Comparative Effectiveness Research and the AHRQ Effective Health Care Program

February 20, 2013
Agenda

- AHRQ and the Effective Health Care Program
- Effective Health Care Program Activities
- AHRQ Effective Health Care Program National Partnership Network
Objectives

- Educate patients and providers about practical uses of the Effective Health Care Program
- Encourage adoption of Effective Health Care Program resources
- Enhance existing Effective Health Care Program relationships and engagement in program
Agency for Healthcare Research and Quality (AHRQ)

- **Mission:** To improve the quality, safety, efficiency, and effectiveness of health care for all Americans
- AHRQ supports research that helps people make more informed decisions and improves the quality of health care services
- **Research:** 80 percent of AHRQ's budget is invested in grants and contracts focused on improving health care

AHRQ Director
Carolyn Clancy, MD
The AHRQ Effective Health Care Program (EHC)

- Provides current, unbiased evidence on clinical effectiveness of health care interventions
- Focuses on patient-centered outcomes
- Helps consumers, providers, and policy-makers make informed choices
- Does not make treatment recommendations
- Long-term goal: Improve health care quality and patient health outcomes through informed decision making by patients, providers and policymakers
What is Comparative Effectiveness Research (CER)?

- Comparative effectiveness research — a type of patient-centered outcomes research — compares drugs, medical devices, tests, surgeries, or ways to deliver health care, so that patients and their families can make more informed choices.
- Findings are descriptive, not prescriptive, and are intended as tools for informed decision making, not recommendations.
- Findings highlight current evidence about effectiveness, risks, and side effects.
Priority Conditions for the EHC Program

- Arthritis and non-traumatic joint disorders
- Cancer
- Cardiovascular disease, including stroke and hypertension
- Dementia, including Alzheimer Disease
- Depression and other mental health disorders
- Developmental delays, ADHD, and autism
- Diabetes Mellitus
- Functional limitations and disability
- Infectious diseases including HIV/AIDS
- Obesity
- Digestive system conditions
- Pregnancy including pre-term birth
- Breathing conditions
- Substance abuse
Effective Health Care Program Products

- Clinician Summaries
- Web Site
- Mobile
- Consumer Summaries
- Patient Decision Aids
- CME Modules & Case Presentations / CE Activities*
- Reports, Research & Other Initiatives
- Faculty Slides
- Conference Series
- Webcasts

Products developed for the Effective Health Care Program by the John M. Eisenberg Center for Clinical Decision and Communications Science at Baylor College of Medicine, Houston, Texas.

* CE activities developed and provided by entities external to the Eisenberg Center.
Knowing and Discussing Treatment Options

- AHRQ research shows that patients most want to receive information about their treatment options directly from their health care professional.
- Comparative effectiveness research is valuable because it reviews alternative treatment options and presents them in an unbiased manner.
- When both clinicians and consumers know and discuss the options, the result is often better care.
AHRQ Products Available

- Research Summaries for clinicians
- Research Summaries for consumers
- CME/CE activities
- Faculty slide library
Comparing Medications for Adults With Type 2 Diabetes

Focus of Research for Clinicians

A systematic review of 166 clinical studies published between January 1966 and April 2010 examined the comparative effectiveness, benefits, and adverse effects of available monotherapy and two-drug combinations of medications for adults with type 2 diabetes (see list on page 3). The review did not cover treatments of type 1 diabetes or gestational diabetes nor do it review evidence regarding the effectiveness of diet, exercise, and weight loss. The full report, listing all studies, is available at http://www.effectivehealthcare.ahrq.gov/diabetes/results. This summary, based on the full report of research evidence, is provided to inform discussions with patients of options and to assist in decision making along with consideration of patients’ values and preferences. However, reviews of evidence should not be construed to represent clinical recommendations or guidelines.

Background Information

The management of hyperglycemia is an important focus of treatment to achieve improved macrovacular and microvascular outcomes in patients with type 2 diabetes. Regulating blood-glucose levels often requires several strategies, including weight loss if needed, dietary control, increased physical activity, and antidiabetic medications.

Treatment regimens include single drugs and combinations of drugs from different classes. Choosing among the available medications requires consideration of benefits, adverse effects, mechanism of action, and cost. In 2007, the Agency for Healthcare Research and Quality published its first systematic review on the comparative effectiveness of oral medications for type 2 diabetes. The 2011 update includes newer medications and two-drug combinations.

Conclusion

Evidence on the comparative effectiveness of antidiabetic medications for long-term macrovacular and microvascular outcomes is limited. However, evidence is available on shortterm outcomes. Many antidiabetic medications given as monotherapy work equally well to lower blood glucose. Two-drug combinations decrease hemoglobin A1c (HbA1c) further. Most agents (except metformin [MET] and glucagon-like peptide 1 [GLP-1] receptor agonists) are associated with increases in weight. The risk of mild to moderate hyperglycemia varies — it is highest for second-generation sulfonylureas (SUs) and is increased for some two-drug combinations over monotherapy. MET may cause gastrointestinal (GI) upset. A United States Food and Drug Administration (FDA) warning indicates that thiazolidinediones (TZDs) are associated with increased risks for edema, fracture, cardiovascular events, hip and nonhip fractures, and other risks in some patients. Tables 1, 2, and 3 summarize evidence about benefits, adverse events, and long-term benefits.

Gaps in Knowledge

Some newer drugs in two-drug combinations show promise for lower levels of weight gain.

Risk of Adverse Effects

SUs and sulfonylureas (SUs) are more likely to cause mild to moderate hyperglycemia than monotherapy with MET, TZDs, or a dipeptidyl peptidase-4 inhibitor (DPP-4i inhibitor). When compared to MET monotherapy, two-drug combinations with MET increase the risk of mild to moderate hyperglycemia, except for MET/DPP-4i inhibitor combinations (4.0% to 6.0%). MET is associated with more GI adverse events when combined with other agents (6.8% to 8.6%). TZDs are associated with a higher risk of congestive heart failure when compared with SUs (0.8% to 2.0%). T2DNs alone or in combination are associated with a higher risk of falls and fractures when combined with other agents (1.9% to 2.4%). FDA warnings indicate that TZDs are associated with increased risk for skeletal fracture, cardiovascular events, fractures, and other risks (see FDA Alerts for T2DNs page 5). TZD alone or in combination are associated with a higher risk of falls and fractures when combined with other agents (4.5% to 5.2%). FDA warnings indicate that TZDs are associated with increased risk for falls, fracture, cardiovascular events, fractures, and other risks (see FDA Alerts for T2DNs page 5).

Strength of Evidence

High: High-quality evidence; directly applicable to the clinical question. Moderate: Lower-quality evidence; findings are supported, but further research could change the conclusion. Low: Low-quality evidence; findings are very limited, or existing studies performed. Insufficient: Evidence either is unavailable or does not permit estimation of an effect.
Reviewing the Clinician Summary

Average Wholesale Prices for Diabetes Medicines (Continued from previous page)

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Generic</th>
<th>Brand</th>
<th>Price for 1-Month Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dipeptidyl Peptidase-4 (DPP-4) Inhibitors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>Januvia*</td>
<td>100 mg once a day</td>
<td>NA</td>
</tr>
<tr>
<td>Saxagliptin</td>
<td>Onglyza*</td>
<td>2.5 mg, 5 mg once a day</td>
<td>NA</td>
</tr>
<tr>
<td>Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exenatide</td>
<td>Byetta*</td>
<td>Injection of 5 mg twice a day</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injection of 10 mg twice a day</td>
<td>NA</td>
</tr>
<tr>
<td>Liraglutide</td>
<td>Victoza*</td>
<td>Injection of 0.6 mg once a day</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injection of 1.2 mg once a day</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injection of 1.8 mg once a day</td>
<td>NA</td>
</tr>
</tbody>
</table>

These prices are the federal median price for generic medicines and the average wholesale price for brand name medicines rounded to the next $5. These prices come from Red Book Pharmaceuticals’ Fundamental Reference, 2014 Edition.

ORDERING INFORMATION

For electronic copies of Medicines for Type 2 Diabetes: A Review of the Research for Adults, visit www.healthcare.gov/medications.

SOURCES

The information in this summary is based on Oral Diabetes Medications for Adults With Type 2 Diabetes: An Update, Comparative Effectiveness Review No. 25 prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 290-02-0018 from the Agency for Healthcare Research and Quality, March 2011. AHRQ Publication No. 11-EHC009-EF. Available at www.effectivehealthcare.ahrq.gov. This summary was prepared by the Eisenberg Center for Clinical Decisions and Communication Sciences at Baylor College of Medicine, Houston, TX.
Most clinician summaries have an accompanying consumer piece

- Supports conversation between patients and health care providers
- Helps lead to shared decisions about the best treatment

Summaries are available in multiple formats

English and Spanish
Consumer Summaries

OVERVIEW

Is This Information Right for Me?
Yes, if:
- Your doctor or health care provider has told you that you have type 2 diabetes and have high blood sugar.
- Your doctor or health care provider recommends that you take medicine to help lower or control your blood sugar.

No, if:
- You are younger than 18 years old.
- You have a different kind of diabetes called type 1 diabetes.
- You are pregnant and have a different kind of diabetes called gestational diabetes.

What is covered in this research summary?
This summary covers the research on the benefits and possible side effects of medicines to lower or control your blood sugar. It will help you talk with your doctor or other health care professional to decide which medicines are best for you.

Where does the information come from?
The information in this summary comes from a review of many studies about type 2 diabetes medicines. The review was conducted by an independent research center in 2007 and again in 2011. Read the full report at www.effectivehealthcare.ahrq.gov/diabetesmeds.cfm.

Understanding Your Condition

What is type 2 diabetes?
- Insulin is a hormone, or chemical, made by the body. It is needed to change food into energy.
- Type 2 diabetes means that your body cannot make enough insulin or that the cells in your body do not use insulin well. This causes blood sugar to get too high.

Why treat type 2 diabetes?
- If your blood sugar level stays high for a long time, you may have a greater chance of a heart attack, a stroke, kidney damage, or blindness. You may also need to have a toe, foot, or leg removed because of poor blood flow.
- Keeping your blood sugar at a good level might lower your chance of having these problems.

How is type 2 diabetes treated?
- The first step in controlling your blood sugar is to eat a balanced diet and be more active. Even small changes in exercise can make a big difference.
- Many people also need medicine to help keep their blood sugar under control.
How do I know the amount of sugar in my blood?

There are two common tests for blood sugar. They can help you and your doctor check how well your blood sugar is under control.

**Finger stick**

One test is a finger (or forearm) stick that you can do yourself. This test is done one or more times a day. You can do it in the morning before you eat (fasting) or at other times of the day, like after a meal. This test tells what your blood sugar level is at that moment in time. The fasting number should be between 80 and 150. After a meal, the target is usually less than 180.

**Blood test**

The other test is a blood test called hemoglobin (Hb) A1C. This test is done at your doctor’s office or at a lab a few times a year. The A1C test shows your average blood sugar level over the past 2 to 3 months. Usually the goal is for your A1C to be around 7. This means that your finger-stick blood sugar level has been in the “good” range over the past 2 to 3 months. If the A1C level is higher than this, changing your medicine might help.

Understanding Your Options

**Are all diabetes medicines the same?**

There are many types of diabetes medicines. Each type works in a different way to control blood sugar.

**How well can medicines lower my blood sugar?**

All the medicines in this summary lower blood sugar. The lab test for blood sugar level (A1C) is the best way to tell how well the medicines work.

- Most diabetes medicines can lower your A1C by about 1 point. This means that if you start with an A1C level of 8, taking one of these medicines could bring it down to 7.
- Combining two kinds of diabetes medicines can lower blood sugar more than taking just one kind. Most combinations of medicines can bring it down about 1 extra point. This means if you start with an A1C level of 9 and can bring it down to 8 with one kind of medicine, you might be able to lower it to 7 by adding a second medicine.
- There is not as much research on some drugs: nateglinide (Starlix®), exenatide (Byetta®), and sitagliptin (Januvia®). This means that we do not know as much about how these drugs compare with other diabetes medicines.
**IMPORTANT QUESTIONS**

**How often will I need to take these medicines?**

- Some diabetes medicines are taken once a day. Others need to be taken more often or with meals.
- No matter which medicines you need, follow the directions for each of them.
- Keep taking your medicines until your doctor tells you to stop. Not taking the medicines, or only taking them for a short time, will NOT help you lower or control your blood sugar.
- Check your blood sugar every day with your glucose monitor, and get your A1C blood tests when your doctor schedules them.

**Where can I get more information about type 2 diabetes?**


**Ask Your Doctor**

Talk with your doctor or health care provider about the information in this research summary.

1. Why are you choosing this diabetes medicine instead of the other medicines?
2. Will this medicine make me feel bad, gain weight, feel different, or cause changes to my body?
3. What is my current A1C number, and what would you like it to be?
4. How often should I check my blood sugar and at what times?
5. How will this medicine affect my daily activities, like working, sleeping, or taking care of my family?

**Write other questions here:**

______________________________

______________________________

**Write the answers here:**

______________________________

______________________________

______________________________
Accessing the Summaries

http://effectivehealthcare.ahrq.gov

Tools and Resources for Clinicians (CME/CE, Slides, etc.)

Research Summaries for Consumers/Clinicians
Relevance to healthcare professionals

- Comparative effectiveness research is relevant to all stakeholders in health care
  - Medical librarians, physicians, pharmacists, health care provider organizations, pharmaceutical manufacturers, employers, insurers, government agencies
- Clinical teams can keep abreast of the latest studies regarding best clinical practices by using the clinician guides, continuing education modules, and other resources.
A Push for Comparative Effectiveness
US Initiatives Aim to Empower Patients, Physicians

Bridget M. Kuehn

SINCE ITS EXISTATION IN 1980, THE Agency for Healthcare Research and Quality (AHRQ) has spearheaded efforts to boost the quality of health care in the United States, including funding research on the comparative effectiveness of interventions. The agency has also helped identify challenges to translating new research findings into practice, pointing out that findings can take as long as 17 years to make their way into practice, often with only limited uptake. However, the Department of Health and Human Services received $3.1 billion in funding for comparative effectiveness research (CER) as a result of the American Recovery and Reinvestment Act (2009), of which $1.5 billion was intended to support research supported by AHRQ. Now, with additional funding for CER from the Affordable Care Act (2010), AHRQ is poised to take an even bigger role in the future of US health care.

“Few agencies in medicine are as well positioned as AHRQ to identify, synthesize, and disseminate cutting-edge research in the area of comparative effectiveness research,” says AHRQ Director Carolyn M. Clancy, M.D. “At the same time, we must do a better job of engaging providers and patients in this important work.”

Clancy and her team worked with stakeholders to create a framework for comparative effectiveness research across federal agencies and to report back to Congress. In 2010, the work was incorporated into the Affordable Care Act. In 2011, the U.S. Health and Human Services released $2.8 billion in funds for CER, and in 2012, Congress authorized $3 billion in funding for a second round of CER.

Clancy: “The goal is to provide clear, evidence-based information that can help patients and practitioners make informed decisions about their care.”

Clancy and her team are working to identify interventions that are effective and to determine how those interventions can be applied in different settings. They are also working to ensure that the research is accessible and understandable to patients and providers.

Clancy: “We need to make sure that the research we conduct is relevant to the needs of patients and providers.”

For more information, see “A Push for Comparative Effectiveness, US Initiatives Aim to Empower Patients, Physicians,” published in the April 12, 2012 issue of the Journal of the American Medical Association (JAMA).

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Effective Health Care Program - Sharing the Resources

- Publish newsletter articles
  - Link to EHC resources from organizational Web site
  - Provide CE/CME modules to members via EHCP online resources or live and pre-recorded Webinars
  - Feature ECHP as breakout session and/or a booth at relevant meetings to encourage understanding and adoption
  - Co-brand EHC resources with logos for local relevance

http://www.ahrq.gov/about/casestudies/compeff/
The National Partnership Network

- **What is the partnership network?**
  - Organizations across the US supporting CER
  - Help create awareness of CER and resources in patient and professional communities
  - Committed to improving quality of health through informed decision-making

- **What types of organizations are partners?**
  - Professional associations
  - Health care providers/clinicians
  - Patient-focused organizations
  - Priority populations
The National Partnership Network

Why become a partner?

- Opportunities to connect with groundbreaking, comprehensive efforts to improve comparative effectiveness research
- Recognition as a partner in AHRQ’s Effective Health Care Program partnership materials
- Free evidence-based resources and tools for your members
- Access to AHRQ Effective Health Care Program updates with the latest research news

Partner Portal:
http://www.ahrq.gov/clinic/partners/buildpartners.htm
The Dissemination Framework

Effective Health Care Program
research and translated products

National awareness of CER and specific findings

National Initiative

Deeper awareness of CER and findings at regional, local, or system level

Regional Offices

Individual clinician education and practice-level implementation

Academic Detailing & Online CE

Evaluation
**Purpose:** Enhance awareness, understanding, and use of CER and EHC Program products in health care decisionmaking at the regional, state, and local levels

**Focus:** The most prevalent health disparities in each region (diabetes ■ heart conditions ■ mental health ■ cancer)

**Strategy: Targeted Partnerships**
- Create collaborative, ongoing and robust dissemination partnerships
- Outreach to local and regional health care organizations, businesses, unions, consumer, and other organizations
- Target audiences: clinicians, patients and the influencers who reach them
Number of Partnerships by State

Regional Partnership Development Offices - Total Number of Pledged Partners

Regional Offices:
- Atlanta Region: 76
- Chicago Region: 71
- Dallas Region: 66
- Denver Region: 66
- New York Region: 70

Total Pledged Partnerships: 369

Total Pledged Partners: 374
Shared Benefits of Partnership

- **Share** resources with your members
  - Use slides, summaries and other materials
  - Make continuing education modules available
  - Create customized or co-branded materials based on Effective Health Care Program content
  - Feature the Effective Health Care Program and existing and new products on organization’s Web site, social media channels, or newsletters
  - Sign up for the Effective Health Care Program email list

- **Contribute** to the research process
  - Shape future research by contributing to or commenting on research suggestions

- **Collaborate** with the regional partnership network
  - Together we can find creative ways to make the resources available to your members
Accessing Free Resources

- To access resources and products online, go to www.effectivehealthcare.ahrq.gov

- To order FREE printed copies (including bulk quantities) of EHC Program reports and summaries, call the AHRQ Publications Clearinghouse at 1-800-358-9295 or email ahrqpubs@ahrq.hhs.gov with the titles (or publication numbers) and quantities you want to order.

- Reference order code C-02
How to Contact the Denver Regional Office Lead

Denver Regional Office Lead: Kate Stabrawa

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QUESTIONS