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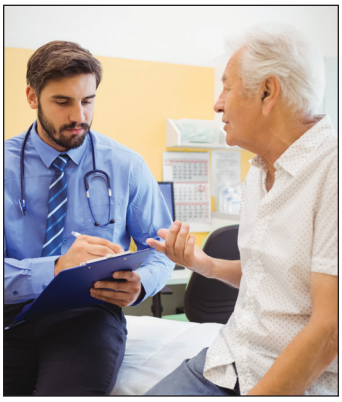

AALNC
AMERICAN ASSOCIATION OF LEGAL NURSE CONSULTANTS

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PURPOSE

The purpose of The Journal is to promote legal nurse consulting within the medicallegal community; to provide novice and experienced legal nurse consultants (LNCs) with a quality professional publication; and to teach and inform LNCs about clinical practice, current legal issues, and professional development.

MANUSCRIPT SUBMISSION

The Journal accepts original articles, case studies, letters, and research. Query letters are welcomed but not required. Material must be original and never published before. A manuscript should be submitted with the understanding that it is not being sent to any other journal simultaneously. Manuscripts should be addressed to JLNC@aalnc.org. Please see the next page for Information for Authors before submitting.

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ARTICLE SUBMISSION

The *Journal of Legal Nurse Consulting* (JLNC), a peer reviewed publication, is the official journal of the American Association of Legal Nurse Consultants (AALNC). We invite interested nurses and allied professionals to submit article queries or manuscripts that educate and inform our readership about current practice methods, professional development, and the promotion of legal nurse consulting within the medical-legal community. Manuscript submissions are peer-reviewed by professional LNCs with diverse professional backgrounds. The JLNC follows the ethical guidelines of COPE, the Committee on Publication Ethics, which may be reviewed at: http://publicationethics.org/resources/code-conduct.

We particularly encourage first-time authors to submit manuscripts. The editor will provide writing and conceptual assistance as needed. Please follow this checklist for articles submitted for consideration.

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- Use Word© format only (.doc or .docx)
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- Put title and page number in a header on each page (using the Header feature in Word)
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- Legal citations: Use The Bluebook: A Uniform System of Citation (15th ed.), Cambridge, MA: The Harvard Law Review Association
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- Submit your article as an email attachment, with document title articlename.doc, e.g., wheelchairs.doc

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Acceptance will be based on the importance of the material for the audience and the quality of the material, and cannot be guaranteed. All accepted manuscripts are subject to editing, which may involve only minor changes of grammar, punctuation, paragraphing, etc. However, some editing may involve condensing or restructuring the narrative. Authors will be notified of extensive editing. Authors will approve the final revision for submission.

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Kim Beladi,
BSN RN LNCC

President, AALNC

President's Update

This is a significant year for the American Association of Legal Nurse Consultants. Do you know why? It is our 30th anniversary! We have so much for which to be grateful. I wish I had the time and resources to handwrite a letter to all the previous volunteers within the organization to thank them individually for all the hard work and progress that comes from forward-thinking leaders. Our founding members' leadership laid the foundations for all legal nurse consultants to advance professionally and personally. To everyone who has volunteered for AALNC, on behalf of all legal nurse consultants today, thank you.

AALNC continues to set the gold standard for education for novice and experienced LNCs. We are always looking for new ways to expand awareness and educational opportunities for our membership. We welcome legal nurse consultants from any educational background and are always delighted to meet new members from different and interesting backgrounds.

Let's take a look at the AALNC committees and what they have been busy working on throughout the year. The **Social Media Committee** has created a wonderful presence on Instagram, LinkedIn, and Facebook with content of interest to legal nurse consultants. This increases our visibility. We continue tracking the effectiveness of the content to identify the most effective ways to maintain these connections.

The **Products and Services Committee** continues to develop and publish reference card tools for legal nurse consultants and their clients based on the memberships needs. This year we have added a sub-committee for publishing an e-book series, currently in the final stages and available later in the year in the **Professional Development Center**.

The **Online Educational and Professional Development Committee** finds interesting topics and knowledgeable speakers for webinars. They track participation numbers to help plan future webinars, always working to find the best fit for education, formats, and content for both members and nonmembers.

The **Journal Editorial Committee** continues to work like a well-oiled machine. Journal Editor Wendie Howland and the volunteers on the committee produce outstanding issues every quarter. New members are welcome; monthly 1-hour calls are like a chapter meeting with ideas and mentors aplenty. All articles are indexed and have doi numbers so they're searchable even if content is moved from one site to another. I'm envious of all the knowledge shared and education we offer for others in the Journal. LNCs often print out articles of interest to use in marketing to future clients.

As we move forward in 2019, we all look forward to our **Annual Forum**. The **Forum Committee** works all year to provide you the very best 2-3 days of education and networking. They have really put together a very nice event. Join us all in Louisville, Kentucky on April 5-6 at the brand new Omni Louisville Hotel. Don't forget to take a look at the Pre-Forum offerings on April 4th. We look forward to seeing you there.

Finally, thank you to all my mentors and friends who have helped guide me along this journey. Thank you to the board of directors who have been a terrific team to work with and provided so much support and professional and personally. Here's to our 30th anniversary and many more to come!

Happy 2019.

Kim Beladi, BSN RN LNCC

Editor's Note

Wendie Howland
MN, RN-BC, CRRN, CNLCP, LNCC
Editor, JLNC

Welcome to our year-long recognition of the 30th Anniversary of the JLNC! You'll see some special decor, and we will be recognized also at the International Academy of Nurse Editors conference later this summer for achieving this milestone. All the people who have volunteered and worked on our issues should rejoice in this accomplishment.

We're happy to present this issue on topics in surgery. We've had fun putting this together. You can expect some interesting material you can use in your practice.

One thing that caught my eye along the way was some online reporting by Kaiser Health News and USA Today on unsafe surgery centers. It begins:

> *When outpatient surgery centers started out 50 years ago, they were envisioned as low-cost alternatives for minor procedures. But as federal officials have sought to reduce healthcare costs, they've been allowed to take on more and more risky surgeries -- without the support systems in place at regular hospitals.*

The report cites the big profits to be made, deaths after increasingly risky surgeries approved by federal regulators, long distances between centers and fully-equipped hospitals, and patients who weren't comfortably snoozing in the car on the way home after discharge, but … dying. Read the full report at https://khn.org/news/medicare-certified-surgery-centers-are-expanding-but-deaths-question-safety/

Asking around, I learned that there are vanishingly few free-standing surgery centers here in Massachusetts anymore. In fact, the only one I could find is a well-established (read: grandfathered) ophthalmological center doing about 40-60 cataract and other day-surgery eye procedures per day. Why? Because in MA anybody wanting to open a free-standing center must make and defend a determination of need application to the state licensing board to explain why area hospitals can't meet this need already. And of course area hospitals are actively expanding their outpatient surgery departments as money-makers, so the free-standing ones are vanishing, never to be replaced. It's not clear how the outcomes are any different for people who are discharged home after their procedures. How is it where you are?

30th ANNIVERSARY

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Our articles here include two pieces on informed consent, with different perspectives, closely followed by an opinion piece on the (not, alas, completely defunct) "Captain of the Ship" doctrine. Moving directly through the double doors to the OR, we have information on the duties and responsibilities of RN First Assistants (RNFA), a detailed account of issues regarding proper positioning during surgery, and a very detailed look at how advances in neurological monitoring work in spine surgery, with specifics and resources for standards. While not mentioned specifically in this article, the neurological monitoring tools and protocols are also used in a variety of other procedures where nerves could be at risk, such as in ENT, urological, and orthopedic surgery, so this article will be helpful to LNCs looking at those cases, too.

(Continued on page 6)

Finally, we have a piece on retained surgical objects, with some good insights on how to investigate these cases. In keeping with our thus far futile history of being unable to obtain reprint permission for apropos cartoons, we refer you to our latest fail, a full-color Sunday strip beginning with the secretary handing the phone to the pointy-haired boss. "It's your surgeon. He says he might have left something inside you." See it at https://dilbert.com/search_results?terms=surgeon

We're looking forward to seeing you at our Annual Forum April 5-6 to talk about the JLNC and announce the 2018 Article of the Year. Bring your ideas and needs!

Wendie A. Howland

Wendie A. Howland MN RN-BC CRRN CCM CNLCP LNCC

UPDATE: NEW ENGLAND COMPOUNDING CENTER (JLNC 28:2, 5-6. SUMMER 2017)

December 13, 2018: A jury found five of six defendants guilty after a week of deliberations in Boston federal court in the third criminal trial for former employees of the New England Compounding Center in Massachusetts, whose injectable steroids contaminated with multiple fungi led to more than 70 deaths and over 700 sickened in a nationwide meningitis outbreak in 2012. The owner and managing pharmacist are already serving prison terms.

SOMETHING JUST DOESN'T SOUND RIGHT?

Perhaps it's our old friend EHR forcing unintended documentation. Check out this link:

https://tinyurl.com/y9qfvhbk

Abbreviations Can Be Scary, IMHO: Mistakes in translation can lead to problems with care

by Fred N. Pelzman, MD
December 14, 2018
MedPage Today

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Informed Consent for Medical or Surgical Treatment

Peter I. Bergé, JD, MPA, PA-C Emeritus

WHAT IS INFORMED CONSENT FOR TREATMENT?

"Did you check to see if there is a 'consent' in the chart?"

"Was the patient consented?"

These questions seem like useful items for a checklist which might help to protect a patient's rights. In fact, they reflect misconceptions that serve as a barrier to efforts to assure that a patient has given informed consent for a particular course of treatment or procedure.

The history of a patient's right to give informed consent for medical or surgical care goes back at least to the late 1800s (Walter 2012) and remains a modern concept. New Jersey's Model Civil Jury charge says

> A doctor must obtain the patient's informed consent before the doctor may treat or operate on the patient. The doctor has a duty to explain, in terms understandable to the patient, what the doctor intends to do before subjecting the patient to a course of treatment or an operation. The purpose of this legal requirement is to protect each person's right to self-determination in matters of medical treatment. (NJ Model Civil Jury Charge 5.50C)

If the reader finds "treat or operate on" to be very broad, that is understandable. In discussing informed consent, I embrace that expansive wording, while cautioning that informed consent must be obtained by any clinician treating the patient, and not only (as implied by the jury charge) by physicians. Further, the basic concept of informed consent applies to any treatment, not just surgical procedures.

A review of the basic elements of the negligence tort may be helpful in uniting the components of an informed analysis in context. The plaintiff in a civil tort claim such as personal injury generally has the burden to prove the case with a preponderance of the evidence, i.e. more than 50%, and must prove all of the elements: duty, breach of that duty, injury, causation (but for the breach of duty the injury would not have occurred), and damages (nature and quantity of compensation reasonably expected to make the injured party whole).

In medical malpractice, "duty" translates both to a general duty to the patient, and the obligation to adhere to the standard of care (SOC, the nature of which would involve a separate and lengthy discussion). "Breach of duty" is a deviation from the standard of care in the medical malpractice context. SOC and deviation are, in most cases, determined by the trier of fact (usually a jury) after presentation of expert testimony in court.

The standard of care regarding informed consent, however, is often established as a matter of law, whether by legislation (e.g., New York State [PBH § 2805-d]) or case law (e.g., New Jersey, see *Matthies v. Mastromonaco*, 733 A.2d 456, 160 N.J. 26, 1999).

The American Medical Association (AMA) Code of Medical Ethics Opinion 2.1.1, describing the informed consent process, appears in figure 1. [SEE FIGURE 1]

American Medical Association

CODE OF MEDICAL ETHICS OPINION 2.1.1

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decisionmaking capacity or declines to participate in making decisions), physicians should:

(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.

(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:

1. The diagnosis (when known)
2. The nature and purpose of recommended interventions
3. The burdens, risks, and expected benefits of all options, including forgoing treatment

(c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.

In emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.

https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-2.pdf

Figure 1

While the law varies among jurisdictions, the core elements usually required are:

1. The reason for the proposed course of treatment (including diagnosis and goals), the intended benefits, and the known, significant risks. Some jurisdictions do not require explanation of commonly known risks, or those with both insignificant clinical impact and low incidence.

2. The risks and benefits of reasonable, accepted alternative courses of treatment, including no treatment.

3. Implicitly, the information is presented to the patient in such a way that the patient has sufficient understanding to make an informed decision regarding which course of treatment the patient wishes to pursue.

Note that a "consent form" is not generally an element required by law, although some jurisdictions may additionally require signing a form under some circumstances. The form, regardless of details, serves only as one element of evidence that the treater has obtained informed consent or, in some cases, of the failure to properly do so. In other words, if the consent form is the only documentation of obtaining informed consent, and the information presented there does not meet the standard of care, the form may inculpate potential defendant or defendants. Still, it is common for institutions, such as hospitals, to require that a signed "consent form" appear in the patient record when surgical or otherwise invasive procedures are to be performed.

A form indicating consent for treatment in general is usually signed prior to admission to a hospital or to an outpatient unit. Prudent practitioners document the informed consent process in the patient record irrespective of the presence or absence of a "consent form." LNCs who review patient records for medical malpractice claims, particularly those involving surgical or other invasive procedures, will often see discussions of the consent process both in progress records and in procedure or surgical notes. While there is no universal legal requirement for such documentation, local or institutional rules may mandate it.

To prove a deviation from the standard of care in obtaining informed consent, a plaintiff must prove that the clinician did not perform all the elements discussed. Even if the risks of the proposed treatment were explained, the standard is not met without discussion of alternatives, including the choice of taking no action, if that is a reasonable option. The patient's consent is not informed without being able to compare the risks and benefits of reasonable alternatives to those of the proposed treatment.

Causation is established not only by linking the treatment actually performed to the claimed injury, but also by comparing the probable results of alternatives, including forgoing any treatment, to the injury resulting from the treatment elected by the clinician. This is critical in jurisdictions that use the "objective" standard of the "prudent patient," i.e., asking if an imaginary reasonable, prudent patient would have elected one of the alternatives if presented with the risks and benefits. (see *Canterbury v. Spence*, 150 U.S.App.D.C. 263, 282). Under that standard it is irrelevant if the plaintiff says, "if I had known, I wouldn't have gone ahead with that treatment." The jury must decide if a prudent patient would have made that decision.

The patient's consent is not informed without being able to compare the risks and benefits of reasonable alternatives to those of the proposed treatment.

Implicit in this analysis is comparing the likelihood of harm from an alternative course, whether it be a different treatment or no treatment. This is essential to determine whether or not the patient would be in the same, better or in a worse position having elected a different course of treatment from the one performed.

It is also insufficient to stop at the point of asking, "if the surgery had not been performed, would that vessel have been cut?" Rather, one must look at the available, reasonable alternatives and their risks and benefits. If the risk of no treatment would likely have been death, then a jury would likely find that a reasonable patient would have elected that surgery despite the risk of cutting the vessel, and the case fails on causation. This is why analysis of the available alternatives is necessary, both for legal and for factual reasons. The plaintiff may not be, or may not have been, reasonable.

Regarding injury and damages, as with any personal injury case, the potential damages must be sufficient to cover the high costs of litigation and still properly compensate the plaintiff for the injuries sustained and the attorney for the investment of time, expertise and expenditures in the management of the case. If they are not, an otherwise meritorious case will likely not be pursued.

CONSENT AND LIABILITY

Some clinicians think that listing a potential complication on a consent form serves as a defense should the complication occur. Defense counsel also attempt to perpetuate that misconception. On deposition, the defense attorney will show plaintiff the signed consent form and ask, "Is that your signature?" And then, "Do you see where it the list includes, 'amputation of the wrong leg'?" as if inclusion of that event somehow absolves the physician of liability. It does not, and defendants will usually acknowledge that they have a duty to take all reasonable precautions to prevent known complications. In fact, inclusion of an event on a consent form, or in a discussion that occurs in order for informed consent to be obtained, highlights the fact that the treating clinician is aware of the potential complication, and has the obligation to take the accepted measures that would reduce the risk of the complication occurring, and to take the actions indicated to mitigate its severity once the complication has been discovered.

Some clinicians think that listing a potential complication on a consent form serves as a defense should the complication occur. It does not.

A signed form indicating consent for treatment may, under some circumstances, serve as a defense against a claim of medical battery. A battery claim is typically distinguished from negligence when the patient denies having given permission to be touched in a particular way, or for a particular procedure to be performed. Battery is a civil (and sometimes criminal) offense distinct from failure to obtain informed consent, a type of negligence (Bradley v. Sugarbaker). Initially obtaining informed consent, however, is not sufficient to forestall a claim of battery. In *Levin v. United States*, 2016 Guam 14, the court cogently discusses the circumstances under which a patient may withdraw consent, adopting the test in *Mims v. Boland*, 138 S.E.2d 902 (Ga. Ct. App. 1964),:

> We hold that in the context of a medical procedure in which consent was previously given by the plaintiff, to constitute an effective withdrawal of consent, (1) the plaintiff must have used language that unequivocally revoked his or her consent and was subject to no other reasonable interpretation, and (2) stopping the treatment or examination must have been medically feasible. (*Levin v. United States*, 2016 Guam 14 at 21)

In *Levin*, plaintiff gave informed consent orally and in writing for cataract surgery. However, he claimed that once he saw the equipment in the operating room of the Navy hospital he withdrew his consent, and did so again once the eye was anesthetized. Then he suffered corneal clouding, a known risk purportedly discussed with him before the surgery. He sued for medical malpractice and for battery. The negligence claim was dismissed on legal technical grounds having to do with sovereign immunity (it was a Navy surgeon and a Navy hospital). Levin appealed, claiming that the relevant cause of action was medical battery due to his allegation that he had withdrawn consent, and the United States Supreme Court held that the government was not shielded from a claim of medical battery by a Navy doctor acting within the scope of his employment. *Levin v. United States*, 568 U.S. 503 (2013)

Absent an unusually compelling claim of battery (medical/civil, or criminal), informed consent claims are rarely sufficient to stand on their own as a cause of action. Typically, the defendant is sued for otherwise deviating from the standard of care, and a count of failing to obtain informed consent appears as an additional claim.

Obtaining informed consent is a process, which involved bilateral communication, assuring that the patient understands the options available, and that the patient still agrees to the course of action discussed if conditions have changed.

WHEN IS INFORMED CONSENT REQUIRED?

Informed consent is required for medical treatment, and not simply for surgical or invasive procedures. That does not mean that a patient must sign a form. A patient prescribed a fluoroquinolone and is not given the option of another class of antibiotic, nor is informed of the black box warnings published for that class of drugs, may have a valid claim should the medication cause one of the serious and permanent injuries associated with its use. The prudent prescriber will not only have such a discussion, in terms that the patient can understand, but will document it in the patient's record for future reference.

SUMMARY

So, what is wrong with those two sentences beginning this discussion? They perpetuate the misconceptions that informed consent consists of having a patient sign a form, and that obtaining informed consent happens at a given moment. Obtaining informed consent is a process, which involved bilateral communication, assuring that the patient understands the options available, and that the patient still agrees to the course of action discussed if conditions have changed. A patient may withdraw consent for treatment, and if that withdrawal is expressed clearly and unequivocally while it is still medically feasible to withhold or stop the treatment, it may be considered medical battery for the clinician to continue.

FURTHER READING

For those seeking a more in-depth discussion on informed consent, I recommend these articles:

Medical Informed Consent: General Considerations for Physicians

DOI: https://doi.org/10.4065/83.3.313 https://www.mayoclinicproceedings.org/article/S0025-6196(11)60864-1/fulltext

Informed Consent - Israel National Commission for UNESCO

The International Center for Health, Law and Ethics http://unesdoc.unesco.org/images/0014/001487/148713e.pdf

To see how jurors are instructed to deliberate informed consent claims, which serves as a lay language explanation, I again refer to NJ Model Civil Jury Charge 5.50C: https://njcourts.gov/attorneys/assets/civilcharges/5.50C.pdf?cacheID=lFksCv8

and also refer to California's Medical Battery–Conditional Consent charge at https://www.justia.com/trials-litigation/docs/caci/500/530b/

Model jury charges in the jurisdiction where you work can be an excellent resource for a basic understanding of legal issues where you are assisting with the analysis.

An in depth discussion of *Levin v. United States* is found in Kels CJ. Liability for Medical Battery in the Military Health System. MILITARY MEDICINE, 179, 1:1, 2014

REFERENCES

Bradley v. Sugarbaker, No. 16-2405 (1st Cir. 2018), available at http://media.ca1.uscourts.gov/pdf.opinions/15-1128P-01A.pdf

Retrieved November 14, 2018

NJ Model Civil Jury Charge 5.50C. Available at: https://njcourts.gov/attorneys/assets/civilcharges/5.50C.pdf?cacheID=lFksCv8

Retrieved November 12, 2018.

NYS PBH § 2805-d. New York Consolidated Laws, Public Health Law - PBH § 2805-d. Available at https://codes.findlaw.com/ny/public-health-law/pbh-sect-2805-d.html

Retrieved November 12, 2018.

Walter 2012. Patients have had to give consent to medical treatment since 1880.

See *State v. Housekeeper,* 16 A. 382, 384 (Md. 1889) (noting that surgeon is justified in performing operation with consent of patient), cited in Walter, Paula (2012) "The Doctrine of Informed Consent: To Inform or Not To Inform?," St. John's Law Review: Vol. 71: Iss. 3, Article

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Doctors Must Obtain Their Own Informed Consents, At Least in Pennsylvania

James Hanus, BSN, MHA, RN, OCN

Keywords: Consent, Informed consent, Surgical consent

Often, registered nurses (RN), nurse practitioners (NP) and physician's assistants (PA) find themselves with a consent form in hand having been told by the physician to get the patient to sign it for a procedure. Sometimes, the RN, NP or PA does not know what the patient and the physician have discussed, or not discussed, regarding the procedure, along with risks, benefits and alternatives to the procedure. In Pennsylvania, the state Supreme Court has recently ruled that the physician to perform the procedure (unless an emergency), and only that physician, must provide the patient with an informed consent and have the patient sign the consent form.

When a physician determines (in non-emergency situations) that a patient requires surgery or other invasive procedure that requires informed consent (e.g., endoscopy, biopsy, cardiac catheterization) it often falls to an RN, NP, or PA to get the patient to sign the consent form. In a 2017 decision, the Supreme Court of Pennsylvania (PA) in Shinal v. Steven Toms, M.D., 162 A.3d 429 (Pa. 2017) http://www.pacourts.us/assets/opinions/Supreme/out/j-106-2016mo%20-%201031419641869416 6.pdf#-search=%22shinal%20v.%20toms%20%27Supreme%2bCourt%27%22 held that only the physician to perform the procedure can get the patient to consent and sign the form.

A brief review of the principles of informed consent will help the LNC

take the Court's decision into perspective. A physician has a responsibility and duty to inform the patient about the proposed procedure, to include the risks, benefits and potential alternatives. The patient being thus informed has the ability to decide about whether or not to undergo the proposed procedure. The physician must know the patient's educational level, cultural background and ability to understand the information to be discussed. The patient usually does not have a medical background, so the discussion must be what a reasonable and prudent patient of like background can understand.

An informed consent has four required components.

- The physician must explain the patient's diagnosis and why it requires the proposed procedure. The physician also needs to explain how the procedure will be performed and how it should correct/resolve/ameliorate the medical condition.
- While every procedure has some degree of risk, the physician must explain what could go wrong, so that the patient can weigh its risks and benefits.
- The physician needs to outline any possible applicable alternative procedures and treatments.
- The patient may always refuse any treatment. The physician must explain any consequences and risk if the patient declines to consent.

Example: *Shinal v. Toms, M.D.* (Montour County Court of Common Pleas September 29, 2014 at No. 588-CV-2009)

Mrs. Shinal had a history of a non-malignant brain tumor. She met with Dr. Toms (Chief of Neurosurgery at local hospital) about removing a new tumor that was causing headaches, had increased in size, and would potentially impact her pituitary, eyesight, and carotid artery. At the trial Dr. Toms testified that during this clinic visit he advised Mrs. Shinal of the risks of the proposed total resection, including damage to the carotid artery and optic nerve, alternatives (subtotal resection), and his recommendation for total resection, which had a better chance to remove the entire tumor.

At the end of a 20-minute clinic visit, Mrs. Shinal agreed to surgery and a date was set, but she had not decided which procedure she wanted to undergo. In the three weeks before the surgery, she talked by phone with the Physician Assistant (PA) regarding the incision, scarring, and whether she would need radiation therapy after surgery.

Mrs. Shinal came to the clinic seven weeks after the meeting with Dr. Toms. The PA did the preoperative history and physical and obtained her signature on the consent form (the Court's decision does not identify what surgical procedure the patient consented to). There is no documentation that the patient ever saw Dr. Toms again before the day of surgery.

According to the Court's decision, Dr. Toms attempted total resection of the tumor via open craniotomy; during the procedure, Mrs. Shinal's carotid artery was perforated. This resulted in hemorrhage, stroke, brain injury and partial blindness. Eleven months later, Mrs. Shinal and her husband filed a medical malpractice suit in the Court of Common Pleas of Montour County that Dr. Toms had failed to obtain an informed consent from Mrs. Shinal before the surgery. She also alleged in the suit that Dr. Toms failed to explain the risks of surgery or to discuss the lower risk procedure of a sub-total resection.

During the trial, Dr. Toms testified that he had explained the risks, benefits and alternatives to a total vs. a subtotal tumor resection to Mrs. Shinal. However, as the Court's decision points out, the physician could not remember fairly significant information that he might have told the patient during the initial consultation visit. Dr. Toms also testified that "he was responsible to obtain the patient's informed consent," but that he thought he, himself, did not have to have to give the patient information about the proposed surgery and that he could delegate some of the informed consent process to his PA.

Ms. Shinal testified that she could remember no risks of the surgery other than coma and death. She also testified that if Dr. Toms had told her about the option of a subtotal vs. total resection, she would have selected the subtotal procedure. The Court in a footnote reports that the consent form listed the surgical procedure as "Resection of recurrent craniopharyngioma," and does not identify whether the patient agreed to a "total" or a "subtotal" resection.

During the trial, the judge instructed the jury they could consider that "any qualified person acting as an assistant to the surgeon could obtain Mrs. Shinal's consent." The jury found in favor of Dr. Toms; Mrs. Shinal appealed based on the judge's jury instructions.

The patient usually does not have a medical background, so the discussion must be what a reasonable and prudent patient of like background can understand.

Parenthetically, the appeal also included an issue regarding jury selection and peremptory challenges; Mrs. Shinal claimed that jurors favorable to the physician and the hospital where the surgery occurred were seated on the jury.

In the appeal to the Superior (appeals) Court, Mrs. Shinal argued that the judge's jury instruction was improper and cited the Pennsylvania *Medical Care Availability and Reduction Error Act (MCARE)* 40 P.S. Sections 1301.101 – 1301.1006. Section 504 of the Act https://www.health.pa.gov/topics/Documents/Laws%20and%20Regulations/Act%2013%20of%202002.pdf requires that unless there is an emergency, the physician has a duty to the patient to obtain the patient's informed consent. The same Section also requires that for surgery, the informed consent must describe the procedure, along with the risks and alternatives that a reasonably prudent person would need to make an informed decision.

However, the Superior Court agreed with the trial judge's instruction and the jury's decision for Dr. Toms, 122 A.3d 1066(2015) https://scholar.google.com/scholar_case?case=2608806455145996929&q=122+A.3d+1066&hl=en&as_sdt=2006. Mrs. Shinal then appealed to the Pennsylvania Supreme Court.

Consider discussing this Court's decision requiring that the physician performing a procedure must be the one to get the patient's informed consent with your attorney client.

In June 2017, the Supreme Court in a 4-3 decision found that the trial court judge committed an error of law in the instruction to the jury, given the MCARE Act requirements. Justice Wecht, wrote in the majority opinion that:

> *informed consent requires the direct communication between the physician and the patient, and contemplates a back and forth, face to face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent … the duty to obtain the patient's informed consent belongs solely to the physician.*

While this decision only applies to Pennsylvania, the issues involved are significant to LNCs as they review many cases, especially those involving medical malpractice. An LNC reviewing documentation should look at several issues:

- Did the physician to perform the procedure and only the physician inform the patient about the proposed procedure and answer any patient questions?
- Was the physician available to answer new questions that the patient may have?
- Is there thorough physician documentation regarding the consent procedure?
- Does the consent form describe the planned procedure along with the risks, benefits and alternatives to the proposed procedure and that the patient has agreed to the planned procedure?

The Centers for Medicare and Medicaid Services (CMS) Manual 100-07 (State Operations Manual) provide federal regulations regarding informed consent. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf. In Section 482.51(b)(2), CMS requires that the practitioner to perform a procedure is responsible to obtain informed consent. However, CMS defers to the individual hospital and its own policies as to who (e.g., physician, physician's staff) can obtain the consent from the patient.

While the state(s) that you work in may not have an MCARE law, consider discussing the Court's decision requiring that the physician performing a procedure must be the one to get the patient's informed consent with your attorney client. The attorney could then review state law to see if the issues raised in this decision could apply.

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The Captain of the Ship Doctrine in Surgery: That ship has sailed

Mary Flanagan, BSN, RN, CNOR, LNCC

HISTORICAL BACKGROUND

The Captain of the Ship Doctrine (COSD) is the legal principle stating that responsibility and accountability for patient care for direct control of all activities in the operating room (OR) lie fully with the supervising surgeon, regardless of whether that surgeon has directly performed the procedure.

When I agreed to write an article about the Captain of the Ship doctrine (COSD) I thought I knew what it meant. The surgeon was in charge, and I (we) were members of the crew. As a young, inexperienced, and impressionable surgical nurse I worked with several surgeons who were former military, fresh out of Viet Nam. It was, "My way or the highway, yes sir, no sir, right away sir," zero tolerance for error. Later I worked with a prominent Chicago heart surgeon. Likewise, it was zero tolerance for error by nurses, house staff, perfusionists, and anesthesia. His wrath in the OR was legendary. Many stories became part of our local surgical folklore, some passed along with great embellishment. Once he ordered, "Don't breathe," so I held my breath while handing him the sternal saw. (Problem was he was speaking to the anesthesiologist, not me, as he wanted the lungs deflated to avoid damage while splitting the sternum.)

Working for another cardiothoracic surgeon I noticed bubbles coming out of patient tissue around vein harvest sites. I quickly removed the towel covering the aortic line. It should have been full of bright red, oxygenated blood coming from the heart/lung machine but all we saw was a column of air. Quick assessment revealed that the anesthesiologist had attached a potassium drip to the one remaining port on the cardiotomy reservoir without the perfusionist's knowledge, the vent that was always supposed to be open as a vent to prevent air entering the closed system. This was a bona fide surgical catastrophe.

My boss displayed great equanimity, and this was the one and only time I saw him upset in the OR. He directed everyone and every move in the room until we finished including planning to transfer her to another hospital in the area that had a hyperbaric chamber. The helicopter was waiting when we rolled her out. It was as close to controlled chaos as I had ever seen.

Now came the scary part: talking to the family. He asked if I would like to go with him. The family was gathered in a room and we all sat. They had been prepped that there were "complications." He then told them everything that happened. Everything, errors included. He had a gift for taking complex issues and explaining them well with analogies, all without condescension. While knowing it was anesthesia's fault (and the perfusionist's for not noticing) he took full responsibility. He answered every question. He explained what would happen next and her prognosis.

TODAY'S REALITY

Nowadays when the surgeon says to move the patient to ICU post-op, the cascade of events is not directed by the surgeon, but by the bed coordinator, intensivist, and utilization review staff. And, sometimes, their request will be denied.

So, if there is no captain in today's operating room, who is responsible when something goes wrong?

Front line staff are still responsible for successful outcomes. The surgeon still relies heavily on the team of residents, physician assistants, nurses, and surgical technologists. Most prefer, if not demand, to always work with their own team. Trust between surgeons and their teams is hard-won.

But many surgeons today are hospital employees. Decisions about patient care are often made in the board room, not the operating room. Hospitals today consider nurses and other staff interchangeable in their respective lanes of expertise, and expect that everyone can work with everyone else. This leads to frustration and often anger on both sides. This is the big difference between the past and the realities of 21st century health care. Now, OR processes are standardized: surgeons must use this pack, this suture and this block time. Don't fill your block time? Opened to someone who will.

Today, some surgeons don't want to be held accountable. For many years I worked with a general surgeon who deflected any possibility of responsibility to us. Typically, when positioning a patient for surgery, you confirm with the surgeon and anesthesiologist they are OK with the final position before prepping the skin. This surgeon would, for all to hear, say "Are you happy with the position?" He clarified it to everyone who was present he had little or nothing to do with any potential nerve damage, IV extravasation, pressure sore…you name it, and he would deny it before it happened! He was no captain, and very few wanted to be on his ship.

So, if there is no captain in today's operating room, who is responsible when something goes wrong?

ACCOUNTABILITY

The COSD isn't based on maritime lore or military experience, as I used to think. It comes from a 1949 case, McConnell v. Williams (361 Pa.355 (Pa. 1949). While the attending physician was closing a patient following

a Caesarean section, the obstetrical resident attended to the newborn. The resident applied too much silver nitrate into the infant's right eye resulting in blindness of the eye. The Pennsylvania Supreme Court ruled that the surgeon (person in charge) was liable for the team's action even if they were not employed by him and even if the alleged error or negligent action was performed by a supporting member of the team. In law, this established doctrine is called *vicarious liability*.

However, now many states consider COSD anachronistic, and it simply does not resonate in modern courts. The surgeon is ultimately accountable for patient care in the operating room, and members of the team are responsible to function to the best of their abilities in their individual roles and actions. If the circulator nurse says the sponge count is correct and it's not, who is at fault? In Baumgardner v. Yusuf (144 Cal.App.4th.1381) the circulating nurse told the surgeon the sponge counts were correct following a vascular re-operation following an earlier arterial bypass surgery in the patient's right leg. A sponge left in the leg ultimately resulted in partial amputation of his leg. Here the appellate court determined that Dr. Yusuf did not have actual control of the sponge counts and the nurse's actions.

COSD, when used successfully for negligence, must demonstrate a master-servant relationship, narrowly defined. We rarely see this in today's OR.

In another retained surgical item (RSI) case, Van Hook v. Anderson (824 P.2d. 509 (1992) the court determined that the sponge count procedure was established by the hospital, which the staff apparently followed

Modern health care has evolved where the hospitals themselves, not surgeons with private staff, are responsible for staff hiring, training, adherence to standards and procedures, and evaluations.

telling the surgeon that the count was completed successfully. The court ruled the surgeon had no actual control over the counts so the COSD as a complaint was not warranted.

COSD is at best a secondary complainant weapon, as courts now look for actual, effective control of the surgeon in negligence cases. If the surgeon did not hire or select the OR staff and that staff follows, or fails to follow, the hospital's established procedures and standards, the surgeon does not have actual, effective control of everything that happens in the room and cannot be held liable.

Today most states rule against the COSD. As determined in various, recent cases COSD is "no longer viable" (PA), "now largely discredited" (SC), and the "majority of the states are now rejecting it" (WV). Equipment, employee training, nursing standards and procedures are in control of the hospital, not the surgeon. The surgeon does not hire or select the OR staff and does not have direct control of everyone in the room. Various specialists in the modern OR are considered highly trained professionals and colleagues (e.g., anesthesiologists, radiologists), colleagues, not under the surgeon's control. Activities that occur when the surgeon is not in the room (prep, cleaning, set-up, etc.) also would not be under the surgeon's control, limiting the COSD even more. COSD, when used successfully for negligence, must demonstrate a master-servant relationship, narrowly defined. We rarely see this in today's OR. The days of private scrub nurses, working directly for and paid by surgeons in their roles as customers of the hospital, are subjects for the history books.

ROLES AND WHAT TO LOOK FOR

The first assistant should be able to take over the case at any time if the surgeon cannot perform. A first assistant can be another boarded MD, resident in training, RNFA (Ed.: See RNFA, page 22), medical student, surgical assistant, or even a surgical technologist.

The second assistant is less involved, usually retracting and cutting (not tying) suture. They range from a second-year surgical residents to sometimes the scrub person.

In complex cases, the anesthesia team is often an attending MD and a CRNA. If the facility is affiliated with a teaching program, there may be residents and SRNAs.

"Scrub nurse" is another anachronism for the person often just called the "scrub." This can be an RN, surgical technologist, student surgical technologist, or the occasional LPN.

The circulator must be a licensed RN. Often the circulator will be accompanied by an orientee or nursing student. The circulator, not the surgeon, is in charge of managing all of the extra people in the room (such as technical support/sales reps, radiology techs, neuromonitoring techs, ultrasound techs, medical students, nursing students, PT students, PharmD students, faculty, even photographers and videographers). This means responsibility for traffic management and the potential for contaminating the field.

The circulator also is responsible for documenting all this.

SUMMARY

In today's courts, COSD doesn't generally apply because team members are considered highly trained professionals and colleagues. Modern health care has evolved where the hospitals themselves, not surgeons with private staff, are responsible for staff hiring, training, adherence to standards and procedures, and evaluations. Because the surgeon no longer controls means and methods in the modern OR, courts now consider COSD a throwback to a time when hospitals had charitable immunity and plaintiffs needed a source of recovery for malpractice, properly replaced with the more relevant direct control argument.

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RN First Assistant (RNFA)

Stormy Green Wan, RN, BSHS, RNFA

When reviewing operative records, the LNC will often see "RNFA" listed as the first or second assistant on a procedure. The surgeon's operative report names each assistant and the assistant's title (e.g., M.D., D.O., PA-C, RNFA). Identification of assistants will also be found on the circulator's intraoperative nursing record along with the times each person performed in the role during the case.

RNs have a long history of assisting on surgical procedures, this practice being supported by the American College of Surgeons since 1977. However, it wasn't until 1984 that the Association of periOperative Registered Nurses (AORN) adopted its first "Official statement on RN first assistants (RNFA)" (AORN, 2018).

AORN defines the RN First Assistant (AORN, 2018) as a perioperative registered nurse who

- works in collaboration with the surgeon and other health care team members to achieve optimal patient outcomes
- has acquired the knowledge, judgment, and skills specific to the expanded role of RNFA clinical practice
- intraoperatively practices at the direction of the surgeon
- does not concurrently function as a scrub person.

The RNFA does not document the details of the surgical procedure. The Centers for Medicare & Medicaid Services (CMS), American Medical Association (AMA), and American College of Surgeons (ACS) all state the surgeon who actually performed the procedure must document the details.

The RNFA does not document the details of the surgical procedure. The CMS, AMA, and ACS all state the surgeon who actually performed the procedure must do this.

However, RNFAs who additionally provide care besides assisting on the surgical procedure will document those encounters with the patient. For example, many RNFAs are also nurse practitioners who provide preoperative and postoperative care.

Typically, RNFAs are hired by physicians or facilities but sometimes they function as independent contractors, billing for their own services. While all states now recognize the role of the RNFA as within nursing practice, protocols sometimes vary greatly, so the LNC must be familiar with applicable state nursing practice regulations.

As with physicians and physician assistants, each facility has a process by which clinical privileges are granted to first assisting by RNs. These records may be accessed via the medical staff office. In addition, each facility will have a policy delineating the role of the RNFA.

REFERENCES

For more details:

Association of periOperative Registered Nurses (AORN August 2018)

https://www.aorn.org/guidelines/clinical-resources/rn-first-assistant-resources

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Stormy is an RN and nurse consultant in San Bernardino, CA. A nurse for well over 40 years, her professional career has been based in perioperative services. Her primary focus was on surgery with a specialty in heart and vascular surgery, and extensive experience in the surgical areas of orthopedics, general, OB/GYN, urology, surgery, and more. In addition, she has experience in PACU, Pre-op, GI Lab, and numerous other areas such as women's health. Stormy functioned in various roles including clinical nurse, RN first assistant, educator, and administrator. Stormy has owned and operated a successful consulting business, Green Legal Nurse Consultants, since 2013. Her company offers consulting services including medical cost projections, DME/IME attendance, medical record analysis, and various types of reports throughout the nation for both plaintiff and defense attorneys. She loves teaching and welcomes opportunities to collaborate and share her expertise with others.

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OR Positioning Primer for the LNC

Nancy Radoslovich, RN, MA, CPSN, CLNC

Keywords: OR positioning, patient safety, positioning guidelines

For the non-perioperative nurse, the operating room is a clinical area that represents a black hole. Most nurses have limited surgical experience, if any. The policy and procedures are far more complicated than anywhere else in the hospital. There are rules for everything, from what to wear to how to count and even when you can go to the bathroom. Life in the operating room can be misunderstood by those unfamiliar with it. Patient safety dictates every thought and action.

INTRODUCTION

For the non-perioperative nurse, the operating room is a black hole. Most nurses have limited surgical experience, if any. The policy and procedures are far more complicated than anywhere else in the hospital. There are rules for everything, from what to wear to how to count and even when you can go to the bathroom. Life in the operating room can be misunderstood by those unfamiliar with it. Patient safety dictates every thought and action.

The goal of this article is to summarize the common surgical positions and provide information on what the legal nurse consultant should look for during an operative record review. This type of case is best reviewed by a perioperative expert with surgical experience and an

in-depth knowledge of surgical procedures, basic nursing assessment skills, proper positioning guidelines, operating room policies and procedures, and standards of care.

Intraoperative positioning is one cornerstone of safe perioperative nursing care. Guidelines for safe positioning are established by AORN, and hospitals develop policies based on these guidelines. Staff follow these recommendations every time a patient enters the operating room. The circulating nurse documents to ensure the operative record reflects what occurred. However, correct and safe positioning is essential and the responsibility of the entire surgical team: surgeon, assistants, nurses, and anesthesiologist. If an injury occurs, it is devastating to both the patient and surgical team. The injury can range from short term neuropathy, to profound loss of sensation and function (Chandler, 2007) that leads to a permanent injury.

Prolonged stretch and compression due to improper positioning and a lack of padding of peripheral nerves can cause a nerve injury. (Fritzlen, 2003) The AANA Foundation analyzed 44 closed malpractice claims with nerve injuries. The most common nerve injuries were: brachial plexus (15), ulnar nerve (7), radial nerve (5), peroneal nerve (4), paraplegia (4), lumbosacral injury (3), and other injuries (8) (Fritzlen, 2003)

RECORDS REVIEW

The LNC's primary focus will be the intraoperative nursing notes. Do they completely reflect care provided? Was something documented that was not done? Was something omitted?

Review the history and physical. Did the patient have risk factors? Risk factors include diabetes mellitus, peripheral vascular disease, renal failure, prior neuropathy, and obesity. Were they adequately addressed? Was the patient properly padded? Was the patient positioned correctly? Was the position documented correctly? Could anything have been done differently? An experienced LNC operating room nurse will be able to read between the lines and see what others cannot.

FACTORS TO CONSIDER

The patient relies on the surgical team's knowledge and expertise to provide

SURGICAL POSITIONS

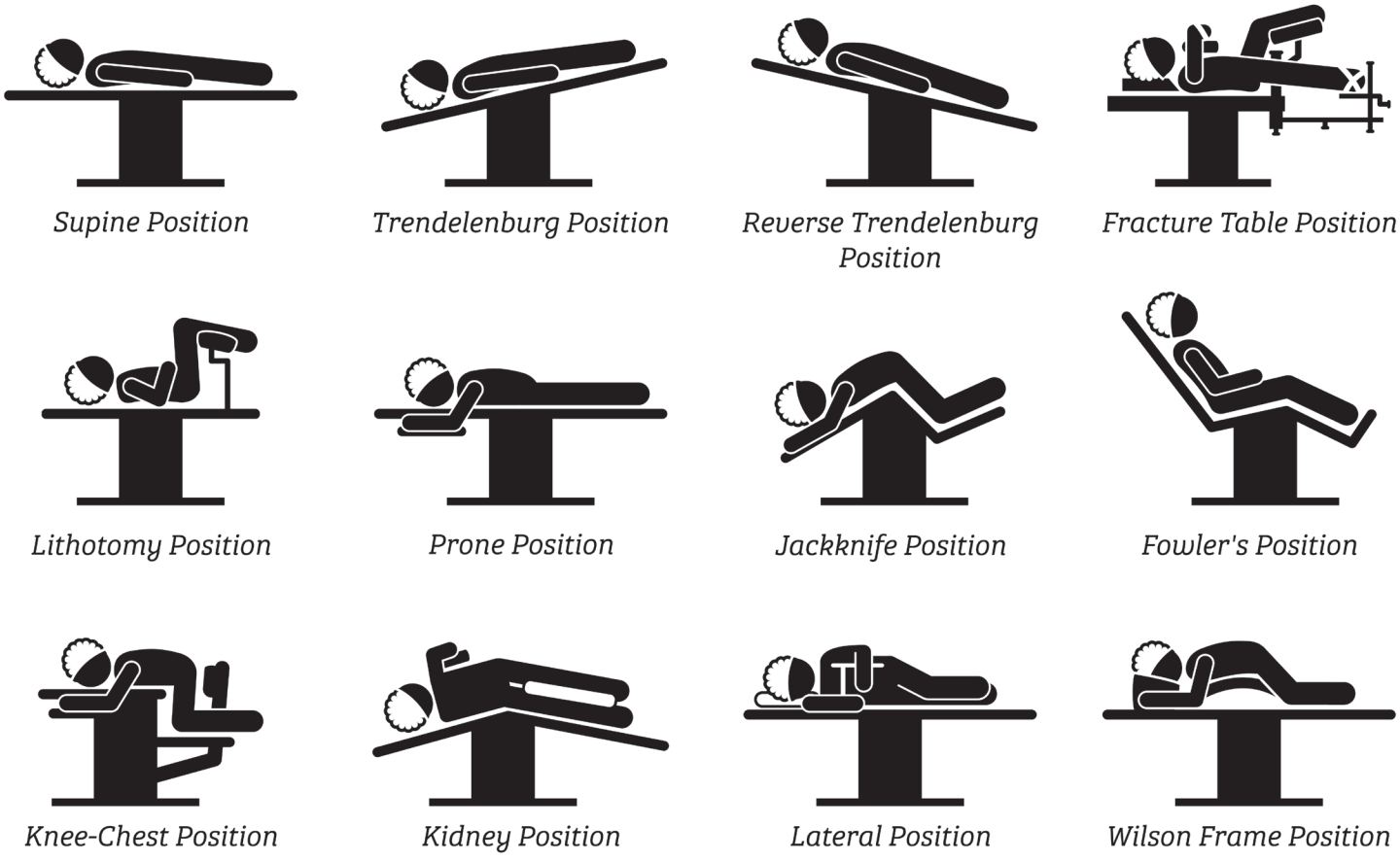


TABLE 1 (adapted from AORN positioning guidelines, 2018)

POSITION	KEY SAFETY POINTS	COMMON COMPLICATIONS
SUPINE	• Most common position • Causes extra pressure on occiput, scapulae, elbows, sacrum, coccyx, and heels • Maintain neutral position • Elbows and hands are padded • Arms are positioned on arm boards, palms up (supinated) • Safety strap, above knees • Legs parallel and ankles uncrossed • Pillow under knees to prevent lower back issues • Eyes closed with ointment and taped	• Hyperextension of elbow can stretch median nerve, causing upper extremity neuropathy. • IV infiltration from tucking the patients arms at side. • When arms are pronated, ulnar nerve is vulnerable to compression • Brachial plexus injury increases when arms are placed on the arm board lower than OR mattress, and when arms are abducted over 90 degrees • Placing the safety strap over the knees increases risk from nerve injury • Prevents corneal abrasions
TRENDELENBERG	• The patient's feet are higher than the patient's head by 15 to 30 degrees. • Implementation should be taken to prevent the patient from slipping on the OR bed. • Arms should be tucked at side • Do not use shoulder braces • Position should not be used for the extremely obese >BMI 40	• Increased intraocular pressure (leads to vision loss) • Rhabdomyolysis- the breakdown of muscle tissue that can lead to kidney damage (medlineplus.gov Jan 2019) • Sliding of arms on arm boards can cause brachial neuropathy. • Compression over the acromion can injure the brachial plexus
REVERSE TRENDELENBURG	• The patient's head is 15 to 30 degrees higher than the feet • Padded foot board to prevent patient from sliding down	• Hypotension from venous pooling • Venous air embolism is potentially lethal complication • Peroneal and tibial nerve injury from foot and ankle flexion
LITHOTOMY	• The legs and pelvis are elevated • Leg holders at an even height • Legs should not rest against leg holders • Hips positioned to prevent excessive flexion, rotation or abduction • Legs slowly raised simultaneously with at least two people. • Legs removed from the stirrups in a two-step process using 2 people. First remove the legs and bring them together, then slowly lower them to the bed.	• Raises or lowering legs too rapidly causes fluid volume shifts that can affect blood pressure. • Utilize 2 people to raise and lower the legs to avoid torsional stresses at the hip joint and pelvis
SITTING	• Semi-fowlers/beach chair position • Head elevation should be minimized • Head maintained in neutral position • Arms flexed across the body and secured (non-operative arm) • Buttocks padded • Knees flexed 30 degrees to prevent pressure on sciatic nerve • Safety strap across the thighs after the patient is positioned	• Hypotension, bradycardia (cerebral desaturation) • Flexion or extension of head can cause injury. In rare cases, quadriplegia can result from c-spine ischemia from neck and head hyperflexion (Rozet, 2007) • Safety strap can tighten during positioning • Venous air embolism complication requires prompt recognition. Signs and symptoms include ST depression on EKG, and signs and symptoms of right heart failure (jugular vein distention, pulmonary edema, cardiac ischemia, arrhythmias, hypotension and cardiac arrest) (Gordy 2013) This can occur from the negative venous pressure and exposure of veins and bony sinuses, causing air to enter the pulmonary circulation. Treatment includes irrigation of the surgical site with saline, doing a head tilt down position or lateral decubitus position, and cardiovacusular support with inotropes (Rozet 2007)

TABLE 1 (adapted from AORN positioning guidelines, 2018) continued

POSITION	KEY SAFETY POINTS	COMMON COMPLICATIONS
LATERAL	• Positioned on non-operative side • Head pillow under head • Arms supported on 2 level and parallel boards • Axillary support • Spinal alignment is maintained by the bottom leg flexed at hip and knee with top leg straight. Pillow placed between legs • Dependent knee, ankle and foot padded	• Vulnerable to injuries on dependent side • Bilateral radial pulses should be checked after positioning and placement of axillary support
PRONE	• Obese patients have increased intraabdominal and central venous pressures in prone position. • Positioned in neutral position • Placed on 2 chest supports from clavicle to iliac crests • Prevent pressure on patient's eyes • Arms tucked at side or placed on arm board parallel to bed • Padded arm boards • Arms should not be positioned above the patient's head • Hands pronated • Arms and wrist in neutral alignment • Arms secured to padded arm boards (padded arm boards prevent some neuropathy • Knees should be padded	• Increase in cervical spine and brachial plexus injury by excessive stretch by flexion extension and lateral rotation • Incorrect placement of chest supports can cause nerve injury or inadequate chest expansion. • Brachial plexus injury risk is increased when patient's arm is abducted over 90 degrees. • Positioning the arms above the head can cause a stretch in brachial plexus

an experience free from injury and complication. Patient position is determined by the surgeon after discussion with the surgical team and a thorough preoperative assessment. Factors to consider include

- procedure
- length of the procedure
- type of exposure needed
- age
- weight
- preexisting medical conditions
  - vascular, neurological disease, obesity, respiratory issues, nutritional status, medications, overall health and mobility
- Anesthesia: general block, combination, or various levels of sedation

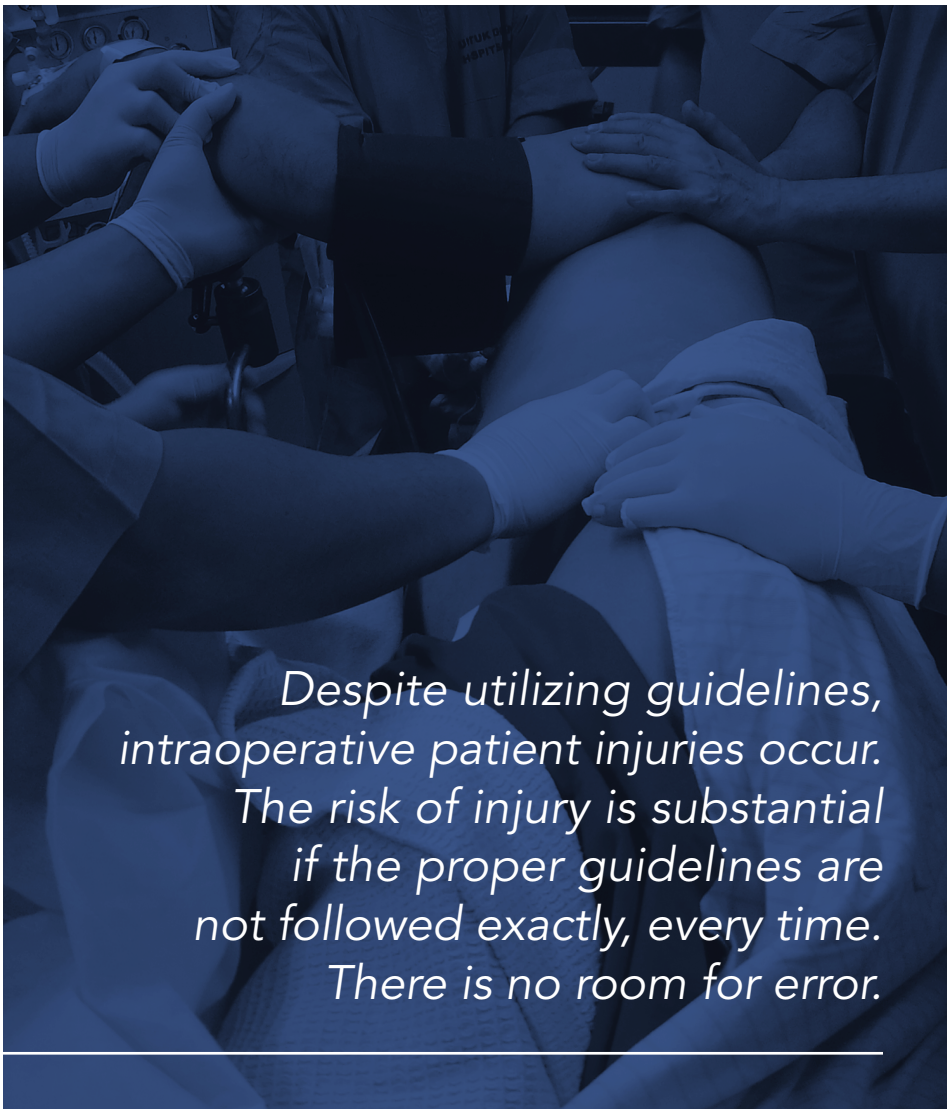
The best position gives the surgeon optimal access to the surgical site, the anesthesiologist access to the patients' airway and IV, and minimizes patient risk.

Goals include maintaining proper body alignment, reduction of pressure on bony prominences, and avoidance of awkward positions that can cause injury and postoperative pain. The anesthetized patient cannot speak, move, or comment on an uncomfortable position. They count on the advocacy of the surgical team to ensure their needs are meet and they are kept from harm.

The most common surgical positions are summarized in Table 1.

Each position is supported by various devices: arm boards, leg holders, blankets, pillows, gel pads, sand bags, shoulder rolls, axillary rolls, safety belt, or straps. Devices should be used for what they are intended for and not altered. The patient must be maintained in proper body alignment, secured to the OR table and supported using the appropriate adjuncts so

Records review: An experienced LNC operating room nurse will be able to read between the lines and see what others cannot.



the surgeon has the best access to the surgical field.

Positioning documentation is recorded in the intraoperative nursing notes. It must include who positioned the patient, what devices were used, and the time. Reassessment and updated documentation must be done if the position is altered during the procedure, and after prolonged time intervals. Once the procedure is finished, the patient is returned to supine position. The circulating nurse should do a complete body check for reddened pressure points. The OR team transfer to the post-anesthesia care nurse provides operative information, including position, adjuncts used, and events that may have occurred during the procedure that may contribute to an injury.

Breaches in standard of care can include:

- Failure to position correctly
- Failure to maintain proper body alignment
- Failure to adequately pad extremities
- Failure to advocate for the patient as to position
- Failure to document care given
- Inaccurate documentation

Despite utilizing guidelines, intraoperative patient injuries occur. The risk of injury is substantial if the proper guidelines are not followed exactly, every time. There is no room for error.

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Test Your Case Screening Skills

CASE #1

Mary had 2 herniated discs. In 2009, Dr. Klein told her it would be another 10 years before she needed surgery. In 2013, Mary started losing balance, her foot started to drag and she was in chronic pain. She went to her PCP numerous times and complained of her symptoms. PCP told her it was anxiety, that lots of people have these problems and that she needed to calm down, never sent her for any neurological testing, reprimanded Mary for coming into the office.

Symptoms got progressively worse to the point where she was weak, could not walk or drive. Went to Mercy ED on April 6th or 7th, 2014. They did not do any neurological testing. PA called PCP who told PA that Mary had anxiety. PA discharged Mary.

Mary has 2 children, ages 12 and 14. Ex-husband took the kids for a while. She kept falling and had bruises all over herself. On April 13, 2014, she was fatigued and had no energy, she fell and smashed her head on her hardwood floors. Taken by ambulance to Southbend Hospital. A CT scan wasnegative. Later MRI was done. A doctor came in and told Mary to call her family as she need emergency surgery. Her mother and father were told that she might be in a wheelchair for the rest of her life. She was diagnosed with spinal stenosis and underwent spinal fusion with laminectomy in her cervical spine. Basically, her spinal cord was getting crushed in 3 different areas. Mary was in the hospital for 3 weeks. She had to re-teach herself how to shower, dress, tie her shoes, button her shirts, etc. She still uses one crutch to get around at times. Mary has been on SSI since April/April 2015. She lost her home to foreclosure 2015. She is now renting a townhouse.

Damages include chronic pain syndrome and gait disturbance precluding employment.

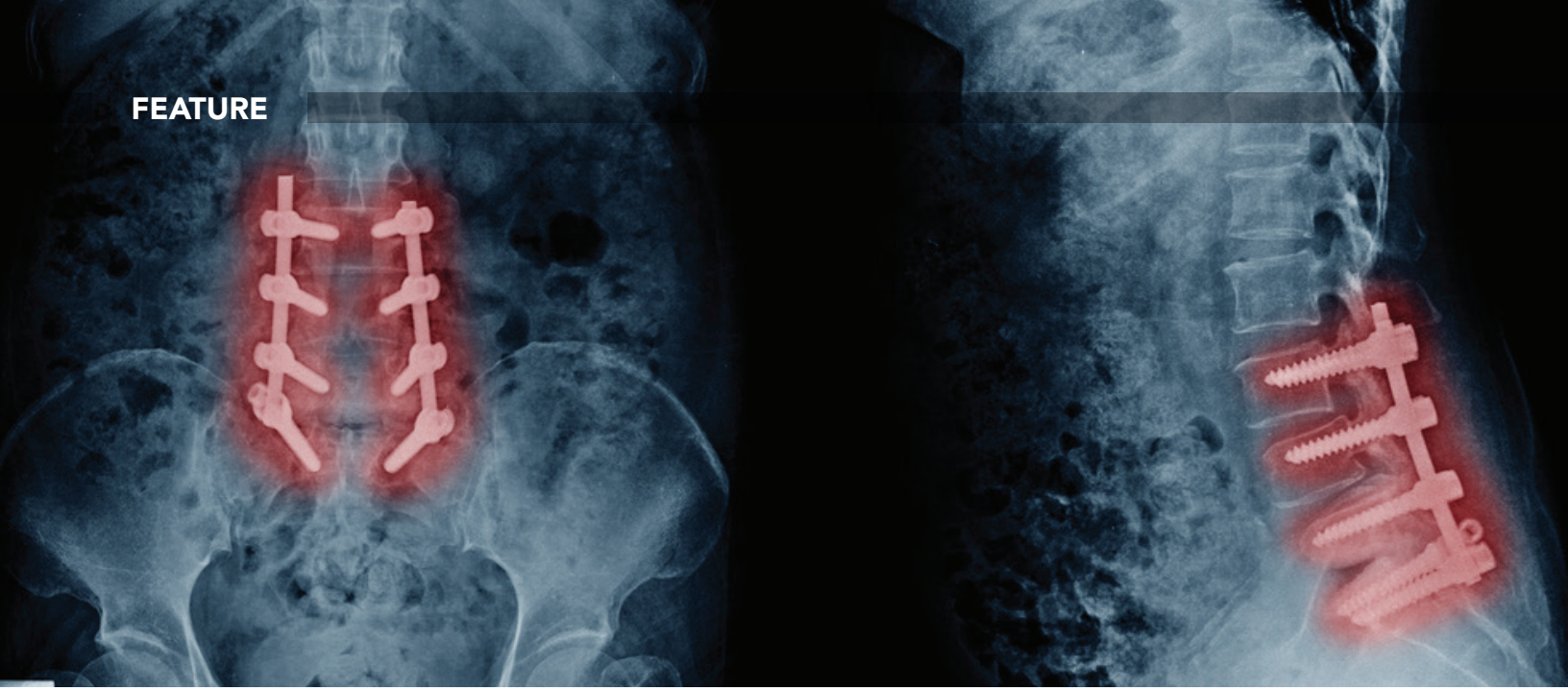
Test Your Case Screening Skills

You decide: reject, or investigate?

CASE #2

On 02/23/18 Ms. Sanders went to Mercy ED with severe abdominal pain. They performed an EKG and took blood work. She was placed in a room for a few hours, then was discharged. Ms. Sanders was in pain and did not understand why they were discharging her. The nurse said her condition was not critical enough and no other further testing was needed. They told her it was gas, gave her Pepcid and discharged her. Ms. Sanders went home that night and was sick all weekend, could not get out of bed. Monday she saw her PC who sent her immediately back to the ER. This time she went to St Mary's Hospital where abdominal CT-scan showed appendicitis. On 02/27/18 Ms. Sanders had emergency surgery and as soon as they touched her appendix, it burst. Ms. Sanders remained in the hospital for 6 days, she is doing much better. Ms. Sanders feels if Mercy Hospital had done more testing they would not have discharged her. Ms. Sanders is also concerned with $6-7,000.00 she has to pay out of pocket (she has high deductible) due to Mercy Hospital misdiagnosis.

Check your answers on page 37.



Understanding the Role of Neuromonitoring in Spine Surgery

Susan Yatvin BSN,RN,CNOR

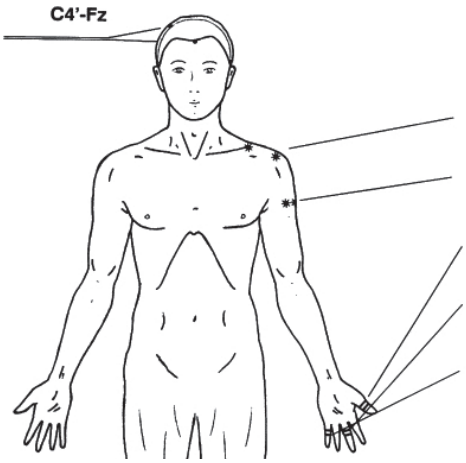
Keywords: Intraoperative Neuromonitoring (IONM), Somatosensory Evoked Potentials (SSEP), Electromyography (EMG), Train of Four (TOF), Motor-evoked Potentials (MEP), Pedicle Screw Stimulation (PSS), Total Intravenous Anesthetic (TIVA).

Intraoperative neuromonitoring, first applied in the 1960s, is still in use in complex spine surgery. It provides real-time feedback for surgeon, anesthesiologist, and neuromonitoring team as a first alert to potential neurologic damage and assists with the safe delivery of care. Legal nurse consultants can contribute to the attorney's understanding of neuromonitoring modalities, anesthetic agents, and physiologic changes effecting quality of monitoring during spine surgery.

UNDERSTANDING INTRAOPERATIVE NEUROMONITORING IN SPINE SURGERY

Intraoperative neuromonitoring (IONM) has been utilized in neurosurgical procedures since the mid-1960s. It provides real-time functional neuronal analysis, serving as an early warning sign of impending damage, identifies structures that cannot be recognized visually, detects and quantifies changes in function, and can provide feedback on effectiveness of nerve root decompression procedures. Adhesive or hypodermic needle electrodes at distal and proximal limb sites create conduction pathways. Somatosensory evoked potentials (SSEP), transcranial motor evoked potentials (TCeMEP) free run electromyography (EMG), train of four (TOF), and pedicle screw stimulation (PSS) are used in combination in spine surgery.

SSEP (Fig. 1) looks at sensory pathways from sites distal to the structure at risk to the sensory cortex of the brain. SSEP is monitored in real time, looking at sensory cortex or spinal cord perfusion, spinal cord structural functional integrity, and nerve root and peripheral nerve integrity. Increased latency (delay time between stimulation and response) reflects neuronal firing desynchronization. Diminished amplitude (strength of response to stimulus) demonstrates a decreased number of responding neurons. Anesthesia, blood pressure, temperature, spinal cord or nerve manipulation, instrumentation, ischemia, and anoxia can all cause these effects. SSEP cannot provide feedback as to specific nerve root injury as it does



LEVEL	ELECTRODE	CATHODE PLACEMENT	ANODE PLACEMENT
C4	EEG disc	7 cm medial to head of humerus	Head of humerus
C5	EEG disc	16 cm distal to acromial process	5 cm lateral to cathode
C6	Ring	PIP joint of the thumb	DIP joint of the thumb
C7	Ring	PIP joint of the middle finger	DIP joint of middle finger
C8	Ring	PIP joint of little finger	DIP joint of little finger

Figure 1. Somatosensory evoked potentials (SSEP),

not look at motor pathways in the anterior cord; for this MEPs are necessary (Toleikis, 2010).

TCeMEP are electrical signals recorded from muscles after direct stimulation of the motor cortex, used in surgery risking motor system injury. However, patients with chronic paralysis and no useful function are not likely to benefit (MacDonald, Skinner, Shils, & Yingling, 2013). MEP deterioration often occurs before and sometimes without SSEP changes, suggesting a greater chance of early detection and intervention (MacDonald, Skinner, Shils, & Yingling, 2013).

Train of Four (TOF) evaluates the extent of general muscle relaxation, i.e., after sedation, with electrodes attached over muscle. Muscle twitches after stimulation are measured and conveyed to the anesthesia team so they can adjust anesthetic agent dosing. Total relaxation (zero twitches) is desirable during initial nerve root exposure, and a lighter anesthetic state allowing twitches is desirable during stimulation of motor pathways and insertion of hardware.

Intraoperative Free-run EMG detects motor nerve root compromise during decompression for spinal stenosis and spondylosis, correction of spinal deformity, radiculopathy after disc herniation, and neural tumor removal in anterior and posterior surgical approaches (Chung & Grigorian, 2012). Electrodes over muscles enervated by specific nerve roots assess their status and guide correct spinal hardware placement (Chung & Grigorian, 2012). Baseline recordings before anesthesia identify any pre-existing nerve injury. EMG recordings are run continuously throughout the surgical procedure.

PSS (Fig. 2) works on the principle that electrical resistance of the pedicle bone is greater than in surrounding soft tissue. Applying electrical current to the screw should not stimulate the nerve if the screw is placed properly, allowing for immediate repositioning if indicated.

COORDINATION OF TEAM MEMBERS

Intraoperative monitoring is performed by a trained technician and is directly supervised by a professional. The American Board of Neurophysiologic Monitoring (ABNM) recommends certification or the equivalent as a measure of professional qualification. Certification requires (Toleikis, 2010):

- an advanced degree: Masters, PhD, MD, or DO
- documented clinical experience of at least 300 monitored cases over at least three years
- surgeon attestations regarding monitoring experience
- passing oral and written examinations

The monitoring physician should be licensed in the state and privileged in the hospital in question. The professional may supervise the case on site or remotely and is limited to monitoring not over three cases simultaneously. Remote monitoring professionals must communicate with operating room staff and interpret data in real time. (American Clinical Neurophysiology Society, 2009).

However, there is neither any formal state or federal licensing for IONM technicians nor standard for credential-

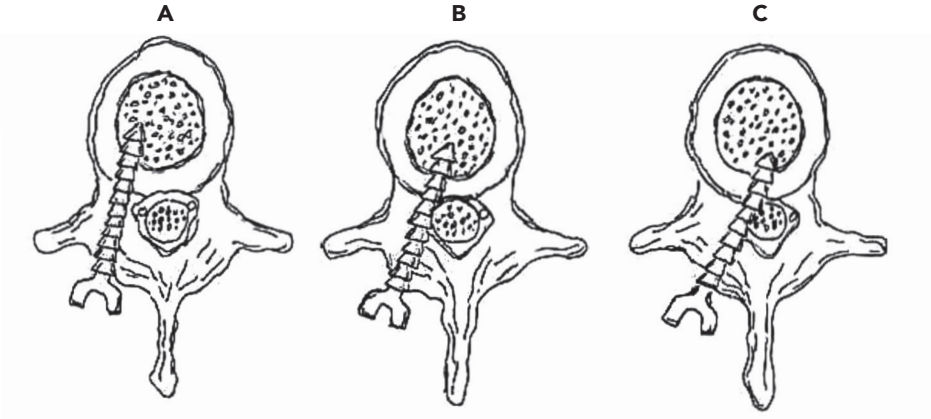
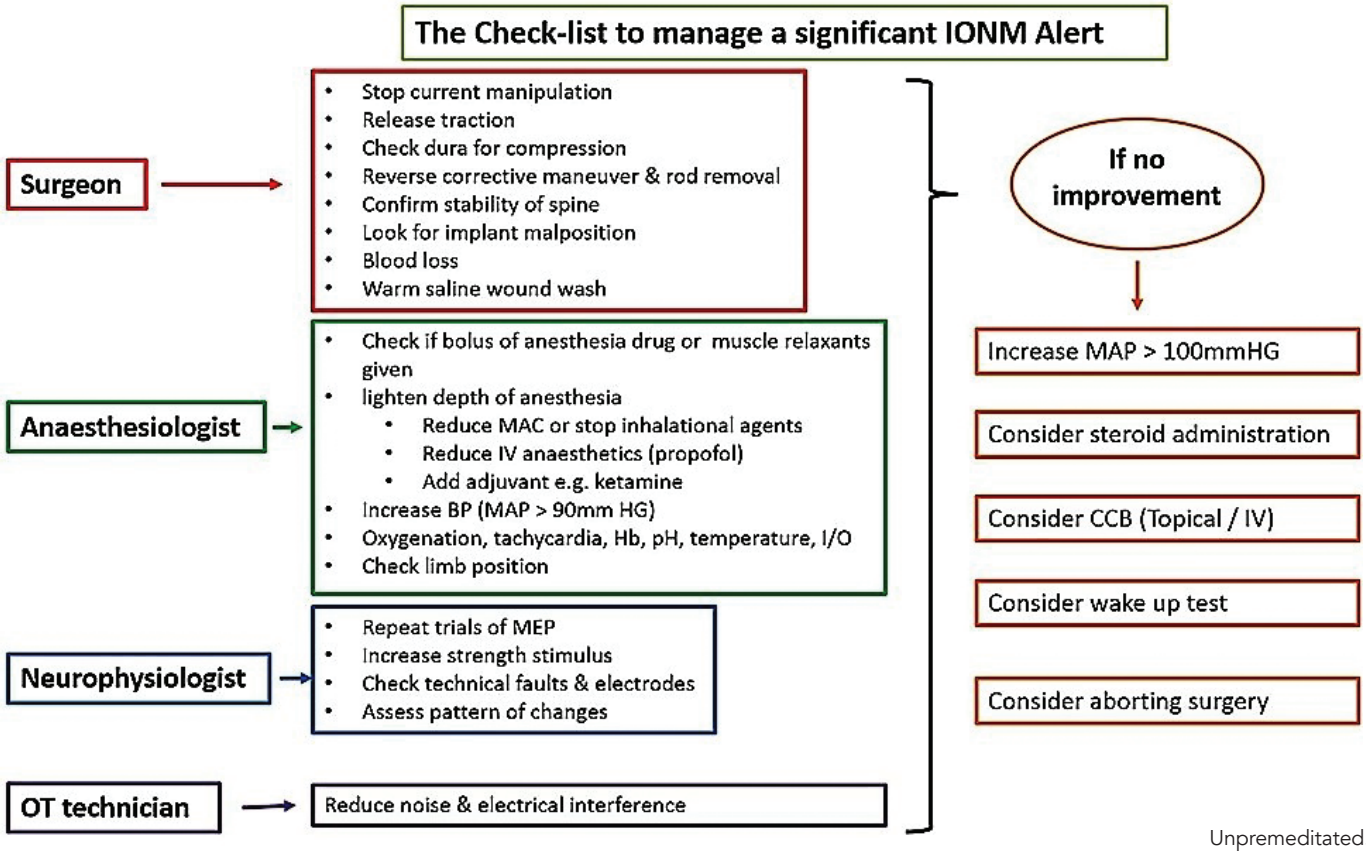


Image A shows proper screw placement.
Images B and C show improper screw placement.

Figure 2. Pedicle screw placement.



Unpremeditated.net

ing IONM physicians. The American Society of Neurophysiological Monitoring (ASNM) published "Practice guidelines for the supervising professional: intraoperative neurophysiological monitoring," a guideline to understanding intraoperative neurophysiologic monitoring and best practices. (Goldberg-Hoss & Degan, n.d.)

Surgeon, technician, and anesthesiologist must coordinate to produce effective intraoperative monitoring during surgery. The surgeon will specify IONM modalities appropriate to the planned procedure. The technician places leads and provides specialized equipment, and anesthesia gives agents to elicit the desired effects at the anticipated times throughout.

ANESTHESIA CONSIDERATIONS (TOLEIKIS, 2010)

Anesthetics involve complex decisions about patient pathophysiology, surgical requirements, and specific neuromonitoring modalities.

For example, halogenated inhalant anesthetics (e.g., desflurane, enflurane, halothane, isoflurane, sevoflurane) can increase SSEP latency and decrease cortical amplitude. If monitoring cortical SSEP is essential, nitrous oxide should be avoided.

Intravenous agents can be combined to produce total intravenous anesthetic (TIVA) which interferes less with monitoring. Common agents include analgesics (opioids or ketamine) and sedative agents (barbiturates, benzodiazepines, etomidate, propofol or droperidol. Because the effects of opioid administration are less than those of inhalation agents, opioid-based anesthesia is frequently administered when cortical responses are utilized for monitoring.

Body temperature and blood pressure also affect neuromonitoring. Cold operating rooms, lengthy procedures, unwarmed IV fluids and inhaled gases, evaporative losses, and the amount of surgical wound exposure all affect patient core temperature. This in turn affects drug metabolism and neural conduction. Blood pressure affects neural perfusion; if oxygen demands are not met, nerve electrical activity will shut down. The degree of permanent neurologic damage is directly related to how long oxygen demands are unmet. (Toleikis, 2010).

ELECTRICAL SAFETY

IONM equipment must meet electrical safety standards. Anesthetized patients cannot report or react to pain. Malfunctioning equipment may cause burns, or worse. The intraoperative record should document correct grounding pad placement. Hospitals should keep records documenting inspections and maintenance for all system components. Equipment must also be able to accommodate the appropriate number

of channels for the modalities required during the procedure.

The technologist should be present to place electrodes, hook up equipment to appropriate channels, monitor readings, and disconnect the patient from equipment at the end of surgery. Changes to skin integrity should be reported to the circulating nurse.

DOCUMENTATION

Most systems do not permit storing continuous, raw, unaveraged data, such as free running EMG signals (American Clinical Neurophysiology Society, 2009) but a complete record of averaged waveforms should be retained. IONM records should contain times of blood pressure and temperature, surgical events, procedure alerts, and medication administration. Significant changes in physiological conditions should be filed in the patient chart and long-term storage of the records, as required by law (American Clinical Neurophysiology Society, 2009). These records should include all communications to and from neurophysiology team members and the surgical and anesthesia team.

LITIGATING MEDICAL MALPRACTICE CASES INVOLVING IONM IN SPINE SURGERY

Hospitals routinely fail to provide certain records related to IONM. Attorneys should routinely request all IONM records incorporating: (Goldberg-Hoss & Degan, n.d.)

- communications between the surgeon, anesthesia, and technologist in the facility
- communication between on-site personnel and any offsite interpreting physician
- raw data from the IONM system itself

Once a lawsuit has commenced, the following should be considered: (Goldberg-Hoss & Degan, n.d.)

Properly applied, IONM serves as an early alert of neuropathway interruption, allowing for immediate correction to limit or reverse neurologic damage.

- Identity of individuals involved, including anesthesia team, surgeon, technician
- Individual responsible for IONM interpretation
- Location of the IONM interpreting data during the surgery
- Number of IONM surgeries monitored by that individual that day
- Employer of individual team members involved in the IONM
- Educational background of the monitoring team, including inhouse orientation, refreshers, and training on specific system(s) in use
- Make and model of the IONM system
- All applicable rules, regulations and policies of the institution

CONCLUSION

Intraoperative neuromonitoring during spine surgery is a complex process, involving team coordination and communication to protect the patient's neurologic structures. Properly applied, IONM serves as an early alert of neuropathway interruption, allowing for immediate correction to limit or reverse neurologic damage. Records can be of great help in IONM malpractice cases.

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Retained Surgical Items (RSI)

Mary Flanagan, BSN, RN, CNOR, LNCC

Keywords: Retained surgical item, RSI, Gossypiboma, Surgical counts, Sentinel event, Never event, Foreign body or object, Medical malpractice, Surgical sponges, Lap sponges, Surgical towels, Perioperative nursing data sheet (PNDS), Data-matrix-coded sponge (DMS) or towel, Embedded radio frequency (RF) chip

This article focuses on successfully addressing retained surgical items (RSI) as the basis of medical malpractice complaints. Despite count policies, staff education, and adjunct technologies available to operating room staff, RSIs remain the number one reported sentinel event in the U.Ss. (Accreditation Insider, 2018)

Reviewing an RSI case requires deep understanding of how, what, and why an item was lost or forgotten. Using a combination of personal case studies, in-depth research, and incisive guidance, the author presents the essentials every LNC requires to successfully address RSI cases.

INTRODUCTION

Whether called a retained surgical item or an unintended retained foreign body, an RSI is anything unintentionally left behind or forgotten in a patient following an invasive procedure or surgery. The group NoThing Left Behind® uses California's Health and Safety Code 1279.1 to define a retained surgical item as: "retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained," and notes an alternative, "a surgical item that was not intended to remain in a patient, found in any part of the patient's body after an operation, procedure or vaginal birth ends" (NoThing Left Behind, 2019). The Joint Commission (TJC) uses "unintended retained foreign object," URFO, and defines that as "any item or foreign object related to any operative or invasive procedure that is left inside a patient" (TJC, 2013)

SCOPE OF THE PROBLEM

Sponges and surgical towels are the most common RSIs, but anything we use during the case has the potential to become lost, forgotten, or retained. An attorney I worked with refused to use the word *retained*, preferring *forgotten*. She felt that no matter how slight, *retained* inferred vicarious liability of the patient. Cautery tips, sharps, bulldogs, cotton pledgets, and vessel loops are but a few of the many items that should be counted and accounted for in many

procedures. Counting instruments is not always necessary and varies by institution, however the scrub person should be able to account for all the instruments throughout the case, not just when closing, even those discarded from the field. It is all about awareness.

RSIs occur in approximately 1 in 5500 surgeries out of the 48-51 million reported operations performed annually in the US, or about 9,200 instances per year (Cima et al., 2008). In 2016 and 2017 they came in as #1 on the top 10 Sentinel Events (SE) reported to the Joint Commission (Accreditation Insider, 2018).

Most RSIs occur in the operating room with labor and delivery a close second (Steelman, 2018). The numbers may be even greater as not all events are reported. Injuries to the patient can include reoperation and readmission with prolonged hospital stay, infection or sepsis, bowel obstructions, and even death.

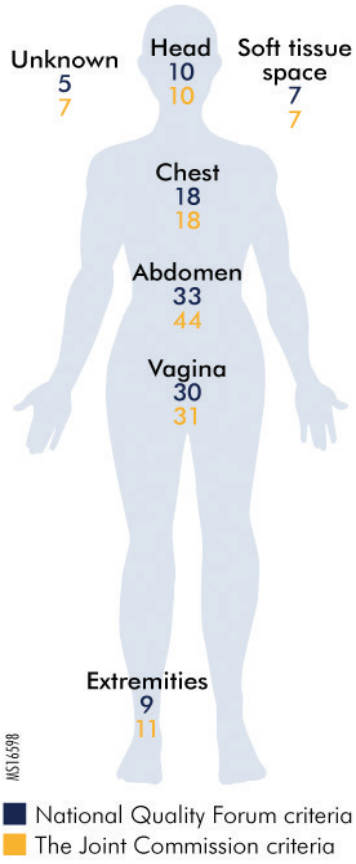

Figure 1

PA Patient Safety Authority

http://patientsafety.pa.gov/ADVISORIES/Pages/201703_RSI.aspx

So how do items become retained, lost, or forgotten? And how can this devastating event (both to the patient and the staff) be prevented? Lots of ways. Initial incorrect count, using towels without radiopaque markers in the wound, not counting small soft goods, inattention during the counts, hurried counts. One of the most common ways sponges are retained is the use of gauze 4x4s in the abdomen or chest. When saturated with blood, a 4x4 sponge can be mistaken for tissue (Fig. 2). But it isn't always a sponge that is left behind.

Sharps, cautery tips, vessel loops, bulldog clamps, even the plastic tip protectors found on many of our disposable devices can be retained. One of my most interesting cases involved a retained Glassman visceral retainer, aka "Fish™," sometimes used when closing a large abdominal wound. It anchors the omentum and prevent nicks and punctures of the intestines. It has a ring attached to a string designed to hang out of the incision during closing as a visual reminder it to be removed. Before the last few stitches are placed, the pliable Fish™ is tugged on and folds on itself and is removed and discarded. We used them frequently when open abdominal aortic aneurysm repair was the norm. I once received a call from an attorney saying a Fish™ was left in a patient. "No way", I responded. "Yes, way" he said. This must be my once-in-a- lifetime case, I thought. Incredibly, a mere 6 months later I was hired on another retained Fish™ case. Why? A scrubbed team member cut off the ring and threw the scissors and the ring into the metallic kick bucket. The busy circulator heard the loud clunk and assumed the entire Fish™ had been discarded.

Distractions abound. Cell phones, pagers, doors opening and closing,

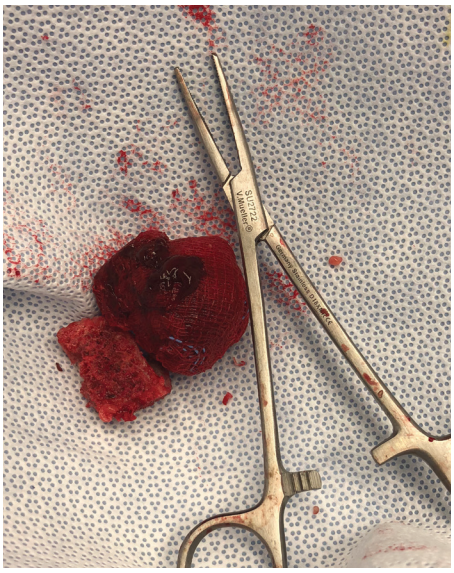

Figure 2

irrelevant conversation, loud music, environmental noise generated by equipment all contribute to miscommunication, or worse, no communication among the team, especially when counting. AORN considers counting a critical phase of any operation, where distractions and noise must be kept to a minimum (AORN, 2014). Yet, often when we are closing, the music is turned up, the atmosphere is more relaxed, and frequently the scrub person is replaced because "anyone can close."

Policies and procedures are important in preventing RSIs. However, any policy is only as effective as the people who follow it. AORN recommends surgical counts be performed before patient arrival, when a cavity within a cavity is closed, once general closure has begun, and again when the skin is closed. Novices in the OR often learn by example. If a veteran nurse omits a sponge count because it's a laparoscopic case and "that could never happen," the novice circulator may interpret this as acceptable practice. An attorney I once worked with dubbed this "a culture of complacency." It can never happen, until it does.

Sponges and surgical towels are the most commonly retained items. A retained sponge, or more formally, *gos-*

sypiboma, was first reported in medical literature in 1880. The word gossypiboma is from the Latin *gossypium*, textile or cotton, and *-oma*, tumor or growth. (Fig. 3) Most cases I review involve gauze 4x4s and laparotomy (lap) sponges. According to the group NoThing Left Behind®, the most frequent areas where a sponge is left are the abdomen/pelvis, the vagina and then the chest (NoThing Left Behind, 2019). An incision of any size can cause a lost sponge; I had a case where a 4x4 was left after a small generator (battery) was placed in the patient's back.

Advances in technology offer two systems to promote more accurate sponge counting. One is the use of embedded radiofrequency (RF) chips in sponges. The patient is scanned with a "wand" at the end of the procedure to detect them. The other involves a data-matrix-coded sponge (DMS) or towel with a unique identifying code that must be scanned at the beginning and end of the procedure to account for it. (Cima, Kollengode, et al. 2011)

An RSI legal case is governed by the principle of *res ipsa loquitor*, Latin for "the thing speaks for itself." This generally means that the very presence of an RSI implies negligence. If the patient had not undergone surgery or an invasive procedure, nothing could have been left behind. The role of the testifying expert is narrowly focused on the perioperative time line. The LNC may need to comb through multiple medical records to find germane facts, because often RSIs are not detected for weeks, months, or even years. This means preparing a chronology of post-operative events highlighting symptoms,

Figure 3: Gauze encapsulated in a cover of connective tissue.

tests performed, labs, ED visits, and readmissions. Research documenting sentinel events at the facility where the surgery occurred might be indicated. Perhaps the attorney will need a pain and suffering report, a life care planner, and other experts.

COUNT DOCUMENTATION

People often ask about surgical sponge and instrument count documentation. Every RSI case I have worked on had documented correct counts. If counts are part of the dictated operative report, they, too, typically include "Sponge, needle, and instrument counts reported as correct." Was the surgeon or surgical resident dictating the case in the operating room or remotely, and were they told the counts were correct? I would suggest not spending too much time here.

Many ORs use whiteboards to keep a tally, some use institution-created flow sheets. The paper should be an accurate account of what was counted, by whom, and hand-off counts when breaks and lunches take place. Typically, the count work sheets are just that, something to keep track of items throughout the case but not part of the medical records. What is required are the names and roles of the OR staff involved, if available to you. If you can't find the intraoperative nursing data sheet or similar document, tell your client the chart is incomplete.

PERSONNEL

Most likely everyone will be listed on the complaint by name in the filing, with some names eliminated as the legal case progresses. For example, perhaps an anesthesia tech present in the room helping with an arterial line may appear in the filing and have nothing to do with any surgical count. This is important for you to tell your client and is one of the many ways where you add value to the legal case. Note how many (or few) staff were involved and their roles. Was there an orientee scrub or circulator? You may assist your attorney writing questions for deposition once you know all the players.

Another thing to consider when reviewing an RSI legal case is what procedure the surgeon performed. Was it a laparoscopic case converted to open for some reason? Did an unexpected finding result in another surgeon being called to consult? How long did the procedure take? Did the case involve a change of shifts? How much did the patient weigh? In RSIs, size matters. The higher the patient's BMI, the greater the chance of something being lost.

NEXT STEPS

Obtain a copy of the facility's count policy and whether they include a scenario where an intraoperative x-ray is required. If such an x-ray were taken, who read it? Does the facility rely on the surgeon to read the film? Or, to minimize liability, does facility policy require a radiologist? If radiology was involved, was the physician told what to look for or just that the count was off? Look for documentation of what type of x-ray was done. Was it a flat plate or fluoros-

Any retained item can cause significant harm to the patient ... and serious, long-lasting effects on the staff.

copy? Where was it done? In the OR, PACU, radiology suite? Who read it, what was found (or not), and who communicated the findings to the surgeon?

Most likely you will find no event reporting as part of the patient's medical records. These are typically protected by privilege. A few of my case records have contained a copy of an incident report/variance report/QI report or similarly titled document. While interesting to read they shed little light on the subject. Ask your client if this is something they would like you to pursue. Something else to consider is obtaining the surgeon's preference card for the procedure. It may list what type of sponges and soft goods were opened for the case. A copy of the OR charges may indicate how many sponges and other items were used; the more sponges, the greater the risk for missing one.

CONCLUSION

For an event never supposed to happen, RSI is the most frequent sentinel event in U.S. healthcare. Be familiar with the complexities of the OR to understand what factors are at play that result in these unfortunate events, or consult an OR nurse expert. Know what was lost or forgotten following surgery or an invasive procedure. Understand the burden of responsibility for assuring all items are accounted for by members of the OR team in relation to their individual roles. Any retained item can cause significant harm to the patient and serious, long-lasting effects on the staff.

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Check Your Answers

Test Your Case Screening Skills Page 29

Case #1 Disposition: Investigate

Case investigated with positive expert reviews on both liability and causation. 7 figure settlement just prior to trial. Both PCP and ED provider were defendants.

Case #2 Disposition: Reject

Initial diagnosis may have been reasonable. Sometimes appendicitis is difficult to diagnose. Also, she should make a full recovery and thus, damages are limited and do not offset the cost of litigation. Even if the diagnosis could and should have been made at initial ER visit, she still would have needed surgery and a period of recovery, had some pain and suffering and incurred out of pocket medical expenses.

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