

## EHC Spotlight: The Diabetes Multi-Center Research Consortium

**COMPARATIVE EFFECTIVENESS AND EFFECTIVENESS RESEARCH** includes two equally important arms of the Effective Health Care (EHC) Program: systematic reviews of existing evidence and the generation of new scientific evidence. One of the sources for newly generated evidence within the EHC Program is the DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Network, a collection of research centers created in 2005.

The Network more recently has also created several consortia to meet the needs of significant priority conditions affecting large populations such as cancer and cardiovascular disease. One of these is the Diabetes Multi-Center Research Consortium (DMCRC), which was formed in 2008. The DMCRC supports innovative new research that is responsive to stakeholders, is protocol-driven, is based on established principles of good research practice, and includes analyses of both existing and newly collected data. The consortium also supports studies that address research gaps identified in systematic reviews, such as those produced by the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers (EPCs).



Currently, more than 23 million people in the United States have diabetes. According to the 2007 national diabetes statistics compiled by the National Institute of Diabetes and Digestive and Kidney Diseases, type 2 diabetes accounts for 90 to 95 percent of all cases in the United States. The estimated diabetes-related health-care cost in the country is \$174 billion.

Four DEcIDE Network research centers make up the DMCRC: John Hopkins University, RTI International, Vanderbilt University, and the HMO Research Network (HMORN), a collection of 15 United States health plans. Kaiser Permanente

---

*“Currently, more than 23 million people in the United States have diabetes.”*

---

of Northern California is the lead center for the DEcIDE DMCRC and is part of the HMORN.

Goals of the DMCRC include the harmonization of DEcIDE studies on diabetes, including the incorporation of recently funded diabetes research projects into the consortium. These projects

### IN THIS ISSUE:

- Page 2 **New Model Employed to Prioritize Research on Uterine Fibroids**
- Page 3 **New Research: Clinical Effectiveness of Coronary Stents in the Elderly**
- Page 3 **Comparative Effectiveness Review Summaries Get a New Look, Expanded Product Line**

### ALSO IN THIS ISSUE:

- Page 2 New “Data Points” Products on the Horizon
- Page 4 Communicating Outcomes to Patients: Can Less Be More?

### EDITOR’S NOTE:

*In this issue of Comparative Effectiveness News, several of our stories focus on the ever-increasing involvement of “stakeholders,” individual citizens from medicine, industry, education, patient advocacy organizations, professional associations, and priority populations who provide context and insight to ensure that the research conducted by the Effective Health Care Program remains useful to the needs of clinicians, consumers and policymakers. Comparative Effectiveness News will continue to provide information about these efforts in future issues, so that readers can learn of the many ways in which the Program interacts collaboratively with stakeholders to make scientific medical research more relevant to clinical practice.*

include a comparative effectiveness review of the oral agents used to treat diabetes type 2 as well as a comparative effectiveness review of the effects of oral hypoglycemic drugs on chronic kidney disease. Other projects include a comparative effectiveness review on bariatric surgery versus usual care for obesity and a statistical brief that highlights the current and changing patterns of diabetes care. ◀



## New Model Employed To Prioritize Research on Uterine Fibroids

### A ONE-DAY CONFERENCE PRIORITIZING RESEARCH ON UTERINE FIBROIDS

piloted a new collaborative approach by the Effective Health Care (EHC) Program of the Agency for Healthcare Research and Quality (AHRQ) in determining future research agendas. “Research on the Comparative Management of Uterine Fibroid Disease,” held in Rockville, Maryland on March 4, brought together a broad group of researchers, clinicians, and consumer advocates to explore and prioritize the unanswered questions surrounding the evaluation, management, and treatment of uterine fibroids. Their discussions produced a prioritized research agenda that will be made available to the greater community of researchers, policymakers, and consumers concerned with women’s reproductive health and uterine fibroid disease. The event was planned and facilitated by the DEcIDE (Developing Evidence to Inform Decisions and Effectiveness) Network, Outcome Sciences, Inc., and the Center for Medical Technology Policy (CMTP).

The meeting sought to accomplish five goals: (1) to identify clinical areas for new research in the care of uterine fibroid disease to support treatment decisionmaking; (2) to identify the clinically and policy relevant research questions related to clinical and comparative effectiveness of uterine fibroid treatment and management; (3) to propose and design a research protocol for a multicenter prospective study of the comparative effectiveness of diagnostic tools, management strategies, coordinated care, and treatments of uterine fibroids; (4) to discuss a preliminary analysis of existing

data to inform protocol development and to assess the research questions identified by stakeholders; and (5) to synthesize a prospective multi-stakeholder research agenda for uterine fibroid disease from the findings of the project research-prioritization process and to disseminate it to stakeholder partners and other stakeholder groups.

While collaboration with multiple stakeholders is not new to the Effective Health Care Program, the March 4 event offered a novel approach to prioritizing a broad research agenda for a priority condition. Attendees of this conference included representatives from public and private payers, Federal agencies, patient/consumer groups, foundations, product developers, and professional societies, together with researchers from AHRQ’s Evidence-based Practice Centers (EPC). The group discussed and prioritized each of the research questions, producing a final list that identifies the research question of highest priority in the field of uterine fibroid disease. A final discussion explored the feasibility of studies and research-design issues for the questions of highest priority.

Now with four of the five goals achieved, the final goal — dissemination of the findings — is underway. The prioritized research questions and records of the discussions form the foundation of a white paper describing the broad research agenda. Researchers will have new insight and guidance to generating evidence about the management of uterine fibroids. The EHC Program has adopted this process as a working model for future projects. ◀



## New “Data Points” Products on the Horizon

A NEW SERIES OF STATISTICAL INFORMATION BRIEFS titled “Data Points” are being produced by the DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Network. These briefs will focus on existing and emerging diagnosis and treatment modalities. The products will help policymakers and researchers identify research questions and design patient-centered outcomes research.

Data for the series will initially be derived from Medicare administrative data files, which account for approximately 45 million beneficiaries. Over time, it is expected that other sources of data will be used for the Data Points series. The series will contain information such as frequencies and rates of service utilization, mortality and morbidity, hospital readmissions, and other key outcomes for AHRQ priority conditions.

The first Data Points briefs are scheduled for publication in early 2011. The initial topics include diabetic foot ulcers, erythropoietin-stimulating agents, cancer treatment biologics, and utilization of diabetes medication and antihypertensive medications. Publication notices of these briefs are available by joining the Effective Health Care Program E-mail list. ◀

# New Research: Clinical Effectiveness of Coronary Stents in the Elderly

## A DEcIDE (Developing Evidence to Inform Decisions about Effectiveness)

Network report on drug-eluting stents published in January 2010 found that patients who were treated with drug-eluting stents had significantly better clinical outcomes than their counterparts who were treated with bare metal stents. Using data from the American College of Cardiology's National Cardiovascular Data Registry of 262,700 patients, the DEcIDE Network investigators found that the better clinical outcomes were not associated with increases in bleeding or stroke and persisted throughout 30 months of follow-up and across all prespecified subgroups.

While not a definitive study, the research report provides additional knowledge concerning the benefits and outcomes for many patients in the United States who have stents implanted to open a coronary vessel that has been blocked because of atherosclerosis. Currently, little is known about the comparative benefits and harms between drug-eluting stents and bare metal stents across patient populations. A comparative effectiveness review published by the Effective Health Care Program in October 2007 identified the need for pooled individual patient data from stent-era trials, as well as additional study of drug-coated stents to determine the differences in outcomes when compared with bare metal stents.

The study is one of several new research projects being undertaken by the DEcIDE Cardiovascular Consortium. Other studies have used patient databases to better assess the use of clopidogrel following implantation of a drug-eluting stent. Additional studies are being planned to evaluate predic-

tors of the clinical outcomes of using drug-eluting and bare metal stents in coronary interventions across patient subgroups.

The dramatic reductions in restenosis (the recurrence of vessel blockage) and in repeat revascularization procedures associated with drug-eluting coronary artery stents has led to a rapid increase in their use. Filling in knowledge gaps by studying a contemporary real-world cohort is critical to ensure that the effectiveness and safety of these interventions are better understood.

AHRQ and the United States Food and Drug Administration commissioned the formation of a nationally representative database of patients with coronary occlusion who have been treated with percutaneous coronary intervention. The DEcIDE Cardiovascular Consortium created the database by linking the American College of Cardiology National Cardiovascular Registry (ACC-NCDR®) with the Centers for Medicare and Medicaid Services (CMS) national claims database. ◀

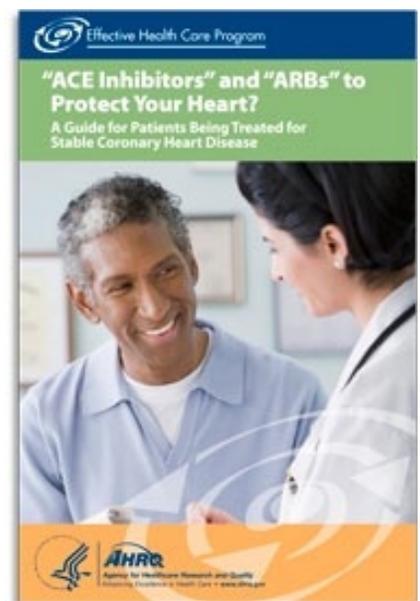


# Comparative Effectiveness Review Summaries Get a New Look, Expanded Product Line

## SUMMARY PRODUCTS AND GUIDES

from the Effective Health Care (EHC) Program sport a new look this spring following a collaborative redesign by the John M. Eisenberg Center for Clinical Decisions and Communications Science and the Office of Communication and Knowledge Transfer at the Agency for Healthcare Research and Quality (AHRQ). The aesthetic changes increase attractiveness and ease of product recognition for the consumer and clinician guides and policymaker summaries — all of which are created as easy-to-read contextual summaries of systematic reviews.

The traditional look of the guides, which emphasized the Effective Health



Re-designed consumer guide, "ACE Inhibitors' and 'ARBs' to Protect Your Heart?"

Care Program colors of blue and orange, now use a full-color print scheme. Full-color consumer guides provide a brighter, more inviting visual experience to patients and caregivers. Clinician and

*Continued on Page 4*

# Communicating Outcomes to Patients: Can Less Be More?

**PICTOGRAPHS — SIMPLE GRAPHIC DEPICTIONS** of outcome ratios using an icon array that shows the number of patients receiving the outcome per 100 — have been well established by research as an effective tool in communicating outcomes to patients. Now, a recent study has found that a “less is more” approach that omits redundant mortality outcome statistics may be more preferable when using visual formats such as pictographs.

A 2008 study by Zikmund-Fisher, Fagerlin, and Ubel published in *Cancer* found that pictographs were preferred to the four horizontal bars used to represent outcomes in the online decision tool Adjuvant! Version 8 ([www.adjuvantonline.com](http://www.adjuvantonline.com)). Adjuvant! calculates tailored estimates of the mortality risks, recurrence risks, and potential benefits of adjuvant therapy options such as hormone therapy or chemotherapy for breast cancer patients.

More recently, the same group of researchers tested the Adjuvant! graphs using only survival rates to see if the simplified versions would also enhance decisionmaking. The simplified pictographs were viewed by 832 participants, who were tested for comprehension, cognitive effort, treatment intentions, and graph evaluation ratings. A replication study was also conducted with 714 participants to ensure reliability of the findings.

In both randomized experiments, women who viewed the pictographs that only communicated survival rates comprehended the information as well if not better than those who viewed graphs depicting both survival and mortality rates. The survival-only graphs also had significantly higher evaluation ratings than the multi-outcome graphs. Interestingly, women who saw the survival-only graphs indicated an increased intention to select hormone therapy alone over a

combination of hormone therapy and chemotherapy, a finding that the researchers admitted might be due to a bias created by presenting only survival rates.

Several limitations of the study reinforce the need for additional investigation. The researchers did not use breast cancer patients, who might have different responses to the graphs given their personal experience, and no demographic information was collected to determine what role patient subgroup differences may have played into the findings.

The researchers conclude, “By using a ‘less is more’ approach and stripping the risk graphics shown to our participants down to the bare minimum (the chance of survival), we increased participants’ satisfaction with the materials while simultaneously supporting risk comprehension that was at least as good as that achieved with more complex graphics.”

Subscribers to *Medical Decision Making* may access the full article on the OnlineFirst Web site.

Source: Zikmund-Fisher BJ, Fagerlin A and Ubel PA. A demonstration of “less can be more” in risk graphics. *Med Decis Making Online-First*, published on April 7, 2010 as doi:10.1177/0272989X10364244. ◀

---

*“By using a “less is more” approach and stripping the risk graphics shown to our participants down to the bare minimum (the chance of survival), we increased participants’ satisfaction with the materials while simultaneously supporting risk comprehension that was at least as good as that achieved with more complex graphics.”*

---

— Researchers Zikmund-Fisher, Fagerlin, & Ubel

---

## Comparative Effectiveness Review Summaries Get a New Look, Expanded Product Line

*Continued from Page 3*

policy maker guides will each be assigned one of the four primary colors for quick product recognition. Both the clinician and policy maker guides can now be identified by the priority and secondary condition addressed in the research for easy filing and selection.

In addition to the aesthetic changes, the EHC Program has also added several new summary products, including a set of

slides for medical faculty members who wish to teach a lesson on the comparative effectiveness research findings, as well as a fully accredited online continuing medical education (CME) activity for clinicians who want to study the findings for CME credit. A set of faculty slides and CME products will be available on the EHC Program Web site, along with printed and online summary products with the new design and colors, in late spring. ◀