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HIPAA rule finalized to reduce worst of consent burden, prevent marketing use

As work begins on compliance, many providers are way behind

Some of the worst nightmares embedded in the Health Insurance Portability and Accountability Act (HIPAA) were removed from the final version of the rule, but there still is a great deal to be done if you are to make the compliance deadline.

To some observers, many risk managers are allowing their organizations to bog down in overwrought analyses instead of formulating the policies and procedures that must be in place within a few months.

When the Department of Health and Human Services (HHS) issued the final HIPAA rule recently, some provisions that had caused consternation over the past year were reworked significantly or deleted altogether. The most significant change involved whether explicit written consent would be required from patients for the disclosure of medical information during routine health care operations. Previous versions of the rule had required that providers obtain written consent from the patient for the use of protected medical information during treatment, and treatment could not proceed without that expressed permission. But in the final HIPAA rule, HHS took a less strict stance and said that such explicit consent is not necessary.

Instead, covered entities will have to provide patients with a written statement explaining the provider's privacy practices and individual privacy rights. HHS still wants providers to try to obtain a patient's written acknowledgment of that statement, but if that is not possible or practical, it is sufficient to show that the provider made a good-faith effort.

Barrie K. Handy, JD, an attorney with the law firm of Davis Wright Tremaine in Seattle, says HHS has responded to the concerns of many risk managers that the notice of privacy practices was too long.

"The preamble encourages use of a 'layered notice' — a short, summary notice that is placed on top of a longer notice containing all the required elements," he says. "This grant of authority, though it comes in the preamble rather than in the rule itself, will be welcome news to a vast number of plans and providers."

In addition, the final rule allows disclosure for treatment, payment, and certain health care operations of other covered entities; reduces accountable disclosures; and permits an extra year to achieve compliance for pre-existing business associate agreements. Covered entities, meaning nearly anyone who transmits patient information to another party, will have until April 14, 2003, to comply with HIPAA.

Signing cover sheet is enough proof

When providing the patient notice of privacy practices, the patient's acknowledgment must be in writing, but the rules do not prescribe a form, or require the individual's signature to be on the notice itself. Instead, a covered health provider may, for example, have the individual sign a separate sheet or simply initial a cover sheet of the notice.

Handy says that in emergency situations, the notice must be provided as soon as is reasonably practical, and an acknowledgment is not required. If a provider cannot obtain the written acknowledgment, it must document its efforts and the reason for its inability to obtain the acknowledgment. The attempt must be made no later than the date of first service delivery, including service delivered electronically. A health care provider whose first treatment encounter with a patient is over the telephone may satisfy the notice requirement by mailing it to the individual no later than the day following the telephone conversation, he says.

HHS recommends that the notice include a tear sheet or other document that requests an acknowledgment be mailed back to the provider. If the individual chooses not to mail the acknowledgment back, the provider has made the necessary effort. If the health care provider's initial contact with the patient is simply to schedule an appointment, the notice and acknowledgment requirements may be satisfied when the patient arrives for the appointment.

Most of the final HIPAA rule was the same as the revisions proposed in March 2002, but health care providers apparently are not getting started on compliance until the last minute, says **Jack A. Rovner**, JD, partner and co-chair of the Chicago Health Law Practice Group with the law firm of Michael Best & Friedrich in Chicago. He works closely with risk managers and others responsible for complying with HIPAA, and says he is dismayed at what he has seen so far.

"What I see them doing and what they should be doing are not necessarily the same thing," Rovner says. "If you haven't started drafting your policies and procedures, that's what you should be working on right now. The secret to compliance is having a set of policies and procedures that actually reflect your business processes, and implementing privacy requirements that address your actual business. I don't see a lot of that happening yet."

Many health care providers have been working on HIPAA compliance for months, Rovner says, but they often get bogged down in the analyses and retrospective assessment of how they have handled privacy issues in the past. That kind of analysis has a place in planning for HIPAA compliance, but many providers devote way too much time to it, he says.

"People have avoided focusing on the hard work of drafting policies and procedures, and instead they're spending time on gap assessments — saying this is what we used to do and this is what we need to do," he says. "You feel like you're doing something; but if you do too much of that, you'll find yourself without policies and procedures on April 14."

Rovner advises risk managers to avoid focusing on what they did with private health information last year. That's not so important, he says. The more important question is what you will do with it next year. He points out that health care organizations already protect private health information and always have to some extent, so it's not like HIPAA requires a wholesale reworking of your system. The biggest challenge, he says, will be to effect a cultural change that prompts your employees to think more about protecting a patient's privacy to make that attitude second nature.

One major headache from the proposed HIPAA rule was eliminated by changes that assure health

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care providers won't be prevented from carrying out normal, necessary transmissions of information. Previous versions led to fears that no information could be sent from one provider to another without the patient's specific permission. But the final rule allows a covered entity to disclose protected health information to any provider for the latter's treatment activities and to another covered entity or any provider for its payment activities. Rovner explains that the rule also allows a covered entity to disclose protected health information to another in order for the second organization to conduct quality control, competency control, or fraud control operations, as long as each has a relationship with the patient and the information pertains to that relationship.

Though HHS eased its position on some HIPAA issues, it took a hard line on marketing. The final HIPAA rule still prohibits providers from selling patient names to any marketers, such as pharmaceutical companies, without first getting the patient's specific authorization. That was exactly the situation that led to a class-action lawsuit recently in Florida. The suit alleges that Walgreens pharmacy, a local hospital, three doctors, and Indianapolis drug manufacturer Eli Lilly & Co. misused patient records for a marketing campaign that mailed free samples of Prozac to people whose records indicated they might benefit from the drug. One recipient filed a lawsuit, saying he felt his privacy was invaded when Holy Cross Hospital in Fort Lauderdale, FL, and three doctors provided specific patient information for the drug marketing.

And to address a gray area that some providers had noted, HHS made clear that covered entities cannot use business associate agreements to get around HIPAA's requirements regarding marketing. The final rule explicitly prohibits pharmacies or other covered entities from selling personal medical information to a business that wants to market its products or services under a business associate agreement.

Handy says the business associate agreements need the attention of risk managers. HIPAA permits a covered entity to disclose protected health information to a business associate who performs a function or activity on behalf of the covered entity that involves the creation, use or disclosure of protected health information, so long as the covered entity enters into a contract with the business associate containing specific privacy safeguards, Handy explains. The April 2003 compliance date may not provide enough time for large hospitals to reopen and renegotiate their business associate agreements unless you start working immediately, he says.

The final rule takes the same approach to the "minimum-necessary" concept as generally proposed in March. Handy explains that the concept of minimum necessary means that covered entities and their business associates should not use or disclose protected health information beyond what is reasonably necessary for the purpose of the use or disclosure. But HHS allows for some exceptions. For example, minimum necessary does not apply to a covered entity's use or disclosure to another health care provider for treatment purposes. However, it does apply to uses or disclosures for payment and health care operations.

The final rule exempts from minimum necessary restrictions all uses or disclosures for which the covered entity receives an authorization from the individual to whom the health information pertains or the individual's authorized representative. HHS emphasizes that any authorization must include a description of the information covered "in a specific and meaningful fashion."

Like Rovner, Handy cautions that there is significant work to be done before April 2003. They both advise reading the HIPAA rule carefully, including the preamble, to determine what changes may be necessary in your policies and procedures. HHS's explanations in the preamble probably "create or enhance legal duties that covered entities need to

identify and keep in mind for risk management purposes," Handy says. (To see the entire HIPAA rule at the HHS web site, go to www.hhs.gov/ocr/hipaa.)

However you approach HIPAA compliance, Rovner says you must avoid being paralyzed by the fear that HIPAA will turn your world upside down. That fear is not justified, he says.

"I don't think people have taken a rational approach to HIPAA and that's why we're not very far along in compliance," he says. "There's too much hysteria. It's complicated and requires work, but it's not what everyone has made it out to be. It is not the end of health care as we know it." ■

Sentinel events now linked to nursing shortage

New information shows that the nursing shortage is responsible for a quarter of sentinel events and poses a major risk to patient safety.

Now the Joint Commission on Accreditation of Healthcare Organizations says the time has come to act. The Joint Commission recently issued a major report, "Health Care at the Crossroads: Strategies for Addressing the Evolving Nursing Crisis," and held a news conference to call for immediate action. Broad changes are needed in the health care industry to keep patients safe, says **Dennis S. O'Leary**, MD, Joint Commission president.

"We now have clear data linking nurse staffing levels to quality of care," he says. "We didn't have that before."

The report states that the nursing shortage "is putting patient lives in danger and requires immediate attention," leading a special Joint Commission roundtable to develop a set of recommendations. Some of those recommendations involve legislation and other action on a nationwide level, but O'Leary says there also is much to be done in individual facilities. A primary goal of the roundtable's recommendations is to improve the work life of nurses.

He and the other roundtable members stress that the nursing shortage is no longer just an administrative problem. The data now show a direct, troubling link between the nursing shortage and major medical errors that lead to sentinel events. **Marilyn P. Chow**, RN, DNSc, FAAN, vice president of patient care services for the California Division of Kaiser Permanente, says, "We have elements of a perfect storm brewing. Aging nurses and faculty, fewer people coming into the profession, and an aging population. We need to intervene now to prevent that perfect storm from occurring."

O'Leary called the nursing shortage "a prescription for disaster."

He and the other experts repeatedly draw attention to the data, to illustrate that the connection between patient safety and the nursing shortage is more than just theoretical. Joint Commission analyses show that nurse-staffing levels have been a factor in 24% of the 1,609 sentinel events that have been reported to the Joint Commission over the past five years. Chow says that nursing shortages could be an underlying cause when other contributing factors, such as patient assessment, caregiver orientation and training, communication, and staff competency led to the sentinel event.

The link can be broken, O'Leary says. Studies have shown a positive impact on patient safety when nurse-staffing levels are optimized. More nurses mean fewer complications, fewer adverse events, shorter lengths of stay, and lower mortality, he says.

The nursing shortage didn't happen overnight and won't be solved overnight, O'Leary says. For years, providers have seen a combination of long-standing shortages in the nursing field and rapidly increasing demands for more nursing care. More than 126,000 nursing positions are unfilled now, and O'Leary says that figure will climb as 78 million aging baby boomers begin placing unprecedented demands on the country's health care system.

"Ninety percent of nursing homes report an insufficient number of nurses to provide even the most basic of care, and some home health agencies are being forced to refuse new admissions," he says.

To make things worse, currently working nurses are aging right out of the workplace. The average age of a working registered nurse today is 43.3, according to the Joint Commission, and that average age is increasing at a rate more than twice that of all other work forces in this country. Researchers project that by 2010, the average age of the working registered nurse will be 50.

Too few nurses and overworked nurses put patients directly at risk, says **Sally A. Sample**, RN, MN, FAAN, moderator of the Joint Commission's nurse staffing roundtable and former commissioner

of the Joint Commission. In a recent survey cited in the Joint Commission's report, 31% of nurses reporting that patients in their last shift did not receive necessary skin care, 20% saying patients did not receive oral care, and 28% saying that they were unable to provide adequate education and instruction to patients and their families. Studies also have shown that overworked nurses don't wash their hands often enough, leading to more nosocomial infections.

When nurses are in such short supply, you also may end up with more new, inexperienced nurses. That can be a significant liability risk when patient safety is threatened, Sample says. Experienced nurses are better able to do several things at once without sacrificing quality of care, she says. Too many of those experienced nurses are quitting the nursing profession or moving on to more appealing work environments such as home care.

"The newer nurses are not as capable of doing these multiple tasks, and that poses an increasing risk to patients," she says. "You may have replaced a nurse with another nurse, but the quality of care isn't the same."

16 steps you can take to address the problem

The Joint Commission's roundtable recommended 16 steps that providers can take immediately to help address the nursing shortage. The roundtable members urge risk managers and other hospital leaders to organize local solutions and not depend entirely on the work being done on a national level. These are the Joint Commission's recommendations:

1. Create a culture of retention for nursing staff.
2. Adopt the characteristics of magnet hospitals to foster a workplace that empowers and is respectful of nursing staff.
3. Provide management training, as well as support, to nurse executives.
4. Delegate authority to nursing executives and other nurse managers, and in turn to staff nurses, for patient care and resource deployment decisions.
5. Positively transform nursing work through the use of information and ergonomic technologies. Adopt information, ergonomic, and other technologies designed to improve workflow and reduce risks of error and injury.
6. Minimize the paperwork and administrative burden that takes nursing time away from patient care.
7. Measure, analyze, and improve staffing effectiveness.
8. Set staffing levels based on nurse competency and skill mix relative to patient mix and acuity.
9. Limit the use of mandatory overtime to emergency situations.
10. Adopt zero-tolerance policies for abusive behaviors by health care practitioners who work with nurses.
11. Diversify the nursing work force to broaden the base of potential caregivers.
12. Increase funding for nursing education, including endowments, scholarships and federal appropriations.
13. Establish a standardized, postgraduate nursing residency program.
14. Emphasize team training in nursing education.
15. Enhance support of nursing orientation in-service and continuing education in hospitals.
16. Adopt fair and competitive compensation and benefit packages for nursing staff. Use nursing career ladders commensurate with educational level and experience. ■

Creative solution allows trauma center to reopen

A unique solution allowed a Nevada trauma center to reopen 10 days after it closed because liability concerns forced almost all of its orthopedic surgeons to quit treating patients.

The experience shows just how hard the country's liability crisis can hit a single hospital, and it also illustrates a creative remedy that other facilities might be able to use.

The malpractice insurance crisis has hit Nevada physicians particularly hard because, unlike many states, they are not protected by a cap on pain and suffering. A history of multimillion-dollar jury awards combined with other pernicious trends in the insurance industry to cause staggering increases in medical malpractice liability premiums for Nevada physicians, especially those involved in high-risk surgery such as orthopedics. In July, the burden became too much for the 70 orthopedic surgeons on call for the University of Nevada Medical Center in Las Vegas, says hospital spokesman **Rick Plummer**.

"One trauma surgeons' liability insurance went from $40,000 to $250,000 a year," he says. "If they paid that, they would actually be paying more than they make. So they said no; they'll have to go

practice somewhere else."

In July, almost all of the orthopedic surgeons resigned from the trauma unit at the medical center, which treated 11,439 people in 2001. When the surgeons resigned, the hospital had no choice but to close down the trauma center immediately.

"We have other surgeons on call, but orthopedic surgeons are called in on most of the traumas because people are coming in broken up from accidents," Plummer says. "You can't run a trauma center without orthopedic surgeons, and they're taking on patients who are at high risk, with very serious injuries."

The surgeons were not employed by the hospital; they were all individual surgeons or members of surgery groups that were privileged at the hospital. They all resigned from the trauma center over the course of a few days, and hospital officials knew it would be nearly impossible to replace them. Nevada usually ranks 49th or 50th (depending on the source) among states in physician-per-capita ratios, and many physicians are leaving the state because of the liability crisis, Plummer says. St Paul's, a major player in the malpractice insurance business, recently pulled out of Nevada because the lack of liability caps left the insurer holding the bag for major awards.

Since St. Paul's had marketed aggressively against other insurers, Plummer says the insurer's withdrawal from the state left 60% of Nevada physicians scrambling for coverage just as their rates were climbing sky high. **(See p. 115 for more on the continuing liability crisis and the federal government's response.)**

More than 1,300 hospitals in the United States have curtailed service or closed units because of the liability crisis, according to a recent survey by the American Hospital Association. The survey found that 20% of the nation's hospitals had cut back on services and another 6% had locked the doors on treatment units. Many of those were obstetric units, where escalating malpractice premiums drove physicians out of practice.

Hospital hires surgeons to protect them

Closing the trauma center was a major blow to the community because it would mean Las Vegas residents would have to go at least 180 miles to the nearest trauma center. Members of the emergency room staff at the University of Nevada took classes in trauma procedures, and other hospitals in the area set aside operating rooms to handle trauma cases that otherwise would have gone to the university's trauma center. But those steps were inadequate, and it was clear to everyone that drastic action was needed to reopen the trauma center, Plummer says.

Government officials initiated action on two levels. First, Nevada Gov. Kenny Guinn called a special session of the state Legislature to consider a measure that would permanently cap jury awards in malpractice suits. But in the meantime, the University of Nevada needed to find a way to reopen its trauma center as quickly as possible. Thinking creatively, they found a temporary measure that worked.

"Our county commissioners actually hired these orthopedic surgeons under contract, on a temporary basis," Plummer explains. "By hiring them, they were protected under the medical center's liability cap, which limits punitive damages to $50,000 because we're a public county hospital. By putting them under a 45-day contract, we were able to reopen while waiting for the special legislative session."

The biggest hurdle in implementing that solution was determining whether the medical center's caps would extend to the physicians under the temporary contract. The county requested an opinion from the state attorney general, who determined that the caps did apply. With that assurance, the orthopedic surgeons agreed to work under the temporary contract and the trauma center reopened 10 days after it closed.

A special session by the state legislature resulted in new liability caps for Nevada physicians — $350,000 for pain and suffering and $1 million combined liability for a single malpractice case. With those caps in place, orthopedic surgeons in Nevada were expected to have an easier time finding reasonable malpractice premiums after the 45-day hospital contract ended.

The American Medical Association (AMA) has repeatedly expressed concern about the liability threat facing trauma centers. In the most recent situation getting the AMA's attention, tens of thousands of West Virginians found themselves without a Level I trauma center. The West Virginia Department of Health and Human Services recently downgraded the Charleston Area Medical Center to Level III status because the center does not have enough orthopedic surgeons to staff the center 24 hours per day, seven days per week. The shortage of orthopedic surgeons was caused by the same problem seen in Nevada — liability concerns.

The only other Level I trauma center in West Virginia is more than 150 miles from Charleston

and frequently inaccessible by helicopter during the fall and winter months.

The AMA strongly supports reforms contained in HR 4600 and S 2793 — federal legislation based on California's MICRA law, which has protected California's patients and physicians for more than 25 years. Medical liability reform is the AMA's top legislative priority, according to **Donald Palmisano**, MD, president of the AMA.

"While lawmakers debate the merits of much-needed, long-term liability reform, they should realize that continued inaction means more patients will have a harder time finding needed medical care as specialists continue to leave the state and fewer, if any, physicians begin a practice in West Virginia," Palmisano says. "This is as dire as it gets."

The situation was very similar in Nevada, Plummer says. Physicians and risk managers had complained long and hard about the growing liability crisis, but legislators had not acted. It wasn't until St. Paul's left the state, leaving so many physicians without coverage, that the issue came to a head and a special session was called.

"I would hope that others states and other hospitals would learn from Nevada and not let it go as far as we did," Plummer says. "Nevada was one of nine states without a cap on punitive damages or pain and suffering, and every single state is facing what Nevada faced. Even though we got our trauma center back open, this was a tough experience." ■

HHS calls for federal action to stem malpractice crisis

The malpractice crisis is so bad that the federal government should take action to rein in the trial lawyers and others who abuse the system, according to a new report from Health and Human Services Secretary Tommy G. Thompson. His report calls for new federal legislation to "squeeze the excesses and abuses out of the malpractice litigation system," but it also calls on providers to admit their errors and offer compensation quickly.

The report says Americans increasingly are finding that their doctors are closing their practices, limiting the types of patients they will see, or leaving communities where they have long practiced because they cannot afford the rapidly increasing cost of malpractice insurance or because it is simply not available.

Thompson called for an end to "the malpractice litigation lottery that favors a handful of powerful personal injury lawyers." The report, "Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs By Fixing Our Medical Liability System," highlights the problems created by the rising costs of malpractice insurance for doctors and hospitals — particularly in states that have not reformed their legal systems. The report cites estimates showing the cost of malpractice insurance for specialists has risen more than 10% in recent years and could increase by an average of 20% or more this year. States without any limits on noneconomic malpractice damages are experiencing the sharpest increase — from 30% to 50%.

It also details these other threats to quality health care caused by rising malpractice costs:

- **Patients undergo unnecessary tests and treatments as doctors and hospitals practice "defensive medicine" to ward off potential malpractice lawsuits.** This exposes patients to additional risk and drives up the cost of health care.
- **Fears of malpractice litigation may stop doctors and hospitals from reporting adverse events and potential errors to quality improvement groups — reducing the chances that potential threats to patient safety are identified and corrected before anyone is hurt.**
- **Doctors are avoiding high-risk specialties, such as obstetrics and surgery, due to the excessive costs of malpractice insurance.** Hospitals also may drop high-risk services, such as trauma care and emergency departments, to reduce their insurance costs.
- **Fearing malpractice litigation, retired physicians and others health care professionals are choosing not to volunteer their services at community clinics and other locations that people without health insurance rely on for needed care.**

The report calls for key national reforms that would both strengthen patient safety and quality improvement efforts by making it possible for doctors to collaborate to identify problems and fix them, and establish reasonable limits on noneconomic damages in malpractice cases. The report also suggests ways to reform the way lawsuits are conducted and to avoid litigation in the first place. It suggests adoption of a plan called Early Offers that would encourage doctors to offer economic compensation to injured patients soon after an adverse event and encourage patients to accept them. In this way,

patients would be assured of fair compensation quickly and without having to undergo the long delays, great expense and trauma of litigation.

The report also suggests adoption of strengthened medical review panels that would provide streamlined disposition of malpractice claims, with incentives for doctors and patients to use them and accept their judgments. ■

Doc suspended for leaving patient in OR to go to bank

A Massachusetts doctor has been suspended for leaving a patient on the operating table so he could rush to the bank and deposit a paycheck.

The state board of medicine suspended David Arndt, MD, an orthopedic surgeon, saying he posed "an immediate threat to the public health, safety, and welfare" of patients. The doctor is accused of leaving in the middle of spinal surgery so he could make it to the bank before closing. The patient was left in the care of the rest of the surgical team and apparently did not suffer any adverse outcomes.

"In its Statement of Allegations, the Board charged that Dr. Arndt abandoned his anesthetized patient in the Mount Auburn Hospital operating room to go to a bank in Harvard Square during the surgery," the board wrote. Documents provided by the board indicate that the surgeon who remained with the patient was not qualified to complete the surgery, and that Arndt was gone for 35 minutes. After returning from his errand, Arndt, a graduate of Harvard Medical School, completed the surgery in a few hours. The patient was anesthetized the entire time.

According to the board's Statement of Allegations against the doctor, Arndt explained that he was eager to deposit his paycheck because he had overdue bills to pay. The hospital suspended him the next day and reported the incident to the state board. ■

Newest patient safety goals require immediate action

Confusion in identifying patients, miscommunication among caregivers, wrong-site surgery, infusion pumps, medication mix-ups, and clinical alarm systems are the focus of the National Patient Safety Goals for 2003 set by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Each of the National Patient Safety Goals is accompanied by recommendations to help health care organizations reduce specific types of health care errors. Beginning Jan. 1, 2003, the more than 17,000 JCAHO-accredited health care organizations that provide care relevant to the goals will be evaluated for compliance with the recommendations or implementation of acceptable alternatives. The 2003 goals were developed by an expert advisory group composed of physicians, nurses, risk managers, and other professionals, says **Henri R. Manasse Jr.**, PhD, chair of the Sentinel Event Advisory Group, executive vice president and CEO of the American Society of Health-System Pharmacists, and past chair of the National Patient Safety Foundation.

The goals and related recommendations were drawn from the 25 issues of the Joint Commission's *Sentinel Event Alert* publication. The advisory groups identified a total of 44 expert- and evidence-based recommendations from the publication that include the 11 associated with the 2003 goals. The remaining recommendations may be used for developing future National Safety Goals, Manasse says.

"The goals and recommendations selected by the advisory group are all high-impact, low-cost targets," he says. "This initiative should really make a difference in improving patient safety."

Here are the 2003 National Patient Safety Goals and Recommendations:

• Goal 1: Improve the accuracy of patient identification.

Recommendations:

— Use at least two patient identifiers (neither to be the patient's room number) whenever taking blood samples or administering medications or blood products.

— Prior to the start of any surgical or invasive procedure, conduct a final verification process, such as a "timeout," to confirm the correct patient, procedure and site, using active — not passive — communication techniques.

• Goal 2: Improve the effectiveness of communication among caregivers.

Recommendations:

— Implement a process for taking verbal or

telephone orders that requires a verification "read-back" of the complete order by the person receiving the order.

— Standardize the abbreviations, acronyms, and symbols used throughout the organization, including a list of abbreviations, acronyms, and symbols not to use.

• Goal 3: Improve the safety of using high-alert medications.

Recommendations:

— Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units.

— Standardize and limit the number of drug concentrations available in the organization.

• Goal 4: Eliminate wrong-site, wrong-patient, and wrong-procedure surgery.

Recommendations:

— Create and use a preoperative verification process, such as a checklist, to confirm that appropriate documents, (e.g., medical records, imaging studies) are available.

— Implement a process to mark the surgical site and involve the patient in the marking process.

• Goal 5: Improve the safety of using infusion pumps.

Recommendations:

— Ensure free-flow protection on all general-use and PCA intravenous infusion pumps used in the organization.

• Goal 6: Improve the effectiveness of clinical alarm systems.

Recommendations:

— Implement regular preventive maintenance and testing of alarm systems.

— Assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit. ■

Physician surveys could be used in malpractice cases

Attorneys commonly hire experts to provide testimony about whether the way a physician cared for a patient was negligent or met customary care standards, but too often that testimony of expert witnesses may be biased or uninformed. New research suggests that a better way of providing expert opinion on standard of care in medical malpractice cases may be to randomly survey a group of peer physicians and use their collective responses to identify customary care.

Research from the University of Iowa in Iowa City suggests that the survey method could yield more useful information than expert testimony. *[J Gen Intern Med* 2002; 17(7):546-55]. The survey method shows promise as an objective method to assess usual practice for specific medical problems, says **Arthur Hartz**, MD, PhD, the Quality in Medicine Professor in the University of Iowa Department of Family Medicine and the study's principal author. Results from such surveys can be used in court or in settling a case before trial, he says.

The investigators focused on seven primary care medical malpractice cases: three actual closed cases, three variations of two of those cases, and one active case. In all the cases, the facts of a patient's symptoms were not disputed, but the physician did not make the correct diagnosis or failed to refer the patient to a specialist.

Survey could address question of bias

The important question was whether the majority of peer group physicians would have made referrals or ordered diagnostic tests, necessary steps to make the correct diagnosis, Hartz says. Cases where the issue is failure to diagnose in a timely way make up about one quarter of all medical malpractice cases nationwide.

"Underlying such cases is the question of customary care — whether the defending physician practiced mainstream medicine," Hartz says. "Because referrals and tests are costly and sometimes risky to the patient, they cannot be ordered in all cases. The question in medical malpractice cases is whether most physicians would have ordered the tests for patients who are similar to the plaintiff."

Typically, jurors must decide how most physicians practice based on the testimony of a few medical experts, who may give conflicting opinions. Because jurors lack the medical expertise to judge the substance of the testimony, Hartz says they must rely on the experts' style and credentials, which are fallible indicators of accuracy.

"The most common criticism of expert witnesses is they are biased because they are hired and prepared by each party's attorney. To reduce bias, it has been suggested that judges, not lawyers, bring in one or two medical experts. However, unbiased witnesses may also be wrong," Hartz says. "Few physicians know how others practice. Our research suggests that most physicians think others practice

the same way they do."

Michael Green, JD, a former faculty member of the University of Iowa College of Law who contributed to the study and now is at Wake Forest University School of Law in Winston Salem, NC, says the system of using expert witnesses is disliked by nearly everyone — even those who use it regularly — so a new survey system might be welcomed.

"The difficulties with adversarial expert witnesses are well known and have generated significant efforts at reform," Green says.

The physicians surveyed in the study all practiced in Iowa. The surveys included responses from 219 of 350 queried community family physicians (an almost 63% response rate) and 110 of 216 queried community specialists (a 51% response rate). In addition, responses were received from 91% of 54 academic family physicians and 51% of 54 academic specialists.

For the three closed cases, 47%, 78%, and 88% of the family physicians surveyed said they would have made a different referral decision than the charged doctors did. For these three cases, testimony was available from the opposing medical experts on the actual case. In addition, for each closed case, 65% or more of the surveyed physicians disagreed with testimony from one medical expert.

The three variations on two of the actual cases helped the investigators determine that physician judgments depended on the quality of the medical management more than the severity of the outcome. In one case, the patient died of a heart attack but had atypical symptoms of heart disease. The majority of physicians determined that the physician charged with malpractice had acted adequately even though the patient died.

In another of the closed cases, a young woman did not receive a timely diagnosis of appendicitis. She survived, but suffered due to the missed diagnosis. In that case, the vast majority, 80%, of the physicians surveyed determined that the defending doctor had provided inadequate diagnostic care, even though the case did not result in death.

"That type of information may be more helpful to the jury than the conflicting testimony of two adversarial experts, or it may help the jury break a tie when confronted with conflicting testimony," Green says.

To survey physicians, the researchers summarized each medical malpractice case with a one-page abstract. "We were able to simplify the cases without distorting them," Hartz said.

In addition, the study showed that physicians were interested in medical expert testimony. Hartz said he expected a 25%-35% response rate; instead, 63% of the family physicians contacted responded to the survey.

"This high response rate without compensation shows that physicians believed the study was important and not burdensome," Hartz says.

Hartz says that response rates may be even higher if the surveys are sponsored by medical societies and physicians are compensated for their time. However, the authors also recognize that it is a big step from testing this method in a research study to having it widely adopted in the courts.

"The research shows that the surveys are practical and provide valuable information. The next step is to find out how they can be used in practice. We want to find lawyers who will use this method," Hartz says.

He added that a serious concern, usually held by plaintiff's lawyers, in medical malpractice cases is whether physicians are prone to professional allegiance and will, unconsciously or not, strive to protect one another. He says the study revealed that, overall, physicians are willing to criticize each other.

"There may be a small group of physicians who will not criticize care they know to be bad. However, the majority of the physicians in our study were critical of the physician defendants. When surveyed physicians supported the defendant, the support was usually well reasoned," Hartz says. He calls the current malpractice system unfair to both physicians and patients.

"If physicians have a chance to improve the system, they will. They would only hurt themselves by defending bad care," he says. ■

Jury awards $2.2 million for shoulder dystocia case

A Berks County, PA, jury awarded an infant and his parents $2,289,856 against the Reading Hospital and Medical Center and Fredericka Heller, MD, in a medical malpractice case involving issues surrounding the labor and delivery of the baby.

Bailey Boyer was born on May 8, 1998.

During the course of the delivery, Bailey developed shoulder dystocia. The issues at trial concerned Heller's efforts to dislodge the shoulder, as well as those of the nursing staff in attendance. The plaintiffs alleged at trial that Heller

used improper techniques and excessive traction in attempting to dislodge the shoulder, causing several of the major nerves of the brachial plexus to be torn from Bailey's spinal cord. This left him with severe and permanent limitations in the use of his right arm and hand.

Central to the plaintiffs' allegations was the fact that the actions allegedly taken by Heller and the nursing staff to dislodge the shoulder were not documented in the hospital records, says **Wayne R. Spivey**, JD, an attorney with the Philadelphia firm of Shrager, Spivey, and Sachs. The plaintiffs established at trial that Bailey had been turned 180 degrees after the shoulder had impacted but before any of the standard maneuvers had been performed. The plaintiffs contended that the avulsion or tearing of Bailey's spinal cord nerves occurred during the course of this 180-degree turn and was the result of excessive traction applied to the baby's head.

The defendants denied responsibility and claimed that standard and accepted procedures were followed in the management and care of Bailey's shoulder dystocia. Bailey subsequently underwent three surgical procedures at Texas Christian Hospital in Houston in an effort to restore some function to Bailey's arm and hand. The plaintiffs proved at trial that the severity and permanency of Bailey's brachial plexus injury would require him to undergo multiple additional surgical procedures in the future as well as extensive physical rehabilitation and therapy. As a further result of the permanent physical limitations associated with Bailey's brachial plexus injury, the plaintiffs also established at trial that Bailey had suffered a significant lifetime loss of earning capacity.

The jury found that both defendants were negligent in the labor and delivery of Bailey and apportioned liability evenly — 50% against Reading Hospital and Medical Center and 50% against Heller. ■

Hospital fined, live liver transplants banned

Serious safety violations in the live liver transplant program at Mount Sinai Medical Center in New York City warrant an indefinite ban on the procedure and $66,000 in fines, according to **Antonia C. Novello**, MD, New York state health commissioner. The state's action prevents the hospital from performing a procedure that has been growing in popularity and which is seen as a giving new hope to patients needing transplants.

The ban and fine were the result of what Novello calls the state's largest-ever investigation into a health institution. The inquiry found 33 serious violations, mostly in the liver transplant unit, and the commissioner levied fines of $2,000 each, the highest allowed by law. Novello said in a news conference that the findings were disturbing.

"Due to the severity and widespread impact of these violations, I cannot allow Mount Sinai Medical Center to reopen its living donor adult liver transplant program," she said.

The investigation was prompted by the death of a healthy 57-year-old man who was donating part of his liver to his brother. According to the health department, the donor choked on his own

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blood in a ward filled with 34 postoperative patients under the care of one first-year resident. The health department already has imposed a $48,000 fine after an initial investigation revealed that the death was caused by "woefully inadequate post-surgical care." Further investigation revealed more problems, such as the failure of a surgeon to check on a patient after an operation, and failure to protect patients from falling. Records indicated that in 10 transplant cases, the surgeon named on the consent form was not the surgeon who performed the procedure.

To revive its live transplant program, Mount Sinai must develop a comprehensive plan to address the problems and undergo a thorough inspection by the health department, Novello said. Mount Sinai issued a statement saying that many of the problems already have been addressed and that the hospital is working closely with the health department. ■

Audio conference clarifies final EMTALA regulations

The final version of the recently proposed changes to the Emergency Treatment and Labor Act (EMTALA) is expected to become effective on Oct. 1. Issues in the final regulations could include changes to physician on-call requirements, "comes to the emergency department" definitions, later-developed emergencies, non-hospital entities, and prior authorization. With all the confusion surrounding the proposals during the past year, make sure you know what it takes to comply with the final regulations.

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Brain damage leads to partial paralysis and a $3.25 million New York settlement

By **Jan J. Gorrie**, Esq., and **Seema Patel**
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News: A patient suffered a grand mal seizure, and CAT scans indicated the cause as an arachnoid cyst. The attending neurosurgeon recommended surgery to drain the cyst, relieving the pressure and seizures. The patient and his wife were given an explanation of a relatively simple stent procedure. However, after plaintiff was under anesthesia, the surgeon described to the wife a far more complicated procedure requiring a stent be placed into the basilar cistern of the brain. When the wife asked the surgeon to consult with her husband before performing the more complex procedure, he ignored her and performed the more difficult procedure.

The surgeon hit the basilar artery and its vasculature when he inserted the stent, causing brain damage.

The case settled for $ 3.25 million, with both the physician and hospital contributing.

Background: Although the patient was a healthy 49-year-old man with no prior history of seizures, he suffered a grand mal seizure at his home. He was taken to the hospital emergency department, where a CAT scan showed that an arachnoid cyst had triggered the seizure. The neurosurgeon advised the patient that treatment included surgical procedure to drain the cyst.

The neurosurgeon told the patient and his wife stating that the surgical procedure involved making an opening in the skull, running a drain down only as far as to the layer of the cyst, draining the fluid in the cyst, and placing a peritoneal shunt so that the fluid would continue to drain. As described by the neurosurgeon to the patient, the shunt was a tube, which would be placed in the hole in the skull and through the gap of the arachnoid layer just below the first layer of the skull. The tube would run under the skin behind one ear, through the neck and chest, and into the abdomen. Although the procedure sounded complicated, the neurosurgeon described it as relatively simple because it did not require cutting into the brain. The patient and his family agreed to the procedure, which was to be performed three days later.

On the day of surgery, the patient was given a pre-anesthesia sedative and prepped for the procedure. The neurosurgeon met the patient's wife in the waiting area and explained the procedure. However, this time the neurosurgeon described that he would be placing the stent into the basilar cistern of the brain, which required him to cut into brain tissue. The patient's wife said that was not the treatment explained to them previously. The neurosurgeon said he had consulted his partners and decided to place a tube from the cyst through the folds of the brain into the basilar cistern at the base of the brain stem because this would minimize any potential problem of the peritoneal shunt malfunctioning in the future. The surgeon also stated that he had asked someone from his office to

call and explain this to the patient. She said no one had called her to advise her or her husband about the change. The patient's wife explicitly asked that the neurosurgeon consult with her husband before performing the more complex surgery.

The neurosurgeon proceeded to perform the more invasive surgery without the patient's consent. When the patient awoke from the surgery, he complained of a severe headache and nausea. Hours later, he became neurologically unresponsive and paralyzed from the eyes down. A CAT scan showed evidence of air buildup at the site of the cyst in the brain and bleeding in the brain. After 10 days of hospitalization, the patient's wife noticed that he seemed to be aware of his surroundings. At trial, she testified that although he could not talk or move he was mentally aware, that he used an alphabet board and eye blinks to communicate with her.

Once discharged from the hospital, he was admitted to a rehabilitation facility. After extensive inpatient treatment he could walk one-eighth of a mile using a cane and with a strap around his waist, although he usually uses a motorized scooter to get around. He also regained 70% use of his left arm and, after speech therapy, could speak. At the time of trial he was participating in rehabilitation activities, attending outpatient sessions three times a week for four hours per day. His progress was attributed by the rehab facility to his determination and motivation.

Although the neurosurgeon was not employed by the hospital, the plaintiff brought suit against the hospital as well as the surgeon. The neurosurgeon had admitting privileges at the hospital and also at his private practice, which was in the hospital complex. The neurosurgeon and his private practice partners were the hospital's exclusive neurosurgery group, with one of the partners acting as chairman of the hospital's neurosurgery section.

In his case against the physician, the plaintiff claimed that when the tube was placed in his brain it hit the basilar artery and its vasculature, which nourishes the pons of the brain stem. The plaintiff contended this damaged the brain stem and resulted in his suffering a stroke from the shut-off of blood to the brain pons. In addition to the medical negligence claim for placing the tube so deep that it hit his brain stem, the plaintiff also claimed that he did not give informed consent to the procedure performed by the neurosurgeon.

The neurosurgeon claimed that the change in type of tube used was an exercise of appropriate medical judgment. He also denied causation stating that the tube did not cause the infarction. As for the claim regarding informed consent, the neurosurgeon maintained that he had consent because he described the procedures to the plaintiff and told him that he would operate on his skull and place the drain.

The plaintiff also claimed that the hospital violated the jurisdiction's hospital regulations, which require the hospital to obtain written consent and document it in the patient's chart before surgery starts. The hospital relied on the neurosurgeon to explain the procedure and then obtain written consent and document it in the patient's chart. The hospital contended that it did not know what the physician told the plaintiff before surgery and that it relied on the consent form signed by the physician as certification that the physician had described the procedure to the patient. This part of the consent form was not signed by the neurosurgeon who performed the surgery; it was signed by one of his partners more than two months after the surgery. The same partner also signed the operative note and discharge summary, which had been dictated by the operating surgeon's physician assistant. The signing partner serves as the hospital's section chair. The plaintiff argued that this partner never examined him and never read any of the operating neurosurgeon's notes.

Prior to going to trial, this action settled confidentially for $3.25 million, with both the hospital and physician participating.

What this means to you: Generally, it is the physician's responsibility to describe various treatment options to patients, complete with explanations of the risks and benefits associated with each. This is particularly true in nonemergent situations in which the patient is competent.

"Although the patient presented early morning to the emergency department with an emergency condition, the situation did not call for immediate surgery. In fact, surgery was not preformed until three days later, and so presumably the neurosurgeon had plenty of time to explain the options to the patients and should have had the time to confer with his partners and describe additional options as needed," notes Lisa Winton, RN, LHRM, CPHQ, CHSP, manager of risk management; Gabrielle Smith Morley, RN, LHRM, risk specialist; and Lucy Newell Gurka, RN, risk specialist, all at Tampa (FL) General Hospital. "There was no need for the surgeon to wait until the patient had been sedated to

explain his preferred course of treatment to the competent patient's spouse. Further, when the spouse did protest to the physician's proceeding with the surgery her husband had not consented to, the physician had a duty to abide by the health care surrogate's wishes."

Informed consent is an integral component to the delivery of health care. It is the mechanism that ensures appropriate communication between the provider and their patient. "As such, informed consent cannot be delegated to nonmedical staff personnel and should not be delegated to one's partners. The signing of the informed consent two months after the surgery by the neurosurgeon's partner appears to be in direct conflict with prevailing state regulations. And, although the partner signed all of the pertinent documentation from consent from to operative notes and discharge summary, it does not seem that he participated in the care of the patient. Interestingly, since the signing partner was also the section chair, it would be interesting to know how the peer review of the case was handled. Finally, hospitals should have policies and procedures in place that pertain to verification that informed consent had been obtained as well to verification of the surgical procedure," adds Winton.

"Finally, as to the adverse outcome, one questions whether or not the physician was credentialed to perform the more complex surgery. And, if he was, the follow up question is how many procedures of this had he performed and what was the associated complication rate," conclude Winton, Morley, and Gurka.

Reference

• Michael and Nancy Strack v. St. Peter's Hospital and Dr. Bruce Chozick, Albany County (NY) Supreme Court, Index No. 4428/99. ■

Heart attack and triage: $1.25 million FL settlement

News: In a hospital emergency department (ED), a 42-year-old insulin-dependent diabetic gave a triage nurse his personal and family history of cardiac disease, and reported the classic symptoms of pending myocardial infarction. The triage nurse told him to wait until his name was called. While he waited for an hour in the ED waiting area, he suffered a massive heart attack. He died 11 months later. His estate brought suit against the hospital and his cardiologist. The matter settled prior to trial for $1.25 million.

Background: A 42-year-old police officer who was an insulin-dependent diabetic with the known history of cardiac disease in his family, consulted with his cardiologist for a prophylactic evaluation of his health. Months later, he experienced extreme cardiac symptoms of chest pain, nausea, sweating, and shortness of breath. Rather than going to the hospital, he called on his physician, who saw him later that day. His cardiologist performed an EKG, which came back abnormal, but did not refer him for immediate hospital admission. Instead, the cardiologist requested that the patient come back next week for a stress test.

The man went home and continued to have chest pain. On his wife's insistence, he went to the ED. The man gave the triage nurse his history of insulin-dependent diabetes and his family history of cardiac disease, and he presented the classic symptoms of a pending myocardial infarction — chest pain, nausea, sweating, and shortness of breath. The triage nurse instructed him to wait until his name was called.

After waiting an hour for his name to be called, he suffered a massive heart attack while in the ED waiting room. He suffered severe damage to his heart muscle and underwent interventional cardiac surgery. The heart attack and surgery left him disabled and he could not return to his duties as a police officer. After 11 months, he died of congestive heart failure.

His wife brought suit against the cardiologist and the hospital. According to a hospital nurse's deposition, the patient made no further complaints to any nursing staff during the hour he waited and that he "simply fell through the cracks." The cardiologist settled the case for the policy limits of $250,000 prior to the case being filed. The hospital settled the case for $1 million prior to trial.

What this means to you: Medical errors are made, and patients are overlooked. Occasionally, hospitals and health practitioners must own up to it. This case is one of those times.

"The scenario described in this instance is a clear breach of the standard of care," states Sam Bishop, ARM, CHPA, vice president of compliance and insurance services, WellStar Health System in Marietta, GA. "Patients presenting to the emergency department with chest pain

should be triaged as top priority and escorted directly to treatment. And certainly a patient reporting not only the chest pain but also all of the other classic health attack symptoms combined with his underlying diabetes and family history of heart disease should be rushed to a trauma room and monitoring and treatment begun immediately. To have done otherwise is substandard care for handling an emergency cardiac patient."

For this patient, the hospital's breach of the standard of care was preceded by the breach of care of his treating cardiologist.

Unfortunately for this patient, the hospital's breach of the standard of care was proceeded by the breach of care of his treating cardiologist. The cardiologist had been caring for the patient for at least six months prior to his heart attack, and he was aware of his patient's underlying risk factors. Not only did the patient present to his office on an emergency, unscheduled basis with classic myocardial infarction symptoms, the cardiologist had the benefit of the EKG results, which indicated that there was a problem. And yet, the cardiologist sent the patient home instead of the hospital.

When medical malpractice is evident and that deviation from the standard of care results in an adverse income, risk managers and insurers must consider settlement as an option. "In cases where the liability is clear with no possibility to defend — settle. And, as seen in this case, providers prudently settled as soon as possible," concludes Bishop.

Reference

• Laura Pruette as PR of the Estate of Barry Pruette v. Adventist Health Systems/Sunbelt Inc., d/b/a Florida Hospital, Altamonte, Orange County (FL) Circuit Court, Case No. C10 00-348. ■

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