

# **Social Work Research and Comparative Effectiveness Research (CER):**

**A Research Symposium to Strengthen the Connection**

**Background Information and Preliminary Considerations**

**Prepared by**



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## Introduction

On November 16, 2009 the Social Work Policy Institute (SWPI) will convene a think tank meeting, *Social Work Research and Comparative Effectiveness Research (CER): A Research Symposium to Strengthen the Connection*. This symposium will examine how the social work profession might best contribute to the expanding attention to CER. The goal is to develop an agenda for action that addresses areas for further social work research, training of researchers, interdisciplinary collaborations, research/practice connections, and communication and outreach efforts.

SWPI created this briefing paper to present background information on CER to stimulate issues for consideration for the upcoming symposium. It describes CER legislation through provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Public Law No. 111-5), and the work of the Federal Coordinating Council (FCC) on CER, and the Institute of Medicine's (IOM) development of CER priorities (Section 804). It also highlights the funding plans for the allocation of ARRA funds in the Office of the Secretary for the Department of Health and Human Services (DHHS), the Agency for Healthcare Research and Quality (AHRQ), and the National Institutes of Health (NIH). Preliminary identification of potential CER issues for social work research and practice are identified. The appendix includes resources on CER grants, and information drawn from discussions about CER structure, legislation, concerns and priorities. Resources on evidence based practice and research synthesis are included as well as comments provided by the Institute for the Advancement of Social Work Research (IASWR) to the Federal Coordinating Council (FCC) on CER.

## Legislation to Fund Comparative Effectiveness Research

The American Recovery and Reinvestment Act (ARRA) contained \$1.1 billion for Comparative Effectiveness Research (CER)<sup>1</sup>. These funds are designed to support research assessing the comparative effectiveness of health care treatments and strategies through efforts that:

1. Conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions.
2. 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.<sup>2</sup>

ARRA provides:

- \$400 million for the National Institutes of Health (NIH)
- \$400 million for the Office of the Secretary of the Department of Health and Human Services (DHHS)
- \$300 million for the Agency for Healthcare Research and Quality (AHRQ)

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<sup>1</sup> *Text of the Recovery Act Related to Comparative Effectiveness Funding*. Excerpt from the American Recovery and Reinvestment Act of 2009. March 2009. <http://www.hhs.gov/recovery/programs/cer/recoveryacttext.html>

<sup>2</sup> <http://www.hhs.gov/recovery/programs/cer/recoveryacttext.html>

## Federal Coordinating Council (FCC) and its Report to the President and the Congress on CER

To help develop a consistent understanding of CER and advise federal agencies receiving CER stimulus funding, the ARRA directed DHHS to create a 15 member Federal Coordinating Council (FCC) (Section 804).<sup>3</sup> After conducting three public listening sessions and gathering input from a variety of stakeholders, the FCC for CER released its *Report to the President and the Congress*<sup>4</sup> on June 30, 2009. This report includes a recommended definition, prioritization criteria, strategic framework, a long term outlook, and next steps.

### *Summary of FCC Report*

#### FCC Definition

“Comparative Effectiveness Research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat, and monitor health care conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other 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 and sub-groups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.
- This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.”

#### Prioritization Criteria

The report specifically suggests focusing on research that addresses the needs of underrepresented populations such as racial and ethnic minorities, persons with disabilities, children, veterans, the elderly, and patients with comorbidities.

#### Research Challenges

The report highlights several research challenges related to priority populations:

- Evaluating and identifying interventions that are tailored for priority populations
- Creating and enhancing potential databases looking at interventions for priority populations
- Increasing the number of community-based studies
- Increasing cultural competency
- Building workforce capacity
- Developing and implementing outreach strategies to various racial, ethnic, and health disparity populations for participation in research protocols

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<sup>3</sup> The FCC includes social worker Peter J. Delany, PhD, LCSW-C, a Rear Admiral in the United States Public Health Service, and director of the Substance Abuse and Mental Health Services Administration’s Office of Applied Studies

<sup>4</sup> <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>

### Strategic Framework

The report specifies four core categories for CER activities and investments:

1. Research – Primary or meta-analysis
2. Human and Scientific Capital – Enhance U.S.’s capacity for CER by strengthening relevant research skills or advancing CER approaches and methodologies (e.g., training and workforce development)
3. CER Data Infrastructure – Creation of research data sets and repositories, aggregation of existing data sources, development of new tools to query and analyze existing data sets, or creation of standards for new data collection
4. Dissemination and Translation of CER – improving processes for distribution and developing relevant practice guidelines

Themes for the research that cut across all core categories should focus on:

1. Conditions – Focus on specific conditions highlighted in the IOM’s 100 priorities (see below)
2. Priority Populations – Focus on populations outlined in the prioritization criteria
3. Types of interventions – Focus on medications, medical and assistive devices, procedures, **behavioral change**, diagnostic testing, and **delivery system strategies**

### Gaps in Current CER Landscape and Investment Opportunities

- Current CER and collection and organization of data – there is no specific comprehensive picture of CER in the U.S.
- CER data infrastructure – need for patient-level databases to support researchers
- Need for formal mechanisms to disseminate and translate CER from research agencies to delivery systems.
- Training to conduct CER research
- Coordination across the CER framework
  - Limited coordination with private sector CER efforts
  - Unrealized benefits of stakeholder involvement – need to increase involvement to a wide array of stakeholders
- Research
  - “Practical” vs. “pragmatic” trials – “threats to internal validity of CER for causal effects of interventions on outcomes and external validity of CER to heterogeneous patient groups and routine health care settings.”
  - Many research questions for important clinical health care decisions remain unanswered

## **Institute of Medicine’s (IOM) Initial National Priorities for CER**

Congress, through the ARRA, also requested that the Institute of Medicine (IOM)<sup>5</sup> convene a study to identify the *Initial National Priorities for CER*,<sup>6</sup> giving consideration to the FCC’s report to the President and the Congress.

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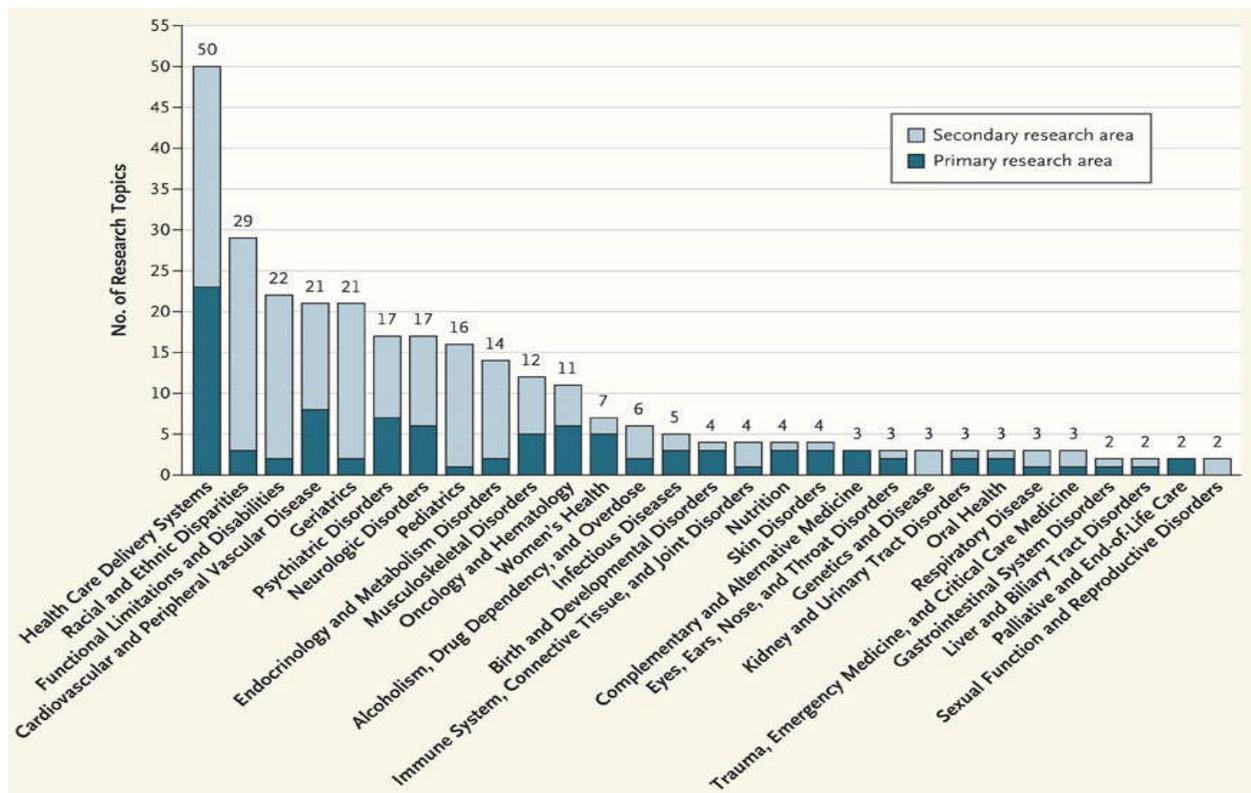
<sup>5</sup> The IOM group developing the top 100 priorities included Katie Maslow, MSW of the Alzheimer’s Association.

The IOM report defines CER as follows:

“Comparative effectiveness research (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 to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.”

The distribution of research priorities was chosen based on criteria developed by the IOM. Criteria were divided into two sections, condition-level criteria and priority-topic level criteria. Condition-level criteria includes burden of disease, cost, variability, and appropriateness for CER; priority-topic level criteria includes gaps in existing knowledge and the likelihood that the results would improve health. The IOM committee went through three rounds of voting to establish the national priorities for CER.

Figure 1: The IOM Report identified the distribution of CER national priorities as follows:



The IOM concluded in its report that the science of CER cannot be advanced without the creation of a supporting infrastructure and large-scale data networks. Capacity also needs to be built within the current CER workforce to ensure that the needs and provisions of CER as defined in ARRA are met. The IOM’s top 100 priorities for CER are divided into four quartiles (25 each) with the first quartile being the highest priority group and the fourth quartile being the lowest. According to the IOM report, the listed priorities are a starting point and will evolve as the research initiative progresses. The IOM priorities overwhelmingly focus on healthcare delivery, racial and ethnic disparities, and functional disabilities. All of these areas can involve social work interventions and CER methodologies could be utilized to determine best practices. The following page identifies priorities that are especially relevant to social workers and social work research.

<sup>6</sup> [http://books.nap.edu/openbook.php?record\\_id=12648&page=R1](http://books.nap.edu/openbook.php?record_id=12648&page=R1)

## IOM Priorities Relevant to Social Workers and Social Work Research

### A. These first quartile priorities pertinent to social work call for researchers to compare the effectiveness of:\*

1. Dissemination and translation techniques to facilitate the use of CER by patients, clinicians, payers, and others.
2. Comprehensive care coordination programs, such as the medical home, and usual care in managing children and adults with severe chronic disease, especially in populations with known health disparities.
3. Effectiveness and costs of alternative detection and management strategies for dementia in community dwelling individuals and their caregivers.
4. Pharmacologic and non-pharmacologic treatments in managing behavioral disorders in people with Alzheimer's disease and other dementias in homes and institutions.
5. School-based interventions involving meal programs, vending machines, and physical education, at different levels of intensity, in preventing and treating overweight and obesity in children and adolescents.
6. Various strategies to prevent obesity, hypertension, diabetes, and heart disease in at-risk populations such as the urban poor and American Indians.
7. Various primary care treatment strategies for attention deficit hyperactivity disorder (ADHD) in children.
8. Wraparound home and community-based services and residential treatment in managing serious emotional disorders in children and adults.
9. Interventions to reduce health disparities in cardiovascular disease, diabetes, cancer, musculoskeletal diseases, and birth outcomes.
10. Literacy-sensitive disease management programs and usual care in reducing disparities in children and adults with low literacy and chronic disease.
11. Clinical interventions to reduce incidences of infant mortality, pre-term births, and low birth rates, especially among African-American women.
12. Innovative strategies for preventing unintended pregnancies.

### B. These second quartile priorities pertinent to social work call for researchers to compare the effectiveness of:\*

1. Therapeutic strategies for different autism spectrum disorders (ASD) at different levels of severity and stages of intervention.
2. The co-location model (psychological and primary care practitioners practicing together) and usual care (identification by primary care practitioner and referral to community-based mental health services) in identifying and treating social-emotional and developmental disorders in children ages 0-3.
3. Diverse models of comprehensive support services for infants and their families following discharge from a neonatal intensive care unit.
4. Mindfulness-based interventions (e.g., yoga, meditation, etc.) and usual care in treating anxiety and depression, pain, cardiovascular risk factors, and chronic diseases.
5. Shared decision making and usual care on decision outcomes in children and adults with chronic disease such as stable angina and asthma.
6. Strategies for enhancing patients' adherence to medication regimens.
7. Patient decision support tools on informing diagnostic and treatment decisions for elective surgical and nonsurgical procedures-especially in patients with limited English-language proficiency, limited education, hearing or visual impairments, or mental health problems.
8. New remote patient monitoring and management technologies and usual care in managing chronic disease, especially in rural settings.
9. Diverse models of transition support services for adults with complex health care needs after hospital discharge.
10. Accountable care systems and usual care on costs, processes of care, and outcomes for geographically defined populations of patients with one or more chronic diseases.
11. Different residential settings in caring for elderly patients with functional impairments.
12. Coordinated care (supported by reimbursement innovations) and usual care in long-term and end-of-life care of the elderly.
13. Pharmacologic treatment and behavioral interventions in managing major depressive disorders in adolescents and adults in diverse treatment settings.
14. An integrated approach (combining counseling, environmental mitigation, chronic disease management, and legal assistance) with a non-integrated episodic care model in managing asthma in children.
15. Treatment strategies for Post-Traumatic Stress Disorder stemming from diverse sources of trauma.

## IOM Priorities Relevant to Social Workers and Social Work Research (Cont'd)

### C. These third quartile priorities pertinent to social work call for researchers to compare the effectiveness of:\*

1. Effectiveness and cost-effectiveness of conventional medical management of type 2 diabetes in adolescents and adults, versus conventional therapy plus intensive educational programs or programs incorporating support groups and educational resources.
2. Alternative redesign strategies-using decision support capabilities, electronic health records, and person health records- for increasing health professionals' compliance with evidence based guidelines and patients' adherence to guideline-based regimens for chronic disease care.
3. Different quality improvement strategies in disease prevention, acute care, chronic disease care, and rehabilitation services for diverse populations of children and adults.
4. Different benefit design, utilization management, and cost-sharing strategies in improving health care access and quality in patients with chronic diseases.
5. HIV screening strategies based on recent CDC recommendations and traditional screening in primary care settings with significant prevention counseling.
6. Comprehensive, coordinated care and usual care on objective measures of clinical status, patient-reported outcomes, and costs to care for people with multiple sclerosis.
7. Management strategies (e.g., inpatient psychiatric hospitalization, extended observation, partial hospitalization, intensive outpatient care) for adolescents and adults following a suicide attempt.
8. Different strategies to engage and retain patients in care and to delineate barriers to care, especially for members of populations that experience health disparities.

### D. These fourth quartile priorities pertinent to social work call for researchers to compare the effectiveness of:\*

1. Smoking cessation strategies in smokers from understudied populations such as minorities, individuals with mental illness, and adolescents.
2. Care coordination with and without clinical decision supports in producing good health outcomes in chronically ill patients, including children with special health care needs.
3. Coordinated, physician-led, interdisciplinary care provided in the patient's residence usual care in managing advanced chronic disease in community-dwelling patients with significant functional impairments.
4. Traditional behavioral interventions versus economic incentives in motivating behavior changes in children and adults.
5. Different techniques (e.g., audio, visual, written) for informing patients about proposed treatments during the process of informed consent.
6. Different disease management strategies for activating patients with chronic disease.
7. Different treatment strategies in the prevention of progression and disability from osteoarthritis.
8. Different treatment strategies on the frequency and lost productivity in people with chronic, frequent migraine headaches.
9. Different treatment approaches in avoiding early mortality and comorbidity among people with serious and persistent mental illness.
10. Different treatment strategies for depression after myocardial infarction on medication adherence, cardiovascular events, hospitalization, and death.
11. Different strategies for promoting breastfeeding among low-income African American women.

\*Note: Numerical indicators to not indicate level of priority within a quartile and are strictly for reference purposes within this document

## Federally Proposed Breakdown of Funding for Priority Activities

Based on the recommendations in the FCC report and the collaboration of the CER Advisory Council, which include a senior advisor from the Office of the Secretary of DHHS, the Director of AHRQ, and the Director of NIH, the following CER funding priorities have been established.

The FCC report<sup>7</sup> recommends that the Office of the Secretary of DHHS place funding emphasis on:

- a. Primary funding focus - CER data infrastructure
- b. Secondary funding focus – Dissemination and translation of CER and themes of CER on priority populations and types of interventions established by the IOM Priorities
- c. Supporting investments – Human and scientific capital, research, and priority conditions (these are historically areas of concentration for AHRQ, NIH, and VA)

According to the AHRQ Operation Plan<sup>8</sup>, AHRQ has placed its funding priorities on:

- a. *Horizon Scanning* - Identify current or emerging medical interventions available to diagnose, treat, or otherwise manage a particular condition. (\$9.5 million)
- b. *Evidence Synthesis* – Review and evaluate of current CER research for approaches to established priority subjects. (\$25 million)
- c. *Identifying Evidence Needs and Gaps* – Produce recommendations for bridging the gap between existing medical research and clinical practice. (\$25 million)
- d. *Evidence Generation* – Fund research to address gaps in research (\$173 million)
- e. *Dissemination and Translation* (\$34.5 million)
- f. *Research Training and Career Development* (\$20 million)
- g. *Citizen forum* on Effective Health Care that engage a wide array of stakeholders (\$10 million)

According to the NIH Spending Plan<sup>9</sup>, NIH has placed its funding priorities on:

- a. Identifying previously peer reviewed and approved projects (\$40 million)
- b. Research
  - i. Challenge Grants – focus on health and science programs where significant progress can be made in a two-year time frame (\$125 million)
  - ii. GO Grants – support high impact ideas that require significant research for a discrete time period to lay the foundation for new fields of investigation (\$125 million)
- c. Other activities (\$110 million)
  - i. Administrative supplement grants
  - ii. Acceleration of the time-frame of already funded research
  - iii. Contracts for a specific expertise
- d. Projects may focus on one or multiple portions of the core categories outlined in the FCC report (research, training/career development activities, infrastructure, dissemination of the research findings)

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<sup>7</sup> <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>

<sup>8</sup> [http://www.aapmr.org/zdocs/hpl/ARRA\\_CER\\_funding.pdf](http://www.aapmr.org/zdocs/hpl/ARRA_CER_funding.pdf)

<sup>9</sup> <http://askican.com/pdf/NIHCERSpendPlan.pdf>

## Preliminary Social Work-CER Related Issues

The FCC's *Report to the President and to the Congress* and the IOM's *National Priorities for CER* are the first steps in recommending development of the necessary infrastructure to advance CER methodologies in the United States. Social worker involvement in these developments is important as we work with many priority populations highlighted in the FCC and IOM reports and social work practice and research can contribute to CER. The following identifies a range of issues addressing scope of CER research, methodology, treatment and service delivery gaps, translational research and research synthesis.

- Scope of CER
  - Social workers should advocate for CER to stress clinical and health outcomes. In addition to doctors and nurses, social workers are integral to providing the best possible outcomes for patients and their families.
  - The AHRQ CER Plan<sup>10</sup> discusses barriers to implementation of CER and methods for incorporating key stakeholders through its Effective Health Care (EHC) forum. A challenge for social work is to be a stakeholder, and to ensure mental health and psychosocial interventions are incorporated into research on medical interventions.
  - “Horizon scanning” and the identification of current and past research should include social work research. However, database search engines identified by AHRQ and NIH may be absent of substantial social work researchers’ work. Systematic review databases, such as the Campbell Collaboration along with other psychosocial research databases must be included in horizon scanning efforts.
  - CER should not be used strictly for cost containment. There should be links between cost effectiveness, cost benefits, comparative effectiveness and the implementation and feasibility and adaptability of interventions. CER related to psychosocial interventions should cover these areas.
- Challenges and gaps in methodology and validity for social work CER
  - Methodological aspects of psychosocial research look at complex variables of human behavior as well as organizational, community and social contexts. These require use of multiple measures and methods. A viable CER framework for psychosocial researchers must be established and funded to advance CER that can evaluate behavioral change and delivery system strategies as identified in the FCC report.
- Challenges and gaps in treatment/delivery systems
  - Social work researchers are part of interdisciplinary teams that can examine CER related to comprehensive treatment to fully address issues related to patients’ daily living activities, quality of life, and impediments to treatment access. The IOM report stresses the importance of evaluating comprehensive treatment, behavioral elements of treatment, and adherence aspects of strictly medical interventions. Social workers and social work researchers can provide valuable input to these goals.
  - Is there sufficient infrastructure to address these critical issues and carry-out such research?

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<sup>10</sup> [http://www.hhs.gov/recovery/reports/plans/ahrq\\_cer\\_plan.pdf](http://www.hhs.gov/recovery/reports/plans/ahrq_cer_plan.pdf), Section K

- Translational research
  - All agencies stress the need for better dissemination of effective interventions into real world settings. Focus should be placed on how social work research on practice and outcomes can contribute to translational research and be disseminated within the social work practice community as well as to other disciplines. There needs to be an increased focus on comparative effectiveness of implementation of evidence-based practices into real world settings, considering different populations, cultures, age groups and co-morbid conditions.
  - Effectiveness vs. Efficacy vs. Implementation - The FCC and IOM reports stress the need for evaluating and comparing outcomes of interventions in routine conditions vs. controlled environment.
    - Efficacy is the determination of how well a treatment works in a controlled setting (stronger internal validity). Effectiveness is the determination of how well a treatment works in routine conditions (stronger external validity). Effectiveness is a better indicator of how well a treatment will perform in the real world with the general population. For now, CER may be most relevant to implementation with diverse populations in situations where there are already numerous well-researched effective interventions.
    - It is difficult to compare effectiveness if there are few well-researched effective interventions. A challenge for researchers is to compare effective interventions that are implemented in real world settings.
    - Research design must focus on developing CER that most emulates real conditions of the diverse populations being studied.
    - Special attention should be placed on populations with comorbid illnesses and how individual treatments can be developed and tested effectively.
- Research synthesis
  - It is important to ensure that social work interventions are included in the research synthesis carried out by AHRQ and by the Campbell and Cochrane Collaborations and other relevant CER synthesis efforts.

## APPENDIX A: Federal Resources and Articles on CER

### CER Reports and Documentation

- **DHHS CER Website** - At the home site for the Department of Health and Human Services (DHHS) there are links to direct you to the Federal Coordinating Council for CER and the draft documents that they released containing the Draft Definition, Prioritization Criteria, and Strategic Framework.  
<http://www.hhs.gov/recovery/programs/cer/index.html>
- **Federal Coordinating Council's Report to the President and Congress on Comparative Effectiveness Research** - June 30, 2009  
<http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>
- **Institute of Medicine's Report of 100 National Priorities for CER**  
[http://books.nap.edu/openbook.php?record\\_id=12648&page=R1](http://books.nap.edu/openbook.php?record_id=12648&page=R1)
- **AHRQ Operation Plan for CER**  
[http://www.aapmr.org/zdocs/hpl/ARRA\\_CER\\_funding.pdf](http://www.aapmr.org/zdocs/hpl/ARRA_CER_funding.pdf)
- **NIH Spending Plan for CER**  
<http://askican.com/pdf/NIHCERSpendPlan.pdf>
- **AHRQ Effective Health Care Forum**  
AHRQ has used a portion of its funding from ARRA to further develop its Effective Health Care Forum to include CER. The goal is to create a mechanism for disseminating funded CER and practice guide developed based on research outcomes. Even during the research process, a summary of the study and process is available so as to inform practitioners and researchers of current research and anticipated research outcomes.  
<http://effectivehealthcare.ahrq.gov/healthInfo.cfm?infotype=all>
- **AHRQ Selected Current Studies Related To Psychosocial CER**
  - Comparative Effectiveness of Therapies for Children with Autism Spectrum Disorders (still in research in progress stage)  
<http://effectivehealthcare.ahrq.gov/healthInfo.cfm?infotype=rr&ProcessID=106>
  - Comparative Effectiveness of Non-Pharmacologic Treatments for Refractory Depression (still in research in progress stage)  
<http://effectivehealthcare.ahrq.gov/healthInfo.cfm?infotype=rr&ProcessID=76>
  - Comparative Effectiveness Methods – Clinical Heterogeneity (still in research in progress stage)  
<http://effectivehealthcare.ahrq.gov/healthInfo.cfm?infotype=rr&ProcessID=93>
  - Comparative Effectiveness Research Priorities: Identifying Critical Gaps in Evidence for Clinical and Health Policy Decision Making (research completed)  
<http://effectivehealthcare.ahrq.gov/healthInfo.cfm?infotype=rr&ProcessID=102>  
Full report at:

<http://journals.cambridge.org/action/displayFulltext?type=6&fid=5961400&jid=THC&volumeId=25&issueId=03&aid=5961396&fulltextType=RA&fileId=S0266462309990225>

## Federal CER Grant Announcements Examples

- AHRQ has also recently released two announcements for funding grants related to CER:
  - **Recovery Act 2009 Limited Competition: Innovative Adaptation and Dissemination of AHRQ Comparative Effectiveness Research Products (iADAPT) (R18)**  
*Submission deadline: December 16, 2009*  
This AHRQ grant requests proposals for “innovative customization or adaptations to the content presentation and/or delivery mechanism(s) of one or more CER Review Products.” AHRQ is particularly looking for submissions that transform the Comparative Effectiveness Research Summary Guides (CERSGs), which were prepared by the John M. Eisenberg Center for Clinical Decisions and Communications Science as part of the AHRQ Effective Health Care Program, into a uniformly searchable and digestible format. A total of \$29.5 million will about 20-25 awards. Each participant’s budget cannot exceed \$1.5 million and must be completed within 3 years.  
<http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-10-004.html>
  - **Recovery Act 2009 Limited Competition: AHRQ Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE) Grants (R01)**  
*Submission deadline: December 16, 2009*  
This AHRQ grant is requesting proposals for large CER projects that focus on “the generation and translation of new scientific evidence and analytical tools in an accelerated format and the integration of evidence into practice and decision-making in the health care system.” Higher attention will be given to proposals look at underrepresented and AHRQ priority populations. A total of \$100 million fund 10 awards. Budgets must not exceed \$10 million over a course of 3 years and costs in any one year must not exceed \$4 million. (R01 Grant)  
<http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-10-003.html>
  - **AHRQ Clinical and Health Outcomes Initiatives in Comparative Effectiveness (CHOICE) Grants (RFA) HS-10-003 – Questions and Answers**  
AHRQ has recently released answers to questions submitted before October 23, 2009 regarding the CHOICE grant listed above (R01). The document covers topics such as priority research and populations, scope of interventions, outcomes measurement, study design, use of retrospective research of databases, collaboration expectations, review criteria, researcher status, application information, and funding specifics.

## APPENDIX B: Selected Legislative Actions and Statements on CER

### Text of the American Recovery and Reinvestment Act of 2009 Related to Comparative Effectiveness Funding

#### American Recovery and Reinvestment Act of 2009

An Act making supplemental appropriations for job preservation and creation, infrastructure investment, energy efficiency and science, assistance to the unemployed, and State and local fiscal stabilization, for the fiscal year ending September 30, 2009, and for other purposes.

#### Sec. 804. Federal Coordinating Council for Comparative Effectiveness Research

- (a) ESTABLISHMENT— There is hereby established a Federal Coordinating Council for Comparative Effectiveness Research (in this section referred to as the 'Council').
- (b) PURPOSE— The Council shall foster 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.
- (c) DUTIES— The Council shall—
  - (1) 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, to coordinate the conduct or support of comparative effectiveness and related health services research; and
  - (2) advise the President and Congress on—
    - (A) strategies with respect to the infrastructure needs of comparative effectiveness research within the Federal Government; and
    - (B) organizational expenditures for comparative effectiveness research by relevant Federal departments and agencies.
- (d) MEMBERSHIP—
  - (1) NUMBER AND APPOINTMENT— The Council shall be composed of not more than 15 members, all of whom are senior Federal officers or employees with responsibility for health-related programs, appointed by the President, acting through the Secretary of Health and Human Services (in this section referred to as the 'Secretary'). Members shall first be appointed to the Council not later than 30 days after the date of the enactment of this Act.
  - (2) MEMBERS—
    - (A) IN GENERAL— The members of the Council shall include one senior officer or employee from each of the following agencies:
      - (i) The Agency for Healthcare Research and Quality.
      - (ii) The Centers for Medicare and Medicaid Services.
      - (iii) The National Institutes of Health.
      - (iv) The Office of the National Coordinator for Health Information Technology.
      - (v) The Food and Drug Administration.
      - (vi) The Veterans Health Administration within the Department of Veterans Affairs.
      - (vii) The office within the Department of Defense responsible for management of the Department of Defense Military Health Care System.

- (B) QUALIFICATIONS— At least half of the members of the Council shall be physicians or other experts with clinical expertise.
- (3) CHAIRMAN; VICE CHAIRMAN— The Secretary shall serve as Chairman of the Council and shall designate a member to serve as Vice Chairman.
- (e) REPORTS—
  - (1) INITIAL REPORT— Not later than June 30, 2009, the Council shall submit to the President and the Congress a report containing information describing current Federal activities on comparative effectiveness research and recommendations for such research conducted or supported from funds made available for allotment by the Secretary for comparative effectiveness research in this Act.
  - (2) ANNUAL REPORT— The Council shall submit to the President and Congress an annual report regarding its activities and recommendations concerning the infrastructure needs, organizational expenditures and opportunities for better coordination of comparative effectiveness research by relevant Federal departments and agencies.
- (f) STAFFING; SUPPORT— From funds made available for allotment by the Secretary for comparative effectiveness research in this Act, the Secretary shall make available not more than 1 percent to the Council for staff and administrative support.
- (g) RULES OF CONSTRUCTION—
  - (1) COVERAGE— Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer.
  - (2) REPORTS AND RECOMMENDATIONS— None of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.

## **Title VIII—Departments of Labor, Health and Human Services, and Education, and Related Agencies**

### *Department of Health and Human Services*

#### Agency for Healthcare Research and Quality

##### Healthcare Research and Quality (Including Transfer of Funds)

For an additional amount for 'Healthcare Research and Quality' to carry out titles III and IX of the Public Health Service Act, part A of title XI of the Social Security Act, and section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, \$700,000,000 for comparative effectiveness research: *Provided*, That of the amount appropriated in this paragraph, \$400,000,000 shall be transferred to the Office of the Director of the National Institutes of Health ('Office of the Director') to conduct or support comparative effectiveness research under section 301 and title IV of the Public Health Service Act: *Provided further*, That funds transferred to the Office of the Director may be transferred to the Institutes and Centers of the National Institutes of Health and to the Common Fund established under section 402A(c)(1) of the Public Health Service Act: *Provided further*, That this transfer authority is in addition to any other transfer authority available to the National Institutes of Health: *Provided further*, That within the amount available in this paragraph for the Agency for Healthcare Research and Quality, not more than 1 percent shall be made available for additional full-time equivalents.

In addition, \$400,000,000 shall be available for comparative effectiveness research to be allocated at the discretion of the Secretary of Health and Human Services ('Secretary'): *Provided*, That the funding appropriated in this paragraph shall be used to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies, through efforts that: (1)

conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions; and (2) 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: *Provided further*, That the Secretary shall enter into a contract with the Institute of Medicine, for which no more than \$1,500,000 shall be made available from funds provided in this paragraph, to produce and submit a report to the Congress and the Secretary by not later than June 30, 2009, that includes recommendations on the national priorities for comparative effectiveness research to be conducted or supported with the funds provided in this paragraph and that considers input from stakeholders: *Provided further*, That the Secretary shall consider any recommendations of the Federal Coordinating Council for Comparative Effectiveness Research established by section 804 of this Act and any recommendations included in the Institute of Medicine report pursuant to the preceding proviso in designating activities to receive funds provided in this paragraph and may make grants and contracts with appropriate entities, which may include agencies within the Department of Health and Human Services and other governmental agencies, as well as private sector entities, that have demonstrated experience and capacity to achieve the goals of comparative effectiveness research: *Provided further*, That the Secretary shall publish information on grants and contracts awarded with the funds provided under this heading within a reasonable time of the obligation of funds for such grants and contracts and shall disseminate research findings from such grants and contracts to clinicians, patients, and the general public, as appropriate: *Provided further*, That, to the extent feasible, the Secretary shall ensure that the recipients of the funds provided by this paragraph offer an opportunity for public comment on the research: *Provided further*, That research conducted with funds appropriated under this paragraph shall be consistent with Departmental policies relating to the inclusion of women and minorities in research: *Provided further*, That the Secretary shall provide the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate with an annual report on the research conducted or supported through the funds provided under this heading: *Provided further*, That the Secretary, jointly with the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, shall provide the Committees on Appropriations of the House of Representatives and the Senate a fiscal year 2009 operating plan for the funds appropriated under this heading prior to making any Federal obligations of such funds in fiscal year 2009, but not later than July 30, 2009, and a fiscal year 2010 operating plan for such funds prior to making any Federal obligations of such funds in fiscal year 2010, but not later than November 1, 2009, that detail the type of research being conducted or supported, including the priority conditions addressed; and specify the allocation of resources within the Department of Health and Human Services: *Provided further*, That the Secretary, jointly with the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.

*Text of the Recovery Act Related to Comparative Effectiveness Funding.* Excerpt from the American Recovery and Reinvestment Act of 2009. March 2009.

<http://www.hhs.gov/recovery/programs/cer/recoveryacttext.html>

**Statement from Senator Max Baucus (D-Montana) and Peter Orszag of the Office of Management and Budget (OMB)**

- CNSNEWS.COM - *June 10, 2009* - Several bills have been introduced advocating for increased federal support of CER. Senate Finance Chairman Max Baucus (D-Montana) has been a substantial proponent of CER legislation, including supporting the CER Act of 2008<sup>11</sup>, which was passed, but was vetoed by President Bush. Controversy has developed regarding the eventual outcomes of CER on healthcare practice. Many fear that it will lead to rationing of health care practices or further restriction of procedures by insurance companies or the government, based on the findings of CER. In this article, Baucus and the Director of the Office of Management and Budget, Peter Orszag advocate that CER is structured to provide information to physicians and patients to make more informed decisions about treatment and specifically prohibits CER research from creating a healthcare rationing environment. However, Baucus stresses that he will take the concerns about CER leading to rationing practices seriously. Orszag also said the focus of the legislation was to increase information to physicians and health care practitioners. In fact, Baucus states that CER language leaves out substantial discussions of cost-effectiveness because the focus is on how best to treat patients, not control costs. Baucus is also advocating that control of CER be removed from the government spectrum, so as to further insure political policy issues do not effect research questions or outcomes, which was how the CER Act of 2008 was structured. However, there is concern of influence from board members who may have conflicts of interests because of affiliations with other organizations. Baucus believes that future legislation will maintain the integrity of CER and its originally intended purposes.  
<http://www.cnsnews.com/public/content/article.aspx?RsrcID=49357>

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<sup>11</sup> <http://finance.senate.gov/healthreform2009/finalwhitepaper.pdf>

## APPENDIX C: Non-Governmental Information and Input on CER Structure and Priorities

- American Psychological Association - *March 21, 2009*– As the IOM was developing the top 100 priorities for CER, The President of the American Psychological Association, James H. Bray, PhD, testified about the need for inclusion of behavioral and psychosocial interventions in CER. He highlighted the fact that “modifiable behavioral factors” often contribute to several chronic illness in America. Bay also called for team-based systems of care to be examined against more routine-style care, a priority that was eventually drafted in the FCC and IOM reports. Lastly, Bray called for research that stretches across the lifespan and more specific focus on CER with populations that suffer health disparities. A variety of advocates from psychosocial backgrounds have substantially influenced the inclusion of psychosocial research in CER in the reports by the FCC and the IOM. Efforts, like the SWPI CER Symposium will help develop methods and considerations for furthering the hard work of psychosocial research advocates. <http://www.emaxhealth.com/2/95/30020/federal-treatment-effectiveness-research-should-include-behavioral-psychosocial-intervent>
- Evidence-Based Behavioral Practices Website - *May 11th, 2009* . Former President of the APA and staff director for Sen. Daniel K. Inouye (D-Hawaii), Pat DeLeon, PhD, provides insight into CER and the details of its implementation. DeLeon notes the issue of trial and error treatment of both medical and psychosocial conditions. This causes inflated treatment costs and undue burden on patients. Treatment that considers the whole individual and uses a wide range of researched outcomes will cut down on unnecessary treatment interventions and thereby reducing overall costs. His largest concern is that after medical and psychosocial research is conducted, as laid out in the FCC and IOM reports, it will not be synthesized so that it can be applied to comprehensive treatment plans. <http://ebbp.org/wordpress2/?p=17>
- *Millbank Quarterly - Spring 2009*. In recent years, several other countries have established agencies to evaluate health technologies and broader management strategies to inform health care policy decisions. This article reviews experiences from Britain, France, Australia, and Germany and how they might inform practice of CER in the United States. It identifies ten core attributes of CER in these countries: (1) a stated purpose and objective of CER and its influence on policy and practice; (2) the scope of assessment, ranging from health technology, to specific medical treatment, to psychosocial research and delivery systems; (3) development of a prioritization process for selecting topics for research consideration; (4) determination of the types of research used and mechanisms to synthesize outcomes; (5) sustained interaction with academic and professional research groups; (6) ensured translation of outcomes to practice; (7) consistency in funding and budgeting; (8) considerations of cost in treatment (was added because researchers said it limited ability to completely assess treatment feasibility); (9) determine structure of how outcomes are suggested and supported to clinicians and patients; and (10) dissemination and implementation of outcomes. Common principles of CER for these countries include: (1) “independence from central government, insurance agencies, and industries”; (2) “transparency in the way topics are selected, the evidence is synthesized and assessed, and the final decision is made”; (3) “inclusiveness” of a variety of clinicians involved in treatment; (4) “scientific rigor” of outcomes of research; (5) ability to appeal findings of CER organization; and (6) disseminating information while a treatment or technology is in early stages of development. Unlike other countries, ARRA’s construction of CER specifically “precludes conclusions from CER from being used to determine coverage or reimbursement policies of private and public payers or to inform national clinical guidelines.” <http://www.milbank.org/quarterly/8702feat.html>

- Friends of Cancer Research - *Summer 2009* - This report uses cancer as a case study to recommend ways in which CER can improve treatment decisions. The report stresses the need to link public and private data from CER, so that clinicians can consider all the most recent research when developing a treatment plan. Further, they call for comprehensive techniques, including behavioral and psychosocial interventions. This would yield the highest benefit of CER funding because it would make applicable already existing and highly relevant data.  
[http://focr.org/files/CER\\_REPORT\\_FINAL.pdf](http://focr.org/files/CER_REPORT_FINAL.pdf)

### **CER Considerations for Various Populations**

- CER and Health Disparities - *August 2009* – This article from Families USA addresses the concern that CER will accurately address health disparities in minority populations. Suggestions to utilize CER to reduce health disparities include: Improve inclusion criteria in studies to reflect the diversity of the U.S. population, recruit and do outreach with organizations in communities of color, use research that accounts for multiple chronic illnesses, evaluate the effect of interventions in the context of communities to consider the social context of interventions, and ensuring that research outcomes are translated into culturally relevant practices.  
<http://www.familiesusa.org/assets/pdfs/health-reform/comparative-effectiveness-research.pdf>
- CER and Rural Health – *September 2009* - This policy brief by the Upper Midwest Rural Health Research Center addresses issues related to CER and dissemination in rural areas. Issues are raised about the lack of rural patients in clinical trials, the lack of timely practice guidelines for rural environments, and the lack of availability of current evidence-based information for rural physicians. Also included are potential strategies for AHRQ, NIH, CDC, etc. for combating these issues with respect to CER.  
[http://www.uppermidwestrhc.org/pdf/policybrief\\_effectiveness.pdf](http://www.uppermidwestrhc.org/pdf/policybrief_effectiveness.pdf)

### **Institute for the Advancement of Social Work Research Comments**

***Submitted June 10, 2009 to the Federal Coordinating Council on Comparative Effectiveness Research***  
[\(<http://www.blsmeeeting.net/MayFCC/Comments.cfm>\)](http://www.blsmeeeting.net/MayFCC/Comments.cfm)

*Comments regarding Definition, Strategic Framework and Prioritization Criteria.*

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.

## APPENDIX D: CER Resource Information Prior to the Passage of ARRA

### Articles on CER Legislation

- History of CER Legislation - *August 2008* – Many efforts have been made over the last five years to push for CER legislation. Prior to receiving ARRA funding, CER was endorsed in the Medical Modernization Act of 2003, which gave AHRQ “limited mandate to conduct CER.” The article highlights the continuing discussion of whether CER’s ultimate purpose is to inform treatment or to determine cost-effectiveness. This debate has plagued legislative developments. The CER Act of 2008 was largely vetoed for this purpose. The article also highlights IOM and AHRQ’s involvement in CER prior to ARRA funding as well as private and international efforts to develop CER.

[http://www.allhealth.org/Publications/Quality\\_of\\_care/Comparative\\_Effectiveness\\_Better\\_Value\\_for\\_the\\_Money\\_84.pdf](http://www.allhealth.org/Publications/Quality_of_care/Comparative_Effectiveness_Better_Value_for_the_Money_84.pdf)

- Creation of a National Research Center - *November 7, 2006* – Prior to CER legislation in ARRA, there was a push to develop a non-profit CER institute. This discussion is still well alive in the development of the recent healthcare legislation. Gail R. Wilensky, PhD, senior fellow at Project HOPE, and director of HCFA/CMS in the senior Bush administration, assesses the feasibility of an agency devoted to comparative clinical effectiveness research, and examines various options for structure, placement, financing and functions. She concludes that the best way to advance CER would be to develop a federally funded research and development center (FFRDC), which would allow for private funding for up to 30 percent of its budget. However, any CER initiatives, either private or public need to allow for objectivity in the selection of research topics, credibility in the findings, and independence from political pressures and influence from private sector stakeholders. All of these issues continue to be debated for current and new funding of CER.

<http://www.commonwealthfund.org/Content/Publications/In-the-Literature/2006/Nov/Developing-a-Center-for-Comparative-Effectiveness-Information.aspx>

## APPENDIX E: Evidence-Based Practice Research and Research Synthesis

One of the CER priorities established by the FCC report is the use of randomized controlled trials (RCT) for the evaluation of interventions. However, it is not always possible or ethical to conduct RCT in social, health, and human services, and thus there is a lack of that type of research evidence for some interventions provided by social workers. Qualitative research can enhance quantitative research and help us better understand cultural issues and contexts related to interventions.

A number of organizations have attempted to develop objective evidence grading systems to rate the strength of evidence for interventions. Inclusions of results from these systematic reviews with those commonly recognized in the public sector such as the CERSGs from AHRQ's Eisenberg Center will help keep psychosocial research in the CER discussion.

### Independent Health and Behavioral Health Research Synthesis Entities:

- *The Campbell Collaboration (C2)* is an international, nonprofit organization that reviews the effectiveness of behavioral, social, and psychological interventions in the fields of social welfare, criminal justice, and education. The organization helps people make well-informed decisions by preparing, maintaining and disseminating systematic reviews in education, crime and justice, and social welfare. Below is a link to the Campbell Collaboration Library of Systematic Reviews:  
<http://www.campbellcollaboration.org/library.php>
- *The Cochrane Collaboration* is an international not-for-profit and independent organization, dedicated to making up-to-date, accurate information about the effects of healthcare readily available worldwide. It produces and disseminates systematic reviews of healthcare interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions. Below is a link to the Cochrane Database of Systematic Reviews:  
<http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME>