Making a Difference: Motivations and Incentives for Clinicians to Develop and Use CER Best Practices

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Objectives

- Kaiser Permanente - Who we are
- Comparative effectiveness research (CER) overview
- Technology assessment
- Spine case study
- What our physicians are saying
- Necessary conditions for physician adoption of CER
- Summary: The overall benefits and challenges of CER
Kaiser Permanente’s Mission

To provide affordable, quality health care services and to improve the health of our members and the communities we serve.
A few facts about Kaiser Permanente

- Nation’s largest nonprofit health plan
- Integrated health care delivery system
- 8.6 million members
- 14,000 physicians
- 165,000 employees
- Serving 9 states and the District of Columbia
- 36 hospitals and medical centers
- 430+ medical offices
- $40.3 billion annual revenues (2008)
CER overview:
The comparative effectiveness debate

"We don't want [the research] to be used to deny access to care," said Lori Reilly, vice president for policy and research at the Pharmaceutical Research and Manufacturers of America.

Teresa Lee, vice president of the Advanced Medical Technology Association, said using "this research to deny access to appropriate treatments for individual patients with individual medical histories and individual needs should not be the objective."
IOM definition:
What is comparative effectiveness research?

CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a Level, clinical condition, or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.
Or as Dr. Carolyn Clancy put it in the same WSJ article...

“The overarching purpose of the program is to give clinicians and patients information they need to make decisions.”
The need for CER

As advanced as American medicine is, there are clinical areas that contain substantial voids and we need to encourage comparative research to answer real world questions.
Technology assessment in Kaiser Permanente

Interregional new technologies committee

- Monitors new technology
- Evaluates safety, efficacy and effectiveness
- Compares the technology to alternatives
- Makes recommendations
National News
Tuesday, March 03, 2009

- **ImagesMD** will no longer be available through Clinical Library. Use of the site was minimal and the product was difficult to use. We apologize for any inconvenience. [Here are some alternatives.](#)


- [DynaMed](#) is now available! DynaMed is a clinical reference tool, updated daily and contains over 3000 evidence based reviews.

- January 2009 [ABOG Board Certification Reading List, November 2008 L3-ObGyn™](#) and the [2009 ABEM Life Long Learning & Self Assessment](#) have been posted

- CMI launches Pediatric and Bariatric components to their [Weight Management Initiative](#) Web site
Next Interregional New Technologies Committee Meeting

- March 2 - Oakland
- June 1 - Los Angeles (Walnut Center in Pasadena)
- Aug 31 - (teleconference, 10:00 am - 12:00 am PT)
- Nov 16 - Oakland

Download March 2 agenda   Download Materials

Minutes from Previous Meeting on November 17, 2008

- Proton Beam Therapy for Prostate Cancer
- Stereotactic Radiosurgery and Cyberknife
- High-intensity Focused Ultrasound (HIFU) for Prostate Cancer
- Stent Grafts for Endovascular Repair for Abdominal Aortic Aneurysm
- Stent Grafts for Endovascular Repair for Thoracic Aortic Aneurysm
- Applied Behavioral Analysis for Autism
- Femoroacetabular Surgery for Hip Impingement Syndrome
- Retained Foreign Object Prevention with Barcoding or RFID of Surgical Sponges

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The last 115 new technologies examined:

Be Conservative.
- Insufficient quantity and/or quality
- Conflicting or inconsistent
- No evidence

Sufficient & positive
- Do It.
  - 38

Sufficient & negative
- Don’t Do It.
  - 66
  - 3
  - 1
  - 7
An example:

Interventions to treat vertebral fracture
A real problem

- 700,000 new vertebral fractures in U.S. yearly
- Major risk factors are osteoporosis, trauma and malignancy
- Significant cause of pain and disability
- Several treatments available: conservative care, vertebroplasty, kyphoplasty and variations on above
Vertebral fracture

- An estimated $\frac{1}{2}$ of women and $\frac{1}{4}$ of men will have a vertebral fracture in their lives, with only about one third of these cases reaching clinical diagnosis.

- Goals of interventional procedures are to alleviate back pain and stabilize and strengthen the spine — Kyphoplasty also attempts to restore vertebral height.
Percutaneous Vertebroplasty

Bone cement is injected into a diseased vertebral body to provide mechanical support and symptomatic relief.
Percutaneous Kyphoplasty
A variation of Vertebroplasty

A balloon is inserted into the diseased vertebral body, inflated until the collapsed vertebral body is close to its natural height, and then injected with bone cement.
Kyphoplasty
Radiographic images
A real problem redux - small area variation

Clinical questions:

- Is PVP more effective than standard medical management for treatment of vertebral fractures?
- Is PVP more effective than kyphoplasty for the treatment of vertebral fractures?
- What are the adverse events associated with these procedures?
Evidence issues

Studies show rapid, large pain decrease — good enough?

Sources of study bias:

- No randomization/ blinding/ control groups
- Patient selection
- Unknown natural history
- Length of study (long term effects?)
- Incomplete reporting of complications
- Funding source
- Non-standardized techniques
- Non-standardized medical treatment
The body of evidence

<table>
<thead>
<tr>
<th>Vertebroplasty</th>
<th>Kyphoplasty</th>
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<tbody>
<tr>
<td>3 randomized clinical trial</td>
<td>1 randomized clinical trial</td>
</tr>
<tr>
<td>1 prospective case series with comparison group</td>
<td>2 prospective case series with comparison groups</td>
</tr>
<tr>
<td>6+ case series</td>
<td>7+ case series</td>
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Vertebroplasty vs. Kyphoplasty

1 small prospective case series with comparison group

Remarkably similar, findings suggestive of benefit, but studies shared many study limitations.
Adverse events and unknowns

- Localized bleeding, infection and/or resultant pain or neurological symptoms following cement leakage. Leakages have the potential for pulmonary embolism. Leakages infrequently necessitate therapy or surgery.

- It is unknown whether subsequent fractures in adjacent vertebrae is a complication.

- Bone cement is subject to minimal FDA oversight and there have been public health notifications to physicians about the types of complications that can occur.
Reports received in 2008 and 2009 up until Aug. 31, 2009 revealed 23 records. With duplicates removed, the records include:

- 1 report of patient death from patient undergoing several surgeries including multiple spinal implants
- 2 reports of paralysis
- 2 reports of symptomatic cement leakage
- 1 report of allergic reaction
- 1 report of blood pressure drop and breathing problems
- 3 reports of delivery system breakage, no injury
- 1 report of needle breakage, with needle successfully removed
Search for “Kyphoplasty” in the FDA MAUDE database on Aug. 31, 2009

Kyphoplasty 2008 and 2009 reports received up until Aug. 31, 2009 revealed 65 records. With duplicates removed, the records include:

- 12 deaths
- 1 report of patient arrest
- 11 reports of paraplegia, motor loss, cord syndrome, numbness or other long-term complication
- 2 reports of vertebral body collapse or compression fracture
- 3 reports of pulmonary embolism
- 2 cases of pulmonary complications
- 5 reports of pain
- 4 reports of hematoma or hemorrhage
- 1 report of fever and hypoxia
- 6 reports of cement leakage
- 5 balloon ruptures
- 1 report of repeat treatment
- 3 reports of infection
- 1 report of reaction to cement
- 1 report of spinal cord puncture
- 1 report of device issue with no injury report
Conclusions of independent medical reviewers: The Vertebroplasty overturn

- “Vertebroplasty and kyphoplasty have been shown to be very effective for immediate and lasting pain relief. Vertebroplasty has been used for over 10 years with excellent results.”

- “Vertebroplasty and kyphoplasty have a proven place in the treatment of compression fractures.”

- “The clinical efficacy of vertebroplasty and kyphoplasty has not been clearly established. It is unclear whether these procedures will provide significant benefit to the patient.”
Various bone cement and tamps have been FDA approved. In 2002 and 2004 FDA warmings were posted for bone cements for vertebroplasty and kyphoplasty.

No national coverage decision (2009).
What physicians are saying

- I’ve just done 50 Kypho cases- we should be able to figure this out...

- We’re getting consults to do PV at multiple levels- is this right?

- Surgeons should treat patients, not x-rays.
Oh, by the way…

- Supply costs for Kyphoplasty are about $2,500 more than Vertebroplasty per vertebrae.

- And professional fees for Kyphoplasty are twice those for Vertebroplasty.
Now that you’ve seen the evidence…
What to do?

• Ongoing interdisciplinary discussion using published evidence and internal experience

• CER
The right organization of care will promote uptake of CER

- Salaried physicians - not paid per case
- Planned workforce split between primary care and specialties
  (everyone has plenty of useful work to do)
- Data generated as part of routine work
- Professional commitment to provide and improve care based on evidence
In summary

- It’s an uncertain and imperfect world and decisions still have to be made
- The best health care in the world can be even better
- Being explicit and transparent about analytical methods and judgments aids decision making by all
- Proper delivery systems design supports professionalism
- CER can deliver
  - Best treatment options for patients, and possibly
  - Cost savings to our country