

*In the next 3 pages, you will have the opportunity to submit up to 3 comparative effectiveness studies for the committee's consideration. Please rank your suggested CER priorities as first, second, and third by entering them in that order.*

*Once you have submitted your top 3 priorities, you will be asked what criteria you feel are most important in establishing a national set of priorities for CER. You will be asked to select and rank criteria (e.g. disease burden, disease severity, variation in care, cost, public interest, information gap) as well as identify other criteria for the committee to consider.*

*Lastly, you will be asked to provide recommendations to the committee regarding what new or enhanced capacities and infrastructure are needed to sustain a national CER enterprise.*

## **CER Scope**

The committee's working definition for CER is: “The generation and synthesis of evidence that compares the effectiveness of alternative methods to prevent, diagnose, treat, monitor, and improve delivery of care for a clinical condition. The purpose of CER is to assist patients, clinicians, purchasers, and policy makers in making informed health decisions.”

Please consider the following as you develop your suggested priority areas for study:

- **Study Population:** Identify a study population by disease entity, condition, susceptible population, or population affected.
- **Alternative Interventions:** Comparators might include systems of care as well as specific interventions to address the prevention, diagnosis, treatment, monitoring, or delivery of care. One comparator could be the current standard of care or usual care.
- **Outcome of Interest:** Please identify the health related risk, side effect or harm of greatest concern, and/or the health related benefit of greatest interest (e.g., patient-reported outcomes, surrogate endpoints [such as change in tumor size or laboratory parameters], clinical event, death).
- **Study Methods:** CER can include analyses of existing data, observational studies (e.g., Framingham study), prospective trials, and systematic reviews of published studies.

## **Overview of requested information**

We anticipate a high response rate to this questionnaire. Therefore, to facilitate the committee's review of each response, we ask that you characterize each of your priorities by specifying the following:

- **A single sentence that frames your research question** (include condition, comparison, and outcome of interest)

- **Justification for why the question should be a national priority**
  - **Area to be studied** (e.g., cardiovascular and peripheral vascular disease, racial and ethnic disparities in health care, nutrition)
  - **Comparators** (i.e. include a comparison of two or more alternatives for the prevention, diagnosis, treatment, monitoring, or delivery of care for a clinical condition)
  - **Study design** (e.g., analyses of existing data [systematic review], observational studies [such as the Framingham study], and prospective trials)
  - **Study population** (e.g., children/adolescents, elderly, special populations)
- 

## Autism

### Research Question:

Is behavioral intervention with occupational therapy intervention more effective than behavioral intervention (without occupational therapy) to improve the performance of daily tasks and participation in school, home, and community in children diagnosed with autistic spectrum disorders (ASD)?

### Justification:

Behavioral interventions are commonly used to treat autism, but given the high prevalence of sensory issues in children with Autistic Spectrum Disorders (ASD), this approach fails to address what are believed to be underlying reasons for these children's behaviors: i.e., problems with processing sensory information. Occupational therapists can assess and treat sensory processing problems that negatively influence children's behaviors and daily performance. They also can modify environments (e.g., reduce sensory overload) and tasks so that children can perform them as independently and functionally as possible, whether the task is dressing or completing a class assignment.

### Area to be studied:

Functional performance and participation across children's environments

Possible outcome measure:

Child Occupational Self Assessment (COSA) with card sort and visual cues

Comparators: Behavioral intervention vs. Behavioral intervention plus occupational therapy

### Study design:

Prospective trial, matching participants by age, gender, and diagnosis.

### Study population:

Children/adolescents with diagnosis of ASD.

## **Stroke**

### Research Question:

Is bilateral task-based practice more effective than modified Constraint-Induced Movement Therapy (mCIMT) to improve movement and performance of the affected arm in adults who have had a stroke within the past year?

### Justification

Research suggests that task-based practice results in significantly greater strength and function than standard care in individuals with a recent first-time stroke. However, studies have also shown that modified Constraint-Induced Movement Therapy (mCIMT) improves reach, grasp, and measures of arm and hand function. Research has not yet compared bilateral task-based practice and mCIMT on movement and function of the affected arm in adults who have had a recent stroke. Rehabilitation professionals could use the results to design the most effective intervention programs for adults who have sustained a stroke.

### Area to be studied:

Motor Activity Log or  
Wolf Motor Assessment

### Comparators:

Bilateral task-based practice vs. modified Constraint-Induced Movement Therapy (mCIMT)

### Study design:

Randomized controlled trial (baseline, postintervention, 9 mo follow-up)  
Note: The bilateral task-based practice protocol would include weekly homework and goals, to match the hours of therapy from the mCIMT program.

### Study population:

Adults 18 y.o. and up, first-time stroke (within last 12 mos.)

## **Dementia**

### Research Question:

Are intervention programs that facilitate routines and environmental cueing, as provided under the supervision of an occupational therapist and under an occupational therapy plan of care, more effective than standard care to improve the performance of daily activities (e.g., toileting, sleeping, taking medications) in people with dementia?

Justification:

Research suggests that routines are beneficial to performance of daily occupations (e.g., sleep) in people with early dementia . While some studies have examined the intervention of routines on behavior and performance, few studies have investigated the effect of routines and environmental cues on performance of activities of daily living (e.g., toileting, sleeping,) and mortality. If the maintenance of daily routines and provision of environmental cues provide purposeful and meaningful activity throughout the day, people with dementia may live longer, have fewer health problems and higher quality of life, which could decrease the stress of caregivers and lower costs.

Area to be studied:

Activities of daily living performance  
Mortality

Comparators:

Facilitation of routines and environmental cueing vs. standard care

Study design:

Observational

Study population:

Middle-aged and older adults with dementia, including Alzheimer's Disease

**Please describe the process used to determine priorities. 100 words or less.**

We read systematic reviews in our field on autism, stroke, and dementia. We identified research gaps and questions. We consulted expert researchers regarding design and question, as needed.

**Recommendations to the committee regarding what new or enhanced capacities and infrastructure are needed to sustain a national CER enterprise (100 words or less)**

MedPAC and other organizations have acknowledged the need for outcomes data to improve effectiveness and efficiency in the delivery of occupational therapy services. However, in order to compare the effectiveness of methods, outcomes data and process data need to be collected in standardized ways, especially in Medicare. Funding is needed to build a national outcomes database for occupational therapy in order to compare interventions relative to patient characteristics and functional status. A national database would provide information about functional improvement which would inform CMS and other health organizations about the most effective interventions and expected outcomes of occupational therapy.