Today’s Objectives

- Identify resources beyond registry data
  - Interregional New Technologies Committee
  - Technology Inquiry Line
- Use these resources to refine clinical questions
  - Identify the elements of a quality research article
  - Discern between high and low quality articles
- Assessing the quality of a research article

Identifying Resources

- Safety and Efficacy
- Evidence Analysis
- Effectiveness
- Comparison
- Long term health outcomes
- Selection and Contracting
- Interregional New Technologies Committee (INTC)
- National Product Council (NPC)
- Interregional Implant Registry Committee (IIRC)
Collaborative Resources

Surgical Outcomes and Analysis
NATIONAL PERMANENT IMPLANT REGISTRIES

Providing product performance and utilization data to the KP National Product Council ...

Providing the KP Interregional New Technology Committee with data to assist in the review and selection of new medical technologies

http://cnwcdwvs008.wcdk.kp.org/NIRW/index.htm

Literature Review Resource

18 members
Interregional and Inter-entity
- Monitors new technology
- Evaluates
  - Safety, Efficacy, Effectiveness
- Recommendations inform regional practices
- Uses internal & external reviews
- PMG expert opinions

Interregional New Technologies Committee (INTC)
National Product Council (NPC)
Interregional Implant Registry Committee (IIRC)

Using this Resource

http://cl.kp.org/national/cpg/intc/index.html
Wait There’s More…

Technology Inquiry Line

- Available by email or phone
- Extensive database of inquiries
- Interregional perspectives
- Access to contracted resources
- Skilled methodologists
- Response time
- Anatomy of an inquiry response
Refining Your Clinical Question

- Learn what is known and not known
- Meet potential collaborators
- Make your clinical question more precise
- Anticipate the critique of your work
- Be more efficient

Make your work have more impact!

Today’s Objectives

- Identify resources beyond registry data
- Interregional New Technologies Committee
- Technology Inquiry Line
- Use these resources to refine clinical questions
- Assessing the quality of a research article
Assessing the Quality of a Research Article

Why Critically Appraise the Literature?
- Are findings reliable?
- Can you make sense of the results?
- What do the results mean in the context of your decision making?

Assessing the Quality of a Research Article

- Design and size
- PICOTS – patient, intervention, comparison, outcome, time frame and setting
- Bias – all types
- Funding and publication
- Transparency of methods and results
- Multi-center
Finding What Works In Health Care

Standards for Systematic Reviews. IOM
- Systematically assess risk of bias
- Assess relevance to the study’s populations, interventions and outcomes
- Assess the fidelity of the implementation of interventions

Assessing the Risk of Bias: AHRQ

Table 6. Design specific criteria to assess for risk of bias for patients

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Design Specific Criteria</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
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<tr>
<td>Reporting</td>
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</tbody>
</table>

Assessing the Quality: How to Learn More

- Finding What Works In Health Care: Standards for Systematic Reviews. IOM
Today’s Objectives

- Identify resources beyond registry data
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- Another data resource you must know!

A Second Resource Beyond Registry Data

Selection and Contracting
- Quality, service, and total value
- Evidence-based analyses
- Appropriate acquisition and utilization of high quality products

Interregional New Technologies Committee (INTC)
National Product Council (NPC)
Interregional Implant Registry Committee (IIRC)

http://insidekp.kp.org/npc/

The NPC ... incorporates evidence-based analyses and internal product performance, practice and health outcome data related to the products under consideration.
The Second Resource: National Product Council

- Sourcing
- Contract Terms and Conditions
- Contract Strategy
- Supplier Conditioning
- Utilization Data
- Pricing Data
- Product Safety and Recall Support
- GS1 Standards Adoption
- FDA Unique Device Identification (UDI) Pilots

Engineered bone morphogenic protein

- A genetically engineered version of a bone growth and healing protein
- FDA approved when the protein is infused into a bovine collagen sponge and placed into a cage-like device
- Majority of use is off-label, packing the infused sponge into the space without using the cage-like device

Evidence Reviews and News

May 25, 2011
New Study Links Spine Product From Medtronic to Risk of Sterility in Men

"Dr. Eugene J. Carragee found that men treated with Infuse developed a condition that causes temporary or permanent sterility at a far higher rate than men who received a bone graft ..."

June 2011
Spine Journal Calls for End to "Years of Living Dangerously" in Promotion of Bone Growth Factors

"... Early industry-sponsored clinical research on rhBMP-2... reported no adverse events or complications in hundreds of patients. However, in recent years, the use of rhBMP-2 has been associated with various early inflammatory reactions, cancer, osteolysis, infection, implant dislodgement and occasional life-threatening complications."
Facing intensifying scrutiny...

August 3, 2011
By Barry Meier

Medtronic Giving Yale Grant to Review Bone Growth Data

"…Medtronic announced …giving a $2.5 million grant to Yale to oversee a complete review of the study data that examined the product's safety and effectiveness."

• Full individual patient data from 17 trials, consisting of 8 pilot studies, 8 pivotal RCTs, and one study of 3 patients that was aborted for commercial reasons. The total number of subjects is 2091, consisting of 1077 rhBMP recipients and 1014 control subjects.

YODA: Yale University Open Data Access Project

A Model for Dissemination and Independent Analysis of Industry Data

Meanwhile at KP...

• Spine registry data is growing and being analyzed
• Approximately 4,500 patients with rhBMP since 2009
• Volume and dosage by procedure and spine level
• Complications
Informing Clinical Practice and Transforming Care Delivery

APPENDIX

Evidence Analysis
Inferior Vena Cava Filters

An implant used to help prevent fatal pulmonary emboli
KP used 3 of 4 suppliers, >$1M/yr
Evidence drove clinical requirements;
KP leveraged lack of evidence
Dynamic Bidding Results

Environmental scorecards were also collected from the suppliers and used in the decision.

Answering the Questions

A registry is needed to:

- Identify patients for safety alerts or recalls
- Enable comparative effectiveness research
- Report utilization and performance data
- Supplement new clinical trial data
- Inform future clinical recommendations