



Agency for Healthcare Research and Quality

Advancing Excellence in Health Care

www.ahrq.gov

Comparative Effectiveness Research: AHRQ & NCI

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Agency for Healthcare Research and Quality

National Cancer Institute Board of Scientific Advisors

Bethesda, MD – November 2, 2009



A Learning Health Care System for Cancer Care



- **Quality and Why It Matters**
- AHRQ Roles & Resources
- Current Activities
- A Look Ahead
- Q & A



Current Challenges

- Concerns about health spending – about \$2.3 trillion per year in the U.S. and growing
- Pervasive problems with the quality of care that people receive
- Large variations and inequities in clinical care
- Uncertainty about best practices involving treatments and technologies
- Translating scientific advances into actual clinical practice and usable information both for clinicians and patients



Case Presentation: Stage III Melanoma

- JG, 70-year-old woman, is diagnosed with Stage III melanoma at a renowned cancer center
- Six years later, she is admitted for diffuse back pain and fatigue, and is found to have extensive metastases
- JG is given palliative care
- She is transferred from the cancer center to a rehabilitation facility, but had extensive difficulty with pain management
- Two weeks later, she is readmitted to the cancer center with extensive pulmonary infiltrates
- JG expires within 48 hours

This Case Illustrates

- Suboptimal quality of care
- Poor patient adherence
- How bad a disease cancer is



Quality and Why It Matters

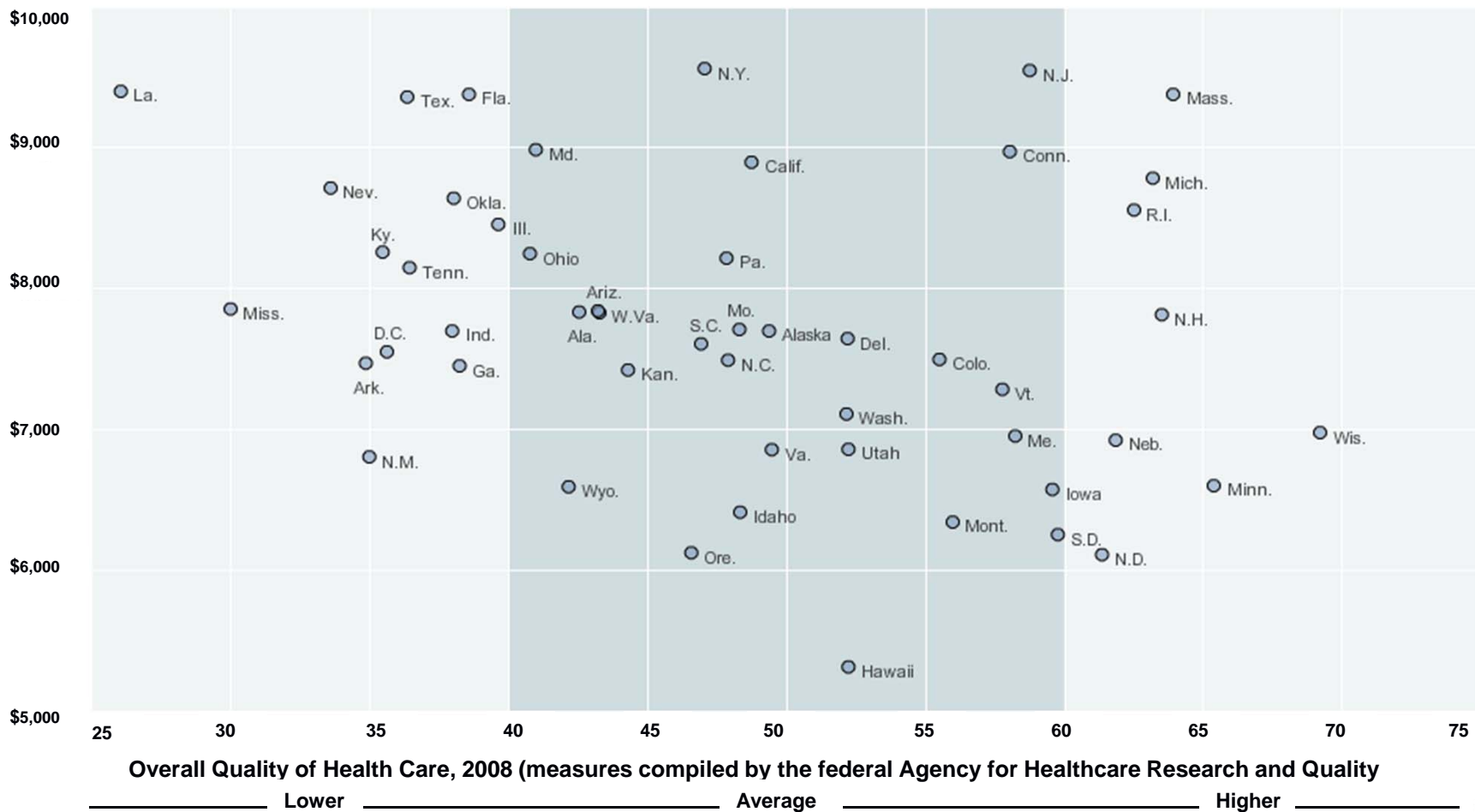


- Varies – **A LOT**; not clearly related to money spent
- Matters – can be measured and improved
- Measurement is evolving:
 - Structure, process and outcomes
 - Patient experience is essential component*
- Strong focus on public reporting
 - Motivates providers to improve
 - Not yet ‘consumer friendly’



Huge Geographic Variations: Higher Prices Don't Always Mean Better Care

Medicare Spending Per Beneficiary, 2006 (according to the Dartmouth Atlas of Health Care)



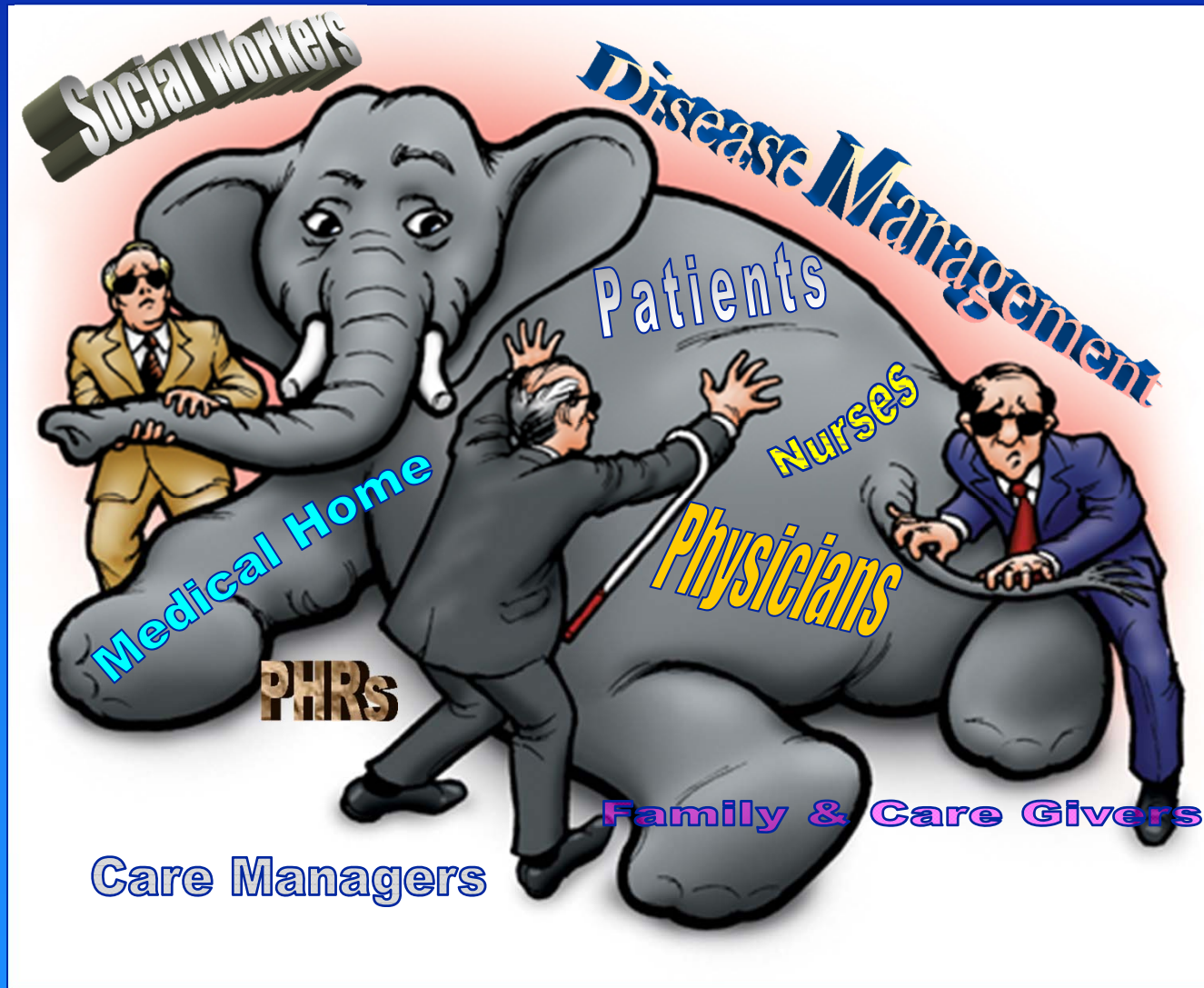
New York Times, September 8, 2009

Driving Factors in Quality

- Focused attention to the Institute of Medicine's 6 quality aims:
 - Safe, Timely, Effective, Efficient, Equitable, Patient-Centered
- Public demand to know
- Linking payment to quality of care
- Priority: transparency



Coordination of Care





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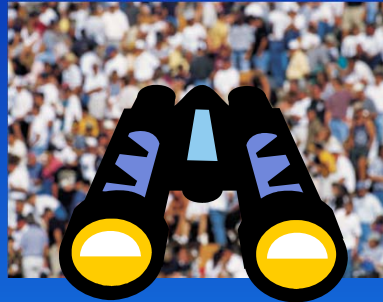


HHS Organizational Focus



NIH

Biomedical research to prevent, diagnose and treat diseases



CDC

Population health and the role of community-based interventions to improve health



AHRQ

Long-term and system-wide improvement of health care quality and effectiveness



AHRQ Roles and Resources



Health IT Research Funding

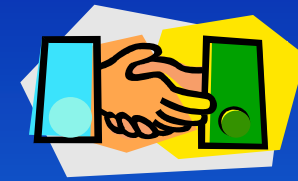
- Support advances that improve patient safety/quality of care
- Continue work in hospital settings
- Step up use of HIT to improve ambulatory patient care



Develop Evidence Base for Best Practices

Four key domains:

- Patient-centered care
- Medication management
- Integration of decision support tools
- Enabling quality measurement



Promote Collaboration and Dissemination

- Support efforts of other Federal agencies (e.g., CMS, HRSA)
- Build on public and private partnerships
- Use web tools to share knowledge and expertise

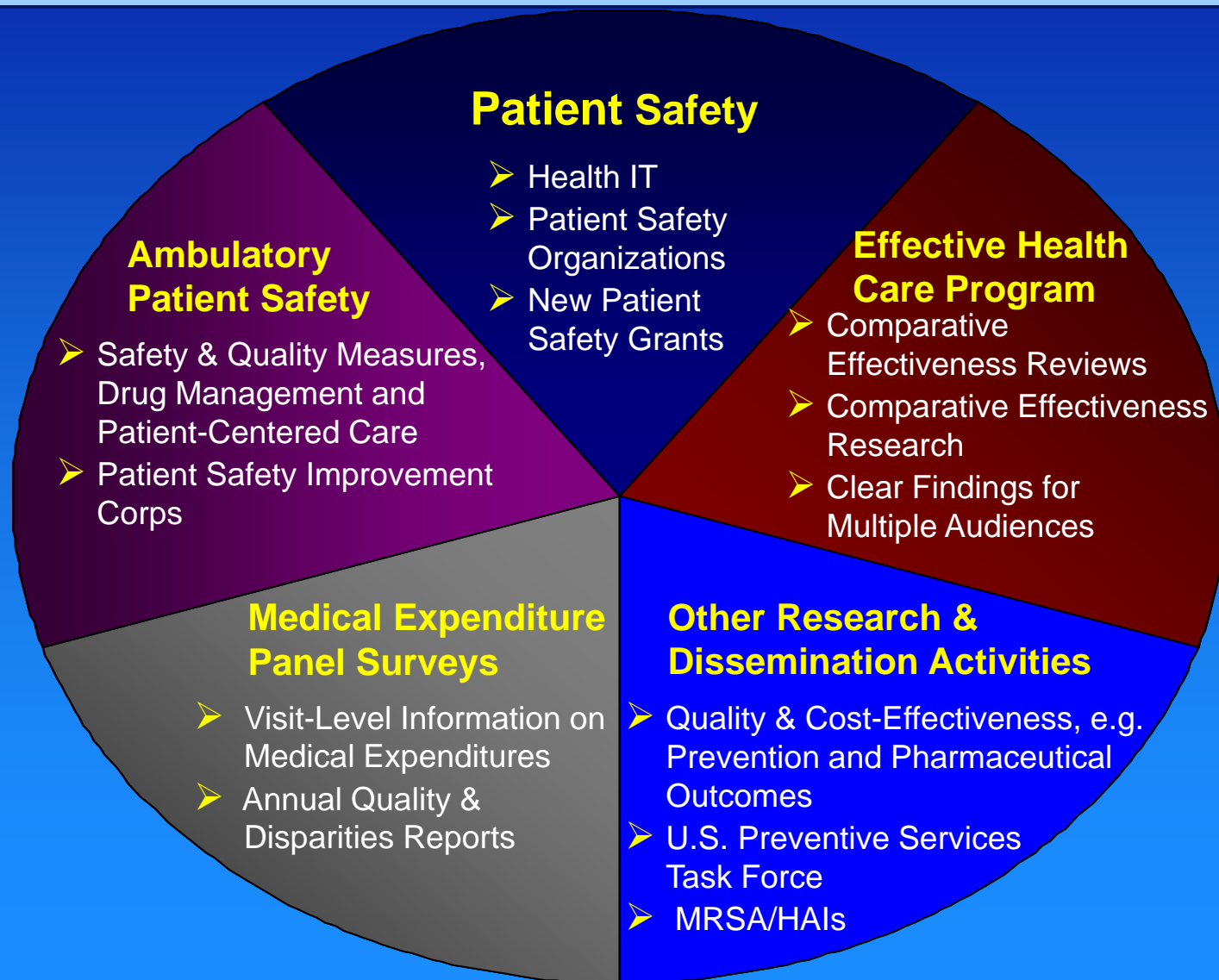


AHRQ's Mission



Improve the quality, safety, efficiency and effectiveness of health care for all Americans

AHRQ Priorities





AHRQ 2009: New Resources, Ongoing Priorities

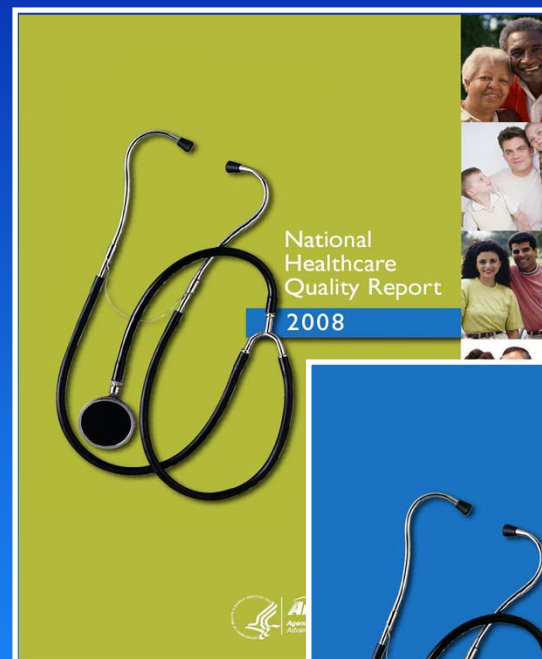
- \$372 million for AHRQ in FY '09 budget
 - \$37 million more than FY 2008
 - \$46 million more than Administration request
- FY 2009 appropriation includes:
 - \$50 million for comparative effectiveness research, \$20 million more than FY 2008
 - \$49 million for patient safety activities
 - \$45 million for health IT



AHRQ's National Reports on Quality and Disparities

Key themes in 2008 reports:

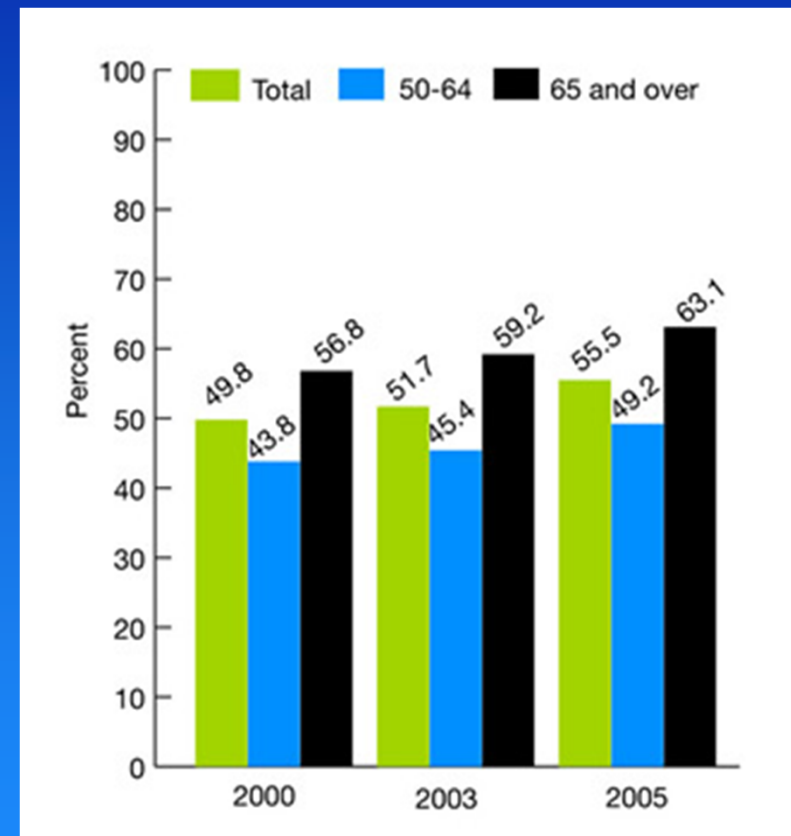
- Quality is suboptimal and improves at a slow pace (1.4% for all measures)
- Reporting of hospital quality is spurring improvement, but patient safety is lagging
- Disparities persist in health care quality and access
- Magnitude and pattern of disparities are different within subpopulations
- Some disparities exist across multiple priority populations





Key Findings: Quality Report

- Colorectal cancer screenings: only 55 percent of patients 50 and over
- Geographic variation for colonoscopy or sigmoidoscopy widespread
- Percentage of women under age 70 treated for breast cancer with breast-conserving surgery who received radiation therapy to the breast within 1 year of diagnosis virtually unchanged between 1999 and 2005

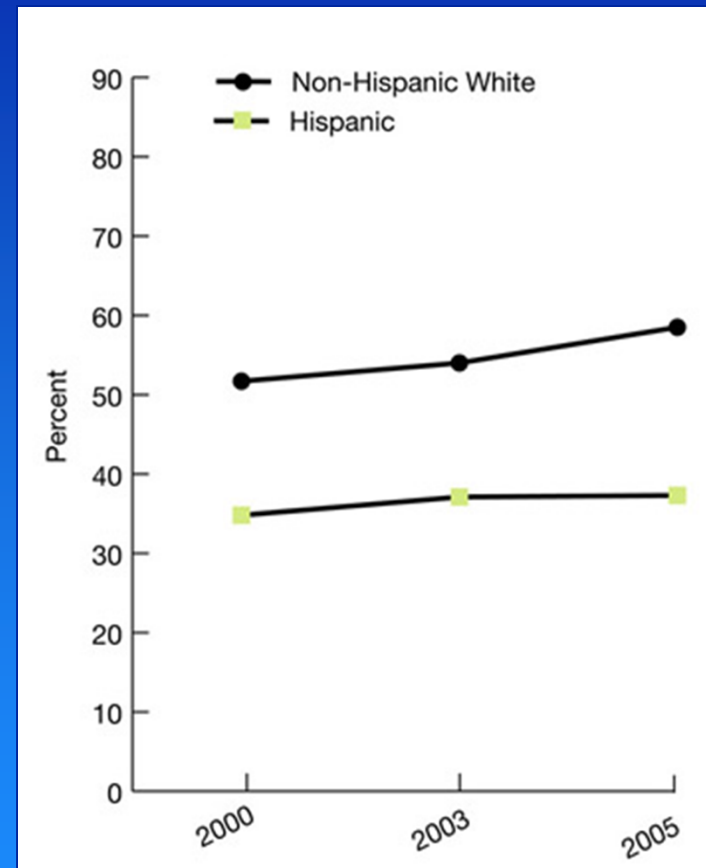


Adults age 50 and over who ever received colorectal cancer screening), 2000, 2003, and 2005



Key Findings: Disparities Report

- AI/AN adults were less likely than Whites to receive colorectal cancer screening
- From 2000 to 2005, the percentage of Asian women age 40 and over who reported they had a mammogram within the last 2 years improved. The gap between AIs/ANs and Whites who did not receive a mammogram decreased.
- From 1999 to 2005, the gap between Black and White women under age 70 treated for breast cancer with breast-conserving surgery who received radiation therapy to the breast within 1 year of diagnosis remained the same.



Adults age 50 and over who received colorectal cancer screening by ethnicity 2000-2005

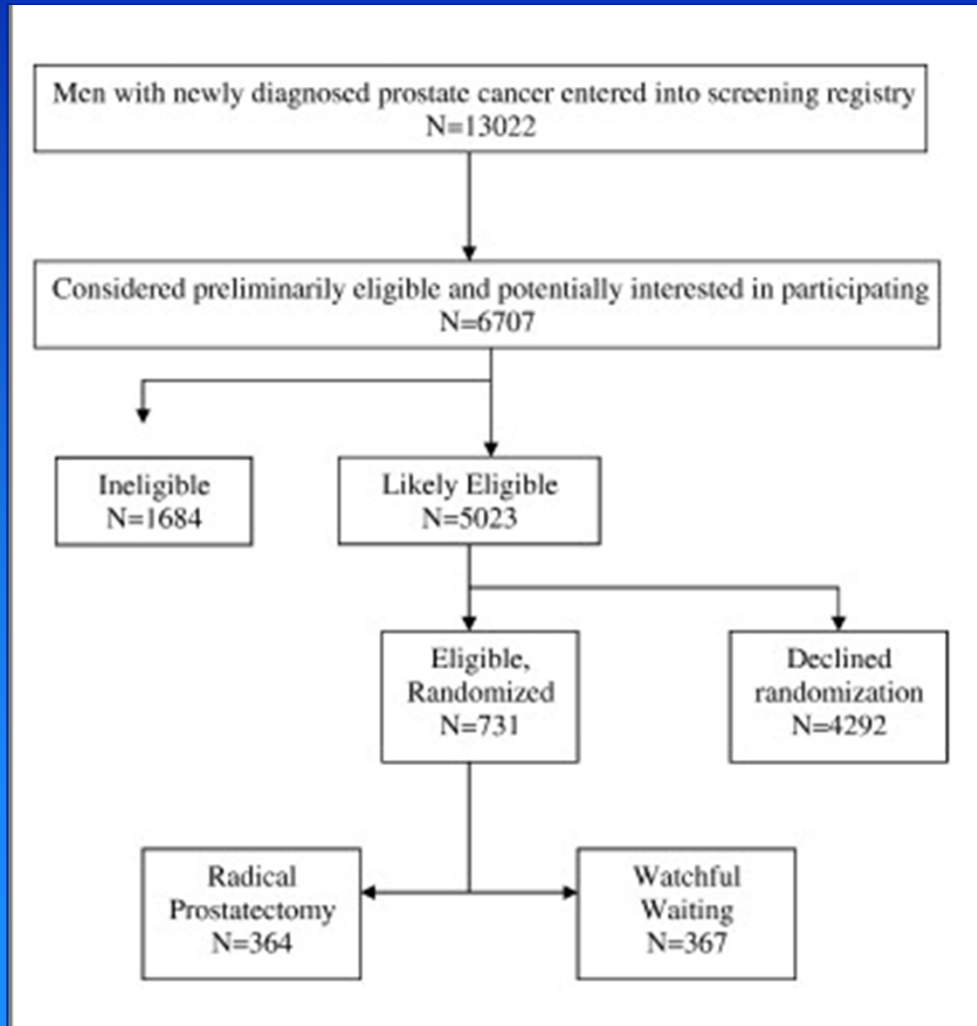


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VA/NCI/AHRQ Cooperative Studies Program



PIVOT Participant Flowchart

■ Prostate Cancer Intervention Versus Observation Trial (PIVOT)

- Designed to compare the benefits of radical prostatectomy and watchful waiting
- Results expected in mid-2010



NCI and the AHRQ Health Care Innovations Exchange

- NCI involved in funding at least seven projects in the Innovations Exchange
- Engaged in developing at least two

The screenshot shows the AHRQ Health Care Innovations Exchange website. The header includes the AHRQ logo and the text 'Agency for Healthcare Research and Quality'. Below the header, there is a search bar with the text 'AHRQ HEALTH CARE INNOVATIONS EXCHANGE' and a search button. The main content area displays search results for 'National Cancer Institute', showing 7 Innovation Profiles and 57 QualityTools. The first three Innovation Profiles are listed:

- Culturally Competent Outreach Programs Increase Cervical Cancer Screening** (10/14/2009)
The Chinese Women's Health Project uses two approaches to promote cervical cancer screening among women—mailing Chinese-language written materials to women, and home visits by bicultural workers.
- Individualized Stress Management Program Encourages Healthy Behaviors** (02/11/2009)
An individualized, self-directed tailored intervention assists adults in effectively managing stress, including through exercise, socialization, meditation, and/or relaxation.
- Educational Programs Bridge Communication Gaps Between Providers and Patients to Enhanced Knowledge about Cancer Among Deaf and Hard-of-Hearing Patients**
Targeted educational initiatives, such as a medical fellowship program on American Sign Language and videos on cancer education, improve access to medical care for people who are deaf or hard of hearing.

Below the Innovation Profiles, there is a section for QualityTools with the following list:

- Childhood Acute Lymphoblastic Leukemia Treatment – Physician Data Query (Professional Version)** (04/11/2008)
This PDQ cancer information summary for health professionals provides comprehensive, evidence-based information about the treatment of childhood acute lymphoblastic leukemia (ALL).
- Taking Time: Support for People with Cancer and the People Who Care About Them**
This tool for patients provides information about the psychological and social aspects of cancer.
- Ovarian Epithelial Cancer Treatment – Physician Data Query (PDQ®)** (Health Professional Version) (04/11/2008)

<http://www.innovations.ahrq.gov>



NCI/AHRQ Collaboration

Agency for Healthcare Research and Quality
Evidence Report/Technology Assessment
Number 122

Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials

Summary

Authors: Ford JG, Howerton MW, Bolen S, Gary TL, Lai GY, Tilburt J, Gibbons MC, Baffi C, Wilson RF, Feuerstein CJ, Tanpitukpongse P, Powe NR, Bass EB

Introduction

The burden of cancer falls disproportionately upon the medically underserved, and research studies are essential to improving health care in general, including for medically underserved populations. Clinical trials are used to evaluate efficacious prevention and treatment interventions; however, studies often fail to recruit the planned number of participants.¹ Trials often do not include an adequately diverse population to ensure broad generalizability of results.² Recent studies of patients enrolled in cancer treatment trials sponsored by the National Cancer Institute (NCI) have demonstrated that the following populations are underrepresented in terms of their participation in cancer treatment trials: the elderly, those of low socio-economic status, those living in rural areas and Latino/Hispanic, Asian/Pacific Islander and American Indian/Alaska native men and women, as well as African-American men.^{3,4} Since the 1980s cancer prevention trials have been conducted with participants at highest risk for disease to reduce the cancer burden, and as in treatment trials, adequate representation of underserved populations in prevention trials is desirable. Questions remain regarding the appropriate level of inclusion, i.e., whether it might depend on the prevalence of the condition/disease studied in the overall population. This issue has not been addressed adequately in the literature. Moreover, there is substantial uncertainty about what are important barriers and promoters of recruitment

of underrepresented populations, and what evidence-based interventions would address them.

At the request of and with the financial support of NCI, AHRQ commissioned a systematic review of the existing evidence on the recruitment of underrepresented populations into cancer clinical trials, to be performed by the Johns Hopkins University EPC. Specifically, the EPC investigators were asked to consider six key questions:

- Key Question 1: What methods (e.g., survey studies, focus groups) have been used to study strategies to recruit underrepresented populations into cancer prevention and treatment trials? We defined underrepresented populations as including the elderly, adolescents, those of low socioeconomic status, those living in rural areas, African Americans, Hispanics/Latinos, Asian Americans, and American Indians.
- Key Question 2: What measures of success (e.g., proportional representation relative to the U.S. population; proportional representation relative to incidence in a specified population) have been used to evaluate the efficacy and/or effectiveness of strategies for recruitment of underrepresented populations into cancer prevention and treatment trials?
- Key Questions 3 and 4: Which recruitment strategies (e.g., media appeals, incentives, etc.) have been shown to be efficacious and/or effective in increasing participation of



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Evidence-Based
Practice

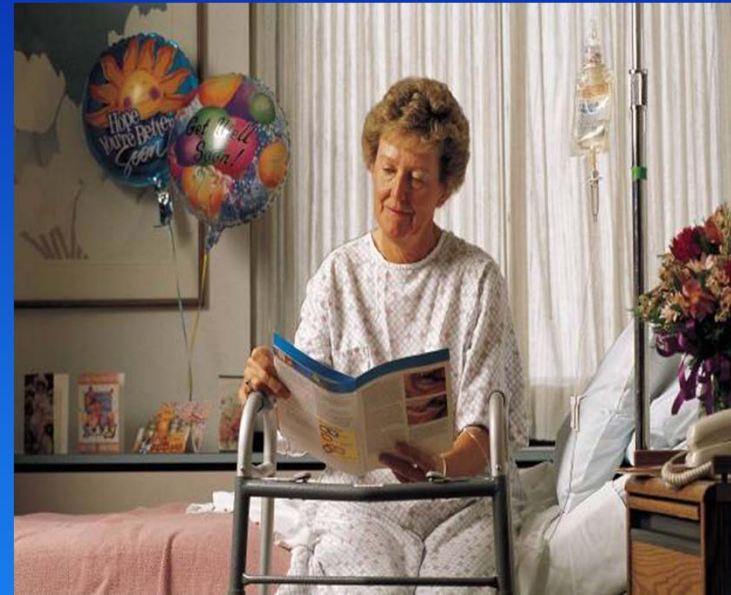
- AHRQ systematic review of existing evidence on recruitment of underrepresented populations to participate in cancer clinical trials
- Requested and supported by NCI
- Conducted by the Johns Hopkins University EPC

Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials, AHRQ – June 2005



CAHPS: The Importance of the Consumer's Voice

- Consumer Assessment of Healthcare Providers and Systems (CAHPS): Surveys in which consumers can assess the quality of care they receive
- Surveys developed for care in:
 - Ambulatory settings (e.g., health plans, physician offices)
 - Facilities (e.g., hospitals, nursing homes, dialysis facilities, home health care services)



More than 130 million Americans are enrolled in plans or have received treatment in facilities for which data are collected



CAHPS Survey for Cancer Care

- Collaboration between AHRQ and NCI
- October 2009 through September 2011
- Survey results to be used for QI and consumer choice
- Survey and instructions available free of charge
- Stakeholders to be involved in development
- Rigorous cognitive and field testing





CAHPS Questions: Potential Content

■ Patient-centered care

- Information sharing, coordination of care, management of symptoms, provider communication

■ Treatment alternatives

- Was information about treatment alternatives offered? Information about side effects?

■ Patient safety

- Were procedures used to ensure that right treatment was given to the right patient?





U.S. Preventive Services Task Force (USPSTF)

The USPSTF has issued at least 20 recommendations involving cancer since 1996, including five since 2007

Cancer Recommendations	Grade
Screening for Skin Cancer	I
Tobacco Counseling and Interventions	A
Screening for Colorectal Cancer (Ages 50-75)	A
Screening for Prostate Cancer (75 or under)	I
Routine Aspirin or NSAIDs – Colon Cancer	D



Comparative Effectiveness: AHRQ Effective Health Care Program



- Created in 2005, authorized by Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003
- To improve the quality, effectiveness, and efficiency of health care delivered through Medicare, Medicaid, and S-CHIP programs
 - Focus is on what is known **now**: ensuring programs benefit from **past** investments in research and what research **gaps** are critical to fill
 - Focus is on **clinical effectiveness**



AHRQ Comparative Effectiveness Research

AHRQ Home | Questions? | Contact Us | Site Map | What's New | Browse | Información en español | E-mail Updates

Effective Health Care Program

Helping You Make Better Treatment Choices

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Research for Policymakers, Researchers, and Others

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Submit a Suggestion for Research

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Newsletter

What is Comparative Effectiveness Research

What is the Effective Health Care Program

Who is Involved in the Effective Health Care Program

Better Methods for Better Research

Read the latest chapters in the Effective Health Care Program's Methods Guide for Effectiveness and Comparative Effectiveness Reviews.

[More Info >](#)

1 2 3 4 || ▶

Available for Comment

Key Questions

Open for comment until Nov. 5, 2009

[Comparative Effectiveness of Diagnosis and Treatment of Obstructive Sleep Apnea in Adults](#)

The Effective Health Care Web Site has a New Design

The Effective Health Care Web site has been redesigned and customized to improve your experience. Some of the new features include:

- Easier searching for reports by date, condition, audience, or keyword.
- Links to audience-specific offerings from any page.
- Expanded information on comparative effectiveness research.
- A redesigned dynamic newsletter.
- Easy-to-find opportunities to comment on the Program's projects.

Product Announcements

Oct. 19, 2009
[Comparative Effectiveness of Angiotensin Converting Enzyme Inhibitors or Angiotensin II Receptor Blockers Added to Standard Medical Therapy for Treating Stable Ischemic Heart Disease – Final Research Review](#)

Oct. 8, 2009
[Comparative Effectiveness of Diagnosis and Treatment of Obstructive Sleep Apnea in Adults – Draft Key Questions](#)

Sept. 22, 2009
[Assessment of the Need to Update Comparative Effectiveness Reviews: Report of an Initial Rapid Program Assessment \(2005–2009\)](#)

Number 2

Effective Health Care

Effectiveness of Noninvasive Diagnostic Tests for Breast Abnormalities
Executive Summary

Effective Health Care Clinician's Guide

Treatments for Clinically Localized Prostate Cancer

This guide summarizes clinical evidence comparing the effectiveness and safety of treatments for clinically localized prostate cancer. It discusses expectant management and three active treatments (radical prostatectomy, radiation therapy, and hormonal therapy). This guide does not cover nutritional supplements. It also does not cover some newer treatments (cryotherapy, high-intensity focused ultrasound, and laparoscopic or robotic-assisted prostatectomy) for which there is little research about comparative effectiveness. This guide does not address strategies to prevent or screen for prostate cancer or strategies to treat advanced prostate cancer.

Effective Health Care

Treating Prostate Cancer

A Guide for Men With Localized Prostate Cancer

Most men have time to learn about all the options for treating their prostate cancer. You have time to talk with your family and to discuss your options with your doctor or nurse. This guide can help you think about what is best for you — now and in the future.

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<http://effectivehealthcare.ahrq.gov>



Essential Questions Posed by Comparative Effectiveness





Essential Questions Posed by Comparative Effectiveness



Is this treatment right?

Is this treatment right for me?



Priority Conditions for the Effective Health Care 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, attention-deficit hyperactivity disorder 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



AHRQ EHC Products Specific to Cancer

- **Particle Beam Radiation Therapies for Cancer –**
Technical Brief, *Published September 2009*
- **Comparative Effectiveness of Medications to Reduce
Risk of Primary Breast Cancer in Women –**
Comparative Effectiveness Review, *Published September
2009*
- **Stereotactic Radiosurgery for Extracranial Solid
Tumors –** Technical Brief, *Draft Completed*
- **Comparative Effectiveness of Core Needle Biopsy and
Surgical Excision Biopsy for Diagnosing Breast
Lesions –** Comparative Effectiveness Review, *Draft
Completed*
- **Comparative Effectiveness and Safety of
Radiotherapy Treatments for Head and Neck Cancer –**
Comparative Effectiveness Review, *Draft Completed*



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Comparative Effectiveness and the Recovery Act

- The American Recovery and Reinvestment Act of 2009 includes \$1.1 billion for comparative effectiveness research:
 - AHRQ: \$300 million
 - NIH: \$400 million (appropriated to AHRQ and transferred to NIH)
 - Office of the Secretary: \$400 million (allocated at the Secretary's discretion)



Federal Coordinating Council appointed to coordinate comparative effectiveness research across the federal government



Definition: IOM

- Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers and policy makers to make informed decisions that will improve health care at both the individual and population levels.

*National Priorities for Comparative Effectiveness Research
Institute of Medicine Report Brief*

June 2009

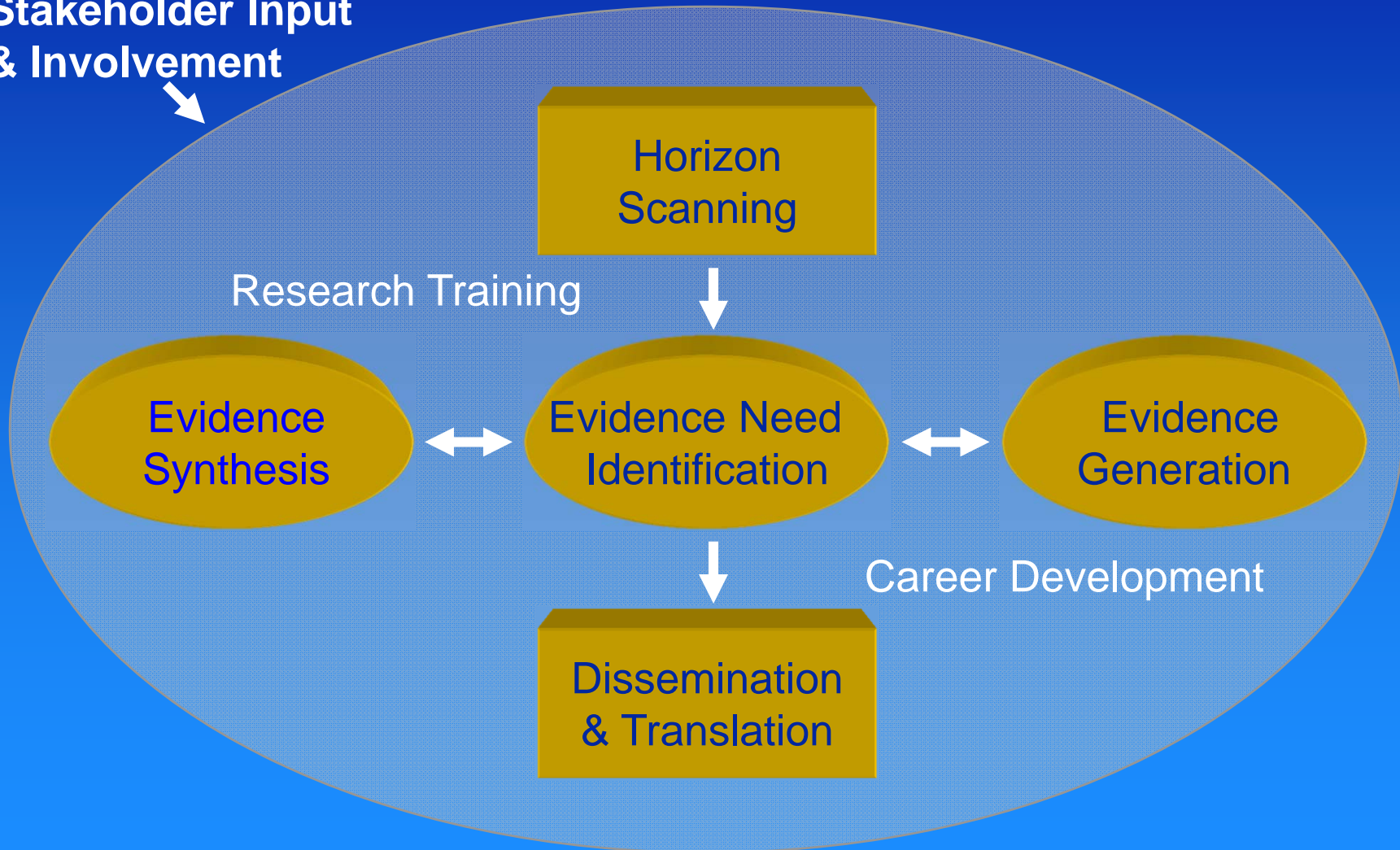


Definition: Federal Coordinating Council

- CER is the conduct and synthesis of research comparing the benefits and harms of various interventions and strategies for preventing, diagnosing, treating, and monitoring health conditions in real-world settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision makers about which interventions are most effective for which patients under specific circumstances.

Conceptual Framework

Stakeholder Input
& Involvement





AHRQ Operating Plan for Recovery Act's CER Funding

- **Stakeholder Input and Involvement:** To occur throughout the program
 - **Horizon Scanning:** Identifying promising interventions
 - **Evidence Synthesis:** Review of current research
 - **Evidence Generation:** New research with a focus on under-represented populations
 - **Research Training and Career Development:** Support for training, research and careers
-



IOM's 100 Priority Topics

- *Initial National Priorities for Comparative Effectiveness Research (June 20, 2009)*
- Topics in 4 quartiles; groups of 25.
- First quartile is highest priority. Included in first quartile:
 - Management strategies for localized prostate cancer
 - Imaging technology for diagnosing, staging and monitoring patients with cancer
 - Genetic and biomarker testing

Report Brief Available At <http://www.iom.edu>





Translating the Science into Real-World Applications

- Examples of Recovery Act-funded Evidence Generation projects:
 - Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE): First coordinated national effort to establish a series of pragmatic clinical comparative effectiveness studies (\$100M)
 - Request for Registries: Up to five awards for the creation or enhancement of national patient registries, with a primary focus on the 14 priority conditions (\$48M)
 - DEcIDE Consortium Support: Expansion of multi-center research system and funding for distributed data network models that use clinically rich data from electronic health records (\$24M)



Additional Proposed Investments

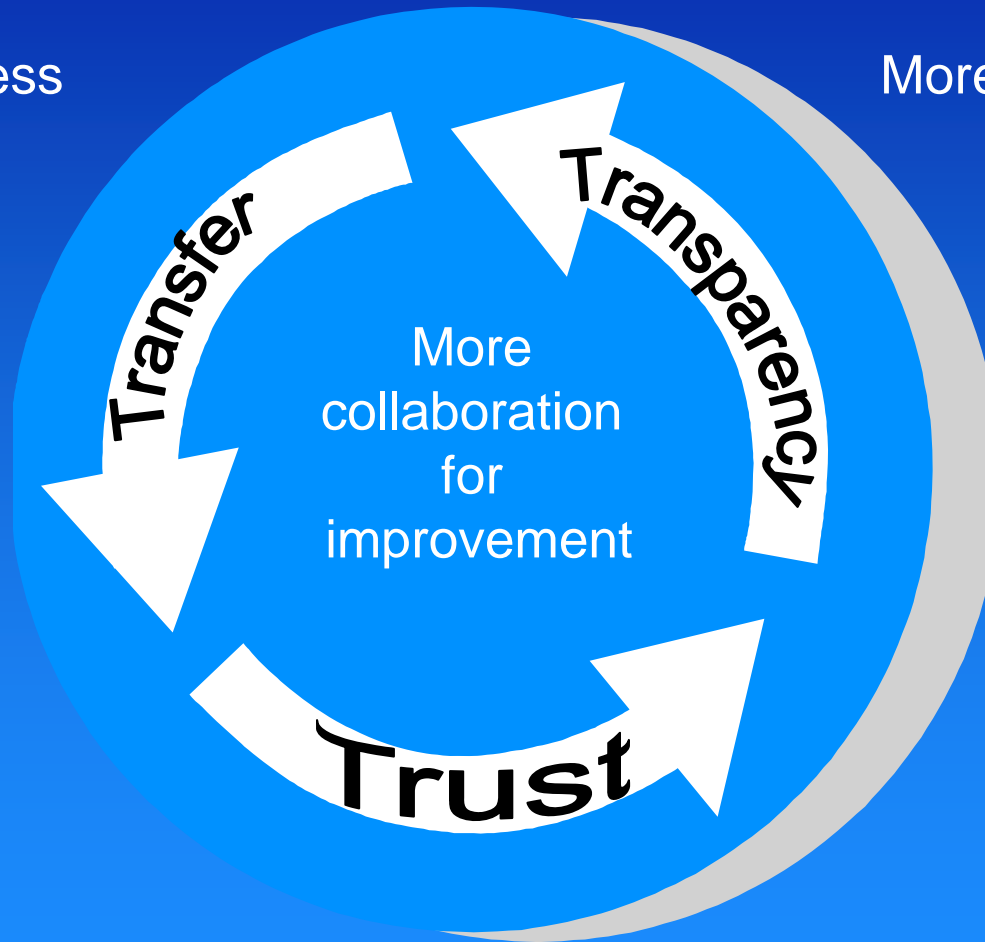
- Supporting AHRQ's long-term commitment to bridging the gap between research and practice:
 - Dissemination and Translation
 - Between 20 and 25 two-three-year grants (\$29.5M)
 - Eisenberg Center modifications (3 years, \$5M)
 - Citizen Forum on Effective Health Care
 - Formally engages stakeholders in the entire Effective Health Care enterprise
 - A Workgroup on Comparative Effectiveness will be convened to provide formal advice and guidance (\$10M)





Transparency and Transformation

More effortless
information
sharing with
health IT



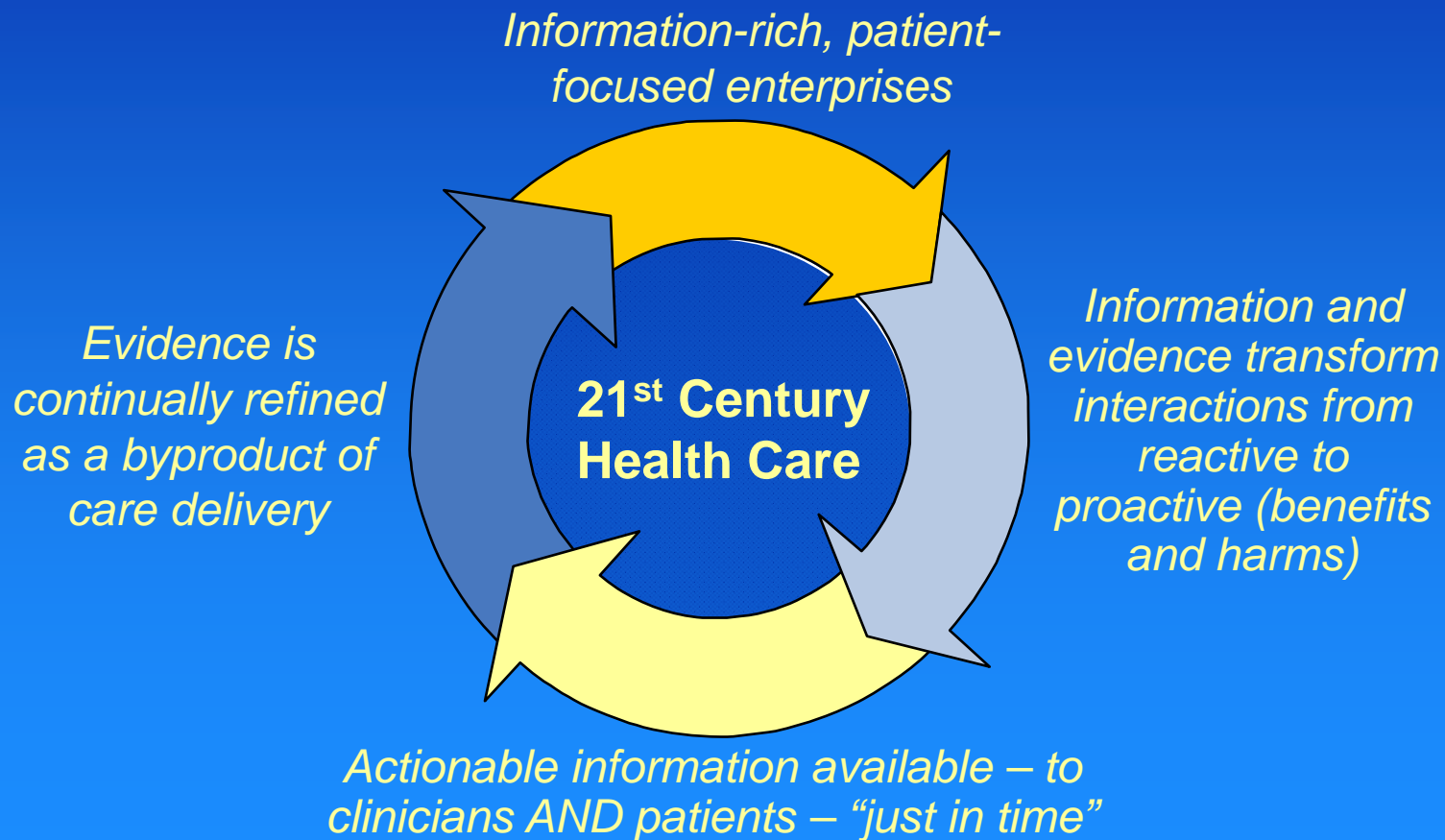
More transparent
cost/quality
information

More trust among purchasers, providers, and consumers



Would Anything Have Helped Aunt Jeanne?

It's unlikely, yet potential exists for major breakthroughs in a transformed health care system





Getting to Best Possible Care

- **Moving the ball right now:**
 - Increased public reporting
 - Payment initiatives
 - Common performance measures for public and private sectors
 - Local collaboratives
- **Longer-range goals:**
 - Reform leading to quality improvement
 - P4P: Rewarding the 'leading edge' *and* bringing others along
 - Better information for consumers
 - Effective use of health IT



CER and Innovation



- CER will enhance the best and most innovative strategies
- Can open up new populations for which something can be useful in
- Can bring early attention to potential issues



Where to From Here?

- Anticipate downstream effects of policy applications
 - Make sure that comparative effectiveness is "descriptive, not prescriptive"
 - Create a level playing field among all stakeholders, including patients and consumers
 - Use research to address concerns of patients and clinicians
 - Address gaps in quality and resolve conflicting or lack of evidence about most effective treatment approaches
-



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