



# **The Role of Pharma, Biotech and Device Enterprises in Enhancing Healthcare Quality**

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WE HAVE TWO OPTIONS.  
EITHER AN EVIDENCE-  
BASED TREATMENT OR  
AN EXCITING, RISKY  
ALTERNATIVE.



# Overview

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- *What is AHRQ?*
- Innovation
- Lessons learned
- Challenges and Opportunities
- New Effectiveness Program

# AHRQ Mission Statement

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*To improve the quality,  
safety, efficiency, and  
effectiveness of health care  
for all Americans*



**Information for Better  
Decisions in Health Care**

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# AHRQ: Context

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- **NIH** -- focuses on specific disease to identify what might improve prevention, diagnosis, and treatment through biomedical research
- **AHRQ** -- focuses on how to improve the efficiency of the systems through which we receive personal health care and the effectiveness and comparative effectiveness of services
- **CDC** -- focuses on population health and the role of health departments and community-based interventions to improve health

# AHRQ focuses on the Health Care System

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- Assess the *effectiveness, comparative effectiveness, and cost-effectiveness* of health care services
- Identify ways to improve *patient safety and quality* of health care systems
- Advance the appropriate use of *health information technology*
- Understand *system issues*: role of organizational design, management, workflow, management, and incentives on efficiency and effectiveness
- Develop *data* on the health care system for monitoring and decision-making

# AHRQ Strategic Direction

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## Accelerating the Pace of Innovation

- *Ensuring Value* through More Informed Choice
- *Assessing* Innovation *Faster*
- *Implementing* Effective Interventions *Sooner*



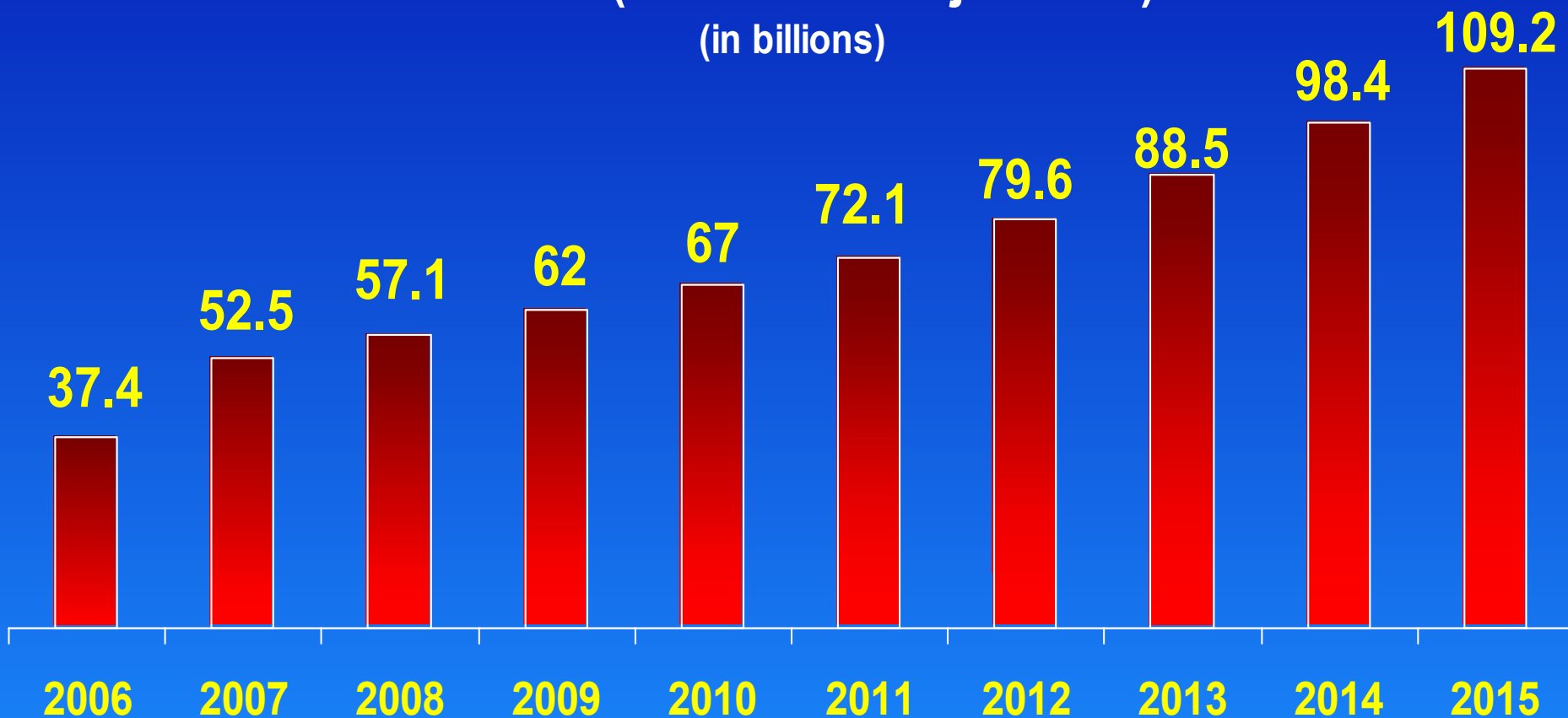
# Areas of Emphasis (Cross-cutting Portfolios)

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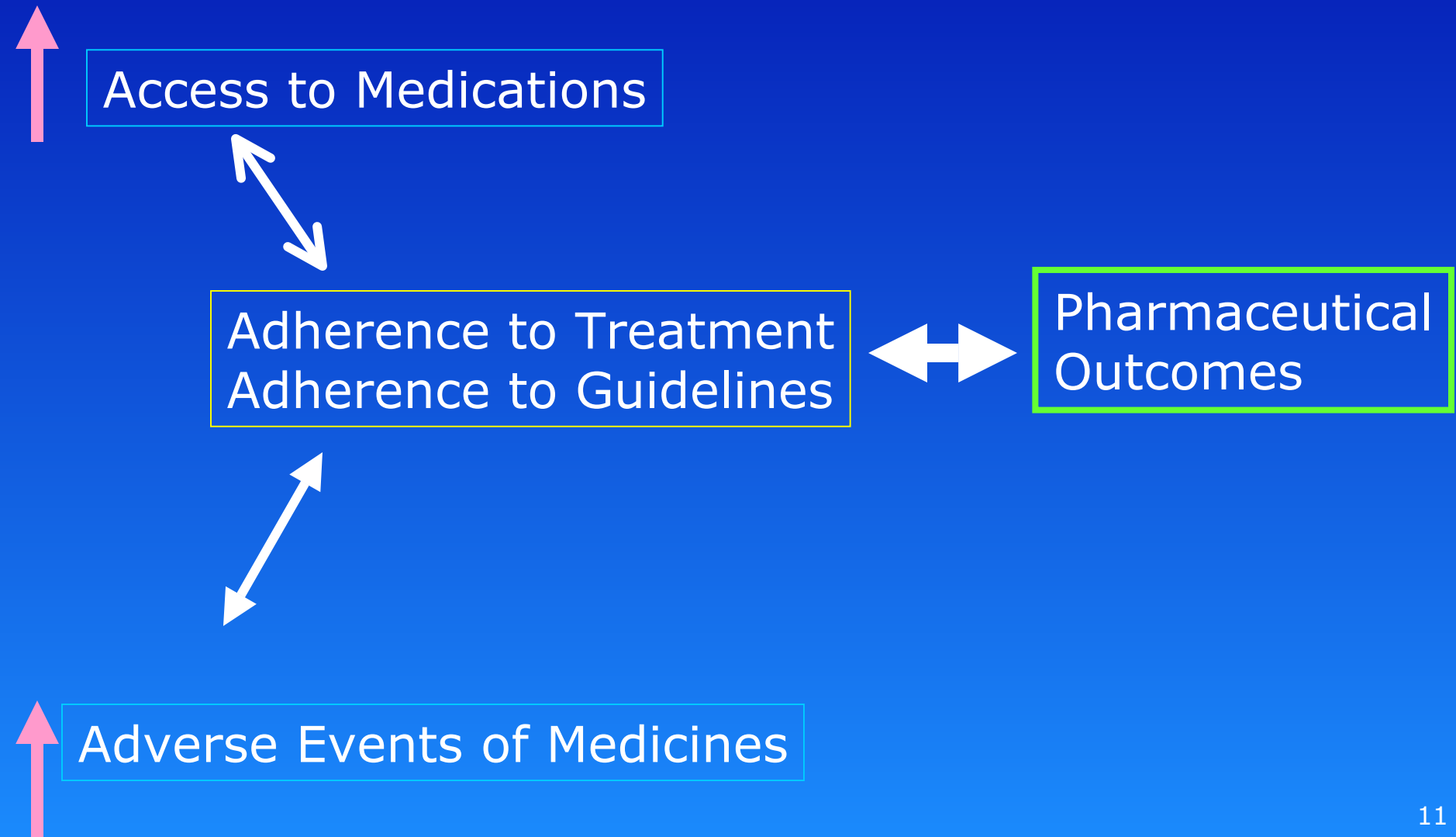
- Prevention
- Health Information Technology
- Quality/Safety of patient care
- Care management
- Data development
- System capacity and bioterrorism
- Long-term care
- Pharmaceutical outcomes
- Cost, organization, and socio-economics
- Training

# Net Federal Cost of Medicare Rx Drug Benefit

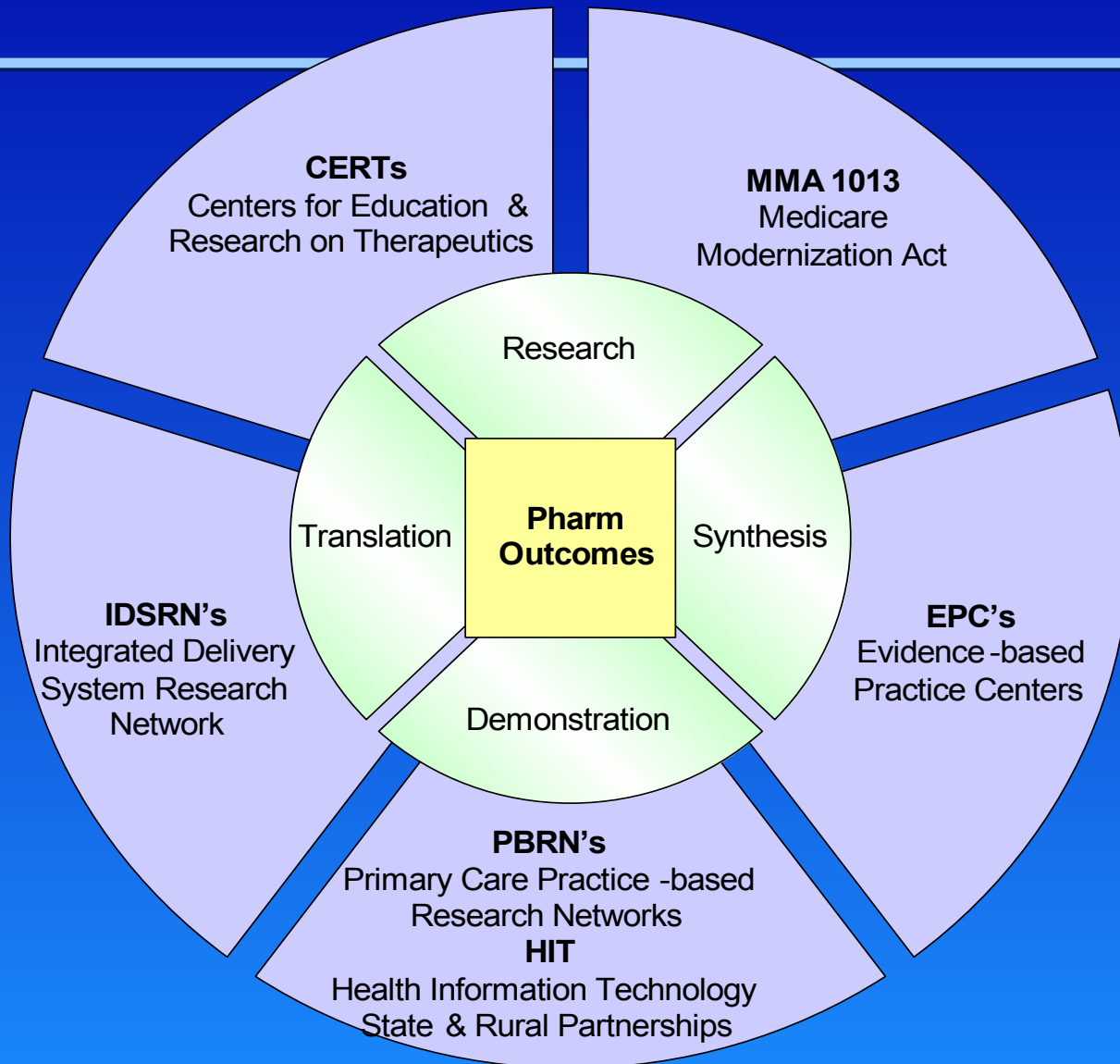
Net Federal Cost of the Medicare Prescription Drug Benefit (HHS 2005 Projections)  
(in billions)



# Framework for Pharmaceutical Outcomes Research



# AHRQ & Pharmaceutical Outcomes



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# Remarkable Innovation

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- Statins
- H2 agonists
- Protein pump inhibitors
- SSRIs
- Advances in HIV treatment
- Percutaneous transluminal coronary angioplasty
- Diagnostic imaging

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# Lessons from Success

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- Better understanding of the biomedical processes of disease
- Communication about risks and benefits critical
- Understanding that all medications carry risk

# Effective but Reasonable?

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Gas powered hearing aid

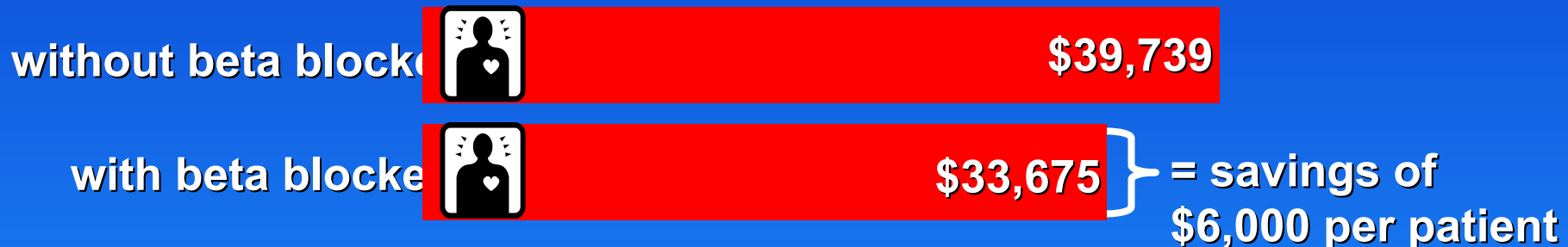


Gas powered pacemaker

# AHRQ Research Study: Cost of \Beta Blockers in Heart Failure Patients

- Major Finding: Decision model indicates that Medicare costs would decrease if the use of beta blockers were more widespread for patients with heart failure

Estimated cost for Medicare to treat heart failure per-person over 5-year period

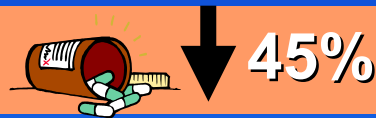


Duke Center for Education and Research on Therapeutics, Economic effects of beta blocker therapy in patients with heart failure, *American Journal of Medicine*, January 2004

# AHRQ Research Study: Drug Co-Payments and Patient Use of Medications

- **Major Finding:** Increasing patients' co-payments for prescription medications leads to decreases in use of eight classes of drugs

**Decrease in drug use after doubling co-payments in a typical 2-tier drug plan:**



**Anti-inflammatory drugs and antihistamines**



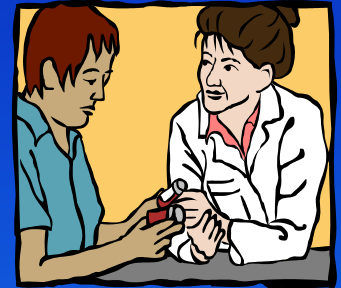
**Cholesterol-lowering drugs and drugs to treat ulcers**



**High blood pressure, depression, and diabetes treatment drugs**

# AHRQ Research Study: Cost-Related Medication Underuse

- **Major Finding:** About 2/3 of chronically ill adults don't tell their clinicians that they don't take their medications because of high cost
- Clinicians should take a more proactive role in identifying and assisting patients who have problems paying for prescription drugs
- Patients were most likely to find clinicians helpful if they provided free samples, asked about problems paying for prescriptions, and offered advice about how to pay for current regimens



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# Challenge and Opportunities

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- Managing increased costs due to the proliferation of new innovations
- Improving the availability of information to help clinicians and patients make decisions
- Improving communication of message that all drugs carry risks
- Understanding that errors are everyone's problem and that everyone is part of the solution
- Increasing number of patients who take multiple medications
- Exciting role of health information technology



"The red are for the illness, the blue are for the side effects of the red and the green are for the effects of the blue."



# Patient Information Resource: *Your Medicine: Play It Safe*

- 12-page brochure outlines steps to help patients use prescription medicines safely
- Includes detachable pocket-sized medicine record form



# Five Steps to Safer Health Care



# 1

## Ask questions if you have doubts or concerns.

Ask questions and make sure you understand the answers. Choose a doctor you feel comfortable talking to. Take a relative or friend with you to help you ask questions and understand the answers.



# 2

## Keep and bring a list of ALL the medicines you take.

Give your doctor and pharmacist a list of all the medicines that you take, including non-prescription medicines. Tell them about any drug allergies you have. Ask about side effects and what to avoid while taking the medicine. Read the label when you get your medicine, including all warnings. Make sure your medicine is what the doctor ordered and know how to use it. Ask the pharmacist about your medicine if it looks different than you expected.



# 3

## Get the results of any test or procedure.

Ask when and how you will get the results of tests or procedures. Don't assume the results are fine if you do not get them when expected, be it in person, by phone, or by mail. Call your doctor and ask for your results. Ask what the results mean for your care.



# 4

## Talk to your doctor about which hospital is best for your health needs.

Ask your doctor about which hospital has the best care and results for your condition if you have more than one hospital to choose from. Be sure you understand the instructions you get about follow-up care when you leave the hospital.



# 5

## Make sure you understand what will happen if you need surgery.

Make sure you, your doctor, and your surgeon all agree on exactly what will be done during the operation. Ask your doctor, "Who will manage my care when I am in the hospital?" Ask your surgeon: Exactly what will you be doing? About how long will it take? What will happen after the surgery? How can I expect to feel during recovery? Tell the surgeon, anesthesiologist, and nurses about any allergies, bad reaction to anesthesia, and any medications you are taking.



U.S. Department of Health and Human Services in partnership with



American Hospital Association



American Medical Association

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# Treatments Thought to Work but Shown Ineffective



- Sulphuric acid for scurvy
- Leeches for almost anything
- Insulin for schizophrenia
- Vitamin K for myocardial infarction
- HRT to prevent cardiovascular disease
- Flecainide for ventricular tachycardia
- Routine blood tests prior to surgery
- ABMT for late stage Breast CA

BMJ February 28 2004; 324:474-5.

# What is Section 1013 of the MMA?

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- To improve the quality, effectiveness and efficiency of health care delivered through Medicare, Medicaid and the S-CHIP programs
- \$15 million is appropriated in Fiscal Year 2005 for the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research with a focus on outcomes, comparative clinical effectiveness and appropriateness of health care items and services (including pharmaceutical drugs), including strategies for how these items and services are organized, managed and delivered

# What is Section 1013?

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- By June 2004, the Secretary shall establish an initial list of research priorities (including those related to prescription drugs)
- Priorities may include health care items and services which impose a high cost on Medicare, Medicaid or S-CHIP, including those that may be underutilized or over utilized

# Working Definitions

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## ■ Effectiveness

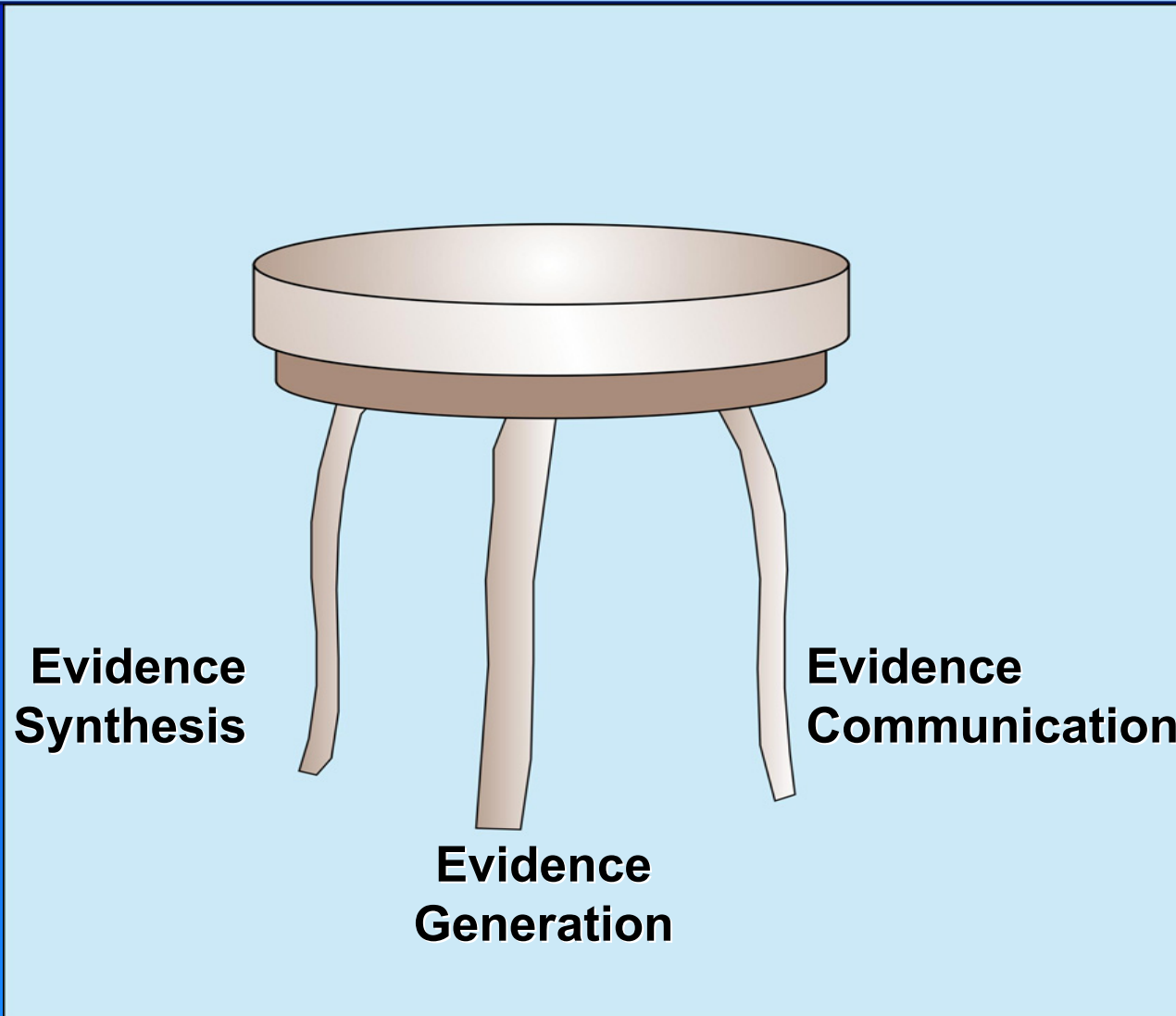
- Can it work?
- Does it work in practice?
- Is it worth it?

Haynes B Can it work? Does it work? Is it worth it? *BMJ*1999;319:652-3

## ■ Comparative Effectiveness

- Comparison of the effectiveness of various treatments and procedures - looking at which treatments for specific clinical problems work best for whom

# Legs of the Program





# Staging Considerations

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- Initial effort must focus on evaluating and synthesizing **available data** related to the identified priorities
- Studies to generate **new knowledge** needed quickly
- Broad and **sector-relevant dissemination** mandatory

# Top 10 Conditions Affecting Medicare Beneficiaries

- \$15 million initiative, authorized by MMA Section 1013, to develop state-of-the-art information about effectiveness of interventions, including prescription drugs, for top 10 conditions affecting Medicare beneficiaries:

Arthritis and non-traumatic joint disorders

Cancer

Chronic obstructive pulmonary disease/asthma

Dementia, including Alzheimer's disease

Depression and other mood disorders

Diabetes mellitus

Ischemic heart disease

Peptic ulcer/dyspepsia

Pneumonia

Stroke, including control of hypertension

# Approaching Knowledge Gaps

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- Not always head to head
- Need to be creative
- Explore new methodologies
- Examine existing or forthcoming data sources
- Reserve most expensive approaches for the most important and controversial questions

# How has practice changed?

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**Your Questions?**