



Annual Report 2011-2012

Centers for Education and Research on Therapeutics (CERTs)

Annual Report

October 1, 2011– August 31, 2012

Introduction

In October 2011, six research centers and a scientific coordinating center were funded through cooperative agreements with the Agency for Healthcare Research and Quality (AHRQ), extending the Centers for Education and Research on Therapeutics (CERTs) Program for 5 years. This report summarizes the work of the CERTs Program from October 2011 through August 2012. In addition to describing accomplishments for 2011-2012, this report provides background information about the purpose and components of the ongoing CERTs Program.

CERTs Program Purpose

The CERTs Program is a national initiative established in 1999 to conduct research and provide education that advances the optimal use of drugs, medical devices, and biological products, collectively described as “therapeutics.” The CERTs Program has three major aims, as established by Congress:

1. **To increase awareness** of the uses and risks of new drugs and drug combinations, biological products, and devices, as well as of mechanisms to improve their safe and effective use.
2. **To provide objective clinical information** to patients and consumers; health care providers; pharmacists, pharmacy benefit managers, and purchasers; health maintenance organizations (HMOs) and health care delivery systems; insurers; and government agencies.
3. **To improve quality while reducing the cost of care** by increasing the appropriate use of drugs, biological products, and devices and by preventing their adverse effects and consequences of these effects (such as unnecessary hospitalizations).

The CERTs are also authorized to conduct research on the comparative effectiveness, cost-effectiveness, and safety of therapeutics.

CERTs Program Components

In addition to the AHRQ-funded research centers and a scientific coordinating center (the **Scientific Forum**), the CERTs network includes a steering committee and numerous partnerships with public and private organizations dedicated to improving the quality and safety of therapeutics. The **Steering Committee** offers guidance to [the Scientific Forum \(described below\)](#) and research centers, and includes representatives from the drug and device centers of the U.S. Food and Drug Administration (FDA), each research center's principal investigator, an at-large representative of Federal health agencies, and leaders in health care, private industry, and consumer and patient advocacy. The diversity of committee member perspectives ensures that the CERTs remain well informed and on the cutting edge of significant and emerging health care issues.

CERTs Steering Committee, 2011-2012

Chair	Chair-elect
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Craig Brater, M.D.
Chair, CERTs Steering Committee, Indiana University School of Medicine

David Ballard, M.D.
Chair-elect, CERTs Steering Committee, Baylor Health Care System

CERTs Principal Investigators

David Bates, M.D., M.Sc.
Principal Investigator, Brigham and Women's Hospital CERT

Carole Lannon, M.D., M.P.H.
Principal Investigator, Cincinnati Children's Hospital Medical Center CERT

Stephen Crystal, Ph.D.
Principal Investigator, Rutgers, The State University of New Jersey CERT

Eric Peterson, M.D., M.P.H.
Principal Investigator, Duke University Medical Center CERT

Mark C. Hornbrook, Ph.D.
Principal Investigator, CERTs Scientific Forum Kaiser Permanente Center for Health Research

Kenneth G. Saag, M.D., M.Sc.
Principal Investigator, University of Alabama at Birmingham CERT

Bruce Lambert, Ph.D.
Principal Investigator, University of Illinois at Chicago CERT

AHRQ, FDA, and At-Large Government Members
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Anne Trontell, M.D., M.P.H.
Program Director, Centers for Education and Research on Therapeutics, Agency for Healthcare Research and Quality

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Gwen Zornberg, M.D., Sc.D.
Team Leader, Regulatory Science, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration

Scott Smith, Ph.D.
Director, Pharmaceutical Outcomes Research, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality

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Senior Vice President and Chief Medical Officer, Medco Health Solutions, Inc.

Gilbert J. L'Italien, Sc.D.
Executive Director, Global Health Outcomes & Epidemiology, Bristol-Myers Squibb

Arthur Levin, M.P.H.
Director, Center for Medical Consumers

Newell McElwee, PharmD, M.S.P.H.
Executive Director of U.S. Outcomes Research, Merck & Co., Inc.

The CERTs Scientific Forum is the scientific coordinating center for the CERTs Program and in 2011-2012 was led by Principal Investigator Mark Hornbrook, Ph.D., of the Kaiser Permanente Center for Health Research in Portland, Oregon. The Scientific Forum catalyzes and supports collaborative research and translational activities in therapeutics, supports the CERTs Steering Committee, and serves as the program's communications and translation hub. The Scientific Forum also cultivates **partnerships** with public and private entities to help the research centers leverage their funded research into additional projects and to extend their impact. All public-private partnerships are reviewed for potential conflicts of interest using established CERTs principles and practices.

Each **CERTs research center** organizes its research and educational activities within a defined thematic area of therapeutics, which may represent a vulnerable population, a group of related medical conditions, or a specific methodological approach, such as health information technology. The six research centers are listed in Table 1, with their thematic focus and Principal Investigator.

Table 1. CERTs Program, Research Centers 2011-2012

CERTs	Thematic Focus	Principal Investigator
Brigham and Women's Hospital (BWH)	Health Information Technology	David Bates, M.D., M.Sc.
Cincinnati Children's Hospital Medical Center (CCHMC)	Pediatrics	Carole Lannon, M.D., M.P.H.
Duke University Medical Center (Duke)	Cardiovascular Diseases	Eric Peterson, M.D., M.P.H.
Rutgers, The State University of New Jersey (Rutgers)	Mental Health	Stephen Crystal, Ph.D.
University of Alabama at Birmingham (UAB)	Musculoskeletal Disorders	Kenneth Saag, M.D., M.Sc.
University of Illinois at Chicago (UIC)	Tools for Optimizing Medication Safety	Bruce Lambert, Ph.D.

Highlights

In 2011-2012, the six research centers across the United States worked to improve the use, safety, and effectiveness of therapeutics. The CERTs Program developed and applied health information technology tools, conducted studies to understand disparities in treatment, and advanced research methods.

Protecting Patient Safety using Technology. Computerized Provider Order Entry (CPOE) systems are increasingly used in hospitals and outpatient care and may include alerts to warn health care providers of potential mistakes when they are ordering a medication or procedure. Although alerts are intended to keep patients safe, they may become counterproductive if they are poorly designed. Previous research has shown that human factors principles are important in effective alert design. In 2012, BWH CERT researchers created a measurement tool to assess the use of these principles in drug-drug interaction alerts and to inform the design of future alerts.

In related work on indication-based prescribing practices, researchers at the UIC CERT found that computer alerts that ask prescribers if they want to add a diagnosis to a patient's record when a medication is ordered without a corresponding indication can prevent doctors from ordering medications for the wrong patient. The UIC CERT created a product that will allow any hospital with CPOE to implement indication alerts, and are sharing it widely ([See UIC CERT, Indication Alerts Prevent Wrong Patient Errors, below](#)).

To prevent adverse drug events, researchers at the CCHMC CERT developed and deployed an automated trigger tool within the electronic medical record to identify children at risk for developing medication-associated acute kidney injury. The tool triggers consultation to care teams on how to optimize medication dosing and monitoring to prevent acute kidney injury.

Understanding and Addressing Disparities in Treatment. The Duke CERT explored factors associated with uncontrolled high blood pressure among patients from a wide range of backgrounds, and found that control rates varied six-fold depending on the treating clinician. This variability presents an opportunity for quality improvement.

Rutgers CERT researchers found that among people with a schizophrenia disorder, living in a county with high rates of clozapine use, rather than treatment resistance or any other clinical factor, had the largest effect on whether patients were started on clozapine. The findings suggested that regional variations in patient use of clozapine should be addressed.

Advancing Research Methods. UAB CERT researchers worked to improve procedures for enrolling participants in research studies. They interviewed physicians and their staff at two Practice-Based Research Networks to assess whether a computer tablet-based tool might streamline screening and informed consent procedures for a pragmatic clinical trial. They found that most physicians and staff were optimistic about the tablet technology for reducing administrative burden, and began testing a beta version of the tool.

CERTs Collaborations

In 2011-2012, the CERTs collaborated with one another and with a diverse range of public and private entities to advance research, advise Federal and State policymakers, and provide evidence-based, objective information to educate patients, doctors, pharmacists, and others about therapeutics.

Collaborating to Improve Medication Management. In 2012, all of the CERTs embarked on a collaborative effort to improve interventions that support medication adherence. The topic was selected by the CERTs National Steering Committee in December 2011. The goal of this collaborative effort was to set a research agenda on interventions to improve “patient-centered medication management.” The decision to take a patient-centered approach was bolstered by an AHRQ evidence report¹ suggesting that the most effective adherence interventions were multi-modal, high intensity, and personalized.

The collaborative effort was directed by the Collaborative Project Steering Group (CPSG), a working group with members representing each of the research centers, the Scientific Forum, and patients. Two patient representatives were selected to contribute their patient or caregiver perspective. The Scientific Forum developed meeting agendas and materials, led webinar presentations and discussions, and carried out decisions made by the CPSG.

The CPSG developed a framework to guide a literature review and to aid planning for a stakeholder workshop to explore and develop a research agenda. The literature review identified and summarized available evidence regarding the use of interventions to improve patient-centered medication management, such as decision aids, enhanced medication review and follow-up, patient education, enhanced provider feedback, motivational interviewing, and shared decision making. Preliminary results of the literature search were used to develop background materials and the agenda for the stakeholder workshop, and a narrative review manuscript is in preparation.

The CPSG, with guidance from the CERTs Steering Committee, identified and invited workshop stakeholders representing diverse perspectives in health care, including patient advocates, providers, payers, research funders, manufacturers, and policymakers. The workshop to create an agenda for future research and action on patient-centered medication management was planned for October 2012. A full report on the workshop’s process and findings will be included in the CERTs Annual Report for 2012-2013.

Collaborating to Improve Patient Safety. As part of its CERTs grant, the UIC CERT, which focuses on patient safety, established an ongoing partnership with the National Patient Safety Foundation (NPSF), a Boston-based nonprofit advocacy organization, to disseminate the results of its research through outlets such as newsletters and webinars. A story on the NPSF website led to an important collaboration between the UIC CERT and The PSO Advisory, a patient safety organization in Providence, Rhode Island, that is providing a real-world perspective to the UIC CERT as it studies drug-name confusion.

The UIC CERT extended its partnership with the NPSF to include other CERTs as well. UIC and CCHMC presented together at the NPSF’s 14th Annual Patient Safety Congress, held in May 2012 in Washington, D.C. UIC researchers reported on their core medication safety projects, and CCHMC researchers discussed improvements in patient outcomes that resulted from a quality improvement intervention. The UIC CERT also worked with the Scientific Forum to produce an article for the NPSF’s *Focus on Patient Safety* newsletter, co-authored by principal

investigators from four current and former CERTs, that highlighted health IT and patient safety research across the CERTs Program.

Hornbrook MC, Pope J, Vandermeer M, Rumpitz M, Bates D, Strom B, Woosley R, Lambert B. Spotlight on CERTs research: health IT and patient safety. Focus on Patient Safety 2012; 15(1)1-2, 5-6. Select to access the [abstract](#).

¹ Viswanathan M, Golin CE, Jones CD, et al. Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review. Ann Intern Med 2012 Dec 4;157(11):785-95. Select to access the [abstract](#).

Collaborating to Improve Informed Consent. The UAB CERT worked with the Center for Medical Technology and Policy and the Johns Hopkins Berman Institute of Bioethics, both in Baltimore, Maryland, to engage community physicians affiliated with two Practice-Based Research Networks to improve informed consent processes for patients to participate in research studies. Researchers worked with community practitioners, and their clinical and administrative staff, to identify factors that hinder or facilitate the provision of informed consent for pragmatic or “real world” clinical trials ([see Program Activities, UAB CERT, for more detail](#)).

Collaborating to Guide Policy. The Medicaid Mental Health Network for evidence-based treatment, called MEDNET, was a collaboration run by investigators of the Rutgers CERT that built on prior CERTs-funded projects (MEDNET itself was supported by Recovery Act funding through the AHRQ Center for Delivery, Organizations, and Markets or CDOM.) In MEDNET, Rutgers investigators worked with Medicaid and mental health agencies in Washington, Texas, Missouri, California, Oklahoma, and Maine to encourage safe, effective, and evidence-based use of antipsychotic medications. MEDNET facilitated translation of effective practices across states by creating a multi-stakeholder quality collaborative within each participating State to encourage uptake of evidence-based strategies. Key accomplishments were the joint development of a core set of quality measures and outreach through means such as peer-to-peer communications. The resulting State-based initiatives targeted specific Medicaid populations ranging from children—including foster care youth—to the elderly.

The Rutgers CERT also lent its expertise to Federal and State policymakers seeking guidance on mental health policies, particularly on antipsychotic use in children and other vulnerable populations. The Rutgers CERT’s expertise led the Department of Health and Human Services (DHHS) Administration for Children, Youth and Families and the Children’s Bureau to ask this CERT’s researchers to serve as expert advisors on Federal initiatives to improve psychotropic medication practices for children in foster care. Rutgers CERT researchers briefed Federal policymakers on their findings in this area, served on an expert panel, presented a national webinar for more than 400 State leaders, and helped create an Information Memorandum that requires States to develop plans to monitor medication for youth in foster care.

Collaborating to Prevent Hypertension. In 2012, Duke CERT researchers began a joint effort with researchers at the University of North Carolina to prevent high blood pressure and to improve its management across clinics at both institutions. Researchers shared de-identified datasets, and will analyze the data to look for differences in how high blood pressure is

managed at the two institutions. The researchers plan to implement an intervention to improve management of high blood pressure at both institutions.

Collaborating to Guide Quality Improvement. The CCHMC CERT teamed up with the American Board of Pediatrics and the Children's Hospital Association to host two invitational meetings in November 2011, *Building Competencies for Leadership in Pediatric Quality and Safety* and *National Meeting on Collaborative Improvement Networks*. To disseminate the findings, nine manuscripts were produced and published as a supplement in June 2013 in *Pediatrics—Pediatric Collaborative Improvement Networks: Bridging Quality Gaps to Improve Health Outcomes*.

Lannon CM, Miles PV. Pediatric Collaborative Improvement Networks: Bridging Quality Gaps to Improve Health Outcomes. *Pediatrics* 2013; 131:Supplement 4 S187-S188. Select to access the [abstract](#).

Collaborating to Evaluate Decision Support Alerts. In concert with researchers at nine other sites, BWH CERT researchers are evaluating the use of human factors principles in the design of drug-drug interaction alerts. BWH CERT researchers created the Instrument for Evaluating Human-Factors Principles in Medication-Related Decision Support Alerts to assess the use of these principles in the design and display of alerts. They hope the instrument will improve usability and acceptance of alerts to meet clinicians' needs ([See Program Activities, BWH CERT, for more detail](#)). The other participating institutions are:

- Erasmus University Medical Center, Rotterdam, The Netherlands
- University Hospitals Birmingham NHS Foundation Trust, Birmingham, England
- ASAN Medical Center, Seoul, Korea
- Regenstrief Institute, Indianapolis, Indiana
- Faulkner Hospital, Boston, Massachusetts
- Newton-Wellesley Hospital, Newton, Massachusetts
- University of Pennsylvania, Philadelphia, Pennsylvania
- Veterans Affairs Hospitals
- Partners Healthcare, Boston, Massachusetts

In addition, BWH researchers began work on a Medication Safety Task Order for the FDA on computerized provider order entry. Researchers used tools from different CERT projects, including those that measure human factors related to screen design, workflow, and measurement of accepted and overridden alerts. The UIC CERT team is one of five sites involved in this project, along with Kaiser Permanente Northwest, Montefiore Medical Center (Bronx, NY), University of Pennsylvania, and Harvard Vanguard.

Program Activities 2011–2012

The six research centers covered a broad range of pressing issues in health care, from evaluating health information technology to investigating disparities in treatment for vulnerable

patient populations—including children with chronic illnesses, people with serious mental illness, and the elderly—to evaluating promising research tools.

The following sections present a selection of the research and educational projects completed between October 2011 and August 2012, the first year of the current CERTs 5-year funding period. In addition, the report highlights the accomplishments and ongoing projects of the six research centers which bridge the past and current CERTs funding periods. The content is organized by center and each project description is followed by a published paper citation, or, in some cases, a link to another type of product. In addition, we provide a full list of CERTs publications for the year at the end of this report.

Brigham and Women's Hospital CERT

The Brigham and Women's Hospital (BWH) CERT focused on Health Information Technology. As the United States makes substantial investments in technologies such as electronic medical records, systems that enable doctors to enter their orders into computers (Computerized Provider Order Entry or CPOE), and systems designed to help physicians and other health professionals make better-informed decisions (Clinical Decision Support or CDS), there is a pressing need to evaluate how well these systems are working for patients. Researchers at the BWH CERT worked to ensure that health IT interventions improve safety and avoid the inadvertent introduction of other errors for patients, whether they are outpatients, inpatients, or transitioning out of the hospital.

Preventing Adverse Drug Events Using Publicly Available Tools

In 2011, researchers at the BWH CERT studied whether adverse drug events (ADEs) arising from multiple drugs being used for inpatients might be preventable if hospitals used publicly available CDS tools. Community hospitals use such tools if they cannot afford to buy a commercially available CDS system. The study found that a substantial number of actual ADEs—defined as an injury or adverse patient response resulting from the administration of a medication—as well as potential ADEs—medication errors that did not result in patient harm, either because they were intercepted or because no adverse event was observed—in the community hospital setting may be preventable through the use of publicly available CDS knowledge bases. The majority of actual ADEs were due to drug-drug interactions, most commonly involving opioids, benzodiazepines, or cardiac medications; about 75 percent of the potential ADEs involved excessive doses resulting from order duplication or combining drugs with overlapping ingredients.

Wright A, Feblowitz J, Phansalkar S, et al. Preventability of adverse drug events involving multiple drugs using publicly available clinical decision support tools. *Am J Health Syst Pharm* 2012 Feb 1;69(3):221-7. Select to access the [abstract](#).

Examining Human Factors Principles in Decision Support Alerts

As hospitals implement electronic systems to support patient care, health care stakeholders need to assess how well the systems are working. CPOE systems may use automated alerts to

tell physicians when they may be making a medication error. Although alerts can relay key information to help keep patients safe, they risk becoming too numerous or disruptive to workflow, causing “alert fatigue” and their being overridden or ignored. The way alerts are designed is thus very important.

Previous research* by BWH researchers and others has identified human factors principles as important in alert design, ranging from the philosophy behind the alert—the logic that underlies the determination of an event as unsafe—to the placement of the alert on the user’s screen, but researchers have lacked the tools to measure such principles. In 2012, BWH CERT researchers created the Instrument for Evaluating Human-Factors Principles in Medication-Related Decision Support Alerts to assess the use of these principles in drug-drug interaction alerts. Researchers considered user feedback on nine institutions’ different electronic medical record systems as they developed the instrument ([See CERT Collaborations, Collaborating to Evaluate Decision Support Alerts, above](#)). They also gathered preliminary evidence to validate the instrument. The final version of the instrument, which included 26 items associated with nine human-factors principles, will be used to inform the design of future alerts.

Zachariah M, Phansalkar S, Seidling HM, et al. Development and preliminary evidence for the validity of an instrument assessing implementation of human-factors principles in medication-related decision-support systems—I-MeDeSA. *J Am Med Inform Assoc* 2011 Dec;18 Suppl 1:i62-7. Select to access the [abstract](#).

*Phansalkar S, Edworthy J, Hellier E, et al. A review of human factors principles for the design and implementation of medication safety alerts in clinical information systems. *J Am Med Inform Assoc* 2010;17:493–501. Select to access the [abstract](#). (*This research was not funded by the CERTs Program.*)

Using e-Pharmacovigilance to Monitor Side Effects

Researchers at the BWH CERT have developed an intervention that uses automated phone calls and interactive voice response (IVR) technology to monitor side effects of newly prescribed medications. They are testing the intervention in a randomized, controlled trial (RCT) among patients who receive new medications for diabetes, hypertension, depression, or insomnia. Researchers will assess how well the IVR system reaches people and how well it monitors side effects. Patients will get an automated call about 4 weeks after they get a new prescription and a follow-up call about 6 months later. The RCT is recruiting patients from 14 primary care clinics within Brigham and Women’s Hospital.

Cincinnati Children’s Hospital Medical Center CERT

The Cincinnati Children’s Hospital Medical Center (CCHMC) CERT focused on the safe and effective use of medications in children. Under that broad umbrella, two specific themes were patient safety and improving outcomes through multi-site clinical specialty networks. Since 2007, the CERT has supported a collaborative project to improve care for children with inflammatory bowel disease. This network of collaborating clinical practices, called ImproveCareNow, is helping children feel better and move into remission. Building on the

lessons learned from this work, the CCHMC CERT also supported research and quality improvement networks for infants with complex congenital heart disease and for children with juvenile idiopathic arthritis. Many of the networks have already shown improvements in care delivery and outcomes for children.

ImproveCareNow Network

In 2011, the ImproveCareNow Network, which aims to improve care and outcomes for children with inflammatory bowel disease (IBD), had evolved into a 29-site, international practice-based research network. Since the network began, the percentage of children with Crohn's disease and ulcerative colitis who are in remission has increased from 50 to 75 percent. These improvements were achieved by increasing adherence to protocols for using existing therapies.

Crandall WV, Margolis PA, Kappelman M.D., et al. Improved outcomes in a quality improvement collaborative for pediatric inflammatory bowel disease. *Pediatrics* 2012 Apr;129(4):e1030-41. Select to access the [abstract](#).

Solutions for Patient Safety

Building on a previous CCHMC CERT project, all eight Ohio children's hospitals have collaborated to improve outcomes in medication safety and surgical site infections. Between January 2009 and December 2010, the Solutions for Patient Safety project resulted in a 60 percent reduction in surgical site infections in designated procedures and a 34.5 percent reduction in adverse drug events, saving an estimated 3,576 children from harm and more than \$5.2 million in health care costs.

Vermaire D, Caruso MC, Lesko A, et al. Quality improvement project to reduce perioperative opioid oversedation events in a paediatric hospital. *BMJ Qual Saf* 2011 Oct;20(10):895-902. Select to access the [abstract](#).

Ohio Perinatal Quality Collaborative

This collaborative is a statewide consortium of clinicians, hospitals, and policymakers that aims to improve outcomes for preterm newborns. Initial projects resulted in a 20 percent reduction in bloodstream infections among premature infants, 12,000 fewer births at 36-38 weeks, and 150-250 fewer near-term infants admitted to the neonatal ICU per year.

Kaplan HC, Lannon C, Walsh MC, Donovan EF; Ohio Perinatal Quality Collaborative. Ohio statewide quality-improvement collaborative to reduce late-onset sepsis in preterm infants. *Pediatrics* 2011 Mar;127(3):427-35. Epub 2011 Feb 21. Select to access the [abstract](#).

Donovan EF, Lannon C, Bailit J, Rose B, Iams JD, Byczkowski T; Ohio Perinatal Quality Collaborative Writing Committee. A statewide initiative to reduce inappropriate scheduled births at 36(0/7)-38(6/7) weeks' gestation. *Am J Obstet Gynecol* 2010 Mar;202(3):243.e1-8. Select to access the [abstract](#).

The Joint Council on Congenital Heart Disease National Pediatric Cardiology Quality Improvement Collaborative

Teams from 46 pediatric cardiology centers worked to reduce mortality and readmissions, optimize growth, and improve care transitions for infants with congenital heart disease (CHD). This network has developed two tools: 1) a nutrition algorithm for infants with complex CHD associated with improved growth, and 2) a checklist to improve care transitions.

Anderson JB, Iyer, SB, Beekman RH III, et al. National Pediatric Cardiology Quality Improvement Collaborative: Lessons from development and early years. *Prog Pediatr Cardiol* 32 (2011):103–109. Select to access the [abstract](#).

Anderson JB, Iyer SB, Schidlow DN, et al. Variation in growth of infants with a single ventricle; National Pediatric Cardiology Quality Improvement Collaborative. *J Pediatr* 2012 Feb 14. Epub ahead of print. Select to access the [abstract](#).

Pediatric Rheumatology—Care and Outcomes Improvement Network

In 2011, this network focused on improving outcomes of children with juvenile idiopathic arthritis. Eleven teams began to focus on interventions for tuberculosis screening, uveitis (an inflammatory eye condition), and counting of involved joints, as well as monthly data collection for a registry.

Predicting and Preventing Acute Kidney Injury in Hospitalized Children

CCHMC CERT researchers developed a trigger tool, deployed within the electronic medical record (EMR), designed to identify hospitalized non-critically ill children who were at risk for developing medication-associated acute kidney injury (AKI), and provided consultation to the patient's care team on how to optimize medication dosing and monitor kidney function. The intervention improved safety by avoiding harm from nephrotoxic medication-associated AKI. This project shifts the current paradigm of trigger tool methodology from documenting adverse drug events that have occurred to predicting and preventing harm. Work continues to automate and harmonize trigger and AKI reports within the EMR, and researchers have developed a toolkit to guide implementation at other sites.

Goldstein SL, Kirkendall E, Nguyen H, et al. Electronic health record identification of nephrotoxin exposure and associated acute kidney injury. *Pediatrics*. 2013 Sep;132(3):e756-67. doi: 10.1542/peds.2013-0794. Epub 2013 Aug 12. Select to access the [abstract](#).

Optimizing Medications and Shared Decision Making in Juvenile Idiopathic Arthritis (JIA)

Until recently, there were no decision aids to support families facing treatment decisions about JIA. This project, which takes place within the Pediatric Rheumatology Care and Outcomes Improvement Network (PR-COIN), is addressing that need. It seeks to optimize the use of medications for juvenile idiopathic arthritis using a shared decision-making strategy.

After consulting with stakeholders, including patients, parents, and clinicians, and conducting interviews and clinic observations, researchers created a set of cards to promote shared decision making among parents, patients, and providers regarding treatment. Providers at the PR-COIN sites tested the cards in practice, and researchers gathered feedback on their use to refine the tool.

After creating a decision aid in both pamphlet and digital form, researchers widely distributed it to all PR-COIN sites for implementation in routine clinical care. Next steps include preparing PR-COIN collaborative-wide patient decision support aids to support implementation in routine clinical care across the network. Researchers are also developing a survey instrument so they can measure how the decision aid is affecting decision quality. Researchers will collect data from PR-COIN sites to measure how use of the shared decision aid is impacting parent and patient knowledge and preferences. They are also developing metrics and collecting data to assess care delivery changes associated with the shared decision aid.

Duke University Medical Center CERT

The Duke CERT focused on cardiovascular (CV) disease—the leading cause of illness and death in the United States. Duke’s CERT team identified gaps in CV care and their consequences, generated evidence on the safety and effectiveness of treatments, and translated knowledge into practice through work with providers around the country.

To improve outcomes for patients, the Duke CERT published papers on gaps and disparities in care and the comparative effectiveness of treatments, identified factors that affect whether patients take medications as prescribed, and created feedback reports for participating hospitals on their adherence to care guidelines. These efforts will generate evidence that can be used to modify and improve providers’ behavior and patient education.

Understanding Reasons for Variability of Care

Researchers must understand what contributes to a problem if they are to generate information to help solve it. In past work, Duke CERT researchers found that hospitals varied considerably in the speed of giving recombinant tissue plasminogen activator to patients who had a stroke. They explored reasons for this by interviewing hospital staff and found five factors associated with better performance: 1) communication and teamwork, 2) clear treatment protocols, 3) a supportive organizational culture, 4) performance monitoring and feedback, and 5) identifying and overcoming barriers.

Olson DW, Constable M, Britz GW, et al. A Qualitative Assessment of Practices Associated with Shorter Door-To-Needle Time for Thrombolytic Therapy in Acute Ischemic Stroke. *J Neurosci Nursing Res* 2011;43(6):329-336. Select to access the [abstract](#).

Another study sought to explore and reduce racial differences in decisions to get an Implantable Cardioverter Defibrillator (ICD). Research shows that black patients are much less likely to receive an ICD than white patients. Duke researchers found that among ICD-eligible patients, a

video decision aid increased patient knowledge and reduced racial differences in patient preference for an ICD.

Thomas KL, Zimmer LO, Dai D, et al. Educational videos to reduce racial disparities in ICD therapy via innovative designs (VIVID): A randomized clinical trial. *Am Heart J* 2013 Jul;166(1):157-163.e2. Select to access the [abstract](#).

Factors Associated with Uncontrolled High Blood Pressure

In 2012, the Duke CERT built on its past research expertise to explore factors associated with uncontrolled high blood pressure among patients in ambulatory care clinics. Despite increases over the past 10 years in awareness about high blood pressure, fewer than half of adults with high blood pressure controlled it in 2007–2008, according to the Centers for Disease Control and Prevention. Undiagnosed and uncontrolled high blood pressure increases the risk of heart attacks, strokes, and other cardiovascular illnesses.

Duke CERT researchers conducted a retrospective study involving 5,979 patients with high blood pressure who were routinely followed in a Duke cardiology clinic by 47 physicians. Most evaluations of practice-level high blood pressure control rates are limited to primary care settings and not cardiology specialists' care. Patients in this study came from a wide range of social and economic backgrounds. Overall, 30.3 percent of the patients had suboptimal control (blood pressure $\geq 140/90$) at the end of a 13-month follow-up period.

Patient factors associated with high blood pressure being under control were: younger age, being male, being white, having a primary care provider at Duke, having private insurance, having Medicare/Medicaid coverage, and having co-occurring diagnoses of heart failure or coronary artery disease. However, even after adjusting for patient factors, patients' odds of high blood pressure control varied six-fold depending on the cardiologist they saw. Researchers also found that in chart reviews (300), cardiologists failed to document a plan to address high blood pressure for 38 percent of patients. This variability, along with evidence that elevated blood pressure is often not acted on during clinic visits, presents an opportunity for quality improvement.

Navar-Boggan AM, Boggan JC, Stafford JA, et al. Hypertension control among patients followed by cardiologists. *Circ Cardiovasc Qual Outcomes* 2012 May;5(3):352-7. Select to access the [abstract](#).

Answering research questions using real-world data

Duke CERT researchers are combining a variety of data sources to evaluate long-term outcomes for patients with acute coronary syndromes (ACS) related to the blockage of one or more coronary arteries. These sources include disease-specific clinical registries, Medicare and Medicaid insurance claims, pharmacy data, and electronic medical records. In contrast to data from clinical trials, these kinds of data provide a “real world” look at the use of medications, procedures, and outcomes over time.

One example started in 2007 is the Acute Coronary Treatment Intervention Outcomes Network—Get With The Guidelines Registry (formerly the ACTION Registry), which is the nation's largest ACS registry. More than 700 U.S. hospitals currently participate. The registry provides detailed in-hospital care and outcomes data. Duke researchers have linked several sources of patient data, and are studying:

- a) effectiveness and safety of aldosterone antagonist use after ACS.
- b) effectiveness of triple anticoagulation therapy in ACS patients with atrial fibrillation.
- c) use and effectiveness of cardiac rehabilitation programs among patients after a heart attack.

Rutgers, The State University of New Jersey CERT

The Rutgers Mental Health CERT served as a national resource for improving the safety and effectiveness of treatments for mental health problems. In 2011-2012, the Mental Health CERT partnered with the American Psychiatric Association and Columbia University to assemble an extensive database that allows researchers to address a range of mental health issues, including the safe and effective use of psychotropic drugs and antidepressants, especially among young people and the elderly. This CERT's educational initiatives included quality-improvement collaborations with state mental health and Medicaid officials, and development of national treatment guidelines.

Antipsychotic Medication in Nursing Home Residents

In 2011, Rutgers CERT researchers studied the use of antipsychotic medications in nursing homes. Despite safety concerns, these medications are widely used in nursing homes across the United States. Several analyses examined both patterns of antipsychotic use and their safety and effectiveness in this population. One study examined the factors influencing State and facility rates of antipsychotic use in nursing homes, finding that use of regulatory tools was effective in reducing reliance on these medications.

Bowblis, JR, Crystal, S, Intrator, O, et al. Response to regulatory stringency: The case of antipsychotic medication use in nursing homes. *Health Economics* 2012 Aug;21(8):977-93. Epub 2011 Sep 1. Select to access the [abstract](#).

In a paper that examined why antipsychotic treatment choice across nursing homes varies widely, researchers found that nursing homes' prescribing tendencies explained more of the variance in prescribing than did patient or facility characteristics. This suggested that a nursing home's tendency to utilize specific antipsychotics merits further exploration.

Huybrechts KF, Rothman KJ, Brookhart MA, et al. Variation in antipsychotic treatment choice across US nursing homes. *J Clin Psychopharmacol* 2012 Feb;32(1):11-7. Select to access the [abstract](#).

Another paper using medical claims data observed that compared with risperidone, nursing home residents treated with haloperidol had an increased risk of mortality, and users of quetiapine a decreased risk. The risk of mortality appeared to increase with higher doses.

Huybrechts KF, Gerhard T, Crystal S, et al. Differential risk of death in older residents in nursing homes prescribed specific antipsychotic drugs: population based cohort study. *BMJ* 2012;344:e977. Select to access the [abstract](#).

The Rutgers CERT also advanced research methods. In studies that rely solely on insurance claims data, selective prescribing of conventional antipsychotic medication to frailer patients is thought to have led to overestimation of their observed association with mortality. Rutgers CERT researchers assessed the validity of different analytic techniques to reduce such confounding. Using multiple different methods, they found little change in the estimated association with mortality. Using high-dimensional propensity-score methods based on claims alone resulted in estimates that were at least as good as those from conventional analyses using claims enriched with clinical information.

Huybrechts KF, Brookhart MA, Rothman KJ, et al. Comparison of different approaches to confounding adjustment in a study on the association of antipsychotic medication with mortality in older nursing home patients. *Am J Epidemiol* 2011 Nov 1;174(9):1089-99. Epub 2011 Sep 20. Select to access the [abstract](#).

Guiding Appropriate Treatment of Aggression in Youth

Antipsychotic medications are known to be used to manage aggressive behavior among children and adolescents, but the FDA has not approved the use of these drugs for this purpose among children. The Rutgers CERT joined with the States of New York and Texas, the Resource for Advancing Children's Health (REACH) Institute (thereachinstitute.org), The Annie E. Casey Foundation, and other organizations to develop evidence-based treatment recommendations for maladaptive aggression in youth. The guidelines were published in *Pediatrics*.

Knapp P, Chait A, Pappadopulos E, et al. Treatment of maladaptive aggression in youth: CERT guidelines I. Engagement, assessment, and management. *Pediatrics* 2012 Jun;129(6):e1562-76. Select to access the [abstract](#).

Scotto Rosato N, Correll CU, Pappadopulos E, et al. Treatment of maladaptive aggression in youth: CERT guidelines II. Treatments and ongoing management. *Pediatrics* 2012 Jun;129(6):e1577-86. Epub 2012 May 28. Select to access the [abstract](#).

Comparative Effectiveness of Alternative Pharmacotherapy Strategies for Treatment-Resistant Schizophrenia

In 2012, Rutgers CERT researchers conducted a study using Medicaid claims data from 45 States for 326,119 people with a schizophrenia disorder to examine their use of clozapine, which is the only antipsychotic medication deemed effective by FDA for treatment-resistant schizophrenia. Researchers investigated whether patient factors and county of residence were associated with beginning treatment with clozapine. They found that living in a county with high rates of clozapine use had the largest effect on whether patients started treatment with

clozapine. The clozapine initiation rates were low compared to the expected proportion of patients whose history of antipsychotic use suggested they had treatment-resistant schizophrenia and who thus may benefit from a therapeutic trial of clozapine. The large variability in clozapine initiation by local treatment practice suggests further exploration of clozapine use is warranted.

Stroup TS, Gerhard T, Crystal S, et al. Geographic and clinical variation in clozapine use in the United States. *Psychiatr Serv* 2013 Nov. Epub ahead of print. Select to access the [abstract](#).

Impact of a Health Home Model on Use of Therapeutics

Rutgers CERT researchers' ongoing work is assessing a model of medical health care delivered in community mental health centers (CMHCs)—the Missouri Community Mental Health Center Health Home Initiative. This initiative makes use of Affordable Care Act incentives for state Medicaid programs to establish specialized health home programs for beneficiaries with chronic conditions, including severe mental illness. These specialized health homes are designed to provide comprehensive care management that coordinates physical care, mental health care, and community-based services. Rutgers CERT researchers are working with Missouri State officials to assess how well clinics are implementing core concepts of the CMHC Health Home Initiative, including key program features, changes in staff roles, clients' use of services, and clinical outcomes. The goal is both to improve programs in Missouri and share lessons learned with other States.

University of Alabama at Birmingham CERT

The University of Alabama at Birmingham (UAB) Deep South Arthritis and Musculoskeletal CERT seeks to improve the safety and effectiveness of musculoskeletal therapeutics, educate health care practitioners, insurers, and policymakers, and broaden the impact that musculoskeletal research has on public health. This focus is both important and timely, given the rising burden of musculoskeletal diseases in an aging society.

Since 1999, the UAB CERT has successfully conducted more than 50 projects, creating new knowledge and products, disseminating research and education, and improving public health. The UAB CERT invests substantial resources for infrastructure research as well as specific research projects. In the current reporting period, research included the use of large administrative databases to examine serious adverse events associated with biologic therapies, methods development in pragmatic clinical trials, and efforts to promote adherence to therapies and reduce disparities in risk assessment and communication.

Improving Pragmatic Clinical Trials

Randomized clinical trials (RCTs) have long been considered the gold standard in research, but they have drawbacks; because they often restrict which participants can enroll, they often do not reflect the diversity of patients and circumstances seen in usual clinical practice. Thus, their findings, while true for the patients involved in the study, are not necessarily true for the general population. Pragmatic clinical trials seek to enroll the usual patients and treatments seen in

clinical care and thus improve the generalizability of RCTs, but these newer trials can be large, costly, and cumbersome to carry out.

In 2011, the UAB CERT proposed several ways to improve pragmatic trials, including: (1) making the best use of community-based practices by partnering with Practice Based Research Networks (PBRNs); (2) using information technology to simplify recruitment, consent, and randomization; and (3) utilizing linkages to large administrative databases, such as Medicare, to capture outcomes and other important variables while decreasing the burden of data collection for researchers and participants.

Saag KG, Mohr PE, Esmail L, et al. Improving the efficiency and effectiveness of pragmatic clinical trials in older adults in the United States. *Contemp Clin Trials* 2012 Nov;33(6):1211-6. Select to access the [abstract](#).

Improving Informed Consent

In 2012, the UAB CERT built on this foundation, following its own recommendations to improve pragmatic clinical trials. UAB CERT researchers and collaborators ([see CERTs Collaborations, Collaborating to Improve Informed Consent, above](#)) engaged community physicians and their staff to identify ways to provide the best informed consent procedures for a pragmatic clinical trial to study osteoporosis. In a research study, informed consent involves asking a potential study participant for his or her permission to be in the study after making sure he or she fully understands what participating entails, including potential risks and benefits. Researchers interviewed physicians and their staff at two PBRNs—the Alabama Practice Based Research Network (APBRN) and DARTNet Institute, and their clinical and administrative staff—to understand challenges they face, and to ask whether a computer tablet-based tool might streamline screening and informed consent procedures.

Participants' views differed on how best to introduce the tablet informed consent tool, where to do so, who should do it, and how long the process should take. Physicians and staff who had conducted clinical trials suggested more modifications for the tablet programming and expected more flexibility in its use. Interviewees at rural practices were more concerned with low verbal and technological literacy of their patient populations. Most interviewees were optimistic about the tablet technology for reducing administrative burden. The study concluded that incorporating practice-level preferences and allowing for flexibility in screening and consent procedures may reduce some barriers to practices' participation in research. A beta version of the tablet informed consent tool has been developed, in collaboration with Mytrus, Inc., and researchers have begun pilot-testing the tool against a traditional paper and pen model.

Study to Evaluate Pain Relievers

The UAB CERT is working with the University of Massachusetts on a study that evaluates the comparative effectiveness and safety of pain relievers after total joint replacement. The study is examining the use and outcomes of non-steroidal anti-inflammatory drugs versus narcotics.

Researchers are expanding the data captured in an AHRQ-supported nationally representative registry of 30,000 patients undergoing elective joint replacement surgery (FORCE-TJR). They will assess comparative effectiveness of the two groups of pain relievers by measuring pain severity, knee and hip joint function, health-related quality of life, and patient satisfaction at 2 weeks, 8 weeks, and 6 months after surgery. The study will compare minor side effects, such as heartburn and nausea, as well as serious adverse events, such as gastrointestinal bleeding, liver failure, or cardiac complications, for those 65 years of age or older during a 6-month follow-up. The study will yield important information about comparative effectiveness of pain relievers and patient-reported outcomes in patients undergoing elective joint replacement surgery.

University of Illinois at Chicago CERT

The University of Illinois at Chicago (UIC) CERT focused on tools for optimizing the prescribing of drugs, as well as monitoring drugs once they are prescribed and educating clinicians about better prescribing practices. This CERT studied ways to prevent medication errors by linking data systems—for example, pulling in data from patients' lab tests to inform the ordering of medications. Researchers also tested automated alerts that warn clinicians of potential errors as they enter their orders into computer systems.

UIC CERT researchers educated students, medical residents, and physicians about the role of the formulary—the committee that decides which prescription drugs a health care plan will cover—with the belief that formulary committees can have a strong positive influence on prescribing. In 2012, researchers also gave presentations on “principles of conservative prescribing” to a variety of audiences, and created a course for pharmacy students on critical analysis of pharmaceutical marketing.

Since becoming a CERT in 2007, the UIC CERT has amassed a body of work that shows how clinical decision support tools can help make drug therapy safer and more effective. In 2012, the UIC CERT focused on making connections between drugs and patient diagnoses as a means to improve the safety of medication taking.

Improving Prescribing Practices

In 2011, researchers from the UIC CERT described principles of conservative prescribing, a statement of the core philosophy that guides the CERT's approach to medication safety. In brief, these principles urge clinicians to: (1) think beyond drugs—consider nondrug therapy, underlying causes, and prevention; (2) practice more strategic prescribing; (3) be more vigilant about monitoring adverse drug effects; (4) exercise caution about new drugs; (5) work with patients to find a shared medication agenda; and (6) consider long-term impacts.

Schiff GD, Galanter WL, Duhig J, et al. Principles of conservative prescribing. *Arch Intern Med* Sep 12 2011;171(16):1433-1440. Select to access the [abstract](#).

A related recent project sought to guide formularies in their decision making. This project urged formularies to adopt a conservative approach to medications to maximize benefit and minimize harm from drugs. UIC CERT researchers developed and refined a framework to guide the

process of formulary decision making, which can be highly variable. They published the framework to make it widely available.

Schiff GD, Galanter WL, Duhig J, et al. A prescription for improving drug formulary decision making. *PLoS Med* 2012;9(5):1-7. Epub 2012 May 22. Select to access the [abstract](#).

Indication Alerts Prevent Wrong Patient Errors

Building on recent work that showed how clinical decision support (CDS) tools in the electronic medical record can improve the safety of medication therapy, UIC CERT researchers set out to determine whether indication alerts—alerts triggered by a prescription for a condition that is not listed on a patient’s problem list and inviting an addition to the list—might also prevent doctors from ordering medications for the wrong patient. Researchers retrospectively analyzed a large database of indication alerts—127,320 alerts over a 6-year period. They found that alerts designed to improve problem list completion also prevented “wrong-patient” errors. The alerts resulted in 32 intercepted wrong-patient medication errors, at a rate of 0.25 per 1,000 alerts. In these instances, clinicians recognized and canceled pending errors. In 59 percent of the intercepted errors, the prescriber had two patients’ charts open at the same time. The work demonstrated that real-time alerts that remind prescribers about drug indications can also prevent wrong-patient medication orders.

Such alerts could be implemented independently in CDS systems, or in combination with other error-reduction strategies. Researchers created a product that describes the clinical logic for the alerts and are sharing it with health systems and hospitals (access at: <http://www.uic.edu/com/dom/qim/TOPMEDS/>). The product will allow any hospital with a Computerized Provider Order Entry system and an electronic medical record to implement these alerts.

Galanter W, Falck S, Burns M, et al. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc* 2013 May 1;20(3):477-81. Select to access the [abstract](#).

Promoting Safe and Appropriate Drug Use among Patients with Diabetes

During their 2011 – 2016 funding, UIC CERT researchers are studying whether written materials designed for diabetes patients with low literacy can improve outcomes. The study will randomize 300 patients with diabetes who are on at least three chronic medicines to the intervention and 300 to usual care.

Patients in the study’s intervention arm will get a pre- and post-visit medication list to help them with medication reconciliation, and one-page fact sheets about each newly prescribed drug, all available in Spanish and English. Patients will be interviewed after their first study visit and again one month later. Researchers will look at outcome measures such as medication reconciliation and adherence, as well as clinical outcomes such as systolic blood pressure, cholesterol, and hemoglobin A1C. The study is taking place at UIC’s general medicine clinic,

where recruitment, clinician notification, and real-time printing of study materials are all automated within UIC's electronic medical record system.

CERTs Scientific Forum

In the first year of the CERTs cooperative agreement, the CERTs Scientific Forum supported the work of the CERTs Program by convening Steering Committee meetings and chairing Public-Private Partnership (PPP) Committee meetings. With the guidance of the CERTs Steering Committee, the Scientific Forum also directed the implementation of a CERTs collaborative project ([see CERTs Collaborative Activity, above](#)). The Scientific Forum also disseminates research and educational materials developed by the six research centers. The Scientific Forum supports two public websites—the AHRQ CERTs website (www.certs.hhs.gov) and the Clinician-Consumer Health Advisory Information Network (CHAIN) Online website (www.chainonline.org), through an exclusive agreement with Baylor College of Medicine to disseminate CERTs work (see CHAIN Online, below).

CHAIN Online: Disseminating Projects and Findings of the CERTs

The CHAIN Online website (www.chainonline.org), developed and hosted by Baylor College of Medicine (BCM), is a dissemination vehicle for CERTs. BCM redesigned the website over the course of 2011-2012, simplifying the navigation and updating the look and feel. The updated website, launched in September 2012, offers articles and tools for patients and practitioners, and recently began offering tools for researchers, including articles on methods, recent CERTs publications, and features on CERTs research. A BCM editorial board ensures that there is a range of materials and topics representing CERTs that will appeal to all visitors. Three posted articles feature CERTs projects completed or published in 2011-2012:

1. 2012 Updated Recommendations for Treating Rheumatoid Arthritis
2. New Guidelines for Treating Maladaptive Aggression in Youth
3. Achieving Quality Hypertension Care: Missing the “Low-Hanging Fruit” in Quality Improvement, a CME activity

BCM may also work with a CERT to turn research findings into a Continuing Medical Education (CME) activity, as it did for “Achieving Quality Hypertension Care: Missing the ‘Low-Hanging Fruit’ in Quality Improvement.” This effort was based on a May 2012 study by the Duke CERT ([See Program Activities 2011–2012; Factors Associated with Uncontrolled High Blood Pressure, above](#)) showing that up to one-third of patients under the care of cardiologists have suboptimal blood pressure control, with wide variability in performance across individual clinicians. The CME activity based on these findings focused on describing the consequences of poor blood pressure control for individuals and for larger groups, prompted physicians to document actions when blood pressure was out of range, described accepted methods of treatment intensifications, and discussed how to implement such techniques in practice.

To ensure that the information reached patients as well as clinicians, BCM worked with the Duke CERT to develop a companion article for patients, “What You Need To Know and Do To

Control Your Blood Pressure: You and Your Doctor Working Together,” and a companion handout, “If You Have High Blood Pressure.”

To disseminate the CME activity to health care professionals, BCM actively engaged in outreach, including placing articles in AHRQ’s *Inside Track*, a monthly electronic publication of the Effective Health Care Program. In addition, BCM announced its availability in The Association of American Medical Colleges’ newsletter, on the Duke CERT website, in an email announcement to the CHAIN Online subscriber list, and via links to the CME activity on the several CME/CE listing web sites.

As a result, in the 8 months after the CME activity was posted, it was visited nearly 1,712 times and 452 CME certificates were issued to participants who completed the course requirements. Eighty-seven percent of participants reported that they would definitely or probably change their practice behavior as a result of the activity.

CERTs Publications: 2011-2012

2011

A-E

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F-I

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2012

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