Evidence-Based Medicine & Comparative Effectiveness Research

Kent Bottles, MD
President of ICSI, Bloomington, MN, www.icsi.org
Though Results Are Unproven Robotic Surgery Wins Converts

G. Kolata, NY Times, Feb 14, 2009

• Robotic surgery costs more
• $1,500 to $2,000 per patient
• Not clear if outcomes are better, worse, or the same as surgery without robot
• No large studies planned or under way
Though Results Are Unproven Robotic Surgery Wins Converts  
G. Kolata, NY Times, Feb 14, 2009

- Medicare study 2003 to 2007
- Compared 6,899 4 inch incision v. 1,983 laparoscopic surgery (many with robot)
- Lap: shorter stays, less blood, less resp/surg complications, more incontinence and impotence
Though Results Are Unproven Robotic Surgery Wins Converts

G. Kolata, NY Times, Feb 14, 2009

- Marketing has driven demand
- 2009
  - 85,000 had prostate surgery
  - 73,000 had robotic surgery
  - 86%
  - 8 years ago 5,000 had robotic surgery
Though Results Are Unproven Robotic Surgery Wins Converts  
G. Kolata, NY Times, Feb 14, 2009

• “There is no question there is a lot of marketing hype. I just think that in this particular instance, with this particular robot there hasn’t been a quantum leap in anything.” Dr. Gerald Andriole, Wash U

• “I say robotic surgery has to be better to justify its learning curve, to justify its unknown cancer control, to justify its increased cost.” Dr. H. Lepor NYU
Though Results Are Unproven Robotic Surgery Wins Converts

G. Kolata, NY Times, Feb 14, 2009

• “From Day 1, when I sat down at that robotic console, I knew we would give patients a better outcome.” Dr. Vipul Patel

• It takes 200 to 300 robot-assisted surgeries to become highly proficient

• “The battle is lost. Marketing is driving the case here.” Dr. Jeffrey Cadedu
“Doctors and medical centers advertise it, and patients demand it…. [creating a] “folie a deux.””  Dr. Michael J. Barry, MGH

“With the stream of prostate cancer patients that come through this is a big, big business.”  Dr. Jason Engel, GWU

Hospital investment
- $1.39 million for the robot
- $140,000 a year for the service contract
A Simple Health Care Fix Fizzles Out
Keith J. Winstein, WSJ, Feb 11, 2010

• Courage Study, NEJM, 2007
• 2,287 patients studied for 5 years
• Patients with chronic chest pain usually receive no benefit from stents when used with cocktail of generic drugs
• Cardiac stress testing should be done before stent placement to see what causes pain
A Simple Health Care Fix Fizzles Out
Keith J. Winstein, WSJ, Feb 11, 2010

• Boston Scientific shares fell on day study published

• US stent implants declined 13% in the month after the study published

• “Most haven’t voluntarily incorporated the Courage criteria into their practice. What’s going to continue to drive practice is reimbursement.”—Dr. William Boden
A Simple Health Care Fix Fizzles Out
Keith J. Winstein, WSJ, Feb 11, 2010

• Sanjay Kaul, cariologist at Cedars Sinai estimates US could save $5 billion a year if all doctors follow Courage criteria
• Most pts do not receive stress test before receiving stent
• Courage’s finding apply to 1/3 of pts receiving stents
A Simple Health Care Fix Fizzles Out
Keith J. Winstein, WSJ, Feb 11, 2010

• Invasive cardiologists average $500,000 a year in 2008
• Up 22% from 1998
• Pts have little incentive to decline stent
• Cardiologist get $900 per stent procedure
• Medicare is legally barred from considering treatment benefit when deciding how much to pay MD for procedure
A Simple Health Care Fix Fizzles Out
Keith J. Winstein, WSJ, Feb 11, 2010

• Washington State Health Technology Assessment Program tried to put Courage criteria into practice

• “We don’t want to end up being our own willing executioners” Mitchell Sugarman

• “There were some sincere and also probably some not-so-sincere questions” about definition of stable chest pain
A Simple Health Care Fix Fizzles Out
Keith J. Winstein, WSJ, Feb 11, 2010

• Blue Cross Blue Shield of western and northeast New York
• Requires stress test before stent will be paid for
• Patients must try drug therapy for 1 year before receiving elective stent
• “Bill Bolden has been telling me, we’re looking at a potential of $8 billion in savings,” Cynthia Ambres, CMO
A Simple Health Care Fix Fizzles Out
Keith J. Winstein, WSJ, Feb 11, 2010

• Steven Nissen, MD called study a “blockbuster”

• “It’s certainly remarkable that nothing has been done to put some checks and balances. I have a very strong disagreement with cardiologists who see no reason to do the stress test.” Eric Topol, MD, CAO Scripps
Evidence-based Medicine

- “Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.”
  - Analysis of literature
  - Pick best treatment
  - Movement
Evidence-Based Medicine & Patient-Centered Choice

Canadian Cancer Society RFP
Manske SR, et.al., AJHP 18:409-423, 2004

• Do group counseling programs for smoking cessation work?
• What is the best content for such a session?
• How many sessions should be offered?
• Who should facilitate such sessions?
Canadian Cancer Society RFP
Manske SR, et.al., AJHP 18:409-423, 2004

• 40 year comprehensive literature review
• Deficiencies in purpose, design, and reporting
• Research could only answer one of the four questions posed by Cancer Society
Evidence-based Medicine
ICSI Evidence Grading System

• Primary Reports of New Data Collection
  – Class A: Randomized, controlled trial
  – Class B: Cohort study
  – Class C: Nonrandomized trial, case controlled
  – Class D: Case series, case reports

• Reports that Synthesize Primary Reports
  – Class M: Meta-analysis, decision analysis
  – Class R: Consensus statement, consensus report
  – Class X: Medical Opinion
Evidence-based Medicine
Conclusion Grading System

Grade I: Conclusion is supported by good evidence
Grade II: Conclusion is supported by fair evidence
Grade III: Conclusion is supported by limited evidence
Grade not assignable
Evidence-based Medicine

- Why would anyone be against that?
- Demotes ex cathedra statements of experts to least valid form of evidence
Why do Some Doctors Reject EBD?

- Psychological immune system that operates unconsciously to maintain our positive image of ourselves
- “When it comes to maintaining a sense of well-being, each of us is the ultimate spin doctor.” Gilbert and Wilson
- Humans are hardwired to think highly of themselves & their abilities as physicians
- Cornell study shows subjects over-estimated their own charity purchases, but were accurate about other people’s action
- MBA students estimate of their own contributions to team projects at 139%
Evidence-based Medicine

– Tonelli believes EBM discounts clinical experience
– Certain groups (women, minorities, pts with multiple conditions, etc) are under-researched
– Funding sources dictate what gets researched
– Does measurement and science explain everything that is important in the world?
– EBM does not evaluate tacit knowledge
American Medicine Gets It Right

55% of the time

RAND Study Details

- Alcohol dependence 11%
- Peptic ulcer 33%
- Diabetes 45%
- Prenatal care 73%
- Breast cancer 76%
- Cataracts 79%
Improving the Quality of American Health Care in the 21st Century

- Not about motivating clinicians to work harder or be concerned about safety
- “The complexity of modern American medicine exceeds the capacity of the unaided human mind.” D. Eddy, MD
- It is about system leadership providing doctors with the IT data feedback tools to save more lives
Complexity of Medicine

- 6,000 articles / day
- 150,000 articles / month
- 300,000 RCTs
- 20,000 biomedical journals
Complexity of Medicine

“Asking an individual doctor to rely on his memory to store and retrieve all the facts relevant to patient care is like asking travel agents to memorize airline schedules.”

L. Weed, M.D.
Protocols Can Improve Care

- Measure, learn from, and eliminate variation arising from professionals; retain variation arising from patients.
- Select a high priority care process.
- Adopt an evidence-based best practice guideline.
- Blend the guideline into clinical work.
- Use the guideline as a shared baseline with clinicians free to vary based on individual patient.
Developing A Center For Comparative Effectiveness  
Health Affairs, 11/7/2006

- Australia: Pharmaceutical Benefits Scheme
- UK: National Institute for Health and Clinical Excellence
- Canada: Common Drug Review
- Germany: Institute for Quality and Efficiency
National Institute for Health and Clinical Excellence (NICE)

• Postcode lottery scandals
• 270 member staff and $50 million per year
• Usually does not recommend treatments whose cost per quality-adjusted-life-year is more than $40,000
• Publishes appraisals of treatments for NHS
  – Based on clinical effectiveness
  – Based on cost effectiveness
National Institute for Health and Clinical Excellence (NICE)

- Consultee and commentator organizations
- Independent academic center writes “assessment report”
- “Evaluation report”
- Independent Appraisal Committee writes “final appraisal determination”
National Institute for Health and Clinical Excellence (NICE)

- Royal National Institute of Blind People accused NICE of “incompetence” over delay in approving drug used in Scotland
- Renal Cell Carcinoma treatments
  - Bevacizumab, sorafenib, sunitinib
- Alzheimer’s disease treatments
  - Donepezil, galantamine, memantine
Saying NoIsn’t NICE

• “NICE can be viewed as either a heartless rationing agency or an intrepid and impartial messenger for the need to set priorities in health care.”

• NICE has to “be fair to all the patients in the National Health Service…If we spend a lot of money on a few patients, we have less money to spend on everyone else. We are not trying to be unkind or cruel. We are trying to look after everybody”
The opposition to cost-effectiveness analysis comes from two distinct groups

“The first group includes individuals or enterprises that book other people’s health care spending as their own health care income”

“The second group…includes individuals who sincerely believe that health and life are ‘priceless’ -- for them cost should never be allowed to enter clinical decisions”
Uwe E. Reinhardt

- “It is an utterly romantic notion and, if I may say so, also an utterly silly one. No society could ever act consistently on such a credo”

- “In their daily decisions, American citizens and their political representatives routinely trade health and life for money, which allows economists to infer the value-per-life-year the decision makers had in mind.”
US to Compare Medical Treatments  R. Pear, NY Times, February 16, 2009

- Doubters
  - Betsy McCaughey
  - Rush Limbaugh
  - Congressional Black Caucus
  - Society for Women’s Health Research

- Proponents
  - Senator H. Clinton
  - Rep. Pete Stark
  - Consumers Union
  - Dr. Elliott Fisher
Harnessing Comparative Effectiveness:

An Initiative to Improve the Value of Care for Localized Prostate Cancer

For further information:

www.icer-review.org

Steven D. Pearson, MD, MSc, FRCP
## ICER Integrated Evidence Rating

### Comparative Clinical Effectiveness

<table>
<thead>
<tr>
<th>Superior A</th>
<th>( \text{Aa} )</th>
<th>( \text{Ab} )</th>
<th>( \text{Ac} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incremental B</td>
<td>( \text{Ba} )</td>
<td>( \text{Bb} )</td>
<td>( \text{Bc} )</td>
</tr>
<tr>
<td>Comparable C</td>
<td>( \text{Ca} )</td>
<td>( \text{Cb} )</td>
<td>( \text{Cc} )</td>
</tr>
<tr>
<td>Unproven U/P</td>
<td>( \text{Ua} )</td>
<td>( \text{Ub} )</td>
<td>( \text{Uc} )</td>
</tr>
<tr>
<td>Insufficient I</td>
<td>I</td>
<td>I</td>
<td>I</td>
</tr>
</tbody>
</table>

### Comparative Value

<table>
<thead>
<tr>
<th>a</th>
<th>b</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Reasonable/Comparable</td>
<td>Low</td>
</tr>
</tbody>
</table>
The Project to Improve Prostate Cancer Care

• Localized prostate cancer: the opportunity
  – Approximately 4,200 new cases per 1 million men
  – Significant variation in care patterns across the US
  – Patients and clinicians have time to consider options
  – Approximate prices paid for radiation therapy options
    • 3D-CRT = $10,000
    • Brachytherapy = $10,000
    • IMRT = $20,000-$40,000
    • Proton beam = $50,000-$80,000
## Radiation for prostate cancer

### Comparative Clinical Effectiveness

<table>
<thead>
<tr>
<th>Superior</th>
<th>A</th>
<th>Ab</th>
<th>Ac</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incremental</td>
<td>Ba</td>
<td>Bb</td>
<td>IMRT Bc</td>
</tr>
<tr>
<td>Comparable</td>
<td>Ca</td>
<td>Cb</td>
<td>Cc</td>
</tr>
<tr>
<td>Unproven</td>
<td>Ua</td>
<td>Ub</td>
<td>Uc</td>
</tr>
</tbody>
</table>

### Comparative Value

- a: High
- b: Reasonable/Comparable
- c: Low

- **Proton Beam Therapy = Ic**
From Comparative Effectiveness to Medical Policy

- **Brachytherapy (Ba)**: Patient information
  - Premium price
  - 0% co-pay
  - ++ Pay for performance

- **IMRT (Bc)**: Patient information
  - Lower reimbursed price
  - 20% co-pay
  - -- Pay for performance

- **Proton Beam (Ic)**: Patient information
  - Non-coverage
  - Reference price/CED