

ROLE OF THE SPINE SURGEON; ADVOCACY AND LEADERSHIP

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DISCLOSURES

- SAB; K2M, Osprey, Nanovis, Clariance
- Stock ownership; Surgical Ventures, Morphogeny, Amedica, Surgifile
- Royalties; K2M, Osprey

Burden of Spine Problems

- Healthcare expenditures related to spine problems totaled \$86 billion in 2005; a 65% increase from 1997
- The overwhelming majority of these expenditures related to the nonsurgical management of spinal pain (Rihn, 2009 JAMA)

Economic Burden of Spine disorders

- CLBP remains a significant burden
- Total US costs (direct and indirect) \$100-200 billion/year (Katz 2006)
- Indirect costs are a large portion of total chronic back pain costs
 - 2/3 of total US costs
 - productivity losses are \$28 billion/yr (Nguyen 2007)
 - 85-90% of total costs in Sweden & Netherlands (Ekman 2005; Zampolini 2007)

Thorpe, Which Medical Conditions Account for the Rise in Health Care Spending. Health Affairs. 2004

15 medical conditions account for half the growth in health care spending 1987-2000


1. Heart Disease
 2. Pulmonary
 3. Mental Disorders
 4. Cancer
- **#10 Back Problems**



OBAMACARE



Media focus on negatives, Spine Surgery Under Attack



- NY Times "An Operation to Ease Back Pain Bolsters the Bottom Line, Too" - 12/31/03

New York Times February 2006

"Evidence emerging the medical profession has sold its soul in exchange for..."

Bribes? Consulting fees? Clinical grants, free meds, expense to attend meetings? What about free drug samples??

The Contract - Historical

- sole practitioner
- patient payer > individual covenant
- accountable to patient
- minimal accountability to society
- unquestioned authority and autonomy
- opportunities to demonstrate altruism
- high level of trust

Persists in our self-Image and in society's view of physicians and surgeons.

The Contract - WHAT CHANGED

- Questioning society
 - blind vs earned trust
 - altruism
- New levels of accountability
 - to payers
 - to society

Are Surgeons Stakeholders ?



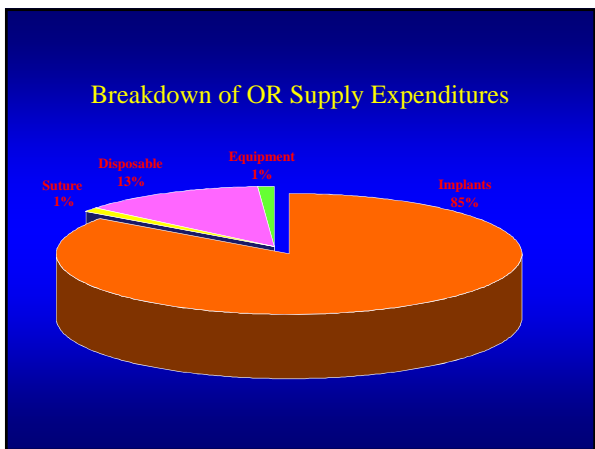
Who's More Trustworthy ?



- Growing costs
- Scrutiny of surgical treatment
- Concerns about value for money

Technical Cost Breakdown of Spinal Cases

• Nursing	10%
• Lab	3%
• Radiology	1%
• Pharmacy	4%
• Operating Rooms (Labor & Supplies) – Equipment, Implants, Disposables, Staff	67%
• Anesthesia	6%
• Other	9%



Key Economic Concepts

- Resources are scarce
- Wants are limitless
- Tradeoffs are inevitable
- Societies and individuals make choices

Thinking as an Economist About Healthcare

- Why are health and health care different than other areas of the economy
- The relationship between health and healthcare
- The role of government in health care markets
- The need to measure value

What Has Been Measured?

- **Technical aspects of surgical treatment**

Radiographic criteria
Process measures such as:
operative time
intraoperative blood loss
length of stay
readmission rate

- **Pain and disability**

sometimes included as secondary measure
in clinical trials

What do Payers Care About?

- Clinical evidence influences payers
- eg Aetna added coverage for LTDR as an alternative to spinal fusion surgery after reviewing evidence (2009)
- However CMS excludes coverage for LTDR partly due to exclusion of those over the age of 60 in two IDE trials

Most Appropriate Value in Spine Care

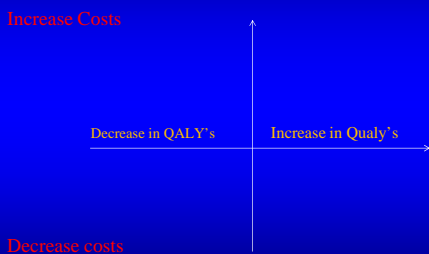
Key Considerations for Value

- Defining value depends on standardized accurate methods of measuring outcomes and costs (Rihn 2009)
- What are the appropriate clinical outcomes to measure?
- What are the appropriate economic outcomes to measure?

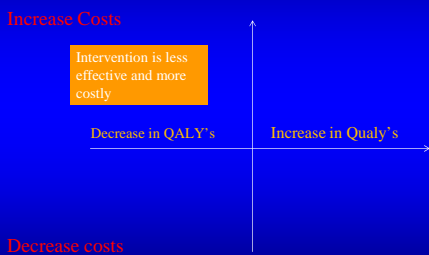
Quality Adjusted Life Years (QALYs)

- **What is it?**
a measure that combines morbidity and into one number
- **Strengths**
Frequently used in:
 - health technology assessment
 - population health monitoring
 - overall estimates of burden of disease
 - comparing relative impact of specific illnesses and conditions
- **Weaknesses**
 - may not capture full benefits of treatment
 - various methodological limitations

The Cost-Effectiveness Paradigm



The Cost-Effectiveness Paradigm



The Cost-Effectiveness Paradigm

Increase Costs

Intervention is less effective and more costly

Decrease in QALY's

Increase in QALY's

Intervention is more Effective and less costly

Decrease costs

Nelson et al, 2009
Annals of Internal Medicine

The Cost-Effectiveness Paradigm

Increase Costs

Intervention is less effective and more costly

Decrease in QALY's

\$100,000 QALY

\$20,000 QALY

Increase in QALY's

Intervention is more Effective and less costly

Decrease costs

Nelson et al, 2009
Annals of Internal Medicine

So – what is of real concern to us?



	Not important at all (%)	Unimportant (%)	No opinion (%)	Important (%)	Very important (%)
Expanding health care coverage	5.26 (15)	8.77(25)	18.95 (54)	49.12 (140)	17.95 (51)
Physician reimbursement	1.4 (4)	.35 (1)	10.5 (30)	37.9 (108)	49.8 (142)
Improving quality of healthcare through value based purchasing	2.81 (8)	5.26 (15)	25.6 (73)	42.4 (121)	23.9 (68)
C.E.R.	2.11 (6)	3.51(10)	21.1 (60)	47.4 (135)	26 (74)
Providing access new technology	1.4 (4)	4.9 (14)	18.6 (53)	43.2 (123)	31.91 (91)

What is Advocacy?

- The act of supporting a policy
- An essential tool for changing practices and policies
- Advocates use their voices to share ideas and persuade others to create change



Why do we need Advocacy?

- As physicians we are witnessing the deterioration of the doctor/patient relationship
- Made worse with an increased volume of bureaucratic red tape

Why do we need Advocacy?

Regulators, third party payers, and trial lawyers are actively supporting policies that are harming our practices

Advocacy Tools

- Understand the issues
- Write letters to/visit policymakers
- Congress, third party payers
- Educate our patients
- Work with others; societies, media, patients
- Donate to PAC's, fundraising
- Research

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INDUSTRY FUNDED RESEARCH

Industry Funded Research

- Industry funded FDA approval pathway studies have been the most meticulous and complete for outcome assessment
- Now held under suspicion as a consequence of their industry sponsorship

Industry Funded Research

- Industry funding in orthopedics is strongly associated with favorable outcomes
- Strong pattern of favorable results to the sponsors is seen in $\frac{3}{4}$ of studies in spinal devices

Gelberman et al, JBJS AM, 2010

Industry Funded Research

- Shah et al reports odds ratio of 3.3 favoring industry supported trials published in the journal SPINE

SPINE 2005; 30

Comparative Effectiveness Research



Federal Coordinating Council for Comparative Effectiveness Research

- Authorized by the American Recovery and Reinvestment Act of 2009
- "... the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a 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." Institute of Medicine statement on CER (Donald Berwick's old group)
- **Pragmatic Trials** – measure effectiveness as opposed to clinical trials which measure efficacy – does it work or not work?

Evidence-based Medicine and Advocacy

Evidence-based Medicine

Evidence-based Medicine is an approach to patient care that emphasizes a knowledge of the current and best clinical evidence available for making treatment decisions with our patients

The Practice of EBM

Practicing Evidence-based Medicine is the integration of the clinical literature's **Best Research Evidence** with the clinician's **Clinical Expertise** and the patient's **Values**

David Sackett

Best Research Evidence

- Note that EBP does not depend on **all** the research evidence available to answer a clinical question, rather only on the **best** evidence, as determined by reviewing and rating the relevant literature
 - Level of Evidence
 - Grades of Recommendation

Are Surgeons Stakeholders ?



YES



Role of Surgeon

- Get involved
- Write a letter
- Speak to your patients
- Support your PAC
- Research
- Information is power

Education

It ain't what you don't know that gets you into trouble. It's what you know for sure that just ain't so."

– Mark Twain



Thank You

Clinical Expertise: **Education**

“Half of what you have learned here in medical school is false—we just cannot tell you right now which half.”

Apocryphal Ivy League Graduation Speech

Clinical Expertise: **Education**

- A great deal of the residency and fellowship experience is **training** and not **education** (history of medicine-pass downs from mentor to mentee over decades)
- Most major textbooks are 2-3 years out of date at publication
- The **old** textbooks from your training years look nice on your bookshelf – AND they should stay there!

Clinical Expertise: **Education**

And a scan of PubMed this year (2014) indicates there are now 52 spinal specialty journals

Clinical Expertise: Education

- Bottom line on education is –
 - What you think you know may no longer be valid
 - What you want to know is impossible to completely assimilate
 - What you need to know may be very hard to find

Clinical Expertise: Experience

- These simple effects suggest that certain clinical events might influence practice out of proportion to their clinical importance
 - Primacy = Early medical training
 - Recency = This meeting
 - Von Restorff = That “unusual” case

EBM and NASS Policy/Advocacy

- Mission Statement:
 - *NASS is a multidisciplinary medical organization dedicated to fostering the highest quality, ethical, value-based and evidence-based spine care through education, research and advocacy*
 - This statement has remained unchanged for the last 2 years but is reviewed yearly at the BOD meeting

The Coverage Task Force

- Evidence will be the foundation for each Coverage Decision when available
- Task Force members will be trained in EBM
- A structured and systematic process will be applied to determine each Coverage Decision

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Best Research Evidence

- It is this use by the clinician of the best research evidence in answering clinical problems that is the **self-correcting** mechanism within the practice of EBM
 - Reduces bias
 - Minimizes outside influences
 - Promotes **ethical** clinical decision making

Clinical Measures

Evidence-based Medicine

EBM can only be meaningfully applied to **clinical research**

- Research investigating the diagnosis and treatment of disease in live, real human beings
- Research whose intent is to evaluate the effectiveness of diagnostics and treatments in the real world on real patients
