Comparative Effectiveness Research: AHRQ & NCI

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National Cancer Institute Board of Scientific Advisors

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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)

Overall Quality of Health Care, 2008 (measures compiled by the federal Agency for Healthcare Research and Quality

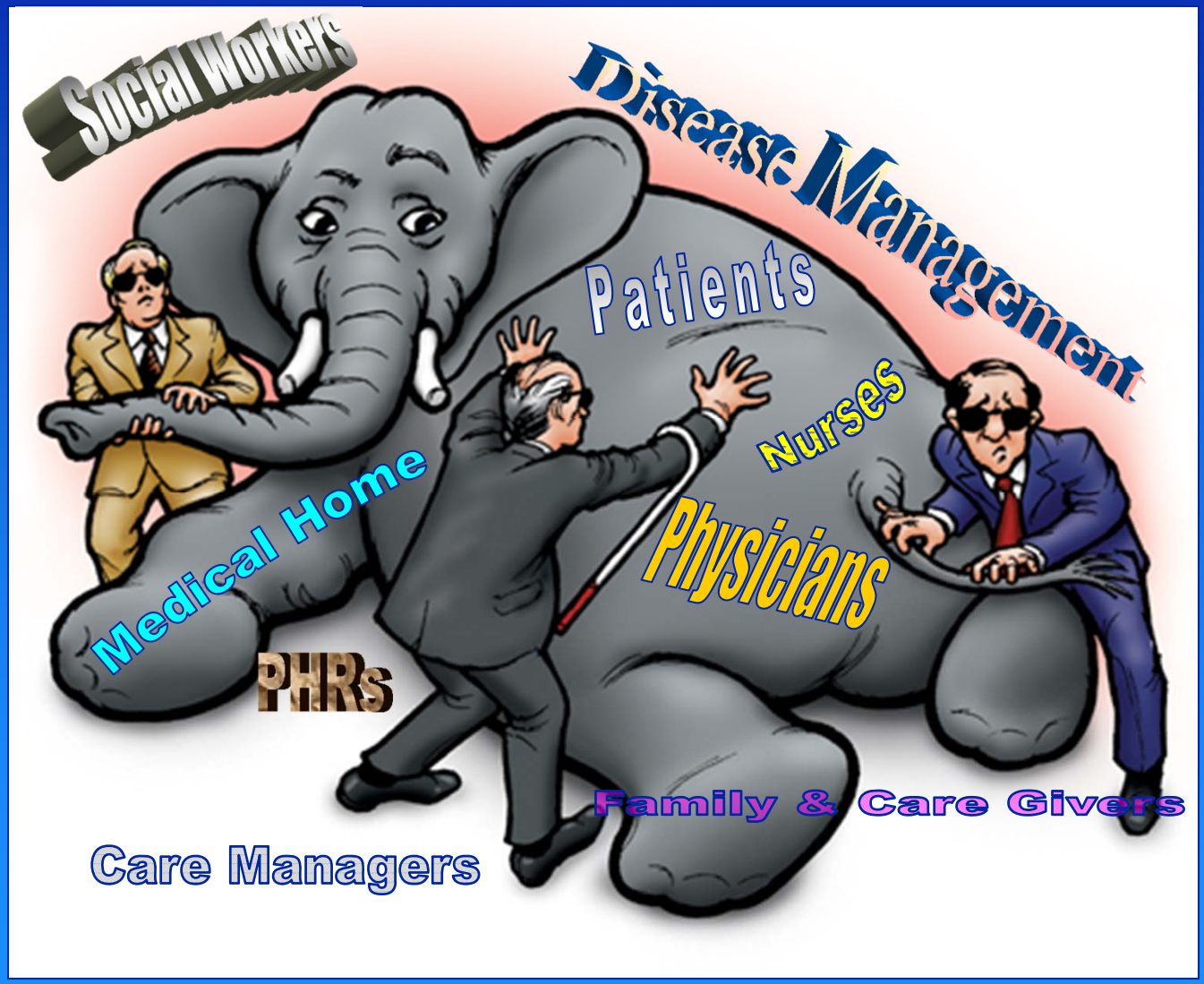
Lower — Average — Higher

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

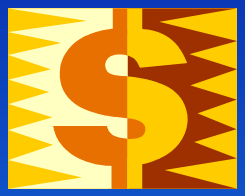
CDC

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



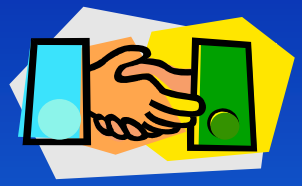
Health IT Research Funding

- 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



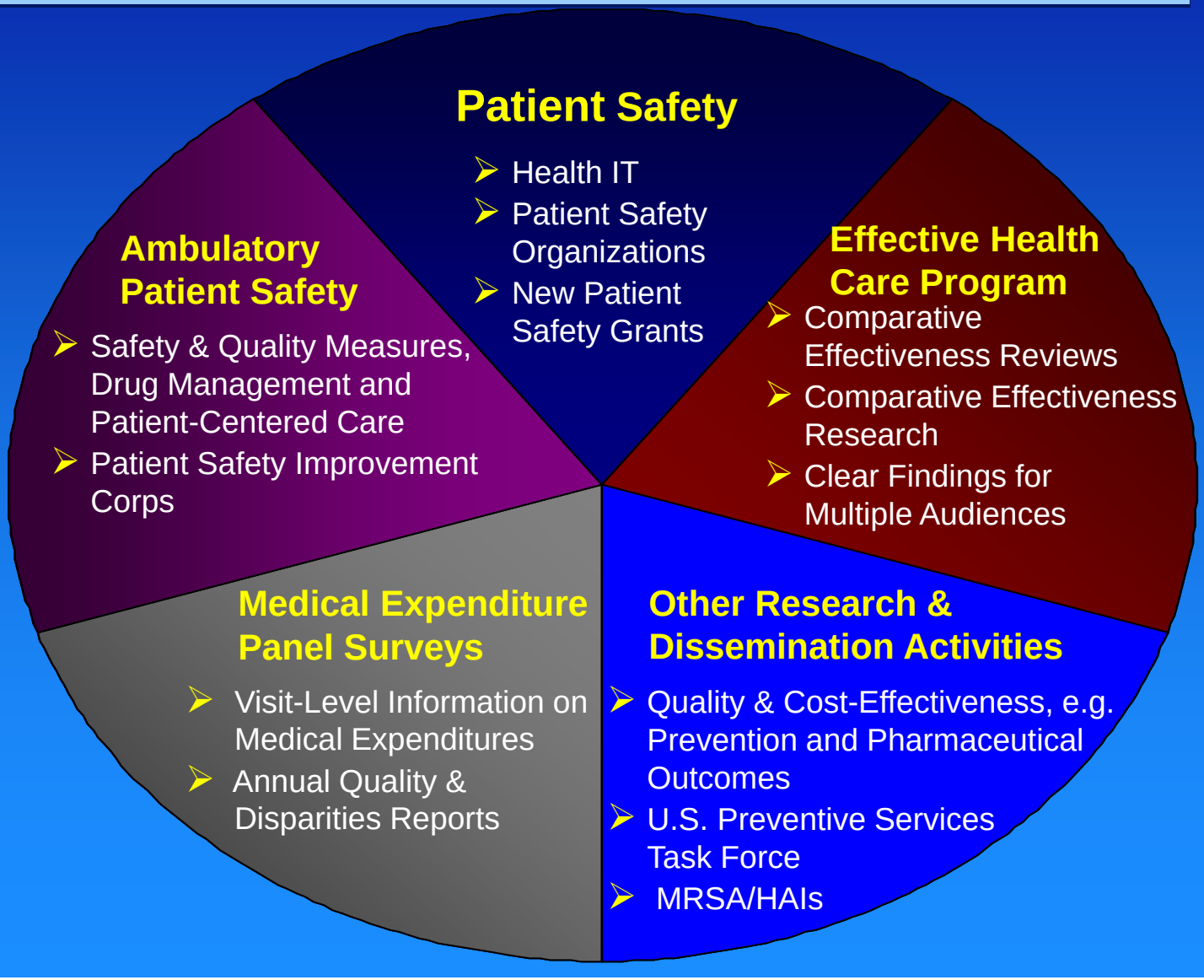
Promote Collaboration and Dissemination

- 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



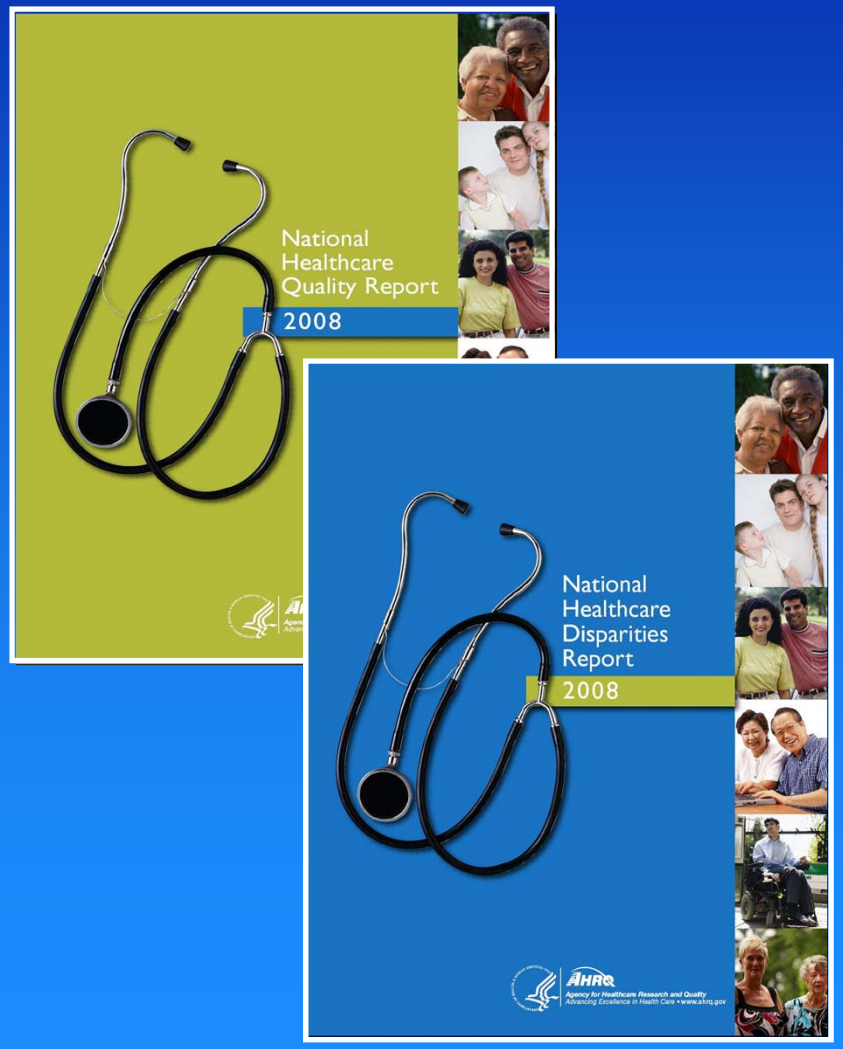
AHRQ 2009: New Resources, Ongoing Priorities

- $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

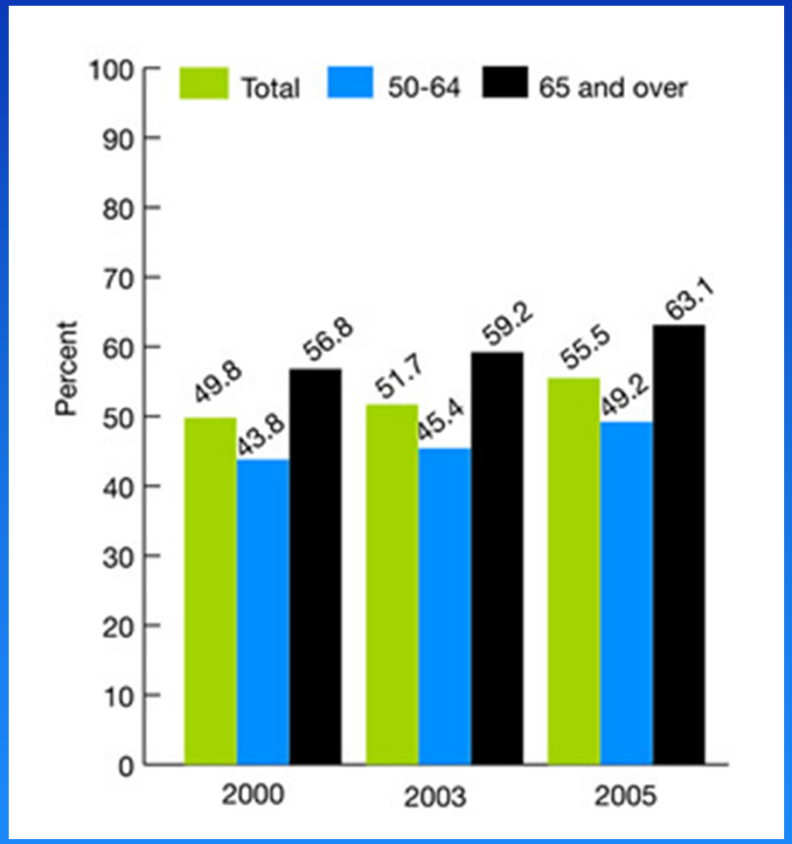
Key themes in 2008 reports:

- 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

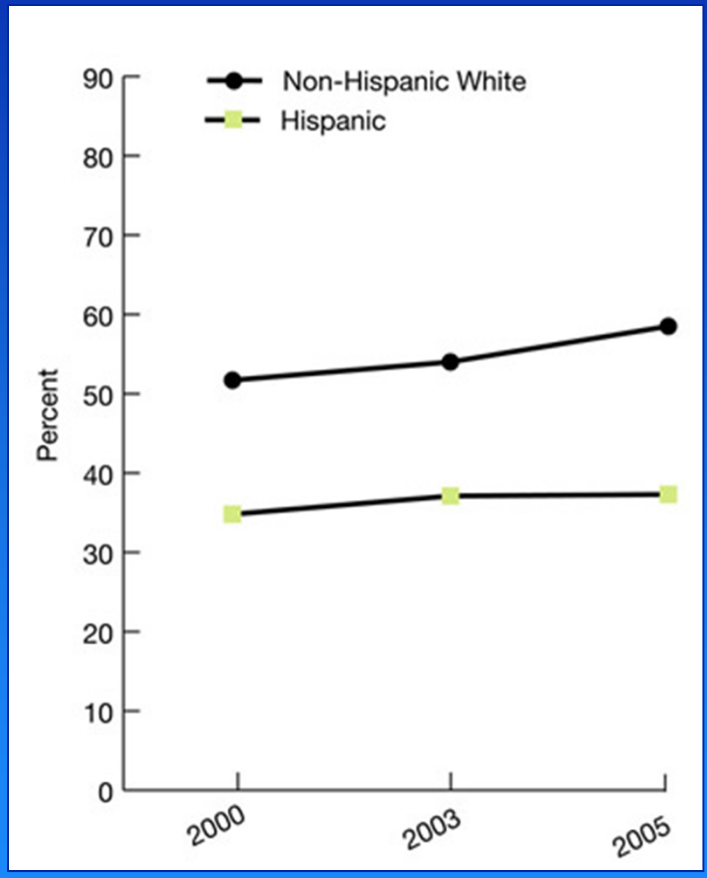
- Colorectal cancer screenings: only 55 percent of patients 50 and over
- Geographic variation for colonoscopy or sigmoidoscopy widespread
- Percentage of women under age 70 treated for breast cancer with breast-conserving surgery who received radiation therapy to the breast within 1 year of diagnosis 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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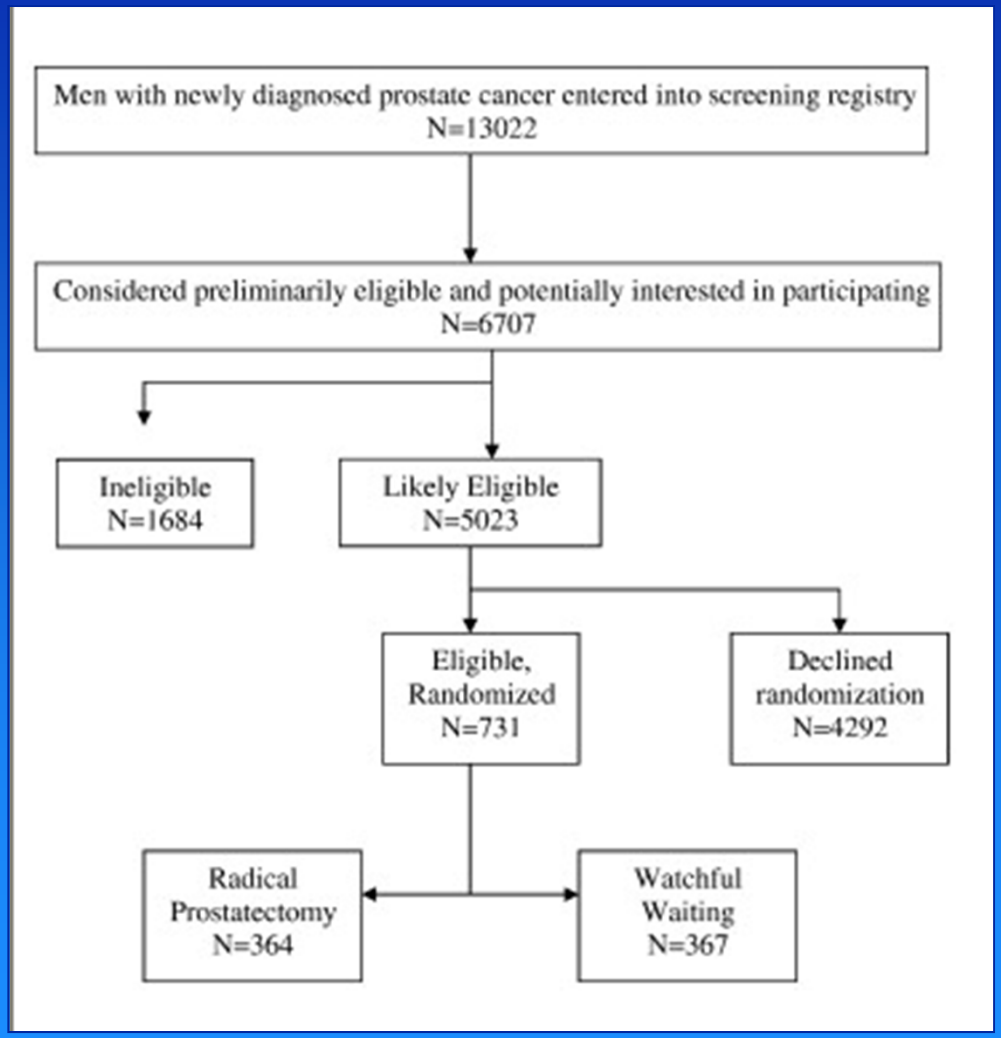
VA/NCI/AHRQ Cooperative Studies Program



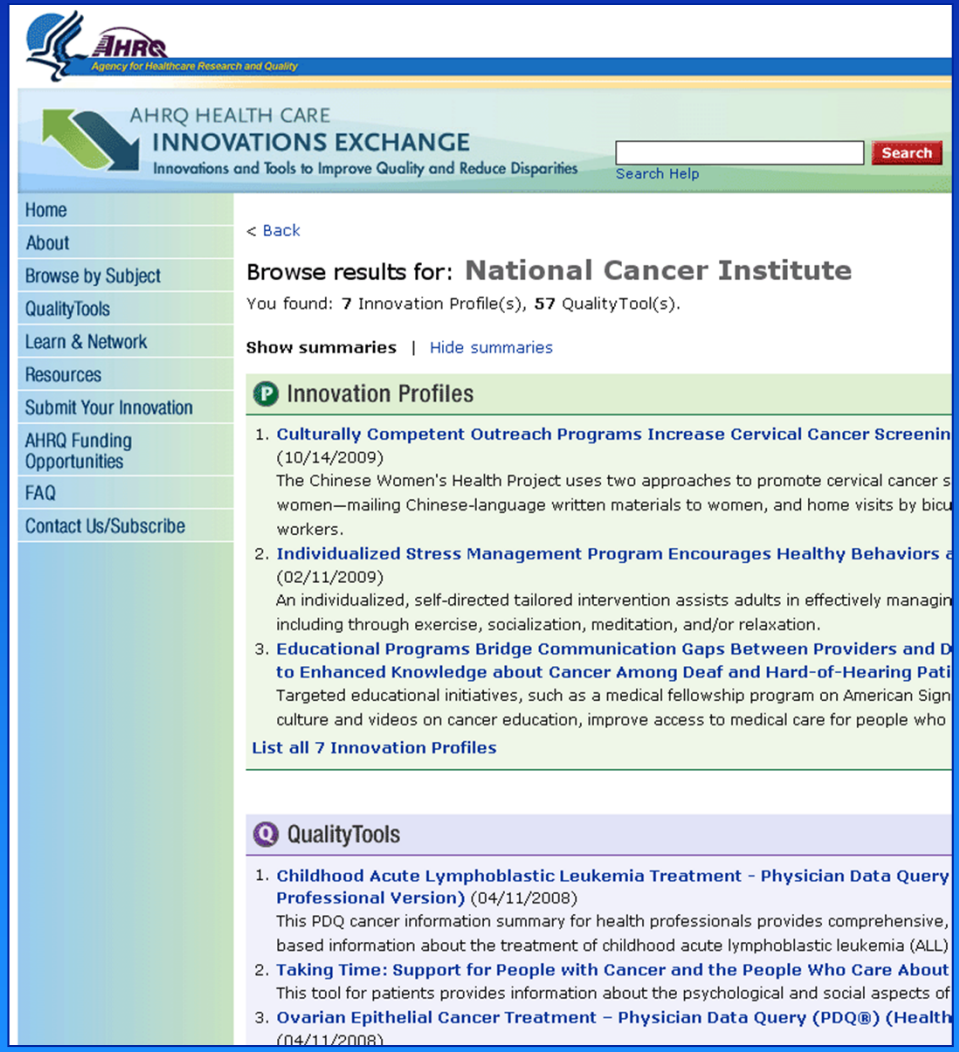
PIVOT Participant Flowchart

- Prostate Cancer Intervention Versus Observation Trial (PIVOT)
  - Designed to compare the benefits of radical prostatectomy and watchful waiting
  - Results expected in mid-2010

Contemporary Clinical Trials. 2009;30(1):81-87

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



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

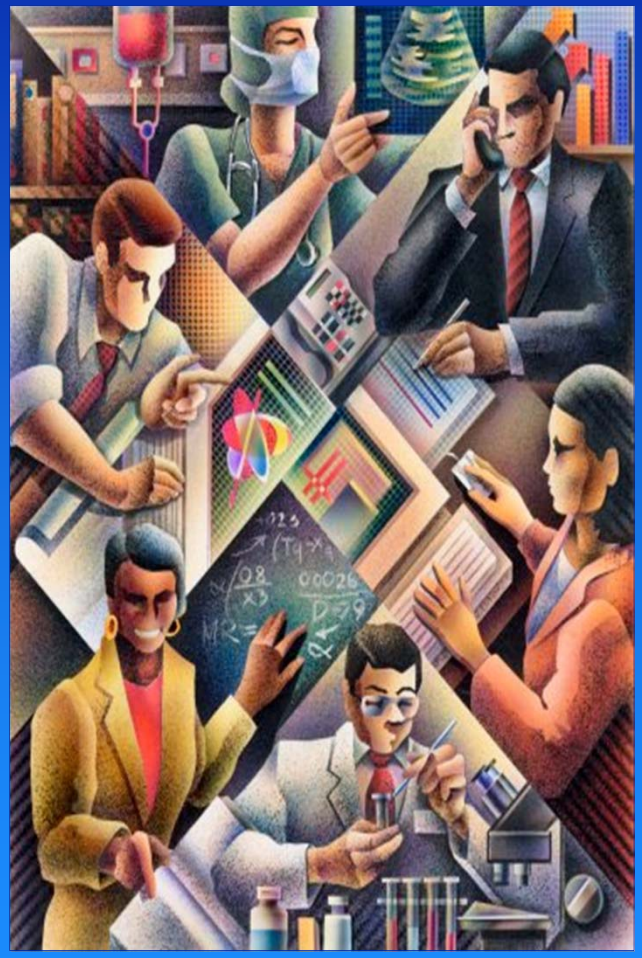
- **Patient-centered care**
  - Information sharing, coordination of care, management of symptoms, provider communication
- **Treatment alternatives**
  - Was information about treatment alternatives offered? Information about side effects?
- **Patient safety**
  - Were procedures used to ensure that 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

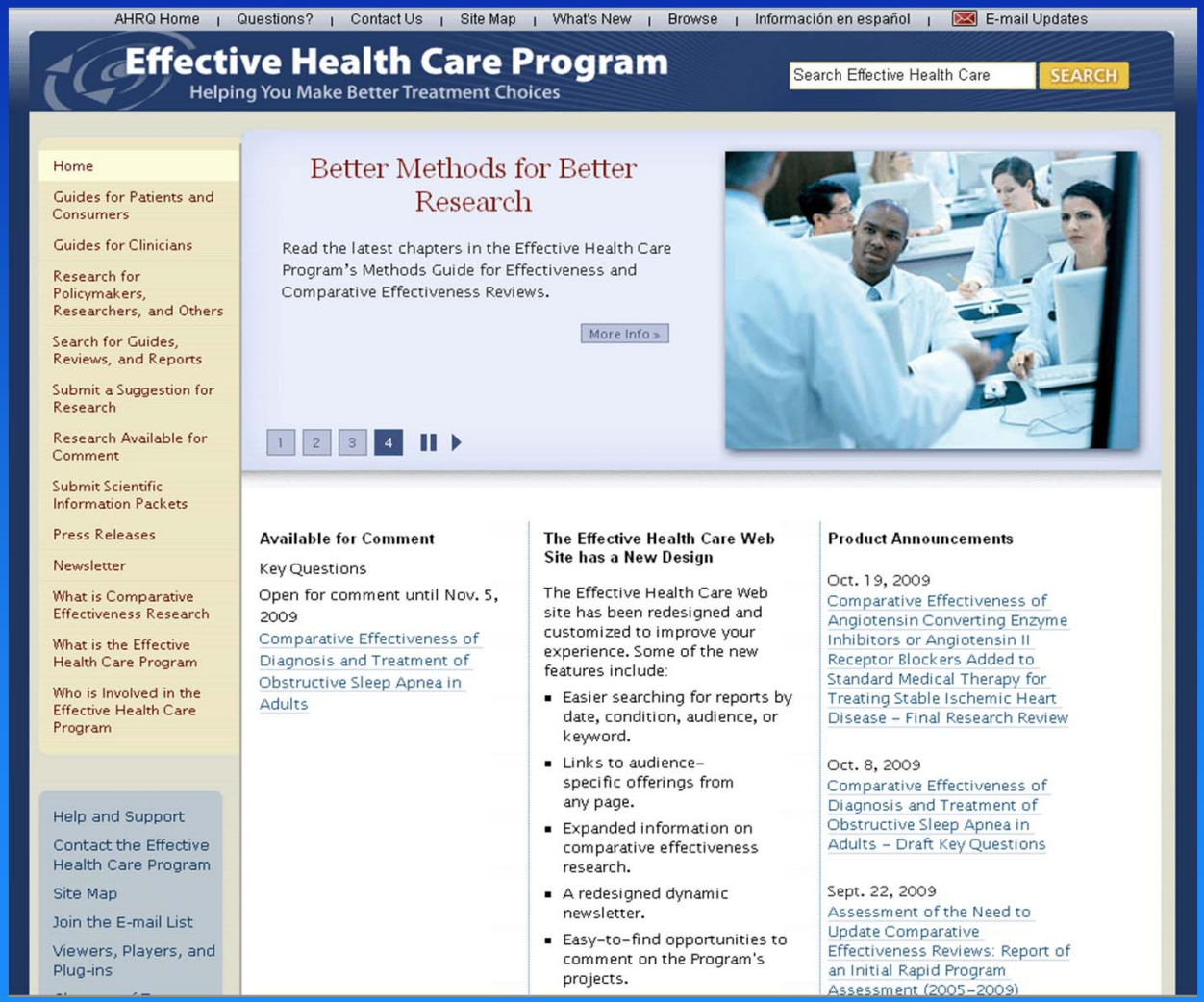
Cancer Recommendations	Grade
Screening for Skin Cancer	I
Tobacco Counseling and Interventions	A
Screening for Colorectal Cancer (Ages 50-75)	A
Screening for Prostate Cancer (75 or under)	I
Routine Aspirin or NSAIDs – Colon Cancer	D

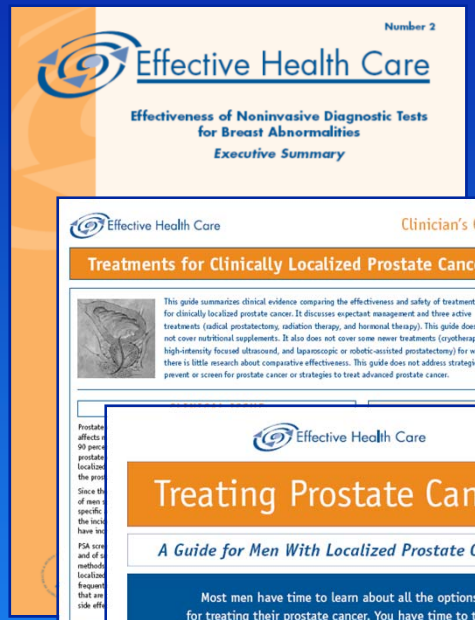
Comparative Effectiveness: AHRQ Effective Health Care Program

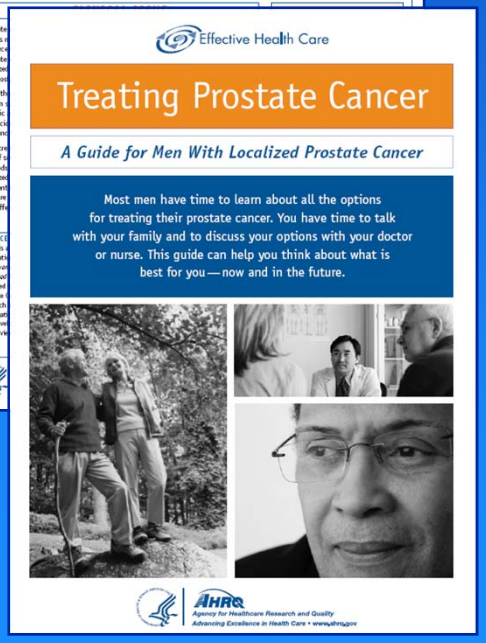


- Created in 2005, authorized by Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003
- To improve the quality, effectiveness, and efficiency of health care delivered through Medicare, Medicaid, and S-CHIP programs
  - Focus is on what is known ***now***: ensuring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

AHRQ Comparative Effectiveness Research







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

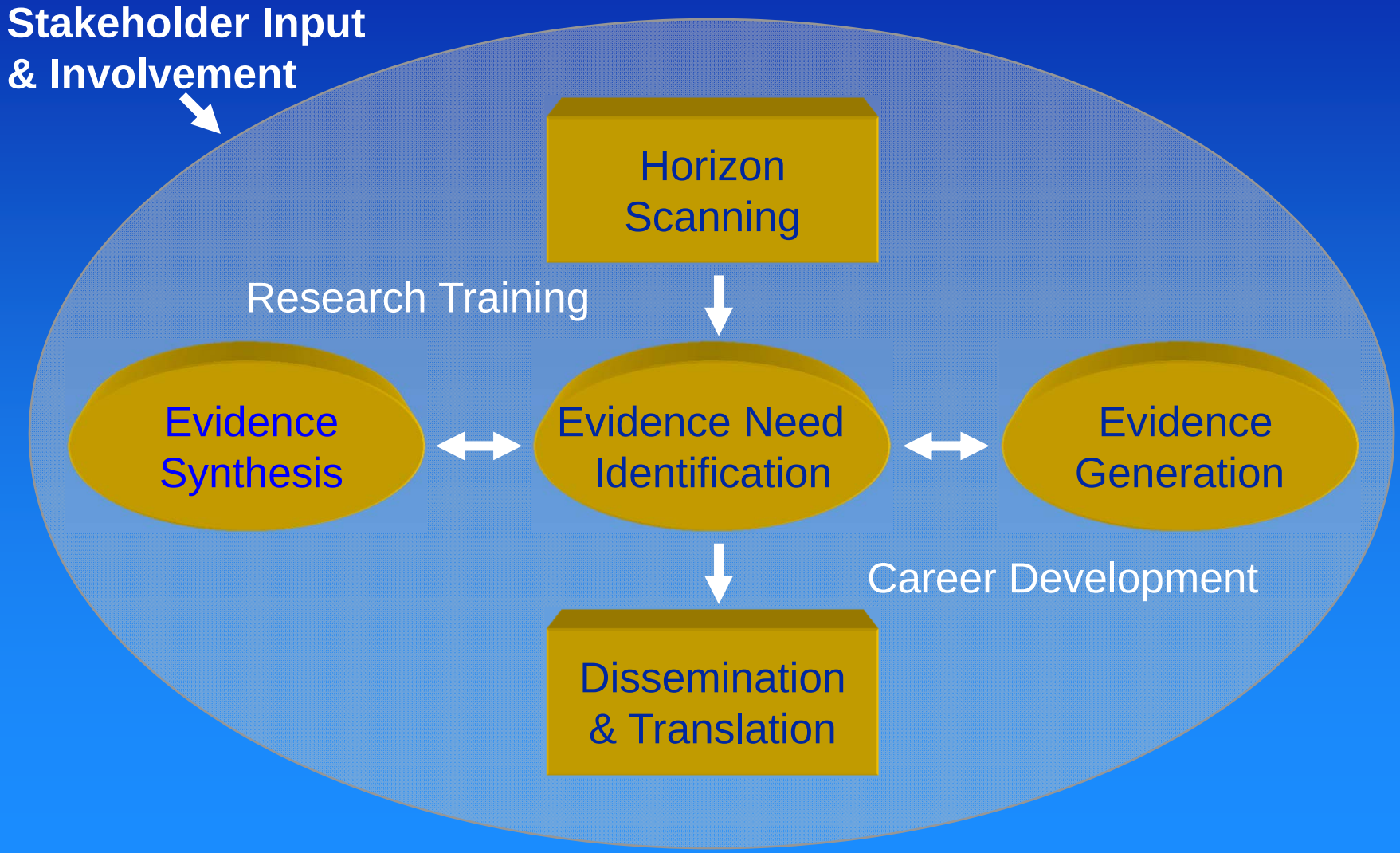
- Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers 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



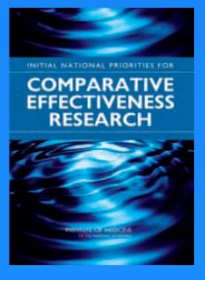
AHRQ Operating Plan for Recovery Act's CER Funding

- **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

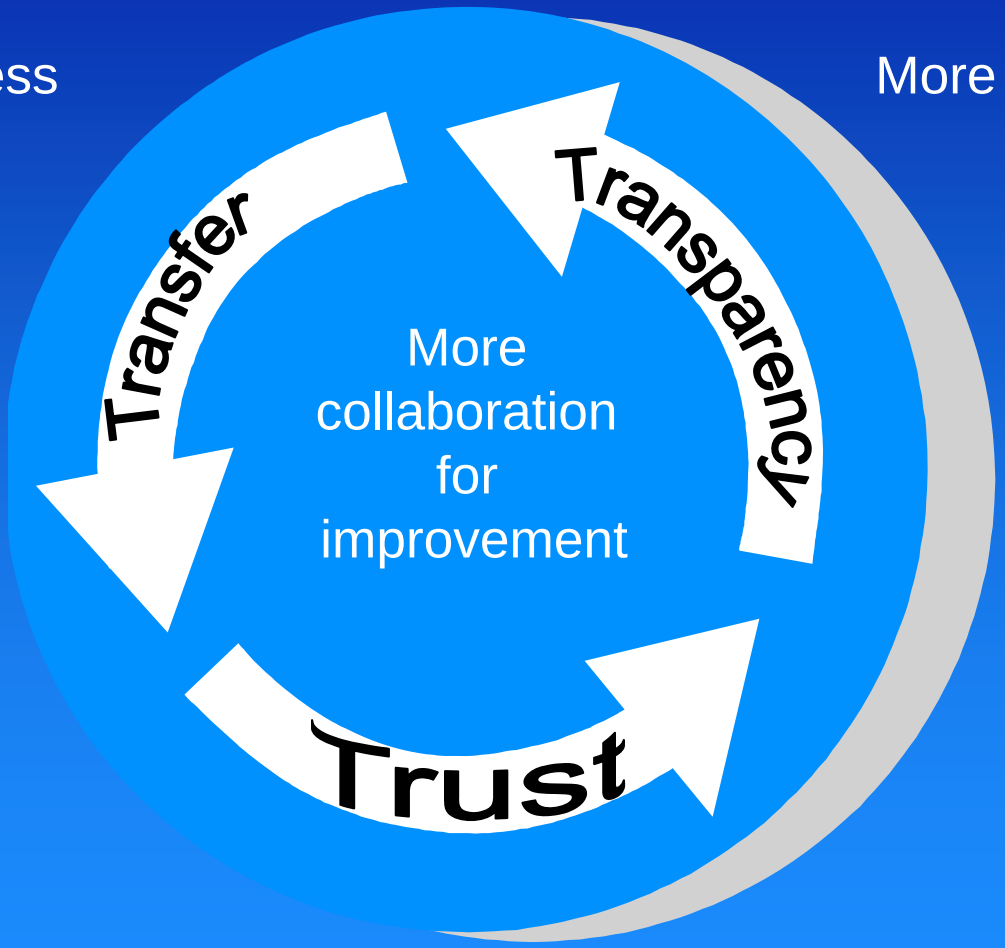
- Examples of Recovery Act-funded Evidence Generation projects:
  - Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE): First coordinated national effort to establish a series of pragmatic clinical comparative effectiveness studies ($100M)
  - Request for Registries: Up to 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

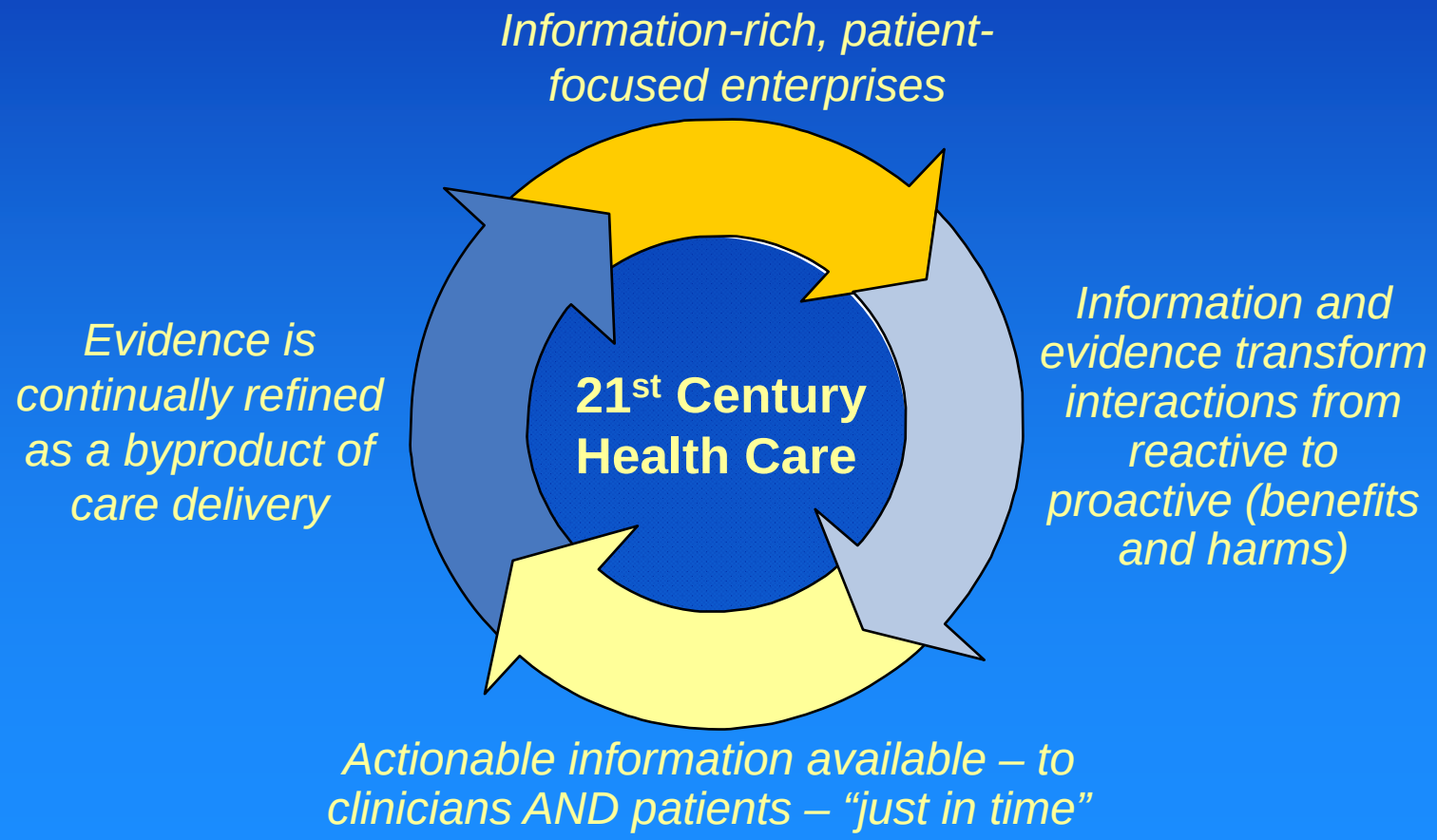


More transparent cost/quality information

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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