Influence of Imaging-Related CER on Health Policy Decisions in the United States

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• Healthhelp (utilization review) – Consultant
• GE Healthcare (CER Advisory Board)

Talk Outline
• Comparative Effectiveness Research
• BOLD
• Healthcare Reform in the U.S.

Talk Outline
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• Healthcare Reform in the U.S.
Inappropriate Imaging

- 30-40% of imaging studies in the U.S. may be inappropriate

Picano E. Sustainability of medical imaging. BMJ. 2004;328:578-580

- CER helps to define appropriate

Talk Outline

- Comparative Effectiveness Research
- BOLD
- Healthcare Reform in the U.S.

CER vs. CEA

- Generates scientific knowledge
- Real world settings
- Compares viable clinical alternatives
- Guides healthcare decisions to promote optimal results
- Uses patient perspective

CER

5 Ways to Allocate $1 Million

Lives saved

X is cheap to dx and tx, Y is expensive

5 Ways to Allocate $1 Million

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<th>Lives saved</th>
<th>X is cheap to dx and tx</th>
<th>Y is expensive</th>
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Allocating Scarce Resources

- Only 6% chose most cost-effective option
- ? due to perception that strategy V unfair since it didn’t insure against a disease that’s more costly to treat

Oregon Health Coverage Experience

- 1989- tried to expand Medicaid by limiting what was covered
- Panel (pts, providers) ranked >700 services
- Threshold identified
- Process failed because of lack of consensus re what was not covered
- Implementation controversial and difficult

CER & Translation

Bench to Bedside ➔

Bedside to Benefits ➔

INVEST-Why Evidence Matters

A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures

INVEST Key Results

- Pts undergoing vplasty improved
- Improvement similar to other studies
- Control group improved similarly
- Independent study from Australia had similar results

Roland Score

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Health Affairs 2011

Can Coverage Be Rescinded When Negative Trial Results Threaten A Popular Procedure? The Ongoing Saga Of Vertebroplasty

Wulff et al

Recommendations

- Promote coverage w/ evidence development
- Engage stakeholders (pts and clinicians) in research design
- Reward evidence-based practice
- Support national structure for generating evidence

Talk Outline

- Imaging appropriateness
- Comparative Effectiveness Research
- BOLD
- Healthcare Reform in the U.S.
Back pain Outcomes using Longitudinal Data (BOLD)  
• CER for seniors with back pain  
• $10 million project  
• Part of $1.1 billion American Recovery and Reinvestment Act (ARRA)

CER/Outcomes Research  
• Generates scientific knowledge  
• Real world settings  
• Compares viable clinical alternatives  
• Guides healthcare decisions to promote optimal results  
• Uses patient perspective

BOLD: 3 Aims  
1. Establish BOLD Registry as a resource for back pain in seniors (5,000 patients)  
2. Conduct observational cohort study of early imaging  
3. Conduct RCT of epidural steroid injections plus local anesthetic (LA) vs. LA alone

BOLD CHOICE  
• Aim 1: establish sustainable registry to evaluate effectiveness, safety, and cost-effectiveness of interventions for pts > age 65 with back pain  
• Setting: HMO Research Network  
• Sites  
  – Kaiser Northern CA  
  – Henry Ford Health System Detroit  
  – Harvard Pilgrim/Vanguard Boston

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Aim 1: To establish the BOLD registry  
• 5000 patients ≥ 65 with new primary care visits for back pain  
• Identify patients using Health Care Information Systems (HCIS)  
• Available for further studies
Aim 1: Registry Measures

- 1) Roland-Morris Questionnaire
- 2) 0-10 pain NRS-avg pain past 7d
- 3) pain interference with activity
- 4) patient expectation re recovery
- 5) PHQ-4 Depression/Anxiety
- 6) EQ-5D
- 7) Brief fall screen

Aim 2: Early Imaging Cohort

- Observational cohort
- Compare effectiveness of early imaging to no early imaging in elderly with new episode of LBP
- Outcomes
  - Disability (RMDQ)
  - Pain
  - Subsequent resource utilization

Aim 2: Early Imaging Cohort

- Primary hypothesis- pts receiving early imaging will have worse RMDQ scores at one year c/w those who do not receive early imaging
- Propensity score matching for baseline back-related disability, pain severity, duration and co-morbidities

Aim 3: RCT of ESI

**Lumbar Epidural Steroid injections for Spinal Stenosis (LESS) Trial**

Janna Friedly M.D.
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Department of Rehabilitation Medicine

LESS: Objective

To conduct a double-blind RCT testing the hypothesis that the effectiveness of ESI plus local anesthetic (LA) is greater than epidural injections of LA alone in elderly patients with lumbar spinal stenosis.

BOLD Data Management: Web Page
https://www.backpainproject.org

BOLD Enrollment Graph

UW CHASE- Centers for
Comparative and Health Systems
Effectiveness
• CECORC- Comparative Effectiveness, Cost
and Outcomes Research Center
• HIPRC- Harborview Injury Prevention Center
• SORCE- Surgical Outcomes Research
Center
• PORPP- Pharmaceutical Outcomes
Research and Policy Program
• SeaQoL- Seattle Quality of Life Group
• UW Dept of Health Services
• VAHSR&D- VA HSR and Development

Healthcare Reform 2010
• Patient Protection and
Affordable Care Act of 2010
(PPACA)
• For CER, builds on American
Recovery and Reinvestment
Act (ARRA) $1.1 billion

How Does U.S. Health
Care Reform Address
Evidence and
Appropriateness?
Patient-Centered Outcomes Research Institute: PCORI

- Independent organization
- Goal to help patients, clinicians, purchasers and policy makers make better informed health decisions
- Will spearhead CER

PCOR Trust Fund

- 2010-2012: $210 million
- 2013:
  - $150 million general revenues
  - $1/Medicare beneficiary + private plans
- 2014-2019
  - $150 million general revenues
  - $2/Medicare beneficiary + private plans

Who vs. What

- To date, debate has focused mostly on which groups to cover
- In future, debate likely to shift to what the benefit package should have

The Big Picture

Comparative Effectiveness

Evidence Based Practice

Healthcare Reform

Barriers to Implementing CER