A HISTORY OF WRONG SITE SURGERY IN RHODE ISLAND

Robert S. Crausman, M.D., and Bruce McIntyre, J.D.

ABSTRACT

Wrong site, side and patient surgeries continue to occur with alarming frequency. Increasing attention to the critical role of patient safety systems and a culture of safety are important. However, the individual professionals and the boards that regulate them are also important. As the patient safety movement has evolved so has our state medical board's response to wrong site, side and patient surgeries.

Between 1998 and 2008 the Rhode Island Board of Medical Licensure and Discipline investigated reports of 10 wrong side, site and patient surgeries or procedures. Four were neurosurgeries, two orthopedic and one each gynecologic, ENT, ophthalmologic and vascular.

INTRODUCTION

Wrong site or wrong patient surgery has been appropriately termed a "never-event." Unfortunately, despite years of attention from hospitals, medical societies, accreditation counsels, regulatory boards, health insurers and federal authorities these never-events continue to plague our health care system with eight to 12 reports of wrong site surgery being made to the Joint Commission each month.[1] The Agency for Healthcare Research and Quality estimates the occurrence rate at one event per 110,000 surgical cases or one such event per five to 10 years per general hospital.[2] Certain specialty surgeries such as hand (wrong finger)[3] and spine (wrong level) occur at a much higher rate. While most such events have good patient outcomes, clearly some do not.

These events have a pernicious effect on the entire health care system by undermining confidence that there are appropriate safeguards for patient protection. Current thinking has increasingly emphasized the role of safety systems and culture as the ultimate safeguard. The fallibility of human practitioners is assumed, and errors happen when redundant safety's fail; the so-called "Swiss-cheese" model in which errors occur when multiple "holes" in overlapping patient care safety systems line up.[4]

The state of Rhode Island has had its share of wrong site/wrong patient events in recent years. While not disproportionate when compared to other states, there can be little satisfaction with this "average" record. The state medical board has a unique perspective with its focus on physician involvement. Medical boards are charged with protecting the public by assuring professional accountability for meeting acceptable standards of practice. Although seemingly contradictory the regulatory board's perspective is actually complementary to that of the patient safety movement. The patient safety movement acknowledges the fallibility of professionals but makes no excuse for frank medical negligence. However, while the patient safety movement favors protected reporting and remediation, the regulatory board is generally required by statute to publicly discipline physicians for unprofessional conduct.

What follows is a 10-year review of the Rhode Island experience, highlighting both our state's evolution towards interdisciplinary investigation and increasingly comprehensive corrective action; and an assessment of recurrent or thematic underlying causative factors. All information presented is available from public sources such as formal board orders[5] or final case findings.

RHODE ISLAND EXPERIENCE, A CASE SERIES

In 2000 the Rhode Island Board of Medical Licensure and Discipline was notified that an attending physician, the chief of otolaryngology at the state's largest academic medical center, had performed in adenoidectomy and bilateral myringotomy with tubes on the wrong patient. The family was informed of the error and steps were taken

on a hospital-wide basis to prevent similar wrong patient surgeries. The board elected not to sanction this physician and instead entered into a public consent order with a focus on systems improvement. This physician agreed to take lead role in the program designed to prevent such errors in the future.

In 2002 the board was notified of a wrong site burr hole for drainage of a subdural hematoma. The procedure had been performed by a sixth-year neurosurgical resident under the supervision of the neurosurgeon-in-chief again at our state's largest academic medical center. An investigation found that while the attending physician was scrubbing for surgery the senior neurosurgical resident hung the CT scan facing in the wrong direction on the view-box and prepared the patient for a left sided operation when the intended surgery was scheduled for the right. The attending physician authorized the procedure after observing the drawn incision marks on the draped patient. After the burr hole was made and a small piece of bone removed the dura was opened and no clot was found. The error was recognized when the CT scan was reviewed. The board again elected not to sanction the attending physician and again entered into a public consent order whereby the neurosurgeon-in-chief would use his position to solve problems relating to medical errors and patient safety at the hospital.

In 2002, the board was notified of an older case through malpractice reporting, a wrong knee arthroscopic surgery performed in 1998 at a nonacademic community based general hospital. An experienced orthopedic surgeon had scheduled a patient for a left sided procedure to treat Osgood-Schlatter disease but the right knee was inadvertently prepped and draped by the operating room staff. During the course of the procedure the physician discovered the error and stopped the surgery, closed the wound and sent the patient to recovery. The board found that this practice was a violation of RIGL 5-37-5.1 which defines unprofessional conduct in the practice of medicine for his failure to identify the correct site for the surgical procedure. He was assigned a sanction of Reprimand and required to pay an administrative fee of $750.

In 2004 the board was notified of the wrong site insertion of a Swan-Ganz right heart catheter by an attending anesthesiologist at an academic medical center. The patient had been scheduled for an elective cardiac revascularization and right internal carotid endarterectomy. The right carotid artery was identified for surgery and marked in a fashion not consistent with the Joint Commission standards at the time. The physician inserted a right internal jugular catheter pre-operatively which necessitated the cancellation of the procedure. The physician noted that he did not see the surgical site identification marking and that it had not been placed in a position that could be viewed after the patient was prepped and draped for surgery. Again the board found that this practice was a violation of RIGL 5-37-5.1 and assigned a sanction of Reprimand and an administrative fee of $500.

In 2006 the board was notified of a wrong procedure obstetrical surgery being done without the patient's consent. The physician had performed a vaginal hysterectomy and oophorectomy on a patient who had completed informed consent for vaginal hysterectomy only. An investigation revealed that when the patient was first seen six weeks prior to surgery in the physician's outpatient practice, a second patient with the same last name had also been seen who had been scheduled for prophylactic oophorectomy. At the time of surgery an appropriate "time-out" was conducted and all team members agreed that the procedure was a vaginal hysterectomy and oophorectomy. After the time-out but before the surgery commenced the circulating nurse called attention to a discrepancy between the planned surgery and that described in the consent form. The attending physician was certain of the planned procedure and the surgery was authorized to proceed. Postoperatively the patient expressed that she had not desired an oophorectomy. The physician provided full disclosure. Again the board found that this practice was a violation of RIGL 5-37-5.1 but assigned neither a sanction nor an administrative fee.

In 2006 the board was notified of a wrong site craniotomy for drainage of a traumatic left-sided epidural hematoma at an academic medical center without a neurosurgical residency program. The patient had been admitted to the emergency room on a weekend morning with head trauma and was emergently transferred to surgery. The attending neurosurgeon saw the patient in the emergency department and noted in his history and physical that the lesion was on the contralateral side. This type of procedure was not routinely performed at this hospital. An investigation revealed communication issues between the emergency room physician and neurosurgeon, consistency issues between the presentation of radiographs at this institution versus another in the area, and significant documentation issues. In this case the board did not find this practice to be a violation of RIGL 5-37-5.1

In 2007 the board was notified of a wrong site bedside burr hole placement to evacuate a subdural hematoma performed by a senior neurosurgical resident at the state's largest academic medical center. The resident realized the error after making the skin incision but before drilling the burr hole. Investigation found that there had been a documentation error in the medical record that day regarding the side of the lesion made by the resident and cosigned by the attending physician; that the required bedside procedure for side/site verification had not been completed according to policy; and that key elements of the post procedure documentation had been completed pre-procedure. In this case the board did not find this practice to be a violation of RIGL 5-37-5.1, given that the residency program had implemented both a punishment and plan of remediation.

In 2007, shortly after the resident procedure, the board was notified of another wrong side neurologic surgery for emergency evacuation of a subdural hematoma again at the state's largest academic medical center. The attending physician previously involved in the wrong-side epidural drainage was asked to treat an elderly patient with a left-sided subdural hematoma who was deteriorating clinically. The patient was emergently transferred to the operating room from the emergency department, bypassing the preoperative staging area where site marking typically was performed. Of note, it was recognized pre-operatively in the operating room that the surgical consent form was mute with regard to side. The surgeon after discussion with the circulating nurse amended the form from memory. When the error was discovered the correct side was immediately evacuated successfully. The hospital temporarily restricted the physician's privileges during a period of investigation. The board entered into an interim consent order with a physician for him to voluntarily cease all hospital neurosurgery and to undergo a physical and mental health evaluation. Subsequently after successful completion of these evaluations a final order was entered for a two-month suspension of his surgical privileges and requirement to pay an administrative fee of $2,000. This case marked the first truly collaborative effort of investigation and correction taken by the Rhode Island Department of Health (DOH). The DOH Office of Facilities Regulation, and medical and nursing boards worked jointly, simultaneously. The hospital was sanctioned by public order, required to pay a fine of $50,000 and to obtain outside consultation on their neurosurgical program.

In 2007 the board received a report of a correct intra-ocular muscle but incorrect surgery to repair a one-eye strabismus. Specifically, one side of the muscle was weakened when it should have been strengthened and the other side was strengthened when should have been weakened. The error was recognized intraoperatively, corrected and reported to both the family and the facility. An investigation found that the physician had performed three similar surgeries one day prior to the case where she was required to weaken the muscle first. She also was new to practice at the surgical center and had a new team of rotating assistants. In this case the board did not find this practice to be a violation of RIGL 5-37-5.1.

In 2008 the DOH was informed of a wrong site arthroscopic surgical procedure on the knee of a patient at one of the state's major academic medical centers. The wrong site surgery was not recognized until the patient called attention to it in the recovery area. The DOH undertook a multi-disciplinary investigation in order to determine the root cause of the surgical error and to mandate appropriate corrective action.

This investigation identified multiple systems and personnel failures relating to applicable policy: Failure to verify the site marking is visible in surgical field during the time out process, to verify that the site which is marked and draped is consistent with imaging tests, inconsistency between policy and procedures; confusion amongst staff as to what "site verification" means and what it should entail during the time out; lack of an adequate system and culture of near miss reporting and evaluation.

The board found that this practice was a violation of RIGL 5-37-5.1. for the surgeon's failure to identify the correct site for the surgical procedure. He was assigned a sanction of Reprimand and required to pay an administrative fee of $1,000. The hospital was also sanctioned and required to bring in consultants to develop a more robust near-miss reporting system and to contract with a patient safety organization.

DISCUSSION

Many in the patient safety movement have pointed to successes in industry and aviation as a guide to improve safety in the practice of medicine.[6,7] Others have argued that the metaphor is inappropriate since patients are not widgets and the operating room is not a flight deck. The practice of medicine is a complex blending of art and science that must often be individualized for specific patient needs and preferences. However, there are portions that can be segmented that are most analogous to indus-

try and readily addressed by rigid algorithmic processes. One such practice segment is that of patient, side, site and procedure verification prior to operation.

Unfortunately technical fixes through written policies and procedures have been unsuccessful at fully addressing the problem and wrong site surgeries continue to occur with frightening regularity. A culture of safety has been cited as the missing necessary ingredient for truly transformational change. With our most recent wrong site surgeries we have adopted this perspective and attempted to facilitate this cultural evolution locally. Still, professional responsibility and the preeminent role of the attending surgeon in the operating room require a high measure of personal accountability.

A review of our state's experience suggests a number of risk factors for wrong site surgery. First, an overreliance by the operating surgeon on the remainder of the operating room team for patient, site, side and procedure verification was thematic. In interviews the notion that such verification is "administrative" and a nursing or an anesthesia function was raised numerous times over the decade despite repeated institutionally based education efforts.

The type of surgery confers risk. Neurosurgery for evacuation of hemorrhage accounted for four of 10 events; orthopedic surgery knee arthroscopy for two. With neurosurgery a combination of factors including the radiographic presentation of the brain offering a reverse perspective from that of the operating neurosurgeon at the head of the patient and a failure to review radiographs at the time of surgery were problematic. With orthopedic surgery in each case the attending surgeon was outside of the room at the time that the patient was prepped and draped. Whether the missing element was actual participation by the surgeon or a manifestation of a "negative" Hawthorne effect[8] is unknown but suggests a testable hypothesis. The Hawthorne effect explains the well-described performance improvement frequently noted when workers are observed by a supervisor; a "negative" effect is a postulated performance decrement below standards in the absence of such senior supervision.

In two cases incomplete or incorrect surgical consent forms were identified just prior to surgery. In each case based solely upon the attending surgeons confident recollection the case was allowed to proceed in error. The fact that signed informed consent documents would be knowingly superseded by entire operating teams based upon the memory of single individuals suggests that pubic priorities and expectations are not effectively mirrored by health care professionals and their institutions.

In two cases the procedures were emergencies and usual protocols were bypassed. Neither circumstance was truly unique and could have been readily anticipated by institutions and had been by other facilities highlighting the lack of an effective exchange of lessons learned and thoughtful troubleshooting in a competitive health care marketplace.

Inadequate guidelines for resident supervision and participation were also cited in several. In Rhode Island guidelines for the supervision of physicians in training are relegated to the training programs. The wisdom of this approach is an area of renewed deliberation for our board.

While not addressed specifically in any public document, the interpersonal dimension must be considered.[9] In interviews it was asserted that at least one of the operators was a "disruptive physician" and several others were considered to be unreasonably demanding, habitually late or unpleasant to work with. The salutary role of a comfortable work environment and the negative impact of an uncomfortable one merits further attention.

Our board's approach has evolved over the decade. Our earlier investigations regarding physicians were conducted separately and independently from the DOH investigation of the facility. Early on despite our mandate to "discipline," the approach was primarily to educate. Our underlying assumption was that education alone was sufficient. We also overestimated the impact and control that physicians, even physicians-and-chief, can exert over their practice environment. Later, our board determined as a general standard that wrong site, side, patient surgeries constituted medical negligence and consequently unprofessional conduct. In doing so the board brought attention to individual professional responsibility to meet minimal practice standards while simultaneously developing a focus on systems improvement. Assigning discipline for failure to meet minimal practice standards is felt to be complementary and not counter to a systems focus. More recently our board has joined with the Rhode Island Board of Nurse Registration and Nursing Education and the DOH Office of Facilities Regulation to conduct coordinated, synchronous investigations of these events followed by collaborative development of corrective plans. Institutional discipline has been applied to foster meaningful institutional change and to highlight the role of the institution in establishing the culture of safety.

Although in absolute terms few patients are directly affected by wrong site, side, patient surgery, the deleterious impact upon our health care system is profound. Our regulatory systems' failure to substantially impact upon occurrence rates suggests a general flawed approach. For many, this represents a minimal litmus test for patient safety raising broad concerns for the remaining 90 percent of the iceberg below the surface.

The patient safety movement is finally gaining traction and the development of federal regulations to support the development of a national system of patient safety organizations offers the potential for truly transformational change in our approach to medical errors and patient safety. Clearly, this systems focus is long overdue as failing or inadequate systems have placed an undue burden upon physicians and nurses at the cost of professional burnout and preventable medical errors.

This new emphasis, however, must not be allowed to eclipse the need to maintain focus upon individual health care professionals and professional accountability; carelessness, imprudence and substandard practice cannot be simply attributed to an inadequate safety net. The response of state medical boards to this changing regulatory dynamic will be an important determinant of their future relevance to our health care system.

AFFILIATIONS

Correspondence to: Robert S. Crausman, M.D., M.M.S., Chief Administrative Officer, Rhode Island Board of Medical Licensure and Discipline, Associate Professor of Medicine, Alpert School of Medicine at Brown University, 3 Capitol Hill #205, Providence RI 02908, (401) 222-7888. Bruce McIntyre J.D., Deputy Legal Counsel, Rhode Island Health Department, 3 Capitol Hill #205, Providence RI 02908, (401) 222-7890

REFERENCES

1. Freyer, State reprimands Miriam Hospital for surgical error. *Providence Journal*. Oct. 11, 2008
2. Kwaan, M.R., Studdert, D.M., Zinner, M.J., Gawande, A.A., Incidence, patterns, prevention of wrong site surgery. *Arch Surg*. 2006; 141:353-358
3. Meinberg, E.G., Stern, P.J., Incidence of wrong site surgery among hand surgeons. *J Bone Joint Surg Am*. 2003;85:193-197
4. Reason, J., Human error: models and management. *BMJ*. 2000;320:768-770
5. Disciplinary actions, Rhode Island Board of Medical Licensure and Discipline. http://www.health.state.ri.us/hsr/bmld/disciplinary.php
6. Kao, L.S., Thomas, E.J., Navigating towards improved surgical safety using aviation-based strategies. *J Surg Res*. 2008 Apr;145(2):327-35.
7. Day, S., Dalto, J., Fox, J., Allen, A., Ilstrup, S., Utilization of failure mode effects analysis in trauma patient registration. *Qual Manag Health Care*. 2007 Oct-Dec;16(4):342-8
8. Elton, Mayo, Hawthorne and the Western Electric Company, *The Social Problems of an Industrial Civilization*, Routledge, 1949.
9. Clarke, J.R., Johnston, J., Blanco, M., Martindell, D.P. Wrong-site surgery: can we prevent it? *Adv Surg*. 2008;42:13-31.

From: Richard D Thomas <thfcfanatic@yahoo.com>
To: Mary Salerno <Mary.Salerno@health.ri.gov>
Date: 4/8/2009 10:03:11 PM
Subject: Re: RI Licensure

Hi Ms Salerno

My training was entirely in England with the exception of a 1 year Fellowship in Radiology at The State University of New York, Buffalo, (SUNY, Buffalo), performed at Children's Hospital of Buffalo, (CHOB).

The American Board of Radiology required that I spend an additional year at a teaching hospital before I could sit the clinical (film-viewing) part of the boards. I spent that year (1996-7) at CHOB once again, passing the ABR in summer 1997, and in fact remained at CHOB until 2001, holding positions of Chief of Fluoroscopy & Chief of MRI, as well as being an Associate Professor in Radiology at SUNY Buffalo from 1997-2001.

My MD diploma was granted by NY State after I had been a State License holder for 8 years. It represented a conversion of my English qualification, and was not based on additional education. I do not know whether my previous association with SUNY, Buffalo had any impact on that or not. I was advised that I might be eligible for a conversion, contacted the State and was requested to apply. It was a brief process that took a couple of months and consisted of form filling and a fee.

I hope this helps, and am happy to answer any additional questions.

I would also ask whether there is a different requirement for teleradiology reading?

Thank you, and The Board, for taking the time to consider my situation.

Richard D Thomas, MD

From: Mary Salerno <Mary.Salerno@health.ri.gov>
To: Richard D Thomas <thfcfanatic@yahoo.com>
Sent: Wednesday, April 8, 2009 2:30:09 PM
Subject: RI Licensure

Hello Dr. Thomas,

The Board reviewed your inquiry today and has questions. They would like detailed information regarding your MD degree in the US and your US training before they can recommend that you do or do not apply for licensure. You may send that information to me by e-mail, fax (401-222-2158), or mail at:

Mary Salerno
RI Board of Medical Licensure and Discipline
3 Capitol Hill
Room 205
Providence, RI 02908

Thank you.

Mary E. Salerno, MAT