

# THE LNC NEWSLETTER

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## Medical-Legal Interface

### Babies are at Risk from Free Hospital Gifts

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I shudder to think the liability the hospital is open to by giving out discharge formula bags with cans of powdered formula inside the bag.

In most hospitals, mothers are given gifts when they deliver. Moreover, mothers are very excited to receive the gifts.

One of the most popular items is the cute formula gift bags. The formula companies have gone to great expense to market these bags. Some of the bags even come with a breast pump. Nevertheless, they all come with coupons for xyz formula and a can of powdered xyz formula.

In the hospital, when a baby needs

nourishment and even if the mother is breastfeeding the mother is given formula that is in ready to feed containers for the baby. The formula comes in a 2-ounce infant bottle and all that is needed for the cap to be removed and for a newborn nipple to be attached.

The problem comes after the mother goes home and she has this can of powdered milk. I believe the hospital has a responsibility and should teach the mother how to prepare properly the type of formula she will be using at home. Mothers are not taught how to mix their infant's formula. Oh, yes, how hard could it be? You just use one scoops of formula for every 2 ounces

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### Aspiration Pneumonia in Long-Term Care

Maggie Driscoll BSN RN CCRN CLNC

Aspiration pneumonia is an inflammation of the lungs and bronchial tubes caused by inhaling foreign material, usually food, drink, vomitus, oral or gastric secretions from the mouth into the lungs. The volume and type of material aspirated, the frequency of aspiration episodes, and the adequacy of host defenses influence whether aspiration pneumonia will develop after an episode of aspiration. Pneumonia is most likely to occur if the resident aspirated a large amount of material or material with a low pH or high bacterial content.

Nursing home acquired pneumonia is one of the most common causes of infection in long-term care facilities and a significant infection-related cause of mortality and morbidity. Residents in long-term care facilities are especially at risk for aspiration pneumonia. Through proper risk identification, measures of prevention and coordination of care across the healthcare continuum, aspiration pneumonia can be minimized.

#### Common Causes

There are three common causes of aspiration pneumonia: *chemical pneumonitis*, *bacterial*, and

*mechanical obstruction*. **Chemical pneumonitis** occurs when aspirated material is directly toxic to the lungs. It causes what is described as a "chemical burn" to the lungs. One the most common clinical causes of chemical pneumonitis occurs after aspirating gastric contents that have a pH < 2.5-3. An acute inflammatory process is often associated with acute shortness of breath, rapid respiratory rate, and tachycardia (heart rate above 100 beats per minute). Common associated findings are cyanosis, bronchospasm (clamping of muscles around the airways of the lungs), fever, and sputum that is often pink and frothy. Elderly patients are less likely to present with acute symptoms from chemical pneumonitis because their gastric pH tends to be less acidic.

For these patients, aspiration pneumonitis is often indistinguishable from pneumonia.

**Bacterial infection** is the most common cause of aspiration pneumonia. Anaerobic bacteria that colonize the oral cavity are commonly associated with bacterial aspiration pneumonia in community-acquired infections. Poor dental hygiene

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when you make that cake or muffins do you follow the directions exactly or do you just dump all ingredients into the bowl and mix? In this case, we are talking about feeding an infant.

We are not talking about making a cake or muffins; it does make a difference which ingredient is put in first. If the powder is put in first, the formula is more concentrated. If the formula is too concentrated, this

becomes a big problem for the immature infant kidney. If less powder is used the feeding is more dilute. If the family is financially strapped the mother may use less powdered to water ratio, thus making for a dilute formula. Both extremes can be very harmful to the infant and may even cause serious permanent injury to the infant.

Babies have been on more than occasional episodes been

hospitalized because of over or under-concentrated formula feeds. However, many mothers are not given this formula mixing information and therefore I believe hospitals that fail to provide this education are at risk. We owe it to our new mothers to provide them with this basic but very information about the dangers of not mixing powdered formula carefully.

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and an impaired cough reflex can contribute to bacterial causes of aspiration pneumonia.

Residents in nursing homes are more likely to suffer from bacterial aspiration pneumonia from a different set of bacteria than those found in the community. Certain medications and treatments such as antacids, H2-blockers (famotidine for example), proton pump inhibitors (such as Propulsid) and enteral feedings (tube feedings) change the environment of the stomach. This change can lead to colonization of the stomach with enteric bacilli. Dental plaque in long-term care residents who more commonly receive these treatments have been noted to be colonized by bacteria associated with the stomach, such as gram-negative enteric bacilli and *Staphylococcus aureus*. Both aerobic and anaerobic bacteria are culprits of bacterial aspiration pneumonia in this population.

The onset and progression of disease from bacterial infection is often more insidious than that of chemical pneumonitis. Residents

usually present with fever, malaise, dehydration, weight loss, and cough for 1 to 2 weeks.

Leukocytosis (an elevated white count) is common. Chest films show infiltrates in dependent lung regions and may reveal secondary complications, such as lung abscess and empyema.

**Mechanical obstruction** can occur in the elderly when oral feedings are aspirated into the airways. Obstruction in the lower airways can result in an irritating persistent cough and sometimes in repeated infections below the obstruction. Recurrent parenchymal infections in the same segment of lung may also aide in the diagnosis. Bronchoscopy can be used to remove the offending object.

The location of the pneumonia depends on the position of the patient when aspiration occurred. Because most patients are supine when they aspirate, most lung infiltrates observed on x-ray and most aspiration pneumonia occur in segments of the right lung. If aspiration occurs when patients are

lying on their right side, the pulmonary infiltrates most likely involve the right upper lobe. If patients are lying on their left side, the most likely location of the infiltrates is the left upper lobe. If patients are supine and the aspiration is massive, bilateral infiltrates involving multiple lung segments or lobes are possible. The chest films may appear much like left sided heart failure or acute respiratory distress syndrome, making the clinical diagnosis of aspiration pneumonia less obvious.

### Risk Factors

Identifying those who are at risk for aspiration pneumonia in the long-term care setting is the first step towards prevention. Studies have shown that healthy adults aspirate small amounts of oral secretions into their lungs without causing pneumonia. Residents in long-term care facilities are at increased risk for developing pneumonia from aspiration due to chronic conditions that affect level of consciousness, gastric motility, immune response and swallowing ability (dysphagia). Cont on p 3

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Residents most at risk include those with:

- A decreased level of consciousness related to factors such as sedative medications, neurological conditions, debilitation and infection
- Neuromuscular disorders such as Parkinson's Disease
- Stroke
- Chronic lung disease
- Mechanical devices such as tracheostomy
- Gastroesophageal reflux
- Diabetes
- Depressed immune function
- Poor oral health
- NPO status (nothing by mouth)

### Prevention

Preventing aspiration pneumonia requires a multi-disciplinary approach. Proper positioning, mobility, oral hygiene and timely recognition of resident condition changes can help prevent aspiration. Studies have shown that tube feeding does not necessarily prevent aspiration and the decision not to feed a patient orally should be carefully considered. Residents who are no longer orally fed receive oral care with less frequency.

Every resident should receive a careful oral evaluation by the nursing staff. A care plan should be developed that includes interventions to prevent aspiration in those residents identified to be at risk. Residents should see a dentist for immediate oral health problems and should have routine visits to the dentist thereafter.

Daily oral hygiene recommendations include:

- Brush teeth with toothpaste after meals.
- Floss at least once a day.
- Brush dentures after meals and

remove at night to soak in an appropriate solution.

- Rinse mouths (with or without teeth) with antiseptic mouthwash.
- Inspect mouth frequently for sores, bleeding, or signs of infection.

Efforts to maintain proper positioning and mobility should include:

- Encouraging residents to be up in a chair for all meals and for 30 to 60 minutes after meals;
- Placing residents in an upright position for all food, beverage, and medication presentations;
- Elevating the head of the bed at all times for residents with GERD and/or those receiving tube feedings; and
- Encouraging sedentary residents to stand, walk, or propel their wheelchairs.

Nursing staff should perform ongoing clinical assessments of gastrointestinal tolerance of tube feedings that include:

- Abdominal distention
- Fullness
- Discomfort and/or cramping
- Constipation/diarrhea
- Assess for presence of aspiration/regurgitation - food in lungs/food in mouth and nose during routine oral care
- Assess for presence of vomiting
- Assess gastric residuals (residuals cannot be checked in residents with jejunostomy feeding tubes).

Each facility may have its own guideline or protocol for the care of resident's who are being tube fed. Intolerance of tube feedings should be reported to the physician so that the rate or type of formula can be adjusted. If the following signs of intolerance are present; the tube feeding should be stopped and the physician should be notified:

- Change in respiratory rate, rhythm, or breath sounds; coughing; swallowing or gagging; vomiting. Suctioning may be necessary.
- If the resident exhibits distention, cramps, constipation, diarrhea, or signs of thirst
- Residuals greater than 150mL and/or greater than twice the hourly rate (this parameter tends to vary between facilities and practitioners)

Medications that cause sedation, dry mouth, or dysphagia should be reviewed by the attending physician. Residents who cough, choke, drool or make a wet "gravel" sound when speaking after taking food or fluids orally should be assessed for dysphagia (difficulty swallowing) by a speech therapist. The addition of blue dyes to tube feedings can be dangerous and is no longer recommended to assist staff in identifying possible aspiration.

As the population ages, the number of long-term care residents is expected to rise. Careful assessment, planning, intervention and evaluation of residents at risk for aspiration pneumonia among nurses, physicians, dietitians and speech therapists, can lead to better outcomes and better quality of life for our aged population. Medical-legal professionals examining long-term care records where death or injury from a preventable cause of aspiration pneumonia may benefit by identifying risk factors, assessing the care plan, the timeliness and thoroughness of interventions, problem identification, physician notification and the re-evaluation process.

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## Watch That Whirlpool When Evaluating Quality of Treatment Claims

Robert Morrison, RN BSN

When the attorney is evaluating the merits of a new medical malpractice lawsuit or Worker's Compensation claim there are many things to examine. First and foremost, all of the applicable medical records need to be obtained. There are many things to extract from these records—names of providers and facilities, a timeline of events and outcomes, identification of procedures performed, dates of service and expenses just to name a few. As we go along we have also discovered things that we would have never thought to look for in the beginning.

We all know that you need to check each provider for qualifications, experience, certifications, etc. However, when attorneys look through a medical record they are primarily focused on the names of the facilities as a means of finding where any records may be located, in order to investigate the people involved. The facility itself, and all of its equipment, should also be assessed for its role in the case.

A Worker's Compensation claim involves an employee who was in an industrial accident in which his foot became trapped between two pieces of equipment, causing traumatic amputation of three toes. Following emergency surgery the wound care is primarily performed in the employer's facility, by the on-site RN staff. Daily whirlpools and debridement are done to promote wound healing, followed by dressing changes. The staff is working within the orders of the treating physician and performing care that is usually done in the physical therapy setting. The employer's rationale for this approach was that it saves expenses for the employer while reducing travel time for the employee, particularly after returning to work on light duty.

By the time the case is closed the employee has experienced an infection of the foot that requires additional surgery and months of

intensive cleaning and care. As the claim is being evaluated by the LNC it becomes apparent that the infection was caused by the portable whirlpool equipment that the employer's nurses used to clean the wound. The LNC and the attorney then interview the employee to determine exactly what was done during these therapy sessions.

The equipment was made by putting a portable air compressor unit into a plastic 5-gallon bucket. The dressings consisted of sterile wet-to-dry dressings and over wrap. It is the air compressor unit that is the source of the problem. Specifically, the nurses are not adequately cleaning the parts and the bucket after each use. The employer's policies and procedures are then subpoenaed to determine whether the nurses followed their own requirements.

The above scenario illustrates the need for close teamwork and the ability to look outside the usual bounds of investigation. While the incidence of infection caused by healthcare equipment is very rare, it does happen. And it may be more likely in non-traditional settings such as the employer's health services office. Less familiarity with the equipment can lead to poor cleaning and monitoring.

Spas and whirlpools are a prime breeding ground for pathogens. A warm, moist environment of re-circulating water that may be used by many different people is the ideal place for bacteria to thrive. The only defense is vigilant and effective cleaning. This adds to the issues to investigate in the scenario above. Were the nurses properly trained in how and when to clean the equipment? Was there a policy regarding this equipment, and did the nurses follow the requirements of the policy? What did they clean it with and why? How and where was it dried after cleaning?

The CDC has published

guidelines to help prevent the spread of infection in hydrotherapy tanks and pools. It may be useful to assess the equipment and staff in question relative to these guidelines. The following steps, according to the CDC, should be followed to properly care for such equipment.

- Drain and clean the equipment after each patient's use and disinfect surfaces and components with an EPA-registered product;
- Clean and disinfect equipment after using tub liners;
- Clean and disinfect inflatable equipment, unless they are single-use items;

Other things to look for include: assess the infection control staff for active involvement in making, promoting, and evaluating adherence to policies and procedures; documentation regarding equipment storage and cleaning and the staff's adherence to P&P; state or local health departments with documentation of prior problems with the facility.

As more employers are looking for ways to cut Worker's Comp costs and insurers are moving care to the home health setting the risk of such infection transmission becomes larger. Without the in-house infection control experts and the budget capabilities of hospitals or therapy centers it can be much harder to maintain the same level of cleanliness.

*Source: MMWR- Recommendations and Reports, Vol. 52, Number RR-10, June 6, 2003*

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## The Vioxx Debauchery, Who's as Fault?

Pattie Patterson RN LNCC CLCP

Vioxx—a member of the family of nonsteroidal anti-inflammatory drugs (NSAIDs) called COX-2 inhibitors. Other drugs in this family include Bextra and Celebrex. Unlike the older NSAIDs, such as aspirin, Motrin and Naprosyn, the COX-2 inhibitors do not interfere with COX-1, which has a protective effect on the stomach lining, and thus considered less likely to cause stomach ulcers. They also don't have the blood-thinning effects that the older NSAIDs do. For this reason, the COX-2 inhibitors were considered a wonderful discovery for those suffering from chronic pain from things such as osteoarthritis, rheumatoid arthritis, and acute conditions such as dysmenorrhea (painful menstruation). Vioxx hit the market around 1999 and it was considered one of the new miracle drugs for treatment of these aforementioned ailments. By the time it was pulled from the market on September 30, 2004 there were 2 million Americans taking it. It was also being marketed on more than 80 countries with worldwide sales totaling \$2.5 billion in 2003.

The reason Merck finally pulled Vioxx from the market is because a new study they performed showed a higher rate of heart attacks and strokes in patients taking the drug than those who were taking a placebo. But Steve Galson, the acting director of the FDA's Center for Drug Evaluation and Research was quoted in USA Today as saying "We have been concerned and aware of the potential for cardiovascular effects for the last few years. This is not a total surprise." What he didn't say, however, is that as early as April 2000, the FDA required Merck to add labeling information about a possible link to these problems. This was brought to light after a study Merck did to try to prove that Vioxx was safer on the digestive tract than

naproxen (Naprosyn). Merck did this study in an effort to get the FDA to authorize removal of the digestive tract warnings from their labeling. Though the study did prove this, it also proved that Vioxx doubled the risk of cardiovascular problems. Merck did inform this to the FDA, the scientific community and the media. But they put a positive spin on the data in a press release on March 27, 2000. They started by saying that Vioxx caused fewer digestive problems than naproxen. They went on to say that there were significantly fewer thromboembolic events (heart attacks and strokes) were observed in patients taking naproxen. Their stance, however, was not that Vioxx caused cardiovascular problems, but that naproxen protected against them. This was their stance for the next 4 ½ years.

In September 2001 the FDA ordered Merck to send out a letter to doctors to inform them of the false or misleading information about Vioxx's effect on the cardiovascular system. In April 2002 the FDA required that Merck note a possible link to heart attacks and strokes on Vioxx's label. Merck was spending more than \$100 million a year in direct-to-consumer advertising, which is also regulated by the FDA. Merck continued to minimize the cardiovascular effects of Vioxx. Not until the most recent study was performed and it was found that a significant increase in heart attacks and strokes in the patients on Vioxx as opposed to those on the placebo did Merck accept the findings, as this time there was no other drug to divert blame away from Vioxx. But the interesting thing about this study is that it again was for a different purpose other than cardiovascular effects of the drug. This study was actually to see if Vioxx could claim, like Celebrex, that it protects against the recurrence of colon polyps, which can become

cancerous.

Even as late as August 26, of this year Merck continued to minimize the unfavorable findings, stating in a press release, "Merck stands behind the efficacy, overall safety and cardiovascular safety of Vioxx."

From the time Vioxx came on the market through 2003 more than 27,000 heart attacks or sudden cardiac deaths nationwide have been linked to Vioxx.

So if the FDA was "concerned" as far back as 2000, why didn't they require more stringent studies when the concerns were first brought to light? A better question, though, might be why are these drugs being approved without studies before the fact, not after the fact? If Vioxx were the first such incidence I might not be so concerned, but this seems to be becoming the pattern for the FDA as opposed to an isolated incidence.

As to who is to blame, well, I think there's enough blame to go around, but from a truly functional standpoint, the FDA is a government organization who's primary function is to protect public health. They are supposed to regulate these medications, but where was their regulatory power when they gave Vioxx a stamp of approval? Yes, Merck is culpable as well, but until the FDA starts doing their job there will be more and more of these medications with fatal side effects prescribed to unsuspecting US citizens.

Already, there are studies that show that Celebrex and Bextra also increase the risk to the cardiovascular system by 2.5 times but these drugs have yet to be pulled from the market by Pfizer, their manufacturer, or by the FDA. Once again the FDA is left with egg on its face. Do you ever think they will catch a clue?

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