

Comparative Effectiveness Research and the AHRQ Effective Health Care Program

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Agenda

- AHRQ and the Effective Health Care Program
- Comparative-effectiveness research and pharmacy
- AHRQ Effective Health Care Program National Partnership Network
- Telehealth – AHRQ: Shared Benefit

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

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
- Peptic ulcer disease and dyspepsia
- Pregnancy including pre-term birth
- Pulmonary disease/Asthma
- Substance abuse

Effective Health Care Program Products



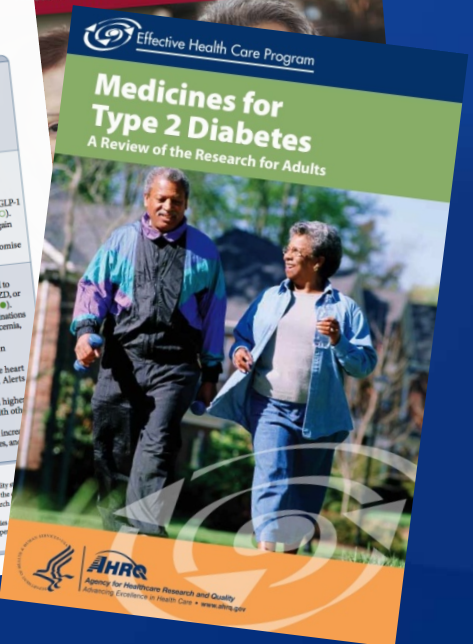
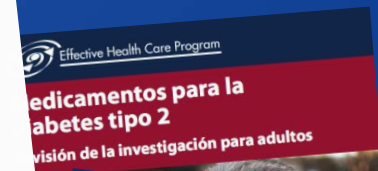
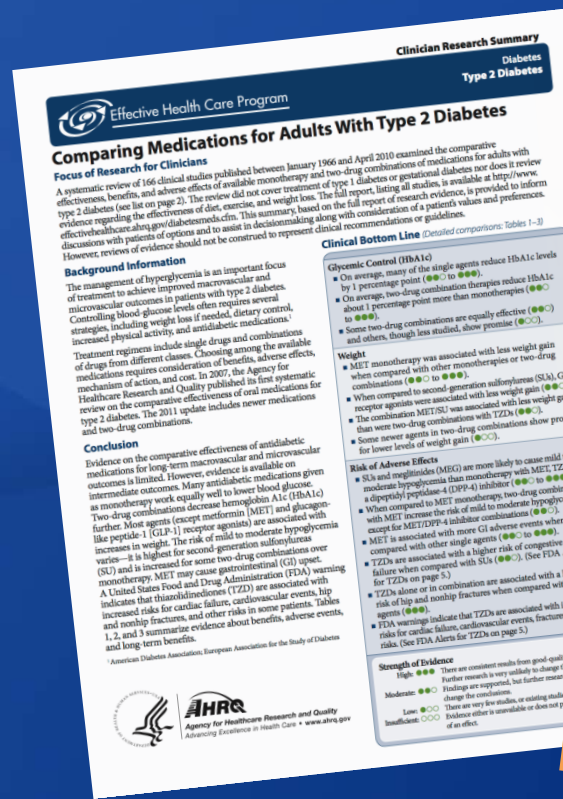
Products developed for the Effective Health Care Program by the John M. Eisenberg Center for Clinical Decisions and Communications Science at Baylor College of Medicine, Houston, Texas
 * CE activities developed and provided by entities external to the Eisenberg Center.

Knowing and Discussing Treatment Options

- AHRQ research shows that patients most want to receive information about their treatment options directly from their healthcare 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 To Support the Work of Healthcare

- Research Summaries for clinicians
- Research Summaries for consumers



Reviewing the Clinician Summary

OVERVIEW

CLINICAL ISSUE


CONCLUSION

GAPS IN KNOWLEDGE

CLINICAL BOTTOM LINE

BENEFITS/ADVERSE EVENTS

CONFIDENCE LEVELS

Effective Health Care Program

Diabetes
Type 2 Diabetes

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 2). The review did not cover treatment of type 1 diabetes or gestational diabetes nor did 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/diabetesmeds.cfm>. This summary, based on the full report of research evidence, is provided to inform discussions with patients of options and to assist in decisionmaking along with consideration of a patient's 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 macrovascular and microvascular outcomes in patients with type 2 diabetes. Controlling blood-glucose levels often requires several strategies, including weight loss if needed, dietary control, increased physical activity, and antidiabetic medications.¹

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 macrovascular and microvascular outcomes is limited. However, evidence is available on immediate 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 hypoglycemia varies—it is highest for second-generation sulfonylureas (SU) 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 (TZD) are associated with increased risks for cardiac failure, 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.

¹American Diabetes Association; European Association for the Study of Diabetes

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Advancing Excellence in Health Care • www.ahrq.gov

Clinical Bottom Line (Detailed comparisons: Tables 1–3)

Glycemic Control (HbA1c)

- On average, many of the single agents reduce HbA1c levels by 1 percentage point (●●○ to ●●●).
- On average, two-drug combination therapies reduce HbA1c about 1 percentage point more than monotherapies (●●○ to ●●●).
- Some two-drug combinations are equally effective (●●○) and others, though less studied, show promise (●●○).

Weight

- MET monotherapy was associated with less weight gain when compared with other monotherapies or two-drug combinations (●●○ to ●●●).
- When compared to second-generation sulfonylureas (SUs), GLP-1 receptor agonists were associated with less weight gain (●●○).
- The combination MET/SU was associated with less weight gain than were two-drug combinations with TZDs (●●○).
- Some newer agents in two-drug combinations show promise for lower levels of weight gain (●●○).

Risk of Adverse Effects

- SUs and meglitinides (MEG) are more likely to cause mild to moderate hypoglycemia than monotherapy with MET, TZD, or a dipeptidyl peptidase-4 (DPP-4) inhibitor (●●○ to ●●●).
- When compared to MET monotherapy, two-drug combinations with MET increase the risk of mild to moderate hypoglycemia, except for MET/DPP-4 inhibitor combinations (●●○).
- MET is associated with more GI adverse events when compared with other single agents (●●○ to ●●●).
- TZDs are associated with a higher risk of congestive heart failure when compared with SUs (●●○). (See FDA Alerts for TZDs on page 5.)
- TZDs alone or in combination are associated with a higher risk of hip and nonhip fractures when compared with other agents (●●●).
- FDA warnings indicate that TZDs are associated with increased risks for cardiac failure, cardiovascular events, fractures, and other risks. (See FDA Alerts for TZDs on page 5.)

Strength of Evidence

High: ●●● There are consistent results from good-quality studies. Further research is very unlikely to change the conclusions.

Moderate: ●●○ Findings are supported, but further research could change the conclusions.

Low: ●○ There are very few studies, or existing studies are flawed.

Insufficient: ○○ Evidence either is unavailable or does not permit estimation of an effect.

Reviewing the Clinician Summary

PATIENT
DISCUSSION
POINTS

PATIENT
RESOURCES

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

Drug Type			Price for 1-Month Supply	
Generic	Brand	Dose	Generic	Brand
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors				
Sitagliptin	Januvia*	100 mg once a day	NA	\$230
Saxagliptin	Onglyza*	2.5 mg-5 mg once a day	NA	\$220
Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists				
Exenatide	Byetta*	Injection of 5 mcg twice a day	NA	\$300
		Injection of 10 mcg twice a day	NA	\$330
Liraglutide	Victoza*	Injection of 0.6 mg once a day	NA	\$160
		Injection of 1.2 mg once a day	NA	\$315
		Injection of 1.8 mg once a day	NA	\$470

*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: Pharmacy's Fundamental Reference*, 2011 Edition.

XR/XL = extended release NA = not available as a generic

What To Discuss With Your Patients

- Establishing a goal for HbA1c and strategies to help accomplish that goal, including weight loss, exercise, and consistent use of medication.
- Strategies to increase adherence, including creating a medication schedule, addressing the costs of medications, and reporting adverse effects in a timely manner.
- The need for regular glucose testing and routine blood tests for HbA1c.
- What side effects to expect from the chosen medicines, and when to contact you if side effects occur.

Resource for Patients



Medicines for Type 2 Diabetes, A Review of the Research for Adults is a companion to this clinician research summary. It can help people talk to their health care professionals about medications for type 2 diabetes. It provides information about:

- Types of diabetes medications.
- The benefits and risks of medications.
- Costs of medications.

Ordering Information

For electronic copies of *Medicines for Type 2 Diabetes: A Review of the Research for Adults*, this clinician research summary, and the full systematic review, visit www.effectivehealthcare.ahrq.gov/diabetesmeds.cfm. To order free print copies, call the AHRQ Publications Clearinghouse at 800-358-9295.

Source

The information in this summary is based on *Oral Diabetes Medications for Adults With Type 2 Diabetes: An Update*, Comparative Effectiveness Review No. 27, prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 290-02-0018 for the Agency for Healthcare Research and Quality, March 2011. AHRQ Publication No. 11-EHC038-EE. Available at: www.effectivehealthcare.ahrq.gov/diabetesmeds.cfm. This summary was prepared by the Johns Hopkins University Center for Clinical Decisions and Communications Science at Baylor College of Medicine, Houston, TX.

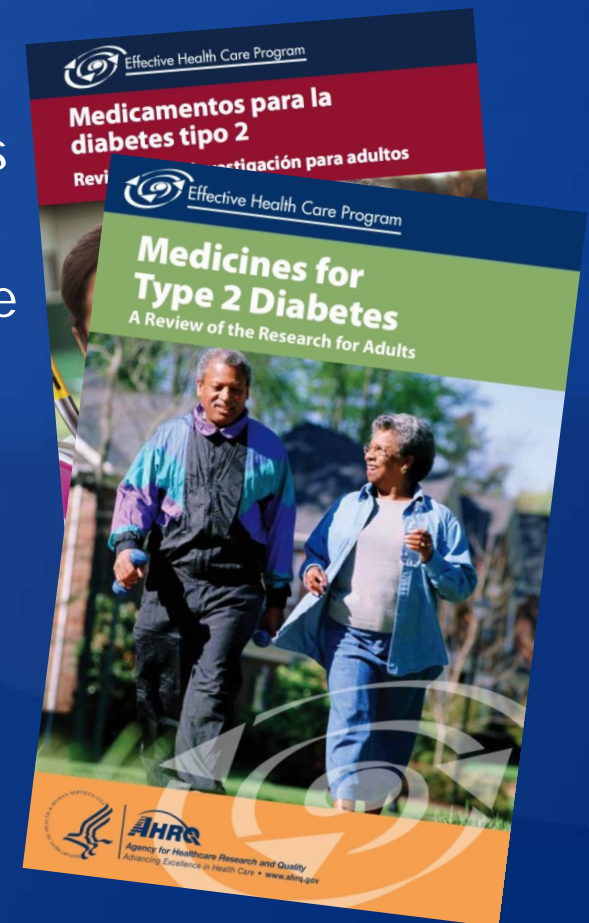
AHRQ
AHRQ Pub. No. 11-EHC038-3
June 2011

ORDERING
INFORMATION

SOURCES

Consumer Summaries

- Most clinician summaries have an accompanying consumer piece
 - Supports conversation between patients and healthcare 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.

Consumer Summaries

OVERVIEW

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 120. 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.



2

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.

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Consumer Summaries

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?

For more information about diabetes, visit the Medline Plus Web site: www.nlm.nih.gov/medlineplus/diabetes.html.



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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:

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Accessing the Summaries

<http://effectivehealthcare.ahrq.gov>

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

Research Summaries
for Consumers/
Clinicians



New AHRQ Initiative - For Health Care Professionals and Consumers

- **Promotes** new free resources for health care professionals and consumers to keep momentum growing for evidence-based health resources
- **Invites** national and regional partners to join in the effort to empower consumers with and inform health care professionals about reliable tools to make informed health care decisions

For Consumers - AHRQ Treatment Options: Explore. Compare. Prepare.

- **Visit and promote** the initiative's Web page for employees: www.ahrq.gov/treatmentoptions
 - Promotional videos to help newly diagnosed and existing patients, as well as their caregivers
 - Text messaging program: text COMPARE to 22764 to get the latest health updates

- **Share** free resources and tools
 - Treatment Options Facebook pages
 - In English: www.facebook.com/yourtreatmentoptions
 - En español: www.facebook.com/AHRQehc.espanol
 - Patient brochures (in English and Spanish) and public service announcements to help compare treatment options; fact sheets with ideas for how to get involved and a comprehensive list of resources
 - Online and digital tools to share with others

For Consumers: AHRQ Treatment Options: <http://www.ahrq.gov/treatmentoptions>

Treatment Options
EXPLORE > COMPARE > PREPARE

SELECT A HEALTH TOPIC ▾

Everyone can benefit from the facts.

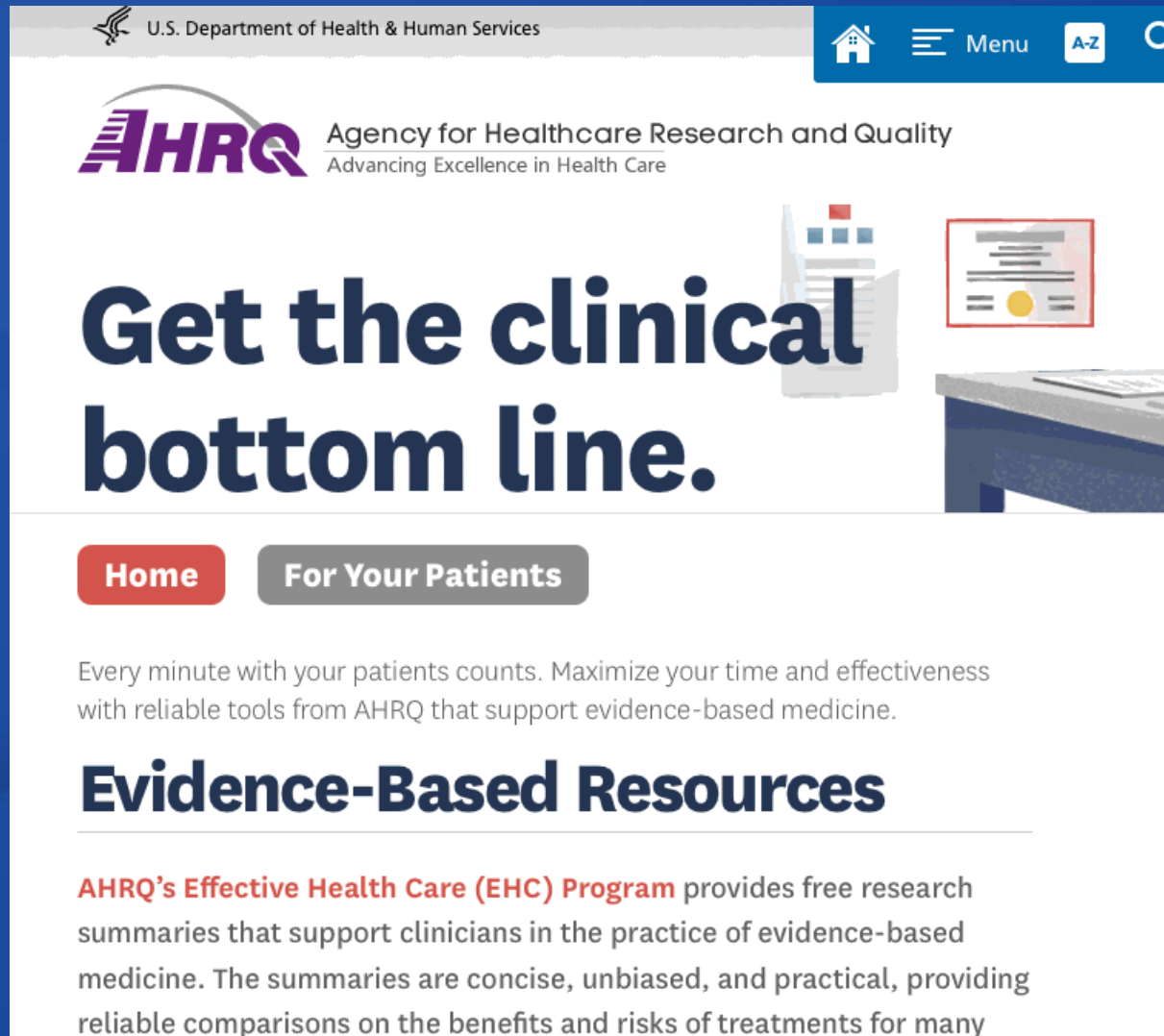
Explore treatment options. *Compare* benefits and risks. *Prepare* for your medical appointments. Get clear, unbiased information about treatments for common health conditions. Watch the videos below.



For Clinicians: AHRQ Treatment Options: Get the Clinical Bottom Line.

- **Visit and promote** the initiative's Web page for health care professionals:
www.ahrq.gov/clinicalbottomline
 - Access the clinician treatment summaries, as well as companion summaries for patients and caregivers
- **Share** free resources and tools
 - Patient brochures (in English and Spanish) and public service announcements to help compare treatment options; fact sheets about the initiative and how to get involved; comprehensive publication list
 - Online and digital tools to share with others

For Clinicians: AHRQ Treatment Options: [Http://www.ahrq.gov/clinicalbottomline](http://www.ahrq.gov/clinicalbottomline)



The screenshot shows the AHRQ website homepage. At the top, there is a header for the U.S. Department of Health & Human Services with a navigation bar containing a home icon, a menu icon, an 'A-Z' icon, and a search icon. Below the header is the AHRQ logo and the text 'Agency for Healthcare Research and Quality' and 'Advancing Excellence in Health Care'. The main heading is 'Get the clinical bottom line.' with an illustration of a clipboard and a certificate. Below this are two buttons: 'Home' (highlighted in red) and 'For Your Patients'. A paragraph states: 'Every minute with your patients counts. Maximize your time and effectiveness with reliable tools from AHRQ that support evidence-based medicine.' Below this is the section 'Evidence-Based Resources' with a sub-section 'AHRQ's Effective Health Care (EHC) Program' which provides free research summaries that support clinicians in the practice of evidence-based medicine. The summaries are concise, unbiased, and practical, providing reliable comparisons on the benefits and risks of treatments for many

U.S. Department of Health & Human Services

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Get the clinical bottom line.

Home For Your Patients

Every minute with your patients counts. Maximize your time and effectiveness with reliable tools from AHRQ that support evidence-based medicine.

Evidence-Based Resources

AHRQ's Effective Health Care (EHC) Program provides free research summaries that support clinicians in the practice of evidence-based medicine. The summaries are concise, unbiased, and practical, providing reliable comparisons on the benefits and risks of treatments for many

Relevance

- Comparative effectiveness research is relevant to all stakeholders in health care
 - 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.

Application Examples

- **American Nurses Association** has incorporated evidence-based information from AHRQ's EHC Program into a toolkit that members are using in both academic and practice research.
- **Maryland Department of Health and Mental Hygiene** used materials created by AHRQ's EHC Program to help set up a new program for appropriate use of antipsychotic medications in children.
- **IBM Integrated Health Services** incorporated AHRQ's EHC consumer summaries and US PSTF recommendations into their annual online annual Health Risk Assessment and Preventive Care Rebate Program.
- Case Studies link - <http://www.ahrq.gov/policymakers/measurement/case-studies/index.html>

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 decisionmaking

■ What types of organizations are partners?

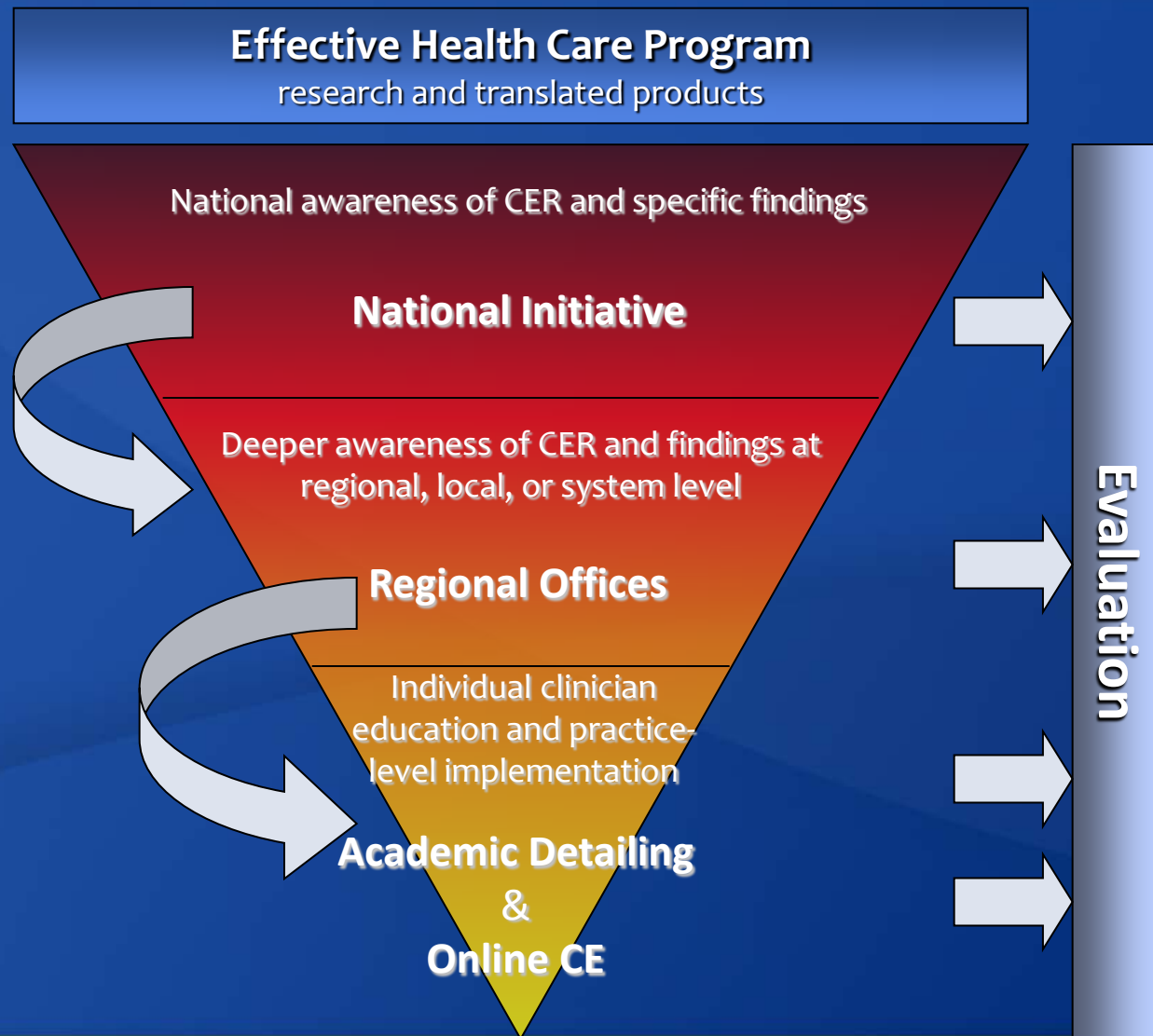
- Professional associations
- Healthcare providers/clinicians
- Patient-focused organizations
- Priority populations

The National Partnership Network

■ Why become a partner?

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

The Dissemination Framework



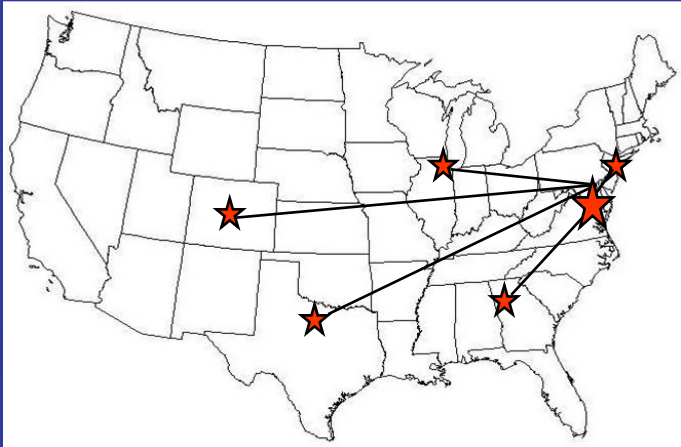
Regional Partnership Development Offices

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

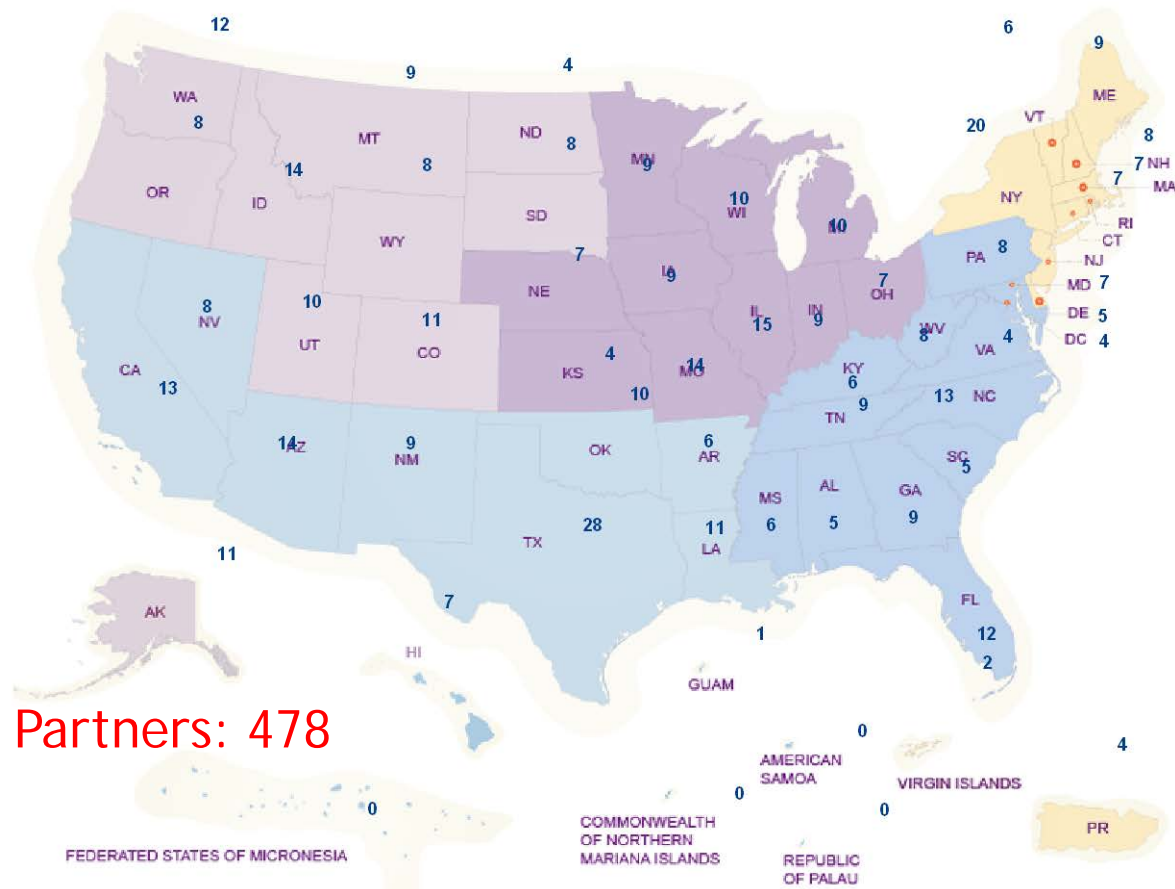


Regional Partnership Development Offices - Total Number of Pledged Partners

REGIONAL OFFICES

Atlanta Region	(96)
Chicago Region	(94)
Dallas Region	(107)
Denver Region	(95)
New York Region	(85)

Total Pledged Partnerships: 477



Telehealth - AHRQ: Shared Benefits of Partnership

- **Share** resources with your stakeholders
 - 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
- **Contribute** to research process
 - Shape future research by participating in Community Forum activities
- **Collaborate** with our regional partnership network

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**

QUESTIONS

