

Comparative Effectiveness Research

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The National Cancer Advisory Board

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Presentation Overview

CER
definition &
importance

The American
Recovery and
Reinvestment
Act (ARRA) &
CER

CER Policy
context and
background

Process for
spending
funds at NIH

AHRQ and
HHS/OS plans
for ARRA CER
funds

Learn
more
about CER

What is Comparative Effectiveness Research (CER)?

- Definition of CER has evolved over time
- Various parties involved, including Congressional Budget Office (CBO), Office of Management and Budget (OMB), and White House
- Federal Coordinating Council (FCC) definition is currently used HHS-wide

CER Definition

The conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor 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, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

- To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and subgroups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.
- This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

Types of CER Research

- Clinical Trials
- Observational studies and modeling
- Secondary data analysis using registries and linked databases

Importance of CER



CER and evidence-based medicine included in most healthcare reform initiatives



IC Directors agree unanimously that NIH has an important role to play in CER



In total dollars, NIH funds the largest amount of CER in HHS



The NCI Community has substantial experience, expertise, and infrastructure relevant to CER

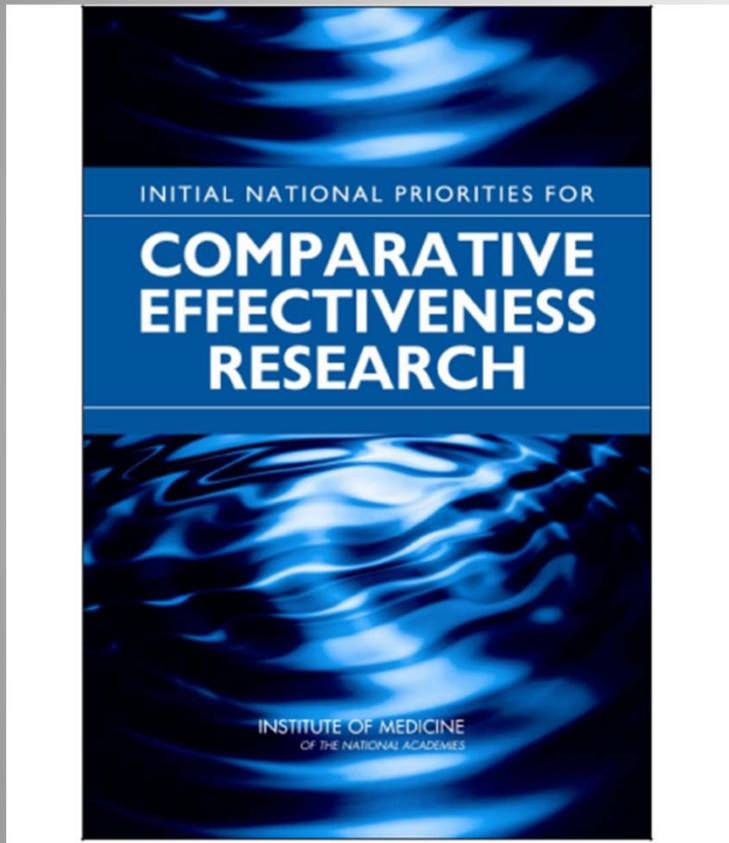
CER Policy Context: Outline

- Congress and the American Recovery and Reinvestment Act (ARRA)
- Institute of Medicine (IOM) CER Report
- Federal Coordinating Council for CER (FCC)

ARRA CER Bill Language

- Conference Agreement and Bill Report noted that FCC can not mandate coverage, reimbursement, or other policies of public or private payers
- CER will not include national clinical guidelines or coverage determinations
- The HHS Secretary required to:
 - Publish information on awards
 - Disseminate research findings to clinicians, patients, and the general public
 - Ensure that the recipients of the funds offer an opportunity for public comment on the research
 - Annually report on the research conducted or supported

IOM CER Report

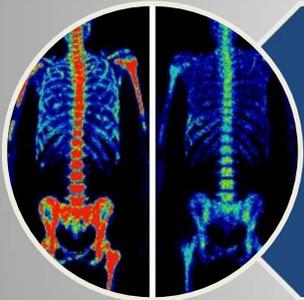


- Required under ARRA
- Released 6/30/09
- Lists 100 national priorities for CER
- Informed by testimonials given by advocacy, industry, and other groups

IOM CER Report: Examples of Cancer Priorities



Compare management strategies for localized prostate cancer on survival, recurrence, side effects, quality of life, and costs



Compare imaging technologies in diagnosing, staging, and monitoring patients with cancer including PET, MRI, and CT



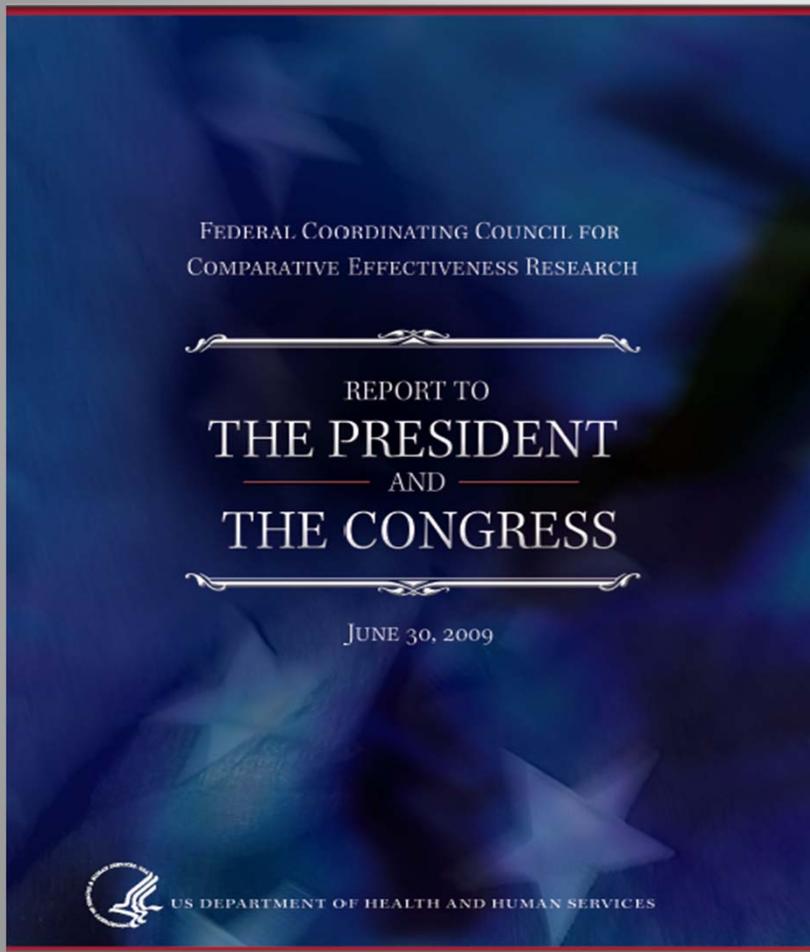
Compare genetic and biomarker testing and usual care in preventing and treating breast, colorectal, prostate, lung, and ovarian cancer, and possibly other clinical conditions

IOM CER Report:

Recommendations for long-term investment

- Ensuring meaningful consumer, patient, and caregiver participation
- Building robust information systems and research methods
- Development and support of a highly skilled CER workforce
- Support efforts to translate CER knowledge into everyday clinical practice.

Federal Coordinating Council for CER



- Released report 6/30/09
- Required by ARRA
- Lists priorities for spending HHS/OS \$400M
- Elizabeth Nabel, Director, NHLBI was a member
- CER definition released is now used HHS-wide

CER ARRA Allocation

\$400M
NIH



\$300M
AHRQ



\$400M
HHS OS

\$1.1B

Overview of NIH CER Process

NIH CER Committee (NIH CC) formed to guide process



NIH CC asked ICs for ideas and lists of potential applications to fund



NIH CC met to review and select grants to recommend for funding



NIH CC recommendations presented to NIH Director



NIH Director reviewed and approved final grants to be paid in FY 2009

NIH CER Committee

- Co-Chaired by Betsey Nabel (NHLBI) and Richard Hodes (NIA)
- Dr. Niederhuber serves as NCI's voting member
- Other voting members include:
 - Barbara Alving (NCRR)
 - Josie Briggs (NCCAM)
 - Tom Insel (NIMH)
 - Barry Kramer (ODP)
 - Walter Koroshetz (NINDS)
 - Rod Pettigrew (NIBIB)
 - Griff Rodgers (NIDDK)
 - John Ruffin (NCMHD)
 - Lana Skirboll (DPCPSI)
- NCI's Dr. Robert Croyle and Dr. Martin Brown also attend most meetings

NIH CER Committee: Criteria Used to Make Funding Recommendations

Primary Question:

Does the project meet the definition of CER?

Secondary considerations:

-IC priority rank of submitted projects

-Alignment with:

- Priorities in IOM and FCC reports
- Medicare Modernization Act (MMA) 14 diseases and conditions
- AHRQ evidence gaps

\$400M
NIH

Primary Spending areas*

- CER related grants with scores beyond institute paylines
- Grand Opportunity (GO) Grants
- Challenge Grants
- Competitive Revisions
- Administrative Supplements
- Other projects, such as NIH signature initiatives
- Contracts
- Spending of remaining dollars TBD in FY10

**All spending is pending final approvals*

\$400M
NIH

NCI's approach to securing NIH CER funding

Grand
Opportunity
Grants

- 2 Announcements from NCI directly related to CER
- CER in Genomic and Personalized Medicine
- CER in Cancer Prevention, Screening and Treatment

Challenge
Grants

- NCI Received over 4,000 applications
- Many were in response to the 69 NIH wide announcements that were CER-specific

Other examples of NCI Involvement in CER Activities

NIH Fingerprinting subcommittee

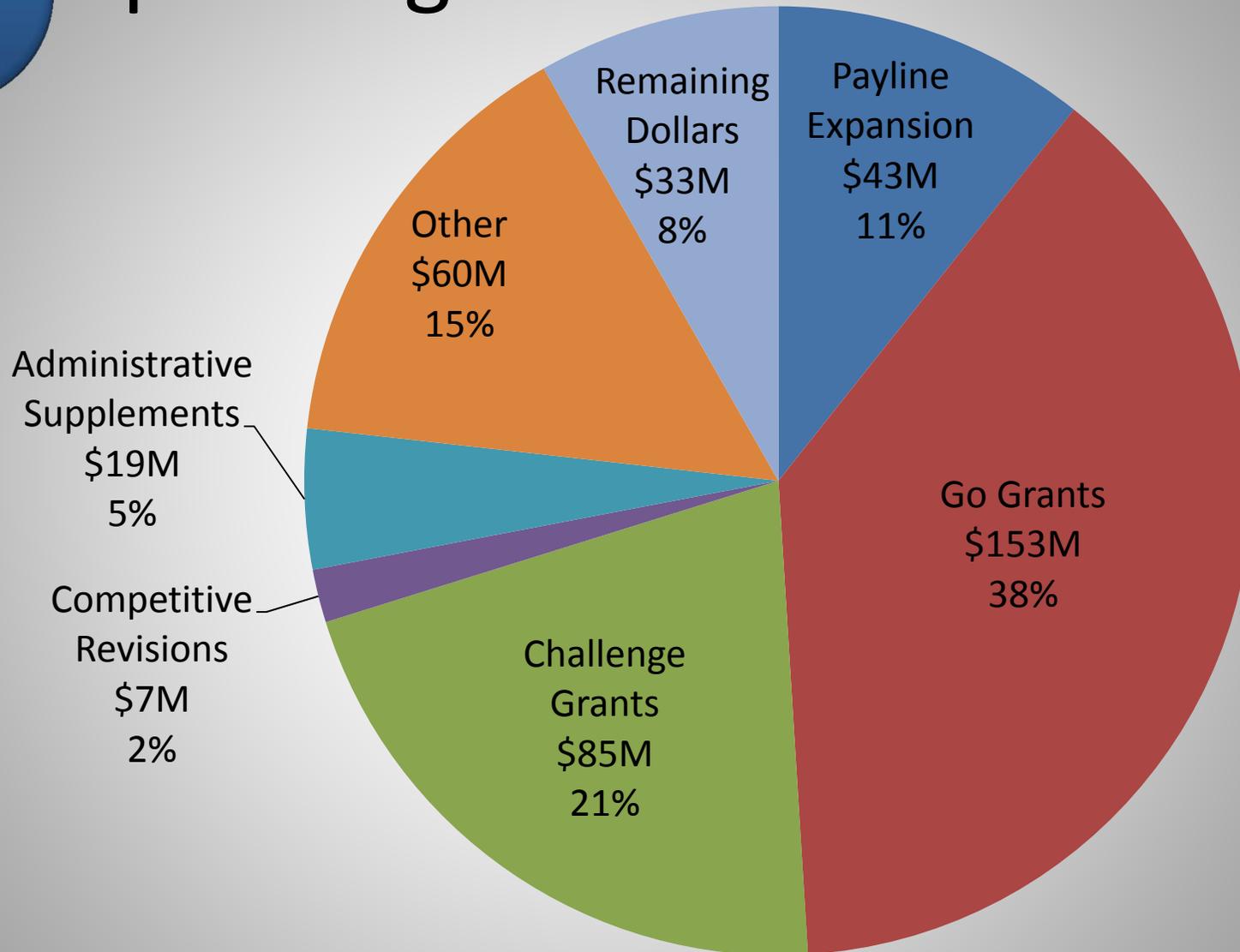
- Created to help determine how to flag grants as CER

Trans-NIH CER Portfolio Workgroup

Trans-NCI CER Workgroup

\$400M
NIH

Spending Plan*



*Dollars are rounded. "Other" category includes contracts and grants, for example NIH signature projects. All final funding decisions are pending administrative approval. Remaining dollars will be spent in FY10 on projects TBD.

\$400M
NIH

Projected Funding*

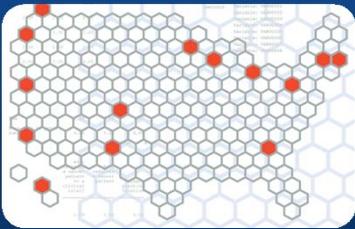
Spending Category	Total NIH	NCI Portion	% of total for NCI
GO Grant (RC2)	\$153	\$47.9	31.3%
Challenge Grant (RC1)	\$84.8	\$13.4	15.8%
Competitive Revision	\$7.2	\$3.4	47%
Administrative Supplements	\$19.1	\$0.5	2.6%
Payline Expansion	\$42.9	\$19.3	45%
Other	\$60.1	\$0.0	0%
(Dollars in Millions) Total	\$367	\$84.5	23%

*All dollars are rounded. "Other" category includes contracts and grants, for example NIH signature projects. All final funding decisions are pending administrative approval.

Examples of NCI CER Topic Areas



Surgical treatment options for prostate cancer



Enhancing surveillance capabilities



Colon cancer screening methods



Genomic medicine in cancer

Examples of NCI CER Topic Areas



Smoking cessation trials



Risk behavior interventions in health care settings



Lymphadenectomy trials



Remote genetic counseling in underserved populations

\$300M
AHRQ

Spending Plan

\$100M for Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE)

\$48M for national patient registries

\$29.5M to support innovative CER translation and dissemination grants

\$20M to support training and career development in CER

\$9.5M to establish infrastructure to identify new/emerging issues for CER review investments

\$10M to establish a citizen's forum to formally engage stakeholders and expand public involvement

\$80M additional grants and contracts for evidence generation, synthesis and translation

\$3M for staff

\$400M
HHS OS

Spending Plan

- Influenced by FCC and IOM reports
- Primary goal is to complement AHRQ and NIH spending
- General areas of spending, final plan not yet released
 - Conduct CER
 - Develop clinical registries, clinical data networks, and other forms of electronic health data

Learn more

- NCI Cancer Bulletin Spotlight on CER
 - <http://www.cancer.gov/ncicancerbulletin/051909/page6/print?page=&keyword>
- Federal Coordinating Committee report on CER
 - <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>
- IOM report with recommendations on the priority areas that HHS should address with its CER funding.
 - <http://www.iom.edu/?ID=71025>
- Friends of Cancer Research report calling for a “new paradigm” on CER and offering cancer care as a case study
 - <http://www.focr.org/comparative-effectiveness>
- Academy Health – Cost of CER in the U.S., June 2009
 - <http://www.academyhealth.org/>
- Brookings hosted a CER Workshop which included speakers: Carolyn Clancy, Peter Orszag, Mark McCellan, Robert Rubin and Max Baucus
 - http://www.brookings.edu/events/2009/0609_health_care_cer.aspx

Questions for NCAB

- How can the remaining ARRA CER funds best be leveraged to more broadly engage the cancer and chronic disease communities?
- How can NCI best ensure that the CER is used appropriately to inform policy formation?
- What other opportunities might there be to synergize evidence synthesis, dissemination, and implementation of cancer related CER findings?
- How can we ensure CER incorporates contemporary molecular oncology and personalized medicine?