



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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Federal Coordinating Council on Comparative Effectiveness Research
Office of the Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Members of the Federal Coordinating Council:

Comparative Effectiveness Research

The American Academy of Orthopaedic Surgeons (AAOS) appreciates the opportunity to share our perspective on setting priorities and processes for comparative effectiveness research (CER). The AAOS represents over 17,000 board-certified orthopaedic surgeons and has been a committed partner in patient safety and quality health care. The AAOS looks forward to providing input as priorities are developed, and we invite you to call on the AAOS for any additional feedback from our surgical and specialty perspective.

The AAOS shares the perspective that patients and their physicians deserve access to high quality information that optimizes their capacity to identify which diagnostic, treatment, and prevention services are most effective and under what conditions. There is strong evidence that the lack of this type of information compromises the ability of patients and physicians to choose the best treatment options.

The American Academy of Orthopedic Surgeons (AAOS) believes that developing high quality, objective information will improve informed patient choice, shared decision-making, and the clinical effectiveness of physician treatment recommendations.

Steps the Federal Coordinating Council (Council) should consider to ensure mutually supportive public and private-sector efforts in the area of comparative effectiveness research

The AAOS has renewed its efforts to provide high quality, evidence-based information to its members through both evidence-based Clinical Practice Guidelines and Technology Overviews. Indeed, our evidence-based efforts meet the highest standards of evidence-based methodological rigor, and we provide extensive documentation for each of these publications. This information is available on our website for verification by any interested party.

We are concerned, however, that if CER efforts follow existing models of clinical research and evidence-based medicine, their impact on clinical practice will be blunted or delayed. Additional pertinent issues include: (1) There is little if any published, peer-reviewed data showing that previously published, evidence-based systematic reviews (including CERs) have been successfully translated into practice (either on their own or through clinical practice guidelines prepared by specialty societies), (2) A lack of integration between public and private efforts and specialty society clinical practice guidelines could create competitive (if not conflicting) efforts, and (3) There is no method to coordinate dissemination of CER and the evidence-based efforts of specialty societies. In short, we are concerned that efforts made to produce and disseminate CER in the absence of significant specialty society involvement will lead to research that is not effectively translated into practice.

Given these concerns, we strongly suggest that CER efforts be closely coordinated with specialty societies. This type of coordination should take place at both the development and dissemination phases of a CER issue. It should take place at the development stage because our experience, as well as that of others, shows that pre-existing systematic reviews often do not include studies of patients that are of interest to clinicians. Similarly, existing reviews often do not acknowledge many of the more technical details of clinical practice. Evidence-based reviews that do not consider the patients and subtleties of interest to clinicians will have limited impact. They are likely to come to conclusions different from the evidence-based efforts of specialty societies, which can only create confusion. This possibility is supported by published, peer-reviewed evidence suggesting that one of the major reasons that the conclusions of systematic reviews differ is because they include different articles. Published literature also supports the idea that conflicting results among evidence-based documents is not limited to conflicts between the conclusions of specialty societies and others, but spans the entire range of academic medicine.

Coordination should take place prior to the dissemination phase because there is limited (if any) evidence that publically and privately prepared evidence-based reviews have had a significant impact on clinical practice. There is some evidence, however, showing that evidence-based guidelines impact practice, at least when they are appropriately disseminated. Given that; (1) specialty societies make their practice recommendations through clinical practice guidelines, (2) that these societies have existing means of information dissemination, and (3) that these means are likely more effective than those available to either public or private entities, we suggest that the CER be performed in coordination with, or integrated into specialty societies' evidence-based, clinical practice guideline efforts (especially those specialty societies that employ highly rigorous evidence-based processes and methodological standards of guideline development).

The AAOS believes, consistent with published peer-reviewed evidence, that CER developed and disseminated according to current models will have limited impact on clinical practice, unless it is closely coordinated with specialty societies.

Comparative effectiveness (CE), in its broadest sense, refers to the evaluation of the relative clinical effectiveness, safety, and value of two or more medical services, drugs, devices, therapies, or procedures used to treat the same condition. Many organizations and institutions,

including the AAOS, have a long history of both individual and combined efforts in developing and encouraging the use of this type of information. Recent announcements of both the development of CER and its subsequent deployment have generated concerns among certain health care stakeholders. These concerns, in large part, are due to the perception that given the difficulties in measuring and comparing clinical outcomes among treatment options, CER will focus exclusively on the cost of care. Unfortunately, a coordinated effort to educate the many stakeholders and clearly define “comparative effectiveness” has been lacking. We believe that efforts to measure and compare the effectiveness of various treatment options should include explicit consideration of the quality (as measured by both objective and subjective measures of patient-specific health outcome), safety, and true value of a health care intervention. This will require increased emphasis on developing and reporting patient-specific, risk-adjusted measures of health outcome.

Components of Comparative Effectiveness Research (CER)

The AAOS understands there are many parts to CER, including clinical effectiveness, cost effectiveness, and safety. We encourage CER entities to focus on the clinically effective value of a treatment or service due to its potential to improve the quality of care provided to our patients. While cost effectiveness attempts to standardize the unit of measuring the health benefit of a dollar spent across different fields of medicine, quantifying health outcomes remains a complex and difficult task. Since this metric is a ratio, it can increase when the incremental improvement in health outcomes (clinical effectiveness) is small or the difference in cost is large. In developing CER data, special consideration should be given to the concept of clinically significant results to patients versus statistical significance alone. Also, safety is often not considered explicitly as a component of CER. This is especially true of devices which frequently receive FDA approval based on “substantial equivalence” to previously approved devices. Any comprehensive policy to deploy the results of CER must obviously include this important parameter.

Types of investments in infrastructure and the framework for Comparative Effectiveness Research (CER)

The Entity

The AAOS believes that an independent public-private entity should be established to conduct, prioritize, and coordinate Comparative Effectiveness Research. This entity should focus and be built on the following characteristics to provide high quality information to inform patients and their providers in their choice of alternative treatments and services.

- Single entity coordinating CER initiatives to avoid redundant efforts
- Administrative and political independence
- Stable dedicated financing (public and private)
- Transparent trustworthy methods
- Produce objective timely research
- Legitimate governance and organizational structure with broad stakeholder representation
- Broad public input including public meetings and comment periods
- Centralized data base of all CER activities accessible to all stakeholders

- Wide dissemination of information on a regular and recurring basis
- Provide a forum for addressing conflicts
- The entity should not have a role in payment or coverage decisions

The Scope

The CER entity should have broad authority to set priorities for the research conducted. These primary and secondary research priorities should be established with input from all relevant and appropriate stakeholders. Research methodology should include a blend of systematic reviews, analysis of claims records, medical registries, randomized controlled trials and recently described pragmatic or practical clinical trials that address the specific gaps in evidence.

Establishing the scope of potential CER is complicated by issues such as the fact that outcomes with medical devices, unlike those with pharmaceuticals, depend not just on the device but also on the skill of the operator and procedural technique. Initial outcomes and total costs associated with new therapies might not be favorable, but over time, with greater operator expertise and a better understanding of how to use the device, this therapy may become more valuable and clinically effective.

The AAOS believes that in establishing the scope of Comparative Effectiveness Research careful consideration should be given to aligning research priorities with real-world questions faced by patients and providers in their medical decision making.

Issues in Deploying Comparative Effectiveness Research Results

Potential Adverse Effects on Quality

Recent federal cost savings projected from deploying CER results show that net savings in the cost of health care will only be possible if there was a resultant change in payment rules or cost sharing requirements. Without these changes, the cost of conducting CER would equal or exceed the projected cost savings. This fact will potentially drive an effort to use CER to set payment and inform coverage decisions. The AAOS is concerned that if a CER entity focuses on the cost of care we risk the counterintuitive result of decreasing quality.

Potential Adverse Effects on Innovation

New technologies and innovations, when first introduced, frequently do not demonstrate favorable comparative effectiveness ratios. Learning curve issues and the lack of refined clinical indications frequently impact early measurements of comparative effectiveness. We believe comparative effectiveness should not stifle innovation and the development of new technologies. We also believe it is important to consider special populations when developing CER. Patients are quite diverse and a one size fits all approach will not improve the quality of care for our patients.

Federal Coordinating Council's federal government activities in the area of CER

- The AAOS believes that the Council should first focus on their congressionally mandated task of coordinating all CER activities in the departments and/or agencies of the federal government as it relates to CER. These activities should be appropriately prioritized and disseminated among these departments and agencies in addition to all CER stakeholders.
- As another priority, the Council should recommend to Congress the establishment of a single independent public-private entity to conduct, prioritize, and coordinate CER activities in both the public and private sectors.
- For the longevity and ultimate success of CER, the Council should recommend a consistent funding source as a necessary component that does not solely rely on the instability of political and administrative funding.
- The Council should prioritize the funding of CER not solely based on the IOM recommendations but also to include areas where there are clearly defined gaps in evidence.

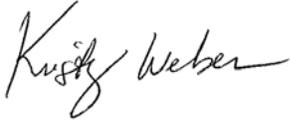
Useful information on the Federal Coordinating Council's activities

The AAOS believes it is important and useful for all information on the Council's activities to be shared. We believe it is necessary for the Council to act in a transparent, consistent manner. Transparency facilitates coordination and participation among stakeholders. Sharing the activities and priorities of the Council allows the private, non-government entities to coordinate their initiatives, as previously mentioned, and reduce overlapping efforts. Also, a lack in transparency and dissemination of information creates a distrustful environment and in turn inaccurate assumptions. The AAOS believes that the Council and other CER stakeholder groups will benefit from the sharing of information and collaboration of a shared initiative.

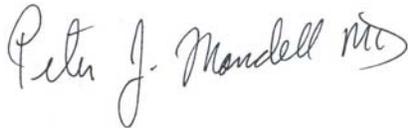
The AAOS is committed to working with a broad range of public and private entities, including governmental agencies, medical professionals, patients, and others to improve the quality and accessibility of information available to patients, providers, payers, and policymakers regarding the value of different health care interventions. This will require a concerted multi-stakeholder effort to develop and report patient-specific, risk adjusted measures of health outcome, as opposed to relying exclusively on cost of care as the basis for comparing treatment interventions.

The AAOS looks forward to working with the Federal Coordinating Council in the future for setting comparative effectiveness research priorities in orthopaedics. We invite the Federal Coordinating Council to use the AAOS as a resource whenever possible and necessary.

Sincerely,

A handwritten signature in cursive script that reads "Kristy Weber".

Kristy L. Weber, MD
Chair, Council on Research, Quality Assessment, and Technology
American Academy of Orthopaedic Surgeons

A handwritten signature in cursive script that reads "Peter J. Mandell MD".

Peter J. Mandell, MD
Chair, Council on Advocacy
American Academy of Orthopaedic Surgeons