The Journal of

Legal Nurse Consulting

Volume 20 ▲ Number 2 ▲ Spring 2009

- Do You Have the Right to Copy?
- The Pharmacist's Responsibility in Adverse Reactions and Medication Abuse
- Unnecessary Drugs in Nursing Facilities
- Normal Pressure Hydrocephalus
- Review of Voluminous Medical Records
- Book Review: Proving Conscious Pain and Suffering

20th Anniversary

AALNC

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The Journal of Legal Nurse Consulting

Purpose

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

Manuscript Submission

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

Manuscript Review Process

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

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.

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LEGAL NURSE CONSULTING
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*** Do You Have the Right to Copy?** 3
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To assist the legal nurse consultant (LNC) in becoming familiar with copyright and the consequences of violating copyright law, this article has provided information regarding the copyright law (Title 17, United States Code), how the copyright law applies to the practice of legal nurse consulting, fair use and the fair use defense, the cost of copyright infringement, and suggestions for the LNC in complying with copyright law.

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** These articles have been selected for inclusion in the 2009 JLNC Nursing Contact Hour Program. Participants of the program will be able to earn nursing contact hours for completion of an online post-test on this article. Please see the conclusion of the articles for more detailed instructions.*

Our Infinite Possibilities

Dear Readers:

Being a product of the late 1950's, I am all too familiar with the repeated cycles of dire predictions for humankind. These constant predictions have swirled like a dry-ice fog around my feet for as long as I can remember. (In elementary school, we even had atomic bomb drills for the inevitable destruction. Later, I realized getting under your desk and covering your head with your hands would offer amazingly ineffective protection.) These prophets of doom and gloom for the human race have been an unwelcome companion all the way into adulthood. It seems a daunting task to escape the negative messages from all sides regarding the collapsing economy, the decay of the environment, and the escalation of tensions between nations.

So how do you counter-balance the constant eroding of your optimism? You remind yourself of your passions, whatever they are. Whatever stirs your soul and takes your breath away with its beauty, you make time for in your life. You make a list. Here are just some of mine in no particular order: unsung heroes, tall ships at full sail, the medieval artwork and jewelry at the Metropolitan Museum in Manhattan, newborn babies, Victorian architecture, wild mustangs allowed to run free on protected land, the majesty of the mountains, learning as much as I can about everything I can… Your list will be different; it should be. But what the list will have in common is the effect of reminding us of the infinite possibilities of the human spirit.

Our feature article is a great informational piece from Diane and Leroy Ellenberger on copyright law and its importance to the practicing LNC. Additionally, the article addresses how the courts have viewed copyright violation. It is one of two nursing contact hour offerings. Our second nursing contact hour offering introduces our readers to two areas significantly impacting the practice of the licensed pharmacist. Pharmacist Rolando Morales analyzes and discusses the pharmacist's responsibility and legal exposure in adverse drug reactions and pharmaceutical abuse. On a related topic, William Simonson examines the issue of "unnecessary drugs" in the long-term care setting. A consultant pharmacist, he reviews the defining criteria, controlling regulations and indications for auditing these drugs.

Among our regular highlights: this issue's Questions & Answers column is contributed by Rose Clifford, who generously provides key information for developing your skills in organization and preliminary medical record review. *The Journal* also reviews Lorna Morelli-Loftin's tremendous primer on *Proving Conscious Pain & Suffering*. Both the Clinical Maxim and the References & Resources are devoted to the often-misdiagnosed condition of Normal Pressure Hydrocephalus.

As the readers noticed in our clinical offering on CES last issue, the piece was accompanied by professional illustrations. Just like providing professional illustrations in trial enhances the juror's understanding, so too the illustrations help to demonstrate the pathophysiology and process. On behalf of *The Journal*, I would like to extend a special thank you to the staff of Medical-Legal Art for their time and talent in generously providing their professional medical illustrations to accompany our clinical offering.

Best regards,

Kara DiCecco, MSN, RN, LNCC

Kara DiCecco, MSN RN LNCC
Editor, *The Journal of Legal Nurse Consulting*

Do You Have the Right to Copy?

Diane M. Ellenberger, MS RN LNCC, & C. Leroy Ellenberger, MBA MS B

KEY WORDS
Copyright, Fair Use

To assist the legal nurse consultant (LNC) in becoming familiar with copyright and the consequences of violating copyright law, this article has provided information regarding the copyright law (Title 17, United States Code), how the copyright law applies to the practice of legal nurse consulting, fair use and the fair use defense, the cost of copyright infringement, and suggestions for the LNC in complying with copyright law. This article is part of the 2009 JLNC Nursing Contact Hour Program. Please see the conclusion of the article for more detailed instructions.

Many, if not most, attorneys have not even been exposed to copyright or intellectual property law because those courses in law school may have been an elective in their curriculum. Many legal nurse consultants (LNCs) may only be aware of the copyright law by the sign over photocopying machines in the library:

> **PHOTOCOPY WARNING:**
> **NOTICE WARNING CONCERNING COPYRIGHT RESTRICTIONS**
>
> *The copyright law of the Untied States (Title 17, United States Code) governs the making of photocopies or other reproductions of copyrighted material.*
>
> *Under certain conditions specified in the law, libraries and archives are authorized to furnish a photocopy or other reproduction. One of these specific conditions is that the photocopy or reproduction is not to be 'used for any purpose other than private study, scholarship, or research.' If a user makes a request for, or later uses, a photocopy or reproduction for purposes in excess of 'fair use,' that user may be liable for copyright infringement. (37 C.F. R. §201.14)*

[Sign over the photocopier at Becker Medical Library, Washington University School of Medicine, St. Louis, Missouri]

Copyright is, literally, the "right to copy." Only the copyright holder has the exclusive right to duplicate the work. The rightsholder also has the right to be credited for the work, distribute the work, determine who may modify or adapt the work, and who may financially benefit from the work. According to the copyright law, anyone who violates the exclusive rights of the copyright owner is an infringer.

The copyright law was changed in 1909 from an understanding of the exclusive right to *publish* to a prohibition of *copying* material (Copyright Act of 1909). Since that time, the right to copy has belonged to the author or the rightsholder. Unless one holds the right to a work, one does not have the right to copy either by photocopy or electronically another's work. For the past 20 years, the use of a copyright notice has been optional; therefore, all works whether in hardcopy or digital/electronic form should be considered copyrighted and not part of the public domain.

The 1976 copyright law, Title 17 of the U.S. Code, Section 107, provided a "fair use" exemption, which indicated that copying for "purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research is not infringement of copyright." The use of copyrighted works for educational purposes within the context of a for-profit enterprise is probably not considered "fair use." The Copyright Act "fair use" privilege applies to limited portions of copyrighted works, not the whole work, and the type of education considered is classroom in not-for-profit institutions, not self-education. No internal use or business exception exists in the Copyright Act. The distinction between fair use and infringement has been "unclear and not easily defined," according to the U.S. Copyright Office (2006).

Section 107 sets out four factors taken into consideration when determining fair use:

1. the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
2. the nature of the copyrighted work;
3. the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
4. the effect of the use upon the potential market for or value of the copyrighted work.

Section 108 (e) (1) of Title 17 provides that a library may provide document delivery of a copy of a work if the library has no notice that the copy would be used for "any purpose other than private study, scholarship or research."

What Does that Have to do with Legal Nurse Consulting?

Generally, any time a copyrighted work is photocopied or electronically transmitted, it is infringement unless one has the right to do so through a license or other permission, a valid fair use defense, or exemption. According to Fischer and Sennott (2007), "Fair use is a defense and not an absolute right." However, Heilman (2006) admonished not to presume that the fair use doctrine can be used as a defense.

When a literature search is performed and photocopies are obtained at the library or from another source such as a document delivery service, instead of thinking about the "fair use" defense, permission should be obtained to photocopy the articles from the rights holder directly (usually the publisher) or from their agent, the Copyright Clearance Center (**www.copyright.com**). In the alternative, a reprint of the article may be requested from the author or publisher.

When services are provided by the LNC to obtain articles or book chapters for the attorney client, that service is "document delivery" for which compensation is being provided. Permission to photocopy the article or book chapter from the rightsholder and payment of the applicable fee is required, which is then passed on to the client attorney. Delivery of the photocopy by facsimile (fax) is encompassed in the photocopy permission fee. Sending the document to the client electronically by portable document format (pdf) requires a separate permission and fee payment, according to the 1998 Digital Millennium Copyright Act for electronic media, which replaces the photocopy permission. The photocopy that is scanned for electronic delivery serves a transitory role solely for the purpose of facilitating the delivery. Typically, the licenses for libraries to access copyrighted content electronically do not permit the direct distribution of the licensed material in any electronic or digital form.

Medical Review Services, a Katy, Texas, legal nurse consulting business, was contacted late on a Friday afternoon in 2003 by a potential client with a "rush" request for five articles to be sent by pdf, as well as the hard copy by mail (L. Roundy, personal communication, April 25, 2004 and May 24, 2004; Ellenberger & Silverman, 2005). The business owner checked the potential client on the Internet and found the Website; therefore, they trusted the source of the request. The articles were obtained and sent by e-mail and U. S. mail. Four months later, the business owners received a complaint filed in Federal Court (*American Chemical Society, et al. v. Loren Mateo Roundy dba Medical Review Services*, 2003) by the five publishers of the five articles requested – American Chemical Society, Elsevier, Inc, Marcel Dekker, Inc, SAGE Publications, Inc, Wiley Periodicals, Inc. – with five counts of infringement for photocopying the articles without obtaining permission and five counts for transmitting the articles electronically without obtaining permission in violation of the 1976 Copyright Act and the 1998 Digital Millennium Copyright Act. Medical Review Services had apparently been found through advertisement on the Internet as providing photocopies of articles. The business declared bankruptcy and ceased operation, subsequent to which the publishers' suit against Medical Review Services was not pursued further.

Most of the suits for copyright infringement are settled either before or after the filing of a lawsuit and do not come to trial. Most of those who settle pay extra for the settlement for the particulars not to be publicized to avoid embarrassment (Kirby, 2007). During the 1980s, the suits brought by publishers were brought against pharmaceutical companies for distributing copyrighted publications within their company or re-publishing copyrighted materials (Gassaway, 2004). During the 1990s and early 2000s, the suits have been against document delivery services and those printing companies selling course packs to college students, as well as law firms whose litigation involved intellectual property.

Fair Use as Defense, not a Right

Contrary to most thinking about fair use, that fair use does not entitle duplication of intellectual property such as articles, books, photographs, artwork, etc. Fair use does not apply to activities involving duplication of intellectual property that are commercial, that is for making money. LNCs photocopy articles to support a case or to provide the material to a client for financial remuneration, not for private, personal purposes.

One problem with claiming fair use is that belief cannot guarantee that a use will be actually determined to be fair use. Using fair use in defense of those who have been sued for copyright infringement has not been successful. Even if the court is convinced that the use is fair use, complying with fair use guidelines, any benefit derived from the use of the material may not be worth the time and expense of litigation.

Fisher and Sennott (2007) provided an example of a fair use defense for attorneys, which involved the providing of an interesting article to clients. They indicated that, even though a fee would not be charged for the article directly, the copying and distribution of the article would certainly be believed to be commercial in nature by the court. They further indicated that the plaintiff would allege potential harmful effect or loss to the copyright holder through the unauthorized reproduction and distribution of the article. Those two findings, commercial nature and harm to the copyright holder, would work against a fair use defense. They recommended obtaining permission to photocopy or purchase a blanket license from the CCC.

Texaco was sued by multiple publishers (*American Geophysical Union v. Texaco, Inc.*, 1992) and used the fair use defense. The scientists photocopied articles from circulated journals for their own files, many of which were not even read. The suit contended that their photocopying of the articles from copyrighted journals without payment of copyright permission fees or purchase of additional subscriptions harmed the publishers. Texaco lost their case on the basis of fair use when the court found that their photocopying was not directly related to laboratory research and archival in nature and that the plaintiffs were deprived of revenue from either additional subscriptions or payment for permission to photocopy. The court decided that use of photocopies of scientific and technical journal articles for profit (Texaco was in business for profit) violated fair use of the 1976 Copyright Act.

A fair use defense was used by Legg Mason, a global financial services firm based in Maryland (*Lowry's Reports v. Legg Mason*, 2003), in the suit brought by newsletter publisher Lowry's Report in the U. S. District Court for the District of Maryland. Legg Mason was charged with routinely copying, faxing, e-mailing, and disseminating unauthorized copies of Lowry's newsletter *New York Stock Exchange Market Trend*

Analysis after purchasing only a single subscription of the daily newsletter. Another of Legg Mason's defenses was that posting the newsletter on its intranet was a mistake made by low-level employees, but Lowry contended that Legg Mason failed to train their employees in the legalities of technology.

The court evaluated the four factors of Legg Mason's fair use defense. The commercial nature of Legg Mason went against fair use. Since an annual subscription cost $700 and Legg Mason only purchased one subscription, the amount and substantiality also went against Legg Mason because they duplicated the entire publication. The effect on the market was also taken into account because Lowry was a small firm with only one product. Taking into account those three factors, the court found no fair use on the part of Legg Mason.

The Software & Information Industry Association (SIIA), a Washington, DC based firm, brought copyright infringement claims against Knowledge Networks, a market research firm based in Menlo Park, California, for internally distributing press packets that contained copyrighted materials from SIIA members and various publishers (Software & Information Industry Association, 2007). A complaint in this case was never filed in the court; Knowledge Networks settled to avoid being sued (S. Bain, personal communication, March 4, 2009). The attorney for the SIIA, Scott Bain, indicated that "If a company is routinely making copies of materials to which it doesn't have a license," it is unlikely that it is fair use (Shah, 2007).

Georgia State University was recently sued through their principals in the Georgia Northern District Court, Atlanta, Ga. on April 15, 2008 by three publishers (*Cambridge University Press, et al. v. Carl V. Patton, et al.*, 2008; Justia.com, 2009) for violating the copyright laws in digitally distributing course work from various books and journals to students without obtaining permission from the rights holders or paying licensing fees, as reported in *The New York Times* on April 16, 2008. This lawsuit is noted to be the first of its kind; previous suits have been instituted around photocopied course packs, but this is the first regarding electronic material. After prior negotiations with Georgia State by attorney R. Bruce Rich, Esq., of Weil, Gotshal & Manges, for the plaintiff publishers, officials from Georgia State University in a letter "indicated their view that all of their practices are covered under the fair use doctrine" (Hafner, 2008). A legal consultant was noted in the article to indicate that, while the school may be not-for-profit, the students presumably pay money for the materials being provided to them.

What's Copyright Infringement Worth?

For copyright infringement or "piracy," according to the Copyright Act, the court can award statutory damages in lieu of actual damages from $750 to $30,000 for infringement of a single work. Willful infringement can carry statutory damages of up to $150,000 per infringement (Heilman, 2006; Kirby, 2007), which also increases the likelihood of being responsible for attorney fees with litigation.

The price for Medical Review Services in Katy, Texas, was to declare bankruptcy and go out of business in order to prevent further litigation, investigation, fines, and continuous oversight by the Copyright Clearance Center (CCC).

After losing at trial in New York's Southern District Court with the decision upheld on appeal in 1994 in the Second Circuit Court of Appeals, Texaco agreed in 1995 to purchase an internal license from the CCC, with a settlement in the amount of seven figures (Gawlicki, 2006).

The federal jury awarded Lowry's Reports nearly $20 million in the copyright infringement lawsuit against Legg Mason for lost revenue and copyright violations. Later they settled for a reported $12 million after an appeal was denied. The size of the jury award was based on the willfulness of the infringement and therefore placed the award in the statutory range.

In the SIIA v. Knowledge Networks matter, a settlement of $300,000 for copyright infringement was eventually agreed upon in August, 2007. The attorney for SIIA indicated that the settlement would have been larger except that Knowledge Networks would have gone bankrupt (Kirby, 2007).

An intellectual property law firm, Collier Shannon & Scott, Washington, DC, was sued by Washington Business Information (*Washington Business Information Inc. v. Collier Shannon & Scott*, 1991) for in-house photocopying of their newsletter. That case was settled for an undisclosed amount. LeBoeuf, Lamb, Green & MacRae of New York, which practices intellectual property law, settled with the CCC and four publishers for an undisclosed amount and by purchasing an internal license in order to avoid an infringement suit for in-house photocopying (CCC, 1999; Heller, 2000; Heller, 2002).

Who's to Know?

Most information leading to enforcement of copyright infringement is provided innocently to publishers; however, disgruntled former employees, competitors, or other whistleblowers also may provide information to either the CCC or publishers. Thomas Kirby, the attorney who litigated the Lowry's Reports v. Legg Mason case and also settled the SIIA case against Knowledge Solutions, has been retained by other publishers to develop detection materials for copyright infringement detection including features of Adobe software that report when pdfs are printed and other commercial monitoring technologies.

The suit against Legg Mason was started because of the innocent report of a former employee to the newsletter publisher, Lowry. According to Kirby, in an interview with the CCC in 2005 (CCC, November 29), the former broker contacted the publisher after having read the newsletter at his former brokerage. When asked by the agent at Lowry how the broker had heard of the newsletter, he volunteered that when he was at Legg Mason, they sent copies of the newsletter around. The publisher's agent then informed the head of the company.

The SIIA offers rewards to informants who report violations that range from $500 to $1 million, depending on the amount of the settlement for information of copyright infringement. The SIIA passes the information received on to publishers for enforcement and/or litigation. A confidential tipster reportedly was awarded $6,000 for information relating to Knowledge Networks' infringement (Software & Information Industries Association, 2007). Reporting may be made at **www.siia.net/piracy/report**.

When the Medical Review Services in Katy, Texas, was sued, part of the discovery was the request for the names of clients who had been provided articles without paying the copyright fees. If a document delivery service is not obtaining copying permission and not paying the fees, and is sued by the publishers for copyright infringement, any business employing that service may be at risk of being disclosed as receiving articles for which permission was not obtained.

What Does Copyright Compliance Cost?

The CCC was organized at the suggestion of Congress in 1978 as a not-for-profit corporation to assist with copyright compliance. **www.copyright.com** can be accessed to determine whether permission to photocopy an article will be granted and the charge for photocopying the article. Not all publications are registered with the CCC, however, and the publisher or rightsholder must be contacted directly. Corporate rightsholders almost always charge a fee, but individual rightsholders such as authors will often not charge a fee. For each additional copy made from a photocopied article, book chapter or portion of a written work, a separate copyright fee is required.

In the Texaco case, the court also found that the CCC provided a convenient and *nominal* method for seeking copyright permission. The CCC emphasizes that the rightsholders set the fees, and the CCC is the collection agent. At the time, the fees were *nominal* at about $3, but presently (as of January 2009), Elsevier, for example, charges $36 per photocopy of an article, which is not nominal. (For reference, Lippincott charges $35, Blackwell $45, NEJM $15, and JAMA $17 per article.) The CCC also adds a service charge of $3 per item for low-volume users or $1 per item for high-volume users (more than $10,000 per year in fees).

The permission fees for book chapters can range from $0.17 or $2 per page to $20 or $30 per chapter.

Usually, however, recent textbooks are not registered with the CCC, and permission needs to be obtained from the rightsholder directly. Recently, Elsevier assessed a permission fee of $169 for a 13-page chapter from a 1998 textbook. Purchase of a used copy of a textbook may be more economical.

The permission fee for electronic, i.e., pdf, delivery is usually the same as the photocopy permission fee but may be more or less. Whereas photocopy permissions and fee payments through the CCC may usually be registered online immediately using the Transactional Reporting Service (TRS), permission for electronic delivery usually requires contacting the rightsholder directly, which typically entails a delay of a week or more. Articles purchased directly online from the publisher for a fee are for *personal* use, not for business use. For articles purchased directly from the publisher and downloaded from the Internet in pdf, a fee for permission is also required if the use is for business.

For Elsevier publications (i.e., Mosby, W.B. Saunders, Churchill Livingstone, et al.), to pay the copyright fee the "Permissions" button can be accessed on the site where the article is downloaded and the directions followed or the CCC can be contacted directly. For publications from other publishers such as Lippincott, the fee should be paid through the CCC or to the publisher directly. Articles offered for *free* download by publishers and organizations are for personal use; if the article is being used for business, permission and fee are required. Photocopying a downloaded article also requires permission and fee payment for each additional copy. According to the CCC, even though copyrighted material may be publicly accessible, it does not mean that one has copyright permission to reproduce or repurpose the material. Permission must be obtained for use of the material.

Licenses can be purchased from the CCC to allow in-house photocopying, intranet transfer of materials in-house, and retrieval of photocopies brought into the firm from a library by an employee. The CCC can provide different licensures to meet the photocopying needs of the firm.

What Is the LNC to Do?

Unless you are the rightsholder, you do not have the right to copy the intellectual property of others. Consider that anything written, published, or created is copyrighted; a © symbol does not need to be attached to the work to be considered copyrighted. The copyright extends to all types of media, including materials such as images downloaded from the Google Web site.

Although the chance of getting caught at copyright infringement or piracy may be 1 in a 1000 or more, the first decision a LNC needs to make is whether the chance of getting sued for copyright infringement is worth the risk if copyright fees are not being paid. Commercial use of copyrighted material is not "fair use," and formal education such as elementary, high school, and college classroom education is the type of education meant as "fair use" (Teper, 2007). "Innocent infringement," according to current copyright law, is still infringement (Campbell, 2007). More importantly, risk of criminal or civil action aside, copyright infringement is an ethical violation.

Attorneys litigating suits for publishers and organizations against infringers recommend obtaining permission to copy and paying the copyright fees to the CCC and rightsholder or obtaining an internal license from the CCC for firms reproducing multiple materials. An intellectual property attorney contacted regarding the issue of copyright permission and fees, recommended at $350 per hour to "pay the fees."

Suggestions for the LNC Regarding Copyright Compliance
• Go to the medical library and read the hard copy article or book or read the article on line if it is available and take notes.
• Purchase subscriptions for journals routinely used for review of cases.
• Link onto **www.copyright.com** to determine permission and fees and set up an account with the CCC.
• U S government publications are generally in the public domain and so labeled, such as *Environmental Health Perspectives* and *Journal of the National Cancer Institute*, and do not require permission to photocopy or distribute.
• Purchase used books on Amazon.com or other Internet source for used medical books. One book that should be especially purchased would be the Physicians' Desk References (PDRs) whose publisher charges $25.00 per page for photocopy permission *if they approve your use*.
• Use a document delivery service or article retrieval service to 1.) obtain the articles, 2.) obtain the permission and 3.) pay the fees which are then passed on to you which you pass on to your client.
• Purchase and download articles in pdf directly from the Internet and pay the permission fees by clicking on the "Permissions" button on the site, contacting the publisher directly or contacting the CCC.
• When you are obtaining medical articles and/or book chapters for an attorney, you are acting as a document delivery service and are legally obligated to pay copyright permission fees in that capacity.
• When you are being asked to provide reference articles, provide the citation or the URL where the article may be obtained by the client.
• Be aware that sending copyright materials by pdf is in violation of the Digital Millennium Act of 1998 unless permission is obtained and the permission fee paid.
• Consult a copyright attorney if you are in doubt about your assessment of your fair use.

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Two Roles Examined: The Pharmacist's Responsibility in Adverse Reactions and Medication Abuse

Rolando Morales

KEY WORDS
Adverse Drug Reactions, Medication Abuse, Pharmaceuticals, Pharmacist

Pharmacists have a duty to all clients under their care. Just as the pharmacists have emerged from behind the counter, their duty has emerged beyond merely dispensing the correct medication. The duty of pharmacists to their clients includes monitoring the medication profile for any medications that may produce adverse drug reactions (ADRs), as well as being observant for abuses of controlled substances. This article will discuss the duty of the pharmacist in preventing, detecting, and reporting these occurrences. This article is part of the 2009 JLNC Nursing Contact Hour Program. Please see the conclusion of the article for more detailed instructions.

The Role of the Pharmacist in Preventing, Detecting, and Reporting ADRs

An adverse drug reaction (ADR) is defined as, "Any undesirable effect of a medication beyond its anticipated therapeutic effects occurring during clinical use" (Pirmohamed, 1998). The financial impact of ADRs is significant for both consumers and providers. Inpatient clients who develop ADRs experience an average increase in hospital stay of 8 to 12 days longer than clients who do not experience ADRs. The resulting increased hospitalization cost can be $16,000 to $24,000 (Agency for Healthcare and Research Quality [AHRQ], 2001). With the new Center for Medicare Services (CMS) guidelines, which will not reimburse a preventable hospital error, this could have dramatic impact on already strained budgets.

The FDA has started posting a list of medications under investigation for safety concerns. Updated quarterly, the list can be viewed at **www.fda.gov/cder/aers/default.htm**. Lamb (2007) identifies the ten most common medications involved in ADRs requiring consumers to seek treatment in a hospital emergency department are listed in descending order, with rate of frequency of involvement in parentheses:

1. Insulin (8%)
2. Anticoagulants (6.2%)
3. Amoxicillin (4.3%)
4. Aspirin (2.5%)
5. Trimethoprim-sulfamethoxazole (2.2%)
6. Hydrocodone/acetaminophen (2.2%)
7. Ibuprofen (2.1%)
8. Acetaminophen (1.8%)
9. Cephalexin (1.6%)
10. Penicillin (1.3%)

Pharmacists also have the duty to prevent and detect ADRs caused through incorrect or excessive dosages by monitoring the amounts or levels of medication (Fong, 2008). The pharmacist's responsibility includes notifying physicians immediately of a possible ADR (AHRQ, 2001). Such notification may prevent mild medication reactions from escalating into a severe ADR.

Signs and symptoms documented in the medical record, which may indicate that an ADR occurred, include rash; diarrhea; fever; changes in respiratory rate, heart rate, hearing, or mental state; seizure; and/or anaphylaxis. The pharmacist has a duty to report these findings to the physician. In 99% of cases of physicians being notified by a pharmacist of an allergic reaction to a medication, the physician prescribed a different medication (AHRQ, 2001).

Another responsibility of the pharmacist is to maintain a safe inventory by monitoring recalls, market withdrawals, and safety alerts issued by the Food and Drug Administration (FDA). Medications purchased online, via mail order, and/or in foreign countries pose unique challenges. Consumers buy up to $40 billion in counterfeit medications every year. Canadian Web sites may provide a false sense of security (Howell, 2007). A recent FDA search at United States airports found that 85% of medications labeled as "Canadian" originated in other countries (Kostick, 2007).

Home pages of legitimate online sites will display the Verified Internet Pharmacy Practice Sites (VIPPS) seal of approval granted by the National Association of Boards of Pharmacy, indicating that the site follows the same standards and regulations as traditional pharmacies. Only 13 online pharmacies have qualified to date. A complete list of these pharmacies may be found at **www.nabp.net**. Qualified Web sites ensure that the pharmaceuticals contain the right dose of the right medicine and have not reached their expiration date. The VIPPS seal also indicates that the business is U.S.-based, which is one of the only countries to regulate the online sale of prescription medications.

When purchasing online, consumers should be asked for a prescription, doctor's contact information, and the name of their insurance provider if not paying out of pocket. To ensure appropriate pricing, the Web site **www.pharmacychecker.com**

compares prices between sites on common prescription medications (American Association of Retired Persons [AARP], 2005).

Actions to prevent ADRs include identifying medications that are inappropriately prescribed, such as Duragesic for post-operative pain, as Duragesic requires 8 to 10 hours before absorption begins after initial application (Whacker, 2009). Pharmacist can also monitor duration of treatment for appropriateness. During 2001, the Agency for Healthcare Research and Quality (AHRQ) funded grants to reduce hospital-based medical errors by combining best practices, provider education, and advances in information technology. Some of the best practices included pharmacists accompanying physicians on patient rounds, computer prompts for required laboratory monitoring, and medication algorithms (AHRQ, 2001).

Computerized monitoring systems may reduce ADRs 28% to 95%, while computerized medication order entry may prevent 84% of dose, frequency, and route errors. This could translate into a $500,000 annual savings in direct costs to hospitals (AHRQ, 2001).

The usual cause for ADRs requiring consumers to seek hospital treatment is noncompliance issues such as taking incorrect doses, taking doses at the wrong times, forgetting to take doses, and/or stopping the medication too soon (Lamb, 2007). Pharmacists are uniquely qualified to both detect medication incompatibilities and non-adherence patterns that may lead to ADRs and to educate the clients on the importance of taking scheduled medications as instructed. Pharmacists must ensure that the name of the medication (brand or generic) and the directions for use provided by the pharmacy are the same as those written down by the prescriber.

Consumers should review the list of medications with the pharmacist for additional safety. Consumers have the right to counseling by the pharmacist for any questions. The pharmacist has the duty to explain how to properly take the drug, the side effects of the drug, and actions to take if side effects are experienced. As many as 90% of prescription errors can be detected in this process (O'Donnell, 2007).

All health care professionals and consumers have the duty to report serious problems associated with the medications and medical devices they prescribe, dispense, or use. Med Watch, the FDA Safety Information and Adverse Event Reporting Program, offers reporting online, by phone, or by submitting the MedWatch 3500 form by mail or fax. For more details, visit **www.fda.gov/medwatch/**.

Role of the Pharmacist in Preventing, Detecting, and Reporting Substance Abuse

In addition to their work in preventing ADRs, pharmacists also have the duty to prevent, detect, and report medication abuse to ensure that medications provide the intended benefit and better quality of life for those entrusted to their care. According to the 2004 National Survey on Medication Use and Health, 22.5 million Americans ages 12 years or older abused or were dependent on alcohol or medications during 2003. This translates to 9.4% of the U.S. population (Kenna, 2006). Health care workers are not immune. The American Nurses Association (ANA) has estimated that drug diversion is the number one reason for disciplinary action by state boards, with as many as 8% of nurses using alcohol or drugs while on duty (NSO, 2008).

Substance dependence includes behavioral and physiologic symptoms with continual, compulsive use of self-administered substances, which continues despite use-related problems. According to Kenna (2006), addiction is identified when a qualified medical professional identifies at least three of the following behaviors in a 12-month period:

- Tolerance;
- Signs of withdrawal (varies by substance);
- Use of larger amounts of the medication or for a longer time period than intended;
- Persistent desire or unsuccessful efforts to cut down or control use;
- Continual use despite adverse consequences;
- An excessive amount of time and effort spent obtaining the medication; and
- Giving up or reducing social, occupational, or recreational activities.

The pharmacist has the duty to recognize the signs of medication abuse and to help those struggling with the addictive properties of medications. Although the pharmacy profession shares the nursing duty to "first do no harm," even a legal and valid prescription can lead to an uncontrollable addiction. Signs of abuse may include clients who insist on paying cash for their prescription pain reliever, consecutive narcotic refills from multiple prescribers, or questions regarding the maximum dose of the medication or which medication is more potent. Some of the first signs of developing abuse may be changing patterns in the medication usage profile and refill patterns, as well as changes in a client's behavior. When such signs are noted, pharmacists should verify any trends in office visits or complaints of increasing chronic pain with the physician. The pharmacist may also address this pattern with the client. The pharmacy code of ethics states that a client's well-being is the center of professional practice (Fong, 2008).

Confrontation of those patients demonstrating signs of dependence will likely be a highly emotional and stressful time for both parties, but it serves to reaffirm the pharmacist's commitment to the client's well-being. The pharmacist should select an area that provides privacy to avoid any public embarrassment and should comply with privacy laws without sacrificing personal safety (Fong, 2008).

Prescriptions should be reviewed carefully, focusing on the quantity, strength, refill amounts, and date of prescription. Any alterations, erasures, different colored ink, or different penmanship are cause to suspect forgery or tampering. Multiple clients presenting with prescriptions for the same medication by the same prescriber within a short time indicate that the prescriptions may be fraudulent. If any part of the prescription looks suspicious, the prescriber should be contacted for verification.

Drug diversion by health care professionals may be detected by monitoring unwitnessed narcotic wastes. Affected employees may request additional hours, especially when supervision is minimal.

"Pharm parties" are becoming increasingly more popular among teens. Bowls and baggies filled with random pills are called "trail mix," and collecting pills from the family medicine chest is called "pharming." Pharmacist can identify doctors who prescribe inordinate amounts of narcotics and identify Internet pharmacies that ship drugs with little medical consultation (Leinwand, 2006). Pharmacists should educate clients in the proper storage and disposal of medications. Although not required to take back unused medications, some pharmacies and drugstore chains do sponsor regular "clean out the medicine cabinet" drives where customers can return old, expired, or unused medications, supplements, and other over-the-counter products to prevent such abuse, as well as preventing the introduction of medications into municipal water supplies when improperly disposed of down the drain (Eustice, 2007).

Symptoms of withdrawal include agitation, paranoia, and other aberrant behavior. The goal of treatment is complete freedom from addiction. Resulting benefits may be seen in improved personal relationships, workplace function, and community involvement. While behavioral and pharmacologic therapy are necessary to prevent relapse, pharmacotherapy typically lasts about 6 months, while individual counseling, cognitive-behavior therapy, support groups, recovery programs, and educational or informational classes are typically a lifelong commitment. Treatment location and duration should be tailored to each client. When medication abuse is verified, reporting to law enforcement is mandated, as well as the professional regulatory board in the case of drug diversion by a professional.

Resources available to help those addicted and their families include Narcotics Anonymous (**www.na.org**), Nar-Anon for spouses (**www.nar-anon.org**), and Buprenorphine Physician and Treatment Program Locator (**www.buprenorphine.samhsa.gov**). Resources to aid in prevention include National Institute on Medication Abuse Fact Sheets for Parents of Teens (**www.nida.nih.gov**) (Fong, 2008).

In conclusion, the duty owed to all clients under a pharmacist's care includes preventing, detecting, and reporting ADRs and issues of narcotic abuse. This is a literal

example of an ounce of prevention being worth a pound of cure in financial and human terms.

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Unnecessary Drugs in Nursing Facilities

William Simonson, PharmD FASCP CGP

KEY WORDS
Nursing Homes, Pharmaceuticals, Unnecessary Drugs

Elderly individuals are at increased likelihood of experiencing problems with drug therapy including, but not limited to, adverse drug reactions and interactions, excessive or suboptimal dosing, complications resulting from inappropriate monitoring of therapy, and therapeutic duplication (Simonson and Feinberg, 2005). This concept is becoming increasingly pertinent as the number and types of care environments, especially for the elderly, continue to grow. This article discusses the criteria for defining an "unnecessary drug." It concludes with a discussion of possible medical-legal implications for the legal nurse consultant involved in a case regarding unnecessary drugs. Editor's note: The term "unnecessary drugs" is intentionally used repeatedly to preserve the intent of the article. Because it is important to be exact when using specifically defined terms in the context of their legal criteria, a measure of repetition is deemed necessary to maintain the clarity of the article's intended message.

One way to optimize therapy in nursing facilities (commonly known as nursing homes) is to avoid the use of medications that are not necessary for the resident's well-being. In the Centers for Medicare & Medicaid Services (CMS) Guidelines to Nursing Home Surveyors, Tag F329 "Unnecessary Drugs" requires that each resident's drug regimen be free from unnecessary drugs as defined by the following criteria: "when used in excessive dose (including duplicate therapy), for excessive duration, without adequate monitoring, without adequate indications for its use, and/or in the presence of adverse consequences which indicate the dose should be reduced or discontinued" (CMS, 2008). (See Table 1.)

Table 1. Unnecessary Drugs in Nursing Facilities.

Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
(i) In excessive dose (including duplicate therapy); or
(ii) For excessive duration; or
(iii) Without adequate monitoring; or
(iv) Without adequate indications for its use; or
(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
(vi) Any combinations of the reasons above.

Centers for Medicare & Medicaid Services, 2008

Nursing facility surveyors may cite a facility when use of one or more unnecessary drugs is observed. The consequences of a citation pertaining to Tag F329, as well as other F-Tags (the alpha-numeric labeling system used in the State Operations Manual to determine regulatory compliance in nursing homes), depend on the scope and severity of the offense, and can range from requiring a facility to change procedures to significant financial penalty and even the facility's closure (U.S. Department of Health and Human Services, 2006).

Excessive Doses

Skilled geriatric clinicians typically follow the adage, "Start low and go slow," which refers to initial medication dosage and speed of upward dosage titration (Cohen, 2001). Since elderly patients may be more sensitive to the adverse effects of a medication, the use of relatively small "geriatric dosages" and a slow upward dosage titration can reduce the chance of a serious adverse drug event.

Age-related changes in anatomy and physiology typically result in alterations in the pharmacokinetics of a medication. Pharmacokinetics refers to a medication's movement into, through, and exit from the body. This process often affects its absorption into the bloodstream, distribution throughout the body or to a specific target tissue, metabolism via the liver, and excretion through the kidneys. In addition, a drug's pharmacodynamics (its effects on an individual patient) may be altered in the elderly, often increasing the individual's sensitivity to the drug's effects.

Pharmacokinetic and pharmacodynamic changes may increase the likelihood of an adverse response to a therapy, an eventuality that might be lessened by appropriate medication dosage. Typically, in the elderly, appropriate dosage equates to the use of a smaller dosage than that used in younger, potentially healthier adults. Many medications, such as certain sedative/hypnotic agents used for sleep (e.g., Restoril®, Ambien®, Sonata®, and Lunesta®), have a decreased "geriatric dosage" recommendation that is lower than the normal adult dosage (American Medical Directors Association [AMDA], 2006).

Excessive Duration

While many medications used to manage chronic conditions such as hypertension, Parkinson's disease, and hypothyroidism are appropriately used indefinitely, others are more appropriately used for a limited time. Examples of these medications include sedative/hypnotics that lose their effectiveness with chronic administration, antibiotics used short-term for treatable infections, and certain medications

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Miscellaneous
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Legalization of Marijuana
Athletic Injuries: Medical-Legal and Malpractice Standards in Treatment
Evaluation of Hearing Loss
Ambulatory Care/Outpatient Care Settings
Latex Gloves/Sensitivities
Fraud: Medical Bill Review

used for control of behaviors related to dementia (American Society of Health-System Pharmacists, 2008; McHenry Martin and Saxton-McSpadden, 2007).

When inspecting a nursing facility, surveyors will examine drug regimens for medications that have been administered for an inappropriate duration of therapy. Citations may be given if it is determined that the nursing home facility used therapy for an excessive duration.

Inadequate Monitoring

Once a drug therapy is initiated, it should be monitored by facility staff for both therapeutic effect and adverse consequences. Depending on the medication, monitoring may be accomplished by simple observation of the resident. For example, in the case of a resident taking a sleep medication, facility staff should note when the resident falls asleep and/or whether the resident is overly groggy the next morning due to residual effects of the medication (AMDA, 2006). For some medications, adequate monitoring may also include evaluation of laboratory tests, such as with the cholesterol-lowering medication Lipitor®. This medication generally requires blood work to measure beneficial changes in cholesterol level and detect any evidence of hepatotoxicity, an uncommon but possible adverse effect of this drug.

Depending on the individual medication(s) the resident is taking, surveyors will observe to determine whether proper monitoring has taken place; laboratory work was completed, analyzed, and appropriately documented in the record; and responsive action was taken. This is accomplished through auditing the record and interviews with facility nursing staff.

Inadequate Indications for Use

All medications prescribed in nursing facilities must have a reason for use and this must be documented in the resident's record. This seems to be a simple requirement, yet failure to document could potentially result in a citation because a resident's medical condition may change thus negating the indication for the medication's continued use. For example, a resident who experienced a bout of transient dyspepsia may benefit from a course of a histamine-2 receptor blocker such as Zantac® or a proton pump inhibitor such as Prilosec® (Chitwood, Carlson, and Zhang, 2004). If therapy is allowed to continue after the problem has resolved, however, it could be considered to be an unnecessary drug because it would no longer be providing a therapeutic benefit but could be putting the resident at increased risk for adverse reactions and drug interactions.

Adverse Reactions Necessitating Dose Reduction or Discontinuation

Nursing home surveyors look to see if facility staff has been vigilant to detect adverse reactions to drug therapy. These reactions can range from subtle to obvious, from minor to life-threatening, or may even have lethal consequences. Interpretation of drug reactions is crucial because even subtle adverse reactions can have severe consequences. For example, a reaction such as anorexia resulting from digoxin toxicity could result in malnutrition, which could be a life-threatening condition in the elderly.

It is important for facility staff to not only monitor residents for manifestations of adverse consequences of medications (including behavioral or physiological changes, laboratory results, physical findings, etc.) but also to document the findings. Documenting adverse consequences as part of a resident's medical record demonstrates to state surveyors that the nursing facility has sought to maintain compliance with federal requirements but more importantly has addressed issues of patient safety.

Medical-Legal Implications

The likelihood of a nursing facility's being cited during state survey is increased when surveyors observe two or more of the above criteria. Nursing facilities must, therefore, be vigilant to address all issues pertaining to unnecessary drug use.

Proper attention to drug therapy is important to protect nursing facilities from citation for deficiencies during state surveys. Adherence to appropriate policies/procedures and correct techniques for medication ordering, administration, and monitoring, as well as diligent follow-up of residents to determine whether they meet the published survey criteria, should largely prevent the use of unnecessary drugs in nursing facilities.

Attorneys involved in nursing home litigation can regard state and federal nursing home regulations as quintessential guidelines to establish the standard of care. When rules and regulations such as those involving unnecessary drugs are admitted into evidence as the accepted standard of care, the admission may constitute evidence for the jury to consider in determining the issue of negligence. Those named in litigation could potentially involve the facility administrator, director of nursing, nursing staff, consultant pharmacist, nurse practitioners, attending physician, and/or medical director.

The presence of unnecessary drugs could also be used to impugn the policies and procedures of the nursing facility and/or the provider pharmacy, and to question whether appropriate policies and procedures were either nonexistent or were not followed.

Conclusion

While the CMS F-Tags apply only to nursing facilities, the criteria defining unnecessary drugs are based on sound medical and pharmaceutical principles and standards of practice. Because drug therapy problems such as adverse drug reactions and interactions affect individuals regardless of where they are being cared for, these criteria could be applied to other care environments such as assisted living and related institutional settings. This concept is becoming increasingly pertinent as the number and types of care environments, especially for the elderly, continue to grow.

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Normal Pressure Hydrocephalus

Kara L. DiCecco, MSN RN LNCC

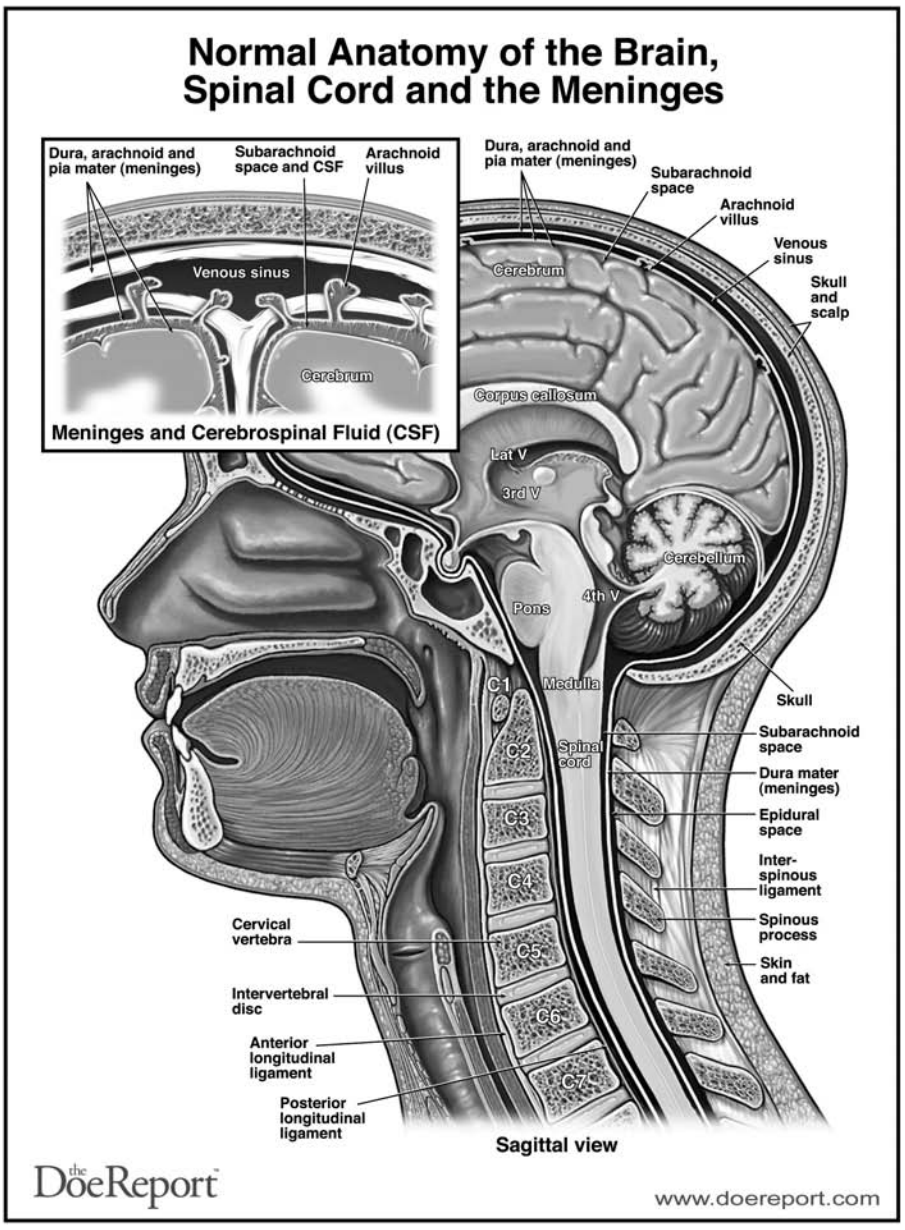
The topic matter offered in The Clinical Maxim *column is not meant to provide medical or legal advice, only to acquaint the reader with an overview of clinical conditions and/or diseases as well as their and their clinical/legal implications. As with any medical-legal matter, the reader is admonished to consult the services of a medical and/or legal professional, respectively. The reader is also reminded to critically analyze and evaluate the sources offered here and confirm their reliability independently.*

Normal Pressure Hydrocephalus (NPH) is a potentially reversible dementia that may be mistakenly misdiagnosed as a classic, progressive dementia with little hope for successful treatment. The triad of presenting clinical symptoms may lead the diagnostician to conclude that they are dealing with routine age-related difficulties superimposed on an Alzheimer's-ravaged mind. Further confounding the clinical picture are the normal pressure readings at an opening lumbar puncture in the work-up for hydrocephalus. Taken as a whole, on the other hand, a sharply focused picture can emerge, which may provide hope for patients and their families. Familiarity with the clinical signs and symptoms, along with a heightened awareness of the legal pitfalls, will serve to provide the LNC researcher with a starting point for case evaluation.

Anatomy

Cerebrospinal fluid (CSF), the fluid inside and around the brain and spinal cord, is produced within cavities of the brain called ventricles. These ventricles communicate by way of small channels. Once the cerebrospinal fluid leaves the ventricles, it circulates around the brain and spinal cord. After the fluid has completed its course around the brain, it is absorbed across tube-like structures (villi) and enters into the blood stream (see Figure 1). NPH is a mechanism of decreased CSF absorption in which the arachnoid granulations fail to maintain the baseline removal of

Figure 1



CSF (a.k.a. communicating hydrocephalus). Ultimately, stagnant CSF (increased accumulation of fluid) leads to increased pressure, causing ventricular enlargement that allows CSF pressure to return to normal but may displace brain tissue (Dalvi, 2007; Pikul, 2004).

Etiology

The enlarged ventricles (ventriculomegaly) place pressure on brain tissue. The distortion of the central portion of the corona radiate includes the sacral fibers that innervate the legs and bladder, which leads to altered gait and urinary symptoms. Altered cognition results from the distortion effect on the periventricular limbic system (Neumiller, Gates, Setter, and Greeley, 2007).

Idiopathic NPH is usually diagnosed in the sixth or seventh decade of life. In many cases, the cause of NPH is unknown and the NPH is classified as primary NPH. When the cause is known (such as trauma or infection), the NPH classified as secondary NPH (Pikul, 2004). The following may be precursors for secondary NPH:

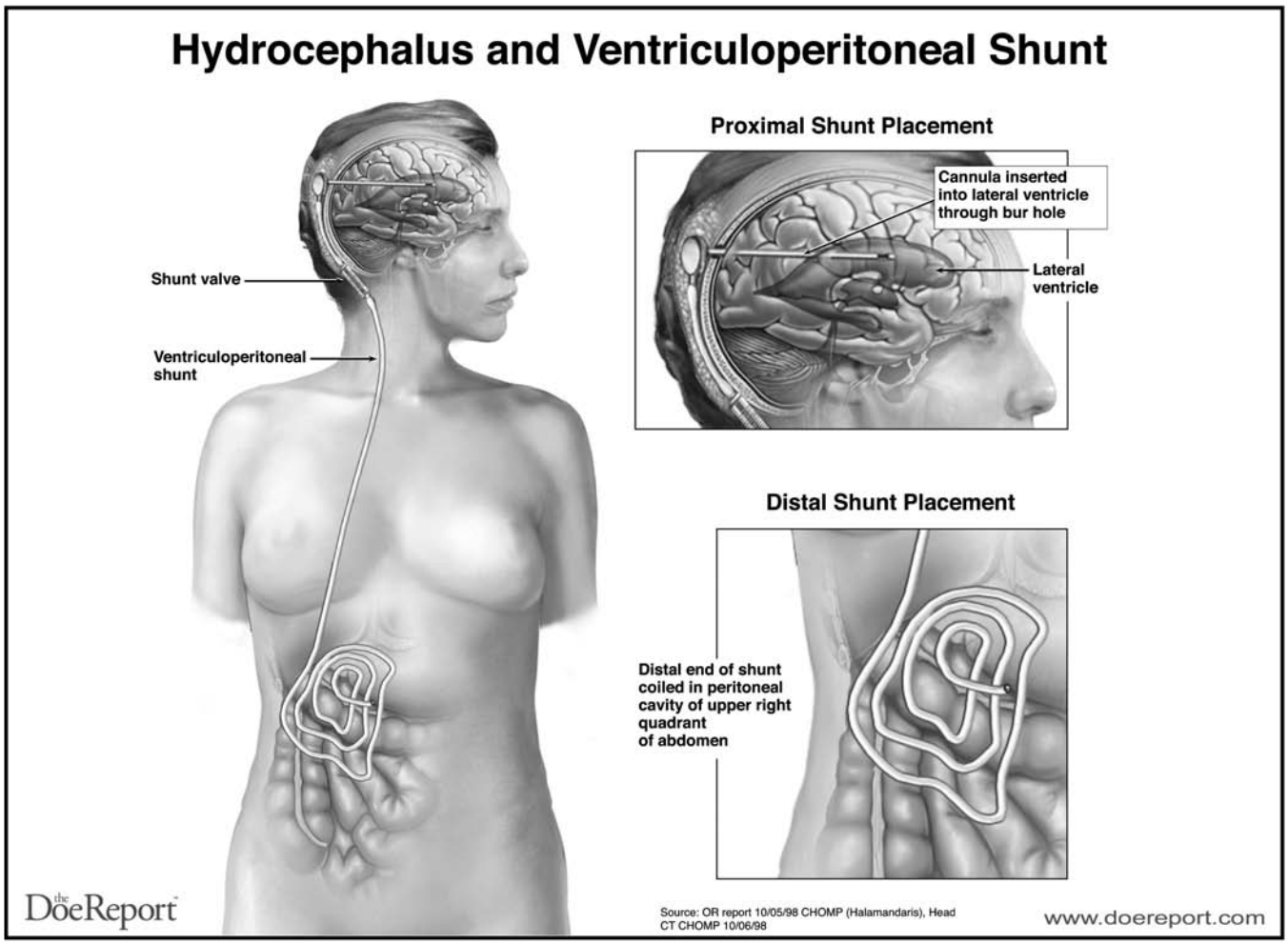
- Subarachnoid space occupying lesion or hemorrhage
- Chronic meningoencephalitis
- Changes following acute bacterial meningitis or spinal anesthesia
- Carcinomatosis of the meninges
- CNS Tumor
- Head Trauma
- Infection
- Aqueductal stenosis (Verrees & Selman, 2004)

Signs and Symptoms

The hallmark triad of symptoms in NPH are dementia, altered gait, and urinary incontinence.

- Apraxic gait (bradykinetic, broad-based, shuffling, hesitation may occur). Patient may describe that feet feel "stuck." This is often the first presenting symptom.
- Dementia, specifically subcortial cognitive deficits, forgetfulness, decreased attention, inertia, bradyphrenia (slowed thought process)
- Urinary urgency, frequency (at onset)/incontinence (may include fecal)
- Ventricular enlargement on diagnostic imaging with normal CSF pressure readings (NINDS, 2009)
- Absence of papilledema (Pikul, 2004)

Figure 2



Diagnostic Testing

Determining or confirming the cause of NPH may warrant limiting or expanding individual testing, based on specific clinical presentation.

- Large-volume lumbar puncture to remove 40-50 ml CSF and monitor for patient response in 4-6 hours, compared to initial baseline evaluation (particularly gait). In the alternative, insertion of spinal catheter to continuously remove CSF 10 ml/hr for 48-72 hours may yield improvement in symptoms. With positive response (i.e., improvement of gait and urinary difficulties), ventricular shunting will likely be the recommended treatment (Williams and Rigamonti, 2006) (see Figure 2).
- Magnetic Resonance Imaging (MRI) to look for cerebral vascular disease and changes consistent with central atrophy (Dalvi, 2007).
- Computerized Axial Tomography (CAT) Scan may show enlarged ventricles (Dalvi, 2007).
- Lumbar puncture to obtain pressure readings in the cerebrospinal fluid (CSF).
- RHISA/Radionuclide Cisternogram/Cysternography may show latent tracer activity and impedance to CSF outflow.
- Single-Photon Emission Computerized Tomography (SPECT) to evaluate blood flow.
- Neuropyschological testing for cognitive dysfunction.

Legal Considerations

- Misdiagnosis is common due to the complexity of the pathology and symptoms often attributed to age-related complications and/or similar clinical presentations to Parkinson's, Creutzfeldt-Jakob Disease (CJD), and vascular dementia with Lewy bodies (NINDS, 2009).
- Family members' input should be elicited for accuracy of diagnosis and treatment (not otherwise obtainable from the patient themselves, as they may be unable to recall or report symptoms accurately).
- Symptoms of NPH are usually progressive if not treated (temporary remission possible).
- Shunt malfunction is possible, due to improper insertion or infection.
- Diagnostic interpretation is difficult because ventricles tend to enlarge normally with aging.
- Diagnosis is a composite of factors in the individual, and not all triads of similar presentation are NPH.

A Look at Case Law and Resources

An informal search of online case law was conducted using the GOOGLE search engine and keywords (in quotes) "normal pressure hydrocephalus", "reversible dementia", "medical malpractice", "negligence", and "case law" in alternating string searches. A review of the information retrieved provided both formal and informal sources. The majority of case law located focused on the issues of competency in estate and guardianship matters. From a failure to diagnose evaluation, a window of opportunity for the successful reversal of dementia may be at issue, although this is controversial from a medical standpoint. A sampling of the *preliminary results* via Internet retrieval is provided here.

http://www.apa.org/pi/aging/diminished_capacity.pdf
PDF of Assessment of Older Adults with Diminished Capacity: A Handbook for Lawyers. Collaborative effort of the American Bar Association and the American Psychological Association.

http://prevention.healthline.com/search?q1=normal+pressure+hydrocephalus+risk+factors&imuid=4984576
Listing of articles on NPH

http://www.lifebridgehealth.org/body.cfm?id=4249
Consortium of Sinai Hospital in Baltimore and related facilities. Adult Hydrocephalus Center at Life Bridge Health Brain & Spine Institute provides support, education, research for patients and their families.

http://www.medtronic.com/hydrocephalus/nph/nph_subs/nph_complications.html#symptomsanchor
Resource from Medtronic on signs of shunt malfunction.

http://www.justice.org/resources/PNLR2006December.pdf
Wilson v. Washington Brain & Spine Inst., P.C. (2006) Case cited in Professional Negligence Law Reporter (ATLA) resulting in a $22.61 million verdict.

http://foodpoisoning.pritzkerlaw.com/archives/cat-our-services.html
Interesting connection made by private law firm between food poisoning (listeriosis) and NPH.

http://www.rishabhdara.com/sc/view.php?case=90823
A sample of case law from India on estate and competency issue.

Potential Experts

- Neurologists (for diagnosis) and neurosurgeons (for shunting)
- Neuropsychiatrists/Neuropsychologists
- Internal medicine and family practice as treating primary physician
- Geriatric specialists
- Radiologists and/or neuroradiologists (for an addition diagnostic perspective)

Damages

- Theory supporting the earlier shunting intervention for dementia, the better prognostic outcome; i.e. delay in treatment may lead to irreversible dementia, urinary incontinence and gait disturbance.
- Sequelae of misdiagnosis, impact on psychological and psychosocial factors (such as depression and/or suicidal ideation)
- Complications from diagnostic shunting may lead to seizures, stroke, or subdural hematomas.

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Book Review

Proving Conscious Pain and Suffering: Harnessing the Medical Evidence

By Lorna Morelli-Loftin, RN LNCC
Publisher: LawBulletin Publishing Company
$49.95 (softbound), available at ***www.lawbulletin.com/404.php?pagePK=40***

Reviewed by Kara L. DiCecco, MSN RN LNCC

With rare exception, a comprehensive review of a plaintiff's medical records will likely find the legal nurse consultant (LNC) conducting research on conditions that are not necessarily familiar or common to the consultant's primary area of practice. But just as medical-surgical nurses must have an impressive grasp on the vast array of medical conditions and procedures, so too must the LNC have a vital understanding of the numerous components needed to support and confirm medically-related damages.

Screening for merit in personal injury and other damage-driven claims requires an intuitive skill for locating reliable information to form and sustain the LNC's position. LNCs must learn what they don't know and research what they don't understand. Finding tools to develop and enhance these skills makes all the difference in providing exceptional service to the attorney-client. This is where *Proving Conscious Pain and Suffering: Harnessing the Medical Evidence* surpasses most medical texts.

Experienced author Lorna Morelli-Loftin is a Registered Nurse and Legal Nurse Consultant Certified, in addition to a frequent and well-received lecturer at American Association for Justice (AAJ) seminars. In her primer, Morelli-Loftin has assembled a straightforward resource of information on the concept of pain and suffering as evidence in litigation. The manifestation of pain, whether acute or chronic, is a core component in numerous areas of tort law, including personal injury, social security, worker's compensation, medical malpractice, and disability claims. The list goes on of where and when the LNC will encounter pain management issues and the affect it has on the attorney's client, in addition to the impact it has on a potential claim for damages.

In five logically sequenced chapters, the primer introduces the trial lawyer and their LNC to the importance of quantifying the plaintiff's pain for the judge and jury. The author addresses the hurdles that the trial team can anticipate in communicating the presence of pain and offers practical advice on helping the jury understand how to fairly evaluate the damages from a life-altering injury. She specifically explains five obstacles that may lead to a jury's reluctance to award for pain and suffering and how we have come to over-rely on signs more than symptoms in evaluating the patient's pain. The author has included visual aids for pain measurement tools, as well as commonly encountered medication flow sheets. Particularly informative are the sections that address the standards of care as they relate to pain management (including a sample corporate policy on pain management) and the responsibilities of the individual health care disciplines in responsibly documenting a thorough and ongoing assessment of pain in the facility setting.

Despite the admonition, "Pain is what the patient says it is," even health care providers themselves do not universally accept this standard. The problem of inadequate pain control is ever-present, and many providers continue to falter in addressing their patient's chronic pain issues. If health care providers, with their advanced knowledge, have difficulty accepting the existence or degree of subjective reports of pain, that which falls to the periphery of scientifically measurable pain it is likely to be judged by even harsher standards in jury deliberations by laypeople. Without instruments systematically yielding black and white results of exact pain levels, the triers of fact are left to draw on personal experience and their own perceptions of pain. Science and medicine have only to look at the phenomenon of "phantom pain" to humble themselves and admit that we have much to learn and appreciate in understanding the individual response to pain. (I, too, must admit that I am from the traditional school of "grin and bear it," so I must learn to expand my thinking as well.)

There are a variety of noteworthy additions to this primer. Notwithstanding the diverse amount of medication flow sheets and forms available to the reader, there are several treatment algorithms outlining the diagnostic work-up of pain. Of particular interest are the role-specific checklists that help to guide the LNC's review process on matters that are to be addressed by the various health care professionals. A truly unique provision of this primer is the inclusion of numerous case summaries and jury verdicts in pain-related claims, including anesthesia awareness. The reference list provides an excellent resource for further independent research. Both the attorney and the LNC will find the primer an excellent inspiration for developing questions for the expert medical witness' deposition.

This primer is clearly written from a viewpoint sympathetic to the plaintiff and their counsel, but trial teams on either side of the bar stand to gain invaluable insight into

Continued on page 24

Hydrocephalus

The following sites provide online resources for research, education and support for the clinical condition of Normal Pressure Hydrocephalus. It is not meant to be all inclusive of the potential resources available. This list is provided as a general reference source for the LNC and is not an endorsement of any listed sites or services. As with any online resource, the reader must confirm its authority and credibility independently.

Research

http://brain.oxfordjournals.org/cgi/content/abstract/131/11/2904
Research article on why motor activity increases after CSF drainage in NPH

http://www.treatnph.com
Informative site from Medical College of Georgia

http://hopkinsneuro.org/hydrocephalus/disease.cfm/condition/Normal_Pressure_Hydrocephalus
John's Hopkins Medicine Neurology/Neurosurgery Hydrocephalus Center

http://www.cochrane.org/reviews/en/ab003157.html
This posting is from 2002 but states there is no evidence that shunting is effective for NPH due to lack of random control studies

http://my.clevelandclinic.org/disorders/hydrocephalus/hic_normal_pressure_hydrocephalus.aspx
Good explanation and illustrations, including the Cleveland Clinic's NPH Protocol for diagnosis

http://www.healthsystem.virginia.edu/internet/neurogram/neurogram3_3_nph.cfm
University of Virginia Health System, introduction of Codman Hakim Programmable Valve for CFS shunting. Also provides information on co-morbidity in NPH

http://www.ajnr.org/cgi/content/abstract/19/5/813
Article from the American Journal of Neuroradiology MR on the differential diagnosis of NPH versus Alzheimer's and the significance of perihippocampal fissures (1998)

http://www.harrisonspractice.com/practice/ub/view/Harrison's_Practice/Normal%20Pressure%20Hydrocephalus/141386/0
Harrison's Practice Preview on NPH

Pathophysiology and Anatomy

http://www.medicallegalart.com
Illustrations, models, animation, and more for demonstrative evidence. Also has excellent articles and resources for medical-legal professionals.

Education

http://www.neurologychannel.com/NPH/index.shtml
Commercial site providing education and a forum for support

http://www.csmc.edu/6625.html
Cedars-Sinai Medical Center informative article in Neurosciences Report that discusses NPH and predictors for shunting candidates (Fall 2004)

http://www.nlm.nih.gov/medlineplus/ency/article/000752.htm
National Library of Medicine/National Institutes of Health Informative site with illustrations and explanations regarding NPH

http://www.nph.vcu.edu/brochure.htm
In conjunction with Virginia State Legislature and the Virginia Department of Health, Medical College of Virginia of Virginia Commonwealth University patient brochure with dynamic links to research, services and scientific literature

http://www.emedicinehealth.com/normal_pressure_hydrocephalus/article_em.htm
Excellent overview and detail of NPH

http://www.medtronic.com/hydrocephalus/nph/index.html
Available downloads on living with NPH and informative information and links

http://www.wrongdiagnosis.com/n/normal_pressure_hydrocephalus/intro.htm
Requires discriminating eye for appropriately related NPH material but offers several resources, a forum for discussion and overview of NPH

Support for Patients and Families

http://www.hydroassoc.org/docs/AboutNormalPressureHydrocephalus-A_Book_for_Adults_and_Their_Families.pdf
34-page informational booklet from the San Francisco Hydrocephalus Associations (2002). Cites Dr. Hakim's 1964 hallmark study on NPH

http://www.lifebridgehealth.org/body.cfm?id=4252
Lifebridge Health is a consortium of regional health care centers, such as Sinai Hospital in Baltimore, that offers an resource for support groups and a hydrocephalus center specializes in NPH and related conditions

http://www.hydroassoc.org
Non-profit organizations for research/advocacy, education and support

http://ghrf.Homestead.com/ghrf.html
Non-profit organization that offers networking for patients and families. Main focus is pediatrics but offers resource for Adult Onset Hydrocephalus as well.

http://nhfonline.org
Resources from the National Hydrocephalus Foundation (Illinois based) provides information on shunting, research, support, education. Specific link for NPH under Info on Hydrocephalus

Approaching the Initial Review of Voluminous Medical Records

Rose Clifford, RN LNCC, AALNC Lexington, Kentucky, Chapter President, 2008

Q: How do you approach the initial review of voluminous medical records without being so overwhelmed by the thought of it that it paralyzes any efforts to begin?

A: Begin knowing that you have specialized knowledge in medical record reviews and start with a simple plan of how to break the task down into smaller more achievable tasks. Begin with an established process.

It is always exciting to receive a new case, no matter where you are in your legal nurse consulting practice. When the medical records are thousands of pages in volume and contained in multiple banker' boxes, however, it can be suddenly overwhelming and difficult to begin. Recognizing that you are not alone in your feelings is the first step in starting the process.

Every expert consultant has, at one time or another, experienced similar thoughts and feelings. Sometimes it is difficult to know just where to begin, but keep in mind that most law firms are not going to send their consultants small, easy cases. Those cases they will do themselves or have their in-house staff do them. It is the more difficult and voluminous cases that they are going to send out to their experts. So where does one begin?

As simple as this may sound, begin with the knowledge that it is a:

1. Compliment to your expertise in the field to receive difficult and voluminous records.
2. Testament to the confidence that the law firm places in your ability to decipher such complicated, difficult to read, and often illegible records accurately.
3. Measure of security in assuring future casework.

Begin with a basic plan. First, determine what medical records you have actually received from your attorney. The records they intend to send are not always the records you receive, so double-checking is important. The easy yet seemingly most arduous action is to begin by pulling the medical records out of the boxes and displaying them on a conference table in the order in which they were inserted into the boxes. Sometimes the order in which the attorney has inserted the records will give a preliminary sense of organization that will help expedite your review, or it may give some indication as to what is most important in the records and where to begin. At this point, do not organize the records. Simply start the process by pulling them out of the boxes.

Next, assess the records in the order in which you received them. Quickly go through the records page-by-page, listing the medical records by dates of service. Do not look at the total volume. Concentrate on each individual page. You are looking for face sheets, admission records, discharge summaries, consults, and/or coding sheets to glean the information. Include in your listing the facility name, the purpose of the visit, the type of visit, and the treating health care provider's name.

Be sure to include the bate page numbers, if provided, and make a note as to whether the medical records provided are certified copies. Sometimes this is important to the attorney to know. Do not bate-stamp the pages at the initial stage of listing the records if they are not already stamped. It may prove to be a waste of time if the case turns out to be non-meritorious.

In fact, if you do receive the records already numbered, be sure to use this same system for your review, as the attorneys will likely have a set to match and your review should align with their numbering. Organization is sometimes done by attorney preference, so you may want to confirm if they prefer a particular style or approach.

Initially, listing the medical records will give you a feel for the kinds of records you have in hand, such as emergency department records, in-patient hospital admission records, clinic visit records, physician office visits, therapy records, or urgent treatment records. Following this procedure will help you identify the number of records, number of emergency department and in-patient visit records, the time period over which the records span, the completeness of the records provided, and the extent of the care required by the

plaintiff or defendant, along with any pre-existing care and/or subsequent treatment.

Do not get caught up in reading the records for content at this point. You are merely gathering factual visit information. The initial goal is to get a handle on the volume of records and gain a sense of direction with which to accomplish a more detailed review.

Once you have completed your initial read-through, you can establish organization of the material in two ways:

1. Physically organize the medical records in chronological order by year, month and dates; or
2. Organize the medical information in your initial report.

The choice, as to whether or when to organize the medical records, is yours. It depends on your level of review experience, personal need to organize, type of case, and purpose of the review. It may also depend on the way you process large amounts of factual information.

If you are visual, you may find it helpful to space the physical layout of the medical records in chronological order grouped by years. This will give you a sense of organization. If you are analytical in nature, then visual organization may not be a necessity. If you are dealing with one admission, such as a nursing home record, organization in the initial stage of the review may take too long. But if you are dealing with a criminal case that contains 12,000 pages of various medical records encompassing 150 combined emergency room visits and in-patient hospital admissions, interspersed with a variety of clinic visits, physical therapy visits, physician office visits, and ambulance runs records, then physical organization may be warranted. Again, it depends on the reviewer's ability to process the information quickly and the purpose of the review.

After you have been through the records once and have established a good understanding for what you have in hand, you are past the stage of feeling overwhelmed by the sheer volume and well into processing the records with a purpose. Familiarizing yourself with the records in stages makes you more comfortable with the volume. You are now ready to start your review of the medical records for content and substance.

Rose Clifford, RN LNCC, is an independent legal nurse consultant with more than 20 years of experience. She is executive director of Medical Analysis Resources, Rose Clifford LNC Internships (**www.roseclifforddinternships.com**) and editor of The Medical-Legal News (**www.medical-legalnews.com**). She may be reached at **Cliffordrz@aol.com**.

Book Review: Proving Conscious Pain and Suffering: Harnessing the Medical Evidence

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the essential components of how pain should be documented and tracked, the absence of which may very well block the true intent of the law to *fairly* adjudicate the issue. Whether supporting or refuting the plaintiff's claim, the knowledge gained from reviewing this primer will assist a dual audience in assessing the strengths and weaknesses of their position. Whether acute or chronic, the issue of pain is intrinsic to representation and evaluation of damages when an injury is sustained, regardless of the legal orientation.

AALNC
AMERICAN ASSOCIATION OF LEGAL NURSE CONSULTANTS

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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.

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Manuscripts should not exceed 3,000 words in length. 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.

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Manuscripts should be sent to the JLNC Managing Editor via e-mail at **JLNC@aalnc.org**, as a Microsoft Word attachment. (If not possible, an electronic copy on CD can be mailed to the JLNC Managing Editor; address above.) Use a minimum of formatting: do not use unusual fonts or a variety of type, and do not insert headers or footers except for page numbers. Create a separate file for tables and figures—do not insert them into the text file. Clearly label your e-mail (or CD) with the submission title, word processing program name and version, and name of the corresponding author.

Style and reference guidelines
JLNC follows the manuscript style and reference guidelines of the *Publication Manual of the American Psychological Association* (5th 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.

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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 should be labeled sequentially (e.g., Figure 1, Figure 2 or Table 1, Table 2) and should 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.

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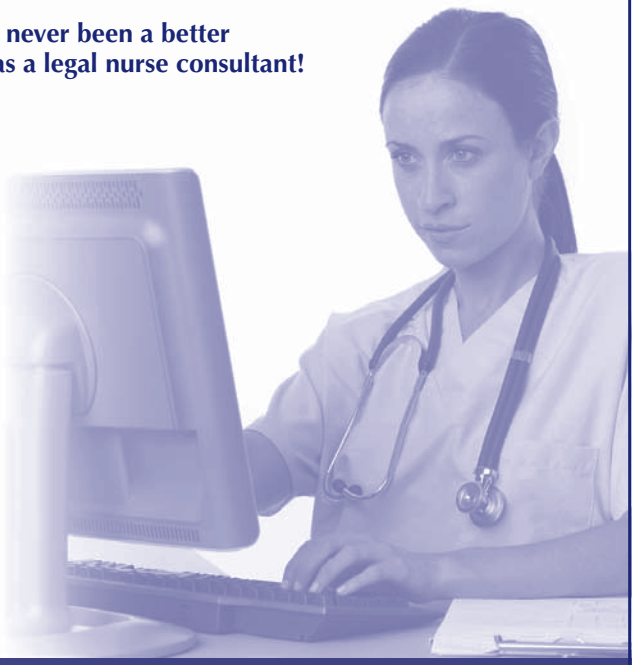

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