Comparative Effectiveness Research: What's at Stake for Radiation Oncology

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The good old days

Impetus for change

- Policy givens:
  - Unsustainable cost increases linked in part to overuse of technology
  - Unexplainable variation in practice patterns
  - Not enough evidence for decisions about treatment options
- International efforts (health technology assessment)
  - NICE in England
- Comparative effectiveness in the stimulus bill
  - $1.1 billion
    - $400 million NIH, $300 million AHRQ, $400 million HHS
    - Federal coordinating council to advise on HHS priorities
    - IOM "shopping list" for first topics created June 2009

Ready for his signature

- CER in the Senate Bill
  - Independent non-profit Patient-Centered Outcomes Research Institute (PCORI)
  - Stakeholder Governing Board
  - ~$500 million per year from Medicare and insurers
  - Many intersecting advisory committees
  - Acknowledgment of role of professional guidelines
  - Limitations on use of CER assessments:
    - Not hard wired to coverage decisions at Medicare
    - No direct use of cost-effectiveness thresholds

Comparative Effectiveness Research

- Evidence generation
  - Prospective head-to-head trials
  - Observational studies using clinical registries
- Evidence synthesis
  - Systematic evidence review
  - ? Cost-effectiveness analysis

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Evidentiary Challenges for Radiation Oncology

- Evidence of variation in practice patterns and rapidly increasing costs
- Techniques and devices are constantly evolving
  - Potential for future innovation/improvement not important
- Few RCTs or other high-quality designs
- May not compare to best alternatives
- Lack of consistency in outcome measures
- Lack of evidence from use in representative patients
- Short-term results
- Best hands problem

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What will payers do with CER assessments?

- Medicare
  - Integration of CER assessments into National Coverage Determination (NCD) process
  - Future applications to reimbursement?
- Private payers
  - Initial coverage decisions
  - Payment and Benefit Design

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ICER evaluations of radiation therapy for localized prostate cancer

- 2007: IMRT vs. 3D-CRT
- 2008: Brachytherapy, proton beam, IMRT
- 2009: Active surveillance and prostatectomy
- 2009: Summary report on all management options for localized prostate cancer

Evidence Quality

- 4 RCT reports
  - None explicitly compared treatments of interest
- 1 report from non-randomized controlled study
  - Brachytherapy vs. IMRT (Eade, 2008)
- Remaining studies all case series
  - Mostly single-center, mostly uncontrolled

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Evidence Quality (cont.)

- Comparisons of benefit/harm complicated by
  - Variable biochemical failure and toxicity definitions
  - Definition and proportion of low-risk populations
  - Detail in reporting of adjuvant treatment received
  - Population demographics
- Pooled estimates subject to high degree of heterogeneity
  - Extremely wide ranges of rates for many estimates
  - Data on PBT particularly sparse

ICER Integrated Evidence Rating

Comparative Clinical Effectiveness

	a High	b Reasonable/ Comparable	c Low
Superior A	Aa	Ab	Ac
Incremental B	Ba	Bb	Bc
Comparable C	Ca	Cb	Cc
Unproven U/P	Ua	Ub	Uc
Insufficient I	I	I	I

Comparative Value

Radiation for localized prostate cancer Compared to IMRT

Comparative Clinical Effectiveness

Comparative Clinical Effectiveness	a High	b Reasonable/ Comparable	c Low
Superior A	Aa	Ab	Ac
Incremental B	Ba	Bb	Bc
Comparable C	**Brachytherapy Ca**	Cb	Cc
Unproven U/P	Ua	Ub	Uc
Insufficient I	I	I	**PBT = Ic**

Comparative Value

Comparative Effectiveness: Demonstration kickoff meeting

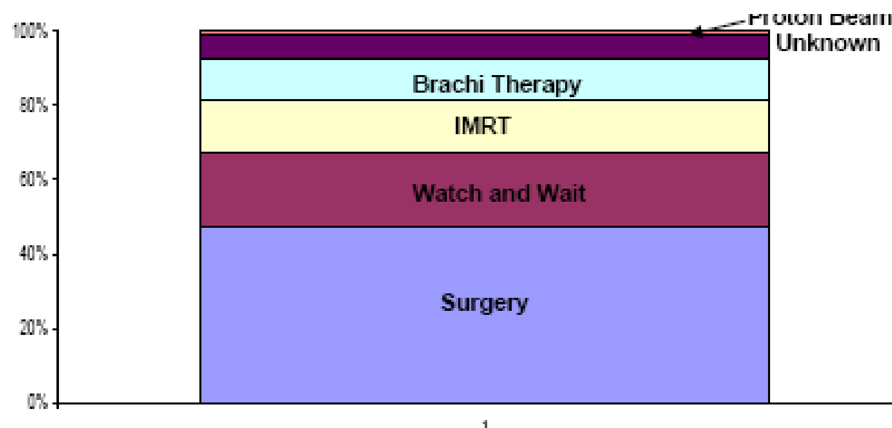
March 18, 2009

EACH members

EACH
Employers Action Coalition on Healthcare

Providers	Health Plans	Employers	Other

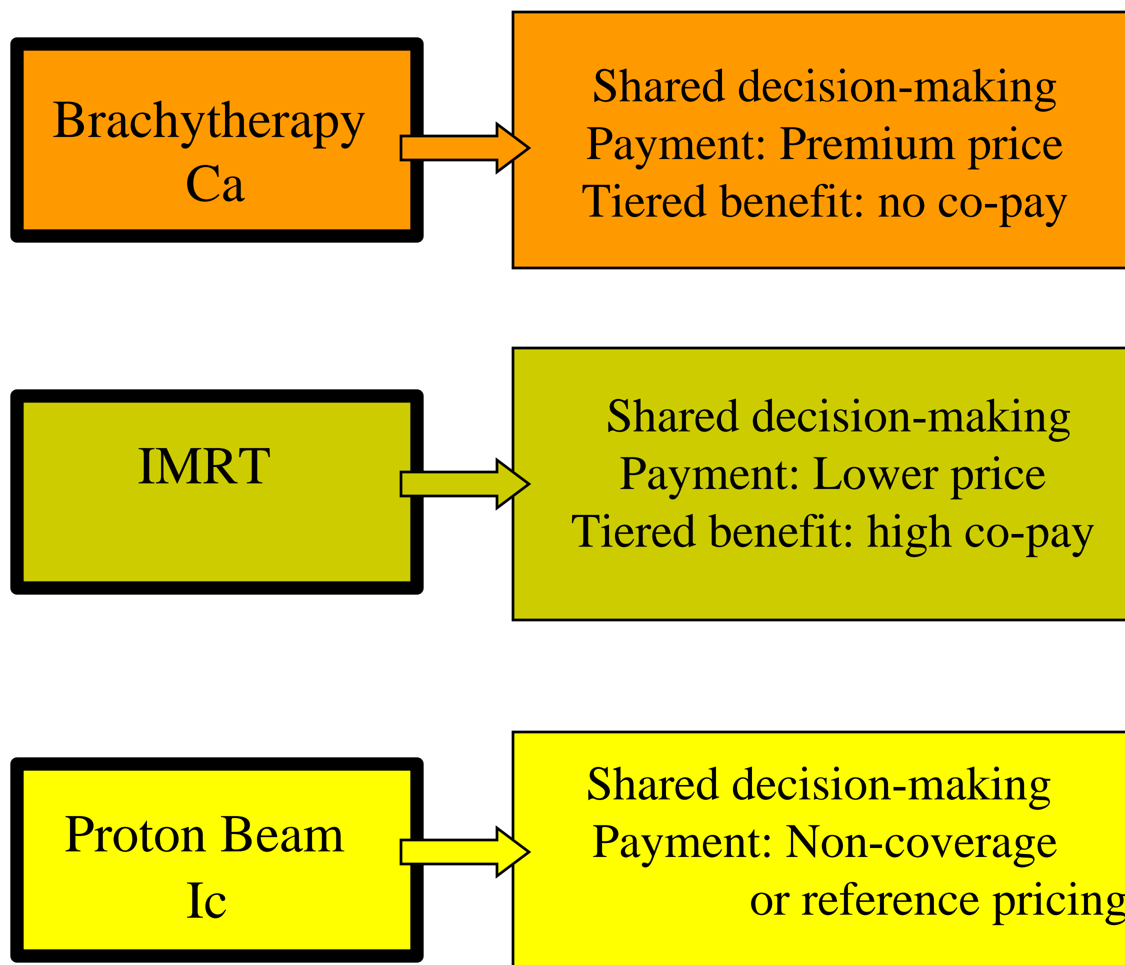
One view of the mix of therapies



Type of Therapy	Total %	Range Across [redacted] Hospitals Reviewed
Surgery	48%	38%-64%
Watch and Wait	20%	8% - 28%
IMRT	14%	6% - 21%
Brachi Therapy	12%	5% - 21%
Unknown	5%	0% - 11%
Proton Beam	1%	0% to 3%

PreliminaryChartReviewData

From Comparative Effectiveness to Medical Policy



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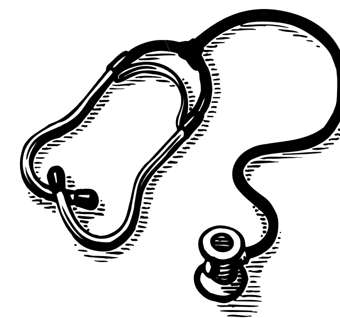
PROSTATE CANCER

A diagnosis of prostate cancer can be overwhelming. Here, we present the results of a comprehensive review of the many management options available for men with low-risk prostate cancer. This patient decision aid is designed to give you an idea of the clinical effectiveness, side effects, and costs of the various options and to empower you to have the knowledge you need to make an informed decision with your health care providers. We also provide a list of key questions to ask your doctors about the different management options. The content of this website is based on a comprehensive appraisal of the different options for low-risk prostate cancer conducted by the Institute for Clinical and Economic Review. The content was created in consultation with clinical experts from (list provider groups? List health insurers?). The Employers Action Coalition on Healthcare (EACH), an initiative of several employer groups, providers and health insurance companies, supported the development of this patient-decision aid.

This website is intended for patients who have a diagnosis of low-risk prostate cancer. It is important for you to confirm with your doctor that this information is right for you. If you have any questions or concerns about the use of this site, please contact your health care provider.



About Prostate Cancer

Benefit Design and CER

- Oregon experiment
  - "Preference-sensitive" interventions trigger 50% co-insurance
    - All CT scans
    - All MRIs
    - All angioplasty and CABG
- California purchaser
  - Tiered benefit design for low back pain services

Where should you go from here?

Conclusion

- Comparative effectiveness research will have a significant impact on the development, evaluation, and adoption of technologies
- Specialties that have the infrastructure to develop and implement evidence to guide better decision-making will have a significant advantage
- Action this day: Organize for evidence
  - Seek participation in the national CER entity
  - Standardize outcome measures
  - Push for comparative research of complementary designs
  - Collaborate with evidence review groups to learn and teach as you develop guidelines or other evidence guidance

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