The Advantages and Consequences of Disruptive Business Models in Spine Surgery Practices

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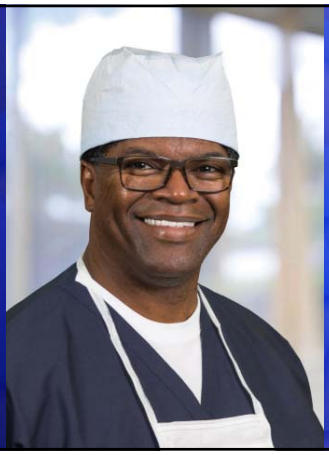
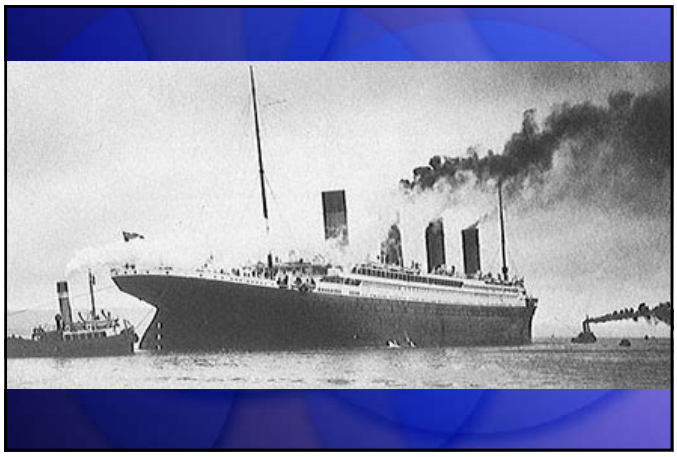
CAHILL SPINE INSTITUTE

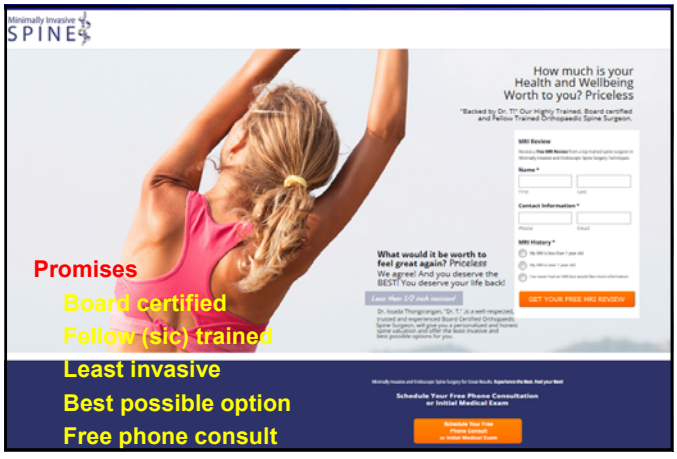
USF HEALTH





Epidemiologic and Economic Impact

- LSI: “Since 2005, we have helped more than 60,000 patients”
- Profit margins are about 34%
- Alfred Bonati has a net worth of over $2,000,000,000 (St. Petersburg Times) after 35,000 operations http://www.tampabay.com/news/courts/civil/dr-alfred-bonati-of-bonati-institute-in-hudson-must-pay-12-million/1070762
- http://www.tampabay.com/news/courts/civil/doctors-legal-battle-reveals-potential-art-trove/1155579
- 93 ambulatory surgery centers in US that are spine-focused http://www.beckersasc.com/lists/90-orthopedics-driven-ascs-to-know.html (Feb. 16, 2016)



Marketing Concerns

- Consultation across State lines often without a license in that state
- Consultation without examining patient
- "Board Certified" surgeons
- "Fellowship Trained" surgeons
- We "will give you the least invasive and best possible options for you" is biased
- Promise of "Band-Aid" surgery in writing and in marketing material

Marketing Issues

- BI claims a 94-98% patient satisfaction rate
- LSI claims a 96% satisfaction rate
- Is this credible when satisfaction forms are filled out on the day of surgery (after sedation and/or general anesthesia), and long term follow-up consists of a phone call at 8 weeks according to the LSI website
- Patients with LBP or leg pain frequently improve spontaneously or with conservative therapy, even without surgery

Training Concerns

- Drs. Bonati and St. Louis are not Board Certified by an ACGME recognized board
- Dr. Bonati trained Dr. St. Louis, founder of LSI
- "LSI surgeons are uniquely trained through a Laser Spine Institute fellowship, in addition to the required university testing and residency programs"
  - —No mandate that surgeons have spine specialty training before coming to LSI
  - —The LSI and BI "Fellowship" is only 6 months long and not ACGME certified. A "certificate" is awarded
  - —Some surgeons lack hospital privileges, or the training to convert an endoscopic procedure into an open one

Indications for Surgery

- High "yield rate"
- Does everyone that comes to one of these centers need surgery, because they wouldn't have come if they didn't need it?
- "Sales commissions and bonuses such as Bahamas trips—are based on both the volume of surgeries booked and the patients' satisfaction" (Jimmy St. Louis, COO of LSI)

Regulatory Issues for Surgery

- Surgical techniques (as opposed to devices) are not regulated by the FDA
- There is virtually no Federal regulatory oversight for the effectiveness of a surgical technique
- Unlike drug maker's ads, surgical adds do not need to disclose indications and risks
- Rather than focus on risks, ads may even show two topless women in bikini bottoms, their backs to the viewer. One of them wears a Band-Aid. "Who just had back surgery?" a caption asks.
- This creates unbalanced expectations

Outpatient Surgicenter Regulatory Issues

- A medical license *in any specialty* is adequate in a surgicenter
  - —As of 2011, there were 36 lawsuits against a single laser-surgery practitioner in Ohio who was an *anesthesiologist*
- Less oversite on requirements for
  - —Training
  - —Board certification
  - —Accredited fellowship training
  - —Inpatient operating privileges

Surgical Unbundling Policy

- Typical surgical plan, *before starting first operation*:
  1. L34 left
  2. L34 right
  3. L45 left
  4. L45 right
  5. L5S1 left
  6. L5S1 right
- Typically, the first operation is for about $35,000 cash, and a $5,000 "discount" is offered for subsequent operations, totaling $185,000 for treating L3-S1 stenosis
- Insurance may be billed about $500,000 per patient

Unbundling Definition

- Improper coding might occur through "unbundling" or "fragmentation." Medicare and Medicaid often will have lower reimbursement rates for groups of procedures commonly performed together, such as incisions and closures incidental to surgeries. Unbundling or fragmenting billing codes illegally increases a provider's profits by billing bundled procedures separately, which results in higher reimbursement from Medicare and Medicaid.

Unbundling Concerns

- "The Bonati Spine Institute is not a Medicare/Medicaid provider, but can treat persons insured by Medicare on a "self-pay" basis"
  https://www.bonati.com/financing-available/
- Patients who could have one operation to fix 3 level stenosis, covered by insurance via standard procedures, may instead forgo their insurance to have 6 unbundled operations, and only receive minimal reimbursement.
- Some patients have used their retirement plans or home equity loans to pay for operations at LSI or BI that are otherwise covered by their insurance.

Electronic Operative Report Concerns

- "Drop down" operative reports are frequently used.
- At some institutions, it is not possible to add specific information not included in the EMR operative forms
- Patients can have numerous operations, for example for CSF leaks or other complications, with the exact same operative report and intraoperative findings

Insurance Billing and Coding Concerns

- Billing for what is dictated vs. performed
- Insurance billing for unbundled procedures
- There is less than one day from the time the patient meets the surgeon to surgery
- The patient is only at the facility for a few days before surgery
- Therefore, the insurance certification process likely begins before the patient even is examined
- Insurance precertification is therefore likely to be based on review of records and films, in the absence of examination or even meeting the patient in person

Informed Consent Concerns

- Patients often meet their surgeons on the day of surgery, in the surgical facility
- They may be told that they will have surgery by "any of the qualified surgeons"
- They may have already paid very high cash fees for their workup and surgery before informed consent is obtained
- They are frequently living in hotels, in an unfamiliar city, without ability to obtain second opinions on the same day as surgery

Informed Consent Concerns

- Because patients come from out of town for surgery, there is no real ability to try additional conservative therapies
- There is no time to try additional conservative therapies, give more time for pain to improve spontaneously, undergo meaningful smoking cessation, etc.

Informed Consent for Elective Surgery in the Outpatient Setting

- There is little clear legal guidance in the US on the question of when and where to initiate consent discussions for elective medical interventions
- The goal is for the patient to make a free and informed decision, free from coercion and duress.

Informed Consent Guidelines: Royal College of Surgeons

- "Obtain the patient's consent prior to surgery and ensure that the patient has sufficient time and information to make an informed decision. The specific timing and duration of the discussion should take into account the complexity and risks of the proposed procedure. **A patient's consent should not be taken in the anaesthetic room."** https://www.rcseng.ac.uk/standards-and-research/gsp/domain-3/3-5-1-consent/

Informed Consent Regulations (UK)

- **"For consent to be valid the patient must …not be acting under duress."**
  - Department of Health (UK). Good Practice in Consent Implementation Guide: Consent to Examination or Treatment. London: Department of Health publications, 2001. Available at http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Consent/ConsentGeneralInformation/fs/en
  - Department of Health (UK). Reference Guide to Consent for Examination or
  - Treatment. London: Department of Health publications, 2001.
  - Available at http://www.dh.gov.uk/PolicyAndGuidance/
- "If doubts arise on the day of surgery, the patient may feel under duress to proceed, as all the arrangements have been made."
  - Informed consent for elective surgery—what is best practice? Owen A Anderson, Mike J Wearne.
  - J R Soc Med 2007;100:97–100

Implications of the Location for Obtaining Informed Consent

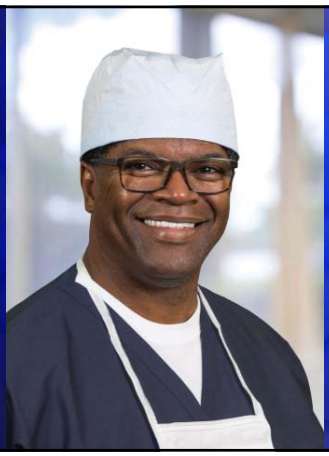
- **"In malpractices cases alleging inadequate informed consent, consents obtained in the preoperative holding area, compared to in the surgeon's office, resulted in significantly higher legal expenses and indemnity payouts – $322,000 higher, on average, for the orthopedic procedures studied"**
  - **Bhattacharyya T, Yeon H, Harris MB. The medical-legal aspects of informed consent in orthopaedic surgery. *J Bone Joint Surg Am*. 2005;87(11):2395-400. http://jbjs.org/content/87/11/2395**

Management Surgical SAEs

- **No emergent way to manage intra-abdominal vascular injury, chest pain, MI, malignant hypertension, PEs, or to discharge the patient to rehab or SNF**
- **CSF leaks may be managed in a hotel with a visiting nurse**
- **Delayed epidural hematomas**
  - **—LSI and BI close at night and on weekends**
- **Patients or visiting nurses in hotel rooms need to call 911 for emergencies**

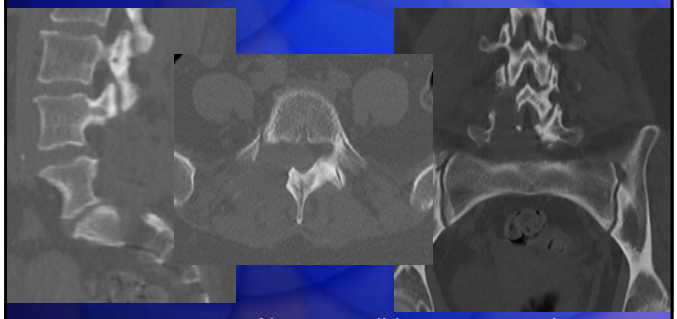
Management of Surgical SAEs

- This is similar to outpatient facilities where cardiac catheterization is performed, without emergent open heart surgery backup available
- This leads to emergent transfers to hospitals both in and out of State
- Often done without formal transfer agreements due to lack of inpatient hospital privileges by the operating surgeon



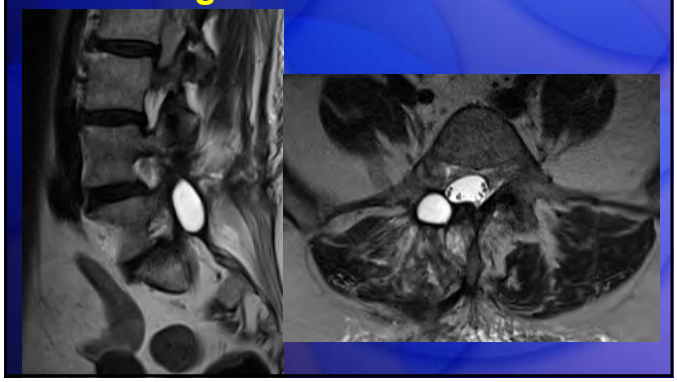
Happy Birthday!

Surgical Destabilization

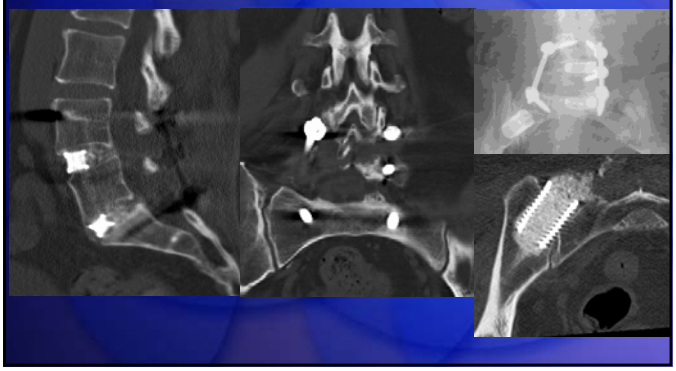


"Least amount of bone possible was removed"

Surgical Destabilization



Surgical Destabilization Salvage



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