

PROGRAM BRIEF

Medicaid Uses of Research From the Centers for Education & Research on Therapeutics (CERTs)

Agency for Healthcare Research and Quality • 2101 East Jefferson Street • Rockville, MD 20852



www.ahrq.gov

AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes; quality; and cost, use, and access. The information helps health care decisionmakers—patients and clinicians, health system leaders, and policymakers—make more informed decisions and improve the quality of health care services.



U.S. Department of Health
and Human Services
Public Health Service

Background

The goal 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). Administered by the Agency for Healthcare Research and Quality (AHRQ), in cooperation with the Food and Drug Administration (FDA), the CERTs program seeks to increase awareness of the benefits and risks of new, existing, or combined uses of therapeutics and thereby improve the effectiveness and safety of their use.

Seven centers, a Coordinating Center, a Steering Committee, and numerous partnerships with public and private organizations make up the CERTs program. Collectively, the CERTs program centers (see box) are a national resource of experienced researchers and more than 20 unique data sources. CERTs data, which represent over 50 million people, can be used for large population-based studies. Thus, Medicaid officials can look to the CERTs program to provide evidence when evaluating policy options and a sentinel surveillance system when assessing the effects of policy decisions.

The Coordinating Center can serve as a central point of contact for persons interested in CERTs evaluation of therapeutics-related policy questions. Recently, the Centers for Medicare & Medicaid Services (CMS) increased reimbursement for the use of drug-coated stents before they were approved by FDA. This unprecedented decision highlights the increasingly difficult choices facing policymakers in determining which policies to adopt relative to new therapies and their associated costs.

CERTs and Medicaid

Since the CERTs program began in September 1999, the centers have developed a portfolio of more than 120 completed and ongoing studies, the results of which address important issues to advance the best use of therapies. Several of these projects have been conducted within Medicaid populations, and even more have generated results that can apply to these patients.

The Vanderbilt center has a long history of providing technical assistance to the Tennessee Medicaid program, under a contract between the two parties that has been active since 1972. At present, this is a no-cost contract, with the State providing data to

CERTs Program Centers

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

- Duke University – therapies for disorders of the heart and blood vessels
- HMO Research Network – usefulness of HMOs in studying drug use, safety, and effectiveness
- University of Alabama at Birmingham (UAB) – therapies for disorders of the joints and bones
- University of Arizona – drug interactions, particularly in women
- University of North Carolina at Chapel Hill (UNC) – therapies for children and adolescents
- University of Pennsylvania (Penn) – therapies for infection
- Vanderbilt University – prescription drug use in a Medicaid population

Vanderbilt and Vanderbilt providing the State two types of services: data archiving/access and policy evaluation. Specific examples are provided below for the periods both before and after Vanderbilt became part of the CERTs program, which serve as models for the kinds of services the CERTs program may provide to Medicaid in the future.

In addition, Vanderbilt and other centers are conducting studies that will provide information that Medicaid programs can use to make coverage and other policy decisions related to: prescription drugs, long-term care, and health care for low-income children.

Prescription Drugs

Drug effects and use. All Vanderbilt studies on drug effects/drug use are provided to Tennessee's Medicaid Formulary and Quality Control units. The State can then use these data for interventions as appropriate. For example, a study showing substantial inappropriate use of cisapride in the Tennessee Medicaid population was to serve as the basis for an intervention, but the drug was taken off the market before the intervention was implemented.

Prior authorization for nonsteroidal anti-inflammatory drugs (NSAIDs).

The Vanderbilt center conducted a study of a State prior-authorization program for expensive NSAIDs. Over \$12 million was saved over 2 years, with no evidence of unexpected harmful effects. This study was published in the *New England Journal of Medicine*.¹

Drug utilization review. The University of Pennsylvania center recently completed a study of the effectiveness of retrospective drug utilization review (RDUR), which is required in all Medicaid programs at substantial cost. The study found no effects of the RDUR program either on prescribing for Medicaid patients or on their clinical outcomes. An abstract of this work has been presented, and a manuscript is in development.

Economic effects of beta-blocker therapy in heart failure.

The Duke University center has evaluated the economic effects of using beta-blockers to treat heart failure from various perspectives (societal, physician, hospital, and Medicare). From the societal and Medicare perspectives, the use of beta-blockers in Medicare patients would reduce costs, mostly via fewer hospitalizations. Further, even if Medicare completely reimbursed for the drug costs, the program still would spend less than if the drugs were not used; the researchers suggest that a similar cost reduction might be expected from a Medicaid perspective as well. The Duke center is planning to expand these analyses, to assess economic effects of other cardiovascular therapies.

Drug interactions. Drug interactions are a special problem in the Medicaid population because of the large numbers of drugs being used simultaneously. The Arizona center is developing 1) better methods to detect the coprescription of interacting drugs and 2) tools to detect and prevent adverse reactions caused by drug interactions. One of these tools, an

¹ Smalley WE, Griffin MR, Fought RL, et al. Effect of a prior-authorization requirement on the use of nonsteroidal anti-inflammatory drugs by Medicaid patients. *N Engl J Med*. 1995 Jun 15;332(24): 1612-1617.

online educational module entitled “Preventable Adverse Drug Reactions: A Focus on Drug Interactions,” was developed in collaboration with FDA and is available at: www.fda.gov/cder/drug/drugReactions/default.htm.

Long-Term Care

OBRA antipsychotic requirements for nursing homes.

As a result of provisions in the 1987 Omnibus Budget Reconciliation Act (OBRA), CMS (then the Health Care Financing Administration) required that nursing homes take active steps to reduce the use of antipsychotics (“chemical restraints”). Medicaid funds about 70 percent of long-term nursing home care. A Vanderbilt evaluation of this policy showed approximately a 25-percent reduction in antipsychotic use with no evidence of dangerous substitutions. This not only confirmed that the policy effectively reduced drug use but also that it caused no harmful collateral effects. The findings were useful for CMS policymakers throughout the United States. This study was published in the *Journal of the American Medical Association*.²

Prevention of falls in nursing homes.

Vanderbilt has conducted a series of fall-prevention studies among nursing home residents, most of whom are insured by Medicaid. These studies showed that careful prescribing can substantially reduce falls and associated injuries. These materials have been provided to the State Medicaid program and to quality improvement organizations in Tennessee and other States.

Reimbursement for community providers of long-term care.

A coalition of providers of long-term care asked the Tennessee legislature to enact full Medicaid reimbursement for all long-term care services provided in the community. Their request was based on the premise that community-based services were substantially more economical than those provided in nursing homes and that this change would not only meet public demand for such services but also reduce Medicaid costs substantially. Vanderbilt’s analysis of this issue concluded that the change should not be implemented based on anticipated cost savings.

Evaluation of a nursing home dispensing change.

Tennessee regulations limit nursing homes to dispensing only a 7-day, unit-dose packaged supply of pharmaceuticals. This rule was enacted to ensure that drugs are not wasted, given the high turnover rates for residents. Most residents stay longer than 7 days, however, and pharmacy providers find this regulation onerous. Thus, many States now permit dispensing of a 30-day supply of drugs, and a large nursing home pharmacy vendor has requested that this policy also be adopted by TennCare—Tennessee’s managed care health insurance program for poor, disabled, or uninsured residents. The TennCare program, concerned about the potential for waste (largely theft), has requested that CERTs aid in an evaluation of this issue. Vanderbilt has begun a study comparing wasted doses with 7- versus 30-day supplies of drugs.

Fractures from osteoporosis. Elderly patients who require nursing home care after a fracture due to osteoporosis are at particularly high risk of further fractures. Collaborating with quality improvement organizations and other academic partners, the University of Alabama at Birmingham center is developing multifaceted interventions that aim to prevent second fractures among nursing home patients who have had a fracture. The investigators are interested primarily in changing the behavior of the nursing home physicians, seeking to increase their prescription of bone-strengthening drugs. If the trial is successful, these interventions could be adapted to other health care organizations to improve the treatment of patients with osteoporosis and associated fractures.

Health Care for Low-Income Children

Efficacy and toxicity of drugs used in pediatric AIDS.

Many patients with AIDS take drugs called protease inhibitors, which block production of an enzyme needed for the AIDS virus to replicate. The University of North Carolina (UNC) center is developing tests that can measure the level of protease in the blood; this measure then can be used to determine whether patients are receiving adequate dosages of the drugs. Inadequate protease inhibition, even briefly, is associated with rapid development of tolerance and poor therapeutic response. Exposure to excessive protease levels is associated with increased toxicity. Reliable and rapid measurement of protease levels should lead to more effective, less toxic, and individualized

² Ray WA, Taylor JA, Meador KG, et al. A randomized trial of a consultation service to reduce falls in nursing homes. *JAMA*. 1997 Aug 20;278(7):557-562.

dosage regimens which, in turn, should confer better outcomes and some cost savings.

North Carolina Asthma Improvement Project.

The UNC center, collaborating with others, developed an educational program that provides clinicians with practical tools and effective strategies for improving the care of children with asthma in the State. About 600 physicians participated in 3-hour educational workshops; after the workshops, they reported significant improvements in their care of children with asthma. Because of the positive response to the asthma sessions, the North Carolina Division of Medical Assistance expressed support for intensive improvement efforts involving several practices in the Access I Medicaid network (which currently has no specific disease-management program).

Prevalence of type 2 diabetes mellitus in children.

The UNC investigators studied the prevalence of type 2 diabetes in children, with two main goals: 1) to determine the prevalence and predictors of glucose intolerance and type 2 diabetes in adolescents and young adults, and 2) to examine changes in these predictors over time, using data collected from these patients during childhood. Although the researchers found fewer cases of diabetes than expected, they found surprisingly high levels of heart disease and high cholesterol levels, even among the adolescents.

Improving prescribing and treatment for otitis media.

In this project, involving North Carolina Medicaid patients with ear infections, the UNC

center determined the effect of the drug chosen on the costs of treatment and the effectiveness of a targeted letter on physician prescribing practices and per-patient costs of treatment. First, patients receiving first-line antibiotics had fewer return visits than did patients receiving second-line antibiotics. Given the better outcomes (and the corresponding lower costs), the research indicates that physicians should be encouraged to prescribe first-line antibiotics as the initial treatment for patients with acute otitis media.

Prevalence of vitamin D deficiency rickets in minority infants.

Researchers at the UNC center published a study showing a link between rickets in breast-fed children and a lack of vitamin D supplementation, especially among black infants.³ Because of this study, the North Carolina Department of Health and Human Services made vitamin D available free to breast-feeding women through its Women, Infants, and Children (WIC) program.

Looking to the Future

The CERTs program centers will continue to conduct research and educational projects, such as those described above, that study and report the effects, safety, use, and cost effectiveness of various therapies. The results of completed and future CERTs projects can be used by States to make coverage and other policy decisions for Medicaid beneficiaries to provide the highest quality, most cost-effective care possible.

The centers also will continue to study current and potential approaches that

³ Kreiter SR, Schwartz RP, Kirkman HN Jr, et al. Nutritional rickets in African American breast-fed infants. *J Pediatr* 2000 Aug; 137(2):153-157.

Recent CERTs findings as well as information on other program activities and recent developments can be found on the CERTs

Web site: www.certs.hhs.gov

Medicaid, Medicare, and other third-party payers institute to improve quality and address cost concerns. For example:

- The Vanderbilt center has been asked to provide assistance with the conduct and evaluation of a new TennCare strategy of partnering with pharmaceutical companies to implement disease-management programs.
- The HMO Research Network soon will manage Medicaid data for several health care providers in New Mexico, which could lead to opportunities for research similar to that done by Vanderbilt; e.g., the data could be used to compare costs, especially prescription drug costs, between staff models and network physicians serving Medicaid patients.
- Through its otitis media project, the UNC center has established a State agency-to-agency relationship with North Carolina Medicaid and is negotiating for a contract relationship that will provide full access to all Medicaid data. This, in turn, may allow the CERTs program to become more involved in various aspects of the North Carolina Medicaid program, including evaluation of individual therapies or classes of therapies and policy research on benefit structure and related matters.

For More Information

More information on the CERTs program is available from:

Lynn Bosco, M.D., M.P.H.
Director, Pharmaceutical Studies
Center for Outcomes and
Effectiveness Research, AHRQ
Phone: 301-594-2416
Fax: 301-594-3211
E-mail: lbosco@ahrq.gov

Judi Consalvo
Program Analyst
Center for Outcomes and
Effectiveness Research, AHRQ
Phone: 301-594-0602
Fax: 301-594-3211
E-mail: jconsalv@ahrq.gov

In addition, the CERTs program welcomes input about the types of research and education that Medicaid programs need to better address costs, effectiveness, and safety issues related to the use of therapeutics. Comments may be sent to CERTs program staff at AHRQ (see above), or to:

Leanne Madre, J.D., M.H.A.
Program Manager
CERTs Coordinating Center
Phone: 919-668-8354
E-mail: madre005@mc.duke.edu

AHRQ, in consultation with FDA, administers the CERTs program.

More information about AHRQ projects and programs in addition to CERTs is available on AHRQ's Web site: www.ahrq.gov



AHRQ Pub. No. 03-P010
January 2003