

Commentary: Plus ça Change...

by
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Claims naming a surgeon or listing surgery as the responsible service represent more than 40 percent of all CRICO cases opened over the past five years and 44 percent of the total incurred losses. Plastic surgery, neurosurgery, vascular surgery, thoracic surgery, and urological surgery represent the top five defendant specialties. In light of these facts, this issue of *Forum* focuses on the details behind surgery-related claims and offers loss prevention suggestions in areas where surgeons have been found to be vulnerable.

The most notable changes in the clinical practice of surgery, other than advances in anesthesia, have been the move to more minimally invasive surgeries and the shifting of more procedures to ambulatory settings. One result is lost opportunities to identify operative and postoperative problems early on. Another is that pre- and postoperative patient education efforts suffer. The need for more rigorous postoperative observation and careful discharge planning is particularly important for patients whose hospital stay is only a few hours, rather than a few days. This goes a long way toward optimizing follow-up and future care. It can also help protect the physician and the institution from charges of missed complications, premature discharge, or patient abandonment.

Techniques Change, Risks Don't

A good example of a change in practice leading to increased risk is laparoscopic electrosurgery. Over the past 10 years, use of this procedure has greatly expanded as an increasing number of surgeons have switched from traditional methods of open surgery to minimally invasive techniques. By the year 2000, at least half the surgical procedures in gynecology, urology, and general surgery across the country will be minimally invasive. The increases in the overall number of surgical procedures and in the use of laparoscopic electrosurgery has been accompanied by an increase in the number of related claims. They speak to the need for training and credentialing physicians in these procedures, and timely recognition and repair of injuries occurring during surgery.

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Despite many changes in the clinical practice of surgical specialties, much remains the same about the malpractice claims attributed to those services. Claims data comparing the past two five-year periods indicate that in both time periods: 1) the claims are primarily against attendings, not house staff; 2) the most frequent allegation is "improper performance of surgery;" and 3) the primary site is the operating room—although with increasing frequency it is the ambulatory surgical site, rather than the inpatient operating room.

CRICO's Professional Liability Claims 1992-96

	All CRICO	Surgery-related*
Number of Cases	1,038	425
Percent Closed	62%	57%
Incurred Losses	\$238 million	\$103 million
Average Indemnity Payment	\$99,101	\$104,125
Median Payment	\$40,000	\$50,000

*Excluding Obstetrics

Opportunities for Improvement

Other changes in the health care delivery system offer opportunities for improved care and the potential to reduced risk among surgical patients. In

settings where the team concept of care is embraced, elements of patient care pass more easily and logically to other team members. This includes patient education before and after surgery, including, in some instances, the reasons why watchful waiting may be a better alternative to higher-risk surgery. Under a capitated system of care where economic goals are aligned among institutions and providers, the patient is more likely to be placed in the care that has the most appropriate supports of equipment and personnel. When the recovering patient is placed where the focus is on recovery, rather than mingled with the acutely ill, risk can be reduced.

...Plus c'est la Mème Chose

Even with the best risk management practices in place, the rate of claims against the surgical specialties will likely remain high. The technical nature of the care, patients' sometimes unrealistic expectations of what surgery will afford in terms of quality of life, and the relatively short period that the surgeon spends with the patient are likely to keep the rate of malpractice claims against surgeons high. Opportunities for improvement lie in those risks: a clear and complete informed consent process, maintenance of technical surgical competence, and taking the time before and after a surgical procedure for communication with the patient and family—a time in which listening is as important as speaking. ■

CRICO Claims Involving Surgery

Fast-paced development of new surgical procedures, public demand for the latest technology, and advances in post-surgical care have promoted, in part, unrealistic expectations. These factors also leave many physicians questioning old practices while the window of opportunity to initiate new, more complex treatments continues to narrow.

At the same time and just as rapidly, health care delivery systems are changing. With increased pressure by third-party payors and others to perform more complicated procedures and treatments in ambulatory care settings, the level of illness of the patient and the complexity of the care required are changing and increasing risks. Against this backdrop is a growing perception among the public at large that the system meant for healing is causing harm.

To better understand the challenges facing today's surgeons, Harvard Risk Management (HRM) staff analyzed 425 claims and suits filed from 1992-96 in which a surgeon was named as a defendant or co-defendant, or in which surgery was listed as the responsible service. For the surgical specialty groups facing complex new technologies, malpractice claims activity has a tendency to lag behind technology. The safety and efficacy of surgical advancements can take years to clarify. Thus, newly designed procedures, as well as changes in health care systems, may not be fully reflected in data from the 1992-96 period.

Claims Review Highlights

Figure 1 identifies the specialties involved in the reviewed cases (cases relating to obstetrical care were excluded). The *defendant* rate per 100 physician coverage years (PCY) shown here (6.2 for 1992-96) is higher than the *claims* rate per 100 PCY (4.8) because more than one physician can be named in a claim. Nevertheless, the claims rate for surgeons is considerably higher than the 3.1 rate for all CRICO¹ insured physicians during the same five-year period.

The 425 surgery-related cases reviewed:

- represent 41 percent of all CRICO cases opened during this five-year period;
- account for 44 percent of the total incurred losses;²
- named 372 surgeons from 16 surgical specialties, along with 81 physicians from 14 additional non-surgery related specialties;
- closed without payment 61 percent of the time, (CRICO's overall rate = 60 percent); and
- resulted in \$32 million in total indemnity payments (ranging from \$500 to \$2.5 million), with a median payment of \$50,000.

Figure 2 details 25 of the 91 claims in this study that were settled with a payment to the plaintiff. These illustrate several of the leading causes of malpractice suits within surgical specialties. From the perspective of risk management, less visible factors include misinterpretation of test results and limited attempts to review the progression of symptoms or to follow a patient's illness with any sense of continuity.

For the surgical specialty group, postoperative complications loom large. Many complications noted in this study occurred even with the best of care. Some were indeed inherent in the disease process or were simply the results of atypical manifestations; many were common risks, some were rare occurrences, while others were related to errors in judgment or technique. Of special concern were those cases that were potentially preventable. Cases involving delays resulting from misinterpretation of typical signs and symptoms associated with complications, and untoward surgical results head this list.

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CRICO's Rate of Named Surgical Defendants Per 100 Physician Coverage Years^a

Figure 1

Specialty	1996	1992-96	1987-91	Average Indemnity (1992-96)
Gynecology	(13/77) ^b 16.8	8.2	7.1	\$492,000
Thoracic Surgery	(3/24) 12.7	9.7	8.1	0
Neurosurgery	(5/45) 11.1	11.9	15.8	\$411,000
Orthopedic Surgery	(12/147) 8.1	9.1	9.9	\$216,000
General Surgery	(21/310) 6.8	7.4	6.1	\$198,000
Vascular Surgery	(2/32) 6.3	9.8	5.8	\$65,000
ENT	(5/84) 5.9	8.6	7.2	\$998,000
Plastic Surgery	(2/37) 5.4	13.6	10.4	\$96,000
Ophthalmology	(7/166) 4.2	1.7	2.4	\$724,000
Urology	(2/56) 3.6	9.6	5.6	\$391,000
Dentistry	(4/133) 3.0	2.4	3.3	\$15,000
Oral Surgery	(1/34) 3.0	6.3	7.9	\$167,000
Cardiac Surgery	(1/40) 2.5	5.8	14.4	\$210,000
Ob/Gyn ^c	(5/250) 2.0	3.1	4.5	\$125,000
All Surgery	5.7	6.2	6.3	\$305,000

a One coverage year is credited for each full year of physician coverage per specialty.

b Number of defendants/physician coverage years.

c Excludes Obstetrics-related cases.

Selected CRICO Surgery-related Claims (1992-96) that were Settled with Payment

SPECIALTY/ ALLEGATION	AGE/SEX	DIAGNOSIS/PROCEDURE/COMPLICATION	OUTCOME	PAYMENT RANGE
General Surgery				
1 Delay in diagnosis	40/F	Progression of disease (breast cancer)	Death	high
2 Unnecessary surgery	31/F	7 mo. pregnant w/bilateral bulges. S/p C-section herniorrhaphy performed with no evidence of hernia	Infection requiring surgery for chronic draining sinus tract	middle
3 Improper surgery	31/F	Renal artery clamped during bilateral adrenalectomy	Nephrectomy	high
4 Failure to diagnose	25/F	Pt. presented to ED w/abd. pain. Exam neg. except blood in vagina.	HCG(+); attempts to reach patient unsuccessful; Ectopic pregnancy	middle
5 Improper surgery	48/M	Common bile duct divided during open cholecystectomy; injury recognized and repaired	Developed chronic hepatic duct stricture; choledochojejunostomy	low
6 Wrong diagnosis	37/F	Referred with diagnosis of ZES; underwent Whipple, numerous post-op complications	Unnecessary surgery: ultimate diagnosis, irritable bowel syndrome w/achlorhydria	≥ \$1 million
7 Failure to diagnose	23/M	Appendicitis	Appendectomy & cecostomy followed by double barreled colostomies	middle
8 Improper technique	59/F	Wedge resection of gastric ulcer; readmitted 4 mo. later for high subtotal gastric resection w/gastrojejunostomy	Perforated esophagus	middle
ENT				
9 Improper surgery	30/M	Intranasal polypectomy - laceration of anterior cerebral artery	Death	≥ \$1 million
10 Failure to diagnose oral cancer	39/M	Metastatic squamous cell cancer	Death	≥ \$1 million
11 Improper surgery	62/F	Intranasal polypectomy-perf. of cribriform plate	Short-term memory loss; rt. side weakness	≥ \$1 million
Obstetrics/Gynecology				
12 Failure to diagnose	29/F	Intermenstrual bleeding, Pap smears read as neg.	Death	high
13 Improper surgery	44/F	Abdominal hysterectomy w/lymph node dissection	Surgical clip obstructed ureter; chronic infections	middle
14 Improper technique	48/F	Yag laser ablation for endometriosis	Uterine/small bowel perforations	middle
15 Improper surgery	33/F	Laparoscopic lysis of peritubal adhesions	Emergency laparotomy; bleeding corpus luteum cyst, DIC	middle
16 Improper surgery	33/F	Laparoscopy converted to open laparotomy for rt. salpingectomy	Perforation of colon requiring colostomy	middle
17 Unnecessary surgery	36/F	Partial vulvectomy for vestibulitis; path report showed mild chronic inflammation	Continued discomfort; plastic surgery required	middle
18 Improper procedure	28/F	Underwent tubal ligation	Pregnancy	middle
Urology				
19 Delay in surgery	Day-old/M	Bilateral testicular torsion	Orchiectomy	high
20 Improper medication regime	32/M	Hypospadias repair; DVT developed and heparin started. D'cd on Coumadin which was subsequently stopped due to impending surgery. Recurrent DVT.	Chronic venous insufficiency	middle
Vascular Surgery				
21 Unnecessary surgery	40/M	Rt. femoral bypass graft instead of left	Wrong site	middle
Cardiac Surgery				
22 Improper surgery	66/M	Aortic valve replacement	Entrapment of aortotomy by strut of A-V prosthesis; death	high
Neurosurgery				
23 Improper surgery	67/F	Diskectomy of L4-5 instead of L5-S1	Wrong site	low
24 Lack of inf. consent	11/M	Anterior rhizotomies	Paralysis	middle
25 Delay in diagnosis	21/M	Craniotomy w/microvascular decompression, increasingly somnolent; arrested	Death	≥ \$1 million
Low range = < \$99,999 Mid range = \$100,000 - \$499,999 High range = \$500,000 - \$999,999				

Claim Frequency

The total number of surgery-related claims opened in 1992-96 was 19 percent higher than the prior five-year period. But, when balanced by the increase in the number of surgeons insured by CRICO, the total overall *rate* of claims was slightly lower in 1992-96 (4.8 per 100 PCY), as compared with 1987-91 (4.9).

Beyond the increase in providers, possible factors for the increase in the number of claims include:

- the greater potential for miscommunication as patients navigate between multiple health care providers, many of which involve complicated judgments and a shared decision-making process;
- the proliferation of new and different drugs;
- the plethora of high-tech, bedside diagnostic procedures, representing new opportunities for error; and
- the ever-enlarging role of the media as participants in shaping consumer attitudes about health care.

Defendants

When looking only at the surgeons named in the reviewed claims, residents and fellows composed 22 percent of defendants in 1992-96. This is down from 30 percent in 1987-91. Inversely, the numbers for attending surgeons have increased, from 70 to 78 percent. These numbers mirror those for all CRICO defendants over the same five-year period.

Patient Demographics

Fifty-eight percent of claimants in the cases from 1992-96 were female; 16 percent were 65 years of age and older (up from 10 percent in 1987-91). The percent of outpatient claimants rose from 40 in 1987-91 to 50 in the more recent five-year period, reflecting the fact that many diagnostic work-ups and surgeries are now completed in ambulatory care settings (*Figure 3*).

Of the 68 ambulatory surgery claims from 1992-96, 11 (16 percent) have closed, with payments totaling \$3 million dollars. Example events from these cases include: 1) needle perforation of the globe during retrobulbar injection resulting in legal blindness (to a patient who was already legally blind in the opposite eye), 2) incorrect dose (20cc instead of 1cc) of Aristocort, resulting in cushingoid symptoms

(in an 8-year-old child), 3) uterine and small bowel perforations following Yag laser ablation of endometrium, and 4) a finger amputation following an osteotomy which was complicated by a tendon laceration. As the increasing volume of surgical claims involving ambulatory care close, HRM will be studying the risk factors and loss trends involved.

Nature of Allegations

The top allegations in CRICO’s surgery-related malpractice claims have remained unchanged over the past 10 years: surgical treatment, medical treatment, diagnosis, communication, and medication. The most frequent (in 169 out of 425 cases) was “improper performance of surgery” e.g., the alleged problem occurred during the surgical procedure.

Allegations involving delayed diagnosis increased from three percent (10 cases) in 1987-91 to six percent (27 cases) in 1992-96. Postoperative complications can occur despite excellent medical care. However, allegations of delays in diagnosing *typical* signs and symptoms associated with complications that increase danger are difficult to defend.

Some important concepts contributing to the growing prominence of delayed diagnosis claims relate to shortcomings of the process of care. With the press for shorter hospital stays and a diminished safety net in the community at large, some patients develop early danger signs of complications outside the hospital setting. This, along with incomplete communication, poorly coordinated discharge plans, unclear overlap of responsibilities, and administrative delays maximize liability concerns. Other critical factors contributing to communication breakdowns relate to multiple providers seeing the same patient on different visits and sometimes at different locations, each having quite a different piece of information about the patient. In the end, the fact remains that when the patient’s health care team does not function as a team, the risk for errors increases.

High-exposure Surgical Claims

Analysis of the data provides some insights into operative complications as well as overall management issues in 11 cases that closed with payments of \$500,000 or more in 1992-96 (*Figure 4*).

- ◆ The five high-exposure cases (45 percent) that occurred in non-hospital settings accounted for 48 percent of indemnity payments (\$6,955,000).
- ◆ The five cases that occurred in the operating room accounted for 46 percent of indemnity paid (\$6,665,000).
- ◆ Five of the 11 high-exposure cases alleged delayed diagnosis. These were triggered by underlying causes such as communication breakdowns (i.e., telephone-related assessments, covering physician issues); others involved getting the right resources.

	1987-91 N=357	1992-96 N=425	-/+ %
Operating Room	160 45%	154 36%	(- 9)
Non-hospital based*	61 17%	91 21%	(+4)
Ambulatory Day Surgery	39 11%	68 16%	(+5)

* Health centers, satellite facilities, university health services, and private MD offices.

Loss Prevention Strategies

Risk areas that can be targeted for improvements include:

Clinical Competence

- Maintaining technical surgical competence.
- Addressing medical error in a non-threatening, non-punitive way.
- Resolving differing clinical assessments as soon as possible within the clinical setting.
- Increasing awareness of misplaced optimism (i.e., misreading typical signs and symptoms of complications).
- Carefully evaluating the patient—avoiding being misled by another clinician's diagnosis or by chronic conditions.

Communication

- Resisting the urge to always know what is best for the patient—the patient and family need to be central to the equation.
- Understanding sources of communication error among the team.
- Being aware of the potential for miscommunication when evaluating a patient via a phone call.

Documentation

- Documenting participation in postoperative care (attendings).
- Delivering better educational material to compensate for shorter hospital stays and documenting materials in the medical record.
- Documenting clearly and completely the informed consent process, especially when possibilities exist of an additional procedure or when the initial plan discussed may need to be abandoned in the best interest of the patient. (*These are key factors in establishing reasonable expectations, and help diminish any future perception of medical negligence.*)

Adverse Events

- If you are uncomfortable delivering bad news to a patient (or family), identify someone on the team who can facilitate the process with you. Documentation of the discussion should be complete, and carefully worded.
- When addressing an unfavorable turn of events with the patient and family, avoid conducting a well-orchestrated meeting that allows “no room” for the patient's input. Focus attention on what *they* want from the meeting.

Figure 4

CRICO's Surgery-related Claims 1992-96: Payments ≥ \$500,000

Claims and Suits Opened	
Number of cases	11
Number of defendants	13
MD Staff (12)	12
Residents (1)	1
Disposition	
Suit/claim settled	8
Mediation	2
Trial verdict-plaintiff	1
Top Allegations	
Diagnosis-related	6
Improper Performance of Surgery	4
Delay in Surgery	1
Top Risk Management Issues	
Technical performance	
Selection/mgmt of surgical invasive procedure	
Misinterpretation of diagnostic studies	
Communication among providers	
Payments	
Total	\$14,490,000
Average	\$1,268,000

Conclusion

By no means are all surgical adverse events the result of preventable errors. But identifying the ones that are and developing strategies to prevent recurrence is necessary. Familiar errors *still* recur.

To that end, each member of the surgical team must equally recognize that he or she greatly impacts outcome. Technical skill aside—failure of communication, failure of education, failure of candor, haste, fatigue, lax supervision, and overconfidence on the part of the surgical team may all be important influences in this regard.

The fundamental basis for the rising number of claims quite possibly has less to do with the quality of surgical care than with traditional risk management factors: communication, documentation, and underlying systems issues. Certainly, managing patient and family

expectations following an unexpected bad turn of events remains center stage. Here, the emphasis is on allowing the patient to express emotion.

With new advances in diagnostics, monitoring, and therapy that promise reduced complications and shorter lengths of stays for both in- and outpatients, opportunities for effective communication lessen. In a broader context, with intense pressure in many health care organizations to shorten office visits, the capacity for patients to connect with their surgeons becomes more elusive and even more problematic. Equally challenging is seeing that the medical record thoroughly reflects the care provided. When the quality of care is questioned, more cases seem to be lost due to poor documentation than poor care.

In summary, the aggregate claims data and individual case details do flag areas of concern and opportunities for improvement. Increased attention and efforts can reduce preventable surgical mishaps and associated factors that might harm patients. To do this effectively, significant attempts at improvement at all levels of health care organizations are warranted. In general, managing the current reality, at least in part, may be one of the greatest challenges facing physicians, who in a sense, feel less in control than ever before. ■

Notes & References

- 1 Controlled Risk Insurance Company (CRICO) provides professional liability insurance to health care institutions, their employees, and affiliated physicians.
- 2 Included payments to patients on closed cases, and expenses and reserves on open cases.

Review of CRICO's Orthopedic Claims

Orthopedics has historically and nationally been one of the top five services named in malpractice claims. Even when a claim is successfully defended, the cost in time and money defending the case, as well as the deleterious effect to the defendant surgeon, is great. While past reviews of national data (and CRICO's¹ orthopedic claims) have yielded many useful findings and recommendations, the perspective of a review by practicing orthopedists offers the benefit of being carried out by someone who has actually been there. Analysis, and subsequent recommendations stemming from a review by fellow orthopedists, offers a credible teaching tool to attendings and house staff within the CRICO institutions.

Ninety-one CRICO claims in orthopedic surgery from 1987-96 were analyzed to assess the risk factors involved. Each claim was evaluated by looking at both the medical and legal records for variables including:

- parties involved (plaintiff and defendants),
- case type (trauma, congenital, degenerative, etc.),
- anatomic site involved,
- location where alleged negligence arose (operating room, outpatient visit, emergency department, etc.),
- plaintiff's allegations,
- primary issue of prevention, and
- disposition of the claims.

The Findings

- ◆ The 82 adult plaintiffs had a bimodal age distribution with peaks at age 30-39 and at age 50-59.
- ◆ Attending staff and institutions are most at risk for being named, but residents, fellows, and ancillary staff are not immune from being named.
- ◆ Nearly 60 percent of the claims involved acute trauma and degenerative disease.

- ◆ The majority of the lower extremity cases involved the hip or knee joints; the upper extremity cases mostly involved hand traumas.
- ◆ Just over half the claims (N=48) involved events in the operating room. Another 25 percent involved management in the outpatient setting.

- ◆ Improper performance of surgery (33 claims) and diagnostic error (22) accounted for more than half of all allegations. Another 20 percent involved improper management/judgment.
- ◆ Identification of a risk management issue correlates to indemnity payments.

Risk Management Issues

For each claim, an attempt was made to identify the primary risk management issue. This is what the reviewers felt (and not necessarily what the plaintiff allegation suggests) was the main issue to focus on for prevention in each individual claim. The following list of risk management issues generated was more diverse than what the allegations reflect:

- Poor communication with patient/family (9 claims)
- Wrong anatomic site (7)
- Improper use of equipment (7)
- Diagnostic error (6)
- Surgical/technical error (5)
- Failure to document consent (3)
- Failure to document decision-making process (2)
- Clinical decision error (2)
- Poor/delayed follow-up (2)
- Failure to follow up on diagnostic test (1)
- Poor communication between physicians (1)
- Improper informed consent (1)
- Alteration of medical record (1)
- Failure to document H&P and operative note (1)
- Poor rapport with patient (1)

CRICO's Orthopedic Claims: 1987-96 (N=91)

Claimants	91
Female (50)	
Male (41)	

Defendants	183
Institution	56
Physicians	113

Orthopedic Attending (66)	
Orthopedic Fellow (6)	
Orthopedic Resident (22)	
Anesthesia (9)	
Radiologist (3)	
Pathologist (3)	
Other (4)	
Non-Physicians	14
Physician Assistant (5)	
Nurse Practitioner (3)	
Podiatrist (2)	
Other (4)	

Case Type	91
Acute Trauma	32
Degenerative Disease	30
Sports-related	9
Neoplastic	5
Chronic Trauma	5
Other	10

Anatomic Site	91
Lower Extremity	52
Spine	20
Upper Extremity	17
Other	2

Disposition	91
Defense Finding	56
Dismissed (24)	
Denied (14)	
Jury Verdict (12)	
Arbitration (4)	
Plaintiff Finding	35
Settled (31)	
Jury Verdict (2)	
Mediation (2)	

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In 13 of the claims, a risk management issue was suggested either by the plaintiff's allegation or by unanswered questions that arose in review of the case. In these cases, the issue could not be confirmed or refuted based on the available information. These claims were then labeled as having a question of a risk issue. In the remaining 27 claims, based on evaluation of the plaintiff allegation and review of the case, the reviewers found no risk issue and assumed that the case was appropriately managed. These claims were labeled as having no identifiable risk issue. Therefore, 40 of 91 claims had no definitively identifiable risk management issue.

Correlation of Outcomes to Risk Management Issues

Separating those cases with an identifiable risk management issue from those without identified a striking correlation with outcome of the malpractice case. Of the 40 claims with no clear risk management issue, only two had an outcome for the plaintiff. One had a question of a surgical/technical error. One settled for issues unrelated to the orthopedic care provided.

Of the 51 claims in which a risk issue *was* identified, 33 had an outcome in favor of the plaintiff. All seven claims involving operating on the wrong anatomic structure were resolved in favor of the plaintiff. Six of seven claims in which improper use of equipment was implicated resulted in indemnity payments; all six claims that involved a missed or delayed diagnosis went in favor of the plaintiff. The three claims with poor follow-up on a patient or a test result all went in favor of the plaintiff.

Opportunities for Improvement

Develop systems to ensure appropriate anatomic site/structure:

This includes appropriate level for spinal surgery, appropriate digit for hand and foot surgery, and appropriate side (right/left) for extremity surgery. This is aided by having preoperative notes and radiological studies in the operating room and insisting on adequate intraoperative radiological confirmation—especially in spinal surgery—for appropriate level.

Structure ongoing training for the proper use and maintenance of surgical equipment:

Common misuse of equipment includes use of cast saws which require proper maintenance with sharp blades and preventing saw burns or cuts to patients. Equipment use also includes positioning devices in the operating room. Care must be taken to prevent skin irritation, burns, and nerve pressure in anaesthetized patients.

Focus on areas of potential diagnostic difficulties:

Diagnostic problems most commonly involve trauma-related problems, including hip fractures, shoulder dislocations (especially posterior), and hand injuries, including nerve and tendon lacerations as well as hand fractures that require extra attention (special splinting or surgery). Failure to diagnose also commonly involves inadequate diagnostic testing (poor quality or inadequate views on X-ray).

Evaluate and enhance communication with patients and family members:

Communication is the primary mode of ensuring efficient outpatient management, proper follow-up, effective informed consent, and satisfactory patient rapport. All of these areas have been implicated in claims when a failure in communication arises.

Common pitfalls include operating on the wrong anatomic site, missed or delayed diagnosis, misuse of equipment—including cast saws and positioning devices—and finally, poor communication with patients.

Summary

Analysis of 91 orthopedic closed claims over a 10-year period reveals that the vast majority of claims with no clearly identifiable risk management issue had an outcome in favor of the defense. However, when a risk management issue was identified, the majority of plaintiffs prevailed. Common pitfalls include operating on the wrong anatomic site, missed or delayed diagnosis, misuse of equipment—e.g., cast saws and positioning devices—and finally, poor communication with patients. By addressing these common pitfalls, appropriate care for patients can be enhanced while the exposure to claims is minimized. ■

Notes & References

- 1 Controlled Risk Insurance Company (CRICO) provides professional liability insurance to health care institutions, their employees, and affiliated physicians.

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Malpractice Claims Involving Bile Duct Injuries During Laparoscopic Cholecystectomy

The benefits of laparoscopic cholecystectomy have been achieved against the backdrop of increased bile duct injuries. In 98 studies that examined the outcomes of 78,747 laparoscopic cholecystectomies, the incidence of bile duct injuries ranged from 0.35-0.47 percent.¹ However, selection bias, underreporting, and lack of long-term follow-up underestimate the incidence of injuries. At Cedars-Sinai, a study was undertaken to increase awareness of the types, consequences, and financial impact of laparoscopic bile duct injuries.

Material and Methods

Forty-six medical malpractice cases (brought in several states from 1990-96) involving bile duct injury sustained (from 1990-96) during laparoscopic cholecystectomy were reviewed (Figures 1, 2). Medical records, intraoperative cholangiograms (in 16 cases), the postoperative cholangiograms, and (for six cases) videotapes of the operation, were examined.

Results

- The cases involved 41 females (average age, 37 years) and five males (average age, 50 years)
- Bile duct injuries occurred in operations performed by both inexperienced and experienced surgeons (Figure 3).
- 13 injuries (28 percent) occurred in the presence of acute inflammation (seven severe, six moderate).
- 33 injuries (72 percent) occurred in conjunction with chronic scarring (one severe, 14 moderate, 18 minimal).
- 37 injuries were not recognized during the initial surgery.
- In 54 percent, the surgeon did not cite a complication in the operative report or patient chart following laparoscopic cholecystectomy.
- eight cases involved a "short cystic duct," but these were only noted after recognition of the injury.

Figure 1

Bile Duct Injuries During Laparoscopic Cholecystectomy: Classification (N=46)

	Bismuth level	Number
Transection (15)	1	1
	2	10
	3	1
	4	3
Excision (11)	1	0
	2	7
	3	3
	4	1
Clip impinging (8)	1	2
	2	6
	3	0
	4	0
Laceration (6)	1	1
	2	3
	3	1
	4	1
Burn (3)	1	1
	2	0
	3	1
	4	1
Other (3)		3

Figure 2

Mechanisms of Injuries

Inadequate Calot dissection or confusion of normal anatomy	22
-misidentify CBD as cystic	
-clip impingement	
-misidentify CHD	
Misinterp. of cholangiography	11
Blind clipping/caut. near hilum	5
Unknown/unrecognized	6
Fail to recognize Luschka duct	2

Figure 3

Physician Experience

N=27*

MD Experience	Injuries
10 or fewer procedures	7 (26%)
50 or fewer	11 (41%)
100 or fewer	4 (15%)
More than 100	5 (18%)

* Information was available for 27 of the 46 cases studied

Cholangiography

Cholangiography was not associated with decreased injury severity in this study. However, 11 of the 16 intraoperative cholangiograms were misinterpreted. Correct interpretation could have prevented more severe excisional injuries. Conversely, in 23 out of 30 cases where cholangiography was not performed intraoperatively, surgeons failed to recognize iatrogenic injuries.

Delays (Figure 4)

Postoperatively, the average delay in recognizing bile duct injury was 10 days with a range of 3-31 days. Additional delays in postoperative diagnosis of the injury for 27 of 37 patients were caused by:

- endoscopic retrograde cholangiogram unsuccessful or misinterpreted (6 cases),
- biloma dismissed as a duct of Lushka leak or minor cystic duct leak (6),
- symptoms misdiagnosed as common duct stone or ulcer (5),
- sub-hepatic fluid collection dismissed as irrigant or blood (4),
- patient initially refused testing (4),
- shoulder/abdominal pain not evaluated (2).

Repairs

The 46 injuries were treated as shown in Figure 5. Primary surgeons were successful in six (27 percent) of the 22 repairs they attempted; surgeons at a tertiary center with special expertise were successful in 19 (79 percent) of the 24 repairs they performed.

Other Complications

Complications other than the initial bile duct injury occurred in most patients. Eight (89 percent) of the nine patients who had immediate recognition and attempted repair of the duct injury had postoperative complications of either leak or stricture resulting in cholangitis.

by
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M.D., Matthias
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Twenty-three of the 37 patients who had delayed recognition of injury had one or more complications including:

- leak/stricture (12 cases),
- abscess (3),
- small bowel obstruction (3),
- wound infection (1),
- dehiscence (1),
- ventral hernia (1),
- gastrointestinal bleed (1),
- ARDS (1), and
- death (1).

The one death was due to bile peritonitis and sepsis that resulted from a cystic duct leak. This 63-year-old patient had undergone re-exploration with drainage on the seventh postoperative day.

Disposition of Claims

To date, litigation has been resolved in 30 of the 46 cases studied:

- 21 were settled with payments ranging from \$30,000 - \$1,300,000 (average \$221,000).
- Five plaintiffs prevailed at trial with an average award of \$214,000 (range \$125,000 - \$240,000).
- Four cases ended with a jury verdict for the defense.

In three defense verdicts, the injury was caused by clip impingement. The fourth defense verdict was a case that involved an excision of a segment of the common hepatic duct in an inflamed acute case without cholangiography. Diagnosis was delayed, but repair at a tertiary center was successful.

Discussion

The spectrum of iatrogenic bile duct injury ranges from minimal to life threatening. Since the cases reviewed represent only those patients involved in litigation, they do not necessarily represent the frequency of *all* bile duct injuries. Nevertheless, all major injury types—from clip impingements to excision of the entire extrahepatic biliary tree—are represented. Injuries diagnosed and treated at the time of injury, as well as injuries identified and treated later by the treating surgeon and experts, are represented.

Some events seem more likely to result in allegations of malpractice; for example, patients who had failures of immediate repairs, or complications

Figure 4

Bile Duct Injuries During Laparoscopic Cholecystectomy: Post-op Signs (N=37)

Elevated LFTs	34 (92%)
Pain Ab/Shoulder	32 (87%)
Nausea/Vomiting	17 (46%)
Fever	9 (24%)
Ileus	6 (16%)
Leukocytosis	5 (14%)

following delays in diagnosis. The vast majority (86 percent) of cases in this study were resolved in favor of plaintiffs through settlements or verdicts.

The high rate of biliary injury associated with laparoscopic cholecystectomy has been attributed to the “learning curve”.^{2,3} Other reports have noted an ongoing problem well past the learning period.^{4,5} Of the injuries in the studied cases, nine occurred after the surgeon’s 50th case and five after the 100th case (including ductal transections and excisions). Clearly, no surgeon is immune from the risk of bile duct injury and no case is “routine.”

Most injuries were the result of technical errors. Injuries resulted from misidentification of normal

anatomy in 48 percent of cases. Seventy-two percent of injuries occurred in non-acute cases. The majority of injuries resulted when the common bile duct was mistaken for the cystic duct due to inadequate dissection in the triangle of Calot, failure to identify the underside of the gallbladder, and possibly due in part to excessive upward tension placed on the duct.

Other technical errors, such as cautery injury and blind or close clipping to the common duct, occurred in 11 percent of the cases. We recommend using blunt dissection starting postero-laterally at the presumed cystic duct/gallbladder junction, avoiding cautery, sharp dissection, and clipping until the triangle of Calot and the underbelly of the gallbladder is fully exposed both laterally and medially.

All injury types (lacerations, excisions, burns, and clip impingements) were seen with or without intraoperative cholangiography. Even when cholangiography was performed, misinterpretation of radiographic evidence of bile duct injury occurred frequently. The most common cholangiographic abnormalities associated with bile duct injuries were non-visualized intrahepatic ducts and contrast extravasation. A

cholangiogram must show contrast in both hepatic ducts and the duodenum. Extravasation of contrast can mean an injury is present. Intraoperative review of cholangiograms by an experienced radiologist can be helpful.

Though the involved surgeons retrospectively indicated short cystic ducts, acute inflammation,

Continued on next page

Primary surgeons were successful in 27 percent of the repairs they attempted; surgeons at a tertiary center with special expertise were successful in 79 percent of the repairs they performed.

Figure 5

Bile Duct Injuries During Laparoscopic Cholecystectomy: Treatment (N=46)

Types of Repair	Number	Success
Choledocho/hepatico-jejunostomy	29	11 (38%)
Primary end to end repair	7	3 (43%)
Closure with T-tube	4	3 (75%)
Drain only	3	N/A
Remove clip on CBD	1	1
Stent only	1	1
Ligation CBD (in error)	1	N/A

chronic scarring and excessive bleeding—*obvious* problems—were not encountered during the initial surgery in 54 percent of these cases. Thus, use of selective cholangiography only in cases with a recognized problem, confusion of anatomy, or possible common duct stones will not impact the incidence or severity of bile duct injuries. Cholangiography should prevent the most devastating of injuries—a misidentification of the common for the cystic duct with excision of the extrahepatic bile ducts. Liberal use of cholangiography will increase surgeons' awareness of normal, abnormal, and incomplete studies. It will also improve their ability to perform cholangiography so fewer studies will be aborted when they are needed.

The injuries that were not recognized during surgery presented with post-operative symptoms. The average delay in diagnosis was 10 days—even though almost all patients were seen within seven days of surgery. Diagnostic delays, associated with complications that increased damages in 62 percent of cases, resulted from misinterpretation of the typical signs and symptoms of bile leak or duct obstruction including protracted complaints of shoulder and abdominal pain, nausea, vomiting, and elevation of liver function tests. The absence of fever, leukocytosis, and ileus did not preclude the presence of bile duct injury, especially duct obstruction. Noninvasive studies starting with ultrasonography or HIDA scan are highly sensitive. Endoscopic retrograde cholangiography is usually definitive and allows for both precise diagnosis and treatment, though several ERCPs failed or were misinterpreted in this review.

The Benefits of Early Recognition and Repair

Long term morbidity of biliary injury is also related to the location and extent of injury. Higher ductal injuries (especially Bismuth 4) are associated with increased risk of post-reconstructive failure even after appropriate repair.⁶ Early recognition and repair of a bile duct injury by an experienced surgeon increases the chance for an improved outcome.⁷ In this series, 20 percent of repairs were performed immediately, but outcomes were poor anyway. Of nine immediate repairs, eight ultimately failed, requiring re-operation.⁸

Surgeons performing laparoscopic cholecystectomies may encounter problems while attempting to repair bile duct injuries because of inexperience with the repair procedure. Primary surgeons tried to avoid major duct reconstruction in the hope that repair over a T-tube would suffice and would be easier to explain than hepatico-jejunostomies. Those patients with a failed initial attempt at end-to-end repair

underwent an average of two subsequent percutaneous balloon dilations and two re-operations prior to successful recovery. Several patients had injuries worsened by inappropriate attempts at primary repair. For example, a 3-0 silk suture end-to-end repair under tension was performed.

Surgeons with expertise in bile duct repairs had superior results compared with primary surgeons (79 percent vs. 27 percent success) in spite of the fact that they were dealing with more challenging patients who were often in poor condition. When a surgeon diagnoses a bile duct injury, consideration should be given to the resources and circumstances in which the surgeon and the patient find themselves. In some situations, appropriate care calls for placing a catheter in the injured duct, draining the area, and transferring the patient for definitive care to a tertiary center.

If an injury is suspected postoperatively, thorough evaluation prior to re-operation is advised. Specific identification of the site of injury can usually be accomplished before re-operation. Stabilization of the injury with stents placed by ERCP or percutaneous transhepatic radiographic procedures and percutaneous drainage can be achieved in most cases. If bile duct reconstruction is required, appropriate referral can be made electively.

Bile duct injuries will always be the worst complication of cholecystectomy. Though they will always take place, the incidence and the severity can be reduced. Knowledge of how and why they occur, coupled with the liberal use of cholangiography can go a long way toward preventing debilitating and life threatening sequelae. ■

Two-thirds of the 16 intraoperative cholangiograms were misinterpreted. Correct interpretation could have prevented more severe excisional injuries.

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- 8 Patients who had successful immediate repairs were less likely to be included in this study because they were less likely to sue.

Non-medical Factors that Influence Claims Resolution

by
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Every court action consists of one party who voluntarily has chosen to enter the system and the other who is part of the system only as a result of that other's choice. One side chooses litigation because they believe justice will occur. The other side can only hope that justice will occur.

In a medical negligence claim, the voluntary participant (plaintiff) chooses counsel and prepares for the filing of suit. The plaintiff controls how far things go, and can stop at any point with or without receiving a payment. Before the suit is filed, the involuntary participant—the defendant health care provider—

- 1) may not even know that suit is being considered,
- 2) has no control of the timing of the filing, and
- 3) does not control the termination of the suit (although the defendant is involved in the process).

If the plaintiff does not dismiss the action, the defendant must participate through settlement or trial.

Stranger in a Strange Land

Medical malpractice defendants not only lack control of the process, they often lack trust in the legal system, one quite different from their own. The fact that a claim was even made (and the language of the complaint) is antithetical to how physicians picture themselves or their actions. A physician is trained to diagnose, to treat, and hopefully to cure—knowing *that* is not always possible. Those goals are in mind with every facet of their participation with a patient. The language of the lawsuit claims that either by intention or by lack of skill or care, those goals have not been met. In this context, a physician enters into the world of courts, paid experts, lawyers, and juries.

While lawsuits are supposed to be a search for the truth, each side claims that the truth is solely theirs. The final arbiter of this “truth” is a jury composed of people from any and all walks of life, selected simply because they have no knowledge or opinion about the issues involved. One must never lose sight that the case must be presented *to the jury*.

Problems Specific to Surgical Cases

Physician-patient communication almost always plays a role in malpractice claims. In modern medicine, the contact between surgeon and patient often differs from that between a patient and the primary care physician. Depending upon the situation and the institution, patient and surgeon may have little contact prior to hospitalization (or no prior contact if the first visit is as a result of a hospital surgical consult). Surgeons have little time to develop any enduring relationship with the patient or the family. Discussions about what is proposed, the risks and

benefits of the procedure, and the surgeon's availability to respond to inquiries from the patient and patient's family take on much greater importance when the result of the treatment is other than expected. Some point *after* an unexpected outcome is too late to build the relationship of trust, and returning the phone call from the unhappy patient or angry family is often left to the last and sometimes even avoided. This perception of a physician too busy to respond is often what has to be countered at the time of trial.

Problems with Documentation

Experts on both sides of a medical malpractice action primarily rely on the records to formulate their opinions. In the courtroom, more so than the operating room, the result may be dependent more upon the records than on what was done. This is because the records may be the only indication of what *was* done. The hand-written record is often brief and illegible. The dictated or electronic record—more reflective of all that was done and descriptive of the nature of the discussion had with the patient—is often the only tool that the surgeon has to defend a claim tried years after the care was given, when the memory of the care is dependent on the record kept.

Since no surgeon can recall with precision each surgical procedure, hospitals require operative notes. An operative note dictated months after the procedure will not suffice as a record to defend. An operative note dictated by the resident that may reflect anatomic or operative inconsistencies cannot be used as a tool to defend even if co-signed by the attending.

Assessing a jury's understanding of the medical complexities of a malpractice suit is almost impossible. For that reason, the defense attorney has to understand the medical issues well enough to explain them to people with no medical training. This is also the nature of what a surgical specialist does with every patient. The final outcome of a malpractice suit is determined more by the physician-defendant than by expert testimony. If the jury believes the physician, understands what was done and why, and also sees that the records support the reasonableness of the medical judgments, then more often than not that jury will find for the defendant.

All who have reached the point of being a specialist in any area of surgery have reached that point through training and work that few of us could imagine. To have reached that point and then to have an attorney who appears to have little or no

Continued on next page

understanding of medicine question decisions and judgments made can anger and frustrate the clinician defendant. While often justified, if that anger and frustration surfaces during trial, the jury may perceive it as arrogance. Perceived or real, arrogance on the part of the defendant physician is rarely compatible with a good result.

Just as every case is unlike any other case—both in medicine and law—every physician is unlike any other. The strengths of the records as well as the strengths of the physician must be recognized by counsel and be presented to the jury in such a fashion that the jury can understand what happened and why. If that understanding holds after all the evidence is presented, then truth and justice may truly be on the side of the physician. ■

An interview with Leslie S. Libow, M.D.

Ensuring Patient Safety from Care Site to Care Site

Shorter hospital lengths of stay means earlier discharge of sicker patients to subacute or rehabilitation facilities, or to home with home health care supports. The need for careful discharge planning for each transfer, and for coordination between caregivers at the transferring and receiving sites, is essential to maintain quality of care and reduce risk.

Potential liability arising from an “early” discharge, or the failure to make an appropriate discharge plan, is increasing. If a patient’s condition deteriorates, or the patient is harmed by leaving the hospital prematurely, the hospital and physician could be found liable. Medicare or Medicaid can impose financial penalties for the cost of re-admission after premature discharge.

Jewish Home and Hospital for the Aged (JHH) has 100 subacute beds among its three facilities in Manhattan, the Bronx, and Westchester County, New York. Since 1984, patients have been transferred to JHH from acute care facilities to continue recovery from strokes, fractures, or limb loss. Last year, the hospital added a medical-surgical subacute unit and began caring for patients who are recuperating from treatment for congestive heart failure, gallbladder surgery, cancer treatment, and other conditions. The majority of their patients are elderly, but the number of younger patients is increasing.

Forum talked with Leslie S. Libow, M.D., Chief of Medical Services at JHH, and Geriatrics Professor at Mt. Sinai School of Medicine in New York City. Libow and his staff have developed a transfer model that they believe markedly improves the care of patients admitted to JHH from acute care hospitals.

Dr. Libow, what are the important elements to consider in transferring patients from site to site?

Libow: The information found in the medical record, and telephone conversations with the transferring institution are useful, but we have found out that the ideal way to minimize risk and maximize gain is to have a clinical person from the receiving institution or unit come to the bedside of the patient in the sending institution or unit, to evaluate the patient as appropriate to the strengths of the receiving unit.

What should that evaluation consist of?

Libow: Look at the patient, read the record, and talk. Talk with the providers, the family, *and* the patient.

You want to avoid a mismatch between what the sending site says about the patient and how the receiving site would assess that same patient. Paper records may be inadequate or dated and can lead to the receiving site, for example, giving the wrong medication, or carrying out four-day-old orders.

What the sending hospital thinks is important in the transfer note might focus on the reason the patient came to the hospital, such as a fractured hip. The receiving institution might perceive several additional problems that are relevant to quality care, e.g., mental confusion, gait imbalance, continence problems, appetite changes, multiple medications.

What role do you see in the transition period for the clinical person, whom you call a “bridge nurse.”

Libow: We send a clinician, usually a nurse, to the bedside of the patient we are assessing for transfer. That nurse has been working with the team in our facility, knows what we think is important, and knows what to look for. Sometimes just asking the patient to stand and take a few steps gives you lots of information. That nurse knows what our institution can do with respect to certain kinds of feeding, certain kinds of rehab, certain kinds of mental problems. Sometimes after this visit, we can determine that a precipitous move is liable to end up with a more extensive stay in the subacute setting, or an unplanned re-admission: an event that might be avoided by having the patient stay in the acute care setting one more day.

by
Martha Byington

Martha Byington is a Senior Loss Prevention Consultant for Harvard Risk Management Foundation.

Are you bringing the primary care physician into this?

Libow: Absolutely, the primary care physician (PCP) has to move with the patient across the care settings wherever possible. The family and patient would be very upset if a PCP who wants to be included is excluded, so there are their feelings to consider. The PCP works in parallel with a physician from the receiving site. In our institution, the role of this clinician—whose title I’ve coined “subacutists”—is similar to that of the hospitalist in the acute care setting. The subacutist brings the expertise of the specialty setting, and the PCP brings knowledge of the patient, as well as the responsibility for that patient after discharge.

Currently, none of this works particularly well because the economic incentives are not aligned among the hospital, the subacute facility, and the physicians. Under certain types of capitation, this would be easier to achieve.

Explain what the “subacutist” does.

Libow: Generally, the subacutist is a board-certified specialist in geriatric medicine working full-time at the subacute institutional site. (Specialists in rehabilitation, family practice, and psychiatry also serve this role.) They enhance the effectiveness of this phase of care and recovery by simultaneously applying their skills to the organ illnesses, functional disability, and the long-term plan for life in the community.

What’s your plan regarding discharge from the subacute setting to home?

Libow: Little different from the move of the patient from the hospital to the subacute setting: discharge planning must actually begin during admission. And that planning must occur through a team that asks, “What does this person need in terms of going home and staying home?” Anyone can send a patient home and have him need to be re-hospitalized in 24 hours. We don’t want to do that. So we make a home visit days in advance—with or without the patient. We examine the safety factors, evaluate what’s realistic, and assess the quality of the home maintenance to determine the patient’s capacity for self-care.

At the same time, other aspects of the plan are begun: for example, can this person self-administer medications? I’ve given patients in the subacute setting their medications at the bedside as a sort of mental status test. In one day you know what the patient can do, and then you realize that after spending a lot of time and money on acute and subacute care, this patient can’t self-medicate. Then you have to choose a different medication combination; involve the spouse or a relative, neighbor, or visiting nurse involved; or make a different plan.

For patients moving from one setting to another, talking to the family is critical. Managing family expectations is important to the preparation of a patient changing care sites. As the patient is about to be transferred, the relatives may become concerned.

They may feel coerced to accept the transfer—arguing against it, but accepting it. If the patient comes to the subacute or goes home and takes an unpredictable bounce, the relatives may feel that steps were missed along the way that could have avoided that. ■

...We have found out that the ideal way to minimize risk and maximize gain is to have a clinical person from the receiving institution or unit come to the bedside of the patient in the sending institution or unit, to evaluate the patient...

Integrating Patient Safety Concepts into the Continuity of Care

While some of Dr. Libow’s ideas, such as use of a “bridge” (or “discharge”) nurse paid by more than one institution, may be costly, they may become a reality within new integrated delivery systems that share common economic goals. The issues he raises, and the solutions he offers, contain elements that can be integrated into any existing continuum of care:

- 1 Conversations between clinical staff are an important adjunct to the medical record for communicating information about the patient to subsequent caregivers.
- 2 Communication should be complete, including physical status, mental status, and functional abilities in areas such as transfer ability, gait, and balance.
- 3 Information should be up-to-date, reflecting all changes and significant events in the treatment and condition of the patient.
- 4 The family should be involved in the transfer of a patient, particularly from one institution to another. Their role should be to support the transfer and to identify potential risks that the patient may not disclose. The family’s buy-in is especially important if a patient is being moved into a less aggressive care setting, such as from the ICU to routine care, or from hospital routine care to subacute or to home.
- 5 Information among caregivers at the receiving site should be aligned; physicians responsible for the patient’s care in the receiving site should be informed about the patient’s treatment plan while in the transferring site, as well as any care that was rendered at home prior to this particular episode.
- 6 By the same token, the patient’s primary care physician, who will be ultimately responsible for the patient once he or she returns home, must be fully informed about the course of treatment in every site of care.
- 7 The goals should always be 1) to treat the patient in the site where he or she can receive optimal care with the right supports for the particular level of illness, and 2) to avoid a return to a more acute setting because of a misunderstanding or misread of the patient’s clinical condition or needs. ■

-Martha Byington

The Evolution of Informed Consent for Health Care Treatment

A woman on a transatlantic voyage hears that the ship's physician will be offering free immunizations to all passengers to facilitate their entry through U.S. Customs. The woman joins the immunization line, holds up her arm to the physician for inspection, remarking that she thinks she already received the appropriate treatment. The physician says he does not see any signs of a previous inoculation, the woman proffers her arm again, and he immunizes her. Once onshore, she sues the shipowner, Cunard, for assault and for negligently vaccinating her.

The case of *Mary O'Brien v. Cunard Steamship Company* was decided more than a century ago in favor of Cunard.¹ Remarkably, many of the questions it raised are still being asked by physicians and patients in current medical malpractice cases involving informed consent: Is the complaint about substandard care or is it about assault and battery? Did the patient consent to the treatment? And what responsibility does the corporation have to the passengers/patients?

Battery or Negligence

At the time Mary O'Brien brought suit, courts treated these as assault and battery cases. Battery is touching someone without express consent, and assault is placing someone in fear of being touched.² The legal inquiry in *O'Brien* was straightforward: did the patient consent or not? In this instance, the court found that by joining the queue and by raising her arm for the inoculation after speaking with the physician, O'Brien consented.

Ideas about consent have changed and these cases are now most often decided as medical negligence actions.³ In some states, patients may still allege battery, but this usually arises in the more limited situations in which a physician undertakes a procedure a patient has already refused (e.g., a blood transfusion for a Jehovah's Witness) or a procedure not previously discussed (removal of appendix during gallbladder surgery, for example).

The shift in emphasis for consent cases coincides with several societal changes in the last century:

- an increase in the education level of the general population;
- the recognition of rights related to health care: e.g., the right to choose abortion,⁴ the right to refuse treatment,⁵ the right to die;⁶ and
- the gradual replacement of a paternalistic model of medicine by a more collaborative model of physician/patient decision making.

Meaningful Consent

Courts and patients were dissatisfied with simplifying consent to a yes/no question and they attempted to define reasonable, meaningful consent. Meaningful consent, courts found, demanded competence to make decisions and adequate understanding of the risks and benefits of the proposed treatment on the part of patients. In the case of *Canterbury v. Spence*, a landmark in the area of consent, the court defined meaningful consent as the patient's "opportunity to evaluate knowledgeably the options available and the risks attendant upon each."⁷

In most medical malpractice cases, courts look to see what an average, qualified *physician* would do in the same or similar circumstances. However, consent cases have a slightly different focus. To determine if a patient's consent is meaningful, many state courts now look to see what a reasonable *patient* in the same circumstances would want to know.

In 1982, the Massachusetts Supreme Judicial Court explained the informed consent standard in the case of *Harnish v. Children's Hospital Medical Center*:

"(A) physician owes to his patient the duty to disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure. The information a physician reasonably should possess is that information possessed by the average qualified physician or, in the case of a specialty, by the average qualified physician practicing in that specialty."⁸

Later in the case, the court defines "materiality" as "the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether to submit or not to submit to surgery or treatment."⁹ A surgeon who knows that his patient and spouse are trying to conceive, for example, should mention even a small risk of infertility associated with a proposed surgery or procedure.

In addition, the Massachusetts Supreme Judicial Court attempted to clarify "materiality" in two later cases. In *Precourt v. Frederick*, the court described materiality as, "the product of the risk and its chance of occurring. A severe consequence, ordinarily of interest to the patient, would not require disclosure if the chance of the consequence occurring was so remote as to be negligible."¹⁰ Recently, in the case of *Feeley v. Baer*, the court reiterated its definition of a material risk as one that is "more than negligible."¹¹

by
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Patient Autonomy Prevails

Both *Precourt* and *Feeley* were decided in favor of the defendant physicians, but both involved patients' consent to noninvasive treatments. In *Precourt*, an eye surgery patient alleged that he did not understand the risks of taking Prednisone and in *Feeley* the patient alleged she did not understand the implications of "expectant management" of her labor and delivery. The willingness of the Massachusetts courts to apply the negligence analysis to noninvasive treatments probably reflects their view of meaningful consent as a matter of patient autonomy.

Patient autonomy poses difficulty for physicians at both ends of its spectrum. Patients may make decisions which seem unsound to their physicians. Courts have expressed an adult's right "to forego treatment, or even cure, if it entails what for him are intolerable consequences or risks, however unwise his sense of values may be in the eyes of the medical profession."¹² At the other extreme are patients who prefer to cede some or all of the decision-making responsibility to their physicians. In these situations, physicians respect their patients' autonomy by confirming and honoring their requests. (Documenting such a consent discussion is extremely important.) Of course, most patients fall between these extremes, desiring information as well as guidance. Physicians who think of informed consent as a collaborative, meaningful decision-making process will strike the right balance.

Patients who have tried to make informed decisions may be understandably upset upon learning that their physicians have somehow disregarded their opinions. Many physicians recognize potential conflicts involving religious beliefs and consent (a Christian Scientist refuses interventions, a Catholic refuses a recommended therapeutic abortion, a Jehovah's Witness refuses blood transfusion) and seek advice in handling these situations. However, some physicians do not apply this same logic to situations in which they wish to go beyond the scope of the treatment or procedure discussed, although patients may find these situations distressing as well.

Must Physicians Disclose Their Experience?

A consent case in Wisconsin, *Johnson v. Kokemoor*, drew national attention recently when a patient sued her neurosurgeon, claiming he should have warned her about his relative inexperience in clipping brain aneurysms.¹³ Johnson (the patient) prevailed in her suit, in part because she convinced the jury that she had been clear about what was important to her, i.e., Kokemoor's qualifications, but he had been unclear in explaining them to her. When Johnson asked how many times he had performed this procedure, Kokemoor replied "several." Asked to elaborate, he said, "dozens—lots of times." Johnson and the jury believed that Kokemoor should have told her that only two of those procedures involved posterior aneurysms such as hers.

This case illustrates that physicians should be as clear as possible when answering patients' questions regarding risk. A patient's questions are often the clearest indication of what risks they consider material. Tempting as it may be to allay patients' fears by being vague, physicians should respond fully when asked about their experience.

Informed consent discussions should include an explanation (and documentation) by the physician of:

- the risks and benefits of a proposed treatment or procedure;
- alternatives to the proposed treatment or procedure;
- the risks and benefits of the alternatives; and
- the risks and benefits of doing nothing.

Although patients will vary in what they want to know, by starting here and responding to patient questions, physicians will address most concerns. This physician-patient dialogue will not only enlist patients as knowledgeable partners in medical decision making, but will also help them to frame more realistic expectations about the outcomes of medical interventions. ■

Notes and References

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- 2 W.L. Prosser, Law of Torts (4th ed., 1971), §10.
- 3 F. Harper, F. James & O. Gray, Torts § 3.10, at 3:45-3:46 (3d ed. 1996), quoted in *Feeley v. Baer*, 424 Mass. 875, 878 (1997).
- 4 *Roe v. Wade*, 410 U.S. 113 (1973).
- 5 *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990).
- 6 *In re Quinlan*, 70 N.J. 10, 355 A.2d 647 (1976).
- 7 464 F.2d 772, 780 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972).
- 8 387 Mass. 152, 155 (1982).
- 9 *Id.* at 156.
- 10 395 Mass. 689, 695 (1985), quoting *Winkjer v. Herr*, 277 N.W.2d 579, 588 (N.D. 1979).
- 11 424 Mass. 875, 877 (1997).
- 12 *Harnish v. Children's Hospital Medical Center*, 387 Mass. 152, 154 (1982).
- 13 199 Wis. 2d 615, 545 N.W. 2d 495 (Wis. 1996).

...Physicians should be as clear as possible when answering patients' questions regarding risk. A patient's questions are often the clearest indication of what risks they consider material.

Closed Claim Abstract

Delay in Diagnosing Perforation

Incident

Ten days after posterior repair, enterocele ligation, and sacrospinous ligament suspension, the patient was diagnosed with a rectal tear.

Background

A 70-year-old patient, with a history of a total abdominal hysterectomy, underwent posterior repair, enterocele ligation, and sacrospinous ligament suspension without apparent complication. The majority of the surgery was performed by the chief resident in Ob/Gyn under the attending surgeon's supervision. The surgery was difficult because, as the operative note states, "a large enterocele covered by preperitoneal fat was immediately apparent, but because of the large amount of surrounding fat, it is difficult to identify clear planes."⁽¹⁾

The attending physician recalled examining the rectum on numerous occasions—during surgery, at completion of the procedure, and also prior to each suture placement to be sure that the sutures were not placed through the rectum. No mention of rectal exams was made in the operative note. On completion of surgery, a vaginal pack was inserted. Estimated blood loss was 350cc.

The postoperative course was essentially uneventful. The patient developed a slight temperature elevation, felt to be secondary to atelectasis. Antibiotics were continued. On the second post-op day, she had a blood tinged rectal discharge after a suppository. The next day, she felt less nauseous, her abdomen was slightly distended but soft, and her diet was advanced. On the fourth post-op day, the patient felt slightly light-headed on passing stool. She was subsequently discharged afebrile and was given written instruction to call with any problem, particularly diarrhea or constipation.⁽²⁾

Three days after discharge, the patient vomited large amount of bilious material and developed copious foamy diarrhea. Two days later, the frequency of the diarrhea had increased to every two hours and the patient was seen by a senior surgeon who was covering for the attending. Rectal exam was performed and was negative and the vaginal exam revealed no tenderness. Imodium was prescribed. Over the next four days, the patient continued to have diarrhea with increased use of Imodium each day. The (covering) physician recalled having one or two subsequent conversations with the patient and her daughter before it became apparent that she was not getting better.

Ten days after discharge from the hospital, the patient presented to the emergency department with abdominal pain and fever. She was diagnosed with a perforated rectum and underwent an exploratory laparotomy, repair of rectal perforation (anteriorly), and transverse colostomy. The operative note for this procedure states "...the obvious rectal tear was closed with four 3-0 silk sutures."⁽³⁾ The patient subsequently underwent closure of loop colostomy, surgical treatment of an abdominal wall abscess, and repair of a ventral hernia.

The patient filed a malpractice claim against the attending surgeon and senior resident for negligence in the performance of surgery resulting in a rectal tear which was not immediately recognized at the time of surgery.

Disposition

After three negative reviews, the case was settled in the mid range (\$100,000-499,999) with the senior attending surgeon voluntarily agreeing to have the entire amount allocated against him.⁽⁴⁾

Loss Prevention Notes

- 1 The operative report was dictated by the chief resident and was not reviewed by the attending surgeon until notification of possible lawsuit. Taking the time to review and sign operative reports are important responsibilities. Careless record keeping may be construed to imply that the defendant is also a careless physician.*
- 2 The discharge summary was dictated by the chief resident seven months after discharge. Juries have difficulty believing that an accurate record could be created months after the event. As a result, credibility issues weaken the defense's case.*
- 3 With a damaging operative note, no one wins. Criticisms of other providers merely alerts reviewers to weaknesses in the care and reflects negatively on the professionalism and integrity of those involved.*
- 4 Overall, the experts had difficulty figuring out why the surgeons did not recognize the perforation at the time of surgery. They were concerned that the surgeons operated too far up in the abdominal cavity. The laceration or stitch likely would have been identified after the enterocele repair, when trying to dissect fat away, although the area was possibly just above where the fingertips could detect. In this instance, the decision to settle was prompted by the technical issues. However, poor record keeping can render even the most defensible case indefensible.*

by
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