practice for these drugs to be prescribed to a kidney cancer patient. Advancing comparative effectiveness research in the U.S. can be a positive tool for patients and providers, only when it focuses on clinical comparative effectiveness.

NPAF also believes that a national comparative effectiveness program should prioritize the linking of data from federal and private entities to build upon existing data collection efforts and research capabilities. Insufficient funding for any public or private entity responsible for aligning and maintaining a robust data network has resulted in isolated clinical outcomes research efforts. Expansion of CER activities should include public-private coordination of data collection and interoperability of both clinical research networks and healthcare databases in order to increase the available data.

CER should support for the development of "personalized" or stratified medicine by further examining individual factors that contribute to disease susceptibilities and differences in clinical outcomes.

NPAF urges you to consider these issues as the Council makes its recommendations to the Secretary on comparative effectiveness research priorities so that comparative effectiveness research will have beneficial long-term consequences for patient care and access.

Submitted by
Fred Edwards
Director of Government Relations
The Society of Thoracic Surgeons
Washington, DC
[personal information redacted]

The Society of Thoracic Surgeons (STS) appreciates the efforts of the Federal Coordinating Council for Comparative Effectiveness Research in soliciting input for consideration of priorities for comparative effectiveness research studies as called for in the American Recovery and Reinvestment Act of 2009 (ARRA). We welcome the opportunity to submit the following testimony as you consider recommendations on research priorities.

STS is a not-for-profit organization representing cardiothoracic surgeons, researchers, and allied health professionals worldwide who are dedicated to ensuring the best possible surgical care for patients with diseases of the heart, lung, esophagus, and other organs in the chest. Founded in 1964, the mission of STS is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research and advocacy. STS supports data-driven approaches to quality measurement, quality improvement, and quality reporting because we

recognize that the collection of clinical data and the feedback of those data to physicians improve patient outcomes.

The STS National Database is the premier voluntary clinical data registry for cardiothoracic surgery; it includes three component parts: the Adult Cardiac Surgery Database, the General Thoracic Surgery Database, and the Congenital Heart Surgery Database. Surgeons add new patient data to the database semiannually or quarterly each year, thereby providing a highly dynamic, up-to-date picture of cardiothoracic surgical practice.

Our comments focus on the Adult Cardiac Surgery Database that contains detailed clinical information relevant to the processes and outcomes of care in adult cardiothoracic surgical procedures (STS ACD). This information, collected over a 20-year period, has been used to improve the quality of care for patients undergoing cardiothoracic surgical procedures. The STS ACD captures data on all adult patients undergoing cardiac surgical procedures performed by participants throughout the United States and, with more than 960 participants representing more than 2,800 individual surgeons, STS estimates that it captures approximately 90 percent of all adult cardiac surgery performed nationwide. Currently, the STS ACD contains more than 3.6 million surgical records and is the largest clinical cardiac surgery database in the world.

Clinical registries developed by STS and the American College of Cardiology (ACC) have been at the forefront of quality improvement activities in cardiovascular medicine for a number of years. Combined, STS and ACC databases cover virtually the entire spectrum of cardiovascular care. The STS ACD and the ACC's National Cardiovascular Data Registry (ACC NCDR) have provided clinicians with important feedback on their practice patterns and performance, and are invaluable tools for use in real world medical practice and health services research. The ACC NCDR is the ACC's group of clinical databases that measure and quantify outcomes in the delivery of quality cardiovascular patient care. It is designed to improve the quality of cardiovascular patient care and to identify gaps in care by providing information, knowledge and tools, implementing quality initiatives, and supporting research that improves patient care and outcomes.

The information in these registries supports performance assessment, and comparative effectiveness studies, as well as the integration of new treatments into routine clinical practice. These registries contain detailed information, including demographics, cardiovascular history, patient risk factors and co-morbid illnesses present on admission, interventions, care processes, and risk-adjusted outcomes surrounding specific clinical events. The STS ACD and ACC NCDR represent the "gold standard" of clinical databases in the country and can serve as the prototypes for registries across medicine.

Specific provisions in the ARRA call for funding to accelerate the development of research assessing the comparative effectiveness of health care treatments and strategies, through efforts that encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data. STS believes that by linking clinical data from the STS ACD and the ACC NCDR with Centers for Medicare and Medicaid Services (CMS) administrative data, a powerful, longitudinal data set could be produced. Such a data set would contain process, outcomes, utilization, pharmacy, and

cost data spanning at least a three to five year period. This linking project has the potential to cover virtually the entire spectrum of care for cardiovascular disease. Ultimately, the information obtained from this collaborative effort will produce new insight into the comparative effectiveness of coronary revascularization treatment strategies, such as coronary bypass grafting and stenting procedures. Because the STS and ACC databases are mature, there exists the real potential to achieve extraordinarily meaningful results in a timely manner, certainly within the time frame set forth to fund comparative effectiveness research projects under the ARRA.

A similar collaboration between STS and ACC is also under way in congenital heart surgery. ACC is collaborating with STS in the development of its pediatric database, harmonizing data definitions with STS's Congenital Heart Surgery Database. Down the road, this collaboration will facilitate following patients through episodes of care as well as longitudinal follow-up and comparison of outcomes.

The approach used in this project can be adopted by other specialties and their professional societies for comparative effectiveness studies and quality improvement. The techniques of analysis will have broad application to the entire field of medicine.

The results of these comparative effectiveness studies will almost certainly improve the care of cardiovascular patients while shedding new light on ways to provide care more efficiently. The above mentioned linked data set would also be a valuable source of data to examine appropriate use criteria, efficiency of care, cost of care, and value-based health care. Accordingly, we urge the Council to strongly support the development of this collaborative STS-ACC project that would reflect and effectuate the intent of the ARRA to utilize clinical registries in the analysis of comparative effectiveness research studies.

Additionally, we ask the Council to strongly consider the following comparative effectiveness research studies in cardiothoracic surgery:

1. STS-CMS longitudinal follow-up to assess the long-term impact of compliance with NQF-endorsed performance measures;
2. STS-CMS assessment of comparative effectiveness of valve replacement and repair procedures;
3. STS-CMS longitudinal follow-up of patients undergoing surgery for various forms of lung cancer treatment; and
4. Using IT links between the STS National Database, the ACC NCDR, and the CMS MEDPAR dataset, examine the comparative effectiveness of percutaneous *versus* surgical treatment of atrial fibrillation.
5. Assessment of the comparative effectiveness of new technologies and treatments as they are introduced;
6. IT Projects Facilitating Healthcare Data for Research;

We applaud the Council for convening this meeting to obtain input from various stakeholders and inform its development of priorities for comparative effectiveness research. Thank you again for this opportunity to provide testimony.

Submitted by
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Standard Biologics, Inc., is a U.S. Registered and Resident Corporation. Mr. Joseph A Cerceo, is the President and Founder of Standard Biologics, Inc. ('S.B.Inc.').

Mr. Cerceo has many very successful years of experience in the field of **Scientific Applications Research** including work on behalf of the **US Government**.

After studies that involved Chemistry for the Health Sciences; The Vitamins; Advanced Nutrition, Macronutrients and Micronutrients; Nutrition and Exercise Immunology; Nutrition and Gene Expression; Nutrition applied to Sports Medicine and Injury Rehabilitation; Athletic Injuries and Rehabilitation; Cell Biology of Trauma; Endocrine Physiology; Bone, Fracture Repair and Regeneration and the Bioavailability of Nutrients Mr. Cerceo discovered the extensive natural medicinal abilities of a **very high quality Proteolytic enzyme** (i.e. a Protease, termed by S.B.Inc. also as its 'Protocol').

Several years of research were completed culminating in the successful Application of a US Patent that covers inter alia the invention of the techniques of successful assessments for treatment of patients and methods of the Administration of the Protease to mammals (and, by extension, to a broad diversity of other animals) with the initial very successful treatments being of **inflammation** and **trauma** in their *many manifestations*.
The Proteolytic enzyme is attracted to and acts rapidly at sites of inflammation in the host.

So effective are such capabilities of the Protease that lives that could well have been lost due to uncontrollable inflammation occurring post surgery and otherwise, were saved by the administration of the Protease following Mr. Cerceo's invented Administration techniques. S.B.Inc. has documents related to this point in formats applicable to technical explanation as well as several 'Proof of Concept' statements.

Further research and development and a substantial number of 'Proof of Concept' trials firmly established further extremely important capabilities of the Protease that can be described in relation to the dictum, "**Inflammation is everything** !!"

Additional important aptitudes relating to the Protease's beneficial powers are in respect of:

The treatment of **Cancer tumours** including those in inoperable or life-threatening bodily positions thereby helping to reduce dangerous invasive surgery.
The Protease suppresses angiogenesis (the development of the vasculature of the tumours), that 'feeds' the tumour, thereby starving the tumour. A precautionary course of anti-biotics can be applied to treat potential secondary infection from the resulting necrotic tumour tissue.
A consequent further advantage is that there will be a range of cancer cases **where treatment of the patient by radiotherapy and chemotherapy will be unnecessary** with all the benefits to both the patient and to the finite treatment resources available that that advantage will bestow – the avoidance of those treatments will not be the case for all cancer patients.
The neutralization of VEGF, vital to the progress / metastasis of such as bone cancer. **VEGF** is promoted by inflammatory proteins which are hydrolyzed by the Protease.

Cell-signalling, i.e. the utilisation by the Proteolytic enzyme of this phenomenon to enhance its ability to identify and attack non-self proteins - including the hydrolyzation of a **variety of viruses and pathogens** (not just individual viruses or pathogens) such as various strains of Influenza, Common Cold, HCV / HIV (these are currently under long-term trial), and such other serious viruses as Avian Influenza, Ebola hemorrhagic fever, Rift Valley and Yellow Fevers and so on (a capability enabled by a characteristic of the Protease of having a **broad spectrum peptide specificity**).
Other non-self protein-bearing pathogens may be hydrolyzed such as Malarial protozoan parasites and Babesiosis and other zoonotic parasites similarly with non-self proteins (as detailed by Professor Brian Greenwood of the London School of Hygiene and Tropical Medicine).

Pain Medication is brought about in varying meaningful degrees by the beneficial impact of both S.B.Inc. products on the body's pain response mechanisms.

Importantly, this 'Protocol' has the Approval of **EPA** and **FDA** and also it is approved by FDA as a Food Grade Additive (it is considered as safe as any other food ingredient monitored by the US Government).

NB: **An important attribute** of this Company's products is that when they are administered to a patient in accordance with our straightforward and not unpleasant procedure(s) ***NO adverse side-effects are experienced in virtually ALL patients***.
An American adage with particular relevance to our Adjuvant *Anti-Inflammatory Protocol*, our enzyme, is that it is analogous to 'Chicken Soup', i.e. the enzyme can't hurt; it will only do good. The human body produces, normally, a very small amount of such an enzyme and the corollary is that **the mammalian system actually welcomes the administration of our Protease**.

Product costs: Standard Biologics, Inc. confidently expects that both its medical treatment developments – the Proteolytic enzyme and the complementary Therapeutic Nutritional Supplements will prove to be substantially less costly than pharmaceuticals measured as at both point of use and also when costed taking into consideration that they do not cause adverse side-effects that can be expensive and resource-consuming to treat.

Standard Biologics, Inc., ('S.B.Inc.') has either sent or will send shortly Corporate and Product Information to:

BARDA (Biomedical Advanced Research and Development Authority) @ H&HS;

The DTRA at the DOD;

CDC - The Influenza Division;

CDC - The NCHHSTP Division;

The NIH – the Office of Dr. Anthony Fauci, M.D., Director of NIAID;

U.S. Homeland Security Department;

The Department of State – the Office of the Global Aids Coordinator;

United States Army Institute of Surgical Research, Fort Sam Houston, Texas 78234-6315;

USDA - ADOL in East Lansing, Michigan;

USDA – SEPRL in Athens, Georgia;

And other U.S. Government areas.

Submitted by
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I am Sam Lin, a Family Physician, representing the *American Medical Group Association* based in Alexandria, Virginia. *AMGA* is a professional medical association representing some of this nation's largest, best known, and prestigious integrated health care delivery systems. More than 95,000 physicians practice in *AMGA* member organizations and provide health care services for approximately 95 million patients.

Today, in the context of the Comparative Effectiveness Research to be funded by the Recovery Act, you are hearing comments with a focus on disease conditions and treatments. And while those viewpoints are critical to the discussion, it is imperative that we also examine the context in which healthcare is given. Unless the delivery system is considered, we otherwise would continue to promote fragmented care, leaving our patients to wander on their own. *AMGA* supports the fundamental concepts of comparative effectiveness information use in health care delivery, but we also believe that delivery systems matter. There is an emerging body of evidence that supports this idea, and this premise is also being tested in several CMS demonstration projects. We, therefore, strongly recommend that the Coordinating Council consider comparative effectiveness in its broadest terms and not be limited only to research on treatments and devices alone.

CER should be undertaken for quality, efficiency, effectiveness, and other appropriate dimensions for health care delivery systems along the entire spectrum of systems integration. This spectrum should include integrated delivery systems, multi-specialty group practices, single-specialty groups, "virtual" groups such as IPAs, PHOs, and small medical practices (solo, duo, small groups), and perhaps others.

Use of comparative effectiveness information on delivery systems would facilitate and strengthen provision of patient care, disease states, and related financial determinations. By knowing what works best in treating patients, this nation's healthcare delivery system could make substantial strides toward improving clinical outcomes and closing gaps in geographic and population variations, while reducing health care expenditures. While we favor CER, we temper that view with a caution that such information must be objective, developed by disinterested parties, and should be equally applied.

Submitted by
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University Hospitals (UH) is a world-renowned academic health care facility located in Cleveland, Ohio with research specialties that span 21 academic and clinical departments. UH is also the primary affiliate of Case Western Reserve University School of Medicine (CWRU). Together, UH and the CWRU form the largest biomedical research center in the state of Ohio. In order for UHC to continue to provide effective, quality health care for its patients, the need for comparative effectiveness research (CER) must be met. The mission of UH is To Heal. To Teach To Discover. This drives the ability to responsibly grow research and scientific innovation to improve patient care. In order to achieve the organization's overall mission, the research arm must provide sufficient infrastructure to drive the To Heal part of the mission. CER is a necessary component of that research infrastructure and without out CER the link back to patient care would not be as direct. CER at UH is primarily driven in two ways: 1) interdisciplinary outcome databases to record patient treatment information from admission to discharge are created and maintained throughout the organization; and 2) the large clinical populations in the areas of Surgery, Oncology, Pediatrics, Cardiovascular Medicine and Neurology drive the innate ability to conduct large scale CER.

1) Department of Surgery: Serving as the tertiary referral hub for UH, the Department of Surgery is comprised of the Divisions of General Surgery, Vascular Surgery, Cardiac and Thoracic Surgery, Plastic Surgery and Pediatric Surgery. Surgeons have faculty appointments at Case Western Reserve University School of Medicine and are either Board Certified or Board eligible in their respective surgical disciplines. Across the United States, most hospitals use several databases to record patient treatment information from admission to discharge. To date, such databases are typically unable to communicate with each other, thereby making it time consuming (if not impossible) to efficiently and accurately track patient treatment and outcomes information. Therefore, physicians (and hospitals) are unable to routinely monitor and compare the effectiveness and true costs of different treatments/procedures as well as physician performance. An example of this needed database is currently being developed on a small-scale pilot basis "in-house" by UH physicians in the Department of Surgery to readily view patient outcomes by surgical sub-specialty. This is helping to overcome the difficulties in having so many disparate clinical information systems and makes the data more valuable than before. This program interfaces with each hospital database to extract the information necessary to recreate a patient's hospital stay from admission to discharge, as well as the occurrence of any readmissions and outpatient visits and procedures. It provides physicians and hospitals with treatment and outcome information that was previously unavailable such as: true patient treatment history, including physician's costs and data, combined with hospital costs and data; comparison of recovery time and costs for competitive treatments (e.g., laparoscopic versus open); physician performance (operating room time, recovery time, length of stay, etc.); readmissions based on type of surgery, physician, etc.; and research or educational purposes (for example, outcomes relating to a particular surgery with patients having particular complications or diagnoses). However, this type of database is needed not just for one clinical and academic department, but for all UH and CWRU departments;

2) Cancer Care: The Ireland Cancer Center at UH is one of only 39 Comprehensive Cancer Centers in the country designated by the National Cancer Institute. (NCI), allowing Ireland to offer cutting-edge treatments earlier than most other cancer centers. Our affiliation with CWRU provides ongoing studies aimed at cancer treatment and prevention. Cancer therapies change on a case by case basis and most institutions are turning to a multidisciplinary approach, employing experts in surgery, medical oncology, radiation therapy, pathology, nursing, social work and psychology working together to create a personalized treatment plan that meets the physical, emotional and spiritual needs of patients. Moreover, new treatments and investigational procedures are tested every day in cancer patients. At UH alone there are more than 300 cancer clinical trials, many of them featuring new drugs developed by our own clinician-scientists. With such a large group of medical care providers and variety of cancer treatments, Federal funding for CER is needed not just to continue expanding available cancer treatments, but also to standardize and prioritize these cancer therapies based on patient outcomes to ensure proper allocation of resources.

3) Children's Health Care: Rainbow Babies and Children's (RBC) Hospital at UH is one of the top Children's Hospitals in the world. RBC is a world leader in the treatment of children with heart disease , cystic fibrosis, sickle cell disease and endocrine and metabolic disorders . As part of the Ireland Cancer Center, RBC's comprehensive pediatric cancer center offers the most promising treatments to children. RBC is ranked #2 in neonatal care/NICU and among the top 10 best hospitals in the country for neurology / neurosurgery and respiratory disorders[7]. Children receiving medical care are at risk because the devices and treatments given to them are often not adapted or tested for pediatric care, but rather for adult care. This results in a focus on pediatric disease treatment instead of pediatric disease prevention even though research is beginning to show that early intervention is not only clinically effective, but also cost effective. While some Federal support has already been given to stimulate pediatric medical device development, there is currently no consensus on the priorities for products needed by pediatric healthcare providers based on verifiable reference data, and there is no roadmap for companies, investors, and grantors seeking to focus on developing the most needed and most feasible products. Federal support is needed to (1) create priorities and focus CER in pediatrics, (2) develop treatments and devices specific to children and specific to preventative care, and (3) generate quality system processes to deliver pediatric care.

4) UH has assembled an integrated team of some of the country's foremost experts in cardiology, interventional cardiology, heart failure and transplant, electrophysiology, cardiac and vascular surgery. This highly specialized team of experts forms the foundation of University Hospitals Harrington-McLaughlin Heart & Vascular Institute, a

[7] US News and World Report 2008

premier center for comprehensive care of patients with diseases affecting the heart and vascular system. Our goal is to create a national center of excellence in cardiovascular research and physician education, as well as patient care. A terrific example of CER under way in the Heart & Vascular Institute has been a large program for calcium screening through computed tomography with the aim of early detection and treatment of cardiovascular disease. In the past year alone over 3,000 people have been screened with this method and today there are significant efforts at putting these data into research databases for CER research. The CER protocols have been developed and approved by the IRB. Federal funding in this area could greatly help expand the significant screening that is already underway and could help to establish a valuable CER database for future development of clinical care screenings.

5) Neurologic Care: The Neurological Institute of UH is the first designated institute in Northeast Ohio dedicated to improving outcomes in patients with diseases affecting the nervous system. The institute includes 14 Centers of Expertise that provide patients access to services at locations across Northeast Ohio. UH offers the latest in innovative technology for the diagnosis and treatment of all neurological conditions and is committed to expanding and integrating translational research into clinical practice. The collaboration with CWRU allows basic science research and clinical trials to be quickly translated to offer patients direct and rapid access to leading-edge treatment alternatives. This is all accomplished through the use of CER methodologies that are in need of additional infrastructure in order to be expanded and maintained on a large scale over time.

UH has been, and needs to continue to be, pre-eminently positioned to design, conduct and report on CER for the benefit of the patients served not only in Northeast Ohio, but regionally, nationally and internationally. The significant resources and efforts described herein provide a snapshot of the already significant programs in this area and outline the basic needs necessary to continue to pursue these lines of scientific and clinical inquiry. Academic Medical Centers like UH and CWRU together have the obligation of providing CER data to physicians and other health care professionals in order to arm the next generation of providers with the information necessary to prevent, treat and cure diseases in the future.

Submitted by
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Good afternoon. My name is Cynthia Reilly and I am the Director of the Practice Development Division at the American Society of Health-System Pharmacists. ASHP represents 35,000 pharmacists, pharmacy students, and pharmacy technicians who practice in hospitals and health systems. Pharmacists' expertise in medication use ensures that drug therapies are used safely, effectively, and in a cost-conscious manner. I appreciate the opportunity to present the

Society's perspective on comparative effectiveness research, or CER, to the distinguished members of the Federal Coordinating Council for Comparative Effectiveness.

ASHP is a member of the Alliance for Better Health Care, which advocated for inclusion of comparative effectiveness research funding within the American Recovery and Reinvestment Act of 2009. The Society is also publisher of *AHFS DI*, a comprehensive, independent reference on the clinical use of medications, which is recognized through federal legislation under Medicare Part B, Medicaid, and Medicare Part D as an official compendium. For over 50 years, *AHFS DI* has followed sound and high-quality editorial processes to synthesize complex evidence for dissemination and use by a broad range of stakeholders, including prescribers, pharmacists, individuals who make health-policy and coverage decision, patients, and others. ASHP believes there is significant need to compare the effectiveness and safety of specific drug therapies within pharmacologic classes, drug therapies within different classes, and drug therapies with other treatment modalities. *AHFS DI* can serve as a foundation for medication information to support CER and ASHP looks forward to participating in this research.

Today, ASHP requests that the Council consider three CER recommendations related to health care delivery systems that represent critical information needs to improve patient outcomes:

- Optimal practice models for delivery of patient care,
- Strategies for using IT-enabled decision support for delivery of CER, and
- Best practices for disseminating and implementing CER.

As described by the Dartmouth Atlas, the quality and cost of care is inconsistent across geographic regions, with much of this inconsistency attributed to variation in the care setting and the health care professional that provides the service. Under Medicare Part D, pharmacists provide medication therapy management services that include formulating medication treatment plans; monitoring and evaluating patients' response to therapy; performing medication reviews to identify, resolve, and prevent medication-related problems; and coordinating and integrating MTM services within the broader health care services provided to patients. Pharmacists also participate in chronic disease management and prevention activities under collaborative practice agreements with physicians. MTM programs and published research have demonstrated that pharmacist management of disease and drug therapy significantly improves patient outcomes, while reducing overall health care costs. However, there is limited research that directly compares this practice model to models in which care is provided by other health care professionals or interdisciplinary teams. ASHP believes such research would demonstrate best practices and strongly recommends models of care as a research priority for CER.

A critical element of CER is ensuring that research findings reach the point of care where clinicians, together with patients, can use the information to make informed treatment decisions. Electronic health records and other technologies are expected to provide point-of-care information; however use of these technologies is currently limited, as described in a recent *New England Journal of Medicine* study that found less than 2% of hospitals have fully implemented an electronic health record with clinical documentation, test and imaging results, CPOE, and decision support. Decision support technology has great potential to deliver CER findings, but strategies for creating and integrating these programs within other technologies, as well as barriers to implementation, are not well-studied. ASHP encourages the Council to support

research that compares approaches for using clinical decision support and other technologies in the translation and implementation of CER.

In addition to technology, other effective dissemination and translation techniques are needed to ensure that CER findings are used to make informed decisions that improve patient outcomes. However, there are significant challenges in these activities. It has been estimated that there is a 17-year lag time between evidence generation and its widespread implementation. Many strategies have been used to enhance the rate and extent of adoption of evidence-based best practices, including clinical guidelines, continuing education for health care professionals, patient education tools, and most recently, academic detailing. However, these approaches are not well studied and results are variable. ASHP would encourage the Council to support research that compares the benefits and limitations of each approach in order to determine the strategy, or combination of strategies, that facilitates use of CER by each audience, including clinicians, patients, and payers.

Finally, based on ASHP experience as a drug information publisher, we encourage the Council to consider that, similar to drug information, CER research and dissemination efforts are not single events, but rather an ongoing process that requires sustainable and ongoing effort to ensure the currency and usefulness of the information as evidence evolves.

ASHP appreciates this opportunity to provide recommendations for CER. Along with our members, we look forward to collaborating with the Council and others to ensure that CER is not only useful, but also disseminated to clinicians, payers, and patients and subsequently translated into practice.

Submitted by
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Chief Operating Officer and
Interim Chief Executive Officer
eHealth Initiative

The eHealth Initiative thanks the Federal Coordinating Council for Comparative Effectiveness Research for this opportunity to comment on the use of real world electronic health care information for comparative effectiveness research. The eHealth Initiative (eHI) is an independent, non-profit multi-stakeholder organization whose mission is to improve the quality, safety and efficiency of health care through information and information technology. eHI engages multiple stakeholders across every sector of health care to reach agreement on and drive the adoption of common principles, policies and best practices for mobilizing information electronically to improve health and health care in a way that is responsible, sustainable, responsive to each stakeholder's needs—particularly patients, and which builds and maintains the public's trust. The eHealth Initiative is involved in work related to comparative effectiveness in several ways: through pilot projects, educational efforts, and a multi-stakeholder working group.

Electronic data sources that capture the experience of millions of patients have developed over the past few decades and will expand further. Where such records are searchable, it is possible to efficiently assess such information using statistical queries and methods. Such methods may be able to sort through this large volume of data to provide important information on the relationship of medical interventions, types of patients, and types of medical conditions. Ultimately, this type of assessment may provide more refined information on the effects of medical interventions on different populations and in the context of different mixes of therapy.

The eHealth Initiative Foundation's Connecting for Drug Safety Collaboration

The eHealth Initiative Foundation's Connecting for Drug Safety Collaboration is a public-private sector effort designed to test and evaluate the feasibility and value of using electronic health information to support post-market surveillance and medical product safety. The findings from the Collaboration are intended to help inform the Food and Drug Administration's Sentinel Initiative. This work is strongly related to comparative effectiveness issues, since many of the same issues regarding uses of different data environments and basic scientific approaches would also apply to comparative effectiveness work.

Guided by eHI's multi-stakeholder Leadership Council and the Connecting for Drug Safety Advisory Board, this collaborative effort initially launched with a focus on two community-based healthcare organizations with advanced stage clinical information systems — Partners HealthCare System in Boston, MA and the Regenstrief Institute in Indianapolis, IN. During the course of the Collaboration's work, the Department of Defense was added as a third research community; findings are expected to be available in the near future. The Food and Drug Administration plays a critical advisory role in the Collaboration. The Agency for Healthcare Research and Quality and the Brookings Institution's Engelberg Center also serve in an advisory capacity.

The eHealth Initiative Drug Safety Collaboration sought to answer two basic questions:

1) What value do the different types of health care data sources bring to post-market drug safety questions?
2) What happens when the same drug safety research question is asked of different groups of researchers with expertise in their own data environments?

The eHealth Initiative Working Group on Using Health It for Comparative Effectiveness and Outcomes Research

The eHealth Initiative has also started a Working Group on Using Health IT for Comparative Effectiveness and Outcomes Research. The new working group brings together leaders from more than 25 organizations representing every sector of health care to learn, discuss, and work on this important theme in health care. Building on eHI's extensive efforts working with diverse

groups of stakeholders to share best practices, test methods in real-world settings, and find common ground on policies, principles and strategies for improving health and health care through health IT and health information exchange

Objectives for Use of Real World Electronic Health Care Data

There is much that we do not know about the value or approaches of such work. It should not be surprising that trying to understand the basic building blocks of this research is itself a difficult matter. One could start by trying to articulate the goals of such exercises. Below are few objectives that may be connected.

1. Providing the most accurate and scientifically supportable assessment of medical conditions and interventions;
2. Gaining new scientific insights;
3. Assuring transparency, objectivity, and comparability in process and methods; and
4. Providing useful information for patients, providers, policymakers and other key stakeholders.

However, there are many stakeholders interested in this area. It will be important to get a clear understanding among stakeholders regarding such objectives.

Many stakeholders have different understandings of the possibilities of this research, reliability of this work, and definitions related to comparative effectiveness. The medical community, appropriately, does not want to oversimplify the importance and complexity of this process. It is important as we proceed that we develop trust and understanding. This means providing a clear framework for such research and finding a means to evaluate and communicate its reliability to a broad range of stakeholders.

Challenges for the Use of Real World Electronic Health Care Data

We need to acknowledge the many challenges of using real world data for comparative effectiveness research. By using real world data, researchers are outside the controlled setting of a clinical trial, and therefore are studying data on patients who may be taking multiple medications or dealing with multiple medical problems. In actual clinical practice, physicians may choose to prescribe one therapy over another on the basis of severity of disease, patient characteristics, and other factors that may not be apparent in health care data bases.
Unlike clinical trials, studies based on “real world” data are more likely to rely on incomplete information, since the data was collected for clinical care, not specifically for research. First, most patients do not have a comprehensive medical history located in one data source. Second, some patient records are not in electronic form and, thus, not practical for large data base studies. Third, claims data is set out for billing purposes and can be misleading with respect to actual diagnoses. Fourth, medical information terminology can vary from data source to data source. Finally, the type and amount of information available on given patients can vary. In such

situations the data may be incomplete or inaccurate. This can also make combining results of analyses from different data sources a challenge.
Studies based on real world data are more susceptible to bias than randomized clinical trials. If one does not design a project to identify and eliminate sources of bias, it will make the conclusions less valid. The process for determining definitions or criteria for "real-world" study populations is important, requires judgment, and is itself a potential source of bias.

Priorities for Research

Among the priorities for research, we want to emphasize the need for research that involves collaborations in different data environments and research that explores the use of different types of electronic health care data. This is important, basic, and practical work that can be very informative in the development of a comparative effectiveness research infrastructure. Using available information, researchers and regulators use scientific procedures and judgment to try to determine the relationship between medical interventions and outcomes among different populations. The use of clinical data, in addition to claims data, as a source of information for adverse event detection is an emerging area. Therefore, researchers are still learning about the application of different methods for using clinical data, and best practices have yet to be defined. Building a base of trust, best practices and appropriate expectations from such comparative effectiveness research will take time. The eHealth Initiative would like to work with you to help develop such a framework.

Another area that needs attention is research on how health information technology and electronic health information exchange can be used to create more robust data sources and to help evaluate comparative effectiveness issues across a broader range of settings.

Finally, it is important to focus on projects that address how research might facilitate or assist in medical decisions. Knowledge that is generated from this comparative effectiveness research could be extremely valuable to the medical decision-making process.

The eHealth Initiative looks forward to working with the Council as it proceeds to develop its recommendations, and thanks the Council for this opportunity for comment. If you have any questions, please feel free to contact me at Jennifer.Covich@ehealthinitiative.org.

Submitted by
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Thank you for this opportunity to provide comments on behalf of the American Psychological Association (APA) regarding national priorities for comparative effectiveness research. I am Dr.

James Bray, APA President and Associate Professor of Family and Community Medicine and Psychiatry at the Baylor College of Medicine.

APA is the largest scientific and professional organization representing psychology with 150,000 members and affiliates. APA is also the largest publisher of behavioral science research, with 52 premier scholarly journals.

Comparative effectiveness research is a critically important tool for advancing an evidence-based approach to health care decision-making. However, the full public health benefits of such research will only be realized if behavioral, psychosocial, and medical interventions for the prevention and treatment of mental and physical health conditions are evaluated individually and in combination. Even when strictly medical treatments are compared, it is important to expand the range of outcome measures to include behavioral and psychological outcomes, such as quality of life and adherence to treatment protocols. It is also essential to evaluate promising new models of care, such as the use of integrated, interdisciplinary behavioral and medical teams in primary care settings. And finally, the effectiveness of health interventions across the lifespan and for different minority and gender groups must be considered.

Therefore, APA is recommending that comparative effectiveness research focus on these five areas:

We encourage research that compares different behavioral and psychosocial interventions for the prevention and treatment of specific health conditions. This research is crucial given that the leading causes of chronic health problems and mortality in the United States—such as heart disease, diabetes, and many forms of cancer—are due to modifiable behavioral factors, such as smoking, improper diet, lack of physical activity, and excessive alcohol consumption, among others. In addition, mental disorders, such as depression, represent a significant disease burden in the U.S. and worldwide. Fortunately, effective behavioral and psychosocial interventions exist to reduce life-threatening behaviors and treat health conditions, such as depression, heart disease, chronic pain, and diabetes. Now is the time to test the comparative effectiveness of these interventions to improve the health of the public.

Next, we strongly encourage research that compares behavioral and psychosocial interventions with medical interventions, and combinations thereof. This type of research allows for an examination of the relative and combined effectiveness of behavioral and medical interventions for specific health conditions.

A classic example of the value of this form of comparative research comes from the randomized controlled trial of the Diabetes Prevention program, which found that intensive lifestyle intervention, as compared to placebo or medication, reduced the incidence of type 2 diabetes to half that of placebo, and was significantly more effective than medication alone. Enhanced outcomes have also been found for combined behavioral and pharmacological interventions for depression and smoking.

Next, we should pursue research that compares integrated systems of care comprised of interdisciplinary teams of medical and behavioral health providers versus routine medical

care. There is some indication that co-locating medical and behavioral health providers improves patient access and health outcomes.

For example, the integrated care approach has shown the largest reduction in depression levels and highest patient satisfaction. Interestingly, mortality was reduced on one recent large trial of integrated, primary care-based treatment of depression.

We also believe that all health research studies should include measures of behavioral and psychosocial outcomes, such as life quality, adherence to treatment protocols, behavioral functioning, depression, and anxiety. Such attention to patient-centered care builds upon the IOM's own definition of evidence-based practice.

As new life-saving medical advances are developed, we must strive to maintain patient quality of life. For example, depression and anxiety have been shown to increase in heart disease patients using implantable cardioverter defibrillators. Both the positive and negative outcomes of medical procedures need to be considered and evaluated before they are adopted as standard practice.

And finally, research that examines health intervention outcomes across the lifespan and for different minority and gender groups is needed to understand the effectiveness of interventions within and between population groups. This type of comparative research is important given the well documented health disparities that exist between different racial/ethnic, age, socioeconomic status, gender, and sexual minority groups, and because it is not clear if specific behavioral and medical interventions are equally effective across groups. This type of comparative research is critical as the U.S. population becomes more diverse.

Thank you for the opportunity to provide this brief statement. The American Psychological Association looks forward to the outcome of your deliberations.

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The ACC strongly supports investment in comparative effectiveness research (CER). Given the high prevalence of heart disease-related illnesses, along with the documented variability in the use of procedures used to treat and/or diagnose it, comparative effectiveness research could yield high returns in terms of improving patient outcomes and reducing costs.

Specifically, comparative effectiveness research is an essential building block to understanding the populations that may benefit from the many treatment options associated with cardiovascular disease, including medical therapy, stents, surgery and defibrillators. Understanding the comparative effectiveness of both diagnostic and treatment strategies in different patient populations, especially the elderly, is very important. Effective detection and risk assessment of coronary artery disease can help physicians determine the most appropriate care for their patients, whether it be more aggressive therapy and procedures or less intensive cardiac follow-up.

In particular, comparative effectiveness research of diagnostic imaging is a high priority for the ACC (see list of top CER priorities below). Understanding the comparative effectiveness of various cardiac imaging and diagnostic tests could help better target the use of these beneficial technologies and help inform policy decisions related to the use of these technologies. Randomized trials and registries will be important to understanding the role of imaging and other diagnostic tests in not only diagnosis but their impact on downstream treatment and outcomes.

Facilitating linkages of clinical and administrative databases is crucial to developing this research agenda (see infrastructure priorities below). Inpatient and outpatient registries could help track key elements of comparative effectiveness, including laboratory results, medication adherence and diagnosis decisions. Translation of the results of comparative effectiveness research will require transparency in terms of how users discuss certainty of the resulting evidence, the trade-off of different types of risks and benefits, and what it means for two or more strategies to be equally effective.

Cost-effectiveness must also be a critical priority for health reform given the reality of finite financial resources and rising costs. However, the College strongly believes comparative effectiveness research must remain strictly focused on comparative clinical science, such that decisions regarding cost effectiveness can be made sequentially later. This segregation of these important processes will be essential to ensuring physician and patient trust in the ethics and integrity of such work.

Comparative effectiveness research has the potential to make it much easier for patients and their doctors to choose the best treatment and avoid unnecessary treatment for not only heart disease, but other diseases a well, thus improving quality and ensuring greater patient value. The College looks forward to working with you on this endeavor.

Top Comparative Effectiveness Research Priorities

1. **Comparison of diagnostic tests for suspected Coronary Artery Disease (CAD) (Randomized Clinical Trial).** Compare the effectiveness of stress electrocardiography, stress echo, coronary computed tomography angiography (CCTA), and single-photon emission computed tomography (SPECT MPI) for the diagnosis and risk assessment of coronary artery disease in adult, intermediate pre-test probability patients with stable chest pain by assessing impact on detection and risk assessment, subsequent treatment (medical and procedures), prior and subsequent invasive and non-invasive cardiac imaging utilization, major adverse cardiac events, and cost. As several proposed trials were submitted to NHBLI in February, this project is “shovel ready.”

2. **Comparison of diagnostic tests for Coronary Artery Disease (CAD) (Registry).** Compare the effectiveness of stress electrocardiography, stress echo, coronary computed tomography angiography (CCTA), and single-photon emission computed tomography (SPECT MPI) for diagnosis and risk assessment of coronary artery disease by assessing appropriate use patterns based on published criteria, prior and subsequent invasive and non-invasive cardiac imaging utilization, subsequent procedures, overall radiation dose and other safety issues, major adverse coronary events for normal studies, and testing and downstream costs.

3. **Compare preventive strategies guided by coronary artery calcium scoring versus usual care (RCT).** Compare the effectiveness of using a coronary calcium screening directed prevention strategy versus usual care in asymptomatic individuals who have low

4. **Linking STS, NCDR, and CMS databases.** By linking the clinical data from the Society of Thoracic Surgeons National Database and the ACC National Cardiovascular Data Registry with Centers for Medicare and Medicaid Services (CMS) administrative data, a powerful, longitudinal data set could be produced. Such a data set would contain process, outcomes, utilization, pharmacy, and cost data spanning perhaps a three to five year period. This linking project has the potential to cover the continuum of care for cardiovascular disease. Ultimately, the information obtained from this collaborative effort will aid in the analysis of the comparative effectiveness of coronary revascularization treatment strategies, such as coronary bypass rafting and stenting procedures.

5. **Ablation versus cardioversion.** Compare the effectiveness of ablation therapy for the treatment of atrial fibrillation versus electrical cardioversion by assessing cardiac function, mortality, major adverse cardiac events, quality of life, and cost in a real world setting by paralleling the current randomized clinical trial.

Top CER Infrastructure Initiatives (What types of investments in infrastructure for comparative effectiveness research should the Coordinating Council consider?)

1. Creation of robust national registries for tracking both short- and long-term performance of therapeutic strategies, drugs, or devices
2. Clinical registry development, application, and networking
3. Clinical data pooling and mining support
4. Capacity to use electronic health records for safety and effectiveness monitoring
5. Clinical trials support (e.g., ad hoc collaborations)

Criteria for Setting Priorities (What criteria should the Coordinating Council consider when evaluating different investment options?)

1. variability in care
2. potential to act on the information once generated
3. disease burden
4. utility of the answer for decision-making
5. cost

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The focus of this testimony is on the contribution comparative effectiveness research can make to the extension of the newly developed consensus standards for treatment of substance use

conditions, published by the National Quality Forum (NQF). The Treatment Research Institute and the UCLA Integrated Substance Abuse Program have been asked to provide leadership for the dissemination and adoption of the consensus standards by States financing treatment in the public sector.

Despite the knowledge that addiction to alcohol and drugs is a treatable health condition, the failure to provide care consonant with scientific evidence is manifest in the lack of ongoing care for substance dependence consistent with the condition's chronic nature. Scientific advances have resulted in a spectrum of evidence-based psychosocial and pharmacologic treatments for individuals with unhealthy use or dependence on alcohol and/or drugs----treatments whose results compare well with those obtained with treatments for other chronic illnesses. It is increasingly apparent that patients with more chronic forms of substance use disorders require and do well with appropriately tailored continuing care and clinical support as in other chronic illnesses such as cardiovascular diseases and diabetes.

There are gaps, however, in knowledge of which evidence-based therapies are better than others, how to treat multiple co-morbidities present in so many patients, and how to care for some population subgroups. Despite these gaps, there has been an impressive increase in the number and quality of studies on efficacious therapies for adolescents and adults. Yet, there remain large gaps in the research on the *effectiveness* of these treatments when delivered in usual settings of care, especially on how the costs of treatment are integrated into the research. In particular, there are significant gaps in the efficacy and effectiveness research related to individuals who are neither "unhealthy" but risky users of alcohol and/or drugs nor chronically and severely dependent. For this "middle" group comparative effectiveness research seems particularly critical.

Developing standards of care for addiction treatment in the public and private sectors is a relatively recent activity. Between 2005 and 2007, with funding from the Robert Wood Johnson Foundation and the Federal Center for Substance Abuse Treatment/SAMHSA, the National Quality Forum (NQF) conducted a consensus process to identify evidence-based organizational and clinical practices for treatment of substance use disorders. The basic principles outlined by the NQF and the specific standards and practices that were identified should serve as the basis for moving forward with comparative effectiveness research in addiction treatment. In addition to publishing the standards and practices, the NQF recommended additional research be conducted to improve the identified practices and the development and implementation of performance measures related to each practice standard.

There are differing views about the acceptability of various forms of evidence, what level of evidence is necessary for a practice to be endorsed as "evidence-based," and whether knowledge of evidence-based care for a population can be adapted to meet an individual's unique needs. Although the Agency for Healthcare Research and Quality has (AHRQ) identified sound methods for rating the strength of scientific evidence, its findings have not resolved debates about whether a given intervention is evidence-based, for whom, and under what conditions.

The focus on randomized clinical trials, while the gold standard for generating clinical evidence, cannot be relied upon exclusively to identify evidence-based care due to the sheer numbers of

possible psychosocial and pharmacological interventions for substance use disorders. Furthermore, clinical trials do not generally include economic and cost analyses essential for comparative effectiveness research. Costs are borne not only by individuals and families, but by treatment organizations and, in the case of substance use disorders, almost entirely by the public sector. By 2014, the estimates made by a study of national expenditures funded by SAMHSA and published in *Health Affairs* (2008) show that we can expect about 85% of treatment expenditures for substance use disorders to be paid for with public financing—Federal, State, and local dollars.

Of critical importance to advancing the consensus standards identified by the NQF is a focus on the systematic analyses necessary to translate the evidence being generated in scientific research into clinically useful practice guidelines. Many of the numerous professional groups involved in treatment of substance use disorders have conducted their own reviews of the evidence and promulgated their own practice guidelines. The guidelines include little discussion of what might be included in comparative effectiveness research----the characteristics of the individuals targeted for specific interventions, the structural and financing characteristics of organizations that are necessary for adoption of specific guidelines, the costs of the identified interventions to treatment organizations that are responsible for implementation related to training and staffing requirements, and the like. Numerous studies have identified clinicians' departures from evidence-based practice guidelines for opioid dependence and other substance use disorders.

If we expect improvement in the quality of care for treatment of substance use disorders, the clinical appropriateness of such variations needs become a focus of performance measurement. Performance measurement for addiction treatment at the treatment system level (health plans, States, and Counties) was first advanced by the Washington Circle Group (WCG). The WCG, a group of researchers, policy makers, States, and practitioners, since 1998 has worked to identify the processes of care necessary for addiction treatment, specify and test performance measures, and work with accrediting bodies and purchasers to adopt and utilize the measures. If we want an "uptake" in the use of evidence-based practices, measures are necessary, in addition to comparative effectiveness research, to be able to assure treatment organizations and clinicians that the evidence-based standards and practices they are being asked to adhere to have clear advantages in effectiveness and cost-effectiveness relative to the practices they are employing.

Submitted by
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Members of the Federal Coordinating Council (FCC), I am Andrew Sperling, Director of Legislative Advocacy for the National Alliance on Mental Illness (NAMI). NAMI is the largest national organization representing individuals living with serious mental illness and their families. Through our more than 1,100 affiliates in all 50 states NAMI is engaged in support, education and advocacy around serious mental illness.

NAMI believes strongly in the promise of comparative effectiveness research to improve quality and outcomes in health care. As a member of the Partnership to Improve Patient Care (PIPC), NAMI has endorsed a set of principles that we believe can help ensure that comparative effectiveness meets its full potential and does not become a blunt instrument that limits patient choice and results in cost becoming the dominant factor in guiding treatment decisions. Among these principles for ensuring that comparative effectiveness research is patient-centered:

- Defining CER as a tool to improve patient care;
- Focusing on communicating research results to the public, not making centralized coverage and payment decisions;
- Providing information on clinical value and patient health outcomes, not cost effectiveness assessments;
- Recognizing the diversity, including racial and ethnic diversity, of patient populations and communicating results in ways that reflect the differences in individual patient needs;
- Examining all aspects of health care – including medical interventions, care management, benefit design, and processes of care – that can improve care quality and reduce health care disparities; and
- Requiring open and transparent processes where all stakeholders have equal voice in governance and input into research priorities.

In moving forward to develop recommendations and research priorities for the Secretary, NAMI urges the Coordinating Council to think big and undertake research directed at the most important challenges facing our nation's health care system. The Coordinating Council should resist any focus on short-term clinical trials that simply compare two distinct interventions such as head-to-head comparisons of two medications. Rather, comparative effectiveness research should examine the range of issues that affect the quality of patient care (medical tests and treatments, health care delivery and organization, benefit designs and care management). All of these elements of health care affect patients' quality of care and health outcomes. These elements of care also have a significant impact on health care disparities. Research is needed to identify the best approaches to reducing disparities. In addition, sound comparative effectiveness research should include the different factors important to consumers, including quality of life, independence, productivity and recovery.

CER that starts with cost containment as a central goal will not lead to studies that answer these questions, and will likely result in misapplication of findings in order to achieve cost-cutting objectives. By contrast, CER that begins with the goal of quality improvement can help everyone in health care make better decisions and will ultimately lead to better health care value and greater cost efficiencies. This requires addressing the different factors that can help decide which treatment is optimal for the individual, such as the patient's particular medical condition, past treatment history and genetic variations.

Basing Public Policy Decisions on Comparative Effectiveness Has Limitations

NAMI would like to caution the Coordinating Council with regard to the limitations and difficulties associated with using existing comparative effectiveness studies that are now being used to drive policies related to treatment choice and prescribing decisions. There is no better

example of this than the NIMH CATIE trial on antipsychotic medications. The Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) was the first large scale attempt to compare five different medications used to treat people living with schizophrenia. The study included both newer (atypical) and one older anti-psychotic medication. In general terms, the study found that there was relatively little difference in the effectiveness of any of the medications. Without regard to which medication was randomly assigned, patients discontinued the use of medications at similar rates due to intolerable side effects or failure to adequately control symptoms.

It is important to note that CATIE used discontinuation as a proxy for efficacy. Further, the protocols for the study required that patients be "randomized" to one of the five drugs. In NAMI's view, this randomization does not reflect best clinical practice which calls for a dialog between a medical professional and consumer that helps determine a best-choice medication based upon treatment goals and risk of side-effects. In addition, CATIE was only 18 months in length, not enough time to accurately measure serious neurological side effects known as extrapyramidal symptoms (EPS) and movement disorders such as Tardive Dyskinesia associated with the older antipsychotic medications.

More importantly, CATIE is NOT the basis for any conclusion that "the older antipsychotic medications are just as good as the newer ones." In fact, 69% of the participants switched to a different medication at least once during the trial and just over half switched twice or more. If anything, CATIE supports a strong conclusion that there is no "one size fits all" in any aspect of schizophrenia treatment. At the systems level, patients and their support system should be skeptical of any attempt to change medications if treatment is demonstrating progress. NAMI believes that states should never engage in the practice of medicine.

Roles and Responsibilities for the Federal Coordinating Council

The announcement for this Listening Session in the Federal Register details 6 specific questions on which the Coordinating Council is seeking input from stakeholders and the general public. NAMI would like to address each of these questions separately

1. What types of investments in infrastructure for comparative effectiveness research should the Coordinating Council consider?

Investments in infrastructure of CER should be carefully considered. The $1.1 billion included in the ARRA is not a permanent authorization and it is uncertain whether Congress will continue to appropriate funding for CER beyond the 24 to 36 month time period authorized in the law. While investment in multi-site clinical trial networks and training for researchers and investigators are critical to furthering research and discovery, they cannot sustain themselves without ongoing funding from Congress over the long-term – far beyond the ARRA timeframe.

NAMI urges that these ongoing costs associated with high quality biomedical research continue to be a part of the NIH where they can be more appropriately maintained and developed over time.

2. What criteria should the Coordinating Council consider when evaluating different investment options?

As noted above, NAMI recommends investment of CER resources into the most difficult challenges facing our health care system, especially in the area of chronic disease management of conditions that represent the greatest public health burden. Investment in short-term head-to-head comparisons of specific interventions may be quicker and easier, but they will not help us move forward in addressing the most costly and difficult challenges such as the growing prevalence of obesity, diabetes heart disease, COPD, etc. The Coordinating Council should set forth criteria that prioritize examination of effective multi-systemic interventions in real world treatment settings among patients with multiple co-morbidities. NAMI would note for the record that adults with serious mental illness are experiencing significantly higher rates of the medical co-morbidities and experience (on average) as much as 25 years of lower life expectancy according to a 2006 study from the National Association of State Mental Health Program Directors (NASMHPD).
http://www.nasmhpd.org/general_files/publications/med_directors_pubs/Mortality%20and%20Morbidity%20Final%20Report%208.18.08.pdf

3. What Federal government activities in the area of comparative effectiveness research should the Coordinating Council focus its attention on?

NAMI urges the Coordinating Council to adhere to the activities set forth by Congress in establishing the Council as part of the ARRA, i.e. fostering coordination and advising the President and Congress. We note that the ARRA specifically bars the Coordinating Council from mandating coverage or reimbursement decisions or policies for both public and private payors. In addition, the ARRA explicitly states that Council recommendations shall not be construed as mandates or clinical guidelines for payment coverage or treatment.

4. How can the Coordinating Council best foster integration of these activities across the programs managed by the Departments of Health and Human Services, Defense, and Veterans Affairs?

NAMI urges regular meetings of the Coordinating Council and an open and transparent process that allows for maximum participation for all stakeholders, including patients. This should include the participation of disease advocacy organizations as the voice of patients, as opposed to the more general views of "consumer organizations." This distinction is critical since individuals living with chronic and life threatening illnesses (including serious mental illnesses) and their families are likely to offer unique perspectives on the importance of maintaining broad access to widest array of therapies and inventions. Inclusion of all stakeholders will also help ensure that unique needs of subpopulations, especially racial and ethnic minorities are integrated into these discussions. It is a perspective distinct from a "consumer" voice for the "average" patient.

5. What steps should the Coordinating Council consider to help ensure that public- and private-sector efforts in the area of comparative effectiveness research are mutually supportive?

Continuing regular public meetings such as this Listening Session will be critical to establishing a mutually supportive environment for public and private CER investments. NAMI also urged that, to the maximum extent possible, all Coordinating Council activities and meetings adhere to the standards in the Federal Advisory Council Act – advance public notice of meetings and meeting agendas, a public record, opportunity for public comment, etc.

6. What information on the Coordinating Council's activities would be most useful?
NAMI would be most interested in viewing information provided to the Coordinating Council by individual federal agencies and officials. It would therefore be helpful if any and all submissions from federal agencies be posted to the Council's website. Likewise NAMI recommends that all of the Committee's deliberations be conducted in public.

Submitted by
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Dear Dr. Conway:

The Suicide Prevention Action Network USA (SPAN USA) welcomes the opportunity to submit comments regarding the Federal Coordinating Council on Comparative Effectiveness Research (FCC-CER). SPAN USA is a 501(c)(3) organization dedicated to preventing suicide through public education and awareness, community action and federal, state and local grassroots advocacy. As you know well, suicide is the 11th leading cause of death in America and the third leading cause of death for younger Americans age 15-24. In addition, it is estimated that there are 800,000 suicide attempts each year. Reducing the number of suicides and suicide attempts among our nation's citizens is a criterion that the Coordinating Council should consider when evaluating different investment options.

As noted in the Federal Register Notice, there are investments in infrastructure for comparative effectiveness research that are needed. Currently, there is woefully inadequate data on suicide and suicide attempts in America. No government agency or private entity can determine exactly how many veterans die by suicide each year across America or how many murder-suicides have occurred. The National Violent Death Reporting System collects data from medical examiners, coroners, police, crime labs, and death certificates to understand the circumstances surrounding violent deaths including suicide. This information is important to develop, inform, and evaluate suicide prevention programs. However, the system does not operate in every state, but the Centers for Disease Control and Prevention (CDC) has the capability to continue expanding the system until all 50 states are covered. The Coordinating Council should consider investment in data systems infrastructure for suicides in order for comparative effectiveness research to be as useful as possible.

SPAN USA recommends focusing attention on government activities involving comparative effectiveness research on best practices for early intervention and prevention of suicide. The federal government has undertaken a number of activities to complete the goals and objectives of the National Strategy for Suicide Prevention. Unfortunately, at this time there are only 16 interventions listed in the Substance Abuse and Mental Health Services Administration's National Registry of Evidence-Based Programs and Practices. Additional research to determine

evidence-based programs and practices that reduce suicide and suicide attempts are vital to reducing the public health problem of suicide.

For example, SPAN USA recommends a study to compare the safety and effectiveness of inpatient psychiatric hospitalization vs. the use of alternative service options (e.g., extended observation, partial hospital, and intensive outpatient care) for individuals following a suicide attempt. Following a suicide attempt, it is necessary to evaluate and monitor individuals in safe and risk-appropriate settings. An important research priority is to determine whether psychiatric inpatient hospitalization is the most cost-effective and least restrictive manner of providing care to acutely suicidal individuals, mindful of safety concerns. The use of alternative crisis services — e.g., extended observation beds, intensive outpatient services — may result in fewer repeat inpatient admissions while also allowing patients greater autonomy and increasing their collaboration with community-based treatments. Fear of adverse outcomes has hampered necessary, well-designed, risk-attentive comparative studies.

The Coordinating Council can foster integration of suicide prevention comparative effectiveness research activities across the programs managed by the Departments of Health and Human Services, Defense, and Veterans Affair by working with the Federal Working Group on Suicide Prevention that is co-chaired by staff from SAMHSA and the U.S. Marine Corps. Integration of suicide prevention research is already taking shape in the form of a $50M research study being conducted by the National Institute of Mental Health and the U.S. Department of Army. However, more research specific to comparative effectiveness for treatments, programs and practices to reduce suicide among veterans and military personnel is needed.

Once again, SPAN USA appreciates the opportunity to share our comments with the FCC-CER. Please do not hesitate to contact me at: baltman@spanusa.org or 202-449-3600 with any questions or concerns.

Submitted by
Rachel Groman
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American Association of Neurological Surgeons/Congress of Neurological Surgeons
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On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), which together represent 4,000 practicing neurosurgeons across the United States, I would like to thank the Federal Coordinating Council for Comparative Effectiveness Research for giving us the opportunity to comment on comparative effective research priorities. My name is Rachel Groman, and I am the Senior Manager for Quality Improvement and Research in the AANS and CNS Washington Office.

Organized neurosurgery supports a ***well-designed*** comparative effectiveness research system that strengthens physician and patient decision-making, improves quality, and supports continued medical progress. Our members are committed to determining what medical treatments work best for their patients and our specialty is taking a variety of steps to ensure that the care neurosurgeons deliver is evidence-based. We have a robust practice guidelines development

program and our specialty recently created a new clinical data registry entity called NeuroPoint Alliance. The NeuroPoint Alliance is partnering with Outcome Sciences, Inc. to build a database platform for a specialty-wide patient registry that will serve multiple purposes, including Maintenance of Certification, clinical research, pay-for-performance and other quality improvement programs.

The AANS and CNS are very enthusiastic about partnering with the federal government, third party payers and others to conduct comparative effectiveness research that is important to neurosurgeons and their patients. To that end, we have identified a research priority that affects millions of American -- the treatment of common spinal disorders.

It is no secret that 75-85% of all Americans will experience back pain at some point in their lifetime and that management of chronic spinal conditions in the U.S. is estimated to cost nearly $85-100 billion each year. Despite advances in the surgical treatment of spinal diseases, which has dramatically expanded the treatment options available to patients, there is a deficiency of high quality clinical research to guide practice. This is largely due to the inherent difficulties of performing randomized controlled trials for surgical procedures and disorders characterized by significant heterogeneity, which often results in low patient compliance with randomized assignment. Consequently, many of the current clinical guidelines lack definitive guidance, resulting in marginal consensus among clinicians on what constitutes best practice and overall clinical uncertainty regarding the treatment of common spinal disorders. This has been reflected in significant regional variations in the treatment of neck and lower back degenerative diseases.

The AANS and CNS recently provided the Institute of Medicine (IOM) with specific clinical research recommendations focusing on two degenerative spinal diseases for which there is little high quality clinical research to guide practice: 1) low back pain without neurological deficit or spinal deformity; and 2) cervical spondylotic myelopathy. Low back pain is the fifth most common reason for seeing a physician in the United States, and cervical spondylotic myelopathy is the most common cause of spinal cord injury in both the United States and the world. Given the limitations of randomized clinical trials, we asked the IOM to consider the value of prospectively obtained data collected through patient registries to help identify specific patient characteristics that would serve as predictors of improved outcomes from different surgical and non-surgical approaches to these two diseases. We strongly encourage the Federal Coordinating Council to similarly consider the value of directing comparative effectiveness research funds to the creation and/or administration of a multi-center, prospective patient registry that could collect comparative data on different treatment approaches for degenerative spinal disorders. The AANS and CNS believe that the NeuroPoint Alliance is poised to serve as this registry, since it will produce meaningful data that will help refine indications, guide clinical decision-making, determine best practices, improve quality, and ultimately lower costs.

Thank you again for the opportunity to provide feedback on national comparative effectiveness research priorities. Organized neurosurgery looks forward to further exploring our registry project with the Federal Coordinating Council and to working with the federal government to collect the data needed to determine which treatments work best for neurosurgical patients.

Submitted by

Carolo DiMarco
Deputy Director, Department of Government Relations
American Osteopathic Association
Washington, DC
sfriedman@osteopathic.org

Dear Council Members:

The American Osteopathic Association (AOA) appreciates the opportunity to submit comments on comparative effectiveness research to the Federal Coordinating Council on Comparative Effectiveness Research as established by the American Recovery and Reinvestment Act of 2009. The AOA represents 64,000 osteopathic physicians nationwide, promotes public health, encourages scientific research, serves as the primary certifying body for D.O.s, and is the accrediting agency for all osteopathic medical colleges and health care facilities.

The purpose of our comments is to share our views on clinical and cost effectiveness research, inform the Council about AOA's guiding principles on comparative effectiveness research and its priority areas for comparative effectiveness research.

Clinical and Cost Effectiveness of Comparative Effectiveness Research

The AOA understands the purpose of the Federal Coordinating Council is to assist the offices and agencies of the Federal Government, including the Departments of Health and Human Services, Veterans Affairs, and Defense, and other Federal departments or agencies in coordinating the conduct or support of comparative effectiveness and related health services research; advise the President and Congress on strategies with respect to the infrastructure needs of comparative effectiveness research within the Federal Government; and assure optimum coordination of comparative effectiveness and related health services research conducted or supported by relevant Federal departments and agencies, with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of resources.

A March 19, 2009 News Release of the Department of Health and Human Services states that the Council will help coordinate research and guide investments in comparative effectiveness research and will not recommend clinical guidelines for payment, coverage or treatment. Some Federal officials have stated that a portion of Recovery Act funds could be used for comparative effectiveness research that includes comparisons on the cost of treatments, but that the findings could not be used by Medicare as the basis of coverage decisions.

The AOA believes that it is in the best interests of the patient to exclude cost effectiveness of therapeutic or medical interventions from the decision-making process. Comparing the cost of interventions when the activity occurs between a patient and a physician with the final decision resting with the patient is entirely different from the use of cost effectiveness to deny coverage or treatment based on the cost of the intervention.

In our opinion, for comparative effectiveness research to realize its full potential, it must focus primarily on clinical efficacy. If the primary focus is on clinical efficacy, weighted against efficiency, physicians and patients will have relevant clinical information enabling them to make informed decisions on what is the best course of action. If clinical efficacy is removed as the primary focus, patients and physicians potentially may view such information from a negative perspective and the government's investment in comparative effectiveness research would fall short of our joint goals of improving quality, safety, and efficiency.

As stated in the following AOA Principles on Comparative Effectiveness Research, the physician-patient relationship must be protected. This includes the ability of physicians to provide individualized care using comparative effectiveness research as a recommended course of action, not a dictate and not to deny treatment based on cost effectiveness.

AOA Principles Regarding Comparative Effectiveness Research

Physicians and Patients

- Comparative effectiveness research should enhance the ability of osteopathic physicians (D.O.s) to provide the highest quality care to patients utilizing the best proven and widely accepted evidence based medical information at the time of treatment.
- Comparative effectiveness research should not be used to control medical decision-making authority or professional autonomy.
- Comparative effectiveness research should enhance, complement, and promote patient care, not impede it.
- Guidelines developed as a result of comparative effectiveness research studies should be advisory and not mandatory.
- Comparative effectiveness research should be viewed as a positive development for patients and physicians and a useful tool in the physician's armamentarium, working in concert with patients.
- Physicians in practice should be included in any discussions and decisions regarding comparative effectiveness research.
- Comparative effectiveness research should focus on clinical effectiveness, not cost effectiveness, and should not be used to deny coverage or payment.
- The physician/patient relationship must be protected and the needs of the patients should be paramount.

Location of a Comparative Effectiveness Research Institute

- The AOA would prefer that the Agency for Healthcare Research and Quality (AHRQ) be the home for comparative effectiveness research. Section 1013 of the Medicare Modernization Act (MMA) authorizes AHRQ to conduct comparative effectiveness research. AHRQ has been doing so since 2005. Under its Effective Health Care Program, AHRQ published studies on gastroesophageal reflux disease, renal artery stenosis, osteoporosis, osteoarthritis, rheumatoid arthritis, diabetes, depression, psychiatric disorders, hypertension, and prostate cancer.
- The AOA believes that AHRQ could collaborate with the National Institutes of Health (NIH) and other entities in cases where clinical trials or other resources are needed.

Funding

- The AOA believes that Congress should increase the current $50 million authorized in Section 1013 of MMA to a level commensurate with the funds necessary to carry out an expanded role in comparative effectiveness research.
- The AOA believes that there could be room for private funding provided that contributors are not in a position to influence study outcomes.

Governing Board

- The AOA believes that for comparative effectiveness research to be successful, all stakeholders (physicians, patients, researchers, government, and private sector) must be represented in the decision-making process.

AOA Comparative Effectiveness Research Priorities

On March 27, 2009, the AOA was pleased to submit the following research priorities to the Institute of Medicine (IOM) Committee on Comparative Effectiveness Research Priorities pursuant to the IOM's request for comment to its research priorities questionnaire:

- Compare the effectiveness of adding osteopathic manipulative treatment (OMT) to "best care" in low back pain in the primary care setting.

- Compare the effectiveness of coordinated care in the treatment of diabetics in the community versus standard care.

- Compare models of physician led community primary prevention in progression of glucose intolerance to diabetes.

The AOA thanks the Federal Coordinating Council on Comparative Effectiveness for considering our views.

Submitted by
[personal information redacted]

Comparative effectiveness research is imperative to better understand and improve the provision of care for children with asthma. We recommend prioritizing studies that compare, with respect to both cost savings and clinical outcomes, the effectiveness of an integrated asthma counselor/environmental mitigation chronic disease management model with a non-integrated episodic model for children with asthma. Childhood asthma is a significant chronic disease that has reached epidemic proportions in heavily disadvantaged communities, placing a disproportionate burden on low-income and minority families and communities. Childhood asthma carries high direct and indirect clinical, social, and economic costs - an estimated $20 billion in 2007 alone – in the form of preventable emergency department visits and inpatient hospital admissions, lost productivity, school absenteeism and family stress. Paradoxically, while much is known about effective integrated pediatric asthma management (including USPSTF recommendations for "home-based multi-trigger multi-component environmental interventions" for children with asthma), insurers continue to utilize coverage, cost sharing, and payment design strategies that treat asthma as an isolated episodic illness, and pediatric practice and public health have failed to systematically restructure their approach to emphasize an integrated chronic care/public health intervention.

A proposed model of comparison is an integrated asthma counselor/environmental mitigation chronic disease model with a non-integrated, episodic model of care. This can be accomplished through a range of health services research- including interventions specifically designed to better understand novel treatment pathways and comparisons of the standard of care/ usual care with new models as proposed above. This research should include children of all ages (young children and adolescents) and racial/ethnic minority groups.

The epidemic proportion of asthma among child populations at risk for social risk and heavy disease burden, coupled with the high costs associated with ineffective care, make asthma a prime candidate for comparative effectiveness research in pediatric health. The availability of a growing scientific and public health evidence-base, including appropriate models of integrated chronic disease management, also make asthma a priority where it is possible to improve the quality of life for children and families while reducing health care costs.

Submitted by
[personal information redacted]

The health professional educational system, particularly the education of physicians developed, over the last 100 years as a series of 'fixes' designed to ameliorate perceived gaps and deficiencies at specific points in time. This evolution took hold most notably with the publication of the AMA Council on Medical Education sponsored report of the Carnegie Foundation in 1910. The Flexnor report detailed the significant heterogeneity and inadequacy of physician training as the legacy of the 19th century. Since Flexnor, medical educators have put into place a cornucopia of solutions intended to assure the public that doctors and their care are of high quality care. These include, but are not limited to, medical school accreditation (LCME), residency program accreditation (ACGME), continuing medical education accreditation (ACCME, AMA PRA), board certification (ABMS), and state licensure (NBME, state licensure boards and FSMB).

Similar and parallel structures have developed in efforts to assure the public of the adequacy of nurses, pharmacists and other health professionals' education and maintenance of skills over a professional life. In addition, a concurrent system of public and private systems to evaluate and accredit health care delivery systems has evolved.

Despite these efforts designed to assure high professional standards, it appears that the current educational systems for health professionals are inadequate in providing the requisite skills, knowledge and attitudes to assure the public of the highest standards of safe, quality care. This may be due in part to several factors. While not exhaustive, these include: the learning environment within professional schools, post graduate training programs and systems of continuing education, fragmentation of roles and responsibilities within the delivery system, financial incentives/disincentives which reward technical expertise and fail to penalize significantly for failure to measure, account and improve poor performance.

Unlike a heavy and sustained national investment in biomedical research, and more recently in health services research, there have not been significant resources devoted to developing and sustaining an infrastructure upon which to conduct meaningful and longitudinal research regarding the impact of innovation in health professional education. Limited resources have constrained our ability to understand the most effective methods by which to improve our educational systems and drive them toward expected educational outcomes. The limitation includes resources to conduct pilot, demonstration or multi-institutional collaborative projects, and longitudinal cohort studies of the impact of the educational continuum on practice attitudes, values, behaviors and outcomes. Further, despite the wealth of talent that resides within our institutions of higher education, little effort has been expended to capitalize on knowledge

and learning from other disciplines which could reasonably be expected to have insight into methods to improve outcomes. Mechanisms designed to facilitate interdisciplinary research should be encouraged.

In sum, comparative effectiveness research funding should be considered broadly by the AHRQ and the oversight group. Comparative effectiveness of methods, mechanisms (i.e., tools) and outcomes from the health professional educational system, at all levels (i.e., pre and post degree) and across disciplines (i.e., medicine, nursing, pharmacy, other) should be considered at this time as part of the total research equation to best understand what works and does not work in the health delivery system.

Jibril M Hirsi
Executive Director
SomaliCAN
Somali Community Access Network
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I am the president of the Somali community in Ohio. I would like to suggest an increase in engagement and outreach services to help the Somali American community in the USA.

The Somali American community faces serious physical and mental health challenges including chronic medical problems, adjustment problems, nutrition issues and other hardships associated with the change in their environment. A basic outreach and community health education initiative can change the lives of many Somali Americans for the better.

Please consider this statement for inclusion in the hearing.

Submitted by
[personal information redacted]

Dear Committee,

Real world clinical and cost effectiveness of ICDs are hard to extrapolate from clinical trials. Large health care networks are an ideal place to gather this information. For example, HCA owns hospitals that cross different geographies, practice patterns, and their patients are integrated into the community (as opposed to “captive” health systems). By linking their hospitals with a centralized patient tracking and outcome system, one can both measure treatment effectiveness, and test practice enhancements. This could serve as a test tube for what is possible through a fully integrated national electronic health record.

This registry could assess the effectiveness of ICD therapy and patient screening techniques. Microvolt T wave alternans (MTWA) is an inexpensive and non-invasive technique that has

significant potential to fill this role, but will require government support to fully explore its potential. Many studies have shown MTWA to predict total and arrhythmic death, and patients most likely to benefit from ICD therapy. Recent “negative” MTWA studies, especially the MASTER Trial, have slowed adoption. However these negative studies have significant limitations that could invalidate the conclusions. Also, since MTWA is dynamic, chronic MTWA measurement (which has not been explored) could have additional benefit. More importantly, MTWA could serve as a means for optimizing medical treatment of CAD, heart failure, and arrhythmia—thereby reducing risk of costly hospitalization.

I propose an integrated data collection system within an organization like HCA to explore the "real world" impact of treatments, tests (including MTWA), and practice enhancements.

Submitted by
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Cancer Policy and Clinical Affairs
American Society of Clinical Oncology
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The American Society of Clinical Oncology (ASCO) is the leading specialty society in the United States and throughout the world for physicians who treat patients with cancer and conduct cancer research to improve patient outcomes. ASCO is committed to ensuring that high-quality, evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans. This statement highlights both the importance of comparative effectiveness research in our community today, and offers suggestions for ways to enhance this science moving forward.

Because cancer is a complex illness that touches many aspects of the health care system, oncology can serve as an important laboratory for comparative effectiveness studies. Comparative clinical research is embedded in the culture of oncology. The extensive cancer clinical trials network across the U.S. has a long track record of pursuing comparative effectiveness research. Examples include:

- National prostate, lung, colorectal, and ovarian cancer screening trials;
- A large portfolio of trials and meta-analyses comparing different regimens used for adjuvant therapy of operable breast, colon, and lung cancer; and
- Correlative studies that compare relative effectiveness of alternative drug regimens or targeted agents in patient subgroups defined by presence or absence of specific biomarkers. An important point for this last example is that, for most of these studies, treatment occurred several years ago, outcomes are already known, and banked tumor tissue permitted subsequent evaluation of predictive biomarkers. This provides a useful model for comparative effectiveness research that can lead to individualized treatment choices.

Much of this work has been possible because of our national cooperative group system, including disease site-specific scientific steering committees established by the National Cancer Institute's Coordinating Center for Clinical Trials, broad community involvement through the Community Clinical Oncology Program (CCOPs) and Cancer Trials Support Unit, a national registry program, and the multidisciplinary nature of our specialty. This network is already in place.

As you continue to work on shaping a national program on comparative effectiveness, we strongly recommend:

- Involvement of oncology experts in setting cancer-related priorities,
- Use and strengthening of existing oncology infrastructure to accomplish this work;
- Focus on areas where randomized clinical trials have established baseline data;
- Rigorous, standardized collection and storage of biospecimens in a way that allows broad access;
- Consideration of an oncology-specific evidence-based practice center; and
- Significant investment in expanding, strengthening, and linking national registries to include more robust data on individual patients' baseline characteristics, biomarker assay results, and specific treatment regimens.

Thank you for the opportunity to submit this statement. ASCO looks forward to working with you and others in the medical community as we move forward in this important area.

Submitted by
[personal information redacted]

I am writing this statement to urge the Council to recommend Dr. Adrienne Sprouse's Environmental Control Unit (ECU) for funding. Dr. Sprouse presented her statement at the April 14, 2009 Washington, D. C. Listening Session. The research from the ECU will document and demonstrate causes of illness and effective treatments. The ECU has the capability to study patients from specific ethnic backgrounds as well as the larger American population. The research generated from the ECU will be invaluable to medicine for many years to come.

In 2004, the Milken Institute (non-partisan, non-profit) issued its report, An Unhealthy America: The Economic Burden of Chronic Disease citing the most prevalent chronic illnesses in America as lung disease, heart disease, hypertension, mental illness, cancer, diabetes, and stroke. **Fifty percent of all Americans have at least one of these chronic illnesses. Each of these chronic illnesses has an environmental contribution in its etiology that rarely is identified or evaluated.** Yet billions of dollars are spent---often wasted—by trying to suppress symptoms without identifying the cause of the illness. The healthcare costs and dollars of lost productivity can be found, state by state, on their websitewww.milkeninstitute.org. Comparative Effectiveness Research is essential to determine the etiologies of chronic illness and to determine those treatments that are effective versus those treatments that merely attempt to suppress symptoms while ignoring the underlying cause of the illness.

For years, there has been a debate whether certain chronic illnesses are psycho-somatic, or illnesses emanating from the body with psychiatric sequelae. Those who insist these illnesses are psychosomatic have never fully evaluated the patients to determine whether an underlying physical illness might be contributing to the psychological features. The phenomenon of a healthcare practitioner ascribing a psychiatric diagnosis to a real physical illness is eloquently penned by Harvard researcher Jerome

Groopman , M. D. in his book How Doctors Think. Repeatedly, Dr. Groopman documents that serious and even life-threatening illnesses go undiagnosed by "well-trained" physicians who have a pre-conceived idea of what the patient should have, and are inexperienced in the patient's particular presenting diagnosis. Illnesses from celiac disease to Wilson's disease have been missed by physicians. In both of these cases, the patients would have died without the correct diagnosis which was later made by a more thorough and experienced doctor. This issue of misdiagnosis due to inexperience raises grave questions about medical competency, medical training, patient outcome, and healthcare costs. In every instance of misdiagnosis, the patient is harmed and loses faith in a medical care system that should be wiser.

The Gold Standard research model in medicine which can clarify many issues of accurate diagnosis and effective treatment is the Environmental Control Unit (ECU). Consistent with President Obama's insistence on transparency and integrity in government, there is no area more important than healthcare where transparency and integrity are imperative. We need objective, accurate, non-lobbied data and outcome information if we are to reverse the downward spiral of chronic disease and its enormous financial burden on U. S. citizens, personally and financially. Each of the above seven chronic diseases is on the rise. We must stop this trend by identifying the causes, eliminating them, and provide treatments that restore the patient's health rather than merely medicate the symptoms. An Environmental Control Unit is the research tool that can accomplish our best medical goals with complex medical conditions. An ECU is a set of patient care rooms either on a wing of a medical facility, or located in a free-standing building. The air on the ECU is filtered to be free of any chemicals and the ECU is constructed with low- or no toxicity building materials. No fragrances are allowed on the Unit, and temperature and humidity are controlled. The specially-trained medical staff is instructed in the protocols necessary to identify and monitor the patient's symptoms, obtain baseline data on each patient, and monitor each patient as modifications to the patient's environment (air, food, water) are made. The 24-hour medical staff is available to document the impact of each carefully determined change for each patient. The test results are then assessed by the medical staff, and specific courses of treatment are identified for not only each patient, but also for symptom clusters that were previously considered unrelated. Japan has several ECU's.

This scientific approach is crucial for illnesses thought to be "purely" psychological (mental illness, chronic fatigue, fibromyalgia, etc.) as well as for patients with illness primarily somatic (COPD, cardiac disease, etc.). The data collected through an ECU will demonstrate the etiologies and treatments that are accurate and effective and end the needless and unproductive controversy between psycho-somatic and somatic illness for some well-described disease states. Once delineated, psychological counseling and/or psychotropic medication may be required to stabilize the patient.

Of course there another, related perspective: Those patients with neurological illnesses which have an environmental component as a possible cause. Harrison's Principles of Internal Medicine 16th Edition 2005 New York, McGraw Hill p 2408 , includes the following possible causes for Parkinson's Disease: Valproic acid, Fluoxetine, Lithium carbonate, alpha methyldopa, typical antipsychotic medications, manganese, methanol, carbon disulfide, carbon monoxide, anti-emetics, and possibly n-hexane to name a few. Yet these etiologies often go unexplored in patients with Parkinson's Disease.
Another related area for research funding is evaluating the human health consequences of chronic exposure to low levels of toxic chemicals. Cigarette smoke is a paradigm for many environmentally-triggered illnesses. Once thought to be harmless, with package labeling dispelling any health concerns in the 1960's, through observation and research we have come to learn that cigarette smoke causes multi-system disease that can lead to death. Lung cancer, heart disease, stroke, asthma, vasculitis, and low birth weight are all consequences of exposure to cigarette smoke, whether one smokes or whether one is exposed to second-hand smoke. This is not surprising considering cigarettes contain more than two

hundred chemicals that were applied in the growing of tobacco through the production of the final product.

Other chemicals cause human illness as well, and increased incidence of illness has also been established between environmental chemicals and asthma, prostate cancer, and many other illnesses. These findings have been published in a wide variety of medical journals, and research into the environmental causes of disease is spread among many research institutes, therefore, the vast amount of information regarding the environmental impact on health is poorly centralized.
We already have an unfortunate baseline describing chronic disease as reported in the Milken report. Funding is needed to conduct research that will identify the cause of illness and describe the best treatments. Funding an ECU will accomplish this and spawn an improvement in medical education so physicians will be better trained to diagnose and treat complex medical conditions.

Submitted by
[personal information redacted]

1. [personal information redacted]
2. there needs to be sunset provisions for research focus. tb has had extreme focus for 60 years. we now have autism issues. we need to find out why such a high proportion of boys in nj 1 out of 50 are being autistic. that should assume importance. tb needs to be put to rest for a while. american taxpayers cannot fund EVERYTHING.

3 the influence of big pharma and big medicine needs to be muted. their pushing for products that make them rich and kill fellow americans is as greedy and sick as the sec wall street mess. it is time to tone down the profiteering of big pharma and big medicine. we need common sense funding.

4. autism needs to be given top priority to find out the connection between mercury in vaccines/formaldehyde in vaccines, etc and the effect on the brain of a baby that is 8 lbs where such a massive assault on that baby's system cause brain malfunction.

5. any priority list for funding that you come up with needs to be released to the public for affirmation, as well as the labo tests on animals that you seek to brutally inflict. it is time to stop making animals into test subjects for these stupid tests like smoking tests, etc.

Submitted by
Michael Saliba, MD, Chairman
Saliba Burns Institute

EFFECTIVENESS OF HEPARIN COMPARED WITH CURRENT BURN THERAPY
Presentation of the MD Chairman, CER HHS Listening Session: Chicago IL, May 13th

Burns are painful, blood clotting, inflammatory, ischemic, cellular-destructive injuries with high mortality that heal slowly with residual scars and contractures. Current treatment is suboptimal, difficult, long, surgery intensive and extremely costly. Improvements in treatment and reduction in cost are needed.

Adding heparin on the burns and inside the body produces therapeutic effects which cost-effectively precisely match the burn pathology. Heparin is specific medical burn therapy. Adding heparin vastly improves current burn treatment, results, and survival at affordable costs, often one-tenth or less of current costs.

Heparin reduces surgical procedures, medical procedures, medicines, hospital time, healing time, blood loss, transfusions, and prevents a lifetime of mental suffering with humiliating scars and contractures. Importantly, use of heparin provides prompt, on-site, cost effective therapy for the persons burned in thermal disasters, for which there is now no adequate treatment. Heparin uniquely relieves the pain and initiates therapy.

Hundreds of burn specialist doctors in multiple burn centers in over 20 countries have documented the benefits of heparin in over 32,000 seriously burned patients; and presented the evidence of their research studies in international burn meetings and publications. There are no known negative studies of heparin added to human burns.

This Heparin treatment is not widely used in our United States because USA Burn Care is oriented to surgical removal of the burn as a first treatment, and multiple other surgical procedures in the follow-up care. Adding heparin therapy in the USA is needed and recommended. Heparin is humane affordable burn care which can be legally justified.

SBI recommends CER Officials in HHS gather, evaluate, compare, and recognize the benefits, cost efficiency, and global success obtained by adding heparin first to burn treatment - prior to any surgery, which will be in lesser amount under more improved conditions and results, with much reduced suffering, mortality, procedures, treatment time, and costs. Heparin gives all doctors an opportunity to medically treat burned patients, relieve their pain, initiate therapy, and appropriately reserves the necessary surgery for the surgeons. All doctors can then participate in improving burns care and results at affordable costs.

SBI suggests that once CER Officials in HHS are satisfied by the evidence, they may elect to help SBI disseminate this information within the United States. SBI proposes to prepare scientific books for doctors and ancillary therapists, public information books, training manuals, and videos.SBI plans to arrange and conduct regional treatment information/instruction meetings, and promote heparin instruction in medical schools..

Immediate information is in the Internet Website: http://www.salibaburnsinstitute.org
If anyone expresses a negative statement, request that they provide evidence of it.

Saliba Burns Institute (SBI) is a 501.c.3 public benefit, non-profit, IRS approved entity.

Address: The Saliba Burns Institute, 7660 Fay Ave, H-350, La Jolla, CA. 92037
SBI has researched, developed, and is now disseminating information and instruction.

Submitted by
Susan H. Lin, ScD, OTR/L
Director of Research, American Occupational Therapy Association

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Thank you for this opportunity to provide comments on behalf of the American Occupational Therapy Association regarding the priorities for comparative effectiveness research. AOTA, representing the interests of over 140,000 occupational therapists, occupational therapy assistants and students of occupational therapy, is concerned about the health, active engagement in daily activities, and participation of all individuals. .

Comparative effectiveness research plays a critical role for health professionals, policy-makers, and consumers. However, comparative effectiveness research should be conducted beyond primary care settings, because important health care questions need to be answered in rehabilitation, long-term care, and community settings as well. Occupational therapy practitioners work with infants and elderly, in schools, homes, nursing facilities and hospitals. We strive to improve people's abilities to perform the daily activities that are most meaningful to them, thus improving their functional activities and quality of life. Occupational therapy enables "Living Life To Its Fullest;" and research has shown that occupational therapy, by improving life, can positively affect health outcomes and costs (Hay et al., 2002).

AOTA has completed systematic reviews on Occupational Therapy and children and adolescents with autism, children with behavioral and psychosocial needs, adults with stroke, driving and community mobility for older adults, adults with Alzheimer's disease, and children and adolescents with sensory processing/sensory integrative disorders. However, more reviews are needed to examine the evidence for different health conditions in different health care settings. Additionally, resources are needed to disseminate and promote use of evidence at the point of care, especially in rehabilitation, which can vary among inpatient, outpatient, home, and community settings.

Dr. Carolyn Clancy, Director of AHRQ underscored the need to "focus on patients with multiple **chronic illnesses**, a group of people for whom we spend the most money and provide the worst care" (Clancy, 2008). The diagnoses of autism, stroke, and dementia are often chronic, requiring multiple interventions, including occupational therapy services. Research is needed to determine the optimal dose, frequency, duration and type of occupational therapy interventions for individuals with conditions such as autism, stroke, and Alzheimer's. Such research would aid occupational therapy practitioners to deliver services efficiently and effectively, which is especially important in the context of the current economic climate and the workforce shortage that we are experiencing in occupational therapy. The following studies are examples of research that is needed based upon AOTA's systematic reviews.

Autism

Research Question: Is behavioral intervention with occupational therapy intervention more effective than behavioral intervention (without occupational therapy) to improve the performance of daily tasks and participation in school, home, and community in children diagnosed with autistic spectrum disorders (ASD)?

Justification: Behavioral interventions are commonly used to treat autism, but given the high prevalence of sensory issues in children with Autistic Spectrum Disorders (ASD), this approach fails to address what are believed to be underlying reasons for these children's behaviors: i.e., problems with processing sensory information. Occupational therapists can assess and treat sensory processing problems that negatively influence children's behaviors and daily performance. They also can modify environments (e.g., reduce sensory overload) and tasks so that children can perform them as independently and functionally as possible, whether the task is dressing or completing a class assignment.

Stroke

Research Question: Does rehabilitation with special focus on cognition for functional activities result in better outcomes, long-term recovery, increased productivity, and greater participation in the community, compared to standard rehabilitative care? And does greater cognitive rehabilitation emphasis result in any cost savings over the long-term recovery of individuals who have had a stroke?

Justification:

Each year, 795,000 people have a stroke in the United States, and stroke is the third leading cause of death. Early interventions and rehabilitation post-stroke are crucial to better functional outcomes. And yet, there are variability in the rehabilitation treatment approaches, depending upon professionals' knowledge of the literature, rehabilitation equipment and staffing availability, and even reimbursement policies. Thus, funding for CER should address knowledge translation or knowledge transfer, or else valid effective interventions will not be utilized and patients' potential for better functioning could be unnecessarily limited.

Research suggests that cognition is a mediator of functional outcomes in stroke rehabilitation, but more studies are needed to compare outcomes of rehabilitative approaches. Concurrently, these studies should measure use of health care services and its associated costs, so that we can compare interventions not only in terms of outcomes but costs as well.

Dementia

Research Question: Are intervention programs that facilitate routines and environmental cueing, as provided under the supervision of an occupational therapist and under an occupational therapy plan of care, more effective than standard care to improve the performance of daily activities (e.g., toileting, sleeping, taking medications) in people with dementia? And does the improvement help promote health for caregivers?

Justification: Research suggests that routines are beneficial to performance of daily occupations (e.g., sleep) in people with early dementia. While some studies have examined the intervention of routines on behavior and performance, few studies have investigated the effect of routines and environmental cues on performance of activities of daily living (e.g., toileting, sleeping,) and mortality. If the maintenance of daily routines and provision of environmental cues provide purposeful and meaningful activity throughout the day, people with dementia could live longer,

have fewer health problems and higher quality of life, which could decrease the stress of caregivers and lower costs.

Summary

Occupational therapy promotes the performance of daily activities and participation of individuals who have illnesses or injuries that limit their daily performance and participation in society. We have recommended specific CER studies for autism, stroke, and dementia, but occupational therapy practitioners work with people of all ages, across educational, business, and health care settings. Further research is needed to identify the most effective and efficient occupational therapy interventions, especially in rehabilitative settings and other contexts in which individuals with chronic illnesses are served.

The American Occupational Therapy Association greatly appreciates this opportunity to comment and looks forward to forming partnerships with other organizations to promote the health, productive living, and quality of life of all individuals.

Submitted by
[personal information redacted]

I would like to share my frustration with current policy towards Complementary and Alternative Medicine (CAM).

Over the past few months, I have been educated on all of the used and practices of using alternative medicine to cure, alleviate, and prevent common medical problems. It has become apparent to me that using a CAM approach to current medical practices would be a more beneficial way to treat patients. Not only does alternative medicine come naturally without any serious side effects, but it is available at a significantly lower cost. Educating today's US doctors of all the natural treatments that have been used by the Indian, Chinese, any many other cultures before us will give the doctors more tools and resources in their efforts to combat diseases. The natural healing of these practices has been well documented in many scholarly research papers and journals. To avoid the proof and evidence would be slap in the face to the thousands Americans who have been healed if not saved by these age old natural practices. Also, to not allow these natural healing methods to be further researched and one day allowed to be incorporated into everyday western medicine would be a disservice to the potentially thousands of people that could be treated and helped. Patients must know that there is another way beside taking pills and getting surgery that can alleviate them of their aches and pains. Doctors must know that they have another option besides proscribing patients medicine with possible deadly side effects.

In conclusion, please allow Complementary and Alternative Medicine (CAM) practices to be seriously considered as another form of treatment for patients. Review the scholarly documents and the facts that have accumulated of the centuries regarding the benefits and healing powers of natural ways.

Submitted by

[personal information redacted]

Over the past semester, I have had the honor to be part of a class titled "Issues in Alternative Medicine." This class taught me more about the medical world than I could ever have imagined. I have learned to question what I hear as medical proof and learned to seek for alternative answers when the most common answer does not seem to be the best answer.

A large part of this class focused on the idea that alternative medicine is more effective in a lot of cases as compared to the traditional Western medicine. After listening to a lecture by Professor Gaby, and reading several abstracts of his studies, I realized that not every medical complication has to be solved by some dramatic surgery. Dr. Gaby uses supplemental vitamins in place of drastic procedures, and often, these end up working better than any surgery. Some of his studies that really amazed me were where children had serious otitis media that he was able to cure by locating a food allergy. He was also able to alleviate fibromyalgia symptoms simply by putting his patients on a vegan diet. He was also able to use chromium to improve glucose and insulin variables in individuals with Type-II diabetes as well as using Vitamin-E to make red-blood cells more recpetive to oxygen. It seems remarkable to me that if these effectives are more affordable, why are they not being used more often in the medical field?

The question of cost seems to be the biggest issue facing the health care reform right now. Everywhere costs are trying to be cut, yet people keep going back to the same old tired answers about health care. It seems to me, that if the government is trying to save money, why they don't look at Alternative medicine as an option. There are far too many cases to describe where people with chronic symptoms that have seen every Western doctor there is, are only cured when they finally meet an alternative medicine practitioner. The evidence is there that these practices work, and if they save money, it seems to me, that they should become part of the health care possibilities.

Submitted by
[personal information redacted]

I am a Naturopathic Physician, trained at Harvard and Bastyr Universities, and have been in clinical practice as a wellness-oriented primary health care provider for over 15 years. I understand you are accepting input for developing a system to study the clinical effectiveness of a wide array of modalities both established and relatively obscure (at least to the eye of a strictly conventionally trained doctor).

Established therapies are largely assumed, often erroneously, to be effective, such as arthroscopic knee surgeries for meniscus tears, or proton-pump inhibitors for heartburn. Relatively less known therapies, such as Rolfing, or Therapeutic Touch, or Naturopathic Medicine, all of which require varying degrees of training and licensure maintenance, may be quite effective. In general, the low-tech, low-risk, high-touch approach of CAM modalities pose significantly less risk of pesky to lethal side effects than "conventional" therapies. Besides being safer, CAM modalities may also be very effective, at a fraction of the cost.

Why is that? Because many CAM modalities address the patient as a whole person. Most CAM practitioners are "generalists", not specialists, and do not view the patient's illness as separate from the entirety of the patient's physical, mental and social reality. As a Naturopathic Physician, my aim is to educate my patients to take care of their own health. I typically spend 60 to 90 minutes at a patient visit (for the same price my MD colleague would offer a 7-12 minute visit) and so I have time to perform a thorough physical exam, organize appropriate labs/radiology if necessary, and comprehensively investigate the dietary and hygiene habits of my patient. Often my MD colleagues are trapped by the clock: frequently, all they have time for in a patient encounter is offer a pharmaceutical prescription.

As an example, a Rolfer might help adjust the imbalance in tension between muscles at the front (quadriceps) and back (hamstrings) of the leg which attach to the knee, thus relieving pressure on the meniscus and allowing innate healing. This is likely to be as effective as arthroscopic surgery, from my clinical experience, without the risk and expense of surgery.

In another example, a Naturopathic Physician would address "heartburn" not as a problem of excess stomach acid. but as inappropriate pressure against the lower esophageal sphincter and delayed stomach emptying. Stomach acid is critical to optimal digestion, not to speak of sterilizing our food. It is, in many senses, the primary defense against ingested potential pathogens penetrating more deeply into the body. The Naturopathic Physician (see www.naturopathic.org for access to our 4 plus year post graduate training and licensure requirements) would evaluate and educate the patient on potentially offending foods, would treat the likely hiatal hernia causing the reflux with simple manual therapy which the patient can learn to self-administer, and offer a short-course of natural therapeutics, such as aloe juice, to cure the patient of this ailment. Long term dependency on anti-acids does not address the underlying cause of the ailment, and, more importantly, puts the patient at risk for nutritional deficiencies over the long term -- because hydrochloric acid is critical for optimal protein digestion. Food is not assimilated optimally unless it is thoroughly digested first.

According to some accounts, over 70% of North Americans have used CAM therapies in the past decade. The CAM industry continues to grow: something must be working. Today's consumers are less enchanted with drugs and surgery as the only options in our so-called health care system. Because it is increasingly evident that the current system is actually a disease management system.

Imagine prioritizing our citizens' wellness as a national goal, with the weight of the federal budget behind this concept!

I applaud the concept of investigating the effectiveness of therapies because there is clearly a great deal of waste in the way "health care" is delivered today. I urge your committee to look beyond the AMA and the pharmaceutical and insurance lobbyists when determining the foci of your investigation. Thank you for your important work.

Submitted by
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The American Association for Geriatric Psychiatry (AAGP), the national association representing and serving its members and the field of geriatric psychiatry, is pleased to offer recommendations for consideration by the Federal Coordinating Council on Comparative Effective Research. AAGP is dedicated to promoting the mental health and well being of older adults and improving the care of those with late-life mental disorders. AAGP's mission is to enhance the knowledge base and standard of practice in geriatric psychiatry through education and research and to advocate for meeting the mental health needs of older adults.

Between 2005 and 2030, the number of Americans age 65 and older will almost double in the United States, increasing from nearly 17 million to more than 70 million. Over that time period, those aged 65 and older will increase from 12 percent to 20 percent of the total population. In addition, the racial and ethnic diversity of the older population is changing – with a doubling of African Americans aged 65 and over, and an almost tripling of older adult Latinos in this same time period.

With the graying of the population, mental disorders of aging represent a growing challenge that will require a greater investment in research to develop understanding of age-related brain disorders and to develop new approaches to prevention and treatment.

As the Council considers its recommendations for spending priorities on comparative effectiveness research (CER), as requested in the "American Recovery and Reinvestment Act of 2009," it is critical that comparative effectiveness studies address efficacy, safety, cost, and downstream health services utilization in older Americans.

Specific areas that must be given careful consideration include:

- Generalizations about medical treatments, including psychopharmacological ones, must be made very cautiously. Evidence-based conclusions on comparative efficacy must be balanced by the understanding that group-based conclusions cannot be easily translated to the treatment of the individual patient. Thus, any conclusions drawn from comparative efficacy studies must not be interpreted as producing any sorts of mandated guidelines that limit attention to individual patient difference. Medical science is leading us away from the era of "average" medicine to the era of individualized medicine, and while the full potential of this movement is still just a glimmer, treatment policy must be able to accommodate the discoveries yet to be made.

In the field of mental health, numerous studies have demonstrated that patients respond very differently to powerful psychopharmacological drugs, and it is crucial that psychiatrists be able to have a full range of medications available for their patients. Drug-drug interactions are important causes of hospitalization in the elderly; studies should address which agents are safer and simpler to use in this context, especially in general medical rather than specialty mental health settings.

- Comparative effectiveness studies must also address the length of time that older adults are exposed to different agents. Often clinical trials are much too brief (6 – 12 weeks) to permit a clinically relevant assessment of efficacy and especially of safety/adverse events.

- Comparative effectiveness studies must pay particularly close attention to the needs for specific studies of the effects of therapeutic medications on older adults. Studies of younger and middle aged adults may result in approaches that are entirely inappropriate – and, indeed, harmful – for older adults, and it is crucial that this population not be neglected in any way. In fact, given the Federal government's special responsibilities to the health care of older adults through the Medicare program, Federal resources should be allocated to make sure that their treatments are both safe and efficacious.

Federal approval for most new drugs is based on research demonstrating safety and efficacy in young and middle-aged adults. These studies typically exclude people who are old, who have more than one health problem, or who take multiple medications. As the population ages, that is the very profile of many people who seek treatment, and yet there is very little available scientific information on the safety of drugs approved by the Food and Drug Administration (FDA) in substantial numbers of older adults who are likely to take those drugs. It is crucial that the issue of elderly patients having multiple comorbidities be addressed in these studies. It is simply not adequate to design comparative effectiveness research for the elderly without specifically designing such studies to include patients with multiple comorbid conditions, who represent the vast majority of real-world elderly, especially those with psychiatric illness.

Psychiatric drug treatment is increasingly based on advances in basic and clinical neuroscience, and it has been shown to increase the mental health, overall health, and quality of life of older people with affective, psychotic anxiety and cognitive disorders. However, although older patients, including the frail and chronically ill elderly, are heavy users of multiple psychotropic medications, the research and evidence base underlying this use is limited. In fact, most of the medications used in the elderly, psychiatric medications and others, have been tested only on younger and healthier patients.

Indications that this adequate testing can compromise care come from recent findings from the body of research on geriatric psychopharmacology that is available, including evidence that commonly used antidepressants may have marginal effects for depression in the oldest-old, that another antidepressant that is safe and effective in younger adults may be poorly tolerated in the frail elderly, and that the atypical antipsychotic agents often used for the treatment of the psychotic and aggressive symptoms that can complicate Alzheimer's disease may be associated with increased mortality in nursing home residents.

- Finally, these comparative studies should evaluate the extent to which disease management strategies can improve the efficiency and value of pharmacological treatments for the elderly and should also support studies of the comparative effectiveness and value of pharmacological and time limited behavioral treatments.

More comparative effectiveness work is needed on efficient and effective models of mental health services delivery similar to IMPACT, PROSPECT, PRISME, and RESPECT. These care delivery programs were emphasized in the recent Institute of Medicine report, *Retooling for an Aging America: Building the Health Care Workforce*. Pilot studies of geriatric mental health service delivery in the general medical sector as well as other points of service need to be tested, compared, and evaluated. These models need to be straightforward and allow access to consultation with geriatric mental health specialists for the management of the more severe or difficult treatment cases.

We thank the Council for consideration of our issues and would look forward to further discussion of these topics, as well as other issues impacting the mental health of older adults

Submitted by
[personal information redacted]

It is my pleasure to be addressing you on the topic of comparative effectiveness research. I support the view that this research done correctly can lead to medical breakthroughs, decreased medical cost, better patient care, and more progressive medical products. However, comparative effectiveness research done incorrectly can lead to a wasted opportunity for important data. As a member of the health care community, it is my sincere hope that the proposed research be managed as effectively as possible. This will not only support the integrity of the research but also the integrity of this industry, which is a paramount of importance

I work with individuals who have been involved in some of the most progressive medical research in the field of spine and orthopedics for the last 10 years and it is my pleasure to say that our research has resulted in better patient outcomes and more efficient medical care from carrying out comparative effectiveness research.

In order to assure the best possible result through comparative effectiveness research, it is imperative that the research is done on a large scale (i.e. multi-center) and those involved work as a team and are experienced in the field of research. If we do not meet these requirements, and instead turn this important task over to hundreds of inexperienced parties working individually, we are assured a dismal outcome.

The need to eliminate bias is the most important aspect in any study and it is the power of many and not the few that can accomplish this research of monumental importance. In order to prove with confidence that a treatment will lead to a preferred outcome, research must be done across thousands of patients in multiple centers around the country. Multi-center coordination is yet another issue. In order to increase enrollment numbers to there most effective levels, a number of centers will likely be used in many projects. This can lead to an enormous coordination

problem during all phases of the study. Further, many previous trials have included poor quality data from which no conclusion could be drawn. Lastly, many of these studies will last 5 to 10 years, and so the issue of center, coordinator and patient burnout is also a significant pitfall. With collaboration and technology we can avoid these pitfalls that happen many times when researchers are isolated.

There is no need to isolate every researcher. The use of the internet has made it easy for researchers all over the world to collaborate and submit data to one database. A researcher in New York can be submitting research data on osteoarthritis at the same time as a researcher in Los Angeles and within seconds a researcher, government worker, or the public, can see the outcome from anywhere in the world. This is the beauty of using the web for real-time data. It is our duty to give researchers the tools and resources they need to effectively carry out their research and assure we get the best possible end result, which can be done through an experienced web-based system of data collection. Partnering with an experienced party to implement data collection and research across many sites will make comparative effectiveness research a huge success.

I am writing to propose the idea of coordinating many of the funded opportunities through a single entity that can plan the execution of the studies and then manage, analyze and distribute the data in many different forms. I am currently working at a company that is the leading provider of post market clinical data management solutions designed to meet the unique needs of the cardiovascular, orthopaedic and spine research communities. We have spent the past 15 years developing skills in multi-center research that has led to significant medical breakthroughs in comparative effectiveness research. PhDx is rooted in the Health Information Platform, a proprietary, comprehensive, scalable platform agile enough to take on the most complex multi-site multi-year studies. By offering a web-based solution that has been refined over years to help with patient follow-up in a longitudinal study, data capture, and outcomes reporting, the task of carrying out comparative research is efficient and credible. In addition, creating a single database for comparative effectiveness researchers across the United States will allow for easy collaboration between researchers and the capabilities to easily manage and analyze data on a large scale. For example in the past eight years we have made it possible for hundreds of physicians to collaborate and study adult and pediatric scoliosis even though their centers remains in different parts of the United States.

I believe the comparative effectiveness research by the US government can achieve the same success we have been able to see with careful planning and technology that allows collaboration between researchers.

Submitted by
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Policy on Comparative Effectiveness Research

The National Alliance for Caregiving believes that for a comparative effectiveness program to be successful, it cannot be used as a "tool" to simply ration health care. It must improve patient outcomes, and include the front-line defenders in chronic care coordination and management--the family caregivers.

Together with patients and healthcare providers, family caregivers are a critical part of an interdisciplinary care team helping to meet the needs of individuals with multiple chronic care conditions. There are 44.4 million family caregivers providing unpaid care to a loved one over the age of 18. Approximately 25 percent of these caregivers are caring for someone with Alzheimer's or other dementia. The economic value of caregivers' unpaid contributions is estimated at around $375 billion in 2008, according to AARP's Public Policy Institute. Lack of communication and coordination among the patient and family caregiver and the health care provider produces poor health outcomes such as: medical errors, duplicative or unnecessary tests, inappropriate emergency room visits, hospital re-admissions due to poor follow-up care, inadequate discharge planning, lack of appropriate care and support services upon returning home, adverse drug interactions and ultimately rising medical costs.

We urge the panel to embrace five principals to guide your work:

- Conduct your research in an open and transparent process, one that is open to all stakeholders, including family caregivers;
- Include patients and family caregivers in any review panels for comments about what procedures and decisions are being compared;
- Communicate your findings in a way that is easily understandable to the general public;
- Identify ways to partner with family caregivers in their role as primary care coordinators for patients with chronic care illnesses or disabilities; and
- Ensure the appropriate inclusion of and support for family caregivers in developing long-range goals for health care reform.

Submitted by
Larry Cohen, Executive Director, Prevention Institute
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Larry Cohen is the Executive Director of Prevention Institute, a national non-profit moving beyond approaches that target individuals, one person at a time, to create systematic, comprehensive strategies that impact community health. Prevention Institute is dedicated to translating research into effective community practice and to ensuring that effective community practice is a key component of our national health research agenda.

INTRODUCTION

We ask the Federal Coordinating Council to recommend that significant Comparative Effectiveness Research funding be invested in analysis of primary prevention practices and initiatives.

While we fully recognize that Comparative Effectiveness Research funding must also be dedicated to an analysis of clinical prevention and medical care, we believe that there are many critical reasons for a complementary focus on primary prevention—in other words, the prevention of illness or injury before it occurs. Our learnings show strong reasons to prioritize community-wide interventions: bettering the places where people live work and play can fundamentally improve a community's health and safety outcomes by reducing rates of multiple illnesses and injuries.

Many aspects of health in the United States, from how resources are allocated to who has access to care, reflect a lack of focus on prevention. Far too often, prevention is misunderstood or an afterthought (Cowen, 1987). The dominant approach to health and wellbeing in this country focuses on medical treatment and services, after the fact, for the many Americans who are sick and injured each year. Unfortunately, there is a lack of corresponding emphasis on quality community and large-scale prevention efforts in order to avoid those same illnesses and injuries in the first place.

Comparative Effectiveness Research funding should be invested in primary prevention because:

1. Primary prevention works, saving lives and reducing misery.
2. Primary prevention is cost-effective and has the potential to produce significant savings.
3. Primary prevention will lessen the burden on our crumbling healthcare system.
4. Health is more than healthcare. Primary prevention addresses other, more impactful causes.
5. Investment in primary prevention is supported by a majority of the American public.
6. Primary prevention can help eliminate health disparities.
7. Primary prevention is consistently neglected, leading to unnecessary illness and injury.

Effectively addressing the range of health and social problems of the twenty-first century requires a fundamental paradigm shift that generates equity for the most vulnerable members of society and maximizes limited resources: moving from medical treatment after the fact to prevention in the first place, and from targeting individuals to a comprehensive community focus. The imperative for this shift in thinking is best described by psychologist and noted prevention advocate Dr. George Albee (1983), who noted that "…no mass disorder afflicting mankind is ever brought under control or eliminated by attempts at treating the affected individual…"(p.24).

THE CASE FOR PRIMARY PREVENTION

Primary Prevention Works

Many injuries have been averted and lives saved through primary prevention measures. One well-known and very successful example of primary prevention is the National Minimum Age Drinking Act of 1984, which required all states to raise the minimum age to purchase alcohol to twenty-one or risk losing major transportation funding. The National Highway Traffic Safety Administration (NHTSA) estimates that as a result of minimum-drinking-age laws, 18,220 lives

were saved between 1975 and 1999 (U.S. Department of Transportation, 1999). Other examples include:

- *Antismoking legislation*. California's aggressive anti-tobacco effort under Proposition 99 results in thirty-three thousand fewer deaths from cardiovascular disease in the first three years (Kuiper, Nelson, & Schooley, 2005).
- *Water fluoridation*. Water fluoridation is effective in reducing dental decay by 20 to 40 percent (American Dental Association, 2005).
- *Motorcycle helmet laws*. Motorcycle helmet laws, enacted in six states (California, Maryland, Nebraska, Oregon, Texas, and Washington) since 1989, have successfully reduced motorcycle fatalities by an average of 27 percent in the first year (NHTSA, 2004).

Clearly, prevention on a community level has a substantial impact.

Primary Prevention is Cost-Effective

"If we are serious about improving the health and quality of life of Americans AND keeping our health care budget under control . . . we cannot afford to ignore the power of prevention." (CDC, 2003, p.6)

Healthcare is among the most expensive commitments of government, businesses, and individuals combined. A targeted investment in prevention not only decreases the financial burden on the healthcare system, it staves off unnecessary and rising medical costs. According to the US Preventive Services Task Forces' (1996) Guide to Clinical Preventive Services, primary prevention is generally considered the most cost-effective way to provide effective healthcare, due to its role in alleviating the unnecessary suffering and high costs of specialized care associated with disease.

More specifically, research recently conducted by Prevention Institute, Trust for America's Health, the Urban Institute, and the New York Academy of Medicine concluded that (p.3, 2008):

- "An investment of $10 per person per year in proven community-based disease prevention programs could yield net savings of more than $2.8 billion annually in health care costs in one to 2 years, more than $16 billion annually within 5 years, and nearly $18 billion annually in 10 to 20 years (in 2004 dollars)."
- "With this level of investment, the country could recoup nearly $1 over and above the cost of the program for every $1 invested in the first one to 2 years of these programs, a return on investment (ROI) of 0.96. Within 5 years, the ROI could rise to 5.6 for every $1 invested and rise to 6.2 within 10 to 20 years."
- "This return on investment represents medical cost savings only and does not include the significant gains that could be achieved in worker productivity, reduced absenteeism at work and school, and enhanced quality of life."

Submitted by
Richard Browdie, President/CEO
The Benjamin Rose Institute
[personal information redacted]

The Benjamin Rose Institute recently celebrated its 100th year of providing services to the older people of North East Ohio. For nearly fifty years, we have operated a research institute, named after its founding principle investigator, Margaret Blenkner. Our growing body of research is now well known and, we believe, well-regarded in the gerontological field. We focus on applied research, and have produced a number of studies on the impact of interventions, including some that have found their way into the compendia of evidence practices at the Carter Institute and the Administration on Aging.

The Administration's commitment to comparative effectiveness research (CER) is both laudable and timely. As a long time observer and consumer of research results myself, and as an administrator of services to older people using public funds for all but a few of my 39 years in the field, it has become very clear, sometimes painfully so, that a great deal of money is spent without knowing what actually works, not to mention knowing how well things work comparatively. So, my first objective is to heartily endorse this new emphasis to inform the practical consequences of policy decisions, both programmatic and financial.

My second objective is to raise with you the concern that research often ignores the impact of interventions on the lives of older people, their families, and the employees of the enterprises that deliver services. Put another way, research tends to focus on statistical results and clinical data that is reported by the entities or individuals that billed the government for the services supplied. There are a lot of good reasons for this, and I am not making the case that this should not be the primary avenue that is pursued. My point is that this sort of analysis ignores the experience of the consumer or patient and others around them, and in many areas, those impacts are of equal importance to effectiveness.

A brief example, albeit only one of many that could be offered and thus perhaps not even the most telling, has to do with strategies designed to assure compliance with exercise and drug regimens. The influence of family, friends, and even paid caregivers on the ability and even the willingness of older people to follow through and stick with a regimen have rarely been examined. Yet, these individuals are important components of the milieu in which older people live and function and play a strong role in encouraging or discouraging (or enabling or disenabling) an older person doing what would appear to the professional to be in their best interest.

For a treatment strategy or clinical intervention to be effective, particularly in an era where treatment occurs in very time-constrained and highly technical environments and the follow through increasingly happens in homes and other settings that lack all of the controls that treatment settings may have, it has to work with real people in real environments. The reality is that American communities are just as dynamic and diverse as they ever were, and getting more so. Certainly many medical procedures and pharmaceutical products can be studied through statistical means using traditional methods. But interventions that are intended to impact anything that needs to be addressed over time, from chronic condition interventions to long term care program strategies, need to be examined for their effectiveness in people's lives over time as well as the people who are involved with them on a daily basis and have a role in their functioning. This includes everything from consumer satisfaction with the results of the intervention to their understanding of the consequences of compliance with a regime.

Thank you for the opportunity to comment.

Submitted by David Juba
American Health Care Association (AHCA)
and its National Center for Assisted Living (NCAL).
Tsmith@AHCA.org

My name is David Juba. I am here today representing the American Health Care Association (AHCA) and its National Center for Assisted Living (NCAL). I want to begin by thanking each of you for making this opportunity available for us to provide brief comments.

By way of background, AHCA is the nation's largest association of post-acute and long term care providers. AHCA represents more than 10,000 non-profit and for-profit assisted living, nursing facility, developmentally-disabled, and subacute care providers nationwide who care for more than 1.5 million frail-elderly and disabled individuals every day and some 3 million individuals annually. Many of these patients leave our facilities and go home.

I am Senior Research Analyst at Fundamental Clinical Consulting, LLC. The Fundamental family of Long Term Care companies comprises one of the largest operators of post-acute care facilities in the United States. I also am currently a member, and past chairman, of AHCA's Health Information Technology Committee.

The adoption and use of health information technology is growing throughout the post-acute and long term care health sector – a sector whose 2007 revenues exceeded $131 billion. Behind hospital care and physician services, post-acute and long term care is third in terms of National Health Expenditures with the Medicare and Medicaid programs funding a vast majority of the care.

I make this point to impress upon you the importance of this sector – one that is fertile ground for important and beneficial comparative effective research. It also allows me to impress upon you the fact that the residents we care for in today's skilled nursing facilities are not those we cared for a few years ago. Increasing numbers of them require short-term rehabilitation care. These are higher acuity patients with multiple diagnoses and co-morbidities. They require multiple medications and IV's.

Given the push for integrated care, coordination across sites and concepts like "bundled payments", assessing the appropriateness and effectiveness of care settings will be an important area for comparative effectiveness research. Post-acute and long term care providers are already doing this.

Within the Fundamental affiliated entities, for example, a computerized system has been developed for collecting and storing data on an array of clinical and operations indicators across facilities and over time. This system has been in place, and evolving, for many years. These data are used to generate a host of routine and special reports – reports that help improve clinical outcomes, increase residents' quality of life and enhance operational efficiency without

compromising resident care. The Fundamental companies also are exploring the potential of telemedicine for improving the clinical care of residents in rural or otherwise remote long term care settings.

With the advent of electronically filing of the MDS (Minimum Data Set) ten years ago, our nation has amassed rich data on each patient, their condition, their needs, and their outcomes. Combine MDS data with pharmacy, laboratory, and multiple other data sets for comparative analysis and you discover powerful findings. Another AHCA member company, Sava Senior Care based in Atlanta, is now doing this with results leading to huge improvements in clinical outcomes that have, among other things, reduced the need for costly re-hospitalizations.

As an industry, we have a long history of working with researchers and sharing data. With the University of Wisconsin and Brown University we were at the heart of groundbreaking quality improvement and quality assessment research. With the University of Colorado our industry focused on staffing level research and demonstrations. Currently, AHCA is working with CMS in the development of its post-acute care assessment tool. All of this work provides data that is ripe for comparative effectiveness research.

There are two major trends at play here, and a growing future reality. The first trend is the need to better understand what works for people 85 and older, those who comprise the fastest growing segment of our population. The second trend is the diversity of lower-cost/higher-quality settings – settings where care is provided. Patients today are highly mobile. They move frequently between acute and post-acute care settings. Their lives are touched by multiple providers.

The growing future reality is that the baby boom generation is aging rapidly. In sheer numbers their care needs will be great and their expectations for quality of care and life will be high. We must be ready for them.

As members of this council, we encourage you to look closely at funding proposals that target today's frail, elderly and those that will seek care in the years to come. Government needs to find a balance in research that sets the stage for meeting the nation's total health care needs.

Thank you.

Primary Prevention will Lessen the Burden on our Crumbling Healthcare System

"America's health care system is in crisis precisely because we systematically neglect wellness and prevention." US Senator Tom Harkin

As the capacity of the U.S. healthcare system approaches a breaking point, (Cooper, Getzen, McKee, & Prakash, 2002), prevention becomes even more critical. We must do better by those who need treatment, while simultaneously reducing the number of people who become ill and injured. Prevention complements medical care and treatment, because the same things that prevent illness and injury often also hasten recovery. For example, we need to live in environments that allow us to buy healthy foods and exercise regularly in order to avoid diabetes—and people who have diabetes need these same opportunities in order to manage their

condition and maintain their health. Community-wide prevention must become a fundamental component of broader healthcare reform efforts: allocation of Comparative Effectiveness Research dollars, and other stimulus funding, is an essential investment in our nation's health.

Health is More than Healthcare

Primary prevention offers the hope of eliminating unnecessary illness, injury and even death. Nearly 50 percent of annual deaths in the United States——and the impaired quality of life that frequently precedes them——are preventable in part because they are attributable to external environmental or behavioral factors (McGinnis & Foege, 1993; Mokdad, Marks, Stroup, & Gerberding, 2004).

According to noted public health expert Dr. Henrik Blum (1980), medical care and interventions "play key restorative or ameliorating roles. But they are predominantly applied only after disease occurs and therefore are often too late and at a great price" (p.43). Despite the widely held belief in the United States that the state of being healthy is derived primarily from healthcare, Blum (1981) notes that in reality, there are four major determinants of health: environment, heredity, lifestyle and healthcare. Research shows that environment and lifestyle represent 70% of the determinants of mortality (Lee & Paxman, 1997). Primary prevention is the best way to shift environments and lifestyles, and we must therefore invest heavily in such approaches.

Primary Prevention is Supported by a Majority of the American Public

On Monday, June 8th, the Robert Wood Johnson Foundation and Trust for America's Health released the findings of a new, national poll, which showed a significant majority of the American public (76%) support increased investment in prevention (2009). Notably, people of all political parties and from all geographic regions would like to see more money put into prevention. The poll found that 86% of Democrats, 71% of Republicans and 70% of Independents believe we should invest more in prevention. Across the country, more investment in prevention is supported by 79% of respondents in the Northeast, 78% in the South, 76% in the West and 72% in the Midwest.

Primary Prevention Can Help to Eliminate Health Disparities

The burden of illness and lack of access to care in the United States is not borne equally across the population. Both frequency of illness and quality of care are often based on socioeconomic status, ethnicity and race (Agency for Healthcare and Quality, 2000). According to the Centers for Disease Control and Prevention (CDC), African Americans, Hispanics, American Indians, Alaska Natives, and Pacific Islanders consistently face higher rates of morbidity and mortality, and compelling evidence indicates that race and ethnicity correlate with persistent and often increasing health disparities compared to the US population as a whole. Research has now shown that after adjusting for individual risk factors, there remain differences in health outcomes among various communities (PolicyLink, 2002). Primary prevention can serve to eliminate underlying health disparities through its upstream population focus. For example, low-income neighborhoods and communities of color are disproportionately exposed to poor air quality—because of factors such as proximity to freeways and other toxic emissions sites and the use of subpar home construction materials. These environmental conditions trigger elevated rates of asthma, which has a long-term impact beyond health, on school and work attendance, academic

achievement, and employment opportunities. Primary prevention interventions to improve housing quality, reduce pollution, and protect residents from known risk factors would ultimately contribute to more equitable life outcomes for all Americans.

BUILDING A PREVENTION MOVEMENT

Today, chronic disease among members of the American population is on the rise, new communicable disease threats have appeared, and, as former Surgeon General Richard Carmona predicted, due to chronic diseases related to poor eating and physical inactivity, this may be the first generation of children whose life expectancies will be lower than their parents (HHS, 2004). Prevention is necessary to address this critical situation.

We appreciate the wide scope of the CER definition, criteria and framework, and urge the Council to expand traditional CER by prioritizing community-level prevention efforts that improve the places where people live, work, and play—as such approaches hold the most promise for reducing disparities, cutting chronic disease rates, and curbing healthcare costs. An investment in CER can serve to build the evaluation basis and methodology for community level prevention and make a strong statement that health is so important that all effective strategies must be employed.

Community prevention strategies have often been overlooked, both because they are harder to evaluate and because there is less opportunity for profit. They cannot, however, be ignored any longer. As Former US Surgeon General Dr. David Satcher once explained, "there is still a big gap between what we know and what we do, and that gap is lethal. When it comes to the health of our communities we must never be guilty of low aim" (2006). We cannot afford to aim low because the wellbeing of our friends, families and communities is at stake. We are getting seriously and unnecessarily injured and ill far too often.

About Prevention Institute

Prevention Institute is a nonprofit, national center dedicated to improving community health and well-being by building momentum for effective primary prevention. Primary prevention means taking action to build resilience and to prevent problems before they occur. The Institute's work is characterized by a strong commitment to community participation and promotion of equitable health outcomes among all social and economic groups. Since its founding in 1997, the organization has focused on injury and violence prevention, traffic safety, health disparities, nutrition and physical activity, and youth development.

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Submitted by
Patricia R. Salber, MD, MBA
Chief Medical Officer and Executive Vice President
Universal American Corporation

Good afternoon. I am Patricia Salber, a board certified internist and emergency physician. I am also the Chief Medical Officer and Executive Vice President of Universal American Corporation, a senior-focused healthcare company that sponsors a number of Medicare programs, including Medicare Advantage plans that focus on coordinating patient care.

We believe that comparative effectiveness research (CER) can inform and help to rationalize all aspects of the healthcare enterprise – ranging from head to head trials of therapeutics to comparisons of the most effective ways to organize and deliver health care services.

With respect to the latter, Universal American uses operational CER to determine not only whether our clinical programs are effective, but also to gain an understanding of which aspects of the programs add value and which add only cost. To achieve our goals, we have engaged an outside, independent researcher, Dr. Thomas Wilson –who testified on behalf of the Population Health Impact Institute in the last listening session—to help us make better resource allocation decisions for our health care dollars.

Based upon our collective work, we have a "learning culture" at Universal American. Here are some of the lessons that we have learned:

1) Involve an evaluation expert at the outset of health improvement program design so that the program is launched in a way that facilitates evaluation of its effectiveness.

2) Front line staff must be involved in the routine and rigorous evaluation of programs but there must also be understanding and support for this type of evaluation from the C-suite

and departments like IT, finance, and marketing.

3) Well-designed randomized, controlled trials are often called the "gold standard," however, they are not always possible – or even desirable – in business settings. In fact, we have found that many valuable insights can be gleaned just from the process of doing the evaluation.

Our learning culture is now informing many of our programs. These programs all employ an observational/quasi-experimental design using a comparable referent. Here are some examples:

- An assessment of a better case management identification system for our Todays Options' Private-fee-for Service case management program
- A prospective randomized study of the impact of a specialized end-of-life support program to help members understand their options, including hospice referral
- Evaluation of the efficacy of a remote alert device designed to improve "peace of mind" of our members and their families as well as reduce ER visits and hospitalizations
- Analysis of the impact of a psychosocial enhancement to COPD disease management to examine re-hospitalizations
- A study to determine effectiveness of a program that engages community pharmacists to encourage patients to take their medications and follow their physician's guidance

Based upon our own experience we would make the following four recommendations:

1) Projects that are dedicated to operations/delivery system assessment, where private sector health plans help lead the way, should be given a funding priority.

2) Operational CER projects that are funded should advance a culture of learning in the health care enterprise

3) Operational CER projects do not necessarily have to be designed to achieve "definitive" results. We can learn and advance operational efficiency and effectiveness with studies of less rigorous design.

4) Consider developing different criteria for assessment of operations/delivery systems research projects that use observational and quasi-experimental study design than those used by peer-reviewers for strongly controlled experimental studies.

In closing, operational CER forms the foundation of "a learning culture" at Universal American. Our programs are now being designed, implemented, studied, modified, and restudied.

We hope that a "learning culture" will be the foundation of a new US health care system as well, with CER as a driver of that culture.

Thank you for the opportunity to comment.

Submitted by

[personal information redacted]

My thanks to the members of the Council and to Dr. Conway for the opportunity to speak today.

My name is [personal information redacted]. My comments are my own and are not delivered on behalf of any entity.

Comparative effectiveness offers the opportunity to transform care by enabling learning and innovation. At the same time, the UK and others have demonstrated that comparative effectiveness can have the unintended consequences of further segmenting care and stifling innovation under a thick blanket of bureaucracy.

Health care has seen many good ideas morph into new mechanisms of administrative control. Capitation under managed care is an infamous example. At present, some programs described as evidence based medicine or pay-for-performance focus on process control and ignore health outcomes. Like capitation gone awry, these have added to the administrative burden of health care, negatively impacting the art of medicine without a concomitant benefit in outcomes or cost.

It doesn't take a sinister bureaucrat's machinations to distort a genuinely good initiative into needless overhead, micro management and destructive control. America needs safer, more effective medicine, not more health care administration.

Our research in care innovation indicates that the most effective comparison efforts use improvement in health outcomes as the measure of effectiveness. They also compare comprehensive care protocols and teams' outcomes, not individual medications or isolated procedures.

Two examples demonstrate the value of success from comparative effectiveness. Pediatric cancer programs around the country have dramatically changed the prospects for children diagnosed with leukemia, bone and other cancers. The improvements in health outcomes resulted from comparing the effectiveness of full treatment protocols delivered by multidisciplinary teams.

Similarly, the life expectancy of a person born with cystic fibrosis nearly doubled between 1966 and 2003. As with pediatric cancer, teams treating CF have compared comprehensive programs of treatment. Through those ongoing efforts, the median life expectancy of a CF patient has gone from 18 to 33 years, while patients in the most effective programs can now expect to live to at least 47. In CF care, the upper end of the curve has been extended as the median has improved.

As the country begins implementing electronic health records, the role of health registries in enabling comparative effectiveness and improving the cost and quality of care is noteworthy. In the US and Europe, health outcomes have been dramatically improved by creating disease and treatment registries that allow researchers to ask clinically meaningful questions about how teams deliver effective care. In addition to focusing on health outcomes and comparing

comprehensive treatment protocols, I would urge this Council to include comprehensive health registries in any comparative effectiveness program.

Thank you.

[personal information redacted]

Submitted by
Niva Lubin-Johnson, MD, FACP,
Chair of the Board of Trustees of the National Medical Association
[personal information redacted]

I am Niva Lubin-Johnson, MD, FACP, Chair of the Board of Trustees of the National Medical Association. NMA represents the over 30,000 African American physicians and the patients we serve. Our vision is we are "the Conscience of society for quality and parity in health care". Our mission is to advance the science of medicine for people of African descent through education, advocacy, and health policy to promote health and wellness, eliminate health disparities, and sustain physician viability.

NMA was founded in 1895 because we were not allowed to join AMA. This lead to health disparities because we could not join the medical staffs of majority owned hospitals until the 1960's. The Flexner Report which was commissioned by the Carnegie Foundation and AMA in the early 1900's lead to the closure of several African American medical schools, subsequently leading to more disparities because of the decreased

numbers of African American physicians educated. Now at a time when the possibility exists for decreasing disparities with President Obama's plan for universal health care coverage for all Americans, NMA is concerned the disparities will continue to exist if Comparative Effectiveness studies have results that do not allow access for the necessary testing and treatment for the population that we serve.

African Americans, as well as others of color, have rarely been represented in clinical Trials in numbers that are at best representative of our numbers in this country. So if some of the comparative effectiveness data is retrospective, this data is flawed to our detriment. If we are not sought out for the studies to come in the future, the data will be flawed, again to our detriment, so the disparities will continue to exist if not accelerated.

We know with the 1.2 billion dollars appropriated in the Stimulus Bill for Comparative Effectiveness research that it is already here, so our hope is that the Secretary and the staff give consideration to our concerns and use the suggestions that I will present today .With research, in the past, for our community, the problems with clinical studies have included a lack of transparency in funding, conflicts of interest with principal investigators and policies developed from research findings to name a few.

Evidence Based Research has lead to conclusions that are not necessarily relevant, undesirable outcomes created or unfair payment systems to physicians and other persons

of color. Transparency must be evident in funding, avoiding conflicts of interests of principal investigators, with implementation based on outcome, cost of treatment, and with public access to data. Eliminating Disparities must be a focal point of expanding coverage by ensuring that the research is relevant to populations and subpopulations, balance cost with effectiveness, have some relation to chronic disease management, and must take into account the human genome for targeting therapies.

We recommend that there be collective decisions by the stakeholders regarding Comparative Effectiveness Research, that there be over sampling of the population, there be community based research, and Patient Centered Effectiveness Research. The National Medical Association has a long history of consistently being an advocate for the dis-enfranchised in our country with our support of the creation of Medicaid and Medicare in the 1960's when other professional medical organizations did not. Our concerns and suggestions presented today demonstrate our continued advocacy for the same and others to ensure that Health Care Reform truly leads to universal coverage and the elimination of health disparities.

NMA has also been trying to solve the problem with Project Impact, our program to train our members to enroll patients in their practices to participate in clinical trials in their offices or refer them to centers to participate in studies. We have also begun development of our Cultural Competency program with a CME program on MedScape, a primer and a tool-kit for physicians to be released this summer. We believe that with a growing diverse population, all physicians must be trained to better communicate with

patients which could possibly lead to their more willing participation in research in addition to improved outcomes because of better adherence to recommended care by physicians.

Once again, thank you for the opportunity to speak with you today. I look forward to the question and answer period to follow and any opportunity for the National Medical Association to work with HHS on this area or any other in the future.

Submitted by
Geraldine Dawson, PhD
Chief Science Officer
Autism Speaks

May 11, 2009

Federal Coordinating Council on Comparative Effectiveness Research
Agency for Healthcare Research and Quality
Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850

Dear Council Members:

I am writing on behalf of Autism Speaks, the world's largest autism science and advocacy organization. In this letter, I outline several priorities for comparative effectiveness research in the area of autism treatment. Autism affects 1 out of every 150 US citizens. Given the very high prevalence of ASD and the fact that ASD is a life-long condition that costs the US approximately $35 billion annually, it is crucial that research identify the most effective treatments of ASD. Few studies have been conducted that make head-to-head comparisons of two or more treatments for autism spectrum disorders. Indeed, in reviewing the list of existing Effective Health Care Program funded projects, it is noteworthy that none addresses autism spectrum disorders (ASD).

Currently, very little is known about best clinical practices and standards of care in autism. As a result, clinical care varies greatly across care providers, and clinicians must make important health care decisions that will have tremendous impact on outcome with little guidance or knowledge. Lawmakers are struggling with how to make the best decisions about policy and funding due to lack of an adequate knowledge base regarding what are the most effective treatments. Parents, similarly, are left on their own to make decisions about their children's health care and, as a result, often fall victim to misinformation because of the void of empirically-tested effective treatments. Thus, studies that can identify the most effective treatments for improving outcomes for individuals with ASD are sorely needed. Such studies would have wide-ranging effects on clinical practice.

The following are high priority areas for comparative effectiveness research:

I. <u>Understanding the combined effectiveness of medical and behavioral treatments for improving outcomes for individuals with ASD.</u> To date, there have been few, if any, studies that have examined the comparative effectiveness of psychopharmacological or other medical treatments when they are administered alone versus combined with behavioral/psychosocial interventions for reducing core or associated symptoms. The following are examples of projects that are needed:

    a. For individuals with ASD who present with severe aggression and irritability, what is the comparative effectiveness of a pharmacological treatment versus pharmacological treatment combined with functional behavioral analysis versus functional behavioral analysis alone for reducing such challenging behaviors?
    b. For children with ASD whose condition is not improving in response to behavioral intervention, what is the comparative effectiveness of conducting a comprehensive medical evaluation to detect and treat commonly associated medical conditions (e.g. sleep disorder, dietary and/or nutritional deficiencies, GI conditions, and allergies) versus continuing behavioral intervention without such medical assessments and interventions?

II. <u>Understanding the key effective ingredients of early behavioral intervention.</u> There are tremendous financial, feasibility, and accessibility challenges involved in provision of early intensive behavioral intervention for young children with ASD.

However, no studies to date have examined the comparative effectiveness of key elements of early behavioral intervention. Among the high priority questions that need to be addressed are:

a. What is the comparative effectiveness of lower versus higher "doses" of early behavioral intervention (e.g. 15 versus 25 hours per week; 2 versus 4 years) for improving long term outcome?
b. What is the comparative effectiveness of early behavioral intervention implemented by highly trained professionals (e.g. Ph.D. Psychologist) versus parents for reducing autism symptoms and improving language, cognitive, and social abilities?
c. What is the comparative effectiveness of two different models of early behavioral intervention (for example, traditional applied behavior analytic early intervention programs versus developmental behavioral early intervention programs) for reducing autism symptoms and improving language, cognition, and social behavior in children with ASD?
d. For children with ASD who fail to develop communicative speech in response to early behavioral intervention, what is the comparative effectiveness of continuing with traditional early intervention approaches versus adding computer-assisted communication augmented devices for improving communication skills?

III. <u>Treating commonly associated medical conditions in ASD.</u> ASD is commonly associated with medical conditions, such as sleep, GI, psychiatric, and other co-morbidities, that have a significant impact on quality of life. Yet, little is known regarding the most effective treatments to address such co-morbidities. The following are examples of the types of studies that need to be conducted:

a. What is the comparative effectiveness of cognitive behavioral treatment versus cognitive behavioral treatment plus a pharmacological treatment versus pharmacological treatment alone in reducing depressive or anxiety symptoms in adolescents and adults with ASD?
b. For individuals with ASD presenting with sleep difficulties, what is the comparative effectiveness of a sleep hygiene program versus a combination of sleep hygiene with melatonin versus melatonin alone in reducing sleep-related problems?

IV. <u>Assessment of the comparative effectiveness of currently implemented community/school based treatment/educational programs</u>. There are many treatment/educational programs that are currently being utilized in the community. Although individually many of these programs have been shown to be effective for promoting positive outcomes, there have been no studies that have compared whether one program is more effective than another. Examples of such programs include:

a. Early behavioral intervention programs administered through the public schools or private agencies

b. Programs for promoting social, language, and cognitive skills for school age children
c. Programs to facilitate transition to adulthood, focusing on vocational and employment related skills
d. Programs designed to promote success for high functioning adults with ASD attending college

Thank you again for the opportunity to provide input into identifying priorities for comparative effectiveness research. Please feel free to contact me if you have any questions about these priorities. I can be reached at gdawson@autismspeaks.org.

Sincerely,

Geraldine Dawson, PhD
Chief Science Officer
Autism Speaks

Research Professor
Department of Psychiatry
UNC Chapel Hill

Submitted by
Sandra Oliver
Vice President, Public Policy and State Government Affairs
Bayer HealthCare LLC

May 29, 2009

Via Electronic Submission

Federal Coordinating Council for Comparative Effectiveness Research
CoordinatingCouncil@hhs.gov

Re: Statement for Consideration by the Federal Coordinating Council for Comparative Effectiveness Research

Dear Council Members,

Bayer HealthCare LLC ("Bayer") is pleased to submit the following comments for consideration to the Federal Coordinating Council for Comparative Effectiveness Research (the "Council"). Bayer appreciates the opportunity to engage in the process by which the Council will develop a national program for coordinating comparative effectiveness research ("CER"). We believe that CER, if undertaken properly, has the potential to improve clinical outcomes and to improve medical decisions. It is important, however, that CER be conducted appropriately,

with the utmost scientific rigor and with all the necessary safeguards in order to ensure that CER does not inadvertently impede patient access to medically appropriate and necessary health care products and services. Without these key elements, CER could harm vulnerable patient subpopulations or interfere inappropriately with the clinical judgment of health care professionals and their interactions with their patients. Bayer looks forward to the opportunity to contribute to the dialogue between the Council, Congress and other relevant stakeholders in developing comprehensive and effective national CER policies.

For over 100 years, Bayer has been dedicated to the development and production of high-quality drugs, medical devices and biologicals that have helped patients lead healthier lives. Bayer is a worldwide leader, with research and business activities focused on oncology, diagnostic imaging, diabetes care, hematology/cardiology, primary care, specialized therapeutics and women's health care. We are committed to providing patients with high quality, safe products and to ensuring appropriate access to our products.

Bayer supports CER initiatives. However, we remain concerned that the Council will inextricably link cost and clinical evaluations. We strongly believe that cost effectiveness should be separate from CER. Comparative effectiveness will be most successful in changing behaviors if these initiatives are designed to enhance health care practitioners' clinical judgment in order to promote patient-centered care. Accordingly, Bayer does not support the proposed CER initiatives that are cost-centric, as we believe that this approach would be unnecessarily contentious and subjective. Further, because there is no consensus as to how to "value" clinical outcomes, the effect of moving forward now with a cost-focused CER program could impede patient access to treatments without any standards for proper assessment. We fear that a cost-based CER initiative would inevitably lead to a "one size fits all" solution that would not respect independent health care practitioner clinical judgment and the needs of individual patients and vulnerable patient subpopulations.

As the Council develops CER policies and initiatives, Bayer respectfully urges the Council to consider the following principles:

- Informed Medical Decisions: CER should not replace individualized medical decisions with rigid treatment formulas for patient care that do not reflect the needs of individual patients. Health care practitioners must maintain their independent clinical judgment. CER should promote the more effective exercise of that judgment, not seek to eliminate or minimize the value of it. CER should not limit a health care practitioner's medical decisions to a uniform approach. Health care practitioners must be able to continue to evaluate individual factors, subpopulation needs, social and cultural influences, complicating psychological issues and a myriad of other special circumstances which often have a significant impact on care.

- Protecting Appropriate Patient Access: Bayer believes that CER can improve the quality and efficacy of health care. However, such research should not be used for coverage decisions by public or private payors. Similarly, CER should not imply or make recommendations to such payors regarding coverage or benefits. To the extent that CER becomes a direct or indirect tool to limit access to care and to ration health care services,

- Inclusive and Transparent Process: Given the Obama Administration's commendable commitment to transparency, we believe that all CER decisions must be developed in a transparent manner. Thus, all assumptions, data, and findings must be made readily available to the public. The public and other interested stakeholders should be permitted to comment on all phases of CER projects, from prioritization of topics through the evaluation phase to the final report. The Council also should hold public forums to allow for stakeholders to provide meaningful input regarding the "standards" to be used in undertaking CER. Only this kind of complete transparency will permit CER information to be positively viewed by the public. Otherwise, CER will inevitably be viewed with suspicion as a means to surreptitiously ration care. If, however, CER and its limitations are clearly communicated and debated, CER will, we believe, have a pervasive and critical impact on health care.

  Accordingly, Bayer urges the Council to ensure that CER is developed through an inclusive and transparent process, which allows for consultation and input from practicing health care practitioners, patients, patient advocacy groups, employers, manufacturers, allied health care professionals, and trade organizations.

- Appropriate Oversight: Bayer believes that any government funded CER initiative, whether conducted through existing agencies or a newly formed organization, should be subject to Congressional and executive branch oversight. For example, the Council should, at a minimum, institute a formal mechanism for the appeal of CER findings, hold an annual public meeting to solicit complaints and proposals for improvements, and implement a mechanism to challenge methods and biases, to raise concerns about human subject protection, and address other threats to the integrity of the process. This will ensure that CER is conducted in a manner that is ethical, transparent, scientifically appropriate, and consistent with applicable law.

- Evaluating the Circumstances of Clinical Trials: Bayer believes that CER policies should require clinical trials used for CER purposes to accurately reflect real world circumstances. Without such a requirement, there is a potential for CER to lead patients and practitioners in a clinical direction which is inappropriate, ineffective, and potentially unsafe. Accordingly, we strongly urge the Council to review the circumstances under which any evidence is collected to ensure that it is appropriate for consideration in this context.

- Interconnectivity: We recommend that the Council require that, wherever appropriate, CER be undertaken in a manner that considers how various interventions work in collaboration with one another. Bayer believes that reviewing interventions in isolation will unnecessarily produce misleading and inaccurate findings.

- Evaluations Should Be Promptly Reexamined When New Evidence Is Available: CER policies must recognize the ongoing nature of innovation and that technology, therapeutic

- Evaluate the Spectrum of Health Care: To improve patient outcomes, CER should be applied to the full range of factors that influence health care and delivery systems, and not just to pharmaceuticals and medical devices, as is all too often the case under some comparative effectiveness or cost effectiveness systems. This should include, for instance, an analysis of the impact of different types of formularies, insurance benefit designs, institutional service models, health care practitioner services, the use of performance and quality measures, adoption of electronic medical records, greater use of information technology, tools to reduce medical errors, improved discharge planning, and the impact of government payors' failure to adequately cover or reimburse medically appropriate services and prevention, compliance, and persistency programs.

- Communicating with Practitioners, Payors, Patients and Others: As the Council considers CER priorities, Bayer believes that the Council must communicate clearly with practitioners, payors, patients, patient advocacy groups, and others regarding the limits of CER studies and the appropriate interpretation of the resulting data. The risks of "over-interpreting" CER are all too real. Findings and preliminary reports should prominently and conspicuously describe any limitations in the data and analysis.

* * *

Bayer strongly believes in patient-centered care and urges the Council to use CER as a mechanism to enhance clinical judgment to promote such care. Only through improved health care practitioner and patient awareness can comparative effectiveness improve health care. We hope that the Council strongly considers our concerns regarding CER initiatives that focus on cost as a factor, as such an approach could seriously compromise patient access to innovative therapies, stifle the exercise of clinical judgment, impede adoption of CER findings, and contribute to the creation of a "second-tier" level of care for the poor and other vulnerable populations.

We thank the Council for the opportunity to comment on the ongoing development of CER policies and initiatives. We look forward to working with the Council as national CER policies and initiatives are developed.

Sincerely,

Sandra Oliver
Vice President, Public Policy and State Government Affairs

Submitted by
Mary McWilliams
Executive Director

April 15, 2009

The Honorable Kathleen Sebelius
Secretary-designee
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Regional Collaboratives as Key Resources in National Health Reform

Dear Secretary-designee Sebelius,

Congratulations on your nomination as Secretary of the U.S. Department of Health and Human Services by President Obama. After meeting you in Seattle in 2005, as a prospective candidate for the first female president, it's no surprise to see you recruited for national leadership.

On behalf of community leaders in western Washington involved in the Puget Sound Health Alliance, I offer information about the progress we've made, as a practical and effective resource for you and your policy team. We hope that you will use the Alliance and other multi-stakeholder coalitions as a vehicle through which funding is allocated to disseminate existing comparative effectiveness research to doctors and consumers, and to expand health information technology.

The Puget Sound Health Alliance shares your commitment to reforming health care, particularly to improve the quality of care and transparency and performance of the U.S. health care system. Established in 2005, the Alliance is a bipartisan nonprofit working to improve quality and efficiency while reducing health care cost increases in western Washington. More than 160 organizations, including Boeing, Starbucks, REI, the State of Washington, health insurers, city and county governments, medical groups, hospitals, unions and consumer groups participate in the Alliance. Our work to advance value and transparency through public reporting and aligning incentives to reward quality and efficiency mirrors the priorities of the Obama-Biden Health Care Plan. In collaboration with local physicians and other providers, we developed and publish a public report comparing evidence-based care provided in more than 170 clinics in this region. The "Community Checkup" report (www.WACommunityCheckup.org) also compares local hospitals, using data from public sources including AHRQ and our State Department of Health.

The next Community Checkup report will be public this summer. The report is based on national standards for effective treatment of chronic conditions and for preventive care. It also measures the degree to which certain types of inappropriate care are avoided and the generic fill rate for four classes of prescription drugs. The report is based on claims data we collect from 16 health plans and self-insured purchasers, reflecting care provided to about 2 million local residents. For the effectiveness of care to be understood and for the information to result in improvement, the Community Checkup report lists specific steps that each stakeholder (providers, patients, plans and purchasers) needs to take to do their part to improve health and health care in this region.

Regional collaboratives like the Alliance play a vital role in improving the quality and cost-effectiveness of health care. That's why HHS designated the Alliance as one of the first Chartered Value Exchanges (CVE), which advance the four cornerstones of Value-Driven Health Care: interoperable health information technology; price transparency; transparency of health care quality; and using incentives to promote quality and cost-efficiency.

In the spirit of bipartisanship, we encourage HHS under your leadership to use the Alliance and other CVEs as a vehicle through which funding can be allocated to disseminate existing comparative effectiveness research to doctors and consumers, and to expand the use and interoperability of electronic medical records and health information technology (HIT), under the American Recovery and Reinvestment Act. This fits well with our public reporting and our work in the Washington Health Information Collaborative, which has awarded more than $2.5 million in grants to clinics and hospitals in the region to adopt HIT. We support the vision of building a common HIT infrastructure in the region to include health information exchange capability with electronic connections among ambulatory, inpatient and public health service providers. This is essential for quality improvement within each setting and for community-wide transparency, as many measures of 'quality' care require information from clinical records plus claims data.

The existing CVE network provides a strong foundation and a practical mechanism for expedited implementation and faster results than could be achieved using other approaches. We appreciate the imperative of quick action, so we hope you will give this idea serious consideration.

We offer our services as a resource and look forward to working with you, your agency and the Obama Administration on initiatives to improve health and the value and quality of health care.

Sincerely,

Mary McWilliams
Executive Director

cc: Harold Miller, NRHI

Compilation of comments submitted online at www.blsmeetings.net/mayfcc

Submitted by
Martyn Howgill
InHealth
mhowgill@inhealth.org

Comment Type: *Definition*

Thank you for the opportunity to comment on the Council s definition of Comparative Effectiveness Research. On behalf of the Institute for Health Technology Studies (InHealth), we offer the following comments:

- We applaud the proposed assessment of a comprehensive array of health-related outcomes for diverse patient populations and want to affirm that this must include comparisons of the broader, longer-range socioeconomic effects of different interventions. We suggest that studies which concentrate on clinical and disability effects alone may ignore important, longer-term values produced for patients, families and employers.
- The Council s first criterion for scientifically meritorious research and investments calls for measurement of impacts based on prevalence of condition, burden of disease, variability in outcomes, and costs of care. We wish to underscore that if these four definitional areas of impact were to exclude either broader or longer-term socioeconomic consequences, then comparisons and contrasts between diagnostic and therapeutic alternatives would be impaired.

Submitted by
Tony Principi
Pfizer Inc
anthony.principi@pfizer.com

Comment Type: *Definition*

Note: we also are submitting these comments in the form of a letter.

On behalf of Pfizer, I am submitting the following comments to the Federal Coordinating Council s (Council) proposal for a framework on comparative effectiveness research (CER). Pfizer is a research based drug developer that sponsors numerous trials in the U.S. and around the world, to support marketing approvals and to assess comparative effectiveness, post-approval.

Pfizer supports the Council s continued commitment to transparency and public engagement through its solicitation of public input on the definition, prioritization criteria, and strategic framework for CER.

Our comments are structured to respond to three elements contained within the draft documents released by the Council. They build on comments we are submitting related to the Council s proposals on prioritization of comparative effectiveness research.

Draft Definition of CER

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

Pfizer recommends that the definition of CER emphasize that the primary intent of CER is to inform patients and providers about which interventions are most effective for a patient s individual circumstances. The inclusion of the term decision-makers following patients and providers detracts from this primary focus and may cause confusion over the primary use of CER. To that end, we recommend deleting the reference to other decision-makers from the second sentence of the definition.

Submitted by
[personal information redacted]

Comment Type: *Definition*

Health resource utilization and cost should be explicitely stated to be included in the scope of the CER.

Submitted by
[personal information redacted]

Comment Type: *Definition*

The definition seems to presume the need for de novo research in the way it is constructed. Surely the Council does not mean to ignore the vast body of existing science that may contribute to the development of a body of evidence that informs questions of comparative effectiveness for prevention, diagnosis, treatment, and health maintenance. A broad definition should encompass

the synthesis of existing knowledge, the identification of gaps in that knowledge, and a process for continual refreshing of the body of evidence as the science advances.

Submitted by
Victoria Dohnal
Biotechnology Industry Organziation (BIO)
vdohnal@bio.org

Comment Type: *Definition*

Dear gentlemen,
I am submitting these comments on behalf of the Biotechnology Industry Organization (BIO).

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO is pleased to have the opportunity to submit comments to the Federal Coordinating Council (FCC) on the draft definition of Comparative Effectiveness Research for the FCC.

As a representative of an industry committed to discovering new cures and ensuring patient access to them, BIO strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making. BIO believes that individual patients and their doctors should be armed with the best available information to help assess the relative clinical benefits and risks of various treatment alternatives. When appropriately applied, comparative effectiveness information is a valuable tool that, together with a variety of other types of medical evidence, can contribute to improving health care delivery. However, BIO is concerned that comparative effectiveness information will be used increasingly as a means to contain costs, rather than deliver health care value by improving patient health outcomes. BIO appreciates the opportunity to comment to the FCC.

We submit the following comments for your consideration on the definition of comparative effectiveness research, draft prioritization criteria, and the strategic framework. We look forward to continuing to work constructively with you in order to realize the full value of comparative effectiveness research.

Draft Definition:

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions.

BIO is pleased that the FCC envisions using comparative effectiveness research to examine strategies to prevent and monitor health conditions. Prevention and wellness strategies are critical to bending the cost curve of health care expenditures in the future. Further, given that

75% of health care costs are related to chronic disease, it is critically important for comparative effectiveness research to examine strategies surrounding chronic disease care.

The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

It is important that the draft definition states the purpose to comparative effectiveness research is to inform patients and providers. BIO believes that comparative effectiveness information should inform clinical judgment and individual needs in medical decision making.

Suggested Modification: BIO is concerned with the vagueness of the term decision- makers in the same sentence. It should be made explicitly clear in the definition that the term decision-makers refers to those involved in the provider-patient interaction (e.g., provider, patient or guardian, as appropriate), and may appropriately be referred to as patient advocates. BIO suggests that the wording be modified to the following: The purpose of this research is to improve patient-outcomes by informing patients, patients advocates, and their providers, responding to their expressed needs, about which interventions and strategies are most effective for which patients under specific circumstances.

The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations.

It is good that the definition recognizes the potential for comparative effectiveness research to advance the goals of personalized medicine through the inclusion of phrases such as which patients under specific circumstances and diverse patient populations.

Suggested Modification: BIO suggests that the definition include the term subpopulations in these sentences so that it would read: The purpose of this research is to improve patient-outcomes by informing patients, patients advocates, and their providers, responding to their expressed needs, about which interventions and strategies are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patent populations and subpopulations. Consistent with our previous comment, BIO also suggests that the term decision-makers be replaced with a clearer reference to patient advocates.

Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions.

BIO is pleased to see the expansive nature of the interventions that are included in the draft definition ranging from medications to behavioral change strategies and from procedures to delivery system interventions.

Suggested Modification: However, BIO believes that comparative effectiveness research should focus on the totality of the health care delivery system not just interventions. Comparative effectiveness information that reflects the interactions among all of the various components of the health care system has the greatest potential to empower clinicians and patients to make more appropriate decisions when faced with real world clinical situations. In addition to comparing specific treatment interventions, research should also focus on how innovations in care delivery models, such as disease management programs, may produce better health outcomes. An explicit inclusion of the phrase totality of the health care delivery system would be worthwhile here.

Submitted by
Richard I. Smith
Senior Vice President, Policy
AcademyHealth
april.falconi@academyhealth.org

Comment Type: *Definition*
AcademyHealth, as the nonpartisan, professional society for nearly 3,600 health services researchers, policy analysts, and practitioners, welcomes the opportunity to submit feedback to the Federal CER Council concerning the draft definition and prioritization criteria for comparative effectiveness research.

We would like to offer our support for your proposed definition, which recognizes that CER goes beyond the evaluation of clinical treatments and includes comparing different interventions and strategies to prevent, diagnose, treat, and monitor health conditions.

We strongly support the development of research that informs not only patients and providers, but also decision makers. A wide variety of public and private policy makers will need this research to inform decisions about coverage and payment. As the Council continues its deliberations with key stakeholders, it will be important to delineate these groups specific expressed needs and how future research will be designed to meet these needs.

AcademyHealth supports having the defined interventions &include& behavioral change strategies, and delivery system interventions. Ultimately we will need to have not only research on which treatments work better, but also research pertaining to the comparative quality and cost-effectiveness of alternative ways to deliver specific services. This research is vital for understanding how to improve health system quality and achieve needed improvements in efficiency.

AcademyHealth commends the Council for highlighting the need to tailor treatments for different populations, assessing a comprehensive array of health-related outcomes for diverse patient populations. We agree that recognizing the heterogeneity of diverse populations will require an extensive evidence-base from which to make informed decisions.

The effectiveness of CER is hinged upon the quality of data and methods used to produce the research. An AcademyHealth study, Lack of Coordination in Comparative Effectiveness

Research Risks Redundancy and Unnecessary Cost revealed the significant need for more formal training in the range of methods used in comparative effectiveness, as there are very few formal training programs in comparative effectiveness research. Training needs are exacerbated by what many view as a fundamental philosophical difference between researchers academically trained to do observational research, and those trained on the job to conduct clinical trials. Furthermore, the ability of health services research to contribute operationally to safety, quality and efficiency of care delivered within particular delivery organizations depends on new training content and modes.

The current lack of methodological training creates problems for the funding, conduct, and review of current comparative effectiveness studies. Because infrastructure is vital to the success of CER, we support the prioritization criteria of potential for multiplicative effect (e.g. lays foundation for future CER or generates additional investment outside government). This is why we are pleased you included the need for a properly-developed infrastructure in order to assess this research, recognizing the necessity to develop and use a variety of data sources and methods to assess comparative effectiveness research.

AcademyHealth represents and supports many of the people who will be called upon to conduct comparative effectiveness research. We believe that your definition and focus on infrastructure will provide much needed support for building the capacity of the field to respond to the growing demand for this research.

Submitted by
Richard I. Smith
Senior Vice President, Policy
PhRMA
adouglas@phrma.org

Comment Type: *Definition*

Dear Federal Coordinating Council Members:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments to the Federal Coordinating Council for Comparative Effectiveness Research on the draft definition of comparative effectiveness research (CER), priority setting criteria, and strategic framework released by the Council.

PhRMA is a voluntary, nonprofit association representing the country s leading research-based pharmaceutical and biotechnology companies, which are devoted to discovering new medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA s member companies play a leading role in discovery of new therapies and advancement of scientific and clinical knowledge.

PhRMA appreciates the Federal Coordinating Council s posting of its draft CER definition, prioritization criteria and strategic framework as a further step in promoting openness and transparency as it carries out its duties under the American Recovery and Reinvestment Act

(ARRA). Specifying a CER definition and criteria for research priorities are important initial steps in establishing a sound CER research program.

As the Council continues implementing its mandate under ARRA, we urge it to maintain open and transparent procedures. In particular, as the Council prepares to submit a report by June 30 making recommendations for CER research to the President, Congress, and the Secretary of the Department of Health and Human Services (HHS), we ask that it explain the substantive reasons for its recommended research priorities. This will enable members of the public to understand how the priorities correspond to the input received from stakeholders, respond to the information needs of patients and providers and meet the other criteria established by the Council. In addition, the Secretary should establish a similar policy as it considers the Council s recommendations, and those of the Institute of Medicine, in establishing research priorities. Open, transparent processes advance research that is credible and relevant to the real-world decisions facing patients and providers as well as reflecting the different needs of racial, ethnic and other patient sub-populations.

PhRMA supports the focus on patient and provider needs in the Council s draft CER definition and criteria for research priorities. This focus also is evident in HHS Secretary Kathleen Sebelius April 21, 2009 comments at the Senate Finance Committee: The goal of such research is to improve the database of information available to a patient and his or her provider so they can make informed decisions about care. The goal is to empower patients and providers with the best information on protocols, procedures, and other relevant issues, not to enable the federal government to dictate broad coverage decisions." In addition, the Council s emphasis on the expressed needs of patients and providers will help ensure that their input is given sufficient weight in the CER process.

The Council appropriately recognizes the importance of accounting for differences in individual patients throughout its draft material. This will help facilitate study designs that recognize and generate data on different patient subgroups, and communication of results that reflect differing patient needs based on genetic, clinical and other factors. These factors are very important to patients but, unless expressly recognized, can be minimized in study designs and communication of results. In a letter last year, the Congressional Black Caucus highlighted the importance of accounting for individual differences in CER research result: All research supported by a comparative effectiveness initiative must recognize variation in individual patients needs, circumstances, and responses to particular therapies. Comparative effectiveness research must enrich our understanding of these variations, rather than ignoring them by focusing on population averages that mean little for any individual patient or subgroup. Without this focus, the results of research could inappropriately be used as a rationale for restricting the treatment choices of those who fall outside the average response.

In addition, PhRMA supports the scope of research included in the draft definition of CER, which encompasses the full range of medical treatments, behavioral change strategies, and delivery system interventions. This broad scope of research is consistent with the Act s mandate for research on health care treatments and strategies. This scope of research reflects the growing recognition that addressing the needs of patients, particularly those with chronic illnesses, requires greater scrutiny of healthcare delivery systems. This includes comparing the

effectiveness of different approaches to care processes, disease management services, care coordination, benefit designs, and other components that directly impact care quality and patient outcomes.

The importance of this aspect of comparative effectiveness research was emphasized in Atul Gawande, MD s, June 1, 2009 New Yorker article: "Congress has provided vital funding for research that compares the effectiveness of different treatments, and this should help reduce uncertainty about which treatments are best. But we also need to fund research that compares the effectiveness of different systems of care to reduce our uncertainty about which systems work best for communities. These are empirical, not ideological, questions.

While the draft definition, prioritization criteria, and strategic framework include many positive elements, we offer the following recommendations to help ensure that CER remains centered on improving health care quality and supporting patient and provider decision-making:

1. Clarify the references to decision makers from the draft definition and federal needs as a basis for setting research priorities.

Defining research priorities and study questions that respond to the information needs of patients and providers is an important, and challenging, early step in CER. While decisions at the policy level should be informed by best available evidence, including comparative effectiveness research, it is important that government-supported CER conducted under ARRA is centered on supporting patient and provider decision-making and improving the quality of patient and provider care. This will help ensure that federally-funded CER meets the goal described in HHS press release announcing the Council, Comparative effectiveness research provides information on the relative strengths and weakness of various medical interventions. Such research will give clinicians and patients valid information to make decisions that will improve the performance of the U.S. health care system. The Council should clarify how federal and other decision making needs will be recognized while maintaining a focus on patients and providers.

2. The council should clarify how the separate elements of the prioritization criteria will be weighed against each other and the minimal feasibility of research criteria should be clarified and moved to secondary list.

The feasibility of research criterion should be moved to the second category of criteria for ensuring scientifically meritorious research and investments, and the Council should clarify how time necessary for research will be used as part of this criterion. The length of the study is an important consideration, but should not be a minimal criteria, as both long- and short-term research can yield findings that are more or less useful to patients and providers. For example, the seven years it took to complete the federally supported Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) reduced its impact, because of the ways the practice of medicine evolved during the study period . At the same time, the time necessary for research should not be used to rule out studies that are longer-term but yield high-value information. Some long-term studies, such as the Women s Health Initiative, provided important information about women and osteoporosis, cardiovascular disease, and cancer and had a

significant impact on patient and provider treatment decisions, even though it had a 15 year time frame.

3. Additional recommendations: clarify variability in outcomes, weighting of criteria, and range of data sources.

The Council should clarify the types of outcome variability it will consider when setting CER priorities. This will facilitate consideration of outcomes variation related to a range of factors, including geographic location, treatment site, provider type, and patient sub-group, consistent with the FCC s definition of CER. Conducting research to address these variations represents a significant opportunity to improve health care.
For example, Addressing this issue October 8, 2007 at the Institute of Medicine annual meeting, Eliot Fischer, MD, MPH, Dartmouth Medical School, said: We need better evidence, both about biologically targeted interventions, but also about care delivery...There is an emerging consensus on need for comparative effectiveness research. I think it s critically important that we broaden that focus to include evidence-based care management and evidence-based care delivery, because that s where all the money is and that s where all the waste is in U.S. health care.

In addition, addressing variability in outcomes within minority groups could help reduce health care disparities . There is a broad range of research that indicates racial and ethnic minorities are less likely to receive medical care we know works very well and experience a lower quality of health services. For instance, the Institute of Medicine report, Unequal Treatment found that racial and ethnic minorities are less likely to be given appropriate cardiac medications or to undergo bypass surgery, and a more likely to receive certain less-desirable treatments, such as limb amputations for diabetes. This is not because of any lack of knowledge about appropriate treatments for conditions such as diabetes or heart disease. Rather, it is because our health system does not implement effective strategies to organize and deliver care to minority populations. Placing a high priority on research to identify the strategies that the health system can use regarding issues such as disease management, use of information technology, benefits design, community outreach, to close this gap is important to improving care in minority communities.

In the definition, the Council should describe the range of data sources and methods it will consider to assess comparative effectiveness, such as randomized controlled trials, meta-analyses, observational analysis or other methodologies. Each research methods offers different strengths and limitations, and providing additional detail in this area could facilitate research that provides information on diverse populations and patient sub-populations, helping to reinforce the Council s commitment to assessing outcomes related to these populations.

4. The process step Potential capacity for translation through Federal delivery systems and public private partnerships under Translation and Adoption of CER should be clarified in the CER Strategic framework.

The Council s strategic framework should maintain a focus on translation and adoption of CER results widely to patients and providers in timely, usable formats. This will help orient research

towards the needs of patients and providers, and avoid access barriers based on average study results that may overlook differences in the needs of diverse patient groups. The strategic framework should clarify how translation of CER through federal delivery systems will support this goal.

The $1.1 billion included in ARRA for CER represents an important opportunity to establish a broad research agenda that supports patient and provider decision-making and improves health care quality. PhRMA supports the steps the Council has taken to help achieve this goal, including high quality, credible CER that has public buy-in. We ask that the Coordinating Council adopt our suggested revisions to the draft definition, priority setting criteria, and strategic framework.

PhRMA looks forward to continued participation in your important work to recommend CER research priorities. Please do not hesitate to contact me if I can be of any other assistance.

Submitted by
[personal information redacted]

Comment Type: *Definition*

I suggest the following edits to the definition:

1. Remove ", responding to their expressed needs," which is redundant (to inform doctors is to respond to their needs).

2. Remove "under specific circusmtances," which is also redundant. It is straightforward and sufficient to state that "which treatment is most effective to which patients", where "which patients" could be with any specific circumstance.

3. The last sentence should end with "and methods to adequately control for confounding" (replacing "method to assess comparative effectiveness"). With this change, the definition highlights two crucial areas in conducting credible CER -- data sources and confounding control.

4. Should "cost" be at least implied in the definition? We could give "cost" a little room by adding "efficient" in the second sentence, "about which interventions are most effective and/or efficient for which patients".

Submitted by
Nancy Smith
Health Advancement Collaborative of Central New York
nsmith@hac-cny.org

Comment Type: *Definition*

We recommend that the definition of research include studies of alternative vehicles for translating findings into practice. Our community, for example, is piloting a physician-driven effectiveness review mechanism for the analysis of local variation in practice patterns relative to best practice standards, and the dissemination of findings to the medical community.

Submitted by
Andrew Sperling
National Alliance on Mental Illness
andrew@nami.org

Comment Type: *Definition*

The National Alliance on Mental Illness (NAMI) is pleased to submit the following comments to the Federal Coordinating Council (FCC) on Comparative Effectiveness Research (CER) on the proposed definition of CER and priorities for CER as part of the $1.1 billion allocated in the American Recovery and Reinvestment Act (ARRA).

NAMI is the largest national organization representing individuals living with serious mental illness and their families. Through our more than 1,100 affiliates in all 50 states NAMI is engaged in support, education and advocacy around serious mental illness.

NAMI Comments Recommendations Regarding the Coordinating Council s Draft Definition of CER

1) Including the voice of patients
NAMI supports the inclusion of voices of patients, family members of patients and disease advocacy organizations as part of any definition CER. Too often in healthcare, the determination of what s best for the patient is made by others, while the patient s views of his or her own needs is ignored or minimized. By identifying the importance of expressed needs, the Council takes an important step towards policy that truly is centered on the needs of the patient and caregiver. The proposed definition could be strengthened by an explicit inclusion of both family members of patients and disease advocates as part of the CER process moving forward.

2) Communicating results to improve patient care
NAMI feels strongly that CER must focus on communicating research results to patients, providers and other decision-makers, not making centralized coverage and payment decisions or recommendations. This focus is consistent with the goal of CER as described in HHS press release announcing the FCC such research will give clinicians and patient s valid information to make decisions that will improve the performance of the U.S. health care system. NAMI would urge additional clarification to the proposed definition of decision-maker. With many competing voices discussing CER, it is important to know which decision-makers are being included in this central definition.

3) Scope of CER

NAMI supports the broad scope of research included in the proposed definition, which states, Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This definition is consistent with the views expressed by many stakeholders, including NAMI, at FCC listening sessions. NAMI believes that in order to improve patient care, CER research should examine the range of issues that affect the quality of patient care. This includes the range of medical tests and treatments, as well as questions related to healthcare delivery and organization such as benefit designs and care management programs. All of these healthcare elements affect patients quality of care.

4) Preventing Misuse of CER by public and private payers

While NAMI supports the focus on patient and provider needs in the draft definition, we also are concerned that, in stating that the purpose of CER is to inform patients, providers and decision-makers, the FCC draft definition of CER has the potential to shift the focus of research away from patients and their doctors towards other decision-makers such as health insurance companies, government agencies and other policy-makers. The strategic framework released on HHS web site on June 1 includes language that underscores this concern. In particular, NAMI is troubled by language in the framework that describes CER research priorities that respond to the expressed public and federal needs for CER, and potential capacity for translation through Federal delivery systems and public private partnerships.

This shift in focus has enormous potential to result in research projects that do not address the clinical information needs of patients and providers, and instead lead to research that is used to restrict patient access to treatment options. This concern is heightened by recent commentary describing the link between CER and these types of access restrictions. For example, a recent Washington Post commentary says, What's known as comparative effectiveness research, which tracks what works and what doesn't, would also require outside boards directing doctors and hospitals about what procedures they could and couldn't use. The language in the proposed CER definition and strategic framework document appears to be at odds with the goal of CER as described by HHS in its press release announcing the FCC.

NAMI is troubled by this shift in focus to CER that restricts patient access to medical care or treatment choices. NAMI would urge the Council to delete the language referencing decision-makers and federal needs as a CER focus. The Council should consider revising the strategic framework so that it focuses on communication and dissemination strategies, rather than use of CER by government agencies.

4) Clinical v. cost effectiveness

Consistent with focus on patient and provider needs, NAMI urges the Council to clarify that research should examine clinical outcomes, not cost-effectiveness. As reflected in the wide range of views expressed during the Coordinating Council listening sessions, inclusion of cost-effectiveness remains controversial for good reason. Cost-effectiveness analysis traditionally has been a tool used by insurance companies and government payers to impose access restrictions based on broad population averages, and some of the most common cost containment

tools tend to obscure differences in patient subgroups by including all patients in a single, average value determination. Particularly given the importance that ARRA and the Coordinating Council have placed on considering the needs of patient subpopulations, NAMI recommends that the Council clarify that it will focus on clinical outcomes.

NAMI Recommendations for Comparative Effectiveness Research Priorities

Within the realm of mental illness treatment, NAMI would like to make the following recommendations for critical priorities designed to improve quality of care and prospects for recovery for individuals living with illnesses such as schizophrenia, bipolar disorder, major depression and severe anxiety disorders.

1) An examination of the real world challenges associated with treatment adherence in serious mental illness --
Major mental illnesses present unique vulnerabilities and challenges. One of the most difficult challenges is a condition known as anosognosia, or literally, the inability to see one's own illness. Anosognosia dramatically reduces medication adherence, and occurs in about half of people with serious psychiatric illnesses. This condition also called lack of insight and is virtually exclusively a concern in our population.

Anosognosia makes research about adherence strategies especially crucial for this population. As noted above, CATIE raises a number of important questions related to treatment adherence with schizophrenia. NAMI believes that this should be a major priority for comparative effectiveness, especially in the context of serious mental illness. The very symptoms of these disorders auditory hallucinations, paranoia, delusional thinking, mania, severe anxiety can make treatment adherence a challenge. Likewise, the difficult side effects associated with psychotropic medications can create enormous barriers to adherence. NAMI would strongly recommend that the Coordinating Council emphasize the need for examination of strategies and treatment models that can improve adherence and ensure better outcomes.

2) An examination of best practices treatment decisions in public programs --
Currently state Medicaid programs across the nation are undertaking cost control strategies that involve strict protocols for prescribing of psychotropic medications. These typically involve aggressive utilization management techniques such as preferred drug lists, prior authorization requirements for specific compounds, fail first requirements for specific medications and step therapy. In NAMI s view, these rules often place the most vulnerable members of our society at risk of poor outcomes such as psychiatric decompensation and re-hospitalization, with little evidence that they save money or improve quality of care over the long-term.

The reality is that these utilization management decisions are driven by cost, not sound clinical research. For the most part, state Medicaid programs are flying blind in undertaking these strategies as there is little if any research out there demonstrating how clinicians can make informed decisions about which medication works best for a particular patient. NAMI believes that comparative effectiveness can be very useful in examining treatment algorithms and prescribing protocols that work best in real world treatment settings where patients (especially

Medicaid beneficiaries) experience multiple medical co-morbidities that complicate the effectiveness of psychiatric treatment.

There are promising alternatives out there such as monitoring outlier prescribing patterns and evidence-based protocols that can help a state control pharmacy costs without resorting to inflexible rules such as prior authorization and step therapy. NAMI would recommend investment in research that compares these strategies to see which is more effective in improving patient outcomes and promoting quality of care.

Thank you for the opportunity to offer NAMI s views on this important issue. NAMI looks forward to assisting the Federal Coordinating Council in moving a sound comparative effectiveness research agenda forward.

Submitted by
[personal information redacted]

Comment Type: *Definition*

In the Definition I suggest you:
1) clarify difference between effectiveness and efficacy
2) clarify whether "...a comprehensive array of health-related outcomes..." includes safety outcomes? patient-reported outcomes, including preferences? compliance/adherence? utilization outcomes? economic outcomes?

Submitted by
[personal information redacted]

Comment Type: *Definition*

I am aware of another statement/definition from the NCI that seems different (and possibly inconsistent) with the definition proposed here. The NCI priorities for CER, as stated in the Grand Opportunities FOA (RC2), are as follows:

A wide range of clinically-based preventive, screening and treatment interventions have been shown to be efficacious for many types of cancer. However, evidence is less complete on the effectiveness of these interventions in actual community practice, among populations and treatment settings and using techniques and practices that may differ markedly from those of initial controlled clinical trials. Effectiveness includes not just the standard core clinical outcomes such as survival, adverse clinical events, quality of life and symptoms, but also domains that affect the use of the treatment, or health care strategy. Factors that affect how treatment is used, and whether one treatment is preferred over another include patient-reported outcomes, acceptability and adherence to treatment, patient-physician communications, health system capacity and organization factors, medical and other resource use, economic cost,

financial stress and broader impacts on the family, work and community, such as impacts on economic productivity and the ability to return to work and resume other normal social functions. Some of these domains have been investigated by NCI, but research in these areas remains underdeveloped in terms of data resources, methodology and research personnel. Also the field remains fragmented in terms disciplinary areas, phases of the cancer continuum explored, and cancer sites investigated.

For the purposes of this announcement, comparative effectiveness research (CER) is defined as a rigorous evaluation of the impact of different options that are available for treating or preventing a given medical condition for a particular set of subjects. Such a study may compare similar treatments or other interventions, such as competing drugs, or it may analyze very different approaches, such as surgery, drug therapy and behavioral interventions. Such research may include the development and use of clinical and population level registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data as they apply to CER.

Submitted by
[personal information redacted]

Comment Type: *Definition*

I believe the the definition (first sentence) needs to include reference to the research being done under conditions our actual practice (effectiveness) so as to clearly distinguish it from the controlled research settings (efficacy) such as that in a traditional RCT.

Submitted by
[personal information redacted]

Comment Type: *Definition*

I believe that your proposed definition of comparative effectiveness (CE) is overly and unnecessarily broad. Specifically

1) the word "systematic" in the first sentence is vague. Systematic is generally used to refer to systematic reviews and CE research may well be a purpose-driven investigation of various interventions. Although such a study could technically be described as "systematic," this adjective is not generally used to describe a research project.

2) More troublesome is the proposed requirement that CE research "must assess a comprehensive array of health-related outcomes for diverse patient populations." CE research that assesses alternative therapies that may not include a COMPREHENSIVE set of alternatives can still provide excellent, useful information. Similarly, if CE is evaluated for a particular population that may not be diverse but is well described, this still could constitute meaningful, reliable,

useful research. e.g., a study in latinos may not include other ethnic groups but would be informative nonetheless.

Submitted by
[personal information redacted]

Comment Type: *Definition*

The wording of the definition is excellent! May want to consider adding a sentence to the definition related to evaluation of new medical therapies and devices as they emerge from the research labs.

The prioritization draft is OK. Some points are a little unclear/vague.

Submitted by
American Medical Association American Medical Association
American Medical Association
sylvia.trujillo@ama-assn.org

Comment Type: *Definition*

The physician and medical student members of the American Medical Association (AMA) commend the Federal Coordinating Council for Comparative Effectiveness Research (Council) for convening a series of public meetings and reaching out to clinicians and medicine to solicit our input on national comparative effectiveness research (CER) priorities as well as comments on the Council s draft CER definition, prioritization criteria, and draft strategic framework. Concerted stakeholder and public engagement will ensure that the funding to support CER will be allocated in an optimal fashion and increase the utilization of CER findings by physicians and patients.

All aspects of the CER process, including priority setting and capacity-building measures, must be transparent and include a central role for physicians in their oversight and governance. Given the nascent nature of this endeavor, the perception among physicians that the CER agenda is being driven by payers who only have cost containment as their goal will seriously undermine efforts to cement physician support as we continue forward on comprehensive health care system reform. It is imperative that physicians, including clinicians and their organizations, have an active, ongoing, and central role at all stages of the CER process. To be clear; the AMA strongly supports CER and looks forward to results that will guide shared decision-making by patients and their physicians.

Physicians today have access to a wide array of medical information. However, there remains far too little rigorous evidence available about which treatments work best for which patients.

The AMA strongly supports increased federal funding of CER. Though there is a broad array of areas where CER would bring benefits, we must strategically target support for CER where it will significantly improve health care value by enhancing physician clinical judgment, foster the delivery of patient-centered care, and produce substantial benefit to the health care system as a whole. As outlined in more detail below, the AMA strongly supports the Council s Draft Definition, Draft Prioritization Criteria for Comparative Effectiveness Research as well as the Draft Comparative Effectiveness Research Strategic Framework.

The AMA supports the view that the priority areas of CER should focus on high volume, high cost diagnostic and treatment modalities, and other health services and strategies for which there is significant variation in practice.

The AMA supports a broad definition of CER that involves a comparison of different modalities to prevent, manage, or treat a specific health problem, condition, or disease. Besides the more typical areas of research such as pharmaceuticals and medical devices, CER should also focus on implementation and dissemination issues that would shed light on the most effective strategies that promote a learning health care system and improved clinical outcomes including behavioral change strategies, and delivery system interventions.

In terms of methodology and study design, CER should include long-term and short-term assessments. CER should not be limited to new treatments. In addition, the findings should be re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data.

AMA Recommended Priority Areas & Infrastructure

Much of the expertise for setting CER priorities focusing on specific diseases and interventions lies within the medical specialty societies. Nonetheless, the AMA offers the following recommendations for CER priorities and offers suggestions concerning two mechanisms that would help build the necessary infrastructure to sustain work in this area.

The AMA strongly believes that the national CER priorities should address the prevention, management, and treatment of preventable disease which collectively represent a major cost driver in today s health care system. Key areas in need of further study and research include cardiovascular, endocrinology and metabolism disorders (including diabetes), and nutrition (including obesity). For example, in the area of wellness, prevention, nutrition, and obesity there is a paucity of CER findings. It is an area with a wide range of available interventions with little clarity about which is most effective.

CER usually considers technology and pharmaceuticals, but behavioral interventions potentially could have the greatest impact for individual patients and the system as a whole. Prioritizing interventions designed to change physician behavior and to effect behavioral change in patients, in addition to other clinical interventions, technologies, and pharmaceutical remedies, is necessary. Because prevalence rates and the most effective interventions for many diseases vary greatly by race, ethnicity, gender, age, geography, and economic status, the AMA strongly

supports the inclusion of racial and ethnic health disparities and health disparities more generally as a CER priority area.

In addition to the foregoing, the National Priorities and Goals report put forth by the National Priorities Partnership (NPP) convened by the National Quality Forum (NQF) provides a rich source of information for the Council to consider. The NPP, comprised of 28 national organizations, focused on achievable goals that would, if implemented broadly, reduce harm, improve patient-centered care, eliminate health care disparities, and remove waste from the system. In preparing the report, the NPP solicited extensive input from broad array of individuals and organizations. Utilizing the NPP National Priorities and Goals as a reference point will help the Council to identify national CER priorities that will build the evidence base in a targeted fashion in the areas that are likely to produce substantial system-wide improvements.

In addition to the NPP report, the AMA convened Physician Consortium for Performance Improvement (PCPI) has developed a valuable survey mechanism that can be utilized by the Council to gather additional detailed information concerning national CER priorities. In order to obtain timely, quality responses from the more than 100 national medial specialty and state medical societies, experts in methodology and data collection, and many others involved in quality improvement and performance measurement, the PCPI constructed a survey mechanism. It is a powerful new tool to identify variations in practice, to assess the evidence base in a wide array of areas, and to identify areas where there are gaps in knowledge. The PCPI plans a significant expansion of these efforts. This provides much needed capacity and infrastructure for priority setting. We would welcome the opportunity to have the Council work with the PCPI to utilize this survey mechanism as it develops the recommendations concerning national CER priorities.

The AMA urges the Council to consider two powerful infrastructure mechanisms, clinical registries and data networks. These have been used by specialty societies such as the Society of Thoracic Surgeons and the American College of Cardiology, and have markedly improved quality and patient safety. The National Surgical Quality Improvement Program (NSQIP) and the Northern New England Cardiovascular Collaborative are examples of utilizing these two mechanisms to advance quality and obtain research data at the point of care, and create what our country needs, a learning network. Expansion of existing clinical registries and databases would provide a strong foundation when conducting CER and at the same time these registries would also provide an excellent beginning point for CER. Utilizing, replicating, expanding, or integrating existing clinical registries would constitute an invaluable investment in the much needed infrastructure for accurately comparing clinical outcomes based on real life conditions where delivery of care settings vary, patients may have numerous co-morbidities, and the patient population is diverse. In turn the clinical registries are not identical and may to greater or lesser extent be able to promote a learning health care environment; thus, evaluating the comparative clinical effectiveness of various clinical registry models and alternatives to them remains a vital priority. Building CER infrastructure and capacity in part upon registries and clinical data networks will leverage CER resources and boost the capacity of the system as a whole to learn and adapt in real time.

AMA Support of Council s Draft Strategic Framework

The AMA generally supports the Council s effort to develop a strategic framework for CER activity and investments in order to categorize current activity, identify gaps, and inform decisions on high priority recommendations with a couple of caveats.

First, the AMA urges the Council to ensure public access to the detailed inventories of Federal CER activities and research/data infrastructure that the Council proposes to create. The AMA agrees that the Council s organizing framework will foster consideration of the balance of activities and priority themes and allow the government to focus on the most pressing needs expressed by patients and clinicians, and allow identification of gaps in the current landscape of CER. We urge the Council to work with the AMA convened PCPI which is already engaged in this activity as discussed above.

Second, the AMA concurs with the Council that CER activities should be grouped into the following four major categories as detailed in the proposed framework:

" research, (e.g., comparing medicines for a specific condition or discharge process A to discharge process B for readmissions).
" human and scientific capital, (e.g., training new researchers to conduct CER, developing CER methodology).
" CER data infrastructure, (e.g., developing a distributed practice-based data network, linked longitudinal administrative or electronic health records databases, or patient registries.)
" translation and utilization of CER, (e.g., building tools and methods to translate CER into practice and measure results.)

While all the above categories are essential components of timely, valid, useful CER, it is important to underscore the essential and central role physicians must play vis-à-vis the last component translation and adoption of CER. The AMA supports the development of practice guidelines by medical specialties and other clinicians in medicine, but would oppose the development of guidelines by the government or another centralized entity. Consistent with the foregoing, to the extent that medical specialties design, implement, and play a central role in clinical registries such as NSQIP that rely upon clinicians to conduct CER, the AMA would support utilization of CER findings generated through clinical registries by the specialties to modify practice guidelines and decision support vis-à-vis the clinical registries.

Conclusion

There is a final cautionary tale. In the February 12, 2009, issue of Journal of American Medical Association there is a description of what can happen when science and politics collide. The Infectious Disease Society of America (IDSA) studied the evidence base for the treatment of Lyme disease and in 2006 issued new guidelines advising against the long-term use of antibiotics. The IDSA was promptly sued by the Connecticut Attorney General alleging violations of antitrust laws and restraint of trade. The case was settled without IDSA admitting any fault and assenting to an ombudsmen-reviewed panel to assess the 2006 guidelines. If we cannot separate science and politics in a case such as this, how will we ever manage to deal with the really hard issues?

CER has the potential to have a profoundly positive impact on the quality of the information available to physicians and patients and, when used appropriately and with care, will address escalating health care costs. The AMA welcomes the opportunity to work closely with the Council to ensure that physicians remain engaged, enthusiastic, and involved stakeholders in this process.

Submitted by
Joe Kanter
Joseph H. Kanter Family Foundation/Health Legacy Partnership
joe.kanter@healthlegacy.org

Comment Type: *Definition*

The Joseph H. Kanter Family Foundation welcomes the opportunity to offer feedback to the Federal Coordinating Council for Comparative Effectiveness Research (Council) on the draft definition of and prioritization criteria for comparative effectiveness research (CER). We heartily endorse the efforts of the Council and other policymakers to improve the evidence base on health outcomes by investing in CER. We believe CER is a necessary first step in our nation s long range goal to harness real time data from personal electronic health records and provide health care providers and average Americans with easily accessible and understandable scientific data to make evidence-based health care decisions and choices.

The Kanter Family Foundation is a nonprofit organization established in 1998 by Joseph H. Kanter following his personal battle with prostate cancer. Unable to quickly and accurately determine the best course of treatment despite access to the best medical resources available, Mr. Kanter recognized that improved access to better health care data could significantly enhance medical treatment for all Americans.

Since then, Mr. Kanter has committed his time and money to his vision for better health and health care. Through The Health Legacy Partnership with the Agency for Healthcare Research and Quality (AHRQ), the Kanter Family Foundation has strived to improve healthcare decision-making. Specifically, we have worked to develop a National Health Outcomes Database that would provide health care professionals and patients useful, scientific evidence on the best treatment options available. When paired with deidentified data from electronic health records, evidence generated through federally funded CER would populate this user-friendly information tool to help providers, patients, policymakers and other decision makers determine what works best, when, under what circumstances, for whom.

The Kanter Family Foundation offers its support for the Council s proposed definition of CER and the accompanying prioritization criteria for research funding. We are pleased that your definition encompasses a broad array of:

" Methodologies and data sources to provide timelier and more comprehensive information about health treatments especially in underrepresented populations than traditional randomized clinical trials currently provide;

" Interventions to be compared including medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions to ensure providers and patients have access to information on the full range of treatment options available; and

" Information users to facilitate shared decision-making and engagement in health care treatment.

We especially support the patient-centeredness of the proposed CER definition, e.g., the purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs. We are pleased that this patient-centric approach is also reflected in your threshold minimal criteria to prioritize research funding, e.g., responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research. Too often, decisions about research funding are made in a vacuum with little consideration to the priorities and needs of the end users, or the practical applications of the information in the real world. As a result, many current research studies only evaluate the experiences of a narrow group of patients under tightly controlled conditions. As you have defined it, CER will study the real world experiences of diverse patient populations, many of whom may be taking multiple prescriptions or have experience with several different approaches to treatment. Knowing how patients respond to treatments and how treatments compare to meet these patients needs is crucial to understanding what works best for patients from diverse backgrounds.

The Kanter Family Foundation also supports the Council s proposed minimal criteria for federal funding: feasibility of research topic, (including the time necessary for research). In our rapidly evolving medical landscape, untimely CER loses relevance and utility as new and ever more innovative treatments enter the market. As the Council evaluates the feasibility of research, we urge the Council to consider not only timeliness but also the usability and translatability of CER. The principal goal of CER is to improve health care quality and value by generating information that is readily accessible and understandable by key users. CER that is likely to be used by patients and providers and can be readily translated to facilitate use by these individuals should receive priority for funding over studies that do not.

The Kanter Family Foundation commends the Council for highlighting the need to tailor treatments for different populations, e.g., CER must assess a comprehensive array of health-related outcomes for diverse patient populations. Studies by federal watch dogs and academics have shown that randomized clinical trials conducted to bring new medical innovations to the market typically do not include diverse populations. Women, elderly, and minorities are underrepresented as companies determine whether or not their new drugs and devices are safe and effective. Such deficiencies can diminish the utility and applicability of drugs and devices in these groups. CER, as the Council has defined it, will help us move beyond does the treatment work? toward for whom does the treatment work? This shift in medical decision-making is

crucial as our society becomes increasingly diverse and disparities in health care remain pervasive.

Patients want and deserve a greater voice in their health care. Advances in information technology have given individuals unprecedented access to health-related information. Individuals can now learn about diagnoses and available treatments, find local support groups, rate physicians and medical institutions, and research dietary and exercise practices. Unfortunately individuals with access to myriad health information often feel they are drinking from a fire hose. With so much information available how does a provider or patient determine what s most appropriate? The next step on the health information continuum is to ensure patients and their providers have access to more and better information about how all available treatments medical and otherwise perform compared to one another in different subpopulations. CER, and its widespread availability and usability, will help get us there.

The Kanter Family Foundation looks forward to collaborating with the Council to ensure evidence generated by federally funded CER is widely disseminated to patients and providers through our National Health Outcomes Database. If you have any questions, please contact Mr. Kanter or the Kanter Family Foundation s Washington representative, Emily Holubowich of Cavarocchi Ruscio Dennis Associates, at eholubowich@dc-crd.com or 202.484.1100.

Submitted by
[personal information redacted]

Comment Type: *Definition*
Although the definition uses the language "delivery system interventions", I fear that this is not precise enough. Delivery systems could mean intranasal vs. intramuscular flu vaccine. What it seems to me is missing from the definition is the appreciation that we are planning to redesign a healthcare system. In my work, I explore health care decision making for diseases (trauma, stroke, cardiac arrest) that require emergent medical intervention from the population level. I interpret delivery systems interventions to include air vs. ground transport of acute stroke patients and tele-medicine with subspecialists not located at the parent facility, but believe the possibility exists to include such broad thinking given the current definition. The institute of medicine called explicitly for a coordinated and regionalized emergency care system - I believe some recognition of the importance of regional or regionalized systems planning is warranted in the definition.

Submitted by
John Cuddeback
Anceta - AMGA's Collaborative Data Warehouse
jcuddeback@anceta.com

Comment Type: *Definition*

We commend the Council on its efforts to clarify definitions and priorities for CER Funding per the ARRA. We are pleased to see the reference to delivery system interventions, but we are concerned that the word interventions could be interpreted to include only projects that prospectively change the delivery system, such as the CMS Physician Group Practice (PGP) demonstration.

Such projects are important, but we should also take advantage of the natural experiments that current practice offers. Care is currently delivered under a wide range of organizational structures, and provider organizations have initiated many changes in care process and supporting infrastructure.

We believe delivery system interventions could be better stated as delivery system strategies, reflecting the phrase comparing different interventions and strategies in the first sentence.

Critical insights can be obtained by studying the replicable factors that drive success in EXISTING delivery systems that engage in organized processes to improve quality and control costs and are willing to bear accountability for results.

As stated in written testimony provided to the Council on April 14, The Delivery System Matters, by Dr. Samuel Lin, on behalf of the American Medical Group Association (AMGA), we need to understand the comparative effectiveness of the organizational structures and processes under which care is delivered. They affect safety, timeliness, efficiency, effectiveness, equity, and patient-centeredness (IOM s STEEEP). We should test the hypothesis that optimal outcomes are attained in delivery systems that exhibit specific aspects of care coordination. Recent papers have suggested that organized systems of care, or accountable care systems, are instrumental in ensuring STEEEP (1-4).

Since Dr. Lin s testimony was submitted, a coalition of organized systems of care has been formed to assess the comparative effectiveness of delivery systems as a priority component of health reform. We are prepared to present oral testimony as to the value and feasibility of this kind of research at the Council s June 10 listening session and to respond to the Council s questions at that time.

-- John Cuddeback, MD, PhD, Chief Medical Informatics Officer, Anceta, AMGA s Collaborative Data Warehouse, on behalf of participating AMGA member medical groups: multi-specialty medical groups and integrated delivery systems ranging from fewer than 200 to more than 1,200 physicians, in rural and urban settings across various regions of the country, including multiple participants in on-going CMS demonstration projects.

1. Shortell SM, Casalino LP. Health Care Reform Requires Accountable Care Systems. JAMA 300(1): 95-97 (July 2, 2008).

2. Fisher ES, Berwick DM, Davis K. Achieving Health Care Reform--How Physicians Can Help. N Engl J Med 10.1056/NEJMp0903923 (published online May 20, 2009).
3. Fisher ES, McClellan MB, et al. Fostering Accountable Health Care: Moving Forward in Medicare. Health Affairs 28(2): w219-w231 (published online January 27, 2009; 10.1377/hlthaff.28.2.w219).
4. Pham HH, O Malley AS, Bach PB, Saiontz-Martinez C, Schrag D. Primary Care Physicians Links to Other Physicians through Medicare Patients: The Scope of Care Coordination. Ann Intern Med 150(4): 236-242 (February 17, 2009).

Submitted by
Vincent Stine
American Association for Clinical Chemistry
vstine@aacc.org

Comment Type: *Definition*

AACC recommends that the definition be modified. We suggest that "diagnostic tests and testing modalities" be included in the following sentence to read:

"Defined interventions compared may include medications, diagnostic tests and testing modalities, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions."

The term modalities is used to reference point-of-care testing, home testing, continuous monitoring.

Submitted by
[personal information redacted]

Comment Type: *Definition*

Threshold Minimal Criteria (i.e. must meet these to be considered)
1. Included within statutory limits of Recovery Act and FCC definition of CER
2. Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research
[Comment:] Expressed needs would seem extremely difficult to evaluate, except to include representatives of each group on each grant application review. No single grant could be expected to meet the expressed needs of all patients, clinicians, and other stakeholders. (Note that this is listed as a Minimal Criterion.)
The report from the Listening Session of the Federal Coordinating Council noted in part the need to enable people to trace backwards from results to inputs, to ensure themselves that the process

was fair. Fairness is probably a better measure than expressed needs. Further, in the Listening Session, there was a citation to assist in clinical decisionmaking by providers and patients. I would add the words informed, rational ahead of clinical. In this way, this stated threshold criterion is not subject to a particular activist community s agenda. Thus, I would re-word this criterion as:
Ability to assist in the rational, informed clinical decisionmaking by patients, clinicians, and other stakeholders, including community engagement in research
I believe the re-worded criterion will lead to many fewer challenges by interested parties.

3. Feasibility of research topic (including time necessary for research)

Prioritization Criteria
The criteria for scientifically meritorious research and investments are:
1. Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care)
[Comment:] The variability of outcomes or variability in costs of care among the total U. S. population is more relevant than the prevalence of the condition or the total costs (e.g 30,000 people with a condition at an average cost of $50,000/patient and a standard deviation of $2,000/patient probably provides less opportunity than 20,000 people with a condition at an average cost of $20,000/patient but a standard deviation of $10,000/patient). If variability can not be traced to the differing illness burdens (i.e.\, co-morbidities) among the population with the condition, then variability indicates that certain treatments don t seem to work as well on a portion of the population. Conversely, variability indicates that some treatments seem to work better than others or better in selected situations.

Submitted by
Jean Iacino
CA Dept. of Public Health
Jean.Iacino@cdph.ca.gov

Comment Type: *Definition*

The California Department of Public Health is concerned that the draft definition and prioritization criteria are too clinical in focus and seem to preclude public health intervention effectiveness research.

Submitted by
[personal information redacted]

Comment Type: *Definition*

1) Does not clearly include methodological work

2) Does not look at subgroups of patients likely to benefit or be hurt by one treatment vs the other
3) the requirement for a comprehensive array of health-related outcomes for diverse patient populations, is likely not practical within one study

Submitted by
[personal information redacted]

Comment Type: *Definition*

The final sentence of the draft definition should be amended as follows:

This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness, as well as the active dissemination of results.

Submitted by
Judith Cahill
Academy of Managed Care Pharmacy
jcahill@amcp.org

Comment Type: *Definition*

AMCP believes that it is essential to the success of comparative effectiveness research that the cost effectiveness of treatments not be precluded as a component of overall research efforts. The Academy s members use various tools and strategies, including the cost effectiveness of treatments, as a means of combating the increasingly high cost of health care. It is vital that research on cost effectiveness be included in any effort to conduct comparative effectiveness research. The Academy strongly recommends that the cost effectiveness of treatments be included in the definition of comparative effectiveness research.

Submitted by
Thomas Novelli
Medical Device Manufacturers Association
tnovelli@medicaldevices.org

Comment Type: *Definition*

The Medical Device Manufacturers Association (MDMA) is a national trade association representing over 200 small to mid-size manufacturers of innovative and lifesaving medical

technologies. MDMA appreciates the opportunity to comment on behalf of our membership, and we commend the Federal Coordinating Council (Council) for engaging all stakeholders on the issue of comparative effectiveness research (CER).

MDMA supports the principles of evidence-based medicine and CER. We believe that patients, physicians and the public should have access to the best information and data on which treatments work best in addition to which treatments are less effective. The availability of this information will be in the best interest of the patient and all stakeholders. As Congress and the Administration work to build upon the Council s efforts on CER, it is important to also examine other areas of the health care delivery system, including wellness, prevention and education.

Definition of Comparative Effectiveness Research

Recently, the Council released its draft definition for CER. Specifically, the Council proposed the following definition:

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

MDMA believes that the proposed definition is a step in the right direction. However, we believe that a few terms within the definition warrant further clarification or modification.

Recommendation #1

The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

MDMA believes that further clarification is needed for the term decision-makers. Specifically, the Council should further define who decision-makers would entail, whether it is the Congress, private insurers, Medicare, Medicaid or other Federal healthcare programs. It is critically important to know which parties will be utilizing this data and for what purposes. MDMA believes decision-makers should be patient s guardians, and family members who may be involved in making health care decisions and not payers.

Recommendation #2

This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

MDMA strongly believes that the Council should further clarify the definition for CER, especially as it relates to the types of data sources and methods to be used to assess comparative effectiveness. The Council should publically state the type of data sources and methods it intends to utilize or exclude. Moreover, it should state whether it is the intention of Federal agencies to generate original data for purposes of CER or if agencies will utilize existing clinical data.

General Comments

The Council would be amiss if it were not to study all factors that are contributing to increased costs within the healthcare system, including the examination of the inherent root causes. For example, we are all sadly aware of the growing obesity epidemic among the nation s adolescent population. Our children are living less-healthier lifestyles than in generations past; they are less physically active and are consuming more unhealthy foods. If our country continues on this path, we can only begin to try to speculate what the related costs will be for treating obesity related conditions, such as diabetes, pulmonary hypertension and heart disease in general. The positive news is that this is a controllable condition, and by increasing education and awareness, we can make an impact. Tackling these issues early-on will likely have a far greater impact on cost savings in the future than our current thinking on CER. To this end, efforts on CER should not be focused exclusively on efforts such as technology assessment. This back-end approach is analogous to trying to plug the dam after it has sprung a leak. Rather, focusing research efforts on wellness and prevention should be complimentary to the current thinking on CER. In this sense, a primary focus of CER and the Council should be to examine the root causes of increased health care spending.

CER should also be used to address disparities in the health care system. Too often is the case that varying patient populations receive disproportionate health care treatment and coverage. The Council has a tremendous opportunity to conduct studies and use the research to address these disparities to ensure that all Americans are receiving the appropriate care.

Finally, the manner in which the Council and related agencies conducts its work and generates data must be as transparent as possible. As is apparent, the work produced by the Council will likely have a significant impact on numerous entities, including patients, payers and the industry. In keeping with President Obama s pledge for transparency in government, it is absolutely critical that the work of the Council remain open and transparent for all stakeholders. This includes allowing stakeholders to submit public comments on the Council s processes and methodologies for comparative studies as well as its results. To this end, it is important that expanded CER initiatives include a formal infrastructure to ensure public input on the work of the Council and related agencies.

The Council should yield caution in expanding the definition of CER to include the study of the cost effectiveness for competing medical therapies and interventions. Although there may be a

tendency for studies to focus on a single episode of care, the costs associated with such care should be measured over a long enough time horizon to capture the true savings of a procedure or therapy. It will be important to consider long-term savings and cost reductions including potential decreased frequency of hospital/physician interactions, increased patient productivity in the workforce, and other measures that would be difficult to capture in a short time horizon.

MDMA greatly appreciates the opportunity to address the panel today. We strongly believe in the goals and mission of the Council and believe that there is a tremendous opportunity to improve the health care delivery system for America.

Submitted by
[personal information redacted]

Comment Type: *Definition*

Firstly, I applaud the concerted effort of the Federal Coordinating Council in producing a draft definition of Comparative Effectiveness Research, and accompanying Prioritization Criteria.

I would propose minor editing to reflect the fact that "research synthesis" is a scientific endeavor in its own right. Therefore, the first sentence should perhaps better read as: "Comparative effectiveness research is the conduct of systematic research synthesis comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions."

I would also suggest that the last sentence be expanded just a bit to provide unequivocal information as to "how" the purpose of comparative effectiveness research is obtained. The last sentence could read: "This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness by means of systematic reviews of the evidence, and acceptable sampling and meta-analysis of the best available evidence."

Furthermore, and pertaining to the criteria (Threshold Minimal AND Prioritization), it seems to me that mention should be made of the ultimate goals of comparative effectiveness research, that is to improve both treatment interventions and policies in light of optimal benefit with minimal costs & risks. As it now stands, neither are mentioned in the list of priorities.

Lastly, I wish to express that I am honored to be part of this critical and timely discussion.

Submitted by
[personal information redacted]

Comment Type: *Definition*

Another Prioritization Criteria that should be considered is the degree to which there is variability in practices for managing a condition proposed for study, and the degree to which that variability drives excess cost without any demonstrated improvement in outcome (value).

Submitted by
Carmella Bocchino
America's Health Insurance Plans
cbocchino@ahip.org

Comment Type: *Definition*

America s Health Insurance Plans (AHIP) appreciates the opportunity to share its member companies perspectives on the proposed definition for comparative effectiveness research (CER) and the strategic framework for such research. AHIP is the national trade association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, disability, and supplemental coverage and also have a long history of participation in public programs.

Proposed CER Definition
Comparative effectiveness research, both through the conduct of original research and synthesis of existing studies, compares treatment, drugs, devices, or procedures and evaluates the benefits and risks of different treatment options for different medical conditions across different patient populations.

The information generated from this research would be made available to clinicians, payers, innovators and most importantly to consumers, to aid in decision-making and selecting therapies.

AHIP Statements on Comparative Effectiveness Research
Unfortunately, there continues to be major gaps in care for diverse populations, many of which have not been part of the traditional clinical research model. Our members support the direction of this definition and offer additional comments to clarify both scope and depth. Therefore, there needs to be a better understanding of these populations and how their culture, race, and ethnicity impact access to care and acceptance of treatment interventions. The development of comparative effectiveness information should focus on both broad and specific sub-populations, to balance the needs of culturally diverse populations.

If we are to change clinical practice, we need to build a sustainable infrastructure not only for robust scientific evidence but for disseminating reliable comparative information to clinicians that can be easily translated into care and discussed with patients at the point of care. While health plans and physicians groups have created disease registries, observational databases and decision-support tools to inform decision-making, much more needs to be done.

Submitted by
Richard I. Smith
Senior Vice President, Policy
Advanced Medical Technology Association (AdvaMed)
tlee@advamed.org

Comment Type: *Definition*
AdvaMed recommends that the purpose of the research in the definition of CER be made consistent with the purpose statement in the draft strategic framework. The current draft definition s purpose statement is vague as to who decision-makers are. By contrast, the draft strategic framework states that the research is to inform health care decision-making by patients, clinicians, and others in the clinical and public health communities. AdvaMed supports articulating a purpose that makes clear that the generation of comparative effectiveness research is intended to assist patients, physicians and other health care professionals. Consequently, AdvaMed recommends replacing the second sentence of the draft definition with the following:

The purpose of this research is to inform health care decision-making by patients, clinicians and other health care professionals, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

Submitted by
[personal information redacted]

Comment Type: *Definition*

In the Draft Definition of Comparative Effectiveness Research for the Federal Coordinating Council the following sentence appears: "Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions." This sentence makes no mention of comparing the effectiveness of different approaches to broadly organizing medical care for an entire region. Regionalization has been very successfully done with specialty trauma care and trauma centers, whose patients experience a significant 25% reduction in mortality because of better regional triage and medical system organization (see Branas CC, et al. Access to trauma centers in the United States. JAMA 2005;293(21):2626-33 and MacKenzie EJ, et al. A national evaluation of the effect of trauma-center care on mortality. N Engl J Med 2006;354(4):366-78). The same successes are also possible for many other types of medical specialty care in the US (see for instance Kahn JM, et al. Regionalization of medical critical care: what can we learn from the trauma experience? Crit Care Med 2008 Nov;36(11):3085-8). These broad, system-wide regionalization strategies that change the fundamental ways in which patients access medical care hold perhaps the greatest promise in improving health and outcomes.

As such, I am requesting that the aforementioned sentence be change to: "Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, delivery system interventions, and regionalization strategies." Thank you for your consideration.

[personal information redacted]

Submitted by
Carol Sakala
Childbirth Connection
sakala@childbirthconnection.org

Comment Type: *Definition*

Thank you for the important work done to date on the nation's CER program. My organization has since 1999 carried out a national long-term program to promote evidence-based maternity care. Based on our considerable experience, we feel strongly that the purpose of Comparative Effectiveness Research in the federal definition must include examination of comparative benefits *and* comparative harms. For example if A and B are equivalent in expected effectiveness for an outcome of interest or A is slightly superior, but A is also associated with increased risk of serious morbidity, many decision makers would be concerned about selecting A.

There is extensive evidence that patients/consumers want to know most or all known harms before making key decisions. Further, when available, information about harms often impacts their decision making. When notable risk of harm is known to be involved in an intervention, many prefer less invasive options or watchful waiting. By law and within the ethical precepts of leading health care organizations, patients/consumers have the right to know about benefits and harms, and make an informed decision on the basis of this knowledge, their own values, their care options, and so forth. It is appropriate for the federal definition to support rights to informed decision making and informed refusal.

Many cases studies, such as the story of the widely prescribed Vioxx, suggest that we should try to avoid standard use of interventions prior to adequate investigation of harms as well as benefits. Hasty implementation can endanger the public, waste scarce resources, and undermine the integrity and authority of agencies and organizations.

Harms are underresearched and underreported both in the literature as a whole and in the promotional efforts of industry. Specifically calling out the importance of knowledge about comparative harms of interventions in the CER definition would provide an important opportunity to help correct this pervasive bias and improve health care decision making for all stakeholders.

Thank you for considering these concerns.

Submitted by
[personal information redacted]

Comment Type: *Definition*

CER Council members,

As Comparative Effectiveness Research is building, its order demands intellectual integrity and its strength will rely upon the collective awareness of many. I applaud the opportunity for constructive feedback and input.

If I were to offer a pedantic suggestion, I would suggest a closer look at the second sentence. Responding to their expressed needs continues to seem awkward to me.

Food for thought here& what if the need is not expressed? For example:

Only minutes ago reviewing data from Analysis of VA Health Care Utilization Among US Southwest Asian War Veterans, VHA Office of Public Health and Environmental Hazards (August 2006) it shows the highest percentage diagnosis of returning Iraq and Afghanistan Veterans is 41.7% - Diseases of Musculoskeletal System/Connective System.

This information shows a need yet it s not expressed. Would it still fit into the definintion?

I ask because with musculoskeletal disorders ranking highest in returning Veterans and national concerns of opioid usages coupled with chronic pain prevalence, this issue has become a high priority. As one of less than 20 DCs in the entire Dept of Veterans Affairs, and as a musculoskeletal expert and chronic pain manager, the demand of service far out weighs the supply. I see where CER would be feasible and effective in identifying the potential impact of not meeting with demand of service by DCs.

Submitted by
Geoffrey Mumford
American Psychological Association
gmumford@apa.org

Comment Type: *Definition*

The American Psychological Association (APA) is writing to provide comment on the draft definition of comparative effectiveness research (CER). Within a list of defined interventions the draft definition indicates that those interventions may include &behavioral change strategies& APA would prefer replacing behavioral change with psychological, psychosocial, and behavioral to provide a more comprehensive description of the interventions research. In addition we recommend that the CER definition include implementation studies and that the Prioritization Criteria also include implementation potential. Thank you for your consideration of our recommendations.

Submitted by
Tina Grande
Healthcare Leadership Council
tgrande@hlc.org

Comment Type: *Definition*

HLC Comment on Draft Definition

The Healthcare Leadership Council (HLC) agrees that the primary purpose of comparative effectiveness research should be the creation of new knowledge to inform patients and their health care providers and empower them to make smarter decisions to the maximum benefit of the patients health, quality of life, and general livelihood. Where this goal can be reached by synthesizing, within tested and proven methodologies for doing so, existing sources of knowledge, it makes sense to do so.

As the definition implies, no two patients are identical in all respects, and therefore this research should be a useful tool, not a yes or no determinant, in guiding health care decisions. We therefore agree that comparative effectiveness research must consider potential differences among diverse patient populations. As medicine becomes more individualized, assessments should recognize that various interventions may work for specific subgroups of the population but not for others, based on genetic variability and other factors. Thus, research must be flexibly designed to target smaller populations with certain characteristics, and the definition should reflect that.

We respectfully ask that effectiveness be further clarified within this definition. In order to be truly patient-centered, it may be necessary to include, beyond medical efficacy, other outcomes in this research. Comparative effectiveness assessments could involve, whenever possible, considerations about quality of life, functional status, economic productivity, and other factors that are important to patients, providers, and society.

HLC also agrees that beyond simply comparing product A vs. product B, properly designed comparative effectiveness research should assess a wide variety of interventions. We agree that delivery system design and patient behaviors, which are usually two very important determinants of health outcomes, should be included for study. In this way, the definition suggests that this research should examine the entire health system, not just a specific sector, which we feel is the correct approach.

We respectfully suggest that the definition should also provide that this type of research, in order to maintain its objectivity and validity, will necessitate that data sources be both timely and accurate. Further, studies will need to be both transparent and periodically reassessed to ensure patients have proper authority on new and emerging interventions and strategies to improve health outcomes.

Submitted by
[personal information redacted]

Comment Type: *Definition*

SUGGESTED REVISION
Comparative effectiveness research examines the relative efficacy of different interventions and strategies to prevent, diagnose, treat and monitor health conditions. This type of research entails use of various data sources/methods; compares an array of interventions (e.g., medications, procedures, medical and assistive devices and technologies, behavioral change strategies, delivery systems); and assesses resulting health-related outcomes for diverse patient populations.

COMMENTS ABOUT DRAFT DEFINITION

* It is too long.

* This phrase s meaning is unclear: responding to their expressed needs.

* This phrase is overly descriptive and cumbersome: conduct and synthesis of systematic research.

* This phrase seems to be expanding upon a sub-issue (varied data methods) that is not central to the task at hand figuring out what medical procedures are most efficacious - This research necessitates the development, expansion, and use of a variety of:.

* This phrase can be dropped as it s reallynot necessary (i.e., to inform patients, providers, and decision-makers). We can assume that the purpose of the research is to inform for purposes of efficacy for use by many parties.

Submitted by
[personal information redacted]

Comment Type: *Definition*

Include "testing" in the second to last sentence of the definition following "Defined interventions compared may include."

"Testing" is certainly consistent with all of the applications stated in the text of the first sentence of the definition concerning "comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions." Much testing and its results are used to support clinical care that is unnecessary, ineffective and even harmful, thus providing an excellent opportunity for comparative effectiveness research.

Submitted by
[personal information redacted]

Comment Type: *Definition*

The notion of cost-warranted care should be included in cost effectiveness definitions and research.

That is, the cost should be warranted by considerations such as the patient's goals for care.

Effectiveness can be defined to include the patient perspective, but it should be more explicit that currently the case.

Thank you for inviting feedback.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Studies comparing new rx. Against placebo is poor science, poor economics , and poor medicine;this is especially true of "me too" drugs in any therapeutic classes.

One potential harm however is the tendency to make "guidelines" the "standard" of care and limit individual physician tailoring therapy to the individual patient!the ultimate inclusion of drugs in any plan's "formulary" is often so restrictive that some truly best drugs based on research papers is often denied as "not approved".

A weakness is the absence of of qualified MDs as the providers of authorization of drugs requiring "prior authorization";these decisions are usually made by nurses,clerks with protocls,or retired general or even pediatric mds ruling on sophisticated medical judgements that would be better made by aqualified specialist withou incentive to be reimbursed a % of revenue created by thei "senials".

Submitted by
[personal information redacted]

Comment Type: *General Comment*

The general statement regarding "comparative effectiveness research" is devoid of serious content. For those who know the existing systems of systematic reviews of evidence regarding medical treatments, interventions, etc., that hold to clinical trial standards of evidence, it appears the intent is to introduce low-level, non-scientific "standards", that if applies seriously would produce ineffective investments or consumption of treatment and mislead the American public. In short, there is nothing here to comment on.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

I just want to make a general comment regarding the form. I am submitting the registration form and you will notice I am not part of any organization. I hope I do qualify to be part of the Federal Coordinating Council for the Comparative Effectiveness Research project. I have many years of experience working with state and federal programs.

Submitted by
Richard I. Smith
Senior Vice President, Policy
American Occupational Therapy Association
slin@aota.org

Comment Type: *General Comment*

Statement of Susan H. Lin, ScD, OTR/L
Director of Research, American Occupational Therapy Association
Submitted to the Federal Coordinating Council on
Comparative Effectiveness Research
May 29, 2009

Thank you for this opportunity to provide comments on behalf of the American Occupational Therapy Association regarding the priorities for comparative effectiveness research. AOTA, representing the interests of over 140,000 occupational therapists, occupational therapy assistants and students of occupational therapy, is concerned about the health, active engagement in daily activities, and participation of all individuals. .
Comparative effectiveness research plays a critical role for health professionals, policy-makers, and consumers. However, comparative effectiveness research should be conducted beyond primary care settings, because important health care questions need to be answered in rehabilitation, long-term care, and community settings as well. Occupational therapy practitioners work with infants and elderly, in schools, homes, nursing facilities and hospitals. We strive to improve people s abilities to perform the daily activities that are most meaningful to

them, thus improving their functional activities and quality of life. Occupational therapy enables Living Life To Its Fullest; and research has shown that occupational therapy, by improving life, can positively affect health outcomes and costs (Hay et al., 2002).

AOTA has completed systematic reviews on Occupational Therapy and children and adolescents with autism, children with behavioral and psychosocial needs, adults with stroke, driving and community mobility for older adults, adults with Alzheimer s disease, and children and adolescents with sensory processing/sensory integrative disorders. However, more reviews are needed to examine the evidence for different health conditions in different health care settings. Additionally, resources are needed to disseminate and promote use of evidence at the point of care, especially in rehabilitation, which can vary among inpatient, outpatient, home, and community settings.

Dr. Carolyn Clancy, Director of AHRQ underscored the need to focus on patients with multiple chronic illnesses, a group of people for whom we spend the most money and provide the worst care (Clancy, 2008). The diagnoses of autism, stroke, and dementia are often chronic, requiring multiple interventions, including occupational therapy services. Research is needed to determine the optimal dose, frequency, duration and type of occupational therapy interventions for individuals with conditions such as autism, stroke, and Alzheimer s. Such research would aid occupational therapy practitioners to deliver services efficiently and effectively, which is especially important in the context of the current economic climate and the workforce shortage that we are experiencing in occupational therapy. The following studies are examples of research that is needed based upon AOTA s systematic reviews.

Autism

Research Question: Is behavioral intervention with occupational therapy intervention more effective than behavioral intervention (without occupational therapy) to improve the performance of daily tasks and participation in school, home, and community in children diagnosed with autistic spectrum disorders (ASD)?

Justification: Behavioral interventions are commonly used to treat autism, but given the high prevalence of sensory issues in children with Autistic Spectrum Disorders (ASD), this approach fails to address what are believed to be underlying reasons for these children s behaviors: i.e., problems with processing sensory information. Occupational therapists can assess and treat sensory processing problems that negatively influence children s behaviors and daily performance. They also can modify environments (e.g., reduce sensory overload) and tasks so that children can perform them as independently and functionally as possible, whether the task is dressing or completing a class assignment.

Stroke

Research Question: Does rehabilitation with special focus on cognition for functional activities result in better outcomes, long-term recovery, increased productivity, and greater participation in the community, compared to standard rehabilitative care? And does greater cognitive

rehabilitation emphasis result in any cost savings over the long-term recovery of individuals who have had a stroke?

Justification:
Each year, 795,000 people have a stroke in the United States, and stroke is the third leading cause of death. Early interventions and rehabilitation post-stroke are crucial to better functional outcomes. And yet, there are variability in the rehabilitation treatment approaches, depending upon professionals knowledge of the literature, rehabilitation equipment and staffing availability, and even reimbursement policies. Thus, funding for CER should address knowledge translation or knowledge transfer, or else valid effective interventions will not be utilized and patients potential for better functioning could be unnecessarily limited.
Research suggests that cognition is a mediator of functional outcomes in stroke rehabilitation, but more studies are needed to compare outcomes of rehabilitative approaches. Concurrently, these studies should measure use of health care services and its associated costs, so that we can compare interventions not only in terms of outcomes but costs as well.

Dementia

Research Question: Are intervention programs that facilitate routines and environmental cueing, as provided under the supervision of an occupational therapist and under an occupational therapy plan of care, more effective than standard care to improve the performance of daily activities (e.g., toileting, sleeping, taking medications) in people with dementia? And does the improvement help promote health for caregivers?

Justification: Research suggests that routines are beneficial to performance of daily occupations (e.g., sleep) in people with early dementia. While some studies have examined the intervention of routines on behavior and performance, few studies have investigated the effect of routines and environmental cues on performance of activities of daily living (e.g., toileting, sleeping,) and mortality. If the maintenance of daily routines and provision of environmental cues provide purposeful and meaningful activity throughout the day, people with dementia could live longer, have fewer health problems and higher quality of life, which could decrease the stress of caregivers and lower costs.

Summary

Occupational therapy promotes the performance of daily activities and participation of individuals who have illnesses or injuries that limit their daily performance and participation in society. We have recommended specific CER studies for autism, stroke, and dementia, but occupational therapy practitioners work with people of all ages, across educational, business, and health care settings. Further research is needed to identify the most effective and efficient occupational therapy interventions, especially in rehabilitative settings and other contexts in which individuals with chronic illnesses are served.

The American Occupational Therapy Association greatly appreciates this opportunity to comment and looks forward to forming partnerships with other organizations to promote the health, productive living, and quality of life of all individuals.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

I have some concerns about the FCC's ability to operate independently of Congressional intervention should they rule adversely towards a mode of treatment backed by financially and politically connected interests. Health care is very big business and the players protect their revenue streams fiercely.

Towards this end, I think that the FCC should try to work with Congress to avoid the equivalent of "line item veto" interventions. One approach that I favor is to present the FCC findings and recommendations to Congress not on an individual study basis, but in the aggregate each year, asking Congress to vote up or down on the entire body of work rather than specific findings relative to a single treatment modality.

The FCC's main objective over the next several years has to be survival and credibility. Good luck in achieving this direction.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

As I review information about Comparative Effective Research, I am excited to hear about the emphasis given on driving Medication Therapy Management. It is great to see that MTM has become a greater requirement within our Medicare Part D programs for 2010 and I see it rapidly expanding. Given that, I feel that you should strongly consider either adding a Phamacist to your Council to help provide guidance in the area of MTM or seek input from pharmacists engaged in that area. As a pharmacist with a strong interest in this area, I feel this is something that should be considered and would consider being an expert in the area if needed.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Maintain perspective.

In particular, remember that patients, their needs and their options change continually, as do the insights, discoveries and innovations of medical and clinical science.

In other words, any results of this research will be outdated long before publication.

Therefore, mandatory obedience, such as by putting any results into legislative or regulatory concrete, is doomed to be counterproductive and very often harmful.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

The Food and Drug Administration currently takes the position that no pharmaceutical, biological, or medical device company may make any statement regarding the comparative effectiveness of its product to any other product until the company has conducted one or more head-to-head clincal trials of the two products and FDA has approved the "claim." Few entities, including AHRQ, hold themselves to that high a standard of evidence for making a comparative effectiveness evaluation. If the US Government or private entities conduct comparative effectiveness studies or analyses, or issue reports on the comparative effectiveness of an FDA-approved medical product using standards less strict than FDAs, then a medical product company may find itself in a position where its product is criticized as less effective, but the company would not be able to respond using the same type of data or analyses. Rather, the company would have to conduct large, long, expensive head-to-head clinical trials to respond to the comparative effectiveness report. It seems to me that there has to be a consistent standard for the conduct, analysis, and reporting of comparative effectiveness research for both the US government, private organizations, and companies so that everyone can speak using the same standards of proof. Simply stated, to do otherwise would be unfair.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

We appreciate your support.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

I appreciate the work that the council has put into these priorities. I think this is a good framework and wouldn't remove anythingt hat you have written but... I worry that it would miss preclude the use of comparative effectiveness for rare diseases where the data is gathered in collections of small trials or studies and a systematic review (comparative effectiveness review) can really help clarify therapies for people without evidence based therapies. I am thinking about disorders such as vasovagal syncope or connective tissue diseases.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

President Obama and I are committed to changing the Political process by growing an organization Founded on broad of support from ordinary Americans. This organization is about the people's interests ahead of the special interests,but to do that,Barack needs help from people like you and me. I've set my own personal fundraising goal for the organization,which you can see in the thermoneter on the website: [personal information redacted]

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and patients, and helps make our practice of medicine more evidence-based. Having read your definition, I am relieved to say I heartily agree with it.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Hello,

The Federal Coordinating Council For Comparative Effectiveness Research will help Congress realize that different Health Care Reform policies can either assist or harm people, who are in need of medical insurance.

Sincerely,
[personal information redacted]

Submitted by
[personal information redacted]

Comment Type: *General Comment*

This needs skills and authorities already found in American College of Wurgeons, American of Academy Science, FDA, DEA, and HHS.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Having read your definition, I am relieved to say I heartily agree with it.

I am particularly glad to see that you have stuck to your evidence-based guns in the face of political pressure and included "cost" as a factor in determining comparative effectiveness. Although it is no means the only factor, I strongly feel that it must be considered where appropriate. I appreciate and applaud you for recognizing that comparative effectiveness research must also look at how much we're paying when treatments are otherwise roughly as effective as one another in terms of health outcomes. Keep up the good work.

Submitted by
[personal information redacted]

Comment Type: *General Comment*
Inclusion of allergy data and possibly immunization data would be helpful also I believe.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and

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[personal information redacted]

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[personal information redacted]

Comment Type: *General Comment*

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Submitted by
[personal information redacted]

Comment Type: *General Comment*

Thank you for supporting comparative effectiveness research.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

To date very little has been written about the need to use CE research to enhance our evidence base for interventions targeted at children. This is disappointing as the evidence base for managing pediatric conditions is appallingly weak, particularly for children with complex chronic conditions, who place a disproportionate financial burden on the healthcare system. Resources from ARRA should be specifically targeted at studying best practices in the management of children's health, both for high volume common pediatric conditions (screening, common infections, mental health) as well as less common but high morbidity/cost conditions (prematurity and its sequelae, neurological disorders, congenital syndromes, congenital heart disease). Research networks will be required to study many of the less common conditions, and money should be dedicated to funding such collaborative research networks. Success in understanding and then implementing best practices through collaborative networks has been demonstrated in cystic fibrosis, which could serve as a model for other relatively uncommon but high morbidity/cost pediatric conditions.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

I use naturopathic drugs and am feeling good these daus after wasting $35,000 trying to diagnose cause and not treat cause.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

None of this bureacracy was around during the nineteenth and twentieth centuries when American physicians put this nation at the very cutting edge of surgical techniques, pharmaceuticals, and innovations of every other kind. It is precisely what we do not need.

It sounds like something out of the old Soviet Union.

Our nation has excellent medical care. When we measure infant mortality, we measure every infant with signs of life, whereas other nations inflate their numbers by NOT doing so- in some cases the child has to live 3 days to be counted a live birth.

We have excellent lifespans when violence is deleted; physicians cannot control the social pathologies involved in violence.

We have much better cancer survival statistics than other industrialized nations.

What we DO NOT need is more government interference in medical care. The more there is, the worse things become. I have seen that very clearly in 27 years of practice, including 8 years emergency room experience in a big city hospital, which went broke because of Medicare and Medicaid.

Let's see this "Comparative Effectiveness " stuff adapted for Congress and the Executive and Judicial branches before we further cripple the nation's physicians with it. Those physicians are getting fed up.

What is needed is a return to true insurance to protect against big losses, not pre-paid medical care in which every cut and sore throat is run through a gigantic, costly bureaucracy.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

CER will be an important component in any reform measure. Hopefully, the agency will, remain true to it's mission and protect the public from those who wish to manipulate medical markets for their personal gain.

As the Administration's efforts towards reform proceed over the next several weeks, it is my hope that ALL proposals be considered, ie, Single Payer Medicare for All. Failure of this Administration to enact true reform for the American people will result in a weakening, not only of our economy, but the very fiber that holds our democracy together.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

I note the following statement in the draft CER definition:"This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness."

I implore the council to set aside proportionate funds to build the methods and informatics base for the scale and quality of comparative effectiveness research that this country needs. In particular, funds should be targeted to ensuring that the design and results of primary comparative effectiveness studies (e.g., interventional and observational studies) are available in

standardized computable form, not just in PDF. Such an informatics infrastructure would increase the efficiency and therefore the value of each dollar spent on CER.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Need to educate public more that doctors don't have time to review hundreds of articles and then make the smartest choice avialable. We are drowning in commericials and pharm rep detailing and super expensive medications and treatments are administered due to lack of information. Media likes sensational news, they will make a huge issue of isolated cases where treatment was difficult to get because of this process. The best defense is offense, so more publicity should be given how this will help far more people than hurt them.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Overall, the focus seems to be on conducting specific CER studies on particular clinical topics. Given the early stage of the formalized CER efforts in the US, more priority might be placed on buliding an infrastructure to facilitate CER across topical areas. While priority 5 alludes to this, the language suggests that the broader benefit would be on top of the conduct of a specific study. Thus neither the definition nor the priority statements make explicit reference to infrastructure elements such as: developing new methods for data analysis and modeling, improving the utility of secondary data sets for CER, establishing practice-based research networks,training new investigators in CER, etc.

Submitted by
[personal information redacted]

Comment Type: *General Comment*
Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and

patients, and helps make our practice of medicine more evidence-based. Having read your definition, I am relieved to say I heartily agree with it.

I am particularly glad to see that you have stuck to your evidence-based guns in the face of political pressure and included "cost" as a factor in determining comparative effectiveness. Although it is no means the only factor, I strongly feel that it must be considered where appropriate. I appreciate and applaud you for recognizing that comparative effectiveness research must also look at how much we're paying when treatments are otherwise roughly as effective as one another in terms of health outcomes. Keep up the good work.

Submitted by
Sandra Oliver
Bayer HealthCare LLC
[personal information redacted]

Comment Type: *General Comment*

Dear Council Members,

Bayer HealthCare LLC (Bayer) is pleased to submit the following comments for consideration to the Federal Coordinating Council for Comparative Effectiveness Research (the Council). Bayer appreciates the opportunity to engage in the process by which the Council will develop a national program for coordinating comparative effectiveness research (CER). We believe that CER, if undertaken properly, has the potential to improve clinical outcomes and to improve medical decisions. It is important, however, that CER be conducted appropriately, with the utmost scientific rigor and with all the necessary safeguards in order to ensure that CER does not inadvertently impede patient access to medically appropriate and necessary health care products and services. Without these key elements, CER could harm vulnerable patient subpopulations or interfere inappropriately with the clinical judgment of health care professionals and their interactions with their patients. Bayer looks forward to the opportunity to contribute to the dialogue between the Council, Congress and other relevant stakeholders in developing comprehensive and effective national CER policies.

For over 100 years, Bayer has been dedicated to the development and production of high-quality drugs, medical devices and biologicals that have helped patients lead healthier lives. Bayer is a worldwide leader, with research and business activities focused on oncology, diagnostic imaging, diabetes care, hematology/cardiology, primary care, specialized therapeutics and women s health care. We are committed to providing patients with high quality, safe products and to ensuring appropriate access to our products.

Bayer supports CER initiatives. However, we remain concerned that the Council will inextricably link cost and clinical evaluations. We strongly believe that cost effectiveness should be separate from CER. Comparative effectiveness will be most successful in changing behaviors if these initiatives are designed to enhance health care practitioners clinical judgment in order to promote patient-centered care. Accordingly, Bayer does not support the proposed CER

initiatives that are cost-centric, as we believe that this approach would be unnecessarily contentious and subjective. Further, because there is no consensus as to how to value clinical outcomes, the effect of moving forward now with a cost-focused CER program could impede patient access to treatments without any standards for proper assessment. We fear that a cost-based CER initiative would inevitably lead to a one size fits all solution that would not respect independent health care practitioner clinical judgment and the needs of individual patients and vulnerable patient subpopulations.

As the Council develops CER policies and initiatives, Bayer respectfully urges the Council to consider the following principles:

Informed Medical Decisions: CER should not replace individualized medical decisions with rigid treatment formulas for patient care that do not reflect the needs of individual patients. Health care practitioners must maintain their independent clinical judgment. CER should promote the more effective exercise of that judgment, not seek to eliminate or minimize the value of it. CER should not limit a health care practitioner s medical decisions to a uniform approach. Health care practitioners must be able to continue to evaluate individual factors, subpopulation needs, social and cultural influences, complicating psychological issues and a myriad of other special circumstances which often have a significant impact on care.

Protecting Appropriate Patient Access: Bayer believes that CER can improve the quality and efficacy of health care. However, such research should not be used for coverage decisions by public or private payors. Similarly, CER should not imply or make recommendations to such payors regarding coverage or benefits. To the extent that CER becomes a direct or indirect tool to limit access to care and to ration health care services, it will be rejected by patients and practitioners alike, and it will fail to realize its potential to support appropriate access by educating patients and practitioners.

Inclusive and Transparent Process: Given the Obama Administration s commendable commitment to transparency, we believe that all CER decisions must be developed in a transparent manner. Thus, all assumptions, data, and findings must be made readily available to the public. The public and other interested stakeholders should be permitted to comment on all phases of CER projects, from prioritization of topics through the evaluation phase to the final report. The Council also should hold public forums to allow for stakeholders to provide meaningful input regarding the standards to be used in undertaking CER. Only this kind of complete transparency will permit CER information to be positively viewed by the public. Otherwise, CER will inevitably be viewed with suspicion as a means to surreptitiously ration care. If, however, CER and its limitations are clearly communicated and debated, CER will, we believe, have a pervasive and critical impact on health care.

Accordingly, Bayer urges the Council to ensure that CER is developed through an inclusive and transparent process, which allows for consultation and input from practicing health care practitioners, patients, patient advocacy groups, employers, manufacturers, allied health care professionals, and trade organizations.

Appropriate Oversight: Bayer believes that any government funded CER initiative, whether conducted through existing agencies or a newly formed organization, should be subject to Congressional and executive branch oversight. For example, the Council should, at a minimum, institute a formal mechanism for the appeal of CER findings, hold an annual public meeting to solicit complaints and proposals for improvements, and implement a mechanism to challenge methods and biases, to raise concerns about human subject protection, and address other threats to the integrity of the process. This will ensure that CER is conducted in a manner that is ethical, transparent, scientifically appropriate, and consistent with applicable law.

Evaluating the Circumstances of Clinical Trials: Bayer believes that CER policies should require clinical trials used for CER purposes to accurately reflect real world circumstances. Without such a requirement, there is a potential for CER to lead patients and practitioners in a clinical direction which is inappropriate, ineffective, and potentially unsafe. Accordingly, we strongly urge the Council to review the circumstances under which any evidence is collected to ensure that it is appropriate for consideration in this context.

Interconnectivity: We recommend that the Council require that, wherever appropriate, CER be undertaken in a manner that considers how various interventions work in collaboration with one another. Bayer believes that reviewing interventions in isolation will unnecessarily produce misleading and inaccurate findings.

Evaluations Should Be Promptly Reexamined When New Evidence Is Available: CER policies must recognize the ongoing nature of innovation and that technology, therapeutic treatments and medical devices are constantly evolving. Accordingly, the determination of comparative effectiveness must be considered against the backdrop of this evolution or CER results will not adequately evaluate quality or efficacy. The Council must allow for a mechanism by which prior evaluations are promptly reconsidered in light of new technological advances or additional data. Stakeholders should have the ability to petition for a re-review of a decision based on new research and/or data that has become available. The Council or the agency responsible for the research should also be required to respond to such petitions within a reasonable time period. In order to be clinically relevant, the Council and the agencies undertaking CER must be prepared to reexamine their findings as new data, technologies, and therapeutic treatments and medical devices become available.

Evaluate the Spectrum of Health Care: To improve patient outcomes, CER should be applied to the full range of factors that influence health care and delivery systems, and not just to pharmaceuticals and medical devices, as is all too often the case under some comparative effectiveness or cost effectiveness systems. This should include, for instance, an analysis of the impact of different types of formularies, insurance benefit designs, institutional service models, health care practitioner services, the use of performance and quality measures, adoption of electronic medical records, greater use of information technology, tools to reduce medical errors, improved discharge planning, and the impact of government payors failure to adequately cover or reimburse medically appropriate services and prevention, compliance, and persistency programs.

Communicating with Practitioners, Payors, Patients and Others: As the Council considers CER priorities, Bayer believes that the Council must communicate clearly with practitioners, payors, patients, patient advocacy groups, and others regarding the limits of CER studies and the appropriate interpretation of the resulting data. The risks of over-interpreting CER are all too real. Findings and preliminary reports should prominently and conspicuously describe any limitations in the data and analysis.

* * *

Bayer strongly believes in patient-centered care and urges the Council to use CER as a mechanism to enhance clinical judgment to promote such care. Only through improved health care practitioner and patient awareness can comparative effectiveness improve health care. We hope that the Council strongly considers our concerns regarding CER initiatives that focus on cost as a factor, as such an approach could seriously compromise patient access to innovative therapies, stifle the exercise of clinical judgment, impede adoption of CER findings, and contribute to the creation of a second-tier level of care for the poor and other vulnerable populations.

We thank the Council for the opportunity to comment on the ongoing development of CER policies and initiatives. We look forward to working with the Council as national CER policies and initiatives are developed.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

The importance of standardization seems to be neglected in these definitions. When making a comparison, the standard measures of that analysis have a direct value on the bias in the effectiveness. Providing a statement or reference to standardization may greatly benefit your mission.

Thanks for the opportunity to comment. Our CaverMap device is a unique standard in surgical technique comparative effectiveness, haven been verified in a Phase 2 multi-center randomized clinical study trial in radical prostatectomy.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

It is worthwhile to consider some of the studies presented online by the NEJM.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and patients, and helps make our practice of medicine more evidence-based. Having read your definition, I am relieved to say I heartily agree with it.

I am particularly glad to see that you have stuck to your evidence-based guns in the face of political pressure and included "cost" as a factor in determining comparative effectiveness. Although it is no means the only factor, I strongly feel that it must be considered where appropriate. I appreciate and applaud you for recognizing that comparative effectiveness research must also look at how much we're paying when treatments are otherwise roughly as effective as one another in terms of health outcomes. Keep up the good work.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

1)Validity of screening for colorectal and prostate cancer in nursing home resident populations.2)Management of acute cardiovascular episodes in nursing home populations---criteria for hospitalization

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and patients, and helps make our practice of medicine more evidence-based. Having read your definition, I am relieved to say I heartily agree with it.

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Submitted by
Rachel Groman
American Association of Neurological Surgeons/Congress of Neurological Surgeons/Congress of Neurological Surgeons
rgroman@neurosurgery.org

Comment Type: *General Comment*

Re: Draft Definition, Prioritization Criteria, and Strategic Framework for Comparative Effectiveness Research

Dear Federal Coordinating Council Members,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), which together represent 4,000 practicing neurosurgeons across the United States, we would like to thank the Federal Coordinating Council for Comparative Effectiveness Research for giving us the opportunity to comment on its draft definition, prioritization criteria, and strategic framework for comparative effectiveness research (CER).

The AANS and CNS recognize that CER can serve as a valuable tool to guide sound clinical decision-making by both patients and physicians. As such, our members are committed to determining what medical treatments work best for their patients and our specialty is taking a variety of steps to ensure that the care neurosurgeons deliver is evidence-based. The AANS and CNS actively participated in previous Council listening sessions and recently presented the Institute of Medicine (IOM) with specific clinical research recommendations focusing on spinal diseases for which there is little high quality clinical research to guide practice. Organized neurosurgery also has a robust practice guidelines development program and recently created a new clinical data registry entity called NeuroPoint Alliance, which is partnering with Outcome Sciences, Inc. to build a database platform for a specialty-wide patient registry that will serve multiple purposes, including Maintenance of Certification, clinical research, pay-for-performance and other quality improvement programs.

The AANS and CNS support a well-designed CER system that is transparent, improves quality, relies on public input, supports continued medical progress, and strengthens physician and patient decision-making while preserving individualized treatment. We greatly appreciate that the Council s definition and framework recognize diverse patient populations and the need to respond to the expressed needs of both patients and providers. CER programs must account for the unique circumstances of patients and preserve the independent judgment of physicians.

However, we request that the Council clarify its intent when it refers to the need for CER to respond to the expressed needs of decision-makers. It is critical that CER focus on communicating research results to patients, providers and other decision-makers, and not on making centralized coverage and payment decisions or recommendations. Without further clarification of this statement, decision-makers could be interpreted as giving the Centers for Medicare and Medicaid Services (CMS) or any other public or private payer the authority to use CER to make coverage and payment decisions.

The AANS and CNS also appreciate that the Council s definition and framework recognize a broad scope of research, including medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. However, we encourage the Council to further strengthen the definition so that it indicates that research on each of these interventions focus on all patient subpopulations and not just a few particular patient groups.

We are very pleased that the Council recognizes the need to rely on a variety of data sources and data assessment methodologies. We encourage the Council to specifically consider prospectively obtained outcomes data collected through patient registries, such as the NeuroPoint Alliance, as one example of a data source that can help to better define indications for certain procedures. Directing comparative effectiveness research funds to the creation and/or administration of patient registries, such as the NeuroPoint Alliance, will ultimately result in the production of meaningful data that will help guide clinical decision-making, determine best practices, improve quality, and ultimately lower costs.

While the AANS and CNS support the Prioritization Criteria outlined in the framework, we are concerned that it fails to specify how these priorities should be developed, reviewed and finalized. It is critical that all relevant stakeholders, particularly those who are clinical subject matter experts and provide direct patient care, have a voice in the process through which CER topics are prioritized.

Finally, we request that the Council s definition explicitly state that the purpose of CER is to provide information on clinical effectiveness and patient health outcomes, not cost-effectiveness assessments. CER must not ebb into cost containment, where life or death medical decisions can be based upon the government s financial considerations. The AANS and CNS believe that if CER is carried out in a sound and transparent fashion, it will naturally rid of inefficiencies in our health care system by directing providers and patients to care that is most effective.

Moving forward, we encourage the Council to continue to preserve transparency throughout the many of aspects of the CER process by ensuring that stakeholders have input into research priorities and design and have an equal voice in the governance of a CER entity.

The AANS and CNS appreciate the opportunity to offer these comments, and we look forward to working cooperatively with the Council to develop a fair and meaningful process through which to compare clinical effectiveness and to ultimately improve patient care. If you have any questions about our comments, please contact Rachel Groman, MPH, 202-628-2072, rgroman@neurosurgery.org

Sincerely,

Troy M. Tippett, MD, President
American Association of Neurological Surgeons

P. David Adelson, MD, President
Congress of Neurological Surgeons

cc: Robert Harbaugh, MD, Chair, AANS/CNS Washington Committee
Dan Resnick, MD, Chair, AANS/CNS Quality Improvement Workgroup

Submitted by
Ulyana Vjugina
American Society of Hematology
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Comment Type: *General Comment*

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To: Federal Coordinating Council on Comparative Effectiveness Research

June 10, 2009

The American Society of Hematology (ASH) appreciates the opportunity to comment on Comparative Effectiveness Research (CER) to the Federal Coordinating Council (Council). ASH represents over 16,000 clinicians and scientists committed to the study and treatment of malignant and non-malignant blood and blood-related diseases such as leukemia, lymphoma, sickle cell disease, anemia and hemophilia.

ASH commends the Council for creating a public forum that underscores the importance of input from a broad range of stakeholders interested in priorities for CER. The Council s charge is consistent with ASH s mission to promote the understanding, prevention and treatment of blood disorders, and improve healthcare and patient outcomes with hematologic disease.

ASH believes that timely CER on the following topics will have the highest impact in hematology based on prevalence, disease burden, variability in outcomes in diverse populations

and costs of care. Research in these areas has the potential to address the gaps in knowledge and uncertainty within the clinical and public health communities, ultimately leading to improved quality of care, outcomes and cost-effectiveness.

I. Management of Patients with Sickle Cell Disease (SCD).

The survival of children with SCD has improved with early identification of affected infants and enrollment in comprehensive pediatric hematology programs. However, there is a paucity of comparable adult-oriented programs and the growing young adult sickle cell populations face ongoing challenges in obtaining effective and comprehensive care. CER should evaluate health care transition training programs for adolescent patients. Many adult patients do not have access to physicians with expertise in sickle cell disease on an ongoing basis. There is a need to evaluate alternative medical care models for patients in the community setting. Examples include co-management with primary care physicians and utilization of telemedicine.

The few randomized clinical studies that have been performed addressing management of patients with SCD have had high impact on improving outcomes. Observational studies have also had major influence on clinical practice (e.g., treatment of acute chest syndrome). There are opportunities to use CER to identify optimal approaches to encourage the adherence to proven preventive and treatment interventions. Administrative and clinical data sets such as state Medicaid claim and hospital discharge files would provide useful resources to assess current practices and measure outcomes of interventions. The following topics are examples to be considered:

A. Pain management. The utility of clinical pathways in the outpatient, emergency department, and inpatient settings needs to be addressed. CER analysis of multidisciplinary and multimodality approaches to pain management for patients with SCD compared with conventional pharmacological therapies would provide opportunities to identify treatments resulting in improved patient quality of life and cost-effectiveness.

B. Hydroxyurea therapy. Hydroxyurea therapy is underutilized in the management of symptomatic adult patients. CER can be employed to evaluate programmatic interventions at the patient, provider, and health care system levels to enhance appropriate use of hydroxyurea therapy.

C. Red blood cell transfusions. Guidelines are available for the use of transfusions in the management of sickle cell complications but they are based on limited data. CER can be used to address questions such as the extent of phenotype matching of red cells used for chronic transfusion and techniques of transfusion administration (simple vs. exchange) for specific acute indications.

D. Clinical decision support tools. Adults often receive their care from physicians with few sickle cell patients in their practices (e.g., community based hematology/oncology and primary care physicians). Management of sickle cell-related issues such as hydroxyurea therapy and health maintenance (e.g., screening for pulmonary hypertension, renal disease, ophthalmologic complications) can be challenging in these settings. CER can be employed to address the utility of clinical assessment tools, electronic health record reminder systems, and other approaches to optimizing receipt of appropriate intervention.

II. Specialized Challenges in Thrombosis.

Insertion of inferior vena cava filters (IVCF) is widely performed in patients with, or at risk of, venous thromboembolism. IVCF likely prevent pulmonary embolism (PE) in highly selected patients with acute venous thromboembolism (VTE) who have absolute contraindications to therapeutic dose anticoagulation. However, the majority of IVCF are placed in patients with either no active VTE (prophylactic IVCF) or those with acute VTE who do not have an absolute contraindication to anticoagulation.

However, there is little evidence to guide the use of IVCF. Only one randomized trial has been performed in which patients with acute VTE were randomized to anticoagulation with or without IVCF. The study demonstrated an acute reduction in PE, with no impact on mortality and an increase in VTE over 8 years of follow-up, leading the authors to recommend against routine use of filters in patients who can be anticoagulated. There have been no randomized controlled trials examining the use of retrievable filters or the use of filters for the prevention of pulmonary embolism in patients who do not have acute venous thromboembolism. Evidence-based guidelines have recommended against the use of IVCF for the prevention of pulmonary embolism in patients who do not have acute DVT. Despite this guideline recommendation, the majority of IVCF in the United States are placed for this indication. For example, IVCF use is routine in some trauma centers. This practice occurs despite the fact that insertion of IVCF is expensive (estimated to cost in excess of US$5000 per use), that IVCF cause otherwise avoidable deep vein thrombosis (at an estimated US$5000 to US$10,000 per event) and that IVCF may provide physicians with an excuse to neglect the administration of a pharmacologic prophylaxis, which is proven to be the most effective and cost-effective treatment for patients at high risk of VTE.

Data on insertion of IVCF should be easily accessible. Indications and complications of their use should be discernible. Comparison of event rates in patients with and without IVCF matched for other co-morbidities should also be available. Such an analysis would likely establish definitively that IVCF use is both more expensive and more toxic than alternate, effective therapies currently recommended by consensus guidelines.

III. Management of Patients with Myelodysplastic Syndrome.

Myelodysplastic syndromes (MDS) affect older adults with a rapidly rising national disease burden owing to the aging of the American population. Patients with MDS have a chronic bone marrow failure disorder often associated with other co-morbidities, and are cared for by primary care and hematology subspecialists. Patients and health care providers must address complications related to the disease process itself that include cytopenia-associated risks for infection or bleeding, the risk for evolution to acute myeloid leukemia (AML), and secondary organ complications arising from red blood cell transfusions and iron overload.

Although evidence-based guidelines provide management pathways for physicians that utilize an array of FDA approved therapeutics, the impact of these costly treatments on the disease natural history and co-morbidities remains largely undefined. Large prospectively randomized therapeutic trials represent the benchmark to define the benefit for most interventions, but size

and the ethical challenge of non-treatment arms prohibits such definitive studies. Important insight into the clinical benefit of interventions could be obtained from the analysis of large federal health claims databases such as the Medicare Standard Analytic File. Data from patients diagnosed in a given year can be mined for subsequent billings for acquired co-morbidities such as diabetes mellitus, cardiac and liver complications, survival and red blood cell transfusions.

Given the large size of the database, important insight can be gathered regarding the success of health care delivery strategies in the U.S. that is applicable to the population of patients at large, rather than to those that meet the restrictive eligibility of registration trials. CER comparing usual supportive care versus care by protocol-driven community-based, advanced health practitioners and teams may lead to a reduction of variability of care, costs, and improved quality of life. Examples of CER that would have an impact on care and provide insight as to the cost benefit of treatments include those related to current management practices for iron loading and disease modifying therapies:

1. Does the use of an iron chelator delay or prevent end-organ co-morbidities, or extend survival in lower risk transfusion-dependent patients?
2. If so, what proportion of patients that may benefit have access to such treatment?
3. Using current practice regimens for hypomethylating agents such as azacitidine or decitabine, is there a demonstrable survival benefit or difference in resource utilization in patients with higher risk disease?
4. How often is the use of an erythropoietic stimulating agent (ESA) effective in preventing the need for transfusion in the lower risk MDS population? What is the impact of ESA response on the natural history of low risk MDS?

Information from an analysis of the latter may support prior ASH recommendations to the CMS against the restriction of ESA access to those individuals with the greatest potential for benefit. Such CER analyses would provide critical information as to the best management strategy for the MDS population at large to modify disease natural history, the magnitude of benefit to patients, and cost-effectiveness.

IV. Use of Transfusions.

Transfusion therapy remains essential to the successful treatment of oncologic and hematologic disorders, many surgical procedures, and traumatic injuries. However, the appropriate threshold for transfusions in various clinical situations as well as the appropriate dose of the blood component transfused remains unclear. Modification of blood components by procedures such as irradiation or leukocyte reduction have an important role in improving transfusion safety; however the indications for such procedures are unclear in many patient populations and are applied heterogeneously. The risks of transfusion beyond that of transfusion-transmitted infection and transfusion reaction remain controversial. For example, there continues to be considerable debate about whether transfusion is associated with an increased rate of cardiac morbidity and multiorgan failure. CER comparing outcomes with different red blood cell transfusion thresholds in patients with cardiac disease, hematologic malignancy or surgery will help to most effectively manage a blood supply that frequently must address shortages. A better

understanding of adverse outcomes related to transfusion will allow physicians to better weigh the risks and effectiveness of transfusion therapy.

Thank you for the opportunity to submit these comments. Please contact ASH Scientific Affairs Manager, Ulyana Vjugina, PhD, at (202) 776-0544 or uvjugina@hematology.org for any additional information.

Submitted by
Andrew Whitman
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Comment Type: *General Comment*

Varian s Medical Systems is the world s leading manufacturer of medical devices and software for treating cancer and other medical conditions with radiotherapy, radiosurgery, proton therapy, and brachytherapy.

We greatly appreciate the opportunity to comment on HHS s implementation of comparative effectiveness research funds allocated to AHRQ, NIH and the Secretary in the American Recovery and Reinvestment Act of 2009.

Varian supported the inclusion of funding for comparative effectiveness research in the American Recovery and Reinvestment Act of 2009. This funding was an important first step that will bring increased quality and transparency to our health care system.

As we continue to reform our health care system, Varian supports the creation of a non-governmental, independent Comparative Effectiveness Institute comprised of experts in the appropriate medical and academic fields to advise and recommend to Congress and the Centers for Medicare and Medicaid Services the procedures that are effective for treatment. These recommendations will be based on research occurring in government agencies, academia, and the private sector. This research will determine the therapies, treatments and diagnostic procedures that are considered a standard of care and should be available to all Americans. In addition, Varian hopes that Comparative Effectiveness Research will lead to a process that rationalizes treatment alternatives. We would like to offer some specific comments and recommendations on comparative effectiveness as it relates to cancer care, and specifically radiation therapy.

Measuring Outcomes

When comparing the outcome of different cancer therapies, survival is the simplest but not always the key metric for measuring outcomes. For example, when comparing the outcomes for early stage prostate cancer, survival from radical prostatectomy and radiation therapy is similar, so one could contend that the outcomes are the same. However, comparative side effects of the treatments are vastly different. As a result, comparative effectiveness studies need to focus not only on survival as an outcome, but also side effect toxicities. This is also true when comparing

radical mastectomy with lumpectomy followed by radiation. Patients will differ widely in their perception of the importance of these side effects.
Some women will be intolerant of losing an entire breast, and some will find it acceptable. When the council compares outcomes from diverse therapies, it will need to accommodate these differences as valid, even though there is no objective standard to compare them.

In addition, outcomes at many small clinics may differ significantly from the outcomes achieved by major research hospitals. When comparing the outcomes of different approaches, the council should not just consider the outcomes of major trials at research institutions, but also the outcome at smaller, lower volume facilities and physicians.

Allowance for the Development of New Technologies

In the case of cancer treatments using radiation therapy, improvements are often made based on input from customers, retrospective studies of the likely causes of poor outcomes, and extensive understanding of the way radiation acts on healthy and diseased organs. Since at times it can take five to ten years to know whether an innovation is clinically effective, physicians use calculated dose distributions and/or imaging techniques as a surrogate to predict improved outcomes. We recommend that the Council develop ways to predict the potential value of new technologies using means other than short term data, and then verify these predictions using long term follow-up studies. In recognition of the fact that new technologies are continually introduced and older ones are modified, the Council should monitor this and allow for comparative effectiveness research to accommodate these developments.

Varian Medical Systems looks forward to working with the Federal Coordinating Council on Comparative Effectiveness and appreciates the opportunity to comment on this important topic.

Submitted by
Andre Williams
Association of Black Cardiologists, Inc
awilliams@abcardio.org

Comment Type: *General Comment*

Patients, doctors and providers with a voice at the table to discuss the future of CER. Moving forward, this is the only way comparative effectiveness will work properly. And when patients come to the table, we must see to it that all patient populations are represented. We will work to ensure that the government includes all people people of color, the elderly and people with disabilities, among others when designing new CER studies. It is only fair that medical innovation and future research benefit the needs of all Americans.

We applaud the Congress for introducing a CER bill that puts patients first. Moreover, we are confident that this approach to new CER will enable patients and healthcare providers of all backgrounds to continue to have access to the best possible care and most accurate information.

The ABC, located in Atlanta, GA, was founded in 1974 to bring special attention to the adverse impact of cardiovascular disease on African Americans. A nonprofit organization, the ABC has an international membership of more than 600 health care professionals. The ABC is dedicated to eliminating the disparities related to cardiovascular disease in all people of color. For more information, call 404-201-6600 or visit www.abcardio.org.

Submitted by
Alexandra Clyde
Medtronic, Inc.
alexandra.clyde@medtronic.com

Comment Type: *General Comment*

Dear Secretary Sebelius and Distinguished Council Members:

Medtronic is the world s leading medical technology company, specializing in implantable therapies that alleviate pain, restore health, and extend life. Our technologies combine advanced therapeutics and diagnostics to assist physicians and patients in the management of chronic conditions such as heart failure, diabetes, Parkinson s disease, and other debilitating illnesses.

Medtronic supports increased investments in comparative effectiveness research (CER) to better inform physicians about treatment options and help patients make decisions about the clinical effectiveness of medical care. We understand the value of using evidence-based approaches to ensure that the right patient receives the right care at the right time, and we are firmly committed to the principles of evidence-based medicine and the continual research and development necessary to support innovative therapies that improve health outcomes for patients and bring value to the healthcare system. Toward that end, our technologies and therapies have withstood rigorous health assessments around the globe.

Medtronic believes that CER should be conducted in a consistent, transparent, and methodologically rigorous manner, allowing input from a broad group of stakeholders at key junctures throughout the topic selection, study design, results interpretation and results dissemination processes. It is clear that broad consensus exists surrounding these principles as evidenced in documents such as the policy options for delivery system reform outlined by the Senate Finance Committee, the Comparative Effectiveness Research Act of 2008 (S.3408), as well as the recently introduced Comparative Effectiveness Research Act of 2009 (H.R.2502)and the Patient-Centered Outcomes Research Act of 2009. This consensus is encouraging as we believe these aspects are critical to ensure that CER findings become a useful and reliable factor in clinical decision-making.

In keeping with the principles outlined above, we offer comments on the following questions outlined in the April 10, 2009 Federal Register notice:

" What information on the Coordinating Council s activities would be most useful?

In order to ensure an appropriate level of transparency the Council should post the following information on a public website:

?A schedule of all meetings the Council is planning over the next year;
?A draft and final list of recommended areas for investment, including the rationale the Council used to identify them;
?A draft of the June 30 report to Congress and Secretary of HHS and solicitation of public comment on this report;
?Drafts of all government-sponsored CER and solicitation of public comment at critical intervals in the process (topic selection and prioritization, draft key questions, study design, and draft report); and
?All public comments the Council receives on its activities and its publications, as well as its responses to these comments;

"What steps should the Coordinating Council consider to help ensure that public-and private-sector efforts in the area of CER are mutually supportive?

Medtronic appreciates the Council s efforts in coordinating public listening sessions to gather input from a broad range of stakeholders. While the listening sessions provide a basic forum for public input, as was emphasized in a number of instances at these sessions, there should be more formal opportunities for broader levels of stakeholder input.

A broad set of stakeholders should be continually consulted to ensure that CER and its findings are relevant to the needs of patients and clinicians. To support this, all public and private agencies receiving American Recovery and Reinvestment Act (ARRA) funds to conduct CER should adhere to the following standards for stakeholder engagement:

?Establishment of a 30-day public comment period on the topic selection, draft key questions, study design, and draft report
?Public posting of comments received, including information on how those comments will be addressed

In addition, the Council should recommend a process to ensure that HHS contracting agencies conducting comparative effectiveness research will follow the methodological standards and processes (e.g., posting reports for public comment, etc.) determined by the Council. We suggest that the Council recommend processes for monitoring and enforcing adherence of the agencies to these standards and processes.

"What types of investments in infrastructure for CER should the Coordinating Council consider?

It is critical that the Council develop and periodically update methodological standards (and procedures for the use of such standards) regarding outcomes measures, risk adjustment, statistical protocols, evaluation of evidence, and conduct of research to ensure accurate and scientifically based CER.

When developing the methodological standards to guide for CER, Medtronic recommends the following:

?Include patient advocates, professional societies, practicing clinicians, leading academic researchers, and industry representatives, in the development of these standards.
?Interventions should be studied in a comprehensive fashion and research should be tailored to the specific intervention being evaluated.
?All study limitations and limitations of the underlying data should be disclosed in the research report in order to prevent confusion and potential misinterpretation by users. All agencies generating research reports appropriately communicate limitations and consider including a formal peer-review of the draft research report in order to ensure that the research limitations have been appropriately disclosed.
?The methodological standards should include a detailed discussion of the research challenges posed by device-related studies and recommendations for how to account for these challenges in the CER methodology. This discussion should include the challenges of randomization and blinding in devices-related studies and the importance of considering the effect of device implant training and experience of the physicians on clinical outcomes.

Medtronic commends the Council for its efforts to coordinate and guide the increased investment in CER. We appreciate the opportunity to provide these comments. If you have any questions related to these comments, please contact me at 763.505.2660 or at alexandra.clyde@medtronic.com .

Sincerely,

Alexandra T. Clyde

Submitted by
Richard I. Smith
Senior Vice President, Policy
Institute for the Advancement of Social Work Research
jzlotnik@naswdc.org

Comment Type: *General Comment*

The Institute for the Advancement of Social Work Research offers the following comments on the Definition and Framework. If you need additional information, we will be pleased to provide it, as Comparative Effectiveness Research must deal with the complexity of not only the individual needs of those requiring health care services, but also the complexity and diversity of service delivery system(s) themselves.

The Institute for the Advancement of Social Work Research (IASWR) would like to commend the Council for its work in providing a broad definition of Comparative Effectiveness Research

(CER). As stated in the draft definition, CER is not only an important piece in helping doctors and patients identify the best strategies for treating certain conditions, but it also goes beyond the bounds of physical health. It is valuable to the field and to consumers, to see a definition that encompasses vulnerable and underserved populations, behavioral change strategies, and delivery system interventions. However, these are complex areas that will require sophisticated and multi-method CER research efforts.

CER needs to be at the forefront in increasing our understanding of how to best meet the health, mental health and psychosocial needs of underserved populations. In a report released on June 9, 2009, HHS Secretary Sebelius reported that:

" Forty-eight percent of all African Americans adults suffer from a chronic disease compared to 39 percent of the general population.

" Eight percent of white Americans develop diabetes while 15 percent of African Americans, 14 percent of Hispanics, and 18 percent of American Indians develop diabetes.

" Hispanics were one-third less likely to be counseled on obesity than were whites -- only 44 percent of Hispanics received counseling.

" African Americans are 15 percent more likely to be obese than whites.

These statistics are not just a snapshot, but a clear picture of the wide array of conditions facing different populations, many of which are vulnerable or underserved. CER strategies must ensure attention to these populations and study mechanisms for receiving adequate and efficient health care.

As highlighted in the definition, assumptions and framework, underserved and vulnerable populations are a priority of CER. This then requires that there be planning to determine studies across and within populations, to fully understand diversity and health disparities. For example, one cannot categorize all Asian populations or African American populations but rather must take into account genetic history, socio-economic and education status health literacy, economic self-sufficiency, access to health care services and health, mental health and psychosocial status. That discussion cannot focus on medical conditions alone, but must also look at the intersection of medical, psychosocial, and mental health, community supports and the organization and availability of relevant health care services.

The provision of services provided to patients is just as vital as the patients themselves. Within the Prioritization Criteria Section there needs to be greater clarification in the third criterion which states:

Uncertainty within the clinical and public health communities regarding management decisions.

From this criterion, it is unclear whether the statement refers to mismanagement of services being provided or something different.

In addition to comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions, CER also needs to include service systems in those comparisons. Without effective service systems, it does not matter how effective the treatment may prove to be. IASWR welcomes the opportunity to work with the Council and with HHS on furthering the utility of Comparative Effectiveness Research, especially in working with individuals and families with complex and co-occurring needs.

The Council also should be commended for recognizing the importance of capacity building related to CER, in regard to both researcher training and methodology. Social work researchers, working in communities, using quantitative, qualitative and action research methodologies can contribute to and also benefit from such capacity development efforts

Once again thank you to the Council for all of its hard work on CER.

Submitted by
Les Paul
National Pharmaceutical Council
lpaul@npcnow.org

Comment Type: *General Comment*

On behalf of the National Pharmaceutical Council (NPC), thank you for the opportunity to comment on the draft comparative effectiveness research (CER) definition, prioritization criteria, and the proposed strategic framework that was developed by the Federal Coordinating Council on Comparative Effectiveness Research (FCCCER). The definition, prioritization criteria, and the strategic framework for CER can play an important role in improving patient health outcomes, and we congratulate the FCCCER on this critical effort.

About the National Pharmaceutical Council

Briefly, the National Pharmaceutical Council sponsors and conducts scientific analyses on the appropriate use of pharmaceuticals and the clinical and economic value of improved health outcomes through pharmaceutical innovation. CER and its foundation of high quality scientific evidence are important areas of focus for NPC. It is our goal to ensure that sound evidence is recognized by independent experts, considered appropriately by private and public payers, reflected adequately in benefit designs, and incorporated into clinical practice. NPC was established in 1953 and is supported by the nation s major research-based pharmaceutical companies.

Draft Definition of CER

When the $1.1 billion in federal funding was first allocated for CER, there were many unanswered questions regarding which projects would be prioritized, what kind of strategic framework would be developed, and how the research would be conducted and disseminated. To address those questions, NPC and other health care stakeholders provided recommendations in previous testimony that priorities for CER should:

* Focus on conditions with the greatest impact on morbidity and cost, such as chronic conditions like cardiovascular disease, chronic respiratory diseases, cancer, diabetes, arthritis, and serious mental health conditions.

* Include all major therapeutic options used to treat those conditions such as drugs, medical and surgical procedures, diagnostics, and medical devices.

* Take into account the needs of patient subgroups who may respond differently to therapeutic options based on demographic characteristics, genetic variation, and coexisting medical conditions; and

* Express clear support for the development of new CER methodologies, such as analysis of non-randomized studies of treatment effects using secondary databases, practice-based clinical practice improvement studies, more accurate modeling and simulation techniques, and methodologies that ensure optimal interpretation and application of CER in a variety of patient care settings.

NPC is pleased that the draft definition of CER encompasses these important concepts in a broad and thoughtful manner.

Draft Prioritization Criteria

The general nature of the prioritization criteria allows for considerable flexibility in their interpretation. While they represent a good foundation, clarification is needed to ensure that CER funding decisions will be made in the best possible manner and result in useful information that improves clinical decision making for health care providers and patients.

In particular, NPC is concerned about the reference to the "time necessary for research," and whether this would preclude lengthy or more in-depth projects from consideration. Proposed prioritization of research topics and studies, their associated research time frames, final study outcomes, and related information should be made transparent to all stakeholders and should be disseminated in a timely manner To maximize this potential, the FCCCER should prioritize the funding of an assessment of strategies to ensure the continuous evaluation of new evidence related to specific health care technologies -- for example, how best to determine when a health technology assessment should be revised based on new clinical information.

The criteria also suggest that CER "lays the foundation for future CER or generates additional investment." CER not only lays the foundation for future CER, but also the foundation for future innovation. How the agenda and conduct of CER develops has the potential to influence incentives for innovation and we would recommend that the study of this important question be an explicit interest of publicly funded CER.

Additional Factors for Consideration in Priority Setting Under the Strategic Framework

Moving forward, it also will be important to consider other key factors in the selection of the highest priority research.

* First, it will be important to conduct research to define rigorous, high quality, and validated CER methodologies that are focused on providing timely, accurate and balanced information in order to assist clinical decision making.

-- These questions include, but are not limited to, defining how best to address the full range of health effects of a new technology including quality of life, functionality, and productivity, as

well as how best to appropriately characterize the strengths, weaknesses, and limitations of various underlying health technology assessment analytic techniques.

-- In order to minimize the likelihood for inaccurate or inappropriate interpretation of CER, we suggest the inclusion of a transparent and readily accessible description of the strengths, weaknesses, limitations, and potential for generalizability of the findings of CER utilizing varied experimental and non-experimental research designs.

* Second, and consistent with our comment on the prioritization of the study of the impact of CER on innovation, the strategic framework should implicitly assume that innovative technology is an external input to the CER framework. It should be encompassed within and considered integral to the framework.

* Third, the agenda for CER should be driven by the condition and the "key unanswered questions" in the context of that condition. Answering these questions may require comparisons between different types of technologies, processes, or procedures that may be considered to treat the condition; for example, the framework should reflect the need for comparisons of drug vs. surgery, drug and diagnostic vs. procedure, procedure vs. surgery, or other combinations.

* Fourth, comparisons should also include delivery system architecture options, insurance plan designs, methods for primary/secondary prevention, and approaches to provider incentives to effect improvements in health.
The National Pharmaceutical Council appreciates the opportunity to take part in this critical dialogue and stands ready to assist FCCCER as it moves forward with the development of the CER definition and criteria. Thank you.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

I wanted to share a HECON model, that I have been working on for almost 7 years, around this area. WHen I worked at a large teaching hospital in Pa, we began to address issues this way. Thanks

Replacing pharmacoeconomics with 'thereconomics'In urging health system pharmacists to move toward a return-on-investment model to rationalize their expenditures, Fred Pane, RPh, of Premier, has coined the term "thereconomics" by combining the words therapy and economics. "For years, pharmacy managers have dealt with the budgetary issues surrounding pharmaceuticals," says Pane. "That economic model is called pharmacoeconomics, created to try to explain the value of drugs. However, it is very difficult to meet with hospital finance staff and explain pharmacoeconomics. It relates only to pharmaceuticals and doesn't address the big issue, which is the various patient treatment options, both drugs and non-drugs, and how they replace each other or support clinical outcomes."

The National Library of Medicine's Medical Subject Headings (MeSH) defines pharmacoeconomics as "economic aspects of the fields of pharmacy and pharmacology as they apply to the development and study of medical economics in rational drug therapy and the impact of pharmaceuticals on the cost of medical care. Pharmaceutical economics also includes the economic considerations of the pharmaceutical care delivery system and in drug prescribing, particularly of cost-benefit values. [sic]"
Pane defines thereconomics as "measuring both the financial and clinical quality outcomes associated with various treatment options, including drugs, devices, and surgical and interventional procedures." He says: "It is therefore all inclusive, which pharmacoeconomics is not, and can be applied to any patient treatment. It maintains a balanced scorecard approach to all pharmaceutical operations, both clinical and financial."

Submitted by
Naomi Aronson, PhD
Executive Director
Technology Evaluation Center
Blue Cross Blue Shield Association
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Comment Type: *General Comment*

The Technology Evaluation Center of the Blue Cross and Blue Shield Association (BCBSA), an association of 39 independent Blue Cross and Blue Shield Plans that collectively provide health insurance benefits to more than 100 million Americans, appreciates the opportunity to comment on the Draft Definition of Comparative Effectiveness Research (CER) for the Federal Coordinating Council.

We support the Federal Coordinating Council for Comparative Effectiveness Research, as authorized by the American Recovery and Reinvestment Act (ARRA), in its work to coordinate research and guide investments in comparative effectiveness research funded by the Recovery Act.

The draft definition, we believe, will result in research that will give clinicians and patients valid information to make decisions that will improve the performance of the American healthcare system

Thank you for giving us this opportunity to express our support.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

What doesn't work for one, amy work for another. Keep all options open - it could be you, or your family who needs them.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

The news that the new health plan will in part contain a singular national insurance plan available to Americans of low income is a favorable and necessry step to address the health care crisis in the US.

I will participate in that program, rejecting the private insurance of Congressional Repulicans who apparently are supporting the status quo of expensive medical industry costs which ONLY benefit practioners and insurance companies.

Once again, I was tortured by SSA/CMS and would appreciate a total revamping of both agencies, who at best have been unresponsive to my needs and decisions.

Submitted by
Joyce Mithcell
American College of Medical Informatics
[personal information redacted]

Comment Type: *General Comment*

We appreciate the efforts of the Federal Coordinating Council in drafting the definition, prioritization criteria, and strategic framework for comparative effectiveness research (CER), and we are grateful for the opportunity to provide feedback on these documents.

Feedback on the definition:

" The Fellows of the American College of Medical Informatics have a vested interest in these documents, specifically as they relate to the role of information systems in CER.

" Currently the nation is embarking on a massive investment to improve the state of Healthcare Information Technology (HIT) throughout the healthcare enterprise. HIT has the potential to fundamentally change the healthcare delivery process. Evaluating the effectiveness of various HIT interventions will be an integral part of evaluating and guiding this massive investment.

" We are concerned that HIT-based interventions are not specifically mentioned in the draft definition. Although some may argue that HIT might be included under any of the phrases,

medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions none of these phrases have traditionally been applied to HIT-based interventions, such as Decision Support Systems, Heath Information Exchanges, or Computerized Order Entry. Thus, whether HIT interventions are ultimately evaluated is left to later interpreters of the definition. This seems to be an unnecessarily high-risk approach.
o We hope that the Council will consider our request to include "information systems and technology" with the examples of interventions provided in the definition of CER.

Feedback on the strategic framework:
" In the third paragraph of the description of the framework (CER investments and activities), we would request that the research example be re-phrased so that it suggests a broader sphere of research than medication-related CER. This could be written as (change is in quotes): Research, e.g., comparing interventions for a specific condition or discharge process A to discharge process B for readmissions.

" In the CER themes: type of intervention should include "information systems": Type of interventions, e.g. devices, information systems, behavioral change, delivery system.

" Figure 2: in the Cross-Cutting Investment Opportunities box, "Under-researched interventions" should include information systems in the list of examples.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Thank you for all the hard work that you do over there at HHS. Unfortunately most Americans, myself included, have little idea of what DOES actually happen at HHS.

But we do know that our perscription drugs cost too much, and have side effects far scarier than the conditions they are meant to treat. Rectal bleeding from a nasal allergy medication?! Seriously?

We also know that many of the allowable additives in our food cause everything from cancer to diabetes, to obesity, and beyond. I'm not trying to to be too fussy, but is there really a reason my dessert should contain several of the same ingredients as my shampoo, and I'm not talking about coconut oil here..

We are 29th on the scale of medical goodness in the world, but we spend more than anyone else. So a part of the healthcare problem, the main part, is that we're not getting a good deal. Americans are doing the equivalent with medical care of someone shopping at the 7-11 for their monthly groceries.

Good luck and keep up the good work, but a word to the wise, you might want a dang good speech explaining some of this stuff.

Submitted by
Ned Norris Jr.
Tohono O'odham Nation
pete.delgado@tonation-nsn.gov

Comment Type: *General Comment*

TOHONO O ODHAM NATION
ARRA/COMPARATIVE EFFECTIVENESS RESEARCH RECOMMENDATIONS

ISSUES:
The American Recovery and Reinvestment Act (ARRA)/Comparative Effectiveness Research (CER) debate has elicited concern by tribal health leaders and health care professionals who conduct research in Indian Country. American Indian tribal leadership will ask, first, How will the Obama Executive Branch implement the standing Presidential Executive Order for tribal consultation (Clinton 2000) and supporting implementation memoranda that require that all Executive agencies ensure that there is meaningful and timely tribal input in formulating and implementing the ARRA of 2009, and subsequent Sec. 804 to establish the Federal Coordinating Council (FCC) CER? Secondly, does the FCC for the CER fully understand the special circumstances that Tribes face, which include the inability of tribal people to access primary, specialty, emergency services due to geographic constraints and by the historic and continuing under funding of the Indian health care system?

The U.S. federal government recognizes the debt owed to tribal governments. In 2000, President William J. Clinton issued the Executive Order #13175, Consultation and Coordination with Indian Tribal Governments , and the Department of Health and Human Services (DHHS) reissued an earlier Department Tribal Policy, requiring that each HHS Operating and Staff Division have an accountable process to ensure meaningful and timely input by tribal officials in the development of policies that have tribal implications. Certainly, the ARRA s CER Policy would be under this umbrella .

RECOMMENDATIONS:
The FCC for CER is charged to develop recommendations to coordinate research and guide the use of resources contained in ARRA to advance improvement in the U.S. health care system. The following recommendations focus on the inclusion of Indian health, tribal and urban Indian health programs in this process

" Allow additional time for HRAC to consider developing a tribal consultation process in order for interested Tribes to provide their input into the FCC/CER plan and implementation.

" Request that AI/AN representative be assigned to FCC/CER from the Indian Health Service of the DHHS.

" Consider establishing separate research guidelines and measures for Complementary and Alternative Medicine (CAM) and AI/AN traditional healing practices, but do not exclude them from future CER consideration.
" Concentration by CER in the areas of health promotion, disease prevention and community based interventions will benefit tribal communities.
" Concentration by CER on clinical effectiveness rather than cost effectiveness will benefit tribal communities.
? CER studies should be broad enough to include an assessment of minority and disability groups and other smaller populations such as American Indian Tribes as it has been noted that in CER minority and disability groups have not been given a broad enough population sample. (Cancer Policy Monitor, 2009).

BACKGROUND:

There are more than 560 federally recognized Tribes in the U.S and a coalition of over 50 health and academic organizations, and individuals dedicated to improving the health care of AI/AN report that the disparity in health care for Indian people continues to escalate nationwide as AI/AN live almost four years less when compared to other U.S. populations because;

1. AI/AN youth are more than twice as likely to commit suicide,
2. AI/AN people are 670% more likely to die from alcoholism,
3. 650% more likely to die from tuberculosis,
4. 318% more likely to die from diabetes, and
5. 204% more likely to suffer accidental death.

(Friends of Indian Health, 2009).

The poor state of health among many Tribes requires community based and culturally appropriate treatment and research methodologies that can help to break the cycle of chronic illness and related disease including addiction.

i. Improving the Quality of Care in the Indian Healthcare System:

The FCC is concerned about the quality of care experienced by individual patients served in federal health care systems. This component of CER is applicable to the Indian healthcare system and would help to identify measures that are needed to improve the quality of care. The IHS Strategic Plan (2011) states that a major strategic objective of the agency is to improve the safety and quality of care in IHS, tribal and urban Indian health care settings. Steps to improve the system include: 1) the identification and reduction in adverse medical events; 2) integration of evidence based practices into clinical, public health and administrative practices; 3) timely adoption of new medical technologies; 4) advance electronic medical record keeping and connectivity within the system; and 5) ongoing cost effectiveness analysis. Should the CER Council recommend an assessment of the strengths and weakness of the Indian health care system this will provide the opportunity for IHS Quality Management (QM) Program to pursue the steps needed to accomplish meeting its own strategic objectives and implement needed systemic changes to resolve problems areas. The IHS QM goals are integrating, evaluating and tracking best practices and expanding best practice administrative and clinical models known as Centers of Excellence that already exist in the system.

ii. Complementary and Alternative Medicine (CAM):

The use of alternative therapies is now appearing in many hospitals, managed care plans, and conventional practitioners are incorporating CAM therapies into their practice, and schools of medicine, nursing, and pharmacy are beginning to teach CAM (National Academy of Science, 2005). The influence of CAM on and off Indian Country is substantial yet much remains unknown about these therapies, particularly with regard to scientific research studies that might convincingly demonstrate the value of CAM in the treatment of diabetes and other chronic disease. Several Tribes incorporate CAM modalities in their healthcare systems. The Pascua Yaqui Tribe of Arizona s alternative healing program has been in existence for a number of years and the San Carlos Apache Tribe in Arizona provides naturopathic services to individuals with diabetes.

iii. American Indian and Alaska Native Traditional Healing and Practices

It should be noted that for AI/AN traditional medicine use and practices are not an alternative (CAM), it is only alternative to allopathic medicine (conventional Western Medicine) and therefore should not be considered a category of CAM; but it s own diverse and culturally-specific healing system(s). AI/AN Traditional Medicine distinction was further discussed among Indian health educators, researchers and practitioners and the consensus was that each tribe's traditional medicine and practices comes from their particular environment whether it be desert, coastline, or forested homelands (20th Annual Native Health Research Conference, 2008)

For example, at its broadest interpretation, the Tohono O odham (Desert People) of southern Arizona, way of viewing the world Himdag embraces an interconnected worldview where healing from medicinal plants, songs and storytelling, spiritual healing, curing and traditional songs, and beliefs and values like respect, games, harvesting traditional foods and hunting, incorporating songs into ceremonies are intricately interwoven (Tohono O odham Nation Constitution 1986, Tohono O odham Nation Language Policy, 1986).

1. For many tribal members of the Tohono O odham Nation and many other U.S. Tribes, it is the community, which recognizes who its healers are, not a Federal or State licensing body (Sequieros, 2009).
2. Several Veteran's Administration regional medical centers have formal agreements with certain Tribes (e.g. Dineh/Navajo Nation) to provide culturally-appropriately compensation to the Dineh Medicine Men for certain ceremonies for veterans (Trujillo, 2009).
3 The Medicine Wheel concept is comprehensive and incorporates mental, physical, spiritual, emotional wellbeing. This concept has been widely adapted by many Native and non-Indian communities to promote wellness.

The IHS established a traditional healing policy that allows the IHS to provide, at the patient s request, an opportunity for traditional healers to conduct healing services within a health care facility. Some Service Units carry out the policy without question; however, at some IHS facilities, patients that request this assistance are sometimes met with reluctance and skepticism by providers unknowledgeable of AI/AN healing ceremonies and tradition. While the openness of the policy allows for varied tribal healing practices to be conducted as appropriate within the confines of the health care facility, systemic barriers exist that include lack of funding for the program, inability to acquire Medicaid reimbursement for the expenses incurred by traditional healers, lack of participation of the traditional healer as a member of the health care team and lack of information to individual patients that the policy exists. The CER may provide an opportunity to further evaluate the effectiveness of culturally based interventions that are utilized

in the Indian health care system and thereby further the development of these interventions as recognized best practices.

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Submitted by
Rachel Groman
[personal information redacted]

Comment Type: *General Comment*

Re: Draft Definition, Prioritization Criteria, and Strategic Framework for Comparative Effectiveness Research

Dear Federal Coordinating Council Members,

On behalf of the undersigned members of the Alliance of Specialty Medicine, a coalition of 11 medical societies, we appreciate the opportunity to comment on the Federal Coordinating Council s draft definition, prioritization criteria, and strategic framework for comparative effectiveness research (CER). The Alliance recognizes that CER can serve as a valuable tool to

guide sound clinical decision-making and to better inform both patients and physicians about what works best in health care.

The Alliance supports a well-designed CER system that is transparent, improves quality, relies on public input, supports continued medical progress, and strengthens physician and patient decision-making while preserving individualized treatment. We greatly appreciate that the Council s definition and framework recognize diverse patient populations and the need to respond to the expressed needs of both patients and providers. It is critical that any CER program account for the unique circumstances of patients and preserve the independent judgment of physicians. However, we request that the Council clarify its intent when it refers to the need for CER to respond to the expressed needs of decision-makers. It is critical that CER focus on communicating research results to patients, providers and other decision-makers, and not on making centralized coverage and payment decisions or recommendations. Without further clarification of this statement, decision-makers could be interpreted as giving the Centers for Medicare and Medicaid Services (CMS) or any other public or private payer the authority to use CER to make coverage and payment decisions.

The Alliance also appreciates that the Council s definition and framework recognize a broad scope of research, including medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. However, we encourage the Council to further strengthen the definition so that it indicates that research on each of these interventions focus on all patient subpopulations and not just a few particular patient groups.

We also thank the Council for recognizing that CER must rely on a variety of data sources and data assessment methodologies. We encourage the Council to specifically consider prospectively obtained outcomes data collected through robust patient registries as one example of a data source that can help to better define indications for certain procedures. Directing comparative effectiveness research funds to the creation and/or administration of patient registries will ultimately result in the production of meaningful data that will help guide clinical decision-making, determine best practices, improve quality, and ultimately lower costs through feedback reports that compare individual data to equivalent comparison groups. The Alliance cautions the Council and other policymakers against linking patient registries to claims data since current privacy laws do not allow for one-to-one linkages, which introduces error and dilutes the sound clinical methodology needed for CER.

While the Alliance supports the Prioritization Criteria outlined in the framework, we are concerned that it fails to specify how these priorities should be developed, reviewed and finalized. It is critical that all relevant stakeholders, particularly those who are clinical subject matter experts and provide direct patient care, have a voice in the process through which CER topics are prioritized.

Finally, we request that the Council s definition explicitly state that the purpose of CER is to provide information on clinical effectiveness and patient health outcomes, not cost-effectiveness assessments. CER must not ebb into cost containment, where life or death medical decisions can be based upon the government s financial considerations. The Alliance believes that if CER is

carried out in a sound and transparent fashion, it will naturally rid of inefficiencies in our health care system by directing providers and patients to care that is most effective.

Moving forward, we encourage the Council to continue to preserve transparency throughout the many aspects of the CER process by ensuring that stakeholders have input into research priorities and design and have an equal voice in the governance of a CER entity.

The Alliance of Specialty Medicine appreciates the opportunity to offer these comments, and we look forward to working cooperatively with the Council to develop a fair and meaningful process through which to compare clinical effectiveness and to ultimately improve patient care. If you have any questions about our comments, please contact Rachel Groman, MPH, 202-628-2072, rgroman@neurosurgery.org

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American Association of Neurological Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Urological Association
Congress of Neurological Surgeons
Heart Rhythm Society
Society for Cardiac Angiography and Interventions

Submitted by
Margaret Anderson
FasterCures
manderson@fastercures.org

Comment Type: *General Comment*

Thank you for the opportunity to comment on the Council's Draft Prioritization Criteria and Strategic Framework. They are both very concise and thoughtful documents with which we substantially concur. We did, however, want to highlight some issues which we don't feel are directly addressed that may inform your thinking going forward.

-- In addition to informing better point-of-care decisions by patients and providers, building the evidence base through comparative effectiveness research can elucidate critical clinical research questions deserving investigation, which will accelerate the development of new and improved diagnostics and therapeutics. If that can be reflected in the prioritization criteria in some way (perhaps under #5, "potential for multiplicative effect"), we believe that would be of great value.

-- We are pleased that the Strategic Framework addresses not only the research studies themselves, but also the human and scientific capital necessary to execute the research -- including, very importantly, developing methodologies needed to conduct the research efficiently

and effectively. We urge you to give this issue the attention it requires. The scientific underpinnings of comparative effectiveness research are still being developed, and it will be important to monitor the progress of the field as early studies funded through ARRA yield results.

-- Also addressed in the Strategic Framework is the data infrastructure supporting CER, another area we hope will be given careful attention. In particular, we hope the Council will make an effort to ensure that investments in health information technology being advanced separately with ARRA funds are supportive of the requirements for conducting CER to the greatest extent possible.

-- We are also pleased to see recognition of the fact that translation, dissemination, and adoption of the results of CER are as important as the studies themselves and hope that funding will be devoted to pursuing this critical goal.

-- We hope and expect that the vision driving federal spending on CER will continue to be enhancing and customizing care for patients, and that it will not be used to limit access to or availability of effective treatments on an individualized basis.

FasterCures' mission is to identify ways to accelerate the discovery and development of new therapies for the treatment of deadly and debilitating diseases both in the United States and around the globe. The organization was founded in 2003 under the auspices of the Milken Institute to aggressively catalyze systemic chance in cure research and to make the complex machinery that drives breakthroughs in medicine work for all of us faster and more efficiently. FasterCures is independent and non-partisan. We do not accept funding from companies that develop pharmaceuticals, biotechnology drugs, or therapeutic medical devices. Our primary mission is to improve the lives of patients by improving the research environment, research resources, and research organizations.

Submitted by
Bart Barefoot
GlaxoSmithKline
bartley.l.barefoot@gsk.com

Comment Type: *General Comment*

GlaxoSmithKline ("GSK") is pleased to submit these comments to the Federal Coordinating Council on Comparative Effectiveness Research (the Council) regarding the Council s draft definition of comparative effectiveness research (CER), draft prioritization criteria for CER funding, and draft strategic framework.

GSK is a world-leading research-based pharmaceutical company whose mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

GSK thanks the Council for soliciting public input on CER generally and on the development of these important guideposts for CER investments under the American Recovery and Reinvestment Act (ARRA). We believe the Council s willingness to engage interested stakeholders through listening sessions and written comment opportunities will produce a strong, credible foundation for CER investments which can improve the quality of clinical decisionmaking and in turn improve patient health outcomes. Indeed, it is apparent from these drafts that the Council has given careful consideration to the public input received thus far and has, working under tight time constraints, proposed a definition, prioritization criteria, and strategic framework that contain many positive elements. Accordingly, the comments we submit today are primarily limited to targeted recommendations to improve specific elements of these draft materials.

DRAFT DEFINITION OF CER

The Council s proposed definition of CER is appropriately broad in scope, encompassing a wide range of interventions and strategies, including prevention, care management, and delivery system interventions, that can affect health outcomes and patient experiences. GSK also appreciates the Council s recognition of the importance of responding to patient and provider needs, accounting for differences among individual patients and subpopulations, conducting research using a variety of data sources, and developing and expanding research infrastructure and methods. We urge the Council to retain these elements in the final definition.

At the same time, we offer for the Council s consideration several small but meaningful modifications that we believe will strengthen the definition.

1. We propose that the Council revise the first sentence to read: Comparative effectiveness research is the conduct and synthesis of systematic ANALYSIS comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions AND APPROACHES TO THE DESIGN AND IMPLEMENTATION OF CARE DELIVERY SYSTEMS. We recognize that the definition s fourth sentence (Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions) incorporates delivery system interventions ; however, the care delivery system is more than just a form of disease intervention. Rather than define CER strictly in relation to disease, we advocate a holistic approach that also seeks to identify approaches to improving care delivery systems in themselves and the quality of care delivered.

2. We suggest that the Council revise the second sentence to read: The purpose of this research is to IMPROVE HEALTH CARE QUALITY AND HEALTH OUTCOMES by identifying, in response to patient, CAREGIVER, provider, and PUBLIC HEALTH needs, which interventions are HIGHLY effective for which patients under specific circumstances. As revised, this purpose statement incorporates these important additions:

" Improve health care quality and health outcomes GSK believes improvements in health care quality and patient health outcomes ought to be the polestar for federally-supported CER. Accordingly, we believe the definition of CER should explicitly reference this guiding principle.

" Caregiver Although patients and providers typically form the nucleus for health care decisionmaking, in many instances, others play a significant role in care decisions and delivery. Alzheimer s and cancer care are just two prominent examples of conditions where caregivers frequently play prominent roles and are impacted by intervention choices. Caregivers offer a unique perspective which too often is overlooked. We believe good CER design and implementation takes into account caregivers perspectives and circumstances where appropriate.

" Public health We recommend substitution of public health for decision-makers. In our view, public health is a broader term that encompasses all who have a particular stake in the improvement of health care decisionmaking, quality of care, and health outcomes.

" Highly effective The draft definition s use of the term most effective implies that CER will conclusively identify a best intervention for a particular circumstance. In actuality, even with respect to patient subpopulations, it is unlikely that CER can pinpoint the most effective intervention for a particular patient. Even among patients who share certain characteristics, each patient is an individual, and there can be no guarantee that an intervention will prove effective. Therefore, it is more accurate to state that CER can help to identify interventions that are highly effective for patients in a particular circumstance.

3. Finally, we propose that the Council revise the definition s last sentence to read: This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative CLINICAL effectiveness. The addition of clinical will more closely align the definition with Congress s stated intent that ARRA funding support research to evaluate and compare clinical outcomes, effectiveness, risk, and benefits.

THRESHOLD MINIMAL CRITERIA

" Please clarify how these minimal criteria would function in practice. For example, are the criteria equally weighted? Can one criterion assume more importance than another? How will research feasibility be measured, and what factors other than time are potentially relevant to feasibility considerations (e.g., cost of the research, methodological challenges, available infrastructure, patient privacy and other legal and ethical issues?)?

" Revise criterion (2) to read: Responsiveness to expressed needs and preferences of patients, caregivers, clinicians and other health care providers, and other stakeholders, including community engagement in research. This change will more closely align this criterion with the definition of CER (see above).

PRIORITIZATION CRITERIA

" In criterion (1), replace costs of care with total cost of care. This change clarifies that it is the total cost burden of a disease or condition, not specific intervention costs, which is a relevant and appropriate factor in prioritizing federal investments in CER. This clarification will ensure that federally-supported research remains appropriately focused on the needs of patients, caregivers, and clinicians and other health care providers.

STRATEGIC FRAMEWORK FIGURES 1 & 2

" Add a fifth category of CER investments and activities CER Evaluation. Equally as important as the four categories of investments and activities outlined in the draft framework is the need to regularly review and evaluate government-supported CER and its impact on clinical care and health care quality. We must understand whether our CER investments produce positive changes. Do the funding choices actually reflect the prioritization criteria? Are the research questions the correct questions? How are the CER results used and by whom? Do patients, caregivers, clinicians and other providers, and the public find the results useful, practical, and actionable? If not, why not? Most importantly, have the CER studies improved the quality of clinical decisionmaking and promoted care of higher value and quality? What changes are needed to improve the conduct and translation of the CER studies? For CER to fulfill its potential to improve health care quality and patient health outcomes, there must be a formal mechanism for continuous evaluation and improvement a feedback loop that incorporates the answers to these and other questions. GSK believes such a mechanism is vital to the success of CER and thus warrants a defined space in the strategic framework.

STRATEGIC FRAMEWORK FIGURE 2

" In column one, Human & Scientific Capital for CER, specify that Methods for patient/consumer engagement includes federally-supported CER education and training for patients and consumers. GSK shares the Council s belief that patient and consumer engagement is critical to the design, credibility, and adoption of CER, and we applaud the Council s focus on developing methods for seeking public input. However, the quality of this engagement depends on patients and consumers awareness of CER design and implementation considerations. Simply put, if they do not possess an adequate understanding of these issues which frequently are complex many patients and consumers will not be equipped to contribute meaningfully to dialogue with other CER stakeholders. Therefore, GSK recommends that the Council explicitly recognize the importance of CER education and training for patients and consumers and identify options for providing this education and training.

" In column two, CE Research Priorities, replace Expressed public and federal needs for CER with Expressed needs of patients, caregivers, clinicians and other health care providers, and other stakeholders. This change will more closely align the strategic framework with the definition of CER (see above).

" In column three, CER Data & Research Infrastructure :
? Clarify and elaborate on the scope of the inventory of existing CER infrastructure (e.g., will this include public and private infrastructure as well as information from other countries?).
? Clarify and elaborate on the scope of evidence generation (e.g., will evidence generation include public and private sources?, will these sources be domestic only?).

" In column four, Translation & Adoption of CER, clarify and elaborate on the scope of the inventory of existing CER translational and dissemination activities (e.g., will this include activities in the public and private spheres as well as information from other countries?).

" In columns one, three, and four, replace Funding based on identified high-priority gaps with Funding based on identified high-value opportunities. This change would create greater consistency among the investment and activity categories and would reinforce the importance of investing federal dollars in areas offering the greatest potential for meaningful improvements in clinical decisionmaking, quality of care, and patient health outcomes.

In conclusion, GSK again thanks the Council for this opportunity to express our views on the draft CER definition, prioritization criteria, and strategic framework. We look forward to continuing to work with the Council in a similarly open and inclusive manner to ensure the fulfillment of our shared goal that our nation s investments in CER will result in improvements in clinical decisionmaking, health care quality, and, ultimately, patient health outcomes.

Please contact Bart Barefoot, Senior Manager, Public Policy and Advocacy at (919) 468-2973 or BARTLEY.L.BAREFOOT@GSK.COM if you have any questions concerning these comments.

Submitted by
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Senior Vice President, Policy
Advanced Medical Technology Association (AdvaMed)
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Comment Type: *General Comment*
AdvaMed has a recommendation regarding the process for collecting comments on these CER topics. AdvaMed greatly appreciates the opportunity to comment and recommends that longer public comment periods (for example, 30 days) be offered to ensure a greater ability to provide meaningful feedback. Many individuals and small organizations have limited resources to expend, and providing additional time would provide an equal opportunity to consider and offer thoughtful comments that could improve the Department s CER-related initiatives.

Submitted by
Emily Wilson
ASTRO

emilyw@astro.org

Comment Type: *General Comment*

ASTRO supports the draft definition of comparative effectiveness research and applauds the leadership of the Federal Coordinating Council (FCC). We also appreciate the FCC's patience during the listening session and its dedication to sorting through various comments to come to broad visionary framework.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

To Whom It May Concern;

I am writing to comment on the possible changes this presidential administration is seeking to make in the health care system of our country.

While the current system is rife with difficulties, there are insurance plans available that make accessing necessary health care easier than others. Much of the time the availability of these better insurance plans can be dependant upon where a citizen resides because some states have been more proactive than others in establishing basic insurance provisions. I find that leaving this issue to the states is a step in the right direction toward preserving liberty in our nation because it is the responsibility of the federal government to respect and preserve states rights.

That said I absolutely do not believe rationed, centrally-pooled healthcare that is facilitated by our federal government would be an effective or efficient means to improve our current health care system. Neither is so-called evidence based medicine. While these may look good to some on paper, the fact is that they cause more harm than good. This is because they would actually diminish in a significant way the freedom of Americans to choose and pursue what we each believe to be the best approach to caring for ourselves. When it comes right down to it, this freedom falls under the umbrella of our rights to "life, liberty, and the pursuit of happiness" as declared in our Declaration of Independence.

Frankly speaking, limiting our choices in healthcare by these means would be another mode of robbing our liberty. It truly is as simple as that. Whether or not it is done under the guise of good intentions is arguable depending upon which political lens you choose to wear. Well I don t wear a political lens, so I don t care about that point of view. It is for this reason I can see this issue from a clear perspective, and that point of view is that government needs to stay out of the health care business. Establishing a federal centrally-pooled, nationalized, socialized, or whatever-you-want-to-call-it medical system is a mistake.

I passionately believe these statements because my family and I have stayed healthy for years. We have had our challenges, but we have always been able to overcome them not because of what someone in the government has figured out for me or dictated to us but because of what we have researched, learned, and implemented on our own to proactively care for ourselves. Yes, what you put into your body is absolutely a key factor, but that is only one of many simple choices we make must daily that play a huge part in wellness. In fact, thanks to all that is provided at public libraries, every citizen, regardless of their income, has equal access to figure out how to improve their health for themselves. Even if you had health insurance, you don t need to it be proactive with caring for yourself. The only requirement is that you possess the desire and patience to learn what to do and make the effort to carry it out. It really isn't difficult.

If the policies promoted by Dr. Steven Eastaugh and our current administration are carried out, I truly believe the state of American citizens health will actually worsen. I know something needs to be done to help our citizenry, but I firmly feel the policies that are the backbone of the healthcare he is promoting are the completely wrong direction for America to go. That is because it would diminish the available resources for consumers to choose from in one way or another. We are a country that promotes choice and freedoms, so do not take steps that would negatively impact our freedom of choice in health care freedoms. I am someone who has not had health care insurance at two different points in my life, yet I still do not want nationalized health care because I strongly believe there is a better way than the paradigm recommended by Dr. Eastaugh.

I know leaning toward a quick fix like nationalized health care is easy because it may appear to be a practical means to address this issue, but in the final analysis, I honestly believe it would be anything but practical for the average citizen to utilize. That would definitely be a step backward from the current goal of improving what is currently available. Thank you for the opportunity to comment on this issue. I appreciate your time and consideration to my views regarding this issue, and I will be following how it transpires.

Submitted by
Diane Dorman
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Comment Type: *General Comment*

Federal Coordinating Council for Comparative Effectiveness Research
Listening Session
June 10, 2009

Thank you for giving the National Organization for Rare Disorders (NORD) the opportunity to address this Council regarding comparative effectiveness research. NORD represents the estimated 30 million men, women and children in the United States affected by one of the nearly 7,000 known rare diseases. For those who may not know what a rare disease is, it is any disease,

syndrome or condition affecting fewer than 200,000 people in the United States, or approximately one in ten. For many it can take many years to be diagnosed, some estimate as many at seven years. Others are never properly diagnosed.

I would like to preface my remarks by saying that NORD strongly supports comparative effectiveness for drugs, biologics and medical devices and treatment protocols. If this country is to address the growing disparities in care, we must find a way to ensure that every American receives the care they need and rightly deserve.

By way of background, there are currently 339 orphan drugs and biologics that treat (according to the FDA) about 12 to million across the country. It is unfortunate that the remaining 18 million have no therapy or treatment protocol addressing their specific disease. It s a hit or miss proposition. As a consequence, most are treated off-label because there is nothing specific to their disease.

As a consequence, many of these people have difficulty gaining access to the treatments they need because the indication is not on the label of the product. Comparative effectiveness research could have a profound impact on these patients should labeling changes be required. Already, insurers continue to deny access to care simply because their disease state is not specified on any labeling.

As you deliberate, we do have a number of general suggestions. We ask that you consider a number of factors:

? Comparative effectiveness research typically compares average results of one therapy or treatment protocol versus another for a study population. However, these do not take into account differences between patients due to genetics, co-morbidities and other important factors.

? Comparative effectiveness research should focus on questions that reflect the interactions among all of the various components of the healthcare system and have the greatest potential to empower medical specialists and patients to make the most appropriate decision when faced with real world clinical situations.

There are specific issues surrounding rare diseases and orphan products that we think are addressed in the newly introduced Patient-Centered Outcomes Research Act of 2009 that was introduced by Senators Baucus and Conrad yesterday.

Specifically, the legislation says that, in the case of comparative effectiveness research studies for rare diseases, that an expert advisory panel assist in the design of such research studies and determine the relative value and feasibility of conducting such research studies.

Draft language we have proposed to the U.S. House of Representatives goes a step further and asks that an Ombudsman be appointed to serve as the single point of contact to patients with rare diseases regarding funding by the Department of Health and Human Services or the Institute of proposed comparative effectiveness studies on rare diseases.

NORD strongly supports this language and we ask that as you remain mindful of those who are considered as outliers, and as you continue your deliberations you remain mindful of the unique needs of rare disease patients and the challenges they face.

Patient-Centered Outcomes Research Act of 2009 introduced by Chairmen Baucus and Conrad. Section (5) (A) (iii) outlines the expert advisory panel for rare diseases.

EXPERT ADVISORY PANEL FORRARE DISEASE. In the case of a comparative effectiveness research study for rare disease, the Institute shall appoint an expert advisory panel for purposes of assisting in the design of such research study and determining the relative value and feasibility of conducting such research study.
(B) COMPOSITION.
(i) IN GENERAL. An expert advisory panel appointed under subparagraph
(A) shall include individuals who have experience in the relevant topic, project, or category for which the panel is established,
including
(I) practicing and research clinicians (including relevant specialists and subspecialists), patients, and representatives of patients; and
(II) experts in scientific and health services research, health services delivery, and evidence-based medicine.

SEC. ___. SPECIALIZED PROCESS FOR COMPARATIVE EFFECTIVENESS RESEARCH ON RARE DISEASES

(a) IN GENERAL. The Institute shall convene a specialized review panel(s) of experts and patients, the Rare Disease Review Panel, to provide technical assistance and make recommendations for any proposed comparative effectiveness studies of orphan drugs, biologics, or humanitarian use devices. The HHS Secretary shall also designate a Rare Disease Ombudsman to serve as the single point of contact to patients with rare diseases and to coordinate with the Institute.

(b) DEFINITIONS.

(1) The term rare disease means a disease that has a prevalence of less than 200,000 persons in the U.S.

(2) The term Rare Disease Ombudsman means the person or office designated by the Secretary from the NIH Office of Rare Diseases to serve as the single point of contact to patients with rare diseases regarding funding by the Department of Health and Human Services or the Institute of proposed comparative effectiveness studies on rare diseases.

(c) DUTIES. The Panel shall

(1) provide technical assistance to the Institute during the public comment process regarding the decision within the Institute on whether to fund a proposed comparative effectiveness study on a rare disease;

(2) review, evaluate and make a recommendation on whether to proceed to fund the study under consideration for comparative research effectiveness purposes;

(3) report to the Board (or appropriate head) and the Rare Disease Ombudsman the reasons why it determined that each proposed study meets or does not meet the standards in subsection (d).

(d) STANDARDS FOR REVIEW, EVALUATION AND RECOMMENDATION. In conducting its review and evaluation and in making its recommendation on each proposed comparative research effectiveness study, the Panel shall assess whether

(1) the study will potentially lead to reduced mortality, morbidity, and/or disability for the condition;

(2) if the study under consideration is not a randomized clinical trial
(A) the clinical evidence is sufficient for the study to proceed; and
(B) it compares current medically accepted treatments for the rare disease; and
(C) it captures the evidence needed to reflect the appropriate time horizon for the use of the treatment in that patient population; and
(D) it gives appropriate consideration to factors that could effect the true comparability of the comparison groups; and
(E) it is sufficiently robust to reasonably be expected to provide relevant information regarding the short and long term clinical benefits and risks of each evaluated treatment.

(3) if the study under consideration is a randomized clinical trial
(A) it is of sufficient duration and the clinical or the surrogate endpoints are sufficiently robust to assess the long term impact on and potential harm or benefits for patients; and
(B) the collected data are sufficiently robust to provide information on potential secondary benefits or side-effects in subpopulations if the Panel believes such data are required or useful for clinical practice and treatment; and,
(C) it compares current medically accepted treatments for the rare disease.

(4) other parameters are considered related to special characteristics for a specific rare disease that are clinically important for the proposed study.

(e) COMPOSITION OF THE PANEL.

(1) IN GENERAL. The members of the Panel shall consist of

(A) at least 4 consumer members (or a family member of such consumer) for that disease;
(B) at least 4 active practitioners in that disease;
(C) a physician or scientific expert from the relevant agency.

(2) QUALIFICATIONS.

(A) each consumer member (or a family member of such consumer), selected as a result of a public solicitation and outreach by the Rare Disease Ombudsman, of the Panel must have been diagnosed with the rare disease that is the subject of the proposed comparative research effectiveness study;

(B) each practitioner member of the Panel shall be a clinical expert, as determined by the Institute after soliciting recommendations from the clinical, scientific and patient community, and shall be currently treating patients with the specific condition or disease that is the subject of the proposed comparative research effectiveness study; and,

(3) CONFLICT OF INTEREST. In appointing members of the Panel, the Institute shall take into account any financial conflicts of interest and apply the relevant standards.

(d) REPORT. If the Panel recommends that a proposed study not be funded, but the Institute nevertheless funds the study, the Institute shall publicly report on the appropriate web site the reasons for the decision to fund the study. Regardless, the Ombudsman will conduct outreach through the media and public meetings to the patient community on the rationale for funding the studies that were recommended or not recommended by the panel.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Perhaps the members of the Council believe that there are enough Americans who are so ignorant of history that this program will be enacted by flying under the radar. However,those of us who are knowledgeable of history know that what is being proposed here is exactly how Adolph Hitler began his program of mass murder. This is simply a fascist policy which is completely un-American. Not only should this Council be ashamed, but you are in fact all indictable under the Nuremberg Laws for crimes against humanity.

Submitted by
Joseph Allen on behalf of ACC
American College of Cardiology
jallen@acc.org

Comment Type: *General Comment*

The American College of Cardiology (ACC) strongly supports investment in comparative effectiveness research (CER). Given the high prevalence of heart disease-related illnesses, along

with the documented variability in the use of procedures used to treat and/or diagnose it, comparative effectiveness research could yield high returns in terms of improving patient outcomes and reducing costs.

The draft definition, prioritization criteria, and strategic framework outline a reasonable approach to comparative effectiveness research. ACC applauds the clarity and conciseness of the current definition and prioritization criteria. However, to further elucidate the intent of CER, the ACC suggests the Federal Coordinating Council consider clarifying and expanding the current draft in the following ways:

1. The Council may consider explicitly defining the relationship between comparative clinical efficacy research and CER. Clinical efficacy research in many cases will form the basis for informing the design of CER.

2. The Council may consider adding tests (laboratory and imaging) to the list of defined interventions. ACC commends the Council for including diagnosis in the list of focus areas, and the addition of tests explicitly to the list of interventions may clarify the intent as not all tests may be viewed as procedures. Imaging and laboratory tests often determine the clinical management of a patient, and thus, comparative methods for diagnosis and risk management facilitated by testing are a crucial component of understanding the appropriate clinical pathway for a patient.

3. The Council may consider modifying the stated purpose of CER to be focused on the relative effectiveness (rather than most effective) of interventions for specific patients under certain circumstances. In many cases, CER may not yield a single most effective intervention or strategy but rather inform decision making about reasonable alternatives. The field of cardiology has many studies which have found interventions to be equally effective for certain patients, including recent studies on stenting compared to bypass surgery and stenting compared to medical therapy.

The Council also may consider modifying the second figure. Currently, it is represented as individual pillars only connected by the priority themes. It also may be productive to view the strategic framework as continuous cycle with each component informing the others. A lack of interaction between these pillars may result in identifying gaps within each area but fail to leverage the knowledge contained in the other pillars. For example, inventories of human and scientific capital can inform the development and framing of research priorities. Translations of prior CER and clinical efficacy may be used to inform the gaps in research. CER data and research infrastructure can be used to both inform research priorities and help monitor translation and adoption. Implementation can help inform the rest of the process. The strategic framework may be able to target research funding more effectively if gaps are identified not only for each area but also through understanding the interactions of the pillars represented in the figure.

Submitted by
Eduardo Siguel

optimalpolicies
coolfoods@hotmail.com

Comment Type: *General Comment*

A substantial proportion of current diagnosis and treatment and alleged best evidence is likely to be based on flawed models and data (according to my research). Current approaches focus on biomarkers that are not the causes but the consequences of the disease.
For many Americans, eating too many calories, bad diets and inadequate exercise contributes to hardening and thickening of arteries. This means the arteries are no adequately flexible, they do not expand appropriately, they have narrow sections. The body feeds cells via its vast system of arteries (pipes). When they are hard and narrow, the heart has to pump harder for the blood to reach places far away. This means the blood pressure inside the arteries has to be higher than normal. We call it hypertension. It is a compensatory mechanism that allows the body to feed far away cells in the brain, kidneys, etc. Hard arteries can also become brittle. High blood pressure carries the risk that the arteries can break. If we treat too much hypertension with drugs, we prevent arteries from breaking but we prevent blood from reaching all cells. Brain and kidney cells die over time (a slow process). It is a trade off, lowering the risk of a bleeding stroke vs. increasing the risk of lower IQ and kidney failure.
Besides increasing blood pressure, the body produces more cholesterol. Cholesterol softens the membranes of the cells, makes them more flexible (I am simplifying things to explain complex concepts in a short space, so key issues are omitted). High cholesterol in many cases is not a disease but a compensatory mechanism.
Diabetes type II is primarily a consequence of eating too many calories, bad diets and inadequate exercise. Hypertension and high cholesterol are some of the ways the body seeks to compensate. The best treatment is to eliminate its causes. Preventing future complications via complex regimes of drugs is unlikely to solve the problem. In my neighborhood, some railings were moldy inside and getting rotted. They did not look good. One solution was to remove the rotted parts, inject wood with mold killing stuff. A lot of work. Another solution was to paint them well. That was easy and the wood railings looked great for a while. In a few years, the mold ate them from the inside and they fell apart. With railings we had a solution not available to people: we replaced them.
It is impossible to conduct clinical trials testing most treatments against other treatments. It is also impossible to evaluate the long term consequences of treatments (20 years into the future). No pair of subjects in a clinical trial will maintain almost identical conditions for 20 years (or 10, or even 5!). Thus, long term evaluations are impractical. Before we proceed with comparative effectiveness research (CER) we need better models of disease. Based on our understanding of disease we can predict what works well and what works poorly. Fortunately, we know the factors involved and have the answers for the conditions responsible for most of the costs and deaths in the US. Smoking. Bad diet. Too many calories. Bad exercise. Eating too many processed foods (particularly highly processed fat and carbohydrates). Not enough fruits and vegetables. Drug, alcohol abuse. Risky behavior (drunk driving, etc.). There is practically no dispute on the risk factors and how to prevent them (and save 100s of billions). Pose yourself this question: you are the CEO of a large corporation. Would you rather invest R&D to market drugs and devices to treat those problems or would you rather train people to grow their own and eat organic

vegetables? (getting exercise and healthy food). Surely Ms. Michelle Obama can do, but they don t live like the rest of us. To get the answer, make a business plan and present at a venture capital meeting. See how many buy the idea of an IPO for growing and eating organic vegetables (selling seeds and organic compost) vs. drug Potentum, a mixture that lowers blood pressure, cholesterol, high glucose, enhances erections, makes you hyper, improves bad breath and includes pheromones. Consider the commercials. People pulling weeds and dispersing organic compost (dirty, smelly) vs. clean people enjoying life, kissing each other, having fun. If you get it, you know why CER and health reform will fail to substantially cut costs or improve outcomes.
E Siguel, MD, PhD, JD
Posted at
http://online.wsj.com/article/SB124441644145192397.html#articleTabs_comments%26articleTabs%3Dcomments

Submitted by
Meryl Bloomrosen
AMIA
meryl@amia.org

Comment Type: *General Comment*

I am pleased to submit comments about the draft definition of comparative effectiveness (CE) on behalf of the American Medical Informatics Association (AMIA). AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare use through the transformative use of information and communications technology. AMIA s 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public health/population, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

In general we are supportive of the proposed definition but are pleased to submit the following suggestions for your consideration. We believe that one topic that is not addressed is the assurance of the quality and rigor of the science conducted. Also, it is not clear to what extent health information technology (including electronic health records, disease registries, telehealth application such as home health monitoring) is considered as one of the potential defined interventions .

The prioritization criterion #1 (Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care) might leave out some key issues that warrant study. We suggest that not all CE questions involve common diseases, and arguably there are less frequent diseases that are particularly likely to raise questions of optimal workup or management.

Again, we applaud the Department s efforts to oversee this important national and public discourse. If I can answer any questions for you, or offer additional information on this subject, please feel free to contact me at detmer@amia.org or 301 657-1291.

Submitted by
Matthew Farber
Association of Community Cancer Centers
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Comment Type: *General Comment*

The Association of Community Cancer Centers (ACCC) is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC s more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60% of all U.S. cancer patients.

ACCC thanks the Federal Coordinating Council (Council) for releasing its Draft Definition of Comparative Effectiveness Research (CER), Draft Prioritization Criteria, and Draft Strategic Framework. ACCC appreciates and agrees with the Threshold Minimal Criteria and also with the Prioritization Criteria laid out in the draft document. ACCC also agrees with the basic framework and cross cutting priorities, such as cancer, announced by Council. We appreciate the Council s transparency and willingness to seek stakeholder input to this important process.

However, ACCC remains concerned that cost effectiveness may be included in future CER. Although the Draft Definition does not refer to cost effectiveness, there still could be opportunities for cost effectiveness to be taken into account in CER. ACCC requests that any guidance on CER include explicit language preventing cost from being considered.

In addition, we are concerned that the Draft Definition s reference to decision-makers, along with patients and providers, as the users of CER could be construed as support for the use of CER in payers coverage decisions. This would be contrary to the American Reinvestment and Recovery Act s (ARRA) express prohibition against the Council mandating coverage, reimbursement, or other policies for any public or private payer. The ARRA conference report also notes that Congress did not intend for CER funding to be used for such purposes. We ask that the definition of CER include explicit language preventing coverage decisions from being based on CER. The Council should clarify that decision-makers refers to patients advocates, including a patient s parents, guardians, and family members who may be involved in making health care decisions.

We are pleased that the Draft Definition appears to recognize that all patients with the same disease may not benefit from the same treatment option. This is especially important in oncology, where the most effective treatment for one person, may not be the same for another

person with the same diagnosis. To further clarify that CER must assess a comprehensive array of health-related outcomes for diverse patient populations, we suggest that the word subpopulations be added to the end of this sentence.

ACCC also is concerned with some of the aspects of comparative effectiveness that were not included in the Draft Definition, Prioritization Criteria, or Strategic Framework. ACCC remains concerned that there is still some confusion as to where this research will take place. The Agency for Healthcare Research and Quality (AHRQ) already is conducting some CER, and the National Institutes of Health (NIH) is also in line to conduct research. We ask the Council to clarify whether other agencies will be involved in CER. We also ask for clarification about the application of the Draft Definition, Prioritization Criteria, and Strategic Framework. Will these terms and structures apply to research already underway, or will they apply only to new research?

ACCC would like to thank the Council for the opportunity to submit comments on the draft definition of CER. If you would like to discuss our concerns further, please contact Matt Farber at mfarber@accc-cancer.org.

Thank you

Submitted by
Nancy Spannaus
[personal information redacted]

Comment Type: *General Comment*

By Nancy Spannaus, U.S. branch of the Club of Life

First, let me say that the Club of Life is an international organization founded in 1982, by Helga Zepp-LaRouche, and dedicated to the promotion of the inalienable right to life for all peoples on this planet, and the defeat of the Malthusian outlook which has taken hold of many too many of our institutions over the past 40 years. We have dedicated our efforts to fighting {for} a new, just world economic system, as a moral and economic imperative, and against the evils of cultural pessimism, which have contributed to the spread of such evils as assisted suicide, the drug plague, and other degradations of the sanctity of human life.

The central question that must be addressed by this Council, I believe, is the question of {mission}. My reading of the work in the area of Comparative Effectiveness has led me to the conclusion that, protestations to the contrary, it is a process dedicated to {reducing} the investment in saving human lives to the lowest possible denominator, in the spirit of cost-effectiveness. Such a mission leads inexorably to the disease which Dr. Leo Alexander, a U.S. psychiatrist aiding the prosecution of the Nazi doctors at the post-war Nuremberg Tribunals, called utilitarianism, an attitude which itself leads down the slippery slope toward designating some lives as ``not worthy to be lived.

Dr. Alexander, who saw the danger of such an idea invading U.S. society as early as 1949,
defined this attitude as Hegelian and cold-blooded. He observed that the Hegelian rational attitude has led [doctors] to make certain distinctions in the handling of acute and chronic diseases. The patient with the latter carried an obvious stigma as the one less likely to be fully rehabilitable for social usefulness. In an increasingly utilitarian society, these patients are being looked down upon with increasing definiteness as unwanted ballast. From that small beginning, that shift in viewpoint, he said, ``the acceptance of the attitude, basic in the euthanasia movement, that there is such a thing as a life not worthy to be lived, comes the horror of mass murder, which Hitler, and his expert Nazi doctors ultimately carried out.

We cannot tolerate any institution that promotes such an attitude, in the governmental structure of the United States.

Dr. Alexander also emphasized that this shift in attitude did not arise primarily within the medical profession, but was imposed by the shortage of funds available, both private and public, for the care of the very sick.

Today s work in comparative effectiveness clearly is proceeding from the standpoint of reacting to a shortage of funds, and making hard choices over who should get care, and who not.
What s the alternative? It begins with valuing every human life, and then fighting to create the thriving economy which is required to provide the hospitals, technicians, researchers, medicines, and
medical equipment required to take care of all of our population. Surely, no one can say that we can t afford quality health care for all if we are throwing trillions of dollars into saving financial derivative markets on Wall Street.

My conclusion is this: If the Comparative Effectiveness Council cannot find a mission in expanding medical resources for all parts of the country, rather than applying Nazi-like cost-cutting
measures on our population, it should be disbanded forthwith.

Submitted by
Al Cors
RetireSafe
acors@retiresafe.org

Comment Type: *General Comment*

On behalf of 400,000 senior-citizen supporters across America, RetireSafe urges you to make every possible effort to ensure that the use of comparative effectiveness research (CER) is never used to deny seniors and others the treatments and therapies they need based on cost. That said, we also urge you to consider the aging of America in all of your studies, as seniors will soon represent a huge portion of our total population, roughly 25 percent. No large study will be valid without that consideration. Because of the huge number of co-morbidities in the senior population, as well as the massive number of senior subgroups, these studies will be complex,

but ever so important to quality health care. We urge your complete consideration of all of these critical factors. Thank you for the opportunity to comment.

Submitted by
[personal information redacted]

Comment Type: *General Comment*

Healthcare choices must be made by the individual and their chosen doctor, not by insurance companies or government bureaucrats.

The government should not expand its role of providing healthcare it should make every effort to reduce it. Neither should it set itself up as the one to decide what is or isn't the most effective treatment.

The individual can be trusted to make wise decisions about their care. The individual must be allowed to make his or her own choices as to health care providers, treatments, etc. not be dictated to by the insurance company. Currently, the health plan decides what is covered and what is not. If the person wants an alternative treatment, they can pay for it on their own.

The high cost of care is partly due to a double standard. If you do not have coverage or have a high deductible, then the provider charges you less, but if you have insurance the provider charges more. No wonder we are paying too much! We need to get back to a market economy for healthcare.

Insurance should provide less. The amount of care covered by insurance should be reduced. It should be for catastrophic care and major illnesses. Not for preventive care. Because we try to provide too much, it is costing too much.

Individuals should be given the option of a Health Savings Account, preferably begun when they are an infant to save for their own care, which the person spends at their own discretion: choosing providers and treatments of their own choice.

Any effort to create comparative effectiveness takes the choice away from the patient and creates the path to drastic rationing.

The US has one of the best health care systems in the world. Please drop the idea of 'pay for performance', comparative effectiveness, or any such nonsense, it will only end up ruining the great system we have now.

[personal information redacted]

Submitted by
Chip Amoe
American Society of Anesthesiologists
c.amoe@asawash.org

Comment Type: *General Comment*

The American Society of Anesthesiologists (ASA) Comments on Comparative Effectiveness Research and the Anesthesia Quality Institute (AQI) Data Registry

In order to produce meaningful and ongoing comparative effectiveness research, it is important to establish the necessary infrastructure. To this end, the American Society of Anesthesiologists (ASA), through its leadership and House of Delegates, has recognized the importance of establishing a national clinical data registry and has created a related but separate organization focused on quality improvement in anesthesiology. The organization, the Anesthesia Quality Institute (AQI), has a vision to become the primary source of information for quality improvement in the clinical practice of anesthesiology. The organization will allow anesthesiologists to maintain and enhance their well earned reputation as the leading medical specialists in terms of quality of care and patient safety. This assistance could be expanded to include other anesthesia service providers and perhaps other perioperative care providers. The AQI seeks to accomplish three primary objectives.

1. Improvement of Patient Outcomes and Quality of Care

The development of a data registry for anesthesiology will help improve patient outcomes and thus raise the quality of care in the specialty in three main ways. First, more anesthesiologists will be able to collect and monitor their own practice data, which is the foundation of quality improvement. Without solid data a physician, practice, or hospital cannot accurately know his or her true level of performance and outcomes. Benchmarking reports will provide anesthesiologists with a mechanism to assess their own practice relative to their peers and will facilitate the development of meaningful report cards on physician and team performance.

Second, the data registry will support the development of products or services to assist anesthesiologists whose practices are achieving relatively lower performance. A number of current data registries collect voluminous amounts of data, but lack a comprehensive ability to analyze and translate that data back into practice and performance improvement. The AQI intends to go beyond mere data collection and close the loop on identified shortcomings through practice improvement materials and processes developed in partnership with ASA and the American Board of Anesthesiology.

Finally, a comprehensive national data registry for anesthesiology would provide new resources for improving the practice of anesthesiology through related research. Researchers could utilize the data registry to answer clinical questions of importance to patients and the specialty. While peer benchmarking will require a stable and standardized collection of data, specific, focused research initiatives can be provided temporary access to the registry to very rapidly acquire a

broad-based sample of clinical information designed to address priority research interests, including comparative effectiveness research. Some of these priority research topics might include the relationship of anesthetic management to tumor biology and cancer survival; the optimal strategies to prevent unintended intraoperative awareness and the impact of anesthetic exposure on cognitive function in the very young and very old.

Much of the potential of an anesthesiology-based clinical registry will be realized through interoperability and partnership with datasets collected by our partners in perioperative care, especially surgical colleagues. These linkages will be challenging and complex and invite a unified, nationally coordinated effort to integrate the related clinical registries.

2. Dissemination of Anesthesiology Specific Information

The data registry will allow the Anesthesia Quality Institute to develop reports for interested parties on either aggregate outcomes information or physician-level measures. As the data set grows increasingly robust and achieves validation, the AQI could partner with public and commercial payers who wish to learn more about anesthesiologists and the quality of perioperative care. Such reports could be used as an alternative to claims-based and administrative datasets which are weaker data sources in anesthesiology than in most other fields of medicine. Finally, ASA and the AQI could use the database to support organizational statements and public understanding about the safety and quality of the practice of anesthesiology.

3. Develop and Further the Specialty of Anesthesiology for the General Elevation of the Standards of Medical Practice

The data registry will elevate the standards of practice by providing evidence for use in future ASA practice statements and guidelines. The registry will demonstrate the validity of the collected data through a risk adjustment methodology and data validation process. Such data could then be sufficient for multiple purposes, including focused research queries, peer-review publications, and evidence to support ASA practice guidelines.

Although it is widely known that anesthesiologists have raised patient safety to nearly the Six Sigma level, this achievement is almost entirely related to the reduction of anesthetic mortality rates. The data registry will help define the current state of practice of anesthesiology by identifying rates of other, less dramatic but still important events and outcomes. Data reporting and comparative analysis is the only route to understanding clinical practice variation, a fruitful route to quality improvement.

Variations are seen throughout medicine and every medical specialty. Registry data will permit understanding of such variation and reduce it through the identification of outliers and dissemination of best practices, which will address important, but currently difficult to recognize, clinical problems in the specialty.

In conclusion, anesthesiologists are deservedly proud of their reputation as leaders in patient safety; however we do not intend to rest on our reputation. We recognize that the time has come

to take the next step and develop a national data registry for anesthesia to help improve the health of our patients, communities and the performance of our practices and hospitals. We therefore request that a portion of the funds, authorized for comparative effectiveness research, be dedicated towards the development of national clinical data registries, such as the Anesthesia Quality Institute. There are many unanswered questions and gaps in knowledge across all specialties and we recognize the federal government cannot fund research in all of these areas at once. However, by funding such registries now, the Administration can build the infrastructure and data sets needed to support comparative effectiveness research today, while also laying the foundation for maintenance and expansion of such research in the future.

Submitted by
Mary Steele Williams
Association for Molecular Pathology
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Comment Type: *Listening Sessions*

Dear Coordinating Council Members:

The Association for Molecular Pathology is pleased to have the opportunity to provide comments to the Federal Coordinating Council for Comparative Effectiveness Research (the Coordinating Council) on the subject of comparative effectiveness research (CER) and share our recommendations on priority areas on which to focus CER activities.

AMP is an international medical professional association representing approximately 1,600 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Since the beginning of our organization we have dedicated ourselves to the development and implementation of molecular diagnostic testing, which includes genetic testing in all its definitions, in a manner consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. Our members populate the majority of clinical molecular diagnostic laboratories in the United States. They are frequently involved in the origination of novel molecular tests, whether these are laboratory developed or commercially developed. Our members proudly accept their responsibilities in assessing the analytical validity, clinical validity, clinical utility, and the clinical utilization of these tests for each specific patient.

CER is garnering substantial attention in Congress and among other policy makers who see it as a method to examine the comparative effectiveness of treatments, including how they relate to coverage and reimbursement decisions. Diagnostic tests will most definitely be included in this paradigm, especially when the effectiveness of treatments will vary among different population subgroups. Unfortunately, the value of diagnostics in improving clinical outcomes has not been

appreciated adequately in the past; therefore, considering the role of genomics under CER will be critical.

In order for CER to be a success, it will be essential to train experts in diagnostics (including molecular diagnostics) in current health services research methods as well as to train health services researchers in the technical areas they will assess. This cross training will be essential to ensure that the research methods are technology appropriate. For example, in molecular diagnostics, there are situations where a prospective, randomized clinical trial will not be feasible and/or a research outcome could be achieved through an alternative study design such as a retrospective analysis of available data. Further, outcomes studies conventionally assess technologies as interventions, often using the diagnostic test as a benchmark or endpoint, without consideration of the characteristics of the diagnostic. There is much less experience in assessing the role of the diagnostic test itself in appropriate and cost effective management of individual patients. Therefore, AMP encourages the Coordinating Council to invest in the cross-training of researchers and diagnostics experts as well as to build the infrastructure within the agencies to understand and review data from different types of technologies.

While not specifically requested for the listening session, AMP would like to provide the Coordinating Council with the following list of high priority areas of CER identified by the Association s membership:

1. Infrastructure. Infrastructure should be developed to design a model and process for CER regarding laboratory tests. This should include the following:

" The creation of a panel of experts consisting of physicians and scientists, including laboratorians with molecular diagnostics expertise, economists, and reimbursement specialists.

" AMP encourages the creation of an electronic clearinghouse for information on CER projects similar to www.clinicaltrials.gov. Reliable tracking and coordination of CER activities will be crucial to avoid duplication and redundancy and to ensure appropriate use of CER funds. Moreover, access to the tracking data should be available to all entities conducting CER, both from the private and public sector.

" AMP encourages the development and adoption of standards for the collection and storage of data from genetic testing laboratories in order to establish an archive, and to ensure interoperability among databases. Moreover, these databases should include information on the reason for the test, the type of test, test results and availability of genetic counseling and testing centers.

" It should be required that data from technologies and tests being assessed be generated from CLIA-, CAP-, ISO-, or FDA- certified institutions. Consulting with or recruiting professionals from the molecular pathology community will aid the assessment committees in evaluating the quality of proposals and the data generated.

2. Clinical Outcomes in Pharmacogenetic Molecular Pathology. As information becomes available that relates clinical outcomes to genetic variations, the regulatory, medical and lay communities expect that it will be immediately incorporated into routine clinical care. FDA

labeling that relates pharmacogenomic response to maintenance dose, for example, has created demand for both testing and reimbursement in the absence of large clinical trials that demonstrate the effectiveness of such laboratory testing by comparison with either usual care or alternative approaches. An example of this is the use of daily home prothrombin time testing under medical supervision during the first few weeks of anticoagulation versus CYP2C9/VKORC1 mutation testing. Funding for large, carefully designed comparative effectiveness trials for molecular tests should be coupled with funding for observational comparative effectiveness studies that complement randomized controlled trials by including patients who may be tested, but do not meet the inclusion criteria for prospective trials.

3. Evaluating the Effectiveness of Genomic Tests and Clinical Molecular Diagnostics Laboratories. For the public to reap the benefits of effective molecular tests, it is critical that all laboratories meet high performance standards and participate in proficiency testing programs utilizing appropriate reference and control materials.

" Development of reference materials. AMP recommends funding for a program to develop reference materials, exploiting traditional and innovative methodologies, to aid the continued advancement of quality measures in the field of laboratory medicine.

" Novel ways to evaluate laboratory proficiency. AMP supports the development of proficiency testing methods as alternatives to distributing surrogate test specimens. As is evident in cytogenetics, it is impossible to send out surrogate specimens for every known translocation and rearrangement. Categorical methodologic proficiency testing should be evaluated as one such alternative.

" Methods to evaluate novel and emerging types of genomic testing. AMP believes efforts should be taken to develop appropriate quality assurance for new technologies such as whole genome sequencing, using carefully designed methods to determine the relative effectiveness of various quality assurance methods in improving laboratory testing and ultimately clinical outcomes.

4. Interpretation and Reporting of Molecular Pathology Test Results. The data collected by AMP s Clinical Practice Committee in recent years indicates there is room for improvement regarding the transmission of genetic test information. The influence of this information on ultimate clinical outcomes cannot be overstated and could be an important area for CER. Studies to evaluate the use of information by clinicians are critical to understanding clinical utility and effectiveness.

5. Valuation and Reimbursement. Government and healthcare payers should use CER to identify which laboratory services add benefit to patient care and work to implement valuation and reimbursement strategies to help improve clinical outcomes. Reimbursement of diagnostics, including molecular based tests, is extremely poor. Despite the possibility of saving the healthcare system thousands of dollars per patient and improving the quality of care, diagnostics have been historically under valued. AMP hopes that any CER activities will include research to explore the value, beyond simply cost, of diagnostic tests to patients, providers, payers and the larger health care system. . It has been noted that the value of diagnostics in general is not well studied. Assessing the role of laboratory information in medical decision making could improve

appropriate utilization of laboratory tests and clinical outcomes, with potential savings to healthcare. Although reimbursement is one important function of the current coding system (CPT), these codes are also intended to reflect clinical evaluation and management practices. AMP believes the health care system is in need of an entirely new coding vocabulary to describe the types of "evaluation" and "management" practices that are emerging with regard to molecular and genomic testing.

6. Comparative Methodology Research. Many different technical approaches are available for generating the same genetic test result. Relating testing approaches to health outcomes is a neglected area of comparative effectiveness research. AMP supports the evaluation of a multiplicity of platforms in the development and evaluation of companion diagnostics. This approach is not only good science in that it promotes refinement and improvement in methodologies, but is critical to the evolution of medicine. There is no question that therapeutic effectiveness is influenced by test methodology. A prime example of this is the selection of patients with breast cancer for treatment with Herceptin. Determination of eligibility for treatment can be through fluorescence in situ hybridization (FISH) testing or through imunohistochemical methods. Discrepancies between the two methodologies have resulted in patients being inappropriately treated, either exposing them to potential drug side effects without therapeutic benefit, or simply in not treating them with a potentially beneficial drug. These data can be obtained using retrospective studies, but they do need to be pursued.

Thank you for your attention and consideration of our comments. AMP hopes to continue to be a valuable resource to you as the Coordinating Council works to implement and advance CER. Please contact us if you need any clarification or further information.

Sincerely,
Jan A. Nowak, MD, PhD
President

Submitted by
Harry Selker
Society of General Internal Medicine
[personal information redacted]

Comment Type: *Listening Sessions*

Society of General Internal Medicine Statement for Federal Coordinating Council for Comparative Effectiveness Research Listening Session, June 10, 2009
Harry P. Selker, MD, MSPH

The Society of General Internal Medicine, an organization of academic general internists focused on research, education, and primary care, and which has a long history of researchers in comparative effectiveness research (CER), is delighted to have the opportunity to provide a statement to the CER Federsal Coordinating Council. Today SGIM wishes to urge the Council that, to preserve the highest standards of science and independence from conflicts of intereset,

the American Recovery and Reinvestment Act (ARRA) of 2009 funds for CER should be directed in a way that preserves the conduct of CER at AHRQ, NIH, and other extant federal science agencies. We believe this will be in the best interest of the healthcare system and it will serve as a model for future CER activities at a time when the quality and integrity of CER will become of increasing national interest.

Potential outcomes of CER include scientific knowledge, improved health, and financial impact. Across the spectrum of CER, from structured analyses of prior studies, databases, and registries, to the conduct of large clinical effectiveness trials, the scientific objective is rigorous reliable information about what treatments are best for what patients, and under what circumstances. Unless the conduct or public release of such research is compromised by poor quality or conflicts of interest, such information should have a direct positive impact on health.

The economic consequences are likely to be substantial, but vary for different stakeholders. For the nation, even if total costs of healthcare do not fall, CER should have a positive impact on cost-effectiveness we would be spending healthcare dollars more wisely, on the most effective care. For those who sell treatments, the consequences are mixed. Pharmaceutical manufacturers may benefit financially because CER will compare drugs to not only other drugs, but also to medical devices and procedures, which could expand the number of conditions for which their drugs might be used, and enlarge their market. However, CER might show that some new on-patent drugs are not more effective than earlier off-patent versions available at far less cost, and this could compromise sales of pharmaceutical manufacturers most profitable drugs. For medical device companies also, profits could be reduced. Because currently FDA s statute mandates less evidence of treatment benefit for medical devices than for drugs, a new requirement for rigorous testing of effectiveness would require extra time and money, and ultimately likely would likely show that at least some devices have undiscernable treatment benefits, which would curtail sales.

These adverse effects on manufactures profits are the other side of the coin that should result in greater cost-effectiveness, which should be attractive to healthcare payers, including insurers, self-insured companies, the government, and utlitmately, the public. Reliable well-accepted information on treatment effectiveness on which to base payment decisions would be very helpful. Also, there is general consensus that generating such information without insurers using their own funds, and without violating anti-trust rules against colluding with competitors about business decisions, but rather, using public funds, is very attractive. However, for insurers, that they may be mandated to provide access to treatments found to be effective, and that their decision-making about coverage would be potentially limited based on such data, are concerns.

Some healthcare industry advocates want stakeholder governance input into the conduct of CER rather than as now done at Federal medical or healthcare research agencies. What are the alternatives? Currently, the private sector puts a relatively small amount of into CER, generally focused on their own products or services. The objectivity of this research is suspect, and results may be buried if not in concert with a company s objectives, even if they would have been helpful to the healthcare system and to the health of the public. In comparison, the Agency for Healthcare Research and Quality (AHRQ), already mandated by law to do CER, and the National Institutes of Health (NIH), where CER is also done, both have long-standing high

standards of research transparency and disclosure, with results available for public scrutiny. The credibility of these science agencies has led to acceptance of their findings by the medical community and dissemination of practice improvements, supporting improved care by all clinicians and payers.

The stakes are very high, not only for industry, but more importantly, for the nation and for the public. There is a high road that has made the biomedical research of this nation the best on the planet: the retention of the long-developed peer-review processes and increasingly strict protections against conflicts of interest embedded in the operations of the NIH, AHRQ, National Science Foundation (NSF) and other Federal research agencies. On the other hand, industry concern about healthcare coverage decisions based on CER being done in a research agency does have merit. Payment coverage decisions should not be the purview of science agencies this would only distract -- these decisions should be made by other entities under the extant rules for healthcare coverage.

These considerations lead to specific recommendations for the conduct of CER:

1) Comparative effectiveness research is research intended to affect treatments of people, and for that reason, like all biomedical research, it deserves to be done at the highest standards of science and free from conflicts of interest. Thus it should be done at a science agency, not at a new hybrid entity that will have to build an entirely new science infrastructure and that will involve in its governance those with a direct stake in the results. Indeed, the latter risks a situation rife with conflict of interest and compromised scientific quality.

Public input to research agenda is a social good, and should be sought. It is very reasonable that agencies doing CER and healthcare research have a high-level public/private advisory board. However, it must not be a governing board, which would constitute an avenue for conflict of interest that scientists, clinicians, policy-makers, and the public would, and should, find objectionable.

The AHRQ has the most broad experience and expertise for CER, and could continue as a lead agency for CER. The NIH also has a very important role to play, and both are likely to benefit from collaboration with FDA, CDC, and other agencies. For example, based on these agencies respective expertise, AHRQ could be responsible for research looking at effectiveness, harm, and safety done by analyses of current evidence, healthcare databases, and healthcare delivery, and NIH could be responsible for large randomized comparative effectiveness trials needed to do accurately assess benefits of a treatment. A joint committee could coordinate these efforts, much as there is currently cooperation between program staff among the agencies for joint projects, and this would presumably be in synchrony with the CER Federal Coordinating Council. Also, this link may be facilitated by the NIH Clinical and Translational Science Awards (CTSAs). With the mission of promoting of the wide spectrum of research that can improve the public s health, many CTSA institutions already have AHRQ CER centers (e.g., AHRQ Evidence-based Practice Centers, AHRQ/FDA Centers for Education and Research on Therapeutics, and AHRQ DeCIDE [Developing Evidence to Inform Decisions about Effectiveness] Network centers), and thus could be an excellent link to AHRQ around CER and a portal to NIH Institutes and Centers and potentially to other agencies.

2) Coverage decisions should not be the purview of the CER done at these research agencies; those decisions would be made at the Centers for Medicare and Medicaid Services (CMS) and by other payers, as they are now. For the future, presumably this will be addressed as part of the Healthcare Reform effort. Assessments of the effectiveness of treatments should be central to the output of CER; specific payment decisions about issues of policy, cost, equity, compassionate care, among many, should done by and overseen by agencies under long-established procedures.

We believe it was an excellent sign that ARRA recognized the importance of CER, and that its natural home is in science agencies, viz., AHRQ in conjunction with NIH, where peer review processes and research infrastructure are in place to ensure the highest quality science. This will benefit the entire healthcare system and the public through promoting more effective care. As the impact CER might have on payments plays out in politics, it is important that this research type not be divided from the rest of the biomedical research enterprise. Thus we encourage the Coordinating Council to allocate the ARRA funds for CER in a way that preserves the conduct of CER at AHRQ, NIH, and other extant federal science agencies, and that serves as a model that will serve future CER activities, and will thereby maximize the important impact of CER on healthcare and the public s health.

Submitted by
Sarah Hicks
National Congress of American Indians
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Comment Type: *Listening Sessions*

The National Congress of American Indians (NCAI) appreciates this opportunity to provide comments to the Department of Health and Human Services (DHHS) on comparative effectiveness research (CER). DHHS listening sessions are an important step in the consultative process in deciding how to award the $1.1 billion in ARRA-appropriated CER research grants.

NCAI is the oldest, largest and most representative organization of American Indian and Alaska Native (AI/AN) tribal governments in the nation. DHHS policies on CER have significant potential impacts on AI/AN communities, some of which might improve the quality of health care while other unintended impacts could be detrimental. Consistent with the larger DHHS policy of tribal consultation, we recommend that there should be ongoing discussion with a broad range of stakeholders in AI/AN communities about CER. These consultations should continue throughout all phases of CER policy development and implementation, including: 1) defining the scope of CER and methodologies for this kind of research, 2) the drafting of grant announcements and awarding of funds, 3) and the application of research findings to clinical practice, including changes to reimbursement rates or clinical priorities given to different treatment options. The way that CER is defined will impact what kinds of research will be

funded and likely will also affect what kinds of treatments will be supported by federal health care systems, including the Indian Health Service.

CER is generally defined as a research method for comparing the clinical efficacy of different kinds of drugs, treatments, medical devices, and medical procedures, as well as different approaches to the same procedure. These types of studies could have a positive impact on AI/AN communities if they are included in these kinds of research studies. The clinical efficacy of medications, for example, can vary by ethnic group, and so study results in non-Indian populations should be cautiously interpreted and cannot always be reliably applied to AI/AN individuals. CER studies examining clinical efficacy of different treatments should purposively include AI/AN individuals, who should be included as a large enough proportion of the sample to ensure adequate statistical power. Studies might also be conducted on existing clinical data available through the Indian Health Service s (IHS) medical records system. The outcomes for patients receiving different treatments could be compared using this large existing data set. Similarly, Tribal Epidemiology (Epi) Centers might also be able to conduct regional studies evaluating clinical outcomes of different treatments.

Due to their relatively small population and other factors, AI/AN communities have historically not always been included in research which could be of substantial benefit to them. We recommend that DHHS require researchers conducting national CER studies to include members of ethnic minority groups in those studies, and specifically to oversample diverse AI/AN populations. Furthermore, we also recommend that grant funds be made available to tribal governments, tribal colleges, the IHS, the Native American Research Centers for Health program, Tribal Epi Centers, urban Indian organizations, and other institutions with a history of conducting culturally-sensitive and respectful research in AI/AN communities. Given the mixed history of research in AI/AN communities, it may be difficult to include AI/AN individuals in CER research without involving trusted organizations and institutions in such studies. Studies conducted on tribal lands should also be required to have the approval and support of tribal governments, and tribal processes for research review should be respected. Similarly, studies conducted in urban Indian communities should be approved by and involve urban Indian organizations when applicable. In the evaluation of grant applications for studies to be conducted in AI/AN communities, the potential risks and benefits to both individual community members and the community as a whole should be considered. If possible, AI/AN reviewers or other individuals with knowledge of AI/AN communities should be included on grant review panels. Finally, grant announcements should require community-collaborative research methods, such as community-based participatory research (CBPR), as these methods prioritize community needs.

The chronic underfunding of the IHS is a critical context for considering the broader potential impacts of CER on AI/AN communities. If specific treatments are found to be more clinically efficacious in AI/AN communities, these communities could benefit from having those treatments made more widely available in IHS clinics. The IHS limited financial resources could be better used if channeled toward treatments that have been shown to be clinically efficacious in AI/AN populations. However, even if the treatments found to be clinically effective are relatively expensive, adequate funding should be provided to IHS to support the use of these treatments. Furthermore, it is critical that funding to IHS be increased to an adequate level for the provision of needed medical services, both related to treatment and prevention of disease.

Adequate funding for all necessary medical treatments is a prerequisite for the scientific evaluation of those treatments. Without an increase in resources for the IHS, CER could result in increased emphasis on cost-cutting and rationing of medical care. This potential negative outcome should be proactively avoided by increasing funding for IHS and by focusing the application of CER in IHS clinics primarily toward clinical efficacy with cost-containment as a secondary priority. CER studies conducted in AI/AN communities and elsewhere should not focus on cost-effectiveness at the expense of clinical efficacy.

Definitions of CER and associated research methodologies should be broad and flexible enough to incorporate the worldviews of culturally-diverse communities, including AI/AN peoples. In order to maximize the potential benefits of CER to AI/AN communities, it is important that local contexts and community perspectives are part of determining research topics and methods. Different communities may have diverse forms of healing that they wish to evaluate as part of CER. For example, traditional healers provide care in many AI/AN communities along with Western medical providers. Complementary and alternative medical (CAM) practices (e.g., acupuncture, naturopathy) are also used in some AI/AN communities. Traditional healing and CAM should be included as potential study topics in CER grant announcements. The methods used to evaluate such healing methods may be different from standard biomedical research designs. Established biomedical research designs, such as randomized clinical trials, are not always culturally appropriate for AI/AN communities because some of them find placebo groups (i.e., lack of treatment) unacceptable. In addition, it may not be culturally appropriate to observe or record some traditional ceremonies. These cultural norms do not always preclude the scientific study of traditional healing, but new and creative research methodologies may need to be developed to evaluate its use in AI/AN communities. Finding new ways to study traditional healing and CAM is important for increasing the scientific evidence base for these health systems, and by extension, support for these kinds of healing by federal funding sources and private insurance payers.

Community knowledge and values are important resources in defining study questions, research design, and measures of efficacy or success. As sovereign governments, tribes should be able to determine what healing practices should be studied, what kinds of data should be collected, and how clinical efficacy is defined. Healing practices that are used widely in a community often are successful for community members, which is why these practices are prevalent (regardless of whether they have been scientifically studied). Accumulated community knowledge and evidence of these healing practices success might best be studied by research methodologies other than clinical trials. Such research designs could include long-term observation of the impacts of traditional healing practices (ethnographic research) or using the paradigm of practice-based evidence, where commonly-used healing practices and community knowledge are used as the starting point for study design and data variables, rather than beginning with a priori hypotheses. The scientific strength of these research designs is that they are grounded in community knowledge and provide information specific to local contexts.

While CER specifically is focused on comparing different treatments, treatments are always prescribed and used in a broader context. We recommend that CER study designs and policy applications of studies take into account broader contextual factors for communities and individuals, including socioeconomic status, cultural beliefs, the health of families, and other

aspects of patients environments. We also suggest that CER grant proposals examine the intersection of physical and mental health (e.g., comparing physical and mental outcomes in situations where trauma and mental health concerns are addressed versus when they are not treated). CER study results should also be applied with caution in different local contexts. Available resources and the structure of local health care delivery systems vary widely, and so local communities and health care providers should have some autonomy in determining how to implement CER study results. Similarly, individual patients often have complex medical conditions which do not match the idealized characteristics of study populations, and so health care providers should be free to use their clinical judgment in individualizing treatments for their patients.

In sum, given the wide variation in local contexts, AI/AN communities should be consulted as DHHS defines CER, prepares related grant announcements, and as national health care guidelines and federal reimbursement rates for treatments/interventions are reshaped using CER study findings. Thank you again for the opportunity to provide comments on CER.

Submitted by
[personal information redacted]

Comment Type: *Listening Sessions*

Re: Reading level of participant materials

If potential subjects are given written materials that are above the 8th-grade reading level, many will not be able to read and understand the information. Will subjects say, I can t read this, will you explain it to me? Probably not. They will just sign the forms. This is not informed consent.

The National Institutes of Health Plain Language Coordinating Committee recommends a reading level of 4th-8th grade for public information materials and public notices. http://execsec.od.nih.gov/plainlang/guidelines/engaging.html

I have been a medical writer for 18 years and have written materials for clinical studies for 4 years. My goal is 6th-grade reading level. I often meet with resistance. Researchers tell me: We don t want to sound unprofessional or unscientific. Or this gem: We re more comfortable above 8th grade level. Of course they are more comfortable; they have advanced degrees. Unlike many Americans, they do not struggle with two- and three-syllable words.

Most researchers simply do not understand the scope of the problem of low health literacy in this county, so they will not voluntarily produce easy-to-read participant materials. Thus, we need to set a rule.

I call on the Federal Coordinating Council to require that all materials for participants in clinical studies be at a reading level of 4th to 8th grade.

Submitted by
[personal information redacted]

Comment Type: *Prioritization Criteria*

I am surpised by the lack of a criterion which allows you to prioritise a proposal that uses more rigorous research designs over one whihc uses less rigorous study designs.

I suggest that a criterion should be included which says something like the following:

The most rigorous design possible is used, appropriate to the question and circumstances.

Submitted by
Tony Principi
Pfizer Inc
anthony.principi@pfizer.com

Comment Type: *Prioritization Criteria*

Note: we also are submitting these comments in a separate letter.

On behalf of Pfizer, I am submitting the following comments to the Federal Coordinating Council s (Council) proposal for a framework on comparative effectiveness research (CER). Pfizer is a research based drug developer that sponsors numerous trials in the U.S. and around the world, to support marketing approvals and to assess comparative effectiveness, post-approval.

Pfizer supports the Council s continued commitment to transparency and public engagement through its solicitation of public input on the definition, prioritization criteria, and strategic framework for CER.

Our comments are structured to respond to three elements contained within the draft documents released by the Council. They build on comments we are submitting related to the Council s proposals on prioritization of comparative effectiveness research.

Draft Prioritization Criteria for CER
" The prioritization criteria are divided into two categories:
o Threshold Minimal Criteria (i.e., investment must meet these to be considered)
? Included within statutory limits of the Recovery Act and Council s definition of CER

? Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research
? Feasibility of research topic (including time necessary for research)
o Prioritization Criteria (i.e., the criteria to be deemed scientifically meritorious)
? Potential impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care)
? Potential to evaluate comparative effectiveness in diverse populations and patient sub-populations
? Uncertainty within the clinical and public health communities regarding management decisions
? Addresses need or gap unlikely to be addressed through other funding mechanisms
? Potential for multiplicative effect (e.g., lays foundation for future CER or generates additional investment outside government)

Pfizer agrees with the criteria to be used to prioritize investments and agrees with the proposed criteria and offer two comments.

First, we recommend the Council call for development of a detailed priority-setting framework that implements rather than just informs the proposed criteria. As it stands now, it is unclear how the proposed criteria are interrelated and how they will be used when the Council identifies CER investments. As the only entity mandated by Congress in the American Recovery and Reinvestment Act to prioritize and coordinate Federal efforts in CER, the Council must develop a clearly defined, agreed-upon, and actionable priority-setting process.

The priority-setting process must:

1. Integrate the values of the users of the research.

2. Consider the information needs of the user by conducting CER on the full spectrum of healthcare interventions used to manage conditions.

3. Be efficient by seeking broad input at the outset, but also having a relatively simple mechanism to identify important research topics.

4. Be sensitive to its political context; be objective, open, and fair; invite input from a broad spectrum of stakeholders; and present the logic of the process clearly and carefully to others.

5. Maintain a transparent process in which methods are explicitly defined, consistently applied, and publicly available for comment.

6. Allow for multiple points of engagement from a diverse group of stakeholders throughout the priority-setting process.

7. Allow for meaningful input from patients and clinicians.

Second, specifically related to the proposed criteria, we recommend the Council make three clarifications: (1) clearly define the term feasibility in the third threshold criteria; and (2) include both public and private funding mechanisms in the fourth prioritization criteria and (3) recommending an explicit emphasis on known gaps in evidence.

1. While we recognize that all research needs to be done in an efficient and economical manner, we believe that the merit of research projects should be judged, first and foremost, on their potential benefit to the patient or patient population. As presented, the criterion may be interpreted to suggest that research that is expensive, difficult or time consuming may not be considered or prioritized. To that end, we recommend the Council clarify the definition of feasibility so that it is explicit that it is the Council s intent is to fairly and appropriately consider research projects and to balance the cost, complexity or time-frame for completion against the benefit or likely benefit to the patient population or to improving public health.

2. With respect to the fourth prioritization criterion, we are concerned that it does not explicitly recognize CER investments made by the private sector (e.g., industry, private plans, professional societies, and academic research centers). To ensure that the Council appropriately identifies unmet needs or gaps in research, it is important that any analysis take into account the work of the private and public sector. To that end, we recommend the criterion should be re-worded to include public and private before the term funding.

Third, while we recognize that the prioritization criteria emphasize research that is unlikely to be addressed through other funding mechanisms, we would like the Council to prioritize investments in interventions, populations, and conditions where known gaps exist. This is an important distinction because the program s ability to have maximum impact is predicated upon investing in those areas where current incentives, opportunities, and capacity are limited. Furthermore, the inclusion of such a criterion is actually consistent with the strategic framework that was proposed by the Council; it explicitly calls for investments in under-studied populations and interventions (e.g. procedures).

Submitted by
Tina Grande
Healthcare Leadership Council
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Comment Type: *Prioritization Criteria*

HLC Comment on Draft Criteria

The Healthcare Leadership Council (HLC) applauds the inclusion, as a minimal criterion, the requirement that comparative effectiveness research studies be responsive to the needs and preferences of patients. We believe this reflects the spirit of the American Recovery and

Reinvestment Act (ARRA) and is an important primary goal towards ensuring comparative effectiveness research is used to improve individual patient and public health.

While we question the rationale behind using time necessary as a prioritization factor, we understand that pursuing low-hanging fruits might be the most attractive option when deciding how best to spend the substantial yet limited amount of ARRA funds appropriated for federal CE projects. We respectfully note however, that in some instances, while a study may require a relatively longer length of time to conduct, the benefits of the information generated may be valuable enough so as to more than outweigh the cost in funds and time needed to reach completion. In this instance, prioritizing according to time needed may discourage valuable and important research questions.

We also agree that this research should, in setting priorities, target diseases and conditions with the greatest prevalence, including those that impose the greatest clinical and economic burden on patients and health care spending, respectively. We also note that, while variability in outcomes is an important phenomenon on which to focus these efforts, the research should not necessarily equate this with variability in intervention utilization.

We wish to re-emphasize the importance of designing this research to ensure it can evaluate and discern differences within appropriate subpopulations and we therefore strongly support using the potential to do so as a prioritization factor.

Submitted by
[personal information redacted]

Comment Type: *Prioritization Criteria*

EIGHT SUGGESTED ADDITIONS TO STATEMENT: IN QUOTES BELOW (placed within original statement)

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform

SUGGESTED ADDITION #1: and positively impact

patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients

SUGGESTED ADDITION #2: and consumers

under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations

SUGGESTED ADDITION #3) and methods to effectively communicate the results to significant stakeholder in the health care marketplace.

Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness,

SUGGESTED ADDITION #4) as well as to assess the value of comparative effectiveness research itself to the public.

Threshold Minimal Criteria (i.e. must meet these to be considered)

1. Included within statutory limits of Recovery Act and FCC definition of CER
2. Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research
3. Feasibility of research topic (including time necessary for research)

SUGGESTED ADDITION #5: "4. Commitment to timely and public reporting of baseline methods, preliminary results, and final results

Prioritization Criteria
The criteria for scientifically meritorious research and investments are:
1. Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care)
2. Potential to evaluate comparative effectiveness in diverse populations and patient

SUGGESTED ADDITION #6: and consumer

sub-populations

SUGGESTED ADDITION #7: and to effectively communicate methods and results to these groups.
3.

SUGGESTION ADDITION #8: Different levels of

uncertainty within the clinical and public health communities regarding management decisions
4. Addresses need or gap unlikely to be addressed through other funding mechanisms

Submitted by
[personal information redacted]

Comment Type: *Prioritization Criteria*

EDIT SUGGESTIONS FOR THRESHOLD MINIMAL CRITERIA

PUT THIS SECOND AS IT S A HIGHER CONSIDERATION AND MODIFY PARENS EXPLANATION AS NOTED BELOW
Feasibility of research topic (e.g., cost, time necessary to complete research)

PUT THIS THIRD BUT ALSO CLARIFY AS NEEDS AND PREFERENCES SHOULD BE TIED TO PUBLIC WELFARE PRINCIPLES AND NOT BE LOOSELY DETERMINED BY VARIOUS PARTIES SUGGESTED EDITS AS FOLLOWS.
Responsiveness to tangible research priorities (e.g., disease prevalence, cost of care) that are identified by various parties
NOTE: WITH CURRENT CRITERON, THIS PHRASE IS UNCLEAR AS TO MEANING
>>including community engagement in research

PRIORITIZATION CRITERIA
THESE ARE GENERALLY FINE AS IS. HOWEVER, CLARIFY MEANING OF THIS CRITERION: Uncertainty within the clinical and public health communities regarding management decisions

Submitted by
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Comment Type: *Prioritization Criteria*

America s Health Insurance Plans (AHIP) appreciates the opportunity to share its member companies perspectives on the proposed definition for comparative effectiveness research (CER) and the strategic framework for such research. AHIP is the national trade association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, disability, and supplemental coverage and also have a long history of participation in public programs.

Prioritization Criteria Comments
Our members question how the National Priorities Partnership and their significant contribution to focus all stakeholders on key areas of overuse and gaps in care can be considered or incorporated into the draft prioritization criteria.

Submitted by
Andrea Douglas

PhRMA
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Comment Type: *Prioritization Criteria*

Wednesday, June 10, 2009

VIA E-MAIL

Dear Federal Coordinating Council Members:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments to the Federal Coordinating Council for Comparative Effectiveness Research on the draft definition of comparative effectiveness research (CER), priority setting criteria, and strategic framework released by the Council.

PhRMA is a voluntary, nonprofit association representing the country s leading research-based pharmaceutical and biotechnology companies, which are devoted to discovering new medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA s member companies play a leading role in discovery of new therapies and advancement of scientific and clinical knowledge.

PhRMA appreciates the Federal Coordinating Council s posting of its draft CER definition, prioritization criteria and strategic framework as a further step in promoting openness and transparency as it carries out its duties under the American Recovery and Reinvestment Act (ARRA). Specifying a CER definition and criteria for research priorities are important initial steps in establishing a sound CER research program.

As the Council continues implementing its mandate under ARRA, we urge it to maintain open and transparent procedures. In particular, as the Council prepares to submit a report by June 30 making recommendations for CER research to the President, Congress, and the Secretary of the Department of Health and Human Services (HHS), we ask that it explain the substantive reasons for its recommended research priorities. This will enable members of the public to understand how the priorities correspond to the input received from stakeholders, respond to the information needs of patients and providers and meet the other criteria established by the Council. In addition, the Secretary should establish a similar policy as it considers the Council s recommendations, and those of the Institute of Medicine, in establishing research priorities. Open, transparent processes advance research that is credible and relevant to the real-world decisions facing patients and providers as well as reflecting the different needs of racial, ethnic and other patient sub-populations.

PhRMA supports the focus on patient and provider needs in the Council s draft CER definition and criteria for research priorities. This focus also is evident in HHS Secretary Kathleen Sebelius April 21, 2009 comments at the Senate Finance Committee: The goal of such research is to improve the database of information available to a patient and his or her

provider so they can make informed decisions about care. The goal is to empower patients and providers with the best information on protocols, procedures, and other relevant issues, not to enable the federal government to dictate broad coverage decisions." In addition, the Council s emphasis on the expressed needs of patients and providers will help ensure that their input is given sufficient weight in the CER process.

The Council appropriately recognizes the importance of accounting for differences in individual patients throughout its draft material. This will help facilitate study designs that recognize and generate data on different patient subgroups, and communication of results that reflect differing patient needs based on genetic, clinical and other factors. These factors are very important to patients but, unless expressly recognized, can be minimized in study designs and communication of results. In a letter last year, the Congressional Black Caucus highlighted the importance of accounting for individual differences in CER research result: All research supported by a comparative effectiveness initiative must recognize variation in individual patients needs, circumstances, and responses to particular therapies. Comparative effectiveness research must enrich our understanding of these variations, rather than ignoring them by focusing on population averages that mean little for any individual patient or subgroup. Without this focus, the results of research could inappropriately be used as a rationale for restricting the treatment choices of those who fall outside the average response.

In addition, PhRMA supports the scope of research included in the draft definition of CER, which encompasses the full range of medical treatments, behavioral change strategies, and delivery system interventions. This broad scope of research is consistent with the Act s mandate for research on health care treatments and strategies. This scope of research reflects the growing recognition that addressing the needs of patients, particularly those with chronic illnesses, requires greater scrutiny of healthcare delivery systems. This includes comparing the effectiveness of different approaches to care processes, disease management services, care coordination, benefit designs, and other components that directly impact care quality and patient outcomes.

The importance of this aspect of comparative effectiveness research was emphasized in Atul Gawande, MD s, June 1, 2009 New Yorker article: "Congress has provided vital funding for research that compares the effectiveness of different treatments, and this should help reduce uncertainty about which treatments are best. But we also need to fund research that compares the effectiveness of different systems of care to reduce our uncertainty about which systems work best for communities. These are empirical, not ideological, questions.

While the draft definition, prioritization criteria, and strategic framework include many positive elements, we offer the following recommendations to help ensure that CER remains centered on improving health care quality and supporting patient and provider decision-making:

1. Clarify the references to decision makers from the draft definition and federal needs as a basis for setting research priorities.

Defining research priorities and study questions that respond to the information needs of patients and providers is an important, and challenging, early step in CER. While decisions at the policy

level should be informed by best available evidence, including comparative effectiveness research, it is important that government-supported CER conducted under ARRA is centered on supporting patient and provider decision-making and improving the quality of patient and provider care. This will help ensure that federally-funded CER meets the goal described in HHS press release announcing the Council, Comparative effectiveness research provides information on the relative strengths and weakness of various medical interventions. Such research will give clinicians and patients valid information to make decisions that will improve the performance of the U.S. health care system. The Council should clarify how federal and other decision making needs will be recognized while maintaining a focus on patients and providers.

2. The council should clarify how the separate elements of the prioritization criteria will be weighed against each other and the minimal feasibility of research criteria should be clarified and moved to secondary list.

The feasibility of research criterion should be moved to the second category of criteria for ensuring scientifically meritorious research and investments, and the Council should clarify how time necessary for research will be used as part of this criterion. The length of the study is an important consideration, but should not be a minimal criteria, as both long- and short-term research can yield findings that are more or less useful to patients and providers. For example, the seven years it took to complete the federally supported Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) reduced its impact, because of the ways the practice of medicine evolved during the study period . At the same time, the time necessary for research should not be used to rule out studies that are longer-term but yield high-value information. Some long-term studies, such as the Women s Health Initiative, provided important information about women and osteoporosis, cardiovascular disease, and cancer and had a significant impact on patient and provider treatment decisions, even though it had a 15 year time frame.

3. Additional recommendations: clarify variability in outcomes, weighting of criteria, and range of data sources.

The Council should clarify the types of outcome variability it will consider when setting CER priorities. This will facilitate consideration of outcomes variation related to a range of factors, including geographic location, treatment site, provider type, and patient sub-group, consistent with the FCC s definition of CER. Conducting research to address these variations represents a significant opportunity to improve health care.
For example, Addressing this issue October 8, 2007 at the Institute of Medicine annual meeting, Eliot Fischer, MD, MPH, Dartmouth Medical School, said: We need better evidence, both about biologically targeted interventions, but also about care delivery...There is an emerging consensus on need for comparative effectiveness research. I think it s critically important that we broaden that focus to include evidence-based care management and evidence-based care delivery, because that s where all the money is and that s where all the waste is in U.S. health care.

In addition, addressing variability in outcomes within minority groups could help reduce health care disparities . There is a broad range of research that indicates racial and ethnic minorities are less likely to receive medical care we know works very well and experience a lower quality of health services. For instance, the Institute of Medicine report, Unequal Treatment found that racial and ethnic minorities are less likely to be given appropriate cardiac medications or to undergo bypass surgery, and a more likely to receive certain less-desirable treatments, such as limb amputations for diabetes. This is not because of any lack of knowledge about appropriate treatments for conditions such as diabetes or heart disease. Rather, it is because our health system does not implement effective strategies to organize and deliver care to minority populations. Placing a high priority on research to identify the strategies that the health system can use regarding issues such as disease management, use of information technology, benefits design, community outreach, to close this gap is important to improving care in minority communities.

In the definition, the Council should describe the range of data sources and methods it will consider to assess comparative effectiveness, such as randomized controlled trials, meta-analyses, observational analysis or other methodologies. Each research methods offers different strengths and limitations, and providing additional detail in this area could facilitate research that provides information on diverse populations and patient sub-populations, helping to reinforce the Council s commitment to assessing outcomes related to these populations.

Finally, the council should clarify how individual priority setting criteria are weighted. This will help stakeholders further understand the rationale behind recommended priorities.

4. The process step Potential capacity for translation through Federal delivery systems and public private partnerships under Translation and Adoption of CER should be clarified in the CER Strategic framework.

The Council s strategic framework should maintain a focus on translation and adoption of CER results widely to patients and providers in timely, usable formats. This will help orient research towards the needs of patients and providers, and avoid access barriers based on average study results that may overlook differences in the needs of diverse patient groups. The strategic framework should clarify how translation of CER through federal delivery systems will support this goal.

The $1.1 billion included in ARRA for CER represents an important opportunity to establish a broad research agenda that supports patient and provider decision-making and improves health care quality. PhRMA supports the steps the Council has taken to help achieve this goal, including high quality, credible CER that has public buy-in. We ask that the Coordinating Council adopt our suggested revisions to the draft definition, priority setting criteria, and strategic framework.

PhRMA looks forward to continued participation in your important work to recommend CER research priorities. Please do not hesitate to contact me if I can be of any other assistance.

Submitted by
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Comment Type: *Prioritization Criteria*

Consistent with the comment AdvaMed submitted regarding the definition of CER, AdvaMed recommends that the second threshold minimal criterion be clarified to specify who the other stakeholders are. AdvaMed recommends that the second criterion read as follows:

2. Responsiveness to expressed needs and preferences of patients, clinicians, and other health care professionals, including community engagement in research.

AdvaMed also has the following three comments on the draft prioritization criteria. First, AdvaMed supports consideration of potential impact in prioritizing research and has the following comments to offer regarding this criterion.

" Potential impact should include consideration of outcomes such as change in quality of life or functional status, risk reduction, and treatment satisfaction. Therefore we suggest adding this language to the current parenthetical.
" Prevalence of condition is an appropriate factor. The Federal Coordinating Council should explain, in subsequent reports and plans, how rare diseases (with small population impacts) will be addressed in comparative effectiveness research initiatives.
" The term costs of care should be defined inclusively to take into consideration all costs of care, including reduced hospital admissions, length of stay, and other resource utilization. Therefore we suggest total cost of care rather than costs of care .

Second, AdvaMed supports evaluating comparative effectiveness in diverse patient populations and sub-populations, however greater clarification as to how this criterion will be made a factor would be helpful in subsequent reports and plans. Depending on the study objectives and the study design, there may be challenges in assessing diverse patient populations in a manner that yields statistically significant results for every sub-population. For example, assessing diverse patient populations may be best accomplished through the development of clinical registries, analysis of clinical data networks and electronic health data, and other methods. The observational nature of such study designs and data sources, however, might potentially present issues with drawing definitive conclusions about which interventions are most effective under which circumstances, a significant objective of CER.

Third, regarding consideration of uncertainty within the clinical and public health communities regarding management decisions, AdvaMed recommends better defining the term uncertainty. The following parenthetical should be added following the word decisions : (e.g., areas for which there is insufficient evidence to guide clinical decision-making or patient management).

Submitted by
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Comment Type: *Prioritization Criteria*

The Comparative Effectiveness Research Workgroup for Humana has reviewed the proposed definition of Comparative Effectiveness Research (CER) and prioritization criteria. We agree with the coordinating council that the definition of CER should encompass a broad array of interventions and strategies; however, we suggest that CER should also include measurements of standardized cost or relative resource consumption of interventions of strategies when comparing their effectiveness. This will allow an assessment of the overall value of various interventions and could identify important differences in the cost-effectiveness of interventions between different sub-populations. Thus, we suggest the following change to the third sentence of the definition:

To provide this information, comparative effectiveness research may include a broad array of health-related and cost-related outcomes for diverse patient populations.

If the aforementioned change is made to the definition of CER, then we believe that the threshold minimum criteria and prioritization criteria are appropriate. However, we are concerned that the current wording of the first threshold minimum criterion would appear to exclude anything not explicitly mentioned in the definition and therefore may exclude the measurement of cost and/or relative resource consumption in CER studies. While measurement of costs may not be required of every CER study, it should also not be excluded from consideration as a useful variable in a CER study.

Submitted by
American Medical Association American Medical Association
American Medical Association
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Comment Type: *Prioritization Criteria*

The physician and medical student members of the American Medical Association (AMA) commend the Federal Coordinating Council for Comparative Effectiveness Research (Council) for convening a series of public meetings and reaching out to clinicians and medicine to solicit our input on national comparative effectiveness research (CER) priorities as well as comments on the Council s draft CER definition, prioritization criteria, and draft strategic framework. Concerted stakeholder and public engagement will ensure that the funding to support CER will be allocated in an optimal fashion and increase the utilization of CER findings by physicians and patients.

All aspects of the CER process, including priority setting and capacity-building measures, must be transparent and include a central role for physicians in their oversight and governance. Given the nascent nature of this endeavor, the perception among physicians that the CER agenda is being driven by payers who only have cost containment as their goal will seriously undermine efforts to cement physician support as we continue forward on comprehensive health care system reform. It is imperative that physicians, including clinicians and their organizations, have an active, ongoing, and central role at all stages of the CER process. To be clear; the AMA strongly supports CER and looks forward to results that will guide shared decision-making by patients and their physicians.

Physicians today have access to a wide array of medical information. However, there remains far too little rigorous evidence available about which treatments work best for which patients. The AMA strongly supports increased federal funding of CER. Though there is a broad array of areas where CER would bring benefits, we must strategically target support for CER where it will significantly improve health care value by enhancing physician clinical judgment, foster the delivery of patient-centered care, and produce substantial benefit to the health care system as a whole. As outlined in more detail below, the AMA strongly supports the Council s Draft Definition, Draft Prioritization Criteria for Comparative Effectiveness Research as well as the Draft Comparative Effectiveness Research Strategic Framework.

The AMA supports the view that the priority areas of CER should focus on high volume, high cost diagnostic and treatment modalities, and other health services and strategies for which there is significant variation in practice.

The AMA supports a broad definition of CER that involves a comparison of different modalities to prevent, manage, or treat a specific health problem, condition, or disease. Besides the more typical areas of research such as pharmaceuticals and medical devices, CER should also focus on implementation and dissemination issues that would shed light on the most effective strategies that promote a learning health care system and improved clinical outcomes including behavioral change strategies, and delivery system interventions.

In terms of methodology and study design, CER should include long-term and short-term assessments. CER should not be limited to new treatments. In addition, the findings should be re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data.

AMA Recommended Priority Areas & Infrastructure

Much of the expertise for setting CER priorities focusing on specific diseases and interventions lies within the medical specialty societies. Nonetheless, the AMA offers the following recommendations for CER priorities and offers suggestions concerning two mechanisms that would help build the necessary infrastructure to sustain work in this area.

The AMA strongly believes that the national CER priorities should address the prevention, management, and treatment of preventable disease which collectively represent a major cost

driver in today s health care system. Key areas in need of further study and research include cardiovascular, endocrinology and metabolism disorders (including diabetes), and nutrition (including obesity). For example, in the area of wellness, prevention, nutrition, and obesity there is a paucity of CER findings. It is an area with a wide range of available interventions with little clarity about which is most effective.

CER usually considers technology and pharmaceuticals, but behavioral interventions potentially could have the greatest impact for individual patients and the system as a whole. Prioritizing interventions designed to change physician behavior and to effect behavioral change in patients, in addition to other clinical interventions, technologies, and pharmaceutical remedies, is necessary. Because prevalence rates and the most effective interventions for many diseases vary greatly by race, ethnicity, gender, age, geography, and economic status, the AMA strongly supports the inclusion of racial and ethnic health disparities and health disparities more generally as a CER priority area.

In addition to the foregoing, the National Priorities and Goals report put forth by the National Priorities Partnership (NPP) convened by the National Quality Forum (NQF) provides a rich source of information for the Council to consider. The NPP, comprised of 28 national organizations, focused on achievable goals that would, if implemented broadly, reduce harm, improve patient-centered care, eliminate health care disparities, and remove waste from the system. In preparing the report, the NPP solicited extensive input from broad array of individuals and organizations. Utilizing the NPP National Priorities and Goals as a reference point will help the Council to identify national CER priorities that will build the evidence base in a targeted fashion in the areas that are likely to produce substantial system-wide improvements.

In addition to the NPP report, the AMA convened Physician Consortium for Performance Improvement (PCPI) has developed a valuable survey mechanism that can be utilized by the Council to gather additional detailed information concerning national CER priorities. In order to obtain timely, quality responses from the more than 100 national medial specialty and state medical societies, experts in methodology and data collection, and many others involved in quality improvement and performance measurement, the PCPI constructed a survey mechanism. It is a powerful new tool to identify variations in practice, to assess the evidence base in a wide array of areas, and to identify areas where there are gaps in knowledge. The PCPI plans a significant expansion of these efforts. This provides much needed capacity and infrastructure for priority setting. We would welcome the opportunity to have the Council work with the PCPI to utilize this survey mechanism as it develops the recommendations concerning national CER priorities.

The AMA urges the Council to consider two powerful infrastructure mechanisms, clinical registries and data networks. These have been used by specialty societies such as the Society of Thoracic Surgeons and the American College of Cardiology, and have markedly improved quality and patient safety. The National Surgical Quality Improvement Program (NSQIP) and the Northern New England Cardiovascular Collaborative are examples of utilizing these two mechanisms to advance quality and obtain research data at the point of care, and create what our country needs, a learning network. Expansion of existing clinical registries and databases would provide a strong foundation when conducting CER and at the same time these registries would

also provide an excellent beginning point for CER. Utilizing, replicating, expanding, or integrating existing clinical registries would constitute an invaluable investment in the much needed infrastructure for accurately comparing clinical outcomes based on real life conditions where delivery of care settings vary, patients may have numerous co-morbidities, and the patient population is diverse. In turn the clinical registries are not identical and may to greater or lesser extent be able to promote a learning health care environment; thus, evaluating the comparative clinical effectiveness of various clinical registry models and alternatives to them remains a vital priority. Building CER infrastructure and capacity in part upon registries and clinical data networks will leverage CER resources and boost the capacity of the system as a whole to learn and adapt in real time.

AMA Support of Council s Draft Strategic Framework

The AMA generally supports the Council s effort to develop a strategic framework for CER activity and investments in order to categorize current activity, identify gaps, and inform decisions on high priority recommendations with a couple of caveats.

First, the AMA urges the Council to ensure public access to the detailed inventories of Federal CER activities and research/data infrastructure that the Council proposes to create. The AMA agrees that the Council s organizing framework will foster consideration of the balance of activities and priority themes and allow the government to focus on the most pressing needs expressed by patients and clinicians, and allow identification of gaps in the current landscape of CER. We urge the Council to work with the AMA convened PCPI which is already engaged in this activity as discussed above.

Second, the AMA concurs with the Council that CER activities should be grouped into the following four major categories as detailed in the proposed framework:

" research, (e.g., comparing medicines for a specific condition or discharge process A to discharge process B for readmissions).
" human and scientific capital, (e.g., training new researchers to conduct CER, developing CER methodology).
" CER data infrastructure, (e.g., developing a distributed practice-based data network, linked longitudinal administrative or electronic health records databases, or patient registries.)
" translation and utilization of CER, (e.g., building tools and methods to translate CER into practice and measure results.)

While all the above categories are essential components of timely, valid, useful CER, it is important to underscore the essential and central role physicians must play vis-à-vis the last component translation and adoption of CER. The AMA supports the development of practice guidelines by medical specialties and other clinicians in medicine, but would oppose the development of guidelines by the government or another centralized entity. Consistent with the foregoing, to the extent that medical specialties design, implement, and play a central role in clinical registries such as NSQIP that rely upon clinicians to conduct CER, the AMA would support utilization of CER findings generated through clinical registries by the specialties to modify practice guidelines and decision support vis-à-vis the clinical registries.

Conclusion

There is a final cautionary tale. In the February 12, 2009, issue of Journal of American Medical Association there is a description of what can happen when science and politics collide. The Infectious Disease Society of America (IDSA) studied the evidence base for the treatment of Lyme disease and in 2006 issued new guidelines advising against the long-term use of antibiotics. The IDSA was promptly sued by the Connecticut Attorney General alleging violations of antitrust laws and restraint of trade. The case was settled without IDSA admitting any fault and assenting to an ombudsmen-reviewed panel to assess the 2006 guidelines. If we cannot separate science and politics in a case such as this, how will we ever manage to deal with the really hard issues?

CER has the potential to have a profoundly positive impact on the quality of the information available to physicians and patients and, when used appropriately and with care, will address escalating health care costs. The AMA welcomes the opportunity to work closely with the Council to ensure that physicians remain engaged, enthusiastic, and involved stakeholders in this process.

Submitted by
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AMDeC
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Comment Type: *Prioritization Criteria*

As the Federal Coordinating Committee deliberates regarding priorities for comparative effectiveness research, the Academy for Medical Development and Collaboration (AMDeC) would like to offer its perspective.

AMDeC is a non-profit consortium of 28 of New York s premier research institutes, medical schools, and universities seeking to collaborate to advance biomedical research. We believe that greater coordination of the various research efforts and the cross-institutional data collection and analysis are keys to optimizing patient outcomes and containing costs. AMDeC has developed innovative research models and infrastructure toward that end. We hope that the suggestions we offer based on our experience in this field will add value to your decision-making process.

We believe that the Coordinating Council should consider investing in projects that leverage existing infrastructures and research methodology that are proven. The infrastructures should be flexible in terms of their ability to be replicated and scaled/expanded, as well as to provide ease of use across institutions. Architectures such as a federated virtual data warehouse that allows for a single, unified interface to data from multiple sources without additional expensive investments in new hardware, software packages, databases, or personnel re-training is ideal.

AMDeC believes a number of criteria should be considered as investment decisions are made. Comparative Effectiveness Research inherently appreciates the value of sharing information. Therefore, projects based on meaningful collaboration and leverage health information technology (HIT) infrastructure/tools among institutions should receive priority. Public investments must focus on projects that can demonstrate the practice of sound science to ensure quality outcomes. In addition, it is critically important that federal and state governments invest in CER data infrastructure and translation/adoption of CER in conjunction with their HIT efforts so that a comprehensive, inter-operable data infrastructure and implementation strategy are in place to produce multiplicative effect by exponentially advancing the utility of the electronic data collected in this new digital, prevention-driven environment. Stakeholder incentives including CMS payments for data reporting, provider needs for an improved understanding of best care processes, and payor calls for accountability and improved metrics for healthcare utilization need to be built as part of the overall CER strategic framework to ensure that CER research findings can effectively be translated into clinical outcomes and health care improvements.

Quality and quantity of the data to be analyzed and evaluated should be carefully considered in terms of the diversity of the population that is included in studies. Clearly there are many factors that affect health care and response to treatment. The more factors that can be taken into consideration and effectively analyzed, the better research outcomes can be derived to effectively improve health care delivery and treatments, including pharmacy, lab tests, demographic information, compliance indicators, claims data, and other medical record data. Comparison of the cost and clinical effectiveness as well as the safety of different treatments, medications, care delivery, etc. should enable specific focuses on un- or under-studied populations as defined by co-morbidities and demographics.

A primary concern with any data collection is security and privacy. Any project that is funded should meet the highest standards of patient confidentiality and data security. Extensive safeguards should be introduced at every step of the process for all involved parties while building trust among clinicians, patients and other stakeholders for full acceptance, support, and involvement.

Finally, evaluation measures should be considered. A critical component to ensuring successful impact of CER is to build in evaluation measures from the initial stage. Regular and timely reporting of assessment and evaluation progress should be established to ensure that priorities and implementation activities are indeed aligned or re-aligned with periodic evaluation results and performance standards.

Academy for Medical Development and Collaboration (AMDeC)
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Submitted by
[personal information redacted]

Comment Type: *Prioritization Criteria*

Consider revising both the Threshold Minimal Criteria and the Other Criteria based on pragmatic considerations in operationalizing these and to more specifically indicate that comparative effectiveness research needs to improve decision making applicability.

Suggested Revisions to Threshold Minimal Criteria:

a. Included within the statutory limits of Recovery Act and FCC definition of CER
b. Responsive to expressed needs and preferences of patients, clinicians, OR OTHER DECISION-MAKERS TO ADDRESS UNCERTAINTY WITHIN CLINICAL AND PUBLIC HEALTH COMMUNITIES REGARDING MANAGEMENT DECISIONS.
c. Feasibility of research topic (including ETHICAL CONSIDERATIONS, RESEARCH INFRASTRUCTURE REQUIREMENTS, AND time necessary for research)

Suggested revisions to the Prioritization Criteria (based on moving up the original criterion c and adding an additional criterion):

a. Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, cost of care)

b. ADDRESSES comparative effectiveness in diverse populations and patient subpopulations, WITH POTENTIAL TO IMPROVE EXISTING HEALTH DISPARITIES OR TO INFORM PERSONALIZED MEDICINE.

c. POTENTIAL FOR IMPROVEMENT IN HEALTH CARE DECISION-MAKING OR PRACTICE WITH ADDITIONAL RESEARCH

d. Addresses need or gap unlikely to be addressed through other funding mechanisms

e. Potential for multiplicative effect (e.g., lays foundation for future CER or generates additional investment outside government)

Submitted by
[personal information redacted]

Comment Type: *Prioritization Criteria*

Council:

"Prevention and wellness" must be our top priority. It is the best way to impact the use of resources and to improve the health and wellness of our citizens.

The recent NIH Challenge Grant priorities were listed in a 52-page document; only a handful related to prevention and wellness. We have got it backwards when we allocate $90B to "Improving and Preserving Health Care," but only $1B to prevention and wellness.

We will all benefit from a much closer look at prevention strategies and the comparative effectiveness of wellness-related interventions.

Submitted by
[personal information redacted]

Comment Type: *Prioritization Criteria*

It is critical to put in place means that reduce duplication and allow better coordination of comparative effectiveness research (CER) investments and activities across the federal government and, to the greatest extent possible, with the private sector and with international bodies. The volume of research questions and critical comparative effectiveness needs outstrip our ability to fund and conduct new research in a timely manner. It is critical to increase our ability to access planned, in-progress, and completed comparative effectiveness research of all types (systematic reviews, trials, observational studies of all types). This could occur by registries/databases of protocols for all types of CER studies and via better library and database tagging. Otherwise, it is nearly impossible to ensure that we do not duplicate existing applicable work in response to requests from the public, nor to take advantage of piggy-backing additional questions onto in-process projects. There is a growing understanding of this critical need to improve CER information retrieval in both the US and internationally.

Submitted by
Victoria Dohnal
Biotechnology Industry Organziation (BIO)
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Comment Type: *Prioritization Criteria*

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO is pleased to have the opportunity to submit comments to the Federal Coordinating Council (FCC) on the draft definition of Comparative Effectiveness Research for the FCC.

As a representative of an industry committed to discovering new cures and ensuring patient access to them, BIO strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making. BIO believes that individual patients and their doctors should be armed with the best available information to help assess the relative clinical benefits and risks of various treatment alternatives. When appropriately applied, comparative effectiveness information is a valuable tool that, together with a variety of other types of medical evidence, can contribute to improving health care delivery. However, BIO is concerned that comparative effectiveness information will be used increasingly as a means to contain costs, rather than deliver health care value by improving patient health outcomes. BIO appreciates the opportunity to comment to the FCC.

We submit the following comments for your consideration on the definition of comparative effectiveness research, draft prioritization criteria, and the strategic framework. We look forward to continuing to work constructively with you in order to realize the full value of comparative effectiveness research.

Draft Prioritization Criteria

Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research

BIO is pleased that the FCC wishes to be responsive to the expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research.

Suggested Modification: In order for the research to have the greatest possible benefit, as BIO has previously commented to the Institute of Medicine (IOM) on the composition of the Committee to establish Comparative Effectiveness Research Priorities (Committee), it is critical that all stakeholders be involved and represented in these efforts. Including all stakeholders at the table will enhance the Committee s discussions and deliberations. Each group of stakeholders brings different and valuable perspectives, and it is important that all perspectives are able to have a voice and be heard as part of the Committee. The IOM Roundtable recognized this principle and stated, The determination of the priorities to pursue is a policy exercise in which all relevant stakeholders have a right to engage and to which they can add value. Therefore, stakeholders should be afforded the opportunity to serve on the Committee as well as provide meaningful input into all steps along the study process, including the identification of priority areas to research, study design and research methods, and dissemination of results. Having all stakeholders at the table with full disclosure of potential conflicts of interest is a good way to manage potential biases and conflict of interest. Disclosure and broad representation are critical to ensure a balanced end product.

Submitted by
[personal information redacted]

Comment Type: *Strategic Framework*

The strategic framework seems developed from a perspective of the need for de novo research. While we certainly need to invest in more research that evaluates the effectiveness of interventions and how they compare, we should first examine the vast science (including all study designs that are well executed and relevant to the clinical question) already available to determine where gaps exist. I propose that a framework for action allows for the synthesis of existing knowledge and supports improvements in methodology to do so with minimum bias. When gaps in knowledge are identified, and they will be, we can focus our limited resources toward the conduct of studies to generate new knowledge where the greatest gaps exist. We must also plan for identification of new areas for research and for continually staying current with the best science. We may consider translating existing knowledge to action even while we plan for new knowledge generation, as we may have sufficient evidence to guide some action ahead of the results of studies to provide more complete guidance strategies.

Prioritization of which topics remains important throughout.

Submitted by
[personal information redacted]

Comment Type: *Strategic Framework*

CER
The definition is inappropriate. which interventions are most effective for which patients under specific circumstances.

Strategic framework. Too many diagrams. Not operational (see term from operations research).
First task is to create methods to evaluate CE
It is impossible to study all possible diagnosis and treatments. Create a method to establish priorities.

Create mathematical models for decision making under CE conditions.
Create mathematical models that predict disease and outcome. At least $300M should be devoted to this task, the most important and promising one to improve outcomes and save costs. Today the technology exist to drastically improve diagnosis by minimizing the use of diagnostic tests (using decision theory and biochemical models). Same for treatment.

Identify data bases that are useful for diagnosis and treatment.
Provide $50M for seed money to develop prototype data bases for conditions. Provide guidelines for data to be gathered as part of Health IT, medical records. Uniform, standard output formats for medical records for data analysis on conditions, outcomes.

Medical/research data are very difficult to interpret. All recipients of federal funding ought to provide their results in a manner that can be incorporated into models of disease diagnosis, treatment.

All data from federally funding research ought to be available for further research.

Focus on the 10 conditions that account for most morbidity, mortality, # of people, and costs. If uncertain, rank on each factor and chose the top 10 in each group.

Focus on getting CER results that substantially improve health care outcomes and lower costs.

Spend $100M on population models to evaluate the impact of alternative diagnosis, treatment, behavioral choices, etc.
See articles by Siguel for how to make these models. Ask him
Siguel E, Seubold F. Potential 10 Year Savings from HMO Development Part 1, Health Maint Org. Hearings before Subcom. on Public Health and Env, 92nd Congress, US Gov Print Off, p. 92-95, 1972.
Siguel E. The Application of Computer Simulation to the Evaluation of Income Maintenance Programs. Inst. of Electr. and Electronic Eng, Trans. on Systems, Man and Cybernetics, 1976: 695-98.

Spend $100M on models of preventive health care. What is the impact (benefits, outcomes) of different types of prevention.
Ex: perhaps eating fewer trans fats prevents heart disease. The cost of changing foods is huge. Furthermore, trans fats are replaced by other fats that could be more dangerous. Perhaps the cost of treating the few who get heart disease due to trans fats is smaller than the cost of changing the food industry.

If we had to focus, what are the best recommendations for people? What is the range of ideal weight? At what weight disease starts to increase dramatically? What is the impact of eating healthy foods? What do models predict about disease prevention associated with eating vegetables and fruits, vs. more disease associated with French fries (if any)

The definition is inappropriate. which interventions are most effective for which patients under specific circumstances.
It is not interventions for patients, but interventions for a population of similar patients given known environmental, genetic, financial, social, etc.
Patients may chose what is best for them without regard for the consequences or costs to society and health consequences for others.
$1B spent providing 3 months extra life to 10 people could be better spend providing speech therapy to 10 children and correct a developmental delay problem.

If costs are irrelevant as a screen, then CE would spend all its time and money evaluating the most expensive and high tech arm replacement or brain replacement or cancer treatment optimized for specific cells (feasible today).

A grandfather with prostate cancer may chose to postpone treatment for several years rather than risk death until his grandson is 3 years old. Or he may have a grandson that is 16 and may chose to wait until he is 18 and takes over the management of family trusts. Or a 50 yo who just met a wonderful girl and is planning to have a family may chose to wait 1 year (even though he could freeze semen) before starting a treatment that could alter his genes or damage reproductive ability. The examples are endless.

CE does not exist in a vacuum of costs, behavior, environment, and accurate models.
Every statistical analysis, every clinical trial has an implicit mathematical model. It starts with the selection of variables to consider or ignore, markers to measure or ignore. Many trials involve drastic assumptions.
Beware of the physicist who seeks to predict horse races by assuming that horses are symmetrical balls moving on a surface with constant friction.

Population issues. Consider an ear or throat bacterial infection. There are 3 antibiotics, Ab1, Ab2, Ab3. Assume they all have the same risks. Ab1 costs $3 and has a 70% cure rate. Ab2 costs $100 and has a 85% cure rate. Ab3 costs $1,000 and has a 99% cure rate. Without treatment, cure rate is 60% (numbers are fictitious). If everyone chose Ab2, soon Ab2 would lose its effectiveness and resemble Ab1. If every patient chooses Ab1 (instead of nothing), soon Ab1 could be less effective than nothing. If many people chose Ab3, it would lose its effectiveness as bacteria evolve.

Who decides? IF only the individual s perspective matter, if costs are not an issue, Ab3 is the best choice. From a population and public health, for the benefit of most people, the best choice is to treat only the most complex cases, and start with Ab1, limiting Ab3 to very rare cases even if more people die of infection. This approach maximizes population benefits for the long term, but not individual benefits, particularly those who died who could have been cured if immediately treated with Ab3.

If we add costs to the decision, then who should make the decision? If payors pay all costs, so costs are distributed across the population, and everyone is allowed to use Ab3, costs would be beyond reason. Because resources are not infinite, the decision of one patient affects the decisions of other patients.

The appropriate model to evaluate CE is Bayesian statistics or Bayesian inference statistical inference in which evidence or observations are used to update or to newly infer the probability that a hypothesis may be true. The name "Bayesian" comes from the frequent use of Bayes' theorem in the inference process. See Wikipedia.

CE definition should be operational, something measurable. It should be along these lines:
Probability of (Disease/Diagnosis) = ..?
Probability of (treatment improve outcome/disease, alternative treatments) =
In CE we seek to identify the relative effectiveness of treatment. But those probabilities are not constant over time. They change according to data, treatments used by other people, etc. The effectiveness of Ab3 depends on how many people used it. Because that data is not available real-time, the effectiveness depends on models of use of Ab3. If suddenly Ab3 is given away for

free and everyone starts using it as the first choice, then bacteria are likely to change and Ab2 replaces Ab3 for serious cases.

Submitted by
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Comment Type: *Strategic Framework*

The Association of Clinical Research Organizations (ACRO) appreciates the opportunity to provide additional comments to the Federal Coordinating Council on Comparative Effectiveness Research. Our previous comments and testimony focused on broad policy issues of comparative effectiveness research (CER), including prioritization, methods of research and models for public-private coordination of research.

In this comment, we want to focus the Council on certain data use disincentives resulting from provisions of the American Recovery & Reinvestment Act (ARRA) that could severely limit the ability to conduct CER. These data use restrictions go well beyond the privacy rules established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and constitute a de facto transition to HIPAA 2.

Under current HIPAA regulations, Covered Entities (CEs) - such as health care providers, health plans, and claims clearinghouses use or disclose Personal Health Information (PHI) without consent for treatment, payment and health care operations. With some exceptions, including for public health and research activities, all other uses or disclosures of data require an individual s authorization. Business Associates (BAs) may work under contract for or on behalf of CEs, but have the same limitations on uses and disclosures of PHI as do CEs.

In general, clinical research organizations (CROs) are neither CEs nor BAs; we receive clinical trial data and other PHI from a CE an investigator - under an individual s authorization and informed consent. CEs may disclose PHI for research purposes with individual authorization or, under limited circumstances, without individual authorization. For instance, PHI may be disclosed without individual consent: if a waiver is obtained from an Institutional Review Board (IRB) or Privacy Board; if the PHI is of decedents; if the PHI is used for preparatory research, such as patient screening; if the PHI is used for the purposes of activities related to the quality, safety or effectiveness of (emphasis added) FDA-regulated products; or the PHI is part of a limited data set that does not include direct identifiers and is used with a data use agreement that prohibits re-identification or attempts to contact individuals.

De-identified data removes all names and 17 other identifiers, including all dates (DOB, admission date, discharge date, prescription date, etc.). Fully de-identified data is often of minimal utility for research. A limited data set , on the other hand, removes names and other direct identifiers, but allows zip codes and dates of service, for instance. Limited data sets are extremely useful in many areas of research, including CER.

One ARRA privacy provision prohibits a CE from receiving any remuneration for electronic health data, including limited data sets. While exceptions to this prohibition are made for public health and research , the research exception limits the remuneration to the costs incurred in preparing and transmitting the data set, thus creating a serious financial disincentive to make the data available.

Further, recent guidance from the Department of Health and Human Services regarding the definition of when data can be considered unusable, unreadable or indecipherable to unauthorized individuals has the effect of imposing breach reporting requirements on CEs that use or disclose limited data sets, establishing another significant disincentive to working with large clinical databases.

The unintended consequence of these disincentives to the creation and use of limited data sets will create substantial barriers to conducting comparative effectiveness research. For example, the use of retrospective chart reviews to perform CER would be restricted because, to conduct optimal analysis, data elements such as age, service dates and geography are needed. Similarly, these same data elements would be desired for administrative claims research related to CER using data from Medicare (de-identified), AHRQ Nationwide Inpatient Sample (limited data set) and the Behavioral Risk Factor & Surveillance System (de-identified).

ACRO urges the Council to use its authority and charter to alert the agencies of the Federal government regarding these onerous restrictions to research data that do little if anything to protect personal privacy. Specifically, we hope that the Council will work with the Department of Health and Human Services to pursue a policy of ensuring the use of limited data sets for research purposes, including CER.

Thank you for your consideration of this important issue, which we feel has been overlooked in the recent discussion surrounding comparative effectiveness research. Please do not hesitate to contact ACRO for additional information.

Submitted by
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Comment Type: *Strategic Framework*

America s Health Insurance Plans (AHIP) appreciates the opportunity to share its member companies perspectives on the proposed definition for comparative effectiveness research (CER) and the strategic framework for such research. AHIP is the national trade association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace

including health, long-term care, dental, disability, and supplemental coverage and also have a long history of participation in public programs.

General

In general, our members believe that the draft CER strategic framework provides solid, unifying principles for CER. However, there are some concerns regarding the scope and clarity within the framework. In terms of simple readability, we recommend that the order within both graphics for the CER Investments and Activities (Research, Human and Scientific Capital, CER Data & Research Infrastructure, Translation and Adoption) remain the same for both versions, as the first two categories have been transposed within the graphics, potentially leading to confusion.

While the purpose of CER is clearly stated within the framework, there is no overarching goals statement. We recommend a goal statement that aligns with the purpose, but addresses the needs of those who will be using CER data the most frequently, such as:

"The goal of comparative effectiveness research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances and produce the best outcomes for the best value, within a given level of resources.

While this framework was developed by the Federal Coordinating Council for CER, to coordinate CER across the federal government and to make recommendations for federal funding priorities, the stated purpose is to inform patients, providers, and decision-makers about which interventions are most effective. As such, the descriptions of necessary inventories of CER activities only mention inventories of federal activities. Our members strongly believe that any CER strategic framework should be inclusive to both public and private CER efforts and activities, and, therefore, we recommend that the framework be revised to include private CER efforts. While the original charter for the Federal CER Coordinating Council directed efforts for federal programs, private sector CER efforts also need to be considered.

For example, concerning the heading, Inventories of Existing CER Infrastructure, our members are concerned with the potentiality that any federal effort to develop an inventory would not include current and existing CER capacities in both the public and private sector. We recommend that the fourth process step bullet (Inventories of existing federal CER translation & dissemination activities; funding based on identifies high-priority gaps) be revised to state, Inventories of existing federal, public (e.g., state activities), and private CER efforts& in order to encompass all current CER efforts. In addition, under the heading, Human and Scientific Capital for CER, an inventory of existing CER capabilities and personnel in the public and private sectors should be added, since investment in training and methods development should start with understanding the current baseline status.

Within Figure 2, under the CER Data & Research Infrastructure box, our members are concerned with building future CER efforts on a medical research enterprise which is currently researcher-centric and not always focused on asking the most appropriate questions that get to the answers that improve outcomes for patients. There should be a step taken prior to Inventories of Existing CER Infrastructure, where current research methods are reviewed and best practices and barriers

to providing useful and beneficial CER results are considered. There still remain major questions that can only be answered by large multicenter, multi-specialty, multi-population, and competitively bid randomized controlled trials. Instead of the current focus on the publish-or-perish mentality of the researcher-centric model, incentives should be developed for performing CER with societal impact, credit for updating research with emerging evidence, and improvements in diverse clinical trial enrollment. In addition, there should be mention of the need to develop an infrastructure for priority setting, such as a box between Inventories of Existing CER Infrastructure and Evidence Generation. As mentioned above, there are multi-stakeholder efforts underway, such as the National Priorities Partnership, whose contributions to the discussion should be recognized.

Also in Figure 2, under Human & Scientific Capital for CER, we recommend that there should be mention of training researchers in the evaluation of clinical evidence, not only CER methods and development. It will be very important to ensure that the strategic framework does not ignore utilizing the scientific evidence that already has been developed, and provides the required infrastructure for re-evaluating that data.

Realizing that this is a framework, and cannot detail every aspect of CER that should be considered, our members have concerns that there are several important topics that are not addressed, neither within the graphics nor the narrative, which are believed to be vital to the successful development and implementation of a CER infrastructure to the US healthcare system. These topics include: the development of a hierarchy of clinical evidence; identification of health services in common use that are not supported by clinical evidence; addressing bias and conflict of interest in the development and review of clinical evidence.

Translation and Adoption

Of the four CER Investments and Activities headings detailed within the draft framework, our members are most concerned with the efforts organized under Translation & Adoption, as this is the main purpose of CER and has been the most difficult CER action to accomplish. Currently, the headings under this category include: Inventory of Existing CER Translational & Dissemination Activities and Potential Capacity for Translation through Federal Delivery Systems and Public-Private Partnerships. Our members have raised questions regarding the inadequacy of these headings and the fundamental need to understand best practices and barriers to adoption of CER, which we recommend be the third heading under Translation & Adoption. Within the draft strategic framework narrative, we also recommend that the different settings in which CER should be translated and adopted should be highlighted: clinical practice, consumer decision-making, and coverage and reimbursement systems (both public and private).

Resource Use and Cost

While the focus of comparative effectiveness research must necessarily be on clinical impact, there must also be consideration of resource allocation (including cost effectiveness). Our members believe that comparative information on cost is equally important especially in today s economic environment, and believe that the value of medical devices, medications, and procedures should be a required facet of CER. Understanding the clinical effectiveness and cost of a service or technology as well as its potential impact on reducing the need for other health

care services and expenditures will help consumers and physicians in selecting the right treatment for each patient.

Submitted by
[personal information redacted]

Comment Type: *Strategic Framework*

There is no point in having universal health coverage if the current practice of permitting "military experiments" and "no liability" vaccines is continued. We the people would simply end up paying for the diseases caused by these two factors. We have no idea if our vaccines are actually safe. The statistics suggest that they are useless in preventing disease for animals and people (i.e. people get just as sick with or without vaccines and they almost always get the illness that they have been innoculated against). We get sick from the many military experiments that include the use of electronic frequencies to monitor their effects. These experiments are documented by many Congressional hearings and many complaints. There have even been lawsuits awarding money to Canadians for some of these experiments.

We need honest medical information that includes the importance of nutrition. We need our farmers to use more natural and restorative means of planting and forego the "factory" farm approach that doesn't permit land to be rotated and minerals to be returned to the soil, but relies on nitrogenous fertilizers that further deplete the soil and poison the air. We also need for "fluoridization of the water to be stopped." Not only is this practice useless for teeth health (as many studies have revealed), but it has been correlated with bone cancer in young men, breast cancer and brittle bones in women and problems with hormone balance across the board.

The people are not stupid. The people are not the ones who IRRESPONSIBLY dump pollutants into the water and air and conduct unsafe tests on human subjects.

Submitted by
Tony Coelho
Partnership to Improve Patient Care (PIPC)
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Comment Type: *Strategic Framework*

Dear Federal Coordinating Council Members:

The Partnership to Improve Patient Care (PIPC) appreciates this opportunity to respond to your recently released draft definition and prioritization of comparative effectiveness research (CER).

PIPC is a diverse coalition of over 40 organizations representing patients, healthcare providers, research institutions and medical research companies. PIPC was formed in November 2008 to advance proposals for CER that are focused on supporting providers and patients with the information they need, improving healthcare quality and supporting continued medical progress. Our members are united by a common set of CER principles in support of this goal.

Our partnership appreciates the Federal Coordinating Council s posting of its draft CER definition, prioritization criteria and strategic framework as a further step in promoting openness and transparency. Providing continued openness and transparency in the Council s activities and those of the Department of Health and Human Services will ensure that the perspectives of patients, providers and other stakeholders are considered.

We also commend the focus on the expressed needs and perspectives of patients and providers in your draft definition. PIPC reaffirms our belief that CER must focus on communicating research results to patients, providers and other decision-makers, not making centralized coverage and payment decisions or recommendations. This focus is consistent with the goal of CER as described in HHS press release announcing the Federal Coordinating Council, which stated, Such research will give clinicians and patients valid information to make decisions that will improve the performance of the U.S. health care system.

We support your recognition of the importance of having patients and providers play a central role in defining their own healthcare needs. Too often in healthcare, the determination of what s best for the patient is made by others, while the patient s views of his or her own needs is ignored or minimized. By identifying the importance of expressed needs, the Council takes an important step towards policy that truly is centered on the needs of the patient and caregiver.

PIPC also supports the broad scope of research included in the Council s definition, which states, Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This definition is consistent with PIPC s principles in support of CER and reflects the views expressed by many stakeholders at FCC listening sessions. PIPC believes that in order to improve patient care, CER research should examine the range of issues that affect the quality of patient care. This includes the range of medical tests and treatments, as well as questions related to healthcare delivery and organization such as benefit designs and care management programs. All of these healthcare elements affect patients quality of care.

While PIPC supports the focus on patient and provider needs in the draft definition, we also are concerned that, in stating that the purpose of CER is to inform patients, providers and decision-makers, the Council s draft definition of CER has the potential to shift the focus of research away from patients and providers towards other decision-makers such as health insurance companies, government agencies and other policy-makers. The strategic framework released on HHS web site on June 1 includes language that underscores this concern. In particular, PIPC is troubled by language in the framework that describes CER research priorities that respond to the expressed public and federal needs for CER, and potential capacity for translation through Federal delivery systems and public private partnerships.

This shift in focus likely will result in research projects that do not address the clinical information needs of patients and providers, and instead lead to research that is used to restrict patient access to treatment options. This concern is heightened by recent commentary describing the link between CER and these types of access restrictions. For example, a recent Washington Post commentary says, What's known as comparative effectiveness research, which tracks what works and what doesn't, would also require outside boards directing doctors and hospitals about what procedures they could and couldn't use.

The language of your CER definition and strategic framework document is inconsistent with the goal of CER as described by HHS in its press release announcing the Coordinating Council. PIPC is opposed to the shift in focus to CER that restricts patient access to medical care or treatment choices. We strongly urge the Council to delete the language referencing decision-makers and federal needs as a CER focus. PIPC also urges you to revise the strategic framework so that it focuses on communication and dissemination strategies, rather than use of CER by government agencies.

Consistent with focus on patient and provider needs, we urge the Council to clarify that research will examine clinical outcomes, not cost-effectiveness. As reflected in the wide range of views expressed during the Coordinating Council listening sessions, inclusion of cost-effectiveness remains very controversial. Cost-effectiveness analysis traditionally has been a tool used by insurance companies and government payers to impose access restrictions based on broad population averages, and some of the most common CEA tools obscure differences in patient subgroups by including all patients in a single, average value determination. Particularly given the importance that the American Reinvestment and Recovery Act (ARRA) and the Coordinating Council have placed on considering the needs of patient subpopulations, PIPC recommends that the Council clarify that it will focus on clinical outcomes.

PIPC looks forward to continue working with the Council to foster good and fair processes that will allow future comparative clinical effectiveness research to improve the health and well being of all Americans.

Once again, thank you for the opportunity to participate in this transparent comment process.

Sincerely yours,