Comparative Effectiveness Research: Recent Past to Present

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Objectives of this Lecture

• Define comparative effectiveness research (CER)
• Describe desire for evidence-based medicine, observed small-area practice variation, and the need to bend the cost curve as motivators of CER
“...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.”

----Institute of Medicine, 2009
“Comparative effectiveness research is designed to inform health care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.”

----Agency for Healthcare Research and Quality
CER is all about generating information that helps stakeholders make decisions.
The Problem

“The United States spends more on health care than any other nation in the world, yet it ranks poorly on nearly every measure of health status. How can this be?”

Steven Schroeder, Shattuck Lecture 2007

“Better information about the costs and benefits of different treatment options...could eventually lower health care spending...”

Peter Orszag, Former head of CBO, OMB, 2007

“I think there’s a general recognition that the system we have in America is fundamentally broken. We spend more than any country on Earth. Our health results look like we’re a developing nation.”

Secretary Kathleen Sebelius, HHS, 2009
Two Big Forces Led to a Focus on CER

- Desire to deliver clinical care based on evidence that meets the needs of stakeholders
- Desire to improve effectiveness of care while containing costs
Weak Evidence in Guidelines: Recommendations Based on Randomized Trials

- Atrial fibrillation: 11.7%
- Heart failure: 26.4%
- Peripheral arterial disease: 15.3%
- ST-Elevation-MI: 13.5%
- Perioperative beta-blockers: 12.0%
- Secondary prevention: 22.9%
- Stable angina: 6.4%
- Supraventricular arrhythmias: 6.1%
- Unstable angina: 23.6%
- Valvular disease: 0.3%
- Ventricular arrhythmia: 9.7%
- Percutaneous angioplasty: 11.0%
- Bypass surgery: 19.0%
- Pacemaker: 3.5%
- Radionuclide imaging: 4.8%

Tricoci P et al. JAMA 2009
Early Appreciation of Medical Evidence (late 1980’s)

To ensure high-quality medical care:

1. Analyze evidence of the effectiveness, risks and costs of various medical practices (and define appropriateness of these practices)
2. Monitor existing practices and compare them against accepted standards
3. Change the behavior of practitioners to ensure that care delivered meets the standards

• Gives examples of angioplasty vs. coronary bypass surgery (no RCT’s at the time this article was written)

• Screening for colorectal cancer – difficulties with synthesizing indirect evidence from different sources about immediate risks, immediate long-term benefits, trade-offs, costs

• Little information available on patient-preferences

• Decisions made on “potential benefit”
Their recommendations:

- Formal examination of practices and development of practice standards based on evidence
- Analyses should estimate explicitly the magnitudes of the effects of different options on health and economic outcomes
- Better coordination of research
- Higher standards for publications
The U.S. Preventive Services Task Force est. 1984

- Convened by the U.S. Public Health Service
- Independent panel of experts in prevention and primary care
- Conducts rigorous, impartial assessments of the scientific evidence for the effectiveness of a broad range of clinical preventive services

Cochrane Collaboration est. 1993

- An international, non-profit organization
- Produces systematic reviews of healthcare interventions, and promotes the search for evidence in the form of clinical trials and other studies of the effects of interventions.
Advancement of Health Services Research (circa late 1980’s)

• Prompted by John Wennberg’s research on practice variations and Robert Brook’s research at RAND

Medicare spending per capita in the US, by Hospital Referral Regions in 2008
DENOMINATOR DEFINITION:
100% of Medicare enrollees age 65–99 with full Part A entitlement and no HMO enrollment during the measurement period. Age, gender, race, and eligibility are determined using the Denominator file.

NUMERATOR DEFINITION:
Number of discharges with ICD-9-CM procedure codes 37.22, 37.23; 88.55–88.57.

ADJUSTMENTS:
Rates are adjusted for age, sex and race using the indirect method, using the U.S. Medicare population as the standard. Gender-specific rates are age and race adjusted; race-specific rates are age and sex adjusted.
Age-adjusted death rates; 1988-92
Age-Adjusted Rates of Procedures For Six Common Surgical Procedures In Rhode Island, Maine, and Vermont (1975)

T & A = tonsillectomy/adenoidectomy
Wennberg published a call to action a ---

Recommendations included:

• Closer monitoring of medical practices in local hospital markets using epidemiology
• Researchers must address unanswered questions about the effectiveness of many common therapeutic interventions (are they beneficial and relatively safe)

Robert Brook and colleagues at Rand

• Information is virtually non-existent about the following: why do variations occur, are higher rates sometime appropriate use of services, is health improved by higher procedure rates?

• Urged understanding “clinical links” between the purported needs for use of a procedure or service (“indications”) and the ultimate results of that care (“outcomes”)

*Geographic variations in the use of services: do they have any clinical significance?* Health Affairs 1984 3(2):63-73
Recommendations included:

• Determine whether variation is over- or underuse
• Establish scientific bases for modifying the delivery of medical care in ways that only minimally affect patients’ health
• Develop an economically feasible method to examine the appropriateness of utilization of services (that is acceptable to physicians)
Gains in Health Services Research (circa late 1980’s)

- Concerns on Capitol Hill about health care costs and viability of Medicare
- William Roper was head of Health Care Financing Administration (HCFA, now CMS) got \textit{effectiveness research} as in item in proposed FY 1990 budget
- Later as White House health policy advisor advocated for “effectiveness research”

Clinton Health Reform Activities (1993)

• President Clinton urged Congress "to fix a health care system that is badly broken..."

• “Our system rewards clinicians for providing more services but not for keeping patients healthier [i.e. delivering effective care]. The structure of the health care system should shift toward rewarding doctors and health plans that treat patients with their long-term health needs in mind and rewarding patients who make sensible decisions about maintaining their own health.”
Agency for Health Care Policy and Research Gained Prominence (now AHRQ)

- Promoted by legislation to be a Public Health Service agency (1989)
- Remarkable change in funding for health services research with this move
AHRQ’s Current Mission

To improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Information from AHRQ's research helps people make more informed decisions and improve the quality of health care services.
“While this brave new world of health care presents wonderful opportunities, it also creates challenges. Chief among them is how to evaluate these innovations and determine which represent added value, which offer minimal enhancements to current choices, which fail to reach their potential, and which work for some patients and not for others.”
Premise: it is possible to constrain health care costs both in the public programs and in the rest of the health system without adverse health consequences.

Perhaps the most compelling evidence is substantial geographic differences in spending on health care, which do not translate into higher life expectancy or measured improvements in other health statistics in the higher spending regions.
Hard evidence is often unavailable about which treatments work best for which patients and whether the added benefits of more-effective but more expensive services are sufficient to warrant their added expense.

**Goal of comparative effectiveness research** is to generate better information about the risks and benefits and costs of different treatment options ---- which could eventually alter the way in which medicine is practiced and yield lower health care spending without having adverse effects on health.
OK --- How do we do this? What are methods for generating this information?
Key Methods for CER

Evidence synthesis: systematic literature review and decision-analysis

Evidence generation; experimental and observational methods

Stakeholder engagement methods

Dissemination and Implementation methods

See also: Sox and Goodman, Annu. Rev. Public Health 2012. 33:425–45
Where is CER on the translational science pathway?

**basic science (discovery)**

- How does this molecule affect the function of this receptor on this cell growing in a dish in the lab, or in a mouse?

**early human application**

- Does this molecule affect the function of the cells taken from humans? Does this molecule affect the function of the cell in living humans?

**therapeutic studies (efficacy)**

- Is this drug safe in healthy people at low doses, at high doses? Is this drug safe in sick people? Does the disease improve when people are treated with this drug?

**effectiveness studies**

- Is this drug effective when it is prescribed by doctors in their offices and used by patients who need the drug? Do patients actually take it? Are their barriers to its use?

**implentation research**

- What is the best way to get an intervention to the community that needs it?
Comparative Effectiveness Research: Current Climate
Patient Centered Outcomes Research: Current Climate
Objectives

- Describe how CER has evolved over the last few years
- Highlight the Patient Centered Outcomes Research Institute
Projected Spending on Health Care as a Percentage of Gross Domestic Product

GBO, 2007
2000-2009

- Political environment favoring modernization of health care delivery
- Recognition of the need for *effectiveness* in health care
- Health professionals being trained with increased focus on genomics and informatics (personalization)
- Health research with a growing focus on balancing effectiveness and safety
That was the situation when ARRA became law...
One Hundred Eleventh Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the sixth day of January, two thousand and nine

The American Reinvestment and Recovery Act (ARRA) of 2009

Effective February 17, 2009
The measures are nominally worth $787 billion

**Tax incentives** - includes $15 B for Infrastructure and Science, $61 B for Protecting the Vulnerable, $25 B for Education and Training and $22 B for Energy, so total funds are $126 B for Infrastructure and Science, $142 B for Protecting the Vulnerable, $78 B for Education and Training, and $65 B for Energy.

**State and Local Fiscal Relief** - Prevents state and local cuts to health and education programs and state and local tax increases.
Where Your Money Is Going? Department of Health and Human Services

- Improving & Preserving Health Care: $91.6 B
- Health IT: $25.8 B
- Children & Community Services: $13.3 B
- Scientific Research & Facilities: $10.0 B
- Community Health: $2.8 B
- Patient-Centered Health Care Research: $1.1 B
- Prevention & Wellness: $1.0 B
- Accountability and IT Security: $0.1 B
The American Reinvestment and Recovery Act (ARRA)

- ARRA contained $1.1 billion for comparative effectiveness research.
  - $300 million for the Agency for Healthcare Research and Quality (AHRQ)
  - $400 million for the National Institutes of Health (NIH)
  - $400 million at the discretion of the HHS Secretary

- The legislation called on the Institute of Medicine to recommend research priorities for the Secretary's funds
HHS Awards $473 Million in Patient-Centered Outcomes Research Funding

HHS' Agency for Healthcare Research and Quality (AHRQ) today announced the award of $473 million in grants and contracts to support projects that will help people make health care decisions based on the best evidence of effectiveness.

The funding announced today covers all of AHRQ's allocation and $173 million administered for the HHS Secretary by AHRQ.

The projects will support patient-centered outcomes research, also known as comparative effectiveness research, efforts in many areas, including health care interventions in real world settings, advanced use of the research findings by diverse populations, development of effective patient registries and training and career development for the next generation of researchers.
ARRA spending is up

• All money must be spent by September 2013
• Unlikely that there will be monies of this magnitude to replace it
The next big legislative event ...
Patient Protection and Affordable Care Act March 23, 2010

Included:  Sec. 6301 Patient Centered Outcomes Research
Is comparative effectiveness research the same as patient-centered outcomes research?
SEC. 6301. PATIENT-CENTERED OUTCOMES RESEARCH.

(a) In General.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH"

"COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH"

"SEC. 1181. (a) DEFINITIONS.—In this section:

"(1) BOARD.—The term ‘Board’ means the Board of Governors established under subsection (f).

"(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH; RESEARCH.—

"(A) IN GENERAL.—The terms ‘comparative clinical effectiveness research’ and ‘research’ mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B)."
“(B) Medical treatments, services, and items described.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.
Key Item in Sec. 6301

- Establishment of PCORI: Patient-Centered Outcomes Research Institute
- NOT an agency of the government
- Mission: to assists patients, clinicians, purchases, and policymakers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases...can effectively and appropriately be prevented, diagnosed, treated ... through research and evidence synthesis...and the dissemination of research findings...
“(b) **PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.**—

“(1) **Establishment.**—There is authorized to be established a nonprofit corporation, to be known as the ‘Patient-Centered Outcomes Research Institute’ (referred to in this section as the ‘Institute’) which is neither an agency nor establishment of the United States Government.

“(2) **Application of provisions.**—The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.

“(3) **Funding of comparative clinical effectiveness research.**—For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the ‘PCORTF’) under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.
“(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).
Duties of PCORI

- Identify research priorities
- Define research agenda
- Carry out research project agenda (largely through contracts)

Research will take into account differences between patients
Research will take into account differences in treatments
Structure

- An Institute Board of Governors
- Methodology committee
- May use processes of another agency
- High priority on transparency
- Will support training activities through AHRQ and National Institute of Medicine mechanisms
Board of Governors

- **Debra Barksdale, PhD, RN**, is Associate Professor at the University of North Carolina (UNC) at Chapel Hill School of Nursing in Chapel Hill, NC.
- **Kerry Barnett, JD**, is Group Executive Vice President, Corporate Services, Chief Legal Officer, and Ethics and Compliance Officer for The Regence Group
- **Lawrence Becker** is Director of Strategic Partnerships and Alliances for Xerox Corporation in Rochester, NY, and is responsible for Global HR Vendor Optimization.
- **Carolyn M. Clancy, MD**, was appointed Director of the Agency for Healthcare Research and Quality (AHRQ) on February 5, 2003, and reappointed on October 9, 2009.
- **Francis S. Collins, MD, PhD**, has served as the Director of the National Institutes of Health (NIH) since August 17, 2009.
- **Leah Hole-Curry, JD**, is the Program Director for the Health Technology Assessment (HTA) program of the Washington State Health Care Authority in Olympia, WA.
- **Allen Douma, MD**, is Chief Executive Officer of Empower, LLC, in Ashland, OR, and a member of the AARP Board of Directors.
- **Arnold Epstein, MD**, is the John H. Foster Professor and Chair of the Department of Health Policy and Management at Harvard University School of Public Health in Boston, MA. He is a practicing internist in the Department of Medicine at the Brigham and Women’s Hospital.
• Christine Goertz, DC, PhD, is Vice Chancellor for Research and Health Policy at Palmer College of Chiropractic and Palmer Center for Chiropractic Research in Davenport, IA, where her research focuses on quality of outcomes for patients and the importance of provider collaboration in providing high-quality health care.

• Gail Hunt, is the President and CEO of the National Alliance for Caregiving, a non-profit coalition dedicated to conducting research and developing national programs for family caregivers and the professionals who serve them.

• Robert Jesse, MD, PhD, is the Principal Deputy Under Secretary for Health, Department of Veterans Affairs (VA) in Washington, DC.

• Harlan Krumholz, MD, is the Harold H. Hines, Jr. Professor of Medicine and Epidemiology and Public Health at Yale University School of Medicine in New Haven, CT, and is a practicing cardiologist.

• Richard E. Kuntz, MD, MSc, is Senior Vice President and Chief Scientific, Clinical, and Regulatory Officer of Medtronic, Inc. in Minneapolis, MN.

• Sharon Levine, MD, is Associate Executive Director for The Permanente Medical Group of Northern California; a large multi-specialty group practice in Oakland, CA within Kaiser Permanente’s integrated delivery system.

• Freda Lewis-Hall, MD, is Executive Vice President and Chief Medical Officer for Pfizer Inc, the world’s largest research-based biopharmaceutical company.
• Steven Lipstein, MHA, (vice chair) is President and Chief Executive Officer of BJC HealthCare in St. Louis, MO, a multi-hospital and health services organization with annual net revenues of $3.6 billion.

• Grayson Norquist, MD, MSPH, is Professor and Chairman, Department of Psychiatry and Human Behavior, University of Mississippi Medical Center in Jackson, MS.

• Ellen Sigal, PhD, is Chair and founder of Friends of Cancer Research (www.focr.org), a cancer research think tank and advocacy organization based in Washington, DC.

• Eugene Washington, MD, MSc, (chair) is the Vice Chancellor of UCLA Health Sciences and Dean of the David Geffen School of Medicine at the University of California Los Angeles in Los Angeles, CA.

• Harlan Weisman, MD, is Managing Director of And-One Consulting, LLC., the American College of Chest Physicians, and the American Heart Association.

• Robert Zwolak, MD, PhD, is a vascular surgeon at Dartmouth-Hitchcock Medical Center in Lebanon, NH and professor of surgery at the Dartmouth Medical School.
Overview

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed health care decisions and improve health care delivery. PCORI will commission research that is guided by patients, caregivers and the broader health care community and will produce high integrity, evidence-based information.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI will use a variety of forums and public comment periods to obtain public input throughout its work.

Provide Input

The Patient-Centered Outcomes Research Institute solicits and receives input from the public about its work, as part of its commitment to transparency, credibility and access.

Funding Opportunities

PCORI Announces $26 Million Pilot Projects Grant Program, seeks Patient, Stakeholder and Scientific Reviewers.
PCORI - Funding

- Supported by a trust fund
- Up to 20% of the Fund will support research capacity building and dissemination of results
"SEC. 9511. PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND.

(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the ‘Patient-Centered Outcomes Research Trust Fund’ (hereafter in this section referred to as the ‘PCORTF’), consisting of such amounts as may be appropriated or credited to such Trust Fund as provided in this section and section 9602(b).

(b) TRANSFERS TO FUND.—

(1) APPROPRIATION.—There are hereby appropriated to the Trust Fund the following:

(A) For fiscal year 2010, $10,000,000.
(B) For fiscal year 2011, $50,000,000.
(C) For fiscal year 2012, $150,000,000.
(D) For fiscal year 2013—

(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and
(ii) $150,000,000.

(E) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019—

(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and
(ii) $150,000,000.

The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) shall be transferred from the general fund of the Treasury, from funds not otherwise appropriated.

(2) TRUST FUND TRANSFERS.—In addition to the amounts appropriated under paragraph (1), there shall be credited to the PCORTF the amounts transferred under section 1183 of the Social Security Act.

(3) LIMITATION ON TRANSFERS TO PCORTF.—No amount may be appropriated or transferred to the PCORTF on and after the date of any expenditure from the PCORTF which is not an expenditure permitted under this section. The determination of whether an expenditure is so permitted shall be made without regard to—

(A) any provision of law which is not contained or referenced in this chapter or in a revenue Act, and
(B) whether such provision of law is a subsequently enacted provision or directly or indirectly seeks to waive...
First Task of Methodology Committee: Define PCOR

Patient Centered Outcomes Research (PCOR) helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options. This research answers patient-focused questions:

“Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”

“What are my options and what are the benefits and harms of those options?”

“What can I do to improve the outcomes that are most important to me?”

“How can the health care system improve my chances of achieving the outcomes I prefer?”
National Priorities for Research and Research Agenda

The Patient-Centered Outcomes Research Institute (PCORI) in January 2012 issued for public comment their first draft "National Priorities for Research and Research Agenda".

Dr. Selby said, "The priorities and agenda provide a framework and identify the broad questions that must be addressed so that patients can make better and more personalized decisions in partnership with their clinicians across all areas of health. Our initial research agenda is not prescriptive about which conditions or treatments to study. It is a starting point. We hope that patients and other stakeholders will join with us in the coming months as we apply this framework to identify the specific questions that are most important for PCORI to address."

Public comment was solicited through the PCORI website, email, postal mail and a National Patient and Stakeholder Dialogue event (and webcast) held in Washington, D.C. on February 27, 2012.

PCORI received and analyzed 474 formal comments; PCORI opted not to make substantive changes.

Adopted by the PCORI Board of Governors on May 21, 2012

http://www.pcori.org/what-we-do/priorities-agenda/
Five Priority Areas

1. **Assessment of Prevention, Diagnosis, and Treatment Options** - Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.

2. **Improving Healthcare Systems** - Comparing health system--level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

3. **Communication and Dissemination Research** - Comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision-making between patients and their providers.
4. **Addressing Disparities** - Identifying potential differences in prevention, diagnosis or treatment effectiveness, or preferred clinical outcomes across patient populations and the healthcare required to achieve best outcomes in each population.

5. **Accelerating Patient-Centered Outcomes Research and Methodological Research** - Improving the nation’s capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients and other stakeholders to participate in this research.
Another early project: Methodology Report

Reports addresses:

- “What should we study?”
- “What study designs should we use?”
- “How do we carry out and govern the study?”
- “How do we enable people to apply the study results?”

- **PCORI Methodology Standards** (as adopted by the PCORI Board, Nov. 19; published Dec. 14, 2012)
- **PCORI Methodology Committee Research Recommendations** (as presented to the Board Nov. 19; published Dec. 14, 2012)
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PCORI Methodology Standards

- Standards for Formulating Research Questions
- Standards associated with Patient-Centeredness
- Standards for Systematic Reviews
- General and Crosscutting Methods for all PCOR
- Causal Inference Standards
- Standards for Heterogeneity of Treatment Effect (HTE)
- Standards for Preventing and Handling Missing Data
- Standards for Data Networks
- Standards for Adaptive and Bayesian Trial Designs
- Standards for Data Registries Standard
- Standards for Studies of Diagnostic Tests

http://www.pcori.org/assets/PCORI-Methodology-Standards.pdf
Is cost research okay?
“(e) The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.”.
First Round of Major Funding – Cycle I December 2012

25 projects, totaling $40.7 million, for proposals that address the first four areas National Priorities for Research and Research Agenda.

(not methods projects)
Distinguished by:

• Patient-Centeredness — Is the proposed research focused on questions and outcomes of specific interest to patients and their caregivers?

• Innovation & Potential for Improvement – Might the proposed research lead to meaningful improvement in patient health and is the approach novel or innovative in ways that make it likely to change practice?

• Team & Environment – Do the researchers have appropriate experience and have they included in their team the relevant patients and other key healthcare community members, who are the focus of the study and would use its information?
Future Funding

Expecting to commit to nearly $355 million in research contracts in 2013. That will include Cycles II and III of funding announcements under our first four priority areas, an expected two of three planned cycles under our fifth priority (methods), and at least initial funding for the topic-specific funding announcements we expect to start issuing in early 2013.