



AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

American Society of Consultant Pharmacists  
Comments on Comparative Effectiveness Research  
April 13, 2009

The American Recovery and Reinvestment Act of 2009 (ARRA) allocates \$1.1 billion for comparative effectiveness research. The American Society of Consultant Pharmacists supports the primary purpose of comparative effectiveness research, which is to advance medical knowledge about the relative benefits and risks of alternative strategies for prevention and treatment of illness.

The American Society of Consultant Pharmacists (ASCP) is the international professional association that provides leadership, education, advocacy, and resources to advance the practice of senior care pharmacy. ASCP's 6,000 members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and in home and community-based care.

Adults over the age of 85 constitute the most rapidly growing segment of the United States population. Research on the proper use of medications in this age group is lacking, and clinicians who care for these older adults could benefit greatly from research in this area.

Our comments on comparative effectiveness research (CER) will focus on the benefits and impact of this research on drug therapy for older adults. A key point with respect to older adults is that the safety profile of medications may be as important as the effectiveness, and should be considered a key part of CER. When medications are similar with respect to effectiveness, the safety profile of the medicine becomes a critical factor in the decision of which medicine to use.

In some cases, a medicine that is considered less effective may even be preferred in some older adults. The more effective medicine may be more toxic or may have more adverse effects. The safety profile of a medication includes three important elements:

- Adverse drug reactions, or side effects
- Drug interactions
- Potential for toxicity, or the therapeutic range

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In older adults, one additional element of medication safety is also very important: the potential for the medication to cause or exacerbate geriatric syndromes. Geriatric syndromes, or geriatric conditions, include such issues as falls, urinary incontinence, delirium, and cognitive impairment or mental confusion.

A drug may increase the risk of falls, for example, by causing blurred vision, orthostatic hypotension, dizziness, or other impairments. In younger adults, these same symptoms may only result in minor problems, or may not be present. A fall in an older adult can result in a hip fracture or brain injury that can have permanent consequences, including death.

Clinicians who care for older adults must balance the need to provide proper care for the disease with the need to maintain or improve functional status and quality of life for the patient. The choice of medication also calls for balancing the benefits of the medicine against all the possible risks that the medicine presents.

One of the major challenges for clinicians who care for older adults, especially those over the age of 75 or 80, is the lack of research conducted in this population. Results of studies conducted in younger adults should not be assumed to be applicable to older adults. In the elderly, the benefits of some medications may be less than in younger adults, and the risks may be greater. Older adults are less resilient and more susceptible to adverse effects of medications.

Including the elderly in comparative effectiveness trials is therefore especially important. With respect to drug safety, only research conducted in the elderly can assess the contribution of medications to causing or exacerbating geriatric syndromes.

Another common challenge faced by clinicians who care for older adults is the presence of multiple morbidities. Since medications are a key tool for managing chronic disease, it is not uncommon for older adults to be receiving five or more medications. As the number of medications increases, the risk of drug interactions and adverse reactions multiplies. One strategy used to minimize the number of medications is to try to use one medication that can address two or more problems at the same time. The medication may not be the most effective for both conditions, but may be the best choice for a given patient in order to minimize medication risks while controlling the patient's symptoms.

The key point here is that clinicians who care for the older adult patient must have the freedom to provide optimal care to each individual patient that is tailored to the needs of that patient, taking into consideration all the chronic conditions of the patient, while seeking to maintain or improve the functional status and quality of life of that patient.

By contrast, comparative effectiveness research has a population focus. Different medications or treatment approaches are applied to two different groups of patients. The drug or treatment that produces the better outcome in the group that receives it is considered the superior approach. While the conclusion may be valid for the group as a whole, it is not necessarily valid for each individual patient. Specific patient characteristics may result in a need for a different drug than the one that is generally judged as superior.

The funds available for comparative effectiveness research present an important opportunity to advance knowledge in the management of frail elderly adults with multiple chronic diseases. To maximize the return on the dollars invested in comparative effectiveness research, ASCP offers the following recommendations:

1. When comparative effectiveness research trials involve medications that may be used in older adults, the trials should include older adults in the research, especially adults over the age of 75. Only by including these adults in the trial can the results of the research be applied to the “real world” where 35 to 40 percent of prescription drugs are consumed by those over the age of 65.
2. Comparative effectiveness research should include a focus on medication safety as well as effectiveness. In the elderly, evaluation of medication safety should include the potential for the drug to contribute to geriatric syndromes.
3. Results of comparative effectiveness research trials should not be used to limit access to medications, such as by formulary exclusion or payment restrictions. In older adult patients, clinicians need the flexibility to craft treatment strategies to meet the needs of the entire patient, not just to manage a single disease.

Respectfully submitted,

A handwritten signature in black ink that reads "Thomas R. Clark". The signature is written in a cursive, flowing style.

Thomas R. Clark, RPh, MHS, CGP, DPNAP  
Director of Clinical Affairs