One Hit to the Body - Managing Risk in Bariatric Surgery

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- Co-Chair of Stevens & Lee’s Health Care Department and Chair of Health Care Litigation Group
- Past Chairman of the American Health Lawyer’s Association Healthcare Liability and Litigation Group (2002-2005)
- Works nationally with insurance companies, physicians and health care organizations including hospitals and medical practices in areas of risk management, liability reduction and health law and all litigation related issues
- He is an active trial lawyer – a practice he has sustained for over 25 years – representing physicians in state and federal courts in professional liability cases
- Has used his extensive experience as a litigator to develop new litigation strategies as well as new loss control tools in collaboration with leading experts in high risk clinical areas
- Lectures on litigation and risk management topics and has in excess of 200 articles and six textbooks, created films and is involved in national teleconferences
- Has worked with bariatric surgeons and bariatric programs around the country, helping them to reduce their liability exposure by promoting excellence in patient satisfaction and incorporating certain loss control protocols
- Developed risk reduction strategies for medical practices and captive insurers nationally including Novus RRG, specifically created for bariatric surgeons nationally
- An invited editor for SOARD and a featured contributor for Bariatric Times
- A frequent invitee an national bariatric programs such as the Centers of Excellence where he lectures on bariatric surgery issues and risk reduction
- Keynote speaker at the Allied Health Program, ASBS Annual Meeting, June 2007
What’s Happening Nationally?

- Pay-for-performance
  - Over 100 programs in place nationwide, expected to increase
  - Policy-makers, third-party payors, health plans, and purchasers
  - Tying performance to reimbursement
  - Programs vary on reimbursement conditions
  - This means more important than ever to implement best practices in clinical and risk management
  - Headed to specialty-specific?

- Transparency

- Quality benchmarks
WALL ST. DISCOVERS QUALITY
Pay for performance could yield capital for performance

Last month, Standard & Poor's released a position paper on quality and transparency in health care. The core message: Wall Street is preparing to incorporate quality measures into the assessment of a hospital's credit quality. This is a bold step toward understanding and evaluating hospital operations.

The investment community has been interested in the quality of management and governance since the creation of the tax-exempt hospital bond. Until now, however, ratings analysts have had to rely on a qualitative assessment of operational skill. The creation and widespread availability of consistently measured and monitored outcome indicators, along with reliable benchmark data, will allow ratings analysts to incorporate quality measurements into hospital ratings.

The result could easily be thought of as capital for performance. "Over time, it will become clear which organizations are doing really well with quality," says Lisa Sweeney, an S&P analyst and primary author of the report, "Quality and Transparency Could Transform U.S. Not-For-Profit Health Care." "That's going to create winners and losers and that will drive [credit] ratings."

By implication, lower quality rankings would result in lower credit ratings. That, in turn, would increase cost and decrease access to capital. Transparency will drive the connection between quality and access to capital. "Once transparency improves, health plans will be forced to change who they contract with," Sweeney says. "Low quality will become a barrier to survival for hospitals."

S&P has already begun preparing for this sea change by asking hospitals to discuss quality efforts and to report on specific measures, although that information has not yet been used as the basis of a specific rating change. "This is going to become a new thematic part of responding to rating agencies," says Ken Kraftman, managing partner, Kaufman Hall & Associates, Northfield, Ill. "The observation is that there is a strong relationship between quality and financial performance, but the relationship hasn't gotten that much attention yet."

It will, Kaufman predicts, and the dramatic effect that quality could have on the bottom line implies a key role for the chief financial officer on the quality board's senior leadership. "If we get to the point where statistical base and comparisons are valid, with high credibility, you'll have to submit quality measures to the rating agencies just like you submit your financials," Kaufman says.

S&P is modifying its rating process to incorporate an assessment of quality programs. "We're interested in what's going on at the board level, what's going on at the senior management level. Do they have a specific plan? We're looking for a culture of patient safety," Sweeney says.

While S&P now performs a qualitative overview of these activities, it is preparing for a more hard-nosed approach. "We're also asking hospitals to provide specific metrics," Sweeney says. "Over time, we'll build our knowledge base, which will allow us to do fair comparisons from one organization to another."

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PHOTOGRAPHY BY BRIAN CHICCO
Severity continues to be an issue

Median verdicts are staying too high

- In 2001 the median verdict crested $1 million
- One in four verdicts were over $1.2 million
- In 2004, median award was $1,514,000

We have learned of their plan!

American Medical News
April 19, 2004
Why is Severity Staying High?!

- Selective cases being pursued
- Consolidation of counsel
- Surgical complications coupled with a “plus”
- Subjective, non-economic damages
- Courtroom drama will continue¹

¹ Garrison J. “Lawyers learn to share their pain with jurors: They use a technique called psychodrama to connect better by showing vulnerability.” LA Times 2006, Nov. 25.
Lawyers learn to share their pain with jurors

By Jessica Garrison
Los Angeles Times
November 24, 2006

CARLSBAD — The lawyer stood speaking in the center of a dimly lit conference room, flanked by dozens of other personal-injury lawyers. As the attorney recited the final moments of his mother’s life, his voice cracked and his body shook with unspoken grief. And as the robed judges and lawyers watching him also began to weep. Then the others began to make their own confessions. My parents died, one recalls, his voice husky with tears. I was devastated by my father, another said. All of a sudden, I thought about my mother, a third added.

In the corner, Josie Blake, a tall, charismatic attorney in black pants and black top, sits in her chair, her voice strong and confident. Blake is a trial lawyer specializing in wrongful-death and personal-injury lawsuits, precipitant of psychiatry, a group therapy technique that is becoming increasingly popular with both defense lawyers and plaintiffs — as a way to prepare clients to testify in court.

Blake and her mentor, lawyer and author Gerry Spence, say the technique helps people understand themselves better. Participants also credit that it helps them prepare their cases to force their testimony in court.

Psychiatrists who attend extracurricular sessions on the courtrooms or in the back rooms of lawyers. The case is a landmark of his trial lawyers, a three-week criminal trial in which a psychiatrist, known for his work with San Francisco trial lawyer Thomas Reines, was brought in to help him win a $30-million wrongful-death verdict last year against actor Robert Blake.

'It gets very powerful, very emotional,' said Eric Dubin, an Orange County attorney who credits the technique with helping him win a $30-million wrongful-death verdict last year against actor Robert Blake on behalf of the children of his dead wife, Bonny Lee Bakley.
Changing the liability equation means change
Change the Liability Equation, Fundamentally

- Understand the root cause
  - True cause of clinical clusters that cause adverse outcomes

- Understand the root cause
  - True cause of professional liability issues that cause adverse outcomes

- Creating tools/strategies

- Developing an execution plan, embracing the business goals of the practice

- Change means compliance
What Causes Frequency and Severity of Claims?

- Clinical Clusters
- Professional Liability Risk
How to Change the Liability Equation

- Understanding the risk
- Execution: Using the tools and compliance
- Event management
- Using the evidence created and a different defense

In the first place…Create positive evidence…Build the foundation…Being aggressive—using the evidence
What Causes Frequency and Severity of Claims?

Clinical Clusters

- Post-operative leaks
- Pulmonary embolism
- Leaks
- Bowel obstruction

Professional Liability

- New generation consent form
- Bariatric patient contract
- Event management
- Communication
- Five-star service
Drilling Down on Bariatrics

- Certain Clinical Clusters$^2$
  - Post-operative leaks
  - Intra-abdominal abscess
  - Bowel obstruction
  - Major airway events
  - Organ injury
  - Pulmonary embolism

- Certain Professional Liability Risk Issues
  - Expectation management
    - Patient contract
    - Patient test
  - Informed consent
    - The next generation form
  - Communication
  - Documentation
    - Spousal/Family/Advocate Support
  - Service
  - Lack of event management
  - Defense of claims

The Execution Plan

- **Step One – Understanding**
  - Understanding the specific risks – both clinical and professional liability risks

- **Step Two – A Process that Works**
  - Creating actual tools that impact risk, using them and auditing use

- **Step Three – Diffusing the “Plus”**
  - Event management – Creating the evidence

- **Step Four – A *Different* Defense**
  - Using the evidence created
Novus RRG as a Case Study
Step 1 – Understand the Professional Liability Risk

- Traditional risk strategies lend themselves to bariatric surgery… when taken to a new and serious level
  - Right experience
  - Right setting
  - Right team
  - Good communication
  - Solid informed consent
  - Good documentation
  - Safe and defensible

- Findings confirmed by CMS Ruling, by SRC findings
  - 0.14% hospital mortality

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**Confirmed by COE Statistics and CMS Decision Memo**

- **COE Statistics**
  - Adherence to COE benchmark requirements can positively influence clinical outcomes (more on this later)
  - Our underwriters and underwriting committee look at an applicant’s data

- **CMS Decision Memo**
  - “… the Agency determined that the health benefit of bariatric surgery can only be assured in facilities that do large numbers of these procedures performed by highly qualified surgeons. We have evaluated the certification programs of the American College of Surgeons and the American Society for Bariatric Surgery and believe that those facilities recognized by these organizations as Centers of Excellence will be most likely to produce this high level of results. Thus, CMS will cover these procedures only in facilities certified by these organizations.” (Press Release)
  - Our insureds are either COE-certified or have applied/are applying to COE
Step 1 – Understand the Clinical Risk

- Medicolegal analysis of 100 malpractice claims against bariatric surgeons
  - soon to be released in SOARD

  - 69% of events occurred on day of surgery
  - Co-morbidities
    - Diabetes – 31%
    - Obstructive Sleep Apnea – 38%
  - Death occurred – 53%
  - Post-operative leaks – 53%
  - Bowel obstruction – 18%
  - 42% involved surgeon < one year experience in bariatrics

  BACKGROUND: Very few studies have addressed malpractice litigation specific to bariatric surgery. This study was designed to analyze litigation trends in bariatric surgery to prevent further lawsuits and improve patient care. METHODS: A total of 100 consecutive bariatric lawsuits were reviewed by a consortium of experienced bariatric surgeons and an attorney specializing in medical malpractice. RESULTS: Of the 100 lawsuits, 45% were reviewed for defense attorneys. The mean patient age was 40 years (range 18-65), 75% were women, 81% had a body mass index of <60, 31% were diabetic, and 38% had sleep apnea.

“If all hospitals performed at the level of a 5-star rated hospital, 3,297 out of the 86,520 patients could have potentially avoided one or more major inhospital complications from 2002-2004.”

A patient undergoing a procedure in a 5-star rated hospital would have, on average,
- a 66% lower chance of developing a major inhospital complication in comparison to a 1-star rated hospital...
- and a 40% lower chance compared to a 3-star rated hospital

Mortality rate was significantly lower for 5-star hospitals compared to the national average

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- *National inpatient death rate associated with bariatric surgery decreased 78.7%*

- The total number of bariatric surgeries increased 9-fold
Step 1 – Understanding a Program’s Risk

- On-site practice assessment – baseline
  - Data-driven assessment
  - Ph.D. – level personnel on – site
  - Benchmarking the data
  - Comprehensive report with concrete priorities and tools provided as well as an execution plan
  - “Positive audits”...yes compliance is the king
Making Compliance Work

- Tools that work!
  - Practical
  - Easy to incorporate
  - Support provided
  - Templates
  - An easy to follow explanation for implementation and use
  - An education module
  - Adding economic value in the new environment

5 For example, pay-for-performance, patient satisfaction, transparency, and quality improvement.
Step 2 – Creating Actual Tools and Strategies

- Data with input by clinical, legal and risk management team
- For example,
  - Patient history form – includes introductory verbiage and patient attestation
  - Informed refusals
  - At-risk letter
  - Support group attendance
  - Testing – everyone gets 100%!
  - Educational materials check-off sheet
  - Patient contract
  - Procedure-specific informed consent form
  - Spousal consent
Informed Consent – put in bariatric example

- Patient education…**Informed consent**
- Inform of potential benefits, risks and alternatives
- Procedure-specific
- New model form
- Second generation form
- Technology – web-based enhancement

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**Informed Consent**

**Informed Consent for Laparoscopic Roux-en-Y Gastric Bypass Surgical Procedure**

It is very important that you understand your surgery. I would like to discuss your medical history, surgery options, risks, benefits, and possible complications. I will answer any questions you may have about your surgery.

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**Patient's Name or Authorized Representative:**

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The doctor has explained to the patient the risks and benefits of a Laparoscopic Roux-en-Y Gastric Bypass. Therefore, the patient has signed the following:

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**Consents**

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**Procedures/Supplements**

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**Informed Consent**

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**STEVENS & LEE**

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**24**
**History Form**

**SUGGESTED REVISIONS TO A PATIENT’S HISTORY FORM**

The following paragraph should be placed at the beginning of the history form:

The following information is very important to your health. Please take time to fully and completely fill out this important information. We are counting on you.

The following signature line should be placed at the end of the history form:

**Signature**

**Patient’s**

The above is true and correct to the best of my belief.

**NOTE:** This serves as a helpful reminder to patients that their history is very important. Importantly, it also serves to put the bulk of responsibility in their court. With this form in your chart, it is hard for the plaintiff/patient to say, “I told Dr. Smith that my mother died of breast cancer” when it is asked but not answered on the form. After all, we have told them the information was important, that it was their responsibility to obtain it, and they verified it.

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**At-Risk Letter**

**EXAMPLE OF AT-RISK LETTER**

**Date**

Dear Patient:

It has come to my attention that you are not adhering to the medical regime which I have instructed you to follow. It is necessary for you to [insert the advice, recommendation, or regime] for important health reasons. Specifically, if you fail to do so, it may have the following effects on your health: [insert consequences of not following treatment].

For you to get your treatment back on course, it is necessary for you to [insert what the patient must do to get back on track].

We are committed to providing you with quality healthcare, but to do so, we must count on you to follow your prescribed treatment. You are a critical part of this healthcare team.

If you have any questions about what you must do, please call our office at [insert phone number].

Sincerely,

Dr. Smith
Vitamin & Protein Supplement Contract

Patient Contract

Vitamin and Protein Supplements

This Contract outlines your understanding and responsibilities. It is provided to ensure that you fully understand the information provided, and to point out to us what needs to be clarified and explained to you further. This agreement is important for you to understand because if you fail to meet the responsibilities described below, your surgical team may need to discharge you as a patient from the practice. With that in mind, please review the following, and place your initials to the left of the statement if you understand the statement and agree with it.

1. Roux-en-Y Gastric Bypass is both malabsorptive and restrictive.
2. Malabsorption is not typically a problem after laparoscopic adjustable band.
3. I understand that I am expected to keep food diaries because they help assess nutritional problems, protein and vitamin intake or disordered eating behavior.
4. I can expect lab work done at least annually for the rest of my life, and it is my responsibility to have this done as directed.
5. I understand the importance of protein to health and recognize poor protein intake could lead to hair loss.
6. The malabsorptive and restrictive nature of gastric bypass predisposes me to protein and vitamin deficiencies.
7. I agree to take B-complex and chewable calcium as directed daily.
8. Attention to protein and vitamin supplement begins before surgery and continues for life.
9. I agree to take thiamine supplements along with a quality multivitamin each day as directed by my health care team.
10. Some patients are prescribed vitamins before surgery, and therefore dietary education and nutritional changes must occur even before surgery.
11. It is my responsibility to ask questions when I am uncertain about vitamins and protein supplements.
12. I understand that if I fail to accept my responsibility for care as directed by the team, and as outlined in this document, I could be terminated as a patient from this practice.

Date

Time

Signature of Patient or Authorized Representative

Relationship of Authorized Rep.

The Patient/Authorized Representative read the entire form and had it read to him/her.

The Patient/Authorized Representative expresses understanding of the form.

The Patient/Authorized Representative has no further questions.

Date

Time

Signature of Witness

Printed Name

Bariatric Patient T/F Test

Patient Exam

This examination is given to indicate that you understand the information provided. The following is a written evaluation of your knowledge. Your answers will help us to be certain that you fully understand the information provided, and to point out to us what needs to be clarified and explained to you further.

1. Please indicate if the following statement(s) is true or false.

   True False

   1. Roux-en-Y gastric bypass is both malabsorptive and restrictive.
   True False

   2. Malabsorption is not typically a problem after laparoscopic adjustable band.
   True False

   3. I understand that I am expected to keep food diaries because they help assess nutritional problems, protein and vitamin intake or disordered eating behavior.
   True False

   4. I can expect lab work done at least annually for the rest of my life, and it is my responsibility to have this done as directed.
   True False

   5. I understand the importance of protein to health and recognize poor protein intake could lead to hair loss.
   True False

   6. The malabsorptive and restrictive nature of gastric bypass predisposes me to protein and vitamin deficiencies.
   True False

   7. I agree to take B-complex and chewable calcium as directed daily.
   True False

   8. Attention to protein and vitamin supplement begins before surgery and continues for life.
   True False

   9. I agree to take thiamine supplements along with a quality multivitamin each day as directed by my health care team.
   True False

   10. Some patients are prescribed vitamins before surgery, and therefore dietary education and nutritional changes must occur even before surgery.
   True False

   11. It is my responsibility to ask questions when I am uncertain about vitamins and protein supplements.
   True False

   12. I understand that if I fail to accept my responsibility for care as directed by the team, and as outlined in this document, I could be terminated as a patient from this practice.
Step 3 – Event Management

Appropriate management of an event/incident and disclosure to a patient or to his or her family done in such a fashion that can effectively work to: better the outcome for the patient, while reducing the potential for a lawsuit.
Step 3 – Event Management: Creating Appropriate Evidence

- Event management
  - Preventing the “plus”
  - Guidance in stressful situations
  - Focusing on enhanced communication and documentation
  - Continuous quality improvement
  - Promptly using QA for short and long-term
  - The conduct post-event is evidence!
Collecting the Data

- Customized, blinded database...Early results
  - Overwhelmingly, post-op complications are the clinical cause of events and claims --- 45%!
  - 37% of risk management issues involve
    - Failure to manage patient expectations
    - Failure to explain risks of procedure
    - Failure to explain nature of treatment

- What does it mean?
  - Needed continued focus on informed consent!
  - Need for procedure-specific informed consent form
  - Need for continued efforts at expectation management
The Relationship Bank

First 30 seconds sets the tone

Experience reinforces

What we tell others

Creates relationship or not

Unfortunate event

Reaction
Disclosure After an Adverse Event - Want to Know More?

- With transparency taking on more importance...so does this!
- Patients want to know what occurred...and...why it won’t happen again!
- Not everyone is a good communicator...training and education needed to do this the right way...
- Stevens & Lee has partnered with The Sorry Works! Coalition
  - Providing educational programming to leadership, physicians, and nurses
  - Providing hands-on workshops
  - Training the trainers
  - Providing the tools to keep disclosure concept alive
  - Including a policy and procedure
- Physicians and hospitals collaborating
- Visit: http://www.sorryworks.net/
Step 4 – A Different Defense

- Using the foundation for defense
- You’ve created your own evidence
  - Tools, forms, strategies, enhanced documentation
  - Event management
- Preventing the “plus” (drives severity)
- A national bariatric defense panel
  - We created the premier defense panel with experience in bariatric surgery cases
  - Resources in bariatrics provided
  - We provide them with resources
  - Risk management analysis on all
Again, How to Change the Liability Equation

- Understanding the risk
- Execution: Using the tools and compliance
- Event management
- Using the evidence created and a different defense

In the first place…Create positive evidence…Build the foundation…Being aggressive- using the evidence...
Why Novus Works? ... A Methodical Plan

- Understanding and evaluating bariatric surgery for over three years
  - Researched specific root cause of frequency and severity with an Ethicon grant
- Formal endorsement from ASBS – August 2005
- Comprehensive loss control program infrastructure which has been accepted!
- Bariatric surgeons across the country ARE changing the way they practice
The Ten Critical Success Factors

1. Understanding the **clinical specialty**
2. Understanding the **causes of complications** for it
3. Understanding the **unique professional liability risk**
4. Understanding their **business**
5. Creation and updating **database assessment**
6. Creation of **user-friendly tools** – making execution attainable!

7. Must have **accountability**!

8. 2007-2010 **positive economics**

9. **Disclosure** becoming more important

10. Essentially doctors, hospitals can **reduce risk and enhance their business...**
Stevens & Lee’s 220 lawyer and non-lawyer professionals assist health care providers and organizations meet the challenges they face in a changing and consolidating industry. Our Health Care Department is comprised of approximately 30 professionals – including 19 attorneys whose exclusive practice is in health care – who serve as general counsel to acute care and specialty health care organizations, health systems, physician practices and insurance companies nationally. Stevens & Lee has developed a niche practice representing bariatric surgeons and programs which includes not only lawyers but also other risk consultants in communication, clinical bariatrics, and risk management. Stevens & Lee’s health care team offers a full range of health care litigation services and is highly skilled in counseling health care clients on practice management and risk management issues and in protecting them against claims.

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