By the end of this conference, participants should...

"If you only knew the power of the Dark Side."
—Darth Vader

Conflicts of Interest

- None
- I have no relevant financial relationships to disclose
- I will not be discussing off-label/investigative uses of commercial devices

Three ways evidence-based medicine fails us

- Study results, though initially promising, can’t be reproduced
- The conclusion drawn from the evidence is based on flawed logic
- The evidence is tainted by conflict of interest, or even fraudulent

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The Dark Side of Evidence-Based Medicine

April 3, 2016

By the end of this conference, participants should...
Tabloid vs. scientific journal: What do their editors have in common?

Sometimes Results Can’t Be Reproduced

- How frequently are highly cited studies contradicted by subsequent research?
- “A third of the most-cited clinical research seems to have replication problems”
“Trials with very large effects have limited evidence”
“When additional evidence is obtained, most of the very large treatment effects become much smaller”
“Most large treatment effect estimates should be considered with caution; many are spurious findings”
“Well-validated very large effects for mortality or even life-threatening clinical outcomes are exceedingly rare”

International multi-center trial
- 6104 ICU patients randomized either to:
  - blood glucose 81-108 mg/dl
  - blood glucose less than 180
- Primary end point: Death (any cause) within 90 days
- Intensive glucose control increased risk of death 2.6%

Mistaken design, analysis, calculation
Editors unable/reluctant to take speedy, appropriate action
Journals reluctant to issue retractions; some even fine authors for retractions, or charge to publish letters with corrections
No standard mechanism exists to request raw data

“This metric might not be a valid measure”

J Thorac Cardiovasc Surg. 2014: Reviewed outcome data on 1700 patients after cardiac surgery, with postoperative 6 a.m. glucose < 200 or >200 mg/dl
Level < 200 “not associated with improved risk-adjusted mortality, morbidity, or hospital resource usage”
Conclusion: “postoperative glucose control should not be used as a measure of quality after cardiac surgery”

“Data collection and reporting for SCIP-Inf-4 measure: Cardiac Surgery Patients With Controlled Postoperative Blood Glucose, is suspended immediately”
“There are concerns that it may adversely affect the way clinicians and hospitals provide care”
Flawed logic: The “post hoc ergo propter hoc” fallacy

Polio in 1950s

- 1952 pandemic: 58,000 American children infected; 3,000 died; 20,000 left with significant residual paralysis
- Observation: yearly rates of polio infection rose in spring and summer, as ice cream consumption increased
- Deduction: excess sugar from ice cream increases polio risk

ARB and 30-day Mortality

- Anesthesiology, May, 2015: retrospective review of non-cardiac surgery in 30,000 VA patients 1999-2011
- Patients who resumed ARB by postoperative day 2: 1.3% 30-day mortality
- Patients who did not resume ARB: mortality 3.2%

AIDS in 1980s

Prior to discovery of the human immunodeficiency virus (HIV), the rapid spread of AIDS was associated with the recreational use of inhaled nitrites

Time Out: Cause or Association?

- Could it be that ARBs weren’t restarted because the patients couldn’t tolerate it?
- “It is possible that failure to restart ARB and mortality are common effects of unmeasured aspects of being frail or sick.”
- “Given the retrospective observational nature of the data, we are unable to make statements of causality.”
The Pseudoscience of Quality Improvement

Focus on process of improving quality trumps science and reason

Leaping without looking first

- Point: “We cannot wait — the need to improve quality is urgent”
- Counterpoint: The need to improve treatment of disease is equally urgent, yet we demand rigorous evidence that a treatment works before recommending it
- Law of unintended consequences

Rapid Quality Improvement: Pro & Con

- Point: Any effort to improve quality is better than the present state of affairs
- Counterpoint: Understanding the potential risk and cost of any change is important; net benefit may be zero
- Point: Innovation is good; we should try strategies that have promise though they may be unproven
- Counterpoint: Interventions may turn out to be ineffective or even harmful—but their champions defend them rather than admit failure

The Tension between Needing to Improve Care and Knowing How to Do It

Andrew D. Auerbach, M.D., M.P.H., C. Seth Landefeld, M.D., and Kaveh G. Shojania, M.D.

Surgical Site Infections

2011: Cedars-Sinai Medical Center undertook major quality initiative to reduce SSI in small bowel and colorectal operations

Mandated implementation of “care bundle” with 12 major elements involving changes in practice
Event-free Survival in the Two Years after Noncardiac Surgery among 192 Patients in the Atenolol and Placebo Groups Who Survived to Hospital Discharge.

### Quality leaps forward

- 1996: New ACC/AHA guidelines recommend starting BB before non-cardiac surgery in patients who have hypertension, CAD, "cardiac risk factors"
- SCIP Quality Measure: All non-cardiac surgery patients on BB prior to admission must receive BB on day prior to or day of surgery, and on POD 1 or POD 2

### What are we to do?

- If your patient for non-cardiac surgery is not already on a beta-blocker, don’t start one prophylactically
- If your patient takes a beta-blocker routinely, continue it
- Avoid hypotension
Meanwhile, in Kansas...

- Cynthia Kirk, PhD, filed a whistleblower lawsuit against CareFusion under the False Claims Act.
- As VP of Regulatory Affairs for the Infection Prevention Business Unit of CareFusion, she pointed out compliance violations: ChloraPrep not FDA-approved for prevention of infection or reduction of SSI.
- U.S. government and 31 states joined her lawsuit in 2011, suing for damages arising from Carefusion’s “off-label marketing practices and kickbacks that induced false claims to be made to Medicare and Medicaid”.

ChloraPrep vs. Betadine

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Charles Denham, MD

- He championed a new NQF “Safe Practice” guideline issued in 2010, recommending the use of chlorhexidine/alcohol skin prep to prevent SSI.

The Money, the MD and a $12 Million Patient Safety Scandal

CareFusion to Pay the Government $40.1 Million to Resolve Allegations That Include More Than $11 Million in Kickbacks to One Doctor

CareFusion Corp agreed to pay $40.1 million to settle a federal government lawsuit accusing it of paying kickbacks to boost sales of a pre-surgical skin treatment, and marketing the product for unapproved uses.

The accord announced on Thursday by the U.S. Department of Justice resolves allegations that CareFusion violated the federal False Claims Act by paying $11.6 million to a doctor to promote its ChloraPrep product to healthcare providers.

That doctor, Charles Denham, received the kickbacks while serving as co-chair of the safe practices committee of the nonprofit National Quality Forum, which makes recommendations on healthcare practices, the Justice Department said.
Patient-safety expert Denham will pay $1 million to settle kickback allegations

By Lisa Schencker | March 2, 2015

Dr. Charles Denham, a former leader of the National Quality Forum’s Safe Practices Committee, has agreed to pay the federal government $1 million to settle allegations that he accepted cash in exchange for influencing the committee’s recommendations.

NQF severed ties with Dr. Denham

This concludes our tour of the Dark Side.

Comparative Effectiveness of Skin Antiseptic Agents in Reducing Surgical Site Infections: A Report from the Washington State Surgical Care and Outcomes Assessment Program

Timo W. Heldstab, MD, MSCE, F. Pritchett Dellinger, MD, FAACS, Heather L. Evans, MD, MS, FAACS, Earl Wood Fairall, MD, MPH, Ellen Farnsworth, MD, FAACS, Scott R. Reeves, MD, FAACS, Barbara Thibodeau, MD, FAACS, David R. Blum, MD, MPH, FAACS for the Surgical Care and Outcomes Assessment Program Collaborative

Conclusions

For clean-contaminated surgical cases, this large-scale, state cohort study did not demonstrate superiority of any commonly used skin antiseptic agent in reducing the risk of SSI, nor did it find any unique effect of isopropyl alcohol. These results do not support the use of more expensive skin preparation agents.

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The observations of Koren Solstance Silbert, MD a Los Angeles anesthesiologist, writer, and mother.

Archive for the ‘Evidence-based medicine’ Category