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Avoid legal problems with brain-dead patients: Approach families properly

Don't give away too much responsibility

Terminating life support for a brain-dead patient is never easy. Risk managers and legal experts caution that the decision can lead to difficult court battles if it is not made carefully. The biggest mistake might be giving the family too much authority to make the decision, they say.

The definition of death has been debated in the medical community and in the courts for years, yet risk managers still face thorny situations in which family members or guardians will not accept a doctor's recommendation to discontinue life support for a patient whose recovery is hopeless. Such situations quickly can become disputes with little likelihood of a good resolution because the hospital might be forced to seek a court order terminating medical care against the family's wishes.

Steve Johnson, director of risk management for Wellstar Health System in Marietta, GA, says he has encountered such a dilemma three times, and all were challenges. In each case, the clinicians caring for the patient determined that the patient was brain dead and suggested to the families that they discontinue life support. The families refused, even after doctors and others at the hospital tried to educate them on the finality of brain death, but the medical staff felt strongly that they should not continue caring for a dead patient.

"It can be either that the family is not informed well, or they can be informed and just have a very strong difference of opinion," Johnson says. "Families can misinterpret reflex movements as

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signs that the patient is coming back, or they can just be very hopeful. We've had cases where families resisted initially but then gave in when we educated them, but we've had others with very strong beliefs that there is going to be a miracle."

Difficult when push comes to shove

When the family resists efforts to end life support, Johnson says hospital staff are in a quandary. Staff don't want to actively oppose the family on such a delicate issue at such a difficult time for them, but staff also can feel strongly that it is not right to keep a dead body artificially breathing. In addition to the ethical and moral reasons for not continuing life support, staff can be troubled by the likelihood that the patient's organs will shut down, making organ donation impossible.

The Wellstar system tries to head off such difficulties by encouraging patients to complete advance directives and designate only one person in the family as a spokesperson and decision maker. When a conflict arises, the doctors will involve clergy members, counselors, and, eventually, the risk manager in an effort to persuade the termination.

"The risk management office gets involved when all efforts from the direct care providers have failed," he says. "We're the last step in the chain to assist, and we're there because there is the possibility that the facility will have to go to court to get the life support terminated. We wouldn't do that unless we had every provider behind us and we had exhausted every possible alternative. It is very much a last resort to go to court."

Johnson seriously considered seeking a court order in one case. A long-term patient entered a vegetative state, and all the evaluating health care providers agreed there was no brain function. The family refused to discontinue life support, hoping for a miracle. Several weeks passed, and Johnson was looking into the possibility of a court order when the rest of the patient's body shut down, resolving the issue.

Avoid confrontation by taking charge

One attorney says the best approach is to avoid getting into such a confrontation in the first place. While most risk managers already understand the benefits of educating family members about the nature of brain death, do-not-resuscitate (DNR) orders, and advance directives, **Edmund Gronkiewicz**, JD, says you should pay more

attention to how clinicians present the situation to family members. Now with the law firm of Hinshaw & Culbertson in Chicago, Gronkiewicz has represented hospitals since 1968 and says every risk manager will encounter this kind of dilemma several times in a career.

"In most cases like this, the genesis of the problem is an attempt to get permission to do something you didn't need permission to do," he says.

How much is too much?

Many clinicians make the mistake of giving the family too much authority and responsibility in determining when to discontinue life support, he says. The statutes of individual states may come into play when determining how to legally declare a patient dead, but Gronkiewicz says that should be a medical decision made by medical professionals. Once the professionals decide the patient is dead, the family should be *informed* that *medical treatment*, not life support, will be discontinued because the patient *is dead*.

The distinctions are important, he stresses. In such a difficult moment for the family, it makes all the difference in the world how the information is presented.

"People often put the cart before the horse by saying they will remove the life support systems and declare the person dead," he says. "That is confusing. The family can infer that the person is really alive, but the removal of the life support system will end the life. That's different from saying the person already is dead and therefore we will not continue medical care."

Patients don't need to be burdened

When the situation is presented to the family poorly, they can feel a tremendous burden to make a decision to "end" the life of their loved one, Gronkiewicz says. In most cases, that is unnecessary.

"If you say you want permission to cut off the life support system on their brain-dead loved one, you've already created your monster," he says. "You have to show that the patient is dead by all standards and say you are ceasing treatment, period. If you approach it that way, you cut out a lot of potential problems, and you don't have to deal with the question of how to oppose the family's wishes. And actually, you're doing the family a favor by not asking them to make a decision that will be painful and is totally unnecessary."

Gronkiewicz acknowledges that risk managers may be uneasy urging clinicians to unilaterally make such decisions, but he points out that doctors are trusted to make such important calls all the time. He theorizes that the whole debate over when to declare a patient dead is the result of society's disdain for the old-fashioned paternalism that used to be common with doctors. Now doctors are encouraged at every turn to get the patient involved in the decision-making process and to present alternatives for care. Though that approach may be sound in most situations, it is inappropriate when determining a patient's death, he says.

Before approaching the family, doctors uninvolved in the patient's care should go beyond what is legally required to determine the patient's death.

"If your medical professionals have carefully and accurately determined that the person is dead by legally accepted standards, no one can demand that you provide medical treatment to a dead body," he says. "If someone is brought into the emergency room and the doctor determines the patient is dead, even after trying to resuscitate, the family can't just demand that you keep massaging the heart and applying shocks forever."

Before approaching the family, Gronkiewicz says, doctors uninvolved in the patient's care should go beyond what is legally required to determine the patient's death. Many states recognize two flat EKGs in a 24-hour period as indicative of brain death, for instance, so providers in those states could obtain three flat EKGs in a 36-hour period. That information can be presented to the family as proof beyond any reasonable doubt that the patient is dead. If the family is skeptical, you can explain that you went beyond what is required by law because you wanted to be sure.

That extra precaution also provides a basis for a defense if the family sues later.

Gronkiewicz is not suggesting that doctors simply discontinue life support for an intensive care patient without talking to the family first. He sees nothing wrong with that from an ethical standpoint, and it may even be technically OK from a legal standpoint, but as a practical matter, it might be seen as too callous if the family

decided to sue later on, and it could even prompt the family to sue.

The right approach won't prevent all confrontations with the family or guardian, but it will prevent most, he says.

Gronkiewicz points out that it is far better to avoid the confrontation altogether because, inevitably, a dispute will result in bad publicity and is not likely to resolve with anyone truly pleased. Once the family and the hospital are on opposite sides of the issue, there may be no turning back. If the hospital is not prepared to continue life support indefinitely, the only option may be seeking a court order to discontinue it.

Know your state's laws

In a 1999 case, Johnson consulted with Wellstar's outside counsel, **Henry Green Jr.**, JD, of Browning & Tanksley in Atlanta. Green told Johnson that Georgia law is unclear on the question, leaving risk managers without firm legal footing. Pertinent case law will vary from state to state, and Green advises *Healthcare Risk Management* readers to consult attorneys familiar with their own state's case law. But Green tells *HRM* he would expect many risk managers in other states to find themselves in the same dilemma as Johnson.

According to Green's analysis, case law in Georgia makes it clear that hospitals can discontinue life support without any court intervention when the family or guardian agrees, but the law provides no support for hospitals when the family or guardian wishes to continue treatment.

The relevant case, Green says, is *In re: Jane Doe,* 262 Ga. 389, 418 SE2d 3 (1992). In this case, a 12-year-old girl with a history of medical problems suffered a demyelinating brain-stem disorder of unknown etiology, soon becoming comatose and entirely dependent on a respirator. The physicians wished to institute a DNR order, but only one parent consented. The hospital sought a court order to allow the DNR, but by the time of the hearing, both parents opposed it.

The young girl died before the Georgia Supreme Court could rule on the issue, but the court went ahead and issued an opinion. The court noted that while the physicians were recommending DNR orders, the hospital had not argued that continuation of life support constituted "medical abuse."

"The question presented to the court, therefore, was simply, when the physicians recommended discontinuance, and the persons authorized to consent refused to do it, did the physicians and the hospital have the right to discontinue life support anyway?" Green wrote to Johnson when providing legal advice on a similar case. "The answer was no. The court held that where the persons authorized to give consent under law refuse to do so, their wishes could not be overridden."

Green's advice to Johnson was to follow the wishes of the family or guardian unless he were willing to pursue an ugly and very public court battle. And even then, the hospital would have to argue that continuing the life support would constitute "medical abuse," prolonging death, rather than life.

Other than changing the family's mind or going to court, the only alternative might be to transfer the patient to another facility, he says. Discontinuing life support against the family's wishes could subject the facility to claims for medical negligence, plus punitive damages for willful and wanton misconduct, he says.

"It is very clear that we cannot, on our own, discontinue life support in the face of a clear refusal by the appropriate family member," Green wrote to Johnson. "We would most certainly be faced with a lawsuit for wrongful death with a claim for punitive damages attached." ■

Should patients, families be told of mistakes?

A cross section of America's health care risk managers believes patients and families should be told about medical mistakes, according to a national survey.

Conducted in April, the mail survey was reported for the first time in June at a national patient safety symposium, "Building Systems that Do No Harm: Advancing Patient Safety Through Partnership and Share Knowledge." More than 550 physicians, nurses, risk managers, administrators, and other health care professionals participated in the symposium, which was sponsored by VHA Inc.

In explaining why they believe patients and their families should be told about an error, responding risk managers most often chose the statement, "Health care providers have to disclose medical mistakes whether or not there was

an injury, even if it will increase the risk of liability to the provider."

Risk managers responding to the survey said the top barriers to full disclosure were increased exposure to litigation and unwanted adverse publicity, says principal investigator **Kathleen Ruroede**, PhD, RN, of the Finch University of Health Sciences / The Chicago Medical School. She called for more education in the communication skills needed to communicate with patients and families about errors. The survey was funded by VHA Inc., a nationwide alliance of 1,900 hospitals.

Scenario and response

The survey presented risk managers with five hypothetical scenarios drawn from real cases: a surgical mishap, an unneeded mastectomy due to an erroneous lymph node diagnosis, two medication overdoses, and a child who wandered away from a pediatric unit through an unlocked door to a roof before being found unharmed. The surgical mishap scenario involved an inadvertent laceration of the pulmonary artery and the resulting death of a 70-year-old tuberculosis patient. A majority (61%) of survey respondents said the family should be told that the pulmonary artery was accidentally lacerated and caused a hemorrhage, resulting in the patient's death.

In the breast cancer case, a large majority said the patient should be told of the diagnostic error, and 61% said the patient should be informed that the mastectomy was or may have been unnecessary. In the child-on-the-roof scenario, 66% of the responding risk managers said the parents should be told the child was found on the roof, upset and crying.

For one of the medication error episodes, involving administration of twice the ordered dose of the anti-convulsant Cerebyx, 57% of respondents indicated that the family should be told that the patient received an overdose that may have or probably contributed to his death.

The other medication overdose scenario, involving the administration of the anticoagulant heparin at 10 times the ordered dose, did not result in any apparent harm. Instead, the patient's clotting times were tested immediately and every four hours for the next 24 hours. Sixty-four percent of the risk managers responding to the survey said the patient should be told that the additional testing was being done because too much heparin had been administered. The survey results, which were statistically significant, were based on 650 responses to questionnaires sent to 3,389 risk managers nationwide, representing a 20% response.

Also at the meeting, **Gordon Sprenger**, past president of the American Hospital Association, challenged the leadership of the health care industry to make patient safety a board-level priority and adopt full-disclosure policies in their organizations' strategic plans. Sprenger, chief executive officer of Allina Health Systems, joined **Julie Morath**, chief operating officer of Children's Hospitals and Clinics of the Twin Cities, in outlining a primary issue in creating a safer environment for patients: changing the culture of medicine from one of blame and secrecy to one of disclosure and learning.

"Patient safety should be on the personal agenda of every hospital CEO as it is the foundation for improving health care quality."

"Patient safety should be on the personal agenda of every hospital CEO as it is the foundation for improving health care quality," he says. "To promote the culture change within our organizations that is necessary to reduce medical errors, we must shift the reporting emphasis to 'What happened?' away from 'Who did what?'"

Morath adds that reducing medical errors "will take nothing less than making patient safety the first priority of hospitals' strategic plans. To undertake such a vast cultural revolution means commitment to patient safety must be comprehensive, driven by leadership, with an emphasis on education as much as on changing infrastructure and systems."

How hospitals should proceed

Morath says a hospital's plan to improve patient safety should include these elements:

- educational sessions and materials designed to promote an understanding of how systems can be changed to reduce the potential for harm;
- a full-disclosure policy to guide, support, and direct staff who interact with patients and families following medical accidents;
- a blameless reporting system designed to encourage staff to report "near misses";
- review and implementation of appropriate

"best practices" that have been identified through the available research (for example, removing potassium chloride concentrates from units and 24-hour availability of pharmacists);

• regular reports to the CEO and board of directors. ■

AORN says operating room visitors OK with guidelines

But hospital must take precautions

The Association of periOperating Room Nurses (AORN) in Denver recently announced two policy initiatives with bearing on risk management, addressing the risk of having salespeople in the operating room and endorsing the use of active electrode monitoring to reduce electrosurgery accidents.

At the recent AORN 2000 National Congress in New Orleans, the group announced a new position statement that says industry salespeople and other visitors are acceptable in the operating room as long as the hospital takes precautions to protect the patient. Facilities should enact strict policies on how visitors are allowed, AORN says.

The position statement came as the result of concern in the health care industry about the way OR visitors have become commonplace. Nearly every hospital allows such visitors at some time, says ECRI, the nonprofit health research agency in Plymouth Meeting, PA. Visitors can threaten both patients and the hospital if the practice is not closely supervised, ECRI says.

Who makes authorizations?

ECRI recently conducted a survey of 180 hospitals and found that 95% allow "outsiders" in the OR during surgery.[1] Of those that allow visitors, 86% have a policy to protect patients. More than three-quarters specify what the sales representative can and cannot do in the OR, and more than half require that the patient consent to the presence of visitors during the procedure. Sixty-seven percent require that hospital administrators approve the presence of the visitor, and another 13% said verbal approval was acceptable. Those most likely to be authorized to grant the request were the chief of surgery, surgeon, perioperative nurse manager, OR manager, head nurse, OR supervisor, charge nurse, OR committee, materials manager, and director of purchasing.

Like AORN, ECRI recommends close supervision of any OR visitors. There have been reports of salespeople participating in surgery, ostensibly to show the surgeon how to use equipment, and incidents of visitors compromising patient safety by violating the sterile field, for instance.

More than half of the facilities surveyed by ECRI report that they require the patient's consent for visitors in the OR, usually with a general statement in the operative consent form that the surgeon and facility may allow observers for professional reasons. That may be sufficient in most cases, though ECRI advises playing it safe and obtaining specific consent for visitors during the procedure.

In its "Position Statement on the Role of the Health Care Industry Representative in the Operating Room," AORN emphasizes that patient safety must be the top priority. AORN also advises making the patient aware of the visitor's presence.

AORN's position

These are excerpts from the AORN position statement:

• "In defined conditions, AORN believes that health care industry representatives, by virtue of their training, knowledge and expertise, can provide technical assistance to the surgical team, which expedites the procedure and facilitates desired patient outcomes. The purpose of this statement is to affirm the valuable role health care industry representatives play in the care of surgical patients and to assist the perioperative team in maintaining the patient's safety, right to privacy, and confidentiality when a health care industry representative is present during a surgical procedure.

• "A health care industry representative may be present during a surgical procedure under conditions prescribed by the facility. AORN recognizes there is a wide range of geographic and regional variations regarding the activities of the health care industry representative in the operating room. This statement provides general guidelines to assist the individual facility in developing policies best suited to its community standards.

• "The policy should be developed in collaboration with the facility's risk management and/or legal counsel to ensure compliance with applicable laws. Each facility should develop a system

that addresses informed patient consent regarding the presence and role of a health care industry representative in the operating room during a surgical procedure in both routine and emergency situations. This system should include documentation in medical records.

• "As the patient's advocate, the RN responsible for the patient's care during the procedure is accountable for maintaining the patient's safety, privacy, dignity, and confidentiality. To achieve this, the RN should monitor the health care industry representative's activities whenever possible and facilitate the representative's service to the patient and the perioperative team. The RN should be informed prior to the procedure that a health care industry representative will be present and about his/her purpose for being there.

"Each facility should develop a system that clearly delineates limits on the health care industry representative activities in the operating room based on community standards."

• "Perioperative team members are responsible for acquiring instruction on new procedures, techniques, technology, and equipment with which they are not familiar prior to their use in a surgical procedure. This instruction may be provided by the health care industry representative. The facility should maintain evidence of documented competencies for health care professionals, especially when introducing new procedures, techniques, technology, and equipment as required by the Joint Commission on Accreditation of Healthcare Organizations.

• "Each facility should develop a system that documents that the health care industry representative has completed instruction in the principles of asepsis, fire and safety protocols, infection control practices, bloodborne pathogens, and patient's rights. Based on community standards, this may range from maintaining up-to-date documentation provided by the health care industry representative's employing company to providing facility-specific instruction and training.

• "The health care industry representative's presence and purpose should be pre-scheduled with the designated operating room management authority and the surgeon in accordance with the facility policy.

• "The health care industry representative should wear identification while in the facility.

• "Each facility should develop a system that clearly delineates limits on the health care industry representative activities in the operating room based on community standards. The health care industry representative should not scrub in.

• "The health care industry representative with specialized training may perform remote calibration to adjust devices to the surgeon's specification (e.g., pacemakers, laser technicians)."

It's now the standard

AORN recognized active electrode monitoring technology as an "AORN Recommended Practice" for minimally invasive surgery, a major endorsement of a tool that the manufacturer says can prevent many electrosurgery injuries. Electrosurgery injuries are a leading cause of malpractice claims in minimally invasive surgery.

A panel consisting of operating room directors and managers concluded that the technology is becoming the standard of care in minimally invasive surgery. The panel advocated integrating it into their practice as they had with previous technical innovations in electrosurgery. The system is manufactured by Electroscope in Boulder, CO.

Active electrode monitoring technology helps minimize accidental electrosurgical burns during minimally invasive surgery. Two years ago, active electrode monitoring was recommended by legal experts involved in laparoscopy litigation and by an independent testing organization. **Antonios Tsarouhas**, JD, an attorney with Perantinides & Nolan in Akron, OH, and vice chairman of the Laparoscopic Surgery Litigation Group, a subgroup of the Association of Trial Lawyers of America, says electrosurgery injuries are among the biggest malpractice risks in minimally invasive surgery.

A group's recommendations

The litigation group is made up of plaintiffs' attorneys who have a special interest in pursuing cases related to laparoscopy. A significant number of the malpractice cases that already have been litigated involve the accidental injury of nontarget tissue by stray electricity emanating from the laparoscopic monopolar electrosurgical instruments, usually traced to long-term degradation of electrical insulation or capacitive coupling.

The laparoscopic litigation group recommends the use of active electrode monitoring systems to avoid stray current injuries. That recommendation was echoed by ECRI. The agency's independent evaluation of the Electroshield system convinced the researchers that the product performs as it should and can prevent many injuries in laparoscopy.[1]

ECRI concludes that "we therefore encourage use of electrode shielding, such as that offered by the evaluated Electroscope Electroshield System . . . during laparoscopic monopolar electrosurgery." ECRI calls it "the most effective means currently available of minimizing the potential for patient injuries" from certain kinds of electrosurgery accidents.[2]

Electroshield in detail

In addition, several medical malpractice insurers have recommended the Electroshield system. Recommendations to consider the system have appeared in publications of American Physicians Insurance, Mutual Insurance Company of Arizona, and Copic. The Electroshield system has a list price of more than $3,000, with the exact costs depending on how many accessories are purchased, according to information from the manufacturer.

The Electroscope product conducts potentially dangerous current leakage from the laparoscopic electrosurgical active electrode shaft away from the patient and alerts the surgical team to a problem with the monopolar electrosurgery equipment. A standard electrode is inserted through the Electroshield's cylindrical conductive shield, and the electrode and shield then are introduced through a cannula.

When the conductive shield is connected to a monitoring unit and the return electrode, stray current from the electrode has a safe return path, so it does not travel through the patient. The monitoring unit also issues an alarm and deactivates the monopolar electrosurgery unit if the stray current exceeds a preset level, the manufacturer reports.

References

1. ECRI. Managing the risk of sales representatives in the operating room: An HRC survey. *The Risk Management Reporter* 1996; 15:1-7.

2. ECRI. Monopolar electrosurgical safety during laparoscopy. *Health Devices* 1995; 24:11-17. ■

Guidelines offered to help radiologists avoid lawsuits

Mission statements are key

Radiologists should clearly say in their mission statements that "productivity is a far less important factor in the determination of income" than "optimal care," says **Leonard Berlin**, MD, a well-known expert in malpractice issues in radiology. In an article in the July 2000 *American Journal of Roentgenology*, Berlin recommends a risk management approach to avoid lawsuits.

He cites an unusual malpractice suit against a radiologist filed by a 54-year-old woman whose mammograms showed a cancerous breast lesion missed by the same radiologist in a screening one year earlier, a case that claims the doctor

The plaintiff's lawyer alleged that 162 radiographs in one day demonstrated "a wanton disregard of patient well-being by sacrificing quality patient care for volume in order to maximize revenue."

missed the diagnosis because he had read too many radiographs in one day and was "overworked."

In the lawsuit, the plaintiff alleged that the radiologist missed the diagnosis on the earlier mammogram because he had read 162 radiographs on that day, more than the average of 50 to 70 per day cited in published studies. The plaintiff's lawyer petitioned the court for punitive damages, alleging that reading so many X-rays in a day demonstrated "a wanton disregard of patient well-being by sacrificing quality patient care for volume in order to maximize revenue."

The radiologist himself discovered his error after comparing the newer images to those taken the year earlier. He saw that the front part of the lesion had shown previously in one view but not in the craniocaudal view because the breast had not been properly positioned.

He included in his report after the second year's screening that the lesion had been present the year before, although not reported at that time, and recommended the patient undergo a

prompt biopsy. The woman underwent a mastectomy as a result and filed the lawsuit eight months later.

"Risk management in radiology practice can lessen the likelihood of incurring a medical malpractice lawsuit, maximize the chances for a successful defense if a suit is filed, and at the same time enhance patient care," Berlin writes. He also presents these recommendations to radiologists to improve their performance:

1. Radiologists should be aware of published studies that show the average workload for a radiologist to be 50 to 70 diagnostic procedures a day, while noting these studies contain disclaimers showing that many factors affect daily workloads for radiologists. Those factors include type and complexity of the radiologic procedures; external diversions such as consultations with colleagues; any teaching, research, and administrative duties a radiologist may have; radiologists' personal work speeds; and the length of their workday.

2. Radiology practices "should consider including in their group or department policy a reference to workload parameters."

3. "To minimize the potential allegation that radiologists are overworked because revenue is placed before patient care," groups or departments should include in their policies or mission statements "a pledge that although a percentage of revenue may be distributed according to productivity, productivity is a far less important factor in the determination of income than the providing of optimal patient care."

4. Radiology groups should implement a "performance improvement plan" they can cite as an indication of their excellence in quality radiology care.

5. Radiologists must commit to "nothing less than 100% of their expertise and knowledge when interpreting all radiologic studies."

About the last recommendation, Berlin states, "The last radiologic examination of the day commands the same full attention . . . as the first of the day," adding that radiologists who become too tired to provide their peak performance should either delay the interpretation or ask a colleague to fill in. ■

Surgeon sues device maker for patient death

Trocar cited as cause

A surgeon is suing a huge medical device manufacturer on the grounds that one of its surgical trocars led to the death of his patient, a case in which he was sued for malpractice and won.

Franklin Chow, MD, filed suit recently in federal court in Denver against Norwalk, CT-based U.S. Surgical Corp., alleging that one if its trocars contains a serious product defect. In the lawsuit, Chow, a board-certified obstetrician and gynecologist, claims that the disposable trocar he used to perform an elective laparoscopic-assisted vaginal hysterectomy in 1995 malfunctioned and ultimately caused his patient's death. The lawsuit was filed by the Dallas law firm of Sayles, Lidji & Werbner.

Trocars are sharp-tipped tools used by surgeons to penetrate the body for insertion of endoscopic instruments. U.S. Surgical's trocar has a pyramid-shaped, razor-sharp tip that is used to penetrate a patient's abdominal wall during laparoscopic procedures.

Once inside the abdominal cavity, the trocar's spring-operated plastic sleeve is supposed to slide down and cover the tip of the trocar to prevent internal injury. The device's sleeve tip is not found on most trocars, and it is designed to avoid a common hazard of laparoscopy — jamming the sharp trocar tip into internal tissues and organs after it pops through the abdominal wall.

'Undeserved damage'

Chow claims that, while performing the 1995 surgery, the plastic sleeve on the trocar failed to slide down and cover the blade, thereby causing the patient's right internal iliac vein and artery to be severed. Chow converted to an open procedure immediately to repair the damage, but the patient died.

The patient's family filed a wrongful death lawsuit against Chow in 1996. On May 11, 2000, an Eagle County, CO, jury vindicated his surgical performance, finding no negligence in his care of the patient, says **Mark Werbner**, Chow's attorney.

"Despite the favorable jury verdict, the incident and subsequent lawsuit caused considerable

undeserved damage to Dr. Chow's reputation and his medical practice," Werbner says. "Dr. Chow hopes this lawsuit will bring public attention to the dangers of this defective surgical instrument. We believe the evidence will show that U.S. Surgical knew of the problems with its trocar, and while informing the FDA of some of the many serious incidents with defective trocars, concealed the information from doctors and hospitals."

U.S. Surgical did not return calls seeking comment on the lawsuit. ■

GAO: More study needed on reuse of disposables

Public health concerns raised

Although there is little evidence that the reprocessing and reuse of "single-use" medical devices (SUDs) is a threat to public health, the practice does warrant more intensive study and oversight, the General Accounting Office (GAO) told a Senate committee recently.

"The practice of SUD reprocessing reduces the costs of medical devices for hospitals and other health care facilities, but it also raises public health concerns, primarily regarding the potential risks of infection and device malfunction," GAO's **Janet Heinrich** told the Senate Committee on Health, Education, Labor and Pensions.

"We believe that the recent proliferation of costly devices labeled 'for single use' that have replaced viable reusable products has contributed to the strain on health care resources."

Heinrich said the GAO found evidence demonstrating the safety of reprocessing some devices, such as electrophysiology catheters. The study also found that some highly publicized reports of adverse events attributed to the reuse of SUDs "were inaccurate, did not involve the type of reprocessing discussed here, or were difficult to interpret." For example, she said, while the Food and Drug Administration (FDA) received a report of the tip of a reused electrophysiology catheter that broke off and lodged in a patient's heart, "FDA also received two reports of similar injuries resulting from procedures with new electrophysiology catheters," Heinrich told the committee.

At the same time, she said, the dangers are more than theoretical. "It is also clear that some SUDs cannot be safely reprocessed, procedures for safe reprocessing are not always followed, and the limitation of the information available about SUD reprocessing argue for monitoring the practice," she said.

An FDA representative provided similar advice to the Senate committee. The director of the Center for Devices and Radiological Health, **David Feigal**, MD, outlined the agency's proposal for oversight of the practice. "Despite a lack of clear data that directly link injuries to reuse, FDA has concluded that the practice of reprocessing SUDs merits increased regulatory oversight," he said. "Our plan is to phase in additional oversight based on our assessment of current practice and potential risk."

A longtime practice

Another speaker represented the American Hospital Association. **John Clough**, MD, chair of health affairs at the Cleveland Clinic Foundation, told the committee that "hospitals have been reprocessing medical devices for decades. If this practice threatened patient safety, epidemiologists would have identified long ago clusters of infection developing. However, as the FDA and the GAO confirm, there is no evidence to support the notion that reprocessing is a risk to public health."

Clough also noted that original equipment manufacturers have little incentive to label devices as reusable and, in fact, have financial incentives to designate devices as "for single use."

"Manufacturers appear to use the term 'for single use' as part of their labeling without justifying whether, in fact, the device can be safely reprocessed for subsequent use," he said. "In the last two years at the Cleveland Clinic, we have observed products, such as saw blades, that have been labeled historically as reusable, arriving with the 'for single use' label with no observable change in the product. We believe that the recent proliferation of costly devices labeled 'for single use' that have replaced viable reusable products has contributed to the strain on health care resources." ■

CMA offshoot to offer on-line security system

Prompted by HIPAA regulations

The increasing emphasis on health care privacy has prompted an arm of the California Medical Association (CMA) to offer a system to ensure secure electronic transmission of sensitive medical information.

MEDePass, the CMA's high-tech branch, recently started offering a solution to on-line security concerns when it issued its first digital certificates, computer files that act as electronic identification cards, or signatures. The certificates enable physicians and others in the health care industry to verify their on-line identities and conduct protected electronic communications via e-mail and the Internet.

As federal Health Insurance Portability and Accountability Act (HIPAA) regulations go into effect over the next few years, physicians, health plans, insurers, e-commerce health care vendors — in fact, all sectors of the medical community — must have technology to protect the confidentiality of medical information. Failure to comply with HIPAA regulations carries federal penalties as high as $250,000 and / or 10 years in jail.

Addressing the fear of theft

In announcing the new technology, MEDePass says it also can address the risk that e-mail and other Internet-based communication is subject to tampering. Anyone with basic technical savvy can spoof an e-mail address to make it appear as if the sender is someone known to the recipient — in effect, stealing the e-mail address holder's identity, the company says. In the absence of technical safeguards, it is impossible for the person whose identity has been stolen to deny he or she sent the fraudulent e-mail.

Fears about the lack of on-line security have discouraged physicians and other health care providers from using the Internet to transmit patient-identifiable information such as medical bills, colleague-to-colleague consultations, and e-commerce orders, says **Jack Lewin**, MD, MEDePass chief executive officer and CMA executive vice president. With the proper security tools, however, he says physicians can be assured that every time they e-mail a patient, exchange patient information with a colleague, go on-line to buy regulated medical supplies such as syringes, or bill an HMO, they are communicating with the party they intended to, and the information they transmit is accessible to the intended recipient only.

While the financial community has used similar technology behind these certificates for years (as has the Department of Defense to encrypt military information), MEDePass is the first to secure medical information using what is known as "public key infrastructure." Other entrants in the race to protect medical communications include the American Medical Association and private vendors.

California physicians who wish to preregister for MEDePass digital certificates can do so at www.medepass.com. ■

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Malpractice insurer endorses system for electronic prescribing

The Doctors' Company (TDC), the nation's largest physician-owned medical malpractice insurer, has announced a program to provide a financial incentive to physicians who adopt the iScribe system, a mobile, handheld, wireless, electronic prescribing technology.

TDC customers will receive a discount on their medical malpractice insurance premium after using iScribe's electronic prescribing systems for one year. The system is manufactured by iScribe, based in San Mateo, CA.

"We believe this partnership can help medical practitioners reduce medication prescription errors," says **Richard Anderson**, MD, chairman of the TDC board of governors. "We believe their system will have a profound impact on the reduction of medication errors by introducing greater information, efficiency, and accuracy into the process of prescribing drugs at the point of care. We feel so strongly about the benefits of the iScribe system that we have contacted other medical malpractice insurers to alert them to this technology and encourage them to implement similar discount programs with the iScribe system."

"We believe this partnership can help medical practitioners reduce medication prescription errors."

TDC initially will offer the iScribe system to its highest-prescribing physicians. Eventually, all TDC member-physicians who choose to participate will receive the system. Under the program, iScribe will provide its electronic prescribing systems free of charge to these physicians, including delivery and installation of the iScribe handheld device, a wireless printer, a radio frequency network for larger practices, and unlimited toll-free customer support. The first installations will begin in the third quarter of 2000.

David Levison, president and chief executive officer of iScribe, notes that a study conducted by the Physicians Insurers Association of America (PIAA) identified prescription medications as the second most frequent and second most expensive procedure in claims against physicians insured by PIAA-member companies. Of medication error claims, 42.4% involved significant permanent injury, and 21.1% resulted in death.

Doctors who use iScribe's systems can write accurate legible prescriptions with just a few taps on the handheld device. The system checks for interactions with other drugs that the patient is taking and checks that the drug is covered by the patient's insurance plan before the prescription in written. The system then prints out an accurate, legible prescription that patients can take with them to the pharmacy.

TDC is the nation's largest physician-owned medical malpractice insurer, with 18,000 policyholders in all 50 states. ■