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Cerebral palsy report: It's no panacea, but it could be major defense in court

Plaintiffs likely to challenge report as biased

A recently issued report will be a boon to defendants in cerebral palsy malpractice cases, but it won't eliminate this brand of high-dollar cases or create an insurmountable burden for plaintiffs' attorneys, experts say.

The report, from the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP), is indisputably good news for any provider threatened by charges that a cerebral palsy outcome is birth-related though the ultimate value remains to be seen.

The ACOG/AAP report concludes that the majority of newborn brain injury cases do not occur during labor and delivery. Rather, most instances of neonatal encephalopathy and cerebral palsy are attributable to events occurring before labor begins.

Neonatal encephalopathy is a condition characterized by abnormal consciousness, poor muscle tone and reflexes, difficulty initiating or maintaining breathing, or seizures, and may or may not result in permanent neurologic impairment. In contrast, cerebral palsy is a chronic developmental disability of the central nervous system recognized by uncontrollable movement and posture.

Risk managers should welcome the report as a significant addition to their defense strategies for cerebral palsy, says **R. Stephen Trosty**, JD, MHA, CPHRM, director of risk management for the Mutual Insurance Corp. of America in East Lansing, MI. While he still wants to see evidence that the report is scientifically valid, Trosty says he expects the report to be very significant.

"I think it's fantastic, because up to this point there hasn't been a scientific study to prove what innately a lot of people believed was true. Now there is," he says. "Hopefully, it will prove credible enough to become strong evidence."

If so, the evidence would be adopted eagerly by defense attorneys and risk managers grappling with these difficult cases. Trosty notes that cerebral

palsy cases have always been especially challenging, partly because the economic damages for lifetime medical care can be astronomical and also because juries tend to have great sympathy for the children.

"If you look at all the malpractice suits brought, those alleging cerebral palsy have the greatest percentage of plaintiffs succeeding," he says. "It always ranks first or second in the highest awards granted. These cases are not exceedingly high in frequency, but they're very, very high in severity and the percentage of wins for the plaintiffs."

Data from 2001-02 show that, on average, plaintiffs tended won 39% of cases across the board, but they won in 54% of cerebral palsy cases, Trosty says.

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Report says 90% of CP cases not birth-related

The report, *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology*, gives evidence that the vast majority of neonatal encephalopathy and cerebral palsy originate from developmental or metabolic abnormalities, autoimmune and coagulation defects, infection, trauma, or combinations of these factors. The report has received the endorsement of six organizations, including the National Institute of Child Health and Human Development of the National Institutes of Health and the Centers for Disease Control and Prevention. Newborn encephalopathy and cerebral palsy are associated with significant mortality rates and long-term morbidity and have been central in the assignment of blame in obstetric litigation.

However, the report confirms that hypoxia (insufficient supply of oxygen) during labor or delivery is not a significant cause in most of the cases of neonatal encephalopathy or cerebral palsy, with less than one-quarter of infants with neonatal encephalopathy having any evidence of hypoxia during labor. The report also concluded that an underlying event before labor was the primary factor for the adverse outcome in 70% of neonatal encephalopathy cases and contributory in another 25%.

A helpful aspect of the report is that it lists the criteria to define and evaluate the probability that encephalopathy and cerebral palsy were a result of actions during labor, says **Gary D.V. Hankins**, MD, chair of the ACOG task force that developed the report.

"By helping to understand the causes of neonatal encephalopathy and cerebral palsy, our efforts may lead to clinical interventions that will reduce the rates of these serious pathologies," he says.

For years, adverse neurologic outcomes of pregnancy, including cerebral palsy and neonatal encephalopathy, have been assumed to be the effect of events occurring during childbirth. In the face of a bad outcome, many faulted OB/GYNs. That should change now, says ACOG president **Charles B. Hammond**, MD.

"We now know that less than 10% of cases of neurologic impairment in newborns are the result of events occurring in labor and, of these, the majority were not preventable. This report provides a better understanding of the causes of these two conditions and should serve as a valuable

resource for the entire medical community, the courts, and for all those who care for infants and children with these disabilities," he adds.

Plaintiff will challenge report as biased

Trosty says the report provides, for the first time, scientific evidence that can be used to authoritatively show that defendant clinicians are not responsible for a child's cerebral palsy.

"Prior to this, there really was nothing," he says.

That doesn't mean the defense will be a slam-dunk from here on out. You still will have to establish the report as expert testimony, which means proving that it is scientifically valid. And the plaintiff's attorney will be working hard to prove otherwise. Trosty expects plaintiff's attorneys to argue that ACOG is biased in favor of its member physicians, producing a report intended to protect them from malpractice verdicts.

And that is exactly what **Andrew Slutkin**, JD, says he plans to do. He is a partner with Snyder, Slutkin & Lodowski, a law firm in Baltimore that has represented nearly 50 plaintiffs in cerebral palsy cases over the past 10 years.

"ACOG has a history of trying to limit its members' liability in birth trauma and other malpractice cases," he says. "So anything ACOG does is viewed with skepticism by plaintiffs' attorneys. Attorneys bringing these cases, including myself, usually portray ACOG as simply trying to protects its doctors."

The same thing happened years ago when ACOG published Technical Bulletin 156, which aided cerebral palsy defense by establishing four criteria that had to be met for relating cerebral palsy to the birth process. That report provided another hurdle for the plaintiff in some cases, but it wasn't the end cerebral palsy lawsuits.

"In a case where there are not good facts supporting the plaintiff, this report will help the defense," Slutkin says. "But in a case where the facts are good, where there is clearly fetal distress and they're not delivering the child in a timely manner, then it could be less useful. It will depend on the facts of the case."

He says the ACOG report will be another hurdle for the plaintiff, but it won't end or even significantly slow the rate of cerebral palsy cases.

"It's one more thing to argue about in court," Slutkin says.

Trosty says it is important for risk managers to be aware of the study and actually have a copy. Any physician involved in a cerebral palsy case also should study the report, along with all members of the defense team.

"Aside from eliminating 90% of the cases as not related to what the doctor did, equally important is the fact that the outcome that occurred could not have been prevented," he says. "So not only was it not caused by something the physician did, there was no intercedent action that could have been done to prevent this outcome. Again, this is the first time we have something scientific that establishes this."

The report was developed by an ACOG task force formed in 1999 and was co-authored by the AAP. The task force was composed of a multispecialty panel of medical experts representing the specialties of maternal-fetal medicine, pediatrics, neuroepidemiology, radiology, and pathology. The report complements and updates a 1999 consensus statement by the International Cerebral Palsy Task Force that was published in the *British Medical Journal*.

AAP president **E. Stephen Edwards**, MD, issued a statement saying, "The AAP welcomes this important report. It confirms that most brain injuries are not due to the events occurring during labor, delivery, resuscitation, or treatment immediately following birth. We remain concerned about infants with neonatal brain injury, and will continue our commitment to our Neonatal

Resuscitation Program that assures pediatricians and other medical professionals receive the most up-to-date instruction in resuscitation skills."

The report was also endorsed by these professional organizations: the March of Dimes Birth Defects Foundation, the Society for Maternal and Fetal Medicine, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the Society of Obstetricians and Gynaecologists of Canada. The Child Neurology Society recommends the report as a valuable reference tool. Trosty says those endorsements could be important in deflecting charges that ACOG is biased and only trying to protect its members.

"The report can be a big benefit, but we don't know yet if it will be the saving grace. Ultimately the question is how well you can convince a jury that this is scientifically valid," Trosty says. "And you also will have to show that this particular case is not among the 10% that can be caused by the physician's actions. Plaintiffs are suddenly going to start arguing that their case is among that 10%." ■

Cerebral palsy not usually related to birth process

This background on cerebral palsy and summary of the new findings was provided by the American College of Obstetricians and Gynecologists (ACOG):

Neonatal encephalopathy and its subset of hypoxic-ischemic encephalopathy (HIE) are conditions defined in and described for term and near-term infants. Neonatal encephalopathy is defined clinically on the basis of a constellation of findings to include a combination of abnormal consciousness, tone and reflexes, feeding, respiration, or seizures and can result from myriad conditions. Neonatal encephalopathy may or may not result in permanent neurologic impairment.

It can be stated with certainty, however, that the pathway from an intrapartum hypoxic-ischemic injury to subsequent cerebral palsy must progress through neonatal encephalopathy.

In contrast, cerebral palsy is a chronic disability of central nervous system origin characterized by aberrant control of movement and posture, appearing early in life and not as a result of progressive neurologic disease. Research supports that spastic quadriplegia, especially with an associated movement disorder, is the only type of cerebral palsy associated with an acute interruption of blood supply. Purely dyskinetic or ataxic cerebral palsy, especially where there is an associated learning difficulty, commonly has a genetic origin and is not caused by intrapartum or peripartum asphyxia. Similarly, absent cerebral palsy, neither epilepsy, mental retardation, nor attention-deficit hyperactivity disorder are caused by birth asphyxia.

Historically, the factors used to define perinatal asphyxia, such as meconium-stained amniotic fluid and Apgar scores, were not specific to the disease process leading to neurologic damage. For instance, Nelson and associates have shown that use of nonreassuring fetal heart rate patterns to predict subsequent cerebral palsy had a 99% false-positive rate. Use of such nonspecific markers for perinatal asphyxia identifies a large number of individuals as being exposed to inappropriately diagnosed "perinatal asphyxia." Thus, it is not surprising that removing exposure to such nonspecific markers has failed to change the risk for the disease.

Epidemiologic studies have shown that only 19% of cases of neonatal encephalopathy met what were very nonstringent criteria for intrapartum hypoxia, with another 10% experiencing a significant intrapartum event that may have been associated with intrapartum hypoxia. Even with such inexact markers for intrapartum fetal hypoxia, they demonstrated that of all cases of neonatal encephalopathy, 69% had only antepartum risk factors, 25% had both antepartum and intrapartum risk factors, 4% had evidence of only intrapartum hypoxia without identified preconceptional or antepartum factors that might have contributed to neonatal encephalopathy, and 2% had no identified risk factors.

Thus, approximately 70% of neonatal encephalopathy is secondary to events arising before the onset of labor. The overall incidence of neonatal encephalopathy attributable to intrapartum hypoxia, in the absence of any other preconceptional or antepartum abnormalities, is estimated to be approximately 1.6 per 10,000. It is again emphasized that HIE is but one subset of neonatal encephalopathy; other subsets include those resulting from prenatal stroke, infection, cerebral malformation, genetic disorders, and many other conditions.

These are the criteria to define an acute intrapartum event sufficient to cause cerebral palsy, as

modified by this task force from the template provided by the International Cerebral Palsy Task Force:

• **Essential criteria (must meet all four):**

1. Evidence of a metabolic acidosis in fetal umbilical cord arterial blood obtained at delivery (pH <7 and base deficit =12 mmol/L) >
2. Early onset of severe or moderate neonatal encephalopathy in infants born at 34 or more weeks of gestation
3. Cerebral palsy of the spastic quadriplegic or dyskinetic type
4. Exclusion of other identifiable etiologies such as trauma, coagulation disorders, infectious conditions, or genetic disorders

These are criteria that collectively suggest an intrapartum timing (within close proximity to labor and delivery, e.g., 0-48 hours) but are nonspecific to asphyxial insults:

• A sentinel (signal) hypoxic event occurring immediately before or during labor

• A sudden and sustained fetal bradycardia or the absence of fetal heart rate variability in the presence of persistent, late, or variable decelerations, usually after a hypoxic sentinel event when the pattern was previously normal

• Apgar scores of 0-3 beyond five minutes

• Onset of multisystem involvement within 72 hours of birth

• Early imaging study showing evidence of acute nonfocal cerebral abnormality

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Reader Question

EMTALA requires docs to be on call, but not 24/7

Reader question: Does the Emergency Medical Treatment and Labor Act (EMTALA) require that our hospital's medical staff be required to provide on-call physician services 24 hours a day and 365 days a year? We know the law requires that physicians be on call if we provide emergency service, but that requirement creates a lot of scheduling headaches and doctor/hospital friction for risk managers, so we're wondering if the hospital's medical staff are required to provide on-call physician services at all times.

Answer: The answer is "not necessarily," says **Lowell Brown**, JD, a partner with the law firm of Foley and Lardner in Los Angeles and an expert in EMTALA interpretation. As with most legal issues, the exact answer will depend on the particulars of your own situation. But one thing is clear, he says: EMTALA does not require every hospital to have every specialty on call at all times.

"This question comes up all the time. It's one of the hottest questions there is right now regarding EMTALA compliance," Brown says. "There is a succinct way to describe the obligation, but it takes a lot of thought to apply it. The basic requirement is that you must have a call panel, no exceptions. But it should be a reasonable reflection of the active medical staff."

"Active" is the key word in interpreting what kind of call panel you must have in place. Most hospitals have some physicians who are on staff at a courtesy level that requires only a few patients a year to remain, while "active" status usually requires much more frequent use of the hospital. Your EMTALA call panel should represent all active physicians but not necessarily any courtesy-level physicians. Part of the reason, Brown says, is that you should be able to vouch for the competence of physicians you put on call panels. Their level of activity should be high enough to allow you to do that.

EMTALA requires that an individual be evaluated and provided with medical support services and/or transfer arrangements that are consistent with the capability of the institution and the well being of the patient. The Social Security Act at §1866(a)(1)(I)(iii) requires that hospitals have a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition. The hospital's capabilities include the skills of a specialist who has staff privileges to the extent that the hospital requires the specialist to furnish these services. If a physician on the list is called by a hospital to provide emergency screening or treatment and either refuses or fails to arrive within a reasonable time, the hospital and that physician may be in violation of EMTALA.

The Centers for Medicare & Medicaid (CMS) State Operations Manual (SOM) further clarifies a hospital's responsibility for the on-call physician. The SOM (Appendix V, page V-15, Tag A404) states that "each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients," and "physicians, including specialists and subspecialists (e.g., neurologists) are not required to be on call at all times. The hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control."

Available physicians will dictate on-call panel

The issue has confused many providers, so much so that some professional organizations have offered guidance. The American Academy of Orthopedic Surgeons (AAOS), for instance, provides an opinion based on Memorandum Ref #S&C-02-34, "On-Call Requirements — EMTALA," published June 13, 2002, by CMS and the American Medical Association's EMTALA *Quick Reference Guide For On-Call Physicians*. Using those references, "The AAOS interprets the statute and the State Operations Manual to mean that CMS does not require that a hospital's medical staff provide on-call coverage 24 hours a day and 365 days a year." When a hospital does not have on-call coverage for a particular specialty, "that hospital lacks capacity to treat patient needing that specialty service and it is therefore appropriate to transfer the patient because the medical benefits of transfer outweigh the risks," the AAOS advises.

The simple number of physicians involved also will influence how much you have schedule physicians for your EMTALA coverage. Sometimes you just won't have enough to do a 24/7/365 call panel; and if so, that is not an EMTALA violation, Brown says.

Applying that advice means that if you have a large hospital and many physicians in every specialty, then you have to cover those specialties 24/7/365 on your EMTALA call panel. If you have a hospital on the other end of the spectrum, such as a small rural facility, there may be, for instance, only one neurosurgeon on the staff.

"He doesn't have to be on call 24 hours a day and seven days a week," Brown says. "You can set up a schedule when he is on call. It might be only one day a week, and six days a week you can't provide EMTALA coverage for neurosurgery. As long as he and the hospital adhere to that schedule, then you won't be violating EMTALA."

But even that hospital with one neurosurgeon still must schedule him or her *some*, to whatever degree seems reasonable. It's not acceptable to say that since you have just one neurosurgeon, your EMTALA call panel won't cover neurosurgery. Since your hospital provides that service, it must be reflected on your EMTALA call panel even if the frequency is nowhere near 24/7.

"It becomes a question of reasonableness," Brown says. "If you have one guy and he's on call once a year, that's probably not going to pass muster."

Brown cautions that physicians will sometimes take advantage of these distinctions to avoid your EMTALA call panel. If you restrict your call panel to members of your active staff, some physicians may decide to reduce their activity level so that they are only on courtesy staff and don't have to take calls. Then they will go to the hospital across town where they aren't required to take calls and be more active.

"That happens all the time, unfortunately," he says. "It's a very unfair provision of the law that it forces this obligation on the hospitals, when in most cases they don't employ the physicians and don't have any control over them."

Brown cautions that risk managers can't use this advice as a loophole when you're having trouble scheduling physicians. The requirements for your call panel are based on what physicians practice at your facility, independent of how willing or unwilling those doctors are to serve on your EMTALA call panel.

"This doesn't mean you can schedule a particular specialty only once a month because the physicians don't want to do it any more often. That physicians don't want to take call is not an excuse," Brown says. "It comes down to what I call the straight-face test. If you can say with a straight face that, yes, this is a reasonable reflection of our active staff and we're offering this in good faith, then you'll probably be OK." ■

Pelvic exams by students, residents are growing risk

The public is becoming aware of a practice that makes even some experienced medical professionals uncomfortable, greatly increasing the

chances that an irate patient will sue for malpractice or even file charges of assault. Though it has been common practice in many health care institutions for decades, the practice is increasingly coming under fire from critics who say it just isn't right.

The practice: medical students and residents performing pelvic exams on women who have been anesthetized for surgery, without any medical need, and usually without consent. Several hospitals report they have recently revised policies to prohibit the practice.

Concerned medical professionals are speaking out and sparking a barrage of criticism from both the health care community and the public. While this educational practice poses no physical harm to the patient, most people are shocked to hear that such an invasive exam is performed without the patient's knowledge, says **Peter Ubel**, MD, director of the University of Michigan (U-M) Medical School's Program for Improving Health Care Decisions, and associate professor of internal medicine, in Ann Arbor. Research shows that most women are willing to allow medical students to perform the examinations, but with the proviso that permission is asked for and granted, he says.

Nevertheless, many OB/GYN departments do not regularly inform women when they will be undergoing pelvic examinations by medical students while under anesthesia. In addition to the possible malfeasance against the patient, he says such policies may encourage a more callous or lackadaisical attitude about informed consent among young physicians. Pelvic exams aren't the only activity that should cause concern, but Ubel says they are the most likely to produce outrage from patients.

"Pelvic exams carry a special concern in terms of privacy," he says. "This is a very emotional issue. People use terms like rape, which it clearly is not, but it makes people think of that. People say they would feel violated. They wouldn't feel the same if a student came in and palpated the abdomen to feel a mass or stuck their fingers in the mouth to feel an oral mass."

A growing risk

Ubel suggests that risk managers should see this issue as a growing risk because patients are becoming more aware of it, leading to the possibility of lawsuits or even charges of assault. While he knows of no such legal action so far, Ubel points out that most patients who were examined are left with no clue that the violation took place. He also suggests that the blanket informed consent used by some teaching hospitals might not fend off a lawsuit if the patient feels her privacy was violated.

"Many times people will come into a teaching hospital and will see somewhere in the mass of paperwork a couple of lines indicating that they will be interacting with medical students," Ubel says. "But that doesn't mean that students and trainees can be involved in every aspect of care without further permission. Those lines don't mean that the patient has signed on for whatever else the teaching hospital decides to do. I think a patient can very easily say they didn't see those lines in the consent form or didn't realize it would involve this kind of exam."

Ubel says he and his fellow researchers wondered whether completion of an OB/GYN clerkship was associated with a decline in the perceived importance of securing permission from patients before conducting pelvic examinations under anesthesia. Their research suggests the answer is yes, he says.

"We found that medical students who have not yet done their OB/GYN clerkship place more value on securing consent than do medical students who have completed the OB/GYN clerkship," Ubel says. "The OB/GYN clerkship seems to be the defining event in this erosion, as opposed to gradual erosion throughout students' many clerkships or rotations."

A question of consent

In a recent study, Ubel and his colleagues looked at questionnaires that were distributed in 1995 to all 4,511 medical students at five Philadelphia-area medical schools *(Am J Obstet Gynecol* 2003; 188:575-579). Students were asked how important it would be for a patient to be told that a medical student is going to perform a pelvic examination under anesthesia. Researchers tested for associations between completion of an OB/GYN clerkship and attitudes toward pelvic examinations using linear regression to adjust for gender and total amount of clerkship experience.

"Something clearly happens during OB/GYN clerkships that is associated with students placing less importance on consent for pelvic examinations under anesthesia," says Ubel, who was on the faculty at the University of Pennsylvania's Center for Bioethics at the time the study was conducted.

The experiences of two of the authors as medical

students suggest that consent is either not routinely obtained for educational pelvic examinations performed by medical students in the operating room or, at best, somewhat murky.

"In our medical student experiences, we were unclear whether the patients we were asked to examine had given explicit consent to be examined. The study suggests that similar experiences are associated with a decline in the importance students place on seeking permission for such examinations," Ubel says. One of the authors refused to conduct such exams when he was a medical student, he says.

The norm

At the U-M Health System, however, policy and practice are in unison, and patient consent is the norm, says **Maya Hammoud**, MD, clerkship director at U-M's department of obstetrics and gynecology.

"It is the nature of education that students learn both by observation and by doing. We place a great value on developing a sense of professionalism in our medical students, and we expect faculty to follow policies about informed consent so medical students can emulate what they see in a positive way," she says. "In addition, here at UMHS, patients are informed that pelvic examination under anesthesia are conducted when necessary to assure safer performance of the operation, and that medical students may participate in these examinations."

Ubel says he and his colleagues believe the data may reflect students' strategies for coping with the knowledge that they participated in an activity that, if discovered, could cause patients to feel violated. As a result, some students may simply deny the importance of obtaining consent in the first place.

"Medical educators can remedy this decline in students' attitudes toward pelvic examinations under anesthesia by making sure that students perform such examinations only on patients who have explicitly given their consent," he says. "Students will still have a good learning experience, and they'll also learn important lessons about medical professionalism and ethics."

Altered policies

Several health care providers have announced recently that they have altered their policies to prohibit pelvic exams on unconscious patients if they have not given prior consent. Harvard Medical School adopted such a policy in the mid-1990s, and in addition, required that the student be a part of the medical team treating the patient. The University of California — San Francisco School of Medicine responded to complaints in the 1990s by adding a line to its consent form indicating that women undergoing gynecological surgery may be given a pelvic exam by medical students while they are anesthetized.

Policies vs. behavior

While not criticizing those particular institutions, Ubel says such policies may not be enough.

"Lot of places came out and said we have policies about this, but written policies don't do any good if people don't modify their behavior," he says. "Word needs to come down from the chair of OB/GYN. Maybe risk managers can whisper in their ears and say, 'Tell all your faculty. No student exams in the operating room without permission. Period.'"

Ubel notes that the pelvic exam comes under particular scrutiny because many patients would see it as an invasion of privacy, but it is not the only procedure worth considering. A rectal exam might pose the same sort of problem, he says.

"But taking blood pressure or listening to someone's heart? Probably not a problem," he says. "If someone is asleep in the operating room and the doctor calls the student over to listen to a heart murmur, I have a hard time getting excited about that." ■

OSHA issues ergonomic rules for nursing homes

In a move that will add one more regulatory concern to the risk manager's plate, the Occupational Safety and Health Administration (OSHA) recently issued the first in a series of industry-specific guidelines for the prevention of musculoskeletal disorders in the workplace. Its target: nursing homes.

The good news, however, is that the guidelines could help reduce workers' compensation expenses and other costs related to ergonomic injuries, and the guidance is equally applicable to other health care settings.

OSHA's Guidelines for Nursing Homes focuses

on what the agency calls practical recommendations for employers to reduce the number and severity of workplace injuries by using methods found to be successful in the nursing home environment. OSHA administrator **John Henshaw** announced the guidelines by saying they were the result of a close collaboration with the long-term care industry.

The guidelines are divided into five sections: developing a process for protecting workers; identifying problems and implementing solutions for resident lifting and repositioning; identifying problems and implementing solutions for activities other than resident lifting and repositioning; training; and additional sources of information.

OSHA emphasizes that specific measures or guideline implementations may differ from site to site. Still, the agency recommends that all facilities minimize manual lifting of residents in all cases, and eliminate such lifting when feasible. Further, OSHA encourages employers to implement a basic ergonomic process that provides management support while involving workers, identifying problems and implementing solutions, addressing reports of injuries, providing training, and evaluating ergonomics efforts.

"Nursing home workers are suffering too many ergonomics-related injuries," Henshaw said. "But the experiences of many nursing homes provide a basis for taking action now to better protect these workers. These guidelines reflect best practices for tackling ergonomic problems in this industry."

Industry leaders say guidelines are good

The ergonomic guidelines were endorsed by the American Health Care Association (AHCA) and the American Association of Homes and Services for the Aging (AAHSA), which issued statements saying the guidelines demonstrate an understanding of the complexities involved with applying ergonomics to the lifting, transferring, and repositioning of nursing home residents.

Praising OSHA for its inclusion of key stakeholders early on in the process, AHCA president and CEO **Charles H. Roadman II**, MD, CNA, says the guidelines specifically appear to acknowledge the indelible connection between patient handling tasks and clinical care, by recommending the use of the Minimum Data Set to assess resident handling tasks.

"Nursing home professionals are in the business of caring for the frail, elderly, and disabled. When we talk about ergonomic safety for our staff, we aren't talking about moving boxes. We are talking about moving real people," he says. "We cannot ignore the clinical needs of our patients when discussing employee safety, and the OSHA guidelines recognize this."

Similar praise comes from **William L. Minnix Jr.**, DMin, president and CEO of AAHSA. He commends OSHA for making sure the guidelines take into account the groups' experience-based understanding of ergonomics in nursing homes.

"These final guidelines are far superior to the draft guidelines issued last summer in large part because OSHA listened to what we had to say and worked with us," Minnix says. "As a result, these guidelines not only are stronger and will do a better job of protecting our direct care staff, but they are more realistic."

In April 2002, OSHA issued a comprehensive plan to reduce ergonomic injuries through a combination of industry-targeted guidelines, tough enforcement measures, workplace outreach, advanced research, and dedicated efforts to protect immigrant workers.

Secretary of Labor Elaine L. Chao subsequently announced the first industry-specific guidelines to reduce ergonomic-related injuries would be developed for nursing homes. Information for the guidelines came from numerous sources, including existing practices and programs, trade and professional associations, labor organizations, the medical community, individual firms, state OSHA programs, and available scientific information.

Minimize manual lifting of residents

Arranged into five sections, the guidelines open with a seven-point process to protect workers. The guidelines provide recommendations for nursing home employers to help reduce the number and severity of work-related musculoskeletal disorders (MSDs) in their facilities. MSDs include conditions such as low back pain, sciatica, rotator cuff injuries, epicondylitis, and carpal tunnel syndrome.

The guidelines are designed specifically for the nursing home industry. However, OSHA officials emphasize that they hope employers with similar work environments, such as assisted living centers, homes for the disabled, homes for the aged, and hospitals also will find the information useful.

In its primary suggestion, OSHA recommends that manual lifting of residents be minimized in

all cases and eliminated when feasible. It also recommends that employers develop a process for systematically addressing ergonomics issues in their facilities and incorporate this process into an overall safety and health program. OSHA says an effective process will include these components:

• ***Provide Management Support.*** Employers should develop clear goals, assign responsibilities to designated staff members, provide resources, and ensure responsibilities are fulfilled. A sustained effort is paramount.

• ***Involve Employees***. Encourage employees to submit suggestions or concerns; discuss workplace and work methods; participate in training and procedural designs; respond to surveys; and participate in task groups with ergonomics responsibilities.

• ***Identify Problems.*** Establish systematic methods for identifying ergonomic concerns in the workplace, e.g., analyze information from OSHA injury and illness logs, workers' compensation claims, insurance company reports, etc.

• ***Implement Solutions***. Effective solutions usually involve workplace modifications that eliminate hazards. Changes can include the use of equipment, work practices, or both. (The guidelines include solution examples in Sections III and IV.)

• ***Address Reports of Injuries***. Manage work-related MSDs in the same manner and under the same process as any other occupational injury or illness. Like many injuries and illnesses, employers and employees can benefit from early reporting of MSDs. These reports also can help the establishment identify problem areas and evaluate ergonomic efforts.

• ***Provide Training***. Provide ergonomics training to nursing assistants and other workers at risk of injury, charge nurses and supervisors, and designated program managers.

• ***Evaluate Ergonomics Efforts***. Evaluation and follow-up are central to continuous improvement and long-term success. They help sustain the effort to reduce injuries and illnesses, track whether or not ergonomic solutions are working, identify new problems, and show areas where future improvement is needed.

OSHA offers other resources

The guidelines list a number of protocols designed to help employers with resident assessment and the determination of appropriate methods for transferring and repositioning residents. Some examples include the Resident Assessment Instrument published by the Centers for Medicare & Medicaid Services.

This information can be accessed at www.cms.hhs. gov/medicaid/mds20/. OSHA also recommends the *Patient Care Ergonomics Resource Guide: Safe Patient Handling and Movement, published by the Patient Safety Center,* Veterans Health Administration and the Department of Defense. This information is available at www.patientsafetycenter.com.

OSHA notes that a number of work-related MSDs occur in activities other than resident lifting. Some activities a nursing home operator may want to review include bending, lifting food trays above shoulder level or below knee level; waste collection; pushing heavy carts; lifting and carrying while receiving and stocking supplies; and laundry removal from washing machines and dryers. ■

Reader Feedback

Reader: Consent and its role in reprocessed SUDs

To the Editor: I read with interest the article about the study by the Center for Patient Advocacy involving reprocessed single-use devices (SUDs) in the February 2003 issue of *Healthcare Risk Management*. Included in the article is advice about obtaining informed consent when using these devices. Interesting information, but, there are other perspectives on the issue.

Although Neil Kahanovitz, MD, notes that the use of SUDs "is a safety issue for patients," other than the opinions of the health care providers in the polls, he provides no evidence that patient safety is truly at risk.

In testimony by David Feigal, MD, MPH, director of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) before the House Committee on Commerce, Subcommittee on Oversight and Investigations on Feb. 10, 2000, Feigal noted that

a review of Medical Device Reports submitted to the CDRH between August, 1996 and December, 1999, "[f]rom this data, we can discern no pattern of failures with reused SUDs that differs from patterns observed with the use of SUDs."

Although Feigal also mentions that it is difficult to draw absolute conclusions about the safety of such devices, my own experience as a risk manager has been that infections traced back to devices have, without exception, involved reusable devices, not reprocessed single-use devices. Improper sterilization is apparently the culprit in these cases, not the device itself.

With respect to the issue of informed consent, most state laws require the disclosure of "material risks" to patients. In the absence of any compelling data to suggest that reprocessed single-use devices have a higher degree of risk associated with their use than original SUDs, there really isn't anything to disclose. With respect to many of the reprocessed SUDs in use in the acute care setting, physicians and nurses would not be able to identify which is which under any circumstances.

If a hospital uses the services of established, FDA-compliant third-party processors, the risk of infection or failure associated with reprocessed devices is demonstrably no greater than new ones.

Consequently, as a greater risk in the use of reprocessed SUDs has not been clearly established, their use does not constitute a "material risk," obtaining special consent for their use is simply not necessary. As we know, given the choice between a used device and a new one, patients would invariably choose the new one, irrespective of any qualitative differences between the two. It's human nature.

If we agree that, based upon current information, the risks associated with the use of reprocessed SUDs are not demonstrably different than with new ones, the results of these consent discussions could be expected to lead to greater, unnecessary expense to the hospitals and a surge in profits for the manufacturers. Interestingly, manufacturers are insistent about the desirability of obtaining patient's informed consent when using reprocessed devices, but not for new ones.

As the overwhelming majority of reported cases to the CDRH involve failures and problems with new devices, not reprocessed ones, I believe that device manufacturers may have an ulterior motive in adopting their position on this issue.

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CE instructions

Nurses participate in this continuing education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. This is the last month of the semester. **After completing this semester's activity, you must complete the evaluation form provided and return it in the enclosed reply envelope to receive a certificate of completion.** When your evaluation is received, a certificate will be mailed to you. ■

COMING IN FUTURE MONTHS

- Universal consent form useful but has limitations
- Computerized order entry reduces errors
- Simplest tactics for reducing falls are also best
- Patient safety goals: Beware when others write policies
- Crew resource management: What it is and how it can help

CE objectives

After reading this issue of *Healthcare Risk Management,* the CE participant should be able to:

1. Describe legal, clinical, financial, and managerial issues pertinent to risk managers in health care.
2. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.
3. Identify solutions for hospital personnel to use in overcoming challenges they encounter in daily practice. Challenges include HIPAA and EMTALA compliance, medical errors, malpractice suits, sentinel events, and bioterrorism.
4. Employ programs used by government agencies and other hospitals (such as EMTALA, HIPAA, and medical errors reporting systems) for use in solving day-to-day problems. ■

CE Questions

If you have any questions about this testing method, please contact customer service at (800) 688-2421.

21. Referring to the report issued recently by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, ___ of cerebral palsy cases may be related to the birth process.
A. 0%
B. 10%
C. 30%
D. 60%

22. In the list of criteria for defining an acute intrapartum event sufficient to cause cerebral palsy, how many of the four essential criteria must be met?
A. At least one
B. At least two
C. At least three
D. All four

23. According to Peter Ubel, MD, director of the University of Michigan Medical School's Program for Improving Health Care Decisions, which is the best policy regarding pelvic exams performed by medical students on unconscious patients?
A. They should be prohibited entirely.
B. They should be allowed with no restrictions.
C. They should be allowed if the patient was notified generally that students might be involved in their care.
D. They should be allowed only if the patient was asked for permission and specifically consented.

24. Specify the primary recommendation in OSHA's ergonomic guidelines for nursing homes.
A. Minimize manual lifting of residents.
B. Provide ergonomically designed chairs for office workers.
C. Implement the use of back support belts for all clinicians.
D. Increase the nurse-to-resident ratio.

Answers: 21-B; 22-D; 23-D; 24-A.

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Swarm of fire ants attacks nursing home patient resident: $5.35 million Alabama verdict

By **Edward J. Carbone**, Esq., **Jan J. Gorrie**, Esq., and **Richard Oliver**, Esq.
Buchanan Ingersoll Professional Corp.
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News: One summer evening, fire ants attacked a 79-year-old nursing home patient resident as she lay in her bed. The next day, the patient's daughter took her to a regularly scheduled doctor's appointment outside of the facility, and the physician aggressively treated her for multiple bites. The fire ants attacked again that night and the patient was severely bitten. Because of the severe bites, she developed a staphylococcal infection and and the trauma further exacerbated her dementia. The nursing home resident brought suit against the nursing home facility and its pest control company. The jury awarded her $5.35 million and attributed fault equally between the defendants.

Background: One the evening of Aug. 22, 1999, the 79-year-old nursing home patient resident, who suffered from dementia, was attacked by fire ants. On several occasions that summer, nursing home employees had identified the presence of fire ants within the facility. Cans of spray insecticide were distributed for workers to use as needed.

The following morning, the patient's daughter picked up her mother for a routine office visit with her private physician. She complained of itching and burning in her legs, but her daughter remained unaware of the attack by the fire ants. Through the course of her examination, The physician determined that the source of the patient's leg discomfort complaints was fire ant bites. When the daughter returned to the nursing home facility with her mother, she notified the facility staff about the bites.

The next night, the fire ants returned. A nursing home employee discovered the patient covered by a swarm of fire ants. Physical proof, as well as testimony at the trial, established that thousands of fire ants had swarmed over the elderly and confused patient. She had ants coming out of her ears, mouth, nose, and in her genital area. The nursing home personnel immediately placed the patient resident in the shower in an attempt to repel the ants and wash them off the patient's body. In the process of assisting the patient resident, the workers suffered approximately 70 bites from the swarm.

The patient suffered from multiple, severe fire ant bites and developed a staphylococcal infection. The strain of the impact of the injuries and nature of the incident exacerbated the patient's pre-existing delusional symptoms, leading to an increases in hallucinations. Her medical bills for treatment of the fire ant bites and staphylococcal infection alone totaled more than $120,000.

The patient brought suit against both the nursing home and the facility's pest control company. She sought compensatory and punitive damages from both defendants. As to the nursing home, the plaintiff noted that the fire ants had been identified on the property for several weeks and that the nursing home failed

to timely contact its pest control company to investigate and intervene — particularly in light of the fact that the facility was on notice that the fire ants were known to have previously had harmed the patient. The plaintiff averred claimed that, given the patient's resident's underlying mental condition in this case, the nursing home failed to ensure the safety and health of this mentally diminished impaired patient resident. The pest control company was criticized for failing to properly treat the nursing home for fire ants. While a proper pest control treatment of the facility should have taken approximately 45 minutes, the plaintiff introduced evidence that the pest control company's treatments at the facility took only eight minutes.

In its defense, the nursing home argued that the fire ant attack was not foreseeable. While conceding to isolated instances in which fire ants were noted by staff, the facility claimed it had no reason to expect an imminent infestation on the scale of the one that ultimately occurred. The nursing home claimed that it acted reasonably in contracting for pest control, reporting the presence of fire ants to the pest control company and relying upon the pest control company to adequately treat the facility.

The primary defense raised by the pest control company was to argue that the court lacked subject matter jurisdiction because of a binding arbitration provision in the contract between the nursing home and pest control company. The plaintiff argued that she was not bound by an arbitration provision contained in a contract to which she was not a party. The court agreed and retained jurisdiction.

The pest control company then filed suit in federal court. Even though the federal case had not yet been heard, the state trial court judge refused to delay trial any further. At trial, the pest control company then advised that instead of using the corporate representative it had produced during the depositions for deposition, it would rely on a local manager to conduct support its defense. The plaintiff moved that the original representative should appear at trial. The court concurred and ordered his presence. The pest control company sought a writ of mandamus on this issue; its motion was denied.

At trial, the pest control company argued that its treatments were sufficient under the terms of its contract with the nursing home. After eight days of trial, the jury awarded $5.35 million to the nursing home resident. The verdict was assessed equally between the defendants and equally between compensatory and punitive damages.

The nursing home motioned moved for a new trial; it claimed the verdict was excessive and that its corporate net worth was only $200,000. It further argued that punitive damages were not warranted because its conduct constituted only simple negligence, not wantonness, saying that although the fire ants had been randomly seen before the attacks, there was no prior sign of an infestation. The pest control company filed its own post-trial motion, stating that its conduct was inextricably linked to the its contract with the nursing home and that the verdict was excessive.

What this means to you: Nursing home litigation and fire ants have become like the plague in some jurisdictions. This case demonstrates what can happen when the two forces are combined.

Fire ants are a serious and even deadly threat to children, aged adults, animals, and — under the right conditions — just about every living thing. Those of us who live with the threat of fire ants know how much more deadly they are because they do not tumble buildings and you don't usually know you have them until the pain of the bite is felt.

"Unfortunately, the elderly and young are not as able to escape from harm's way and, as seen in this case, even the more agile health care workers fell victim to the swarming attackers," says **Judy Kyle**, RN, JD, of Young Bill & Fugett, PA, in Pensacola, FL.

The nursing home staff in this case not only did not appreciate the threat of the fire ant infestation, they did not understand the resistance of the fire ants to over-the-counter remedies in building infestations. The facility's reaction to the fire ants' presence was uninformed and, consequently, inadequate. While the nursing home did engage the services of a pest control company, neither seemed to adequately address the situation and each appeared unaware of the extent of the infestation.

"Yet, the facility had the resources it needed to understand and respond appropriately to the threat: a phone call or an Internet search. Each state government regulates, usually through its agriculture department, the pesticide chemicals and companies that apply them. The states employ entomologists who could have informed

the facility of the dangers and difficulties associated with fire ant infestations. They could have provided a list of firms that were licensed and insured to exterminate the fire ants. By creating a record of an informed response, the facility might not avoid all bad outcomes but, if it had acted reasonably, it might have avoided liability and the payment of damages to the injured persons," Kyle says.

Facilities are not guarantors of perfect environments that prevent all harm to their residents. The facility only needs to act appropriately, reasonably, and with sufficient documentation of these responses to reduce or eliminate the legal consequences of an injurious event.

"Often we think of the quick, commercial response without becoming an informed consumer. When you have an invasion by ants, wasps, and a variety of other pests, the first thing to do is to gather information from an unbiased expert and then to request appropriate assistance if necessary. In the past, there was an excuse regarding the time it took to locate the information needed; now the same computer the business uses to bill the residents can be used to access the information to protect the residents. From a liability standpoint, an ineffective, uninformed response is worse than no response because the threat can be characterized as foreseeable," adds Kyle.

Despite the defendants' best efforts to use procedurally maneuvers to avoid liability and place to point the finger of blame with at the other, in the end, there was no escape for either from the swarm of fire from liability unleashed by the plaintiff.

Reference

• *Devers v. Greystone Retirement Center and Terminex International,* Madison County (AL) Circuit Court, Case No. 99-2477. ■

Psychosurgery leads to a $7.5 million verdict in Ohio

News: For years a woman suffered from an obsessive-compulsive disorder, which she believed would be corrected through psychosurgery. The procedure resulted in complete incapacitation, and she brought suit against the provider. She was awarded $7.5 million in damages for past and future medical care, pain and suffering, and loss of consortium for her spouse.

Background: A 58-year-old woman, who suffered from an obsessive-compulsive disorder that caused her to wash her hands and shower excessively since age 28, learned about psychosurgery on the Internet.

She made an appointment and was assessed as a viable candidate for the procedure. The surgery was successfully performed; however, post-surgery she developed a brain infection, leading to brain damage, which rendered the plaintiff unable to care for herself. She now requires around-the-clock care and suffered a loss of short-term memory. She is unable to walk, stand, eat, or use the bathroom by herself.

The plaintiff brought suit against the provider and alleged negligent technique and lack of informed consent and claimed she thought she was undergoing a single-part procedure called a cingulotomy, when in fact an experimental two-part surgery called a cingulotomy with a capulotomy was performed.

The plaintiff also claimed that the brain infection was due to the presence of an intestinal organism and was caused by improper sterilization techniques. Furthermore, the plaintiff maintained that she was not a proper candidate for the experimental surgery because she had not been thoroughly evaluated for the procedure that was actually preformed.

In its defense, the provider argued that the plaintiff's informed consent had been properly obtained and that the plaintiff's infection was a known risk of the procedure. At trial, a $7.5 million verdict was returned. The award included $300,000 for past medical care, $1.1 million for pain and suffering, $5 million for future medical care, and $1.1 million for loss of consortium for the patient's spouse.

What this means to you: "The importance of a thorough and well-documented informed consent and patient evaluation cannot be overlooked as demonstrated by this case. In this instance, because of the patient's history of obsessive-compulsive disorder, the surgeon might have considered videotaping his conversation with the patient as part of the informed consent process. It would be interesting to know how the procedure was actually listed on the

consent form signed by the patient. Full disclosure must be given to the patient of all intended and possibly intended procedures. For example: 'laparoscopic cholecystectomy and possible open exploratory laparotomy and cholecystectomy,'" says **Patti Ellis**, RN, BSN, LHRM, a risk management consultant in Miami.

The consent form should include a statement about emergency procedures to correct unforeseen conditions that may arise during the course of surgery, she adds.

"With regard to the specific possibility of infection, I don't think I've ever seen or heard of an informed-consent process where the surgeon did not identify infection as an inherent risk of the procedure. Again, a thorough and well-documented informed consent consisting of the most common risks of the procedure as well as those specific to the patient's medical condition are crucial to the informed consent process.

"It is unclear in this particular case whether the experimental capulotomy was associated with any additional risks that were not inherent in the cingulotomy procedure. If that were the case and in fact these additional risks were not disclosed to the patient, then the surgeon would be held liable as the jury found here.

"Although this patient suffers from a long-standing history of obsessive compulsive disorder, she still has the capacity to give informed consent unless otherwise determined to be legally incompetent by a court of law," adds Ellis.

"While there are no guarantees that a health care provider won't be sued, practicing within the standards of acceptable medical practice, the importance of informed consent process and excellent documentation can't be stressed enough.

"The return of such a large award by the jury in this case seems to be consistent with the excessive jury awards across the country," concludes Ellis.

Reference

• *Mary Lou Zimmerman and Sherman Zimmerman v. The Cleveland Clinic Foundation,* Cuyahoga County (OH) Common Pleas Count, Case No. 399411. ■