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Medicolegal Issues: The Pitfalls and Pratfalls of the Bariatric Surgery Practice

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Historical Perspective

There was an explosion in the number of medical malpractice lawsuits filed in the early part of this century, and general surgeons experienced the effects of this boom in and out of the operating room. While medical negligence lawsuits have been recognized for over two centuries, the modern-day impact of this type of litigation in the United States has been simmering for decades. With litigation reaching crisis proportions in the mid-1980s and again in the last decade, medical risk management has become an integral part of every surgical practice [8].

The legal theory behind medical malpractice claims originates in English jurisprudence dating back to the eighteenth century; however, lawsuits alleging medical malpractice were filed sparingly in the United States until the middle of the nineteenth century [9]. By 1850, medical malpractice litigation as we know it today was entrenched in the American legal landscape. Historians have attributed the precipitous increase in professional negligence actions in the United States to the cultural decline in fatalist philosophical thought and the marked increase in religious perfectionism, both concepts having grown out of the Christian revivals of the 1820s and 1830s [10]. The increase in the number of suits filed in later decades of the nineteenth century has been attributed to the birth of what has been called "marketplace professionalism" [11]. The concept of marketplace professionalism, unique to the United States during this stage in the country's development, illustrates the most dramatic American divergence from traditional European models of professional evolution [11]. Historically, the learned professions of Western Europe were granted authority by the ruling class. In the United States, however, this sanction was not embraced by American society and became most evident in the 1830s when concepts of social status, economic class, monopoly, and elitism garnered great public criticism [11]. The professions, including law and medicine, were thrust into the marketplace to fend for themselves in an environment of Darwinian competition. Consequently, the medical profession expanded to include those who were trained and untrained, alternative, and traditional, with little quality control. At the same time, lawyers found themselves in an equally hostile culture of competition, and medical malpractice became an area of growth for the legal profession [11].

The result of this fight for professional survival was an unprecedented increase in the number of medical malpractice suits filed in the United States. Between 1840 and 1860, the number of lawsuits alleging medical negligence grew by 950 % [11]. Although medical malpractice litigation exploded onto the scene in the middle of the nineteenth century as a result of a cultural shift, the phenomenon has perpetuated in response to both scientific innovation and the call for professional regulation. Historically, with every new era of medical innovation or expansion came an increase in claims for negligence. Once the innovation became passé, the wave of litigation abated but it never fell back to zero [12].

Despite the recognition that medicine is not perfection and physicians are fallible, our culture demanded a standard by which mistakes could be measured. Accordingly, the mid-nineteenth century saw the advent of various professional organizations, including the American Medical Association. As a result of this self-regulation, unqualified physicians were identified and driven from the profession. However, the impact on those who remained was the creation of uniform standards by which medical professionals would be judged. In the wake of these new licensing requirements and standards of care, the profession was exposed to more litigation as lawyers now judged physicians by the profession's own standards [12].

Finally, the introduction of professional liability insurance in the late nineteenth century proved to be both a champion and an enemy of the physician. Insurance virtually erased risk to the financial survival of the individual practitioner, but at the same time it guaranteed resources to the malpractice plaintiff [13]. As a result, the introduction of insurance to the profession effectively guaranteed the survival of medical malpractice litigation into the twentieth century and beyond [13]. Today, medical malpractice litigation

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is pervasive. One economic study by the Joint Economic Committee of the US Congress suggests that the current state of the medical malpractice litigation system has had a negative impact on the access to and the cost of professional liability insurance, the quality of health care, and the cost of and access to health care in this country [14]. While the future of the current medical liability system in the United States is unknown, the prudent bariatric surgeon must be able to identify potential risks associated with litigation and how best to avoid it.

Medical Negligence Litigation and Recent Trends

Despite having preconceived ideas of how they will be perceived, physicians should be reassured to learn that juries usually "get it right." Over 30 years of data show us that outcomes in medical malpractice litigation are remarkably consistent with the quality of care provided to a patient as critiqued by physician peers [15]. In general, physicians win 80–90 % of those cases where other physicians conclude there is weak evidence of medical negligence, 70 % of the borderline cases, and 50 % of cases where other physicians believe that the plaintiff should prevail [15]. In fact, one study suggested that favorable physician outcomes in the face of no documented evidence of negligence have improved and that the perception of a broken American tort system is misplaced [16].

After the litigation crises of the mid-1980s and early 2000s, a 2006 study by Aon, a global provider of risk management and insurance and reinsurance brokerage, revealed that claims against hospitals and physicians began to stabilize. In its seventh annual Hospital Professional Liability and Physician Liability Benchmark Analysis, Aon attributed the decrease in frequency and increase in severity to claims management, tort reform, and patient safety and quality assurance efforts [17]. This stabilization in frequency of claims remained true for several years until the economy took a turn for the worse [18]. A new study suggests that by the end of 2012, claim severity for hospitals and physicians nationwide had increased by 2.5 % with claim frequency increasing by 1 %. In its 2012 Benchmark study, Aon and the American Society for Healthcare Risk Management concluded that we should expect to see a sharp increase in medical malpractice claims and warn that loss rates for both hospitals and physicians are projected to grow by 3.5 % by 2013 [19].

Medical Negligence Litigation and the Bariatric Surgeon

What is medical malpractice? How does a plaintiff prove medical malpractice? Why the surge in medical malpractice claims involving bariatric surgery? Why do people sue their physician? What is the impact of a medical malpractice lawsuit on the physician's career? What is the impact on the physician's job satisfaction and personal happiness? These are the questions that cause the medical profession angst, despair, and insomnia. For some, the topic inspires only ire and frustration.

The word *malpractice* has been defined as "any professional misconduct, unreasonable lack of skill or fidelity in the profession or fiduciary duties, evil practice or illegal or immoral conduct" [20]. The term *medical malpractice* is derived from the Latin *mala praxis*—bad practice—and was first applied to the profession of medicine by Sir William Blackstone in 1768 [21]. To prevail in a medical negligence suit, the plaintiff must prove by the greater weight of the evidence all four elements of the cause of action. That is, to prove a prima facie case of medical negligence, the plaintiff must establish:

1. A duty to the patient
2. A breach of that duty or standard of care
3. A compensable injury
4. Proximate causation to the injury or damages [22, 23]

Once the physician–patient relationship is established, the physician owes his or her patient the duty of due care. "Due care" is defined as the care required of a reasonably prudent physician in the same field of practice under the same or similar circumstances [24]. In most cases, the duty of due care—or the standard of care—must be proved through expert testimony. Likewise, any alleged breach of the standard of care and proximate causation must be proved through the introduction of expert testimony. The plaintiff often uses documents such as medical records, medical literature, and demonstrative aids such as models, charts, medical chronologies, and diagrams at trial as well.

Physicians are sued for myriad reasons, from the sublime to the ridiculous. That said, most suits for malpractice allege the following:

- Failure to communicate or miscommunication
- Failure to diagnose
- Failure to treat
- Failure to document appropriately
- Failure to perform a procedure appropriately
- Failure to get appropriate consultations
- Inappropriate orders or delegation of duties
- Breach of confidentiality
- Failure to admit a patient to the hospital or premature discharge
- Failure to order appropriate diagnostic tests or studies
- Misinterpreted diagnostic tests or studies
- Bad outcomes and unreasonable expectations
- Complications and failure to timely address recognized complications
- Inadequate informed consent or no informed consent
- Failure to follow up or patient abandonment

In recent years, there has been a focus on finding data to support why plaintiffs choose to sue healthcare practitioners.

One recent survey reveals that the number of years in practice dictates the likelihood of being named in litigation. A 2011 survey sent out by the ASMBS Patient Safety Committee determined that the probability of reporting at least one lawsuit independently increased with the number of years a surgeon was in practice [25]. Another study revealed that only about 5 % of physicians are sued annually but that 42.2 % of physicians have had medical malpractice claims filed against them during their career [26]. Pediatricians and psychiatrists were sued least often with their colleagues in surgery and obstetrics/gynecology having higher frequency data [26]. That said, a subsequent American Medical Association study revealed that 55 % of all cases filed against physicians are dismissed, with less than 5 % of cases making it to trial [27]. Of those cases tried to a judge or jury, 79.6 % of cases resulted in verdicts in favor of the physician [27]. The study involved claims closed between 2002 and 2005 and outcomes varied across specialties, with medicine-based specialties enjoying the highest rate of dismissal (61.5 %) and pathologists suffering the lowest (36.5 %) [27].

So why do surgeons get sued? Anecdotally, we know that bad clinical outcomes are at the heart of most litigation. The data shows that those bad clinical outcomes can be tied to injury to adjacent organ or anatomic structure. In a 2008 survey of 91 lawsuits against general surgeons, 30 % of those suits involved iatrogenic injury to adjacent structures, 37 % of which involved nerve injury [28]. However, patients and their families also sue because they are angry, offended, or grieving. As well, experience tells us that plaintiffs often use the litigation process to apportion blame, shift accountability, manage guilt or grief, and seek closure.

Bariatric surgeons see claims of malpractice for similar reasons, although weight-loss procedures and morbidly obese patients are unique in the medical litigation mise-en-scéne. Cases against bariatric surgeons include many of those claims delineated above but also may include the following allegations:

- Inexperience of the operator
- Inadequate facilities or equipment for the bariatric patient
- Failure to monitor or inadequate postoperative monitoring
- Failure to diagnose or to timely diagnose a lethal complication
- Inadequate preoperative workup or substandard patient selection
- Contraindications to surgery, including history of gallstones or cholecystitis
- Poor follow-up support after surgery
- Unrecognized or unaddressed psychiatric issues
- Misguided motivation for surgery

Today, the lion's share of litigation involving weight-loss procedures concentrates on allegations of negligence during the postoperative period, immediate postoperative inpatient care, and follow-up once the patient is discharged to home [29]. Specifically, postoperative leaks and delayed diagnosis of recognized complications of the procedure are the most common cause for a subsequent medical negligence claim [30]. Regardless of the theory of liability against the bariatric surgeon, the suits continue to be filed across the nation.

Informed Consent

Informed consent is a process, not a piece of paper. It is a common misconception that one proves informed consent with a signed "consent for treatment" form. To the contrary, the signed consent form is merely one piece of evidence that the attending physician completed the informed consent process. The doctrine of informed consent is based on the premise that people have a right to decide what happens to their own bodies and minds. It is based on the concept of autonomy—a concept firmly grounded in philosophy, not law. Autonomy—or self-determination—embraces the notion that people have the right to choose the course of their own medical treatment in accordance with their own values, mores, religious beliefs, and life goals. The principle is also grounded on the premise that no other person, institution, or other entity should be permitted to intervene to overrule an individual's wishes, whether or not those wishes are "right," as long as the decision does not negatively affect another individual [31]. That choice, however, must be based on information regarding diagnosis, prognosis, risks, and benefits of the procedure or course of therapy, as well as the consequences of refusing treatment.

The doctrine of informed consent is composed of two discrete components: permission and knowledge. A patient is entitled to give express permission for any touching by another and that permission is to be based on information that is deemed to be important by the patient's physician. That is, it is incumbent on the medical practitioner to impart all information necessary for the patient to make a well-reasoned, educated choice regarding treatment. Informed consent is of paramount importance when dealing with elective procedures, as consent is implied in the case of an emergency. As bariatric surgery is a high-risk elective procedure by its very nature, the informed consent process must be well planned and well executed.

Causes of action involving issues of informed consent fall into two categories: the tort of battery (no consent) or negligence (inadequate consent). Battery—or unauthorized touching—occurs when the physician fails to obtain informed consent or if the touching exceeds the scope of the informed consent. Negligent informed consent is consent that is based on inadequate information. In most jurisdictions, informed consent is based on the "reasonable" man standard; that is, consent is informed when it is based on the information that a reasonably prudent surgeon would convey to his or her patient during the informed consent process. Suits alleging negligent informed consent usually require expert testimony on the subject; cases alleging battery do not.

Generally, the informed consent process should include the following:

1. A discussion in laymen terms regarding the description of the surgical procedure to be performed
2. A discussion of the significant risks and benefits of the procedure to be performed
3. A discussion of the alternatives to the proposed surgical procedure
4. A discussion of the consequences of the procedure being declined by the patient
5. Documentation of the informed consent process *and* the actual consent, including a signed consent form, a note in the physician's progress notes, in the patient's clinic chart, and in the operative report

It is important to be sensitive to false or unrealistic expectations in the patient population and to dispel any misconceptions about the procedures of anticipated outcome. It is reasonable to assume that any representation about obesity surgery made on a Web site, in promotional materials, or in informational pamphlets or videotapes will be relied upon by patients and their families. Surgeons should be wary of making promises and predictions.

Documentation

The most credible piece of evidence in litigation is medical record documentation. Accordingly, the medical record must be complete, concise, accurate, legible, timely, and authentic. While this may seem a daunting task, physicians may be asked to interpret or rely upon a medical record several years after the provided care and treatment to a patient. In the busy practice, particularly one in the academic milieu, it is of paramount importance to maintain an accurate and comprehensive medical record.

Why document in the medical record? Is the documentation strictly used to defend the surgeon who finds himself embroiled in litigation? No. The medical record memorializes care and treatment contemporaneously in an effort to promote continuity of care, accurate communication among the care team members, and data for retrospective review and analysis and to defend surgeons who find themselves embroiled in litigation.

Accurate and complete documentation may prove to be the most important tool in the management of the bariatric patient. In this highly specialized practice of surgery, both the pre- and postsurgical phases of treatment require effective communication among various disciplines (i.e., medicine, surgery, nutrition, psychology, and occupational and physical therapy) and adequate data to provide comprehensive, timely, and safe treatment to this unique patient population. In general, effective inpatient documentation describes in an objective manner all noteworthy data regarding a patient's presentation, history and physical, recommendations for treatment, actual ongoing care and treatment, and follow-up. It is important to include the most current information available, which will ensure that the patient's chart will be the most reliable resource for ongoing patient care and the best evidence that appropriate and timely care was provided. As the medical record is the primary conduit for continuing care and communication among a patient's care providers, it should include all pertinent clinical information, including the physician's assessment and reaction to laboratory reports, radiology, and other studies. Surgeons often fail to include their rationale for clinical decisions, including data to support the differential diagnosis; however, this information is critical. Physicians should be sure to document a differential diagnosis when the facts permit a reasonable inference that something other than the primary diagnosis may be valid. It is far more difficult to allege that a surgeon failed to consider all of the options when faced with clinically pertinent data if it is documented in the medical record, especially in an area of medicine where potential complications are many, are potentially lethal, and often occur quickly.

Regardless of the procedure, the operative note should be dictated expeditiously—ideally on the same day—and should include all findings and complications encountered and the related management of those findings. Operative notes dictated weeks or months after the procedure are a "red flag" in litigation, particularly in situations where complications were encountered by the surgical team. Despite the routine nature of some surgical procedures, the prudent surgeon should avoid using "boilerplate" language, rather endeavoring to personalize the operative note to the individual patient. Furthermore, all dictation should be reviewed, corrected, and signed promptly and include the results of the sponge and instrument counts. Likewise, postoperative orders should be legible and signed by the operating surgeon, and follow-up and discharge instructions should be signed by the patient or his or her responsible party.

In the bariatric clinic setting, it is important to document all preoperative patient encounters, referrals, and consultations. Preoperative screening should be comprehensive and noted in the patient's chart, as well as all relevant discussions with the patient and family and any consultants. All consultation reports should be contained in the record, as well as preoperative laboratory results, radiology, and other screening exams pertinent to the bariatric patient headed for surgery. When documenting the informed consent process, include the risks, benefits, and alternatives discussed, as well as whether additional information was provided to the patient and family (e.g., videotape, brochure, pamphlets, referral to support groups, or other forms of patient education). In most cases, the informed consent process for bariatric procedures is lengthy, is candid, and may be included in the patient screening mechanism. That being said, it should be well documented to protect the care team from claims alleging inadequate consent after a bad outcome.

Postoperative follow-up is arguably the most important phase in caring for the bariatric patient. Accordingly, the surgeon or professional staff should document clearly all follow-up instructions, appointments, referrals, prescriptions and refills, and the plan of care going forward. As the medical record is used as a communication tool and for documentation of continuing care, it is critical that all telephone communications are entered in the chart, as well as missed, canceled, and rescheduled appointments. Above all, document and include all correspondence related to the physician's decision to terminate the physician–patient relationship or when the patient informs the physician that the physician's services are no longer necessary.

Do's of Effective Charting

- Do use precise, concise, specific language.
- Do use objective, factual statements.
- Do document a patient's verbatim statements.
- Do date and time each entry in the medical record.
- Do make sure the patient's name appears on the page before writing.
- Do draw diagonal lines through all blank space after an entry.
- Do document adverse reactions to medications or therapy.
- Do "red flag" all allergies.
- Do ensure that all procedure notes and chart entries are timely and accurate.
- Do be sure to read a medical record entry before cosigning.
- Do include time and specific action in all discharge instructions.
- Do include all pertinent communications with residents, attending physicians, nursing staff, and consults.
- Do include an addendum or late entry if necessary.
- Do include the words "addendum" or "late entry"; time and date the note.

Don'ts of Effective Charting

- Do not alter the medical record… ever. This is a criminal act.
- Do not obliterate errors or remove pages from the chart.
- Do not use personal abbreviations, initials, or ditto marks.
- Do not include derogatory or discriminatory remarks.
- Do not document conflicts with other physicians or nursing staff.
- Do not use subjective statements about prior treatment or poor outcomes.
- Do not include a late entry after an adverse event.
- Do not include non-patient care information.
- Do not perpetuate incorrect information.
- Do not write any finger-pointing or self-serving statements.
- Do not alter existing documentation or withhold portions of the chart once a claim has been made or after the record has been copied.
- Do not use phrases that imply a risk.
- Do not include incident reports, quality assurance information, or documents involving the legal process in the patient chart… ever.

While the patient chart is first and foremost a medical document, it is also a legal document. It is the best defense to any claim of medical malpractice and should reflect the attention to detail required of the prudent bariatric surgeon.

Confidentiality

Since the Clinton Administration, patient privacy and medical record confidentiality have garnered much public and political attention. Congress passed the Health Insurance Portability and Accountability Act (HIPAA), historically known as the Kassebaum-Kennedy Law, in 1996 [32]. Its primary purpose was to improve continuity and portability in the delivery of health care while preserving the privacy of certain sensitive health information [32]. Furthermore, it seeks to "combat waste, fraud and abuse in health insurance and health care delivery… [and] simplify the administration of health insurance" [32]. In an effort to carry out these purposes in the age of technology, HIPAA targets three areas of the healthcare industry: (1) insurance portability, (2) fraud enforcement, and (3) administrative simplification [33]. It is the administrative simplification section of HIPAA that concentrates on patient privacy and that is of most interest to healthcare professionals and their staff [34].

The privacy regulations (Privacy Rule) of HIPAA are designed to provide patients a process by which to maintain the confidential nature of certain protected health information (PHI). The final Privacy Rule was published in December 2000, to be effective in April 2001 [35]. It applies to specific "covered" entities including health plans, healthcare clearinghouses, and healthcare providers who transmit health information in electronic form related to a transaction covered by the federal regulations [36]. The final modifications to the Privacy Rule were published in August 2002 [37], and the previously specified entities were required to comply with the Privacy Rule by April 14, 2003 [38].

The Privacy Rule protects individually identifiable health information (the PHI) that is maintained or transmitted by a covered entity, whether oral or written [39]. Individually identifiable health information includes even the most basic demographic information collected from an individual patient [39]. It also includes any information created by or received by a health plan, a patient's employer, a healthcare clearinghouse, or a healthcare provider that relates to past, present, or future physical or mental health condition of an individual [39]. Further, the Privacy Rule relates to information regarding the past, present, or future payment for health care by the individual, if the information identifies the individual patient [39].

The Privacy Rule does not prohibit disclosure of PHI; rather, it requires that the information be disclosed only in accordance with the provisions of HIPAA [40]. That is, when a covered entity discloses PHI or when it is requesting protected information from another covered entity, it must make reasonable efforts to limit the transmission of protected information to the minimum disclosure necessary to meet the requirements of the request [40]. However, the Privacy Rule requirement does not apply to the release of PHI in the following scenarios:

1. Requests from or disclosure to a healthcare provider for the purpose of medical treatment
2. Release of PHI to the patient himself
3. Disclosure of PHI to the US Department of Health and Human Services
4. Disclosures or requests required by law
5. Release of or request for information in accordance with the Privacy Rule [41]

The Privacy Rule requires that a covered entity not disclose or use PHI without an authorization, unless the disclosure is contemplated by the regulations [42]. For an authorization to be valid under HIPAA, it must include the following:

1. A description of the information to be disclosed
2. Identification of the persons or class of persons authorized to use or disclose the PHI
3. Identification of the persons or class of persons to whom disclosure will be made
4. A description of the purpose of the use of disclosure
5. An expiration date certain or precipitating event
6. The individual's signature and date
7. A description of the authority of the signatory to act on behalf of the individual, if signed by a personal representative [43]

The authorization for disclosure under HIPAA must also include the following:

1. A statement that the individual may revoke authorization and instructions regarding how to do so.
2. A statement that medical treatment, payment, enrollment in a plan, or eligibility for benefits may not be predicated on obtaining the authorization from the individual if such a condition is prohibited by the Privacy Rule. To the degree it is not prohibited, the authorization must include a statement about the consequences of not authorizing use and/or disclosure.
3. A statement about the likelihood that the recipient will disclose the PHI [43].

Patient authorization is *not* required for disclosure in accordance with public health activities; reporting victims of abuse, neglect, or domestic violence; health oversight activities; judicial and administrative proceedings; or law enforcement purposes (i.e., pursuant to court order or subpoena) [44].

As one would expect, patients are granted rights to their own PHI under HIPAA's Privacy Rule. Specifically, patients may request certain restrictions be placed on the disclosure of their PHI [45], the right to review and copy their PHI [46], the right to amend their PHI [47], the right to receive a copy of the HIPAA notice from the covered entity [48], and the right to receive an accounting of disclosures of PHI [49].

It is important to note that any provision of the HIPAA Privacy Rule that is contrary to individual state law preempts that provision of state law [50]. That being said, federal law will not preempt state law if the state law is promulgated to prevent fraud and abuse related to payment for medical services; to ensure state regulation of the insurance industry and healthcare plans; to report on the delivery of health care and related costs; to serve a compelling need related to public health, safety, or welfare; or to regulate controlled substances [51]. Furthermore, HIPAA will not preempt the state law if the state law is more restrictive than the federal statute [51]. It is extremely important for physicians to be aware of their state's confidentiality statutes that control when and how private health information may be disclosed.

Under the American Recovery and Reinvestment Act of 2009, the federal government included a set of provisions titled the Health Information Technology for Economic and Clinical Health Act (HITECH) that advance the use of technology in health care. The Act encourages physicians and hospitals to purchase and incorporate electronic medical record systems (the Act calls them electronic health records (EHR)) into their practice before the end of 2015. The goal of the Act is to improve quality of care and to control escalating costs associated with the delivery of health care in the United States. In an effort to facilitate and ease the transition from paper-based medical records to EMR, the Act includes incentive payments to qualifying professionals and hospitals.

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare and Medicaid EHR incentive payments to eligible physicians, hospitals, and critical access hospitals [52] as they "adopt, implement, upgrade, or demonstrate meaningful use" of EMR technology. An estimate of $27 billion has been set aside to accomplish the Act's goals and specifically to assist in the implementation of the EMR, with roughly $17 billion going toward incentives. The incentive payments are available to hospitals and physicians when they adopt certified EMR and the numbers are significant. In recent years—and in large part due to these incentives—EMRs are being adopted, implemented, and used by hospitals and surgeons in increasing numbers. The process has not been seamless for most and the transition has been, and will continue to be, fraught with complications and unintended consequences. Nevertheless, the EMR is here to stay.

Along with the implementation of this technology in the office, clinic, and hospital setting comes new requirements for maintaining confidentiality. The HIPAA/HITECH Final Rule was published by the Department of Health and Human

Services, Office for Civil Rights (OCR) on January 25, 2013 [53]. The effective date is March 26, 2013, and compliance is required by September 23, 2013. The HITECH Act required that certain aspects of HIPAA be modified, including the August 24, 2009, interim final rule on Breach Notification for Unsecured Protected Health Information; the October 7, 2009, proposed rule modifying the HIPAA Privacy Rule as required by the Genetic Information Nondiscrimination Act (GINA); the October 30, 2009, interim final rule adopting changes to the HIPAA Enforcement Rule; and the July 14, 2010, proposed modifications to the HIPAA Privacy, Security, and Enforcement Rules [54].

It is important to be aware that the new rules include (1) the redefinition of "business associate" under HIPAA; (2) the broader liability application to business associates and their agents and subcontractors; (3) changes to the breach standards; (4) prohibitions regarding the sale of PHI without authorization; (5) new rules related to fundraising, marketing, immunization information to schools, and the disclosure of deceased patients' PHI; (6) broader individual access to electronic PHI; and (7) penalties associated with violations of these and other provisions of HIPAA. For purposes of this chapter, we will only discuss the changes to patient access to electronic PHI.

As with the original Privacy Rule, patients have the right to access their own health information. Under the HITECH Act, Congress gave patients the right to electronic *copies* of PHI in EHR; however, in the new rule, OCR expanded this right to include all electronic designated record sets (DRS). Accordingly, if an individual requests an electronic copy of PHI that is maintained electronically in more than one DRS, the provider must produce it in the electronic form and format requested, if it is readily reproducible. If it is not readily reproducible in the requested form or format, it must be produced in a readable electronic form and format as agreed upon by the parties. If the individual declines to accept any format that is readily reproducible by the provider, then the provider may produce a hard copy. There is no requirement that the provider scans paper copies. Finally, providers must comply with individuals' requests that their PHI be sent directly to another person if that request is in writing, is signed by the individual, and clearly identifies the designated person to whom the PHI should be sent.

The provider, at his or her discretion, may accept verbal requests for PHI or require written, signed authorizations. You have 30 days to provide access to a patient's PHI, and a 30-day extension may apply in situations where a hard copy or electronic PHI must be retrieved from off-site storage or where other time constraints make the extension necessary. Nonetheless, the provider must apprise the individual of any delay in making the PHI available if not within the 30-day period and provide a date when the information may be reasonably expected. If not otherwise provided by state law, the final rule permits providers to charge reasonable cost-based fees for complying with a request for PHI. This fee may include actual labor costs for copying PHI in paper or electronic form, actual costs for technical staff to create and copy electronic files, and costs for postage and supplies.

There is no requirement that a provider use portable devices brought by patients or other individuals (i.e., flash drives), as these pose a security risk. A provider may send PHI in an encrypted email; however, they must first advise the individual that there is some level of risk associated with email and that the PHI may be accessed and read by a third party [55].

With continued attention to patient privacy, surgeons and their professional staff have become increasingly more sensitive to the requirements of HIPAA and the HITECH Act; however, the principles behind the law have been part and parcel of good medicine for centuries. The concept of patient privacy is based on the principles of fidelity and confidentiality; two ideals articulated in the Oath of Hippocrates and the Prayer of Maimonides. Accordingly, the ethics of HIPAA and the requirements to keep private that information imparted to the surgeon for purposes of treatment shall remain tantamount to the prudent practice of medicine.

Risk Management and Prevention

Physicians in modern American society cannot control whether or not they are sued; they can, however, control how they defend themselves. The best defense in litigation amounts to the best practices of the profession.

The Physician

While an excellent education is imperative to the practice of surgery, experience is the keystone to a successful bariatric surgery practice. Because obesity surgery has been in the media spotlight in recent years, dozens of surgeons have broadened their practices by adding weight-loss procedures. By the surgical community's own admission, the procedures generate revenue and the practice area has proven to be lucrative. It has also provided hope and recovery to a large portion of the population for whom other weight-loss programs have proven to be a miserable failure. It saves lives. However, a fact that must not be ignored is that bariatric surgery is extraordinarily dangerous at the hand of the inexperienced or under-experienced surgeon. Obesity surgery was not included in the general surgery residency training as a matter of course until recent years and is not widely available even today. Accordingly, many surgeons learn the procedures in weekend classes and mini-fellowships. This training, while provided by the professional community's finest bariatric surgeons, is inadequate to arm the general practitioner with the skills and experience necessary to maintain a safe surgical weight-loss practice.

Continued Assessment of Outcomes

It is recommended that the local facility review the surgeon's outcome data within 6 months of initiation of a new program and after the surgeon's first 50 procedures (performed independently) as well as at regular intervals thereafter, to confirm patient safety. In addition, the surgeon should continue to meet Global Credentialing Requirements for bariatric surgery at the time of reappointment. Documentation of continuing medical education related to bariatric surgery is also strongly recommended.

In addition to the ASMBS, the American College of Surgeons (ACS) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) have crafted guidelines and resources for credentialing bariatric surgeons. Further, the Metabolic and Bariatric Accreditation and Quality Improvement Program (MBSAQIP) is a national program that maintains a data registry and provides guidance and standards for quality improvement for bariatric surgery. It is important for physicians to be aware of these recommendations even if the hospital at which they seek privileges has not adopted the ASMBS or other guidelines, as the recommendations were crafted and endorsed by the leaders in bariatric surgery. It is noteworthy that literature published in 2010 suggests that these credentialing initiatives for training and practice are justified in light of improved clinical outcomes for bariatric patients [56]. In the current litigation climate where the experience of the operator increasingly has been called into question, expertise may be the best defense to such allegations at trial.

As discussed earlier in the chapter, the physician's best line of defense in litigation is documentation. The physician should be concise, clear, and complete, as malpractice litigation is often won or lost on the content and quality of the medical record. The documentation the physician creates today may be used years later in litigation; therefore, good record keeping should be an integral part of the bariatric surgeon's daily routine. Because meticulous medical records constitute the very best evidence at trial, this aspect of malpractice litigation remains in the exclusive control of the practitioner: Document, document, document… and document well.

Patients and their families sue for a variety of reasons, some that are within the control of the surgeon and some that are not. The most important human relationship in bariatric surgery exists between the patient and the surgeon, not between the surgeon and his or her attorney. Accordingly, surgeons should treat the physician–patient relationship with as much care as they treat the actual patient. This interpersonal relationship is becoming more important in the increasingly more hostile healthcare environment. Patients who are treated with compassion and respect are less likely to resolve their feelings or disagreements in court. Physicians must give the patient their time and their undivided attention.

While bad outcomes are not always preventable, it has been suggested that physicians who apologize for bad outcomes are less likely to be the subject of a malpractice claim. Because anger is often the driving force in a lawsuit, contrition and honesty have been shown to dispel anger long before litigation is ever contemplated [57]. Good communication between physician and patient has been linked to a decrease in physician shopping, noncompliance, and malpractice claims as well [58]. Not only have communication and honesty been shown to positively impact the physician–patient relationship, but the manner in which the information is communicated may dictate the likelihood of a lawsuit resulting from a bad outcome [59].

The Facility

With the unprecedented growth in obesity surgery programs nationwide, more and more hospitals are providing the surgical venue, but without the appropriate facilities and equipment for the bariatric patient population. The key to a successful and safe surgical weight-loss program is strategic planning for this unique population, adequate spending to retrofit or build the appropriate facilities, and appropriate staffing and staff education.

While bariatric procedures are elective, they are not cosmetic surgery. Because bariatric patients are often very ill and require complex care, hospitals and staff must be prepared and equipped to manage their preoperative, perioperative, and postoperative courses. Accordingly, facilities should be equipped with appropriately sized surgical instruments, blood pressure cuffs, endotracheal and nasogastric tubes, and adequate imaging equipment including computed tomography and magnetic resonance imaging. Further, surgical weight-loss patients require specialty beds, chairs, and intensive care unit facilities.

Outpatient facilities should include large examination tables and enough chairs to accommodate patients and their families. It is important to be aware of the needs of this patient population and to respect their unique perspective. Every detail should be taken into consideration down to the magazines available in the waiting room.

In 2000, the American College of Surgeons published recommendations for facilities caring for the morbidly obese [60]. These comprehensive guidelines provide facilities with recommendations for equipping and managing a safe and appropriate venue for weight-loss surgery and for the even more important follow-up period.

Staff education is as important as having the appropriate equipment. As the bariatric surgeon cannot be at the bedside 24 h a day, well-trained staff must be the eyes and ears of the surgical team. Precious time is lost when postoperative complications manifest if the condition is not diagnosed and treated immediately. Accordingly, nursing staff must be

attuned to the special needs of the bariatric population and must be quick to recognize and react to pertinent clinical information. The best solution is to have a devoted bariatric service and floor of the facility. When such a solution is unavailable, specialized training and education of hospital medical-surgical staff is the best defense to allegations of missed postoperative complications and negligent nursing care.

The Program

Bariatric surgeons treat the most complex patient population in the general surgery community—the morbidly obese. Bariatric surgical candidates often have multiple and varied comorbidities, which make the care and treatment of these special patients challenging. Patients who meet the criteria for weight-loss surgery present with myriad health problems, including asthma and sleep apnea, gout, heart disease, stroke, diabetes, gallbladder disease, hypertension, hypercholesterolemia, osteoarthritis, and a higher incidence of cancer. As a result, many of these patients have low reserves and a profoundly compromised ability to recover from the many complications associated with surgical weight-loss procedures. A comprehensive preoperative screening process, detailed informed consent discussions, and an appropriate and a well-supported long-term follow-up program are of paramount importance to the successful bariatric practice.

The safest and most successful bariatric surgery programs are built on an interdisciplinary approach to health care. This interdisciplinary approach contemplates the special needs of the morbidly obese and the health concerns with which they present. A successful program includes a comprehensive introduction to weight-loss surgery, patient/family education, and sensitivity to the patients served.

The program should include a thorough preoperative workup and a well-documented informed consent process based on the interdisciplinary approach. Morbidly obese patients come with myriad diagnoses, which require attention and management throughout the patient's journey from surgery to follow-up. Therefore, preoperative and postoperative care should include consultations with various subspecialties of internal medicine (including cardiology, endocrinology, pulmonology, etc.), psychiatry, nutrition, and physical and occupational therapy. The program should include a process for choosing the appropriate weight-loss procedure for the individual patient, based on the patient's diagnoses, risk factors, and other needs. This decision should be well documented, including the thought process employed by the surgeon in formulating the patient's plan of care.

The prudent program should also include long-term follow-up with appropriate specialists, support staff, and a mechanism to ensure the continuity of care. Patients who are provided quality care and treatment in a friendly and respectful environment, by compassionate and patient practitioners, are likely to be happy and healthier. Likewise, a deliberate program designed to care for the morbidly obese protects the surgical professional from allegations involving poor planning, inadequate facilities, inappropriate equipment, and inadequately trained staff.

Conclusion

It is safe to expect that the bariatric surgical community will continue to thrive as the demand for weight-loss surgery continues. As we move toward the future of bariatric medicine, it is important to recognize the risks of practicing in this exciting and rewarding field. With education, conscientious bariatric surgeons can avoid many of the legal pitfalls, despite the fact that it is impossible to insulate your practice from lawsuits. Nevertheless, prudent practices, complete medical record documentation, appropriate informed consent, and a healthy physician–patient relationship will provide the best defense for surgeons who find themselves exposed to the litigation process.

Review Questions and Answers

1. What must the plaintiff prove in order to prevail in a medical malpractice lawsuit?
   A. Duty
   B. Breach
   C. Proximate causation/damages
   D. All of the above

   Answer: D

2. What organizations do not provide guidance for credentialing bariatric surgeons?
   A. ASMBS
   B. ACS
   C. SSAT
   D. SAGES

   Answer: C

3. Q: True or false: After an increase in litigation in the early 2000s, there was a decrease in frequency of filing medical malpractice lawsuits until 2012.

   Answer: True

References

1. Mathias JM. Increase in bariatric surgery brings a surge in legal cases. OR Manager 2002;18(2).
2. Kowalczyk L. Gastric bypass risk is linked to inexperience. Boston Globe 2004 Jan 4.
3. Alt SJ. Market memo: liability insurance premiums on bariatric surgery soar. Health Care Strategic Manag. 2004;22(1):1.
4. Rice B. How high now? Med Econ. 2004;81:57–9.
5. Twiddy D. Associated Press 2004 Aug 26.

6. Nguyen NT, Masoomi H, Magno CP, Nguyen XT, Laugenour K, Lane J. Trends in use of bariatric surgery, 2003–2008. J Am Coll Surg. 2011;213(2):261. doi:10.1016/j.jamcollsurg.2011.04.030.
7. Livingston EH. The Incidence of bariatric surgery has plateaued in the United States. Am J Surg. 2010;200(3):378–85. doi:10.1016/j.amjsurg.2009.11.007 [Epub 2010 Apr 20].
8. For a more extensive discussion about the current medical malpractice crisis in the United States, see Studdert DM, Mello MM, Brennan TA, Medical malpractice. N Engl J Med. 2003;348(23):2281, corrected in N Engl J Med. 2003;349(10):1010; and Mello MM, Studdert DM, Brennan TA. The new medical malpractice crisis. N Engl J Med. 2004;350(3):283.
9. Mohr JC. American medical malpractice litigation in historical perspective. JAMA. 2000;283(13):1731.
10. Mohr JC. American medical malpractice litigation in historical perspective. JAMA. 2000;283(13):1732.
11. Mohr JC. American medical malpractice litigation in historical perspective. JAMA. 2000;283(13), citing Mohr JC. Doctors and the law: medical jurisprudence in nineteenth-century America. New York: Oxford University Press; 1993.
12. Mohr JC. American medical malpractice litigation in historical perspective. JAMA. 2000;283(13):1734.
13. Mohr JC. American medical malpractice litigation in historical perspective. JAMA. 2000;283(13):1735.
14. Miller D. Liability for medical malpractice: issues and evidence. Joint Economic Committee, U.S. Congress, Vice Chair Jim Saxton (R-NJ), May 2003. www.house.gov. Accessed 6 Sept 2004.
15. Peters PG. Twenty years of evidence on the outcomes of malpractice claims. Clin Orthop Relat Res. 2009;467:352–7.
16. Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C, Puopolo AL, Brennan TA. Claims, errors, and compensation payments in medical malpractice litigation. N Engl J Med. 2006;354:2024–33. doi:10.1056/NEJMsa054479.
17. Aon Seventh Annual Hospital Professional Liability and Physician Liability Benchmark Analysis. 2006. www.aon.com/hpl_study.
18. See Aon Hospital Professional Liability and Physician Professional Liability Benchmark Analysis 2007–2010. www.aon.com/hpl_study; Zurich 2010 Claims Benchmarking Perspective. 2010;16(3). www.zurichna.com/internet/zna/SiteCollectionDocuments/en/Products/healthcare/HC_Perspectives_newsletter_Fall.pdf.
19. Aon 2012 Hospital Professional Liability and Physician Liability Benchmark Analysis. 2012. www.aon.com/hpl_study.
20. Black's Law Dictionary, citing Mathews v. Walker, 34 Ohio App.2d 128,296 N.E.ed 569, 571.
21. Mohr JC. American medical malpractice litigation in historical perspective. JAMA 2000;283(13):1731, citing Blackstone W. Commentaries on the Laws of England, vol. 3. Oxford, England: Clarendon Press, 1768:122.
22. See, generally, Fiscina S et al. Medical liability. Eagan, MN: West Group; 2004:209. West Publishing; 1991.
23. It is important to note that the law of torts is customarily controlled by the individual states. Accordingly, medical negligence case law may vary from jurisdiction to jurisdiction, although it is based on the more general common law.
24. Pike v. Honsinger, 155 N.Y. 201, 49 N.E. 760 (1898).
25. Dallal R. Survey: long surgical career raises likelihood of lawsuit. Clinical Endocrinology News Digital Network 2012 Jul 12.
26. American Medical Association Policy Research Perspectives. Carol K. Kane, Medical Liability Claim Frequency: A 2007–2008 Snapshot of Physicians. AMA Economic and Health Policy Research, 2010 Aug.
27. Outcomes of medical malpractice litigation against US physicians. Arch Intern Med. 2012;172(11):892–94.
28. van Heerden JA, Farley DR. Why do surgeons get sued? Common causes revealed. Contemp Surg. 2008;64(6):284–5.
29. Misreading Obesity Surgery Risk. www.rmf.harvard.edu. Accessed 7 Aug 2004.
30. Cottam D, Lord J, Dallal RM, Wolfe B, Higa K, McCauley K, Schauer P. Medicolegal analysis of 100 malpractice claims against bariatric surgeons. Surg Obes Relat Dis. 2007;3(1):60–6; discussion 66–7 [Epub 2006 Dec 27].
31. Furrow BR et al. Bioethics: health care law and ethics. 3rd ed. St. Paul: West.
32. Pub. L. No. 104–191,110 Stat. 1936 (1996) (codified in portions of 29 U.S.C., 42 U.S.C., and 18 U.S.C.).
33. For a more comprehensive discussion of the administrative simplification process, see Perrow et al. The Health Insurance Portability and Accountability Act: An Overview of Administrative Simplification, XIV J. Civ. L. 231 (2002).
34. 42 U.S.C. § 1320d et seq (2002).
35. Standards for Privacy of Individually Identifiable Health Information. 65 Fed. Reg. 82462 (December 28 2000).
36. Standards for Privacy of Individually Identifiable Health Information. 45 C.F.R. § 164.502 (2001).
37. Standards for Privacy of Individually Identifiable Health Information. 67 Fed. Reg. 53181 (August 14, 2002).
38. 42 U.S.C. § 1320d-3 (2002). Small health plans must have complied by April 14, 2004. Ibid.
39. 45 C.F.R. § 164.501 (2001).
40. 45 C.F.R. § 164.502 (2001).
41. 45 C.F.R. § 164.506.
42. 45 C.F.R. § 164.508 (2001).
43. 45 C.F.R. § 164.
44. 45 C.F. R. § 164.512 (2001).
45. 45 C.F.R. § 164.522 (2001).
46. 45 C.F.R. § 164.524 (2001).
47. 45 C.F.R. § 164.526 (2001).
48. 45 C.F.R § 164.520 (2001).
49. 45 C.F.R. § 164.528 (2001).
50. 42 U.S.C. § 1320d-7 (2002). "Contrary to state law" is defined as impossible to comport with both state and federal law or that the state law is a major obstacle to the implementation to the Privacy Rule. 45 C.F.R. § 160.203 (2001).
51. 45 C.F.R. § 160.203(a) (2001).
52. Critical access hospitals (CAH) are small facilities (25 beds or less) located in geographically remote areas that provide acute care services to the community. To be designated as a CAH by CMS, a hospital must be located in a rural area, provide 24-hour emergency services; have an average length of stay for its patients of 96 hours or less; be located more than 35 miles (or more than 15 miles in areas with mountainous terrain) from the nearest hospital or be designated by its state as a "necessary provider."
53. 78 Fed. Reg. 5566 (Jan. 25, 2013).
54. HIPAA Administrative Simplification Regulations are found at 45 C.F.R. Parts 160, 162, and 164. To learn about the Rulemaking History of the HIPAA Enforcement Rule, see 42 C.F.R. Part 160, subparts C, D, and E.
55. 42 CFR §164.524.
56. Kohn GP, Galanko JA, Overby DW, Farrell TM. High case volumes and surgical fellowships are associated with improved outcomes for bariatric surgery patients: a justification of current credentialing initiatives for practice and training. J Am Coll Surg. 2010;210(6):909–18.
57. Zimmerman R. Doctors' new tool to fight lawsuits: saying "I'm sorry." The Wall Street Journal 2004 May 18.
58. Levinson W, Roter DL, Mullooly JP, Dull VT, Frankel RM. Physician–patient communication: the relationship with malpractice claims among primary care physicians and surgeons. JAMA. 1997;277:553–9.
59. Ambady N, LaPlante D, Nguyen T, Rosenthal R, Chaumeton N, Levinson W. Surgeon's tone of voice: a clue to malpractice history. Surgery. 2002;132:5–9.
60. Bariatric surgery: American College of Surgeons recommendations for facilities performing bariatric surgery. Bull Am Coll Surg. 2000;85(9).