Comparative Effectiveness Research: Why It Can Add Credibility to Complementary and Alternative Medicine

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Introduction

Defining Comparative Effectiveness Research (CER)

When purchasing almost any product on the market, it is natural to compare the risks and benefits of competing vendors so that one can make an informed decision. National publications such as Consumer Reports® offer "unbiased advice" on household goods, cars, appliances, and electronics, but it is much more difficult to find reliable, objective information for the consumer of health care. Comparative Effectiveness Research (CER) is one of the newest strategies for addressing this problem as it helps to ensure that consumers' health care dollars are spent wisely on treatments that have been proven to work.

The U.S. Agency for Healthcare Research and Quality (AHRQ) defines CER as a "type of research that compares how different treatments, tests, or procedures have worked for others."[1] The Institute of Medicine (IOM) takes this definition further by saying that CER is "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or improve the delivery of care."[2] In other words, CER compares the effectiveness, benefits, and risks of different treatment options, heralding the American ethos of consumer choice so that one can make an educated, cost-efficient decision based on their individual needs. CER is a process through which new treatments for a given condition are compared against the standard treatment for that condition instead of simply to a placebo.

There are seven steps involved in conducting CER that must be followed to ensure continued development of the infrastructure to advance these efforts: 1) Identify new and emerging clinical interventions; 2) review and synthesize current medical research; 3) identify

gaps between existing medical research and the needs of clinical practice; 4) promote and generate new scientific evidence and analytic tools; 5) train and develop clinical researchers; 6) translate and disseminate research findings to diverse stakeholders; and 7) reach out to stakeholders via a citizens forum.[3] The first step is key to deciding which treatments should be tested using the CER approach. For the second and third steps, researchers must look at what studies, if any, have already been conducted for these treatments and identify where CER can fill in the gaps. The fourth and fifth steps are the meat of the process and constitute the actual research itself. The last two steps involve public outreach and circulation of research findings which is critical to achieving the goal of making Americans more educated consumers of health care treatments and services. A report is published and summary guides of the research review are compiled for different groups such as consumers, clinicians, and policymakers.[4]

CER as a Tool for Testing Complementary and Alternative Medicine (CAM)

CER has the potential to be an especially useful tool for testing the effectiveness of Complementary and Alternative Medicine (CAM). CAM is difficult to define because the field is so broad and constantly evolving, but the National Center for Complementary and Alternative Medicine (NCCAM) characterizes it as "a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine."[5] For these purposes, conventional (or Western/allopathic) medicine includes medical doctors, doctors of osteopathy, and allied health professionals such as registered nurses, physical therapists, and psychologists. "Complementary medicine" refers to practices such as acupuncture that are often used alongside conventional medicine to relieve pain. In contrast, "alternative medicine" is used as a substitute for conventional medicine.

Most CAM treatments are complementary, not alternative and can be grouped into three broad categories: natural products, mind-body medicine, and manipulative and body-based practices. Traditional/spiritual healing, homeopathy, naturopathy, energy work, Chinese medicine, and movement therapies such as the Alexander Technique, Pilates, and Rolfing Structural Integration are other examples of CAM. [6] The 2007 National Health Interview Survey revealed that CAM is used by 38 percent of American adults and 12 percent of children. The most common types are: non-vitamin, non-mineral natural products (17.7 percent), deep-breathing exercises (12.7 percent), meditation (9.4 percent), chiropractic or osteopathic manipulation (8.6 percent), massage (8.3 percent), and yoga (6.1 percent).[7]

Although few rigorous scientific studies have been conducted on CAM treatments, it is likely that many are in fact effective since Americans continue to use them even in cases where a treatment is not covered by health insurance. In 2007, spending on CAM in the United States was $30 billion per annum, surpassing out-of-pocket expenditures for conventional treatments by primary care physicians.[8] Yet, most types of CAM have never undergone the kind of rigorous controlled trials that standard treatments must go through; therefore, CAM is often questioned for its legitimacy as a body of treatments for health concerns, dissuading many people from considering treatments that could potentially help them. At the same time, because there is so little research, people are prone to waste money on CAM that is not effective. CER can help to address this problem by funding studies that will provide more definitive answers about which types of CAM should be taken seriously.

The present paper argues that CER can be used to add credibility to certain types of CAM and examines some of the issues that could surface if CER becomes the new way of testing this type of medicine. **Section One** briefly covers the political evolution of CER in Washington since

2009. As of this writing, CAM has received little attention in public debates on CER. That said, an understanding of how CER has progressed through the national agenda is helpful for explaining the context in which CAM advocates will have to operate if they hope to get funding to test the effectiveness of their treatments. **Section Two** highlights some of the major reasons why CER should be used to evaluate CAM such as the need for a new research strategy and the fact that there is growing public support for CAM and CER as joint national priorities even though CAM was not a major issue in legislative debates. While not exhaustive, **Section Three** addresses areas of concern for CER, focusing on areas that directly relate to CAM such as cost effectiveness, the difficulties in defining "effectiveness," and challenges in conducting blind clinical trials on CAM. Finally, the **Conclusion** makes recommendations for a CER public relations strategy and how CAM patients and practitioners can work towards gathering support for CER funding.

Section One: The Political Evolution of CER

CER Under the Recovery Act

CER first entered the national spotlight when President Barack Obama created the Federal Coordinating Council for Comparative Effectiveness Research as part of his federal stimulus package known as the American Recovery and Reinvestment Act of 2009. Under the Recovery Act, Obama authorized $1.1 billion for the fifteen member council which was charged with assisting federal agencies to coordinate comparative effectiveness and related health services research, but was not allowed to recommend clinical guidelines for payment, coverage or treatment.[9] Health and Human Services (HHS) and the National Institutes of Health (NIH) received the largest appropriations of $400 million each. AHRQ followed close behind with

$300 million.[10] Most council members are clinicians and were selected because they represent sub-populations such as disabilities and minorities. Notably, not one member of the Council was affiliated with CAM.

The Opposition in Washington

Supporters of CER view it as a rational means of making Americans smarter consumers of health care, but as with any political initiative, it has faced opposition from stakeholders who view it as a threat to the status quo. Formation of the Council led to a fierce debate in Washington over whether additional backing of CER should be included in Obama's national health reform legislation, known as the Patient Protection and Affordable Care Act (PPACA), enacted in March 2010. Most congressional Democrats supported CER, but Republicans feared that the research would lead to a "government takeover" and rationing of health care or that it would create a cookie cutter recipe for health care, deciding that what is effective for most people is the right solution for everyone, ignoring issues such as race and sex when treating individual patients.[11]

A case in point is Representative Tom Price (R-GA), a physician who sent out an "alert" through the Republican Study Committee in February 2009 claiming that CER would destroy the doctor-patient relationship, creating "a permanent government rationing board that would prescribe care."[12] Other outspoken Republican critics of CER included House Minority Leader John Boehner of Ohio; Representative Phil Gingrey of Georgia, another physician; Senator John Kyl of Arizona; and Senator Pat Roberts of Kansas. Interest groups also played a role in the debate. The Cato Institute asserted that government provision of CER would do nothing to increase efficiency and The Heritage Foundation expressed concern that CER would lead to

denials of coverage based on cost. Ironically, Republicans had been strong advocates of CER until Obama was elected in 2008. [13] While conservatives spoke out against CER for many reasons, CAM was not discussed in these debates, perhaps because at that point few people saw the potential for CER to be used as a tool for testing CAM.

CER Under National Health Reform

Despite the backfire against CER, in October 2010, Obama authorized a new public-private partnership for CER under the Affordable Care Act. The partnership, known as the Patient Centered Outcomes Research Institute (PCORI) is funded through the Medicare program and contributions from private insurers. Experts predict that its annual funding may grow to about $500 million within a few years depending on how future federal budget battles play out.[14] According to the U.S. General Accountability Office (GAO), PCORI's mission is to "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by carrying out research projects that provide quality, relevant evidence on how diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed."[15] The legislation allows the effectiveness of not just individual treatments, but entire programs to improve public health, to be compared. This could improve care for minorities and other groups historically left out of much medical research, or for those with mental illnesses.[16]

While the formation of PCORI was a major achievement, Obama did not authorize it without making some concessions. For example, Republicans demanded prohibition of the use of a metric known as quality-adjusted life-years (QALYs) which are used to aid in cost-effectiveness analyses worldwide.[17] As a compromise, Democrats agreed on language stating

that PCORI "shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended."[18] Republicans were opposed to the use of QALYs because they had become code language for government-run health care systems and rationing.

In order to placate conservative interest groups who feared that CER would threaten biomedical innovation and restrict patients' access to costly new treatments, Obama gave them seats on PCORI's Board of Directors. The Affordable Care Act directs the GAO to fill all twenty-one slots on the board with representatives of specific interests: consumers; hospitals, industry; nurses; payers; physicians; researchers; surgeons; and two government agencies, AHRQ and NIH.[19]

Ultimately, the diversity on the board appealed to both Democrats and Republicans, but there is still room for improvement, especially in the area of CAM. Sarah Kuhel, a Democratic staffer on the Senate Budget Committee involved in drafting the language creating PCORI, says that "one of the ways supporters of the institute hope to foster its acceptance is though having a wide variety of participants in the health care system on the board of the institute."[20] The board does include a wide range of representatives from major research universities, health plans, and private sector organizations, but as with the Council originally established under the Recovery Act, there is very little representation of CAM. Only one member of PCORI's board is affiliated with the CAM industry. That individual is Christine Goertz, DC, PhD, Vice Chancellor for Research and Health Policy at Palmer College of Chiropractic and Palmer Center for Chiropractic Research in Davenport, IA, and a former program officer of NCCAM.[21] The GAO announced these appointments on September 23, 2010.

PCORI's last meeting took place January 19-20, 2011. Among the goals of the meeting were to "continue to build the board" and "advance the framework and criteria for project funding and identify options for initial funding."[22] The fact that PCORI is still in the nascent stages of development leaves room for CAM advocates to petition for more slots on the board and possibly receive consideration for CER funding proposals. Yet, this may be difficult because there is not currently an effective lobbying group for CAM interests.

Section Two: Why CER Should Be Used to Evaluate CAM

The Need for a New Research Strategy

The fact that CAM patients and practitioners laude its benefits while published studies show it has limited or no efficacy, indicate that current biomedical and research strategies may be inappropriate for testing treatments within a branch of medicine that does not neatly fit into the standard mold. Some experts suggest that this "gap" can be partly attributed to the present focus on placebo-controlled randomized trials which are considered the gold standard for testing pharmaceutical agents, but may not be the best way to evaluate CAM. In an effort to accommodate conventional assessment tools, CAM treatment approaches have been dissected into standardized and often simplified treatment methods, resulting in limited outcomes.[23] As discussed earlier, CER offers a way of addressing this problem by comparing CAM against the standard treatment for a given condition instead of to a placebo.

CAM practitioners argue that one reason why placebo-controlled randomized trials are not optimal for evaluating CAM is that they discount the synergetic effects of treatments which cannot be split up into parts that can be investigated separately. They claim that the total effect adds up to more than the sum of its parts. A prime example is acupuncture where studying only

the specific effects of inserting a needle into a patient overlooks other potentially important aspects of the intervention initiated by the acupuncturist. If CAM is to be given justice, a better strategy is to extend the research focus to all aspects of the treatment approach. [24] CER offers a means of achieving that goal, but to do so public funding is crucial. As the following paragraphs demonstrate, CAM and CER are in the early stages of becoming joint national priorities, but advocates have a long road ahead.

Growing Public Support for CAM and CER

In recent years, the federal government has recognized CAM has an area worthy of further investment and research using funds for CER. In compliance with the Recovery Act, in June 2009, the IOM came out with a report, *Initial National Priorities for Comparative Effectiveness Research*. Stakeholders were asked to rate their top three areas of study for how CER funding should be spent based on a list of 32 areas provided by the Committee. Of all the areas, CAM received the nineteenth highest number of submissions,[25] indicating that public support is strong, but not overwhelming for CER investment in CAM. Among the report's 100 initial priority topics, mindfulness-based interventions such as yoga, meditation, and deep breathing are listed in the second quartile of priorities in terms of how these practices can be used to treat anxiety, depression, pain, cardiovascular risk factors, and chronic diseases. The report lists acupuncture in the third quartile, specifying that the effectiveness of this treatment should be tested for various indications using a cluster randomized trial. Dietary supplements (nutriceuticals) are also listed in the third quartile. The fact that CAM is included in the IOM report offers hope that with the appropriate marketing, more federal dollars can eventually be designated to test its effectiveness using CER techniques. At the same time, more breadth in the types of CAM that the government is willing to invest in is desirable.

While the IOM report outlines goals for future investment, the Federal Coordinating Council for CER released its own report around the same time, detailing the progress that had been made in CER since Obama authorized the Council in March 2009. The report estimates that "alternative medicine" comprised 8 percent of federally funded CER studies at the Department of Defense, 2 percent at the AHRQ, and a mere 1 percent at the Veterans Health Administration. Overall, only 2 percent of all federally funded CER studies were focused on CAM with no studies funded at NIH.[26] At public listening sessions, a few people talked about the role of studying alternative treatments including homeopathy,[27] but not enough for CAM to make its way into the final section of the report where the Council makes recommendations to the U.S. Secretary of HHS. The Council's report reveals that while CAM has been gaining national attention, more publicity is needed to ensure it is allocated sufficient research funds so it can be taken seriously by the government and the public.

Even though the Council's report does not specifically list investment in CAM among its recommendations, it can be argued that CAM could be a means of addressing one of the secondary level recommendations in the report relating to prevention, that is: "comparing two interventions to prevent or decrease obesity."[28] Nutritional supplements such as Hoodia,[29] a cactus-like plant native to southern Africa that is marketed as an appetite suppressant for weight loss is one example of CAM (in pill form) that could be compared to a standard treatment such as weight loss pills to see if the supplements are equally effective and have fewer side effects.

Section III: Areas of Concern in CAM and CER

Issues of Cost-Containment

Medical research is one of the primary factors that determines whether insurance companies will cover a given treatment; therefore, even supporters of CER may wonder how much more health care costs will increase if CER proves the effectiveness of certain types of CAM which are then included in benefit packages. Stakeholders who offered input for the above mentioned IOM report expressed concern that CER might persuade payers to support or improve reimbursement for certain services including CAM.[30] Higher reimbursement rates for CAM would result in higher insurance premiums, making care less affordable for everyone including individuals who do not believe in non-conventional medicine.

Reimbursement for CAM may also cause insurance companies to compete over CAM coverage as a "luxury benefit." Instead of simply breaking even, the insurance industry could see CAM as a major source of profit, increasing premiums by more than what would be necessary to cover the reimbursement of CAM practitioners. One means of keeping costs down for consumers is for insurance companies to create "premium" or "Gold" level plans that cover CER validated CAM treatments and services. This way, those who plan to use CAM can have it covered and those who do not care for it will not experience an increase in their premiums. Of course, in order for these plans to allow better access to CAM, the premium increase would need to be less than what a consumer would pay out of pocket for uncovered CAM services.

While CAM coverage has the potential to drive up insurance premiums, there are many reasons why it would ultimately be valuable for CER validated types of CAM to be part of benefit packages. Since few health insurers currently reimburse for CAM treatments, there are no

financial gate-keepers and CAM remains a highly unregulated industry which raises issues of safety and quality. Furthermore, CAM treatments are in such high demand that a lack of reimbursement does not mean a treatment will disappear from the market.[31] This holds true if no CAM services are covered by a given insurance plan, but if certain types are, people are more likely to try those first which would serve the ultimate goal of CER: helping consumers spend their money wisely and safely.

Another question with respect to cost-containment is how much more effective a new treatment needs to be for the benefits to outweigh the additional cost of recommending it to patients. *The Healthcare Economist* offers an example where Treatment A costs $1,000 and has a cure rate of 90 percent and Treatment B costs $10,000 and has a cure rate of 95 percent. According to CER, Treatment B should be used, but this will substantially increase costs. In the case of a serious illness, it makes sense to use Treatment B, but for a case of the common cold is a 5 percent increase in effectiveness worth spending ten times the money?[32] These questions require legislators, consumers, and health care professionals to make value based judgments about trade-offs. Where does one draw the line?

Defining Effectiveness

Defining effectiveness is an issue with CER in general as more diseases become chronic or possible to manage over the long term, rather than fatal. CER is intended to compare treatment A to treatment B, but often, combinations of therapies are best used for serious conditions. An example is metastatic breast cancer. In a November 2009 study, Berlinger et. al. found that combination approaches for this disease yielded both higher objective response rates and higher toxicity. Does this mean that the individual drugs are more effective when used independently or

together? The answer varies depending on the individual patient's treatment history and quality of life needs. There is no gold standard for whether combination approaches are more effective than individual agents.[33] Higher toxicity could be tolerable if the goal is to cure the disease, but if the goal of the intervention is to help the patient live with a chronic disease which the patient will probably die from anyway, a combination approach may not be considered "effective." Combination approaches add another layer to how CER trials can be conducted.

Defining effectiveness becomes even more difficult when CAM enters the picture because it often has different goals than conventional medicine which emphasizes treatment more than prevention. Comparing St. John's Wart to SSRI drugs for treating depression is an example of a straightforward CER study, but what if a patient with a family history of depression takes St. John's Wart as a preventive measure (something that would be more difficult to do with a drug requiring a prescription) and the patient does not become depressed while taking the herb even though he recently experienced a traumatic event? It is harder to prove that a treatment of any kind prevented an imbalance in the patient's serotonin levels than it is to show that the same treatment corrected for an imbalance. The synergistic nature of many CAM treatments also makes it challenging to define effectiveness.

Challenges in Conducting CER Studies on CAM

Ensuring random selection and random sampling for CER studies involving CAM is challenging because most study participants who are willing to consider CAM treatments already have an orientation towards non-conventional medicine and a researcher cannot ethically force someone to forgo the standard treatment for the sake of a study. While blinding of the patients and treatment providers may not be feasible, blinding of the outcomes evaluators can ensure an

unbiased comparison of the outcome assessment.[34] Still, these are issues to consider when determining whether a certain type of CAM has been tested rigorously.

Conclusion and Recommendations:

The Need for an Effective Public Relations Strategy

Because of its formidable opponents, the way CER is branded and marketed across all types of research is paramount to its success. As *The Commonwealth Fund* puts it, "the effort to find out what works in medicine is going to require a good public relations strategy as much as a scientific one."[35] This is especially true for CAM since non-conventional treatments tend to be overlooked to begin with and CER offers one of the best hopes for raising awareness of its benefits.

A good public relations strategy for CER will emphasize how this research can benefit consumers. Currently, PCORI has virtually no information on its website which needs to quickly change. The Obama Administration should create links on The White House and HHS websites respectively with information that can easily be printed out and placed in doctor's offices. PCORI should allocate money in its budget for television and radio advertisements as well as ads on bill boards and in subway stations in major cities. In order for CAM to be included in this outreach, its advocates need to be better organized.

The Importance of Advocacy Efforts

There are many vocal advocates for CER, but fewer for CAM which does not have a well-funded lobbying force in Washington. The American Holistic Medical Association (AHMA) is the closest thing to a national umbrella organization or interest group for CAM that

exists. The AHMA claims to promote "integrative medicine," but their website reveals no public action agenda and they do not have a lobbyist listed on their staff.[36] If CAM patients and practitioners want this branch of medicine to gain credibility and become more mainstream through rigorous CER testing, the industry needs to petition for more seats on PCORI's Board of Directors which requires having a stronger voice in Washington.

CER: A New Spin on an Old Strategy

In conclusion, it should be noted that CER is not as novel an idea as many Washington insiders believe. The truth is that CER has long been the classic method for conducting clinical trials of new cancer interventions,[37] yet, it did not gain widespread attention until there was a consumer education component and the Obama Administration suggested that public money be used to pay for it. If PCORI plays its cards right, CER can have a significant role in lowering the cost and improving the quality of American health care since consumers will be more likely to spend money on treatments they know have been proven to work, weeding ineffective treatments off the market. In deciding what areas to invest CER dollars in, it is the hope of this writer that PCORI will choose to follow IOM's recommendations for studying certain types of CAM and that with increased advocacy more types can be studied using CER in the future.

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