

*The Journal of*

# Legal Nurse Consulting

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Setting the Standards**
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Collaboration Strategies for Creating Safe,  
Positive Workplace Cultures**



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# Something for Everyone



Dear Colleagues,

This issue has a variety of topics that the legal nurse consultant will enjoy and find beneficial. I learned a great deal as I read and reviewed these articles and the authors have provided many meaningful areas for discussion and reflection.

In this issue of the *Journal* we have several wonderful topics presented. To begin, Cynthia Maag and Debbie Winters present a thoughtful case study and review on inflammatory breast cancer which is a rare and aggressive form of cancer. In this article, the authors provide a detailed analysis of the history of the case and point out the importance of gathering all case documents and providing a careful review of all records. The case was very complex and involved many health care providers and radiographic readings. The importance of having a good knowledge of the disease process and treatments, and comparing and contrasting the findings of the mammograms and other reports from different diagnostic facilities is emphasized.

A very important part of the legal nurse consultant's practice is providing critical information related to medical record documentation. Ann Peterson has written a two-part article (the second part will appear in the next *Journal* issue) which delves into the medical record as a legal health care document from the context of standards and compliance (Part 1) and documentation (Part 2). In this article, the author describes the legal requirements related to medical records. There are numerous federal laws that require specific types of records and documentation, such as the Health Insurance Portability and Accountability Act, and federal regulations for nursing home, hospitals, and community-based institutions that must comply with regulations for Medicare reimbursement. Relevant state regulations are also discussed.

An interesting clinical topic on injuries from high pressure injection is described by Thomas Quail. These types of injuries can be life-changing and often can result in severe injuries to the head and torso as a result of lacerations and perforations, and also require amputation of extremities. The injectate itself can be very toxic to body tissues producing systemic illness. Healthcare professionals must be alert to signs/symptoms of this type of injury by conducting a thorough history and assessment. The author describes the importance of treatment based on symptoms, time, and type of injectate material and emphasizes prevention measures that must be taken. Three case scenarios are provided for discussion.

Apology laws can vary from state to state, and not all states have these laws. Wes Myers presents an excellent overview and discussion of what laws exist nationwide as they relate to expressions of sympathy. The author describes four categories of apology laws, where they exist, and how they are interpreted. The question is what is the impact of these types of laws.

The article by Beth Boynton discusses important strategies to foster positive workplace cultures, the absence of which can lead to negative work environments and potential errors in care. The author discusses the complexity of care delivery and the needed leadership to promote both organizational and behavioral changes including active communication, role modeling skills, and creation of opportunities for team growth.

In our regular departments, we have some wonderful topics presented. Erin Gollogly and Kara DiCecco provide this issue's Clinical Maxim giving an overview of sleep disorders including pathophysiology of selected disorders, high risk profiles, and legal considerations. Also, as supplement to the Maxim are References and Resources that provide numerous link accesses to lots of informative materials for sleep disorders. From our professional practice issues, Eileen Watson discusses how moral distress affects the practice care environment. Included in this discussion are sources and symptoms of moral distress and several strategies are identified to help manage the distress felt in the practice environment. The use and value of patient safety technology is addressed by Judy Bulau as to its effect on patient safety...does it give a false sense of security? The message given by the author is that while patient safety technology can help to improve patient care, in order for it to be effective, it must be used appropriately and correctly by clinicians.

I hope you will enjoy and learn much from the articles in this *Journal* issue – as much as I did!

Bonnie Rogers  
JLNC Editor

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# Breast Cancer Case Review: A Case Study

Cynthia A. Maag, RN, BA, LNCC

Debbie Tipton Winters, RN, NCSN, MSN, MSS

## KEY WORDS

Breast Cancer, Inflammatory, Mammogram, Ultrasound, Radiologist

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*According to the NCI, breast cancer is the most common type of cancer among women in the United States (other than skin cancer), and one of the leading causes of cancer death among women of all races. Inflammatory breast cancer is a rare and very aggressive disease and accounts for about one to five percent of all breast cancers. Five-year survival for patients with inflammatory breast cancer is between 25% and 50%, which is significantly lower than survival for patients with non-inflammatory cancer. This article points out the importance of knowing the patient diagnosis for the type and stage of breast cancer when evaluating a claim of misdiagnosis as well as the extensive record review required. The names in this case have been changed to protect the parties involved.*

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## Introduction

Breast cancer is often considered one of the treatable malignancies, especially if found at an early stage. Therefore, a potentially “missed diagnosis” can bring about fear, mistrust, and perhaps a “viable claim” (e.g., could have been found in an earlier, curable stage) for the increased risk of harm resulting from failure to diagnose and lack of timely treatment.

Inflammatory breast cancer (IBC) is an uncommon form of breast cancer and usually accounts for only one to six percent of all breast cancer diagnoses. It is a form of invasive breast cancer that progresses quickly and the prognosis is poor, even if the disease is apparently localized (Kleer, van Golen, & Merajver, 2000).

Three biological features make inflammatory breast cancer unique (United States Department of Health and Human Services, National Cancer Institute [NCI], 2006).

1. It progresses rapidly and is considered the most lethal type of locally advanced breast cancer.
2. It is highly angiogenic (new blood vessels provide nutrients to proliferating cells), angioinvasive (invading walls of blood vessels), and staged T4 immediately upon diagnosis.
3. Its aggressive behavior is characteristic of the tumor from its inception.

The designation “inflammatory” stems from the clinical appearance which mimics an acute inflammation of the breast. Inflammatory breast cancer is considered a clinical diagnosis. Pathologists rely on the finding of dermal lymphatic involvement to confirm the clinical diagnosis (Kleer et al., 2000). At first presentation, patients diagnosed with IBC are often treated for mastitis. While most breast infections respond to antibiotics, IBC does not, as the dermal involvement (inflammation) is not from infection, but from the blood vessel wall invasion, and dilated dermal lymphatic vessels clogged by tumor emboli. In fact, symptoms of IBC usually do not get better or worse from the antibiotics as an infection would. Therefore, when symptoms (i.e., mastitis, tenderness, nipple retraction) persist more than two or three

weeks despite treatment, more definitive testing and a breast biopsy should be performed to determine whether cancer is present (NCI, 2006).

This case review illustrates some of the strategies used to defend a radiologist. It required testimony of not only expert radiologists, but also of a breast surgeon and pathologist.

The review involves a case in which our firm represented a radiologist from a small hospital. His role in this case, though seemingly minimal, became more primary once discovery was completed. This review will demonstrate how location of the tumor as well as the histology helped the jury find in favor of the radiologist.

## The History

In October 1996, the plaintiff underwent a mammogram which revealed scattered calcifications, dense breast tissue, and benign changes that were considered stable. During a primary clinic visit in June 2000, a certified nurse practitioner and the clinic physician evaluated the plaintiff. At that time the plaintiff was 62 years of age, and the standard of care was a yearly mammogram. As it had been nearly four years since her last mammogram, a mammogram was ordered and completed in July 2000. There was no indication in the records that a breast examination was performed. The screening mammogram report was read by a radiologist as incomplete, needing additional imaging evaluation (representing a Category 0 according to BI-RADS standards). A nodular density was noted on the right side, and an ultrasound and spot compression view was ordered. The screening report noted a small nodule outer right breast which was new since October 1996.

In early September 2000, the plaintiff underwent additional testing at the local hospital. A radiologist (and the defendant in this case) performed a spot compression mammogram and right breast sonogram. The spot compression mammogram, as reported by the defendant radiologist, revealed a four millimeter nodular density localized on cone down magnification (used for a closer

view of an area of concern), smoothly outlined, and of low density radiopaque character, probably representing a small fibroadenoma or cyst. The sonogram noted, at the 10 to 11 o'clock position of the right breast, a 0.5 cm smoothly outlined nodule with no posterior acoustic shadowing which was solid in nature with no adjacent mass. The recommendation was for a repeat bilateral mammogram in one year.

The plaintiff continued with follow up at her primary care clinic in February, March, and April 2001 for routine physical examination, illness, and smoking cessation advice respectively, but without breast complaints. The medical records did not indicate that a breast examination was performed during those visits.

In November 2001, a clinic physician evaluated the plaintiff for pain, swelling, discoloration, and soreness of a lump in her right breast which the plaintiff had noticed about a week earlier, and had worsened. On physical examination, the left breast was normal. The plaintiff reported an exquisitely tender right breast inferior and lateral to the nipple. There was no dimpling of the skin and no retraction, but there was some mild erythema localized inferior to the nipple. The physical examination showed the lump to be rather soft and consistent with an underlying cystic area with no nipple discharge or lymphadenopathy. The assessment demonstrated mastitis and probable cyst in the right breast. The plan entailed a mammogram to be scheduled for early December 2001 and placing the plaintiff on a 14 day regimen of amoxicillin/clavulanate potassium (Augmentin®). Her yearly mammogram had been due in September of 2001, but had not been performed.

The plaintiff returned to her primary care physician at the clinic in early January 2002 complaining of pain with persistent redness and now swelling of her right breast, noting no improvement from the amoxicillin/clavulanate potassium (Augmentin®) treatment. The right breast examination demonstrated induration around the nipple with erythema and no definitive mass. The nipple showed mild retraction and a palpable, tender 1 cm right axillary lymph node, not noted on the examination documented 2 months prior. The physician ordered a different antibiotic, a hot pack to the affected breast four times per day, and a diagnostic mammogram with ultrasound (because the plaintiff had not made an appointment for the ordered mammogram in December 2011). After the mammogram was completed on January 9, 2002 and read by a staff radiologist as negative, the ultrasound was cancelled. When the plaintiff returned to her primary care physician the following week for an examination, the right breast remained indurated, but improved. The physician diagnosed mastitis and prescribed additional antibiotics with a follow up appointment in three weeks.

The plaintiff called her primary care clinic office at the end of January with a status report that her breast had not improved, and she was advised to undergo ultrasound and a biopsy. An ultrasound evaluation was ordered on 18 February 2002 and showed a hypoechoic [...ultrasound image in which the echoes are weaker or fewer than normal...]

(*Stedman's Medical Dictionary for the Health Professions and Nursing*, 2005, p.707)] nodule at approximately 10 o'clock to 11 o'clock in the affected breast. No history or indication for the examination was documented on the report.

The primary care clinic physician referred the plaintiff to a consulting breast specialist in St. Louis, Missouri on February 20, 2002. The breast specialist noted that the plaintiff's right breast demonstrated patchy distributed edema with erythema of the lower two-thirds of the breast. Induration of the breast existed between the 6 and 9 o'clock positions near the nipple. However, extensive edema interfered with locating a definitively palpable mass. The consulting physician noted evidence of *peau d'orange*, "a French term, meaning orange peel" (*Stedman's Medical Dictionary for the Health Professions and Nursing*, 2005, p. 1094), which showed a swollen and pitted skin surface accompanied by stromal infiltration and lymphatic obstruction with edema. The physician also palpated within the axilla two distinct firm mobile areas of lymphadenopathy, with lymph nodes measuring to 3 cm. A biopsy revealed grade III/III infiltrating ductal carcinoma with extensive lymphovascular space invasion.

The consulting physician diagnosed the plaintiff with inflammatory breast cancer [T4] due to the clinical characteristics, which were supported by biopsy, and referred the plaintiff to a medical oncologist for further treatment. The tumor was estrogen and progesterone receptor negative and human epidermal growth factor receptor 2 (HER2/neu) overexpression as documented by immunohistochemical studies. The plaintiff underwent a regimen of anthracycline and taxane which led to marked reduction of edema and complete resolution of the *peau d'orange*. No underlying masses remained evident. The plaintiff completed four courses with this chemotherapeutic combination in May 2002, followed by four courses of docetaxel (Taxotere®) alone, completed in July of 2002.

On August 26, 2002 the plaintiff noted a new onset of erythema in the right breast. With the plaintiff's chemotherapy regimen completed, she was referred to a breast surgeon for further treatment. The surgeon scheduled the plaintiff for a right modified mastectomy in September 2002. The pathology report revealed infiltrating ductal carcinoma, grade 2 of 3, measuring 0.9 cm with involvement of 14 of 15 axillary nodes and extensive involvement of axillary angiolymphatic spaces and focal extension beyond her lymph node capsules. A consulting radiation oncologist explained that the plaintiff was at high risk for distant and loco regional recurrence due to the presence of multiple positive lymph nodes, the large size of her primary tumor prior to chemotherapy, the presence of inflammatory disease, as well as the extracapsular nodal extension seen on dissection.

## The Case

In October 2002 the plaintiff filed suit against the radiologist who interpreted the spot compression and ultrasound radiographs in September 2000, the hospital where those radiographs were performed, the corporation that owned the

hospital, and the plaintiff's primary care clinic and physicians. This article addresses only the defense of the radiologist who interpreted the spot compression and ultrasound radiographs. The allegations were that the radiologist:

- Misread the mammogram
- Misread the sonogram
- Failed to diagnose the plaintiff as having infiltrating ductal carcinoma
- Failed to recommend a biopsy of the plaintiff's right breast to rule out carcinoma
- Misinterpreted the nodule as benign
- Was negligent in his recommendations, given the facts surrounding the plaintiff's illness history

In January 2003 the defendant radiologist met with his attorney to discuss his involvement in treatment of the plaintiff. His only involvement was to perform a spot compression film and ultrasound of the right breast in September 2000. The plaintiff had undergone a screening mammogram which one of his partners read in July 2000. After review of those specific mammography radiographs, and all mammograms taken prior to and after that date, the defendant radiologist maintained his initial interpretation that the nodule he evaluated remained in the right breast even after the biopsy for suspected breast cancer (the cancer was found in a different part of the breast). Accordingly, he believed that a benign finding was indeed appropriate and was not cause of concern to the physicians who suspected the plaintiff had breast cancer.

Two radiologists, both breast imagers from separate institutions, were consulted to review the films read by the defendant. Both consulting radiologists agreed with the interpretation made by the defendant radiologist. The spot film of September 2000 showed the nodule which had smooth margins and did not appear suspicious. The ultrasound, which both radiologists agreed was not a clear film, showed the oval shaped nodule, which also did not appear suspicious.

The plaintiff's expert witness radiologist practiced at a women's center for radiology located in Florida. He was not sure when the plaintiff developed breast cancer in her right breast, but believed it was present in July 2000, two months before the defendant radiologist's involvement. He stated that the previous mammogram of 1996, which he believed showed an ovoid mass measuring five millimeters compared to the mammogram of July 2000, indicated a small interval change in terms of measurement. The plaintiff's expert witness radiologist attested that as of September 2000, the mass comprised a six to seven millimeter lesion with irregular borders and that this lesion represented a small invasive cancer, probably infiltrating ductal carcinoma. He further asserted that between September 2000 and January 2002, the cancer changed to inflammatory breast cancer. The problem with this assertion is that inflammatory breast cancer is "inflammatory" from inception. IBC is an aggressive form of breast cancer that is highly angioinvasive and angiogenic, and these characteristics are present from its inception. Signs

and symptoms are rapidly progressive with a median duration before diagnosis of less than two months (Kleer et al., 2000).

The main criticism made by the plaintiff's expert witness radiologist of the defendant radiologist was that he recommended the plaintiff return in 12 months for follow up imaging. The plaintiff's expert radiologist believed that the defendant radiologist identified the lesion as a solid lesion rather than cystic, and that the defendant should have commented that the borders were somewhat irregular and suspicious, possibly indicating cancer. (The defendant actually read and reported that the nodule represented either a small fibroadenoma or cyst). The plaintiff expert witness radiologist believed that the standard of care dictated a recommendation for the plaintiff to return no later than six months for a subsequent evaluation.

The defense expert radiologists were then asked to review and compare the radiologic films from October 1996, July 2000, September 2000, January 2002, and February 2002 overall, mammogram to mammogram, and ultrasound to ultrasound. Both defense expert radiologists requested the original films for review. However, it was discovered the original films had been given to the plaintiff's attorney who indicated the radiographs were lost in the mail when sent to the plaintiff expert radiologist for review. Second generation copies of the radiographic films were obtained for the radiologists to review. (When obtaining films, rather than copies on disk, first generation copies are always the "clearest" to review. There is no overshadowing on a first generation copy as there is when, for example, a copy of a copy is made. The more copying that is done, the muddier the films become – and they ultimately become unreadable).

Both defendant expert radiologists, each separately, reviewed the 1996 mammogram to determine the location a 5 mm ovoid mass reported by the plaintiff's radiology expert. Both defendant expert radiologists reported no such mass was visible and neither found anything on the radiographic film that could have been interpreted as a lesion. They reviewed the July 2000 mammogram and noted a nodule measuring about five to six millimeters, but it was not irregular. The reading radiologist in July 2000 noted this nodule to be "new" when compared to the 1996 film and therefore, by inference, that reading radiologist also did not note a lesion in the 1996 film. The defense expert radiologists reviewed the September 2000 spot film performed by the defendant radiologist and noted a nodule with a portion of the margin not visible, but that the visible margin was smooth. Additionally, the defendant expert radiologists reviewed the September 2000 ultrasound and noted the nodule as being oblong and unsuspecting.

The American College of Radiology (ACR) 2000 guidelines recommend a repeat mammogram one year after unsuspecting (or benign) findings (ACR, 2002). This was recommended by the defendant radiologist, in accordance with the dictated standard of care.

Separately, each defendant expert radiologist reviewed the January 2002 mammogram. While both noted significant changes in this radiographic film, they interpreted the findings



as benign. Both further noted an enlarged lymph node in the axillary region which had not been reported in the January 2002 mammography report. Each separately reviewed the February 2002 ultrasound and noted diffuse shadowing in the area of the areola as well as inflammatory changes and thickened skin – indications that are highly suspicious for a breast cancer. Important in this 2002 radiographic film was that the five to six millimeter nodule was still located in the same place it had been seen in September 2000 and was unchanged. Therefore, both defendant expert radiologist witnesses believed this nodule was not cancerous.

Approximately one month before trial, the defendant radiologist's legal counsel contacted the plaintiff's surgeon, who was not being called as a witness in this case by either side, to discuss the case. On interview, the plaintiff's surgeon recalled that she had only reviewed the 2002 diagnostic radiographic films when she had met with the plaintiff prior to her surgery. The defendant radiologist's legal counsel scheduled a meeting with the surgeon and brought the radiographic films of July 2000 (mammogram) and September 2000 (spot compression and ultrasound) for her to evaluate. Based on her observation (the nodule mentioned in both reports), and stipulating that she was not a radiologist, the surgeon asserted that she would not have been alarmed by what she observed and would not have chosen to perform a biopsy.

The plaintiff's surgeon stated she did not believe that the nodule found on the July 2000 mammogram and the September 2000 spot compression radiographic film was a source for the IBC diagnosed in February 2002. The surgeon also stated that diffusion from disease would have markedly changed the appearance of the nodule, thus making it unidentifiable by 2002. She stated, "IBC does not slowly smolder for two years, but is in fact incredibly fast growing."

Further, the pathology report from the mastectomy performed in September 2002 indicated that a 0.9 cm nodule was found in the posterior central locale of the right breast. (As previously mentioned, mammogram and ultrasound reports from September 2000 revealed a five to six millimeter nodule in the right outer breast.) The surgeon believed that, post chemotherapy, this nodule was most likely residual from the original tumor. She also indicated that based on location of the inflammation noted at diagnosis, this area was very likely the original source of the cancer, and that the nodule in the right outer breast was simply a benign process which, had it been otherwise, would have been noted in the mastectomy September 2002 pathology report.

## The Trial

At trial, the plaintiff's experts (a surgeon and radiologist) and her treating medical oncologist presented the following key points:

- Tumors generally grow in size and would be expected to grow in the normal course of disease progression.
- It is possible to have cancer in one breast and not the other. Further, one can have a non-cancerous mass and a

different cancerous mass, both concurrently in the same breast.

- The pathology report neither asserts nor denies the previously detected nodule was the subsequently detected cancer.
- Those testifying on behalf of the plaintiff believed a biopsy in September 2000 would have revealed a 4 mm invasive ductal carcinoma. At that point (Stage 1), one would expect a 95 % five-year survival rate.
- Seventy percent of breast cancers occur in the outer part of the breast, closest to the axilla.
- Chest wall recurrence carries a 5 to 10 % five-year survival rate.
- The risk of recurrence in any IBC is 50 % at the time of completion of radiation. One-half of patients detected with IBC develop metastatic disease.
- The lymph nodes were removed to reduce the likelihood of recurrence in this patient and to evaluate the efficacy of preoperative chemotherapy. In this patient, 14 of 15 nodes proved positive for tumor at the time of mastectomy and post chemotherapy.
- A patient is never "cured" of breast cancer.
- Two equally trained and qualified radiologists may examine a film and interpret it differently, but if this happens, one of them is probably deviating from the standard of care.
- There is evidence of right breast cancer dating to July 2000 which some examiners might have diagnosed as early as June 2000.
- A recommendation of repeat bilateral mammograms in one year is misleading, because it suggests that there was no significant finding.

The defendant's experts (a radiologist and pathologist) and the plaintiff's treating breast surgeon presented diagrams indicating where the nodule was located in the July 2000 mammogram and where the tumor was found in the mastectomy specimen. They asserted the following key points:

- The plaintiff's cancer was not related to the nodule found in September 2000. This nodule was stable for at least 15 months.
- Biopsy is not indicated for small fibroadenomas of less than 0.5 cm.
- Biopsy is appropriate only when fibroadenomas are large, about three times larger than the one noted in this case, or if they grow over time.
- Infiltrating ductal carcinoma with extensive lymphovascular space invasion was found below the nipple in the deep part of the breast.
- The defendant radiology expert witness stipulated that the defendant acted within the standard of care in his reading of the spot compression and ultrasound performed in September 2000.
- If the nodule found in September 2000 had been cancerous, it would have changed in size, shape, and location over time, but it did not.

- This nodule was not consistent with malignancy and appeared to be benign, contrary to testimony by the plaintiff's radiology expert.
- Fibroadenomas commonly appear in women of this age.
- One year follow up evaluation was appropriate.
- The nodule biopsied by the plaintiff's surgeon was located in the midline of the breast behind the nipple and was not in the same area as the nodule previously discussed which was located between the 10 to 11 o'clock positions.

The trial took place over a three-day period. The co-defendant (plaintiff's primary clinic physician) entered a Motion for Directed Verdict at the close of all evidence, and was sustained, indicating that the plaintiff was unable to prove a case against him. The defendant radiologist's Motion for Directed Verdict was over-ruled, indicating that the plaintiff could show cause. The case went before the jury on day three at 3:05 in the afternoon and, after deliberating only 30 minutes, a verdict in favor of the defense was returned.

## Discussion

Breast cancer, as well as all cancers, is often a topic filled with emotion in a courtroom because of the long term consequences and survival. In this case, the plaintiff was present at the trial, having surpassed the five-year survival statistics.

When evaluating an oncology case, it is important for the legal nurse consultant to have a thorough knowledge about the specific cancer including symptoms, tests required for diagnosis, pathology (e.g. grading, immunohistochemistry panels, and differentiation), staging, and treatments. It is also important to determine early identification and prognosis.

In this case it was important to obtain all of the previous mammograms for comparison from the various institutions. This was essential in order to determine exactly when this nodule was first seen, and if there were any new findings. A significant and important point in this case was the nodule remained in the same location after biopsy. Because breast cancers change over time, and because IBC develops rather quickly, it was highly unlikely that this was the origin of the cancer.

The legal nurse consultant provides strategic expertise while researching specific information related to the case in

question and a thorough comprehensive review of all medical records from all sources. By doing so, comparisons can be made based on the evidence.

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# Medical Record as a Legal Document Part 1: Setting the Standards

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## KEY WORDS

Accreditation, Documentation, HIPAA, Medical Record, Policy, Procedure, Regulations, Standardize Procedures, Standards

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*A medical record may be accessed for treatment purposes, payment purposes, or healthcare operations, that is, peer review activities, quality management, documentation reviews, and teaching. This article is presented in two parts; Part 1 addresses the medical record as a legal document and Part 2 will address documentation within the medical record. As a legal healthcare business document, medical record management must adhere to applicable federal and state regulations and meet minimum professional standards set by accrediting agencies and institutional policies. Healthcare providers are responsible for knowing the regulations and standards affecting their practices.*

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The medical record is a legal document intended to communicate pertinent information such as diagnosis and treatment, reduce medical errors, and ensure patient safety and continuity of care. Electronic medical record (EMR) systems are expected to improve documentation as well as the quality of patient care delivered. Currently, there is ongoing development of standards with only 2% of acute care hospitals having a fully implemented and comprehensive system and 8% to 12% who have a basic system. So, this goal has not yet been met [Centers for Medicare & Medicaid Services (CMS), 2011; Jha, et al., 2009; Health Level Seven International, n.d.]. The principles of documentation in the medical record are applicable whether hard copies or electronic records are used. A record must be documented and kept during the course of care, made at or near the time of the matter recorded, and made by the healthcare provider having knowledge of treatments, events, and diagnoses. Electronic medical systems must have a mechanism to control access, authenticate the signature of the actual provider of care versus another person entering or altering data, provide an audit trail of all transactions and activities within the record, and there must be a backup plan in case of system failure [American Health Information Management Association (AHIMA), 2005].

The purpose of complete and accurate patient record documentation is to foster quality and continuity of care. It creates a means of communication between providers and between providers and patients about health status, preventive health services, treatment, planning, and delivery of care. As a legal document it must be maintained in accordance with applicable regulations, accreditation standards, and professional standards of practice.

## Medical Record Ownership

The medical record is the property of the facility but the information contained in the record must be accessible to the patient and his or her legal representative upon request and authorization by the patient. A director of medical records is responsible for assuring there is a complete and accurate

medical record for each patient and that records are kept in a safe and secure area to prevent loss, destruction, and/or tampering. All medical records must be retained for at least as long as required by state and federal law and regulations. To protect information, the medical record should be shredded before disposal.

## Legal Requirements

The American legal system is rooted in federal and state constitutions, federal and state statutes, administrative agencies' rulings, and court decisions. The Constitution establishes the organization of the federal government and grants limited expressed, and implied powers to three branches: legislative, executive, and judicial. The power to collect taxes is an example of *expressed* power while the right to enact laws is *implied* as necessary to exercise its other powers. Federal law established within the scope of the federal government's power is absolute and cannot be superseded by state or local laws (Roach, Hoban, Broccolo, Roth, & Blanchard, 2006).

Legislative bodies enact statutory laws with federal legislation taking precedence over state legislation unless Congress has explicitly or implicitly exempted the states from compliance with the federal law. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Employee Retirement Income Security Act (ERISA) of 1974 are two laws affecting healthcare that are subject to exemptions (Roach et al., 2006).

## Federal Law

### Privacy and Security Rules

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule of 1966 (Public Law 104-191), set the standards for electronic privacy, security, and exchange of health information (Annas, 2003). Privacy and security rules are applicable to healthcare providers, health insurance companies, healthcare organizations, and entities that transmit any health information in an electronic form. Workers who have access to medical records must be

educated about privacy rules and procedures and sanctions levied against workers who violate the policies and procedures related to the Privacy Rule.<sup>i,iii</sup>

The Privacy Rule guards an individual's right to privacy and control of disclosure of certain health information. Enforced by the Department of Health and Human Services' (DHHS) Office for Civil Rights (OCR), the Privacy Rule is applicable to personal health information, whether oral, written, or electronic, and regulates who can access or receive a copy of a patient's health information. "Protected health information," is defined as *identifiable* demographic information including name, birth date, and social security number, that can be correlated to an individual's past, present, or future physical or mental healthcare provided, or payment for the treatment provided to an individual.

A disclosure is defined as "the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information."<sup>iii</sup> Disclosure of protected information is allowable if an individual (or the personal representative legally authorized to make healthcare decisions on an individual's behalf) has authorized the release of information in writing. Authorization for disclosure of protected information must clearly specify the information to be disclosed, the name of the person receiving the information, the purpose for disclosure, and the expiration date of the authorization. The entity providing the information must make every reasonable effort to provide only the *minimum necessary* and not release the whole medical record. Facilities should have policies and procedures in place outlining criteria of what is reasonable when determining the minimum necessary. The principle of minimum necessary does not apply to the disclosure to the person who is the subject of the medical record and/or who has authorized the disclosure, or to requests by another healthcare provider for the purpose of treatment. Nor does it apply when the DHHS requires disclosure of information in the course of an investigation and enforcement of regulations. The Health Information Technology for Economic and Clinical Health Act (HITECH) adds to HIPAA protection by giving patients the right to know who has accessed their EMR. Title 45 of the Code of Federal Regulations (CFR) § 164.528(a) (1) requires an accounting of each disclosure to include the name and address of the individual receiving the information, a brief description of the disclosure, and a brief statement of the purpose of the disclosure.

A notice of privacy practices must be provided by each covered entity to individuals seeking healthcare on the first encounter, or, in the case of an emergency, as soon as practicable. The notice must state the entity's duty to

protect the individual's privacy, its privacy practices, and the individual's rights, including the right to file a complaint with the DHHS. Acknowledgement of the privacy practices should be obtained from the individual receiving it.

Designated record set defines the group of records maintained to support treatment decisions and records related to billing. Designated record set may be subject to disclosure on specific request or subpoena. Individuals have the right to request these records for review and to request that inaccurate or incomplete information be amended. If denial of this request is made, it must be in writing. If desired, the individual can prepare a statement of disagreement which is to be added to the record. An individual can also request a list of disclosures made and may request restrictions be put in place. If accepted, requested restrictions must be complied with except in emergency medical situations.<sup>iv</sup>

The HIPAA Security Rule sets the national standard for security of EMRs and is enforced by the OCR. It requires safeguards to be in place to protect confidentiality, integrity, and availability of protected health information. Confidentiality means the information is not to be disclosed to unauthorized individuals, integrity means the information in the record is not to be altered or destroyed, and availability means the information is to be available and usable to authorized individuals (Aikins, 2000). Risk analysis and management of the security process should be periodic and ongoing.

Safeguards include limiting access to authorized individuals by means of passwords, access codes, and key cards to authenticate the signature of the staff member making entries. Technical safeguards also include a system to audit activity and ensure information is not altered or improperly destroyed and to protect information being transmitted over an electronic network. Policies and procedures should be at each workstation to be sure protected health information is not removed, transferred, or re-used without authorization.<sup>v</sup>

#### **Patient Bill of Rights (PBOR) and the Patient Protection and Affordable Care Act**

Many states recognize that patients have the right to be treated with respect, to make choices about treatment and end-of-life decisions, to informed consent, to obtain a copy of their medical records, and to privacy (Roach et al., 2006), but few states had enacted a patient bill of right's (legislation, deferring to federal regulations. HIPAA guidelines have been individualized to each state and are available to consumers.<sup>vi</sup> State governments are the largest purchasers of health insurance and it was feared that the cost of premiums would rise dramatically and liability would be increased (Brunner, 2000).

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i. Copy of the law may be retrieved from <https://www.cms.gov/HIPAAgenInfo/Downloads/HIPAALaw.pdf>

ii. Center on Medical Record Rights and Privacy based at Georgetown University's Health Policy Institute provides information to stakeholders regarding medical record privacy accorded by HIPAA. (<http://hpi.georgetown.edu/privacy/records.html>)

iii. 45 CFR § 160.103

iv. 45 CFR Parts 160, 162, and 164 Retrieved from <http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/adminsimpregtext.pdf>

v. 45 CFR Part 160, and 164

vi. A Guide to Consumer Rights under HIPAA. Retrieved from <http://ihcrp.georgetown.edu/privacy/stateguides>

While the federal healthcare reform law is predicted to cut premiums, at least 45 states challenging the constitutionality of the bill either oppose or propose legislation to limit or alter the Affordable Care Act (Cauchi, 2012).

Efforts to secure a PBOR failed to pass the United States Congress; however, the American Hospital Association (AHA) recommended and The Joint Commission (TJC) set a PBOR as one of the criteria for accreditation (Paache-Orlow, Jacob, Hochhauser & Parker, 2009). The AHA's PBOR points out the need for "collaboration between patients and physicians and other healthcare professionals" (AHA, 1992)<sup>vii</sup>. Each state regulates licensing of healthcare professionals and healthcare facilities; however, patient rights, unless protected by state law, were subject to being preempted by the Employee Retirement Income Security Act (ERISA) of 1974 (The White House, n. d.). ERISA, which is a federal law that sets the standards for pension plans in private industries, provides health benefits through self-insured health plans; however, terminology is not precise, leaving the Supreme Court to interpret the law on a case-by-case basis (Chaikind, 2003).

The Patient Protection and Affordable Care Act (Affordable Care Act)<sup>viii,ix</sup>, opposed by at least 45 states, (Cauchi, 2012; Rivkin & Casey, 2011),<sup>x</sup> is predicted to enhance the quality of care for Americans, by expanding healthcare coverage to make it accessible and affordable to all Americans, implementing the Patient's Bill of Rights,<sup>xi</sup> encouraging the use of EMR, and setting new standards for securing and electronically transferring health information. The effect of the Affordable Care Act (slated to be fully implemented in 2014) on HIPAA, and individual state laws that have influenced the impact of HIPAA in the matter of confidentiality of medical records and patient rights, will not be fully evident until the expanded provisions and operating rules have been adopted and are in place, and court rulings are finalized.

### Nursing Home Regulations

In 1987 President Reagan signed into law the Omnibus Budget Reconciliation Act (OBRA' 87), which established the rights of nursing home residents and set the expectation that facilities receiving Medicare or Medicaid funding provide services that ensure a resident can "attain and maintain his

or her highest practicable physical, mental, and psychosocial well-being."<sup>xii</sup> This law, also referred to as the Nursing Home Reform Act, attempts to improve the quality of care and the quality of life for residents of skilled nursing facilities. Title 42 Part 483 of OBRA' 87, as delineated in revisions of the State Operations Manual (2011) requires the following:

- The facility ensures that resident and facility records are well maintained, complete, and accessible for review by regulatory agencies. (42CFR 483.75(l) (1) F514)
- The facility ensures comprehensive assessment of each resident. (42CFR 483.20(b) F272)
- The facility provides a prompt assessment after residents experience significant changes. (42CFR 483.20(b) (4) (iv) F274)
- The facility develops comprehensive care plans for each resident that include measurable objectives and time tables to meet each resident's medical, nursing, and mental needs. (42CFR 483.20(d) F279)

The DHHS is authorized under the Social Security Act (SSA) to specify a minimum of core assessments of nursing home residents and to designate a resident assessment instrument. All residents in Medicare or Medicaid certified nursing facilities, whether or not the residents are receiving Medicare or Medicaid, are mandated to undergo a clinical assessment using the Minimum Data Set (MDS) process.<sup>xiv</sup> Assessment of a resident's needs must be comprehensive and the process must include direct observation and communication with the resident and communication with all direct care staff on all shifts. MDS 3.0, to be used in all nursing facilities nationwide as of October 2010, seeks to standardize assessment and facility care management in nursing homes.<sup>xv</sup> Designed to improve reliability, accuracy, and usefulness, the MDS should include resident input in the assessment process and follow standard protocols.

The MDS process includes the Resident Assessment Instrument (RAI) providing a comprehensive assessment of each resident's functional capabilities and helps nursing facility staff identify health problems.<sup>xvi</sup> There are three basic components of the RAI: MDS version 3.0, Care Area Assessment (CAA) process, and Utilization Guidelines which together provide information about a resident's functional status, strengths, weaknesses, and preferences.<sup>xvii</sup> The MDS screens a resident's clinical and functional status; the CAA

vi. A Guide to Consumer Rights under HIPAA. Retrieved from <http://ihcrp.georgetown.edu/privacy/statelguides>

vii. Available at <http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml>

viii. Affordable Care Act Pub. L. 111-148 amended ERISA to include HIPAA and make healthcare coverage more portable

ix. Available at <http://housedocs.house.gov/energycommerce/ppacacon.pdf>

x. States seeking to appeal the Affordable Care Act: Alabama, Alaska, Arizona, Colorado, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Louisiana, Maine, Michigan, Mississippi, Nebraska, Nevada, North Dakota, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Utah, Washington, Wisconsin, and Wyoming

xi. Available at <http://www.healthcare.gov/law/features/rights/bill-of-rights/index.html>

xii. CFR 42 §483.25 Quality of Care

xiii. Sec. 1819. [42 U.S.C. 1395i-3] Retrieved from [http://www.socialsecurity.gov/OP\\_Home/ssact/title18/1819.htm](http://www.socialsecurity.gov/OP_Home/ssact/title18/1819.htm) Defines skilled nursing facility and the scope of services that must be provided.

xiv. Social Security Act §1819(f)(6)(A-B)

xv. *MDS 3.0 for nursing homes and swing bed providers*. Retrieved from [http://www.cms.gov/NursingHomeQualityInits/25\\_NHQIMDS30.asp](http://www.cms.gov/NursingHomeQualityInits/25_NHQIMDS30.asp)

xvi. 42 CFR 483.20(b)(1) and 483.20(c)

xvii. CMS's RAI Version 3.0 Manual, Chapter 1: RAI, section 1.1

helps the clinician develop a potential problem list and determine whether a care plan is needed; and the Utilization Guidelines provide instruction on how to complete the RAI.

A RAI specified by the state should be used and at a minimum, the assessment should include:

- Identification and demographic information
- Customary routine
- Cognitive patterns
- Communication
- Vision
- Mood and behavior patterns
- Psychosocial well-being
- Physical functioning and structural problems
- Continence
- Disease diagnoses and health conditions
- Dental and nutritional status
- Skin condition
- Activity pursuit
- Medications
- Special treatments and procedures
- Potential for discharge

Assessments must be authenticated as complete by the individuals performing the assessments. False statements are subject to a civil monetary penalty of up to \$1000 for each assessment.

### Hospital Regulations

Hospitals accepting Medicare must comply with 42 CFR §482.24 which requires a medical record be maintained for each individual seen and treated in the hospital and to “ensure prompt completion, filing, and retrieval.” Section 482.24(c) of the regulation states the medical record, for both inpatient and outpatient (which includes departments such as radiology, laboratory, and physical therapy), must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services.” Section 482.24(c) (1) requires records to be “legible, complete, dated, timed, and authenticated in written or electronic form” by the person responsible for providing services. All orders should be dated, timed, and authenticated promptly by the ordering practitioner. Verbal orders must be authenticated within 48 hours (or less if required by State law).

Documentation of the following is required:

- A medical history and physical examination completed within 24 days before or 24 hours after admission must be placed in the record with 24 hours of admission or registration. If surgery or a procedure is to be performed, the history and physical must be completed prior to anesthesia being administered
- Admitting diagnoses



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- Results of consultative evaluations
- Notation of complications, infections, and/or adverse reactions
- Consent forms for procedures
- Healthcare provider notes, for example, physician orders and progress notes, nursing notes, radiology and laboratory results, and vital signs
- Discharge summary that includes outcome of hospitalization, disposition, and provisions for follow-up care
- Final diagnoses is to be entered into the medical record within 30 days following discharge

Records must be retained for five years.

### Community-Based Ambulatory Care Regulations

Community-based ambulatory settings are free standing facilities not directly related to a hospital, such as a community health center, student health centers, employee health center, correctional facility health centers, ambulatory surgical center, private practices, health maintenance organizations (HMOs), renal dialysis centers, cancer treatment centers, rehabilitation centers, and home health and hospice programs. Ambulatory care centers that participate in the Medicare program and use EMRs must satisfy the HIPAA conditions (Lessig, 2001). In an attempt to define the MDS and promote uniformity in medical records, the DHHS promulgated the Uniform Ambulatory Care Medical Data Set (Jackson, Krueger, & Densen, 1975; Perrin, et al., 1974). Medical records should include patient and provider encounter information such as:

- Patient identification information, that is, sex, birth date, residence, source of payment
- Place and reason for encounter
- Visit date, length of visit, and provider
- Services provided, that is, procedures, diagnostic test results
- Findings, that is, relevant history of the illness/injury and physical finding and clinical observations, diagnostic test results
- Diagnostic impression
- Referral, disposition, and pertinent instructions

Other information to be included:

- Immunization record
- Allergy history
- Problem list
- Growth charts for pediatric patients
- Return visit date

## State Laws

### Practice Acts

Practice Acts (e.g., the Nurse Practice Act) are laws promulgated by each state to protect the public health by defining the licensing provisions and the scope of a healthcare provider's practice within the state's jurisdiction. These broadly written laws provide the healthcare provider with legal authority for common practice functions and procedures

to, directly or indirectly through delegation, ensure the safety and comfort of patients and to provide disease prevention and restorative measures. Healthcare providers are responsible for practicing in accordance with their discipline's regulations.

## Institutional Policies and Procedures

Healthcare institutions must meet requirements enacted by law or may set stricter requirements and thereby raise the standard of care. Medical record standards are guided by written institutional policies and procedures that reflect the requirements established by federal and state laws and regulations. Institutional policies are the institution's regulations and set minimal standards for clinical practice for that facility. Policies or protocols explicitly outline the required procedures to be followed to ensure the medical record is created and maintained in accordance with statutes. Confidentiality, access, identification information, completion, timeliness, late entries, authentication, ownership, retention and storage are among the issues addressed.

The definition of medical protocol proposed by the Connecticut Hospital Association and approved by the Connecticut Board of Examiners for Nursing follows:

a medical protocol is considered to be a set of predetermined criteria that defines appropriate interventions that articulate or describe situations in which the nurse makes judgments relative to a course of action for effective management of common patient care problems (Connecticut Board of Examiners, 2004).

Protocols are important formalized tools used to support diagnosis and treatment decisions, reduce variations in care while improving the quality of care, and improve cost efficiency. Formalization of a protocol attempts to limit ambiguity, incompleteness, inconsistency, and redundancy. Protocols target a particular discipline (e.g., physician or nurse), cover a particular clinical diagnosis or treatment (e.g., diabetes mellitus), provide a plan of action, and specify a time span although with some execution time flexibility. A protocol plan may be divided into subplans allowing for individual circumstantial variability while maintaining the intention of the protocol (Del dof, 2002).

Procedures provide guidelines on achieving activities required by institutional policies. Guidelines are recommendations intended to assist the healthcare provider's decision-making. As recommendations, guidelines do not set standards but are expected to be adapted as necessary to meet clinical needs [American Society of Anesthesiologists (ASA), 2012]. However, some courts and state statutes find that guidelines promulgated by consensus of an authoritative body do reflect standards of practice.<sup>xviii,xix,xx</sup>

Procedures differ from standardized procedures. A standardized procedure, established as a permissible function by state regulations, and created in collaboration of an interdisciplinary healthcare team, should be in writing, dated,

and signed by an authorized facility agent, and is subject to periodic reviews. It should specify the procedure functions and requirements that need to be met as well as the scope of supervision required, and qualifications and the experience of individuals authorized to perform the procedure. In addition, circumstances requiring the practitioner to communicate with the physician regarding the patient's condition should be clearly stated and medical record documentation requirement specified (California Board of Registration of Nursing, 2011). Examples of standardize procedures include policies authoring and defining the scope of practice for nurse practitioners or defining a patient restraint policy.<sup>xviii</sup>

## Professional Standards

Professional organizations (e.g., American Hospital Association, American Medical Directors Association, American Nurses Association, American Physical Therapy Association, and American Occupational Therapy Association) supplement statutory regulations and promote quality patient care by setting the standards of competency and conduct for practitioners. A standard reflects the minimal requirements and a standard of care holds a person of exceptional skill or knowledge to a duty of acting as would a reasonable and prudent person possessing the same or similar skills or knowledge under the same or similar circumstances. For instance, a nurse will be judged against another nurse with similar qualifications in similar circumstances.

Standards and scopes of practice are subject to review and revision to keep pace with changes in practice, role expansion, and new technology. The American Nurses Association, in seeking member input into revising standards, pointed out:

"When malpractice or inappropriate professional conduct is alleged against a nurse, the nurse's actions are often evaluated using the ANA standards as well as facility policy. As a practicing professional, the nurse has a responsibility to know and act in concert with standards of practice" (Di Leonardi, n. d.).

In addition to monitoring changes in practice, professional organizations monitor legislation affecting practice. Legal advisories and guidelines are published to advise members of key issues and initiatives in a practice area. Resources are made available to members to help them meet the mandated and recommended changes, for example, the American Hospital Association (2010) issued *Legal Advisory: HITECH's Modifications to HIPAA Requirements: The Proposed Rule*. Initially issued in 1973, the ANA's *Patient's Bill of Rights*, has been updated and expanded to include patient

responsibilities and is found in hospitals and healthcare organizations throughout the United States.<sup>xxii</sup>

## Accreditation Organizations

Healthcare accreditation organizations seek to improve healthcare delivery by evaluating healthcare facilities and promoting safe and high quality care. Such organizations assess medical records to ensure the required records are maintained (e.g., physician's orders, progress report, nurse's notes etc.) and that they are organized, well documented, authenticated, legible, and timely. The process ensures the standards are met versus setting the standards.

Participation in Medicare or Medicaid programs requires a healthcare organization meet eligibility requirements for program participation. The accreditation process requires periodic unannounced on-site surveys to determine if a facility meets pre-defined standards with the goal of improving the quality and safety of care provided. Accreditation is a formal self-assessment and external peer assessment process to determine if a healthcare facility is in compliance with conditions of participation (CoP). The 19 areas of concern reviewed to determine if a hospital meets CoP are as follows:

1. Compliance with federal, state, and local laws
2. Governing body
3. Quality assurance
4. Medical staff
5. Nursing services
6. Medical record services
7. Pharmaceutical services
8. Radiologic services
9. Laboratory services
10. Food and dietetic services
11. Physical environment
12. Infection control
13. Surgical services
14. Anesthesia services
15. Nuclear medicine services
16. Outpatient services
17. Emergency services
18. Rehabilitation services
19. Respiratory care services (United States General Accounting Office, 1990).

Each service is looked at with respect to rights of patients, governance, administration, quality of care provided, quality management and improvement, clinical records and health information, infection prevention and control, and facilities and environment. Medical records are reviewed for organization and consistency in documentation of the

xviii. *Pollard v. Goldsmith*, 572 P.2d 1201 (Ariz. App. 1977)

xix. Me. Rev. Stats. Ann. §2975

xx. Ky. Rev. Stat. §342.035

xxi. University of Connecticut John Dempsey Hospital Administrative Manual Restraint policy is available at [http://nursing.uhc.edu/hosp\\_admin\\_manual/docs/08-045.pdf](http://nursing.uhc.edu/hosp_admin_manual/docs/08-045.pdf)

xxii. A copy of AHA's Patient's Bill of Rights is available at [http://www.qcc.cuny.edu/socialsciences/ppectorino/MEDICAL\\_ETHICS\\_TEXT/Chapter\\_6\\_Patient\\_Rights/Readings\\_The%20Patient\\_Bill\\_of\\_Rights.htm](http://www.qcc.cuny.edu/socialsciences/ppectorino/MEDICAL_ETHICS_TEXT/Chapter_6_Patient_Rights/Readings_The%20Patient_Bill_of_Rights.htm)



**Table: Accreditation Organizations with “deeming authority” granted by CMS**

ORGANIZATION	FACILITY
<p><b>The Joint Commission (<a href="http://www.jointcommission.org">http://www.jointcommission.org</a>)</b>                      The Joint Commission (TJC), the oldest and largest standard-setting agency founded in 1951, is an independent not-for-profit organization that accredits and certifies more than 19,000 healthcare organizations and programs in the United States. It published <i>Standards for Hospital Accreditation</i> in 1953, began accrediting long-term care facilities in 1966, psychiatric facilities in 1970, ambulatory healthcare facilities in 1975, managed care in 1989, home health agencies in 1993, clinical laboratories in 1995, and office-based surgeries in 2001 (TJC, 2011). On-site surveys are conducted every three years, supplemented by annual performance reviews.</p>	<ul style="list-style-type: none"> <li>• Acute care hospitals</li> <li>• Critical access hospitals</li> <li>• Long-term care facilities</li> <li>• Ambulatory surgery centers</li> <li>• Office-based surgery</li> <li>• Behavioral/mental health facilities</li> <li>• Home health agencies</li> <li>• Hospice programs</li> <li>• Clinical laboratories</li> </ul>
<p><b>Det Norske Veritas (<a href="http://dnvaccreditation.com/pr/dnv/default.aspx">http://dnvaccreditation.com/pr/dnv/default.aspx</a>)</b>                      Det Norske Veritas, better known as DNV, was granted deeming authority in 2008 and offers an alternative to TJC. As of 2011 DNV had accredited over 250 hospitals in the United States. During its annual assessments it focuses on clinical, management, and environmental safety (DNV, 2011).<sup>xxiii</sup></p>	<ul style="list-style-type: none"> <li>• Acute care hospitals</li> </ul>
<p><b>Accreditation Commission for Healthcare, Inc. (<a href="http://store.achc.org/">http://store.achc.org/</a>)</b>                      Accreditation Commission for Healthcare, Inc. (ACHC), a not-for-profit organization, began offering accreditation services in 1996 and was granted for home health in 2006 and for hospice in 2009.</p>	<ul style="list-style-type: none"> <li>• Home and community-based healthcare organizations</li> <li>• Hospice</li> </ul>
<p><b>American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)</b></p>	<ul style="list-style-type: none"> <li>• Ambulatory surgery facilities</li> </ul>
<p><b>Community Health Accreditation Program (CHAP) (<a href="http://www.chapinc.org">http://www.chapinc.org</a>)</b>                      The Community Health Accreditation Program, Inc. (CHAP) is an independent, non-profit accrediting organization. Established in 1965, CHAP publicly certifies home and community-based healthcare organizations.</p>	<ul style="list-style-type: none"> <li>• Home health and hospice agencies</li> <li>• Community nursing centers</li> <li>• Private duty home care organizations (New Jersey and Colorado)</li> </ul>
<p><b>Healthcare Facilities Accreditation Program (American Osteopathic Association Healthcare Facilities Accreditation Program) (<a href="http://www.hfap.org">http://www.hfap.org</a>)</b></p>	<ul style="list-style-type: none"> <li>• Acute care hospitals</li> <li>• Critical access hospitals</li> <li>• Ambulatory surgery centers</li> <li>• Office-based surgery</li> <li>• Behavioral/mental health facilities</li> <li>• Clinical laboratories</li> </ul>
<p><b>Accreditation Association for Ambulatory Healthcare (<a href="http://www.aaahc.org">http://www.aaahc.org</a>)</b>                      Accreditation Association for Ambulatory Healthcare, with deemed authority since 1996, focuses exclusively on ambulatory healthcare to measure quality of services rendered to the nationally recognized standards. On-site visits are scheduled and tailored to meet the type, size and range of services a facility offers and areas surveyed include Rights of Patients, Governance, Administration, Quality of Care Provided, Quality Management and Improvement, Clinical Records and Health Information, Infection Prevention and Control, and Facilities and Environment.</p>	<ul style="list-style-type: none"> <li>• Ambulatory surgery centers</li> <li>• Community health centers</li> <li>• Home health agencies</li> <li>• Managed care organizations</li> </ul>

patient’s care plan, treatment and medications, diagnostic test results and follow-up, progress and compliance reports, and record confidentiality, security, retention, and destruction.

Conditions are revised or updated to keep pace with evolving developments in scientific evidence and technology. In 2007 the guidelines for isolation precautions (Siegel, Rhinehart, Jackon, Chiarello, & Healthcare Infection Control Practices Advisory Committee, 2007) were revised to reflect concern for evolving known pathogens (e.g., *C. difficile*, and community associated MRSA, the emergence of new pathogens (e.g., SARS-CoV), and the development of gene therapy. In November 2011, in keeping with advances in technology, it was decreed that it was unacceptable for

physicians or licensed independent practitioners to text orders to a healthcare facility as the identity of the person sending the text could not be verified nor was it possible to maintain the original text as validation of what is entered into the medical record (The Joint Commission, 2012).

Accreditation is a voluntary option but one required of healthcare facilities wishing to participate in and receive payment from Medicare and Medicaid. Although there are multiple organizations devoted to ensuring high quality patient care, accreditation surveys must be conducted by a state agency approved by CMS or by private independent agencies *deemed* by CMS as having authority to accredit organizations. In 2008, there were seven deemed national

xxiii. A comparison of Accreditation Organizations (TJC and DNV) can be retrieved from [http://www.dnvaccreditation.com/pr/dnv/document/comparison-dnvhc\\_to\\_tjc\\_tcm4-358498.pdf](http://www.dnvaccreditation.com/pr/dnv/document/comparison-dnvhc_to_tjc_tcm4-358498.pdf)

accreditation organizations (Hamilton, 2008). Regardless of whether a private or state agency conducts the accreditation assessment, a facility's medical records will be evaluated for compliance with established standards.

## Summary

Medical records are legal documents regulated by federal and state statutes and documentation in the medical record must meet standards set by regulations, professional organizations, and institutional policies. Healthcare providers with authorization to access and document in a patient's medical record are held responsible for knowing documentation requirements and are held accountable for entries or omissions to the medical record.

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# High Pressure Injection Injury

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## KEY WORDS

Amputation, Emergency Medicine, EMS, High Pressure Injection, Legal Nurse Consultant, LNC, Poison Control Centers, Pre-Hospital

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*This article provides the legal nurse consultant with background information on high pressure injection injuries (HPI). These injuries can be devastating and often lead to finger amputations. Amputation rates are from 16% to 88% depending on the amount of pressure released, the substance injected, and the time to treatment. High pressure injection injuries have occurred to the head and torso resulting in cervical spine injuries, diaphragmatic tears, fractures, inferior vena cava tears, liver lacerations, ruptured globes, subcutaneous emphysema, and perforations of the small bowel (Bussewitz, Littrell, Fulkert, & Van Court, 2010; Connolly, Munro, Hogg, & Munnock, 2010; Estera, Aucar, Wall, Granchi, & Mattox, 1999; Gao, Wu, Chen, Chen, Xu, Li, et al., 2011; Goel, Johnson, Phillips, & Westra, 1994; Kessel, Eliam, Ashkenazi, & Alfici, 2004; Sharma & Oswanski, 2002; Steffen, Wedel, Kluckert, Lange, & Zerz, 2009; Verhoeven & Hierner, 2008). High pressure injection injuries typically require multiple debridement surgeries, and follow-up care may last months to years. This article identifies key issues in pre-hospital and emergency department management and the evolution and current treatment recommendations of HPI injuries. The legal nurse consultant must consider all aspects of the practice area when providing recommendations to the attorney.*

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## Introduction

High pressure injection (HPI) injuries typically involve the patient's hand, finger, or foot (Hogan & Ruland, 2006; Neal & Burke, 1991; Schoo, Scott, & Boswick, 1980; Stark, Ashworth, & Boyes, 1967; Valentino, Rapisarda, & Fenga, 2003). The outcome of these injuries can be debilitating and catastrophic resulting in multiple surgeries, long term disabilities, and permanent defects or disfigurement. Even with appropriate treatment, gangrene and amputation may result (Hart, Smith, & Haq, 2006; Lee & Yong, 2005; Mason & Queen, 1941; Nahigian, 1966; Rees, 1937; Stark, Wilson, & Boyes, 1961; Stark et al., 1967; Watt, Shin, Vedder, & Chang, 2010; Wieder, Lapid, Plakht, & Sagi, 2006). Long term rehabilitation and follow-up management of HPI injury have ranged from 6 months to 12 years (Christodoulou, Melikyan, Woodbridge, & Burke, 2001). If legal action is invoked by the patient, the legal nurse consultant (LNC) must consider all aspects of a LNC practice area when making recommendations to the attorney. This includes functional capacity, damages for pain and suffering, complications of surgery, injury management, life care planning, medical malpractice, missed diagnosis, personal injury, product liability, toxic torts, and worker's compensation (Bryan v. Sherick, 2007; Clark v. Safety Kleen Corp. XYZ, 2004; Holloway v. Midland Risk Insurance, 2006; Ritchie v. Glidden Co., 2001; Williams v. Enriquez, 2006).

## History

High pressure injection injury initially was referred to as "grease gun injury," and primarily was limited to mechanics working with pressurized grease guns. This type of injury commonly occurred when the mechanic lubricated

machinery, cleaned clogged nozzles, replaced gun cartridges, repositioned the gun, or experienced a ruptured pressurized hose (Foresman-Capuzzi, Tadduni, & Callahan, 2006; Hart et al., 2006; Kaufman, 1968b; Valentino et al., 2003). The first reported case of material injected under pressure was in 1937 by Rees (1937). This was an injection of diesel fuel from a fuel injector jet. Rees reported that the jet exuded approximately 4,000 pounds of pressure per square inch (psi) to the patient's third finger, later resulting in gangrene and amputation.

## Pressurized Equipment

High pressure equipment is used by commercial industry, emergency first responders, medical personnel, and consumers. The high pressure equipment uses air or fluid under pressure to operate hydraulic hoses, nozzles, or valves. Examples of high pressure equipment include, but are not limited to:

- air compressors
- airless paint sprayers
- auto-extraction devices
- bolt drivers
- car washers
- cement guns
- compressed gas cylinders
- drilling machines
- hydraulic rams
- jack hammers
- log splitters
- pressure washers
- sandblasting guns
- snow plow equipment
- steam cleaners
- undercoating wands.

## Injectate

The pressurized equipment injected material (injectate) is often a toxic chemical that has the potential to produce systemic illness (Kaufman & Williams, 1966; Wermeling & Kasdan, 2011b). Oil-based solvents such as grease, paint, and paint thinners are especially hazardous (Pinto, Turkula-Pinto, Cooney, Wood, & Dobyns, 1993; Stark et al., 1967). Acute lead toxicity has been reported after HPI of lead-based paints and acute renal failure has occurred from injected wax solvent (Gargasz & Laurentin, 2011). Injectates are mostly

**Table: Injectate Associated With High-Pressure Injuries**

Air (Compressed)	Molding Plastic
Air With Rust	Molten Metal
Auto Undercoating/Rust Proofing	Mud
Cement	Oil (Machine, Motor, Crude)
Compressed Gas (Oxygen)	Paint (Latex, Lead, Oil, Silica)
Creosote	Paint Thinner / Solvents
Diesel Fuel	Paraffin / Wax
Dry Cleaning Solvents	Sand
Epoxy (Stucco, Paint)	Sealers
Freon	Sesame Oil
Gasoline	Silicone
Grease	Soda Lime
Hydraulic Oil/ Fuel	Toluene
Indium	Transmission Fluid
Isopropyl Alcohol	Vaccines (Animal)
Linseed Oil	Water

heterogeneous and are listed in the Table (Hogan & Rutland, 2006; Neal & Burke, 1991; Schoo et al., 1980; Stark et al., 1967; Valentino et al., 2003).

## Frequency

The literature remains vague on the exact number of HPI injuries that occur. Most evidence of HPI injuries are from case reports. Schoo et al. (1980) reviewed the literature and identified 127 HPI hand injuries from 1937 to 1976. They then performed a retrospective analysis of medical records from their medical center and estimated the rate of occurrence of HPI injuries was 1:600 hand injuries. Neal and Burke's (1991) retrospective five-year review from their medical facility, averaged one per four HPI injuries per year. Based on a literature review from 1966 to 2003, Hogan and Rutland (2006) identified 435 HPI injuries of the upper extremity, averaging 11.4 HPI injuries per year. However, some of these injuries had previously been reported by Schoo et al. (1980). Injuries occur because of carelessness, foolish behavior, inexperience with the equipment, and a lack of training (Stark, Ashworth & Boyes, 1967; Valentino et al., 2003).

## Pressures

High pressure injection injuries occur even when wearing protective garments, gloves, and shoes (Calhoun, Gogan, Viegas, & Mader, 1989; Wieder et al., 2006). High pressure equipment is known to deliver pressures ranging from 100 to 100,000 psi (Bourget & Perrone, 2011; Connolly et al., 2010; Estera, Aucar, Wall, Granchi, & Mattox, 1999; Morley, 1967). Equipment that contains a nozzle attachment decreasing the area of spray, conversely increases the pressure of the injectate (Foresman-Capezzi, et al., 2006; Kaufman, 1968b; Morley, 1967). If a nozzle is clogged, it is difficult

to accurately assess how much residual pressure is delivered when the obstruction is cleared.

Equipment with pressures as little as 100 psi when delivered from a distance of 5 inches is sufficient to penetrate the skin and cause severe tissue damage (Goel, Johnson, Phillips, & Westra, 1994; Kaufman, 1968a, 1968b). Pressures greater than 5,800 psi are capable of cutting through bone (Connolly et al., 2010).

Pressurized water jets and nozzles deliver velocities up to 900 miles per hour with pressures up to 12,000 psi (Estera et al., 1999; Schnall & Mirzayan, 1999; Sharma & Oswanski, 2002; Valentino et al., 2003). Bussewitz et al., (2010) report, "...some *industrial-strength jets extrude fluid capable of cutting through concrete and steel...*" (Bussewitz et al., 2010. p. 399 e17). Others have described the force delivered as the equivalent of the velocity of a shotgun blast (Estera et al., 1999; Loveday, I., 2007; Mrvous, Dean, & Krenzelok, 1987; O'Reilly & Blatt, 1975).

There is an impression that pressurized equipment delivering pressures of 7,000 psi or greater are associated with a 100% amputation rate to the affected extremity (Locker & Carstens, 2010; Schoo et al., 1980). The consensus, however, is that the injury itself is not exclusively from the high pressure but from the pervasive delivery of foreign material injectate in conjunction with the high pressure (Craig, 1984; Dickson, 1976; Gelberman, Posch, & Jurist, 1975; Lewis, 1985; O'Reilly & Blatt, 1975; Schoo et al., 1980).

Kaufman (1968a) performed research by injecting cadavers' hands to determine the actual amount of kinetic energy dissipated upon impact, the extent of tissue damage, and to calculate the velocity of the injectate stream. He injected wax at 750 psi and determined that the force delivered was equal to a "*one ton weight (being) dropped on a hand from the height of 124 feet*" (Kaufman, 1968a, p. 344).

## Injury Site

The location of a HPI injury site is extremely important in determining the injury pattern. The injury site is typically the non-dominant hand, to the index finger, followed by the palm, and then the long finger (Kaufman, 1968b; Schoo et al., 1980; Stark et al., 1961). If the injectate strikes tendons it may puncture and fill the sheath. If the injectate strikes a bony structure, it may be deflected medially and laterally (Booth, 1977; Wermeling & Kasdan, 2011a). However, if the finger tip or palm is the injection site, the injectate may be forced in a direct longitudinal pattern, proximally to, and as far away as the elbow, axilla, or mediastinum (Hogan & Rutland, 2006; Kennedy & Harrington, 2010; Mrvous et al., 1987; Neal & Burke, 1991; O'Reilly & Blatt, 1975; Schoo et al., 1980; Steffen, Wedel, Kluckert, Lange, & Zerz, 2009; Verhoeven & Hierner, 2008).

High pressure injection injury sites to the head and torso have resulted in cervical spine injury (Gao, Wu, Chen, Chen, Xu, Li, et al., 2011), diaphragmatic tear (Kessel, Eliam, Ashkenazi, & Alfici, 2004), extensive subcutaneous emphysema (Bussewitz et al., 2010), fractures (Connolly et

al., 2010; Goel et al., 1994), inferior vena cava tear (Esterá et al., 1999), liver lacerations (Sharma & Oswanski, 2002), perforations of the small bowel (Kessel et al., 2004; Sharma & Oswanski, 2002; Steffen et al., 2009; Verhoeven & Hierner, 2008), and a ruptured globe (Goel et al., 1994).

### Inflammatory process sequelae

The pathophysiology of HPI injuries resulting from grease-guns was first explained by Mason and Queen in 1941. They divided each progression into stages classified as acute, intermediate, and late, and their description remains undisputed (Harter & Harter, 1986; Mason & Queen, 1941). Wermeling and Kasdan (2011a) later revised Mason and Queen's (stages) into *phases* described as: *acute inflammatory* (acute), *intermediate granulomatous* (intermediate), and *chronic ulcerative* (late).

The acute stage represents symptoms which appear immediately as a result of the injectate and mechanical compression entering the tissue under high pressure. During this stage there is immediate edema to the affected area and a sudden increase in interstitial pressure. As the tissue distention increases, vascular circulation is compromised and the area becomes white and anesthetic (Mason & Queen, 1941; Wermeling and Kasdan, 2011a).

The intermediate stage is characterized by the formation of "oleogranulomas". Oleogranulomas (oil tumors) are nodular tumors resulting from foreign body tissue inflammation reaction to injectate that contains mineral oil (Dickson, 1976; Gelberman et al., 1975; Vinogradov, 1936 as cited in Moore, 1946).

Hesse first described this human tissue reaction by the injection of oils and waxes (Hesse, 1925 as cited in Moore, 1946). The phenomenon primarily occurred to Russian men who injected mineral oil and paraffin into their ankles, calves, and knees. This behavior was practiced so high military boots would not properly fit in order to avoid mandatory military service (Dickson, 1976; Webb, 1969; Wermeling et al., 2011a). Oleogranuloma sites may remain benign for many years; however, as fibrosis progresses the affected part loses mobility and function (Kaufman, 1968b; Mason & Queen, 1941).

The late stage is identified by "oleomas" {sic} that break down near the surface of the skin, producing widespread subcutaneous and cutaneous lesions. Persistent sinuses and ulcers may occur with discharge of foreign material for many years and may become secondarily infected. Eventually the skin is thick and pitted, resulting in loss of function and permanent disfigurement (Mason & Queen, 1941; Geller & Gursel, 1986; Kaufman, 1968b; Lee & Young, 2005).

Vinogradov (1936), Hesse's assistant, described late results from Hesse's cases. This paper is the only one in the literature that provides a complete natural history of oleogranuloma from the early stages to the development of late sequelae. He notes that in advanced cases nodular tumors have caused lymphatic obstruction, elephantiasis, and in one case, squamous cell carcinoma (Vinogradov, 1936 as cited in Moore, 1946).

### Initial Patient Presentation

Health and medical professionals such as EMTs, triage nurses, primary care physicians, and emergency department (ED) physicians must remain vigilant and recognize the potential dangers associated with HPI injuries (Gutowski, Chu, Choi, & Friedman, 2003; Hart et al., 2006; Neal & Burke, 1991). The clinical history of HPI injury is very consistent in the literature. Initially, a small puncture wound is present with minimal edema, and little or no pain and injectate may be observed oozing from the puncture site. Patients may refuse or not seek medical treatment believing the injury is minor (Hogan & Rutland, 2006; Morley, 1967; Neal & Burke, 1991; Schoo et al., 1980; Stark et al., 1967; Stark et al., 1961; Valentino et al., 2003; Vaughn & Kulkarni, 2011).

As symptoms progress the injured site becomes distended producing subcutaneous vessel compression and ischemia, as Mason and Queen (1941) described in their acute state. The patient then presents to the ED several hours after the injury, complaining of severe pain and edema (Hogan & Rutland, 2006; Neal & Burke, 1991; Schoo et al., 1980; Stark et al., 1967; Stark et al., 1961; Valentino et al., 2003; Vaughn & Kulkarni, 2011). Patients who present late



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often complain of an excruciatingly painful, pale, sometimes mottled, extensively edematous, hand or finger, with diffuse paresthesia. Compartment syndrome may occur manifested by the six "P's of pain, pallor, paralysis, paresthesia, pressure, and pulselessness (Bussewitz et al., 2010; Dailiana, Kotsaki, Varitimidis, Moka, Bakarozzi, Oikonomou, et al., 2008; Daniels, Zook, & Lynch, 2004; Geller & Gursel, 1986; Loveday, 2007).

### Treatment based on symptoms

Many views exist, some controversial, in an effort to formulate HPI injury treatment protocols and symptomatology algorithms in order to achieve a positive outcome (Baylor, Samuelson & Sinclair, 1973; Hogan & Rutland, 2006; Craig, 1984; Goel et al., 1994). Wong and Wu (2005) managed patients according to the severity of the HPI injury based on a severity classification system developed by the authors consisting of mild, moderate, and severe injury. Patients were then classified according to: extent of soft tissue involvement, injectate, neurovascular state, and time to treatment. Conservative treatment was implemented for mild injury and aggressive treatment for moderate and severe injury.

Wong and Wu (2005) recommend that to avoid medical-legal issues later, patients must be properly informed before conservative treatment or when finger retention and reconstruction is implemented, especially if the finger later becomes ischemic and results in amputation. They state that "... amputation is a complication of the injury and not of the surgery" (Wong & Wu, 2005, page 592).

### Treatment based on time

The overall rate of amputation from a HPI injury is as high as 55% (Lewis, Clarke, Kneafsey, & Brennen, 1998; Schoo et al., 1980; Verhoeven & Hierner, 2008). This results in part from a delay in treatment which occurs because the severity of the initial wound is underestimated by both patient and clinician (Booth, 1977; Goel et al., 1994; Neal & Burke, 1991; O'Reilly & Blatt, 1975; Smoot & Robson, 1983; Stark et al., 1961; Valentino et al., 2003). Oil-based solvents such as grease, paint, and paint thinners are especially hazardous (Hogan & Rutland, 2006; Pinto et al., 1993) and injection of these materials is associated with an amputation rate of 88% whether presentation is early or late (Schoo et al., 1980; Stark et al., 1961; Valentino et al., 2003; Vaughn & Kulkarni, 2011; Verhoeven & Hierner, 2008).

It is thought that when patients present with no puncture wound and who remain asymptomatic for a minimum of four hours, the likelihood of complications remains low. These patients may be safely discharged from the ED with close follow up (Mrvous et al., 1987).

Neil and Burke (1991) commenting on Stark et al. (1967) recommended that treatment include "...early decompression to avoid ischemic gangrene and surgical removal of foreign material to reduce fibrosis and scarring" (Neal & Burke, 1991, p. 470). Stark et al. (1967) reported that patients who underwent

decompression within 10 hours would have an extremity that survived and regained "adequate function."

In the mid 1960s, Kaufman (1966b) suggested that when a single digit is involved with a 50% or greater loss of function, early amputation is recommended which he believed resulted in less impairment of function to the hand and adjacent fingers and complete recovery in 1½ to 2 months. However, Kaufman (1968b) and others concluded that regardless of the device responsible for the injury, prognosis and morbidity remained poor, for up to two years (Kaufman, 1968b; Verhoeven & Hierner, 2008).

Mann's (1975) literature review identified 73 HPI injuries including 30 injuries from a grease gun and 28 injuries from a paint gun. Of these, 53 patients (73 %) required amputations with 12 from a grease gun and 10 from a paint gun. Mann (1975) recommended immediate decompression and warns that "...to treat these wounds by expectant observation can cause catastrophic results with eventual amputation of digits" (Mann, 1975, p. 933).

Pinto et al. (1993) disputed Kaufman's (1968b) treatment citing that 4 of his 25 patients (16%) underwent amputation because of a delay presentation. The remaining 21 patients received wide debridement, drainage, open wound packing, repeated debridement, and delayed wound closure. Sixty-four percent had normal function at the time of their last follow up visit, up to two years post injury.

Christodoulou et al. (2001) reported the time factor is not always the most important variable and is "overestimated". The authors state: "... if the pressure is high and the injected material (injectate) is toxic enough to cause vascular damage, it may not be possible to salvage the digit, however early the decompression is performed" (Christodoulou, et al., 2001, p. 719).

### Treatment based on injectate

Verhoeven and Hierner (2008) and others report there are several mechanisms responsible for the irreversible damage to tissue. Severe tissue damage is a result from ischemia, chemical irritation, inflammation, tissue necrosis, functional impairment, and possibly sepsis (Arneja & Gellman, 2011; Lewis, 1985; Verhoeven & Hierner, 2008). Verhoeven and Hierner (2008) developed an algorithm based on the nature of the injectate. Treatment was then implemented according to three sub-categories: air and water; grease and oil; and paint solvents.

Estera et al. (1999) recommend even when air, gas, or water is injected caution should be used. Treatment may only require decompression and observation; however, if there is any evidence of vascular compromise and/or a significant risk for infection, a surgical consult is prudent. Bekler, Gokce, Beyzadeoglu, and Parmaksizoglu (2007) recommend a greater emphasis is required for these injuries such as decompression of the affected compartments, because 4 of their 14 patients (29%) developed restrictive functional outcomes. Calhoun et al. (1989) reported that a patient required hyperbaric oxygen to treat his continued pain, edema, and extensive subcutaneous emphysema after HPI of water. In addition,

patients who have presented with minimal to no outward sign of soft tissue injury have sustained diaphragmatic tears, fractures, large intestine and liver lacerations, massive subcutaneous emphysema, and perforations of the cecum, ileum, and inferior vena cava (Connolly et al., 2010; Daniels et al., 2004; Estera et al., 1999; Kessel et al., 2004; Lee & Young, 2005; Neill & George, 1969; Sharma & Oswanski, 2002; Verhoeven & Hierner, 2008; Watt et al., 2010; Weltmer, & Pack, 1988).

Any injectate must be positively identified to rule out generalized intoxication, especially when the injectate is lead or mineral spirits. A poison control center should be contacted and/or the material safety data sheet (MSDS) should be obtained from the worksite, if available (Mrvovs et al., 1987; Verhoeven & Hierner, 2008). Systemic effects rarely occur unless large volumes of toxic injectate are introduced (Verhoeven & Hierner, 2008). Mann (1975) reported that "... grease gives a delayed reaction, with late fibrosis and stiffness while paint causes an acute inflammatory reaction, with fever and leukocytosis" (Mann, 1975, p. 933). Systemic effects, however, have also included renal failure, air embolism, allergic response, hemolysis, and lead intoxication (Gargasz & Laurentin, 2011; Neal & Burke, 1991; Wermeling & Kasdan, 2011b). If systemic toxicity is anticipated and/or secondary trauma has occurred, the patient should be admitted to the hospital and observed for additional symptoms and treated accordingly (Kaufman & Williams, 1966; Verhoeven & Hierner, 2008). Daniels et al. (2004) and Kaufman (1968b) recommend obtaining liver studies, blood urea nitrogen (BUN), and creatinine levels due to injectate which may be hepatotoxic. Patients who present with a history of HPI injury alone, even with no apparent injury, should be admitted to the hospital and closely observed for evolving signs of injuries.

## Treatment: Prevailing view

The recommended treatment protocol is to first treat life threatening injuries, associated trauma, and shock. Both prehospital and ED personnel must obtain a detailed history which includes the mechanism of injury, time of injection, and type of injectate (Arneja & Gellman, 2011; Kaufman & Williams, 1966).

The injured extremity should be palpated for distal pulses and capillary refill times obtained. If needed, the extremity should be splinted. Patients with injuries other than extremity injuries should be immobilized as a precaution. Intravenous fluids should be started and nothing given by mouth. Necrosis may occur when heat or ice is used which should be avoided (Baylor et al., 1973; O'Reilly & Blatt, 1975; Verhoeven & Hierner, 2008).

Once the injury is confirmed as a HPI injury, the patient requires emergent transport to a trauma center for evaluation and a surgical consult, even when there is little to no evidence of penetration (Kessel et al., 2004). Neal & Burke, (1991) state, the: "...failure [of medical professionals] to refer early is

*becoming an increasing focus of negligence claims*" (Neal & Burke, 1991, p. 470).

When penetration does exist a light dressing may be applied to allow for pressure and injectate to be released. Cleansing of wounds with solvents to remove injectate before or during debridement may cause tissue necrosis, and should never be used (Neal & Burke, 1991; Schoo et al., 1980; Verhoeven & Hierner, 2008; Watt et al., 2010). In addition, infiltration by digital block may only serve to exacerbate ischemia and should be avoided (Hogan & Rutland, 2006; O'Reilly & Blatt, 1975).

Plain radiographs, xeroradiographs, computerized tomography, and magnetic resonance imaging have been shown to be useful diagnostic tools for various reasons (Bussewitz et al., 2010). Many substances are radiopaque such as lead-based paint, lithium grease, or metallic foreign body debris. Grease contains 88% mineral oil, graphite, and detergent (Crabb, 1981; Curka & Chisholm, 1989; Geller & Gursel, 1986; Goel et al., 1994; Locker & Carstens, 2010; Mrvovs et al., 1987; Smoot & Robson, 1983; Verhoeven & Hierner, 2008). Radiographs and imaging may also identify the tract and spread of the injectate (Crabb, 1981; Geller & Gursel, 1986; Smoot & Robson, 1983) and detect fractures (Bussewitz et al., 2010; Valentino et al., 2003). Angiographic imaging may assist to identify unperfused areas and may be useful (Valentino et al., 2003). Subcutaneous emphysema is a positive indication of injection (Watt et al., 2010); however, it is not always visible on imaging (Sharma & Oswanski, 2002). Typically, a finger injury requires radiographs of all areas distal to the elbow (Curka & Chisholm, 1989).

Chemical and non-chemical chronic infection must be suspected in all HPI injuries that have occurred for many years (Daniels et al., 2008; Lee & Yong, 2005; Lewis, 1985). Tetanus prophylaxis and a broad spectrum antibiotic should be provided despite the lack of positive cultures. The use of corticosteroids remains controversial (Bottoms, 1962; Hogan & Rutland, 2006; Phelps, Hastings, & Boswick, 1977; Verhoeven & Hierner, 2008).

Patients confirmed with a HPI injury are surgical emergencies requiring aggressive treatment (Booth, 1977; Bourget & Perrone, 2011; Bussewitz et al., 2010; Valentino et al., 2003). The treatment of choice for achieving the best possible result includes immediate surgical intervention, decompression, and debridement (Baylor et al., 1973; Craig, 1984; O'Reilly & Blatt, 1975; Valentino et al., 2003). This should be accomplished under general anesthesia following the accepted principles of hand surgery.

In all cases, removal of injectate by full debridement with excision of the affected fat and fascia, and irrigation, is performed (Craig, 1984; Mann, 1975; Smoot & Robson, 1983; Verhoeven & Hierner, 2008). Wounds should then be left open for optimal drainage and further debridement on an as needed basis (Pinto et al., 1993). Grafting at a later date versus delayed closure may be necessary and close follow up care for many years is mandatory (Neal & Burke, 1991; Schoo, et al., 1980).



## Outcome

Verhoeven and Hierner (2008) state “... *the final hand function is mainly stipulated by the circumstances of the accident.*” They identified five factors that influence the prognosis and functional outcome of the affected extremity (Verhoeven & Hierner, 2008, p. 30):

- **Latency time to treatment** – The greater the time before treatment begins the greater the risk for amputation
- **Nature of the injectate** – Paints and solvents have worse outcomes than air or water
- **Pressure of the gun** – High pressure equipment causes more tissue damage
- **Site of injury** – Palm site dissipates injectate better than finger tip site
- **Volume of injectate** – Larger volumes create greater tissue pressures, risking neurovascular bundles and increasing vascular compromise

Limited studies have addressed post injury functional outcomes; however, the outcome measure varied from study to study. All patients with a HPI injury have sequelae (Wieder et al., 2006) with the majority reporting cold intolerance, functional impairment, hypersensitivity, pain, and paresthesia (Hart et al., 2006; Watt et al., 2010).

The best functional outcome after HPI injuries have been achieved by early and aggressive management (Pinto et al., 1993). Neal and Burke (1991) recommend patients must begin intense and immediate physical therapy for an optimal recovery which is supported by Pinto et al. (1993) and Valentino et al. (2003). Sixty-four percent of Pinto’s patients had essentially normal hand function at the time of their last follow-up. The duration of this follow up ranged from 4 to 85 months (Pinto et al., 1993).

The study by Christodoulou et al. (2001) revealed significant reduction in muscle testing and reported that patients will likely be permanently compromised in terms of reduced strength, power, and sensation. Wieder et al., (2006) and Christodoulou et al. (2001) agree that patients sustaining HPI injury may be forced to change their occupations as a result.

## Prevention

Hart et al. (2006) recommend that additional measures must be taken in order to reduce the number of injuries. They recommend:

- Targeting safety education to the high risk groups
- Decreasing the gun pressures
- Adding trigger locks and pressure relief valves
- Performing regular hose maintenance and hose changes
- Performing injury surveillance, with accurate data collection to document the actual number of (HPI) injuries and the mechanism of such injury
- Mandating legislation for oversight and compliance
- Providing financial incentives to develop and implement engineering and design changes to high pressure equipment

## Legal Cases

There are several legal cases that demonstrate the serious injuries that can occur as a result of HPI injury. Three will be described.

**Case 1:** Plaintiff Williams sustained a HPI injury to his hand from a hydraulic hose which ruptured. The plaintiff was treated by an ED physician approximately one hour after the injury. The plaintiff’s wound was cleaned and a drain was sutured in place with instructions to follow up with an orthopedic surgeon the next day. On the following day the orthopedic surgeon performed emergency surgery on the hand. The plaintiff remained in the hospital for 47 days requiring an additional 14 surgical procedures eventually leading to amputations of his right index and third digits. The plaintiff filed suit against the ED physician for not advising him of the “immediate need for surgical intervention.” The trial court rendered a judgment approving a settlement agreement between the plaintiff and the ED physician.

**Case 2:** Plaintiff Ritchie sustained a HPI injury to her index finger from an airless spray paint gun. She was immediately treated at the local hospital and endured six surgeries which later resulted in an amputation of her index finger. The plaintiff brought a products liability action against the manufacturer and her employer for their failure to warn of the safety hazard of the high pressure paint gun. Both the manufacturer and employer argued that the plaintiff had not presented sufficient evidence to meet all the elements under the state product liability act. Summary judgment was granted to the manufacturer and employer. The plaintiff appealed the decision claiming that the district court erred in finding that there was no issue of material fact regarding whether the pump involved in the accident left the manufacturer’s control without proper warnings. During the trial employees testified they had not been aware of the specific danger of paint injection and that no formal training or safety instruction about its use was provided to the employee. In addition, there were no warning labels on the airless spray paint gun. The decision was reversed in favor of the plaintiff.

**Case 3:** Plaintiff Holloway, a firefighter, sustained a HPI injury from a hydraulic rescue tool while trying to extricate the driver from a motor vehicle which had crashed into a tree, trapping the driver. As the rescue tool was being repositioned, the hydraulic hose ruptured injecting fluid into the plaintiff’s gloved hand. He was transported to the local hospital and immediately underwent surgery to remove hydraulic fluid and repair tendons and nerves severed by the pressurized fluid. Three surgeries later, the plaintiff was informed by the physician that his hand would not return to its original normal state. The plaintiff participated in physical therapy every day and was able to return to work five months after the injury. Two months later, the plaintiff required additional surgical procedures to drain purulent material from the healed hand.

The injury resulted in a permanent loss of function and range of motion to his hand.

The plaintiff filed a petition for damages against the manufacturer of the rescue tool and the driver's automobile insurance company. The plaintiff alleged that the manufacturer was liable for damages caused by defective rescue equipment and a failure to warn under the state products liability act. A jury verdict determined the manufacturer was 100% at fault in causing the plaintiff's injury and awarded him damages. The automobile insurance company was dismissed from the suit on an exception of no cause of action.

## Role of the Legal Nurse Consultant

HPI injuries are challenging cases for medical and legal personnel. Over the last 97 years, the medical community has struggled to determine an appropriate treatment plan based on injectate type, injectate volume, injury site, pressure, symptoms, and time to treatment in order for the best possible patient outcome. These three cases represent only a slight insight into what might be involved when reviewing a HPI injury. Verhoeven and Hierner (2008) state that even after immediate and adequate treatment, the "...outcome after a HPI injury is frequently disappointing" (Verhoeven & Hierner, 2008, p. 32).

The challenge for the LNC is multi-dimensional especially when so many elements of the patient's injury must be investigated throughout the continuum of care. The LNC must have an extensive understanding of the potential effects of a HPI injury, standards of care and treatment, and impact on the outcome. While not a complete list of all aspects of a patient's care, the LNC needs to:

- Have an understanding of the effects of a HPI injury
- Have an understanding of the different types of injectate and their effects
- Assess if medical personnel recognized the injury as a potential catastrophic and career ending injury
- Assess if medical personnel demonstrated immediate and aggressive treatment
- Assess if medical personnel made an immediate and appropriate referral
- Review surgical procedures and post-operative care for standards of care
- Identify the patient's comorbid conditions
- Determine if follow up care/case management was done
- Identify if aggressive physical therapy and rehabilitation were performed
- Determine the patient's final outcome
- Determine the patient's ability to function to their fullest capacity
- Determine the patient's ability to return to their former career
- Determine if appropriate education and instruction of high pressure equipment was provided to the patient by the employer
- Determine if safety equipment was available and used by the patient

- Determine if the high pressure equipment had appropriate safety devices and warnings
- Determine if the high pressure equipment was properly maintained and serviced according to the manufacturers recommendations

## Conclusion

Health and medical professionals must recognize a HPI injury as a surgical emergency with potential long term complications, even though the initial presentation may appear minimal. The mechanism of injury alone is enough of a history to warrant immediate emergency transport and treatment in a trauma center. Air, gas, and water as injectate have complications just like other injectate. Regardless of the injectate involved, secondary injury must be ruled out.

The management, treatment, and disposition of HPI injuries remain controversial; however, the prevailing view is to provide aggressive and immediate treatment to ensure a better outcome. However, even after immediate and adequate treatment, the outcome is frequently disappointing. LNCs must be aware of the devastating effects, complications, and long term implications to the patient suffering from a HPI injury.

High pressure equipment manufacturers should:

- Alert healthcare providers to recognize the dangers of a HPI injury
- Design safety features to high pressure equipment
- Provide consumers with safety information
- Provide industry with comprehensive training programs

In addition, more oversight by the industry and government agencies may prove beneficial.

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# The Repercussions of Expressions of Sympathy Versus Expressions of Fault: It All Depends on Where You Practice

Wesley T. D. Myers

## KEY WORDS

Apology Law, Expression of Sympathy, Statement of Liability, Statement of Fault, Adverse Outcome, Negligence, Lawsuit

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*This article provides a brief nationwide overview of the so called “apology laws” which exist in varying degrees in most states so as to afford protections to health care providers that expressions of sympathy or benevolent gestures will not be admissible in court as a statement or admission against interest. However, the article attempts to convey that there is a marked difference between an expression of sympathy and an admission of liability, and the legal ramifications differ for these statements depending upon the state in which the practitioner practices.*

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## Introduction

The British pop performer, Sir Elton John, sings a song entitled, “Sorry Seems to Be the Hardest Word.” While the song has nothing at all to do with medical negligence, the title resonates with health care providers who are all too often faced with the dilemma of whether to offer words of sympathy or apology to patients and/or the families of patients who have experienced adverse outcomes.

This topic is hardly novel. Articles addressing whether or not medical professionals should offer words of condolence or apology have been published in periodicals from the American Medical News to USA Today (O’Reilly, 2010). Of particular recent notoriety has been a 2001 program initiated by University of Michigan Health System designed to encourage health care providers to inform patients of errors made while under their care and to apologize for them, while offering the patient or their family “fair compensation” (Boothman, 2009). The university hospital system boasts statistics that new legal claims fell by 40% as a corresponding result. While critics highlight that the “fair compensation” aspect of the program arguably skews the statistics, they admit that the Michigan program is a “step in the right direction” and falls into a large and growing body of evidence reflecting that “when doctors openly acknowledge their errors, patients are less likely to look for a lawyer.” (www.stltoday.com, Sept. 1, 2010).

However, the purpose of this article is not to focus on whether a healthcare provider should or should not apologize for adverse events. That is a question for healthcare providers

themselves to ponder, frequently with the assistance of their attorneys, risk managers, and/or insurance representatives. Rather, this article seeks only to educate the reader as to the perceived difference between an expression of sympathy and an expression of fault, and highlight that the distinction does matter, especially under the laws of the state in which the health care provider practices.

## Evaluation of the Statutes Nationwide

At least 35 states plus the District of Columbia have adopted laws offering some form of protection against statements of sympathy being used against a health care provider to establish liability for adverse outcomes. In such jurisdictions, statements or expressions of sympathy are expressly barred from being admitted in a court of law in civil cases to prove liability on the part of the health care provider who uttered the statement or made the sympathetic gesture. However, even among these states, laws differ as to whether statements or admissions of fault, whether part of or in addition to, a statement or gesture of sympathy, would be excluded from such protections.

On June 29, 2011, the Ohio Ninth District Court of Appeals issued their opinion in the case of *Davis v. Wooster Orthopaedics & Sports Medicine, Inc.* (Davis v. Wooster Orthopaedics & Sports Medicine, Inc., 2011). This case arguably offers one of the best nationwide assessments of the so called “apology laws” to date. In *Davis*, the court was forced to address a question of first impression – the interpretation of the Ohio law precluding the admission of an apology but allowing the jury to hear an admission of liability.<sup>1</sup>

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i. Under the Ohio apology law R.C. 2317.43(A)(West 2011), “[i]n any civil action brought by an alleged victim of an unanticipated outcome of medical care . . . . Any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence that are made by health care provider or an employee of a health care provider to the alleged victim, a relative of the alleged victim, or a representative of the alleged victim, and that relate to the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care are inadmissible as evidence of an admission of liability or as evidence of an admission against interest.”

*Davis* involved a woman who underwent back surgery during which her iliac artery was severed. Following her death, the surgeon expressed his sympathy to the family and admitted that he had nicked the artery, taking full responsibility for the error. The family subsequently sued, and during the trial, the judge excluded the expression of sympathy made by the physician but allowed the family to testify about the surgeon's admission that he nicked the artery. The jury found in favor of the family, and the surgeon appealed on the grounds that the court incorrectly permitted the statement of the physician to go before the jury, as it was part of the expression of sympathy protected from admission under the Ohio apology statute. In rendering their decision upholding the jury verdict, the Ohio appellate court confirmed that the Ohio apology law, although unclear on its face, was intended to protect only expressions of sympathy, and drew a distinction between expressions of sympathy and admissions of fault. However, to assist in reaching its decision, the Ohio appellate court performed a national assessment of apology laws, essentially dividing the states into four categories: (1) states where expressions of sympathy are protected, but admissions of fault are not; (2) states where both expressions of sympathy and admissions of fault are excluded; (3) states where the statutes do not clearly distinguish between expressions of sympathy and statements of fault; and (4) states where no apology statutes yet exist as law.

### 1. States Where Expressions of Sympathy Are Protected, but Admissions of Fault Are Not

Of the approximately 37 states which have adopted "apology laws", 18 have explicitly distinguished between expressions of sympathy and admissions of fault in the statutes themselves, permitting the exclusion of expressions of sympathy from admission into evidence, but allowing for admissions of liability to be used against the health care provider who made the admission of liability.<sup>ii</sup> As an example, the Texas communication of sympathy statute reads:

A court in a civil action may not admit a communication that . . . expresses sympathy or a general sense of benevolence relating to the pain, suffering, or death of an individual involved in an accident . . . and is offered to prove liability of the communicator in relation to the individual. . . Notwithstanding, . . . a communication including an excited utterance . . . which also includes a

statement or statements concerning negligence or culpable conduct pertaining to an accident or event, is admissible to prove liability of the communicator. (Tex. Civ. Prac. & Rem. Code Ann. § 18.061, 2011).

Thus, the Texas statute, like those of the other states in this category, clearly distinguishes a difference between the use of expressions of sympathy and expressions of fault. As pointed out by the *Davis* court when discussing a similar Hawaiian statute, "The Hawaii legislature explained its intent by commenting that its rule excluding expressions of sympathy while permitting expressions of fault 'favors expressions of sympathy as embodying desirable social interactions and contributing to civil settlements'" (*Davis v. Wooster Orthopaedics & Sports Medicine, Inc.*, 2011).

While case precedent on apology laws is still rather sparse, the supreme court of South Dakota recently addressed the distinction between expressions of sympathy and expressions of fault in the state's apology law in the case of *Ronan v. Sanford Health*.<sup>iii</sup> Therein, it noted that, while statements of apology are not admissible to prove negligence, statements against interest by the health care provider may be used for the purpose of impeachment.<sup>iv</sup>

Consequently, as a practical note for health care providers in such states, specific care should be taken when communicating to a patient or their family members following an adverse event to avoid making admissions of liability, as such expressions are not protected from being subsequently used against the provider in a court of law.

### 2. States Where Expressions of Sympathy And Admissions of Fault are Excluded

By contrast, eight states, which have explicitly made the identical distinction between expressions of sympathy and admissions of fault in their respective apology statutes, have elected to exclude both types of statements from admission into evidence.<sup>v</sup> Colorado's apology statute, for example, notes in part:

"[A]ny and all statements . . . expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a healthcare provider . . . to the alleged victim [or] a relative of the alleged victim . . . which relate to the discomfort, pain, suffering, injury, or death of the alleged victim

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ii. See (California) CAL. EVID. CODE 1160(a)(West 2011); (Delaware) DEL. CODE ANN. TIT. 10, § 4318 (2011); (Florida) FLA. STAT. ANN. 90.4026 (West 2011); (Hawaii) HAW. REV. STAT. ANN. 626-1, Rule 409.5 (West 2011); (Idaho) IDAHO CODE ANN. 9-207 (2011); (Indiana) IND. CODE. ANN. 34-43.5-1-4 and 34-43.5-1-5 (West 2011); (Louisiana) LA. REV. STAT. ANN. 13:3715.5 (2010); (Maine) ME. REV. STAT. ANN. TIT. 24 § 2907 (2011); (Maryland) MD. CODE ANN., CTS. & JUD. PROC. § 10-920 (West 2011); (Massachusetts) MASS. GEN. LAWS ANN. CH. 233, 23D (West 2011); (Michigan) MICH. COMP. LAWS ANN. 600.2155 (West 2011); (Missouri) MO. ANN. STAT. 538.229 (West 2011); (Nebraska) NEB. REV. STAT. ANN. 27-1201 (West 2010); (New Hampshire) N.H. REV. STAT. ANN. 507-E:4 (2011); (South Dakota) S.D. CODIFIED LAWS § 19-12-14 (Mitchie 2012); (Tennessee) TENN. R. EVID. 409.1 (2010); (Texas) TEX. CIV. PRAC. & REM. CODE ANN. § 18.061 (Vernon 2011); (Virginia) VA. CODE ANN. 8.01-52.1.

iii. *Ronan v. Sanford Health*, No. 25813, 2012 WL 312266 (S.D., Feb. 1, 2012) (involving statements by risk manager and chief operating officer saying, "I am so sorry we failed you," "we let you down," "Dr. Hruby got the whole thing off on the wrong track and it snowballed," and it was an example of "When people don't do their jobs.").

iv. However, in *Ronan*, the South Dakota Supreme Court upheld the exclusion of the statements as they had not been used for impeachment and had been offered through notes as opposed to oral testimony.

as the result of the unanticipated outcome of medical care shall be inadmissible as evidence of an admission of liability or . . . as evidence of an admission against interest. (Col. Rev. Stat. 13-25-135, 2011).

Health care providers in these states are afforded much greater protections as to their communications with patients and their families following adverse events. Consequently, they do not have to walk as thin a tightrope to ensure that potential admissions of liability intermingled with expressions of sympathy will be later used against them in a court of law.

This concept is illustrated through the Georgia case of *Airasian v. Shaak*, in which the Georgia Court of Appeals upheld the exclusion of the comment, “This was my fault,” made by a surgeon following a botched colon surgery resulting in necrotic bowel having to be removed via emergency colostomy. (*Airasian v. Shaak*, 2008). The statement had subsequently been excluded from evidence at trial on the grounds that such expression was protected under the Georgia apology statute, which met with approval by the Georgia Court of Appeals.

### 3. States Where The Statutes Do Not Clearly Distinguish Between Expressions of Sympathy and Statements of Fault

Nine other states maintain apology laws that do not make clear in their language a distinction between statements and gestures of sympathy versus expressions of liability or fault.<sup>vi</sup> One of these is Ohio, for which the interpretation of the apology statute was at the heart of the controversy in the aforementioned *Davis* case.<sup>vii</sup> According to the *Davis* court, the apology statutes in many of the states in this category are nearly identical and were all adopted since 2003 (*Davis v. Wooster Orthopaedics & Sports Medicine, Inc.*, 2011). Moreover, until the issuance of the *Davis* opinion, there had been no cases litigated in these states so as to establish legal precedent as to how their respective state courts would interpret the apology statutes. That being said, for health care practitioners in these states, discretion in communications of sympathy following an adverse event is strongly recommended, as no baseline has been established (except in Ohio) as to whether a distinction will be drawn between expressions of sympathy and admissions of liability.

Further, caution is advised in any of these states which maintain apology laws that the existence of an apology statute alone does not mean that it has a retroactive application. As illustrated in the case of *Johnson v. Smith*, which involved a physician stating “I take full responsibility” for an error

during gall bladder surgery, the Ohio 11th District Court of Appeals reversed a trial court’s decision to exclude the physician’s statement, which was made prior to the enactment of the statute but during a trial which occurred well after its enactment into law (*Johnson v. Smith*, 2011). Hence, a practitioner should consider the consultation with legal counsel in his or her respective state to confirm the position of that jurisdiction’s courts on retroactive applicability of such statutes, if a question arises.

### 4. States Where No Apology Statutes Yet Exist As Law

In the remaining 15 states, either: (1) no apology statutes exist; (2) despite current legislative efforts, no apology statutes have yet been effectively passed into law; or (3) the previously existing apology statute was found to be unconstitutional.<sup>viii</sup> Therefore, with no statutory protections available to health care providers in these states for expressions of sympathy or condolence, arguably any such statements can subsequently be used against the health care provider as a potential admission of liability or admission against interest at trial. Consequently, health care providers in such states should exercise an extreme degree of caution when communicating with patients or their families following an adverse event.

## Conclusion

Given the vast differences in apology laws throughout the country, Elton John’s words, “Sorry Seems to be the Hardest Word,” ring unfortunate, but ironically true. So what are health care practitioners to do to better protect themselves and take advantage of any legal safeguards offered by the apology statutes in the jurisdictions in which they practice? Arguably the most sound recommendation would be to first familiarize oneself with the apology laws of the state. Armed with that information alone, one will have a better idea of whether legal protections exist at all and whether repercussions for statements of liability versus statements of sympathy could have a bearing on a future legal proceeding. Planning for communications with patients and/or their families following an adverse event can then be adjusted accordingly.

Studies argue that medical malpractice lawsuits are often driven by a lack of disclosure (*Wei*, 2006). Patients and families are forced to file lawsuits to gain any substantive information about what caused an adverse event, as litigation-worthy health care providers offer few answers. It is in resolving these more universal issues that programs like those offered through the University of Michigan Health System are suggested to be a “step in the right direction.”

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v. See (Arizona) ARIZ. REV. STAT. ANN. § 12-2605 (2011); (Colorado) COLO. REV. STAT. ANN. § 13-25-135 (West 2011); (Connecticut) CONN. GEN. STAT. ANN. 52-184d (West 2011); (Georgia) GA. CODE ANN. § 24-3-37.1 (West 2010); (South Carolina) S.C. CODE ANN. § 19-1-190 (2010); (Utah) UTAH CODE ANN. § 78B-3-422 (West 2010); (Vermont) VT. STAT. ANN. TIT. 12 § 1912 (2011); and (Washington) WASH. REV. CODE ANN. § 5.64.010 (2011).

vi. See (Iowa) IOWA CODE ANN. § 622.31 (West 2011); (Montana) MONT. CODE ANN. § 26-1-814 (2009); (North Carolina) N.C. GEN. STAT. § 8C-1, Rule 413 (2012); (North Dakota) N.D. CENT. CODE § 31-04-12 (2009); (Ohio) R.C. 2317.43 (West 2011); (Oklahoma) OKLA. STAT. ANN. TIT. 63, 1-1708.1H (West 2011); (Oregon) OR. REV. STAT. § 677.082 (2011); (West Virginia) W. VA. CODE ANN. § 55-7-11a (West 2011); and (Wyoming) WYO. STAT. ANN. § 1-1-130 (2010).

vii. See the Ohio statute in n. 1, *infra*.

viii. These states include: (1) Alabama; (2) Alaska; (3) Illinois; (4) Kansas; (5) Kentucky; (6) Minnesota; (7) Mississippi; (8) Nevada; (9) New Jersey; (10) New Mexico; (11) New York; (12) Pennsylvania; (13) Rhode Island; (14) West Virginia; and (15) Wisconsin.

Yet, with respect the simple question of whether to offer an apology or words of condolence, the recognition of where to “draw the line” concerning what is said to patients and/or their families is arguably the real key. This concept is also not unique, as articles have show that some malpractice insurers have begun offering premium discounts to those who attend seminars on the subject of disclosure and apology (O’Reilly, 2010). Insurers understand the idiom: an ounce of prevention is worth a pound of cure, and this idiom ideally summarizes this article.

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# Nurse Leaders' Critical Role in and Collaboration Strategies for Creating Safe, Positive Workplace Cultures

Beth Boynton, RN, MS

## KEY WORDS

Complexity Nursing, Sentinel Events, Human Factors, Constructive Feedback, Emotional Intelligence, Assertiveness, Organizational Culture Change

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*This article bridges empirical data about root causes of sentinel events with elements of human behavior that contribute to them. Legal nurse consultants (LNCs) will gain insight into the complexity of nurse practice and the importance of qualitative leadership strategies that promote behavioral changes and assertiveness. LNCs can utilize these concepts to inform clients about individual and organizational behaviors that may contribute to unsafe care and explore accountability for untoward outcomes from a systems' perspective. A case scenario highlights the relationship of nursing error to workplace dynamics and the limitations of typical incident reporting.*

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## Introduction

Developing cost-effective strategies that optimize safety and promote client and staff satisfaction is a daunting responsibility for nurse leaders at all levels and in all specialties. With staggering and persistent statistics on medical errors plaguing every healthcare setting, creating positive workplaces is a topic warranting our attention and begging for innovative interventions. Although legal nurse consultants (LNCs) are typically contacted after an untoward medical outcome, the insights and leadership roles they have, place them in positions of valuable resources for prevention. In addition, as we move towards more accountability from a systems' perspective, LNCs must understand complexity science and its application to the practice of nursing. The article is written to enhance both of these roles.

Not too long ago, I was speaking to over 100 nurse leaders in Washington State. While standing there with my microphone, power point, and some anxiety, I shared a story about asserting myself regarding a staffing and safety concern I had experienced two weeks earlier in my per diem role as a staff Registered Nurse (RN), "I have a graduate degree, have written a book, and have been a nurse for 25 years, and yet taking my concern to my supervisor, the scheduler and ultimately the Director of Nurses, was harder for me to do than to stand in front of you giving my first Keynote Address today"! Intellectually, assertiveness and listening are simple, but developing and practicing these skills are extremely complicated and nurse leaders are in a critical role to pave the way.

## Empirical Data, Behavioral Factors, and Call to Action

Legal nurse consultants are likely aware of The Joint Commission's (TJC) statistics on root causes of sentinel

events that are regularly updated on its website (TJC, 2012). There is a list of 18 categories and subcategories of commonly identified root causes. Among these categories are 'leadership', 'communication' and 'human factors'. A close look at these three categories is important for two reasons: first, they are listed as the most frequently identified root causes of sentinel events in 2009, 2010, and 2011, and second, they raise questions about the influence of human behaviors on medical errors and workplace culture. This is why it is important to focus on behavioral change efforts in addition to more typical intellectual approaches in order to be successful in providing safe care. To bring this point home, examine the categories of root causes in this report and consider what aspects of human behavior and/or workplace interactions might be part of the story. For instance, many of the descriptors in the 'leadership' category include some behavioral component often associated with emotional intelligence:

"Organizational planning, organizational culture, community relations, service availability, priority setting, resource allocation, complaint resolution, leadership collaboration, standardization (e.g., clinical practice guidelines), directing department/services, integration of services, inadequate policies and procedures, non-compliance with policies and procedures, performance improvement, medical staff organization, nursing leadership" (TJC, 2012, p.6).

Self-expression, self-efficacy, attitudes about diversity, and conflict management are examples of the 'behavioral component' while assertiveness and respectful listening represent the related skills used in manifesting current behaviors and those needed to practice and develop new behaviors. Building healthier communication skills is an inherent part of the process of behavior change efforts. For

nurses, in particular, this translates into such important abilities as:

- Asking for, offering, and accepting help
- Setting limits, saying “No”, and negotiating compromise
- Respecting self and others

“I need help”, “I can’t work late tonight”, “Dr. Smith, that is the wrong leg” are all assertive comments and there is no such thing as developing selective assertiveness. In other words, there are elements of this teaching that represent personal and professional growth and empowerment. Some leaders may be afraid to help nurses develop more confident voices and advocacy for themselves as well as patients. There may be varying degrees of welcoming these new skills in our workplaces, and validating, advocating for, and setting limits with staff is another challenging part of the work.

Ebright (2010) describes the complexity of delivering patient care along with the importance of supporting RN decision-making and establishing healthy work environments. The author explains the complexity of RN work in terms cognitive functions: organizing, prioritizing and decision-making, mindfulness, previous experience, and examination of causes of errors that includes systems-related factors. This considers the value of complexity science, that is, how adaptive systems such as human beings and organizations function and respond (Ebright 2010). In short, complexity science involves behavior that may be unpredictable and interrelated. Ebright, Patterson, Chalko & Render (2003) provided a description of RN work patterns across medical-surgical units. They identified factors that make the work of nursing care very challenging and germane to our discussion including missing equipment and supplies, interruptions, waiting for needed resources, communication inconsistencies, and lack of time. Ultimately, the connections between the diverse and fluctuating composition of work relationships and evidence-based information on adverse events are difficult to quantify and the communication-based skills are tough to teach, practice, and learn. An additional dimension of challenge lies in the interconnectedness of individual and organizational behaviors. Nevertheless, given their persistent and pervasive presence, sentinel event data seem to be an imperative call to action.

## **Leadership Strategies to Promote Individual and Organizational Behavioral Change**

There are qualitative strategies that can be utilized to create safe, positive workplaces cultures. These strategies arise from expertise in organizational development, emotional intelligence, group dynamics, and effective communication. Building trust and healthy relationships are inherent in all of them. There are many ways to incorporate these suggestions into a process that meets a leadership style and organizational goals, and promotes staff investment.

## **Develop a Plan with Vision, Commitment, and Consensus-Building**

A multi-phased plan with the idea of what the organization wants to accomplish in terms of workplace culture and inter-professional communication should be developed with staff input. Messages can be communicated through preferred methods such as newsletters, meetings, posting, blogging, and word of mouth. For example:

“Over the next year I want to work with you to make sure that we have a safe and respectful work environment for you and our patients. In the process and with your help we will develop a clear vision, share the latest evidence and get your input on what we need to do to make ABC hospital the safest place for our patients and staff and most rewarding career you could imagine.”

Enthusiastic staff members should be encouraged to be part of a committee, other departments asked to be involved, or if in a senior leadership role, engage with the nurse management team. Be sure to include steps to evaluate, revise, implement, and re-evaluate along the way. Always remember that the process itself is extremely important to the outcome, even if it can’t be seen or measured.

## **Incorporate Training and Practice**

Making sure that everyone has training in the basic skills necessary for respectful listening and speaking-up is a fundamental step in developing new norms that will require behavioral changes from individuals, groups, and organizations. There are many consultants who offer such training which can be packaged as giving and receiving constructive feedback or communication skill building. In this step, the focus will be more on the intellectual aspects of communication and making sure that everyone has a baseline from which to grow and meet new expectations.

If there is a nurse management team, consider more in-depth work on giving and receiving constructive feedback and again, a process that builds effectiveness into the management team. These professionals will be in a pivotal position to continue the teaching and ultimately enforce new behaviors. A daylong seminar or brief series of workshops, that focuses on building a cohesive nurse management team while practicing and promoting communication skills necessary to build safe and positive workplace cultures, should include the intellectual learning and facilitated opportunities to practice the skills with peers giving examples from their own experience. Practicing the skills in a safe environment is essential for translating the training into long-term, progressive behavioral change. As a fairly new frontier, it represents exciting challenges for creative application. Some ideas to consider would be to:

- Incorporate communication practice into team meetings. Use case studies of conflict to ask where are there opportunities for improved listening and speaking up.

Appoint a different person in each meeting to ‘monitor’ communication and maintain a focus on the new norm.

- Work with human resources to create opportunities to reward individual, pairs, and team growth. A card to two nurses who worked out a conflict, or pizza for a team who is showing more effective collaboration are powerful and hopefully affordable ways to continue the momentum.
- Coach individuals who may be struggling with new skills. This will demonstrate effective leadership support as well as an opportunity to portray clear expectations. Later on in the learning curve, coaching may be part of a last-effort plan to help the employee keep his or her job with the involvement of human resources and/or outside consultants as part of the process.
- Role model the skills whenever possible (you may even want to point out that you are doing so), and encourage others to do the same. Ironically, assertiveness can be built by asking nurses what is needed in order to meet a performance goal or support a new initiative and listen to the response. This can be followed-up by validating ideas and when possible offering available support or alternatively setting a limit and brainstorming compromise.

Ideas from staff about ongoing communication skills practice should be encouraged. The point is that practice is important. People grow at different paces and with different strengths and needs. Giving and receiving constructive feedback engages profound human development and supporting effective communication can help chip away barriers that may exist in a diverse population including gender, age, experience, ethnicity, and sexuality.

## Discipline

Hopefully, the majority of staff will respond to training, feedback, coaching, and opportunities for learning and practicing new behaviors that support a safe working environment. However, not everyone will be successful in developing the skills needed for respectful collaboration in the workplace and as with any performance issue, discipline must be included. Some staff may not be ready or may need another work environment or life circumstance to continue on with personal growth. How and when to begin addressing an employee’s behavior with a disciplinary process is a judgment call and will inform all stakeholders about behavioral expectations. No mixed messages. No double standards. Staff who can’t or won’t behave appropriately must be placed elsewhere, terminated, suspended, or face some disciplinary measure that will ensure a safe environment for all staff.

## Case Scenario

Sally Jones is a nurse manager who oversees a busy 36 bed medical-surgical unit of a metropolitan teaching hospital. During the day shift there are eight RNs, four Certified Nursing Assistants, (CNAs) and two unit coordinators.

Sally reports to the Chief Nursing Officer (CNO) and has expressed concerns about one of the staff RNs, Mary Smith.

She told the CNO that Nurse Smith frequently creates tension and negativity on the unit with passive aggressive facial expressions such as: smirking, rolling her eyes, and sighing. She also makes sarcastic comments about certain staff or organizational policies. One of the other staff nurses, Jean, has asked to move to a different shift because of Mary’s negativity. However, both unit coordinators say they love working with Mary.

Mary has been with the organization for 10 years and is well respected for her clinical expertise. The problem is complicated by the fact that prior to Sally being promoted to a management position a year ago, Mary and Sally worked together on the unit. In fact, Mary trained Sally.

Sally reports that Mary has been a constant source of criticism, unpleasant remarks, and frequent cold shoulders. Sally also reports that Mary treated the previous manager in a similar way and wonders if that is part of the reason she left.

Last week Jean had to fill out an incident report because she gave one of her patients an intramuscular dose of morphine sulphate six hours after the order had been changed to by mouth percocet. Mary and Jean were both working that shift. The doctor had changed the order while Jean was on break. Mary had spoken with the physician about the new order and stated that she reported the change to Jean. Jean says that Mary did mention the doctor’s visit with the patient, but not the medication change. The patient was ok, but his wife was angry and promised to take her concerns to the CEO of the hospital.

1. What individual and organizational factors may have contributed to the medication error?
2. Which of these factors are likely to be discovered through the incident report? Which may remain hidden?
3. If this incident had resulted in a serious injury or death, how do you think a malpractice case against Jean might unfold? What shortcomings might such a process have on uncovering all the contributing factors?
4. What could Sally do to minimize future errors on the unit? What about the CNO?
5. How do you think the CEO might interpret an angry letter from this patient’s wife?

## Conclusion

Building positive and safe cultures in healthcare is exciting, daunting, profound, and in some areas, tough-to-measure work. Much of what nurses do is evidence-based and this qualitative realm is newer territory for many leaders. Legal nurse consultants who understand the complexity of RN work, related complexity science, behavioral factors which contribute to untoward outcomes and process-oriented solutions will offer clients more effective prevention advice and more astute recognition of organizational culpability

in nurse malpractice cases. For example, a communication failure that results in negligent damages may raise questions about the organization's commitment to communication skills' training and practice in addition to any nurse malpractice. Receptivity to more qualitative aspects of providing safe care is growing. The LNC's perspective on sentinel events along with networking opportunities for those seeking to prevent them and/or hold appropriate stakeholders accountable for them is a valuable contribution to promoting safe, quality care.

## References

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### **YouTubes:**

"Why is Communication So Hard for Healthcare Professionals"  
<http://www.youtube.com/watch?v=IL4mxSadn5Q>

"Interruption Awareness: A Nursing Minute for Patient Safety"  
[http://www.youtube.com/watch?v=PGK9\\_CkhRNw](http://www.youtube.com/watch?v=PGK9_CkhRNw)

## Sleep Disorders

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Being awake for 18 hours leads to a comparable Blood Alcohol Content (BAC) of 0.05 while being awake for 24 hours a BAC of 0.10 (Dawson & Reid, 1997; Williamson et al., 2001). Now consider a BAC of 0.80 is considered legally drunk. Similar to drunk driving, sleep deprivation causes impaired reaction time, vision, and judgment; problems with short term memory and processing information; and increased moodiness and potentially aggressive behavior (Mann, 2003). Based on a 2010 survey conducted by the CDC it is estimated over 30% of civilian employed adults (approximately 40.6 million workers) in the U.S. reported "short sleep duration" of less than or equal to only 6 hours of sleep per night (CDC Morbidity and Mortality, 2012). This issue *The Clinical Maxim* looks at common sleep disorders and their implications.

### Overview of Sleep Disorders:

There are more than 100 different sleeping and waking disorders, which can be grouped into four main categories:

- Problems falling and staying asleep (insomnia)
- Problems staying awake (excessive daytime sleepiness)
- Problems sticking to a regular sleep schedule (sleep rhythm problem)
- Unusual behaviors during sleep (sleep-disruptive behaviors (Sleep disorders, 2011))

There are two states of sleep: Rapid eye movement (REM) sleep is when you dream. Your muscles (except your eyes and breathing muscles) do not move during this stage of sleep. Non-rapid eye movement (NREM) sleep has four stages that can be detected by brain electrical activity (EEG) waves. REM sleep alternates with NREM sleep about every 90 minutes. A person with normal sleep usually has four to five cycles of REM and NREM sleep during a night (Polysonography, 2011).

### Pathophysiology of Chosen Disorders

**Obstructive sleep apnea** occurs when the muscles in the back of the throat relax which causes narrowing, or even closing, of the airway as one breathes in. The brain recognizes the inability to breathe and thus briefly wakes a person so that the airway can be re-opened. This can occur 5 to 30 times per hour, depending on the severity (What is Sleep Apnea?, 2012). Three mainstays of treatment are dental appliance, Continuous Positive Airway Pressure (CPAP) machine or surgery. Two possible surgical options are Uvula excision (surgery to correct elongated uvula)

<http://www.youtube.com/watch?v=JyUA70MazW8&feature=relmfu> or Uvulopalatopharyngoplasty [UPPP] (surgery to remove tonsils, uvula, and partial soft palate removal)

<http://www.youtube.com/watch?v=obEKN18oqrg&feature=relmfu> (Warning: both videos are graphic.).

**Narcolepsy** is a neurologic disorder, the exact cause unknown. It is a chronic disorder of the central nervous

system characterized by the brain's inability to control sleep-wake cycles. It tends to run in families, and may have a component of an autoimmune disorder (<http://www.nlm.nih.gov/medlineplus/ency/article/000802.htm>). At various times throughout the day, people with narcolepsy experience irresistible and sudden bouts of sleep, which can last from a few seconds to several minutes (Narcolepsy Fact Sheet, 2011).

**Excessive Daytime Sleepiness (EDS)** is the symptom most consistently experienced by almost all individuals with narcolepsy, and is usually the first symptom to become clinically apparent. EDS interferes with normal activities on a daily basis, whether or not individuals had sufficient sleep at night. People with EDS describe it as a persistent sense of mental cloudiness, a lack of energy, a depressed mood, or extreme exhaustion. Many find that they have great difficulty maintaining their concentration while at school or work. Some experience memory lapses (Narcolepsy Fact Sheet, 2011).

**Isolated sleep paralysis** is a type of paralysis that occurs with a sleep disorder. Sleep paralysis is the inability to perform voluntary muscle movements during sleep. You feel awake but are unable to voluntarily move. The episodes are self-limited, and may occur with hallucinations (<http://www.nlm.nih.gov/medlineplus/ency/article/000801.htm>).

### High Risk Profile for Sleep Deprivation:

- Young adults 18-29 (especially males)
- Shift workers (working the night shift increases risk of falling asleep by 6%)
- Short sleep duration defined as less than or equal to 6 hours per night per 24 hour period (increases risk of falling sleep by 6%).
- Depression (may manifest as excessive sleep alternating with insomnia) (CDC Morbidity and Mortality, 2012)

### High Risk Profile for Sleep Apnea:

- Obesity
- Hypertension
- Neck circumference greater than 17 inches

- Male gender
- Age older than 65
- Use of alcohol, sedatives, or tranquilizers
- Smoking
- Family history

(<http://www.mayoclinic.com/health/obstructive-sleep-apnea/DS00968/DSECTION=risk-factors>).

### Diagnostic Criteria/Testing:

Determining or confirming the cause of sleep disorders may warrant limiting or expanding individual testing based specific clinical presentation.

### Polysomnography (Sleep Study):

Through the use of monitors, microphones, sensors, and electrodes, the sleep study measures sleep cycles and air flow in and out of the lungs during breathing; blood oxygen levels; body position; brain waves (Electroencephalogram/EEG) and eye movements (Electro-oculogram/EOG); breathing effort and rate; electrical activity of muscles, specifically legs (Electromyogram/EMG); heart rate; and snoring (Polysomnography, 2011).

### Trial of Continuous Positive Airway Pressure (CPAP) Mask:

Used to treat sleep apnea and aids in diagnosis. CPAP Mask Tutorial on YouTube <http://www.youtube.com/watch?v=AXcj0GVIEcE>; How CPAP Works on YouTube <http://www.youtube.com/watch?v=AUXYjPbNwqg&feature=rrelated>.

### Multiple Sleep Latency Test (MSLT):

Determines how long it takes to fall asleep during a daytime nap. Patients with narcolepsy fall asleep much faster than people without the condition. (<http://www.nlm.nih.gov/medlineplus/ency/article/000802.htm>).

### Apnea-Hypopnea Index (AHI):

Results are used to diagnose obstructive sleep apnea.

- 5 - 15 is mild sleep apnea
- 15 - 30 is moderate sleep apnea,
- More than 30 is severe sleep apnea (<http://www.apneahypopneaindex.org/>)

### Legal Considerations

- Maggie's Law in New Jersey: Up to 20 years in jail and \$150,000.00 fine if found guilty of vehicular homicide due to being awake over 24 hours. ([http://www.njleg.state.nj.us/2002/Bills/PL03/143\\_.PDF](http://www.njleg.state.nj.us/2002/Bills/PL03/143_.PDF))
- Prescription medication may interfere with normal sleep cycles

- At the scene of a crash, there is no objective testing to determine driver's drowsiness

## A Look at Case Law and Resources

An informal search of online case law was conducted using the GOOGLE search engine and keywords (in quotes) "driving drowsy", "sleep deprivation", "sleep disorders", "diagnostics," "impaired driving", "glossary," and "case law" in alternating string searches. A review of the information retrieved provided both formal and informal sources. A sampling of the *preliminary results* (though not all-inclusive) via internet retrieval is provided here.

### Articles

Krishnan, V. & Shaman, Z. (2011). Legal issues encountered when treating the patient with a sleep disorder. *Chest*, 139(1), 200-207. doi: 10.1378/chest.09-1962. Retrieved from <http://chestjournal.chestpubs.org/content/139/1/200.full>

Tefft, B. C. (2010). The prevalence and impact of driving drowsy. AAA Foundation for Traffic Safety. Retrieve from <http://www.aaafoundation.org/pdf/2010DrowsyDrivingReport.pdf>

Bonnie, R. J. & George, C. F. (n.d.) Performance and safety risks of sleep deprivation and sleep disorders. Retrieved from <http://www.uptodate.com/contents/performance-and-safety-risks-of-sleep-deprivation-and-sleep-disorders>

Bonnie, R. J. & George, C. F. (n.d.) Liabilities of sleep deprivation and sleep disorders. Retrieved from <http://www.uptodate.com/contents/liabilities-of-sleep-deprivation-and-sleep-disorders>

### Case Law

Article on worker's compensation case law related to sleep disorder and AMA Guides of Impairment 5th edition. <http://www.lexisnexis.com/community/workerscompensationlaw/blogs/workerscompensationlawblog/archive/2012/02/20/catching-up-on-some-zs-in-california-sleep-disorders.aspx>.

*Natalie White Lesser and Harvey Lesser h/w v. Nordstrom Inc., et al.* Issue of fatigued Nordstrom's employee causing vehicular death. Motion granted upholds Summary Judgment in favor of Nordstrom's dismissing case. Retrieved from <http://www.paed.uscourts.gov/documents/opinions/98D0843P.pdf>.

*Hosanna-Taber Evangelical Lutheran Church and School v. Equal Employment Opportunity et al.* Unlawful firing for narcolepsy as disability. Certiorari to the United States Court of Appeals for the Sixth District. 565 U.S. (2012) Retrieve from <http://www.supremecourt.gov/opinions/11pdf/10-553.pdf>.

### Resource

Human Factors in the Motor Carrier Industry in Canada. Excellent resource on driver fatigue. See Phase I Intervention Leads. Retrieved from [http://www.cmmta.ca/english/pdf/human-factors\\_report\\_May\\_2011.pdf](http://www.cmmta.ca/english/pdf/human-factors_report_May_2011.pdf).

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## Parasomnias

Including but not limited to sleepwalking, night terrors, sleep paralysis, nightmares, etc. <http://www.clevelandclinic.org/health/health-info/docs/3700/3728.asp?index=12133>.

## Potential Experts

- Neurologists specializing in sleep disorders
- Otolaryngologist (or Ear, Nose, Throat [ENT])
- Dentists specializing in sleep disorders
- Primary Physician
- Nutritionist
- Psychologist/Psychiatrist

## Damages

- Sequelae of sleep deprivation: impact on psychological and psychosocial factors (such as depression)
- Loss of consortium: Related to spousal sleep disturbance with snoring and alternate sleeping arrangements

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- Dawson, D. & Reid, K. (1997). Fatigue, alcohol, and performance impairment. *Nature*, 388, 235. Retrieved from <http://www.fatiguescience.com/assets/pdf/Alcohol-Fatigue.pdf>.
- Mann, D. (2003). Driving drowsy could land you in jail. Retrieved from <http://www.webmd.com/sleep-disorders/news/20031001/driving-drowsy>
- Narcolepsy Fact Sheet (2011). *National Institute of Neurological Disorders and Stroke*. Retrieved from [http://www.ninds.nih.gov/disorders/narcolepsy/detail\\_narcolepsy.htm](http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm)

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# Online References and Resources

## Sleep Disorders

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To supplement the feature article on sleep disorders, the following sites provide online resources for research, education, and support for sleep disorders. This list is not meant to be all inclusive of the potential resources available. This list is provided as a general reference source for the legal nurse consultant and is not an endorsement of any listed sites or services. As with any online resource, the reader must confirm its authority, currency, and credibility independently.

<b>GLOSSARY</b>	<b>Pub Med Health Sleep Disorders Overview</b> Similar overview of sleep and sleep disorders. <a href="http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001803/">http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001803/</a>
<b>Web MD</b> Good list of frequently used terminology related to sleep disorders and diagnostic treatment. <a href="http://www.webmd.com/sleep-disorders/glossary">http://www.webmd.com/sleep-disorders/glossary</a>	<b>National Institutes of Health National Institute of Neurological Disorders and Stroke</b> Information on narcolepsy and patient's narcolepsy fact sheet. <a href="http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm">http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm</a>
<b>About.com</b> Sleep terminology A-E <a href="http://sleepdisorders.about.com/od/sleepglossaryae/Sleep_Disorders_Glossary_A_E.htm">http://sleepdisorders.about.com/od/sleepglossaryae/Sleep_Disorders_Glossary_A_E.htm</a> Sleep terminology F-K <a href="http://sleepdisorders.about.com/od/sleepglossaryfk/Sleep_Disorders_Glossary_F_K.htm">http://sleepdisorders.about.com/od/sleepglossaryfk/Sleep_Disorders_Glossary_F_K.htm</a> Sleep terminology L-O <a href="http://sleepdisorders.about.com/od/sleepglossarylo/Sleep_Disorders_Glossary_L_O.htm">http://sleepdisorders.about.com/od/sleepglossarylo/Sleep_Disorders_Glossary_L_O.htm</a> Sleep terminology P-Z <a href="http://sleepdisorders.about.com/od/sleepglossarypz/Sleep_Disorders_Glossary_P_Z.htm">http://sleepdisorders.about.com/od/sleepglossarypz/Sleep_Disorders_Glossary_P_Z.htm</a>	<b>Medline Plus</b> Information on idiopathic hypersomnia. <a href="http://www.nlm.nih.gov/medlineplus/ency/article/000803.htm">http://www.nlm.nih.gov/medlineplus/ency/article/000803.htm</a>
<b>GOVERNMENTAL RESOURCES</b>	<b>Mayo Clinic</b> Information on obstructive sleep apnea (OSA). <a href="http://www.mayoclinic.com/health/obstructive-sleep-apnea/DS00968">http://www.mayoclinic.com/health/obstructive-sleep-apnea/DS00968</a> Information on narcolepsy. <a href="http://www.mayoclinic.com/health/narcolepsy/DS00345">http://www.mayoclinic.com/health/narcolepsy/DS00345</a>
<b>US Department of Transportation</b> Federal Motor Carrier Safety Administration <a href="http://www.fmcsa.dot.gov/safety-security/sleep-apnea/sleep-apnea.aspx">http://www.fmcsa.dot.gov/safety-security/sleep-apnea/sleep-apnea.aspx</a>	<b>Chase Sleep Dental</b> Commercial site on oral appliances, non-invasive treatment for sleep apnea, and a wide variety of information for patients. <a href="http://www.chasedentalsleepcare.com/glossary-oral-appliances">http://www.chasedentalsleepcare.com/glossary-oral-appliances</a>
<b>DIAGNOSIS/TREATMENT RESOURCES</b>	<b>PROFESSIONAL ASSOCIATIONS</b>
<b>Polysonogram</b> Medline Plus explanation of sleep study procedure. <a href="http://www.nlm.nih.gov/medlineplus/ency/article/003932.htm">http://www.nlm.nih.gov/medlineplus/ency/article/003932.htm</a> Excellent YouTube videos on the polysonogram procedure <a href="http://www.youtube.com/watch?v=ZHonyCHsZLc">http://www.youtube.com/watch?v=ZHonyCHsZLc</a> <a href="http://www.youtube.com/watch?NR=1&amp;feature=endscreen&amp;v=i1BM6kBE0Uo">http://www.youtube.com/watch?NR=1&amp;feature=endscreen&amp;v=i1BM6kBE0Uo</a> <a href="http://www.youtube.com/watch?v=sUtyaS3ga0A&amp;feature=related">http://www.youtube.com/watch?v=sUtyaS3ga0A&amp;feature=related</a>	<b>American Academy of Sleep Medicine</b> Provides accreditation for those providing sleep medicine services, website hosts practice guidelines, and coding. <a href="http://www.aasmnet.org/">http://www.aasmnet.org/</a>
<b>Trial of Continuous Positive Airway Pressure (CPAP) Mask</b> Downloadable fact sheet on CPAP mask. <a href="http://www.sleepservices.net/documents/cpap.pdf">http://www.sleepservices.net/documents/cpap.pdf</a> Several commercial videos on treatment for sleep apnea and patient education. <a href="http://www.healthchoicesfirst.com/category/sleep-specialists/product/cpap-trial-visit-1">http://www.healthchoicesfirst.com/category/sleep-specialists/product/cpap-trial-visit-1</a>	<b>American Academy of Dental Sleep Medicine</b> An area of practice that focuses on the management of sleep-related breathing disorders including snoring and obstructive sleep apnea, with oral appliance therapy (OAT) and upper airway surgery. <a href="http://www.aadsm.org/">http://www.aadsm.org/</a>
<b>Medline Plus</b> Overview of sleep and sleep disorders. Good selection of information on various disorders. <a href="http://www.nlm.nih.gov/medlineplus/ency/article/000800.htm">http://www.nlm.nih.gov/medlineplus/ency/article/000800.htm</a> Several Interactive videos on sleep disorders. <a href="http://www.nlm.nih.gov/medlineplus/tutorials/sleepdisorders/htm/index.htm">http://www.nlm.nih.gov/medlineplus/tutorials/sleepdisorders/htm/index.htm</a>	<b>American Board of Dental Sleep Medicine</b> Includes guidelines for practitioners. <a href="http://www.abdsm.org/">http://www.abdsm.org/</a>
	<b>American Association of Sleep Technologists</b> Position statements, model legislation, and advocacy information, as well as, information regarding the individual state societies. <a href="http://www.aastweb.org/">http://www.aastweb.org/</a>
	<b>Board of Registered Polysomnographic Technologists</b> Standards, patient information, and position statements for the discipline. <a href="http://www.brpt.org/">http://www.brpt.org/</a>



<b>SUPPORT GROUPS</b>
<b>Narcolepsy Network</b> is a non-profit organization dedicated to individuals with narcolepsy and related sleep disorders. The mission is to provide services to educate, advocate, support, and improve awareness of this neurological sleep disorder. <a href="http://www.narcolepsynetwork.org/">http://www.narcolepsynetwork.org/</a>
<b>ACADEMIC RESOURCES</b>
<b>University Services: Sleep Diagnostic &amp; Treatment Centers</b> Includes both a patient portal and a physician portal for information on sleep disorders and treatment. <a href="http://sleepwell.uservices.com/">http://sleepwell.uservices.com/</a>
<b>Tufts University</b> The Tufts Dental School promotes its mission and is devoted to the multidisciplinary management of sleep-disordered breathing. <a href="http://dental.tufts.edu/1262786838384/TUSDM-Page-dental2w_1262786838465.html">http://dental.tufts.edu/1262786838384/TUSDM-Page-dental2w_1262786838465.html</a>
<b>University of Maryland Medical Center</b> Division of Pulmonary and Critical Care: Sleep Disorders Center The center advertises comprehensive evaluation and management of a wide variety of sleep disorders including sleep-disordered breathing, narcolepsy, insomnia, restless legs syndrome, and many other problems. <a href="http://www.umm.edu/pulmonary/sleep_disorders.htm">http://www.umm.edu/pulmonary/sleep_disorders.htm</a>
<b>JOURNALS/NEWS</b>
<b>Journal of Sleep Research</b> Site promotes top articles from 2010 freely available. Publication of the European Sleep Research Society. <a href="http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1365-2869">http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1365-2869</a>
<b>Sleep</b> Scholarly articles on sleep research. <a href="http://www.journalsleep.org/">http://www.journalsleep.org/</a>
<b>Journal of Clinical Sleep Medicine</b> Official publication of the American Academy of Sleep Medicine. <a href="http://www.aasmnet.org/JCSM/">http://www.aasmnet.org/JCSM/</a>
<b>NON-ACADEMIC RESOURCES</b>
<b>National Sleep Foundation</b> Founded in 1990, seeks to educate scientifically toward improving sleep health and safety through education, public awareness, and advocacy. <a href="http://www.sleepfoundation.org/">http://www.sleepfoundation.org/</a> A resource provided by the National Sleep Foundation. Excellent information on sleep statistics and facts found here. <a href="http://drowsydriving.org">http://drowsydriving.org</a>

<b>American Association of Sleep Apnea</b> Founded in 1990, promotes as its mission dedication to reducing injury, disability, and death from sleep apnea and to enhancing the well-being of those affected by this common disorder. <a href="http://www.sleepapnea.org/">http://www.sleepapnea.org/</a> Exceptional site for information related to sleep disorders <a href="http://sleepapnea.org/resources/links.html">http://sleepapnea.org/resources/links.html</a>
<b>Circadian Sleep Disorders Association</b> The Circadian Sleep Disorders Association provides support for those affected by circadian sleep disorders, and is a resource of information on the disorder(s) to the general public. <a href="http://www.circadiandisorders.org/">http://www.circadiandisorders.org/</a>

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## Moral Distress: Effects on the Practice Care Environment

Eileen Watson, EdD, MSN, RN, ANP, GNP, LNCC

### Introduction

In today's practice care environments, nurses are facing increased exposure to moral distress due to their inability to act in accordance with their ethical judgment caused by internal and external constraints. Moral distress defined in the nursing literature by Jameton (1984) occurs "when one knows the right thing to do, but institutional constraints make it nearly impossible to pursue" (p. 6). Pendry (2007) expanded on the definition of moral distress stating "the physical or emotional suffering that is experienced when constraints (internal or external) prevents one from following the course of action that one believes is right" (p. 217).

**Table 1: Symptoms of Moral Distress**

PHYSICAL	PSYCHOLOGICAL
Headaches	Feelings of guilt
Tiredness	Anxiety
Gastrointestinal symptoms	Frustration
Shaking	Anguish
Pain	Confusion
Insomnia	Feel "bogged down"
Hypertension	Frazzled
Sleeplessness	Social isolation
Nausea	

Note. Adapted from Dickerson, P. (2011). *Moral distress: its impact on nursing*. Retrieved from: <http://www.healthcaredayonline.com/HCTclassroom/coursematerials0910.html>; Epstein, E. & Delgado, S. (Sept. 30, 2010). *Understanding and addressing moral distress*. *OJIN: The Online Journal of Issues in Nursing*, 15(3), Manuscript 1; Ganske, K. (September 30, 2010). *Moral distress in academia*. *OJIN: The Online Journal of Issues in Nursing*, 15(3), Manuscript 6; Pendry, P. (2007). *Moral distress: Recognizing it to retain nurses*. *Nursing Economics*, 25(4), 217-221.

Sources of external constraints have been cited in the medical and nursing literature. Sources identified can include institutions, other health care providers, patients' family members, other patients, the patient, society, "being in-between," and the law. Internal constraints include a nurse's personal value system –influenced by issues such as lack of knowledge, lack of courage, lack of assertiveness, self-doubt, fear of losing one's job, socialization roles, and perceived constraints (Epstein, 2008; Pendry 2007).

**Table 2: Sources of Moral Distress in Clinical Practice Settings**

Non-supportive/non-respectful ethical climate
Nurses core personal values and ethical obligations conflict
Protection of patient rights
Unfair distribution of resources
Scarcity of resources
Short staffing
Nurse-Physician conflicts
Dysfunctional communication
End-of-life care situations
Downsizing
Technological advances
Compromised standards
Medical futility
Reporting/not reporting compromised workers
Advanced directives
Social justice/injustice
Policy and procedures
Patient care concerns
Professional conflict/Role conflict

Note. Adapted from Ganske, K. (September 30, 2010). *Moral distress in academia*. *OJIN: The Online Journal of Issues in Nursing*, 15(3), Manuscript 6; Pendry, P. (2007). *Moral distress: Recognizing it to retain nurses*. *Nursing Economics*, 25(4), 217-221; Zuzelo, P. (May, 2007). *Exploring the moral distress of registered nurses*. *Nursing Ethics*, 14(3), 344-359.

With increased moral distress in the practice care environment, "the focus becomes doing the technical aspects of the job without the caring and critical thinking that is so critical to safe, high-quality nursing practice. Both mental and physical manifestations of stress can impact job performance, leading to errors in patient care. The nurse may have absences from work, may choose to change jobs, or may leave nursing altogether. Ultimately, the patient suffers, and the profession of nursing suffers" (Dickerson, 2011, p. 3).

Research has identified that moral distress is needlessly on the rise and threatens the quality of patient care (AACN, 2006; Baldwin, 2010). Strategies “aimed to minimize the exposure to moral distress situations and augment mechanisms mitigating its effects on nurses are necessary for job satisfaction, retention [and quality patient care]” (Rice et al., 2008 p. 368).

**Table 3: Impact on Practice Care Environment Caused by Moral Distress**

Nurses lose capacity for caring
Nurses withdraw from the bedside
Nurses avoid patient contact
Nurses fail to give good physical care
Nurses leave the profession
Nurses feel loss of integrity and dissatisfaction

Note. Adapted from American Association of Critical Care Nurses (2006). AACN Position Statement on Moral Distress. Aliso Viejo, C: AACN. Retrieved from: [http://www.aacn.org/WD/Practice/Docs/Moral\\_Distress.pdf](http://www.aacn.org/WD/Practice/Docs/Moral_Distress.pdf)

Various strategies have been identified to help relieve moral distress in the practice care environment. Examples include:

- In 1991, The Joint Commission began requiring all health care facilities who receive Medicare and Medicaid funding to have a process in place for resolving ethical problems.
- In 2006, the American Association of Critical Care Nurses (AACN) developed a position statement on moral distress. AACN “asserts every nurse and every employer are responsible for implementing programs to address and mitigate the harmful effects of moral distress in the pursuit of creating a healthy work environment” (p. 1). Resources and programs identified by AACN include knowledge and use of:
  - American Nurses Association Code of Ethics with Interpretive Statements (2001)
  - International Council of Nurses Code of Ethics for Nurses
  - AACN 4 A’s to Rise Above Moral Distress Handbook
  - AACN 4 A’s to Rise Above Moral Distress Facilitators Toolkit
- In the 2007-2008 text edition by the North American Nursing Diagnosis Association, *Nursing Diagnoses: Definitions and Classifications*, moral distress became a new nursing diagnosis. As a nursing diagnosis, “it will provide nurses a means to recognize and intervene with moral distress situations with their patients” (Pendry, 2007, p. 4).
- Ethical Rounds, ethical committees, pastoral services

- Multiprofessional open communication and collaboration for planning patient care
- Interdisciplinary education
- Patient care conferences
- Structured communication methods—SBAR
- Open forums-group discussions of ethical issues
- Debriefing sessions
- Organizational support for nursing (Rice et al., 2008)

On a day-to-day basis, nurses “are likely to face a wide range of ethical situations leading to the experience of moral distress” (Pendry, 2007, p. 6). Nurses must identify the sources of their internal and external constraints in order to work through moral distress. Internally, nurses must examine their own attitudes, beliefs, and values in order to more effectively work through ethical dilemmas. Externally, improved methods of communication and collaboration must be addressed. The outcome goal of developing and implementing strategies for decreasing moral distress is to decrease the negative physical and psychological effects on nurses in the practice care environment and increase their job satisfaction, retention rate, and provide safe and quality patient care.

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# Patient Safety Technology and a False Sense of Security

Judith M. Bulau, MSN, RN

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**Q: Does patient safety technology guarantee safe patient care?**

**A: No. While patient safety technology has significantly improved patient care it can give clinicians a false sense of security because they may not appreciate patient safety technology limitations and how it may contribute to unsafe patient care.**

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Healthcare organizations strive to provide safe patient care using patient safety technology (PST) that has significantly improved patient care. Henneman (2010) categorized PST into four categories (1) those that support the direct hands-on care of the patient; (2) those that support documentation; (3) those that support meeting the needs of patients and families; and (4) those that support the staff caring for the patient and the family. However, there are limitations that pose risks which may contribute to medical errors and adverse patient safety events. PST may create a common misperception that patients are receiving optimal care when, in fact, care maybe compromised. Frush and Ahmad (2008, p. 89) indicate, "In many cases – about 60% of the time – an organization's issues cannot be fixed through technology. When an organization faces underlying cultural issues, such as teamwork, accountability, or reliability problems, technology will not fix those issues and may, in fact, exacerbate them." The use of PST can leave clinicians with perceptions that the type of PST being used may not be the appropriate type of monitoring the patient needs and it can:

- create extra work that may improve one thing, such as documentation, but also distract from direct patient care;
- take too much time to learn how to apply and integrate patient monitoring information in patient assessment and treatment;
- affect their professional values and beliefs about the delivery of care to patients;
- and may slow the delivery of care in emergencies (Henneman 2010).

Well-intentioned nurses may not use available PST such as barcode medication administration systems, because of their professional values and beliefs. For example, a sleeping patient was given an intravenous medication and experienced anaphylactic shock, cardiac arrest, and was resuscitated. Later it was discovered that the administered medication was prescribed for a different patient and that the patient who

received the medication was allergic to it. The nurse said she did not scan the patient's identification band because she did not want to interrupt the patient's sleep. The nurse's decision not to comply with the medication policy almost caused the patient's death. This example demonstrates that PST is effective only if it is used appropriately and correctly by the clinicians who use PST.

Successful use of PST may be affected by the inevitability of PST problems as described by Powell-Cope, Nelson and Patterson (2008, p. 7). "While technology holds much promise, the benefits of a specific technology may not be realized due to four common pitfalls: (1) poor technology design that does not adhere to human factors and ergonomic principles, (2) poor technology interface with the patient or environment, (3) inadequate plan for implementing a new technology into practice, and (4) inadequate maintenance plan." The authors also indicate, "Optimally, technology is designed to minimize errors and buffer the consequences of errors by eliminating error and adverse events; detecting errors early, before injury occurs; and mitigating the effects of errors after they occur to minimize injury. In this 'ideal' scenario, patient care technology would yield positive nurse, patient and organizational outcomes."

Powell-Cope, Nelson and Patterson (2008, p. 4) indicate that, "Nurses may respond to unintended consequences of technology with 'work-arounds,' of temporary fixes to technology problems or malfunctions." They provide an example of early implementation of barcode administration, in which "...scanning devices that were attached to the medication cart with a cord often made it difficult for nurses to scan the patient's identification band due to infection control restrictions. In response, nurses made duplicate armbands that they kept at the medication cart. The duplicate bands allowed for ease in scanning, yet by doing so bypassed the safety feature that required a positive patient identification (scanning the band on the arm) before administering a medication and increased the likelihood of 'wrong patient' errors."

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While it is undisputed that PST has significantly improved patient care, clinicians must pay attention to their false sense of security and the limitations of using PST. Henneman (2010, p. 9) indicates, "There seems to be little question that the aforementioned technologies offer the potential to improve patient safety. On the other hand, they require development, implementation, and reevaluation strategies that are challenging in the current, hectic, and resource-limited health care setting." When PST is used appropriately it can be instrumental in improving patient care.

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