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The Journal of Legal Nurse Consulting

Purpose

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

Manuscript Submission

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

Manuscript Review Process

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

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Feature Articles

Departments

Join Us as an Author for our *Journal*

Dear Colleagues,

Our *Journal* continues to offer a wealth of excellent information for our readers and the content in each article supports the application to practice. As you know we provide several feature articles each issue and also have regular *Journal* departments that feature clinical topics, professional trends, valuable resources, and a question and answer segment. We are always looking for new authors who would be willing to share knowledge and expertise with our readers and colleagues in the field of legal nurse consulting…and having a variety of authors enhances the breadth and depth of the *Journal* content.

I am asking you to consider submitting a manuscript on a topic about a practice issue, clinical issue, research, or a topic of general interest that is relevant to legal nurse consulting. Being an author has many benefits to both the author and the reader. As the author you are helping to build the body of knowledge in our specialty field and increase the visibility of our specialty in professional nursing and within our legal community. By authoring an article you are providing new information, practical updates, and perhaps new ways of problem solving for our readership. Think about a presentation that you may have made that is relevant to legal nurse consulting and turn it into an article for publication. Or if you are a student or recent graduate, consider developing a paper you may have written into a manuscript. Many good, potential articles stay hidden in drawers and would be so valuable for others to read. Our *Journal* reviewers and Editorial Board review all manuscripts submitted for potential publication and provide valuable commentary and insight on all articles. As you read through this issue you will find a diverse group of articles that may wet your appetite to publish….and see your name in print. So, please consider and take this opportunity to contribute to our professional *Journal*. We would be excited to hear from you!

In this issue, you will find Part 2 of an article by Ann Peterson that discusses in detail the many aspects of the medical record as a legal document and standards that prescribe appropriate documentation. Dr. Peterson discusses why documentation is important, various types of charting systems including computerized charting and the categories of records commonly found in healthcare facilities, and the importance of patient notification related to the kinds of information being recorded. Part 1 was in the previous issue of the *Journal*. Both of these articles are well worth you review.

An excellent an informative article on acute pain management is provided by Kathleen Colfer, Elizabeth Woo, and Eugene Viscusi. The authors point out that pain has many faces and describe that pain management is a complex phenomenon that needs to be treated by a variety of analgesic treatment modalities …not limited solely to opioid treatment. Several examples of these treatment options are provided. The authors discuss the importance of recognizing patients at-risk of unintended sedation and respiratory distress when opioids are used. Two case examples are provided. Implications for the legal nurse consultant and pain management resources are provided.

Susan Randolph discusses errors in medication management which are the eight leading cause of mortality in the United States accounting for up to nearly 100,000 deaths per year. Ms. Randolph provides valuable information about the legal aspects of the management of medication and the eight "Rights" related to medication administration. Factors that contribute to medication errors are discussed along with prevention strategies to minimize and alleviate these errors…key in this is to adopt an organizational safety culture to reduce these errors. The role of the legal nurse consultant is provided.

Our final feature article is of significant importance to the field of legal nurse consulting. Lynn Webb and Peg Crowell provide the research that is the foundation for the practice analysis that guides the test specifications for the certification examination in the specialty area. The authors provide significant detail about the study and its results and identify the 5 scope of practice domains along with 13 content areas that relate to the test specifications. This information will be important for updating the certification examination. All practicing legal nurse consultants will want to review this information to give you a glimpse into the future.

In our departments, Deanna McCarthy, in the Clinical Maxim, discusses ischemic heart disease in pregnancy, which is rare but seems to be increasingly prevalent in this population. Important risk factors are described along with how diagnosis is determined and what treatment options are available. In the Professional Practice, Trends, and Issues department, Mary O'Connor provides an excellent description of the health disaster that occurred as a result of contaminated medication from the New England Compounding Center (NECC). To date, 644 cases of fungal meningitis have been determined including 44 deaths. Dr. O'Connor describes problems that were found at the NECC and legal actions that will be brought as a result of the injuries suffered. In our Questions & Answers column, Judy Bulau discusses the question of the risk of intravenous free-flow for electronic devises without free-flow protection. Several recommendations are provided to help prevent these events from occurring and protect the patient.

I know you will enjoy reading these articles and I hope this will encourage you to write an article for the *Journal*. Please let me hear from you.

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

Medical Record as a Legal Document Part 2: Meeting the Standards

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KEY WORDS
Breach, Communication, Documentation, Duty, Negligence, Policy, Procedure, Standards

The medical record provides a tool for communication between healthcare providers that fosters continuity of care. This is part 2 of a two part article. Part 1 focused on the legal, federal, and state regulations and professional standards that determine the components of the medical record. This article focuses on the legal aspects of entering information in the medical record. As a legal document, healthcare providers are held responsible and accountable for maintaining medical records as required by federal and state regulations and professional standards. Failure to adhere to documentation standards can place the patient at-risk for harm and the responsible provider at-risk for allegations of negligence.

Medical records are legal business records, regulated by federal and state statutes, containing legally relevant information about a patient's clinical status, plan of care, medical interventions, and response to interventions. Healthcare providers with authorization to access and document in a patient's medical record are held responsible for knowing documentation requirements and are held accountable for entries or omissions to the medical record.

A properly maintained medical record can improve the quality of care and protect the patient from potential harm by ensuring the continuity of care provided by the multiple healthcare professionals involved in a patient's care. Failure to maintain the medical record according to established standards could place healthcare providers in legal jeopardy. The provider should systematically record the care rendered and the information should be appropriate, relevant, concise, and accurate.

Communication is essential to foster continuity in patient care. Written communication creates a permanent record and should be legible, clear, concise, concrete, and complete. Without being overly wordy, information that is provided should be relevant, unbiased, and specific while answering the basic questions of who, what, when, where, and how. If effectively communicated, the information can help the reader know the status of a patient and implement appropriate actions. Communication tools such as Kardexes, protocols, clinical pathways, incident/accident reports, correspondence, and authorization for release of records may contain information about an individual but are not part of the legal medical record.

Importance of Documentation

Medical record documentation is important to record pertinent facts, findings, and observations relevant to an individual's health. Systematic and chronological documentation contributes to quality care by facilitating the ability of other healthcare providers to access, evaluate, and monitor treatments rendered. A well maintained and documented medical record can help support treatment decisions and protect the patient from medical errors. It may also serve to protect the provider from allegations of malpractice (Karp, Huerla, Dobbs, Dukes, & Kenady, 2008).

Medical Records Standards

Although regulations on documenting in medical records are numerous and can be cumbersome (Price Waterhouse Cooper, n. d.), healthcare providers are responsible for knowing the regulations and professional standards applicable to their area of practice. Regardless of the practice specialty, record organization, or charting system used, the healthcare provider will have a measure of protection against potential allegations of negligence if his or her care and documentation is consistent with standards of practice (Monarch, 2007).

Standards require demographics and medical information regarding services rendered to the patient are documented, entries are consistent and complete, and the records are kept in an organized medical recordkeeping system. Records must have documentation of all services provided entered directly by the practitioner who provided the care services and must be retained and kept confidential by the practitioner and the institution.

Critical Thinking

Critical thinking, as defined in a statement by Scriven and Paul (1987) for the National Council for Excellence in Critical Thinking Instruction, "is the intellectually disciplined process of actively and skillfully conceptualizing, applying, analyzing, synthesizing, and/or evaluating information gathered from, or generated by, observation, experience, reflection, reasoning, or communication, as a guide to belief and action" (p.4). Critical thinking skills also include the ability to think independently, listen critically, and make interdisciplinary connections (Paul, Binker, Jenson & Kreklau, 1990). While critical thinking is a systematic analysis of data, clinical judgment requires:

> …the flexibility and nuanced ability to recognize salient aspects of an undefined clinical situation, interpret their meanings, and respond appropriately using pathophysiological and diagnostic aspects of a patient's clinical presentation and disease and also the illness experience for both the patient and family and their physical, social and emotional strengths and coping resources (Tanner 2006, p. 204).

The healthcare provider uses clinical judgment to apply established policies and to interpret, select, and adapt guidelines to specific clinical problems, and to analyze the outcome. Critical thinking and clinical judgment are important for patient safety when deciding the appropriateness of using established clinical protocols (Facione, & Facione, 2008). By applying the nursing process to critical thinking and clinical judgment, the nurse can develop individualized care plans for clients and maintain or improve a patient's health status (Potter, Perry, & Och 2008).

The nursing process is essential to the practice of nursing and has been incorporated into many state Nurse Practice Acts [National Council of State Boards of Nursing (NCSBN), 2009]. The nursing process is applicable to all practice settings and is an ongoing cyclical process of:

- **Assessment** – collecting of data (physiological, psychological, socio-cultural, economic and spiritual) affecting the health of a patient
- **Diagnosis** – utilizing clinical judgment of the patient's response to actual or potential health conditions or needs
- **Outcome** – identifying attainable and measurable outcomes derived from the diagnosis
- **Planning** – developing a care plan with appropriate interventions with input from the patient, significant others, and other healthcare providers
- **Implementation** – putting into action a care plan
- **Evaluation** – reviewing and modifying as necessary, the treatment/care plan (Anonymous, 2010).

The Problem-Orientated Medical Record (POMR), introduced by Dr. Lawrence Weed in the 1968 New England Journal of Medicine article "Medical Records that Guide and Teach" was developed to provide physicians with an organized approach to complex problems that reflects the logic and the thinking behind each plan. As a medical record framework, the POMR has become an important standardized approach to problems by providing a rationale for diagnoses and plans while helping to protect against oversight in patient management (Mengel, Holleman, & Fields, 2002).

Each medical record should have a readily accessible problem list that provides a dynamic index of a patient's verifiable factual problems. All of the patient's recognizable health problems, developed from the patient history, assessment, and diagnostic studies, are listed by diagnoses, signs and/or symptoms. The order of listing, whether by urgency or chronology, is a judgment call. Once the cause of a sign, or symptom has been determined, the problem is modified to reflect the diagnosis. Every medication, procedure, treatment, and diagnostic test should correlate with a listed problem. The differential diagnosis should not be entered into the list. Problems are noted as active or inactive with the dates of onset and resolution given. Key to the POMR is the charting of the progress note, or narrative of pertinent data relative to a problem (Mengel, & Fields, 1997).

Charting Systems

Documentation systems, which vary among institutions, should make information readily accessible while avoiding duplication. Regardless of the charting system used, fundamental principles of documentation are applicable. The obligation for charting includes signing each entry using first initial, last name, and status (e.g., J. Smith, RN). A line should be drawn from the end of the entry to the signature; if unable to complete notes on a page, sign that page and on the next page note that it is a continuation of the previous note. Sign only those notes that describe care given, supervised or observed, and never add to another's note.

Traditional or narrative style charting is usually used in conjunction with or supplementary to flow sheets or checklists. Narrative notes should be accurate, precise, and objective and, unless pertinent, should not duplicate information on the flow sheets. Alone, narrative notes can be problematic. Illegibility, inconsistency in writing styles, spelling errors, wordiness, imprecise wording, rambling, inappropriate remarks, or personal opinions can distort or make it difficult for the reader to quickly sort through information being communicated, as well as raise issues about the writer's professionalism and competence.

Narrative notes are used to record progress and should be organized in a format that clearly communicates patient assessments, interventions, and outcomes. The SOAP (subjective, objective, assessment, plan) note is just one example of organizing notes. Whatever the format used, it should meet facility policy and provide evidence of critical thinking and a rationale for actions taken.

Progress report periods may be specified by regulations and or institutional policy. For instance, per federal regulations, physical therapists are required to write a progress report once every 10 treatment days or at least once during each 30 calendar days, whichever is less [Centers for Medicare and Medicaid Services (CMS), 2008], and physicians caring for residents in a skilled nursing care facility (CMS, 2011) must write a progress note at least every 30 days for the first 90 days after admission and at least every 60 days thereafter. Institutional policy may require nurses' progress notes be written on every shift or only when pertinent changes in a patient's condition have occurred.

Charting by Exception (CBE) was introduced in the 1980s as a means of reducing charting time and length while promoting efficient use of a nurse's time. Used by many long-term care facilities (LTC), CBE requires narrative documentation only of deviations, abnormal, or significant findings, and uses flow sheets to document normal assessments and routine care in a consistent standardized format. Despite its efficacy CBE can be problematic because it allows large

gaps of time between documentation suggesting a provider's lack of attention to the patient and because it requires clear guidelines on every possible problem on what observations are "abnormal." Legally this system is challenging. Due to the scarcity of entries it may be difficult to verify what was done or not done in caring for the patient (Hartley, 2007; Jaffe, 2011; Murphy, 2003).

Clinical pathways, introduced in the 1990s, have replaced traditional charting in some healthcare facilities. The clinical effectiveness of this charting system remains unclear and legally the "guidelines are not an immutable representation of the standard of medical care," leaving a healthcare provider having to defend the appropriateness of applying a guideline to a specific individual's needs (Cheah, 1998, p. 536). Clinical pathways, which use narrative notes only when the expected outcome is not met, provide multidisciplinary (unlike guidelines or protocols) descriptions of the expected care for a specific illness or condition within a specified timeline. Focused on outcomes and efficient use of resources while still providing quality care, pathways may be used in conjunction with charting by exception (Anonymous, 2011a).

Flow sheets may be used to record relevant information and are quick and easy to use. However, they are space-limited and require a written narrative of abnormal findings in the progress note. The narrative note should clarify information on the flow sheet, not duplicate it. Flow sheets (medication administration, treatments, vital signs, neurologic checks, intake & output, activities of daily living, dietary or eating patterns, blood sugar monitoring, weight checks, restraint observation and monitoring, wound care and monitoring, and postoperative records) may be initialed, however, a key identifying the individual name and initials must be provided within the medial record. Documents with multiple sections or completed by multiple care providers (for example the Medical Data Set) must provide an area for each contributor to sign and date. Preprinted forms, checklists, and educational material should be signed and dated. If a paper record of the flow sheet is transferred to an electronic medical record (EMR), the paper record can be discarded [American Health Information Management Association (AHIMA) e-HIM Work Group Members, 2005; Rosdahl & Kowlaski, 2008].

Computerized Charting

Online documentation of clinical care data is an electronic version of the paper chart, subject to the same regulations and standards of paper records, with the advantage of offering large storage capacity of quickly retrievable information that is readily accessible to people at many sites simultaneously. However, the EMR requires added safeguards to protect patient confidentiality and prevent others from modifying entries. Access to an EMR is limited and each provider must have his or her own username and password to ensure the computer log accurately reflects the provider making a documentation entry. The main concerns associated with EMRs are authorship integrity (assuring information entered is attributed to a specific individual), auditing integrity (having the ability to detect when an entry is modify or misrepresented), documentation integrity (allowing templates for recording pertinent clinical information, deletion of incorrect auto-generated entries, and limited creation of anecdotal information), and patient identification and demographic accuracy (preventing erroneous patient information and theft of patient identity) (AHIMA e-HIM Work Group Members, 2007). As with all computer systems, the possibility of a computer malfunction must be considered and a backup system must be in place.

Charting Procedure Considerations

It is not uncommon for a facility to have two patients with the same or similar name so the first step to charting is to make sure the correct chart is being entered. The patient name or record number should appear on every piece of documentation. For use as a communication tool the medical record should be legible as a lack of legibility may result in the inability to decipher or a misinterpretation of notes leading to patient injury (AHIMA, 2003).

Quality of documentation is seen as a measure of the quality of care delivered (Soto, Kleinman, & Simon, 2002). Healthcare providers are responsible for documenting care

provided in chronological order and within an appropriate time frame. Handwritten entries must be in permanent ink and must be legible. All entries must be authenticated with a signature of the writer (EMR systems must incorporate electronic signature standards) and should specify the date and time of the entry (AHIMA e-HIM Work Group Members, 2007).

As a means of communication among providers, the medical record should be factual and objective. Wording should be precise and vague language, such as "stable" or "confused," should be avoided. Pertinent comments by the patient or family members should be entered in quotes with the source named (Department of the Army, 2010).

Timeliness is important. Documentation should be made as close to the time of service rendered as possible when details are fresh. Most facilities have policies regarding completion of admitting notes, operative procedures, and discharge notes. Medicare and Medicaid regulations regarding time requirements must also be considered (University of California, n. d.).

Continuity of care among healthcare providers requires that the information be sufficient, and accurate to clearly identify the patient, to support the diagnosis, and justify the treatment, its course, and outcome. Information should be complete and reflect the thinking process that led to a conclusion or decision. Vague entries such as "complains of pain" or "large amount" require further clarification. If information is recalled after the note was completed, enter the added information as a late note (Peterson, 2010; University of California, n. d.).

A late entry written to add information that was missed or omitted in the initial entry must be identified as a "late entry." It should be written as soon as possible after an event and should reference the original entry or event, provide a reason for the late entry, and the date and time of the addition should be recorded. An addendum is a late entry intended to provide additional information. It should be pertinent and factual and not be a reflection of the writer's personal opinion, perception, or defense. A late entry or addendum should not be added after the record has been copied or released. Alteration to the documentation of another healthcare provider is prohibited and is a criminal offense (Peterson, 2010; University of California, n. d.).

Incorrect entries may not be deleted but must be corrected, indicating who made the correction and when. Never destroy and rewrite the record. No entries or forms may be deleted or obliterated from the record. If an error is made in an entry, the original inaccurate entry must remain accessible and must not be obliterated. Mistaken entries should be corrected by drawing a single line through the entry so that it is still legible. "Mistaken entry" should be written over or beside the original words, then initialed and dated. The correction must indicate the date, the signature of the person making the revision, and the reason for the correction (University of California, n. d.).

Abbreviations can also be problematic since many abbreviations can be interpreted several ways, for example, ARF can be interpreted as acute renal failure or acute respiratory failure. The Joint Commission created its "do not use" list of abbreviations in 2004 and in 2010 the listing became integrated into the standards for EMR. To avoid confusion and enhance patient safety, healthcare providers should review and adhere to the facility's listing of accepted abbreviations (The Joint Commission, 2011).

Charting in advance, that is, completing portions of records in advance to save time, can lead to problems if events occur that negate the information already entered and can call the credibility of the author into question (Anderson, 2005; Sharpe, 1999).

To ensure confidentiality, records should be put away when documentation is complete. Never step away from the computer when an EMR file is open and be sure to always log out when finished.

Information To Be Documented

The type of facility (e.g. hospital, long-term care, and out-patient) and the facility policy will determine the category of files to be kept in the medical record. Be aware that the titles of similar categories may vary among institutions. A listing of various categories of medical records can be found in the Table.

Factual information about health status, preventive health services, treatment, planning, and delivery of care should be included. Speculation, personal opinion, criticism of another provider, or other inappropriate commentary should not be part of the record (Teichman, 2000). Document all patient encounters, including telephone, fax, and electronic message exchanges. Documentation should also include the following:

- Biographical or personal data, including primary language spoken
- Problem list, including significant current and past illnesses and chronic medical conditions
- Medications listed with the drug, dose, and date prescribed and/or discontinued
- Adverse drug reactions
- Allergies listed in an easily accessible location of the record. If no allergies indicate by writing "No Known Allergies" or "NKA" to confirm the information was assessed
- Smoking status
- History of alcohol use or substance abuse
- Pertinent history
- Physical exams
- Progress notes documenting clinical findings and evaluation (response to medication and treatments, precautions, and preventative measures should be included here)
- Laboratory and other diagnostic studies
- Diagnoses consistent with findings and test results
- Treatment plans consistent with diagnoses
- Preventive services and risk screening

Table: Category of Records Commonly Found in Healthcare Facilities

Category of Record	Hospital	Long-Term Care & Rehabilitation	Primary Care Settings
Problem List	√	√	√
Admission Record	√	√	
Consent Forms (Care, Treatment, Operative, Advance Directive)	√	√	√
Doctor's Orders	√	√	
Physician's Progress Note	√	√	√
Interdisciplinary Progress Notes	√	√	
Nurses' Notes	√	√	
Nursing Admission Assessments	√	√	
Risk Assessments (Fall, Pressure Ulcer, Elopement, Restraint, Side Rail etc.)		√	
Medical Data Set (MDS) Assessments		√	
Care Plans	√	√	
Skin Checks		√	
Diagnostic Test Results	√	√	√
Graphic and Vital Sign Sheet	√	√	
Neurologic Check List	As needed	As needed	
Acts of Daily Living Flow Sheet		√	
Medication Administration Record	√	√	
Treatment Record	√	√	
Immunization Record		√	√
Intake and Output	As needed	As needed	
Consultations (Pharmacy, Psychiatry, etc.)	√	√	
Anesthesia	√		
Intraoperative Reports	√		
Recovery Room	√		
Rehabilitation Therapy (Physical Therapy, Occupational Therapy, Speech and Language Therapy	√	√	
Dietary/Nutrition		√	
Recreational Therapy		√	
Social Service		√	
Pastoral Care	As needed	√	
Patient Family Education	√	√	
Referrals	√	√	√
Emergency Department Records	√	√	
Discharge Summary	√	√	
Discharge Instructions	√	√	
Date For Return Visit			√
Growth Chart (Pediatrics)			√
HIPAA	√	√	√
Patient Rights & Responsibilities	√	√	√

- An advanced directive with documentation of patient execution; information provided to the patient regarding advance directives and if the patient has executed one, placed it in a prominent part of the medical record
- Patient/family education
- Referrals [Anonymous, 2011b; National Committee for Quality Assurance (NCQA), n. d.]

Unlicensed assistive personnel (UAP) reports should be corroborated before documenting (AHIMA, 2012). Be aware that co-signing an entry implies approval and responsibility for the care given. A student report should not be co-signed unless the care delivered was directly supervised (American Speech-Language Hearing Association, 2012). (The nursing instructor is responsible for supervising and co-signing.) Other people or providers should not be criticized in progress notes. Adding to another nurse's entry is prohibited.

Patient Self-Determination

The Patient Self Determination Act is a federal law, effective since 1991, mandating that each patient, upon admission to a healthcare facility receiving Medicare or Medicaid funding, be given written information about advance directives and the right to make decisions about his or her own medical care and about the facility's policies regarding advance directives (American Cancer Society, 2011). An Advance Directive is a written document regarding medical decisions to be made on behalf of a patient in the event the patient becomes unable to make his or her wishes known. It may include a Living Will that specifies the medical treatment the patient does or does not want to receive and/or a Durable Power of Attorney which designates another person to make medical decisions when the patient is deemed incapable of informed consent or of refusal of treatment [American Medical Directors Association (AMDA), n. d.)

Mentally competent patients or someone designated to act on their behalf have the right to withdraw or refuse life saving treatment. Should a patient refuse treatment, the doctor should be informed and should provide and document all information given the patient regarding the consequences of refusal. The patient or the guardian should be asked to sign an Against Medical Advice/ Refusal of Care form and treatment refusal must be clearly documented prior to the physician issuing a directive to forgo treatments. If there is a question of patient incompetence, a court order authorizing treatment should be considered (Roach, Hoban, Broccolo, Roth, & Blanchard, 2006).

Do not resuscitate (DNR) orders must be written by the attending physician if requested by the patient or, in the event of incapacity, by the patient's designated representative. The physician writing the order should also document any oral discussion held with the patient and or the patient's agent regarding withholding or withdrawing life support. A check of state laws regarding DNRs is warranted. Generally a DNR is specific for withholding cardiopulmonary resuscitation, including chest compressions, defibrillation, or ventilation by any assistive or mechanical means. The DNR is limited to resuscitation efforts and if further therapies are to be discontinued, a Comfort Measures Only (CMO) order must be written after the patient or patient's agent have been fully apprised of what this would mean in terms of treatments and outcome. CMO means the patient will not receive basic or advanced life support, further diagnostic tests, or further treatments or transfer to a hospital or critical care unit.

Summary

Patient safety can be affected by the manner in which medical records are maintained. Documentation in the medical record must meet standards set by regulations, professional standards, and institutional policies. In meeting the standards of medical record documentation, protection of a patient's safety is provided while healthcare providers gain protection from future civil and criminal actions.

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Acute Pain Management: Current Trends, Technologies, and New Agents

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KEY WORDS
Pain Management, Acute Pain, Analgesics, Technologies, Opioid Adjuvants

Acute pain management in the hospital setting involves the management of pain in the perioperative period. Research and science have led practitioners beyond the use of opioids alone to treat this pain. The use of opioids alone may compromise patient safety, causing unwanted side effects ranging from nausea, vomiting, and dependence to sedation and respiratory depression. Pain management guidelines currently encourage the use of an opioid-sparing multimodal regimen whenever possible (American Society of Anesthesiologists Task Force on Acute Pain Management, 2012). The regimen incorporates the use of various agents or modalities that target different mechanisms of pain. The purpose of this article is to inform the legal nurse consultant of current strategies, technologies, and new agents used in multimodal regimens for treating acute pain in the hospital setting.

Introduction

Pain management came into the spotlight in 2001 when the Joint Commission instituted new standards for addressing pain issues in the acute care setting. They encouraged health care facilities to make pain assessment the 5th vital sign. In addition, they encouraged the facilities to develop programs to educate providers and patients about pain and treatment options. Subsequently, accreditation includes meeting certain pain assessment criteria and pain management standards (Joint Commission, 2001). As part of the institution of these standards, and public demand for better pain control, pain management societies have developed pain management guidelines. The most common theme among the guidelines is the application of a multimodal regimen in treatment of pain. The American Society of Anesthesiologists recently published an updated report of practice guidelines for acute pain management in the perioperative setting which recommends, whenever possible, a multimodal regimen should be used (American Society of Anesthesiologists Task Force on Acute Pain Management, 2012).

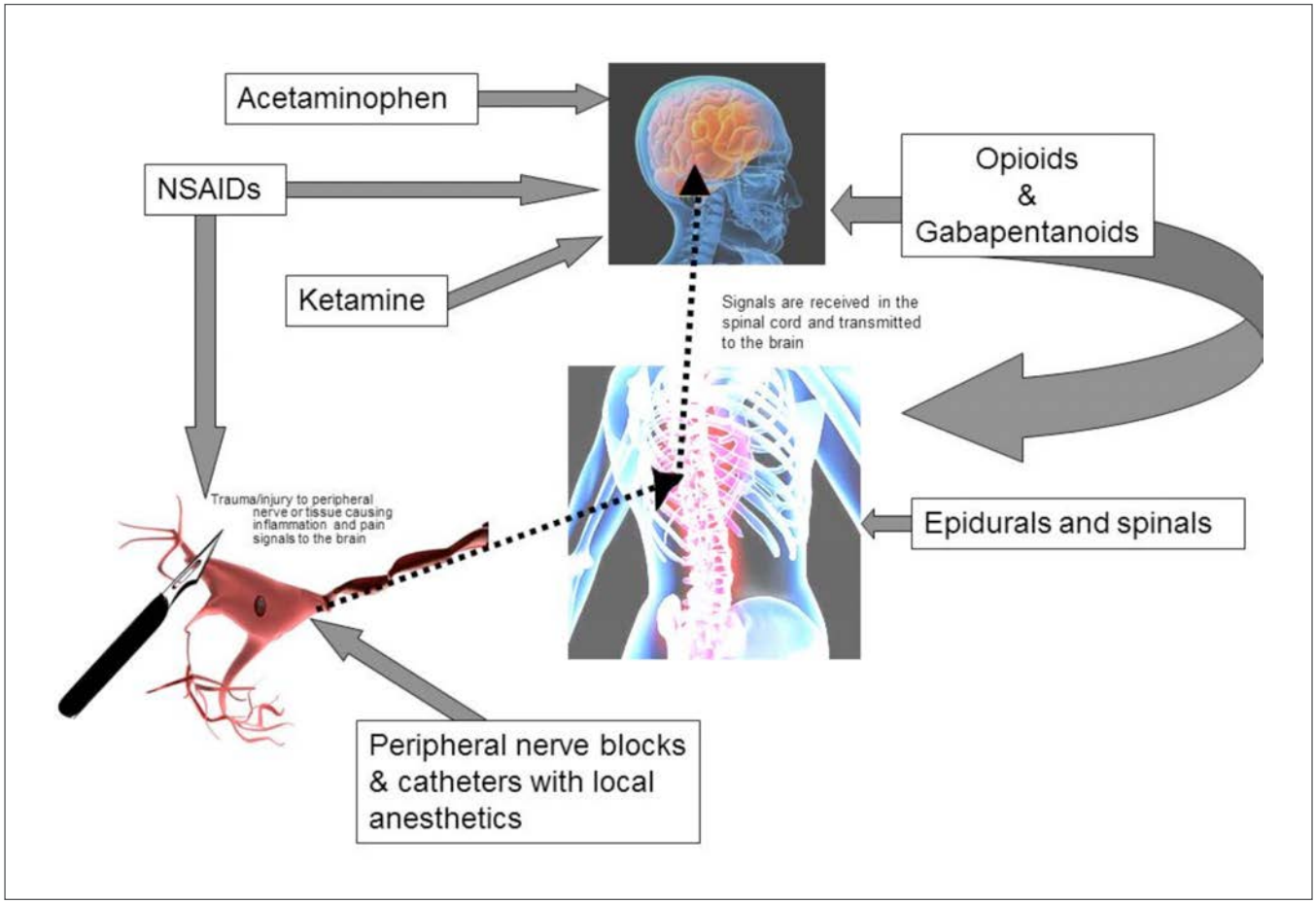
Multimodal analgesia is use of different analgesics that act by different mechanisms and at different sites in the nervous system, resulting in superior pain control over a single agent while simultaneously decreasing adverse side-effects (Kehlet & Dahl, 1993). The two types of pain generally targeted are nociceptive and neuropathic. Nociceptive pain is defined as pain for which there is an identifiable insult causing tissue damage, accompanied by stimulation of nociceptors in somatic or visceral structures such as muscle, bones, or organs. Frequently this pain is described as aching, stabbing, or throbbing (Pasero & McCaffery, 2011). Neuropathic pain results from damage or dysfunction of the nerves in the central or peripheral nervous systems. This pain is frequently described as burning, tingling, numbing, or shock-like (Pasero & McCaffery, 2011). Pain is multi-factorial; therefore, multimodal therapy should address both types of pain and selection of analgesic agents should include those that target various pain pathways (Figure). When different agents are combined a synergistic effect is observed and the side effects of a higher dose of only one agent can be decreased or eliminated (Kehlet & Dahl, 1993). Studies have found that using one or more of the groups can reduce opioid consumption and side effects (Trabulsi, Patel, Viscusi, Gomella, & Lallas, 2010).

Opioids continue to be first choice agents in the treatment of postoperative pain; yet patients' experiences with postoperative pain have not significantly improved despite guidelines and recommendations from pain management societies (Apfelbaum, Chen, Mehta, & Gan, 2003). Opioids produce well-known side effects such as nausea, vomiting, sedation, respiratory depression, confusion, and constipation. Patients will often choose incomplete pain relief to avoid these negative and distressing opioid side effects. (Gan et al., 2004). Healthcare providers also want to avoid the two most serious side effects of unintended sedation and respiratory depression. The implementation of a multimodal regimen, where various agents are used to target different mechanisms, may significantly reduce the number or severity of untoward opioid side effects. The American Society for Pain Management Nursing recently published comprehensive guidelines on monitoring for opioid-induced sedation and respiratory depression (Jarzyna et al., 2011). These guidelines include recommendations for creating individualized plans of care for each patient, for implementation of opioid-sparing pain management regimens, and for nursing education and for monitoring, among others (Table). Use of these evidence-based guidelines will assist the healthcare practitioner in providing safe opioid-sparing pain management and ultimately end in better patient outcomes.

Newest Opioid

In November 2008 the FDA approved the immediate release formulation of tapentadol (Nucynta®; Ortho-McNeil-

Figure: Multimodal Approach to a Multifactorial Problem



Janssen Pharmaceuticals), a schedule II opioid. This agent has a dual mechanism of action as a potent central μ-opioid receptor agonist and norepinephrine reuptake inhibitor. It is indicated for the treatment of moderate to severe acute pain in patients 18 years and older. Tablets come in 50mg, 75mg, or 100mg strengths that can be administered every four to six hours depending on the severity of the pain. Tapentadol extended release, indicated for chronic pain, was just approved by the FDA in August 2011. In two bunionectomy studies, tapentadol showed the ability to achieve analgesia similar to oxycodone. However, there was less nausea, vomiting, and constipation compared to oxycodone in the adverse event profile (Daniels et al., 2009; Daniels, Upmalis, Okamoto, Lange, & Haeussler, 2009). Less gastrointestinal side effects are something that may make this agent more attractive to patients and healthcare providers. It is contraindicated in patients with impaired pulmonary function, paralytic ileus, or the use of monoamine oxidase (MAO) inhibitor within the last 14 days (Janssen Pharmaceuticals, 2011).

Regional Anesthesia

An initial response to the call for improved postoperative pain control was the increased use of regional anesthesia. This involves the use of local anesthetics as either an infusion or single injection aimed at the nerves innervating the surgical site. The local anesthetic provides surgical anesthesia, postoperative analgesia, or both. The types include thoracic and lumbar epidurals, spinal anesthesia, and peripheral nerve blocks. Studies have shown that regional anesthesia helps reduce postoperative nausea and vomiting, improve pain control (Richman et al., 2006), and improve functional outcomes (Capdevila et al., 1999). There is even emerging evidence that it may decrease rates of metastases and death after cancer surgeries (Exadaktylos, Buggy, Moriarty, Mascha, & Sessler et al., 2006).

Although it has been shown time and time again that regional anesthesia has superior pain control, there are several problems with these methods. Epidural placement in patients who will need to be anticoagulated immediately postoperatively can be tricky. Very coordinated efforts are needed to appropriately time the placement and removal of the epidural in relationship to anticoagulation and venous thromboembolism prophylaxis (Horlocker et al., 2010). Hypotension can limit the use of epidurals because of its effect on the sympathetic nervous system. In addition, the pumps may be cumbersome, and until recently could only be used in a hospital setting.

Table: ASPMN Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression

1) All nurses should act as strong advocates for pain management plans that incorporate opioid–sparing strategies
• Advocate early initiation of multimodal opioid–sparing strategies especially on admission, before surgery, during surgery, and early after surgery
• Advocate multimodal analgesic therapy that combines opioids with non-opioids such as acetaminophen, NSAIDs, anticonvulsants, and antidepressants
2) All nurses should develop and implement individualized care plans to assess and monitor patients receiving opioid therapy
• Individualized care plans should include: the level, frequency, and intensity of monitoring sedation and respiratory status
• Establish policies and procedures to ensure nurses are able to assess, document, and communicate risk factors for opioid-induced sedation and respiratory depression
3) All nurses should intervene to prevent the worsening of adverse events
• Track opioid-induced respiratory depression events through quality and safety programs
• Ensure all pertinent information is communicated regarding patient's risk during shift report and across all transitions in care from pre-hospitalization to discharge
• Ensure that all persons involved in the patient's care are informed of potential risks for unintended advancing sedation and respiratory depression with opioid therapy
4) All nurses should be educated to identify patients at-risk for unintended advancing sedation and respiratory depression from opioid therapy, specifically:
• Patients with sleep-disordered breathing (OSA, CSA)
• Patients with preexisting pulmonary diseases: (COPD, Asthma, Chronic Bronchitis)
• Patients with anatomic abnormalities affecting the ability of the patient to otherwise breath normally
• Patients age> 55, especially with multiple co-morbid diseases
• Patients receiving multiple sedating medications which could lead to an additive/synergistic sedative effect

(Jarzyna et al., 2011)

Single shot peripheral nerve blocks have problems as well. Depending on the type of local anesthetic chosen, these blocks may only last the patient 16 to 24 hours. Consequently, significant pain can develop and if this occurs on a weekend or at night, access to pain control may be limited. To remedy this problem, anesthesiologists began placing continuous peripheral infusion catheters. These catheters needed to be attached to complex infusion pumps, and were not practical or safe to send home with patients. Furthermore, peripheral infusion catheters have limitations as to where they can be placed such as in the distal end of extremities (fingers, toes, nose, ears, penis, etc.) where a small amount of fluid build up can lead to ischemic injury or necrosis (On-Q™ by I-Flow).

With the increasing demand to discharge patients home and do more "same day surgery" while still providing the same level of analgesia as a peripheral nerve catheter, there are now disposable elastomeric pumps for use (On-Q™ by I-Flow, INFUSOR™ & INTERMATE™ by Baxter, and Symbios GOPump™, etc.). These pumps are single use, disposable, and approved for use outside the hospital setting. The elastomeric pumps are drug-filled balloon/ball reservoirs, which deliver a medication over a set period of time. Through the inherent elastic properties of the pump, the drug reservoir ball constricts and slowly deflates as the medication infuses. These pumps can be placed immediately preoperatively with a surgical block or intraoperatively just prior to skin closure. Some pumps, like On-Q, have a soft, conformable, and lightweight outer shell. Other pumps, such as some of the Baxter and Symbios pumps, have a non-compressible, protective, and rigid plastic outer shell.

Elastomeric pumps do have some problems such as catheter kinking, pump failure, human error in selection of the correct device, medication, or medication concentration, and an allowable ± 15% variation in the set rate versus delivery rate. The rate further varies with temperature, drug concentration, and altitude such as riding in a plane. Severe complications have been reported with these devices emptying prematurely. It is unknown whether manufacturing defects or external compression of the device leads to the premature emptying of the reservoir, but cardiovascular collapse, seizures, and death from local anesthetic toxicity have been reported (Institute for Safe Medication Practices, 2009).

On-Q pumps do contain latex. The manufacturer states that the latex is in a middle layer of both the tubing and pump, and this layer does not come in direct contact with the patient or the medication infusing into the patient (I-Flow, 2004). This still poses a theoretical risk to the patient, especially if there are defects in the pump or tubing, which could expose the patient to latex, which may cause allergic reactions or anaphylaxis. The manufacturer recommends that each patient have an individual risk-benefit analysis prior to placing the pump. Another concern is the use of these devices in children, pregnant women, and breastfeeding women. The devices contain Bis(2-ethylhexyl) phthalate or DEHP, which is a commonly used plasticizer in medical devices. There is no conclusive scientific evidence to date that exposure to DEHP has a harmful effect on humans. However, the risk and benefit of using medical devices with DEHP for pregnant women, breastfeeding mothers, infants, and children should be evaluated prior to use (I-Flow).

Liposomal Delivery

Liposomes are microscopic vesicular carriers that have an outer wall similar to a cell membrane. These vesicles can be biochemically engineered to carry various medications as well as release the medications over a pre-determined period. Because of the similarity in lipid components of the liposome and the cell membrane, the liposomes can fuse directly with the cell membrane and deliver drugs directly into or near the cell. Liposomal drug delivery is a method to prolong drug delivery and allows for larger doses of a drug to be administered without the toxicities of a large peak effect (Samad, Sultana, & Aqil, 2007). This extended duration of action and one-time application may reduce the need for

patient controlled devises, catheters that can kink and crack, and bulky pumps.

One liposomal carrier form is Depofoam®. It is a multivesicular, extended release liposomal carrier that encapsulates drugs without altering their molecular structure and releases them over an extended period. The Depofoam® particles can be designed to release between 1 and 30 days (Pacira Pharmaceuticals, 2012a). There are two drugs that have been approved by the Food and Drug Administration (FDA) that employ this Depofoam® technology and are applicable to pain management: extended release epidural morphine (EREM)(DepoDur™, EKR Therapeutics, Bedminster, New Jersey) and extended release bupivacaine or depobupivacaine (Exparel™, Pacira Pharmaceuticals, Inc., Parsippany, New Jersey). EREM has been on the market since 2004.

Depobupivacaine (Exparel™) was approved by the FDA in October 2011. It is a liposomal carrier of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. It has not been studied in patients under age 18. The recommended dose is based on surgical site and the volume required to cover the area. The injectable suspension comes in 10ml or 20ml vials with 13.3mg/ml of depobupivacaine. Depobupivacaine is contraindicated in obstetrical paracervical blockade. There are a number of additional warnings and precautions related to mixing with other local anesthetics that should be observed. There is always a risk of severe life threatening adverse reactions with the administration of any bupivacaine containing product; therefore, it is imperative that the administration take place in a setting where there are trained personnel and equipment to promptly treat any signs of neurologic or cardiac toxicity (Pacira Pharmaceuticals, 2012b). Clinical trials done in hemorrhoidectomy, inguinal hernia repair, and bunionectomy patients demonstrated extended duration of analgesic effects, decreases in the proportion of patients who required opioid rescue, delays in time to first use of opioid medication, and reduction in the total amount of opioid used (Bergese, Onel, & Portillo, 2011). Depobupivacaine used as an integral part of the multimodal postoperative analgesic regimen may prove promising. If analgesia is improved and opioid consumption is reduced there may likely be increases in patient satisfaction. It may be some time before widespread use of this agent is seen as marketing and education have just begun.

Ketamine

Ketamine is a dissociative anesthetic that has been used in human and veterinary medicine for decades. It is an N-methyl-D aspartate (NMDA) receptor antagonist. Ketamine binds to the NMDA receptor and mediates the pain producing pathway (Mao, Price, & Mayer, 1995). It is believed to have analgesic mechanisms both centrally and peripherally (Kohrs & Durieux, 1998). Ketamine is used in sub-anesthetic doses for pain management in the opioid tolerant and in certain painful neuropathic syndromes like chronic regional pain syndrome (CRPS), or intractable headaches. A review of 37 trials examining sub-anesthetic ketamine administered perioperatively for acute pain in patients 18 years or older undergoing a surgical procedure found reduced morphine requirements, mild or absent adverse effects, and a reduction in nausea and vomiting (Bell, Dahl, Moore, & Kalso, 2005). Another study demonstrated reduced postoperative pain in spinal fusion patients (Urban, Yadeau, Wukovits, & Lipnitsky, 2008).

Clinically, it appears that the number of opioid-tolerant patients admitted to the hospital for surgery is on the rise. These patients pose a unique problem because they are already taking very high doses of opioids and the usual multimodal regimen of opioids, non-opioids, NSAIDs, gabapentanoids, and muscle relaxers may not be enough to manage their postoperative pain. In response to this problem, acute pain management providers have started to use sub-anesthetic doses of ketamine to manage this intractable pain. Ketamine, at sub-anesthetic doses is very safe. It is a chemical derivative of phencyclidine (PCP), and therefore has the potential to cause psychomimetic effects. This is uncommon in the use of sub-anesthetic doses, but can be attenuated by the administration of an anxiolytic like lorazepam.

In a randomized controlled trial of opioid-tolerant spine surgery patients, there was significantly reduced opiate consumption in the first 48 hours post procedure, and significantly reduced pain intensity scores in the post anesthesia care unit and at six weeks post procedure (Loftus et al., 2010). Reduction of pain scores at six weeks is promising and may be an indicator of reduction in the development of chronic pain.

Gabapentanoids

Gabapentanoids such as pregabalin and gabapentin are medications widely prescribed for diabetic neuropathy and are designed to help attenuate neuropathic pain signals. Pregabalin is indicated for the treatment of neuropathic pain associated with diabetic neuropathy and post herpetic neuralgia, adjunctive therapy for adult patients with partial onset seizures, and fibromyalgia (Pfizer, 2011). Gabapentin is marketed under many names and is approved as an adjunctive therapy in the treatment of epilepsy, post herpetic neuralgia, and in moderate-to-severe primary Restless Legs Syndrome (RLS) in adults (Pfizer, 2002). Both gabapentin and pregabalin have many side-effects, most of which are benign such as dizziness, somnolence, dry mouth, edema, blurred vision, and weight gain (Pfizer, 2011). Due to the fact that both are considered antiepileptic drugs, they carry the warning that they can cause suicidal thoughts or actions in a very small number of people; about 1 in 500 (Food and Drug Administration, 2012). The increased risk of suicidal thoughts or behavior was observed as early as one week after starting drug treatment and persisted for the duration of treatment assessed.

The gabapentanoids are used off label as part of a multimodal approach for pre-emptive pain control,

postoperative analgesia, and prevention of chronic neuropathic pain. Researchers have looked at optimal doses and timings of the gabapentanoids in the perioperative period. In one study, perioperative administration of pregabalin 150 mg one hour before surgery, with the dose repeated after 12 hours was effective in reducing early postoperative pain in robotic- assisted thyroidectomies (Kim et al., 2010). A meta-analysis of gabapentanoids dosed 1 to 2 hours prior to surgery effectively reduced postoperative pain, opioid consumption, and opioid-related adverse effects after surgery (Tiippana, Hamunen, Kontinen, & Kalso, 2007). Patients undergoing total knee arthroplasty (TKA) who received pregabalin 300 mg before TKA and for 14 days after TKA had reduced incidence of neuropathic pain for up to six months post-surgery. The patients receiving pregabalin also consumed less epidural opioids, required less oral opioid pain medications while hospitalized, and had greater active flexion over the first 30 postoperative days (Buvanendran et al., 2010).

Intravenous Non-Steroidal Anti-Inflammatory Drugs

Nonsteroidal anti-inflammatory drugs (NSAIDs) are a large class of more than 30 medications (aspirin, ibuprofen, naproxen, etc.) that primarily block the production of inflammatory mediators by inhibiting cyclooxygenase (COX) enzymes (Vane & Botting, 1998). When cells are injured they release many substances that activate the COX enzymes and result in the production of many inflammatory mediators. This complex interaction of inflammatory mediators with the body has several effects on both the peripheral nerves and the brain. By blocking the COX enzymes, it is possible to reduce inflammation in tissues, decrease peripheral nerve sensitization to pain, and help prevent centrally mediated sensitization of nerves (Kroin et al., 2008). There are three subsets of the COX enzyme, two of which are known to play a role in pain and inflammation in humans, COX-1 and COX-2. COX-1 is present in healthy tissues and activation of this enzyme provides protection of the gastric mucosa, allows for normal platelet function, regulates renal blood flow, and plays a role in the sensitization of secondary sensory neurons. COX-2 is responsible primarily for the production of inflammatory and nociceptive chemicals. Each of the medications in the NSAID class has its own individual profile for how it inhibits more cyclooxygenase-1 (COX-1) or cyclooxygenase-2 (COX-2). The ratio of COX-1: COX-2 determines both the side effect profile of the drug and its effect on the body. In the United States, only two parenteral NSAIDS are available, ibuprofen (Caldolor™ by Cumberland Pharmaceuticals, Nashville, Tennessee) and ketorolac. Both drugs can be used as part of a multi-modal approach to treating acute pain, but each carries its own set of contraindications.

Ketorolac has a much more potent effect on COX-1 than on COX-2 (Sinatra & Jahr, 2011). Ketorolac is approved only for use less than five days, cannot be used as a prophylactic analgesic prior to any major surgery, and cannot be used in patients with gastrointestinal (GI) ulcers or with current or recent GI bleeding. Ketorolac causes an increased risk for serious cardiovascular (CV) thrombotic events including myocardial infarction (MI) and stroke and should not be used in the perioperative setting of coronary artery bypass graft (CABG). Due to its effects on renal blood flow it should not be used in patients with advanced renal impairment or patients at risk for renal failure due to volume depletion. Ketorolac cannot be used in patients with suspected or confirmed cerebrovascular bleeding, patients with bleeding disorders, or in patients receiving other NSAIDS or aspirin therapies (Hospira, 2011). It can be relatively contraindicated in patients undergoing plastic and spine surgery due to its effects on platelets and increased risk of bleeding as well as a theoretical risk in orthopedic surgery due to its effect on bone healing (Vuolteenaho, Moilanen, & Moilanen, 2008; White & Kehlet, 2010).

Intravenous (IV) ibuprofen was recently approved for use in the United States in June 2009. Ibuprofen fully inhibits

Case 1: Effective Use of a Multimodal Analgesic Approach in Opioid Naïve

A 49 year old female with no significant past medical history was admitted to the hospital for a total right knee replacement. Preoperatively in the short procedure unit she was given acetaminophen 650 milligrams (mg), celecoxib 200 mg and pregabalin 75 mg as part of a pre-emptive multimodal pain management regimen. Surgery was performed under spinal anesthesia and finished uneventfully. An elastomeric pump with ropivacaine 0.2% was placed by the surgeon into the incision prior to closing. Postoperatively, the patient continued to receive acetaminophen 650 mg every 6 hours, celecoxib 200 mg every 12 hours, and pregabalin 75 mg every 12 hours along with the elastomeric pump infusion of ropivacaine. There was an order for oxycodone 10 mg every 4 hours as needed for breakthrough pain. Four hours after surgery the patient was out of bed, ambulated 10 feet, and sat in a chair. She reported moderate nausea upon ambulation and was medicated with ondansetron 4 mg intravenously. No additional pain medication was needed until postoperative day one, approximately 18 hours after surgery. The patient complained of 6/10 pain in the back of the knee prior to going to a morning physical therapy session. She was medicated with oxycodone 10 mg and was able to complete a physical therapy session in the gym one hour later. The patient continued to take the oxycodone 10 mg approximately every 6 hours until discharge. Recorded pain scores throughout the admission averaged 4/10 and never exceeded 6/10. On day two the elastomeric pump was discontinued and the patient was discharged with a prescription for oxycodone 10 mg every 4 hours as needed. The multimodal pain management regimen allowed this patient to get out of bed the day of surgery, ambulate, perform physical therapy and go home on postoperative day two with well controlled pain.

Case 2: Complications as a Result of Untested Use of an Analgesic Delivery Device

After a left shoulder arthroscopy, an elastomeric infusion devise was placed directly into the patient's intra-articular space in order to deliver a continuous infusion of the local anesthetic bupivacaine over 48 hours for postoperative pain management. Approximately five months after the infusion, the patient developed stiffness, and loss of motion in the left glenohumeral (shoulder) joint. The patient was diagnosed with postarthroscopic glenohumeral chondrolysis which is necrosis and destruction of articular cartilage. According to the report sent to the FDA, the patient required a total shoulder replacement (Todd, J.F., 2010).

The FDA has not approved elastomeric pumps for intra-articular administration of medications. As a consequence of 35 reports of chondrolysis, the FDA now requires elastomeric pain pump manufacturers to warn healthcare providers and patients about the potential for severe joint damage when devices are used for intra-articular anesthetic administration (FDA, 2010). This case example highlights a scenario that may have the potential for litigation. Some points for the LNC to consider in this case are:

- Did the manufacturer warn the healthcare provider of the risks for potential damage if a continuous infusion of local anesthetic was infused intra-articularly
- Did the healthcare provider inform the patient of the possible risks involved with this type of continuous infusion directly into the joint
- Did the manufacturer inappropriately promote the product or drug for use that was not approved by the FDA
- Is there literature or research to support the use noted
- Did the patient give informed consent and understand the potential risks
- Was the patient instructed on signs and symptoms of chondrolysis

both COX-1 and COX-2 with relatively poor selectivity for either enzyme (Warner et al., 1999). Multiple studies have shown that IV ibuprofen is effective for use as a preemptive analgesic and postoperative analgesic without restriction for duration of use (Sinatra and Jahr, 2011). It too carries the warnings of ketorolac and other NSAIDS including increased risk of bleeding, worsening of renal failure, increased risk for serious CV thrombotic events including MI and stroke, and it should not be used in the perioperative setting of CABG.

Newest Non-Opioid, Non-NSAID

In November 2010, the FDA approved IV acetaminophen (Ofirmev™; Cadence Pharmaceuticals). IV acetaminophen is a non-opioid, non-NSAID injectable agent indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever. It has been available in Europe for many years. In numerous clinical trials IV acetaminophen showed analgesic efficacy with an acceptable side effect profile (Sinatra et al., 2005). IV acetaminophen is contraindicated in patients with severe hepatic impairment, severe liver disease, or those with known hypersensitivity to acetaminophen or to any of the pharmacologically inactive substances in the formulation (Cadence Pharmaceuticals, 2011). With most acute pain management treatment aiming toward multimodal therapies, IV acetaminophen is a viable option for pain management treatment in adults and children over age two, because it does not have effects on renal function, bone healing, or platelet activity. Intravenous administration allows for the application of multimodal analgesia in patients who are unable to take pills orally.

Acetaminophen can be found in more than 500 over-the-counter and prescription medications. Therefore, it is important for healthcare providers to be aware of acetaminophen containing medications when ordering or administering IV acetaminophen. The maximum daily dosage of IV acetaminophen in adults ≥ 50kg is 4000 mg, and 75mg/kg for children and adults or adolescents ≤ 50kg (Cadence Pharmaceuticals, 2011). In clinical practice it is not uncommon to see multiple orders for acetaminophen-containing products on one patient. In 2007 the Pennsylvania Patient Safety Authority (2007) issued a report on hospital pharmacy computer system safety. The report suggested that nationwide pharmacy computer systems were not detecting dangerous orders as well as they could be. Findings from 30 Pennsylvania facilities found that users were not using the error catching features to their full potential. It is imperative that prescribers are aware of acetaminophen-containing compounds and possible dangerous duplicate orders of acetaminophen to prevent unintentional overdose. In January 2011, the FDA asked drug manufacturers to decrease the strength of acetaminophen in prescription

drug products, which were predominantly combinations of acetaminophen and opioids. The action limited the amount of acetaminophen to 325mg per tablet, capsule or other dosing unit to make the products safer for patients (Food and Drug Administration, 2011).

Implications for Legal Nurse Consultants (LNC)

The practice of acute pain management encompasses many factors that directly or indirectly affect patient safety. The medication, the provider, and the technology are all sources for causing a compromise in patient safety that may result in undesired outcomes such as prolonged hospitalization, addiction or disability, and possibly death. Pain management may be at the core of various types of litigation such as product liability, medical malpractice, and nursing negligence. The information in this article will be useful in any case involving the use, or lack of use of the agents mentioned, as well as cases that involve the use of elastomeric pumps or excessive opioids. The LNC should use the pain management organizations' guidelines and position papers to help identify deviations in the standard of care, or contact a pain specialist to assist with identification of pertinent issues. Package inserts on products and drugs provide important information to gain understanding of approved and unapproved uses, contraindications, and side effects. A special report from the Institute of Medicine focuses on providing information about pain relief in America (Institute of Medicine, 2011) and offers a blueprint for transforming prevention, care, education, and research in pain management.

Two case examples related to pain management are presented (Box). The first case describes effective use of multimodal pain management treatment and the second case describes complications as a result of untested use of an analgesic delivery device.

Conclusion

In our experience, pain practitioners across the country use an opioid-sparing multimodal regimen that incorporates various combinations of the technologies and agents described in this article. Multimodal therapy is a standard for pain practitioners. However, it may take five years or more for surgeons and medical practitioners, who do not have access to pain management specialists, to incorporate this practice into their current postoperative pain management regimens. Unfortunately, this may prolong the excessive use of opioids, and potentially perpetuate the incidence of litigation related to poor outcomes that result from increased doses of opioids.

As the public becomes more educated in these matters, it is likely that litigation related to pain management will increase. In addition to the material in this article, several pain management resource sites are available which can assist the LNC when reviewing cases that involve some aspect of pain management.

Pain Management Resource Sites:

- http://www.asra.com/
- http://www.aspmn.org/
- http://www.asahq.org/
- http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm
- http://www.fda.gov/MedicalDevices/default.htm
- http://www.apsf.org/
- http://www.ismp.org/

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Medication Management: Ensuring Safe Practice

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KEY WORDS
Medication, Safe Practice, Medication Errors

Medication errors are the eighth leading cause of mortality in the United States and account for 44,000 to 98,000 deaths each year, costing $44.7 billion. While medication administration is an important aspect of nursing practice and guided by state regulations, nurses still make medication errors. This article defines medication errors and describes both personal and organizational factors contributing to medication errors. Policies and procedures for safe practice are discussed along with various prevention strategies, including adopting a safety culture, preventing distractions/interruptions, using bar code technology, and establishing an electronic medication system. Implications for legal nurse consultants are presented.

Nurses are the largest group of healthcare professionals who are involved in the medication use process (Hillin & Hicks, 2010), an important aspect of nursing practice. Medication administration is a complex task that requires extensive knowledge and skill to perform correctly. As licensed healthcare providers, nurses ensure the safety and quality of patient care. Unfortunately, medication errors occur while providing care to clients. "Medication errors, which are preventable, have serious consequences for both patients and health professionals involved" (Agyemang & While, 2010, p. 380). According to Agrawal (2009), "In the USA, medication errors are estimated to harm at least 1.5 million patients per year, with about 4,000 preventable adverse events" (p. 224).

Medication errors are the eighth leading cause of mortality in the United States and account for 44,000 to 98,000 deaths each year at a national price tag of $44.7 billion (Patrician & Brosch, 2009). Medication errors are the most frequently identified errors that occur in healthcare settings in the United States (Jones & Treiber, 2010). Errors continue to occur because the working environment of nurses has not been adequately addressed (Jones & Treiber). Medication errors can lead to patient death and cost healthcare organizations billions of dollars (Nguyen, Connolly, & Wong, 2010).

Legal Aspects of Medication Management

Several state regulations, including the nurse practice act and related administrative rules, pharmacy laws and rules, and medical practice act and rules, regulate medication management by healthcare professionals. Each state has its own nurse practice act. Within that act, the practice of nursing by a registered nurse, licensed practical nurse, and advanced practice nurse is defined. The act also includes a statement about medications, such as, for the registered nurse, "Implementing the treatment and pharmaceutical regimen prescribed by any person authorized by State law to prescribe the regimen" (State of North Carolina, 2009, p. 3). The administrative rules provide further detail about the nurse's responsibility and accountability with medications including recognizing side effects, toxic effects, allergic reactions, immediate desired effects, unusual and unexpected effects, changes in the client's condition that contraindicate continued administration of the pharmaceutical regimen, anticipating those effects which may rapidly endanger a client's life or well-being, and making judgments and decisions concerning actions to take in the event such effects occur (North Carolina Administrative Code, 2004). This is similar in other states and follows safe practice guidelines.

Pharmacy laws define the terms of prescribing, dispensing, and administering in relation to medications and who is authorized to perform these functions. The majority of nurses administer medications, defined as "the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means" (Pharmacy Laws of North Carolina, 2010, p. 1). However, public health nurses and advanced practice nurses may also dispense and/or prescribe medications based on state laws. Medical practice acts also address medications and the delegation from medicine to nursing, generally through the use of standing orders. The nurse must be knowledgeable about these laws and how they relate to nursing practice. A copy of the pertinent laws should be kept in the nursing office or reference library.

'Rights' of Medication Administration

The medication administration process is governed by standards and legal mandate. Originally, the core of these standards, the "5 rights"—right patient, right drug, right dose, right route, and right time, were stipulated (Choo, Hutchinson, & Bucknall, 2010). Nurses were taught these five 'rights' of medication administration (Choo et al., 2010; MacDonald, 2010) as a means to prevent medication errors. Expansion of these five rights occurred over time to include the right documentation, right action, right form, and right response (Elliott & Liu, 2010; MacDonald, 2010). Table 1 lists these medication 'rights' and provides a short explanation of each one. Despite following these rules, nurses still make medication errors due to the complexity of medication

Table 1: 'Rights' of Medication Administration

Rights of Medication Administration	Meaning
Right Patient	• Ensure that the medication is being given to the patient for whom the medication is prescribed • Check the patient's identification (wristband, chart) • Ask the patient to identify him/herself (Please tell me your full name.)
Right Drug	• Check the medication against the physician's order and verify they are the same • If unsure of the name of the medication prescribed, check first before administering (e.g., many medications have similar names) • Make sure patient does not have an allergy to the medication
Right Dose	• Double check the amount of medication before administration • Understand the amount of the medication to be given and that it is within the known dose range
Right Route	• Check the order and appropriateness of the route ordered (e.g., oral, intravenously, intramuscular) • Confirm that the patient can take or receive the medication by the ordered route
Right Time	• Give the medication in compliance with the frequency written in the physician's order (daily, twice daily, every 4 hours, prn, etc.); generally medications are given within one-half hour before or after the scheduled time (or based on agency policy) • Confirm when the last dose was given
Right Documentation	• Record the medication given in the patient's chart and/or medication record • Document the medication name, dose, time, route, reason for administration, and effect achieved
Right Action	• Ensure the medication is prescribed for the appropriate reason • Tell the patient the action of the medication and the reason it is prescribed
Right Form	• Ensure the correct form of the medication is given (tablet, capsule, caplet, syrup, suppository, ampule, etc.)
Right Response	• Monitor the patient to determine if the medication has the desired effect or response (e.g., pain relief, assessment of blood glucose level, vital signs, urine output, etc.)

(Elliott & Liu, 2010)

administration. Nurses administer hundreds of medications daily to multiple patients with multiple disease processes and via multiple routes (Jones & Treiber, 2010). Elliott and Liu (2010) state that nurses must monitor for side effects, adverse effects, and allergic reactions, and that their role and responsibility in ensuring medication safety does not end once the right medication is administered.

Medication Errors

There are several definitions of medication errors. Aspden, Wolcott, Bootman, and Cronenwett (2007) defined medication errors as "any error occurring in the medication-use process" (p. 4). Examples include wrong dosage prescribed, wrong dose administered for a prescribed medication, or failure to give (by the provider) or take (by the patient) a medication (Aspden et al., 2009). The error may cause harm to a client, such as allergic reaction or rash, mental confusion, or loss of function or mobility.

According to the National Coordinating Council for Medication Error Reporting and Prevention (n.d.), A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (¶1)

One-third of all medication errors that cause harm to patients occur during medication administration (Westbrook, Woods, Rob, Dunsmuir, & Day, 2010). Barker, Flynn, Pepper, Bates, & Mikeal (2002) reviewed 36 U.S. health care organizations and found that 19% of administered medications were associated with some form of error. Types of errors included administering medications at the wrong time, giving the wrong dose or an unauthorized medication, and not administering the medication at all.

Factors Contributing to Medication Errors

Personal and organizational factors contribute to medication errors. Examples of personal factors include not following policies and procedures, stress from overwork and fatigue from lack of sleep, inadequate knowledge in the preparation and administration of medications, and lack of medication protocols (Agyemang & While, 2010). The most frequent organizational factors contributing to medication errors are distractions and interruptions during medication administration. Other organizational factors include poorly written prescriptions, heavy workload, and inadequate medication packaging and labeling (Agyemang & While, 2010; Jones & Treiber, 2010; Westbrook et al., 2010).

Jones and Treiber (2010) surveyed registered nurses to identify their perceptions of how and why medication errors occur. Using a 4-point Likert scale, the nurses rated 11

Table 2: Factors Contributing to Medication Errors

Medication Error	Percent
Illegible or unclear physician handwriting	86%
Did not follow "rights"	77%
High patient-nurse ratio	71%
Unclear verbal order	68%
Insufficient staffing	68%
Nurse incompetence	66%
Look alike or sound alike drugs	60%
Large number of medications administered at peak times	58%
Insufficient training	56%
Patient acuity levels	54%
New graduate status	29%

(Jones & Treiber, 2010)

potential medication contributing factors shown in Table 2. The nurses believed that technologies are important strategies to reduce the number of medication errors, such as use of bar codes and medication-dispensing technology.

Cohen, Robinson, and Mandrack (2003) surveyed nurses to identify reasons for medication errors. The top five errors included distractions and interruptions during medication administration, inadequate staffing and high nurse/patient ratios, illegible written medication orders, incorrect dosage calculations, and similar drug names and packaging. This information is useful in creating safeguards to prevent these errors.

Policies and Procedures for Safe Practice

Established policies, procedures, and practices should address overall safe medication management. Standing orders are frequently used to guide implementation of a pharmaceutical regimen. The orders should be signed by the nurse and physician; they need to be reviewed and revised at least annually or as indicated. Protocols, which may include standing orders, support nursing judgment and protect nurses in proving safe, quality care. They should also match the staffing mix of licensed personnel (advanced practice nurse, registered nurse, and licensed practical nurse) and unlicensed personnel (nurse aide, first aider, etc.). The protocols should also be written, dated, and signed by the nurse and physician, as well as reviewed and revised at least annually.

Prevention Strategies

Adopting a Safety Culture

One key step to prevention is recognition that errors occur. A culture change is needed from blame to safety (Walton, 2009). Often a multitude of system errors contribute to medication errors. There is a shift from blaming and punishing individuals to one of safety, reporting errors, and fixing the system problems so as to prevent that particular error from recurring (Walton). As a result, the errors are viewed as opportunities to fix the system. For example, medication error rates can be reviewed to determine the types of errors and how they occurred. Culture change only occurs when leadership is willing to commit to it (Walton).

An organizational commitment is essential to seek ways to improve the culture of the facility, such as an investment of resources for new or updated technologies. Policies can be established to address the source of the error such as incomplete orders. For example, medication error rates should be reviewed to determine the who, what, when, where, and why of the errors. A collaborative and interdisciplinary approach involving nurses, physicians, and pharmacists can also help reduce medication errors.

Preventing Distractions/Interruptions

Nurses who are interrupted while administering medications have an increased risk of making medication errors (Westbrook et al., 2010). Interruptions interfere with working memory and can cause lack of focus (Bennett, Dawoud, & Maben, 2010). If interrupted during medication preparation, nurses may not recall where they were in the process and could either omit or repeat a step.

The implementation of 'Interruption-Free' zones can be used to prevent distractions. A red zone can be established around the medication-dispensing system. Only one nurse or pharmacy technician can be inside the zone at a given time and cannot be interrupted unless there is an emergency or special circumstance. If interrupted, nurses must use the STAR technique (Stop, Think, Attend, Review) prior to resuming passing medications (Trossman, 2010).

Using Bar Code Technology

Bar coding has been used successfully in the retail industry and it is believed that it will be useful in the healthcare industry. Suggested items to be included on the bar code are a unique product identifier, a lot number, and the drug's expiration date (Institute for Safe Medication Practices, 2002). Bar code technology, a type of closed loop medication administration system, can reduce medication errors and contribute to a safer and more efficient healthcare system. It can also decrease transcription and medication administration errors (Trossman, 2010) as the nurse can easily confirm the 'rights' of medication administration. While nurses still must identify the patient according to agency policy, they would also perform a visual 'rights' check of the selected medications. (Marini, Hasman, Huijer, & Dimassi, 2010).

After scanning the bar code on the packaging for each unopened medication and the identification band on the patient, nurses must confirm the matching of the bar codes by the software system. The scanner can also alert nurses to allergies, incompatible drugs, and other potential problems that can lead to mistakes and adverse events (Trossman, 2010). A mismatch between the patient, the drug packaging applied during manufacturing or repackaging, and the patient's medication record would trigger a warning, prompting the

Table 3: Medication Resources

Resource	Purpose
Agency for Healthcare Research and Quality http://www.ahrq.gov/qual/patientsafetyix.htm 301-427-1364	While information is provided on a variety of patient safety concerns, tools, resources, and materials are available on medical errors.
Center for Medication Safety http://medsafety.org 866-200-1968 (toll-free)	Current information, resources, and programs are available on the incidence, implications, and costs of adverse drug effects (ADEs). Useful tools, services, and solutions to improve drug safety and effectiveness are given. Information is available for healthcare professionals and the public.
Centers for Disease Control and Prevention Medication Safety Program http://www.cdc.gov/medicationsafety/ 800-CDC-INFO (800-232-4636)	Information about adverse drug events is available along with other educational materials and fact sheets. A resource library with blogs, videos, podcasts, etc. is available.
Institute for Safe Medication Practices http://www.ismp.org 215- 947-7797	Non-profit organization devoted to medication error prevention and safe medication use. Information is available for healthcare professionals and the public.
National Coordinating Council for Medication Error Reporting and Prevention http://www.nccmerp.org 301-816–8216	Independent body comprised of 27 national health care organizations that meet, collaborate, and cooperate to address the interdisciplinary causes of errors and to promote the safe use of medications. Information is available for healthcare professionals and the public.
U.S. Food and Drug Administration http://www.fda.gov/drugs/drugsafety/medicationerrors/default.htm 888-INFO-FDA (888-463-6332)	The Division of Medication Error Prevention and Analysis (DMEPA) reviews medication error reports on marketed human drugs including prescription drugs, generic drugs, and over-the-counter drugs.

nurse to investigate the discrepancy before administering the medication (Institute for Safe Medication Practices, 2002).

Establishing an Electronic Medication System

Nurses should have input into the design and implementation of any new drug administration system (Choo et al., 2010). They are familiar with the types of data and information required for medication systems, and can help identify key items for clinical judgment and accurate and efficient administration. Computerized physician order entry can also improve patient safety by:

- ensuring the order is legible and complete;
- checking for drug allergies and drug-to-drug interactions;
- providing dosage adjustment calculations;
- checking for baseline laboratory results;
- computing drug-laboratory interactions; and
- updating the prescriber with the latest drug information (Agrawal, 2009).

Education

Healthcare providers can educate patients about their medication regimen including the name and purpose of each drug, when and how to take it, likely side effects, contraindications of the medicine, and what to do if an adverse reaction occurs. It is important to be aware of cultural barriers associated with medications. Providers and consumers should maintain an up-to-date record of medications being administered, including prescription medications, over-the-counter medications, and dietary supplements, as well as known drug and/or food allergies (Aspden et al., 2007). By becoming more informed and engaged, consumers may decrease the probability of experiencing a medication error. Although nurses routinely administer medications, having adequate knowledge is essential. Periodic continuing education may be indicated to reinforce appropriate medication management and to ensure competence in this skill. Medication information resources are listed in Table 3.

Nurses should look up medications that are unfamiliar to them prior to administering the medications to patients. In addition, nurses should not hesitate to question orders that do not seem correct.

Implications for Legal Nurse Consultants

Legal nurse consultants (LNC) may be asked to investigate medication errors and look for deviations from standards of care. By auditing medical records, medication administration records, and medication error incident reports, LNCs can identify the type of medication error (wrong patient, wrong medication, incorrect dose and/or route, etc.) and personnel responsible for the error, and recommend safeguards to prevent the errors. Changes may be needed in communication methods between the physician, nurse, and pharmacy. For example, the use of abbreviations in writing prescriptions has contributed to confusion and misinterpretation on medication names and dosing frequency. To eliminate the problem, the Institute for Safe Medication Practices developed a list of error-prone abbreviations. This list may be recommended for adoption in healthcare institutions. Other modification in workstation design (e.g., lighting) or in medication delivery (design and system used for medications) may be appropriate.

LNCs can serve as consultants not only to attorneys when an error is alleged, but also to institutions interested in obtaining nursing expertise in an effort to address issues of medication safety. They can help educate other nurses

about pitfalls to avoid as well as best practices to use while administering medications. In addition, they may be aware of educational opportunities on safe medication administration. Area Health Education Centers (AHEC) may provide training courses on medications. Some state boards of nursing provide guidance on medication administration curricula which includes, among other content, the correct medication administration procedure, client safety, and error prevention. Through education and experience in nursing and various healthcare systems, the LNC is well positioned to identify medication errors and recommend methods for prevention.

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2012 Legal Nurse Consultant (LNC) Practice Analysis

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KEY WORDS
Certification, Practice Analysis

In 2012, the American Legal Nurse Consultant Certification Board (ALNCCB) and the American Association of Legal Nurse Consultants (AALNC) studied the role of legal nurse consultants (LNCs). An expert panel delineated the scope of practice using 5 domains of major tasks and 13 content areas, and the knowledge required to perform the tasks. An electronic survey of LNCs was used to validate the expert panel's work. Data were collected on how frequently tasks were performed, and the importance of the knowledge areas. A second panel of content experts interpreted the validation study data into test specifications for the LNCC® credentialing program. The current test specifications were changed through additions to the content areas and consolidations in the scope areas of the examination. The 2012 study will be valuable for reviewing aspects of the certification examination and LNC core competencies.

Background

The American Legal Nurse Consultant Certification Board (ALNCCB) credential for legal nurse consultants (LNC) is the LNCC® and the certification program is accredited by the Accreditation Board for Specialty Nursing Certification (ABSNC). The accreditation board provides an independent (third party) review of programs like the LNCC® according to a rigorous set of standards. Standard 7 refers to the validity of a credentialing program, and states:

The certifying organization has conducted validation studies to assure that inferences made on the basis of test scores are appropriate and justified (ABSNC, 2011).

The ALNCCB and the American Association of Legal Nurse Consultants (AALNC) commissioned a practice analysis, also known as job analysis or role delineation study (RDS) for LNCs to ensure that the certification examination accurately reflects the work being done by LNCs. The certification examination for LNCs is built upon a solid foundation from practice analyses (Webb & Hallas, 2008; Magnusson & Garbin, 1999). The 2007 practice analysis was conducted with a logical analysis of the work of LNCs by a panel of content experts, and validated through an electronic survey of practicing LNCs. The 2007 study led to test specifications that included eight scope domains and nine content areas of the examination (Webb & Hallas, 2008).

The 2012 study was planned to take a fresh look at the certification examination. So rather than starting with the test specifications that resulted from the 2007 practice analysis, the complete process of using a logical analysis by a panel of experts, and validating the panel's work empirically through a survey of the LNC field was done. This thorough process meets the letter and spirit of the requirements of ABSNC Standard 7. The rationale for the standard states:

Several measures can be taken to promote the content validity of a certification examination program. One of the most important of these is conducting a job analysis/RDS. The job analysis/RDS should define the tasks (competencies) of a particular job as well as the knowledge required to perform the tasks competently. Skills must also be defined if a practical examination is administered. Linking this information to the examination content is of key importance. Two approaches to conducting a job analysis/RDS, logical and empirical, are commonly used. The use of both approaches strengthens the content-related validity of a test and is preferred (ABSNC, 2011).

Following the standard, the study began with a logical analysis of content by an expert panel, and then used a survey of practicing LNCs to validate the findings empirically.

Methods

A logical analysis of the work done by LNCs was conducted by a panel of experts, which led to a cross-sectional empirical study of practicing LNCs through an electronic survey.

Logical Analysis/Instrument Development

The ALNCCB and AALNC convened a panel of certified LNCs to meet in person to perform the logical analysis of the profession. Six members of the panel were available to meet in person April 1-2, 2012 and included representatives from the AALNC Board of Directors and the examination committee. Two panel members were unavailable to meet in person, but provided independent reviews of the logical analysis. Through these reviews and the in-person panel discussion, all major aspects of LNC work were represented.

The panel had access to the eight scope domains and delineated tasks from the 2007 study. Rather than editing the 2007 document, the panel delineated anew the work of LNCs into a domain and task structure. As was done in the 2007 study, the panel focused on observable tasks that are specific to the work of LNCs. Through an iterative group process led by the psychometrician, 5 LNC content domains, 13 content areas, and 137 tasks were delineated. The panel also delineated the knowledge required to conduct the tasks

and content areas. Finally, the panel discussed demographic items that could be included in the electronic survey to assess whether the respondents represented the field of LNCs.

There were six sections in the survey, including an introduction, verification of working as an LNC in the past 12 months, hours of work in various practice areas, frequency ratings for tasks/domains, importance ratings for knowledge/ability, and demographic items.

The five scope domains, which incorporated the 137 tasks, included:

A. Identify and collect relevant data
B. Analyze data
C. Draft documents
D. Participate in case strategy development
E. Participate in adjudication of legal claims

Initially, two response scales were developed to measure task performance frequency and task importance. The frequency response scale was based on an estimated average number of times per month that each task was performed during the preceding 12 months, using the following scale for the 137 tasks:

5 = >10 times per month
4 = 6-10 times per month
3 = 1-5 times per month
2 = <1 time per month
1 = Do not perform task

Allowing for the possibility that there could be tasks performed by LNCs that were not included in the 137 tasks delineated by the expert panel, the survey included a question about the adequacy of the coverage, and allowed for write-in responses. A 4-point scale for the same tasks was initially planned to measure task importance (4=Essential, 3=Important, 2=Useful, 1=Not important); however, this was eliminated based on pilot data results described later.

To measure knowledge or abilities needed to perform LNC tasks, a 4-point rating scale was included:

4=Essential
3=Important
2=Useful
1=Not important

Allowing for the possibility that there could be knowledge or abilities required to perform LNC tasks that were not included in the knowledge/ability list generated by the expert panel, the survey included a question about the adequacy of the coverage, and allowed for write-in responses.

Demographic items included the one state where MOST of the work as an LNC was done, several experience and practice as an RN and LNC questions, certifications held, AALNC membership, and LNC work for plaintiff or defense.

Pilot Test of Instrument

A draft form of the validation survey was entered into the SurveyMonkey software. The panel members nominated additional LNCs to participate with the panel and the Board in the pilot study of the instrument. Through this process, directions and survey statements were clarified. A significant discussion of the individualistic nature of LNC work ensued during the review of the pilot test data obtained. As the panel explored the reality that many of the tasks subsumed under the umbrella of LNC work are not performed by all LNCs, the importance rating for tasks, described previously, was called into question. Thus, the panel decided to focus the survey on what the LNC respondents actually do, measured in terms of frequency alone, rather than inviting impressions of the importance of tasks for which respondents may have limited or no familiarity.

Data Collection

The electronic survey was distributed to the entire AALNC membership. This is a traditional method of collecting data and is the electronic equivalent of sending hard-copy surveys through the U.S. mail. Additionally, the URL for the survey was posted on websites and a listserv for LNCs to encourage response. The listserv announcement had significant overlap with the AALNC list. Although the additional postings of the survey URL is a great advantage to reach LNCs and remind LNCs, this step invalidates the traditional method of calculating a response rate by dividing the number of people who respond by the number of people who were targeted. However, a response rate can at least be estimated. On May 8, 2012, the survey link (URL) was sent in an announcement letter to the AALNC membership via email and reached 1,670 addresses. A reminder message was sent on May 11, 2012 to the same list of people. In addition, a dedicated message was sent to 26 state chapter presidents asking them to encourage members to complete the survey. Finally, a listserv for LNCs was used to post the survey URL and encourage response. The survey was closed on May 22, 2012. The total number of days for responding was 15.

Survey Results

Response Rate

It seems reasonable to use 1,670 as the denominator. There were 433 openings of the survey file; however, respondents were allowed to complete the survey in more than one sitting. It is common for respondents to look at a survey, and respond later. The first question asked for confirmation that the person worked as an LNC in the past 12 months, and 308 respondents replied positively. However, 103 respondents opted to skip this query. If it is assumed that respondents continued into the survey, the number of responses would equal 308 plus 103, for a total of 411, estimating a survey response rate of 24.6%. This figure could be an over-estimate if the listserv included significant numbers of respondents who were not in the AALNC email blast, or if those who did not answer the first question were not working as an LNC in the preceding 12-month period. It is also important to note that the number of respondents answering each question declined consistently throughout the survey, as is frequently seen in longer surveys such as practice analyses.

Table 1: Experience

Hours per Month Worked as LNC	(N =323)
< 10	13.0%
10 - 39	17.6%
40 - 69	15.8%
70 - 99	7.1%
100-139	12.1%
140-160	13.3%
> 160	21.1%
Years Worked as LNC	**(N=321)**
Less than 1	5.0%
1-2	8.4%
3-5	17.1%
6-10	24.3%
11-15	22.7%
>16	22.4%
Years Licensed as RN	**(N=321)**
1-5	0.0%
6-10	0.9%
11-15	3.4%
16-20	13.1%
20+	82.6%

Table 2: Demographic Characteristics

	YES	NO
Practice as nurse in clinical setting (N=319)	33.5%	66.5%
Worked as LNC during each of past 5 years (N=321)	81.9%	18.1%
Certified in nursing specialty other than LNC (N=316)	43.7%	56.3%
Member of AALNC (N=313)	79.9%	20.1%
Certified as LNCC (N=317)	36.3%	63.7%

Table 3: Setting and Type of Work Performed by LNC

Work setting for Majority of LNC Practice	(N=318)
Law firm	41.2%
Independent	40.3%
Hospital	4.7%
Insurance company	4.4%
Other (please specify)	9.4%
Type of Work Performed	**(N=318)**
Plaintiff	19.5%
Defense	21.4%
Both plaintiff and defense	54.4%
Neither plaintiff nor defense	4.7%

Table 4: Hours Worked Per Content Area

Percentage of Respondents								
Content Areas	**100+ hours**	**75-99 hours**	**50-74 hours**	**25-49 hours**	**1-24 hours**	**0 hours**	**Total %**	**N**
Medical malpractice	48.3	8.3	7.5	8.3	14.5	13.0	100	385
Personal injury	31.5	4.0	7.1	10.2	17.3	29.9	100	324
Long term care litigation	17.7	3.0	5.7	5.7	15.1	52.8	100	299
Product liability	12.4	3.4	6.0	6.7	11.7	59.7	100	298
Toxic tort	5.8	2.9	2.9	3.3	4.3	80.8	100	276
Workers' compensation	11.0	1.4	4.6	6.8	9.6	66.5	100	281
Risk management	10.4	1.4	2.8	3.1	8.0	74.4	100	289
Life care planning	7.2	1.8	2.9	1.8	6.8	79.6	100	279
Regulatory compliance	8.8	2.5	2.5	2.8	5.6	77.9	100	285
Forensic / Criminal	2.9	1.5	1.8	1.5	10.2	82.2	100	275
Civil rights	0.8	0.0	0.4	0.8	3.0	95.1	100	266
Employment discrimination	1.1	0.0	1.1	1.9	4.9	91.0	100	267
Medicare set-aside (MSA)	1.5	1.1	2.6	4.1	9.2	81.5	100	271

Demographic Data

It was planned that the survey respondents would have actual, recent experience in the field to draw upon while answering questions. To this end, if respondents indicated that they had not worked as an LNC in the past 12 months, they were taken to the exit screen after responding negatively. The balance of the demographic characteristics was judged to be appropriate by the expert panel supporting the study.

Many specific variables were analyzed that showed the great variability within the LNC profession. When asked where most of the LNC work was performed, 322 LNC respondents reported representing most of the states and the District of Columbia. The largest number of respondents came from the states of California (8.4%), Florida (7.8%), Pennsylvania (5.6%), Texas (5.9%), and multiple states equally (7.1%). There were only a handful of states that were

not specifically selected by the respondents, and we cannot know whether there were respondents from those states who did not persevere to the end of the survey, or if the states simply were not represented. There was consistent attrition throughout the duration of the survey, and 103 respondents stopped before this demographic item. Which states they represent is unknown. It could be that all states were represented in the content responses to the survey, but there is no way to know.

Respondents were asked about work experience as nurses and as LNCs. As shown in Table 1, more than 95% of respondents have been licensed as a registered nurse for at least 16 years. The respondents' years of experience working as LNCs ranged from less than one to over 16. Nearly 50% of respondents indicated working at least 100 hours per month as an LNC.Other demographic characteristics are displayed in Table 2. Many respondents indicated they worked for a law firm (41%) or as an independent LNC (40%) and worked for both the plaintiff and the defense (Table 3).

Content Areas

Respondents were asked to consider the LNC work performed in the previous 12 months, and to indicate the range of hours worked in each of 13 content areas (Table 4). Glancing across the responses per hours options, one can see the diversity of how LNCs spend their time. For example, in the first content area (medical malpractice), almost half of the respondents indicated spending more than 100 hours per month, but 13% of respondents indicated spending no hours in this content area. Studying Table 4 provides us with an appreciation for the variability in the work across LNCs.

Scope Domains

Respondents were asked to consider the 137 LNC tasks within the 5 scope domains previously identified, and indicate how frequently, on average, the tasks were performed during the preceding 12 months. The mean frequency ratings for tasks presented within the five scope domains (A-E) were calculated and are shown in Table 5, prioritized by mean frequency ratings and showing the domains to which tasks belong. The task reported most frequently was "analyze records and documents." It is interesting to note that 4 of the 5 domains are represented within the 10 highest-rated tasks for frequency, which again emphasizes the great variability in work across LNCs. The tasks within domain E, Participate in Adjudication of Legal Claims, were generally rated lower in frequency than the tasks of the other four scope domains.

Respondents were asked to what extent the 137 survey tasks covered the tasks they performed as LNCs and the response options were "completely," "adequately," or "inadequately." Responses to this question validated the work of the expert panel in that 94% of the respondents indicated that the survey tasks "completely covered" the tasks (47%) or "adequately covered" the tasks (47%) performed as LNCs. Only 6% of survey respondents selected "inadequately covered." The survey provided an opportunity for respondents to add any tasks performed that were not addressed by the survey, and write-in responses were varied. Four respondents wrote "cost research," and that was the largest number of same entries. Respondents were asked "Are there new practice areas in your LNC work (e.g., health informatics) that are not covered in the 137 tasks above? If so, please describe." Varied responses were given by 53 respondents, and the largest number of same entries was 4, for "health informatics."

Knowledge Ratings

The complete list of 49 entries was validated through the survey responses, in that no statements received the majority of responses with a rating of "not important." Table 6 shows the 49 knowledge and ability items and the frequency of each importance rating for the knowledge/ability in the work as an LNC. Using the frequencies instead of a mean importance rating allows one to see the full variability of ratings across respondents.

Survey respondents were asked to what extent the 49 knowledge and abilities covered what is needed to perform the tasks in their work as LNCs, and the options were "completely covered," "adequately covered," or "inadequately covered." Responses to this question validated the work of the expert panel, in that 99% of the respondents indicated that the survey statements "completely covered" the required knowledge and abilities (51%) or "adequately covered" the required knowledge and abilities (49%). Less than 1% of survey respondents selected the option "covered inadequately." The survey provided an opportunity for respondents to add any knowledge or abilities that were not addressed by the survey, and the entries were varied. The highest number of common responses was three, and they related to business skills.

Discussion of Test Specifications

Following the summary of the survey validation data, a content expert group participated in a web meeting to consider test specifications for the certification examination. Test specifications are the delineation of the content covered by the test. The content expert group began with a review of the demographic data to ensure that the field of LNCs was well-represented, which was agreed.

The content expert group next considered the mean ratings for the 137 tasks on the survey. It is common to consider the prioritized list of rated tasks with the purpose of eliminating tasks that cannot be tested in the examination format (e.g., multiple-choice items), or because of low ratings. The first panel (who conducted the logical analysis) focused on tasks that could be observed or delegated, which ensured that the tasks could be tested within the examination's format of multiple-choice questions. The panel also limited the delineation to tasks unique to LNCs (as opposed to all nurses), which increased the likelihood that tasks would receive high frequency ratings and not have to be deleted at the point of deciding test specifications due to low ratings.

The content expert group saw no tasks that should be eliminated based on inability to be tested within a multiple-

Table 5: All Tasks Prioritized by Mean Frequency Ratings with Domain Indicated

Domain Key
A. Identify and Collect Relevant Data
B. Analyze Data
C. Draft Documents
D. Participate in Case Strategy Development
E. Participate in Adjudication of Legal Claims

Mean	Domain	Task
4.02	B	Analyze records and documents
3.91	A	Identify relevant medical records
3.78	C	Summarize medical records and other case documents
3.70	A	Identify standard of care
3.62	B	Analyze medical literature
3.61	A	Identify relevant medical literature
3.60	C	Prepare chronologies/timelines
3.57	B	Organize records and documents
3.53	D	Educate lawyers, paralegals, and their clients about medical issues specific to case
3.45	A	Retrieve medical literature
3.33	B	Evaluate impact of injury or illness
3.17	B	Evaluate causation
3.17	A	Identify relevant non-medical records
3.04	B	Evaluate damages
3.01	B	Determine defensibility of case
2.99	B	Evaluate liability
2.96	C	Generate reports
2.81	A	Collect medical records
2.75	B	Screen potential medical malpractice cases for merit
2.73	B	Analyze expert witness reports, disclosures, or designations
2.70	D	Identify experts
2.70	B	Analyze deposition testimony
2.70	A	Identify potential defendants
2.69	B	Analyze documents produced in response to request for production
2.68	D	Educate healthcare professionals regarding medical legal issues
2.63	B	Analyze complaint or petition
2.61	B	Analyze medical bills
2.56	A	Identify potential conflicts of interest (legal or personal)
2.50	D	Research expert qualifications
2.43	D	Review experts' opinions with appropriate parties
2.32	D	Participate in case strategy meetings
2.31	B	Analyze witnesses' statements
2.31	D	Communicate case status or progress
2.28	E	Update medical records prior to legal proceeding
2.27	A	Conduct investigations on licenses, profiles, or practice information
2.21	B	Analyze answers to interrogatories or bills of particulars
2.21	A	Interview experts or treating health care providers
2.19	A	Identify statute of limitations
2.19	A	Interview client (plaintiff, defendant, third party)
2.17	D	Suggest deposition strategies for attorneys

Table 5: All Tasks Prioritized by Mean Frequency Ratings with Domain Indicated (continued)

Domain Key
A. Identify and Collect Relevant Data
B. Analyze Data
C. Draft Documents
D. Participate in Case Strategy Development
E. Participate in Adjudication of Legal Claims

Mean	Domain	Task
2.17	D	Participate in conference with experts
2.15	B	Analyze case status report
2.13	C	Prepare deposition questions
2.13	C	Prepare written evaluation on causation
2.13	C	Prepare written evaluation on damages
2.12	B	Analyze state rules and regulations
2.12	B	Confirm statute of limitations
2.12	A	Obtain expert or defendant's literature
2.08	B	Analyze IME reports
2.07	A	Collect non-medical records
2.07	B	Analyze responses to requests for admissions
2.07	B	Analyze federal rules and regulations
2.07	A	Obtain state rules and regulations
2.04	E	Recommend exhibits or demonstrative evidence
2.04	C	Prepare expert package
2.01	B	Analyze accreditation standards
2.00	A	Obtain federal rules and regulations
1.99	C	Prepare written evaluation of liability
1.99	C	Prepare memos to legal file
1.95	E	Review experts' prior depositions or trial testimony
1.93	B	Analyze certificate of merit or affidavit
1.90	A	Collect legal documents
1.86	C	Summarize deposition testimonies
1.83	B	Analyze plaintiff demand package
1.82	C	Prepare billing summary
1.78	E	Prepare exhibits or demonstrative evidence
1.77	A	Collect health care facility accreditation / other survey results
1.75	B	Analyze life care plans
1.71	C	Assist in preparing or answering interrogatories or bills of particulars
1.70	C	Assist in preparing status reports
1.70	C	Assist in preparing or responding to requests for production
1.70	D	Recommend IME
1.70	C	Prepare HIPAA-compliant authorizations
1.67	A	Interview fact witness
1.66	A	Obtain witness's prior deposition or trial testimony
1.66	C	Assist in drafting affidavits
1.63	E	Prepare questions for trial/hearing testimony
1.59	E	Attend depositions
1.59	C	Assist in preparing or answering complaint
1.57	E	Testify in your area of nursing expertise

Table 5: All Tasks Prioritized by Mean Frequency Ratings with Domain Indicated (continued)

Domain Key
A. Identify and Collect Relevant Data
B. Analyze Data
C. Draft Documents
D. Participate in Case Strategy Development
E. Participate in Adjudication of Legal Claims

Mean	Domain	Task
1.56	D	Develop medical case management plan
1.52	C	Assist in preparing a complaint or petition
1.51	E	Testify at depositions
1.51	C	Prepare medical cost projections
1.50	C	Assist in preparing or responding to requests for admissions
1.50	E	Testify as an expert on nursing standards of care
1.49	C	Prepare certificate of merit as expert
1.49	A	Attend medical appointments
1.48	E	Attend trial
1.47	C	Prepare letters to governmental or regulatory agencies
1.47	C	Prepare expert witness disclosure
1.46	D	Prepare experts for deposition
1.45	C	Generate claims reports
1.40	E	Attend IME
1.39	B	Facilitate root cause analysis
1.38	A	Conduct independent evaluation of the plaintiff or claimant
1.38	D	Prepare plaintiff or defendant for deposition
1.38	E	Testify at trials/hearings
1.36	D	Prepare fact witness for deposition
1.33	E	Attend mediation
1.32	C	Assist in preparing demand packages
1.32	C	Assist in preparing a subpoena duces tecum
1.30	E	Prepare plaintiff or defendant for trial/hearing
1.30	C	Prepare life care plan
1.30	A	Conduct site inspection
1.30	E	Execute affidavits
1.30	C	Prepare fact witness disclosure
1.30	E	Observe jurors during trial
1.29	E	Prepare experts for trial/hearing
1.29	C	Assist in preparing notices or other legal documents
1.28	E	Assist in preparing settlement package
1.28	E	Testify as a fact witness
1.28	E	Prepare witnesses for trial/hearing
1.27	B	Determine Medicare set-aside (MSA)
1.26	C	Assist in responding to motions
1.25	E	Assist in preparing questions for voir dire
1.22	E	Attend arbitration
1.21	E	Summarize trial testimony
1.21	C	Assist in preparing motions
1.21	E	Schedule trial testimony of healthcare providers

Table 5: All Tasks Prioritized by Mean Frequency Ratings with Domain Indicated (continued)

Domain Key
A. Identify and Collect Relevant Data
B. Analyze Data
C. Draft Documents
D. Participate in Case Strategy Development
E. Participate in Adjudication of Legal Claims

Mean	Domain	Task
1.21	E	Participate in medical review panel
1.20	E	Participate in post-trial evaluation
1.20	C	Prepare appeals to governmental or regulatory agencies
1.18	E	Participate in focus groups
1.18	E	Attend voire dire
1.17	E	Testify at arbitrations
1.16	B	Analyze profit loss statement
1.16	E	Mediate disputes
1.13	E	Attend administrative law judge hearing
1.12	E	Attend workers' compensation hearing
1.12	E	Attend Individualized Education Program (IEP) meetings
1.11	E	Attend functions for administrative law judge hearing
1.10	E	Attend social security disability hearing
1.10	A	Conduct a physical examination to collect evidence
1.08	E	Interview dismissed jurors
1.07	E	Attend school proceedings
1.04	E	Attend discrimination hearing

choice format or because tasks were not unique to the work of LNCs. The content expert group further decided not to eliminate any tasks based on low frequency ratings, because tasks can represent significant work for some LNCs, even if performed infrequently. Additionally, the field of legal nurse consulting is becoming quite diverse in that there are some tasks certain LNCs never perform but those same tasks are performed by other LNCs, depending upon the particular roles and practice settings. An example of such diversity is that some LNCs assist in preparing a summons and complaint, but other LNCs do not. Also, life-care planning LNCs are expert witnesses while other LNCs do not perform the role of expert witness. Medicare set-asides and health informatics are fast-growing areas, but few LNCs are involved at this time.

The five scope domains were summarized by the number of tasks included and the mean task rating. Two common approaches to using validation data for test specifications are to consider the mean ratings weighted by the number of tasks, or unweighted by the number of tasks. Data were prepared using the mean frequency rating for each of the five scope domains (unweighted specifications) and also by considering both the mean frequency ratings and the number of tasks per domain (weighted specifications). The number of tasks can be an indicator for the relative emphasis that a scope domain should have within the test specifications, but it assumes that the tasks are equal in complexity. In discussion, the content expert group indicated that the 38 tasks of Scope Domain E: Participate in Adjudication of Legal Claims, were easily split into a long listing, but, taken together, the elements of the scope domain did not merit an emphasis of almost 20% of the test. By comparison, the 14 tasks of Scope Domain D: Participate in Case Strategy Development are quite important to the work of LNCs, and merit more than 11% of the test. The content expert group endorsed the unweighted test specifications, which are shown in Table 7. The complete delineation of tasks has 138 tasks, to include "Cost Research," a task appended to the list by 4 respondents through write-in responses (see Results section).

The content expert group's final task was to consider the second dimension of the test specifications, the content areas. Reviewing these data is not as straightforward because the attrition of respondents within this survey item was significant. The approach taken focused on the ordinal nature of the data by multiplying the number of respondents who selected each of the hours options (100+ hours, 75-99 hours, 50-74 hours, 25-49 hours, 1-24 hours, 0 hours) by a value for the hours options. Treating the data in this fashion makes a large difference in the emphasis on the first content area, medical malpractice, but little to no difference in the other areas. Emphases for the content areas of the test specifications

Table 6: Proportion of Respondents Selecting Each Importance Rating for Knowledge/Ability

Knowledge/Ability	Essential	Important	Useful	Not important	N
Analytical thinking skills	98.1%	1.5%	0.0%	0.3%	323
Interviewing skills	51.1%	28.2%	17.0%	3.7%	323
Verbal communication skills	88.9%	10.8%	0.0%	0.3%	323
Written communication skills	94.1%	5.6%	0.3%	0.0%	324
Technology skills	54.2%	40.6%	5.0%	0.3%	323
Organizational skills	86.4%	13.0%	0.6%	0.0%	324
Basic concepts of duty, breach, causation, and damage	68.6%	25.8%	4.3%	1.2%	322
Anatomy and physiology	71.3%	27.2%	1.2%	0.3%	324
Health delivery systems	46.3%	42.2%	9.9%	1.6%	322
Pharmacology	43.8%	45.7%	10.6%	0.0%	322
Nursing and medical practice	80.2%	18.0%	1.5%	0.3%	323
Medical terminology	84.8%	13.9%	1.2%	0.0%	323
Pathophysiology	63.0%	33.5%	3.1%	0.3%	322
Time management	77.9%	19.6%	2.5%	0.0%	321
Accessing medical resources	67.6%	26.8%	4.7%	0.9%	321
Statutes and administrative codes	17.7%	37.3%	39.8%	5.3%	322
Sources of standards and guidelines	55.4%	32.5%	10.8%	1.2%	323
Principles of teaching and learning	32.5%	40.2%	24.5%	2.8%	323
Ethical principles	63.2%	25.1%	10.8%	0.9%	323
Rehabilitation principles	14.6%	39.8%	38.5%	7.1%	322
Risk management principles	21.1%	35.3%	36.5%	7.1%	323
Life care planning principles	11.5%	23.6%	47.5%	17.4%	322
Case management principles	16.7%	25.1%	45.2%	13.0%	323
Medical literature research	65.0%	26.9%	7.1%	0.9%	323
Medical malpractice claims	53.8%	25.9%	15.9%	4.4%	320

(continued on p. 34)

(second dimension) traditionally have been presented in ranges. Using the ranges is a somewhat arbitrary procedure, but allows for a bit more flexibility in test development to counter the item banking challenge of addressing two dimensions of content for every test form. The final dimensions of the test specifications are shown in Table 7.

The test specifications are based on what LNCs do, and provide the structure for the emphases within the examination. However, the certification examination questions target what LNCs know, and the prioritized list of knowledge statements (n=49) will be used by the LNCs who serve as item writers and item reviewers for the certification examination to ensure that the test questions are written at a level appropriate for LNCs.

Conclusion

The 2012 practice analysis of LNCs produced data that will be important in updating the certification examination. The diversity of tasks that constitute LNC practice is significant. The new test specifications content areas are expanded to include Medicare set-aside, civil rights, and employment discrimination (including Americans with Disabilities Act). The content area of regulatory compliance will incorporate administrative health law, and the content area of elder law will include long-term care litigation. The content area percentages shifted based on the practice analysis survey.

In the updated test specifications, the scope of examination will have five domains, rather than the current eight domains. Because both communication and education are foundational throughout the LNC tasks, the new test specifications will not list them separately. Testifying as an expert or fact witness was removed from the scope list, because it is part of the adjudication of legal claims. Current questions in the item bank will be reclassified according to the new content area specifications and scope of examination domain tasks. The earliest implementation of the new test specifications will be in 2014-2015. It is anticipated that the next practice analysis study will be conducted in 2018. A complete report on the

Table 6: Proportion of Respondents Selecting Each Importance Rating for Knowledge/Ability (continued from p. 33)

Knowledge/Ability	Essential	Important	Useful	Not important	N
Personal injury claims	42.3%	26.2%	21.9%	9.6%	324
Product liability claims	23.5%	34.1%	25.1%	17.3%	323
Toxic tort claims	15.8%	29.2%	31.7%	23.3%	322
Workers' compensation claims	18.8%	26.3%	32.8%	22.2%	320
ERISA claims	8.5%	22.0%	39.0%	30.5%	318
Legal terminology	41.9%	46.3%	11.9%	0.0%	320
Legal procedural rules	17.5%	41.6%	36.6%	4.4%	320
Legal doctrine	14.2%	35.3%	44.5%	6.0%	317
Administrative health law	13.8%	27.6%	43.9%	14.7%	319
Criminal law	6.0%	18.2%	47.5%	28.3%	318
Forensic law	6.9%	19.5%	48.4%	25.2%	318
Elder law	13.5%	25.4%	43.9%	17.2%	319
Litigation process	41.3%	37.2%	20.0%	1.6%	320
Rules of evidence	28.5%	35.4%	31.7%	4.4%	319
Rules of confidentiality	64.4%	22.8%	10.3%	2.5%	320
Rules of professional conduct	65.0%	23.1%	8.4%	3.4%	320
Rules of admissibility of evidence	26.9%	38.1%	26.3%	8.8%	320
Fraud	25.9%	30.9%	30.3%	12.8%	320
Civil rights litigation	6.0%	19.7%	38.2%	36.1%	319
Correctional medicine (inmate care)	4.4%	14.6%	41.1%	39.9%	316
Alternative dispute resolution (ADR)	7.3%	17.4%	44.5%	30.9%	317
Long term care litigation	18.2%	19.8%	42.8%	19.2%	318
Medicare set-aside	8.9%	21.2%	44.0%	25.9%	316
HIPAA rules	57.1%	24.6%	13.6%	4.7%	317

Table 7: Test Specifications for Content Areas and Scope Domains

Range for Percent of Test	CONTENT AREA
19-23	Medical malpractice
12-14	Personal injury
8-10	Long term care litigation / Elder law
7-9	Product liability
5-7	Toxic tort
6-9	Workers' compensation
6-8	Risk management
5-7	Life care planning
5-8	Regulatory compliance
4-6	Forensic / Criminal
3-5	Civil rights
3-5	Employment discrimination (including ADA)
4-6	Medicare set-aside

SCOPE DOMAIN	Percent of Test
Identify and collect relevant data	23.0
Analyze data	24.5
Draft documents	18.0
Participate in case strategy development	21.5
Participate in adjudication of legal claims	13.0

2012 Legal Nurse Consultant Practice Analysis is available at http://www.aalnc.org/Login.aspx.

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Ischemic Heart Disease in Pregnancy

Deanna H. McCarthy, RN, MSN

Introduction

Ischemic heart disease is rare during pregnancy, occurring in only 1 in 10,000 pregnancies, but the prevalence is increasing due to the changing lifestyles and increasing age of the women becoming pregnant in today's society (Kealey, 2010). This article will discuss morbidity and mortality in older women becoming pregnant with ischemic heart disease and also younger women who have ischemic heart disease due to lifestyle choices who become pregnant.

Prevalence of Ischemic Heart Disease

During pregnancy, the risk of coronary ischemia increases approximately three to four times that of women who are not pregnant (Karamemer & Roos-Hesselink, 2007). Myocardial infarction (MI) occurs in 8.8% of pregnant women age 30-34 compared to 19% of pregnant women age 35-39, and 30.2% of pregnant women age 40 and older (these numbers are based on 100,000 births) (Kealey, 2010).

Risk Factors

Lifestyle factors play a role in the increase of ischemic heart disease in pregnancy. Smoking, obesity, diabetes, older childbearing age, stress, hyperlipidemia (diet), a history of chronic hypertension (stress), and previous use of oral contraceptives are all contributing factors (Kealey, 2010). Other risk factors are a family history of myocardial infarction before the age of 60, congenital heart disease (specifically uncorrected anomalous origins of the coronary arteries or severe aortic stenosis), Kawasaki disease (vasculitis), hypertrophic cardiomyopathy, or spontaneous coronary artery dissection (Kealey).

As mentioned above women with lipid abnormalities are at-risk for ischemic heart disease during pregnancy; however, pregnancy increases the risk with lipid abnormalities because high–density lipoprotein cholesterol decreases significantly, while the low-density lipoprotein cholesterol remains unchanged. This change in cholesterol puts the pregnant woman at increased risk for atherosclerosis (Kealey). While atherosclerotic disease is the primary reason for heart disease during pregnancy, other causes include thrombosis, coronary artery spasm (spontaneous or induced), coronary artery dissection, collagen vascular disease, amniotic fluid embolism, pheochromocytoma, and cocaine use (Kealey).

Kealey reports there are also medical conditions that may occur as part of the pregnancy that can exacerbate underlying conditions that are already present in women who are at high risk for ischemic heart disease. Pre-eclampsia, a medical condition that can occur during the pregnancy (more prevalently in older women), is identified as a risk factor for myocardial infarction by significantly increasing myocardial band necrosis, suggesting increased occurrence of coronary artery spasm as compared to normal. Further, alterations in the coagulation and fibrinolytic system due to pregnancy can also increase the risk of thrombosis during pregnancy by decreasing tissue plasminogen activator activity and reducing functioning protein S levels (Kealey).

Diagnosis

Davies and Herbert (2007) state that making a diagnosis of myocardial infarction in pregnant patients is essentially the same as in non-pregnant patients, keeping in mind that the electrocardiogram (ECG) in normal pregnancy may show several changes, which can make ECG diagnosis of ischemia more challenging. The chest x-ray in normal pregnancy may show straightening of the left heart border, enlargement of the heart, and increased vascular markings. "Creatinine Kinase – cardiac muscle subunit (CK-MB) levels associated with MI in pregnancy- correlates with infarcting non-pregnant patients but may be influenced by placental and uterine stores when tested at the time of labor and delivery"(Davies & Herbert 2007, p. 576). The troponin I level in serum appears to be the marker of choice of myocardial injury in the pregnant patient because levels are not altered by normal pregnancy (Davies & Herbert). Exercise ECG is another tool for diagnosing coronary artery disease, but it is not highly recommended during pregnancy because fetal bradycardia has been reported during maximal exercise in healthy women; therefore, a submaximal exercise protocol can be used with fetal monitoring to evaluate for ischemic myocardial disease during pregnancy (Kealey, 2010).

Kealey states that nuclear imaging should be avoided especially during organogenesis (10 to 50 days) due to the risk of teratogenesis. Nuclear imaging may still pose a risk even in the second and third trimesters causing intrauterine growth retardation, central nervous system abnormalities, and increased risk of malignancy. The author states that the stress echocardiogram is the most reasonable option for assessing ischemia and left ventricle function during pregnancy .

Cardiac catheterization can be performed safely in pregnancy, but it carries risks. The radial or brachial artery approach should be used and the abdomen should be shielded (Karamemer & Roos-Hesselink, 2007; Kealey, 2010). Even though the abdomen is shielded, there is evidence that the

fetus is still exposed to some radiation. Lower fluoroscopy times are recommended to minimize fetal exposure to radiation, because higher doses of radiation place the fetus at risk for spontaneous abortion, organ deformation, mental retardation, and childhood malignancy (Karamemer & Roos-Hesselink, 2007; Kealey, 2010).

Signs and Symptoms

Signs and symptoms cannot be relied upon as diagnostic for ischemic heart disease in pregnant women because they are similar to those of the non-ischemic pregnant patient. Common complaints during normal pregnancy include fatigability, decreased exercise tolerance, and chest pain at rest due to esophageal reflux. However, indicators of heart disease include severe or progressive dyspnea, syncope with exertion, and chest pain related to effort or emotion (Karamemer & Roos-Hesselink , 2007).

Treatment

Medical treatment includes pharmaceutical therapy. Medications that are safe for the pregnant patient to treat ischemic heart disease are aspirin, beta-blockers, nitrates, calcium antagonists, heparin, low-molecular weight heparins, morphine, and anti-arrhythmics, such as lidocaine (Davies & Herbert, 2007 ; Karamemer & Roos-Hesselink, 2007; Kealey 2010) . Medications that are used for patients with ischemic heart disease that are teratrogenic are ACE-inhibitors, coumadin, and statins (Karamemer & Roos-Hesselink, 2007). If a newly pregnant patient is currently on any of these medications they must be discontinued immediately and if possible converted to a compatible drug (Karamemer & Roos-Hesselink, 2007; Kealey, 2010).

Thrombolytic therapy has been used in pregnant patients, but mostly for those with pulmonary embolism, deep venous thrombosis, and prosthetic valve thrombosis. It is unknown whether thrombolytics cross the human placenta (Karamemer & Roos-Hesselink, 2007). "The complications of thrombolytic therapy observed included maternal hemorrhage (2.5%), uterine hemorrhages with emergency cesarean section (2%), preterm delivery (6%), fetal loss (2%), abruption placenta (2.5%) and spontaneous abortion (1.5%)"(Karamemer & Roos-Hesselink, p. 562).

As described earlier, cardiac catheterization can be safely used in the pregnant patient, therefore, percutaneous coronary intervention has been used in pregnancy with the precautions described above (i.e., radial/brachial artery approach, limited radiation exposure, shielding the abdomen). The difference for the pregnant patient as compared to the non-pregnant patient comes with the safety of the use of drug-eluting stents (Kealey, 2010). The safety of the use of these stents is not known in the pregnant patient, nor is the safety of combination antiplatelet therapy to reduce stent thrombosis. "Bare-metal stents may be the preferred option because insertion of drug-eluding stents may mandate a longer period of combination antiplatelet therapy and, thus, increase the risk of bleeding"(Kealey, 2010, p. e186).

Coronary artery bypass grafting (CABG) on pregnant patients has been reported in the literature since 1959. CABG survival rates are equal in the pregnant patient population as in the non-pregnant patient population, but the fetal mortality rate is high with an incident rate ranging from 9.5% to 40% (Karamemer & Roos-Hesselink, 2007; Kealey, 2010). Cardiac surgery should take place in the second or third trimester if at all possible and should be done two weeks after the ischemic episode, as this is considered a period of stabilization and increased survival for the mother and the fetus (Davies & Herbert, 2007). If cardiac surgery must be performed in the first trimester, the fetus is at an increased risk for the occurrence of congenital malformations. During the surgery maternal hypothermia should be minimal, as well as the extracorporeal (bypass machine) time (Kealey, 2010). Pulsatile perfusion is preferred while the patient is on the bypass machine because it offers an improvement in fetal outcome. The fetus should be monitored throughout the procedure; fetal bradycardia and loss of beat-to-beat variability suggest poor fetoplacental perfusion and can be corrected by increasing the flow rate and maternal temperature (Karamemer & Roos-Hesselink, 2007; Kealey, 2010).

Legal Considerations

- The safety of the mother prevails over the possible negative influence of the therapy on fetal outcome.
- Patients at high risk for coronary artery disease should be screened, if possible, before becoming pregnant.
- If the patient has diabetes and/or high blood pressure, these should be adequately controlled before she becomes pregnant.

Potential Experts

- Obstetricians
- Cardiothoracic surgeons
- Cardiologists
- Anesthesiologists
- Gynecologists
- Maternal-Fetal Medicine Physicians
- Neonatologists
- Perfusionists

Damages

Damages in these cases can be severe with loss of the life of the mother and baby being the most extremely significant. For the women, damages can include permanent infertility, stroke, loss of limb(s), and anoxic brain damage. Damages for the fetus can include premature delivery, malformation, stroke, anoxic brain damage, and neural tube defects.

Obviously, this is not a complete list and there can be many more unfortunate outcomes that could possibly occur.

Literature Search

A literature search was performed using Google with the following terms: "pregnancy", "negligence", "malpractice", "ischemic heart disease", "myocardial infarction", and, "heart disease".

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Resources

American College of Cardiology. www.cardiosource.org

American College of Nurse Mid-Wives. www.midwife.org

American Congress of Obstetricians and Gynecologists. www.acog.org

Association of Women's Health, Obstetrics and Neonatal Nurses. www.awhonn.org

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The New England Compounding Center

Mary A. O'Connor, PhD, RN

One of the largest health disasters of 2012 was the fungal meningitis and parameningeal infections that were traced to three lots of contaminated preservative-free methylprednisolone acetate (MPA) injection prepared by the New England Compounding Center (NECC). As of January 2013, 664 cases of the fungal form of meningitis have been recorded, including 44 deaths across 19 states (Centers for Disease Control and Prevention, 2013a). In addition, there are cases of fungal infections of various joints that were injected with fungal contaminated MPA (*New England Compounding,* 2013). The case count continues to climb slowly now, and for those who are infected and lived, or who lost loved ones to the infection, the legal journey is just beginning. To add insult to injury, it is likely that there will be less than 1% recovery of compensation for these damages (Hall, 2012).

Problems at the New England Compounding Center

Problems at the NECC were uncovered long before the cases of fungal meningitis occurred. In 2004, NECC was charged with failing to comply with accepted standards when compounding MPA, the steroid that was found to be contaminated in the fungal meningitis cases. Other problems with the company also surfaced more recently. In July 2012, an inspector with the Colorado Pharmacy Board sent an email to James Coffey, director of the Massachusetts Pharmacy Board, about NECC's violating its state licenses by distributing bulk shipments of drugs to hospitals in Colorado. Both James Coffey and Susan Manning, attorney for the Massachusetts' Pharmacy Board ignored the inspector's 34-page email. James Coffey has since been fired and Attorney Manning is on administrative leave (Lazar, 2012; Wasek, 2012).

Following the fungal meningitis outbreak, Food and Drug Administration inspectors found unsanitary conditions at NECC. Mats that were supposed to trap dust and dirt at doorways were full of dirt. Sterile hoods were not cleaned correctly. NECC shipped compounded vials without waiting for the results of the vials' sterility tests. And, fungus was growing in steroid solutions ("New England Compounding," 2012).

Two of the three lots of preservative-free MPA (80 mg/ml) were found to be contaminated with a fungus Exserohilum rostratumin from NECC (Lot #06292012@26, BUD12/26/2012 and Lot #08102012@51, BUD 2/6/2013). The laboratory confirmation further links steroid injections from these lots from NECC to the multistate outbreak of fungal meningitis and joint infections. Testing on the third implicated lot of MPA and other NECC injectable medications continues. (Center for Disease Control and Prevention, 2013b; DeNoon, 2012).

Injuries

The extent of the injuries for those who survived is extensive. The diagnosis was delayed initially because of the atypical presentation of symptoms of meningitis with the fungal meningitis. Instead of the classic symptoms of meningitis, that is nuchal rigidity, Kernig's sign and Brudzinski's sign, the majority of those affected with the black mold induced-meningitis had "meningitis alone (73%), the cauda equina syndrome or focal infection (15%), or posterior circulation stroke with or without meningitis (12%)" (Kainer, et al, 2012, para.3). Patients presented with symptoms of headache, back pain that was either new in origin or becoming worse, peripheral joint infections of the knee, hip, shoulder, elbow, or ankle, neurological symptoms of sensitivity to light, slurred speech, and delayed thinking, and others, nausea and vomiting; and stiff neck (Hall, 2012; Kainer, et al., 2012; "Meningitis caused by," 2013; *New England Compounding,* 2013). Of the 44 individuals who lost their lives, the most frequent cause of death was a stroke due to fungal meningitis (Grady, 2012).

Unfortunately for those who survived the illness, their problems have not resolved completely. Following lengthy hospitalizations and critical care, patients were discharged in weakened conditions and have required admission to rehabilitation facilities. Residual problems in some instances include paralysis. One of the common complications is an epidural abscess which is unable to be detected except by MRI. In Michigan, approximately one-third of the patients who were treated successfully for meningitis returned to the hospital with an epidural abscess. Left untreated, the epidural abscess can trigger another bout of meningitis. Follow-up care for all patients have required frequent physician visits to monitor for side effects and complications such as the epidural abscess, liver and kidney function (Moisse, 2012). These visits are time-consuming and result in the victims and families losing work time and money for treatments and care. One victim, age 59, claims that he "doesn't have a life anymore. My life is a meningitis life" (Hall, 2012, para. 3).

Legal Actions

Almost immediately after cases of fungal meningitis were reported, lawsuits were filed at both state and federal levels.

On October 11, 2012 a Minnesota woman filed a class action suit against NECC and another class action claim was filed in Massachusetts, and 50 federal lawsuits have been filed in 9 states (Hall, 2012; *New England Compounding,* 2013). Unlike other serious drug injury cases involving large pharmaceutical manufacturers, the NECC is a small company and, prior to the Massachusetts Board of Pharmacy's permanent revocation of its license, was one of 3,000 to 5,000 compounding pharmacies in the United States (Begley, 2012; Horn, 2012). Lawyers representing NECC are determining what its liability insurance covers. A question exists as to whether or not NECC has adequate liability coverage (Hall, 2012).

Both defense and plaintiff attorneys requested consolidating the lawsuits to avoid judges in different jurisdictions making inconsistent pre-trial rulings (Hall, 2012). The plaintiffs' attorneys filed a petition in October, 2012 to the U.S. Judicial Panel for Multidistrict Litigation (JPML) to consolidate the cases in Minnesota's federal courts. The defense attorneys for NECC petitioned for consolidation of the cases in Massachusetts' federal courts ("New England Compounding," 2012). By December, 2012, federal Judge Saylor consolidated the lawsuits against the NECC, but a panel of judges in Washington will meet early in 2013 to determine how the 70 lawsuits from Massachusetts, Minnesota, Tennessee, and Michigan will be handled (Petroni, 2012b).

The lawsuit allegations thus far consist of the following:

1. NECC negligently produced a defective and dangerous product.
2. The dangerous drug caused deaths.
3. The dangerous drug caused physically painful recoveries.
4. The illness resulted in lost wages.
5. The illness resulted in mental and emotional damage (Hall, 2012).

The legal actions filed include "pharmacy malpractice, general negligence, breach of warranties, and other wrongdoing" (Fitzgerald, 2012, para. 2). Under tort law, the injured parties must prove the defendant's liability. The NECC, as the manufacturer, will need to be proven accountable to the defendants for injuries sustained due to the defect in the drugs and this may result in compensatory (medical costs and loss of earnings), hedonic (pain and suffering), and punitive damages (Pozgar, 2012). Massachusetts allows punitive damages only in cases of wrongful death, but because the lawsuits are being filed in many states with different definitions of punitive damages, punitive damage claims may be made in other cases that resulted in harm but not death (Fitzgerald, 2012).

Current Status

Although federal litigation can be very slow as data gathering during discovery could take months, if not years, U.S. District Judge Dennis Saylor in Massachusetts is calling for a stepped up pace with investigating this travesty. Judge Saylor held an expedited hearing before Thanksgiving, 2012 to freeze the $461 million in assets held by NECC, its owners, and two related companies. He also declared that criminal complaints against NECC will have priority over civil litigation (Petroni, 2012b). A criminal investigation into NECC's actions related to the fungal investigations was promised by Massachusetts' Governor Deval Patrick (Petroni, 2012).

The NECC filed for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Court on December 21, 2012 in an effort to protect its assets and set up a Compensation Fund for those with claims against the NECC. The NECC hired Keith D. Lowey, an accountant, as independent director and chief restructuring officer ("New England Compounding," 2012). Mr. Lowey intends to "assemble a substantial" Compensation Fund and through "a cooperative effort…. distribute it fairly and efficiently to those who are entitled to relief ("New England Compounding," 2012, para 3). Further, "Lowey said NECC seeks to forge a consensual, comprehensive resolution of claims which will be funded by agreements reached among the claimants, the Company, its insurers and other parties with potential liability for the meningitis cases. All such claims will be addressed in U.S. Bankruptcy court" ("New England Compounding," 2012, para 4).

The difficulty will be to determine those who are entitled to relief and to determine who else may become a party in the lawsuits. Attorneys for the plaintiffs are also seeking compensation for their clients from the co-founders of NECC, Barry Cadden and Greg Conigliaro, who are brothers-in-law, and sister companies of NECC. Others who may be sued are doctors, hospitals, pharmaceutical distributors, and people who injected the tainted steroid (Hall, 2012).

Conclusion

Congress is now talking about the lack of oversight of compounding companies by the FDA. Concerns are voiced about companies such as NECC being regulated by the federal and the state governments but having no oversight by the board of health. The Framingham Board of Health had no oversight over NECC.

The NECC is not alone with deaths and illnesses related to its compounds. Other compounding companies have experienced problems, but not at the scale of those affected by the NECC contaminated vials. Kaiser Permanente reported that in 2006, 30 million prescriptions for compounded products were written. Between 2001 and 2007, 120 bacterial and viral infections were linked to drugs produced by compounding companies, four of the victims died. In 2011, intravenous medications prepared by a compounding company resulted in nine deaths (Begley, 2012).

It is premature to present a conclusion of what will happen in the 664 fungal meningitis cases caused by tainted

vials of preservative-free MPA from the NECC. Discovery has started and data are being collected. The rest of the story is just beginning.

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Risk of Intravenous (IV) Free-Flow

Judith M. Bulau, MSN, RN

Q: What is the risk of accidental IV free-flow for electronic infusion devices (EID) that do not have infusions set-based free-flow protection?

A: Accidental IV free-flow incidents for EID occur after the removal of an IV administration set that has not been manually closed with a roller or side clamp. IV fluid freely flows into the patient's vein and may cause serious patient harm or death.

The risk of IV free-flow has been reported since the 1980s when these incidents resulted in patient safety events that caused serious patient harm or death. Since then safe administration of IV fluids has been enhanced by the use of EIDs; however, as the Institute of Safe Medical Practices (1998) indicates, "Although most pumps sold today require using sets with a fail-safe clamping mechanism, many hospitals continue to use older unprotected devices, purchase cheaper instruments that function without free-flow protection, or choose to bypass options that would otherwise provide protection against free-flow (p1)." The Institute of Safe Medical Practices also indicated, "The tragedy is that, in spite of all this knowledge, preventable incidents continue to occur (p.1)."

The ECRI Institute (1994) made the following recommendations to help prevent IV free-flow patient safety events:

1. Purchase only EIDs with infusion set-based free-flow protection. Assess and compare several set-based free-flow protection mechanisms for effectiveness and reliability. If set-based free-flow mechanisms are available as an option, they should be purchased and/or implemented as soon as possible.

2. At institutions where EIDs with infusion set-based protection are being phased in, use EIDs with unprotected sets only for noncritical infusions. Use EIDs with set-based protection for critical infusions, that is, when administering drugs that affect the cardiovascular or central nervous systems, control labor, or when delivering drugs to patients who cannot tolerate fluid overload.

3. The following conditions apply when using EIDs with unprotected infusion sets:

- Ensure that only fully trained personnel are authorized to set up, adjust, or remove such infusion sets. Nurses aides, technicians, and orderlies should not remove the set to facilitate treatment, patient positioning, or gown changing (or for any other reason)
- Ensure that all personnel administering IV therapy (including physicians) receive periodic inservice training on the use of EIDs and avoidance of potential problems related to infusions.

4. Regardless of which type of infusion set is used, ensure that inservice education programs provide periodic training to authorized users.

5. Retire from use any EID for which a single action (e.g., opening the door) can result in free-flow.

6. Immediately investigate and periodically review (e.g., every six months) all overinfusion incidents.

7. Do not use limited volume chambers or infusion sets with these chambers and do not alter the concentration of IV drugs or stock multiple drug concentrations as a means of mitigating the effects of potential free-flow infusions.

Following these recommendations will help prevent or reduce the risk of IV free-flow patient safety events.

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