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## **Using Comparative Effectiveness Research to Identify “Marginal Medicine”**

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# CER in the Health Care Reform Bill

- Comparative clinical effectiveness
  - Evidence generation – new studies
  - Evidence synthesis – technology assessments
- Independent non-profit institute (PCORI)
- Stakeholder dominated Governing Board
- Funding builds to ~\$500 million by 2013

# Different Ways to See Clinical “Waste”

- Dartmouth
  - Effective care
  - Preference-based care
  - Supply-sensitive care
- RAND and Professional Societies (ACC)
  - Appropriate/Inappropriate care
- IOM
  - Underuse
  - Misuse
  - Overuse
- ? Comparative Effectiveness

# Comparative Effectiveness Research and “Marginal Medicine”

- Goals
  - Frame the issue in evidence-based categories related to the ways that comparative effectiveness research can identify potential waste
  - Frame in a language that can engage clinicians, patients, and policy makers

# Categories of Marginal Medicine

1. Inadequate evidence of any comparative net benefit
2. Use beyond boundaries of established net benefit
3. Higher cost for comparable clinical benefit
4. Relatively high cost for incremental net clinical benefit

# Category 1

- Inadequate evidence of any comparative net benefit
  - Examples
    - Emerging devices, procedures, some of which may be labeled “experimental”
  - NOT the same as solid evidence that an intervention provides a comparable or inferior net benefit
    - Example: proton beam therapy

## Category 2

- Use beyond boundaries of established net benefit
  - Examples
    - Many off-label uses of drugs
    - Vagus nerve stimulation for depression (FDA approved for seizures)

# Category 3

- Higher cost for comparable clinical benefit
  - Examples
    - Brand vs. generic drugs
    - Alternative diagnostic pathways for DVT

# Category 4

- Relatively high cost for an incremental net clinical benefit
  - Examples
    - Chemotherapy for advanced cancer that extends average life span a few weeks
  - What is “incremental” benefit?
    - Small net benefit for everyone (toenail fungus Rx)
    - Small average gain across widely varying responses (clopidigrel vs. aspirin)
  - What is “relatively high” cost?

# A Real Life Example

- The EACH project

# EACH members

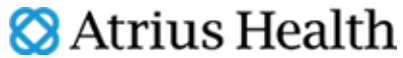


Providers

Health Plans

Employers

Other



# 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

# ICER appraisals of localized prostate cancer treatment options

- Active surveillance
- Radical prostatectomy
- Brachytherapy
- IMRT
- Proton beam

# Radiation for prostate cancer Compared to IMRT

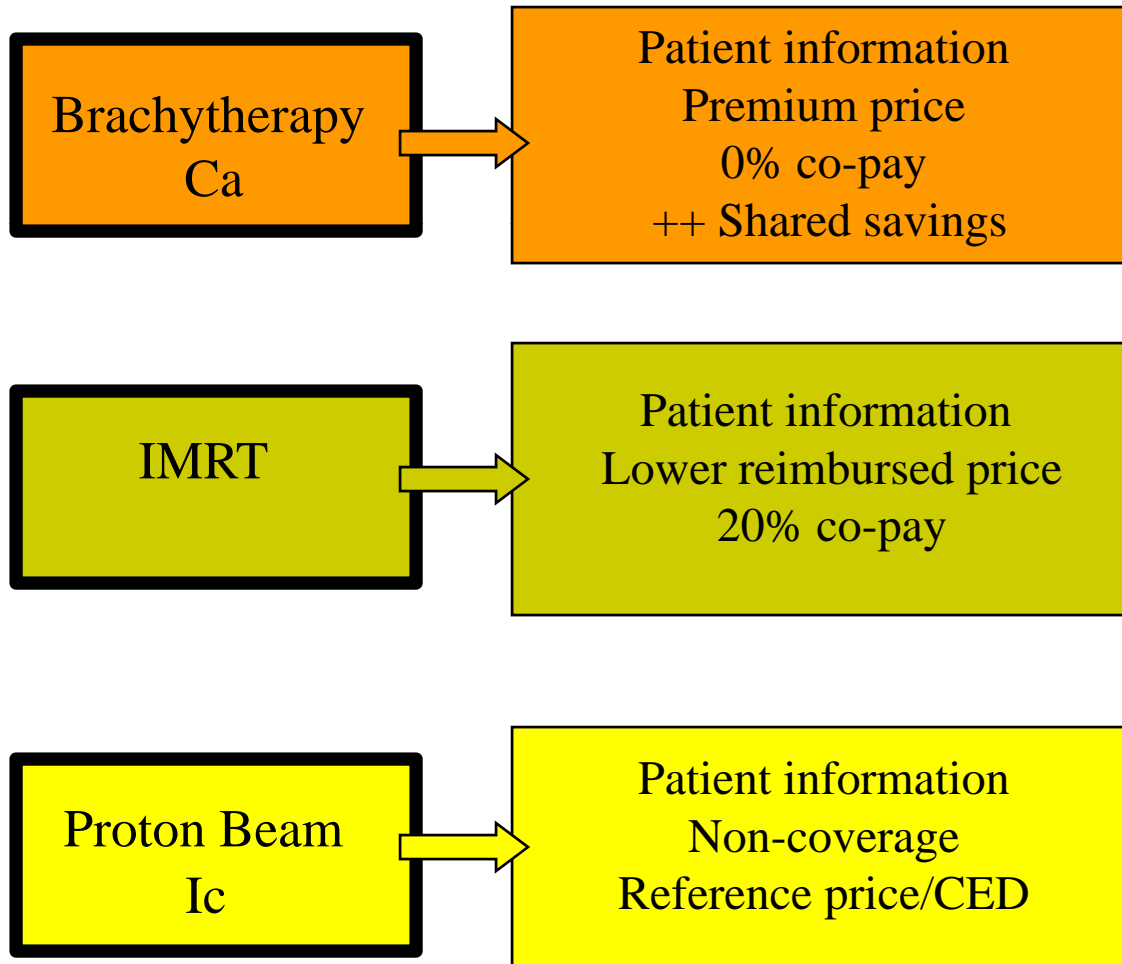
Comparative Clinical Effectiveness	Superior: A	Aa	Ab	Ac
	Incremental: B	Ba	Bb	Bc
	Comparable: C	Brachytherapy = Ca	Cb	Cc
	Inferior: D	Da	Db	Dc
	Unproven/Potential: U/P	Ua	Ub	Uc
	Insufficient: I	I	I	PBT = Ic
		a High	b Reasonable/Comp	c Low
				15
				15

*Comparative Value*

# From Comparative Effectiveness to Medical Policy

- Proton beam for low-risk localized prostate cancer falls into category 1
  - Inadequate evidence of comparative net health benefit
- IMRT for these patients falls into category 3
  - Higher cost for comparable net health benefit

# From Comparative Effectiveness to Medical Policy



# Marginal Medicine and Priority Setting

- Do categories of marginal medicine offer an evidence-based “language” to engage clinicians in discussions of potential waste?
- Which categories are best suited for medical policies related to priority setting?
  - Relative yield?
  - How easy to gain clinician acceptance?
  - Do the policy tools exist to manage it?





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**For further information:**

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