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IN THIS ISSUE

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Waiting room death brings scrutiny of staff training, attitude

Seven hospital employees fired or suspended for failing to respond

A New York hospital is facing a $25 million lawsuit and reeling from devastating media coverage after staff failed to respond when a woman collapsed in the emergency department waiting room. Surveillance footage from a security camera was obtained by the media and played over and over again, showing the woman fall out of her chair, land face down, and then die as hospital staff just looked at her without offering aid.

The incident happened at Kings County Hospital in Brooklyn, NY. Video footage from June 19, 2008, shows 49-year-old Esmin Green, a mother of six, sitting in a waiting room in the hospital's psychiatric ED. She slides off the chair and lands face down on the floor, apparently convulsing. She had been involuntarily admitted June 18 for "agitation and psychosis," according to the hospital.

Green had been waiting nearly 24 hours for treatment, according to the New York Civil Liberties Union (NYCLU), which released the surveillance camera video of the incident. She collapsed at 5:32 a.m. June 19, the NYCLU said, and she stopped moving at 6:07 a.m. Workers at the hospital did nothing until 6:35 a.m., when the tape shows a hospital security guard approaching Green and nudging the woman with her foot but not immediately aiding

EXECUTIVE SUMMARY

Employees of a hospital in New York were fired or disciplined after failing to respond when a woman collapsed in the waiting room. Some health professionals say the death highlights the need for better staff training.

- Relatives of the deceased woman already have filed a lawsuit.
- The hospital acknowledges that staff did not respond appropriately.
- A surveillance videotape of the incident was widely shown in the media.

her. Help was summoned three minutes later.

The hospital's parent organization released a statement saying seven people have been fired or suspended for their alleged involvement in the incident. They are the chief of psychiatry, chief of security, a doctor, two nurses, and two security guards, according to the New York City Health and Hospitals Corp., which oversees Kings County Hospital.

NYCLU also claims that hospital staff falsified Green's records to cover up the time Green went without assistance. "Contrary to what was recorded from four different angles by the hospital's video cameras, the patient's medical records say that at 6 a.m., she got up and went to the bathroom; and at 6:20 a.m., she was 'sitting quietly in waiting room' — more than 10 minutes since she last moved and 48 minutes after she fell to the floor," according to the NYCLU statement.

Systemic problems at hospital?

Similar incidents probably happen regularly in ED waiting rooms across the country but don't gain attention because the patient doesn't die, says **Michael A. Mayers**, CIC, CPCU, AAI, senior vice president, director of risk management services, and corporate risk manager for CBIZ, a consulting company based in Cleveland. The cause can often be traced to overworked ED staff, but Mayers points out that the Kings County Hospital surveillance video that looks so egregious to nonhealth care professionals might elicit more sympathy from hospital workers.

"All kinds of people end up in emergency waiting rooms, in various conditions, some of them just looking for a chair to sit in. The fact that someone falls isn't necessarily going to signal an emergency," he says. "The security person who came and looked at the woman probably had seen this a thousand times before, and it wasn't a medical emergency."

However, staff must be trained not to let their guard down and become complacent, Mayers says. Policy and procedures must dictate that patients are checked frequently, especially if there appears to be any change in their conditions, but he cautions that policies can always be overcome by human nature.

"If you're telling them to do that, to do it properly and stay alert, but then you're keeping them understaffed and overworked, you've created a situation where they cannot succeed," Mayers says.

While there is reason to sympathize with overworked ED staff, says **Martin Kalish**, MD, JD, a partner with the law firm of Arnstein & Lehr in Miami, who previously worked as a physician in several New York facilities, "there is something seriously wrong at the institution." He says he was particularly troubled by footage of the security guard who saw the woman but did nothing.

"To me, that tells me they have the wrong kind of security people working the psychiatric emergency room area," Kalish says. "You need people who are attuned to the kind of people in that area. These may be perfectly fine security guards in other areas, but they need to be trained and

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attuned to the kind of patient they will encounter in these psychiatric areas."

Kalish would advise the risk manager at the hospital to reassess orientation and training of staff, in addition to ensuring there are procedures in place for regularly checking on patients who are waiting. He also questions whether the patient underwent a medical evaluation while waiting for psychiatric care.

"Certainly a risk manager would want to take a look at the operation of the facility from top to bottom. How long does it take to evaluate a patient, and why does it take so long?" he says. "This is an unfortunate example of what can happen if you don't have the proper resources in place to minimize the wait and ongoing monitoring to make sure people don't get lost in the system. It sounds like no one was watching this patient as she got lost in the system."

Hospitals must have systems that prevent patients from being overlooked, says **Jessica Roe**, JD, an attorney with the law firm of Bernick & Lifson in Minneapolis. She recalls an incident in which a blind man went to a hospital ED seeking treatment and did not realize he was supposed to take a number and wait for it to be called. He was there for three hours before another patient realized the blind man never was called and sought help for him. Staff never noticed or made an effort to include him.

"We have to teach staff that it's not just about the procedures in place, not just the numbers," she says. "We have to help people retain some humanity and make sure patients are actually cared for and not just run through the system."

Roe says the Kings County Hospital incident points to a lack of proper staff training. The medical staff should have been trained to watch and monitor patients more closely, and security guards should have been trained to respond better when a patient appears to be in distress.

"Training is the first thing to be cut, because it's not a moneymaking endeavor," she says. "But this case shows just how shortsighted that can be. Not only is a patient dead, but the hospital is facing a real crisis now." ■

New law addresses how homeless are discharged

In response to several high-profile incidents of homeless patients being discharged in a less-than-dignified manner, the city of Los Angeles has enacted a new law that requires obtaining written consent to transport a patient anywhere other than his or her legal residence. Violating the law could result in a misdemeanor conviction.

The problem of how to discharge homeless patients who are medically ready to leave the facility but have no place to go is one that plagues many health care providers, but the topic is on the front burner in Los Angeles. Several providers there have been the subject of highly critical media reports about how the homeless are discharged, including a report in April 2006 that included footage of a 63-year-old homeless woman who had been treated at a Kaiser Permanente facility and then dropped off at a shelter on Skid Row, where she wandered aimlessly on the sidewalk in a hospital gown and socks. The local city attorney filed charges of misdemeanor imprisonment and threatened to pursue the case further, prompting Kaiser Permanente, based in Oakland, CA, to create new protocols for discharging homeless patients. As part of the settlement, Kaiser paid $5,000 in civil penalties, $50,000 in investigative costs to the city attorney's office,

EXECUTIVE SUMMARY

The city of Los Angeles has enacted a new law that makes it a crime to force homeless patients out of a hospital too soon. There have been several incidents of controversial discharge in the past few years.

- Patients must consent to being discharged to a shelter or the streets.
- Hospital leaders say the law may be impractical.
- Some hospitals admit to using poor discharge procedures in the past.

and contributed $500,000 to a charitable foundation benefitting local homeless programs. **(For more on the settlement and the changes promised by Kaiser Permanente, see *Healthcare Risk Management*, July 2007, pp. 73-76.)**

Hollywood Presbyterian was recently sued in connection with the "dumping" of a paraplegic man on Skid Row in 2006. That incident resulted in scandalous media reports of the man falling out of a van and then crawling in the gutter. The hospital acknowledged that the man was not properly discharged. Civil rights attorneys filed the lawsuit in Los Angeles County Superior Court on behalf of the paraplegic man, 42-year-old Gabino Olvera of Los Angeles, seeking unspecified punitive and compensatory damages against the hospital for elder abuse, negligence and infliction of emotional distress, and an injunction that would bar the hospital from "homeless dumping." **(For the initial report on the incident that led to the lawsuit against Hollywood Presbyterian, see *HRM*, April 2006, pp. 45-46. For more on the difficulties in discharging homeless patients, see June 2006, pp. 61-65.)**

The new city ordinance, believed to be the first such law in the nation, prohibits health providers from transporting patients anywhere other than their homes without written permission. The Hospital Association of Southern California (HASC) released a statement saying the new law may be unworkable because homeless patients may have no residence and can refuse to be transported anywhere else, including homeless shelters. Already overburdened hospitals will be forced to house homeless patients who should be discharged, the group says.

HASC has hired an attorney to determine whether the ordinance violates state laws, and the group is investigating the potential ramifications that a conviction might have on a hospital's participation in Medicare, Medicaid, and other federal programs. ■

Hospitals use RRTs to cut peds codes

A protocol built around the use of rapid response teams (RRTs) has reduced incidences of preventable codes among pediatric patients by 20% at a group of hospitals in Ohio, one of the best demonstrations yet of the success of that approach in improving patient safety. One hospital even saw a drop of 40%.

EXECUTIVE SUMMARY

A group of hospitals in Ohio has used rapid response teams to dramatically reduce preventable codes among their pediatric patients. Both staff and family members are able to call the team for help.

- Preventable codes have been reduced by 20% throughout the system.
- Results seem to improve the longer the system is in place at a particular hospital.
- Rapid intervention can help avoid some types of codes resulting from a patient's deteriorating condition.

The protocol has yielded tremendous results for the Ohio Children's Hospital Association (OCHA) and its six member hospitals — Akron Children's Hospital; Cincinnati Children's Hospital Medical Center; Dayton Children's Medical Center; Nationwide Children's Hospital, Columbus; Rainbow Babies & Children's Hospital, Cleveland; and Toledo Children's Hospital. The system recently announced groundbreaking results of the first-of-its-kind collaboration to improve quality in children's hospitals.

OCHA and its six member hospitals created the Ohio Children's Hospital Association's Quality Improvement Collaborative in 2006 to promote improved quality of care at children's hospitals, says **David Kinsaul**, FACHE, president and CEO of Dayton Children's Medical Center and chairman of OCHA. In its first initiative, the collaborative focused on reducing preventable codes — cardiac and pulmonary arrests — occurring outside of the neonatal and pediatric intensive care units. They settled on that specific goal because their internal data analysis revealed that a substantial number of codes occurred outside those areas where one might first assume the codes were concentrated, and where the staff and resources are most ready to respond. **(See p. 102 for more on those data.)**

As a result of its efforts, the collaborative identified a RRT protocol that, when implemented, reduced incidences of preventable codes by more than 20% throughout the six hospitals. The data suggest that the results get better over time, Kinsaul says. One of the hospitals has had the RRT protocol in place for more than three years and has seen a 40% drop in preventable codes.

"To our knowledge, this is the first time in the

nation that a statewide network of children's hospitals has come together to focus on quality improvement to save children's lives," Kinsaul says.

Hospitals developed own RRTs

Kinsaul says OCHA served as the link among the various children's hospitals and helped coordinate the effort. One key, he says, was having all the hospitals agree not to use any successful results to market against their competitors.

"We all agreed that whoever came out with the absolute best results would not use that in advertising against some other children's hospital," he says. "This was not about seeing which hospital was best, but rather how we could improve care. I think this kind of effort is always going to be more successful if you have some type of hospital association that is willing to help facilities come together, put all their data on the table, and not be judgmental of others."

Each participating hospital adapted a RRT model to fit within its own patient care environment and culture," Kinsaul says. Bedside caregivers at participating hospitals were empowered to quickly call on the RRT when the caregiver determined that immediate intervention was warranted. Further, some hospitals created a process that enabled patient families to call upon the RRT when they felt their child was in need of assessment.

Rather than implementing a one-size-fits-all approach, OCHA encouraged each hospital to create its own RRT protocol. The basic plan was for bedside caregivers to assess the patient's status, determine or request a recommendation, and then immediately obtain a review of the situation by an interdisciplinary team of clinicians in less than 30 minutes. Some hospitals went a step further by allowing patients' families to call out the team, on the theory that a parent's intuition can be valuable in assessing the patient.

Aiming to eliminate some codes

Encouraging each hospital to determine the specifics of its own RRTs resulted in more vigorous participation and more buy-in from both hospital leadership and frontline staff, says **Uma Kotagal**, MD, vice president of quality and transformation, Cincinnati Children's Hospital Medical Center, and chair of the OCHA quality improvement collaborative steering committee. Another key to the program's success was meticulous data collection and sharing of that information among all the hospitals, she says.

Kotagal says as good as the results are so far, the project team is not satisfied.

"My goal is to eliminate preventable codes outside the ICU completely, and we're not there yet," she says. "I expect we will get there in the next three to six months. The improvements so far are exceptionally good and we're very pleased, but it makes us think we can do even better."

The hospitals developed their own protocols, but they all involve responding quickly to any signs of distress. Cincinnati Children's Hospital Medical Center, for instance, uses the Pediatric Early Warning Score (PEWS), an assessment tool developed at the Royal Alexandra Hospital for Sick Children in East Sussex, England. With PEWS, all patients are assessed on specific criteria at least every four hours and sometimes more often depending on the results of the previous assessments. The hospital's team also developed an algorithm for what should be done in reaction to each assessment, ranging from no action, to reassessment, to calling out the RRT. **(See p. 102 for an example of how the RRT helped prevent a code at the hospital.)**

The RRT program is built around the idea that increased diligence, that is, simply paying close attention to a patient's condition, will help prevent many bad outcomes, says **Terry Davis**, MD, interim medical director at Nationwide Children's Hospital in Columbus, OH, and a member of the OCHA quality improvement collaborative steering committee.

"We just have to look for patients who are not doing as well as they should," he says. "When a patient has cardiac arrest on the floor, that patient is sicker than we thought and probably shouldn't have been on the floor. We're trying to recognize patients that are deteriorating and escalating their care appropriately."

RRTs promote culture change

The RRT allows escalation when the nurse or someone else thinks something is amiss, even if that person cannot identify exactly what is wrong, Davis says. **(See p. 103 for more on how Davis' hospital clarified when to call out the RRT.)** Nationwide Children's Hospital allows parents to call the RRT, and a placard in every room instructs them on how to call for help. Parents have called out the RRT only twice in the past six months, he says.

SOURCES

For more information on how RRTs can reduce preventable codes, contact:

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"We find that it doesn't happen very often that the parents call the RRT, and it is more likely with chronically ill patients," he says. "The parents know their children better than anyone, particularly if the patient is mentally challenged or has some other issue that the parent is more finely attuned to than the staff. They learn over the years to interpret their child's condition very accurately, so this gives them a way to get help if they don't think the bedside staff is listening to them."

Kotagal says the RRT program has prompted an overall culture change at the hospitals, with staff and physicians feeling more like a hospital-wide team, which makes nurses more comfortable in calling for help when needed.

"In the past, if we had a problem outside the ICU, the specialist who responded might have said, 'Well, if you had done this and this, your patient wouldn't be in this condition," she says. "Now we see much more of a sense of teamwork. Everyone works together and says, 'OK, I'm here. How can we help this patient?" ■

Data show many codes outside ICU

The Ohio Children's Hospital Association (OCHA) and its six member hospitals studied where pediatric codes occur and found that many occur outside the neonatal and intensive care units. To improve safety, the group focused on reducing preventable codes occurring outside those areas.

A preventable code was defined as one that could be avoided by early intervention to improve a deteriorating condition, as opposed to an unpreventable code such as one occurring from a seizure. OCHA studied 180 cases from the six hospitals between Jan. 1, 2004, and Sept. 30, 2007. They found 130 cases of respiratory arrest, six cases of cardiac arrest, and 44 cases of simultaneous respiratory and cardiac arrest. Out of those 180 cases, 142 cases occurred in general inpatient rooms outside of the intensive care unit.

More than 70% of the children's lives were saved and were discharged. Of those 180 cases, 107 were deemed to be nonpreventable, which left 73 cases of preventable cardiac or respiratory arrests. OCHA determined that those were the cases in which quick action could have saved the patient's life, so they focused on developing a response plan to that type of pediatric code, resulting in OCHA's systemwide protocol for rapid response teams. ■

Baby's case shows how RRT works

This example of the rapid response teams (RRTs) at Ohio Children's Hospital Association (OCHA) comes from **David Kinsaul**, FACHE, president and CEO of Dayton Children's Medical Center and chairman of OCHA:

"Baby C.T." was a 6-week old infant who arrived at the Cincinnati Children's Hospital Medical Center emergency department with a two-day history of cough and increasing difficulty breathing. Doctors diagnosed bronchitis, and the baby was admitted to the acute medical inpatient unit.

About two hours after admission, a nurse was conducting a routine assessment when she found signs of respiratory distress, including head bobbing, nasal flaring, and grunting with retractions. The baby's heart rate and respiratory rate were high but oxygen saturation was low.

Using the Pediatric Early Warning Score (PEWS), the nurse determined that the infant's score was 8 and that automatically triggered a call to the RRT. An intensive care fellow, an intensive care unit (ICU) nurse, and a respiratory therapist responded and stabilized the infant, then transferred him to the ICU for further monitoring.

The use of PEWS and the RRT response likely prevented a code and ensured that the patient was transferred to the more appropriate level of care, Kinsaul says. ■

Don't rely too much on triggers for RRTs

Terry Davis, MD, interim medical director at Nationwide Children's Hospital in Columbus, OH, says the hospital had to clarify some initial misunderstandings about when to call its rapid response team (RRT). At first, the clinicians were confused as to when the RRT should be called, as opposed to calling for a pediatric intensive care consult.

Hospital leaders clarified that the RRT was primarily for the times when someone felt his or her concerns were not being heard or the patient was deteriorating rapidly. A pediatric intensive care consult still was the more appropriate first response when the clinician simply wanted an expert opinion.

Davis says the team at his hospital also has learned not to depend exclusively on objective triggers, such as a certain pulse rate, for calling the RRT. Those can be fine for signaling when the RRT definitely should be called, he says, but people should be reminded that they don't have to wait for those triggers.

"Our policy is, 'If you're worried, so are we,'" he says. "If the nurse or the resident or a parent is worried and not getting a good response from those around them, we want to know about it. We don't want them waiting for a numerical threshold before they feel like they can act." ■

Unlabeled syringes are common safety threat

Injectable medications pose one of the highest risks for medication errors, and the risk often is related to identifying the proper drug and dosage in the syringe before administering it. Medication safety experts and risk managers often advise labeling the syringe when it is filled to avoid any confusion, but how often is that actually done? Not as much as you might think.

The truth is that busy nurses often forgo labeling syringes and trust they can remember what is in each syringe when injecting the drugs. And even when a syringe is labeled, it is not always done in a way that facilitates easy reading by all staff under less-than-ideal conditions. The Joint Commission has recognized this problem and made improved medication labeling one of its Patient Safety Goals.

EXECUTIVE SUMMARY

Syringes lacking a label identifying the drug and dosage are surprisingly common in health care. These syringes pose a significant threat to patient safety.

- About a quarter of nurses report they never label syringes.
- Health care facilities must provide a practical way for staff to apply labels.
- Risk managers should assess how syringes are currently labeled.

Improve syringe labeling and you will reduce medication errors, says **Douglas Dotan**, MA, CQIA, president of CRG Medical in Houston, which offers patient safety quality management solutions to health care providers. He also is the outgoing chair of the health care division of the American Society for Quality in Milwaukee. But first you have to know what's really going on in your facility, Dotan says.

"One of the best things a risk manager could do is to go on rounds and see for [him or herself] what is happening when they prepare these syringes," he says. "And you have to remember that it's not just at the patient's bedside. It's in pharmacy dispensing, in the operating room, in the sterile field, all over the facility."

Proper labeling of a syringe should include the nurse's name, the date and time, the drug, and the dosage, Dotan says.

Error traced to lack of label

The hazards posed by unlabeled syringes were addressed recently by the Institution for Safe Medication Practices (ISMP) in Huntingdon Valley, PA. The ISMP calls unlabeled syringes a significant risk, offering this example of how the lack of a label can lead to a tragic mistake: A nurse injected a 15-year-old patient with an unlabeled syringe that was thought to contain Marcaine (bupivacaine) with epinephrine.[1] The syringe actually contained 30 ml epinephrine 1:1,000. The patient's blood pressure increased rapidly after the injection, leading the staff to suspect malignant hyperthermia because the patient had a history of that problem. The medication error was not discovered until the patient

developed ventricular tachycardia and pulmonary edema. The patient recovered.

An investigation revealed that the nurse who had prepared the syringe had intended to add it to several bags of normal saline, the ISMP reports. But she was called away and left the unlabeled syringe on a tray near the patient, where another nurse assumed it had been prepared for that patient.

Nurses say no consistency

A recent survey by the American Nurses Association (ANA) in Silver Spring, MD, suggests that such scenarios are surprisingly common in health care facilities. The survey of more than 1,000 nurses revealed that only 37% report they always label syringes, and 28% report that they never do. **(See article, right, for more on the ANA survey results.)**

ANA president **Rebecca M. Patton**, MSN, RN, CNOR, points out that a substantial majority of the nurses surveyed, 68%, said they believe medication errors can be reduced with more consistent syringe labeling. She agrees.

"Proper and consistent syringe labeling is one way to reduce risks associated with medication errors," Patton says.

Addressing the manner in which staff label syringes is a big part of the solution, Dotan says. Many well-meaning nurses try to label the syringes but find that doing so is just impractical, especially with the small syringes often used with children, because even the smallest stick-on labels or tape can obscure the measurement gradations. Labels also can fall off, leaving the nurse to guess what is in the syringe. Some labels also can make it more difficult to inject the drug, Dotan says.

In addition, some of the writing on syringe labels is so small — often by necessity, because the syringe is so small — that most people can't read the words.

"Once you have nurses over 40 or 50 years old, the experienced ones you trust so much; they can't even read those labels unless you provide them a magnifying glass," Dotan says. "Having a magnifier on every table or every cart can be a simple fix, a cheap and effective solution. But those are the kinds of problems that you have to uncover by going out on the floor and talking to people."

Patton notes that one possible solution is a write-on stripe manufactured on the syringe. One example is the InviroSTRIPE feature of syringes manufactured by Inviro Medical Devices in Lawrenceville, GA. The syringes come with an integral write-on stripe that allows for critical information to be recorded directly onto the syringe barrel. Several manufacturers provide pre-made labels that can be applied to syringes, and some more advanced drug dispensing systems will print a label that includes a bar code identifying the medication and tying it to the patient's records.

"Risk managers need to work with the quality improvement people and the nurses themselves to solve this problem. Be their friend more than their inspectors," Dotan says. "If you can't always use pre-filled syringes, make sure they use the commercially available labels and their units are restocked regularly. Consistency in use is a key to avoiding this type of error."

Dotan recommends getting nurse input when looking for a labeling solution. Let the nurses tell

Nurses report no consistent labeling

Research from the American Nurses Association (ANA) in Silver Spring, MD, shows that even among those who label syringes, there is little consistency in how it is done, says President **Rebecca M. Patton**, MSN, RN, CNOR. And some of the methods are clearly not as efficient or reliable as others, she says.

In a recent ANA survey of 1,000 nurses, 72% of nurses said they label syringes at least sometimes and reported using these different methods:

- Writing on self-adhesive labels then applying to syringe (54%).
- Writing on pieces of tape and adhering to syringe (31%).
- Using a Sharpie pen to write directly on the syringe (11%).
- Writing on paper or sticky note and taping to syringe (4%).

Patton notes that improving the labeling of syringes is not as easy as writing a policy and telling nurses to do it consistently. Challenges often arise when attempting to label a syringe, so practical solutions must be found that facilitate labeling under the real-world working conditions that nurses face, she says.

For instance, some labels can cover the measurement gradations on the syringe barrel, a problem reported by 65% of the nurses surveyed, Patton says. Thirty-nine percent of the nurses reported that a label impairs their ability to accurately check the dosage when comparing it to the order — creating another risk of medication error. ■

SOURCES

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- **Rebecca M. Patton**, MSN, RN, CNOR, President, American Nurses Association, Silver Spring, MD. Telephone: (301) 628-5000. Web site: www.nursingworld.org.

you what really happens on the floor and why it may not be so easy to employ the procedures that seem like they should work. **(See article, below, for possible strategies.)**

"If you see someone not labeling a syringe, stop and ask them why. They'll probably tell you the truth," he says. "Ask the nurses what their concerns are and how they work around some of the limitations to the labeling systems. Those workarounds may lead to the more practical policy and procedure."

The risk manager should be sure to approach nurses in a helpful manner, rather than as an enforcer, Dotan says. Acknowledge up front that it is difficult for nurses to label syringes every time and ask how you can help make that more realistic.

"If you tell me to write on a 2 ml syringe for a neonatal, there's no way I can do that," he says. "So don't just send a memo saying they have to do it every time, because if it is not realistic, if they just can't do it, then you're setting them up for failure."

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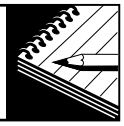
1. Institution for Safe Medication Practices. Errors with injectable medications: Unlabeled syringes are surprisingly common. *Nurse Advise* — ERR 2008; 6(1):1. ■

Good policies help improve labeling

Douglas Dotan, MA, CQIA, president of CRG Medical in Houston, which offers patient safety quality management solutions to health care providers, suggests risk managers consider those policies and procedures that have helped some health care providers reduce errors related to unlabeled syringes:

- **Determine what should happen when a health care provider finds an unlabeled syringe.** Many health care systems expect staff to discard the unlabeled syringe and obtain the needed medication anew. That can be expensive, but the cost of discarding the drugs is one more reason to push for consistent labeling.
- **Follow the golden rule: A syringe should never leave the practitioner's hand without a label.** To be effective, the policy must require immediate labeling, not simply before the drug is injected. Some providers have a habit of leaving the filled syringe next to the medication vial as a reminder of the contents, placing a label on the syringe before moving it to the bedside. That is most common when the nurse is filling more than one syringe at a time. That is not sufficient, Dotan says.
- **Be careful with color-coded labels.** Even with preprinted labels, the user must be careful to read the name of the medication every time before injecting the drug. Some color-coding systems use the same color for a class of drug or a general type, but the printed name of the drug varies. Caution staff not to rely too much on color coding. They always must read the label even if the color is correct. ■

GUEST COLUMN



Genetic law creates new protected class

By **Leila Narvid**, JD
Payne & Fears LLP
San Francisco

Risk managers have a new concern that will require a close review of human resources policies and procedures in order to avoid the improper use and disclosure of genetic information.

On May 21, 2008, President George Bush signed the "Genetic Information Nondiscrimination Act," known as GINA. GINA is far-reaching in that it intersects with many federal laws including Title VII of the Civil Rights Act, The Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Employee Retirement Income Security Act of 1974 (ERISA). While genetic information

EXECUTIVE SUMMARY

A new law bans employers from using a person's genetic information for employment-related decisions. Health care employers will have access to such information and must avoid using it improperly.

- Risk managers should review policies to ensure compliance with the new law.
- It is no longer acceptable to ask employees for a family medical history.
- Inadvertent disclosure of genetic information could still be a violation.

discrimination may not be the most pressing issue faced by employers, GINA nonetheless marks the first significant statutory change to the federal discrimination laws since 1991.

Title I of GINA prohibits all health insurers from basing eligibility or premium determinations on genetic information. Title II bans employers, labor unions, and employment agencies from using individuals' genetic information when making hiring, firing, compensation, and other employment-related decisions.

Employers also may not limit, segregate, or classify employees in a manner that denies employment opportunities to an employee based on genetic information. Labor unions may not exclude, expel, or otherwise discriminate against individuals based on genetic information. In addition, employers, employment agencies, and labor unions may not request, require, or purchase an employee's or an employee's family member's genetic information unless it falls within specific limited circumstances, such as when the genetic information is needed to meet certification requirements of family and medical leave laws, or will be used to monitor the biological effects of toxic substances in the workplace.

GINA broadly defines "genetic information" not just to include the genetic test results of an individual and his or her family members, but also the "manifestation" of a disease or disorder in an individual's family members. For example, information regarding an employee's mother's breast cancer or father's sickle cell anemia would constitute "genetic information" for purposes of the Act. The definition does not include a "manifested disease" in an individual, so that insurers can continue to underwrite health insurance coverage based on an existing illness. The definition does not include information about an individual's age or sex, which already are protected classes.

Title II of GINA applies to employers covered by Title VII of the Civil Rights Act and contains provisions that are similar to many provisions of Title VII. For example, employees must file a charge with the EEOC before filing a discrimination lawsuit and GINA provides for the right to a jury trial and compensatory and punitive damages. It also provides for the recovery of attorney's fees for the prevailing plaintiffs under the fee-shifting statute applicable to Title VII claims. However, unlike Title VII, GINA does not create a disparate impact cause of action for genetic discrimination.

The new legislation includes provisions that are intended to provide increased protection for patient privacy. GINA requires employers, employment agencies, and labor unions that possess any genetic information about employees to maintain that information in separate files and to treat it as confidential medical records. Employers also are prohibited from disclosing an employee's genetic information except upon a specific written request, in response to a court order, to comply with the Family and Medical Leave Act's (FMLA) certification procedures, or other very limited circumstances.

Practical implications

GINA's prohibitions on employment discrimination take effect in November 2009, 18 months after the date of its enactment. The provisions barring genetic discrimination in health insurance apply to health coverage for plan years beginning after the one-year anniversary of enactment of GINA, in May 2009.

Risk managers should review their current policies and human resources practices to make sure that they account for this new protected class. While the practical implications of GINA may be difficult to foresee, the Act itself suggests that risk managers take the following actions:

- Equal employment opportunity statements should include nondiscrimination on the basis of genetic information.
- Discontinue any requests to job applicants and employees to provide a family medical history.
- Evaluate whether any changes are necessary in connection with the employer's administration of health benefits.
- Do not request information about the manifested disorders or diseases of an employee's family members for leave requests that are unrelated to the FMLA or state analogues of the FMLA.

SOURCE

For more information on the Genetic Information Nondiscrimination Act, contact:

- **Leila Narvid**, JD, Payne & Fears LLP, San Francisco. Telephone: (415) 398-7860. E-mail: ln@paynefears.com.

• Implement policies and procedures to prevent the inadvertent disclosure of genetic information.

Risk managers must keep in mind that it is not enough to have policies prohibiting the improper use of genetic information in the workplace. Inadvertent breaches, through the theft of laptops or unauthorized access of health care databases, also can lead to GINA violations. Such data breaches occur regularly and the potential for violating GINA only creates more impetus for ensuring the security of personal data.

*(Editor's note: For more on GINA, see www.genome.gov/24519851. See article, **below**, for information on a recent loss of secure data from a health care provider.)* ■

Health records exposed by security breach

A security breach involving the Walter Reed Army Medical Center in Washington, DC, and other military hospitals exposed sensitive information on about 1,000 patients, according to a statement released by the Army.

The information included names, Social Security numbers, and birth dates, leading to concerns about identity theft for the patients involved. The computer file that was breached did not include information such as medical records, or the diagnosis or prognosis for patients, according to officials with the hospitals involved.

The Army is investigating how the data security was compromised, and Walter Reed officials declined to say exactly what happened until the investigation is complete. A Walter Reed spokesman did confirm that the computer file was found on a "nongovernment, nonsecure computer network."

Officials at Walter Reed learned of the breach on May 21 from an outside data mining company, which found the file while working for another client. The data mining company alerted Walter Reed.

The hospital is working to notify all of those whose information was released, the spokesman says. The data breach only is the latest in a series of such incidents affecting patients in various health systems. The Department of Veterans Affairs acknowledged a massive breach in May 2006, in which personal data on up to 26.5 million veterans was lost. ■

CE objectives

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

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk management in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions, including programs used by government agencies and hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■

COMING IN FUTURE MONTHS

- Liabilities of medical choppers
- Time management for risk managers
- Docs who bully: What you must do
- Proving your value to top execs

CNE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. 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. After completing this semester's activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

9. In videotape surveillance footage from the June 19, 2008, incident at Kings County Hospital, what happened to Esmin Green?
A. Green collapsed at 5:32 a.m. and she stopped moving at 6:07 a.m. Workers at the hospital did nothing until 6:35 a.m.
B. Green collapsed at 5:32 a.m. and was given emergency aid at 5:46 a.m.
C. Green collapsed at 5:32 a.m. and was offered medical aid immediately but refused.
D. Green collapsed at 5:32 a.m. and was evaluated at 5:46 a.m., but a doctor determined she was uninjured.

10. According to David Kinsaul, FACHE, why did his group focus on reducing preventable codes occurring outside of the neonatal and pediatric ICUs?
A. Other groups were addressing how to reduce codes in those units at the same time his team was working.
B. It settled on that specific goal because its internal data analysis revealed a substantial number of codes occurred outside those areas where one might first assume the codes were concentrated, and where the staff and resources are most ready to respond to codes.
C. Preventable codes almost never occurred in those areas.
D. Staff and physicians in those areas strongly resisted any effort to address preventable codes.

11. According to Douglas Dotan, MA, CQIA, proper labeling of a syringe should include:
A. the nurse's name, the date and time, the drug, and the dosage.
B. only the nurse's name.
C. only the patient's name.
D. only the drug and dosage.

12. According to Leila Narvid, JD, which of the following is recommended to avoid GINA?
A. Discontinue any requests to job applicants and employees to provide a family medical history.
B. Begin asking job applicants and employees to provide a family medical history.
C. Specify that it is optional for job applicants and employees to provide a family medical history.
D. Ask job applicants and employees to provide a family medical history only if the health insurer requests it.

Answers: 9. A; 10. B; 11. A; 12. A.

HIPAA Regulatory Alert

Supplement to *Healthcare Risk Management* and *Hospital Access Management*

AAHC: HIPAA deterring biomedical research

Administrative burden, ambiguity also problems

Research vice presidents for academic health centers agree — HIPAA has serious and often detrimental effects on biomedical research. The vice presidents met in focus groups sponsored by the Association of Academic Health Centers (AAHC) to share their concern that problems with HIPAA still have not been addressed in the five years of its existence.

The HIPAA privacy rule, the researchers say, continues to hamper a wide array of health research activities, and corrective action is needed to advance biomedical research and science in the United States.

"Five years after HIPAA's implementation, persistent problems are still creating impediments to valuable and important research," AAHC's statement says. "The AAHC's findings provide new insight on HIPAA while affirming past observations about the impact of HIPAA on research, indicating that the problems that first appeared after HIPAA's implementation in 2003 remain serious and widespread."

Focus group participants were asked to describe how HIPAA has affected different aspects and areas of research. They identified major cross-cutting areas of negative impact, as well as particular categories of research suffering setbacks due to HIPAA.

Concerns for researchers nationwide were:

1. ambiguity and misinterpretation of the rule;
2. administrative burden;
3. recruitment of research participants.

The specific areas of research particularly affected by HIPAA include:

1. access to stored tissue and genetic data sets;
2. data warehouses, Clinical and Translational Science Awards, and medical records;
3. community research.

Together, the researchers said, those concerns show that HIPAA is no small obstacle and that it threatens the social good by seriously restricting biomedical research and unnecessarily slowing the path toward life-saving discoveries.

Confusion and inconsistency

The groups discussed many HIPAA-related problems arising from widespread confusion over the rule's unclear language. Confusion over HIPAA's meaning was found to be common among all players, from research participants to privacy boards to institutions and even states. Participants reported that different institutions and states interpret and implement HIPAA inconsistently, making multisite and interstate research more difficult — if not impossible.

In addition, HIPAA overlaps with other existing regulations governing confidentiality and exchange of clinical research information, and conflicts with others. Concern was raised over a lack of understanding of HIPAA and a fear of violating regulations that discourage community partners such as hospitals from joining or collaborating in research with academic health centers.

AAHC says a recurring focus group theme was that fear of liability causes unnecessarily strict organizational decision making, which seriously impedes research. Drawing attention away from patient care and the need to research future treatments, HIPAA is causing decision makers to focus instead on deciphering unduly complex regulations and protecting institutions from liability, the groups say.

Participants in all the focus groups consistently reported the administrative burden HIPAA creates. They said that by generating additional paperwork and causing confusion and misinterpretation, HIPAA has imposed substantial and

onerous demands on the time of administrative and research personnel.

Since HIPAA took effect, they say, more time is required to: 1) define what does and does not constitute research; 2) complete additional forms and review documents; 3) track unauthorized disclosures of protected health information and requests for amendments; and 4) de-identify data from research participants. HIPAA also has increased the amount of time researchers must spend reviewing legal matters with research participants and decreased the time available for substantive discussions about risk, diagnosis, and clinical treatment issues, the groups say.

The focus groups say the impositions on investigator and research team time and resources are "slowing research unnecessarily" without providing benefit to research or the public. And they say widespread misunderstandings of HIPAA have raised the costs of conducting research because institutions have had to hire additional staff to handle administrative tasks, assist investigators, and conduct training or provide clarification on the rule. Money and resources also are wasted when a study, due to HIPAA complications, cannot conduct follow-up contacts.

Investigators and staff burning out

The research officials say they have seen significant investigator and staff burnout with fewer faculty members willing to participate in clinical research, which further threatens to weaken the clinical research infrastructure — not only for academic health centers but for the entire nation.

The negative impact on participant recruitment was cited as one of greatest threats HIPAA poses to research. Researchers say they often have difficulty accessing patient records for initial review or making initial contact with a patient. When a principal investigator is unable to review patient medical records to identify patients who are eligible for a specific study, that task falls to employees of the health care provider's office. But they often don't have the time for this additional work and are unwilling or unable to help out.

Focus group participants also reported that investigators have been unable to contact participants from past studies to assess their interest in new studies. And recruitment of participants for healthy control groups is hampered by time- and effort-intensive procedures, such as waivers or approval from the institutional review board for amendments, which slow research and limit patient numbers.

The researchers say HIPAA's confusing and legalistic terminology in documents undermines participant recruitment. Since patients are easily overwhelmed by the length and complexity of HIPAA documents, the rule actually appears to make potential participants less likely to agree to join studies. It was pointed out that the length of documentation may discourage potential participants from reading the forms carefully before signing them, thus undermining the notion of "informed consent." It was generally agreed that HIPAA impedes participants' ability to obtain clear, concise, intelligible information about a research study.

In terms of specific research areas, the focus groups reported that de-identified data have diminished value for genetic data sets. Also, several concerns involve future use of data. Because HIPAA presents obstacles in locating patients for follow-up in the months and years after a study, biobanks lose the ability to obtain crucial follow-up data. And researchers may be unable to notify patients in "duty to warn" situations, such as if an adverse mutation is found and a treatment becomes available.

HIPAA also affects data warehouses, Clinical and Translational Science Awards (CTSA), and/or medical records. While CTSAs are a new opportunity for interdisciplinary research at academic health centers, there can be problems with the ability to move data among different sites.

One institution reported that HIPAA regulations stymied efforts to create an integrated electronic medical record system mandated by the CTSA. Another said collaboration in statewide CTSA networks is hampered by institutional policies that preclude direct periodic follow-up with patients to define future medical conditions. Follow-up is only permitted if research participants give permission at the time of sampling to be contacted.

Focus group participants said HIPAA regulations have generally hindered researchers' ability to access electronic medical records and, thus, have generated burdensome requirements for printing, organizing, filing, and securing paper copies of records.

Another development AAHC officials said they find troubling is that hospitals and community physicians are often reluctant to become engaged in research due mostly to HIPAA requirements. AAHC says provider reluctance "often stems from misinterpretation and confu-

sion over the meaning of HIPAA. Many fear liability and punishment for potential privacy violations and misunderstand HIPAA regulations as they pertain to research, which can lead to overly cautious and unduly restrictive interpretation of the rule. Such unnecessarily and excessively strict interpretation has been impeding and significantly delaying research progress."

Recommendations for improvement

AAHC suggests three steps to address HIPAA-related barriers that are impeding research:

1. The Department of Health and Human Services should revise the HIPAA privacy rule to allow it to defer to the Common Rule (the Office of Human Research Protections' Federal Policy for the Protection of Human Subjects) in matters of protecting the privacy of protected health information of research participants. Common Rule guidelines already protect health information, and if an institutional review board thinks that extra protection is warranted, it can require a Certificate of Confidentiality.
2. The Office of Human Research Protections should provide updated guidance to emphasize the importance of preserving the privacy of protected health information.
3. Congress should implement a national genetic privacy act or include such a provision in a HIPAA revision to help resolve the current conflicts and confusion over differences in state genetic privacy acts and HIPAA that hamper genetic data set research.

Oregon Health and Science University's chief integrity officer, **Gary Chiodo**, tells *HIPAA Regulatory Alert* that the HIPAA privacy rule is distracting from protecting human subjects, rather than facilitating that effort. "There are layers of nonunderstandable legal language that people don't care about," he says. "It interferes with the normal informed consent process."

Why no progress in five years?

Chiodo says there is no good answer as to why these problems remain after five years of experience with HIPAA. From the time of implementation, he says, investigators have expressed concerns about the rule. While the Department of Health and Human Services asked for time in which to implement the rule and evaluate its impact, Chiodo says that while some early fears were not on point, there is substantial evidence that other problems do exist as outlined by the AAHC focus groups.

AAHC policy and program vice president **Elaine Rubin** tells *HRA* the group produced its report because it was aware that problems with HIPAA have not been resolved. "HIPAA is synonymous with patient protection so people have been afraid to evaluate it," she says. "Another problem is that not that many people in Congress or some federal agencies really understand the intricacies of research. And they also are not aware of the other regulations and mechanisms that are out there to achieve the patient protection that they want."

Rubin says bureaucracies have been built without assessing the full landscape of existing regulatory agencies and there is a need to harmonize regulations.

*[Editor's note: Download a copy of the report at www.aahcdc.org. Contact **Gary Chiodo** at chiodoga@ohsu.edu. Contact **Elaine Rubin** at (202) 265-9600.]* ■

House health IT bill seeks to protect health information

A House subcommittee approved and sent on to the full Energy and Commerce Committee H.R. 6357, the "Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008," known as the PRO(TECH)T Act, which is intended to strengthen the quality of health care, reduce medical errors and costs by encouraging adoption of health information technology, and further protect the privacy and security of health information in the electronic age.

"Your grocery store automatically knows what brand of chips you bought last year, but your cardiologist doesn't automatically know what prescriptions your family doctor prescribed for you yesterday," said committee chairman **John Dingell** (D-MI). "The PRO(TECH)T Act provides for adoption of standards to allow providers across the country to exchange health information about their patients. It also strengthens current federal privacy protections and expands them to new entities that store your electronic health information."

The legislation promotes nationwide adoption of a health information technology infrastructure and establishes incentives for doctors, hospitals,

insurers, and the government to exchange health information electronically across the country. It also makes permanent the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology and encourages use of an electronic health record for each person in the United States by 2014. And it would strengthen protection of security and privacy of individuals' health information through provisions such as requiring notification when personal health information is breached.

Different from Senate bill

The measure has several parallels to the Wired for Healthcare Quality bill that is pending in the Senate. Like the Wired bill, the House bill would codify in law the Office of the National Coordinator; establish committees to advise on development of health information technology policy and standards; authorize a voluntary product certification program similar to the one in operation at the Certification Commission for Health IT; provide loans and grants to support health IT adoption by doctors and clinics; and update HIPAA's privacy and security provisions.

But there also are some differences, analysts say. Thus, the Senate bill would establish a policy committee in the private sector, while the House measure calls for a federal advisory committee. And the House bill would extend HIPAA privacy and security rules to health information exchanges by defining them as business associates of health care providers, while the Senate measure would use a different means to the same end.

The House bill would empower the federal government to enforce privacy and security requirements that apply to HIPAA business associates and strengthen other HIPAA privacy and security provisions, while the original Senate draft would not address those issues. ■

National Provider Identifier finally takes effect

Mandatory use of the National Provider Identifier (NPI), which had been delayed from 2007, took effect May 23. Centers for Medicare & Medicaid Services officials said there were no early reports of abnormalities or significant problems in implementing the change.

HIPAA mandated use of NPIs to standardize the system of submitting claims and alleviate some of the confusion associated with multiple identifiers. During a grace period from May 1 to May 23, providers were required to use NPIs but could do so in conjunction with other ID numbers. But after May 23, Medicare claims had to list only the NPI to be eligible for payment. Claims coming in with numbers other than NPIs are being returned for adjustment and resubmission.

The NPI is a unique 10-digit number that does not carry other information about the health care providers it identifies, such as the state in which they practice or their medical specialty. ■

Surveys say: HIPAA affects health care IT decisions

Some 91% of health care IT decision makers and executives say that HIPAA regulations influence or strongly influence their IT purchasing decisions, according to a survey by electronic access management tool developer Imprivata. Six percent of respondents said HIPAA regulations were the primary drivers in IT purchasing decisions at their organizations, while 3% said the regulations are not considered very much in purchasing decisions.

And according to a survey by the Healthcare Information and Management Systems Society, 54% of health IT professionals said that the HIPAA privacy and security safeguards are strong enough, while 34% said they are not strong enough and 12% said they didn't know.

One-third of respondents said they believe that recent publicity on patient data breaches will slow electronic health record adoption. But 39% said they did not think it would affect adoption of electronic health records, and 13% said they think it will increase such adoption.

Some 40% of respondents said they believe that paper-based medical information is the most susceptible to a security breach, while 37% said they believe that medical information stored in portable devices is the most susceptible to a security breach, and 15% said medical information stored online poses the greatest risk. ■

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

Failure to diagnose brain abscess brings $3 million verdict in Pennsylvania

By **Jon T. Gatto**, Esq., and **Blake J. Delaney**, Esq.
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News: A woman suffering from headaches went to the hospital, where she was diagnosed with a tension headache and discharged with muscle relaxation and pain medication. Her headaches persisted, so she went to her primary care physician a couple of days later. Because the primary care physicians were not available, the woman was evaluated by a physician's assistant (PA), who diagnosed her as suffering from a sinus infection and prescribed steroids. Five days later, the woman returned to the hospital, at which time a brain abscess was discovered. Emergency brain surgery was performed, and the woman was left permanently debilitated. The woman and her husband sued the hospital, the primary care physician group, and the PA for negligence. After a jury trial, the hospital was absolved of liability, but a $3 million verdict was returned in favor of the plaintiffs and against the primary care physician group and its PA.

Background: A middle-aged real estate agent who had experienced headaches for the past few days went to the hospital, where an ED physician examined the woman, diagnosed her with a tension headache, and prescribed her muscle relaxation and pain medication.

Two days later, the woman still was suffering headaches — albeit not as severe — so she visited her primary care physician. Neither of the practice's primary care physicians was available to see the woman, however, and so she was examined by a PA, who determined that the woman was suffering headaches, nasal discharge, swollen eyes, red sinuses, and nausea. The PA diagnosed the woman's eye swelling as an allergic reaction and prescribed the woman steroids. The PA told the woman to undergo a sinus X-ray and blood work within a week.

Five days later, the woman developed stroke-like symptoms, including facial drooping and disorientation, and was taken back to the hospital. A CT scan performed at the hospital showed a brain abscess, and she was immediately airlifted to another nearby hospital. At the second hospital, doctors performed emergency brain surgery, in which part of her skull was removed and replaced with plastic.

Following the surgery and two months of hospitalization, the woman suffered respiratory failure and she was put on a ventilator. Within the month, she underwent subsequent brain surgeries to further remove the abscess and to repair inflamed brain tissue that had resulted from the prior operations. The woman ultimately lost vision in her left eye. She then entered intensive rehabilitation, during which she re-learned to walk and underwent cognitive treatment.

The woman and her husband sued the first hospital, the primary care physician group, and the physician's assistant for medical professional liability. As for the hospital, the plaintiffs argued that it failed to diagnose the woman's sinus infection upon her initial ED visit. The woman argued that had she been treated with antibiotics at that time, the progression of a brain abscess would have been prevented. To support her claims, the woman offered the testimony of an emergency medicine expert and an otolaryngology expert.

The woman argued that her primary care physician and the PA had breached the standard of care by failing to properly diagnose her with a sinus infection and by improperly prescribing steroids without prescribing an antibiotic along with it. The woman offered expert testimony that the steroids actually masked the sinus infection and exacerbated it. The woman also argued that the PA negligently failed to order tests on an urgent basis, given that she didn't completely know the cause of the woman's symptoms. And finally, the plaintiff pointed out that the primary care physician was approved by the state medical board to have a PA who could examine patients, but only so long as the physician subsequently examined the patient or evaluated the assistant's chart of that patient. The plaintiff contended that her primary care physician did not examine the patient or consult with the PA about her examination, which consequently breached the standard of care.

All of the defendants denied the allegations. The hospital contended that the ED physician properly treated the woman and that it was not negligent to not diagnose her with a sinus infection. The PA maintained that she appropriately treated the plaintiff and that the patient was comparatively negligent for not immediately receiving diagnostic testing following the PA's examination. The PA's internal medicine expert opined that it was unnecessary for the primary care physician to examine the patient or to confer with the plaintiff's chart, and that the physician did not breach the standard of care. And finally, the defendants offered the testimony of a neuropsychiatry expert to establish that the patient had suffered a frontal lobe injury that was fixed in terms of its severity and duration. The expert further testified that the woman's condition could worsen with age, as she was more susceptible to developing dementia, which could exacerbate the injury.

After an eight-day trial, a jury deliberated for five hours before returning a $3 million verdict in favor of the plaintiffs, with $2 million allocated to the woman to cover medical expenses and pain and suffering and $1 million allocated to the husband for his loss of consortium. The jury determined that the physician's assistant and the primary care physician had acted negligently but that the hospital and the ED physician were not liable. The primary care physician's practice indicated after the trial that an appeal would be forthcoming.

What this means to you: "All too often, a patient's initial visit to the emergency department does not resolve the patient's medical problems," says **Ellen L. Barton**, JD, CPCU, a risk management consultant in Phoenix, MD. "Thus, it becomes incumbent on the next provider (whether a return visit to the ED or the patient's primary care physician) to exercise a greater degree of scrutiny in examining, diagnosing, and treating a patient who presents within 24, 48, or 72 hours with the same or similar symptoms."

When the patient presented to her primary care physician's office and found no physician available, she was examined by a PA. "What is interesting is that there are more and more medical professional liability cases involving the actions or inactions of PAs and nurse practitioners [NPs]," says Barton. The roles and responsibilities of these individuals have changed tremendously over the past 40 years. Initially, the roles of PAs and NPs were to assist the physician in the provision of primary care for well children and those with acute minor illnesses. Over time, subspecialty areas developed for NPs and PAs have been used extensively in inpatient and outpatient surgery departments. It is easy to appreciate how economic pressures encouraged their increased use and expanded roles.[1]

Clearly, PAs and NPs can enhance the quality of a medical practice. However, the use of PAs and NPs in private practice can increase the risk of liability if these allied health practitioners' (AHP) roles and responsibilities are not clearly defined. A review of medical professional liability suits found the following factors specific to the practices of PAs and NPs[2]:

- Absence of policies and procedures.
- Absence of written practice guidelines.
- Failure of the PA or NP to refer to or collaborate with a physician.
- Inadequate supervision on the part of the physician.
- Assumption of too much responsibility on the part of the PA or NP.

In this case, the PA was aware that the patient had been seen two days previously in the ED. This should have been a signal to increase the level of scrutiny. Thus, the PA should have called on appropriate physician backup and, if it was not available, should have referred the patient back to the ED. The PA also could have referred the patient to a specialist and/or ordered additional tests (lab or X-ray) on an urgent basis. The PA also could have asked for the ED records and/or consulted with the ED physician so that there could have been a more thorough and collaborative review of the patient's progression of symptoms. The PA should have documented thoroughly and then had the

supervising physician review the case as soon as possible and call the patient within 24 or 48 hours to get a status report and thus create another opportunity to intervene.

Clearly, there was both a failure on the part of the PA to refer to the supervising physician or a specialist as well as inadequate supervision on the part of the physician. There should have been clear protocols on how the PA was to deal with the situation, especially considering that the patient had been to the ED only two days prior to her visit to her primary care physician. Perhaps the protocol would have said patients who are being seen for the same or similar symptoms within two days of a visit to the ED must be referred to a specialist.

Understanding the education and licensure of both PAs and NPs is the first step to developing appropriate roles and responsibilities for them. Based on the education and licensure of the PA and NP, the physician can develop a *Position Description* that specifies the specific duties of the AHP. This position description should define the scope of practice, taking into consideration state law and the education and licensure of the specific AHP. Some physicians may wish to enter into a *Practice Agreement* that details the collaborative practice arrangement between the AHP and the supervising physician as well as any "covering" physicians. Then the physician needs to develop *Policies and Procedures* that outline the hiring, training, evaluation, supervision, monitoring, and dismissal of AHPs. In making the decision to hire an AHP, the physician is committed to performing a *credentialing check*—including verification of education, training, and employment to assure clinical competence, and a criminal background check. Following such policies and procedures, *Practice Protocols* that identify which patients are appropriate for a PA- or NP-only visit, which patients require collaboration, and which require referral to the physician, need to be drafted. Until there is evidence that the PA or NP is practicing competently, the physician should monitor his or her practice closely and delegate more responsibilities only when the AHP's clinical competence is demonstrated.

The existence of these documents will clarify responsibilities so that there can be suitable collaboration and appropriate supervision with each health care provider playing the role he or she is competent to play and providing patients with the level of care they deserve.

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Aneurysm overlooked: $2.1 million verdict

News: A man went to the hospital after experiencing severe headaches. A physician's assistant (PA) diagnosed the man as suffering from a spinal headache, and a blood patch was performed to repair the hole where the spinal fluid was thought to be leaking out. Following the blood patch, the man was discharged home by a physician who did not make any notes in the chart or examine the patient. The man returned to the hospital later that night, and he soon thereafter lost consciousness and became comatose. Doctors eventually determined that the man had suffered a ruptured pseudoaneurysm of the vertebral artery, and surgery was performed to stop the bleeding. The man, who learned he would be wheelchair-bound and severely aphasic for the rest of his life, sued the hospital and the discharging physician for negligence. Shortly after the trial started, the parties settled for $2.1 million.

Background: A 62-year-old salesman underwent a hernia repair under epidural anesthesia. Over the course of the next few days, the man experienced persistent severe headaches. He called his hernia repair surgeon, who told him to go to the ED and who in turn called the ED to alert them that a man would be coming in with a possible spinal headache.

When the man arrived at the ED, a physician's assistant determined that he was having a spinal headache. The PA then spoke to the attending ED physician, who agreed with that determination, even though he never personally examined the patient. The PA then called an anesthesiologist to perform a blood patch to repair a hole where the spinal fluid was thought to be leaking out. Because the anesthesiologist was ending her shift, another anesthesiologist performed the procedure. Following the blood patch, the man was discharged by a physician who did not make any notes in the chart or examine the patient.

The man's headaches continued when he went home, and so he returned to the ED that same night. The attending doctor at the hospital examined the patient and again thought that the man was having a spinal headache. He called the anesthesiologist to perform a second blood patch, but the anesthesiologist refused and said the man needed a neurologist. An hour later, the man lost consciousness and became comatose. A CT scan showed a subarachnoid hemorrhage, and a drain was inserted.

The man was transferred to another hospital the following morning. An angiogram at the second hospital showed a ruptured pseudoaneurysm of the vertebral artery, and surgery — a "coiling" — was successfully performed to stop the bleeding. The patient remained in a coma for several weeks, and after he came out of the coma, doctors determined that the man would be wheelchair-bound and severely aphasic for the rest of his life.

The man sued the doctors, nurses, and PA who treated him at the first hospital, claiming that they failed to diagnose and treat a pseudoaneurysm, resulting in its rupture. The claims against all of the physicians, except for the physician who had discharged the patient, were eventually dropped.

As for damages, the man maintained that he and his wife were planning to move to Florida, but that he was going to work for several years more at his $72,000-per-year job. He consequently claimed loss of income and fringe benefits for five years, as well as past and future medical expenses and past and future pain and suffering.

The remaining defendants — the first hospital and the discharging physician — claimed that it was not negligence to treat the man for spinal headaches. They also claimed that even if he was having a bleeding aneurysm at the first ED visit, it was not clear that intervention was indicated. The defendants finally argued that even if the coiling procedure had been timely performed, the man's condition would not have been significantly different.

Following jury selection but before opening statements, the case settled for $2.1 million. The discharging physician's insurance carriers paid $1.85 million, and the hospital paid $300,000.

What this means to you: "In most, if not all states, a physician assistant is not an independent practitioner and is licensed to practice only under the direction of a sponsoring physician," says **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, LHRM, consultant/principal of The Kicklighter Group in Tamarac, FL. The defense of this case was that it was not negligent to treat the patient for a spinal headache. The question, however, whether the physician's assistant was qualified to make that diagnosis without the physician reassessing the patient personally? It appears that, other than the initial evaluation by the physician's assistant, no physician examined that patient on the first visit.

"Documentation can save you or sink you," she says. As risk managers, we have emphasized the need for legible, complete, and pertinent document as an ongoing campaign. Documentation by all caregivers is the method of communication used most frequently to communicate the status, evaluations and results of the critical thinking of the various caregivers based on this information and data. Incomplete information and data (read: failure to document) lead to incorrect critical thinking conclusions and next steps to care for the patient.

This regrettable situation could have been avoided through better communication. It appears that the "change-of-shift" malady played a large part in the situation. The first anesthesiologist who was contacted to perform the blood patch was leaving at the end of her shift, and the task shifted to the incoming anesthesiologist. It is unclear whether either of the anesthesiologists examined the patient personally, and also unclear whether the information given by the PA to the outgoing anesthesiologist was given to the incoming anesthesiologist.

Further, it is unclear whether the anesthesiologist who eventually performed the blood patch conducted an examination of the patient or reviewed the record to independently determine if the blood patch was the proper treatment. For the discharging physician not to have evaluated the patient prior to discharge and documented that evaluation is unacceptable. In view of the lack of discharge documentation, we cannot confirm whether there was a post-procedure, pre-discharge evaluation. "Handoff" communication between caregivers and at shift change is critical. In fact, it is an area that The Joint Commission assesses in its surveys.

"Lessons should be learned from this scenario," says Kicklighter. To that end, risk management should facilitate a root-cause analysis in that type of situation to identify why this happened and to initiate and facilitate preventive processes. Education of staff regarding legible, complete, and pertinent documentation also is a must in the follow-up of that type of case as well.

Reference

- Case No. 2146/03, Nassau County (NY) Supreme Court. ■