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AALNC

AMERICAN ASSOCIATION OF LEGAL NURSE CONSULTANTS

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The Journal of Legal Nurse Consulting

Purpose

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

Manuscript Submission

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

Manuscript Review Process

Submissions are peer-reviewed by eminent professional LNCs with diverse professional backgrounds. Manuscript assistance can be provided upon request to the editor. Acceptance is based on the quality of the material and its importance to the audience.

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Feature Articles

Departments

Legal Considerations Abound

Dear Colleagues,

In this issue of the *Journal*, we have a discussion of liability issues related to the practice of legal nurse consulting, several featured articles that provide us with important clinical topic information and the legal implications thereof, and excellent resources in the *Journal* departments that help our practice areas. Julie Dickinson and Beth Zorn provide a wealth of information about potential areas of professional liability exposure for legal nurse consultants (LNC). They identify 10 common risk areas and discuss the need for the LNC to assess his/her own consulting practice, and use this knowledge to develop strategies for risk reduction. The authors provide an overview of actual cases and claims involving LNCs and key "take-away" messages the LNC should consider when and if practice modifications are needed. Being familiar with the scope and standards of practice are essential to sound legal nurse consulting practice.

An excellent article is presented by Mary Vrtis on important considerations related to cardiopulmonary resuscitation (CPR). Dr. Vrtis presents a California case and the involvement of the nurse is this case. This article discusses presumed consent when someone is resuscitated and there is no knowledge of advanced directives to the contrary. Dr. Vrtis describes important data about adverse outcomes related to CPR and low survival rates as well as the costs associated with the decision to perform CPR. The author discusses the legal implications related to performing and not performing CPR noting that there are differences state by state. LNCs will need to evaluate the merits of these cases in the course of their practice. Dr. Vrtis offers several questions related specifically to the California case as points of discussion.

Dr. Lee Whitesides has provided an excellent article on dental infections. He describes causes of these types of infections, predisposing factors, and three major sources for dental infections: Osteomyelitis, Ludwig's Angina, and Cervical Necrotizing Fascitis, and discusses in detail the importance of providing a comprehensive evaluation of the patient. While most dental infections are relatively minor, more serious infections can develop, exacerbate, spread to the head and neck, and can be life-threatening. Management and treatment of the dental infection may involve both medical and surgical interventions. Dr. Whitesides describes the important role for the LNC when evaluating a potential dental infection case noting particularly how an infection might have occurred such as patient neglect of dental health or a deviation from the standard of care.

Acetominphen toxicity can result in many health problems including acute liver failure. Thomas Quail and Edward Boyer provide a very in depth discussion of the mechanism of action and use of acetaminophen and note that this medication can be found as an ingredient in many types of over the counter drug products. The authors point out that more than 25 billion doses of acetaminophen are sold each year in the United States and that this drug is the primary ingredient in more than 600 over the counter products resulting in more than 56,000 emergency department visits and 26,000 hospital admissions. Toxicity of this agent is described both acutely and chronically along with phases of acetaminophen poisoning. Several legal case reports are presented that spell out the danger of acetaminophen overdose or poisoning and the role of the LNC in evaluating toxicity risk.

Central line-associated bloodstream infections present substantial risks to patients including 12% to 25% fatality in at-risk patients. Millions of these catheters are inserted into patients each year and if not properly inserted can result in serious complications. Darcy Doellman describes the importance of following the standard of care related to central venous catheter insertion and practice which can significantly reduce these types of infections. The author presents a patient case study and describes what went wrong and how this could be avoided with particular attention to violations of standards of care.

In our departments, Mary O'Connor provides a wonderful array of References and Resources for latex allergy. These include not only government sources and scholarly articles but opportunities identified for continuing education, as well as protocols, and position statements. In our Professional Practice, Trends, and Issues, Eileen Watson discusses elder abuse including re-

cent statistical information on its prevalence and provides definitions, causation and symptoms. It is important to know what the federal and state laws are for elder abuse and neglect in evaluating these cases. In our Question and Answer department provided by Judy Bulau, liability related to patient handoffs is discussed. A statement from The Joint Commission is provided which speaks to the need for a standardized approach to handoff communication. Harm that can occur to the patient is highlighted when there is a breakdown in communication.

I hope you enjoy this issue which will provide you with outstanding information and resources to assist you in your practice.

Bonnie Rogers
Editor-in-Chief, *The Journal of Legal Nurse Consulting*

Liability Lessons for Legal Nurse Consultants Part One: An Analysis of Claims Involving Legal Nurse Consultants

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KEY WORDS
Legal Nurse Consultant Liability, Claims, Risks, Malpractice, Negligence, Lawsuit, Risk Reduction

Legal nurse consultants (LNCs), like members of the healthcare field, must be aware of potential areas of professional liability exposure and employ risk management principles in their practice. This two-part series offers LNCs the opportunity to identify common LNC liabilities, assess their own consulting practice, and apply this knowledge as a means of engaging in risk reduction. In Part One, an overview of actual cases and claims involving LNCs will be offered to highlight the common areas of potential LNC liability, and key "take-aways" will be presented for LNCs to apply to their own consulting practice. An in-depth case study will be provided in Part Two which offers a closer look at an actual lawsuit involving alleged LNC negligence and discusses the principles of risk reduction learned therein.

Introduction

It is judicious for all nurses, regardless of their specialty, to critically analyze their practice to identify and correct potential liability risks or exposures. As such, legal nurse consultants (LNCs) must also be cognizant of ways in which they can improve their consulting practice and mitigate their risk of liability. Engagement in risk reduction through education, awareness, and practice modification is essential in the contemporary legal climate. By reviewing actual claims involving LNCs and analyzing them for lessons applicable to one's own practice, a LNC can engage in effective risk reduction.

Overall, the liability risk assumed by practicing as an LNC is very low. In examining the associated risk factors, there are three features of legal nurse consulting practice that may increase one's risk. First, LNCs who offer expert opinions are at higher risk of being sued than those who work behind the scenes. This is due to the gravity that expert opinions carry in medical-legal cases. Second, LNCs who are independent consultants are at higher risk than those who work in-house for law firms and insurance companies due to the vicarious liability of the latter's employer. Third, it is intuitive that LNCs who work full time in this specialty practice are at higher risk than those who work part time simply due to the volume of work being performed. The more work a LNC does, the more exposure he/she has to potential claims of negligence. However, the overall exposure of LNCs remains small. It is prudent, though, for LNCs to be alert to common liability risks, as such awareness and resultant practice modification can further reduce this potential exposure.

The claims and cases referenced in this article were obtained from three sources. First, legal research was conducted for published state and federal cases that contained the terms "legal nurse consultant," "legal nurse consulting," "legal nurse," or "nurse paralegal." This search yielded 75 cases. Of those, 18 cases addressed potential legal liability of LNCs. Four additional cases were referenced in the original 18, bringing the total number of pertinent cases to 22.

The second source of LNC claims was Nurses Service Organization (NSO), an insurance provider that offers professional liability coverage to nurses, including LNCs. NSO reviewed the common risks associated with the LNCs insured through the organization and supplied that information for the purposes of this article.

Third, the authors are aware, through informal sources, of additional claims, potential claims, and disputes involving LNCs and have shared that information hereto.

The liability risks related to legal nurse consulting were identified through an analysis of the information collected from these three sources. In random order, the most common risks are:

- Real or apparent conflict of interest
- Working on a potential case without attorney involvement
- Insufficient and/or unqualified expert affidavit or opinion letter
- Opining outside of the appropriate scope of expertise
- Failure to maintain opinion / improper withdrawal as an expert witness
- Advice and work of behind-the-scenes consultant
- Fee disputes
- Copyright infringement
- Confidentiality violations
- Malicious prosecution

Real or apparent conflict of interest

A conflict of interest is "a situation where one person has information that may potentially be used to influence a case and cause harm, injury, or prejudice to the client" (Sisko, 2010, p. 659). "Legal" conflicts of interest impact attorneys and their ability to continue representation of a client should opposing counsel argue that by virtue of a relationship with a particular expert or consultant, the attorney has access to "inside" information they would not normally be entitled to during the discovery process. "Personal" conflicts of interest may impact a consultant's ability to objectively opine on the merits of the case in which, for example, one of the named parties is a friend or acquaintance of the consultant.

Screening for real or apparent conflicts of interest is one of the first things that LNCs must do upon receiving a potential work assignment. Furthermore, this process is necessary for compliance with the American Association of Legal Nurse Consultants' (AALNC) Code of Ethics and Conduct, which asserts that "Financial or other relationships that may give an appearance of or create a conflict of interest will be disclosed" (AALNC, 2009, p. 1).

An example of this liability risk is evident in the Louisiana matter *In re Granier* (2005). A judge received public censure for hiring his girlfriend, a registered nurse (RN), as an independent LNC to review and summarize medical records for cases in his court and for authorizing payment from a judicial expense fund to pay for a seminar at which she obtained "legal nurse consulting credentials." While only the judge received a reprimand in this matter, the nurse should have recognized the conflict of interest and declined the work.

Take-away: LNCs must screen for any potential or actual conflicts of interest upon receipt of a new assignment. If any such conflict exists, the LNC must immediately disclose this to the attorney-client, and the assignment may need to be declined.

Working on a potential case without attorney involvement

Persons who are contemplating any type of medical-legal claim are seeking legal services, which mandates the advice and counsel of an attorney. The authors are aware of instances in which LNCs have been asked by patients or their families to evaluate potential medical malpractice claims. The independent LNC should never, under any circumstances, evaluate a potential claim for the lay public without an attorney being involved. LNCs should always work in conjunction with an attorney. If the statute of limitations or some other regulatory deadline or requirement expires while the case is being evaluated by the LNC, the LNC could be sued for malpractice and the unauthorized practice of law.

Take-away: The LNC should never agree to evaluate a case without an attorney being involved. If directly approached by an individual patient or family to screen a case for merit, the LNC should instruct each requester to contact an attorney.

Insufficient and/or unqualified expert affidavit or opinion letter

When a LNC is asked to prepare and sign an expert affidavit or opinion letter that will be affixed to a complaint, the LNC must honestly assess his/her qualifications to do so. In order to ensure qualification and compliance, the LNC must be familiar with the statutory requirements for the state in which the case is being filed. Despite the anonymity in the initial report, the LNC must be able to stand solidly behind the work product and opinions. The LNC's reputation and the longevity of his/her consulting career are at risk if the requisite standards are compromised to fulfill the short-term needs of an attorney-client.

In *Patenaude v. Norwalk Hospital et al.* (2010), the administrator of the decedent's estate alleged a wrongful death from aspiration pneumonia and a bowel obstruction and named the hospital and general surgeon as defendants. Attached to the complaint was a good faith opinion letter authored by an undisclosed healthcare provider, although the letterhead on the document referenced a legal nurse consulting company. The author opined on deviations from the standard of care as to both the hospital and the physician. The hospital filed a Motion to Dismiss stating that the good faith certificate did not satisfy the statutory requirement of being written by a similar healthcare provider. Plaintiff responded by filing a proposed amended complaint with an affidavit signed by the plaintiff's attorney. This affidavit asserted that the author of the good faith opinion letter was an RN who, through experience and training, was familiar with the nursing care of post-operative patients such as the decedent. Because the Motion to Dismiss was already pending, the court could not consider the amended complaint before ruling on the motion. The court described that the opinion letter attached to the original complaint did not identify the medical specialty of the author, thereby preventing the determination of whether the author was a similar healthcare provider. Furthermore, it did not state that the author was familiar with the standards of care for any particular medical specialty. Lastly, it did not identify whether the alleged negligence involved nursing care. The court found that the opinion letter was insufficient and granted the Motion to Dismiss.

The following year, plaintiff filed another suit against the hospital (*Patenaude v. Norwalk Hospital,* 2012) using an RN-authored opinion letter that was nearly identical to that of the earlier action. The only variation was the addition of a paragraph addressing the author's qualifications. However, this new content failed to address the state's statutory requirement of active clinical practice or teaching within the five-year period prior to the date of the alleged incident, and it did not address whether the author had been certified, trained, or experienced in any medical specialty. Due to the

insufficiency of the good faith opinion letter, the defendant again filed a Motion to Dismiss, which was granted.

Similar issues related to the expert affidavit are demonstrated in *Ledesma v. Shashoua et al.* (2007). In this action, plaintiff appealed a lower court decision granting the defendant certified registered nurse anesthetist's (CRNA) Motion to Dismiss. This dismissal was based on the plaintiff's failure to provide an expert report that complied with the applicable requirements under state law. The two expert reports in question were written by RNs, one a certified operating room nurse and the other, a certified legal nurse consultant. Both reports addressed the standards of care applicable to RNs or circulating nurses, not to CRNAs, and one opined on proximate causation. These two reports were deemed inadequate, because they failed to identify the defendant anesthetist at all. Without explicitly naming the defendant, the reader was left to "make an educated guess as to whose actions the expert is complaining." Furthermore, the court determined that only a qualified physician could render expert opinion testimony on causation in this case, which alleged an intraoperative nerve injury to plaintiff's arm due to incorrect intravenous access placement and improper placement and monitoring of her arm. Therefore, plaintiff was unable to meet her burden of proof with regards to the defendant CRNA. The Appellate Court affirmed the district court's judgment.

Similarly, in *Bell v. Hospital of St. Raphael* (2012), plaintiff/administratrix appealed a trial court decision granting the defendant's Motion to Dismiss, which was based on plaintiff's failure to show that the RN who authored the opinion letter was a similar health care provider. The RN opined on the ways in which the hospital failed to meet the standard of care in the emergency department and concluded that these deviations "led to a hemorrhagic stroke and [the decedent's] untimely death." To support its Motion to Dismiss, the hospital filed an affidavit of its vice president/chief medical officer/chief quality officer. This physician stated that, at the time of the incident, care of patients in the emergency room was managed by either a physician or physician's assistant. The trial court stated that an RN was not necessarily precluded from authoring the opinion letter, because the allegations were broad. However, the court noted an absence of information concerning the author's qualifications related to licensure, training, and experience. Therefore, the opinion letter failed to demonstrate whether or not the RN was a similar healthcare provider. The Appellate Court agreed that the opinion letter did not indicate whether the RN's qualifications were appropriate for statutory purposes, and the judgment was affirmed.

In *Royal v. Mancuso et al.* (2010), a licensed practical nurse (LPN) was named as a defendant in a medical malpractice action. She filed a Motion to Dismiss claiming that the author of the opinion letter, an RN, was not a similar healthcare provider as statutorily required. The opinion letter failed to reveal the author's licensure status, education, training, or experience, and the court could not infer whether the author was a similar enough healthcare provider to meet the statutory requirements. The Motion to Dismiss was granted.

Take-away: LNCs need to be familiar with the statutory requirements for authoring expert affidavits / certificates of good faith in the state(s) in which they work. Knowledge of the essential components of these documents is also important to ensure that all required content is addressed. It is imperative that LNCs limit their opinions to their expertise in particular practice areas, standards of care, and, when appropriate, causation and not opine outside of their clinical qualifications and specialty.

Opining outside of the appropriate scope of expertise

When asked to serve as a nurse expert, the LNC must only accept cases involving clinical areas and specialty knowledge in which he/she has expertise. This holds true whether the nurse is asked to opine on liability and/or causation elements.

As previously mentioned, the LNC must be familiar with the specific statutory requirements for experts in the state in which the case has been filed. Generally speaking, it is requisite for the liability expert to be a similar healthcare provider to the defendant. The nurse expert's education, training, licensure, and experience should be in the same specialty as the defendant, and the nurse should be clinically active in that field. Deviating from this scope may expose the LNC to liability of his/her own. It would be in violation of the AALNC Code of Ethics and Conduct which states that "The legal nurse consultant does not purport to be competent in matters in which he or she has limited knowledge or experience" (AALNC, 2009, p. 1-2). Furthermore, the Scope and Standards of Practice for legal nurse consulting cautions LNCs to "confine testimony to the specific area of expertise possessed" (AALNC, 2006, p. 15).

In *Cleveland v. USA* (2006), plaintiff's nurse expert opined that a physician assistant deviated from the standard of care in failing to obtain a chest x-ray and failing to diagnose congestive heart failure (CHF). In her opinion, if the decedent had been treated for CHF by the physician assistant, his subsequent demise could have been prevented. The defense objected to the nurse's admission as an expert witness and argued that, as a nurse, she was unqualified to testify as to the standard of care owed by a physician assistant. The court agreed and excluded her testimony, and the case resulted in a defense verdict. The plaintiff appealed, challenging the exclusion of the nurse expert's testimony. The Appellate Court affirmed the trial court's judgment, stating that a nurse is "not qualified to testify as to a physician's standard of care or the standard of care governing a physician assistant who stands in the place of the treating physician."

A similar issue existed in *Hebert v. USA* (2009). In this case, plaintiff's nurse expert opined that a medical resident violated the standard of care by allowing a patient to walk with a foreign object lodged in her throat. During her

deposition, however, the nurse stated that LNCs "don't testify on physicians. We can only testify to our expertise in nursing." The defense filed a Motion for Summary Judgment (MSJ) stating that plaintiff failed to identify an expert to provide testimony concerning physician negligence. Without this testimony, plaintiff could not meet her burden of proof, and the MSJ was granted.

In addition to liability testimony, the LNC also needs to be cautious to avoid opining outside of his/her area of expertise in causation testimony. The LNC has the responsibility to decline an assignment that calls for testimony that exceeds his/her specialty knowledge-base. Some states have permitted qualified RNs to testify on causation on specific issues, such as pressure ulcers, wound/ostomy care, and infusion therapy (*Gaines v. Comanche County Medical Hospital et al,* 2006; *Barton v. USA,* 2008; *Guardia v. Lakeview,* 2009; *Richardson v. Methodist Hospital,* 2002). The attorney-client should determine what may be allowed under the particular state's rules.

Take-away: LNCs should be aware of the boundaries of their expertise and should opine only within those limits. Adherence to the Code of Ethics and Conduct (AALNC, 2009) and to the Legal Nurse Consulting: Scope and Standards of Practice (AALNC, 2006) is highly recommended.

Failure to maintain opinion / improper withdrawal as an expert witness

The liability risk associated with failing to maintain one's opinion or improperly withdrawing as an expert witness is illustrated in an NSO claim that involved a LNC's withdrawal as an expert witness. The LNC provided an attorney-client with favorable preliminary opinions that were based solely on attorney's iteration of the case facts. However, after receiving and reviewing the medical records, the nurse found no evidence to support the allegations and refused to sign the affidavit or otherwise participate in prosecuting the defendant. Due to difficulty securing payment from the attorney-client, the LNC sued for services rendered, and the attorney countersued for failure to maintain her expert opinion.

Take-away: A LNC should never offer opinions or agree to be an expert prior to actually reviewing all pertinent medical records. As soon as an LNC realizes that he/she cannot support a case, further involvement in the case should be declined. Legitimate and timely withdrawal as an expert will give the attorney an opportunity to obtain additional reviews before statutory deadlines loom.

Advice and work of behind-the-scenes consultant

But for claims related to fee disputes, it is extremely rare for a case or claim to involve a behind-the-scenes consultant, as these consultants practice under the direction of the attorney, who is legally responsible for evaluating the basis for a consultant's opinions. That being said, the following two cases illustrate that the actions of such LNCs can be subject to scrutiny as well.

In *Collett v Steigerwald* (2007), a legal malpractice claim was brought against an attorney who filed a medical malpractice case involving a delay in the diagnosis and treatment of breast cancer. The attorney had the matter reviewed by an LNC who reported that the medical malpractice claim was unlikely to be successful based, in part, on the decedent's failure to undergo a recommended biopsy procedure and the difficulty in proving proximate causation. After researching the medical literature, the LNC prepared an addendum to his report which conveyed that some of the literature caused him to question several of his original conclusions and identified potential areas of further research. Based on the problems initially identified by the LNC, the attorney recommended against proceeding with the case. The plaintiff agreed, and the action was voluntarily dismissed. The subsequent legal malpractice claim included allegations that the attorney failed to have the mammogram films reviewed by a qualified (physician) expert and failed to prosecute several treating physicians in the medical negligence case. Claims against these providers were now time-barred by the statute of limitations. Due to the applicable statute of limitations, the defendant attorney's Motion for Summary Judgment was granted by the trial court, and this judgment was upheld by the Appellate Court.

During the depositions of two of plaintiff's experts in *Stanton v. University Hospitals Health System* (2006), it was acknowledged that both experts had been assisted by a nurse paralegal for plaintiff's counsel in the preparation of their reports. The defendant sought to depose the nurse paralegal, and plaintiff's counsel moved for a protective order. The trial court denied the protective order but limited the inquiry to specific questioning regarding the sole issue of how the expert reports were generated. Plaintiff appealed, but the Appellate Court upheld the judgment.

Take-away: Even though behind-the-scenes LNCs practice under the direction of an attorney, they still have exposure and are accountable for generating opinions and work products that are of the utmost quality.

Fee disputes

Billing concerns are the most likely reason for a dispute between a LNC and an attorney or the attorney's client. Oftentimes, situations involving fee disputes have underlying issues related to other liability risks discussed in this article.

For example, NSO handled a claim regarding a LNC who was hired by plaintiff's counsel to provide expert witness testimony. The LNC grew concerned with how plaintiff's counsel was pursuing the case and decided to remove herself as an expert. A dispute developed between the LNC and plaintiff's counsel over services rendered, and plaintiff's counsel demanded a return of fees.

Another NSO claim involved a nurse who provided legal nurse consulting services for plaintiff's counsel in a medical malpractice case. The plaintiff's estate filed a suit against

both the attorney and the LNC for overcharging of legal fees inclusive of the LNC's consultation services.

The authors are aware of another claim in which a LNC was asked to review a case for merit. After reviewing the initial records, the LNC realized that it was not a case she could support. However, the attorney kept sending her more records, asking her to "dig deeper." The LNC was still unable to support the case and declined to be an expert. The attorney sued the LNC for the fees he had paid her, which were approximately $5,000. When she contacted the liability carrier for her consulting practice, she was advised that her policy does not cover fee disputes with attorney clients. Thus, she hired her own counsel to fight the matter. The claim against her was ultimately thrown out but only after the LNC spent $2,500 in legal fees defending the claim.

Take-away: Transparency in fees and fee schedules contributes to the prevention of billing disputes. Sending invoices at regular intervals, instead of a lump sum at the conclusion of a case, will also help the LNC avoid issues with payment. Also, in the last example above, the LNC should have definitively declined further involvement in the case as soon as she determined she could not support plaintiff's claims related to the nursing care.

Finally, for independent LNCs who purchase professional liability insurance for their consulting or expert work, it is essential to determine the details of the coverage, that is, specifically what it does (and does not) cover. Adherence to the principles of risk reduction discussed in this article will also minimize situations that can lead to fee disputes.

Copyright infringement

Another potential area of LNC liability is copyright infringement. An example of this can be found in *Medical-Legal Consulting Institute v. LNC Education Associates et al* (1998). Plaintiff alleged copyright infringement of 11 protected works which were course materials for LNC educational programs, and judgment was entered against 2 of the 3 defendants. These two defendants had each attended no more than two of plaintiff's seminars several years before they developed their own LNC educational materials. Both had access to the plaintiff's subject works but discarded any of plaintiff's seminar materials prior to planning their own educational program. The majority of both the plaintiff's and defendants' written material contained a "compilation of facts, data, and information generic and common to the legal and medical professions," which was provided in outline form. The court found that the "defendants' accused work had substantially similar, and sometimes identical, verbiage as the protected work." In addition, the order and manner in which the information was laid out was nearly identical. The defendants' work, according to the court, satisfied the "intrinsic test," in that a lay person would subjectively appreciate the similarities between the two materials (Hervey, 2007).

Take-away: LNCs should not plagiarize or violate copyright protection. The Code of Ethics and Conduct calls for LNCs to abide by all local, state, and federal laws and maintain "standards of personal conduct that reflect honorably upon the profession" (AALNC, 2009, p. 2).

Confidentiality violations

As nurses, LNCs are acutely aware of privacy laws and the need to protect patient confidentiality. This obligation translates into the legal nursing specialty as the AALNC Code of Ethics and Conduct charges LNCs with protecting client privacy and confidentiality (AALNC, 2009).

In *Thiery v. Bye et al.* (1999), a client brought a legal malpractice claim against an attorney, law firm, and the employed nurse investigator. The defendant attorney had represented the plaintiff in a personal injury suit. After settlement, he contacted the plaintiff for permission to release her medical records for use by the nurse investigator as a teaching tool for a legal nurse consulting class at a local college. The plaintiff was assured that the records would be redacted prior to distribution, but they were not. The plaintiff also filed a separate suit against the nurse and the college that employed her to teach the LNC course.

Take-away: LNCs must maintain patient confidentiality and strictly adhere to all privacy laws.

Malicious prosecution

Malicious prosecution is defined as filing a lawsuit for an improper purpose and without grounds ("Malicious," 2010). As illustrated in the following NSO case example, malicious prosecution is typically alleged in conjunction with other claims.

A LNC was requested by an attorney to provide an opinion regarding the actions of an urologist in a medical negligence case. The LNC opined that the urologist was negligent and signed an expert affidavit as such. The suit against the urologist was ultimately dropped. Claiming emotional distress, the urologist filed suit against the attorney, his practice, and the LNC for malicious prosecution, bad faith, fraud / misrepresentation, and civil conspiracy. A LNC was hired as a standard of practice expert to review the liability of the defendant LNC. The consultant LNC opined that the defendant LNC acted within the scope of legal nurse consulting practice, because a nurse expert "just does what the attorney tells her to do." The consultant LNC was clearly incorrect in her review of this matter, as the defendant LNC improperly opined on the standard of care owed by a physician.

Take-away: One of the potential implications of engaging in risky or improper practice is being sued for malicious prosecution. As previously discussed, nurse experts must be aware of and adhere to the state's statutory requirements for certificates of merit as well as evidentiary requirements related to expert qualifications and testimony. In addition, the LNC should be aware of and follow the legal nursing specialty's ethical guidelines and scope of practice.

Summary

The Legal Nurse Consulting: Scope and Standards of Practice states that "The legal nurse consultant evaluates one's own nursing practice in relation to professional practice standards and guidelines, relevant statutes, rules, and regulations" (AALNC, 2006, p. 30). While LNCs were named as defendants in only a few of these sample cases, all of them illustrate actual or potential LNC liability exposures and therefore hold invaluable lessons for LNCs of all experience levels. LNCs should evaluate their own practice in light of these common liability risks and apply this knowledge by making any necessary practice modifications to reduce their potential risk. Through the application of the liability lessons discussed in this article, prudent LNCs can improve their consulting practice and mitigate their risk of liability.

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Cardiopulmonary Resuscitation: Legal and Economic Considerations

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KEY WORDS
CPR, Cardiopulmonary Resuscitation, "Costs CPR", "Nurse Refuses to Perform CPR", Legal Economic CPR, Survival Resuscitation

This article addresses the legal and economic considerations of cardiopulmonary resuscitation. Studies continue to show dismal outcomes for cardiopulmonary resuscitation (CPR), yet inaccurate lay perceptions in recent news reports suggest otherwise. In contrast with every other medical procedure for which consent must be authorized, the legal doctrine of presumed consent for CPR in the absence of a do not resuscitate physician's order was adopted by most U.S. states long ago. As a result of presumed consent, individuals with advanced terminal disease are routinely resuscitated when there is absolutely no hope of return of spontaneous circulation, much less survival to hospital discharge. The costs of presumed consent are also discussed. Based on published data, the author estimates that the U.S. annual national cost to train the 9,561,900 healthcare practitioners in CPR is $658,898,350 per year. This is spent to provide resuscitation services for an estimated 83,050 people who survive an in-hospital or out-of-hospital cardiopulmonary arrest to hospital discharge, a total of $7,934 per CPR survivor (for CPR training alone). Successful and unsuccessful plaintiff cases based on the theory of failure to perform CPR are reviewed. The importance of legal nurse consultants in case evaluation for merit, identification of the cascade of preventable errors that led to the cardiopulmonary arrest and subsequent attorney education is discussed.

Introduction

"California Woman Dies after Nurse Refuses to Perform CPR!" the headlines scream. The impassioned voice of the 911 dispatcher is played over and over on TV and on the Internet, as she instructs the independent living nurse to go out on the street to find someone to do CPR to "save this woman's life."

This incident has led to widespread discussion about whether a nurse should or should not be obligated to perform cardiopulmonary resuscitation on every patient, every time, under every circumstance. For the most part, public opinion regarding the nurse's failure to follow the directions of a 911 dispatcher has been overwhelming negative. Whereas the independent living facility initially supported the unnamed nurse for following the policy to stay with the patient until emergency medical services arrived, at the time of this writing, the nurse is "on leave," and her actions are being reviewed by the facility as well as the state board of nursing (Branson-Potts, 2013; Cone, 2013).

A person in need of cardiopulmonary resuscitation is already deceased

According to the "ancient and traditional" definition of death, a person is dead when the heart pump fails to circulate blood and spontaneous breathing has ceased (Joynt, 1984). By definition then, an individual in need of full cardiopulmonary resuscitation (CPR) has already died. Cardiopulmonary resuscitation is actually an attempt (and a futile one in most cases) to raise the dead. The lack of CPR does not *kill* the individual, as the individual is already deceased; it provides a slight opportunity for reversal of that state.

Outcomes for cardiopulmonary resuscitation

For those who suffer an out-of-hospital cardiopulmonary arrest that is not of cardiac origin and without a shockable rhythm and are resuscitated with transport to a hospital, 98% to 99% do not survive to hospital discharge (Berdowski, Kuiper, Tijssen, & Koster, 2010; Herlitz, Svensson, Engdahl, & Silfverstolpe, 2008). For elderly patients in a residential care facility, 98.8% died (Deasy, Bray, Smith, Harriss, Bernard, Davidson, & Cameron, 2011). Overall, 90% of all individuals who receive CPR out-of-hospital (including those with a shockable rhythm) die before discharge from the hospital to which they were transported when the resuscitation was initially successful (CDC, 2011; Shin, Ahn, Song, Park, & Lee, 2012). Death rates to hospital discharge are lower with shockable rhythms, 69.9% to 72% die (Berdowski, Kuiper, Tijssen, & Koster, 2010; CDC, 2011). Death rates were lowest (32%) for an observed cardiopulmonary arrest of cardiac origin in a person with a shockable rhythm who was defibrillated using an automatic external defibrillator (AED) present at the site of arrest (Berdowski, Kuiper, Tijssen, & Koster, 2010). Shockable rhythms include ventricular tachycardia and ventricular fibrillation. Patients who suffer a cardiopulmonary arrest in-hospital fare a little better with death rates prior to discharge ranging from 73.1% to 81.9% (Kutsogiannis, Bagshaw, Laing, & Brindley, 2011; Peberdy, Ornato, Larkin, Braithwaite, Kashner,…& Berg, 2008).

Adverse outcomes are not uncommon post cardiopulmonary arrest. In a study of 88 survivors asked to rate their health post arrest, 30% identified cognitive issues, 13% post-traumatic stress, 19.5% had difficulty performing activities of daily living and 8.5% experienced anxiety and depression (Moulaert, Wachelder, Verbunt, Wade, & van

Heugten, 2010). In another study of 86,748 in-hospital cardiac arrests in 507 U.S. hospitals, although 18.1% survived to hospital discharge, only 13.9% had a favorable neurological outcome (86.1% had a deficit). Post cardiac arrest syndrome may include brain injury, myocardial injury, systemic ischemia/ reperfusion syndrome, and the ongoing underlying disease issues that preceded the arrest (Boutsikaris & Winters, 2012; Reynolds & Lawner, 2012). It is important to recognize that "survival does not equal quality of life" (Taran, Guarino, Kolm, & Petrelli, 2012).

Legal issues

Since the inception of CPR in the 1960s, Americans have accepted mandatory CPR with few questions. Whereas individual patients are routinely expected to sign consent for the vast majority of procedures within healthcare settings, the opposite is true for CPR. Most U.S. states have adopted a doctrine of presumed consent, similar to that stated in the explanation that Georgia provides for citizens:

"Every adult is presumed to have the capacity to make a decision regarding CPR and every patient shall be presumed to consent to the administration of CPR unless there is consent or authorization for the issuance of an order not to resuscitate" (Georgia Department of Health and Human Services, 2012, p. 3).

As a result of presumed consent, individuals with advanced terminal disease are routinely resuscitated when there is absolutely no hope of return of spontaneous circulation, much less survival to hospital discharge. For the most part, legislation forces healthcare providers to perform CPR unless there is a valid (state defined) do not resuscitate (DNR) order or CPR directive. Virginia code provides an example of this:

> "Certification in cardiopulmonary resuscitation; do not resuscitate orders.
>
> The owners or operators of any assisted living facility may provide that their employees who are certified in cardiopulmonary resuscitation (CPR) shall not be required to resuscitate any resident for whom a valid written order not to resuscitate in the event of cardiac or respiratory arrest has been issued by the attending physician and has been included in the resident's individualized service plan" (Virginia Code § 63.2-1807, available at http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+63.2-1807).

Most states also mandate that if the patient has made a decision regarding resuscitation, the patient's wishes must be honored. An example of this is in Virginia's Code:

> "C. Durable Do Not Resuscitate Orders issued in accordance with this section shall remain valid and in effect until revoked as provided in subsection B or until rescinded, in accordance with accepted medical practice, by the provider who issued the Durable Do Not Resuscitate Order. In accordance with this section and regulations promulgated by the Board of Health, (i) qualified emergency medical services personnel as defined in § 32.1-111.1; (ii) licensed healthcare practitioners in any facility, program or organization operated or licensed by the Board of Health, the Department of Social Services, or the Department of Behavioral Health and Developmental Services or operated, licensed or owned by another state agency; and (iii) licensed healthcare practitioners at any continuing care retirement community registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 are authorized to follow Durable Do Not Resuscitate Orders that are available to them in a form approved by the Board of Health.
>
> D. The provisions of this section shall not authorize any qualified emergency medical services personnel or licensed healthcare provider or practitioner who is attending the patient at the time of cardiac or respiratory arrest to provide, continue, withhold or withdraw healthcare if such provider or practitioner knows that taking such action is protested by the patient incapable of making an informed decision. No person shall authorize providing, continuing, withholding or withdrawing healthcare pursuant to this section that such person knows, or upon reasonable inquiry ought to know, is contrary to the religious beliefs or basic values of a patient incapable of making an informed decision or the wishes of such patient fairly expressed when the patient was capable of making an informed decision. Further, this section shall not authorize the withholding of other medical interventions, such as intravenous fluids, oxygen or other therapies deemed necessary to provide comfort care or to alleviate pain" (Virginia Code § 54.1-2987.1, available at http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+54.1-2987.1).

The decision to resuscitate or to withhold resuscitation is a deeply personal one, whether the individual is making these decisions for her/ himself or for a loved one. However, from legal standpoint, physician involvement continues to be required. Colorado is now allowing more flexibility for first responders, including the ability to accept a handwritten CPR Directive; the requirement for a physician signature still continues:

"If I want to make a CPR directive form that EMS personnel would recognize, where can I get one? You may write your own CPR directive or have someone else help you write one. The Board of Health encourages you to use this template: www.cdphe.state.co.us/em/Operations/CPRDirectives/template.pdf

Does a physician have to sign my CPR directive? Yes. The physician you consulted about making your CPR directive must sign it. It does not have to be notarized." (Colorado Department of Health and Environment, 2013, pp. 1-2).

Interestingly, in Los Angeles, where the 911 dispatcher berated a registered nurse (RN) for not initiating CPR, a policy change made in 2007 allowed emergency medical system first responders to forgo resuscitation in specific instances: 1.) asystole of greater than 10 minutes duration, and 2.) a verbal request from a surrogate decision maker (spouse, domestic partner, or first degree relative) or an advanced directive requesting no resuscitation. After implementation of this policy, there were fewer codes and an increase in the number of families opting out of CPR. In addition, there was less documentation of irreversible signs of death (the only acceptable reason to defer CPR prior to the change), such as rigor mortis, lividity, or decomposition (Gruzden, Hoffman, Koenig, Boscarden, Lorenz, & Asch, 2010).

CPR is big business

A Google search for CPR classes conducted in March 2013 yielded over a 100,000 hits with costs ranging from $20 for an online course to $110 for the American Red Cross Healthcare Provider Professional Course (American Red Cross, 2013). An American Heart Association Instructor Package is $96, a package of 72 cards (given to participants) is $48, student manuals are $12 each, a family set of chest only resuscitation manikins (adult, child and infant) is $465, a full body Resuci-Anni with airway is $4,536 (Laerdl). Training AEDs range from $150 to $451 (AED Superstore). In addition to direct suppliers, there are printers, manufacturers and other companies that also support this industry. There is an entire infrastructure of businesses involved in supporting CPR.

Cost versus benefit of presumed consent for CPR

In the U.S. there are a total of 547,000 in and out of hospital arrests yearly. Approximately 338,000 out of hospital cardiac arrests occur in the U.S., with 88% of those happening in the home (American Heart Association, 2011), and approximately 209,000 cardiac arrests are in U.S. hospitals.

There are approximately 9,561,900 healthcare practitioners in positions that would require CPR certification, (U.S. Bureau of Labor Statistics, 2010) and the cost of salary alone, requiring healthcare providers to take a four hour course, would be $935,320,700 (Table). The American Heart Association allows for renewal every two years; however, the American Red Cross still requires annual renewal. The amount was divided by two, thus the annual cost of practitioner time alone is an estimated at $467,660,350. For illustration purposes, a cost of $40 per healthcare renewal class is used (an estimate based on Internet prices). Based on a cost of $40 for each of the 9,561,900 healthcare providers, an additional cost of $382,476,000 for a two year renewal is incurred, or a total of $191,238,000, annually. Combining staff time and class costs, healthcare providers spend a minimum of $658,898,350 educating practitioners in CPR every year.

Table: U.S. Healthcare Providers Requiring CPR Certification

Occupation	Wage	Number of U.S. Jobs	4 Hour CPR Class Costs
Emergency Med Technicians/ Paramedics	$ 14.60	226,500	$13,227,600
Registered Nurse	$ 31.10	2,737,400	$340,532,560
Licensed Practical Nurse	$ 19.42	752,300	$58,438,664
Nurse assistants, orderlies	$ 11.54	1,505,300	$69,484,648
Home health aides/ personal care	$ 9.17	1,878,700	$68,910,716
Surgical technicians	$ 19.19	93,600	$ 7,184,736
Cardiovascular technicians	$ 23.75	49,400	$4,693,000
Medical sonographers	$ 30.95	53,700	$6,648,060
Nuclear med technicians	$ 32.96	29,900	$3,942,016
Occupational therapists	$ 34.77	108,800	$15,131,904
Radiology technicians	$ 26.13	219,900	$22,983,948
Respiratory therapists	$ 26.10	112,700	$11,765,880
Occupational therapy assistants	$ 22.83	36,000	$3,287,520
Physical therapists	$ 36.69	198,600	$29,146,536
Physical therapy assistants and aides	$ 18.13	114,400	$8,296,288
Physicians and surgeons	$ 80.00	691,000	$221,120,000
Physician assistants	$ 41.54	83,600	$13,890,976
Medical assistants	$ 13.87	527,600	$29,271,248
Psychiatric technicians	$ 12.92	142,500	$7,364,400
TOTAL		**9,561,900**	**$935,320,700**

U.S. Bureau of Labor Statistics (2010). Occupational Outlook Handbook. Retrieved from http://www.bls.gov/ooh/home.htm

Using secondary analysis, it costs U.S. healthcare and emergency medical system employers a minimum of $1,274 in *direct* training costs for every cardiopulmonary arrest that occurs in the U.S. If 10% of those who have an out-of-hospital cardiac arrest survive, that is approximately 30,800 people annually. If approximately 25% of those with an in-hospital cardiac arrest survive, that is 52,250 survivors annually. Using the same numbers to calculate the cost of providing CPR education, the national costs per hospital discharge survivor would be $658,989,350 for 83,050 people or $7,934 per CPR survivor.

This does not include the direct and indirect costs involved in providing CPR classes (such as education department salaries), pharmaceuticals and supplies for crash carts, staff time for code teams and committees, time for checking crash carts, etc. In 1992, total costs to maintain a 576 bed hospital's CPR program was $2,352,771, for a total of $60,327 per survivor. This figure did not include the additional costs related to prolonged hospitalization for survivors (Vrtis, 1992a; Vrtis, 1992b). More recent studies could not be found.

Verdicts and settlements related to failure to perform CPR

Due to the generalization of the implied consent concept in the U.S. (American Heart Association, 2000), expert witnesses have sometimes considered failure to perform CPR in a timely manner in a hospital to be a deviation from the standard of care. For example, the family of a three year old who suffered severe brain damage following surgery for an undescended testicle was awarded a $20 million settlement from a Chicago hospital. There was a five minute delay in the initiation of CPR (Byrne, 2013).

In the case of a 55 year old man, nurses failed to recognize an evolving cardiac event that began with an oxygen monitor alarm that was ignored 16 minutes before the code was called. The man was resuscitated, but severely brain damaged. The settlement was $5 million (*Trial Lawyers,* 2008). In a third case, there was an $850,000 settlement after a 29 year old man expired when the hospital's CODE system failed (Allen, Allen & Allen, n.d.).

On the other hand, there was a recent jury verdict in *Losquadro v. Sabbatini* (2011), a case in which CPR was not initiated for a woman with end-stage cancer. The deceased woman's estate filed suit against two physicians, an RN, and Sloan-Kettering Hospital. The plaintiff claimed that a physician enacted a DNR order that had not been signed by the patient and that the patient had stated to her family that she wished to be resuscitated. The patient was 69 years old and suffering from end stage ovarian cancer at the time of admission to the hospital in 2005. She had been diagnosed with stage IV ovarian cancer five years earlier. Scans showed an increase in size and number of metastatic lesions in the liver. The patient had bilateral pleural effusions, ascites and leg edema. Oxygen was given at 3 liters/ minute which was increased to 5 liters/ per minute. Prior to her death from respiratory failure, the patient was not transferred to the intensive care unit and a Code Blue to attempt resuscitation was not called. The plaintiff's physician expert witness opined that "had she been resuscitated, she had a substantial chance of survival, although for a very short period of time." The defense physician expert stated that "in light of the seriousness of the decedent's cancer, she would have only lived for perhaps a few more hours or at most a day, probably under heavy sedation." The suit was filed in 2007 and the jury found for the defense in 2011 (*Losquadro vs. Sabbatini*).

The role of legal nurse consultants

Legal nurse consultants (LNCs) play a crucial role in determining when the standard of care has been met – and when it has not been met. In each of the successfully litigated cases cited above, failure to resuscitate was the final event in a cascade of errors and deviations from the standard of care by several healthcare practitioners. Timely identification of the impending crises, with rapid interventions may well have averted the cardiopulmonary arrests in the first three successful cases discussed. When a case has merit, the cascade of errors is typically very clear to the LNC with expertise in that particular field, and she/ he can educate the attorney accordingly.

In addition, given the limitations of resuscitation, particularly in cases of end stage terminal disease, thorough screening by a behind the scenes LNC expert can be extremely helpful to an attorney. There are few plaintiff firms that can afford to lose a medical malpractice case after four years. Does extension of "life" for "a short while" or "a few more hours" post resuscitation justify the financial burden of such a case on the court system? Does it help a grieving family member go through four years of settlement negotiations, and a trial with a negative outcome? As legal nurse consultants, we have a responsibility to help attorneys separate cases that do and do not have merit – even when that is not what an attorney wants to hear.

Back to the case in the news

According to news accounts, the woman the nurse was with was still breathing, though shallowly. It took seven minutes for the EMS to arrive. The deceased woman's family stated that she had requested a natural death without intervention. The independent living facility failed to support the nurse by revising statements regarding policy given public response to the media spin (Branson-Potts, 2013, Cone, 2013). The police are trying to determine if a crime was committed and the Kern County Aging and Adult Services Department is "looking into elder abuse." A spokeswoman for the Assisted Living Federation of America states that the organization is re-evaluating policies related to CPR for assisted living facilities (Cone, 2013). Yet the family stated clearly that the nurse followed the resident's wishes. Some important questions still need to be asked:

- An independent living facility provides apartments, some support services such as meals and laundry, but not medical care. If this is the case, and residents are aware of this on admission, should a nurse be expected to provide CPR?
- A patient who is breathing with a pulse does not require CPR (Hazinski, 2011), were the instructions given by the dispatcher correct?
- Entry level education for a 911 dispatcher in California is a 120 hour course (California.gov/). Entry level education for an RN is two to four years of nursing education regulated by the State Board of Nursing and accredited by either the American Commission for Education in Nursing (ACEN) or the American Association of Colleges of Nursing (CCNE accreditation). In addition, to obtain the title RN, a nurse must be deemed competent by passing the NCLEX-RN exam. The assumption in the media was that the RN should take instructions from the 911 dispatcher, even though the instructions were incorrect. Should the RN have started CPR on a patient who was breathing?
- Nurses in assisted living and independent living facilities frequently come to know residents quite well. Is it then

appropriate to assume that a 911 dispatcher would have more information about the individual's overall medical condition and co-morbidities than the nurse would?

- Who should define the standard of care on resuscitation issues?
- How should requirements related to resuscitation differ in various healthcare settings?
- Has the time come to stop attempting to resuscitate everyone – even when the probability of survival is zero?
- Presumed consent for CPR is a sacred cow. In this economic environment, is it reasonable for this nation to support the expensive policies and procedures that support mandatory CPR?

Conclusion

This case in the news brings up many issues for discussion. The media response and the 911 dispatcher's response strongly suggest that CPR saves every life, every time, and this is definitely not the case. Lawyers new to the medical malpractice arena may also see a potential case based on these same assumptions. Legal nurse consultants can play a very important role in helping to identify the cases where CPR may well have been lifesaving, for example, in the case of a three year old who had a cardiopulmonary arrest post-op ((Byrne, 2013), from the cases where death was the result of a long and fatal illness. For wrongful death cases with merit, an LNC can work with an attorney to help support those who have lost a loved one. For cases without merit, the LNC can help to avoid long and costly court battles that hurt loved ones, attorneys and the healthcare practitioners who have provided the best care possible in spite of a terminal illness.

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Etiology, Identification, and Management of Infections of Dental Origin

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KEY WORDS
Osteomyelitis, Ludwig's Angina, Cervical Necrotizing Fasciitis. Primary Space, Secondary Space, Dental Infection

Infections of dental origin are prevalent despite advances in health care. Bacteria common to the oral cavity comprise the majority of virulent organisms in these infections. Patient assessment and work-up center around critical evaluation of the dentition, airway, and the patient as a whole. Three common major infections of dental origin, Osteomyelitis, Ludwig's Angina, and Cervical Necrotizing Fasciitis, are examined. Litigation from patients with infections of dental origin typically arises from failure to diagnose and/or treat an infection or from an infection arising postoperatively.

Introduction

Dental infections have plagued mankind for thousands of years. In the pre-antibiotic era, death from a dental infection was not uncommon. At the turn of the 20th century the mortality rate from dental infections was as high as 40% (Robertson & Smith, 2009). The introduction of antibiotics to combat infections and anesthesia to permit controlled surgery has decreased mortality from the dental infections dramatically. That being said, infections of odontogenic origin are often underestimated in terms of their morbidity and mortality. For example, odontogenic infections account for 57% of deep neck infections, such as mediastinitis, which have a mortality rate above 50% (Mihos, Potaris, Gakidis, Papadakis, & Rallis, 2004; Robertson & Smith, 2009; Sancho, Minamoto, Fernandez, Sennes, & Jatene, 1999).

Despite advances in dental health, increased access to dental providers, and modern antibiotics, the acute dental infection patient is still prevalent today. In the United States one in 2,600 hospital admissions and 2.7% of the ER visits are for dental-related infections. Many (47%) of dental infections seen in hospital are mild-to-moderate periapical abscesses, which could easily be treated in the dental office (Graham, Webb, & Seale, 2000; Robertson & Smith, 2009; Wang, Ahani, & Pogrel, 2005).

General dental infections and etiology

Dental infections can range from mild periodontitis to more serious infections that spread though facial planes to compromise the patient's airway and/or produce sepsis. The severity of a dental infection is a function of many factors such as virulence of the microorganism, number of microorganisms, and the defense capability of the host (Baltensperger & Eyrich, 2009; Flynn & Halpern, 2003; Robertson & Smith, 2009).

The bacterial composition of any single infection varies, but generally dental infections are a mixture of aerobic and anaerobic microorganisms, with anaerobes outnumbering aerobes (Brook, Hunter, & Walker, 1984; Robertson & Smith, 2009; *Management and prevention of odontogenic infections*). Aerobic bacteria commonly found in infections of dental origin include: *Streptoccus subspecies,* Lactobacillus subspecies, *Actinobacillus subspecies,* and *Pseudomonas subspecies*. Anaerobic bacteria commonly discovered in dental infections include: the viridians group, *Streptococcus angio subspecies, Prevotella, Fusobacterium, Clostridia subspecies,* and *Bacteroides subspecies* (*Brook et al., 1984; Lewis, MacFarlane, & McGowan, 1990; Robertson & Smith, 2009; Management and prevention of odontogenic infections*). Trauma can also be the etiology of dental infections by serving to introduce normal oral flora deep into submucosal or intrabony defects such as would happen during the fracture of the mandible.

Predisposing factors in the development of dental abscesses include, but are not limited to alcohol/tobacco abuse, compromised systemic health (diabetes, human immunodeficiency virus), history of chemotherapy and/or radiation, lack of access to appropriate dental services, and lower socioeconomic class (Fehrenbach & Herring, 1997; Flynn & Halpern, 2003; Robertson & Smith, 2009; Sandor, Low, Judd, & Davidson, 1998).

Patient presentation and work-up

The patient with a dental abscess typically presents to the emergency room or dental provider with a plethora of signs and symptoms. These may include pain, fever, chills, malaise, dysphagia, shortness of breath, trismus (limited mouth opening), swelling and erythema about the head and neck, and possibly an elevated floor of the mouth. Vital signs, laboratory analysis of blood, and appropriate radiological studies are essential to the evaluation process. Vital signs would typically be elevated secondary to poor oral intake, dehydration, and pain. Laboratory analysis of blood may show an elevated white blood cell count. Radiological studies, such as periapical (small radiograph limited to one of two teeth and designed to show the crown and apices of the teeth) or panoramic plain film (panoramic radiograph of the maxilla, mandible, teeth, and associated structures), or computed tomography (CT) scan will typically show one or more carious teeth (Bagheri & Jo, 2008; Bratton, Jackson,

Nkungula-Howlett, Williams, & Bennett, 2002; Fehrenbach & Herring, 1997; Sandor et al., 1998).

First and foremost, patients with dental infections must have their airway critically evaluated. The majority of dental infections are confined to superficial spaces of the head and neck with limited ability to compromise the patient's airway. However, the simplest dental infection may quickly exacerbate and spread through fascial planes to deeper potential spaces in the head and neck compromising the patient's airway. Dysphagia, odynophagia, or dyspnea may alert the health care provider to potential airway compromise (Bagheri & Jo, 2008; Fehrenbach & Herring, 1997; *Management and prevention of odontogenic infections*).

Simple, limited infections may be appropriately diagnosed with plain films such as a periapical radiograph or panoramic radiograph. More extensive infections which may compromise the patient's airway warrant a CT scan, blood analysis, hospitalization, and appropriate consultation with the infectious disease service (Bagheri & Jo, 2008; Bratton et al., 2002).

Examination of the patient should begin with a thorough head and neck exam including intraoral evaluation of the patient's general dental health. Carious and non-restorable teeth should be noted. Any restrictions in the mouth opening, elevation of the floor of the mouth, or intraoral swelling are key indicators of a serious and potentially life-threatening infection. A more systemic examination should evaluate the patient for signs and symptoms of sepsis and dehydration (Bagheri & Jo, 2008; Fehrenbach & Herring, 1997; *Management and prevention of odontogenic infections*).

Culture analysis is the backbone of good clinical practice in identifying the causative agents of any infection. In infections of dental origin, obtaining the ideal clinical sample for analysis is almost impossible and typically inaccurate due to the location of the abscess and the inaccurateness of an intraoral sample taken through mucosa. For many typical dental infections empiric antibiotic therapy to treat a mixed infection is appropriate without culture analysis. Infections of odontogenic origin which require extra-oral incision and drainage, and thus an operating room environment to properly care for the patient, lend themselves to better sampling of the exudates and thus improve analysis of the bacteria present in the infection (Bagheri & Jo, 2008; Dar-Odeh, Abu-Hammad, Al-Omiri, Khraisat, & Shehabi, 2010; Flynn & Halpern, 2003; Lewis et al., 1990; Mihos et al., 2004).

As stated earlier most dental infections are relatively minor and confined to superficial spaces known as primary spaces. Primary spaces include the submental, submandibular, sublingual, canine, and buccal space (Bagheri & Jo, 2008; Hollinshead, 1982). Infections confined to these spaces may typically be successfully treated with surgery to drain and irrigate the space in combination with oral antibiotics empirically prescribed to target a mixed aerobic and anaerobic infection (Bagheri & Jo, 2008; Sandor et al., 1998; Wang et al., 2005). Frequent patient follow-up is indicated to ensure resolution of the infection.

More serious infections can spread from primary spaces to a secondary space known as the masticator space (Bagheri & Jo, 2008; Hollinshead, 1982). The masticator space is comprised of three separate spaces (superficial temporal, deep temporal, pterygoid space). Masticator space infections are particularly worrisome to the clinician because of the proximity of the masticator space to the airway and lateral pharyngeal space. Patients with masticator space infection typically have severe trismus which compromises the airway and limits treatment access. Such patients should be cared for in a hospital setting where appropriate professionals (anesthesiologist) are present with appropriate equipment (glide scope or fiber optic intubation equipment) at the patient's side to secure the airway before the surgical procedure commences. A lengthy hospital stay and extended use of intravenous antibiotics may be indicated in these patients (Bagheri & Jo, 2008; Srirompotong & Srirompotong, 2002).

The patient management and treatment of infections of dental origin revolve around sound surgical and medical principles. After appropriate assessment of the patient's condition, as well as airway evaluation, treatment of the patient with a dental abscess should concentrate on removing the source of infection, that is, extraction of the teeth, irrigation and debridement of the appropriate fascial space(s), and empiric antibiotic therapy to target the anticipated mixed aerobic and anaerobic bacteria present in most dental infections.

If left untreated or in patients who are medically compromised, simple dental infections may exacerbate and spread to deep spaces of the head and neck. These deep spaces include the lateral pharyngeal space, the retropharyngeal space, prevertebral space, or even the mediastinum or cranium (Bagheri & Jo, 2008; Fehrenbach & Herring, 1997; Mihos et al., 2004; Sakamoto, Karakida, Otsuru, Arai, & Shimoda, 2009). All of these spaces represent a serious life threatening condition to the patient. Immediate hospitalization and surgical treatment in the operating room are prudent to ensure standard of care treatment for such a patient. Consultation with internal medicine physicians and infectious disease specialists may be important to patient survival. Patients with such life threatening infections often require hospitalization in the Intensive Care Unit (ICU) and step down units before they are discharged. They often require out-patient intravenous antibiotics for weeks to eradicate the infection.

Osteomyelitis

Osteomyelitis (OM) of the jaw bones represents an inflammatory process secondary to obstruction of the blood supply to the bone which produces necrosis of the bone (Hudson, 1993). The infection is typically polymicrobial in composition and occurs more often in males than in females (Baltensperger & Eyrich, 2009). Osteomyelitis is more common in the mandible and may result from localized

trauma, surgery, or an odontogenic infection. There are several classifications for osteomyelitis, the most common being acute or chronic depending on patient history, clinical presentation, and radiographic imaging findings (Bagheri & Jo, 2008; Baltensperger & Eyrich, 2009; Hudson, 1993). Risk factors for OM include but are not limited to medically compromised patients, patient with a history of radiation/chemotherapy, tobacco, drug, and/or alcohol abuse, advanced periodontal disease, malnutrition, cancer, acquired immunodeficiency syndrome (AIDS), or the elderly (Bagheri & Jo, 2008; Baltensperger & Eyrich, 2009; Hudson, 1993).

Patients with OM typically present with deep bone pain and edema, usually after a local trauma, such as a tooth extraction. The pain persists despite local measures such as debridement, oral antibiotics, or palliative dressings. Patients may also present with fever, malaise, purulence, exposed bone, neurosensory changes, and/or fistula (Baltensperger & Eyrich, 2009; Hudson, 1993).

Patient assessment should begin with a thorough head and neck examination. Presence of a fistula, exposed bone, altered neurosensory status, purulence, swelling, or acute pain is significant and should be noted. Oral examination should note any recent trauma to the jaws. Vital signs and blood analysis are indicated (Bagheri & Jo, 2008; Baltensperger & Eyrich, 2009; Hudson, 1993). Imaging studies should consist of plain films in conjunction with CT scans of the head and neck. These imaging studies are essential to determine the extent of bone necrosis. The diagnosis of OM, acute or chronic, is often arrived at from a collection of facts both clinical and radiological (Bagheri & Jo, 2008; Baltensperger & Eyrich, 2009; Hudson, 1993).

Treatment of OM focuses on removal of all necrotic bone, adequate soft tissue coverage of the defect, thorough debridement of the wound, and long-term antibiotic therapy. Hyperbaric oxygen has also been described in the literature as contributing to patient recovery from OM (Bhutani & Vishwanath, 2012; Fang & Galiano, 2009; Hudson, 1993). Consultation with an infectious disease specialist may be indicated to assist in long term patient care and choice of antibiotic therapy (Bagheri & Jo, 2008; Baltensperger & Eyrich, 2009; Hudson, 1993).

Ludwig's Angina

Ludwig's angina (LA) is a significant and potentially life-threatening infection typically of dental origin. It has been described as an aggressive cellulitis occupying the bilateral submandibular and sublingual and submental space. Purulence may or may not be present. It is polymicrobial in composition. Ludwig's angina typically occurs in previously healthy adults between 20 and 60 years of age (Bagheri & Jo, 2008; Juang et al., 1989; Juang et al., 1989; Kinzer, Pfeiffer, Becker, & Ridder, 2009; Marcus, Kaplan, & Collins, 2008). Risk factors for LA include poor dental care, diabetes, malnutrition, compromised immune system (HIV+, radiation, chemotherapy), obesity, alcoholism, aplastic anemia, systemic lupus erythematosus, liver disease, and peripheral vascular disease (Bagheri & Jo, 2008; Juang et al., 1989; Juang et al., 1989; Kinzer et al., 2009; Marcus et al., 2008).

Patients with LA typically present to the emergency department or dental professional with a history of acute progressive swelling and pain about the face and neck originating in the teeth-bearing area of the lower jaw. The patient presents with bilateral cellulitis and erythema of the submandibular spaces with concomitant swelling of the bilateral submandibular and submental space. Fever, chills, dysphagia, malaise, change in voice, and odynophagia are also common conditions in patients with Ludwig's angina (Bagheri & Jo, 2008; Juang et al., 1989; Juang et al., 1989; Kinzer et al., 2009; Marcus et al., 2008).

Assessment of the LA patient must first focus on the airway. A thorough examination and evaluation of the head, neck, and airway are essential to the patient's survival. Oral examination should include notation of any carious teeth as they are a likely source of the infection. Vital signs and laboratory blood analysis are indicated. Laboratory analysis of blood should include a CBC with complete metabolic profile as well as culture and sensitivity testing to assist in the choice of antibiotic therapy (Bagheri & Jo, 2008; Juang et al., 1989; Juang et al., 1989; Kinzer et al., 2009; Marcus et al., 2008). Imaging studies include plain films and CT to determine the extent of the infection.

Acute surgical intervention in the LA patient is a necessity. Once a secure airway is established (often via awake fiberoptic intubation) aggressive surgical incision and drainage, as well as elimination of the etiology of the infection, is appropriate standard care of treatment for these patients. All infected spaces must be surgically explored and irrigated to rid the patient of the malevolent bacteria. Drains should be placed to ensure escape of additional purulence and facilitate additional irrigation as the patient recovers. Samples of the purulence should be taken, when possible, in a sterile manner for culture and sensitivity testing. Empiric antibiotic therapy should be promptly initiated at the earliest possible convenience with the goal to cover the mixed aerobic-anaerobic polymicrobial infection common in LA patients. Intravenous fluids must be administered aggressively to combat dehydration. Steroids should also be employed to address pre and postoperative edema. Consultation with an infectious disease specialist may be indicated to discuss in long term patient care and antibiotic therapy options (Bagheri & Jo, 2008; Juang et al., 1989; Juang et al., 1989; Kinzer et al., 2009; Marcus et al., 2008).

Cervical Necrotizing Fasciitis

Cervical necrotizing fasciitis (CNF) is a severe, purulent, and possibly fatal polymicrobial aggressive infection of the head and neck typically of odontogenic origin. CNF characteristically spreads along the fascial planes to involve subcutaneous tissue, fascia, skin, and also muscle. Impressive amounts of foul-smelling purulence are typically produced. As the infection rapidly exacerbates vascular compromise

ensues producing tissue death remarkably fast (Chueng, Clinkard, Enepekides, Peerbaye, & Lin, 2012; Lingaraj, Rao, Kotrashetti, & Narad, 2010; Whitesides, Cotto-Cumba, & Myers, 2000; Yadav, Verma, & Sachdeva, 2012). Risk factors for CNF include, but are not limited to diabetes, malnutrition, compromised immune system (HIV+, radiation, chemotherapy), obesity, liver disease, and peripheral vascular disease (Chueng et al., 2012; Lingaraj et al., 2010; Whitesides et al., 2000; Yadav et al., 2012).

Patients with CNF typically present with elevated body temperature, fetid (foul smelling) body odor, tachycardia, odynophagia, dysphagia, trismus, pain, and severe edema (Chueng et al., 2012; Lingaraj et al., 2010; Whitesides et al., 2000; Yadav et al., 2012). Patient assessment must focus on the patient's airway and the overall condition of the patient as these patients can become septic quickly. A thorough examination and evaluation of the head, neck, and airway are essential to the patient's survival. Oral examination should include notation of any carious teeth as they are a likely source of the infection. Vital signs, laboratory blood analysis including a CBC with complete metabolic profile,and blood cultures for aerobic and anaerobic bacteria are indicated (Chueng et al., 2012; Lingaraj et al., 2010; Whitesides et al., 2000; Yadav et al., 2012). Appropriate radiological studies include standard plain films such as panorex, cephalometric, and PA of the face, in conjunction with CT scan of the head and neck to evaluate the extent of the infection and as well as patency of the airway (Chueng et al., 2012; Lingaraj et al., 2010; Whitesides et al., 2000; Yadav et al., 2012).

Treatment for the patients with CNF of odontogenic origin relies on acute accurate diagnoses and a skeptical appreciation of the patient's condition. Establishment and maintenance of a secure airway is essential to patient survival. Aggressive surgery to remove the etiology of the infection and thorough irrigation and debridement of fascial spaces is important. Removal of necrotic tissue is imperative to promote healing and avoid sepsis. Close post operative observation is required to monitor the patient's recovery. Additional trips to the operating room may be indicated to readdress the infection and revise margins of tissue resection (Chueng et al., 2012; Lingaraj et al., 2010; Whitesides et al., 2000; Yadav et al., 2012).

Empiric antibiotic therapy and steroids must be quickly employed in CNF patients to attack anaerobic and aerobic microorganisms and minimize edema. Culture and sensitivity testing should be obtained in the operating room to assist the doctor in identifying the microorganisms and select the most appropriate and effective antibiotic. Infectious disease specialist consultation may be indicated to evaluate in long term patient care and choice of antibiotic therapy (Chueng et al., 2012; Lingaraj et al., 2010; Whitesides et al., 2000; Yadav et al., 2012).

Hyperbaric oxygen has gained support as an adjunctive treatment for necrotizing fasciitis of odontogenic origin. Hyperbaric oxygen therapy offers the patient the advantage in healing by promoting neovascularization to the remaining tissue (Fang & Galiano, 2009; Hudson, 1993; Whitesides et al., 2000).

Role of the legal nurse consultant (LNC) in evaluating cases involving infections of dental origin

Litigation arising from infections of dental origin has its genesis in two types of cases: failure to diagnose and/or failure treat an infection or post-surgical infections. In both types of cases the patient turned plaintiff may claim negligence if the doctor(s) involved in the patient's care:

- does not properly diagnose the patient's condition;
- does not prescribe appropriate antibiotics;
- does not perform surgical drainage of the infected area or;
- improperly refers or does not refer the patient to a specialist (or hospital) who can appropriately address the patient's condition.

When evaluating a potential dental infection case of the first type (failure to diagnose and/or treat), important case facts the LNC should determine include, but are not limited to:

- Who examined the patient first, a general dentist or an oral surgeon?
- Were American Dental Association guidelines of referral followed (American Dental Association Council on Dental Practice, 2007)?
- If the patient was referred, was the patient given appropriate antibiotics by the first encounter dentist?
- Was a follow-up call to the patient, specialist, or hospital done the next day to determine if the patient actually presented to the doctor or hospital?

Most general dentists who see patients with infections of dental origin are qualified and comfortable treating only the most elementary infections. Infections more serious than periapical infections typically are referred to the oral surgeon because he/ she has the experience, knowledge, and skill to assess both common and complicated dental infections, admit the patient to the hospital for aggressive surgical and/ or antibiotic care, and liaise with the medical community in the hospital to assist in the care of a potentially very ill patient.

Infections of dental origin after oral surgery, periodontal surgery, or root canal therapy occur infrequently despite the preponderance of bacteria in the oral cavity. One would surmise prophylactic antibiotic coverage of any patient having intra-oral invasive procedures (placement of dental implant, extraction of teeth, soft tissue surgery, or root canal therapy) would be a logical and standard practice to improve patient outcome, increase surgical success, and minimize complications. However, review of the literature is mixed and inconclusive (Calvo et al., 2012; Contardo, Meneguzzi, Cadenaro, & Di Lenarda, 2003; Esposito, Grusovin, Loli, Coulthard, & Worthington, 2010; Longman, Preston, Martin, & Wilson, 2000; Mohammadi, 2009; Oomens &

Forouzanfar, 2012; Powell, Mealey, Deas, McDonnell, & Moritz, 2005; Susarla, Sharaf, & Dodson, 2011). Although the post procedure administration of antibiotics for oral surgery, periodontal surgery, and endodontic therapy may be prudent in many cases and practiced widely, it is not absolutely standard of care as definitive double blind studies demonstrating the benefit of such practice have yet to be performed (Calvo et al., 2012; Contardo et al., 2003; Esposito et al., 2010; Longman et al., 2000; Mohammadi, 2009; Oomens & Forouzanfar, 2012; Powell et al., 2005; Susarla et al., 2011). With intra-oral procedures where no infection is present, administration of routine post-operative antibiotics has been shown to be of little or no value (Calvo et al., 2012; Contardo et al., 2003; Esposito et al., 2010; Longman et al., 2000; Mohammadi, 2009; Oomens & Forouzanfar, 2012; Powell et al., 2005; Susarla et al., 2011). The doctor must weigh the risk of infection against the potential harmful effects of the antibiotics for each individual patient.

Conclusion

Despite the many advances in health care, modern surgical techniques and treatment, broad spectrum antibiotics, and anesthesia, the acute dental infection patient may experience a life threatening exacerbation of his/her condition if the nascent infection is allowed to remain untreated. Procrastination of treatment increases patient morbidity and mortality, length of care, and cost of treatment (Graham et al., 2000; Wang et al., 2005).

The majority of dental infections can be successfully treated in the dental office with available antibiotics provided the patient presents to the doctor early in the infection process. Appropriate care includes a dental and systemic assessment complete with vital signs, airway evaluation, and imaging studies. In chosen cases blood analysis and culture and sensitivity testing should be employed to assist in patient care. Consultation with an infectious disease specialist may be indicated in the more severe infection cases (Bratton et al., 2002; Robertson & Smith, 2009).

When evaluating dental infection cases, the LNC must determine if the infection originates from patient neglect of dental health, failure of a dentist to properly diagnoses or treat an infection, or if the infection stems from malpractice post-surgery. Accurate acute diagnosis and treatment are essential to minimize the morbidity and mortality of the patient with an infection of dental origin. The first encounter dentist should prescribe antibiotics and either deliver definitive care or help facilitate definitive care via referral. Since the practice of prescribing post-surgery antibiotics is not universal or standard of care in all cases, it must be determined if antibiotics were warranted in the case. In procedures of the oral cavity even meticulous surgical technique and adherence to standard of care treatment does not guarantee absence of post-surgical infection. The occurrence of such an infection is not *prima fasciae* evidence of malpractice. That being said, each case must be evaluated on its own merits to determine if infection stemmed from deviation from standard of care and what is the standard of care for that particular patient under the presenting circumstances.

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Acetaminophen Toxicity

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KEYWORDS
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In nursing we are constantly learning about medications, their therapeutic dosages, administration routes, adverse effects, and the like. In toxicology we discover how many milligrams of a drug per kilogram body weight the patient needs to consume before it is considered toxic. As legal nurse consultants (LNC) we obtain knowledge from where healthcare and the legal system intersect attributed to medication errors, malpractice, and product liability. This article will address the analgesic acetaminophen. Acetaminophen may be found as a single ingredient or in combination with prescription or over the counter (OTC) products. There are reports of healthcare providers who have inadvertently administered acetaminophen in toxic amounts to hospitalized patients because of calculation errors and/or lack of awareness that acetaminophen was an active ingredient in OTC products patients were taking. This article will address acetaminophen toxicity and the persistent role acetaminophen has in causing acute liver failure. Selected legal actions and reports will be referenced. This article is not intended to provide detailed information on decontamination, treatment modalities, or antidotal therapy.

Introduction

In January 2011, the U. S. Food and Drug Administration (U.S. FDA) took steps to reduce the risks of hepatotoxicity, liver failure, and death related to prescription acetaminophen combination products (Farrell, Tarabar, Burns, Fernandez, & Van De Voort, 2012; U.S. FDA Center for Drug Evaluation and Research (CDER) (2011); US FDA Federal Register, (2011); U.S. FDA Federal Register (2009); U.S. FDA (2009).

The FDA has:

- asked manufacturers to limit the maximum amount of acetaminophen to 325 milligrams (mg) per tablet, capsule, or other dosage unit,
- required a box warning, the agency's strongest warning for prescription drugs, be added to the packaging, and
- required warning labels about acetaminophen's risk for allergic reactions.

History

Spooner et al. (1976) reported that in the 1850s in medicine the "… two major areas of therapy were the relief of pain and relief of inflammation and fever" (p.1). Chemists were trying to find alternatives to using powders and extracts as antipyretic agents; however, most had toxic side effects (Spooner & Harvey, 1976). Acetanilide was synthesized from Aniline in 1852. It was found to be a powerful antipyretic agent; however, when used it caused cyanosis and methemoglobinemia. Chemists heard about this and became interested in other Aniline derivatives that were previously synthesized (Spooner & Harvey, 1976).

Paracetamol was synthesized at Johns Hopkins University in 1877 and essentially ignored because it was believed it had no medicinal purposes. In 1887 Phenacetin was introduced and became the first synthetic fever reducer and was used as an analgesic. It is metabolized to Paracetamol (Silverman, M. Lydecker, M., & Lee, R. (1992).

In 1893, Josef von Mehring, a clinical pharmacologist, published a paper on the clinical results of Paracetamol and Phenacetin, as an analgesic and antipyretic agent. He discouraged its medicinal use due to its undesirable side effect profile (Jackson, Mac Donald, & Cornett, 1984; Makin & Williams, 1997; Shannon & Salhanick, 2007; Silverman, Lydecker, & Lee, 1992; Spooner & Harvey, 1976). Later, Lester, Greenberg, and Carroll, (1947), and Brodie and Axelrod (1948) published data on the metabolism of acetanilide and phenacetin, and found that Paracetamol was not responsible for the toxic side effects as previously reported by von Mehring (Silverman, Lydecker, & Lee, 1992; Spooner & Harvey, 1976). Paracetamol was the agent responsible for the analgesic and antipyretic effects. This made drug companies investigate these findings which led to the "rediscovery" of Paracetamol (Silverman, Lydecker, & Lee, 1992). In 1950 Paracetamol was marketed in combination with aspirin and caffeine as Triagesic; however, again it was abandoned after reports of agranulocytosis associated with its use surfaced, but this was never proven (Jackson et al., 1984; Shannon & Salhanick, 2007; Smilkstein, 1998; Spooner & Harvey, 1976).

Paracetamol continued to be marketed in the United States promoting it as safer to take than aspirin. McNeil Laboratories began selling Paracetamol as a pain and fever reliever under the brand name of "Tylenol®", derived from para-ace**ty**aminoph**enol**. Today acetaminophen uses the names acetaminophen (in U.S.) or Paracetamol (in Europe) or as N-Acetyl-para-aminophenol (APAP). Acetaminophen is the primary ingredient contained in more than 600 over the counter products (OTC) (Colfer et al., 2013; U.S.

FDA CDER, 2011; McNeil Consumer Healthcare, 2012; Smilkstein, 1998). Drugs used for multi-symptom relief such as cough, fever, or insomnia may contain acetaminophen in combination with dextromethorphan, diphenhydramine, pseudoephedrine, or salicylamide (U.S. National Library of Medicine (NLM), 2012; Zhou et al, 2012). Prescription acetaminophen combinations may contain opioids such as butalbital, codeine, hydrocodone, oxycodone, or tramadol (McNeil Consumer Healthcare, 2012).

More than 25 billion doses of acetaminophen are sold each year in the U.S. (U.S. NLM, 2012). Acetaminophen formulations include immediate and extended release products with dosages ranging from 80 mg to 1,000 mg. Available routes of administration include by mouth (PO), intravenous (IV), or per rectum (PR). Daily doses of acetaminophen in adults should not exceed 4 grams in a 24 hour period of time; however, doses of less than 4 grams have been associated with hepatic injury (Dart, Erdman, Olson, Christianson, Manoguerra, Chyka, et al., 2006; Schiødt, Rochling, Casey, & Lee, 1997; Shannon & Salhanick, 2007; U.S. NLM, 2012).

The first clinical evidence of acetaminophen toxicity attributed to hepatic failure and resulting in death was reported in 1966 (Jackson et al., 1984; Makin & Williams, 1997; Shannon & Salhanick, 2007; Wilkes, Clark, & Herrera, 2005). Reports of acute nephrotoxicity after massive overdoses of acetaminophen do occur (McNeil Consumer Healthcare, 2010; Olson, 1999; Perneger, Whelton, & Klag, 1994; Rumack & Matthew, 1975; Treinen-Mosle, 2003). The first published report in the U.S. of a patient who had combined liver necrosis and renal failure was in 1971(Boyer & Rouff, 1971). The first overdose death occurred in 1971 (Wilkes et al., 2005).

Acetaminophen-related overdoses have resulted in more than both 56,000 emergency department visits and 26,000 hospital admissions annually (Nourjah, Ahmad, Karwoski, & Willy, 2006; U.S. FDA Federal Register, 2011). In addition, there are reports of healthcare providers who have inadvertently administered acetaminophen in toxic amounts to hospitalized patients. This occurrence was because of calculation errors and/or lack of awareness that acetaminophen was an active ingredient in OTC products patients were taking (Colfer et al., 2013; Dart & Rumack, 2012; Zhou et al., 2012). In overdose, acetaminophen has a direct effect on the liver and may cause acute liver injury and death from acute liver failure (Shannon & Salhanick, 2007; Smilkstein, 1998; Treinen-Mosle, 2003; U.S. NLM, 2012). Encounters with acetaminophen have resulted in personal injury, death, and legal actions (Bauer, Babel, Giesen, & Patzelt, 1999; Dart & Rumack, 2012).

Poison Control Centers provide information, treatment management, and collect data on drug use, misuse, adverse reactions, overdose, under-dose or therapeutic errors. Each encounter uses the term exposure regardless of the reason for exposure (Bronstein, Spyker, Cantilena, Jr., Rumack, & Dart, 2012). Acetaminophen exposures are the most common pharmaceutical agent reported to Poison Control Centers annually (Smilkstein, 1998).

In 2011, 2.3 million human exposures to pharmaceutical and non-pharmaceutical products were reported; acetaminophen accounted for 165,552 of those exposures (Bronstein et al., 2012). Of the 1,995 deaths in 2011 from pharmaceutical agents, acetaminophen accounted for 345 (17.3%) of these deaths: 183 deaths in which acetaminophen was the primary ingredient, and 162 deaths in which acetaminophen was used in combination with other ingredients (Bronstein et al., 2012). The antidote for acetaminophen toxicity, N-acetylcysteine (NAC), was administered to 25,408 exposed patients in 2011 (Bronstein et al., 2012).

Acute Liver Failure

Acetaminophen-induced hepatotoxicity exceeds other causes of acute liver failure in the U.S., Europe, and Australia (Craig, Bates, Davidson, Martin, Hayes, & Simpson, 2011; Farrell et al., 2012; Sood, Conrad, Luu, Slabinski, & Van Gelder, 2012; U.S. NLM, 2012).

The American Association for the Study of Liver Disease (AASLD) defines acute liver failure as a **rare** condition that occurs in an adult when there is:

- evidence of coagulation abnormality, usually an International Normalized Ratio (INR) greater than or equal to 1.5;
- any degree of mental alteration (encephalopathy) to a patient, without preexisting cirrhosis; and
- an illness of less than 26 weeks duration (Chun, Tong, Busuttil & Hiatt, 2009; Lee, Larson, & Stravitz, 2011; Sood et al., 2012; Squires, Jr., Shneider, Bucuvalas, Alonso, Sokol, Narkewicz, et al., 2006; Stravitz, Kramer, Davern, Shaikh, Caldwell, Mehta, et al., (2007).

Other causes of acute liver failure include autoimmune liver disease, hypoperfusion, shock, viral hepatitis, and sometimes as an unknown cause (Lee et al., 2011; Patel, 1992; Shannon & Salhanick, 2007; Sood et al., 2012). Squires et al. (2006) report the pediatric definition is quite different in that hepatic encephalopathy is "… difficult to assess…and may not be essential to the diagnosis of acute liver failure in children"(p.2). They report that pediatric etiologies differ in that "… children have more indeterminate cases and fewer acetaminophen and viral-induced cases" (p.4). Lee et al. (2011) state, "acute liver failure often affects young persons and carries a high morbidity and mortality"(p.1).

Sood et al. (2012) reported that unintentional (accidental) acetaminophen use accounted for 48% of acute liver failure cases, compared to intentional (suicidal) acetaminophen use of 44%. Approximately 2,000 cases of acute liver failure occur annually, with more than 50% being drug-related and 12% from idiosyncratic effects (Lee, 2004; Lee et al., 2011, Sood et al., 2012).

Of adult acute liver failure patients, 14% to 20% were classified as unknown, whereby no etiology was identified even after extensive history taking and evaluation (Lee, 2004;

Lee, et al., 2011; Squires, Jr. et al., 2006). Recently a newly developed assay acetaminophen-cysteine (APAP-CYS) has proven that some of the unknown adult patients are in fact unrecognized acetaminophen poisonings (Khandelwal, James, Sanders, Larson, & Lee, 2011; Lee 2004). Lee et al. (2012) state, "Any patient with very high aminotransferase and low bilirubin on admission with acute liver failure very likely has an acetaminophen overdose. He continues "… the one possible exception being [are] those patients who enter [present] with ischemic injury"(p.965).

Between January 1, 2010 and June 30, 2012, 163 liver transplant candidates in the U.S. were awaiting transplantation as a result of acetaminophen toxicity. Of these, 57 patients had a transplant and 26 had expired waiting for a transplant (Scientific Registry of Transplant Recipients, personal communication, February 14, 2013).

Pharmacokinetics

Oral acetaminophen is rapidly absorbed from the stomach and small intestine with peak plasma levels within 30 to 90 minutes (Farrell et al., 2012; Jackson et al., 1984). Therapeutic doses of acetaminophen produce plasma concentrations of 5-20 ug/ml and may cause transient serum aminotransferase elevations (Jackson, MacDonald, & Cornett, 1984; Shannon & Salhanick, 2007; U.S. NLM, 2012). After a large overdose acetaminophen plasma concentrations may continue to rise for hours (Dart & Rumack, 2012).

Approximately 90% to 95% of acetaminophen is metabolized in the liver as an inactive and non-toxic water soluble product eliminated in the urine (Farrell et al., 2012). The remaining 5% to 10% of acetaminophen undergoes reductive metabolism by the cytochrome P-450 system (Farrell et al., 2012; Makin & Williams, 1997; McNeil Consumer Healthcare, 2010; Shannon & Salhanick, 2007; Treinen-Mosle, 2003; U.S. NLM, 2012).

Acetaminophen metabolism is dependent on the liver's protective, glutathione stores (Farrell et al., 2012, Lane et al., 2002; Shannon & Salhanick, 2007; Spiehler & Levine, 1999). If there is enough glutathione, the remaining 5% to 10% of the drug will be metabolized. If the glutathione stores are low or have been depleted to less than 30%, then a highly reactive toxic substance, called N-acetyl-p-benzoquinone imine (NAPQI) binds to macromolecules in the hepatocyte, causing cellular death and hepatic necrosis (Byer, Traylor, & Semmer, 1982; Jackson et al., 1984; Lane, et al., 2002; McNeil Consumer Healthcare, 2005; Shannon & Salhanick, 2007; Smilkstein, 1998; Spiehler & Levine, 1999; Treinen-Mosle, 2003; U.S. NLM, 2012; Wilkes et al., 2005).

Metabolism becomes difficult when too much of the drug is present or if there are pre-existing medical conditions (Farrell et al., 2012; U.S. NLM, 2012). Pre-existing conditions include chronic alcohol ingestion, dehydration, fasting, malnutrition, medications used to treat seizures and tuberculosis, and viral illness (Chun et al., 2009; Farrell et al., 2012; Lane, Belson, Brown, & Scheetz, 2002; Makin & Williams, 1997).

Dart and Rumack (2012) state IV acetaminophen "… produces an immediate peak, but the concentration declines rapidly" (p. 351). In theory, IV acetaminophen exposures may be less harmful, even in 10-fold overdoses to the liver, than PO acetaminophen doses, due to the first-pass effect of ingestion (Dart & Rumack, 2012; Spiehler & Levine, 1999).

Rumack-Matthews Nomogram: Risk of toxicity

The first Rumack-Matthews Nomogram was developed in 1975 as a linear graft over time to predict if a patient is at risk for toxicity after a single exposure to acetaminophen (Dart et al., 2006; Rumack & Matthew, 1975; Shannon & Salhanick, 2007). It does not predict a risk for patients who consume acetaminophen on a chronic therapeutic or supratherapeutic basis (Dargan & Jones, 2002; Dart et al., 2006; Dart & Rumack, 2012). In contrast, European countries and Australia and New Zealand use the Prescott Line which identifies different toxic treatment concentration values; this is not the standard in the U.S. and will not be discussed here (Gosselin, Hoffman, Juurlink, Whyte, Yarema, & Caro, 2013; Daly, Fountain, Murray, Graudins, & Buckley, 2008; Prescott, Illingworth, Critchley, Stewart, Adam, & Proudfoot, 1979).

The modified Rumack-Matthews Nomogram (Nomogram) was developed in 1981 and is almost exclusively used in the U.S. and Canada, to predict if a patient is at risk for acetaminophen toxicity (Gosselin et al., 2013). The modified Nomogram plots acetaminophen levels starting at 4 hours descending to 24 hours post ingestion. The modified Nomogram has two distinct parallel lines. The Rumack-Matthews line (upper-dotted line) defines toxicity from 200 ug/mL. at 4 hours to 50 ug/mL. at 12 hours, and less than 5ug/mL at 24 hours (Makin & Williams, 1997; Shannon & Salhanick, 2007). The FDA required Rumack to add a line 25% lower, called the treatment line (lower-solid line) to allow for possible errors for those patients whose time of ingestion was unknown or have a questionable risk of acetaminophen toxicity (Dargan & Jones, 2002; Gosselin, et al., 2013; Makin & Williams, 1997; Shannon & Salhanick, 2007; U.S. NLM, 2012).

The treatment of acetaminophen toxicity is based on a true serum acetaminophen level obtained four hours after an acute ingestion. Acetaminophen levels obtained prior to four hours or after 24 hours can not be interpreted using the Nomogram (Dart, et al., 2006; Gosselin, et al., 2013). In addition, the half-life of acetaminophen is not a predictor of hepatotoxicity and should not be used to determine acetaminophen peak and the need for antidotal therapy (Dart et al., 2006; Gosselin et al., 2013). The Nomogram cannot be used to predict the risk of toxicity when the patient

- history is unknown,
- has consumed low doses of acetaminophen chronically or in supratherapeutic doses,
- has an altered metabolism such as alcohol ingestion or fasting, or

- when the ingestion time is unknown or unclear.

A toxicologist consult would be prudent to determine if decontamination and/or antidote therapy is required. Patients whose true acetaminophen assay is plotted above the treatment line require antidotal therapy of NAC. (Dart, et al., 2006; Lee, et al., 2011; Mc Neil Consumer Healthcare, 2005).

The key to treating the patient and reducing the risk of hepatotoxicity is by obtaining a thorough patient history that includes determining if the patient has been consuming acetaminophen acutely, chronically, or in supratherapeutic doses. The history should identify the exact time of acetaminophen ingestion, and all OTC and prescription drugs the patient has consumed that contain acetaminophen (Dart & Rumack, 2012; McNeil Consumer Healthcare, 2005; Shannon & Salhanick, 2007; Thornton & Minns, 2012).

Dosing

The therapeutic dose is the amount of acetaminophen dosing used to obtain the desired effect in both adults and pediatrics. These doses currently are: (Farrell et al., 2012; Micromedex® Healthcare Series, 2013; McNeil Consumer Healthcare, 2010)

Adult:

- PO: 650 to 1000 mg every four to six hours up to four grams in 24 hours;
- IV: (50 kg or greater): 650 to 1000 mg every four to six hours, up to four grams in 24 hours;
- IV: (less than 50 kg): 12.5 mg/kg to 15 mg/kg every four to six hours, not to exceed 3,750 mg. in 24 hours.

Pediatric

McNeil Pharmaceuticals recommends that healthcare professionals oversee administering acetaminophen to children age zero to 23 months (McNeil Consumer Healthcare, (2010). Current dosing information for ages 2 to 11 years old are:

- PO: 10 to 15 mg/kg every 4 hours up to 60 mg/kg/in 24 hours.
- IV: 12.5 mg/kg to 15 mg/kg every 4 to 6 hours, up to 75 mg/kg/in 24 hours.

Toxicity

An acute ingestion as defined by Dart et al. (2006) is "… any number of ingestions that occur within a period of up to 8 hours" (p.2). A chronic ingestion is defined as a daily ingestion of high-therapeutic doses, such as three grams but less than four grams per day, for more than two consecutive days (Lane et al., 2002; Olson, 1999; Patel, 1992).

To cause an acute toxicity a patient would receive doses of 150 mg/kg or greater or approximately 7 to 10 grams acutely (Dargan & Jones, 2002; Farrell et al., 2012; McNeil Consumer Healthcare, 2005; U.S. NLM, 2012). Patients who unintentionally overdose on acetaminophen OTC products usually know the specific time of ingestion and the amount of drugs taken and can be managed accordingly. Patients who are suicidal are more difficult to manage because their actual time and amount of acetaminophen consumed is often unknown or inaccurate (Sporer & Khayam-Bashi, 1996).

Chronic acetaminophen toxicity is a challenge for clinicians. Patients who are given or consume high dosages of acetaminophen, but below four grams in a two day period, might have a rise in their liver enzymes and become toxic. Dosages of less than four grams have been associated with hepatic injury (American Academy of Pediatrics, 2001; Flanagan, 2001; Shannon & Salhanick, 2007). Patients with pre-existing conditions, or when their medication history is vague, or are taking combination products with acetaminophen as an ingredient, require a toxicology consult. A toxicologist will determine if decontamination and/or antidote therapy is needed (Chun et al., 2009; Dart et al., 2006; Farrell et al., 2012; Rumack & Matthew, 1975; US NLM, 2012).

Supratherapeutic toxicity is also known as a staggered overdose. Dart (2006) defines a supra-therapeutic dose in an adult as "… any pattern of multiple ingestions over a period of greater than 24 hours that results in a total dosage of more than four grams per day" (p.2). Craig et al. (2011) adds a time interval of "…greater than eight hours resulting in a cumulative dose of greater than four grams a day" (p.286).

For the pediatric patient older than six years of age, toxic doses are either at least 10 grams or 200 mg/kg, whichever is less, over a single 24-hour period, or at least 6 grams or 150 mg/kg, whichever is less, per 24-hour period for the preceding 48 hours or longer (Micromedex® Healthcare Series, 2013). Hepatic injury following repeated supratherapeutic ingestions may occur at any dose above the daily recommended dose (Micromedex® Healthcare Series, 2013).

Pregnancy

Acetaminophen is a pregnancy risk B class drug and is readily used safely during pregnancy in therapeutic doses. However, in overdose, acetaminophen crosses over to the fetus during all trimesters with outcomes varying from normal healthy deliveries, spontaneous abortions, fetal demise, and maternal deaths (Byer et al., 1982; Haibach, Akhter, Muscato, Cary, & Hoffman, 1984; Kurzel, 1990; Mc Elhatton, Sullivan, Volans, & Fitzpatrick, 1990; Riggs, Bronstein, Kulig, Archer, Rumack, 1989; Roberts, Robinson, Mughal, Ratcliffe, & Prescott, 1984; Thornton & Minns, 2012; Wang, Yang, Lee, Chao, Yang, & Hung, 1997; Wilkes, Clark, & Herrera, 2005).

Phases

Current published articles and toxicology texts describe four phases of acetaminophen poisoning.

Phase 1 (0.5 - 24 Hr): In phase I the patient may appear to be normal or frequently develops anorexia, nausea, and

vomiting. Some patients may have malaise and diaphoresis. Transaminases levels may be elevated.

Phase II (24-72 Hr): In phase II the anorexia, nausea, and vomiting become less pronounced. The patient complains of right upper quadrant pain as the transaminase levels continue to increase. The bilirubin level may begin to be elevated and the prothrombin time may be prolonged. It is here when renal function may deteriorate.

Phase III (72-96 Hr): Phase III is characterized by sequelae of hepatic necrosis, jaundice, coagulation defects, renal failure, and hepatic encephalopathy. A liver biopsy typically reveals centrilobular necrosis. Death due to multiorgan failure may result.

Phase IV (4-14 Days): If the patient survives to reach phase IV, complete resolution of hepatic dysfunction occurs and the liver heals without evidence of fibrosis.

These phases, symptoms, and approximate time intervals are shown in the Figure.

Figure. Phases of Acetaminophen Poisoning

Phase 1 (0.5 - 24 Hr)

Anorexia, nausea, and vomiting are frequently present.

Malaise and diaphoresis may be present.

Transaminases may be elevated.

Patients may appear normal.

Phase II (24-72 Hr)

Anorexia, nausea, and vomiting become less pronounced.

Right upper quadrant pain may be present.

Transaminase levels continue to increase.

Bilirubin level may be elevated.

Prothrombin time may be prolonged.

Renal function may deteriorate.

Phase III (72-96 Hr)

Characterized by the sequelae of hepatic necrosis: jaundice, coagulation defects, renal failure, and hepatic encephalopathy.

Liver biopsy reveals centrilobular necrosis.

Death due to multiorgan failure may result.

Phase IV (4-14 Days)

If patients survive, complete resolution of hepatic dysfunction occurs and the liver heals without evidence of fibrosis.

Adapted with permission from Haddad and Winchester's Clinical Management of Poisoning and Drug Overdose. 4th Ed. (p. 828). By M.W. Shannon and S.D. Salhanick, 2007. Philadelphia, PA. Saunders /Elsevier.

Legal actions and reports

As of May 16, 2013, 41 Tylenol® related hepatotoxicity lawsuits have been filed in U.S. district courts and an additional 27 cases are pending in federal courts. A motion was filed for all Tylenol® complaints initially in the federal courts, to be centralized in Pennsylvania {McNeil Headquarters}in an effort to reduce duplicative discovery, eliminate conflicting pretrial rulings from different judges, and to increase judicial efficiencies (Kirk, 2013; Malik, 2013). Presented here are five legal cases and reports involving acetaminophen toxicity resulting in personal injury, death, and legal action.

Case 1 *Sechi v. McNeil-PPC, Inc. et al. Case No 1:2012cv12195; Massachusetts District Court.*

Lawsuit filed - November 27, 2012: Breach of implied warranty-design defect and manufacturing defect. The adult patient took Tylenol® Extra Strength tablets (500mg/tab) several times a day for approximately two weeks, ultimately leading to a diagnosis of acute liver failure and hepatotoxicity.

Case 2 *Torres-Ortiz et al v. Johnson & Johnson, Inc. et al. Case No 3:2012cv01746 Puerto Rico District Court.*

Lawsuit filed - September 10, 2012: Torres-Ortiz had chronically used Extra Strength Tylenol® to treat a mild headache. She took two 500 mg tablets on day one. Later that same day she awoke complaining of nausea and vomiting and consumed two additional Extra Strength Tylenol® tablets. Over the next few days, the patient complained of nausea and abdominal pain. She went to the emergency department (ED) and was administered two Extra Strength Tylenol® and discharged. One week later the patient returned to the ED complaining that her skin had turned yellow. She was diagnosed with acute liver failure and required a liver transplant. Her physicians agreed that her liver failure was due to chronic therapeutic Tylenol® toxicity.

Case 3 *Hutto v. McNeil PPC, Inc. 79 So/3d 1199, 2011-609 (La.App. 3 Cir. 12/7/11) Case No. 11–609. December 07, 2011*

Lawsuit filed – June 25, 2010: A one-year-old female had a fever and was vomiting. Her parents administered Infant Tylenol® drops. When the fever did not subside she was brought to the local ED where she was examined by the ED physician and discharged. The ED nurse provided after-care instructions, instructing the mother to administer three-quarters of a teaspoon of Tylenol®. When the mother questioned this dose, the nurse left and later returned with instructions to administer three-quarters to one teaspoon of Tylenol®, explaining that the higher dose would be more effective for her child. This dose was calculated by the nurse and not confirmed by the ED physician. The mother did not know that these instructions referred to Children's Tylenol® liquid (160mg/5ml) used exclusively by the ED, and not Infant's Tylenol® Drops (80 mg/0.8 ml) used by the mother, who had previously shown the container to the nurse.

The mother administered four, one teaspoon doses (640mg) of Children's Tylenol® liquid to the child. The child's fever continued and she became lethargic. The parents brought the child back to the ED and demanded that she be admitted. After some convincing the ED physician admitted the child for further testing. The tests showed the child had an acetaminophen overdose and antidotal therapy was started. Additional testing showed the child also had liver damage and required a liver transplant. The child was transferred to a transplant center, where it was determined she was not a candidate for liver transplantation because her fever was due

to a viral illness. The child later died of liver failure secondary to acetaminophen toxicity.

Case 4 *Dunson v. McNeil-PPC, Inc. 982 A.2d 1222 (2009); 974 A.2d 1196 (2009) Superior Court of Pennsylvania*

Lawsuit filed - July 25, 2006: Dunson sued McNeil for wrongful death of their one year son who died from acetaminophen toxicity, because they failed to warn that their Infant Tylenol® Drops were three times stronger than regular Children's Tylenol®. The parents did not consult their pediatrician prior to administering the Infant Tylenol® Drops (80mg/0.8ml) to their son. They administered two full droppers every four to six hours, over a four day period. On day four, the child still had symptoms of a cold and then began vomiting. The child was taken to his pediatrician arriving listless and lethargic. An ambulance was summoned and shortly after his arrival to the ED, the child died. An autopsy revealed he died of massive liver damage caused by acetaminophen toxicity.

Case 5 *Sophia Marie Regosin-Hodges, a minor, et al.v. McNeil Consumer Products Company, Division of McNeil-PPC, Inc., Case No. A076349. San Francisco County Super. Ct. No. 969265. Jan. 29, 1998.*

Lawsuit filed – December 30, 1998: Hodges sued physicians for professional negligence and the manufacturer for failure to warn of dangers of improper dosing. Infant Tylenol® Suspension Drops (80 mg per 0.8ml) were given to the eight month old patient since she was two months old, under the direction of her pediatrician. There is no dosage prescribed on the product label for children less than two years of age or weight of less than 24 pounds. When the patient was 13 ½ months (21.5 lbs.) she developed a fever and was administered a half dropper of Infant Tylenol® Suspension Drops, by her parents. The child's temperature rose later that evening so her mother administered ibuprofen instead, and called the on-call pediatrician. The on-call pediatrician recommended giving her daughter a teaspoon of Tylenol® every four hours. The mother decided to wait until the next morning and reconfirmed with the on-call pediatrician the dose prescribed. In the conversation there was no mention of whether the dose prescribed was Infant Tylenol® Suspension Drops or Children's Tylenol® Elixer (160mg/5ml).

Infant Tylenol® Suspension Drops (80 mg per 0.8ml) was administered to the child: day one-five teaspoons; day two-six teaspoons. On day three the child became lethargic and was brought to the pediatrician's office who diagnosed her as having the flu. On day three the child received four teaspoons of Infant Tylenol® Suspension Drops; day five-six teaspoons; and on day six-two teaspoons. On day six after receiving now 23 doses of Infant Tylenol® Suspension Drops, the childs' condition deteriorated. She was admitted to the local hospital and was diagnosed with liver failure, requiring a liver transplant.

Report 1 Dart and Rumack (2012) published the first report involving three children who received a 10-fold iatrogenic overdose while in a hospital from IV acetaminophen. Most 10-fold errors occur because of calculation errors (Colfer et al., 2013). This article also notes 23 additional acetaminophen cases of IV dosing errors, including one which was fatal (Dart & Rumack, 2012).

Other reports for reference

July 19, 2012 - Missouri: Woman in Tylenol Coma for Six Weeks: A 55 year old female ingested 6 rapid release Tylenol® (500mg/tab) tablets over 24 hours. She developed liver and kidney failure, remained in the hospital for 2 months before discharge (Mundy, 2012a).

May 21, 2012 – Iowa: My Wife's Liver Failed After Tylenol IV Drip. A 63 year old female recovering from hip replacement surgery was administered Tylenol ® by intravenous drip. She died five months later after complications from a liver transplant. Her diagnosis was drug induced auto-immune hepatitis. The family report the only drug she was took was the IV Tylenol® while in the hospital (Mundy, 2012b).

March 21, 2011 – Florida: Palm City man died after taking too many OTC pain relievers. A 49 year old male

ingested acetaminophen and ibuprofen for several weeks for a toothache. He developed liver and kidney failure and expired before a liver transplant became possible (WPTV.com, 2011).

Conclusion

Acetaminophen is considered a safe and effective drug when used in therapeutic doses. In 2011, 165,552 acetaminophen related encounters (exposures) were reported to U.S. poison control centers (Bronstein et al., 2012). In overdose, acetaminophen toxicity occurs depending on the individual's glutathione stores and pre-existing medical conditions.

Acute liver failure due to acetaminophen toxicity is becoming more frequent because patients and health care providers are not always aware acetaminophen is the primary drug in OTC products (Colfer et al., 2013; Dart & Rumack, 2012; Zhou et al., 2012). In 2011, hundreds of acetaminophen deaths were reported to U.S. poison centers and thousands of patients received the antidote to treat acetaminophen toxicity (Bronstein et al., 2012). The FDA has required manufacturers to address prescription acetaminophen combination products in an effort to reduce the risks of liver injury and liver failure (U.S. FDA CDER, 2011).

Chronic acetaminophen users may become toxic with sub-therapeutic dosing. Chronic and supratherapeutic acetaminophen patients are a challenge to treat especially if their intake history is unknown, vague, or suicidal. A toxicology consult is advised for these patients.

When reviewing potential legal cases for merit or malpractice, it is imperative that the LNC understand acetaminophen's unique metabolism as well as the patient's history and presentation of symptoms. Many medical records must be reviewed by the LNC including but not limited to, admission history and physical examination, ambulance records, emergency department records, laboratory assays, pharmacy records, and physician medication and treatment orders to ascertain if the patient was at risk for toxicity and received the appropriate treatment.

The LNC must seek to answer the same questions as the clinician regarding acute versus chronic versus supratherapeutic dosing/toxicity by identifying other products that contain acetaminophen, the time, and the timeline of ingestion. The LNC should determine if the patient was at risk for toxicity especially in any suicidal attempt, even when the patient denies taking acetaminophen all together. Although considered a safe drug, evaluating the patient to ensure that no toxic effects occur from acetaminophen remains a challenge for healthcare providers.

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The Litigation Environment for Central Line-Associated Bloodstream Infections: Hospitals Face Greater Risk When They Fail to Follow Standards of Care

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KEYWORDS
Central Venous Catheter, Infusion Therapy, Standard of Care, Central Line-Asociated Bloodstream Infection

While central venous catheter (CVC) intravenous lines are needed to deliver vital therapies, they also present substantial risks to patients. One of the greatest risks is a central line-associated bloodstream infection (CLABSI), which is fatal in 12%-25% of cases. To minimize this risk, hospitals are expected to follow professional standards of care (SOC) with CVC insertion and care practices – primarily, the recommendations developed by the Infusion Nurses Society. The recommendations of the Centers for Disease Control and Prevention (CDC) are another important source of guidance. Hospitals that fail to follow SOC risk exposure to lawsuits if a patient should suffer a CLABSI. This article describes a case study that illustrates the clinical and legal risks of CLABSIs. It explores the nature of the environment in which CLABSI-related lawsuits occur. It also examines how the hospital in the case study may have better protected its patient and itself by following specific SOC in caring for the patient.

Introduction

Central venous catheterization is an extremely common yet sometimes risky procedure. Millions of central venous catheters (CVCs) and peripherally inserted central catheters (PICCs), another type of central line, are inserted into patients in U.S. hospitals every year. In the critically ill patient, CVCs and PICCs are the preferred methods of delivering medications, blood products, nutrients, and other fluids if patients need them over an extended period of time (Kusminsky, 2007). CVCs are indicated for short-term therapies that are one week or less, while PICCs may dwell for weeks at a time. These catheters are often considered lifelines for patients, but can also lead to serious complications and death when things go wrong.

One of the most notorious catheter complications is a central-line associated bloodstream infection (CLABSI). Approximately 250,000 CLABSIs occur every year in hospitals nationally (0'Grady et al, 2011). The infections are extremely dangerous with an attributable mortality rate of 12% to 25% (Mermel, 2000).

Hospitals are expected to follow the standards of care (SOC) with CVC insertion and care practices. The term "standard of care" means diagnostic, therapeutic, or behavioral practices considered to produce the most favorable outcomes for patients, according to a consensus of healthcare professionals. Hospitals should draw their institutional policies and procedures from SOC and enforce strict staff compliance with these standards.

In intravenous therapy (IV) , the Infusion Nurses Society (INS) is widely considered the most authoritative source of standards of care (INS, 2011). Its Infusion Nursing Standards of Practice is the foundation document for SOC on all forms of infusion therapy and in all practice settings where such therapy takes place. The 2011 *CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections* is another publication that augments SOC in intravenous therapy. Based on input from regulatory bodies and respected professional organizations, the CDC guidelines include a compilation of evidence-based practices for preventing CLABSIs (O'Grady et al., 2011), and constitute a primary document for educating and training clinicians in catheter insertion and maintenance procedures.

When hospitals fail to follow the SOC for central venous catheters, patients have an increased risk for a bloodstream infection that may lead to discomfort, grievous harm, and death. Such incidents can trigger costly lawsuits – particularly in the current social and legal environment. This article describes a case study that illustrates the clinical and legal risks of CLABSIs. It explores the nature of the environment in which CLABSI-related lawsuits occur. It also examines how the hospital in the case study may have better protected its patient and itself by following specific SOC in caring for the patient.

Clinical case history and legal aftermath

S.G., a 24-year-old female, was admitted into the hospital's intensive care unit with pneumonia. The patient's disease rapidly progressed to respiratory failure which required intubation and mechanical ventilation. It was determined that the patient would need vasopressors (medications that raise reduced blood pressure), total parenteral nutrition (total intravenous feeding), and frequent blood sampling. To

administer the fluids, the patient required a PICC, which was inserted in to the right upper basilic vein and threaded to the cavoatrial junction.

One week after the PICC was inserted the patient developed a fever indicating a potential symptom of a bloodstream infection. To test the blood for bacteria, blood cultures were drawn from both lumens of the dual-lumen PICC and also a peripheral site. All cultures tested positive for coagulase negative staphylococcus, causing the most common form of bacteremia related to indwelling devices such as PICCs and CVCs (Huebner & Goldman, 1999). These results confirmed that the patient had indeed contracted a CLABSI. To treat the infection, the patient was started on the antibiotic vancomycin intravenously. The medication failed to arrest the infection in time. S.G. died of cardiac arrest 12 hours after treatment was begun.

In response to the unexpected death of their daughter, S.G.'s parents hired a malpractice attorney to pursue a potential lawsuit. The attorney conducted an investigation of the circumstances leading up to S.G.'s death, including depositions of three staff nurses involved in S.G.'s care. The investigation uncovered several breaches of relevant SOC.

Failure to perform proper hand hygiene prior to caring for the patient's CVC

Hand hygiene is a fundamental aspect of the aseptic technique that standards of care require for the insertion, care, and maintenance of intravascular devices, including CVCs (INS, 2011; O'Grady et al., 2011). Hand hygiene, as an evidence-based practice for preventing bloodstream infections, is ubiquitous in hospital bundles (groups of evidence-based practices and technologies) related to all aspects of IV therapy. Since 2006, the use of such bundles has resulted in substantial reductions in bloodstream infection rates. More conscientious compliance with hand washing policies is widely seen as crucial to this progress (O'Grady et al., 2011).

Clinicians are considered compliant with hand washing using conventional soap and water or alcohol-based rubs (INS, 2011; O'Grady et al., 2011) before contact with a patient. The staff nurses who were deposed in the current case testified that neither of these hand hygiene techniques was used prior to handling the patient's catheter. This is in spite of the fact that CVCs are known to have greater infection risk than other intravascular devices and that the risk increases in concert with dwell time (Moureau & Dawson, 2010).

Failure to perform needleless connector antisepsis prior to accessing CVC

Disinfection of a needleless connector before the line is accessed is a Category IA (highest level) recommendation from the CDC (O'Grady et al., 2011). It is also an INS Standard of Care (INS, 2011). The rationale for this SOC is obvious to healthcare personnel who perform IV care, due to the known risk of infection. If the needleless connector is not disinfected before the line is accessed, surface bacteria can be introduced into the intraluminal space of the connector and potentially develop into an infection that will enter the patient's bloodstream. The most widely accepted technique for needleless connector antisepsis sometimes called "scrub the hub," involves continually wiping the needleless connector or hub with an appropriate antiseptic – either 70% isopropyl alcohol or chlorhexidine – for 15 seconds and then waiting 30 seconds for the antiseptic to dry before penetrating the hub (Kaler & Chinn, 2007). The depositions revealed the nurses did not properly execute this technique prior to accessing the needleless connector. In addition, the nurses were unaware of the hospital's policies and procedures regarding CVC care.

Failure to use an antimicrobial/antiseptic catheter in a patient who was critically ill and whose catheter was expected to remain in place for more than five days

The CDC Guidelines recommend use of an antimicrobial CVC "in patients whose catheter is expected to remain in place more than five days if, after successful implementation of a comprehensive strategy to reduce rates of CLABSI, the CLABSI rate is not decreasing" (O'Grady et al., 2011 p.15). The INS Standards of Practice suggest that this class of devices, which it calls "anti-infective catheters," be considered in circumstances similar to those described in the CDC guidelines (INS, 2011). The INS Standards also list several patient populations for whom antimicrobial catheters should be considered, including critically ill patients (INS, 2011). The patient met the above criteria in that S.G. was critically ill and the catheter was expected to be in place for more than five days. S.G.'s PICC was not an antimicrobial catheter.

A closer look at violations of standards of care

Examining these three violations of SOC more thoroughly suggests a strategy that might have better protected S.G. from one of the most serious complications of central lines, as well as helped insulate the hospital against a CLABSI-related lawsuit. The three lapses may be equally damning from a legal standpoint but clinically speaking, they are not equal.

Hand hygiene is essential; it should be obvious to every clinician that it is important to wash hands before performing any procedure. Every hospital should repeatedly reinforce the importance of hand hygiene through education, training, and checklists to support compliance. Nevertheless, research shows that hand hygiene compliance is erratic at many institutions (Albert & Condie, 1981; Thompson et al., 1997; Pittet, Mourouga, Perneger, & the Members of the Infection Control Program, 1999). Even though noncompliance is somewhat predictable, compliance is hard to enforce without following clinicians on rounds, a practice to which virtually no hospital can dedicate the resources.

In a similar vein, studies show compliance with needleless connector disinfection to be inconsistent at most facilities due to time constraints or high nurse to patient staffing ratios

(Harnage, 2012a; Harnage, 2012b). Variation in practices may also increase CLABSI risks because the method's effectiveness depends on precise execution (Harnage; Harnage). As with hand hygiene, it is very difficult to audit needleless connector disinfection practices.

Peter Pronovost, M.D., director of the Quality and Safety Research Group at the Johns Hopkins University School of Medicine, has received national attention for (his) efforts to help institutions eliminate CLABSIs (Dreifus, 2010). These efforts include successful behavioral approaches such as specialized vascular access teams, skills day, and CVC maintenance checklists for achieving compliance with hand hygiene and needleless connector antisepsis by rigorously reinforcing their use, making actual supervision less important (Traynor, 2011). S.G.'s hospital apparently did not use such approaches, increasing its potential culpability for S.G.'s death.

Still, Pronovost's successes remain the exception, not the rule. This underscores the usefulness of an antimicrobial catheter as a first line of defense. Hypothetically, a catheter impregnated with an antimicrobial agent can help compensate for lapses in other catheter care and maintenance practices. This is why both the INS and CDC recommend this device for facilities that need to reduce CLABSI rates.

Furthermore, in the CDC's National Healthcare Safety Networks document, 71.7% of Pennsylvania's acute care facilities reported that CLABSIs occurred more than five days after the central line was inserted (Davis, 2011). This adds further weight to the INS and CDC recommendations for use of an antimicrobial catheter when infusion therapy is intended to last more than five days.

Social and legal factors affecting CLABSI-related lawsuits

The factors discussed above are problematic enough for the defense. But developments in recent years have made defending against CLABSI-related litigation even more challenging.

The CMS view

Several years ago, the Centers for Medicare & Medicaid Services (CMS) reached the conclusion that many healthcare acquired infections (HAIs), including CLABSIs, were entirely preventable if hospitals followed the relevant SOC and otherwise established and enforced the appropriate protocols. In late 2008, CMS codified its viewpoint by ceasing to reimburse for treatment of these infections. Once CMS acted, many private insurers followed its example.

The impact of these changes has gone beyond reimbursement to affect liability for CLABSI and certain other HAIs – in part because CMS's opinion that some HAIs are preventable is shared by many infection control experts. In a presentation (September 6, 2011) to the Association of Vascular Access, attorney Ann Zonderman, BSN, JD, CRNI, LHRM, Health Facilities Evaluator at the California Department of Public Health, and vascular access expert Nancy Moureau, BSN, CRNI, CPUI, VA-BC, noted that the "CMS statement that CLABSIs are preventable changes the entire landscape for litigation. Any infection that a patient contracts in a hospital is now considered a breach in care" (Zonderman & Moureau, 2011).

Better-informed patients and family

The abundance of medical information available on the Internet means that many patients and families are now better educated about HAIs, including CLABSIs. The educational process goes beyond the obvious sources including government websites such as the CDC, non-profit organization websites, news sources, blogs, and patient listservs and social media sites. It also includes infection data that hospitals must report because of state mandates (see below) and public ratings of hospitals, which utilize multiple criteria including infection data and patient satisfaction. Individuals who research these matters can become quite knowledgeable about bloodstream infections, hospital protocols, and products such as antimicrobial catheters that are intended to reduce infection risk, as well as the CMS decision. Because lay people are now more knowledgeable about HAIs, it may be more likely that a lawsuit is filed if a family member dies from an infection that is considered preventable by CMS.

Mandatory reporting of CLABSIs

As of this writing, 27 states now require that hospitals publicly report healthcare-associated infection rates. Consumers -- and attorneys -- can compare one hospital's infection rate to data from other hospitals in the same area. Such data can help support a lawsuit when someone is harmed at a hospital with above-average infection rates. In addition, the data constitute evidence that something is awry with the hospital's adherence to, or enforcement of, standards of care.

Zero-tolerance environment

CMS's zero- tolerance stance – which, again, reflects the views of many in the infection control community – helped increase acceptance of a zero CLABSI rate as an achievable goal. This goal is no longer just an ideal. Hospitals that have followed Dr. Pronovost's recommendations have dropped infection rates to zero for sustained periods of up to two years (Traynor, 2011). Independent of Pronovost's efforts, one hospital in California has not had a CLABSI in any central line placed by its vascular access team since it adopted a new central line bundle in January 2006 (Harnage, 2012a; Harnage, 2012b). The hospital, Sutter Roseville Medical Center in Roseville, CA has demonstrated that meticulous attention to SOC and comprehensive adoption of other practices and technologies shown to prevent CLABSIs can eliminate the infections – just as CMS has asserted. Clearly, such achievements weaken the defense of any hospital trying to explain away a CLABSI for which it was sued.

Zero tolerance also affects the decision tree about when to use a device such as an antimicrobial catheter. Zonderman and Moureau (2011) note that hospitals commonly consider using coated catheters, dressings, and other devices when their CLABSI rates are greater than zero. In other words, *any rate greater than zero* should motivate a hospital to consider taking extra preventive steps -- a precaution that S.G.'s hospital did not follow, perhaps increasing its liability.

Given these legal and societal developments -- along with impressive progress in the public-private campaign against CLABSIs -- it is not surprising that CLABSI-related litigation cases have occurred in recent years. Zonderman and Moureau have stated that practicing below the SOC could be considered negligent behavior that increases liability from CLABSI-related lawsuits.

Discussion

Three standards of care appear to have been violated in the care of the patient S.G., who subsequently suffered a CLABSI and died, triggering a lawsuit by the parents. Two of the SOC – hand hygiene and needleless connector antisepsis prior to accessing a CVC – apply to any patient receiving IV therapy. Dedicated resources for educating clinicians on proper CVC care and maintenance is one strategy that may be beneficial for decreasing CLABSI rates. The third, relating to use of an antimicrobial catheter, pertains to S.G who was critically ill and required a CVC for more than five days.

It would be legally prudent for hospitals to consider these SOC not separately but as related to each other. A defense attorney might conceivably argue in court that hand hygiene and needleless connector disinfection are nearly impossible to enforce and that such lapses occur in hospitals nationwide for this very reason. This contention is not difficult to document even if it is not entirely convincing (because it is possible to reinforce the SOC and because numerous hospitals have been successful in doing so as evidenced by their zero CLABSI rates).

It is also legally prudent for hospitals to consider how the social and legal environment related to CLABSIs has evolved. Infection may still occasionally occur despite proper precautions, but many experts do endorse a zero tolerance stance. Now that CMS has codified such a position and articles abound about hospitals maintaining zero CLABSI rates for a period of years, a hospital may not be able to successfully defend itself in CLABSI-related litigation unless it has taken every conceivable step to follow relevant SOC.

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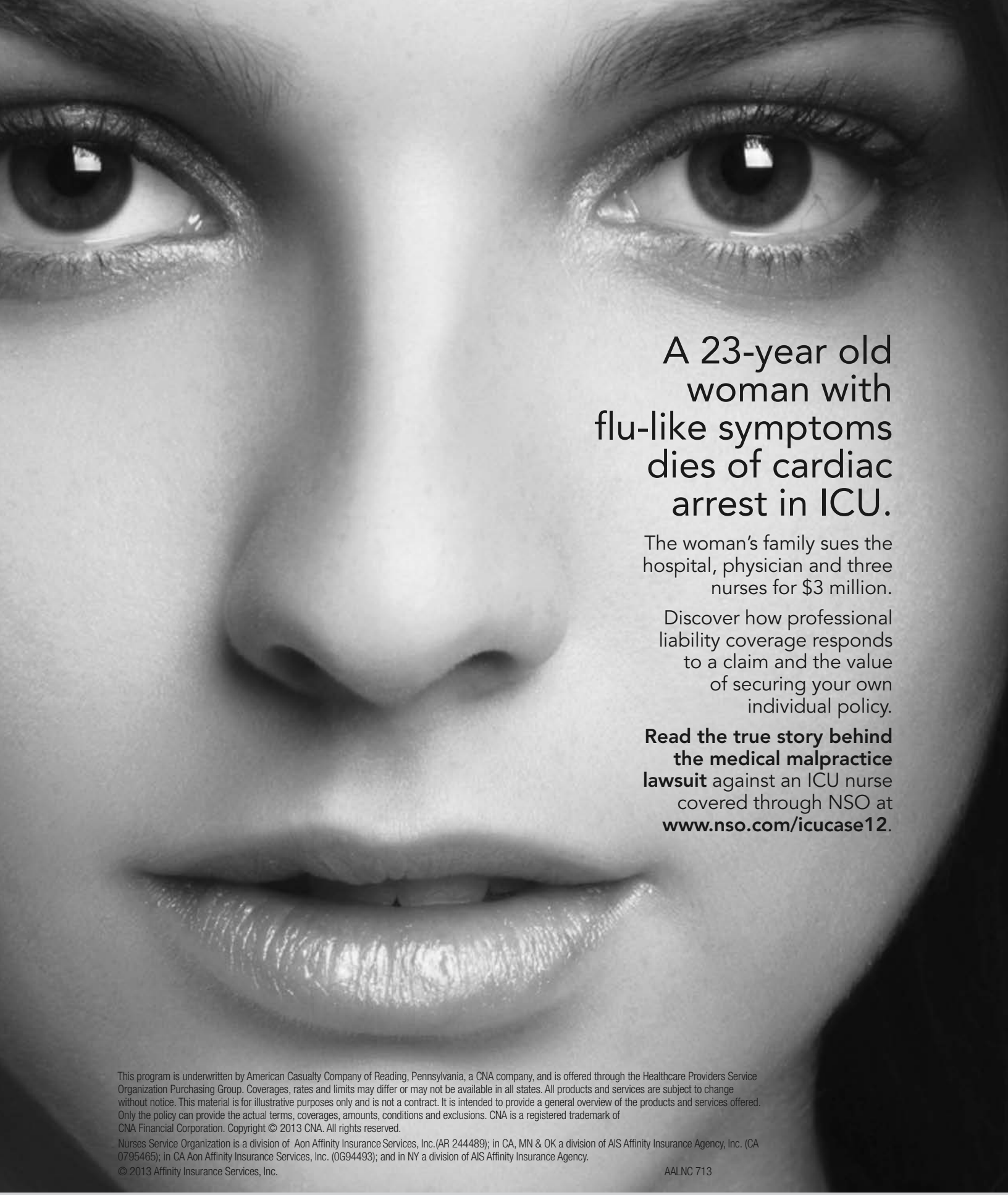

Latex Allergies

Mary A. O'Connor, PhD, RN

The following sites provide online resources for research, education, and support for latex allergies as a general reference source for the legal nurse consultant. The sites are not meant to be all inclusive of the potential resources available and are not an endorsement of any listed sites or services. Online sources change and should be confirmed prior to using as a reference.

Glossary
About.com
Latex Allergy; Could You Be Allergic to Latex? **http://allergies.about.com/od/medicationallergies/a/latexallergy.htm**
Web MD
Allergy to Natural Rubber (Latex) - Topic Overview **http://www.webmd.com/allergies/tc/allergy-to-natural-rubber-latex-topic-overview**
Dental Health and Latex Allergy **http://www.webmd.com/oral-health/dental-health-latex-allergy**
Latex Allergies, includes podcast **http://www.webmd.com/allergies/latex-allergies**
Latex Allergy Treatments **http://www.webmd.com/allergies/latex-allergy-treatments**
Davis, J. (2003). Latex Allergy? Beware Poinsettias; Christmas Flower Related to Rubber Tree. *WebMD Health News.* **http://www.webmd.com/allergies/news/20031124/latex-allergy-beware-poinsettias**
WebMD Allergy app for iPhones and iPod Touch – FREE! **https://itunes.apple.com/us/app/webmd-allergy/id588509171?mt=8**
WebMD Introduces New Allergy App for iPhone (February 2013) **http://www.multivu.com/mnr/60044-webmd-introduces-new-allergy-app-for-iphone**

Governmental Resources
Centers for Disease Control and Prevention The National Institute for Occupational Safety and Health (NIOSH) **http://www.cdc.gov/niosh/topics/latex/**
Contact Dermatitis and Latex Allergy - FAQs - Infection Control in Dental Settings. **http://www.cdc.gov/oralhealth/infectioncontrol/faq/latex.htm**
Occupational Latex Allergies. **http://www.cdc.gov/niosh/topics/latex/**
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FDA Consumer Update: There's No Guarantee of 'Latex Free' (May 2013). **http://www.latexallergyresources.org/news/fda-consumer-update-there-s-no-guarantee-latex-free#sthash.qo84VTPU.dpuf**

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U.S. Department of Labor Occupational Safety and Health Administration (OSHA). Latex Allergy and OSHA Standards. **https://www.osha.gov/SLTC/latexallergy/index.html**
Healthcare Wide Hazards - Latex Allergy. **https://www.osha.gov/SLTC/etools/hospital/hazards/latex/latex.html**
Potential for sensitization and possible allergic reaction to natural rubber latex gloves and other natural rubber products. (January, 2008). OSHA Safety and Health Information Bulletin- Gloves. **https://www.premierinc.com/safety/topics/latex_allergy/downloads/shib012808.pdf**

Diagnosis/Treatment/Resources
Be S.A.F.E. Managing Allergic Emergencies (Anaphylaxis). **http://www.acaai.org/patients/resources/anaphylaxis/managing-allergic-emergencies/Documents/BeSAFEBrochure.pdf**
Latex Allergy, includes video featuring Allergist Dr. David Bernstein on Latex Allergy. **http://www.acaai.org/allergist/allergies/Types/latex-allergy/Pages/default.aspx**
Latex Allergy Symptoms, Diagnosis, Treatment & Management | American Academy of Allergy Asthma & Immunology (AAAAI). An overview of latex allergy symptoms, diagnosis, treatment and management written and reviewed by the leading experts in allergy, asthma and immunology. **http://www.aaaai.org/conditions-and-treatments/allergies/latex-allergy.aspx**
Latex-free Products - This resource provides links to consumer-based and medical latex free products, as well as the opportunity to identify latex free products. **http://www.latexallergyresources.org/latex-free-products**

Downloadable Fact Sheets
Latex Allergy Check List (American Latex Allergy Association, 2013). **http://www.latexallergyresources.org/sites/default/files/article-attachments/ALAA%20Checklist%202013.pdf)**
Patient/Public Education: Fast Facts - Latex Allergy (American Latex Allergy Association, 2013). **http://www.latexallergyresources.org/articles/patientpublic-education-fast-facts**

Nursing Continuing Education on Latex Allergies

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American Professional Associations

American Academy of Allergy Asthma & Immunology (AAAA&I)

The AAAA&I is a professional organization for allergist/immunologists, other specialists and allied health and related healthcare professionals with members in the United States, Canada and other countries. Its purpose is to "…advance of the knowledge and practice of allergy, asthma and immunology for optimal patient care." The AAAA&I sponsors two journals -- *The Journal of Allergy and Clinical Immunology* (JACI) and *The Journal of Allergy and Clinical Immunology: In Practice.*

http://www.aaaai.org

American College of Allergy, Asthma & Immunology (ACAAI)

The ACAAI was established in 1942 as a professional association for allergists/immunologists and allied health professionals.

http://www.acaai.org

Lay Organizations

American Latex Allergy Association (A.L.E.R.T., Inc.)

The American Latex Allergy Association (A.L.E.R.T., Inc.) is a national organization that was originally formed 20 years ago by a group of health care workers who acquired latex allergy and sought to help and support each other. A.L.E.R.T stands for Allergy to Latex Education and Resource Team. The organization increases awareness of latex allergy through education and provides support to individuals diagnosed with latex allergy.

http://www.latexallergyresources.org

Asthma & Allergy Foundation of America (AAFA)

Founded in 1953, the AAFA is the oldest allergy foundation and is the leading patient organization for people with asthma and allergies including latex allergies. The AAFA is dedicated to improving the quality of life for people with asthma and allergic diseases through education, advocacy and research. The AAFA provides practical information, community based services and support to people through a network of Regional Chapters, Support Groups and other Local Partners around the U.S.

www.aafa.org

Professional Journals

Annals of Allergy, Asthma & Immunology. A scholarly medical journal published monthly by the American College of Allergy, Asthma & Immunology to provide allergists and immunologists evidence-based current clinical science in the fields of allergy, asthma, and immunology.

http://www.annallergy.org/

The Journal of Allergy and Clinical Immunology (JACI). Published monthly, the most-cited scientific journal in the field of allergy and clinical immunology.

http://www.jacionline.org/home

The Journal of Allergy and Clinical Immunology: In Practice. Published bi-monthly and presents clinical research and practical management recommendations in allergy / immunology.

http://www.jaci-inpractice.org/

Journal of the American Academy of Dermatology. Dedicated to the clinical and continuing education needs of the entire dermatologic community and is internationally known as the leading journal in the field.

http://www.jaad.org/

Find an Allergist/Immunologist

- **http://aaaai.execinc.com/edibo/FindAnAllergist**
- **http://www.acaai.org/allergist/Pages/locate_an_allergist.aspx**
- **http://www.latexallergyresources.org/locate-an-allergist**

Support Groups
American Latex Allergy Association - The ALAA creates awareness of latex allergies and provides resources for people allergic to natural rubber latex, including latex free alternative product lists, informational packets, and support to individuals. Latex-free Products - Cross Reactive Food - Latex Allergy 101 - About Latex Allergy **www.latexallergyresources.org**
Latex Allergy Support Group | Facebook **https://www.facebook.com/pages/Latex-Allergy-Support-Group/160013217741**
Latex Allergy Support Group, Rubber Latex Allergy - Allergy Discussion Group Talk about natural Rubber latex allergy online. Join 400 others on the four year old Rubber discussion group mailing list; search the Rubber Archives; study latex allergies. **www.immune.com/rubber/**
LAForum : LAForum - Groups - Yahoo! LAF stands for Latex Allergy Forum which is a group created to provide a safe, supportive, free flowing forum to exchange ideas, concerns, and shared concerns. **groups.yahoo.com/group/LAForum/**
Latex Allergy Support Group – BabyCenter Created for moms and mothers of children who have Latex Allergies. **http://community.babycenter.com/groups/a6729467/latex_allergy_support_group**
Latex allergy support groups – Inspire **www.inspire.com/conditions/latex-allergy/**

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Elder Abuse: Definition, Types and Statistics, and Elder Abuse (Mistreatment and Neglect) Laws

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

The National Center on Elder Abuse (NCEA) (2012) reports the United States 2010 Census recorded "the greatest number and proportion of people age 65 and older in all decennial census history: 40.3 million, or 13% of the total population…. In 2010, there were 5.8 million people aged 85 or older" (p. 1). By 2040, 1 in 5 Americans will be age 65 or older (Urban Institute, 2012). A March 2011, U.S. government report cited elder abuse was on the rise involving multiple types of abuse (Pham, 2011). Elder abuse (neglect and mistreatment) is defined as "intentional actions that cause harm or create a serious risk of harm (whether or not harm is intended) to a vulnerable elder by a caregiver or other person who stands in a trust relationship to the elder. This includes failure by a caregiver to satisfy the elder's basic needs or to protect the elder from harm" (NCEA, 2012, p. 1). Types of elder abuse are shown in the Table. In addition, self-neglect on the part of the elder which can include refusing needed help in daily activities, can be self-abusive.

Statistics on types of elder abuse

According to a 2012 report by Statistic Brain (based on NCEA, Bureau of Justice Statistics), the number of elder abuse cases in 2010 were 9.5% of the elderly population. The percentages of elder abuse cases by types reported in

Table: Types of Elder Abuse, Definitions, Causations and Signs and Symptoms

Type	Definition	Causation-Examples	Sign/Symptoms
Physical Abuse	Non-accidental use of force resulting in injury, impairment ,or pain	Hitting, slapping, shoving, force-feeding, restraining by chemical or physical means	Bruising, burns, broken bones, lacerations, scars, welts—check symmetry/asymmetry
Psychological/Emotional Abuse	**Verbal**—Words spoken causing emotional pain or distress **Nonverbal**—Treatment causing emotional pain or distress	**Verbal**—threats, yelling, humiliation, ridicule **Nonverbal**—ignoring, isolating, or terrorizing elder	Withdrawal, evasiveness, refusal to socialize, unexplainable fear or suspicion, depression, mumbling to self
Sexual Abuse	Contact without consent (non-consensual sex act)	Physical sex act, showing elder pornography, forcing elder to undress or watch sex acts	Ripped/torn underwear, bleeding genitals, bruised regions of breasts or genitals, unexplained venereal diseases or vaginal infections, unexplainable vaginal or anal bleeding
Financial Abuse	Unauthorized use of elder's funds or property. Sudden change in financial situations	Illegal taking, misuse, or hiding of funds, property, assets for another's benefit; Stealing, coercion to change a will or assuming power of attorney	Forged signatures on checks, identity theft, large amount of money withdrawn without explanations, missing property
Neglect by Caregiver/Abandonment	Failure by individual caring for vulnerable elder to provide food, water, shelter, protection or health care. Desertion by caregiver from vulnerable elder	**Physical**—failure to provide preventive health care, safety, eyeglasses dentures, or hygiene **Emotional**—failure to provide social stimulation **Financial**—failure to use available resources for well-being of elder	Weight loss, thirst, sunken eyes, lack of assistive devices, bedsores, poor hygiene, unsanitary living conditions

Note. Adapted from:

Robinson, Benedictis, & Segal. (2013, March). Elderbuse and neglect. Retrieved from: http://www.helpguide.org/mental/elder_abuse_physical_emotional_sexual_neglect.htm

Administration of Aging (2013). What is elder abuse? Retrieved from: http://www.aoa.gov/AoA_programs/elder_rights/eEA_prevention/whatis EA.aspx

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2010 include: neglect (58.5%), physical abuse (15.7%), financial abuse (12.3%), psychological abuse (7.3%), sexual abuse (0.04%), all other types (5.1%), and unknown (0.06%) (Statistic Brain, 2012). Elder abuse occurs in private homes, long-term care facilities (nursing homes, assisted living facilities), and hospitals. Approximately 1 out of 14 reported cases of elder abuse occurred in the victim's domestic setting (e.g., home) while physical abuse was identified as the most common type of abuse in nursing homes. (Elder-law.law, 2013). Elder abuse statistics report that for every case of elder abuse reported to authorities, approximately five case go unreported due to a victim's loyalty/fear of his/her abuser; shame for being dependent on the abuser; or being uninformed/misunderstanding about available services.

Elder abuse laws

Both federal and state laws address elder abuse, neglect, and financial exploitation (Center for Elders and the Courts (CEC) (2012).

Federal law

Federal law defines an elderly person as someone age 60 years and older. This definition came from the Older Americans Act of 1965 (42 U.S.C. 3001 et seq.). The Omnibus Budget Reconciliation Act (1987), also known as the Nursing Home Reform Act, has been cited as the most substantial law related to elder abuse (Omalacy, 2012). The law "provides federal statutory protection for residents in certified nursing facilities….Residents have the right to privacy, information on medical changes, the right to voice grievances without discrimination, and accommodation of physical, emotional and social needs" (Omalacy, 2012). The Elder Justice Act of 2009, enacted in 2010 as part of the Patient Protection and Affordable Care Act (H.R. 3500: P.L. 111-148), coordinates elder abuse protection and abuse programs with the Office of the Health and Human Services (CEC, n.d.). Vulnerable Rights Protection Program (1992) promotes the "passage by the states of legislation to prevent elderly abuse and neglect, and provide services to the elderly by providing federal funding for qualifying state programs" (Best, 2012, p. 1).

State laws

All states have laws relating to elder abuse and neglect. State law is the primary source of remedies, sanctions, and protection relating to elder abuse (CEC, n.d.). All states have Adult Protective Services (APS) or Elder Protective Services (EPS) statutes that authorize and regulate services for elder Abuse (Omalacy, 2012). In most states, the first agency to respond to a report of elder abuse is Adult Protective Services (APS). The role of APS is to investigate abuse cases, intervene, and offer services and advice (Robinson, Benedictis, & Segal, 2013). All 50 states have statutes establishing a Long Term Care Ombudsman Program and are administered by a state or local council on aging (CEC, n.d.).

Abuse of elders is a criminal offense in all 50 states. Laws differ by state, but all have systems for reporting suspected abuse. For example, in January 2013, a California law, AB40, Elder and dependent adult abuse: reporting. (2011-2012) was passed to resolve a conflict between federal and state laws related to elder abuse reports. "When abuse occurs in a nursing home, employees are required by law to file a report with the police or the long-term care ombudsman. When reports go to the ombudsman, strict federal confidentiality rules prevent the ombudsman from sending the report to law enforcement for a criminal investigation. The new law requires long-term care facilities to report suspected abuse that results in serious injury within two hours to police" (Perkes, 2013, p. 1). All healthcare providers along with members of the general public need to be aware of the risk factors, warning signs, and effects of elder abuse.

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Liability of Ineffective Patient Handoffs that Cause Patient Harm or Death

Judith M. Bulau, MSN, RN

Q: What is the liability for ineffective patient handoffs that cause patient harm or death?

A: Medical errors that cause patient harm or death during ineffective patient handoffs increase the risk of medical malpractice lawsuits.

Understanding liability for ineffective patient handoff processes begins with understanding what they are and the significant impact they have in causing patient harm or death. The risk of medical errors increases when there is inconsistent, incomplete, ineffective, or no communication about pertinent patient information during transfers of patient care.

In an effort to motivate healthcare organizations to improve their patient handoff processes, The Joint Commission published a 2006 National Patient Safety Goal, for all accreditation programs, which required "…a standardized approach to handoff communication, including an opportunity to ask and respond to questions."

As a result, attention has been focused on understanding the consequences of ineffective patient handoffs. Patterson and Wears (2010, p. 52) indicate that, "Impacts of less-than-ideal handoffs likely include adverse events, delay in medical diagnosis and treatment, redundant activities such as, additional procedures and tests, lower provider and patient satisfaction, higher costs, longer hospital stays, more hospital admissions and less effective training for health care providers." Eaton (2010) warns that, "The primary risk is that clinical judgments will be made with missing or inaccurate data." (p.54). Absences of critical patient information during patient handoffs expose patients to harm and increase the threat of lawsuits. Gallegos (2011) describes an alarming trend in medical malpractice lawsuits in which, "Colorado Physicians Insurance Company (COPIC), a professional liability insurance company based in Denver, has seen rising claims from various types of patient handoffs, particularly during the last five years (p.1). Patient handoffs include transfers from partner to partner, primary care physician to specialist, or vice versa, institution to institution or during shift changes." She notes a case example that ended in a lawsuit, "In one case highlighted by COPIC, a healthy child was born and treated by a neonatologist within the first 12 hours. Although a bilirubin was ordered, another neonatologist discharged the child within 24 hours, unaware of the laboratory results. At 60 hours, the baby visited a pediatrician and a bilirubin was again ordered before the pediatrician left for vacation. At 125 hours, the baby was admitted to the hospital and died of kernicterus (i.e., brain damage that can result from high levels of bilirubin in blood), a preventable disease (Gallegos).

Given the risk of harm to patients when there are communication breakdowns it is imperative that healthcare organizations improve how they share patient information, especially during patient transfers of care. Eaton (2010, p.51) indicates that, "Relevant improvement will only come after understanding that different clinical scenarios require different handoffs." Anderson, J., Shoft. D., Curtis, A., Eldridge, N., Cannon, K., Abrams, T. & Kaboli, P. (2010) discuss what should be included in successful patient handoffs. Current literature suggests that successful handoffs in health care should include the following vital information: contact information for the primary team, complete patient identification data, active problem list, pertinent past medical history, current condition and updated medication and allergy lists, code status, anticipated changes to the next care interval with a recommended course of action, and psychosocial concerns that may influence therapeutic choices. In addition, some have advocated listing the acuity of the patient, cognitive status, cardiopulmonary status, information on venous access, discussions on level of care and listing long-term plans in case families have questions overnight, pertinent laboratory data, pending tests, consults and procedures (p.62).

Runy (2008) provides some tools and techniques hospitals are using to improve the process within their organizations that may be a useful reference for organizations. If healthcare organizations improve their patient handoff processes they will protect their patients from medical errors that can cause harm to patients. This will help prevent organizations from facing allegations of patient harm that may have resulted from ineffective patient handoff processes.

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