

SEMINAR ON HEALTH CARE SYSTEMS INNOVATION

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Comparative Effectiveness— The “Savior”?

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Patient Centered Outcomes Research Institute

- Created by 2010 PPACA
- Independent, non-profit organization
- Funded by Congress
- \$50 M (2011); \$150 M (2012)
- Starting 2013, \$2 for every Medicare Beneficiary trust fund



PCORI Mission Statement

The Patient-Centered Outcomes Research Institute (PCORI) helps people make informed health care decisions—and improves health care delivery and outcomes—by producing and promoting high integrity, evidence-based information—that comes from research guided by patients, caregivers and the broader health care community.



OECD Health Care Expenditure

Image removed due to copyright restrictions. Graph of OECD Health Care Expenditure, Growth as percentage of GDP, in 14 different countries from 1960-2008.

See: <http://www.oecd.org/els/health-systems/health-data.htm> and
<http://www.compareyourcountry.org/health?cr=oecd&cr1=oecd&lg=en&page=3>.

Background: Drivers of Growth in US Health Care Costs

Image removed due to copyright restrictions. Table of Estimated Contributions of Selected Factors to Long-Term Growth in Real Health Care Spending per Capita, 1940 to 1990. "A Federal Perspective on Health Care Policy and Costs." Peter Orszag, Congressional Budget Office. Presentation to the Center for Public Health, Stanford University, September 16, 2008. Page 4.
See: <http://www.cbo.gov/sites/default/files/09-16-2008-stanford.pdf>.

Comparative Effectiveness

Rationale

- U.S. health care costs--\$2.3 trillion annually, 17%+ GDP and rising.
- Large body of research over three decades shows great variation in medical and surgical management of illness (Wennberg; many others).
- Few differences in clinical outcomes, despite great variation in care.
- “Comparative Effectiveness” information largely unavailable.
- If available, should lead to “better” decisions (i.e., those with less intensive resource use).
- Growth in pharmaceutical costs made drugs a (convenient) target.

What Comparative Effectiveness Research Is

“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.”

Federal Coordinating Council on Comparative Effectiveness Research

Source: Alan Garber, Stanford University



Comparative Effectiveness

Background

- 1970s/80s: New practices and technologies called “...culprit behind rising health care costs”.
- Call for formation of “center” to conduct comparative Technology Assessments” to be funded from mix of government and private insurance company money.
- ~1981: National Center for Health Care Technology (NCHCT) founded as a federal government agency.
- NCHCT ☒ AHCPR ☒ AHRQ.
- Never well-funded- budget until recently ~ \$30 million (NIH budget is ~\$30+ billion).
- ~1988: Prohibited from issuing “guidelines” on medical practices.



Comparative Effectiveness

Background *(continued)*

- Successes of other countries that founded agencies with resources and authority.
 - UK: NICE
 - Canada: Ontario
 - Australia
- 2005  Renewed discussion in US at many conferences.
- 2008 (July)-- Legislation introduced in US Senate.
- 2009 (February)-- American Recovery and Reinvestment Act (stimulus package) gives \$1.1 billion for comparative effectiveness research and panels to oversee use of funding.
- 2009 (May)-- Similar legislation introduced in House of Representatives.



“Comparative Effectiveness Research Act of 2008”

Senate Bill S.3408 (Introduced July 31, 2008)

- Creates a “ Health Care Comparative Effectiveness Research Institute”.
- Non-profit organization with ties to the Congress (through the Government Accountability Office) and to the Executive Branch (through Department of Health and Human Services).
- Funding in “ Steady State”: \$75 million from federal government + \$1 (tax) on each privately insured individual (paid by the insurers) to estimated annual funding -- \$200 million.
- In-house and contracted “ Comparative Effectiveness” research.



“

“Comparative Effectiveness Research Act of 2008” *(continued)*

Senate Bill S.3408 (Introduced July 31, 2008)

- Prohibited from conducting cost-effectiveness research.
- Prohibited from developing and releasing clinical “guidelines”.
- Appoints advisory panels.
- Governed by 21-member Board of Governors-- specific public and private sector representation.
- Strict conflict of interest rules.



Comparative Effectiveness Institute

Text removed due to copyright restrictions. Barack Obama and Joe Biden's Plan To Low Health Care Costs And Ensure Affordable, Accessible Health Coverage For All.
See: http://obama.3cdn.net/0f691bbc28f3df1f38_3vramvfx2.pdf.



Comparative Effectiveness Institute

Will the Legislation be Enacted?

(continued)

Text removed due to copyright restrictions. Barack Obama and Joe Biden's Plan To Low Health Care Costs And Ensure Affordable, Accessible Health Coverage For All.
See: http://obama.3cdn.net/0f691bbc28f3df1f38_3vramvfx2.pdf.



“Death Panels”?

“ Giving Government exclusive control over electronic health information and reporting is a step toward ‘comparative effectiveness’ research. That, in turn, will be used to impose price controls and deny some types of medical treatment and drugs. And because Government is able to skew the whole health system through Medicare and Medicaid, comparative effectiveness could end up micromanaging the practice of medicine.”

Wall Street Journal editorial

“A Health-Tech Monopoly,” *The Wall Street Journal*, February 11, 2009.



Comparative Effectiveness Institute

Senate Bill - Projection of Impact

- Impact on US health care costs

Estimates by Congressional Budget Office

- Cost of Comparative Effectiveness Institute (2008-17): \$2.9 billion.
- Reduction in health care costs (2008-17): \$6.0 billion.
- Interpreted to be small benefit (compared to \$2+ trillion in total health care costs).



Potential Savings from CER

- Lewin Group: \$18 billion first year, \$368 billion over 10 years.
- CBO: examined HR3162. 10 years to break even, only \$1 billion or so annual savings to fed government
assumed that CER would not be used to change coverage or reimbursement policy under Medicare or Medicaid.

Source: Alan Garber, Stanford University



What it Means to Apply CER Findings

Shift from more to less expensive procedures of comparable effectiveness.

Source: Alan Garber, Stanford University



What it Means to Apply CER Findings

- Identify interventions that cost more, but are no more effective.
- Select the remaining intervention with the greatest health impact that has an acceptable (incremental) cost-effectiveness ratio.

Source: Alan Garber, Stanford University



Treatment Options for Localized Prostate Cancer

•Treatment

•Active surveillance (watchful waiting)

•Radical prostatectomy (RP)

•Brachytherapy (seed implants)

•External beam radiation therapy (EBRT)

•Intensity-modulation radiation therapy (IMRT)

•Description

• Active plan to postpone intervention, usually involving monitoring with digital rectal exam/PSA-test

• Complete surgical removal of prostate gland, can be laparoscopic or robotic
•Nerve-sparing surgery is latest advance on this technique

• Radioactive implants (I^{125} usually) placed using anesthesia, lower dose/permanent seeds usually used

• Multiple doses of radiation from an external source applied over several weeks •2 dimensional external beams delivered based on plan.

•Not used much anymore, replaced by IMRT as standard XRT option

• Next generation 3D conformal radiotherapy where the radiation dose is consistent with the 3-D shape of the tumor by controlling, or modulating, the radiation beam's intensity.

•Wilt TJ, et al. Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer. Comparative Effectiveness Review No. 13. (Prepared by Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) Rockville, MD: Agency for Healthcare Research and Quality, February 2008.

Source: Alan Garber, Stanford University



Newer Treatment Options for Localized Prostate Cancer

<u>Treatment</u>	<u>Description</u>
• Proton radiation therapy	<ul style="list-style-type: none">• A type of EBRT in which protons rather than photons are used for improved dose distribution• Requires very large proton accelerator (football field size) that costs about \$150 million dollars
• Cryoablation	<ul style="list-style-type: none">• Destruction of cells through rapid freezing and thawing with injected gases
• Androgen deprivation	<ul style="list-style-type: none">• Oral or injection medications, or surgical removal of testicles (orchiectomy) to lower or block circulating androgens that stimulate tumor growth
• High-intensity focused ultrasound therapy (HIFU)	<ul style="list-style-type: none">• Tissue ablation with intense heat created from high-intensity ultrasound

• Wilt TJ, et al. Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer. Comparative Effectiveness Review No. 13. (Prepared by Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) Rockville, MD: Agency for Healthcare Research and Quality, February 2008.

Source: Alan Garber, Stanford University



Comparative Effectiveness Institute

Senate Bill - Projection of Impact *(continued)*

- “Commitments” to make use of Comparative Effectiveness research findings.
 - AARP.
 - Consumer’s Union (publisher of Consumer Reports magazine).
 - Others (insurers, professional societies).
 - Many will adopt “wait and see” approach.



Some Concerns

- Funding, but little power?
- Conflicts of interest? (will board members be able to step out of their regular roles and do what is best for the country?)
- Institute may become politicized.
- Management of this enterprise will be complex.

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