Comparative Effectiveness Research: Implications for Safety Net Providers and the Populations They Serve

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Agenda

- What CER is and isn't
- Where CER is headed
- Outline options for putting CER into practice
- How CER can address health care disparities
- Potential impact of CER on safety net providers

Policy Makers See a Central Role for CER in Health Care Reform

- Need for more comparative clinical effectiveness research
  - "relatively little rigorous evidence is available about which treatments work best for which patients…"*
- Need for more research on promoting use of CER in clinical practice
  - "…the financial incentives for both providers and patients tend to encourage the adoption of more expensive treatments…even if evidence of their relative effectiveness is limited."*

Orszag, NEJM, Nov 2007

Stakeholders agree on- need for CER

- Advisors to Congress: CBO, MEDPAC, IOM
- Health Plans: AHIP; BCBSA
- Employers: eg NBGH
- Drug and Device Manufacturers: PHARMA, ADVAMED, BIO
- Consumer Groups: Consumer's Union, Partnership to Improve Patient Care (PIPC)
- Professional Associations: AMA, Academy Health, ACP, AAFP, ACS, AAMC,

Stakeholders disagree on- a few details

- What is CER?
- Who should pay for it?
- How should it be directed?
- How should it be used?

CER Definitions

ARRA- FCCCER

- research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. medications, procedures,
  - medical and assistive devices and technologies,
  - behavioral change strategies, and
  - delivery system interventions
- to inform patients, providers, and decision-makers, about which interventions are most effective for which patients under specific circumstances."

ACA-

- research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items…
  - health care interventions, protocols for treatment, care management, and delivery,
  - procedures, medical devices, diagnostic tools,
  - Pharmaceuticals…,
  - integrative health practices,
- The purpose …is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions

Defining CER: The Terminology Evolves

- Comparative Effectiveness Research- ARRA
- Patient Centered Outcomes Research- ACA
  - Comparative clinical effectiveness research
- Possible drivers of name change
  - Patient-centered = supporting personalized medicine, rather than population-based decisions?
  - Comparative effectiveness (CE) too easily confused with cost effectiveness (CE)?

Limitations on CER in the ACA

- PCORI "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."

Stakeholders disagree on- a few details

- What is CER?
- **Who should pay for it?**
- How should it be directed?
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Using Appropriations to Pay for CER

- Federal research agencies rely on appropriators' annual support
- CER creates losers who really HATE losing
- Case in point: AHCPR
  - Established 1989
  - 1995: Back surgeon and device manufacturer hostility to PORT back pain research, and related guidelines
  - Funding decline; loss of PORTs and Guidelines functions, name change 1999 (to AHRQ)

Recent Federal Support for CER

- AHRQ MMA Authority (2003)
  - Effective Health Care program
  - CERTs, DEcIDE Network, EPCs, Eisenberg Center
  - Appropriation- $30M
- ARRA $ 1.1 Billion for CER (out of $787 B)
  - $400 M NIH
  - $300 M AHRQ
  - $400 M HHS OS

ACA-Paying for CER LONG-TERM

- **Patient-Centered Outcomes Research Trust Fund**
  - **transfer from the Treasury to the Trust Fund**
    - $10 million in FY 2010,
    - $50 million in FY 2011
    - up to $150 million thereafter.
  - **transfer per Medicare beneficiary ($1 FY2013, then $2)**
  - **FY 2013, health insurers contribute a fee equal to $2 per covered beneficiary.**
  - **By FY 2013 the Trust Fund will provide an estimated $500 to 600 million a year for CER, depending on the number of Medicare enrollees and insured individuals**

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How Should CER be directed?

- ACA establishes the PCORI, a private, nonprofit corporation ("neither an agency nor establishment of the US Government")
- Institute duties
  - Identify national priorities for research
  - Establish research project agenda to address priorities
  - Carry out research project agenda …in accordance with methodological standards adopted
  - Establish Methodology Committee and Advisory Panels

PCORI Board of Governors

- 21 members appointed by Comptroller General
  - The Director of AHRQ (or designee) and Director of (NIH (or designee)
  - Three patient representatives
  - Seven provider representatives
  - Three representatives of private payers
  - Three representatives for pharmaceutical, device, diagnostic developers
  - One quality improvement or independent health services researcher
  - Two members representing government payers (the federal government or the states)

- scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics.

How Should CER be directed?

- Institute contracts for the management of funding and conduct of research
  - PCORI must give preference to AHRQ and NIH
  - If such research is authorized by the governing statutes of the Agency
- 20% of Trust Fund moneys go to HHS for "dissemination and capacity building."
  - 80% to AHRQ for dissemination and training
  - 20% to HHS for building data capacity and networks

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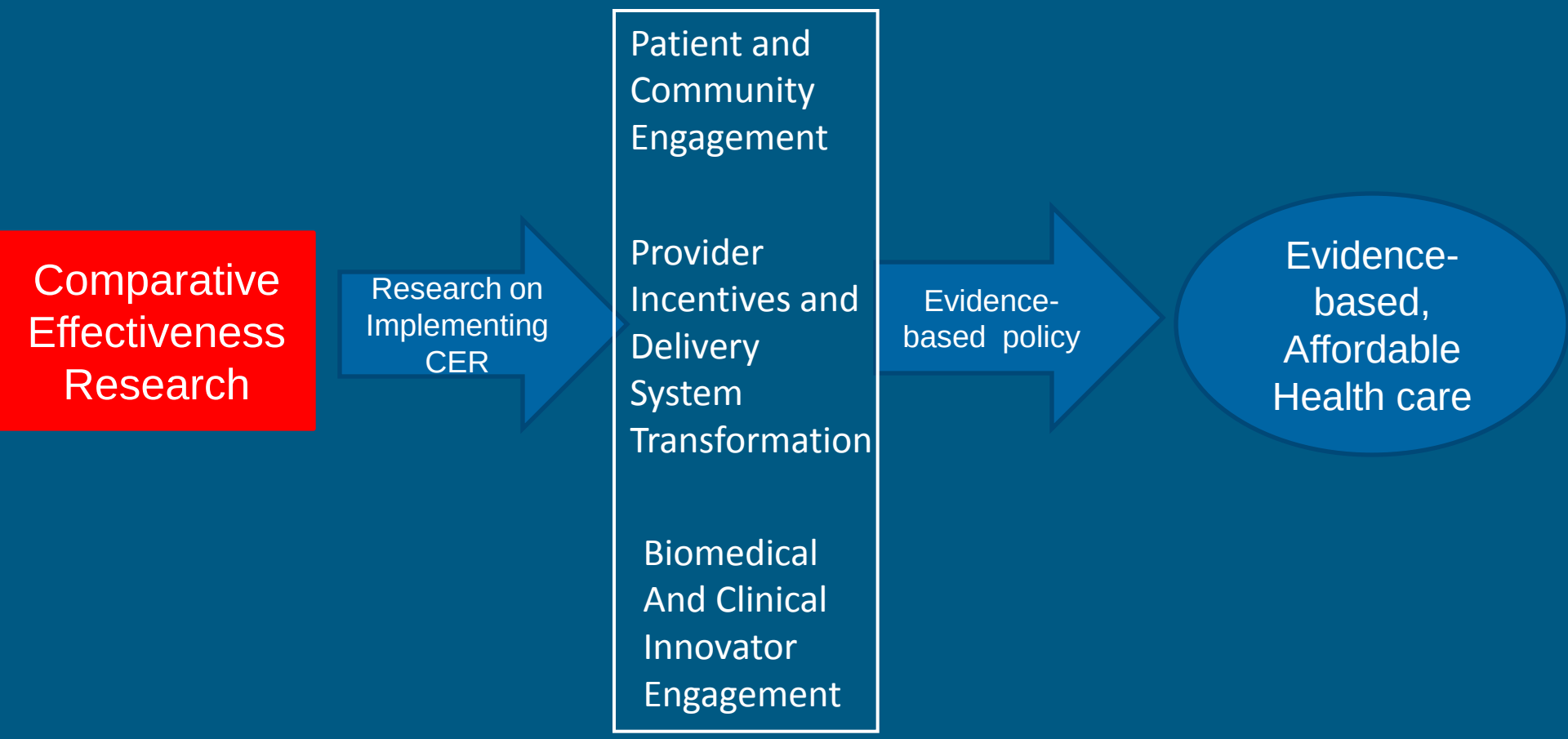
How should CER be used?

- **CBO "Score" for CER**
  - **$2.5 Billion spending on CER 2010-2019**
  - **Federal Health Care savings $.1 Billion-**
    - Medicare savings from CER > spending after 7 years
    - Assumes no changes in Medicare coverage rules
    - Anticipates evidence leads to changes in physician practice and patient choice
  - **Private Health Care Savings ($5 Billion in previous CBO estimate)**
    - Anticipates private insurers would use CER

CBO, analysis of HR 3962, Oct 2009; and ,CBO Report on Comparative Effectiveness of Medical Treatments, Dec 2007

The Evidence Base for Health Care Reform



Engaging Innovators

- Coverage decisions- tightening the standard of evidence for wide coverage of new technology
- "Coverage with evidence development" - speeding collection of additional comparative effectiveness info thru mandated studies or registries tied to coverage
- Risk-sharing arrangements – e.g. manufacturers receive bonuses if projected outcomes are achieved

Consumer Engagement

- Value-based insurance design-
  - no “co-pays” for highly effective therapies
  - Higher “co-pays” for therapies that are very “preference sensitive” or of unclear effectiveness
- Informed patient decision-making modules- helping patients understand evidence of risks and benefits for “preference sensitive” decisions

Engaging Providers and the Delivery System

- Value –based provider payments – e.g. pay providers more for highly effective therapies
- Bundled payment- use CER to guide what mix of services should be included in payment for an illness episode
- Provider feedback- on use of highly effective therapies
- P4P- bonuses for compliance with CER-based guidelines

Engaging Providers and the Delivery System

- Public report cards- e.g. publish provider network rates of delivering highly effective treatments
- Information Technology- building in CER-based computerized reminders, alerts, protocols
- Malpractice reform- e.g. protection from lawsuits for actions based on CER-based guidelines

Using CER: What's off the table in ACA

- Coverage and reimbursement decisions by PCORI
  - PCORI may not mandate coverage, reimbursement or other policies

- PCORI research and reports may not include practice guidelines, coverage recommendations, payment or policy recommendations

Using CER: What's on the table in ACA

- **Dissemination**
  - AHRQ is charged with disseminating the research findings published by PCORI and other CER/PCOR
- **Clinical decision support**
  - PCORI is expected to work to promote use of CER findings via automated clinical support tools
- **Use of PCORI findings in coverage and reimbursement decisions by private insurers**
- **Use of PCORI findings in coverage and reimbursement decisions by public programs**
  - PCORI research findings cannot be SOLE input to Medicare coverage decision
  - But use of CER info not prohibited

How CER can address health care disparities

- CER/PCOR must address concerns and preferences of relevant sub-populations

CER Definitions- Addressing Dispatities

ARRA- FCCCER

- One important consideration for comparative effectiveness research is addressing the needs of priority populations and sub-groups, i.e., those often underrepresented in research.
- The priority populations specifically include…racial and ethnic minorities, persons with disabilities, children, the elderly, and patients with multiple chronic conditions…

ACA-

- Research shall be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations
- such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, research evaluating and or quality of life preferences and include members of such subpopulations as subjects …

How CER can address health care disparities

- CER/PCOR must address concerns and preferences of relevant sub-populations
  - Potential support for facilities and provider networks to conduct/participate in research to address effectiveness in special populations
  - Potential for "coverage with evidence development" while data is collected on effectiveness of innovations for special populations

How CER can address health care disparities

- Reforms to reward use of evidence-based services
  - Value –based provider payments – e.g. pay providers more for highly effective therapies
  - Bundled payment- use CER to guide what mix of services should be included in payment for an illness episode
  - Information Technology- building in CER-based computerized reminders, alerts, protocols
  - Malpractice reform- e.g. protection from lawsuits for actions based on CER-based guidelines
- could incentivize providers committed to reducing disparities in access to, and use of, highly effective care

CER and Safety Net Providers

- Reforms to reward use of evidence-based services
  - P4P- bonuses for compliance with CER-based guidelines
- Could penalize providers serving complex populations
  - Despite their commitment to reducing disparities in access to highly effective care

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