Medicolegal Sidebar

Medicolegal Sidebar: Physician Competence and Skill Part II: Hospital Corporate Responsibility and New Technologies

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Introduction

Our previous column explored the intricacies of the legal doctrine known as Hospital Corporate Liability [1]. To capture the salient points from Part I of this series,

Note from the Editor-in-Chief: We are pleased to publish the next installment of “Medicolegal Sidebar” to the readers of Clinical Orthopaedics and Related Research®. The following is part two of a two-part series on Physician Competence and Skill. Part one addressed the legal doctrine known as Hospital Corporate Liability. Part two will focus on the application of Hospital Corporate Liability to medical advances and new technology. We welcome reader feedback on all of our columns and articles; please send your comments to eic@clinOrthop.org.

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the 1965 legal ruling in *Darling v Charleston Community Memorial Hospital* [2] set forth the key principle that hospitals, as corporate entities, have a direct responsibility toward the patient to ensure the competency of their medical staff, through credentialing, privileging, and oversight, even when medical staff may not be directly employed by the hospital. Prior to *Darling*, hospitals had been able to side-step liability for medical

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errors by arguing that they had no control over the conduct of independent doctors and nurses, and therefore, could not be held accountable for the treatment of the patient. *Darling* imposed upon the hospital a duty to oversee its medical staff's professional conduct, and the failure to provide such oversight has been deemed by courts to be a breach of the hospital's standard of care [2].

In this column, we will focus our attention on the application of Hospital Corporate Liability to medical advances and new technologies. Does a hospital have an obligation to oversee the professional conduct of orthopaedic surgeons, for example, when the surgeons use new technologies or attempt novel surgical procedures? The issue of Hospital Corporate Liability for new technology and procedures usually arises within the context of credentialing and privilege delineation. Credentialing is the process of admitting a physician to the medical staff, and privileging consists of defining the scope of physician practice in the hospital. Additionally, Hospital Corporate Liability can arise

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in the informed consent process since hospitals have a duty to ensure that physicians properly inform patients of risks and alternatives for procedures that are done within the hospital. We will examine the complex and often difficult questions that arise from these considerations.

New Drugs and Technologies

In the pharmaceutical industry, injuries from new drugs and attendant technologies have created significant liability. As an illustration, a federal court jury recently ordered Osaka, Japan-based Takeda Pharmaceutical Co (Takeda) and Indianapolis-based Eli Lilly & Co to pay a combined USD 9 billion in punitive damages after determining the pharmaceutical companies hid the cancer risks of their prescription diabetes medication, Actos [3]. As a partner of Takeda, Eli Lilly & Co was ordered to pay USD 3 billion, though Takeda may be required to pay the final dollar amount in the case due to an agreement between the two companies. Although a reduction in the dollar amount is likely (and both companies have said that they will appeal the outcome of the jury trial), the Actos litigation represents a long trend of major monetary judgments against drug manufacturers whose newly introduced drugs end up

causing injury [5, 6]. These legal cases and verdicts help illustrate that all so-called medical advancements, whether pharmaceutical or otherwise, can carry with them special hazards that result in legal liability. As the author, Nortin Hadler MD has noted, “Ten percent of all drugs approved for marketing by the FDA between 1975 and 1999 were subsequently either withdrawn because of adverse reactions or labeled with a Black Box, indicating special hazards” [4].

The legal liability arising from new drugs also applies to new surgical implants and novel operative techniques. Failed metal-on-metal (MoM) total hips that required premature revision surgery, for example, have created significant liability exposure for several orthopaedic implant manufacturers. In terms of hospital credentialing and privileging, there are three aspects about surgical performance that a hospital may need to monitor in order to avoid Hospital Corporate Liability. These include the competency, proficiency, and qualifications of the staff surgeons.

Physician Competence, Proficiency, and Qualifications

Incompetence claims are based on the assertion that the surgeon did not sufficiently gain the abilities necessary to

properly execute a new procedure. New technologies usually require a different set of surgical skills, aptitudes, and instruments. From a Hospital Corporate Liability standpoint, proper training and mentoring may be required to declare the surgeon capable before he or she attempts it for the first time.

Even if a surgeon can competently perform an operation, he/she may still lack proficiency, which is a skill acquired through experience. Familiarity with an operation in itself does not lead to proficiency. By definition, no surgeon can be adept in the early cases of a new procedure. Advances in surgery and technology will always lead to a lack of proficiency, while the so-called “learning curve” is overcome by the surgeon. Still, the law does not excuse a hospital from legal responsibility simply because a surgical mistake occurred during the early stages of a new operation, or implant. Accordingly, the burden is upon the hospital to assure not only that its medical staff is competent with new technologies, but also that the staff is also proficient. Within hospital settings, proficiency often extends not only to the orthopaedic surgeon, but to the entire operating room team.

The exact qualifications for executing a novel operation are difficult to define, particularly in an orthopaedic setting. While the hospital bears the

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responsibility of ensuring adequate qualification, this obligation has often fallen to industry-sponsored courses that may lack fairness and quality control. In order to avoid claims resulting from errors related to novel procedures and attendant technology, a hospital must assure that the orthopaedic surgeon is competent, proficient, and qualified in performing the surgery. Specific recommendations follow at the end of this article.

Physician Training in New Technologies

As we discussed previously [1], a substantial number of Hospital Corporate Liability cases arose when laparoscopic cholecystectomies were first introduced. When laparoscopic cholecystectomy was merely a novelty, general surgeons would attend industry-sponsored weekend courses where they operated on swine subjects [7]. Following the weekend course, the surgeons would return to their hospitals and operate on human patients, often lacking competence, proficiency, and the qualifications for the new operation (even though they had gained familiarity with it). When patient injuries followed, the hospitals were sued for the failure to provide proctorship for the initial surgical procedures. The evidence showed the

limited nature of training, as well as that many general surgeons were simply unable to acquire the skills to transition from the open procedure to the two-dimensional endoscopic field of view [7].

As the orthopaedic community is well aware, minimally invasive spinal and adult reconstructive procedures are the subject of debate. Whether minimally invasive surgery reflects an important technological advancement to improved patient care, or if it is simply an unreasonable hazard to patients, remains an unresolved quality issue. Regardless of these differing points of view, the question arises as to what responsibility the hospital owes to the patient to monitor and assess an orthopaedic surgeon's performance if he/she elects to perform a minimally invasive procedure like a total knee replacement.

Such operations differ markedly from laparoscopic cholecystectomies. When laparoscopic cholecystectomies were first introduced, the surgeon needed to acquire an entirely new set of surgical skills because the operation went from being open to endoscopic, with entirely new instruments and a different field of surgical view [7]. Minimally invasive orthopaedic surgery, on the other hand, usually required performing the same open operation, although through a shorter incision that limits surgeon

visualization, which may create, particularly in inexperienced hands, safety concerns for the patient. Can an orthopaedic surgeon enter an operating room and perform a minimally invasive elective operation without the hospital proctoring his or her performance? While this remains an unresolved and vexing issue for hospital administrators, there exists plenty of guidance for administrators concerning demonstrably new procedures. From that information, an administrator could logically conclude that any procedure with a learning curve can subject the Hospital to Corporate Liability, as the litigation experience related to the early adoption of laparoscopic cholecystectomy demonstrated. Also, a hospital administrator should logically be concerned if an orthopaedic surgeon is operating outside the scope of what he/she learned in residency training.

The above question is further compounded by the complicating variable of surgeon age. Is there a higher duty on the part of the hospital to monitor, for example, a 75-year-old orthopaedic surgeon — who for business reasons wants to begin performing minimally invasive spine surgery or arthroplasty — when compared to a 35-year old surgeon with the same intentions, and identical level of inexperience with minimally invasive surgery as the 75-year old surgeon? Astute lawyers

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could probably make that argument forcefully.

Informed Consent and Hospital Liability

Another facet to consider when discussing Hospital Corporate Liability and the introduction of new technology is the informed consent process. Often in new surgical technologies, the informed consent process is no different than a routine review of the known risks of the procedure, with a description of the operation and its purported benefits. However, to make an informed decision about a novel operation or new technology, the patient may need additional information. For example, the patient must be informed about the potential risks connected with a new surgical procedure. There could be an instance where the risks for a new procedure have yet to be determined. This is predominantly the case in orthopaedic surgery where seemingly successful novel procedures and implants may become more widespread long before any long-term data concerning the safety and durability becomes known. Thus, the synthetic ACL replacements introduced in the mid-1970s ultimately failed, as did the silastic toe joint prostheses introduced in the 1980s, and the troubles with MoM total hips are following the same trend.

Assumptions About Informed Consent

The above issues of informed consent may be the most challenging ones that a hospital faces in avoiding corporate liability for new technologies. There are certain unwarranted assumptions about the informed consent process. The first assumption by the hospital is that orthopaedic surgeons have good data about the risks of new technology. The second assumption is that all orthopaedic surgeons may be equally equipped to safely perform new technologies. Finally, hospitals may assume that they can safely delegate the informed consent process to the orthopaedic surgeon when new technologies and procedures are performed within the hospital.

All of these assumptions may be incorrect. A hospital may have an obligation to advise the patient that the risks of the new surgical procedure are uncertain. Likewise, it may have an obligation to tell the patient about the background and qualifications of the surgeon who will perform the new procedure, and the background and training of the operating team who will be providing surgical support for the new technologies.

In reality, competitive pressures often conspire to achieve the exact opposite; hospitals are often keen to advertise that their staff is among the

first to perform a novel procedure, or use the latest technological advancement. Like so many issues in law and medicine, the legal liability exposure created by new technologies is often in conflict with marketing and economic considerations. Many of our readers may be familiar with orthopaedic advertisements. Online searches for minimally invasive spine surgery, or minimally invasive arthroplasty, for example, will readily identify many clinical practices, surgeons, hospitals, and device manufacturers, all competing for the consumers' attention. There is little question that competition in orthopaedic surgery is often driven by the ability to demonstrate superiority. This frequently takes the form of marketing new technologies to attract patients. Marketing is a compelling issue for hospitals as well as for orthopaedic surgeons, eager to gain patients. Therefore, there is an incentive for hospitals and orthopaedic surgeons to overstate the advantages of new technologies to obtain an economic advantage over their respective competitors.

Conclusions

Trying to blend the economic advantages of adopting new medical technologies with minimizing the risk of legal exposure is often a daunting

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task, both for the hospital and for the orthopaedic surgeon. Achieving this objective will only be possible if orthopaedic surgeons and hospitals work together to identify and institute quality control measures and disclosure processes that assure the best possible outcomes and honest disclosure to the patient. The following measures may be a helpful starting point: (1) Orthopaedic departments or divisions should provide a working definition for novel surgical techniques, and new surgical technologies. The definition for novel surgical techniques should only describe those techniques that involve a learning curve. The definition of new surgical technologies should define technologies that are markedly different and not simply enhancements of existing technologies. (2) If a staff surgeon wants to perform a novel operation, or adopt a new technology consistent with the above definition, he/she must apply for a new privilege to do so. The hospital should have well-defined protocols in place (such as proctoring the first 10 procedures) and literature that supports the procedure before granting the new privilege. (3) For new technologies and operations, the

patients should be informed of the perceived benefits of the procedure, the known risks, and the knowledge that every new technology has special hazards that may not be foreseeable during the early phases of implementation and adoption. (4) Patient undergoing novel surgical procedures or receiving new technologies should be carefully monitored for complications as well as positive outcomes. (5) Some form of pattern analysis of this monitoring and oversight process should be conducted to assess both the benefits and unforeseen complications of the procedure or technology.

Surgeons and hospitals will continue to promote new implants, instruments, drugs, and operations as they are introduced into the field of orthopaedic surgery. The doctrine of hospital corporate liability has expanded in recent years to place the burden of sufficient credentialing and qualifications of medical staff upon the hospitals where new technologies are deployed, and the risk of patient injury is confronted. All too often, the legal system becomes the ultimate mechanism through which an uncertain balance is reached, between the free market benefits of new and emerging

technology, and the compensable patient injury arising from unforeseeable risk, or a lack of physician competence, proficiency, and qualification, or both.

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