Comparative Effectiveness >A vs. B

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Blue Plans Cover Every Community in the Nation

- 39 Blue Cross and/or Blue Shield Plans
- 98 million members
- Contract with 90% of hospitals, 80% of doctors
- 5-million member FEP Program – Largest private health insurance product in world
- Largest processor of Medicare claims in the nation
- 1985 Technology Evaluation Center (TEC)
Technology Evaluation Center (TEC)

- TEC’s mission is to provide health care decision makers with timely, objective, and scientifically rigorous assessments that synthesize the available evidence on the diagnosis, treatment, management, and prevention of disease.
Technology Evaluation Center (TEC)

- Rigorous assessment of clinical evidence, systematic review with quality appraisal: Does this technology improve health?
- Independent, expert Medical Advisory Panel
- TEC Assessments 3-year inventory at [www.bcbs.com/tec](http://www.bcbs.com/tec)
- Medical Policy Reference Manual (MPRM): a confidential and proprietary inventory of approximately 350 evidence-based policies, updated annually, that is offered to support Blue Plans’ operations*
- Dedicated, interdisciplinary professional staff
- Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center ([www.ahrq.gov](http://www.ahrq.gov)) since 1997
- AHRQ Comparative Effectiveness Review EPC cancer and infectious disease since 2009

*Note: Each Plan, acting independently, may adopt the MPRM, in whole or in part, modify it, or reject it, in making that Plan’s own medical policy decisions.
Comparative effectiveness addresses strategies to manage a condition, taking into account real world practice and variations in patient populations.

Institute of Medicine national priorities for comparative effectiveness research (http://www.hhs.gov/recovery/programs/cer)

100 priority topics
- Half compare the care delivery system ("how or where services are provided")
- One-third address racial and ethnic disparities
- One-fifth address patients’ functional limitations and disabilities

Clinical topic priorities
- Cardiovascular and peripheral vascular disease
- Psychiatric and neurologic disorders
- Cancer
CER > A vs. B: Strategies to Manage a Condition

• Future research on treatments for localized prostate cancer:
  – Focus changed from: Comparative effectiveness of surgery, radiotherapy, etc.
  – To: Who should be treated?
  – (http://effectivehealthcare.ahrq.gov/ehc/products/236/537/Future04--ProstateCancer-09-23-2010FINAL.pdf)

• Accelerated partial breast irradiation after breast-conserving surgery for early stage breast cancer
  – What is the critical length of follow-up to compare recurrence?
  – Is it replacing no radiation therapy or best radiation therapy?
  – What about the use of accelerated whole breast irradiation?
**APBI/WBI History and Context**

- Acceptance of BCS followed long period of RCT follow-up and scrutiny
- Early Breast Cancer Trialists’ Collaborative Group (EBCTCG) and others showed that post-BCS whole breast irradiation (WBI) vs. no WBI significantly reduced IBTR (6.7% vs. 22.9% 5 yr)
- Multivariate analyses found no subgroup with low risk that did not benefit from WBI
- EBCTCG found survival advantage for WBI
- Careful examination of RCT follow-up shows that IBTR risk remains at substantial levels after 5 years: Early Breast Cancer Trialist’s Collaborative Group (2005) patient level meta-analysis (N=6,097) BCS + RT IBTR 6.7% at 5 yr, 10% at 10 yr

IBTR = Ipsilateral breast tumor recurrence
Whole breast external beam radiotherapy (WBI) is standard of care.

EBCTCG (2005)

6097 women with BCS and node-negative disease

5-year gain 16.1% (SE 1.0)

Isolated local recurrence (%) vs. Time (years)

BCS vs. BCS + RT

0 5 10 15

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TEC example:
Accelerated partial breast irradiation (APBI)
(http://www.bcbs.com/blueresources/tec/vols/22/22_04.pdf)

• Issues with whole breast irradiation (WBI)
  – Long process (5 times a week for 5-6 weeks)
  – Contrary to recommendations, many women do not receive WBI after breast-conserving surgery

• Alternative 1—Accelerated partial breast irradiation (APBI)
  – Most recurrences are close to tumor bed: Need to irradiate whole breast? Or focus on tumor bed?
    • Treatment is faster because less area to cover
    • Outcomes may look better (cosmesis)
  – Several types of APBI: interstitial brachytherapy, balloon brachytherapy, external beam RT, combination

• Alternative 2—Accelerated whole breast irradiation (AWBI)
  – Treat whole breast in fewer, higher dose fractions
  – For selected group only
Where Are We Now?

- At least 5 RCTs of APBI vs. WBI are ongoing, mature results (7-8 years) needed to establish relative rates of IBTR

- Clinical context issues:
  - Extent to which APBI is replacing WBI vs. No RT
  - Access
  - Informed consent
  - New developments re positive lymph nodes

- How will AWBI fit in?
Comparative effectiveness “stands on the shoulders” of present knowledge. There are significant obstacles to assessing outcomes.

- Outcome measures don’t measure health
- Progression-free survival
- Inconsistent reporting of adverse effects
- Selective reporting and publication bias
- Gap: efficacy versus effectiveness
- Focus often limited to diagnosis and treatment
Early palliative care in metastatic non-small-cell lung cancer: a randomized controlled trial

Standard oncologic care alone versus standard oncologic care plus palliative care early after diagnosis

- Early palliative care improved quality of life, depression, anxiety
- Decreased resource use and aggressive end-of-life care
- Counterintuitive: longer survival (2 months)
- Generalizability?

Costs: The Third Rail of CER

Spending on Health Care as a Percentage of Gross Domestic Product Under an Assumption That Excess Cost Growth Continues at Historical Averages

Source: Congressional Budget Office, 2007 (15).
Summary

• Comparative effectiveness addresses strategies to manage a condition, taking into account real world practice and variations in patient populations.

• Comparative effectiveness includes systems of care delivery to improve outcomes.

• New questions can lead to new paradigms. Counterintuitively, early palliative care in metastatic non-small-cell lung cancer resulted in less aggressive end-of-life care and longer survival.

• Comparative effectiveness “stands on the shoulders” of present knowledge. There are significant obstacles to assessing outcomes.

• Cost is the “Third Rail” of comparative effectiveness research. Healthcare professionals and patients have a unique opportunity for leadership.