

PROGRAM BRIEF

Medicare Uses of Research from the Centers for Education & Research on Therapeutics (CERTs)

Agency for Healthcare Research and Quality

AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care by:

- Using evidence to improve health care.
- Improving health care outcomes through research.
- Transforming research into practice.

Background

The mission of the Centers for Education & Research on Therapeutics (CERTs) program is to conduct research and provide education that will advance the best use of therapeutics (drugs, medical devices, and biological products). The CERTs seek to increase awareness of the benefits and risks of new, existing, and combined uses of therapeutics, thereby improving the effectiveness and safety of their use.

The program is administered as a cooperative agreement by the Agency for Healthcare Research and Quality (AHRQ), in cooperation with the U.S. Food and Drug Administration. The CERTs receive funds from both public and private sources, with AHRQ providing core financial support. The CERTs comprise seven centers (see box), a Coordinating Center, a Steering Committee, and numerous partnerships with public and private organizations.

Collectively, the CERTs have more than 40 unique data sources and serve as a national resource of experienced

CERTs Program Centers

Each center focuses its educational and research efforts on therapies in a particular population or therapeutic area:

- *Duke University Medical Center*—Therapies for disorders of the heart and blood vessels
- *HMO Research Network*—Drug use, safety, and effectiveness in health maintenance organization populations
- *University of Alabama at Birmingham*—Therapies for musculoskeletal disorders
- *University of Arizona Health Sciences Center*—Drug interactions that result in harm
- *University of North Carolina at Chapel Hill*—Therapies for children
- *University of Pennsylvania School of Medicine*—Therapies for infection; antibiotic drug resistance
- *Vanderbilt University Medical Center*—Prescription drug use in a Medicaid population



Agency for Healthcare Research and Quality

Advancing Excellence in Health Care • www.ahrq.gov



researchers. CERTs data, which represent more than 64 million people, can be used for large population-based studies. Thus, CERTs research results can be useful to the Medicare program when evaluating policy options and assessing the effects of policy decisions.

The recently passed Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) will provide additional prescription drug benefits for Medicare beneficiaries. The new Medicare prescription drug benefit presents a number of new choices for beneficiaries, providers, and policymakers.

CERTs and Medicare

Since the inception of the CERTs program in September 1999, the centers have developed a portfolio of more than 200 completed and ongoing studies with results that address important issues regarding the best use of therapeutics. Several of these projects have been conducted within the elderly population. The following examples show how CERTs studies are relevant to Medicare and the care of elderly patients.

Quality Improvement Initiative

A number of the CERTs centers work with Quality Improvement Organizations (QIOs). QIOs constitute the quality-assurance program for the Centers for Medicare & Medicaid Services (CMS), which currently pays for medical care for 74 million beneficiaries in the United States (38 million in Medicare, 36 million in Medicaid). Both the CERTs and QIOs share the mission of improving the quality of health care for people covered by Medicaid and Medicare.

CMS chooses the clinical topics to be addressed, and the QIOs use a variety of methods to improve care. The

current scope of work includes quality improvement in inpatient hospitals, in outpatient care (diabetes care, cancer screening, adult immunizations), in nursing homes, and in home health.

The Vanderbilt center and the Tennessee QIO jointly completed a project on beta-blocker compliance (see “Beta-Blocker Therapy for Acute Myocardial Infarction”). They have plans for three additional joint projects:

- Patient compliance with prescribed angiotensin-converting enzyme (ACE) inhibitor therapy in heart failure (similar to the beta-blocker project).
- An intervention addressing inpatient care using a computerized provider order entry program.
- Collaboration and consultation to improve nursing home quality.

Prescription Drugs

Drug-drug interactions. Exposure to potential drug-drug interactions has been a focus of investigators at the Arizona center. In particular, their research has found that people age 50 and older are at the greatest risk for drug-drug interactions. This information is consistent with the results of other studies concluding that older Americans have greater exposure to prescription drugs than younger people do and are more likely to take many medications.

Beta-blocker therapy for acute myocardial infarction.¹ The Vanderbilt center conducted a study using data from the Tennessee QIO. The researchers found that more than 15 percent of patients who receive a prescription for beta-blockers when they are discharged from the hospital do not have them filled. Because studies have shown that beta-blockers can improve health outcomes and reduce costs, the investigators suggest that

organizations work to improve patient adherence to prescriptions.

Economic impact of beta-blocker therapy for heart failure.² The Duke center evaluated the economic impact of using beta-blockers to treat heart failure. The impact was considered from the perspectives of society, physicians, hospitals, and Medicare. From the perspectives of society and Medicare, the use of these drugs would reduce costs, primarily as a result of fewer hospital admissions. Based on the predictions, even if Medicare completely reimbursed the cost of beta-blockers, it would still reduce costs. The Duke center has proposed the same type of cost study for several other cardiovascular medications. Similar cost analyses could be applied to other medications proven to save lives.

Partnership with the Coalition for Affordable Quality Healthcare (CAQH). CAQH is mounting a national initiative in collaboration with professional societies such as the American Heart Association to promote continued adherence to beta-blocker therapy in patients who have suffered a heart attack. The decision to focus on beta-blocker therapy was based on results of data generated by the Duke center, which has provided consultation in support of this initiative.

Adherence to guidelines for reducing gastrointestinal complications.³ Several strategies have been shown to reduce gastrointestinal complications for patients taking nonsteroidal anti-inflammatory drugs (NSAIDs). Various groups have incorporated these strategies into guidelines that health care providers can consider when treating patients. After finding that the recommended strategies are not commonly followed in patients age 50 and older in at least one Medicaid program, researchers at the Vanderbilt

center are developing an intervention using computerized provider order entry to increase the use of gastroprotective strategies in high-risk patients taking NSAIDs. If successful, this could be used as a model for Medicare.

Tensions in antibiotic prescribing.⁴ The use of newer antibiotics in cases when older antibiotics would be equally effective promotes the development of resistance to these drugs. The University of Pennsylvania center has examined physician perspectives regarding the tension between patient and public health values in use of antibiotics. A survey of physicians, which was conducted to identify drug choices for patients with community-acquired pneumonia, revealed that both generalists and infectious disease specialists were more likely to prescribe newer antibiotics than older ones.

Prescribing Safety Program. The HMO Research Network center is leading an ambitious drug safety program that includes all seven CERTs research centers. Until now, most work on drug safety has focused on inpatients, even though outpatients receive far more prescriptions. Identifying the most important errors in this largely unexamined setting is a necessary first step to developing methods for preventing them. These two aims—identification and prevention—are the subjects of an AHRQ-funded patient safety grant awarded to the HMO Research Network for the CERTs Prescribing Safety Program.

The project will characterize the frequency and severity of medication errors, focusing on the most commonly misused drugs, drugs with especially strong warnings against misuse, and medication errors in vulnerable populations such as the elderly. Once

the frequency and severity of medication errors have been determined, investigators will test the effectiveness of three interventions for physicians. Two of the interventions are experiments with electronic prescription order entry, which is a system designed to help reduce errors by providing physicians with information about therapies and dosing. The third intervention is a randomized trial that will assess the effects of group physician education.

Medical Devices

Economic impact of drug-coated coronary stents on hospital systems. Recently, the development of stents coated with antithrombotic or antiproliferative drugs has increased the potential benefits of coronary stenting, and early clinical experiences appear promising. The Duke center has developed a model to evaluate the economic impact of these stents on hospitals based on proposed Medicare reimbursements and how reimbursement decisions may affect practice.

Long-Term Care

Prevention of falls. A substantial number of nursing facilities are funded by Medicare, and one of the CMS quality goals is to reduce falls among patients in both intermediate care and skilled nursing facilities. The Vanderbilt center offers an established fall-prevention program that is now being used by the Alabama and Tennessee QIOs. This program puts into practice the results of previous research on the effect of inappropriate use of medications, such as sedatives and tranquilizers, that increase the probability of falls and fractures in the elderly.

Secondary prevention of fractures in patients with osteoporosis living in long-term care facilities. A leading detriment to elderly health is osteoporosis, which results in bone fragility and increases susceptibility to fractures. Elderly people residing in skilled nursing facilities who have already had such a fracture are the most susceptible to the devastating effects of this disease. Several studies have reported inadequate monitoring and treatment of osteoporosis, despite strong evidence for and guidelines on effective prevention strategies. Investigators from the University of Alabama at Birmingham (UAB) center and the Duke center have collaborated with the Claude D. Pepper Older Americans Independence Center and the Health Services Advisory Group, Inc., to develop an intervention study to improve care for such patients in Arizona and North Carolina.

The patterns and predictors of compliance with osteoporosis treatment guidelines by health care providers are not well understood. The purpose of the collaboration between UAB and Duke is twofold: (1) to identify barriers to compliance with current osteoporosis guidelines among skilled nursing facilities in Arizona and North Carolina and (2) to implement and evaluate a randomized, controlled intervention to improve compliance.

The investigators are interested primarily in the prescribing patterns of physicians in skilled nursing facilities for drugs such as Fosamax (alendronate sodium) and Actonel (risendronate sodium), which can prevent fractures.

Home Health

Improving medication use in home health patients.⁵ The Vanderbilt center has published papers that define, quantify, and suggest ways to improve

medication use in patients of home health agencies. Medications are often duplicated in home health patients, and researchers find that medication improvement programs are especially helpful for this common problem and also in increasing adherence to cardiovascular medications. Study results can apply to efforts of home health agencies to meet Medicare requirements.

Mental Health

Effect of changing managed care delivery on the continuity of care.⁶

Medicare includes drug benefits that may involve managed mental health care programs. A recently published study from the Vanderbilt center suggests that changes made to reduce costs in managed mental health care programs can adversely affect the continuity and quality of care provided to patients. These results suggest that changes in mental health care delivery should be designed with safeguards to keep patient care constant.

Looking to the Future

The CERTs continue to conduct research and develop educational projects that study and report the effects, safety, use, and cost-effectiveness of various medical therapies. The centers also continue to study current and potential approaches that Medicare and other third-party payers institute to improve quality and address cost concerns. The results of completed and future projects can be used to make coverage and other policy decisions for Medicare beneficiaries and to help provide the highest quality, most cost-effective care possible.

For More Information

The CERTs welcome input about the types of research and education that Medicare programs need to better



address costs, effectiveness, and safety issues related to the use of therapeutics. More information on the CERTs program is available from AHRQ's Center for Outcomes and Evidence:

Lynn Bosco, M.D., M.P.H.
Director, Pharmaceutical Studies

Phone: 301-427-1490

Fax: 301-427-1520

E-mail: lbosco@ahrq.gov

or

Judi Consalvo

Program Analyst

Phone: 301-427-1489

Fax: 301-427-1520

E-mail: jconsalvo@ahrq.gov

References

1. Butler J, Arbogast PG, BeLue R, et al. Outpatient adherence to beta-blocker therapy after acute myocardial infarction. *J Am Coll Cardiol* 2002;40:1589-95.
2. Cowper PA, DeLong ER, Whellan DJ, et al. Economic effects of beta-blocker therapy in patients with heart failure. *Am J Med* 2004;116:1040-111.
3. Smalley W, Stein CM, Arbogast PG, et al. Underutilization of gastroprotective measures in patients receiving nonsteroidal anti-inflammatory drugs. *Arthritis Rheum* 2002;46:2195-200.
4. Metlay JP, Shea JA, Asch DA. Antibiotic prescribing decisions of generalists and infectious disease specialists: thresholds for adopting new drug therapies. *Med Decis Making* 2002;22:498-505.
5. Meredith S, Feldman P, Frey D, et al. Improving medication use in newly admitted home healthcare patients: a randomized controlled trial. *J Am Geriatr Soc* 2002;50:1484-91.
6. Ray WA, Daugherty JR, Meador KG. Effect of a mental health "carve-out" program on the continuity of antipsychotic therapy. *N Engl J Med* 2003;348:1885-94.





AHRQ Pub. No. 05-P010
March 2005