




REOPERATIVE ABDOMINAL SURGERY

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Chapter 2 The ethical legal implications of reoperative surgery

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UNDER PEER REVIEW

INTRODUCTION

Reoperative abdominal surgery is not an unexpected phenomenon, occurring in both the immediate post operative period and remote from the primary surgery. Acute reoperative surgery generally results from infection, bleeding, or failed procedures, whereas remote occurrence tends to result from late procedure failure, scar tissue development, or other complications. Regardless of when the reoperation occurs, the surgeon is faced with making a clinical judgment as to the best course of action for the patient, as few definitive studies may exist to provide a roadmap for the surgeon and the anticipated anatomy and potential complications may be different than those experienced in an initial operation. Where complications, morbidity, and mortality occur in the medical setting, the stage is set for malpractice claims. Not only must a physician concern himself with a simple negligence claim, he must also consider whether the patient will pursue an informed consent claim.

To illustrate the importance of the necessary clinical judgment, consider Fry and Osler (1991), who noted that care and caution must be exercised when selecting the site for incision in a second abdominal wall surgery due to the potential that adhesions may have developed and attached to the underlying bowel where a previous incision exists, increasing the potential for complications. The authors surmise that a separate incision might be the best course of action to prevent or reduce the risk of complications in a patient undergoing reoperative abdominal wall surgery. They further suggest that the surgeon must have a comprehensive understanding of abdominal wall blood supply so as to avoid serious morbidity associated with a poorly planned site. In a medical malpractice claim, the surgeon is held to the standard of whether his actions were those of a reasonable physician acting under the same or similar circumstances. Assuming Fry and Osler's conclusions are, in fact, the medical standard of care, a surgeon who operates outside of these parameters risks not only being sued under a medical malpractice theory, but potentially found liable for his actions, even where his incision site for a primary procedure may have been appropriate.

Fry and Osler further state that a reoperation of the abdominal wall is associated with an increased risk of complications including dehiscence, infection, or ventral herniation. Infection, potentially the most serious of these problems, can range from a simple wound infection to necrotizing fasciitis. Armed with this knowledge, a surgeon who fails to disclose this known cluster of risks to a patient undergoing abdominal wall reoperative surgery places himself at risk of liability in an informed consent suit, in addition to those pursued for alleged negligence related to either the first operation or performance of the second operation.

As the above example illustrates, complication rates from reoperative surgery vary significantly and are dependent on a host of factors such as the type of surgical procedure to be performed, the previous procedure performed, patient-related risk factors, and surgical skill and experience. Consider for example, the following: Generally, 10–25% of patients who have bariatric surgery undergo such a surgery for either complications arising from initial surgery or for further weight control. It is also known that patients with morbid obesity have a mortality risk of up to 12 times that of the general population. And, in approximately 11% of these bariatric reoperations, serious morbidity will occur (Behrns et al 1993). In ileal pouch reoperative surgery, one study examined the complication rates, finding that two thirds of patients undergoing such a reoperative surgery experienced excellent clinical outcomes but one third did not, and up to one in five patients experienced a loss of their reservoir altogether (Galandiuk et al 1990). This is information most patients would consider critical to their decision making as to whether to undergo additional surgery, and it is incumbent upon the surgeon to stress the risks and potential benefits in obtaining informed consent.

In addition to procedure-specific complication rates, the surgeon must determine whether laparoscopy is available and advisable as a technique. When utilized, consideration must be given as to whether there has been a previous laparotomy, the surgeon's level of experience, the peritoneal access technique to be used, and patient-related factors such as the type and number of previous abdominal operations, the location of previous incision(s), and the likelihood of existing adhesions (Arnell 2006). Indeed, pneumoperitoneum access during laparoscopy can account for significant morbidity. In one report, 40% of bowel injuries occurring during laparoscopy were attributed to the establishment of the pneumoperitoneum – 60% of which occurred in patients who had undergone previous abdominal surgery (Arnell 2006). Finally, as a special consideration, where there has been a complication or other reason for reoperative surgery, the surgeon must disclose to the patient whether there are options for remediation/repair outside the scope of his expertise and should consider consultation with a subspecialist, where appropriate. The surgeon must be honest with himself and the patient regarding what options are available, what procedure best addresses the reoperative need, and whether the surgeon is in the best position to offer that option to the patient. A common theme in lawsuits filed after surgical complication (whether from primary or reoperative care) is that the surgeon was not trained, or was minimally trained in the particular procedure performed or that the surgeon simply did not perform the procedure correctly. The eye on the complication becomes more critical when the surgeon has operative failure a second time.

Thus, certain particularized elements of risk exist and are known at the outset when a decision is made to proceed with reoperative abdominal surgery. The decision to proceed with such a procedure is under the sound discretion of the competent surgeon in conjunction with the patient following a thorough discussion of the risks, benefits, and alternatives to the proposed procedure. This of course, is wholly aligned with the long-standing principles of medical ethics.

MEDICAL ETHICS

I WILL FOLLOW that method of treatment which according to my ability and judgment, I consider for the benefit of my patient and abstain from whatever is harmful or mischievous. . . .WITH PURITY, HOLINESS AND BENEFICENCE I will pass my life and practice my art. Except for the prudent correction of an imminent danger, I will neither treat any patient nor carry out any research on any human being without the valid informed consent of the subject or the appropriate legal protector thereof . . .

—The Hippocratic Oath
Harvard Classics Volume 38

The Hippocratic Oath has long provided physicians with an ethical framework to guide medical practice; however, the advancement of both technology and medical knowledge has resulted in ever increasing moral and ethical dilemmas for today's physicians. Beauchamp's model of ethical and moral principles incorporates the four generally accepted principles of medical ethics: autonomy, justice, beneficence, and nonmaleficence, providing a meaningful ethical framework in today's climate (Beauchamp & Childress 2008).

Autonomy is the principle of self-governance, viewed my many as an irrefutable value, the crux of which is the ability to be one's own person. In the medical ethical arena, autonomy permits a greater equilibrium in the doctor–patient relationship and power structure. It embodies a respect for the patient's wishes and a facilitation of a patient's input into the medical decision-making process. Autonomy requires the physician to not only consult with the patient regarding their care and treatment, but also to obtain their agreement to any proposed treatment prior to performing the procedure. The principle of justice is equated to 'fairness' and the conscious effort not to permit ones prejudices to directly influence their professional work by prejudicing their assessment of a patient's needs or restricting or delaying their access to care. Beneficence is the concept of doing that which benefits one's patients and nonmaleficence involves the avoidance of harm. Thus, a natural conflict arises between upholding each of these principles, as a procedure that is intended to promote the well-being of a patient may carry significant risks and potential harm to the same patient. These principles must, therefore, be considered together. Each proposed action upon a patient requires a careful cost-benefit balancing, the aim of which is to produce a net benefit over harm to the patient. These principles are likewise intertwined with the principle of autonomy. By informing the patient of what the net benefits and risks are to a procedure, a patient is able to deliberate on the options, and participate fully in the decision to proceed.

LEGAL CONSIDERATIONS: INFORMED CONSENT

Background

In the context of reoperative surgery, the aforementioned ethical principles align with the legal doctrine of informed consent. The doctrine of informed consent as pertains to physician–patient relationships reaches far back into the English Common Law. As early as 1767, physicians were charged with the tort of battery if they performed a procedure on a patient without having secured their consent. In an early United States case, Justice Cardoza stated, 'every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages (Schloendorff v. Society of New York Hospital, 211 NY 125, 129-30;1914).' Today, informed consent actions are based in negligence rather than battery and in each of the 50 United States, the requirements are expressed by either case law or statute.

INFORMED CONSENT: REQUIREMENTS

The informed consent process is much more than the obtaining of a patient's signature on a consent form. Rather, informed consent is the process of communication between the physician and patient, which results in the patient's authorization to proceed with a proposed procedure or their decision to refuse the proposed procedure. In discussing a proposed procedure with a patient, a physician should discuss the nature of the proposed procedure, the risks and benefits of the proposed procedure, alternatives to the proposed procedure, risks and benefits of the alternative procedures, and the risks and benefits of choosing not to undergo any procedure. Heightened requirements exist for certain populations, including those participating in human subjects research. Physicians participating in clinical research are encouraged to familiarize themselves with these heightened requirements. As the purpose of informed consent is to enable the patient to make an informed decision, this communications process should provide the patient with the opportunity to ask questions to better understand both his illness and the proposed treatment or procedure. This communications process has long been an ethical obligation of the physician, and today, it is also the legal duty of the physician to engage in this process prior to proceeding with any proposed treatment. Obtaining informed consent is not properly delegated to nurses or nonclinical staff. The communication requires knowledge regarding the patient and the procedure possessed by the surgeon.

Unlike a standard malpractice claim where the patient alleges that the doctor negligently performed a given procedure, the crux of an informed consent action is the patient's allegation that the physician never told him that there was the possibility of the occurrence of a resulting injury or harm and had he known, he would not have undergone the procedure. The patient must prove he experienced a complication of the procedure, and had he known about the specific complication he experienced, he would have opted not to undergo the proposed procedure. In other words, the patient has the burden of showing that the physician's failure to disclose a given risk resulted in the patient having a procedure he would have otherwise refused, resulting in the ultimate harm or injury suffered.

INFORMED CONSENT DISCLOSURE STANDARD

The question often asked, is how much information is adequate when a physician sets out to disclose the risks involved in a given procedure. States are divided in the standards they set forth in this regard (**Table 2.1**). The most widely applied approach is the 'Professional Standard' or the standard of the 'reasonable physician.' States utilizing this approach require a physician to disclose the amount of information, or particularized risks, as would a reasonably prudent physician with the same background, training, and experience in the same or similar situation. This approach is the same standard

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Table 2.1 State-specific informed consent standards (July 2012)

State	Reasonable physician	Materiality standard	Case name or statute
Alabama	x		Giles v. Brookwood Health Services, Inc., 5 So. 3d 533, 554 (Ala. 2008)
Alaska		x	Alaska Stat. Ann. § 09.55.556 (West)
Arizona	x		Shetter v. Rochelle, 2 Ariz. App. 358, 370, 409 P.2d 74, 86 (1965) modified, 2 Ariz. App. 607, 411 P.2d 45 (1966)
Arkansas	x		Ark. Code Ann. § 16-114-206 (West)
California		x	Cobbs v. Grant, 8 Cal. 3d 229, 245, 502 P.2d 1, 11 (1972)
Colorado	x		Gorab v. Zook, 943 P.2d 423, 427 (Colo. 1997)
Connecticut		x	Duffy v. Flagg, 279 Conn. 682, 691-92, 905 A.2d 15, 20 (2006)
Delaware	x		Del. Code Ann. tit. 18, § 6852 (West)
Florida	x		Fla. Stat. Ann. § 766.103 (West)
Georgia		x	Ga. Code Ann. § 31-9-6.1 (West)
Hawaii		x	Carr v. Strode, 904 P.2d 489, 500 (Haw. 1995)
Idaho	x		2012 Idaho Laws Ch. 302 (S.B. 1294), 2012 Idaho Laws Ch. 302 (S.B. 1294)
Illinois	x		Lisowski v. MacNeal Mem'l Hosp. Ass'n, 381 Ill. App. 3d 275, 290, 885 N.E.2d 1120, 1136 (2008)
Indiana	x		Spar v. Cha, 907 N.E.2d 974, 984 (Ind. 2009)
Iowa		x	Kennis v. Mercy Hosp. Med. Ctr., 491 N.W.2d 161, 166 (Iowa 1992)
Kansas	x		Rojas v. Barker, 40 Kan. App. 2d 758, 763, 195 P.3d 785, 789 (2008)
Kentucky	x	x	Ky. Rev. Stat. Ann. § 304.40-320 (West)
Louisiana		x	Hondroulis v. Schuhmacher, 553 So. 2d 398, 411-12 (La. 1988)
Maine	x		Me. Rev. Stat. tit. 24, § 2905
Maryland		x	McQuitty v. Spangler, 410 Md. 1, 18-19, 976 A.2d 1020, 1030 (2009)
Massachusetts		x	Roukounakis v. Messer, 63 Mass. App. Ct. 482, 485, 826 N.E.2d 777, 780 (2005)
Michigan	x		Roberts v. Young, 369 Mich. 133, 140, 119 N.W.2d 627, 630 (1963)
Minnesota	x		K.A.C. v. Benson, 527 N.W.2d 553, 561 (Minn. 1995)
Mississippi		x	Latham v. Hayes, 495 So. 2d 453 (Miss. 1986)
Missouri	x		Wilkerson v. Mid-Am. Cardiology, 908 S.W.2d 691, 696 (Mo. Ct. App. 1995)
Montana	x		Llera v. Wisner, 171 Mont. 254, 262, 557 P.2d 805, 810 (1976)
Nebraska	x		Neb. Rev. Stat. § 44-2816
Nevada	x		Smith v. Cotter, 107 Nev. 267, 272, 810 P.2d 1204, 1207 (1991)
New Hampshire	x		Folger v. Corbett, 118 N.H. 737, 738, 394 A.2d 63, 63-64 (1978)
New Jersey		x	Largey v. Rothman, 110 N.J. 204, 215, 540 A.2d 504, 510 (1988)
New Mexico		x	Gerety v. Demers, 92 N.M. 396, 410, 589 P.2d 180, 194 (1978)
New York	x		N.Y. Pub. Health Law § 2805-d (McKinney)
North Carolina	x		N.C. Gen. Stat. Ann. § 90-21.13 (West)
North Dakota		x	Long v. Jaszczak, 2004 ND 194, 688 N.W.2d 173, 178
Ohio		x	Nickell v. Gonzalez, 17 Ohio St. 3d 136, 139, 477 N.E.2d 1145, 1148-49 (1985)
Oklahoma		x	Parris v. Limes, 2012 OK 18, 277 P.3d 1259, 1263, reh'g denied (May 14, 2012)
Oregon	x		Or. Rev. Stat. Ann. § 677.097 (West)
Pennsylvania	x		40 Pa. Stat. Ann. § 1303.504 (West)
Rhode Island		x	Lauro v. Knowles, 785 A.2d 1140, 1141-42 (R.I. 2001)
South Carolina	x		Melton v. Medtronic, Inc., 389 S.C. 641, 656, 698 S.E.2d 886, 894 (Ct. App. 2010)
South Dakota		x	Wheeldon v. Madison, 374 N.W.2d 367, 374 (S.D. 1985)
Tennessee	x		Tenn. Code Ann. § 29-26-118 (West)
Texas		x	Vaughan v. Nielson, 274 S.W.3d 732, 737 (Tex. App. 2008)
Utah		x	Utah Code Ann. § 78B-3-406 (West)

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State	Reasonable physician	Materiality standard	Case name or statute
Vermont	x		Vt. Stat. Ann. tit. 12, § 1909 (West)
Virginia	x		Tashman v. Gibbs, 263 Va. 65, 73, 556 S.E.2d 772, 777 (2002)
Washington		x	Wash. Rev. Code Ann. § 7.70.050 (West)
West Virginia		x	Cross v. Trapp, 170 W. Va. 459, 468, 294 S.E.2d 446, 455 (1982)
Wisconsin		x	Johnson by Adler v. Kokemoor, 199 Wis. 2d 615, 631, 545 N.W.2d 495, 501 (1996)
Wyoming	x	x	Willis v. Bender, 596 F.3d 1244, 1254 (10th Cir. 2010)

Compiled by Billy Hopkins, summer law clerk, Wyatt, Tarrant & Combs LLP, Louisville, KY, USA (2013)

applied in other medical malpractice actions and requires that a physician expert testify at trial on behalf of the defendant physician as to the appropriateness of the scope of his disclosure. States may expand upon this standard. In Oregon, for example, the physician has a statutory duty to ask the patient if they would like additional information, and if so, must provide the patient with a description of the proposed procedure in substantial detail.

Several states apply what is termed the 'materiality standard' or the reasonable patient standard, another objective standard. These states define appropriate disclosure as including that which a reasonable patient in the same or similar situation would need to know to make an informed and appropriate decision regarding a proposed procedure. In other words, the information deemed 'material' to an informed decision must be provided. Information that is 'material' is that information that a person in the patient's position would be likely to attach significance to in deciding whether or not to undergo the proposed surgery. In these states, no medical expert is required to define the scope of this disclosure, but rather, the jury, who is considered a reasonable group of people, defines the scope of this material disclosure in objective terms. Again, states may vary in their precise standards. For example, in Pennsylvania, the materiality standard is imposed in informed consent actions; however, a physician defendant is permitted to present evidence of the community standard in his defense. Note that both Kentucky and Wyoming standards are hybrids, meaning, they combine the requirements of both the reasonable physician standard and the materiality standard.

Finally, the 'subjective patient standard' is mentioned in various anecdotal reports on informed consent. This standard asks what the particular plaintiff/patient, under his circumstances, would need to know prior to agreeing to proceed with a proposed procedure. This standard would prove very difficult to establish, and the authors were unable to identify a jurisdiction in the United States that applies this standard. Physicians should familiarize with the standard applied in their respective locale to understand the scope of the informed consent duty.

DEFENSES TO AN INFORMED CONSENT CAUSE OF ACTION

There are several scenarios where a defense exists to the physician's duty to obtain informed consent. The best established of these is in an emergency, where any attempt in obtaining informed consent would delay necessary emergency treatment. In such a case, most hospitals require that a physician document in the medical record that informed consent could not be obtained due to the emergency status of the situation. Another viable defense to an informed consent claim is the lack of foreseeability of an injury, or those that are so remote, that they would not give rise to a duty in the physician to advise of its potential. This concept is consistent with both the 'reasonable physician' and 'materiality' standards applied in informed consent actions in the majority of states.

The physician's duty for disclosure may also be successfully defended against in situations where the patient has prior knowledge of the potential risks of a proposed procedure, as in when they have undergone the same procedure previously, or when the potential risks are common knowledge, as in pain after surgery.

Another doctrine that may enable a successful defense against an informed consent claim is what is referred to as the 'therapeutic privilege.' This privilege permits a physician to withhold information from a patient where, in his professional judgment, the physician believes the information would either be too upsetting for the patient to hear, or would in some way interfere with treatment. It seems obvious that reliance on such a privilege ought to be well considered prior to deciding to withhold disclosure of information to a patient, as the patient's right to autonomy is highly regarded. If relied upon, the physician's rationale for withholding certain information must be well documented in the record. This paternalistic approach is one the statutes and case law seek to discourage. Reliance on a single physician's opinion regarding potential harm would provide a weak defense where that physician is also the operating surgeon.

Finally, the best defense in an informed consent action is where the patient has actually been informed of the potential risk and has decided to proceed. A patient's knowledge of these risks is often portrayed by the presence of a written consent form that outlines the risks and benefits of a procedure and includes the patient's signature in acknowledgment thereof and further supported by a written note by the surgeon outlining the consent process. The argument is that the patient knew of the potential risk, and agreed to undergo the operation, despite knowledge of those risks. Notably, Florida's informed consent statute expressly provides for a rebuttable presumption of a valid consent where a signed consent is of record.

Sometimes, a comparative negligence instruction is sought in an effort to share the liability between the patient and physician where a signed consent form exists, yet there is a dispute regarding what was precisely disclosed. As simplistic as this defense seems, it is not always a clean defense. For example, in a recent Kentucky Court of Appeals case, a physician was sued under an informed consent cause of action when his patient suffered postoperative complications after ureteroscopy for removal of a kidney stone. The physician defendant presented a copy of the written operative consent form, signed by the patient, which indicated that the procedure to be performed was ureteroscopy. Despite the presence of the consent form, the Court refused to issue a comparative negligence instruction to the jury because at trial, the plaintiff testified that the only procedure verbally discussed with his wife was shock lithotripsy, the same procedure

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performed on the patient previously, and neither the physician nor the patient could remember what was precisely discussed in advance of the operation. The Court relied on a Wisconsin case that stated that a contributory negligence instruction may apply in an informed consent case, but only in certain extraordinary circumstances (Oghia v. Hollan, March 16, 2012, Ky. App). Thus, reliance on the signed consent form alone may not provide for the defense a physician presumes it does.

CONCLUSION

Performance of subsequent operations for complications or failure is a reality of every surgical practice. As surgeons are aware, each operative and reoperative procedure carries specific risks – those inherent in the procedure itself, and others compounded by certain patient-related and surgeon-related factors, such as skill and experience. The surgeon must determine the options for treatment and remediation of the complication or failure of the initial procedure; the risks inherent with various options; whether he is the person most suited to providing the continuing surgical care; and provide the patient with sufficient information to decide what is best under the circumstances. The obtaining of a patient's informed consent prior to the performance of an operative procedure is both a moral obligation and the legal duty of a surgeon. Physicians are encouraged to familiarize themselves with the standards applied in an informed consent cause of action in their practicing jurisdiction, as the law and standards vary from state to state, and change from time to time.

Because reoperative surgery often carries higher risk than primary operations, the risk that the surgeon may be sued for complications experienced by the patient also increases. The surgeon must arm himself with a thorough progress note detailing informed consent, but equally as important, the surgeon must give thoughtful attention to his own decision whether to act as the reoperative surgeon for repair of his complication. Only after thorough, honest, meaningful discussion between the physician and his patient, and the implementation of a plan of care that balances the beneficence and nonmaleficence components of the physician's oath in the care and treatment of his patients, should he proceed.

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