

The Journal of
**Legal Nurse
Consulting**

Volume 25 ▲ Number 1 ▲ Spring 2014

- ▲ **Liability Lessons for Legal Nurse Consultants
Part Two: A Case Study with Risk Management Strategies**
- ▲ **Introduction to Dental Implants for the Legal
Nurse Consultant**
- ▲ **Acetylcysteine (N-acety-L-cysteine):
Antidote and Toxic Agent**
- ▲ **Nursing Malpractice: Costs, Trends, and Issues**

AALNC

AMERICAN ASSOCIATION OF LEGAL NURSE CONSULTANTS

American Association of Legal
Nurse Consultants
330 North Wabash Ave.
Suite 2000
Chicago, IL 60611
877/402-2562
312/321-5177
Fax: 312/673-6655
E-mail: info@aalnc.org
Web site: www.aalnc.org

Editor

Bonnie Rogers, DrPH, COHN-S,
LNCC, FAAN

Board of Directors

President

Elizabeth Zorn, BSN, RN, LNCC

President-Elect

Julie Dickinson, MBA, BSN, RN, LNCC

Past President

Sharon K. McQuown, MSN, RN, LNCC

Secretary/Treasurer

Kathy Ferrell, BS, RN, LNCC

Directors at Large

Debbie Pritts, RN, LNCC
Varsha Desai, BSN, RN, CLNC, CNLCP
Mary K. Sussex, MBA, BSN, RN-BC, LNCC

The Journal of Legal Nurse Consulting

Editorial Board

Bonnie Rogers, DrPH, COHN-S, LNCC,
FAAN, Chair
Kathleen Ashton, PhD, APRN, BC
Judith Bulau, RN, MSN
Patricia Fedorka, PhD, RNC
James Hanus, RN, BSN, OCN, MHA
Elizabeth Hill, RN, PhD
Diane L. Krasner, PhD, RN,
CWCN, CWS, MAPWCA, FAAN
Mary O'Connor, PhD, RN
Ann Peterson, EdD, MSN, RN,
FNP-BC, LNCC
Eileen Watson, EdD, RN, MSN, ANP,
GNP, LNCC
Debbie Tipton Winters, RN, NCSN, MSN,
MSS

Sharon K. McQuown, RN, MSN, LNCC
Board Liaison

Reviewers

Douglas R. Briggs, DC, Dipl.Ac.(IAMA)
Karen A. Butler, JD, BSN, RN
Cheryl Gatti, RN, BSN, LNCC
Erin Gollogly, BSN, RN
Susan K. House, RN, LNC
Deborah S. (Susie) White

Staff

Executive Director

Kristin Dee

Editorial Assistant

Kelly Rehan

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.

The Journal of Legal Nurse Consulting is the official publication of the American Association of Legal Nurse Consultants (AALNC) and is a refereed journal. Journal articles express the authors' views only and are not necessarily the official policy of AALNC or the editors of the journal. Information for authors is available from the editorial office of *The Journal of Legal Nurse Consulting*. The association reserves the right to accept, reject or alter all editorial and advertising material submitted for publication.

The content of this publication is for informational purposes only. Neither the Publisher nor AALNC assumes any responsibility for any injury and/or damage to persons or property arising out of any claim, including but not limited to product liability and/or negligence, arising out of the use, performance or operation of any methods, products, instructions, or ideas contained in the material herein. The reader shall assume all risks in connection with his/her use of any of the information contained in this journal. Neither the Publisher nor AALNC shall be held responsible for errors, omissions in medical information given nor liable for any special, consequential, or exemplary damages resulting, in whole or in part, from any reader's use of or reliance on this material.

The appearance of advertising in the *The Journal of Legal Nurse Consulting* does not constitute a guarantee or endorsement of the quality or value of such product or of the claims made for it by its manufacturer. The fact that a product, service, or company is advertised in *The Journal of Legal Nurse Consulting* shall not be referred to by the manufacturer in collateral advertising. For advertising information, contact JLNC@aalnc.org or call 877/402-2562.

Copyright ©2014 by the American Association of Legal Nurse Consultants. All rights reserved. For permission to reprint articles or charts from this journal, please send a written request noting the title of the article, the year of publication, the volume number, and the page number to Permissions, *The Journal of Legal Nurse Consulting*, 330 North Wabash Ave., Suite 2000, Chicago, IL 60611; JLNC@aalnc.org.

The Journal of Legal Nurse Consulting (ISSN 1080-3297) is published biannually (Spring and Fall) by the American Association of Legal Nurse Consultants, 330 North Wabash Ave., Suite 2000, Chicago, IL 60611, 877/402-2562. Members of the American Association of Legal Nurse Consultants receive a subscription to *The Journal of Legal Nurse Consulting* as a benefit of membership. Subscriptions are available to non-members for \$165 per year. Back issues are \$20 for members and \$40 per copy for non-members. Orders for back issues are subject to availability and prices are subject to change without notice. Replacements because of non-receipt will not be made after a 3-month period has elapsed. Back issues more than a year old can be obtained through the *Cumulative Index to Nursing & Allied Health Literature* (CINAHL). CINAHL's customer service number is 818/409-8005. Address all subscriptions correspondence to Circulation Department, *The Journal of Legal Nurse Consulting*, 330 North Wabash Ave., Suite 2000, Chicago, IL 60611. Include the old and new address on change requests and allow 6 weeks for the change.

The Journal of LEGAL NURSE CONSULTING

Volume 25 ▲ Number 1 ▲ Spring 2014

Feature Articles

Liability Lessons for Legal Nurse Consultants Part Two:

A Case Study with Risk Management Strategies4

Julie Dickinson MBA, BSN, RN, LNCC, Elizabeth Zorn BSN, RN, LNCC, and Robin Burroughs, RN, CHRM, CPHRM

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 was discussed to highlight the common areas of potential LNC liability, and key “take-aways” were presented for LNCs to apply to their own consulting practice. An in-depth case study is 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 to Dental Implants for the Legal Nurse Consultant8

Lee M. Whitesides DMD, MMSc

Dental implants have been in dentistry for more than 50 years. In that time, the implant has evolved from a simple metal fixture to support a denture to a sophisticated titanium alloy, which can replace many teeth or simply one tooth in form and function. Dental implants have many unique features. They can be placed by any licensed dentist. Although dental implants are highly successful, they are not for every patient. Proper planning and execution of the plan play an important role in the success of the implant. Complications are rare but may be serious if vital anatomy of the jaw is compromised or injured during implant surgery. When reviewing a dental implant malpractice case, the legal nurse consultant must consider many factors, such as the patient’s dental and systemic health, the surgical procedure, the qualifications of the dentist, the informed consent process, the complication that precipitated the malpractice claim, and how the complication was addressed by the dentist.

Acetylcysteine (N-acety-L-cysteine): Antidote and Toxic Agent 14

M. Thomas Quail, MS Ed, R.N., LNC, EMT-B and Edward W. Boyer MD, PhD

This article will address the antidote Acetylcysteine. A brief history of how Acetylcysteine evolved as the preferred antidote for acetaminophen toxicity is provided, even though the exact dose, duration of therapy, and its mechanism of action remain unknown. Included are the current United States (U.S.) Acetylcysteine guidelines. As legal cases are lacking, 15 case reports are identified, whereby minor to severe adverse effects have been attributed to Acetylcysteine therapy. Quality improvement recommendations are provided to assist the legal nurse consultant (LNC) when reviewing Acetylcysteine therapy cases for merit.

Nursing Malpractice: Costs, Trends, and Issues 26

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

Despite continuous efforts to educate nurses on the law and their professional responsibilities through nursing programs and continuing education courses, the number of nurses named as defendants in malpractice actions continues to increase. The National Practitioner Data Board (NPDB) classifies “professional nurses” into five licensure categories: non-specialized registered nurse, nurse practitioner, nurse anesthetist, nurse midwife, and clinical nurse specialist.

Departments

Editorial..... 2

Julie Dickinson & Elizabeth Zorn

A Time of Transition

Clinical Maxim and Professional Practice..... 32

Tammy Bimber, MSN, RN, CEN, SANE-A, SANE-Pc

The Medical/Legal Aspects of Sexual Assault Nurse Examiner (SANE) Programs in Emergency Departments

References and Resources..... 36

Mary A. O'Connor, PhD, RN

Online References and Resources: Palliative Wound Care and End of Life Wounds

Questions and Answers..... 38

Judith M. Bulau, MSN, RN

Liability of Ineffective Patient Handoffs that Cause Patient Harm or Death

Book Review 40

Susan Mikulak Cacciola, RN, BSN, WCC

The Nurse Practitioner's Guide to Nutrition, Second Edition

Correction:

The Spring 2014 issue of *The Journal of Legal Nurse Consulting* originally published Eileen Watson, EdD, RN, MSN, ANP, GNP, LNCC's article under an incorrect title and as a Department. Dr. Watson's article has now been correctly published as a Feature under the original title. *The Journal of Legal Nurse Consulting* regrets this error.

A Time of Transition

Dear Colleagues,

Spring has always been a time of transition, and this year is no different. We are excited to share with you some forthcoming changes in the Journal and for AALNC.

In 2011, due to budget constraints and other factors, publication of the Journal was reduced from four issues per year to two. As shared at the 2013 AALNC Annual Business Meeting, held in conjunction with the Legal Nurse Consulting Educational and Networking Forum in Chicago, AALNC is back on stable financial ground. The Board is reinvesting money into the Association to provide you with the resources you need to succeed in the specialty practice of legal nurse consulting. One such investment is the Journal.

The Journal of Legal Nurse Consulting has long been a valuable resource for legal nurse consultants and other related industry professionals. It is a staple of our Association, and returning the Journal back to quarterly publication has always been the goal of the AALNC Board of Directors. The Board has developed a new vision for the Journal, and we are pleased to announce that we are taking steps to return to publishing four annual issues.

As you can see, the Journal is now digital! We understand how busy you are, and we are confident that you will find this new format to be valuable. Not only is it compatible with smart phones and tablet computers (such as iPhones and iPads), it is also interactive! Click on an item in the Table of Contents to go directly to that article. Click on an advertisement to see the company's website.

In the coming issues, the Journal will also see a transition in its Editor. The AALNC Board of Directors wishes to extend our heartfelt thanks and appreciation to Bonnie Rogers for serving as the Journal's Editor-in-Chief for the past four years. Under her leadership, the Journal has continued its standard of publishing high-quality, peer-reviewed articles, information, and resources to assist you in your practice. In addition, we thank Ann Peterson for serving as the guest Editor of the Fall 2014 issue of the Journal, which will focus on nursing home topics. More information about this specific evolution will be forthcoming.

Despite these transitions, what will not change is the caliber of the Journal. The AALNC Board of Directors and the Journal's Editorial Board remain dedicated to maintaining the standard of excellence upon which the Journal has been built. This unwavering commitment to the Journal and to the Association will also continue through the upcoming transition in AALNC leadership at the 2014 Forum in Denver.

We hope that you enjoy the content in this issue, find the new digital format to be helpful, and embrace this time of transition for AALNC and the Journal of Legal Nurse Consulting.

Respectfully,

Julie Dickinson

President Elect, *American Association of Legal Nurse Consultants*

Elizabeth Zorn

President, *American Association of Legal Nurse Consultants*

Need a Legal Nurse Consultant or Nurse Expert Witness?

The LNC Locator® lets you find one in minutes!

Use the upgraded LNC Locator® the next time you need a Legal Nurse Consultant or Nurse Expert Witness.

- **It's faster** – find an expert in just minutes!
- **It's easier to use** – search by state and specialty area!

The LNC Board Certified expert you need to help you with your case is just a few clicks away. Visit www.aalnc.org and click on LNC Locator®.

AALNC
AMERICAN ASSOCIATION OF
LEGAL NURSE CONSULTANTS



Questions? www.aalnc.org • 877/402-2562 • info@aalnc.org

*Are you or a fellow nurse colleague interested in becoming a
legal nurse consultant?*

The American Association of Legal Nurse Consultants is pleased to offer the...

Legal Nurse Consulting Online Course

Whether brand new or experienced in the industry, there has never been a better opportunity to expand your career and brighten your future as a legal nurse consultant!

Developed from the recommended curriculum for legal nurse consulting, all eight modules have been created by the professional society for legal nurse consultants, AALNC. Each module of the Legal Nurse Consulting Online Course offers the combined knowledge and expertise of LNCs at the forefront of the profession, as well as the knowledge of the renowned course editors, Pat Iyer, MSN RN LNCC, Betty Joos, MEd BSN RN and Madeline Good, MSN RN LNCC.

Each module of the Legal Nurse Consulting Online Course has been approved for nursing contact hours by the Illinois Nurses Association. Visit www.aalnc.org today for detailed information on all eight modules, as well as the many other educational products that AALNC offers for legal nurse consultants.

Questions? Email info@aalnc.org or call 877/402-2562.

AALNC
AMERICAN ASSOCIATION OF
LEGAL NURSE CONSULTANTS



Liability Lessons for Legal Nurse Consultants Part Two: A Case Study with Risk Management Strategies

Julie Dickinson MBA, BSN, RN, LNCC, Elizabeth Zorn BSN, RN, LNCC, and Robin Burroughs, RN, CHRM, CPHRM

KEY WORDS

Legal Nurse Consultant Liability, Claims, Risks, Malpractice, Negligence, Lawsuit, Risk Reduction, Case Study

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 was discussed to highlight the common areas of potential LNC liability, and key “take-aways” were presented for LNCs to apply to their own consulting practice. An in-depth case study is 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

To provide legal nurse consultants (LNCs) with an understanding of potential areas of risk exposure in this specialty practice of nursing, Part One of this two-part series reviewed summaries of actual cases and claims involving LNCs to illustrate these areas, and it offered key “take-aways” for LNCs to apply to their own practice. These principles of risk reduction are further explored in this Part Two article through the examination of an actual lawsuit involving a LNC.

Professional liability claims may be asserted against nursing professionals working in a myriad of specialties, including legal nurse consulting. This case study involves a LNC who provided advice as well as written work products to an attorney-client.

Case Summary:

The insured was an associate’s degree prepared registered nurse who had recently completed her training and certificate course as a LNC. She then advertised her availability to the legal community for screening medical malpractice cases for “merit”. She was engaged by an attorney-client to review the medical records of a client he represented in a medical malpractice action. The attorney-client had managed a small number of medical malpractice cases but had never taken such a case to trial. Neither had the attorney ever engaged the services of a LNC.

The patient had undergone unsuccessful abdominal surgery for removal of a mass. The mass had been identified pre-operatively by both a computed tomography (CT) scan and magnetic resonance imaging (MRI) but could not be found by the surgeon during the operative procedure and

was, therefore, not removed. The patient suffered additional postoperative complications, including the need for additional surgery and sought to sue the surgeon and the hospital for negligence.

The LNC accepted the assignment from the attorney-client to review the client’s medical records and provide her written findings. Following her review, she provided the attorney with a written statement that the surgeon and the hospital were both negligent in the patient’s care. She cited the surgeon’s failure to have copies of the CT and MRI films available in the operating room and the LNC further cited his failure to obtain the assistance of another surgeon when he was unable to locate the mass. She also noted the hospital’s failure to have appropriate procedures in place to ensure the patient’s care and safety. She included a statement in her report that if litigation were pursued, a physician expert witness would be required to medically certify that the surgeon acted outside the standard of care.

The attorney-client had not previously utilized the services of a LNC. In addition to requiring the LNC to review the medical records and provide a written assessment of her findings, he asked her to sign a certificate of merit. The certificate of merit was statutorily required when filing a medical malpractice action to verify that malpractice had occurred. Because of the LNC’s recent entry into the profession, she was unclear about her authority to sign the certificate and initially declined. The attorney and his paralegal repeatedly urged the LNC to sign the certificate of merit, and she eventually agreed to sign the document but did not date it and did not have her signature witnessed.

Approximately three months later, the attorney-client’s paralegal contacted the LNC and after considerable reassurance, convinced her that she indeed was authorized to

sign the certificate of merit. The attorney further coerced her into backdating the document to the date she had originally signed it and submitted her written assessment of the case. The attorney filed the case utilizing this backdated certificate of merit signed by the LNC. This issue became a major factor in the case as the court disallowed the plaintiff's cause of action against the surgeon, in part, because the certificate of merit was not signed by a physician and was improper.

The patient sued the attorney and the LNC for negligence. The surgeon subsequently sued the LNC, her attorney-client and his law firm, alleging that they had engaged in "malicious prosecution, fraud, and civil conspiracy." He further alleged that the LNC had acted outside her scope of practice and inflicted severe emotional distress upon him. The latter allegation pertained to her written report and opinion that the surgeon had breached the standard of care when, as alleged by the surgeon, she was not qualified to provide either a legal or medical opinion regarding the medical standard of care.

Because the surgeon asserted malicious prosecution, in order to successfully defend the LNC, it became necessary to prove that the surgeon had, indeed acted outside the standard of care. A physician expert was engaged and stated that the surgeon and hospital had breached the standard of care by: 1) failing to have the patient's radiographs in the operating suite; and 2) not obtaining/providing assistance in the operating room when the known mass could not be located. The expert further stated that had he been asked, he would have signed the certificate of merit for the lawsuit against the surgeon.

The LNC then sued her attorney-client for repeatedly misleading her regarding her authority and for coercing her into signing and then backdating the certificate of merit. Her attorney-client subsequently entered into a cross-claim against his own LNC, stating she had misrepresented herself as competent to render legal opinions in medical malpractice matters. However, in his deposition testimony, the attorney stated that the LNC recommended consultation with a physician expert if he planned to take the case to trial. Clearly, neither the LNC nor the attorney was certain of the applicable statutory requirements for the certificate of merit or the LNC's scope of practice, representing the primary cause for the subsequent litigation.

Several motions were filed by the multiple parties. The court refused the motion to dismiss the LNC from the surgeon's case. She sought a settlement, but the surgeon's attorney would not agree to a reasonable settlement amount. Court-ordered mediation of the surgeon's case against the LNC was unsuccessful for the same reason.

Eventually, the surgeon's claim against the LNC was settled for a five-figure amount. The LNC and her attorney-client dropped their cross-claims. The attorney-client settled the surgeon's claim against him and his firm with payments on behalf of himself, his law firm, and his paralegal. The settlement amounts were confidential and are not available. Any settlement amounts awarded to the patient by the surgeon or hospital are unknown.

Indemnity Settlement Payment: Low five-figure range

Legal Expenses: Low six-figure range

The indemnity payment reflects only the payment made on behalf of the LNC to the surgeon. Expense payments reflect the cost for engaging the physician expert, court costs and legal fees to defend the surgeon's case against the LNC as well as managing the cross-claims between the nurse legal consultant and the attorney-client.

Resolution

The LNC was deemed to have acted within her scope of practice in her review of the medical records and issuance of her findings. In the state where the incident occurred, only a physician was qualified to sign a certificate of merit. Therefore, by signing the certificate of merit, she transcended the scope of her practice. Further, she backdated a legal document and also signed the legal document outside the presence of a state-required notary public.

Risk Management Comments

The LNC was unclear regarding her scope of practice. She accepted an engagement with an attorney who had never previously worked with a LNC and who was insufficiently experienced in the management of medical malpractice litigation. She used some questionable legal terminology in her written summary of the patient's records, but her opinions were within her area of clinical experience. She was unclear regarding her authority to sign the certificate of merit and did not verify her authority before signing the document. Finally, she backdated the document which she knew to be improper.

Risk Management Recommendations

1. Know and adhere to the American Association of Legal Nurse Consultants' (AALNC) Legal Nurse Consulting: Scope and Standards of Practice (AALNC, 2006).
2. Know and adhere to AALNC's Code of Ethics and Conduct (AALNC, 2009).
3. Ensure the attorney-client is qualified and experienced in the type of case for which the LNC has been requested to work.
4. Clarify the specific roles of all members of the attorney-client's team prior to accepting an assignment, including the roles of the LNC, the paralegal/legal assistant, the legal secretary, and the attorney.
5. Ensure that the attorney-client will provide adequate legal support and supervision to all members of the team.
6. Solicit information from the attorney-client about his or her expectations related to the LNC's work product/advice, including whether the attorney-client desires the nurse to serve as a testifying expert.
7. Know and adhere to the applicable state/federal statutes related to expert qualifications in the state in which the LNC works.

8. Seek an objective legal opinion or contact the American Association of Legal Nurse Consultants for assistance if asked to perform a task that is previously unknown to the LNC or is in any way unclear regarding its appropriateness within the LNC's scope of practice.

Valuable insight can be gained from reviewing real claims involving actual or potential LNC negligence. By learning and applying the risk management lessons discussed in this two-part series, the LNC can strive to minimize his/her liability exposure.

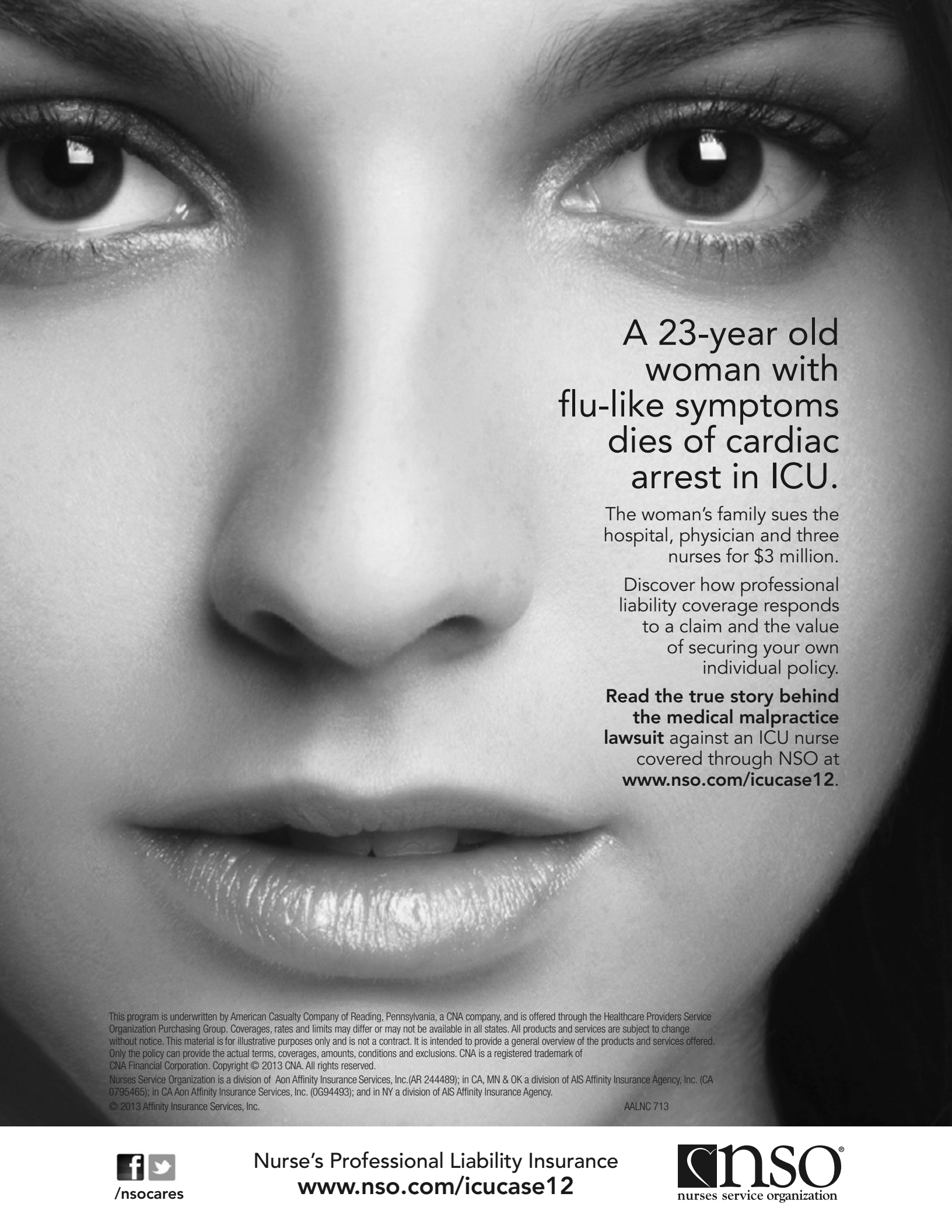
References

- American Association of Legal Nurse Consultants. (2009). Code of ethics and conduct with interpretive discussion. Glenview, IL: American Association of Legal Nurse Consultants.
- American Nurses Association. (2006). Legal nurse consulting: Scope & standards of practice. Washington, D.C.

Julie Dickinson MBA, BSN, RN, LNCC has worked for Fontaine Alissi P.C., a defense law firm in Hartford, CT, since 2008. Since joining AALNC in 2007, Dickinson has been involved in numerous projects and committees and has authored and lectured on a variety of topics for the association. She served for two years as the founding President of the Connecticut Chapter of AALNC and is board certified as an LNCC. Since 2011, Dickinson has served on the AALNC Board of Directors and is currently serving as President-Elect.

Elizabeth Zorn RN, BSN, LNCC has worked as a legal nurse consultant since 1985, initially for a defense firm, and since 1995, for Faraci Lange, a plaintiff law firm in Rochester, NY. As a member of AALNC, she has been involved as an author, editor, committee chairperson and member, and lecturer over the past 7 years. She is board certified as an LNCC. Zorn is co-founder of LNCEXchange (www.LNCEXchange.com), a medical-legal listserv. Since 2010, Zorn has served on the AALNC Board of Directors and is currently serving as President.

Robin Burroughs RN, CHRM, CPHRM is a risk control consulting director with CNA Healthcare. She has been with CNA since 1995 and is responsible for co-authoring CNA's published claims studies for nurses, nurse practitioners, physical therapists, pharmacists, and the aging services industry. She speaks regularly to national, regional, and state level professional groups regarding professional liability and risk control strategies.



A 23-year old
woman with
flu-like symptoms
dies of cardiac
arrest in ICU.

The woman's family sues the
hospital, physician and three
nurses for \$3 million.

Discover how professional
liability coverage responds
to a claim and the value
of securing your own
individual policy.

**Read the true story behind
the medical malpractice
lawsuit** against an ICU nurse
covered through NSO at
www.nso.com/icucase12.

This program is underwritten by American Casualty Company of Reading, Pennsylvania, a CNA company, and is offered through the Healthcare Providers Service Organization Purchasing Group. Coverages, rates and limits may differ or may not be available in all states. All products and services are subject to change without notice. This material is for illustrative purposes only and is not a contract. It is intended to provide a general overview of the products and services offered. Only the policy can provide the actual terms, coverages, amounts, conditions and exclusions. CNA is a registered trademark of CNA Financial Corporation. Copyright © 2013 CNA. All rights reserved.

Nurses Service Organization is a division of Aon Affinity Insurance Services, Inc. (AR 244489); in CA, MN & OK a division of AIS Affinity Insurance Agency, Inc. (CA 0795465); in CA Aon Affinity Insurance Services, Inc. (OG94493); and in NY a division of AIS Affinity Insurance Agency.

© 2013 Affinity Insurance Services, Inc.

AALNC 713



Nurse's Professional Liability Insurance
www.nso.com/icucase12



Introduction to Dental Implants for the Legal Nurse Consultant

Lee M. Whitesides DMD, MMSc

KEY WORDS

Dental Implant, Osseointegration, Abutment, Osteotomy, Nerve Injury, Cone Beam CT

Dental implants have been in dentistry for more than 50 years. In that time, the implant has evolved from a simple metal fixture to support a denture to a sophisticated titanium alloy, which can replace many teeth or simply one tooth in form and function. Dental implants have many unique features. They can be placed by any licensed dentist. Although dental implants are highly successful, they are not for every patient. Proper planning and execution of the plan play an important role in the success of the implant. Complications are rare, but may be serious if vital anatomy of the jaw is compromised or injured during implant surgery. When reviewing a dental implant malpractice case the legal nurse consultant must consider many factors such as the patient's dental and systemic health, the surgical procedure, the qualifications of the dentist, the informed consent process, the complication that precipitated the malpractice claim, and how the complication was addressed by the dentist.

Introduction

Since their introduction into dentistry by Dr. Per-Ingvar Branemark in the 1960s, dental implants have become a highly successful, predictable, and cost-effective method of treatment for patients missing one or more teeth (Wittneben et al., 2013). Dental implants have evolved to become easier to place and restore. The dental implant of today is far superior in composition and compatibility than those of only 20 years ago. Dental implants today provide the patient and dentist with a plethora of options to restore form and function of the natural dentition (Romeo et al., 2004; Wittneben et al., 2013).

There are many brands of implants on the market today. Despite the wide variety of companies making root form dental implants, these devices share some basic concepts. Almost every implant in the market today is threaded like a screw with an internal connection for an abutment. The surface of the implant is roughened to increase the surface area and, hence, bonding strength of the implant to the bone. Many implants are also coated with plasma or hydroxyapatite to accelerate and strengthen bonding to the bone. Lastly, all implants are made of titanium or titanium alloy to ensure biocompatibility. Other implants such as staple and blade implants are available today, but constitute a small percentage of the implant market and thus will not be considered for this article (Aljateeli & Wang, 2013b; Romeo et al., 2004).

Anatomy of an Implant

A dental implant is a titanium fixture (post) that is surgically placed into the patient's jaw bone. Once the dental implant has bonded to the bone (a process called osseointegration), the abutment may be placed (Sakka, Baroudi, & Nassani, 2012). The abutment fits into the center of the dental implant, is held into position with a screw, and protrudes through the mucosa into the mouth. A custom

prosthesis is then fabricated to cover the abutment and service a functioning tooth. (See Box for glossary of terms).

Dental Implant Workup and Evaluation

Evaluation of patients for dental implant treatment includes a review of past medical history to determine suitability as candidates for surgery. Absolute contraindications for dental implants are rare and are a byproduct of the patient's overall systemic health. Relative contraindications include use of tobacco, diabetes mellitus, Sjogren's syndrome, use of bisphosphonates, active infection, heavy bruxism (teeth grinding), extended use of corticosteroids, inadequate interarch space, and advanced periodontal disease (Chanavaz, 1998; Ng, Wong, & Liston, 2012). Clinical evaluation of the patient's existing oral health is also an important part of the workup.

Evaluation and documentation of existing caries, restorations, periodontal health, missing teeth, and occlusion class should be done. Pre-operative radiographs such as periapical (small radiograph limited to one of two teeth and designed to show the crown and apices of the teeth), panoramic plain film (panoramic radiograph of the maxilla, mandible, teeth, and associated structures), and/or panoramic radiographs will assist the dentist in treatment planning in the case. In selected cases, a Cone Beam CT (CBCT) may be appropriate to determine quality and quantity of bone, the proximity of adjacent vital anatomy (infra alveolar nerve, maxillary sinus, roots of adjacent teeth), and appropriate surgical placement of the dental implant (Chanavaz, 1998). The three dimensional rendering of maxilla-facial structures with a CBCT provides the dentist with greater anatomic truth of the patient's anatomy. This increased knowledge can translate into greater success for the implant dentist when employed properly in diagnosis, treatment planning, and treatment execution (Chanavaz, 1998).

If a patient does not have sufficient quantity of bone for dental implant, placement grafting may be done to provide suitable osseous anatomy to facilitate dental implant placement. Graft material can be taken from another species (xenograft) or the same species (allograft). Autografting from the chin, tibia, or hip may be indicated to provide sufficient volume of bone. In selected cases, use of synthetic grafting material, such as rh-BMP-2 may represent a suitable alternative to autografting in cases requiring large volumes of bone for dental implant therapy (AlGhamdi, Shibly, & Ciancio, 2010; Misch & Dietsch, 1993).

Informed Consent

As with all surgical procedures, dental implant placement must be accompanied by an appropriate surgical consent. The consent must include a diagnosis, the proposed procedure, the risk and benefits of the procedure, the possible alternatives to the procedure, and the possible consequences of not having the procedure performed. Factors that should be emphasized in the consent process and document include damage to the inferior alveolar nerve, damage to adjacent anatomy, and possible infection (Curley, 2011; Graskemper, 2005).

Dental Implant Surgery

The placement of a dental implant is a surgical event and thus requires appropriate informed consent. Once the patient is sufficiently anesthetized with local anesthesia, and sedation if preferred, a full thickness incision is made through the mucosa deep to the bone. Soft tissue is then reflected to expose the alveolar bony ridge. Next, using gradually increasing size drill bits, a hole (osteotomy) is created in the alveolar bone to receive the dental implant.

The preparation of the osteotomy is a delicate and precise process. Great care must be exercised to avoid inadvertent contact, damage to adjacent vital structures, and inaccurate placement of the dental implant. The size and position of the osteotomy in the jaw will be determined preoperatively by evaluation of x-rays, models, and the patient. A surgical drill guide, which directs the drill bits generating the osteotomy, may be fabricated to assist the surgeon in the placement of the osteotomy and implant. To minimize heat production when drilling, copious quantities of cool water or normal saline must be employed to prevent bone cell necrosis (Ng et al., 2012).

Once the osteotomy is prepared to the appropriate size, the dental implant is placed either by hand or hand piece under low speed and copious irrigation, until the platform surface of the dental implants is flush with the alveolar ridge. At this time, the initial stability of the implants is tested by reverse torque or radiofrequency analysis (Ahmad & Kelly, 2013; Makary, Rebaudi, Sammartino, & Naaman, 2012; Shokri & Daraeighadikolaie, 2013; Trisi, Todisco, Consolo, & Travaglini, 2011). The more stable the implant is in the bone initially, the more likely it will osseointegrate and be successful (Aljateeli & Wang, 2013a; Sakka et al., 2012).

Postoperative care includes meticulous oral hygiene at the surgery site. Oral rinsing with Peridex® is recommended. Antibiotics after implant surgery is common practice but has been shown to be of limited value (Esposito, Grusovin, Loli, Coulthard, & Worthington, 2010; Powell, Mealey, Deas, McDonnell, & Moritz, 2005). A postoperative visit one or two weeks after the surgical placement of the implant is recommended to assess patient healing. A post placement radiograph (periapical or panorex) is recommended to evaluate implant placement. After three to six months, the implant is uncovered and osseointegration is checked via reverse torque or radiofrequency. If the implant is integrated, it can then be restored (Ahmad & Kelly, 2013; Makary et al., 2012; Shokri & Daraeighadikolaie, 2013; Trisi et al., 2011).

Dental Implant Benefits

Implants offer the patient and dentist many benefits. They function as a foundation upon which a prosthesis can be fabricated to assist the patient in mastication, speech, and aesthetics. Dental implants can replace single or multiple teeth, depending on the patient's needs, without altering the patient's existing dentition. Because the dental implant is an intraosseous device, once restored, it produces stress on the bone. This stress helps to maintain bone volume and facial architecture, and according to Wolff's law, ceases or at least minimizes atrophy of the remaining bone.

Dental Implant Risk

With proper treatment planning, placement, and restoration, properly placed dental implants represent minimal risk to the patient. As with any surgery, pain, bleeding, and possible damage to adjacent anatomy during surgery are possible. Postoperative infection with dental implants is rare but may occur (Wittneben et al., 2013). Dental implants and abutments rarely fracture but may if not restored properly. Failure to properly care for dental implants by practicing good oral hygiene can lead to peri-implantitis with significant bone loss, soft tissue recession, pain, and possibly loss of the dental implant (Sakka et al., 2012; Wittneben et al., 2013).

The Implant Dentist

Dental implants may be placed by any licensed dentist. In the United States, the majority of dental implants are placed by an oral surgeon, periodontist, prosthodontist, and general dentist. When a specialist, such as oral surgeon or periodontist places the implant, the restoration is done by a general dentist or prosthodontist. To increase the success with such team-oriented treatment, appropriate detailed communication between dental providers is essential to provide the patient with the best possible care (Ng et al., 2012).

There are many levels of training pertaining to dental implant surgery and restoration. Since implant surgery and restoration are addressed only on an introductory level in

some dental schools, most dentists and dental specialists placing and restoring implants gain their knowledge and experience through residency programs or through one of the many postgraduate implant institute programs taught in the United States or abroad. Implant teaching programs range from a weekend introductory course to an advanced curriculum lasting up to one year. In general, the longer programs provide more education and practical experience. That being said, attendance at such continuing education dental implant programs is not mandatory for a dentist placing and restoring dental implants (Wheeler & Bollinger, 2009).

There are three principle dental implant-focused organizations active in dentistry today, including the American Association of Implant Dentistry (AAID), the International College of Oral Implantologists (ICOI), and the Academy of Osseointegration (AO). Each organization functions to provide continuing education, credentialing, and mentoring to its dentist members. All have varying levels of educational experience and competence.

Complications

Some of the more common complications of dental implants include non-restorability due to improper placement, peri-implantitis, infection, fracture of the abutment screw, gingival recession, and loss of the implant secondary to its failure to osseointegrate. Most complications are limited and can be successfully addressed with local measures such as antibiotics, debridement, screw replacement, or soft tissue grafting. Failed implants and implants that demonstrates mobility or pathosis must be removed (Kohner, 1992; Wanner, Manegold-Brauer, & Brauer, 2013).

A significant complication of dental implant surgery is an encounter with the inferior alveolar nerve by the drill and/or dental implant. The incidence of documented "sensory disturbance" to the Inferior Alveolar Nerve (IAN) post implant placement ranges from 0% to 40% (Berglundh, Persson, & Klinge, 2002; Goodacre, Bernal, Rungcharassaeng, & Kan, 2003). Trauma to the IAN can occur in the preparation of the osteotomy by an encounter of the drill bit with the nerve, or direct contact of the implant with the IAN, or via pressure on the IAN by encroachment of the implant (Bagheri & Meyer, 2011). Any encounter with the nerve by the drill bit or implant can produce a variety of "neurosensory disturbances," such as pain (allodynia), increased sensation (hyperesthesia), decreased sensation (paraesthesia), or total loss of sensation (anesthesia). The altered sensation of neurosensory stimuli may be transient or permanent depending on the degree to which the nerve is compromised (Bagheri & Meyer, 2011; Gregg, 2000; Meyer, 1996).

Treatment of the IAN injured patient must consider the etiology and type of injury. If post placement radiographs show no contact with the IAN, then it may be surmised injury occurred during osteotomy preparation. If the implant is seen on radiograph to be contacting, transecting, or encroaching on the IAN then the dentist should consider removing the

implant in an attempt to minimize the injury (Bagheri & Meyer, 2011; Gregg, 2000; Meyer, 1996).

Nerve injuries can be divided into three principle categories: neuropraxia, axontomesis, and neurotomesis. In neuropraxia, damage to the nerve is transient and results in temporary interruption of sensory stimuli without damage to the anatomy of the nerve. Recovery should be complete in four weeks. In axontomesis, partial transection of the nerve takes place, producing interruption of sensory stimuli that may or may not recover. In neurotomesis the nerve is completely transected and total interruption of sensory stimuli (anesthesia) occurs. Spontaneous recovery is not possible. Dysethesia (painful sensation upon stimuli) often accompanies such an injury (Bagheri & Meyer, 2011; Meyer, 1996).

Upon recognition of any alteration in neurosensory status, evaluation and appropriate follow-up are important parts of any treatment of a patient with the nerve injury after dental surgery (Bagheri & Meyer, 2011; Strauss, Ziccardi, & Janal, 2006). Frequent, often monthly, evaluation of the nerve injury patient to assess recovery progression is important and can affect the ultimate recovery of the patient. Should recovery cease or the patient's nerve condition exacerbate, appropriate referral to a specialist who addresses such injuries should be facilitated by the operating dentist. This should occur between three to six months post-surgery or immediately after an observed IAN injury (Bagheri & Meyer, 2011; Strauss et al., 2006).

The Legal Nurse Consultant Role in Evaluating Dental Implant Malpractice Cases

When reviewing a dental malpractice case, the legal nurse consultant (LNC) must start at the beginning. Was the patient a suitable candidate for dental implant therapy? As stated earlier, absolute contraindication for dental implant therapy is a factor of a patient's overall health. Thus, a patient with advanced Alzheimer's or Parkinson's disease is not a candidate for dental implant therapy because of the lack of ability to properly care for the implants. Relative contraindications for dental implant therapy previously discussed lower the implant success rate.

The informed consent process should be critically evaluated by the LNC. The dentist must discuss the risk and benefits of dental implant therapy. The many options and alternatives to implant therapy (partial or complete dentures, crown and bridge, or doing nothing) must be addressed. Cost must also be part of the discussion, as finances often play an important and often deciding role in the final treatment plan.

The LNC should evaluate the dentist and/or dental specialist involved in the patient's care. Since no special training is required or mandated to place and/or restore dental implants, lack of continuing education in dental implantation and/or membership in one of the three implant organizations mentioned earlier can indicate the dentist may not be current in his/her education and knowledge of dental

implant therapy. Determining the experience with (volume) implants placed and/or restored by the dentist is an excellent way to assess the familiarity of the dentist with current methods of dental implant therapy.

Complications can and do occur despite standard of care treatment. To properly assess if the treatment was below standard of care, the LNC should examine the case to determine if the dentist executed appropriate treatment planning, demonstrated skill in placement of the dental implant, and followed sound restorative principles in restoring the case. Damage to adjacent anatomy (IAN or teeth) is largely avoidable if appropriate work-up and surgical techniques are exercised. Local infections at the dental implant site are not prima facie evidence of failure to adhere to standard of care treatment. Gingival recession may occur despite exceptional surgical technique and meticulous soft tissue management by the dentist if the patient fails to properly care for the implant. Material failure (broken screw or chipped crown) is an unfortunate byproduct of working with materials in the oral cavity. Sound restorative principles can minimize these happenings but not all are avoidable.

An important part of evaluating a case is examining how the dentist addressed the complication and what steps were taken once the complication was recognized. Acute recognition of the complication and attention to the patient's concerns are important. The dentist should take immediate action to address a patient's complication. If the complication is outside the dentist's comfort zone he/she should endeavor to find the appropriate dentist who can properly address the patient's condition.

The LNC must also exercise wisdom in choosing the appropriate expert to assist in implant malpractice case evaluation. The LNC should interview the expert to determine if he or she can benefit the client. There are many schools of thought in dental implant therapy. Not all dentists place and restore dental implants. Some dentists and dental specialists place and restore many implants while some place and/or restore just a few implants each year. When damage to the IAN is pertinent to the case, the LNC should ask the potential expert about familiarity with such injuries and knowledge of the current literature.

Conclusion

Dental implants represent a superior method of treatment for many patients missing at least one tooth. Proper utilization of implant therapy involves detailed treatment planning, diagnosis, and work-up in conjunction with skilled surgical placement and restoration. To place and/or restore dental implants requires considerable post graduate education via a residency or dental implant training program. Most complications involving dental implants are minor and can be addressed with minimal additional surgical or restorative care. Injury to the inferior alveolar nerve represents a serious condition that must be promptly and properly addressed by the surgeon. In evaluating a dental implant malpractice case, the LNC must consider many issues, including, but not

limited to the patient's acceptance of dental implant therapy, the dentist's experience with implants, complications arising from the dental implant therapy, and the manner in which the complication was addressed by the dental professional.

Glossary

Dental implant: a metal fixture (post) that screws into the bone upon which an abutment and prosthesis are placed

Abutment: a metal or ceramic fixture that is placed into the implant and protrudes through the mucosa upon which a prosthesis is placed

Osteotomy: the hole created in the bone to receive the implant

Crown: the prosthesis that covers the abutment and functions in mastication, speech, and esthetics

Osseointegration: the process by which the bone and the implant chemically and mechanically bond

CBCT: Cone Beam Computed Tomography. A specialized radiological study that provides exceptional anatomic truth of the maxilla-facial structures

References

- Ahmad, O. K., & Kelly, J. R. (2013). Assessment of the primary stability of dental implants in artificial bone using resonance frequency and percussion analyses. *The International Journal of Oral & Maxillofacial Implants*, 28(1), 89-95. doi:10.11607/jomi.2554
- AlGhamdi, A. S., Shibly, O., & Ciancio, S. G. (2010). Osseous grafting part I: Autografts and allografts for periodontal regeneration--a literature review. *Journal of the International Academy of Periodontology*, 12(2), 34-38.
- Aljateeli, M., & Wang, H. L. (2013a). Implant microdesigns and their impact on osseointegration. *Implant Dentistry*, 22(2), 127-132. doi:10.1097/ID.0b013e318278a90b; 10.1097/ID.0b013e318278a90b
- Aljateeli, M., & Wang, H. L. (2013b). Implant microdesigns and their impact on osseointegration. *Implant Dentistry*, 22(2), 127-132. doi:10.1097/ID.0b013e318278a90b; 10.1097/ID.0b013e318278a90b
- Bagheri, S. C., & Meyer, R. A. (2011). Management of mandibular nerve injuries from dental implants. *Atlas of the Oral and Maxillofacial Surgery Clinics of North America*, 19(1), 47-61. doi:10.1016/j.cxom.2010.11.004; 10.1016/j.cxom.2010.11.004
- Berglundh, T., Persson, L., & Klinge, B. (2002). A systematic review of the incidence of biological and technical complications in implant dentistry reported in prospective longitudinal studies of at least 5 years. *Journal of Clinical Periodontology*, 29 Suppl 3, 197-212; discussion 232-3.
- Chanavaz, M. (1998). Patient screening and medical evaluation for implant and preprosthetic surgery. *The Journal of Oral Implantology*, 24(4), 222-229. doi:2
- Curley, A. W. (2011). The law and dentoalveolar complications: Trends and controversies. *Oral and Maxillofacial Surgery Clinics of North America*, 23(3), 475-484. doi:10.1016/j.coms.2011.04.003; 10.1016/j.coms.2011.04.003
- Esposito, M., Grusovin, M. G., Loli, V., Coulthard, P., & Worthington, H. V. (2010). Does antibiotic prophylaxis at implant placement decrease early implant failures? A Cochrane systematic review. *European Journal of Oral Implantology*, 3(2), 101-110.

- Goodacre, C. J., Bernal, G., Rungcharassaeng, K., & Kan, J. Y. (2003). Clinical complications with implants and implant prostheses. *The Journal of Prosthetic Dentistry*, 90(2), 121-132. doi:10.1016/S0022-3913(03)00212-9
- Graskemper, J. P. (2005). Informed consent: A stepping stone in risk management. *Compendium of Continuing Education in Dentistry* (Jamesburg, N.J.: 1995), 26(4), 286, 288-90.
- Gregg, J. M. (2000). Neuropathic complications of mandibular implant surgery: Review and case presentations. *Annals of the Royal Australasian College of Dental Surgeons*, 15, 176-180.
- Kohner, J. S. (1992). Implant team: Problems and solutions with osseointegrated implants. *Practical Periodontics and Aesthetic Dentistry* : PPAD, 4(8), 27-32.
- Makary, C., Rebaudi, A., Sammartino, G., & Naaman, N. (2012). Implant primary stability determined by resonance frequency analysis: Correlation with insertion torque, histologic bone volume, and torsional stability at 6 weeks. *Implant Dentistry*, 21(6), 474-480. doi:10.1097/ID.0b013e31826918f1; 10.1097/ID.0b013e31826918f1
- Meyer, R. A. (1996). Microsurgical repair of nerve injuries associated with dental implants. *The Journal of Oral Implantology*, 22(1), 42-44.
- Misch, C. E., & Dietsch, F. (1993). Bone-grafting materials in implant dentistry. *Implant Dentistry*, 2(3), 158-167.
- Ng, D. Y., Wong, A. Y., & Liston, P. N. (2012). Multidisciplinary approach to implants: A review. *The New Zealand Dental Journal*, 108(4), 123-128.
- Powell, C. A., Mealey, B. L., Deas, D. E., McDonnell, H. T., & Moritz, A. J. (2005). Post-surgical infections: Prevalence associated with various periodontal surgical procedures. *Journal of Periodontology*, 76(3), 329-333. doi:10.1902/jop.2005.76.3.329
- Romeo, E., Lops, D., Margutti, E., Ghisolfi, M., Chiapasco, M., & Vogel, G. (2004). Long-term survival and success of oral implants in the treatment of full and partial arches: A 7-year prospective study with the ITI dental implant system. *The International Journal of Oral & Maxillofacial Implants*, 19(2), 247-259.
- Sakka, S., Baroudi, K., & Nassani, M. Z. (2012). Factors associated with early and late failure of dental implants. *Journal of Investigative and Clinical Dentistry*, 3(4), 258-261. doi:10.1111/j.2041-1626.2012.00162.x; 10.1111/j.2041-1626.2012.00162.x
- Shokri, M., & Daraeighadikolaei, A. (2013). Measurement of primary and secondary stability of dental implants by resonance frequency analysis method in mandible. *International Journal of Dentistry*, 2013, 506968. doi:10.1155/2013/506968; 10.1155/2013/506968
- Strauss, E. R., Ziccardi, V. B., & Janal, M. N. (2006). Outcome assessment of inferior alveolar nerve microsurgery: A retrospective review. *Journal of Oral and Maxillofacial Surgery* : Official Journal of the American Association of Oral and Maxillofacial Surgeons, 64(12), 1767-1770. doi:10.1016/j.joms.2005.11.111
- Trisi, P., Todisco, M., Consolo, U., & Travaglini, D. (2011). High versus low implant insertion torque: A histologic, histomorphometric, and biomechanical study in the sheep mandible. *The International Journal of Oral & Maxillofacial Implants*, 26(4), 837-849.
- Wanner, L., Manegold-Brauer, G., & Brauer, H. U. (2013). Review of unusual intraoperative and postoperative complications associated with endosseous implant placement. *Quintessence International* (Berlin, Germany : 1985), doi:10.3290/j.qi.a29936; 10.3290/j.qi.a29936
- Wheeler, S., & Bollinger, C. M. (2009). Complication or substandard care? Risks of inadequate implant training. *Journal of the California Dental Association*, 37(9), 647-651.
- Wittneben, J. G., Buser, D., Salvi, G. E., Burgin, W., Hicklin, S., & Bragger, U. (2013). Complication and failure rates with implant-supported fixed dental prostheses and single crowns: A 10-year retrospective study. *Clinical Implant Dentistry and Related Research*, doi:10.1111/cid.12066; 10.1111/cid.12066

Lee M. Whitesides DMD, MMSc "Mac" is a native North Carolinian who moved to Georgia after completing his undergraduate work at Davidson College in 1984. He enrolled in the Allied Health School at Emory University to pursue a master's in medical science degree and anesthesia. Upon completion of his master's degree Dr. Whitesides began working as a physician's assistant in anesthesia Crawford Long Hospital.

In 1988, Dr. Whitesides changed careers by entering dental school at the Medical College of Georgia in Augusta. Upon graduation in 1992, Dr. Whitesides enrolled in a one-year general practice residency at Maimonides Medical Center in Brooklyn, New York. From 1993 to 1997, Dr. Whitesides was a resident in Oral and Maxillofacial Surgery at the University of Maryland Medical System in Baltimore under the tutelage of Dr. Robert Ord. He began practicing his profession in Atlanta in 1997 and became Board certified in Oral & Maxillofacial Surgery in the year 2000.

Dr. Whitesides lectures on many contemporary topics in oral-maxillofacial surgery including dental implants, medical emergencies in the dental office, and risk management. He is currently on the faculty at the Medical College of Georgia Maxi-Course and the California Implant Institute.



WIDENER LEADERSHIP WORKS IN HEALTH CARE COMPLIANCE

Every day, Widener Law graduates lead in Health Care Compliance.

At Widener Law, medical professionals like you gain a competitive edge in Health Care Compliance, Regulatory Analysis, and Legal Nurse Consulting.

Widener Law's award-winning online program provides you with a Master of Jurisprudence in Health Law with a Certificate in both Legal Nurse Consulting and Hospital Regulatory Compliance. This powerful combination prepares nurses in these two specialty areas with one Certificate. Further, you can earn your degree in any location, all on your schedule.

Widener Law gives you the leadership skills in Health Care Compliance that can make all the difference in your medical career.

Start earning your MJ degree in Health Law with a Certificate in Legal Nurse Consulting and Regulatory Compliance.

Time is running out. Apply today at law.widener.edu/MJHealthLaw

Widener Law

Acetylcysteine (N-acety-L-cysteine): Antidote and Toxic Agent

M. Thomas Quail, MS Ed, R.N., LNC, EMT-B and Edward W. Boyer MD, PhD

KEY WORDS

Acetylcysteine, N-acety-L-cysteine (NAC), Acetaminophen, Antidote, Legal Nurse Consultant, Liver Failure, LNC, Paracetamol, Toxic Agent, Toxicologist

This article will address the antidote Acetylcysteine. A brief history of how Acetylcysteine evolved as the preferred antidote for acetaminophen toxicity is provided, even though the exact dose, duration of therapy and its mechanism of action remain unknown. Included are the current United States (U.S.) Acetylcysteine guidelines. Since legal cases are lacking, 15 case reports are identified, whereby minor to severe adverse effects have been attributed to Acetylcysteine therapy. Quality improvement recommendations are provided to assist the legal nurse consultant (LNC) when reviewing Acetylcysteine therapy cases for merit.

Introduction

The oral/inhalation formula of Acetylcysteine was approved by the U.S. Food and Drug Administration (FDA) in 1963 and is commonly used as a mucolytic agent for patients suffering from chronic bronchopulmonary conditions and as a preparation for diagnostic bronchial studies.

It is used (off-label) for the prevention of contrast-induced renal dysfunction and distal intestinal obstruction syndrome (meconium ileus equivalent) (Lexicomp Drug Reference Handbooks, 2013; U.S. Food and Drug Administration (US FDA) Approved Drug Products, 2013).

Acetylcysteine has long been used and became the recognized antidote for acetaminophen (paracetamol) toxicity and continues to be extensively studied as an antioxidant agent against other liver toxins (Culley & Krenzelok, 2005.; Dawson, Norbeck, Anundi, & Moldéus, 1984; Lee, Larson, & Stravitz, 2011; McNeil Consumer Healthcare, 2005, 2010; Millea, 2009.; Prescott, et al., 1979; Rumack & Bateman, 2012; Smilkstein, Knapp, Kulig, & Rumack, 1988).

Acetylcysteine is the N-Acetyl derivative of the naturally occurring amino acid cysteine (US FDA Center for Drug Evaluation and Research (CDER), New Drug Application (NDA) # 21-539, 2002). It is also known as Mercapturic Acid, N-acety-L-cysteine, N-acetylcysteine, or NAC (Lexicomp, 2013).

Background

Acetaminophen toxicity is the leading cause of acute liver injury and death from acute liver failure in the U.S. It is the number one analgesic reported to U. S. poison centers due to therapeutic misadventures or overdose (Algren, 2008; Bronstein, Spyker, Cantilena, Jr., Rumack, & Dart, 2012; Farrell, Tarabar, Burns, Fernandez, Van De Voort, 2012; Shannon & Salhanick, 2007; Smilkstein et al., 1988; Treinen-Mosle, 2003).

The latest annual report from the American Association of Poison Control Centers (AAPCC) identified acetaminophen

as accounting for 165,552 (16.3%) therapeutic misadventures to include overdoses (Bronstein, et al., 2012). In addition, the AAPCC reported that acetylcysteine used as an antidote was administered to 25,408 patients (I.V. 18,423; P.O. 6,985) known or suspected to be toxic from acetaminophen (Bronstein, et al., 2012).

A patient who has acetaminophen toxicity has depleted their glutathione stores below 30%. Glutathione is an antioxidant that prevents damage to liver cells. When glutathione is depleted the toxic metabolite N-acetyl-p-benzoquinone imine (NAPQI) becomes readily available. NAPQI binds to the macromolecules in the hepatocyte, causing cellular death and hepatic necrosis (Algren, 2008; Kao et al., 2003; McNeil, 2005, 2010; Quail & Boyer, 2013; Shannon & Salhanick, 2007).

James (2013) reported that "... more than 400,000 preventable adverse events..." contribute to the death of patients while in the hospital each year, far surpassing the 1999 report by the Institute of Medicine (p.127). The LNC must be aware that acetylcysteine therapy is not without its share of controversy, complications, and risks. For starters, the medical literature identifies various treatment protocols, including dosing, ideal routes, and duration of therapy which are misleading and often confusing for the healthcare provider. In addition, a variety of adverse effects have been attributed to acetylcysteine therapy, ranging from nausea to death (Commission on Human Medicines, 2012; McIntyre, McDonald-Taylor & Greene, 2013; Mroz, L.S., Benitez, J.G. & Krenzelok, E.P., 1997; Pakravan et al., 2008.; Sandilands & Bateman, 2009; Waring, 2012.; Zyoud, Awang, Syed-Sulaiman, Sweileh, & Al-Jabi, 2010., Zyoud, Awang, Sulaiman, & Al-Jabi, 2011).

The LNC should be aware that acetylcysteine therapy-related anaphylactoid reactions occur (2%-77%) and iatrogenic dosing errors are common (33%-49%). Finally, children are at a greater risk, due to a potential for fluid overload, and require adjustments to the infusion volume when acetylcysteine therapy is ordered (Algren, 2008;

Beringer, Thompson, Parry, Stoddart, 2011; Commission on Human Medicines, 2012; Dart & Rumack, 2012; Hayes, Klein-Schwartz, & Doyon, 2008; Klein-Schwartz & Doyon, 2011; Mroz, L.S., Benitez, J.G. & Krenzelok, E.P., 1997; National Institutes of Health (NIH), 2010; Pakravan et al., 2008; Sandilands & Bateman, 2009; Schmidt, 2013; Shannon & Salhanick, 2007; Smollin, 2010; Vale, Meredith, & Goulding, 1981; Waring, 2012; Yarema, et al., 2009; Yip, Dart, & Hurlbut, 1998; Zyoud et al., 2010).

LNCs must ensure that healthcare providers who administer acetylcysteine therapy understand these risks, the dosing regime, duration of therapy, and adverse effects associated with this drug. In addition, the LNC must ensure that policies, procedures, and safety measures were in place during the oral (PO) or intravenous (IV) drug compounding, drug administration, and assay monitoring. The LNC must also determine if prophylactic measures, such as antiemetics, antihistamines, or corticosteroids, were provided in order to achieve the therapeutic benefit from acetylcysteine (Waring, 2008, 2012).

Acetylcysteine History

Older published literature tends to use the term N-acety-L-cysteine while newer published literature uses acetylcysteine. Rumack and Bateman (2012) and Waring (2012) eloquently describe the history and rationale for the use of Acetylcysteine as the antidote for acetaminophen toxicity. They also describe how the dose, duration, and continuation of therapy were based on published articles and case reports and not from FDA approved clinical trials. Today there are still many questions concerning Acetylcysteine therapy when determining an optimal dose and concentration, and there is a need to develop a better understanding of its exact mechanism of action (Algren, 2008; Harrison, Wendon, Gimson, Alexander, & Williams, 1991; Perry & Shannon, 1998; Rumack & Bateman, 2012; Sandilands & Bateman, 2009; Shannon & Salhanick, 2007; Waring, 2012).

Rumack and Bateman (2012, p. 91) first acknowledge their colleagues for their many scientific discoveries that led to the development of Acetylcysteine as the antidote for acetaminophen toxicity. These included:

- **1973-1974** Mitchell and colleagues clarified the mechanism of acetaminophen hepatotoxicity, which demonstrated that the alteration of glutathione changed the level of covalent binding of the toxic metabolite NAPQI.
- **1973** Matthew theorized that an acetaminophen half-life was associated with its toxicity.
- **1974** Mitchell and colleagues provided a rationale for therapy in humans, concluding that cysteamine or other nucleophiles [an atom or molecule that donates an electron pair to form a chemical bond], could prevent hepatotoxicity.
- **1974** Prescott- first reported the successful treatment of a series of overdose patients with cysteamine; later identifying it as a less than ideal antidote (Algren, 2008;

Rumack & Bateman, 2012, p.91; Prescott, et al., 1979; Prescott, Stewart, & Proudfoot, 1978; Prescott, et al., 1974; Prescott, Park, Ballantyne, Adriaenssens, & Proudfoot, 1977).

- **1974** Prescott and Matthew first suggested that Acetylcysteine might protect the liver against paracetamol toxicity and debated the use of methionine which continues to be debated today (Senarathna, Sri Ranganathan, Buckley, & Fernandopulle, 2012; Terneus, Brown, Carpenter, Valentovic, 2008; Terneus, Kinningham, Carpenter, Sullivan, & Valentovic, 2007; Waring, 2012, p. 2).
- **1976** Piperno and Berssenbruegge showed that Acetylcysteine replenishes hepatic glutathione stores and demonstrated its superiority over cysteamine and methionine in preventing hepatotoxicity and death (Rumack & Bateman, 2012, p.91; Waring, 2012, p. 2).
- **1979** Prescott and colleagues - demonstrated Acetylcysteine as the treatment of choice for paracetamol overdose with virtually complete protection against severe liver damage if administered within 10 hours (Algren, 2008; Hayes et al., 2008; Prescott, et al., 1979; Prescott, et al., 1977; Waring, 2012).

As a result of these discoveries, Dr. Rumack applied to the FDA for approval of oral acetylcysteine as an antidote for acetaminophen toxicity in the U.S. The FDA required him to perform a prospective clinical trial to demonstrate its efficacy (Rumack & Bateman, 2012). Two published articles questioned the ethics of such a trial, which led the FDA to deny his request.

Rumack and Bateman (2012) reported the efficacy at that time "... was based on a small number of cases [which] showing [sic] substantial benefit" (p.92). Consequently, an understanding of acetylcysteine optimal dose, route, and duration of therapy remain lacking (Klein-Schwartz & Doyon, 2011; Rumack & Bateman, 2012; Smilkstein et al., 1988; Yarema, et al., 2009). In 1985, the FDA granted approval of Acetylcysteine oral formula as the antidote for the treatment of acetaminophen toxicity (Klein-Schwartz & Doyon, 2011; McNeil, 2005, 2010; Rumack & Bateman, 2012; Sandilands & Bateman, 2009; Smilkstein et al., 1988; Waring, 2012; Yarema, et al., 2009).

Next were concerns of controlling the adverse effects caused by the oral Acetylcysteine formula and for those patients who had contraindications to oral therapy. Acetylcysteine clinical effects, combined with the clinical effects seen from acetaminophen toxicity, are nausea and vomiting. Patients who truly cannot tolerate oral Acetylcysteine or who have severe acetaminophen toxicity may develop refractory nausea and vomiting (Kao et al., 2003; Smollin, 2010).

Contraindications to oral therapy are patients with an altered level of consciousness, bowel obstruction, gastrointestinal bleeding, ongoing activated charcoal decontamination, or young children (Algren, 2008; Culley & Krenzelok, 2005; Kao et al., 2003; Smollin, 2010; Yip et al., 1998). These concerns led to an intravenous formula

being developed; however, it was initially only available in European countries.

After years of success using the intravenous formula, U.S. physicians were prompted to develop a protocol and begin administering oral Acetylcysteine intravenously (off-label). This was done by first filtering the oral formula and then injecting it. This decreased the adverse effects from oral Acetylcysteine, hospital length of stay, and the cost. (Algren, 2008; Culley & Krenzelok, 2005; Gonzalez & Hinson, 2013; Kao et al., 2003; Rumack & Bateman, 2012; Sandilands & Bateman, 2009; Tomaszewski, 2006; Waring, 2012; Yip et al., 1998). This latest protocol decreased therapy from 72 hours to 20 hours and from an estimated cost of \$212.30 (IV) to \$ 34.30 (PO given IV) based on 2004 values according to Culley and Krenzelok (2005) study.

In 2004, the FDA approved an intravenous formula of Acetylcysteine to be administered over a 20-hour period, based on Prescotts' 1979 European protocol. The original approval consisted of a loading dose being infused over 15 minutes followed by two maintenance doses being infused over four and 16 hours respectively (Klein-Schwartz & Doyon, 2011; Prescott, et al., 1979; US FDA CDER, NDA 21-539, 2002; Waring, 2012).

In 2006, the loading dose time was changed from a 15-minute infusion to a 30-minute infusion, due to the high rate of adverse effects that were being reported. This resulted in the current 21-hour Acetylcysteine infusion regimen (Culley & Krenzelok, 2005; Elms, Owen, Albertson, & Sutter, 2011; Hayes et al., 2008; Klein-Schwartz & Doyon, 2011; McNeil, 2005, 2010; Smollin, 2010; US FDA CDER, NDA 21-539/S-004; US FDA Approved Drug Products, 2013; Waring, 2012).

Both oral and intravenous formulas of Acetylcysteine are now commercially available in the U.S. (Culley & Krenzelok, 2005; McNeil, 2005, 2010; US FDA CDER, NDA 21-539, 2002; US FDA CDER, NDA 21-539/S-004). The official adopted name designated by the United States Adopted Names Council is Acetylcysteine (McNeil, 2005, 2010).

Acetylcysteine Presumed Mechanism of Action

Acetylcysteine chemical structure is considered comparable to glutathione, the body's protective mechanism against liver toxins. As glutathione becomes depleted, because of acetaminophen toxicity, glutathione stores are activated to defend against the toxic metabolite, NAPQI. If glutathione stores become significantly depleted, the liver cells become necrotic. It is thought that Acetylcysteine acts like glutathione and protects the liver from NAPQI (Sandilands & Bateman, 2009; Shannon & Salhanick, 2007).

Harrison, Wendon, Gimson, Alexander, and Williams (1991) demonstrated that patients with fulminant hepatic failure benefited from Acetylcysteine therapy by increasing tissue oxygen consumption. Klein-Schwartz and Doyon (2011) later reported that NAPQI-induced cellular injury

causes the tissue hypoxia while, "...acetylcysteine improves ... the microcirculatory blood flow in the liver and other organs by increasing oxygen consumption" (p. 120).

Elms, Owen, Albertson, and Sutter (2011) then reported that acetylcysteine has four basic mechanisms of action. It limits acetaminophen toxicity by the following:

- replenishing endogenous glutathione
- directly converting the acetaminophen metabolite NAPQI to a non-toxic metabolite
- facilitating the increased formation of N-acetylpaminophenol-sulfate
- buffering cellular damage from NAPQI by acting as a reducing agent (p.1)

Waring (2012), who later reported in animal studies of paracetamol-induced liver injury, suggested that a "... primary mechanism of acetylcysteine is the provision of cysteine to stimulate replenishment of glutathione to allow for the detoxification of NAPQI" (p.2).

He continued, "...Acetylcysteine prevents glutathione depletion and minimizes hepatocyte injury caused by a number of different toxins" suggesting "...that the therapeutic mechanism of Acetylcysteine may be more complex than [just the] restoration of glutathione alone" (Waring, 2012, p. 2).

Decontamination

Patients suspected of acetaminophen toxicity must first be decontaminated using the current standard of care (activated charcoal). Extended release acetaminophen, massive acetaminophen overdoses, or acetaminophen combination products may require additional decontamination (multi-dose activated charcoal, lavage, hemodialysis, or hemoperfusion), in addition to the administration of Acetylcysteine therapy, all within a timely manner (McNeil, 2005, 2010; Smith, Howland, Hoffman, & Nelson, 2008).

Determine if Toxic

Though Matthew's work (Rumack & Bateman, 2012), theorized acetaminophen toxicity was based on its half-life, clinicians should not determine if a patient is toxic based on acetaminophen half-life when they are considering Acetylcysteine therapy (Dart, et al., 2006; Gosselin, 2013). The clinician determines if the patient is acetaminophen toxic based on the patient's history and a true four-hour acetaminophen serum level plotted on the modified Rumack-Matthews Nomogram (Quail & Boyer, 2013; Shannon & Salhanick, 2007). Acetaminophen levels obtained prior to four-hours or after 24-hours can not be interpreted using the nomogram (Dart, et al., 2006; Gosselin, 2013).

Extended release acetaminophen or acetaminophen combination products require additional acetaminophen assays four to six-hours after the initial assay, to ensure that a peak toxic level has been reached (McNeil, 2005, 2010). Serial acetaminophen levels are not necessary to follow once the acetaminophen assay begins to decline. If either the initial acetaminophen level and/or the true four-hour level is

plotted against the modified Rumack–Matthews Nomogram and either show a risk of toxicity, then Acetylcysteine therapy is indicated (Dart & Rumack, 2012; McNeil, 2005, 2010; Quail & Boyer, 2013).

Patients with an intentional history of overdose are more difficult to manage because their actual time and the amount of acetaminophen consumed is often inaccurate or unknown (Quail & Boyer, 2013; Sporer & Khayam–Bashi, 1996). For patients whose history is suspicious, unknown, vague, have taken super-therapeutic amounts, present late (> 8 hours), or are hepatotoxic; acetylcysteine therapy must begin immediately (Algren, 2008; Craig, et al., 2012; Farrell, Tarabar, Burns, Fernandez, & Van De Voort, 2012; McNeil, 2005, 2010; O' Geen, et al., 2013; Sporer & Khayam–Bashi, 1996). Therapy must continue for the full duration of time even when the acetaminophen level decreases to a non-toxic level (Smollin, 2010).

Craig, et al (2012) reported that the, "... failure to initiate treatment in a timely manner, is associated with a poor outcome in paracetamol-induced [acetaminophen] acute liver failure" (p. 292). Patients considered acetaminophen toxic must be monitored for hepatic effects. Assays include liver function values, (AST, ALT, bilirubin) and an International Normalized Ratio (INR). This is to determine if there is hepatic involvement and to ensure the elevated levels have peaked (McNeil, 2005, 2010).

The length of acetylcysteine therapy is then based on liver function values, clinical effects, physical examination, and serum acetaminophen level(s) (Green, Heard, Reynolds, & Albert, 2013; Shannon & Salhanick, 2007; Ternullo, 2006; Waring, 2012). Algren (2008) states that, "...in cases of hepatotoxicity, NAC [acetylcysteine] should be continued until:

- the serum liver transaminases fall to less than 1000 IU/L
- bilirubin and coagulation studies are normal,
- the patient is clinically well
- the patient receives a liver transplant
- the patient dies" (p. 2).

If liver function values remain elevated a toxicologist consultation must be obtained to determine if acetylcysteine therapy should continue beyond the recommended time intervals (21 or 72 hours). The toxicologist consult is necessary to confirm the current standard of care using evidence-based protocols with accurate dosing and duration of therapy information (Green, et al., 2013, Hayes et al., 2008; Smollin, 2010; McNeil, 2005, 2010; O' Geen, et al., 2013; Waring, 2012).

Intravenous (IV) Versus Oral (PO) Acetylcysteine therapy

Clinicians agree that the early administration of Acetylcysteine has a profound effect on reducing hepatotoxicity (Green, et al., 2013; Klein-Schwartz & Doyon, 2011; McNeil, 2005, 2010). Elms, et al. (2011) reinforced that, "regardless of [acetylcysteine] route of administration

[PO, IV], there has not been a reported treatment failure for [sic] an acute acetaminophen only ingestion... when acetylcysteine was given within 8 hours of [that] ingestion" (p. 1).

Green, Heard, Reynolds, and Albert (2013) meta analysis reviewed 43 years of published literature to determine who developed hepatotoxicity depending on if they received IV versus the PO route of therapy. Both the 21-hour protocol (IV route) and the 72-hour protocol (PO route) equally protect the liver as long as it is administered within 8-10 hours. Hepatotoxicity then increases incrementally if acetylcysteine therapy is delayed (Green, et al., 2013; Klein-Schwartz & Doyon, 2011; Perry & Shannon, 1998).

Acetylcysteine Formulations

Even though both the oral and intravenous formulas are equally effective, the oral formula has less adverse effects and is considered much safer (Algren, 2008; Culley & Krenzelok, 2005; Prescott, 2004; NIH, 2010).

The oral form of Acetylcysteine is supplied in 10 % (100 mg/ml) or 20% (200 mg/ml) sterile vials trademarked under the name of Mucomyst® (Lexicomp, 2013). The intravenous form of Acetylcysteine is supplied in 30 ml (200 mg/ml) single dose sterile vials trademarked under the name of Acetadote® (Acetadote Package Insert, 2013; Lexicomp, 2013).

Dosing Therapy

The LNC must be aware that there are many different Acetylcysteine protocols used for acetaminophen toxicity therapy in the medical literature, within and outside the United States. These include a 24, 52, 62, and 72 hour oral therapy and a 20, 21, 45, 48, and 52 hour IV therapy (Gosselin, 2013; Kao et al., 2003; Perry & Shannon, 1998; Prescott, 2004; Shannon & Salhanick, 2007; Waring, 2012). Smollin (2010) and Hayes, Klein-Schwartz, and Doyon, (2008) report that these different hours of therapy published in the older medical literature has lead to confusion over when to stop treatment, because it varies from the current therapy and protocols and is often misleading. As a result, health care providers have generated Acetylcysteine treatment guidelines that vary from a definitive timeline endpoint, which supports the notion that precise protocols are of lesser importance than the timeliness of Acetylcysteine administration.

PO Formula

Rumack's initial U.S. application for oral Acetylcysteine therapy was based on 60 hours, because of the half-life seen with acetaminophen toxicity. The FDA then added a safety margin to his protocol leading to the current 72-hour oral protocol (Rumack & Bateman, 2012; Prescott, 2004; Waring, W. S., 2012).

Acetylcysteine dosing consists of a "loading dose" followed by "maintenance doses." The loading dose is not well tolerated and approximately 50% of patients vomit (Culley & Krenzelok, 2005; Waring, 2012). If at any time the patient

vomits any of the oral formula dose within one hour after administration, that dose must be repeated until the entire treatment protocol is completed. Methods to decrease the nausea and vomiting include antiemetics, nasogastric tube, and/or using the IV formula (Culley & Krenzelo, 2005; Waring, 2012).

Rumack and Bateman (2012) and others reported, patients who present 16 to 24 hours after ingestion have demonstrated that acetylcysteine oral formula provided a better protection to the liver. This is thought to be most likely due to the quantity of the loading dose and the first pass effect of metabolism (Elms, et al. 2011; Gosselin, 2013; Hayes et al., 2008; Klein-Schwartz & Doyon, 2011; Prescott, 2004; Smilkstein et al., 1988; Ternullo, 2006; Waring, 2012; Yarema, et al., 2009).

Acetylcysteine is thought to be beneficial for patients preventing greater than 24-hours; however, additional research is still needed. A toxicologist consult is prudent for these patients (Lexicomp, 2013; O' Geen, et al., 2013; Rumack & Bateman, 2012; Yarema, et al., 2009).

The recommended standard protocols used in the U.S. that can be modified during a toxicologist consult are:

Acetylcysteine TREATMENT PROTOCOLS (U.S.)

Oral (PO) Formula = 72 hour protocol

Adults and Pediatric Patients

- The 72-hour protocol consists of 18 doses. The total dose delivered is 1,330 mg/kg (Acetadote, 2013).
- Elms, et al. (2011) reported that disadvantages to the oral protocol are poor tolerance and poor adherence to the treatment regime.
- Acetylcysteine has the odor of rotten eggs and may be unpleasant to ingest (Sandilands & Bateman, 2009; Klein-Schwartz & Doyon, 2011).
- Drinking the solution through a straw with the container covered and the formula over ice decreases the odor of the oral formula (Lexicomp, 2013).

PO Dosing

- Dilute oral solution with a soft drink or orange juice to produce a 5% solution.
- Loading dose = 140 mg/kg x 1 dose
- Maintenance doses of 70 mg/kg every 4 hours, times 17 doses until all doses are administered (Lexicomp, 2013; Smollin, 2010).

PO ADVERSE EFFECTS

Mild: Oral acetylcysteine is associated with nausea and vomiting in 50% of acetaminophen poisoned patients. Diarrhea and headaches have been reported (Culley & Krenzelo, 2005; Prescott, 2004; Kao et al., 2003; Waring,

2012). Therapeutic doses of the oral formula may cause a rise in liver function tests (Bailey & Andres, 1987).

Moderate: Refractory nausea and vomiting.

Severe: Angioedema and hypotension.

Intravenous (IV) Formula = 21-hour Protocol

Since the development of the IV formula, there has been a significant shift away from the oral formula. The current IV formula is a 21-hour protocol. It too has a loading dose; however, only two maintenance doses are needed, each with different infusion rates and drug volumes. Patients typically will develop mild to severe adverse effects during the loading dose phase; however, vomiting is less frequent (0-12%) than in the oral formula (Culley & Krenzelo, 2005; Gonzalez & Hinson, 2013; Zyoud et al., 2010).

If adverse effects should occur, the IV may be stopped until the effects subside or are treated. Methods to decrease the adverse effects include antihistamines, corticosteroids, inhaled beta-agonists, and in severe cases, intramuscular adrenaline (Sandilands & Bateman, 2009; Ternullo, 2006; Zyoud et al., 2010). The acetylcysteine infusion should then be restarted until the entire treatment protocol is completed, because a premature discontinuation of IV Acetylcysteine therapy has caused hepatic injury (Yarema, et al., 2009).

The package insert has specific instructions and adjustments regarding fluid volume. In children, the volume must be adjusted accordingly, because of the potential for fluid overload resulting in hyponatremia, seizure, and death. Adjustments are also needed for patients who require fluid restrictions; whose weight is more than 100 kg.; or when the patient's weight is less than 40 kg. (Acetadote, 2013; Elms, et al., 2011; Lexicomp, 2013; Smollin, 2010; US FDA Approved Drug Products, 2013).

IV Dosing

- The total dose of Acetylcysteine is 300 mg/kg over 21 hours administered in three separate doses, with no interruption in therapy.
- IV Acetylcysteine is administered via a 3-bag method each with its own unique volume, rate of infusion, and volume of diluent.
- Acetadote is compatible with the following diluents: 5% Dextrose in Water, 0.45% Sodium Chloride Injection, and Sterile Water for Injection.
- Maintenance dose infusion bag #2 - Infusion rate is 12.5 mg/kg/hour.
- Maintenance dose infusion bag #3 - Infusion rate is 6.25 mg/kg/hour.
- Caution as to not delay Acetylcysteine administration while waiting for the pharmacy to deliver the second and third infusion bags (Elms, et al., 2011).

Patients weigh 5 kg to 20 kg:

- Loading Dose: 150 mg/kg diluted in 3 mL/kg of diluent* administered over one hour

- Second Dose: 50 mg/kg diluted in 7 mL/kg of diluent* administered over four hours
- Third Dose: 100 mg/kg diluted in 14 mL/kg of diluent* administered over 16 hours

Patients weigh 21 kg to 40 kg:

- Loading Dose: 150 mg/kg diluted in 100 mL of diluent* administered over 1 hour
- Second Dose: 50 mg/kg diluted in 250 mL of diluent* administered over 4 hours
- Third Dose: 100 mg/kg diluted in 500 mL of diluent* administered over 16 hours

Patients weigh 41 kg to 100 kg:

- Loading Dose: 150 mg/kg diluted in 200 mL of diluent* administered over 1 hour
- Second Dose: 50 mg/kg diluted in 500mL of diluent* administered over 4 hours
- Third Dose: 100 mg/kg diluted in 1000 mL of diluent* administered over 16 hours

IV ADVERSE EFFECTS

- IV Acetylcysteine usually has more adverse effects than the PO formula (Algren, 2008; Sandilands & Bateman, 2009; Shannon & Salhanick, 2007).
- In therapeutic dosing, IV Acetylcysteine has caused cardiac arrest (Elms, et al., 2011; Cassidy & Tracey, 2008; Sandilands & Bateman, 2009; Sunman, Hughes, & Sever,1992).
- ST depression, T wave inversion, asystole, and myocardial ischemia have all been documented (Elms, et al., 2011).
- Specific ethnic groups were associated with the development of adverse effects (Schmidt (2013).

Mild: Angioedema, flushing, headache, rash, urticaria, vasodilatation.

Moderate: Bronchospasm, hypotension, pruritus, tachycardia.

Severe: Anaphylactoid reactions

- The first reported anaphylactoid reaction from Acetylcysteine was reported in 1982 (Sandilands & Bateman, 2009).
- **Anaphylactoid** reactions are non-immunogenic and "... do not require previous sensitization" unlike **Anaphylactic** reactions which "... require a prior sensitization (Elms, et al., 2011, p.2).
- Anaphylactoid reactions appear to be associated with low serum acetaminophen levels (Elms, et al., 2011; Kao et al., 2003; Schmidt, 2013; Smollin,2010; Waring, Stephen, Robinson, Dow, & Pettie, 2008; Waring, 2012; Zyoud et al., 2010).

PO administered IV Protocols

- Prior to the availability of IV Acetylcysteine or in regions where IV Acetylcysteine was not available; the oral/

inhalation formula would be administered (off label) via the IV route.

- The oral solution prepared as an intravenous solution has an extended stability of 60 hours (Culley & Krenzelok, 2005); however, most PO administered IV protocols afford a 24-hour expiration date.

Preparations

Lexicomp (2013, p.37) Lexicomp makes note that only the 72-hour oral and 21-hour IV regimens are FDA approved. They list under IV administration both the 3-bag method and the PO administered IV. Lexicomp references Yip’s (1998) protocol as follows, *“If the commercial IV form is unavailable, the solution for inhalation has been used. Each dose should be infused through a 0.2 micron Millipore filter (in-line) over 60 minutes. The IV administration of the solution for oral/inhalation is not USP-797 compliant”* (See Legal Risks).

Shannon & Salhanick (2007, p. 830) protocol is, *“The oral preparation... of Acetylcysteine is given as a 5% solution in saline administered through a 22-ug filter. IV dosing is identical to the oral procedure of 140 mg/kg loading dose followed by 17 maintenance doses of 70 mg/kg.”*

Culley & Krenzelok (2005, p. 138-139) protocol is, *“Draw up the desired volume [of inhalation] Acetylcysteine 20% into a syringe and filter the solution using a Millipore filter (0.2 micron preferred). The solution is then injected into a sterile glass evacuated container and a sufficient amount of 5% dextrose in water solution is added to produce a 1:5 dilution.”*

Yip, Dart, & Hurlbut (1998, p. 41) protocol is to “... first obtain informed consent.” Then dilute [oral] 20% Acetylcysteine solution to 3% solution with 5% dextrose in water.

“Administer a loading dose of Acetylcysteine; 140 mg/kg infused through a peripheral intravenous catheter over one hour using an in-line 0.2-u millipore filter. Administer maintenance doses of Acetylcysteine at 70 mg/kg/dose 4-hours after initiating the loading dose, then continue maintenance doses every 4 hours, each infused over one-hour through the in-line filter.”

The protocol is 13 doses, a loading dose and 48-hours of therapy.

PO Administered IV

ADVERSE EFFECTS

- Adverse effects reported from the PO formula administered IV is 0-11%.
- Adverse effects include rash, hives, and dyspnea (Kao et al., 2003).
- Yip, Dart, & Hurlbut (1998) reported his adverse effects were infrequent and mild and did not preclude further IV administration. He cited other case reports as having rash, hives, throat tightness, dyspnea, and bronchospasm.

PRECAUTIONS/ RISK FACTORS

All Protocols

- Caution in patients with previous hypersensitivity reactions to Acetylcysteine.
- Caution in patients with a history of asthma or a history of bronchospasm, which has led to death (Appelboam, Dargan, & Knighton, 2002).

Legal Risks Compounding:

Controversy exists regarding the compounding of Acetylcysteine.

- Culley & Krenzelok (2005) stated, “While there are no laws prohibiting the compounding of inhalation Acetylcysteine as an intravenous preparation, the issue of using an unapproved drug for intravenous use, when an intravenous product is available commercially, creates the potential for significant medical and legal risk” (p. 139).
- Tomaszewski (2006, p. 87) stated, “... the U.S. Supreme Court has ruled that the “off-label usage of medical devices is an accepted and necessary corollary of the FDA’s mission to regulate” (Buckman Co. v. Plaintiffs’ Legal Comm. (98-1768) 531, U.S. 341 (2001); 159 F.3d 817, reversed)
- Tomaszewski (2006, p. 87) continued, “... that health care practitioners can prescribe or administer any legally marketed device to a patient” without limitation or interference. The Center for Drug Evaluation and Research confirmed this stance, stating that “neither the FDA nor the Federal government regulate the practice of medicine,” and “any approved product may be used by a licensed practitioner for uses other than those stated in the product label.”
- U.S. Pharmacopeial Convention (2013). The first set of enforceable sterile compounding standards was issued by the United States Pharmacopeia (USP) National Formulary is Chapter 797 (USP 797). This chapter describes the guidelines, procedures, and compliance requirements for compounding sterile preparations, and it sets the standards that apply to all settings in which sterile preparations are compounded. The IV administration of Acetylcysteine solution for oral/inhalation is not USP-797 compliant.

PREGNANCY RISK

Pregnancy Category B

There are no adequate and well controlled studies in pregnancy. Acetylcysteine should be used during pregnancy only if clearly needed when a patient has acetaminophen toxicity (Shannon & Salhanick, 2007; McNeil, 2005, 2010).

DOSING ERRORS (Under and Overdosing)

Acetylcysteine medication errors are typically classified into three major categories: systemic calculation, mixing, and measuring errors (Elms, et al., 2011; Ferner, et al., 2001). Hayes, et al, (2008) reports that due to, “the complicated regimen, length of therapy, and need for multiple health professionals to administer [Acetylcysteine] doses to a given patient [and] at multiple treatment sites, [it] potentiate[s] the possibility of medication errors” (p. 766).

Ferner, et al., (2001) conducted a prospective study by collecting Acetylcysteine samples (n=184) before and after infusion. He then measured the concentrations in each infusion bag and reported that the intended delivered dose deviated (under or over) from the intended prescribed dose. He found inadequate mixing errors in 9% of the infusion bags, calculation errors in 5%, and drawing up and measuring errors in 3% of the samples.

Elms, et al. (2011) stated that the majority of errors reported are due to the difficulty in preparing and administering the IV Acetylcysteine formula. He reported that errors are as high as 33%, causing 18.6% of the patients to have a delay or an interruption in therapy for greater than one hour.

Sandilands and Bateman (2009) reported that “... patients who receive inadvertent overdoses of Acetylcysteine have an increased rate of anaphylactoid reactions” by 73% (p.85).

European countries who have had 30 years of experience using IV Acetylcysteine reported as having five adverse drug reaction deaths (Commission on Human Medicines, 2012). The National Patient Safety Agency (NPSA) of the United Kingdom reported 645 iatrogenic errors from IV Acetylcysteine between 2007 and 2011. They indicated the incorrect rate of infusion accounted for 39.0% of errors; incorrect infusion volume (13.6%); incorrect solution (11.9%); incorrect dose prescribed (8.4%); and omitted or delayed dose (8.4%) (Commission on Human Medicines, 2012).

Legal Cases

An internet search was performed by author MTQ, for legal actions or settlements, using Find Law, Lexis® Web, and Justia. No legal actions or settlements were located for adverse effects caused from Acetylcysteine under or overdose. A search using the U.S National Library of Medicine Pub Med database; however, yielded many case reports involving adverse effects from Acetylcysteine. These included administering it in therapeutic, over, or under dosing.

Presented here are 15 cases (Table) involving Acetylcysteine administration listed by their various routes. Some of the 15 case reports indicated that legal action was in progress; however, only one case (Case #6) was located indicating that a settlement had been reached. The authors suspect that if other settlements have occurred, the parties

involved may have had to sign a non-disclosure agreement which would not appear when searching the legal web sites.

Discussion and the Role for the LNC

To paraphrase Paracelsus (1493-1541) the father of toxicology, "All substances known to man are poisons, only the dose determines the effect," which is true when administering Acetylcysteine (Gallo, 2003, p.4). Considered almost innocuous and with little to no adverse effects, acetylcysteine is the recognized antidote that protects the liver from the toxic metabolite NAPQI caused by acetaminophen toxicity.

The role for the LNC is to understand acetaminophen toxicity and the rationale for why acetylcysteine therapy was begun in the first place. Clinicians have ordered acetylcysteine therapy prophylactically, while waiting for a true four-hour serum acetaminophen level, causing unnecessary adverse effects, including death (Cases # 3, 10, 12). However, once the patient is considered, acetaminophen toxic Acetylcysteine therapy must be started immediately to protect the liver from further damage and should continue until the patient's clinical effects subside and the liver enzymes resolve to within normal levels. The LNC should now determine if the proper quality control measures were in place and utilized by all staff involved when acetylcysteine is ordered.

Since the IV formula has been available, the medical community prefers to administer it over the PO formula for various reasons as previously mentioned. The IV formula, however, is generally more complicated than the PO formula. Iatrogenic dosing errors may occur in any aspect of the patient's therapy, which may cause severe adverse effects. Two to ten-fold errors have caused seizures, myocardial infarction, electro-cardiogram changes, cerebral edema, and death.

Advocates are attempting to decrease the iatrogenic dosing error rate by standardizing IV acetylcysteine dosing to avoid the current confusion when preparing the three infusion bags. Suggestions include developing a weight-based method, which is controversial and considered an off-label use. Other suggestions include stringent protocols and additional quality improvement guidelines such as:

- Computerized assisted prescribing
- Contacting the local poison control center for guidance and consultation
- Decreasing the loading dose
- Developing simpler dosing regimes such as 1 or 2-bag similar volume therapy
- Improving staff communications at all levels when administering acetylcysteine
- Improving patient handoffs
- Introducing additional safety measures specific to acetylcysteine therapy
- Ongoing staff education
- Pre-treating patients with antihistamines who have known acetylcysteine reactions
- Pre-treating patients with a history of asthma

(Bulau, 2013; Commission on Human Medicines, 2012 Elms, et al., 2011; Ferner, et al., 2001; Hayes et al., 2008; Klein-Schwartz & Doyon, 2011; Laskey, Miller, Hon, Lopez, & Geller, 2013; McIntyre et al., 2013; Schmidt, 2013; Waring, 2012).

LNCs need to identify and weigh the benefits and risks for each patient requiring Acetylcysteine therapy. They should then determine if the appropriate route and precautions were identified and managed prior to and during acetylcysteine dosing, compounding, and administration. These precautions are in place to decrease the adverse effects from iatrogenic Acetylcysteine therapy and to provide the patient with the optimum therapeutic benefit in an effort to decrease the potential for acetaminophen-induced hepatotoxicity.

References

- Acetadote Highlights of Prescribing Information. (2013). Package Insert p. 1-8. Retrieved from http://acetadote.com/Acetadote21-539-12_PI_Clean_June2013.pdf.
- Algren, D.A. (2008). Review of N-acetylcysteine for the treatment of acetaminophen (paracetamol) toxicity in pediatrics. Second meeting of the subcommittee of the expert committee on the selection and use of essential medicines. Geneva, Retrieved from http://www.who.int/selection_medicines/committees/subcommittee/2/acetylcysteine_rev.pdf
- Anonymous (1984). Death after N-acetylcysteine. (New and Notes) *Lancet*. 323(8391), 1421.
- Appelboam, A.V. Dargan, P.I., & Knighton, J. (2002). Fatal anaphylactoid reaction to N-acetylcysteine: Caution in patients with asthma. *Emerg Med J*. 19(6), 594-595.
- Bailey, D. J. & Andres, J.M. (1987). Liver injury after oral and rectal administration of N-acetylcysteine for meconium Ileus equivalent in a patient with cystic fibrosis. *Pediatrics*. 79 (2), 281-282.
- Bailey, B, Blais, R. Letarte, A. (2004). Status epilepticus after a massive intravenous N-Acetylcysteine overdose leading to intracranial hypertension and death. *Ann Emerg Med*. 44(4), 401-406.
- Beringer, R.M., Thompson, J.P., Parry, S., Stoddart, P.A. (2011). Intravenous paracetamol overdose: Two case reports and a change to national treatment guidelines. *Arch Dis Child*. 96 (3), 307-308.
- Bronstein, A.C., Spyker, D.A., Cantilena, Jr., L.R., Rumack, B.H., Dart, R.C. (2012). 2011 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 29th Annual Report. *Clin Toxicol*. 50, 911-1164. Retrieved from https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2011_NPDS_Annual_Report.pdf
- Bronstein, A.C., Spyker, D.A., Cantilena, Jr, L.R., Green, J.L., Rumack, B.H., Giffin, S.L. (2009). 2008 Annual Report of the American Association of Poison Control Centers' National Poison Data System (Npds): 26th Annual Report. *Clin Toxicol*. 47 (10), Case Addendum. 911-1084. Retrieved from

- https://aapcc.s3.amazonaws.com/pdfs/annual_reports/NPDS_Annual_Report_2008_1.pdf
- Bronstein, A.C., Spyker, D.S., Cantilena, Jr, L.R., Green, J.L., Rumack, B.H., Giffin, S.L. (2010). 2009 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 27th Annual Report. *Clin Toxicol.* 48 (10), Case 981. 979–1178. Retrieved from https://aapcc.s3.amazonaws.com/pdfs/annual_reports/NPDS_Annual_Report_2009_1.pdf
- Bulau, J. M. (2013). Liability of ineffective patient handoffs that cause patient harm or death. *J Legal Nurse Consul.* 24 (2), 43.
- Cassidy, N. & Tracey, J.A. (2008). Cardiac arrest following therapeutic administration of N-acetylcysteine for paracetamol overdose. *Clin Toxicol.* 46(9), 921.
- Craig, D.G., Bates, C.M., Davidson, J.S., Martin, K.G., Hayes, P.C., Simpson, K.J. (2012). Staggered overdose pattern and delay to hospital presentation are associated with adverse outcomes following paracetamol-induced hepatotoxicity. *Brit J Clin Pharmacol.* 71(2), 273-282.
- Commission on Human Medicines: Paracetamol expert group. (2012). Benefit risk profile of acetylcysteine in the management of paracetamol overdose. Retrieved from <http://www.mhra.gov.uk/home/groups/pl-p/documents/drugsafetymessage/con184709.pdf>
- Culley C.M., & Krenzelo, E.P. (2005). A clinical and pharmacoeconomic justification for intravenous acetylcysteine: A US perspective. *ToxicolReviews.* 24 (2), 131-143.
- Dart, R.C., Erdman, A.R., Olson, K.R., Christianson, G., Manoguerra, A.S., Chyka, P.A., et al. (2006). Acetaminophen poisoning: An evidence-based consensus guideline for out-of-hospital management. *Clin Toxicol.* 44(1), 1-18.
- Dart, R.C., & Rumack, B.H. (2012). Intravenous acetaminophen in the United States: Iatrogenic dosing errors. *Pediatrics.* 129(2), 349-353.
- Dawson, J., Norbeck, K., Anundi, I., Moldéus, P. (1984) The effectiveness of N-acetylcysteine in isolated hepatocytes, against the toxicity of paracetamol, acrolein, and paraquat. *Arch Toxicol.* 55 (1), 11–15.
- Elms, A. R., Owen, K.P., Albertson, T. E., Sutter, M.E. (2011). Fatal myocardial infarction associated with intravenous N-acetylcysteine error. *Int J Emerg Med.* 4 (54), 1-4.
- Farrell, S.E., Tarabar, A., Burns, M.J., Fernandez, M.C., Van De Voort, J.T. (2012). Acetaminophen Toxicity. *Medscape online.* Retrieved from <http://emedicine.medscape.com/article/820200-overview>
- Ferner, R.E., Langford, N.J., Anton, C., Hutchings, A., Bateman, D.N., Routledge, P.A. (2001). Random and systematic medication errors in routine clinical practice: A multicentre study of infusions, using acetylcysteine as an example. *Brit J Clin Pharmacol.* 52, 573-577.
- Gallo, M. (2003). General principles of toxicology. History and scope of toxicology. In C. Klaassen, & J. Watkins, (Eds), *Casarett & Doull's Essentials of Toxicology* (pp.4). New York, NY: McGraw-Hill.
- Gonzalez, A., & Hinson, D.E. (2013). A Paradigm Shift from PO to IV N-acetylcysteine and the clinical effects seen. *Clin Toxicol.* 51(7), 609.
- Gosselin, S., Hoffman, R.S., Juurlink, D.N., Whyte, I., Yarema, M. Caro, J. (2013). Treating acetaminophen overdose; thresholds, costs and uncertainties. *Clin Toxicol.* 51(3), 130-133.
- Green, J.L., Heard, K.J., Reynolds, K.M., Albert, D. (2013). Oral and intravenous acetylcysteine for treatment of acetaminophen toxicity: A systematic review and meta-analysis. *W J Emerg Med.* 14 (3)
- Harrison, P.M., Wendon, J.A., Gimson, A.E., Alexander, G.J., Williams, R. (1991). Improvement by acetylcysteine of hemodynamics and oxygen transport in fulminant hepatic failure. *N Engl J Med.* 324(26), 1852-1857.
- Hayes, B.D., Klein-Schwartz, W., Doyon, S. (2008). Frequency of medication errors with intravenous acetylcysteine for acetaminophen overdose. *Ann Pharmacother.* 42, 766-70.
- Heard, K., & Schaeffer, T.H. (2011). Massive acetylcysteine overdose associated with cerebral edema and seizures. *Clin Toxicol.* 49(5), 423–5.
- James, J.T. (2013). A new, evidence-based estimate of patient harms associated with hospital care. *J. Patient Saf.* 9 (3), 122-128.
- Kao, L.W., Kirk, M. A., Furbee, R.B., Mehta, N.H., Skinner, J.R., Brizendine, E.J. (2003). What is the rate of adverse events after oral N-acetylcysteine administered by the intravenous route to patients with suspected acetaminophen poisoning? *Ann Emerg Med.* 42(6), 741-750.
- Klein-Schwartz, W. & Doyon, S. (2011). Intravenous acetylcysteine for the treatment of acetaminophen overdose. *Expert Opin. Pharmacol.* 12 (1), 119-130.
- Laskey, D., Miller, S., Hon, S., Lopez, G., Geller, R. (2013). Utility of a one-bag N-acetylcysteine dosing protocol for acetaminophen overdose. *Clin Toxicol.* 51 (7), 608.
- Lee, W.M., Larson, A.M., Stravitz, R.T. (2011). AASLD Position Paper: The management of acute liver failure: Update 2011. *Hepatology.* September 1-22. Retrieved from <http://www.aasld.org/practiceguidelines/Documents/AcuteLiverFailureUpdate2011.pdf>
- Lexicomp Drug Reference Handbooks. (2013). Acetylcysteine. In *Drug Information Handbook.* 22nd Ed. (pp. 35-37). Hudson, OH: Lexi-Comp.
- Little, M., Murray, L., McCoubrie, D. Daly, F. (2005). A potentially fatal prescribing error in the treatment of paracetamol poisoning. *Med J Australia.* 183 (10), 535–536.
- Lorentzen, H., Glenthøj, J. & Olesen, T. (2002). N-Acetylcysteine overdosage after insignificant acetaminophen intake. *Acta Paediat.* 91(8), 984-985.
- Mant, T.G., Tempowski, J.H., Volans, G.N. Talbot, J.C. (1984). Adverse reactions to acetylcysteine and effects of overdose. *Brit Med J.* 289, 217-219.
- McIntyre, S., Mc Donald-Taylor, D., Greene, S. (2013). Introduction of an N-acetylcysteine weight-based dosing chart reduces prescription errors in the treatment of paracetamol poisoning. *Emerg Med Australas.* 25, 28-35.
- McNeil Consumer Healthcare. (2005). Guidelines for the management of acetaminophen

- overdose. Retrieved from http://www.tylenolprofessional.com/assets/Overdose_Monograph.pdf
- McNeil Consumer Healthcare. (2010). Tylenol® Professional Product Information. Retrieved from http://www.tylenolprofessional.com/assets/TYL_PPI.pdf
- Millea, P.J. (2009). N-Acetylcysteine: Multiple clinical applications. *Am Fam Physician*. 80 (3), 265-269.
- Mroz, L.S., Benitez, J.G. & Krenzelok, E.P. (1997). Angioedema with oral- N-Acetylcysteine. *Ann Emerg Med*. 30(2), 240-241.
- Mullins, M. & Vitkovitsky, I. (2011). Hemolysis and hemolytic uremic syndrome following five-fold N-acetylcysteine overdose. *Clin Toxicol*. 49(8), 755-759.
- National Institutes of Health (NIH). (2010). A Multi-center Comparison of the Safety of Oral versus Intravenous Acetylcysteine for Treatment of Acetaminophen Overdose. The Toxicology Investigator Network Authorship Group. *Clin Toxicol*. 48(5), 424-430. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2894984/>
- O' Geen, R., Solleel, D.R., Schauben, J.L., Kunisaki, T.A., Aaronson, P. M., Smotherman, C. (2013). Use of N-acetylcysteine therapy beyond the 21-hour intravenous protocol for acetaminophen toxicity. *Clin Toxicol*. 51(7), 607.
- Pakravan, N., Waring, W.S., Sharma, S., Ludlam, C., Megson, I., Bateman, D.N. (2008). Risk factors and mechanisms of anaphylactoid reactions to acetylcysteine in acetaminophen overdose. *Clin Toxicol*. 46(8),697-702.
- Perry, H.E., & Shannon, M.W. (1998). Efficacy of oral versus intravenous N-acetylcysteine in acetaminophen overdose: Results of an open-label, clinical trial. *J Pediatr*. 132(1), 149-52.
- Prescott, L. (2004). Oral or Intravenous N-Acetylcysteine for acetaminophen poisoning? *Ann Emerg Med*. 45(4), 409-413.
- Prescott, L.F., Illingworth, R.N., Critchley, J.A., Stewart, M.J., Adam, R.D., Proudfoot, A.T. (1979). Intravenous N-acetylcysteine: The treatment of choice for paracetamol poisoning. *Br Med J*. 2 (6198), 1097-1100.
- Prescott, L.F., Newton, R.W., Swainson, C.P., Wright, N., Forrest, A.R., Matthew, H. (1974). Successful treatment of severe paracetamol overdosage with cysteamine. *Lancet*. 1974 303 (7858):588-592.
- Prescott, L.F., Park, J., Ballantyne, A., Adriaenssens, P., Proudfoot, A.T. (1977). Treatment of paracetamol (acetaminophen) poisoning with N-acetylcysteine. *Lancet*. 310 (8035), 432-434.
- Prescott, L.F., Stewart, M.J., Proudfoot, A.T. (1978). Cysteamine or N-acetylcysteine for paracetamol poisoning? *Brit Med J*. 1 (6116), 856-857.
- Quail, M.T. & Boyer, E.W. (2013). Acetaminophen toxicity. *J Legal Nurse Consul*. 24 (2), 22-30.
- Rumack, B.H., & Bateman, D.N. (2012). Acetaminophen and acetylcysteine dose and duration; past, present and future. *Clin Toxicol*. 50 (2), 91-98.
- Sandilands, E.A. & Bateman, D.N. (2009). Adverse Reactions Associated With Acetylcysteine. *Clin Toxicol*. 47(2), 81-88
- Schmidt, L. E. (2013). Identification of patients at risk of anaphylactoid reactions to N-acetylcysteine in the treatment of paracetamol overdose. *Clin Toxicol*. 51, 467-472.
- Selbst, S.M. & Osterhoudt, K. (2012). Pediatric emergency medicine: Legal briefs. *Pediatr Emerg Care*. 28 (12), 1402-1405.
- Senarathna, S.M., Sri Ranganathan, S., Buckley, N., Fernandopulle, R. (2012). A cost effectiveness analysis of the preferred antidotes for acute paracetamol poisoning patients in Sri Lanka. *BMC Pharmacol Toxicol*. 12 (6). Retrieved From <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3350452/>
- Shannon, M.W. & Salhanick, S.D. (2007). Acetaminophen. In M. Shannon, S. Borron & M. Burns (Eds), Haddad and Winchester's Clinical Management of Poisoning and Drug Overdose. 4th Ed. (pp. 825-834). Philadelphia, PA: Saunders/Elsevier.
- Smilkstein, M.J., Knapp, G.L., Kulig, K.W., Rumack, B.H. (1988). Efficacy of Oral N-Acetylcysteine in the treatment of acetaminophen overdose. analysis of the national multicenter study (1976-1985). *New Engl J Med*. 319 (24), 1557-1562.
- Smith, S.W., Howland, M.A., Hoffman, R.S., Nelson, L.S. (2008). Acetaminophen overdose with altered acetaminophen pharmacokinetics and hepatotoxicity associated with premature cessation of intravenous N-acetylcysteine therapy. *Ann Pharmacother* 42 (9), 1333-1339.
- Smollin, C.G. (2010). Toxicology: Pearls and Pitfalls in the use of antidotes. *Emerg Med Clin N Am*. 28, 149-161.
- Sporer, K.A. & Khayam-Bashi, H. (1996). Acetaminophen and salicylate serum levels in patients with suicidal ingestion or altered mental status. *Am J Emerg Med*. 14 (5), 443-446.
- Sunman, W., Hughes, A.D., & Sever, P.S. (1992). Anaphylactoid response to intravenous acetylcysteine. *The Lancet*. 339(8803), 1231-1232.
- Terneus, M.V., Brown, J.M., Carpenter, A.B., Valentovic, M.A. (2008). Comparison of S-Adenosyl-L-methionine (SAME) and N-Acetylcysteine (NAC) Protective effects on hepatic aamage when administered after acetaminophen overdose. *Toxicology*. 244(1),25-34. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2247417/>
- Terneus, M.V., Kinningham, K.K., Carpenter, A.B., Sullivan, S.B., Valentovic, M.A. (2007). Comparison of S-Adenosyl-L-methionine and N-acetylcysteine protective effects on acetaminophen hepatic toxicity. *J Pharmacol Exp Ther*. 320(1), 99-107. Retrieved from <http://jpet.aspetjournals.org/content/320/1/99.full.pdf+html>
- Ternullo, S. (2006). Acetadote (Intravenous Acetylcysteine): Adverse effects more significant than with oral Acetylcysteine. *J Emerg Nurs*. 31 (1). 98-100.
- Tomaszewski, C. (2006). Off-Label: Just What the Doctor Ordered. *J Medical Toxicology*. 2(3), 87-88. Retrieved from http://download.springer.com/static/pdf/572/art%253A10.1007%252FBF03161014.pdf?auth66=1392210049_73ca9fad4b2a4a08e3d12661e677f3b5&text=.pdf.
- Treinen-Mosle, M. (2003). Chapter 13 Toxic responses of the liver. In C.Klaassen & J. Watkins

III (Eds), Casarett & Doull's Essentials of Toxicology. (pp. 194-207). New York:McGraw-Hill

US FDA CDER, NDA 21-539 (2002). Clinical pharmacology and biopharmaceutics review (s). Acetadote® (acetylcysteine) Initial application. Retrieved from http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/21-539_acetadote_biopharmr.pdf

U.S. Food and Drug Administration (US FDA) Approved Drug Products (2013). Acetylcysteine. Retrieved from <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=SearchDrugDetails>

US FDA CDER, NDA 21-539/S-004 Acetadote® (acetylcysteine) Injection Package Insert 2006 Retrieved from http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021539s004lbl.pdf

US FDA CDER, NDA # 21-539, 2002. Intravenous N-Acetylcysteine- Package Insert 2004 http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21539slr002_acetadote_lbl.pdf

U.S. Pharmacopeial (USP) Convention. (2013). USP Compounding Standards & Resources Retrieved from <http://www.usp.org/usp-healthcare-professionals/medicare-model-guidelines>

Vale, J.A., Meredith, T.J., Goulding, R. (1981). Treatment of acetaminophen poisoning. The use of oral methionine. Arch Intern Med. 141(3),394-396.

Waring, W. S. (2012). Novel Acetylcysteine Regimens for Treatment of Paracetamol Overdose. Ther Adv Drug Safety. 3(6), 305-315. Retrieved from <http://www.medscape.com/viewarticle/775254>

Waring, W.S., Stephen, A.F., Robinson, O.D., Dow, M.A., Pettie, J.M. (2008). Lower incidence of anaphylactoid reactions to N-acetylcysteine in patients with high acetaminophen concentrations after overdose Clin Toxicol. 46(6), 496-500.

Yarema, M.C., Johnson, D.W., Berlin, R.J., Sivilotti, M.L., Nettel-Aguirre, A., Brant, R.F., et al. (2009). Comparison of the 20-hour intravenous and 72-hour oral acetylcysteine protocols for the treatment of acute acetaminophen poisoning. Ann Emerg Med. 54 (4), 606-614.

Yip, L., Dart, R.C., Hurlbut, K. M. (1998). Intravenous administration of oral N-Acetylcysteine. Crit Care Med. 26 (1). 40-43.

Zyoud, S.H., Awang, R., Sulaiman, S.A., Al-Jabi, S.W. (2011). N-acetylcysteine-induced headache in hospitalized patients with acute acetaminophen overdose. Fund Clin Pharm. 25(3), 405-410.

Zyoud, S.H., Awang, R., Syed-Sulaiman, S.A., Sweileh, W.M., Al-Jabi, S.W. (2010). Incidence of adverse drug reactions induced by N-acetylcysteine in patients with acetaminophen overdose. Hum Exp Toxicol. 29(3), 153-160.

M. Thomas Quail, MS Ed, R.N., LNC, EMT-B has a background in Emergency Medicine that spans more than 30 years. He has been an EMT for 39 years, an RN for 31 years, and an LNC for 12 years. From 2000-2009, Quail was employed as the clinical coordinator for the Commonwealth of Massachusetts Department of Public Health (DPH), Office of Emergency Medical Services investigating complaints of patient care issues. Quail is currently employed at the DPHs' Bureau of Environmental Health, where he is conducting research to answer public health concerns to see if environmental factors are connected to specific health issues and disease. He conducts medical records reviews with regard to amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, and has assisted in the first ALS Registry named after former Governor Argeo Paul Cellucci. Quail provides continuing education lectures for Nurses and EMTs in pre-hospital emergency medicine, forensics, and toxicology. He has articles published in the field of Emergency Medicine, Forensic Science, Hematology, Law Enforcement, Legal Nursing, Nursing, Pre-Hospital Emergency Care, and Toxicology. He is a member of the Southern New England Chapter of the AALNC and American Academy of Clinical Toxicology; associate member of the American Association of Legal Nurse Consultants and Northeastern Association of Forensic Scientists and a charter member of the National Association of Emergency Medical Technicians. Quail may be reached at tom.quail@state.ma.us.

Edward W. Boyer MD, PhD, is Chief of the Division of Medical Toxicology at the University of Massachusetts. He received his doctorate in chemistry from Columbia University and was a NIH postdoctoral fellow at The Rockefeller University. He earned his MD degree from the Columbia College of Physicians and Surgeons before completing residency in emergency medicine at the Hospital of the University of Pennsylvania. After fellowship training at Boston Children's Hospital, he joined the faculty of the University of Massachusetts, where he is Professor of Emergency Medicine.

| Case # | Authors (Yr. Pub.) | Patient Info. | Acetaminophen Quantity (Level/Time) | Therapy Route (Dose) | Adverse Event | Comments |
|--------|---|--|--|---|---|---|
| 1 | Bailey, et al (1987) | 3- yo M Hx: cystic fibrosis Dx: meconium ileus obstruction | NA (NA) | PO/PR (Therapeutic) | Liver function abnormalities | Two admissions with same diagnosis. Drug induced hepatic injury |
| 2 | Mroz, et al (1997) | 26-yo M Dx: Overdose | 70-80 grams (346 mcg/mL @ 11 hrs) | PO/PR (Therapeutic) | Liver function abnormalities Angioedema No airway compromise | Delayed effects. Recovered |
| 3 | Appelboam et al (2002) | 40-yo F Hx: Asthma, Clear Lung Sounds Dx: Overdose | 15 grams over 24 hrs (NA) | IV (Therapeutic) | Dyspnea, Wheezing Cyanotic, Respiratory Arrest | Death |
| 4 | Cassidy et al (2008) | 38-yo M Dx: Overdose | 20-24 grams 75 minutes prior (362 mcg/mL @2 hrs No true 4-hr level drawn) | IV (Therapeutic) | Flushing, Urticaria, Hypotension, Respiratory, Depression, Bradycardia, Asystole | Recovered |
| 5 | Little et al (2005) | 73-yo F Dx: Overdose | Unk Qty. (410 mcg/mL @6hrs) | IV (10-fold Under dose) | Liver function abnormalities | Recovered |
| 6 | Little et al (2005) | 28-yo F Dx: Overdose | 35 grams (362 mcg/mL @4hrs) | IV (10-fold Under dose) | Liver function abnormalities | Recovered |
| 7 | Heard et al (2011) Selbst et al (2012) | 21-yo F Dx: Therapeutic Error | 7.5-10 grams (128 mcg/mL @ 6-hrs) | IV (Massive Overdose) | Seizures Cerebral edema Uncal herniation | Profound neurological injury. In persistent vegetative state. \$15.5 Million Settlement |
| 8 | Mullins et al (2011) | 21-yo F Dx: Overdose | Unk Qty. (200 mcg/mL @4hrs) | IV (5-fold Overdose) | Hematuria Rise creatinine levels | Required dialysis Dx; Atypical Hemolytic-Uremic syndrome |
| 9 | Elms et al (2011) Bronstein et al (2010) | 53- yo M No cardiac Hx. Dx: Overdose | Unk Qty. (49 mcg/mL @ Unk Time) | IV (Massive 10-fold Overdose) | Peri-orbital edema Rash Bradycardia Hypotension ST Elevation Myocardial Infarction | Death |
| 10 | Bronstein et al (2009) | 18-yo F Dx: Overdose | Unk Qty. (200 mcg/mL @4-hr) | IV (Massive Overdose) | Seizures Cerebral edema Herniation Asystole | Death |
| 11 | Bailey et al (2004) | 30- m F Dx: Unintentional Overdose | Allegedly took ~418mg/kg (Toxic qty.) (NA) | IV (Massive Overdose) Bag 1 10 fold Bag 2 32.5 fold Bag 3 32.5 fold | Myoclonus Respiratory arrest Cerebral edema Uncal Herniation. | Death Later determined child took non-toxic amount |
| 12 | Lorentzen et al (2002) | 14-yo F Dx: Overdose | 4 grams (44 mcg/mL @Unk time) | IV (5-fold Overdose) | Facial flushing Vomiting Angioedema Hypotension | Abnormal Eosinophil levels Recovered |
| 13 | Anonymous et al (1984) | 4-yo M Dx: Unintentional Overdose | 1800 mg (45 mcg/mL @5hr non-toxic level) | IV (2-fold Overdose) | Cyanotic Hypotension Tachycardia Small bilateral subdural hematomas | Death |
| 14 | Mant et al (1984) | 32-yo F Dx: Overdose | Unk Qty. (145mcg/mL @12hrs) | IV (10-fold Overdose) | Flushing Hypotension Disseminated intravascular coagulation Hepato-Renal failure | Death |
| 15 | Kao et al (2003) | 37-yo M Dx: Drug Abuse | Unk Qty. / (80 mcg/mL @unk) | PO Administered IV (Therapeutic) | Hypoxia Apnea Bradycardia Atrial fibrillation Ventricular fibrillation Asystole | Recovered |

Nursing Malpractice: Costs, Trends, and Issues

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

KEY WORDS

Malpractice, Claims, National Practitioner Data Bank (NPDB), Doctrine of Respondeat Superior

The National Practitioner Data Board (NPDB) classifies “professional nurses” into five licensure categories: non-specialized registered nurse, nurse practitioner, nurse anesthetist, nurse midwife, and clinical nurse specialist. According to the NPDB Report (2012), between 1990 and 2011 all types of professional nurses had a total of 9,278 monetary malpractice payments, with an approximate mean of \$282,297 per claim. Nurses must be concerned about malpractice litigation because each nurse is accountable for his or her own acts of negligence. To help decrease the risk of a malpractice claim, every nurse should know his or her nurse practice act, relevant laws and legal doctrines, agency policies and procedures, and applicable standards of care that impact daily clinical practice.

Despite continuous efforts to educate nurses on the law and their professional responsibilities through nursing programs and continuing education courses, the number of nurses named as defendants in malpractice actions continues to increase (Austin, 2009; CNA Health Pros and Nurse Service Organization (NSO), 2009; Croke, 2003; Croke, 2006; Dumrose, 2007; Guido, 2010; Miller, 2011; National Practitioner Data Bank Report (NPDB), 2012; Nolo, 2012a; Rasansky, 2012; Stein, 2000). Various reasons identified in the medical and nursing literature for this continuous trend have included shortage of qualified nurses, healthcare provider fatigue, improper supervision/delegation, miscommunication, early patient discharge, hospital downsizing, increased autonomy, advanced technology, inadequate training, high-level clients, short-staffing, failure to follow standard clinical nursing practice, and better-informed consumers (Austin, 2009; Croke, 2006; Guido, 2010; Nolo, 2012a; Stein, 2000). “Any errors in patient care often result in [a] patient’s death due to multiple complications and [may] lead a nurse into serious medical litigations under the medical malpractice law” (American Society of Registered Nurses, 2007, para 3). In 1999, the Institute of Medicine (IOM) reported that medical errors are responsible for between 44,000 and 98,000 patient deaths annually at an annual cost to the nation of approximately \$37.6 billion and approximately \$17 billion of the annual costs are associated with preventable errors (Graham, 2009).

Nolo (2012a) cites the national average payout for medical (doctor) malpractice negligence is approximately \$285,000.

Malpractice is the legal term for an act of negligence by any licensed professional (Stein, 2000). The Joint Commission (nd) defines negligence as a

“failure to use such care as a reasonably prudent and careful person would under similar circumstances” and malpractice as “improper or unethical conduct or unreasonable lack of skill by a holder of a professional or official position; often applied to physicians, dentists, lawyers, and public officers to denote negligent or unskilled performance of duties when professional skills are obligatory. Malpractice is a cause of action for which damages are allowed” (Croke, 2003, p.54-55).

For a nurse to become liable in a malpractice action, certain legal elements must be proven by the plaintiff before a successful case can be brought against the defendant nurse. Except as noted under the doctrine *res ipsa loquitur*, these liability elements include the following:

- Duty—nurse-patient relationship; employment relationship
- Breach of Duty—act of omission or commission in standard of care (SOC)
- Foreseeability—foresee a certain result based on actions or lack of actions at the time of occurrence
- Causation—breach in standard of care caused injury (cause-effect)
- Injury—physical, financial, emotional
- Damages—monetary awards

Each nurse is responsible for his or her own acts of negligence, but hospitals and doctors can also be held accountable. Under the doctrine of *respondeat superior*, the employer is responsible and accountable for an employee’s negligent acts. Because most nurses are employees of hospitals, hospitals are common defendants in nursing malpractice litigation (Nolo, 2012b). Common reasons for hospital liability for negligence of employees are:

- Negligent hiring or firing of employees
- Failure to ensure competency and continuing competency of employees
- Understaffing of healthcare providers
- Mislabeling medication

- Health Insurance Portability and Accountability Act violations
 - Failure to provide a safe environment
- (Berg, n.d.; "Identifying Nursing Negligence," 2007).

Research has shown that hospitals with high nurse-patient ratios experience higher patient mortality rates, decreased quality patient care, increased complaints of nurse burnout, and job dissatisfaction (Aiken et al., 2002; Aiken et al., 2010; Stanton, 2004)

Jenkins & Lemak (2009) reported "research on jury verdicts indicates that the median plaintiff award against hospitals and their employed health care providers is about \$500,000"... and the average 250 bed hospital spends between \$300,000 and \$1 million dollars annually defending medical malpractice lawsuits, not including settlements and judgments (p. 52). Specialized nurses, known as legal nurse consultants (LNC), often work with attorneys on medical-legal related cases. The LNC helps the attorney "understand and analyze complex medical data" encountered in the client's medical records. Duties of the LNC may include:

- Screening cases for merit
- Locating and interviewing witnesses and preparing witness reports for trial
- Formulating medical-legal theories
- Handling plaintiff's medical records
- Analyzing and interpreting information for defense attorneys
- Serving as an expert witness ("What does a legal nurse consultant," 2013,p.1)

Nurses must be concerned about malpractice litigation because each nurse is accountable for his or her own acts of negligence. To help decrease the risk of a malpractice claim, every nurse should know his or her nurse practice act, relevant laws and legal doctrines, agency policies and procedures, and applicable standards of care impacting daily clinical practice. The following website provides a state-by-state summary of medical malpractice laws.

<http://www.medicalmalpractice.com/lawsuit-and-award-limits/medical-malpractice-statutes.htm>

CLAIMS and COSTS

Nurses and nursing students can be held liable for their actions or non-actions, and thus can be sued (Learning Express Editor, 2011). "Once money is exchanged through an out-of-court settlement or jury award, the nurse's name is automatically reported to the state board of nurse examiners, to insurers, and to the federal government's National Practitioner Data Bank" (NPDB) (Stein, 2000,p.1).

Types of Malpractice Claims Against Nurses

The most common malpractice claims against nurses identified in the medical and nursing literature between 2000 and 2012 include:

- Failure to get informed consent from the patient

- Failure to use a medical device properly
- Failure to follow the standard of care
- Failure to communicate
- Failure to assess and monitor
- Failure to act as a patient advocate
- Failure to update a physician on a patient's condition
- Failure to document
- Failure to properly supervise a patient resulting in harm
- Negligent delegation and supervision
- Medication errors
- Working while impaired: controlled substances, alcohol or fatigue

The NPDB collects information on health care practitioners who, as a result of judgments in malpractice suits, have entered into settlements, had disciplinary action taken against them that resulted in their licenses being revoked or suspended, had their privileges to practice limited, or had to pay monetary awards (Croke, 2003; Croke, 2006).

According to the NPDB Report (2012) (Table 1) between 1990 and 2011 all types of professional nurses had a total of 9,278 monetary malpractice payments with an approximate mean of \$282,297 per claim. The majority of payments made were less than or equal to \$50,000, with the smallest number of payments made for amounts greater than \$2,000,000. Similarly, as shown in Table 2, CNAHealth Pro and Nurse Service Organization (NSO) examined professional nurse liability payments made on behalf of CNA insured professional nurses. Table 2 reports professional nurse indemnity payments for closed claims for four separate CNAHealth Pro and NSO claims analysis periods. The highest and lowest amounts of closed claims awarded with an indemnity payment greater than \$10,000 were made on behalf of registered nurses (RNs) and licensed vocational nurses (LVN/LPN), respectively. CNAHealth Pro and NSO (2011) reported RNs had an average paid indemnity of \$168,438 while LVNs average paid indemnity was \$83,213. Nurse practitioner indemnity payments increased overtime from \$16 million to more than \$44 million. CNAHealth Pro and NSO reported that in 2009, the average paid indemnity for a nurse practitioner closed claim greater than \$10,000 was \$186,282, and increased to an average indemnity payment of \$221,852 in 2012 – a 19% increase (CNAHealth Pro and NSO, 2012). As members of the profession of nursing seek greater autonomy in their clinical practice arenas, outcomes of increased responsibility, accountability, and potential liability arise (DiCicco-Bloom, 2009).

Table 3 shows the top three closed claim clinical practice areas reported by CNAHealth Pro and NSO Reports. The top two clinical practice areas for nurse practitioners' liability have remained consistent through all CNAHealth Pro and NSO Reports – physicians offices and outpatient clinics. For RNs and LVNs the hospital environment has remained the highest area of liability. Painter, Dudjak, and Kidwell (2011) reported a literature review revealed that most

Table 1: NPDB Nursing Malpractice Payment Range by Numbers of Professional Nurse Payments (1990-2011)

| Malpractice Payment Range | Number of Payments |
|---------------------------|--------------------|
| <\$50,000 | 3,185 |
| \$50,000-\$99,999 | 1,368 |
| \$100,000-\$249,999 | 2,019 |
| \$250,000-\$499,999 | 1,239 |
| \$500,000-\$999,999 | 838 |
| \$1,000,000-\$1,999,999 | 434 |
| >=\$2,000,000 | 195 |
| Total Number of Payments | 9,278 |

Note. Adapted from:
National Practitioner Data Bank. Malpractice Payment Range by Number of Professional Nurse Payments. Data Source: National Practitioner Data Bank (2012). Adverse Action and Medical Malpractice Reports (1990-2011).

Table 2: CNAHealth Pro and Nurse Service Organization (NSO) Closed Claims for Professional Nurse Liability

| Claim Study Years | Professional Licensure | Number of Closed Claims Examined With Paid Indemnity Greater than \$10,000 | Total Paid Indemnity Payments |
|-------------------|---------------------------|--|-------------------------------|
| 1994-2004 | Nurse Practitioner | 107 | \$16,453,890 |
| 1998-2008 | Nurse Practitioner | 96 | \$39,067,185 |
| 2006-2010 | Registered Nurse | 474 | \$79,839,387 |
| | Licensed Vocational Nurse | 42 | \$3,494,965 |
| 2007-2011 | Nurse Practitioner | 200 | \$44,370,490 |

Note. Adapted from:
CNAHealth Pro and Nurses Service Organization (2005). Nurse practitioner claim study, 1994-2004. Retrieved from: www.nso.com/NPclaimstudy2005 CNAHealth Pro and Nurses Service Organization (2008). CNAHealth Pro nurse claims study: An analysis of claims with risk management recommendations 1997-2007. Retrieved from: <http://www.nso.com/nursing-resources/claim-studies.jsp>. CNAHealth Pro and Nurses Service Organization (2009). Understanding nurse practitioner liability. Retrieved from: www.nso.com/NPclaimstudy2009. CNAHealth Pro and Nurses Service Organization (2011). Understanding nurse liability, 2006-2010: A three-part approach report. Retrieved from: www.nso.com/rnclaimreport2011. CNAHealth Pro and Nurses Service Organization (2012). Nurse practitioner 2012 liability update: A three-part approach. Retrieved from: <http://www.nso.com/nursing-resources/claims-studies.jsp>

Table 3: Top Three Closed Claim Clinical Practice Areas/Settings Reported by CNAHealth Pro and NSO Reports

| 1994-2004 Nurse Practitioner | 1998-2008 Nurse Practitioner | 2006-2010 Registered Nurse (RN) | 2006-2010 Licensed Vocational Nurse (LVN) | 2007-2011 Nurse Practitioner |
|---------------------------------|---------------------------------|------------------------------------|--|------------------------------------|
| Physicians' Office | Medical Care Office | Hospital PACU | Hospital-Inpatient Surgical Service | Physicians' Office |
| Non-Hospital Based Clinics | Clinic-Non-Hospital Based | OB Outpatient Services | Patient's Home | Community-Based Outpatient Clinics |
| Hospital Inpatient | Nursing Home | Clinic-Hospital Outpatient | Hospital-Inpatient Medical Service | Skilled Nursing Facilities |

Note. Adapted from:

CNAHealth Pro and Nurses Service Organization (2005). Nurse practitioner claim study, 1994-2004. Retrieved from: www.nso.com/NPclaimstudy2005 CNAHealth Pro and Nurses Service Organization (2008). CNAHealth Pro nurse claims study: An analysis of claims with risk management recommendations 1997-2007. Retrieved from: <http://www.nso.com/nursing-resources/claim-studies.jsp> CNAHealth Pro and Nurses Service Organization (2009). Understanding nurse practitioner liability. Retrieved from: www.nso.com/NPclaimstudy2009. CNAHealth Pro and Nurses Service Organization (2011). Understanding nurse liability, 2006-2010: A three-part approach report. Retrieved from: www.nso.com/rnclaimreport2011 CNAHealth Pro and Nurses Service Organization (2012). Nurse practitioner 2012 liability update: A three-part approach. Retrieved from: <http://www.nso.com/nursing-resources/claims-studies.jsp>

Table 4: Top Three Closed Claim Clinical Specialties Reported by CNAHealth Pro and NSO Reports

| 1994-2004 Nurse Practitioner | 1998-2008 Nurse Practitioner | 2006-2010 Registered Nurse (RN) | 2006-2010 Licensed Vocational Nurse (LVN) | 2007-2011 Nurse Practitioner |
|---------------------------------|---------------------------------|------------------------------------|--|---------------------------------|
| Family Practice* | Adult/Geriatric | Neurology/ | Hospital-Inpatient Surgical Service | Physicians' Office |
| Adult/Geriatrics* | Family Medicine | Obstetrics | Home Health | Family Practice |
| Obstetrics/Gynecology | Pediatric/Neonatal | Plastic/Reconstructive | Hospice | Behavioral Health |

Note. Adapted from:

CNAHealth Pro and Nurses Service Organization (2005). Nurse practitioner claim study, 1994-2004. Retrieved from: www.nso.com/NPclaimstudy2005 CNAHealth Pro and Nurses Service Organization (2008). CNAHealth Pro nurse claims study: An analysis of claims with risk management recommendations 1997-2007. Retrieved from: <http://www.nso.com/nursing-resources/claim-studies.jsp>. CNAHealth Pro and Nurses Service Organization (2009). Understanding nurse practitioner liability. Retrieved from: www.nso.com/NPclaimstudy2009. CNAHealth Pro and Nurses Service Organization (2011). Understanding nurse liability, 2006-2010: A three-part approach report. Retrieved from: www.nso.com/rnclaimreport2011 CNAHealth Pro and Nurses Service Organization (2012). Nurse practitioner 2012 liability update: A three-part approach. Retrieved from: <http://www.nso.com/nursing-resources/claims-studies.jsp>

malpractice cases involving a nurse occurred in the acute care hospital and involved non-specialized RNs. Similarly, the Joint Commission (2012, Dec.31) reported the hospital environment has remained the top area for sentinel events from 2004-2012. The Joint Commission defines a sentinel event

“as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness. Sentinel events specifically include loss of a limb or gross motor function, and any event for which a recurrence would carry a risk of a serious adverse outcome” (Wikipedia, 2013, p.1).

Table 4 shows the top three closed claim clinical specialties reported by the CNAHealth Pro and NSO Reports. Family practice and adult/geriatrics have consistently remained the highest clinical practice specialties for liability claims for nurse practitioners. For RNs and LVNs, the only common clinical practice specialty involved the surgical environment.

Reducing Potential Liability

Malpractice litigation is both professionally and emotionally devastating to a nurse. “Each nurse can take steps to help reduce potential liability by using caution and common sense and by maintaining a heightened awareness of his or her legal responsibilities” (Croke, 2003, p.62). The following are ways nurses can help reduce potential liability:

- Using nursing judgment on a case-by-case basis. Utilizing each step of the nursing process and critical thinking may reduce the likelihood of “bad outcomes” that commonly lead to nursing malpractice (Giordano, 2003).
- Maintain open, honest, respectful relationships and communication with patient's family members, and physicians. Poor communication may exist amongst nurse physician, nurse and other healthcare providers, and nurse-patient/family. Timely reporting changes in the patient condition to the physician is the most common communication basis for nursing malpractice. Research has shown patients are less likely to initiate a lawsuit if they believe the nurse has been caring and professional (Croke, 2003; Reising & Allen, 2007).
- Maintain competence in your specialty area of practice. Each nurse needs to attend relevant continuing education programs, remain up to date on professional certification requirements and continue to expand professional knowledge, skills and experience (McCarthy, 2013).
- Each nurse needs to document all pertinent data, and do it contemporaneously – not after the fact. Documentation must reflect the nursing process. Documenting in the medical record after a lawsuit has been threatened by a patient or member of a patient's family – is a common and costly mistake for nurses. Chart – Factually, Accurately, Completely and Timely (Guido, 2014, Stein, 2000).

- Follow chain of command. A nurse's belief on a patient care issue may require action beyond a discussion of the nurse's concerns with the physician. If the nurse's concern is not resolved – the facility's nursing hierarchy chain of command should be activated (Reising & Allen, 2007).
- Obtain informed consent. Obtaining a patient's informed consent is needed to prevent charges of battery against a healthcare provider.
- Practice within the bounds of professional licensure. Each nurse must perform only the nursing skills allowed by the state nurse practice act, and state and federal laws (Croke, 2006; Guido, 2014; McCarthy, 2013; Reising,& Allen, 2007).
- Know your strengths and weaknesses – each nurse must examine if he or she has the skill, knowledge, and experience to carry out the assignment. If the nurse does not believe he or she has the competency – this lack of skill must be reported prior to accepting the assignment (Croke, 2003, Reising, & Allen, 2007).

Hospitals can reduce risk of malpractice claims by increasing RN staffing. Research has shown that limiting nurse workloads has a positive impact on quality and safety of patient care, fewer medical errors, increased nurse satisfaction and nurse retention, decreased adverse patient outcomes, and lowered patient mortality rates (Aiken et al., 2002; Aiken et al., 2010; Stanton, 2004). A facility's communication policy that is known to both physicians and nursing staff can help reduce risk of liability.

Due to an ever-changing practice care environment, nurses are facing a plethora of ethical and legal dilemmas that increase their risk of becoming named in a malpractice litigation process. Nurses are being held accountable to the public for their professional judgment, actions, and outcomes. To help decrease liability, nurses must render safe and competent nursing care, recognize potential problems, identify potential risks in their practice care arena, and remain competent in technology and evidence-based practices (Guido, 2014).

References

- References
- Aiken, L., Clarke, S., Sloane, D., Sochalski, J., & Silber, J. (2002, Oct.) Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. *Journal of American Medical Association (JAMA)*. 288(160, 1987-1993.
- Aiken, L., Sloane, D., Cimioli, J., Clark, S., Flynn, L., Seago, J., ... & Smith, H. (2010). Implications of the California nurse staffing mandate for other states. Retrieved from: <http://www.onlinelibrary.wiley.com>
- American Society of Registered Nurses (2007, Nov.). Examining medication errors. Retrieved from: <http://www.asn.org/journal-nursing/201-examining-medication-errors.html>
- Austin, D. (2009, Feb.). Nurses malpractice-A form of medical malpractice. Retrieved from: <http://ezinearticles.com/?nurses-malpractice-a-form-of-medical-malpractice-on-the-rise&id=1996882>
- Berg, D. (n.d.). Negligence in a hospital setting. Retrieved from: <http://www.medicalmalpractice.com/resources/medical-malpractice/medical-negligence-law>

- CNAHealth Pro and Nurses Service Organization (2005). Nurse practitioner claim study, 1994-2004. Retrieved from: www.nso.com/NPclaimstudy2005
- CNAHealth Pro and Nurses Service Organization (2008). CNAHealth Pro nurse claims study: An analysis of claims with risk management recommendations 1997-2007. Retrieved from: <http://www.nso.com/nursing-resources/claim-studies.jsp>
- CNAHealth Pro and Nurses Service Organization (2009). Understanding nurse practitioner liability. Retrieved from: www.nso.com/NPclaimstudy2009.
- CNAHealth Pro and Nurses Service Organization (2011). Understanding nurse liability, 2006-2010: A three-part approach report. Retrieved from: www.nso.com/rnclaimreport2011
- CNAHealth Pro and Nurses Service Organization (2012). Nurse practitioner 2012 liability update: A three-part approach. Retrieved from: <http://www.nso.com/nursing-resources/claims-studies.jsp>
- Croke, E. (2003). Nurses, negligence, and malpractice. *American Journal of Nursing*, 103(9), 54-63.
- Croke, E. (2006, Summer). Nursing malpractice: Determining liability elements for negligent acts. *Journal of Legal Nurse Consulting*, 17 (3), 3-7; 24.
- DiCicco-Bloom, B. (2009). With increased autonomy comes increased responsibility, accountability, and potential liability. Are we ready? Retrieved from: <http://www.mycentraljersey.com/article/20090102/news/901020350/1003/newsfront>
- Domrose, C. (2007, Sept.). Malpractice suits against nurses on the rise. Retrieved from: <http://news.nurse.com/apps/pbcs.dll/article?aid=2007309030007>
- Giordano, K. (2003). Examining nursing malpractice: A defense attorney's perspective. Retrieved from: <http://www.ccn.aacnjournals.org>
- Graham, M. (2009, August). Statistics on healthcare quality and patient safety problems—Errors and harm. Retrieved from: <http://www.leanblog.org/2009/08/statistics-on-healthcare-quality-and-patient-safety-problems-Errors-and-harm>
- Guido, G. (2010). *Legal and ethical issues in nursing* (5th ed). N.J.: Pearson Hall.
- Guido, G. (2014). *Legal and ethical issues in nursing* (6th ed). N.J.: Pearson Hall
- Identifying nursing negligence. (2007). Retrieved from: <http://www.differenttypesofnurses.net/nursingnegligence/nursingnegligence.html>
- Institute of Medicine (1999, Nov.). To err is human: Building a safer health system. Retrieved from: <http://www.iom.edu/reports/1999/to-err-is-human-buildinding-a-safer-health-system.aspx>
- Jenkins, R. & Lemak, C. (2009, Aug.). A malpractice lawsuit simulation: Critical care providers learn as participants in a mock trial. *Critical Care Nurse* 29(4), 52-60.
- The Joint Commission (2012, Dec. 31). Sentinel event statistics 2004-2012 Retrieved from http://www.jointcommission.org/sentinel_event.aspx
- Kasprak, J. (2008, Aug. 21). Nurse malpractice. OLR Research Report. Retrieved from: <http://www.cga.ct.gov/2008/rpt/2008-R-0483.htm>
- Learning Express Editors (2011). Nursing ethics and legal issues. Retrieved from: <http://www.education.com/print/nursing-ethics>
- McCarthy, D. (2013). Is it malpractice? Retrieved from: <http://nursing.advancweb.com/editorial/content/printfriendly.aspx?cc=266574>
- Miller, K. (2011, Oct.). Malpractice: Nurse practitioners and claims reported to the national practitioner data bank. *The Journal for Nurse Practitioners-JNP*. 7(9), 761-763, 773.
- National Practitioner Data Bank (NPDB) (2012). Adverse action and medical malpractice reports (1990-2011). Retrieved from: <http://www.npdb-hipdb.gov/index.jsp>
- Nolo (2012a). What is the average payout in a negligence claim? Retrieved from: <http://www.medicalmalpractice.com/legal-advice/medical-malpractice/medical-negligence-lawsuits>
- Nolo (2012b). If you are injured by a nurse's negligence, you may have a claim for medical malpractice. Retrieved from: <http://www.nolo.com/legal-encyclopedia/nursing-malpractice-300076.html>
- Painter, L., Dudjak, L., & Kidwell, K. (2011, Oct-Dec.). The nurses role in the causation of compensable injury. *The Journal of Nursing Care Quality*, 26(4), 311-319.
- Rasansky, J. (2012). Nursing errors on the rise in hospitals around the country. Retrieved from: <http://www.jrlawfirm.com/library/medical-malpractice-lawyer-nursing-errors-on-the-rise.cfm>
- Stanton, M. (2004, March). Hospital nurse staffing and quality of care. Retrieved from: <http://www.ahrq.gov/research/findings/factsheets/services/nursestaffing/index.html>
- Stein, T. (2000). On the defensive. More patients are naming nurses in malpractice suits. Retrieved from: <http://www.nurseweek.com/features/00-05/malpract.html>
- The Joint Commission (n.d.). Sentinel event glossary of terms. Retrieved from: http://www.jointcommission.org/sentinelevents/se_glossary.htm
- Watson, E. & Hillman, H. (2011, Fall). Apology laws (I'm sorry)—purposes and legislation. *Journal of Legal Nurse Consulting*. 23(4), 25
- What does a legal nurse consultant do? (2013). Retrieved from: http://degreedirectory.org/articles/what_does_a_legal_nurse_consultant_do.html

Eileen Watson, EdD, RN, MSN, ANP, GNP, LNCC is an Associate Professor of Nursing at California State University, Long Beach, CA where she teaches the course Legal Issues in Health Care. She has been an independent contractor since 1989, specializing in plaintiff and defense medical malpractice. She serves as an expert witness for the California Board of Registered Nursing. She is an adult/geriatric nurse practitioner as well as a civil litigation paralegal. She is a national speaker and author in the areas of informed consent, advance directives and elder abuse. She can be contacted at eileen.watson@csulb.edu.

Wikipedia (2013, April 10). Sentinel event. Retrieved from: http://www.en.wikipedia.org/wiki/Sentinel_event

The Medical/Legal Aspects of Sexual Assault Nurse Examiner (SANE) Programs in Emergency Departments

Tammy Bimber, MSN, RN, CEN, SANE-A, SANE-Pc

Sexual Assault Nurse Examiner (SANE) programs in emergency departments are vital to meeting the medical and legal needs of victims of sex crimes. Sexual assault, sexual violence, and rape are crimes and traumatic events that have a profound impact on the physical and psychological health of its victims with long and complex recovery processes (Taylor, 2002; U.S. Department of Justice, 2013). In 2010, the Centers for Disease Control and Prevention (CDC) reported sexual assault as the sixth leading cause of nonfatal violence-related injury in the United States (US) for all age groups of both genders (CDC, 2007).

Introduction

Sexual assault victims are frequently referred to emergency departments (EDs). Emergency departments are often victims' first contact for assistance with medical, legal, and forensic treatment (Fehler-Cabral, Campbell, & Patterson, 2011; Henderson, Harada, & Amar, 2012). Since most sexual assault victims' injuries are not life threatening (including many who do not have physical injuries) and the diverse needs of sexual assault victims are not understood by many emergency physicians and nurses, the victims of sexual assault are frequently not recognized as requiring priority care in emergency departments (Fehler-Cabral et al., 2011; Ledray, 1999). For these reasons, programs for the care of sexual assault victims should be developed in emergency departments so that compassionate and quality care is able to be provided to these victims.

Rape, Sexual Assault, and Sexual Violence

Rape is a crime that is motivated by power and control and not through sexual desires. The perpetrator's sexual gratification is satisfied by dominating and humiliating the victim (Pennsylvania Coalition Against Rape, n.d.). Greater than 345,000 rapes and sexual assaults occur each year in the US to individuals age 12 and older, or to view this from an alternate perspective, a sexual assault occurs less than every two minutes in the United States (Truman, Langton, & Planty, 2012). One in six women and one in 33 men in the United States have been raped at some time in their lives (Tjaden & Thoennes, 2006). A woman is more likely to be sexually assaulted in her lifetime than to take up smoking (Lee, 2012). Even with such overwhelming statistics, only 3% of rapists will ever spend one or more days in jail (Rape, Abuse & Incest National Network, n.d.).

The U.S. Department of Justice (DOJ) and the CDC define sexual assault and sexual violence as completed or

attempted sexual acts that occur without the consent of an individual (CDC, 2009; The Federal Bureau of Investigation, 2012). In January 2012, the Federal Bureau of Investigation (FBI) announced the revision of the 1927 Uniform Crime Report definition of rape. The current definition of rape is "the penetration, no matter how slight, of the vagina or anus with any body part or object, or oral penetration by a sex organ of another person, without the consent of the victim" (The FBI, 2012, para. 1). The definition now includes male and female victims, victims who are unable to consent to sexual intercourse due to age (according to state statute), and incapacitation related to an individual's mental and physical abilities. The definition also takes into account female perpetrators, oral and anal penetration, and penetration of the vagina and anus with foreign objects thus allowing for more accurate statistics of rape to be reported and accounted for in the national crime data base (The FBI, 2012).

Sexual Assault Nurse Examiners

Sexual Assault Nurse Examiners are registered nurses who receive specialized training in the medical, forensic, and legal treatment of sexual assault victims (U.S. DOJ, 2013). Sexual Assault Nurse Examiners play a vital role in impacting the medical and legal outcomes of victims of sexual assault, sexual violence, and rape (Taylor, 2002). Sexual Assault Nurse Examiners are supported and considered the professionals of choice to conduct sexual assault exams by the American College of Emergency Physicians and the FBI (Houmes, Fagan, & Quintana, 2003).

Sexual Assault Nurse Examiner training initially involves at least a 40-hour didactic component and a clinical preceptorship with an experienced SANE (International Association of Forensic Nurses, n.d.). Complete SANE training is based on the current standards of care established by the International Association of Forensic Nurses (IAFN),

the guidelines of each state's nurse practice act, each healthcare organization's policies and procedures, and the forensic nursing scope and standards of practice (ANA and IAFN, 2009; U.S. DOJ, 2013).

Sexual Assault Nurse Examiners are essential to address the immediate and culturally diverse needs of victims of sexual assault in a caring and compassionate manner. Sexual Assault Nurse Examiners provide victims of sexual assault access to high quality, comprehensive medical and forensic evidence based standards of care. The SANE comprehensively documents victims' history of the assault and the forensic exam findings, properly collects and maintains chain of custody of forensic evidence, accurately interprets findings, and provides fact or expert witness testimonies to the judicial system. Treatment for physical injuries, sexually transmitted infection (STI), and pregnancy prophylaxis are based on victims' needs and beliefs (Taylor, 2002; U.S. DOJ, 2013). Sexual Assault Nurse Examiners refer victims to community agencies to provide a multidisciplinary community approach to help lessen the immediate and long-term physical and mental suffering and adverse health conditions that many victims experience (U.S. DOJ, 2013).

SANE Programs

The first three non-collaborating SANE programs originated in the US in the mid to late 1970s. Almost two decades later, the IAFN was established in 1992 and the ANA acknowledged forensic nursing as a specialty in 1995 (IAFN, n.d.). As a result, there are currently 600 SANE programs in the US (National Institute of Justice, 2012). Even though 90% of SANE programs are operated in emergency departments, when the number of SANE programs is compared to the number of emergency departments in the US, less than 15% of emergency departments have a SANE program (Hsia, Kellermann, & Shen, 2011; National Institute of Justice, 2012).

Sexual Assault Nurse Examiner programs are beneficial because they provide high quality standards of care and evidence collection to victims of sexual assault (National Institute of Justice, 2012). Sexual assault victims cared for at facilities with a SANE program were found to have been offered and have accepted more medical services, such as pregnancy prophylaxis and STI prophylaxis. Victims spend significantly less time in emergency departments with SANE programs and receive more community referrals for follow-up care. Rape kit collection techniques are completed properly and more rape kits are collected in emergency departments with SANE programs (Crandall & Helitzer, 2003; Littel, 2001). Sexual Assault Nurse Examiner programs assist law enforcement as evidenced by higher rates of victim cooperation with police. Victims have a better understanding of and trust in the judicial process, leading to more charges filed, higher arrest rates, higher rates of prosecution, and longer average sentences for perpetrators (Attorney General of Texas, 2011;

Campbell, Patterson, & Fehler-Cabral; Crandall & Helitzer, 2003; Markowitz, 2010; National Institute of Justice, 2012).

Sexual assault victims presenting to emergency departments without a SANE program receive lower standards of care than other victims of trauma. This is evidenced by waits up to 10 to 12 hours for treatment because their complaints and injuries are often viewed as less critical than other types of trauma victims. Physicians or nurses in emergency departments without SANE programs are often not adequately trained or prepared to care for the medical, forensic, and legal needs of victims of sexual assault which often results in poorer documentation of the victims' history and forensic examination, treatment regimes that do not meet the current recommended standards of care, and less time spent by emergency physicians and nurses in performing more thorough forensic exams creates little to no psychological support to these victims. Health care workers may blame these victims for their presenting complaints, causing them to refrain from seeking follow-up care. (Fehler-Cabral, Campbell, & Patterson, 2011; Ledray, 1999; Littel, 2001)

Sexual Assault Nurse Examiner programs should be located at sites that are victim-centered and meet the needs of the victim and the community. Emergency departments offer many advantages of having a developed SANE program over other community based locations. One of the primary advantages is an emergency department's hours of operation. Emergency departments are a protected environment open 24 hours a day, 7 days a week with numerous resources. Emergency departments' physicians are readily available on site for consultation about medications and injuries as needed. Most medications that are ordered can be administered to the victim prior to discharge, ensuring the victim receives the recommended treatment. Laboratory services are readily available to complete tests, such as pregnancy or toxicology screens, and to assist with blood draws if needed. Depending on the severity of the injuries, SANE programs located in emergency departments help to prevent the victim from being sent to another facility for treatment of injuries, which could potentially result in the loss of valuable forensic evidence (Littel, 2001).

Additionally, developing SANE programs in emergency departments would satisfy regulatory compliance. In 1992, The Joint Commission established requirements that each emergency and ambulatory care facility develop policies and practices to care for victims of sexual assault, and ED staff would be trained according to each institution's policy (Ledray, 2001; U.S. DOJ, 2013). The Joint Commission also requires each of these facilities to specify their roles and responsibilities for the forensic evidence collection and preservation (U.S. DOJ, 2013).

Cost Benefit of SANE Programs

In emergency departments without SANE programs, there are unrecognized and overlooked costs that are being absorbed into ED budgets associated with the examination and treatment of victims of sexual assault. The increased time victims spend in emergency departments, consuming more physicians and nursing resources is one of the associated unrecognized costs. The Urban Institute found that costs for forensic sexual assault exams conducted in hospitals are much higher if a physician performs the examinations as opposed to a SANE (Burt, Newmark, Olson, Aron & Harrell, 1997). Factoring costs from 1996 to 2013, a physician conducting an exam in 2013 would cost approximately \$1,200 whereas the cost of a SANE conducting the exam would be approximately \$300 to \$450. Sexual Assault Nurse Examiners completing exams results in a projected savings of up to 75% per exam. Emergency departments completing 25 forensic sexual assault exams per year would recognize an average annual savings of \$19,000 to \$23,000. Estimated startup costs for SANE programs can range up to \$30,000 to \$40,000, depending on equipment and training costs (Houmes et al., 2003). Initial SANE program costs would be easily offset within one to two years by the financial savings gained through SANEs completing sexual assault exams.

Savings to community agencies and the community as a whole occurs through SANE programs' collaboration with community resources. In 2008, each rape in the US was predicted to cost its victim over \$150,000 (Delisi et al., 2010). Not accounting for child sexual abuse cost, the annual bill for rape victims totaled over \$127 billion, making rape the most expensive crime for its victims (Miller, Cohen, & Wiersema, 1996). Victims who receive early community intervention services have better medical and legal experiences with less overall public-associated costs (Campbell, 2006; National Alliance to End Sexual Violence, n.d.). Communities further benefit from SANE programs because more perpetrators are incarcerated for longer periods of time, preventing these perpetrators from reoffending in the community (Attorney General of Texas, 2011).

Conclusion

Victims of sexual assault are entitled to high quality medical and forensic care. The evidence illustrates that SANE programs are a necessary part of emergency departments to provide high quality healthcare standards. Sexual Assault Nurse Examiner programs in emergency departments have many advantages over community-based programs. Collaboration of community resources through SANE programs improves the health and legal outcomes for victims while reducing overall expenses. Education should be provided to hospital administration, hospital board of directors, emergency nurses, emergency physicians, and community agencies on SANE programs to ensure success

in providing care to victims of sexual assault. Sexual Assault Nurse Examiner programs can be developed in any emergency department with thoughtful preparation and planning. Understanding the medical, legal, and forensic advantages, as well as the financial savings of SANE programs, are the first steps towards successful implementation of SANE programs in emergency departments.

References

- American Nurses Association and International Association of Forensic Nurses. (2009). *Forensic nursing: Scope and standards of practice*. Silver Spring, MD: Nursesbooks.org.
- Attorney General of Texas. (2011, March 31). Sexual assault nurse examiner (sane) program: Frequently asked questions. Retrieved from <https://www.oag.state.tx.us/victims/sane.shtml>
- Burt, M. R., Newmark, L. C., Olson, K. K., Aron, L. Y., & Harrell, A. V., U.S. Department of Justice, National Institute of Justice. (1997). 1997 report: Evaluation of the stop formula grants under the violence against women act of 1994. Retrieved from <http://www.urban.org/UploadedPDF/vaw97.pdf>
- Campbell, R. (2006). Rape survivors' experiences with the legal and medical systems: Do rape victim advocates make a difference? *Violence Against Women*, 12(1), 30-45. doi:10.1177/1077801205277539
- Campbell, R., Patterson, D., & Fehler-Cabral, G. (2010). Using ecological theory to evaluate the effectiveness of an indigenous community intervention: A study of sexual assault nurse examiner (SANE) programs. *American Journal of Community Psychology*, 46(3-4), 263-276. doi:10.1007/s10464-010-9339-4
- Centers for Disease Control and Prevention. (2009, November 9). Sexual violence: Definitions. Retrieved from <http://www.cdc.gov/violenceprevention/sexualviolence/definitions.html>
- Centers for Disease Control and Prevention, Office of Statistics and Programming, National Center for Injury Prevention and Control. (2007). 10 leading causes of nonfatal violence-related injury, United States. Retrieved from http://www.cdc.gov/ncipc/wisqars/nonfatal/quickpicks/quickpicks_2007/violall.htm
- Crandall, C. S., & Helitzer, D., U.S. Department of Justice. (2003). Impact evaluation of a sexual assault nurse examiner (SANE) program. (203276). Retrieved from <https://www.ncjrs.gov/pdffiles1/nij/grants/203276.pdf>
- Delisi, M., Kosloski, A., Sween, M., Hachmeister, E., Moore, M., & Drury, A. (2010). Murder by numbers: Monetary costs imposed by a sample of homicide offenders. *The Journal of Forensic Psychiatry & Psychology*, 21(4), 501-513. doi:10.1080/14789940903564388
- Fehler-Cabral, G., Campbell, R., & Patterson, D. (2011). Adult sexual assault survivors' experiences with sexual assault nurse examiners (SANEs). *Journal of Interpersonal Violence*, 26(18), 3618-3639. doi:10.1177/0886260511403761
- Henderson, E., Harada, N., & Amar, A. (2012). Caring for the forensic population: Recognizing the educational needs of emergency department nurses and physicians. *Journal of Forensic Nursing*, 8(2012), 170-177. doi:10.1111/j.1939-3938.2012.01144.x
- Houmes, B. V., Fagan, M. M., & Quintana, N. M. (2003). Establishing a sexual assault nurse examiner (SANE) program in the emergency department. *The Journal of Emergency Medicine*, 25(1), 111-121. doi:10.1016/S0736-4679(03)00159-8

- National Institute of Justice. (2012, May 30). Responses to sexual violence: Effectiveness of SANE/SART programs. Retrieved from <http://www.nij.gov/topics/crime/rape-sexual-violence/response.htm>
- Hsia, R. Y., Kellermann, A. L., & Shen, Y. (2011). Factors associated with closures of emergency departments in the United States. *Journal of the American Medical Association*, 305(19), 1978-1985. Retrieved from <http://jama.jamanetwork.com/article.aspx?articleid=1161864>
- International Association of Forensic Nurses. (n.d.). Becoming a forensic nurse. Retrieved from <http://iafn.org/displaycommon.cfm?an=1&subarticlenbr=577>
- Ledray, L. E. (2001, August). MINCAVA electronic clearinghouse. Retrieved from <http://www.mincava.umn.edu/documents/commissioned/2forensicvidence/2forensicvidence.html>
- Ledray, L.E., U.S. Department of Justice, Office of Justice Programs Office for Victims of Crime. (1999). Sexual assault nurse examiner (SANE) development & operations guide (NCJ 170609). Retrieved from <http://www.ojp.usdoj.gov/ovc/publications/infores/sane/saneguide.pdf>
- Lee, D. (2012, January 6). Rape more common than smoking in the US. Retrieved from <http://preventconnect.org/2012/01/rape-more-common-than-smoking-in-the-us/>
- Littel, K., U.S. Department of Justice, Office for Justice Programs. (2001). Sexual assault nurse examiner programs: Improving the community response to sexual assault victims (186366). Retrieved from https://www.ncjrs.gov/ovc_archives/bulletins/sane_4_2001/186366.pdf
- Markowitz, J. (2010, December). A Prosecutor's reference: Medical evidence and the role of the sexual assault nurse examiners in cases involving adult victims. Retrieved from http://www.aequitasresource.org/Prosecutor_Reference_Medical_Evidence.pdf
- Miller, T. R., Cohen, M. A., & Wiersema, B. National Institute of Justice, U.S. Department of Justice. (1996). Victims cost and consequences: A new look (NCJ 155282). Retrieved from website: <https://www.ncjrs.gov/pdffiles/victcost.pdf>
- National Alliance to End Sexual Violence. (n.d.). Cost, consequences and solutions. Retrieved from <http://endsexualviolence.org/where-we-stand/costs-consequences-and-solutions>
- Pennsylvania Coalition Against Rape. (n.d.). About sexual violence. Retrieved from <http://www.pcar.org/about-sexual-violence>
- Rape, Abuse & Incest National Network. (n.d.). Statistics. Retrieved from <http://www.rainn.org/statistics>
- Taylor, W. K. (2002). Collecting evidence for sexual assault: the role of the sexual assault nurse examiner (SANE). *International Journal of Gynecology and Obstetrics*, 78(1), S91-S94.
- The Federal Bureau of Investigation, U.S. Department of Justice, Office of Public Affairs. (2012, January 06). Attorney General Eric Holder announces revisions to the uniform crime report's definition of rape. Retrieved from <http://www.fbi.gov/news/pressrel/press-releases/attorney-general-eric-holder-announces-revisions-to-the-uniform-crime-reports-definition-of-rape>
- The United States Department of Justice. (2012, June). Retrieved from <http://www.ovw.usdoj.gov/sexassault.htm>
- Tjaden, P., & Thoennes, N. U.S. Department of Justice Office of Justice Programs, National Institute of Justice. (2006). Extent, nature, and consequences of rape victimization: Findings from the national violence against women survey (NCJ 210346). Retrieved from <https://www.ncjrs.gov/pdffiles1/nij/210346.pdf>
- Truman, J. L., Langton, L., & Planty, M., U.S. Department of Justice, Office of Justice Programs Bureau of Justice Statistics. (2013). Criminal victimization, 2012 (243389). Retrieved from <http://www.bjs.gov/content/pub/pdf/cv12.pdf>
- U.S. Department of Justice, Office on Violence Against Women. (2013). A national protocol for sexual assault medical forensic examinations adults/adolescents (NCJ 228119). Retrieved from website: <https://www.ncjrs.gov/pdffiles1/ovw/241903.pdf>

Tammy Bimber, MSN, RN, CEN, SANE-A, SANE-P is the Emergency Department Director at UPMC Northwest in Seneca, PA. She has spent 18 of her 22 years as a Registered Nurse in Emergency Medicine. She has cared for victims of sexual assault since 2000, when she became a Sexual Assault Nurse Examiner (SANE). She is currently certified as an adolescent/adult and pediatric SANE. She is an instructor of the UPMC SANE course. In 2003, Bimber assisted with the development of the SANE program at Warren General Hospital, Warren, PA, and in 2005, was an original member of the Warren County Sexual Assault Response Team (SART) participating in the development of the Warren County SART Protocol. Bimber continued to coordinate the SANE program through 2010. During that time, she provided multiple educational in-services to various local law enforcement agencies on the role of the SANE and was an active member of the Warren County Child Abuse Prevention team.

Since 2010, Bimber has continued to provide educational in-services on topics related to forensic nursing, and she participates in various county and state committees related to improving the care for sexual assault victims, including the Pennsylvania Sexual Assault Evidence Collection Committee.

Bimber is a member of the Emergency Nurses Association, International Association of Forensic Nurses, and Sigma Theta Tau International Pi Rho Chapter.

Online References and Resources

Palliative Wound Care and End of Life Wounds

Diane L. Krasner, PhD, RN, CWS, CWCN, MAPWCA, FAAN

The following sites provide online resources for clinical practice, education, and research and for legal nurse consultant reference. This listing is not intended to be all inclusive of resources available. No endorsement is made of any listed sites or services. Online sources change and should be confirmed prior to using as a reference.

| | |
|---|--|
| <p>Glossary</p> <p>The National Pressure Ulcer Advisory Panel (NPUAP) NPUAP Terms and Definitions of Stages Related to Pressure Ulcers http://www.npuap.org/resources</p> | <p>Lowe, S, Plambeck, A, & Paquet, B. (2013). Latex Allergy Alert. Nurse.com. (1.0 CEU). http://ce.nurse.com/ce152-60/latex-allergy-alert/</p> |
| <p>World Wide Wounds The premier online resource for dressing materials and practical wound management information, including palliative and end of life wound care. http://www.worldwidewounds.com</p> | <p>The National Pressure Ulcer Advisory Panel (NPUAP) White Paper: Pressure Ulcers in Individuals Receiving Palliative Care 2010 http://www.npuap.org/NPUAPwhitepapers</p> |
| <p>WoundSource Features numerous blogs defining and discussing palliative and end of life wound care. http://www.woundsource.com/palliativewounds</p> | <p>Protocols, Position Statements, and White Papers</p> <p>F.R.A.I.L. For Recognition of the Adult Immobilized Life 2002 http://www.frailcare.org</p> |
| <p>Kennedy Terminal Ulcer http://www.kennedyterminalulcer.com</p> | <p>The National Pressure Ulcer Advisory Panel (NPUAP) White Paper: Pressure Ulcers in Individuals Receiving Palliative Care 2010 http://www.npuap.org/NPUAPwhitepapers</p> |
| <p>European Pressure Ulcer Advisory Panel Skin Changes At Life's End (SCALE) http://www.epuap.org/scale-skin-changes-at-lifes-end</p> | <p>European Pressure Ulcer Advisory Panel Skin Changes At Life's End (SCALE) Consensus Document 2009 http://www.epuap.org/scale-skin-changes-at-lifes-end</p> |
| <p>Annals of Long-Term Care: Clinical Care and Aging Skin Failure: Identifying and Managing an Underrecognized Condition http://www.annalsoflongtermcare.com/article/skin-failure-identifying-and-managing-underrecognized-condition</p> | <p>WoundSource White Paper: Perspectives on Palliative Wound Care: Interprofessional Strategies for the Management of Palliative Wounds. http://www.woundsource.com/whitepapers</p> |
| <p>Governmental Resources</p> <p>Agency for Healthcare Research and Quality (AHRQ) Palliative Wound Care at End of Life http://www.ahrq.gov/about/nursing/palliative.htm</p> | <p>Scholarly Articles, Books, and Chapters</p> <p>Brown, P (Ed). (2013). <i>Quick reference guide to wound care: palliative, home and clinical practices</i>. (4th ed.). Burlington, MA: Jones & Bartlett Learning. http://www.jblearning.com/catalog/9781449600112/</p> |
| <p>Downloadable Fact Sheets</p> <p>F.R.A.I.L. For Recognition of the Adult Immobilized Life Palliative Wound Care and Healing Probability Assessment Tool http://www.frailcare.org/projects.htm</p> | <p>Collier, KS, Protus, BM, Bohn, CL, & Kimbrel, JM. (2013). <i>Wound care at end of life: A guide for hospice professionals</i>. Montgomery, AL: HospiScript Services, A Catamaran Company. http://www.amazon.com/Wound-Care-End-Life-Professionals/dp/0988955822</p> |
| <p>The National Pressure Ulcer Advisory Panel (NPUAP) Fact Sheets on pressure-ulcer related terms, stages/categories, prevention and treatment strategies, education http://www.npuap.org/resources</p> | <p>Emmons KR, & Lachman VD. (2010). Palliative wound care: a concept analysis. <i>J Wound Ostomy Continence Nurs</i>, 37(6), pp. 639-4. http://journals.lww.com/jwoconline/Pages/default.aspx</p> |
| <p>Continuing Education, Conferences, and Educational Opportunities</p> <p>Palliative Care Institute, Center for Curative & Palliative Wound Care, Calvary Hospital, Bronx, New York http://www.calvaryhospital.org</p> | <p>Ferris, FD, Al Khateib, AA, Formantin, I, et al. (2007). Palliative wound care: managing chronic wounds across life's continuum: a consensus statement from the International Palliative Wound Care Initiative. <i>Journal of Palliative Medicine</i>, 10(1), pp. 37-39. http://www.liebertpub.com/JPM</p> |
| <p>Palliative Wound Care Conference, Hope of Healing Foundation Biannual conference, next conference May 2015 in Orlando, Florida http://www.HopeOfHealing.org</p> | <p>Kennedy, KL. (1989). The prevalence of pressure ulcers in an intermediate care facility. <i>Decubitus</i>, 2(2), pp. 44-5. [Decubitus is now <i>Advances in Skin & Wound Care</i>] http://journals.lww.com/aswcjournal/pages/default.aspx</p> |
| | <p>Krasner, DL (ed). (2014). <i>Chronic wound care: The essentials</i>. Wayne, PA: HMP Communications LLC. http://www.chronicwoundcarebook.com</p> |
| | <p>Langemo, DK, & Brown G. (2006). Skin fails too: Acute, chronic, and end-stage skin failure. <i>J Wound Ostomy Continence Nurs</i>, 33(4) pp. 206-11. http://journals.lww.com/aswcjournal/pages/default.aspx</p> |

| Scholarly Articles, Books, and Chapters (Continued) |
|--|
| Levine JM. Historical perspective on pressure ulcers: the decubitus ominusus of Jean-Martin Charcot. <i>J Am Geriatr Soc</i> 2005;53(7):1248-51. http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1532-5415 |
| Sibbald, RG, Krasner, DL, Lutz, JB, et al. (2009). The SCALE Expert Panel: Skin changes at life's end. <i>Final Consensus Document</i> . http://www.epuap.org/scale-skin-changes-at-lifes-end |
| Thomas, A. (2010). <i>Surgical dressings and wound management</i> . (2nd ed). Hinesburg, VT: Kestrel Health Information. http://www.woundsource.com/store/10209 |
| Tippett, A. (2005). Wounds at the end of life. <i>WOUNDS</i> , 17 pp. 91-98. http://www.woundsresearch.com/ |
| Woo, KY, Krasner, DL, Sibbald, RG. (2014) Palliative wound care and treatment at end of life. <i>Aging Medicine Series</i> . New York: Humana Press – Springer, (Chapter 10). Thomas, DR, & Compton, G (Eds). (2014). Pressure ulcers in the aging population: A guide for clinicians. <i>Aging Medicine Series</i> . New York: Humana Press – Springer. http://www.springer.com/medicine/family/book/978-1-62703-699-3 |

| American Professional Associations |
|---|
| American Professional Wound Care Association http://www.apwca.org |
| Association for the Advancement of Wound Care http://www.aawc.org |
| Association for the Advancement of Wound Care http://www.aawc.org |
| National Pressure Ulcer Advisory Panel http://www.npuap.org |
| The Hope of Healing Foundation http://www.HopeOfHealing.org |
| Wound Healing Society http://www.woundheal.org |
| Wound Ostomy Continence Nurses Society http://www.wocn.org |

| American Professional Journals |
|--|
| <i>Advances in Skin & Wound Care</i> http://www.aswcjournal.com |
| <i>Journal of Wound Ostomy Continence Nursing</i> http://journals.lww.com/jwoconline/pages/default.aspx |
| <i>Ostomy Wound Management</i> http://www.o-wm.com |
| <i>Wound Repair and Regeneration</i> http://www.wiley.com/bw/journal.asp?ref=1067-1927 |
| <i>WOUNDS</i> http://www.woundsresearch.com |
| <i>WoundSource</i> http://www.woundsource.com |

Diane L. Krasner, PhD, RN, CWS, CWCN, MAPWCA, FAAN is a Board-Certified wound specialist with experience in wound, ostomy, and incontinence care across the continuum of care. Dr. Krasner is a wound and skin care consultant and part-time nursing instructor in York, PA. She serves as an expert witness in legal cases, as lead editor of the Chronic Wound Care Series (www.chronicwoundcarebook.com), and is on the Editorial Board of the Journal of Legal Nurse Consulting. Dr. Krasner may be reached at dlkrasner@aol.com.

Liability of Ineffective Patient Handoffs that Cause Patient Harm or Death

Judith M. Bulau, MSN, RN

Q: Is there liability for ineffective coordination of care that may cause patient harm or death?

A: Yes, medical errors that may cause patient harm or death during ineffective coordination of care increase the risk of medical malpractice lawsuits.

Coordination or transitions of care involve the primary care physician (PCP) or hospitalist, so the delivery of healthcare is seamless, regardless as to whether care is provided in the same healthcare setting or between different healthcare settings. Health Affairs (2012 p. 2) indicates that "...care transition is the continuous process in which a patient's care shifts from being provided in one setting of care to another, such as from a hospital to a patient's home or to a skilled nursing facility and sometimes back to the hospital." The Joint Commission (2013, p. 3) references transitions of care as "...the movement of patients between healthcare practitioners, settings, and home as their condition and care needs change."

However, coordination or transitions of care are often ineffective and result in medical errors. Rabin (2013, p.1) noted that, "Advocates for hospital patients and their families say confusion about who is managing a patient's care – and lack of coordination among those caregivers – are endemic, contributing to the estimated 44,000 to 98,000 deaths from medical errors each year."

In addition, Rabin pointed out that advocates, patients, and others said, "Patients are most vulnerable to coordination problems when their recovery doesn't go as planned or a medical mistake has occurred. That's when complications – and potential liabilities – develop." (2013, p. 2).

Health Affairs (2012 p.10) has indicated, "Researchers have estimated that inadequate care coordination, including inadequate management of care transitions, was responsible for \$25 to \$45 billion in wasteful spending in 2011 through avoidable complications and unnecessary hospital readmissions."

In any discussion about coordination of care, understanding the critical importance of the PCP and hospitalist role in integrating healthcare is paramount in preventing patient harm or death. Ideally, the PCP and hospitalist have the most knowledge about their patients and can orchestrate the involvement and communication among other physicians and healthcare settings so patients do not fall through the safety net of consistent care coordination. However, Health Affairs indicates that, "... one of the biggest barriers to smoother care transitions is the fact that primary care physicians often have little or no information about their patients' hospitalizations." (2012, p. 2)

Hospitalists oversee the PCP's patients in the hospital and may be unlikely to keep the PCP informed about the status of their patients' medical condition because of heavy workloads. As Rabin points out, "Hospitalists routinely work seven to 15 days in a row on shifts that each last 10 to 12 hours to provide continuity." (2013, p. 2)

Health Affairs identifies

"...several root causes of poor care coordination. First, differences in computer systems often make it difficult to transmit medical records between hospitals and physician practices. In addition, hospitals face few consequences for failing to send medical records to patients' outpatient physicians upon discharge. As a result, physicians often do not know when their patients have been released and need follow-up care. Finally, current payment policies create disincentives for hospitals to invest in smoother care transitions." (2012, p. 2)

References

1. Health Policy Brief: Improving Care Transitions. (2012). Health Affairs, September 13, 2012. www.healthaffairs.org/healthpolicybriefs/brief.php?brief-id=76
2. Rabin, R.C. (2013). Health Care's 'Dirty Little Secret': No One May Be Coordinating Care, Kaiser Health News, April 30, 2013, 1-4. www.kaiserhealthnews.org/stories/2013/april/30/coordination-of-care.aspx
3. The Joint Commission. (2013). Transitions of care: The need for a more effective approach to continuing patient care. Hot Topics in Health Care. 1-8. www.jointcommission.org/joint_commission_new_hot_topics_urges_teamwork_transitions.

Judith M. Bulau is a Risk Manager and Patient Safety Specialist at Barnes- Jewish Hospital in St. Louis, Missouri, and a Legal Nurse Consultant. She belongs to Sigma Theta Tau, the National Honor Society of Nursing. She is a member of the Editorial Board for the Journal of Legal Nurse Consulting. She has written five health care books, contributed several chapters to other publications and written numerous articles published in healthcare journals. She holds degrees from the University of Minnesota (MSN, BS) and the Arthur B. Ancker Memorial School of Nursing (RN) and is certified in public health nursing (PHN) by the Minnesota Department of Health.



Call for Case Study Authors – Don't Miss This Opportunity - Submit Today!

- ✓ Have you worked on a case that could provide information and help for other LNCs?
- ✓ Is there a case you have worked on that was especially interesting or instructive?
- ✓ Are you looking for an opportunity to “get published”?

If the answer to any of these questions is “yes”, we invite you to submit your case study abstract today to be considered for publication.

Why should I submit a case study abstract?

As a case study author, you will contribute to the general body of knowledge for legal nurse consultants. You will be making a valuable contribution both to AALNC and to the profession. You will receive personal benefits as well - from the experience of writing for publication to the personal and professional growth which comes from participating in the process of a peer-reviewed project. Case study authorship is one of the building blocks of Legal Nurse Consulting and can help you to contribute your knowledge and expertise to your colleagues and to achieve growth in your own. Don't forget, you can also receive hours towards your LNCC Recertification by authoring a case study.

Know someone who has a great “story to tell” that you would like to recommend as a Case Study Author?

Please submit their name and contact information to speakers@aalnc.org and we will invite them to participate.

Submit your case study abstract for consideration by visiting www.AALNC.org today!

Don't forget - the deadline for submissions is April 15, 2014.



The Nurse Practitioner's Guide to Nutrition, Second Edition - Hark, Ashton and Deen.

Susan Mikulak Cacciola, RN, BSN, WCC

Malnutrition can be defined as an excess or a deficiency of protein, fat, carbohydrate, vitamins, minerals, or fluid intake. Malnutrition is of epidemic proportions in the United States. Who in the patient population is malnourished? Consider the diabetic patient with poor immune response, the cardiac patient with three plus pitting edema, and the dialysis patient with calcium deposits in soft tissues. Identify the female with a history of premature births or spontaneous abortions. Evaluate the child in school who lacks motivation or the obese five year old child. Take a closer look at the teenager with a BMI < 17.5. Consider the nutritional needs of the severely burned patient with sepsis or the post-operative patient whose wound dehisces? Re-evaluate the geriatric patient with a history of frequent falls and the chronic wound patient whose wound remains recalcitrant despite numerous changes in treatments.

Despite the plethora of information about nutrition, it remains one of the most under-addressed areas in health care today. Nutrition is the basis for health and wellness. Nurses are in key positions in the health care delivery system to identify patients with nutritional risk; to educate patients, families, and other caregivers about nutrition; and to make appropriate referrals within the health care delivery system to provide ongoing evaluation and support for nutritional needs. *The Nurse Practitioner's Guide to Nutrition*, second edition, is the comprehensive resource for nurses, nurse practitioners, and legal nurse consultants, providing standards of care, authoritative references, and guidelines for clinical practice. Lisa Hark, Kathleen Ashton, and Darwin Deen are thorough in their coverage of nutritional assessment, nutritional counseling, and practical application across the lifespan. This book enables the nurse and the nurse practitioner to easily identify the "at risk" patients and to develop plans of care to meet the nutritional requirements to maximize health and wellness.

The book is delivered in three sections. Section One discusses nutritional concepts and how they are important to nursing practice. Section Two goes into detail about nutrition as it relates to the journey throughout the lifespan. Section Three discusses nutrition for clinical issues and in clinical settings. Several appendices are provided about food sources related to vitamins and minerals and also nutritional resources.

Chapters one through three provide the basis for the role of nursing related to nutrition, as well counseling for behavioral changes. Chapter four addresses nutrition from pre-conception through lactation. It discusses the importance of the pre-natal evaluation to address nutritional needs to minimize risk and complications for both the mother and fetus. It includes the nutritional needs of the lactating female and management of breastfeeding complications.

Chapter five addresses the nutritional needs from infancy through adolescence, including prevention and treatment of the overweight and obese child. It also includes guidelines to manage the "picky eater," the vegetarian, the athlete, and the child with eating disorders. Chapter six addresses the nutritional needs of the older adult, including identification of the "at risk group" for malnutrition. This chapter includes nutritional assessment tools for the older adult, including the Determine Your Nutritional Health Nutrition Screening Initiative, the Mini Nutritional Assessment, and the Kayser-Jones Brief Oral Health Status Examination. It defines nutritional frailty and discusses the etiology of malnutrition in the geriatric population, providing interventions to stimulate the appetite and supplement the diet for the geriatric cohort.

Chapters seven through twelve discuss disease-specific nutrition as it relates to the obese patient, the cardiac patient, the renal patient, and the diabetic patient. Special attention is also given to the patient with digestive disorders as well as the patient with cancer.

Chapter thirteen provides guidelines for enteral and parenteral nutrition. It includes information regarding formula selection and administration, determining parenteral nutritional requirements, and managing complications of parenteral therapy including refeeding syndrome, glycemic control, and fluid/electrolyte balance.

The handbook concludes with dietary sources for key vitamins and minerals; the Therapeutic Lifestyle Changes Diet and the Dash diet; and recommended Dietary Reference Intake Tables to guide clinical practice.

Legal nurse consultants will find this an authoritative text as they measure nursing care against the standards of practice for patients with nutritional needs. This book will assist the legal nurse consultant to determine deviations from the standards of care, including failure to assess, identify, and develop individualized plans of care to meet nutritional needs; failure to choose the appropriate nutritional support; failure to maximize nutritional support; failure to employ strategies to promote health and a safe environment; failure to coordinate care delivery; failure to provide consultation to

influence the identified plan, enhance the abilities of others, and effect change; failure to use prescriptive authority, procedures, referrals, treatments, and therapies in accordance with state and federal laws and regulations; and failure to communicate and collaborate with the health care team for continuity of care and to effect change and positive outcomes.

Susan Mikulak Cacciola, RN, BSN, WCC, is the CEO of Legal Nurse LLC. She is a Registered Nurse with 35 years of multispecialty and multi-practice area background including critical care, holistic nursing, home care, dialysis, wounds, and medical case management. Cacciola is also a Legal Nurse Consultant, assisting attorneys in the areas of nursing malpractice, personal injury, workers compensation/disability, family law, elder care, and medical coding and billing cases. She provides continuing education for nurses, legal nurses, and attorneys, and was voted "Best of Legal Nurses" by New Jersey attorneys in the NJ Law Journal 2012/2013.

Maximize Your Membership Benefits!

As a member of AALNC, you can increase your legal and medical knowledge, expand your network of contacts, and stay up-to-date on the hottest topics affecting LNCs today!

Membership in AALNC includes:

- **The Journal of Legal Nurse Consulting** – AALNC's official journal is published quarterly. Members are also able to access past issues online through the JLNC Archives (within the Members Only section).
- **Professional Liability Insurance** – AALNC officially sponsors Professional Liability Insurance offered through Nurses Service Organization. The insurance offered through NSO has many exclusive benefits and features that enhance your protection as a practicing LNC and offers discounts not available elsewhere!
- **Attorney Awareness** – AALNC has initiated a dedicated marketing campaign to attorneys from all practice specialties. As a member of AALNC, you know that the

professional organization for LNCs is working to raise awareness of the specialized skills an LNC brings to each case.

- **LNCLocator** – When attorneys need an LNC, they turn to AALNC's public online LNC search engine, the LNCLocator. This tool allows attorneys to quickly and easily search for an LNC by geographic area, nursing specialty, or LNC practice area. Being listed in the LNCLocator is a free membership benefit.
- **VerdictSearch** – AALNC members are entitled to receive 30% off any VerdictSearch print publication, including newsletters, books, binders, and indexes, as well as 30% off the annual subscription price of the VerdictSearch Online Database.

AALNC
AMERICAN ASSOCIATION OF
LEGAL NURSE CONSULTANTS

For more information about AALNC membership and its countless member benefits, please visit www.aalnc.org/membership/.



AMERICAN ASSOCIATION OF
LEGAL NURSE CONSULTANTS

The Journal of Legal Nurse Consulting

330 North Wabash Ave.
Chicago, IL 60611
Phone: 877/402-2562
E-mail: JLNC@aalnc.org

Submission Guidelines

The Journal of Legal Nurse Consulting (JLNC), a refereed publication, is the official journal of the American Association of Legal Nurse Consultants (AALNC). The journal's purposes are to promote legal nurse consulting within the medical-legal community; to provide both the novice and the experienced legal nurse consultant (LNC) with a high-quality professional publication; and to teach and inform the LNC about clinical practice, current national legal issues, and professional development. The journal accepts original articles, case studies, letters, and research studies. Query letters are welcomed but not required. A manuscript must be original and never before published, and it should be submitted for review with the understanding that it is not being submitted simultaneously to any other journal. Once submitted, articles are subject to peer review (publication is not guaranteed).

Manuscript Format

Manuscripts should not exceed 4,000 words in length, and should be accompanied by an abstract of no more than 150 words. All manuscripts should be double spaced. The title page should include the title of the manuscript and the authors' names, credentials, work affiliations and addresses, daytime phone numbers, fax numbers, and e-mail addresses. One author should be designated as the corresponding author. The title page, the tables and figures, and the reference list should each appear on a separate page. Pages, beginning with the title page, should be numbered consecutively.

Manuscript Submission

Manuscripts should be sent to the *JLNC* Editor via e-mail at JLNC@aalnc.org, as a Microsoft Word attachment. Use a minimum of formatting: do not use unusual fonts or a variety of type, and do not insert page headers or footers except for page numbers. Create a separate file attachment for tables and figures—do not insert them into the text file. Clearly label your e-mail with the submission title, and word processing program name and version.

Style and Reference Guidelines

JLNC follows the manuscript style and reference guidelines of the *Publication Manual of the American Psychological Association* (6th ed.). Legal citations must adhere to the guidelines published in *The Bluebook: A Uniform System of Citation* (15th ed.), Cambridge, MA: The Harvard Law Review Association.

Reprint Permission for Copyrighted Material

When using figures or tables from another source, the author must obtain written permission from the original publisher and include that as part of the manuscript submission materials. The author is responsible for obtaining permission for the use of photographs of identifiable persons.

Figures and Tables

Figures include line drawings, diagrams, graphs, and photos. Tables show data in an orderly display of columns and rows to facilitate comparison. Each figure or table must be on a separate page and should be labeled sequentially (e.g., Figure 1, Figure 2 or Table 1, Table 2) and correspond to its mention in the text. All photographs must be black-and-white electronic files.

Manuscript Review Process

Manuscript submissions are peer reviewed by professional LNCs with diverse professional backgrounds. First-time authors are encouraged to submit manuscripts. Manuscript assistance can be provided upon request to the editor.

Acceptance will be based on the importance of the material for the audience and the quality of the material. Final decisions about publication will be made by the editor.

Copyright

Upon acceptance of the manuscript, the author will assign copyright to *JLNC*. Permission for reprints or reproduction must be obtained from AALNC.

Manuscript Checklist

Please use the checklist below to be sure that your submission follows *JLNC* guidelines.

- The manuscript is being submitted exclusively to the *JLNC* and has not been published previously.
- Guidelines in the *Publication Manual of the American Psychological Association* (6th ed.) and *The Bluebook: A Uniform System of Citation* (15th ed.) (for legal citations) have been followed.
- All references cited in the text are included in and match the reference list. References in the reference list appear in alphabetical order and include all the elements described in *Publication Manual of the American Psychological Association* (6th ed.).
- Permission for including or reproducing previously published information (e.g., tables and figures) is enclosed.
- Numbers and percentages have been checked against one another and the text for accuracy.
- Tables and figures reflect the information in the text.
- The manuscript does not exceed 4,000 words in length, is double spaced and includes an abstract of no more than 150 words.
- The title page includes the title of the manuscript and the authors' names, credentials, work affiliations, addresses, daytime phone numbers, fax numbers, and e-mail addresses.
- Graphics are black-and-white electronic files.
- One author is designated as the corresponding author.

Revised 8/2011

AALNC

AMERICAN ASSOCIATION OF
LEGAL NURSE CONSULTANTS

330 North Wabash Ave., Suite 2000
Chicago, IL 60611