

The Comparative Effectiveness Research Landscape

Presentation to the Boston Bar Association

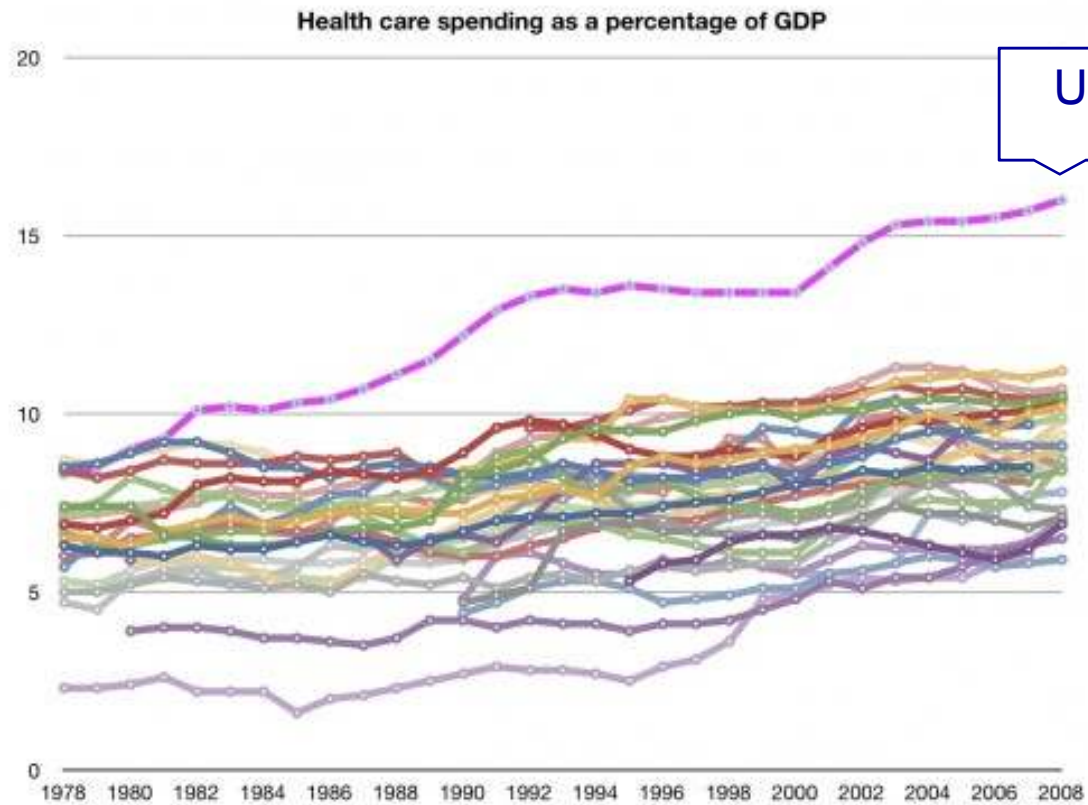
Sarah K. Emond, MPP
Chief Operating Officer

Outline

- What is comparative effectiveness research (CER)?
- CER and national health policy
 - Stimulus funding
 - Health reform
 - PCORI
- Institute for Clinical and Economic Review (ICER)
 - CER review process
 - Implementation
- Looking forward

Background

- Unexplainable variation in practice patterns
- Not enough evidence for decisions about treatment options
- Unsustainable cost increases



USA

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|-------------------|---------------|------------------|
| ○ Australia | ○ Austria | ○ Belgium |
| ○ Canada | ○ Chile | ○ Czech Republic |
| ○ Denmark | ○ Finland | ○ France |
| ○ Germany | ○ Greece | ○ Hungary |
| ○ Iceland | ○ Ireland | ○ Italy |
| ○ Japan | ○ Korea | ○ Luxembourg |
| ○ Mexico | ○ Netherlands | ○ New Zealand |
| ○ Norway | ○ Poland | ○ Portugal |
| ○ Slovak Republic | ○ Spain | ○ Sweden |
| ○ Switzerland | ○ Turkey | ○ United Kingdom |
| ○ United States | | |

Definition

- Comparative effectiveness research is the **conduct and synthesis of systematic research comparing different interventions** and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is **to inform patients, providers, and 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**. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

Comparative Effectiveness Research

- Evidence synthesis (health technology assessment)
 - Systematic evidence review of clinical effectiveness
- Evidence generation
 - Prospective randomized trials
 - Observational studies

CER and ARRA

- Stimulus package (American Reinvestment and Recovery Act) in 2009
- \$1.1 billion for comparative effectiveness research
 - \$300 million for the Agency for Healthcare Research and Quality
 - \$400 million for the National Institutes of Health
 - \$400 million for the Office of the Secretary of Health and Human Services

CER in the Health Care Reform Bill

- The Patient-Centered Outcomes Research Institute (PCORI)
 - Independent non-profit corporation with a stakeholder Governing Board
 - Not a government agency
 - Funding builds to ~\$600 million per year by 2013
 - Establish standing CER methodology committee
 - Develop strategies to disseminate evidence to enhance its uptake by clinicians and patients
 - Commission research from many research groups

PCORI Board of Governors

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Full bios at: <http://www.pcori.org/about/leadership/board-of-governors/>

CER Players

- Government: AHRQ, NIH, USPSTF
- Non-profit: PCORI, ICER
- For-profit: ECRI, Hayes, UpToDate, BCBS
TEC

Institute for Clinical and Economic Review (ICER)

- Research group at MGH and Harvard Medical School with broad stakeholder engagement
- Distinguished by:
 - Deep engagement throughout the appraisal process with all stakeholders
 - Inclusion of economic modeling in every appraisal, and use of an integrated rating system to guide health care decisions
 - Focus on implementation to create innovative decision support tools, insurance benefit designs, and clinical/payment policy.

ICER Appraisal Process

- Topic selection
- Advisory group
 - Patients
 - Clinical and methodological experts
 - Health plans
 - Manufacturers
- Technology assessment
 - Clinical effectiveness
 - Comparative value

ICER Integrated Evidence Rating

Comparative Clinical Effectiveness

Superior: A	Aa	Ab	Ac
Incremental: B	Ba	Bb	Bc
Comparable: C	Ca	Cb	Cc
Inferior: D	Da	Db	Dc
Unproven/Potential: U/P	Ua	Ub	Uc
Insufficient: I	I	I	I

a
High

b
Reasonable/Comp
Comparative Value

c
Low

Topics Reviewed

- Management Options for Low Back Disorders
- Atrial Fibrillation Management Options
- Active Surveillance and Radical Prostatectomy for Clinically Localized, Low-Risk Prostate Cancer
- Coronary Computed Tomographic Angiography for Detection of Coronary Artery Disease
- Brachytherapy/Proton Beam Therapy for Clinically Localized, Low-Risk Prostate Cancer
- CT Colonography for Colon Cancer Screening
- IMRT for Localized Prostate Cancer

Alliance for Appropriate and Affordable Healthcare

- Formerly known as the Employers Action Coalition on Healthcare (EACH)
- Initiative used ICER appraisals on prostate cancer to develop community standard for patient decision support
- Also worked towards provider reimbursement change
- Current project focused on improving value for patients with low back pain

<http://prostateoptions.icer-review.org>

The content of this website was last reviewed and updated July 23, 2010. Next scheduled update January 2011.

Your Options for Low-Risk Prostate Cancer



About Your Diagnosis

A diagnosis of prostate cancer can be overwhelming. Here, we present the results of a comprehensive review of the evidence comparing the management options available for men with low-risk prostate cancer.

[Learn about diagnosis](#)



Your Management Options

This patient decision aid is designed to help you compare the effectiveness, potential side effects, and the number of doctor's visits and tests required for each of the major management options available.

[See management options](#)



Your Next Steps

Empower yourself: identify your preferences and attitudes about your options and print out a personalized set of information and questions to help you have the most productive discussions with your doctors.

[See next steps for you](#)

About This Site

The content of this website is based on a [comprehensive review](#) of the different options for [low-risk prostate cancer](#) conducted by the [Institute for Clinical and Economic Review](#) at the Massachusetts General Hospital in Boston. The review included input from experts around the nation; and the design of this website was created in consultation with experts from Boston Medical Center, Brigham and Women's Hospital, Harvard Vanguard/Atrius Health, Massachusetts General Hospital and Tufts Medical Center.

Throughout this website you can click on videos of doctors from these top clinical groups who will give you further information about your treatment options.



Listen to Terry M. Lindblom, a prostate cancer survivor, talk about making an informed decision about managing your prostate cancer.

CONTENTS OF THIS SITE

[About Prostate Cancer](#) → [Management Options](#) → [Next Steps for You](#) → [Who We Are](#)

[Glossary of Terminology](#) | [Other Resources](#)

[SEARCH](#)

AAAH - Employer Engagement

- Group Insurance Commission (MA), EMC, Partners
- Meetings with health plans (BCBS, Harvard Pilgrim, Tufts) underway
- Goal: choose from menu of possible interventions to reduce costs and improve care:
 - Early access to physical therapy
 - Limited use of epidural spinal injections
 - Patient decision support for back surgery

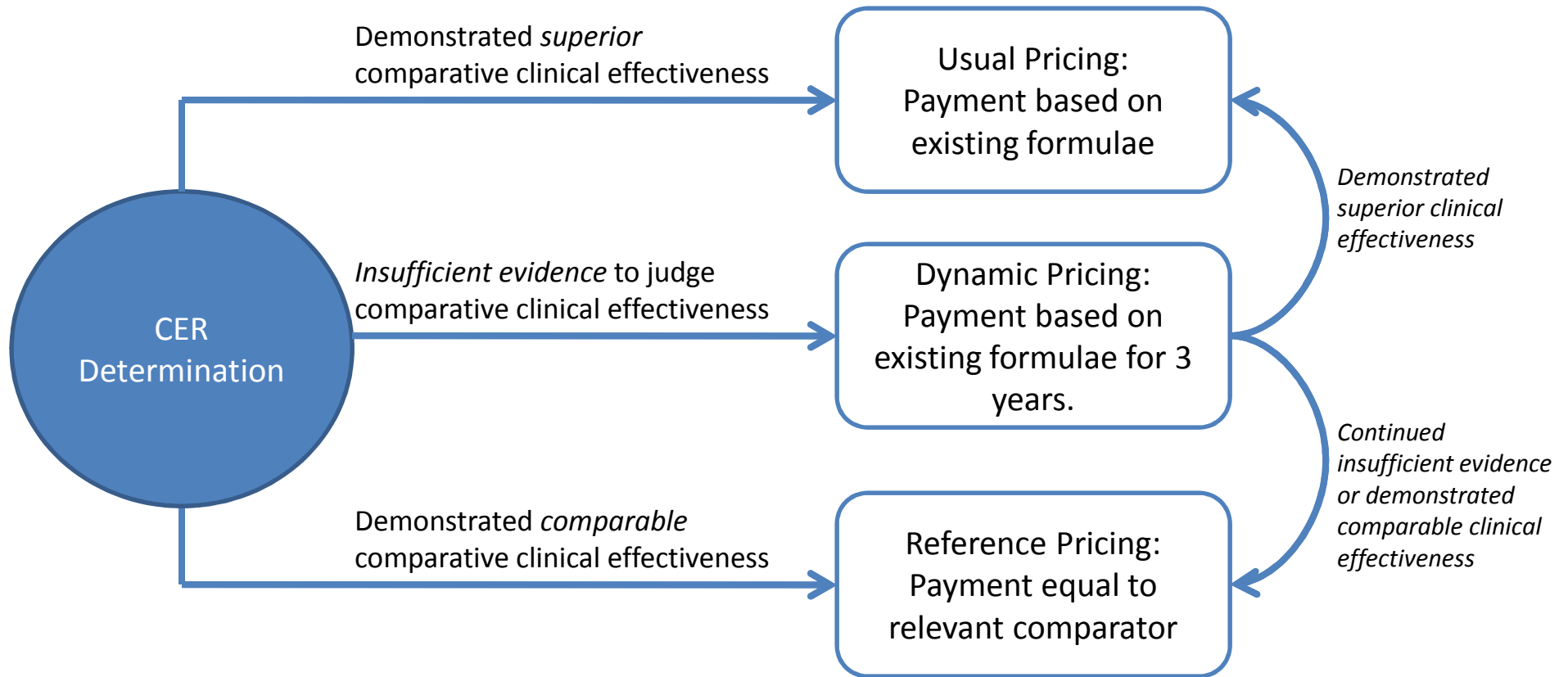
CEPAC

- New England Comparative Effectiveness Public Advisory Council funded by AHRQ grant
- Advisory Board of state Medicaid directors, medical society representatives, regional private insurers, and patient advocates
- 19 Council members (minimum two per state)
 - Independent from state and other payers
 - 2:1 ratio of practicing clinicians and public policy expert members
 - Ex-officio representation of public and private payers

CEPAC Process

- Goal: to “adapt” AHRQ evidence reviews for improved use by New England state public payers and regional private payers
- Adaptation =
 - Supplementary data on utilization, costs, budget impact
 - Costs and cost-effectiveness components added, including global payment perspective
 - CEPAC votes on key evidence questions designed by payers to aid implementation in coverage, payment, benefit design

CER Guiding Pricing for New Treatments



Comparative Effectiveness Research

- Evidence generation



- Evidence synthesis (HTA)



- Evidence dissemination and application

Looking Forward

- CER will continue be critical as rising health care costs continue to be a concern
- Several approaches co-exist to conducting and implementing CER – each with distinct benefits
- Broad stakeholder engagement important to making research actionable
- Improving value in the system ultimate goal

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