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Medical futility is sometimes a tug-of-war between hospitals, families

Hospitals struggle to balance patient, family end-of-life needs

Nearly every hospital has them, and most doctors have seen them, treated them, and agonized over them. They are patients with a slim, if not nonexistent, chance of recovery, who continue to receive intense, invasive, and costly procedures because there is no other clear alternative.

Frequently, such patients are near death, permanently unconscious, and no longer able to make their wishes known. Yet their families, uncertain of what to do or unable to accept the reality that their loved ones cannot be restored to them, continue to insist that "everything" be done.

"Very often we see so much suffering with our patients because families do not understand or don't want to let go," says Sister **Judy Laffey**, RN, chaplain and chair of the ethics committee for the Pittsburgh-Mercy Health Care System, a three-hospital Catholic health system in Pennsylvania. "Sometimes, they don't follow the clear wishes of their family members. I have even seen some disregard a patient's living will."

What options do clinicians have when they believe further treatment of a patient's condition will not be beneficial, and may even prolong a patient's suffering, yet family members continue to insist?

There are no easy answers, and many hospitals' solutions are complex and controversial, health care providers say.

What is futile care?

For many years, medical ethicists and health care providers have struggled with the issue of medical futility: the question of whether physicians and caregivers are obligated to provide care they believe to be of no benefit to the patient.

In fact, the American Medical Association recommended in 1997 that all hospitals develop a medical futility policy governing when hospitals and clinicians could decide to stop treatment or not provide

treatments deemed non-beneficial.

The problem, say many experts, is that no one can agree on what "futile" really means.

Some clinicians feel that any treatment that effects a change in the patient's condition cannot be deemed futile, while others believe that medical treatment should be aimed at restoring a patient to some meaningful function. Otherwise, it should be deemed inappropriate.

"But there you get into the quality-of-life discussion, and that can be a very slippery slope to go down," says **Andrew Blustein**, JD, partner in the health care law firm of Garfunkel, White and Travis in Great Neck, NY.

An individual's quality of life is largely based on his or her own perspective. A life that may not seem worth living to some might be quite valuable to others.

Blustein frequently assists hospital ethics committees in developing guidelines for dealing with questions about futile care. But, he warns, there are also legal implications for these decisions.

"Not every state is the same in terms of what actions are permissible and which individuals can make substituted judgments [medical decisions for incapacitated patients]," he notes. "Sometimes, an ethics committee may decide something that is ethical but not legal in their particular state."

Advance directives should be encouraged

Because determining futility is so difficult, most hospitals have focused on helping patients and families discuss end-of-life issues and on implementing a decision-making process that respects the needs and wishes of both families and patients, says Laffey.

"We are working really hard at our hospitals to get more education to the laity about advanced care planning and starting that conversation with their loved one," she says. "It's the conversation that people just don't want to have. They say, 'I don't want to talk about that now,' and then they never talk about it."

A frequent scenario, she says, is a patient who presents to the emergency department with a catastrophic injury, still living, but with no potential for recovery.

"For example, they present with severe bleeding in the brain, and it becomes apparent that their quality of life is not going to be very viable," she explains. "They might end up spending some time in a nursing home and be on a ventilator or a feeding tube and be in a vegetative state."

The patient will eventually die, but by then he or she will also have undergone several expensive and invasive procedures that had little likelihood of improving the patient's condition.

If such possibilities were discussed in advance, scenarios like these might never occur, she says. "People would know what their loved one would have wanted, and even though it might be hard to allow that person to get comfort care, they

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would know it was the person's wishes."

At Mercy Hospital in Pittsburgh, clinicians usually approach the family of a dying patient about palliative care after caregivers have expressed an opinion that nothing more can be done to improve the patient's condition, says **Kenneth Greer**, MD, medical director of the hospital's intensive care unit.

"In the ICU, or any other unit, the team of physicians caring for a patient, in addition to discussing the patient's care from a technical standpoint, will also raise the question of, 'Where is this patient going? What are we really doing for this patient?'" he says. "Do we think this is a case where we will be able to restore a patient to his or her pre-hospital condition? Or are we not going to be able get them back out of the hospital?"

A representative of the health care team, usually the attending physician, and a family counselor or member of the ethics committee arranges a meeting with the family, Greer says. The hospital staffers then ask the family members whether they knew the patient's wishes regarding his or her care.

"We ask them to try to determine what the patient would want given the situation, not what they would want, but what they think that person would want," he explains. "Let's say the person has had a major stroke, probably will not wake up, and will be in a nursing home, dependent upon someone to feed and care for them, or be on a mechanical ventilator. We present them with the medical data and then we leave it in their hands."

In most cases, the family and the care team will already have had many discussions about the patient's condition, so this one is not a surprise, he adds.

In most cases, once a patient has reached a point where recovery is impossible or highly unlikely, families will choose to focus on comfort-care measures instead of insisting on treatments that are invasive and have little chance of helping the patient, he notes.

It's important to emphasize that refocusing the patient's care does not necessarily mean withdrawing care, Greer says; it simply means making decisions about which treatments would be appropriate given the person's condition.

"Sometimes it involves limitations. Sometimes it involves taking the patient off ventilators or other life-support devices, but the goal is to use pain medication as needed to ensure that the dying process is as painless as possible for the family and patient," he explains. "We as caregivers kind of pull back from going in frequently to check knobs and devices and do tests. We allow the family to be with the patient as much as possible and have as much privacy as possible. We continue to check to see that they are comfortable and that the family's needs are being met."

While this approach works in the majority of cases, it occasionally does not, he acknowledges.

"When there are families who do not see it the way we do, we are very much obligated to continue to treat the patient according to the family members' wishes," he notes.

'It is not our decision, but theirs'

If there is strong disagreement, caregivers may recruit the family's clergy or a member of the ethics committee to continue talking with the family. Still, he says, "It is not our decision, but theirs. We treat the patient as appropriately as possible, realizing we are not going to save the patient but are working within the will and request of the family."

Although the providers at Mercy do a good job of working with families in this situation, it is still very frustrating for clinicians to provide care they believe to be without merit, Laffey adds.

"On one level, I think we have to wait until the family gets to some point where they can let go," she says. "But when you know that nothing you are doing is going to help the patient and the family is waiting for a miracle that just isn't going to happen, it is very frustrating. From an ethical standpoint, you are looking at both the amount of money and resources spent on this patient and also at the suffering that is caused."

One day, health care providers must get to a point where they can determine that certain treatments are no longer in a patient's best interest and act on that determination, she says. But, given the current level of debate over futility, that day is probably very far away, she says. ■

SOURCES

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- **Kenneth Greer**, MD; Sister **Judy Laffey**, Pittsburgh Mercy Health System, 1400 Locust St., Pittsburgh, PA 15219.

UPenn develops guideline for brain-injured patients

Appropriate treatments outlined

Patients with severe, irreversible brain injuries present unique ethical challenges to physicians and hospital ethics committees.

For patients with no chance of recovering an interactive, conscious state, which treatments are appropriate and which are unjustifiably invasive and pointless?

It's a question that has surfaced several times for the ethics committee at the Hospital of the University of Pennsylvania in Philadelphia, says **Horace DeLisser**, MD, the committee's co-chair.

Two years ago, the hospital decided it needed a guideline to direct clinicians in making treatment decisions for severely brain-injured patients, specifically those in persistent vegetative states (PVS) or minimally conscious states (MCS), DeLisser explains.

"This guideline is for patients who sustain acute brain injury and are left with impairments that are chronic and severe," he notes. "We have made a distinction between patients in a vegetative state and those in a minimally conscious state."

Patients in both PVS and MCS are no longer capable of "purposeful or intentional" interaction with other people or with their environment, DeLisser explains.

Patients in persistent vegetative states have sustained injuries that have destroyed the upper hemispheres of the brain, leaving only the brain-stem functions intact. PVS patients still experience cycles of sleeping and waking and spontaneously breathe on their own, but are not capable of awareness.

MCS patients may sometimes respond

"Patients in minimally conscious states are, in a sense, one small step above that," he continues. "They have profound disability. They cannot feed themselves, care for themselves, or speak. They may have some residual higher brain functioning, so that, at times, it may appear that there may be some purposeful or intentional response. Occasionally, you may get a patient who, when you ask them to squeeze your hand, they do so. It may not be consistent, but it does occur enough that you know there is something there."

DeLisser objects to the classification of the UPenn guideline as restricting or limiting care because the measure does not cover withdrawing care that is already being given, but instead acts to guide the types of care that are appropriate going forward.

"I don't see this as a futility guideline," he points out. "This is not a withdrawal-of-care or end-of-life care set of guidelines. In many ways, it speaks to what the goal of medicine is or should be, and in that sense it broaches the issue of futility. Collectively, we believe on some level that certain treatments in certain patients do not advance the goal or are unable to advance the goal of restoring cognition. The treatments may maintain biological life, but medicine is not just about warehousing people and somehow maintaining physiology."

For these patients, for whom there is virtually no hope of restoring cognitive functioning or the ability to interact with their environment, the goal of medical care should be directed at preventing suffering and pain and maintaining the dignity and respect of the individual patient, he asserts.

"We think in these situations that care that is comfort-based or palliative-based, that respects the dignity of the patient and prevents suffering — those goals are much more attainable and achievable, and that is a much better way to expend our efforts for these patients," he explains.

No invasive procedures

In general, the guideline indicates that patients who have remained in specified states for several months should not get invasive procedures or intensive life support.

A draft of the guideline defines "intensive life support" as "invasive therapies that generally require continuous specialized monitoring, typically in an intensive care unit. Examples of these therapies include mechanical ventilation, intravenous infusion of vasopressors, or a variety of types of dialysis. These treatments necessarily entail tissue injury and are associated with a risk of major complications such as infection, stroke, or irreversible major organ failure. A decision to implement intensive life support must include a balancing of the possible benefits and risks for the patient."

The guideline defines "significant invasive procedures" as "any intervention or procedure that

involves penetration or entrance of the body that carries more than minimal risk of harm and for which informed consent is obtained."

These are the kinds of treatments hospital officials feel would be inappropriate for patients in the specified conditions.

"The exception would be if there is evidence that the patient would have wanted these kinds of treatments with this level of severe impairments in consciousness," DeLisser says. "If there is evidence that they would have wanted this kind of care in this state, then we are willing to accommodate them as best we can."

A typical scenario would involve a patient presenting to the hospital emergency room who had been in a persistent vegetative state for six months, he explains. If there is no question about the diagnosis and no evidence the patient would want to continue aggressive treatments, the caregivers will focus on comfort care and palliative measures only.

"They would essentially be getting the same care available to them as an outpatient," he says. "If they are on a ventilator, we maintain that. If they have a feeding tube in, that would stay in place. We would not do anything to end those services. They would still get intravenous medications and treatments. For example, if they came in and cultures showed that the patient had an infection, they could get intravenous antibiotics or antibiotics through their percutaneous feeding tube."

But if the patient needed a medication to maintain his or her blood pressure or some kind of exploratory procedure to identify the source of an infection, or if the patient developed pneumonia and required mechanical ventilation, those treatments would not routinely be a part of the patient's care, DeLisser says.

"These guidelines state that this is the 'routine and ordinary' recommendation, but there may be some situations where we need to deviate from this," he adds. "The attending physician would just need to document this. That is the big difference between this guideline and hospital policy. There is still the flexibility to deviate from the guideline, but we hope that won't be the case in most situations."

Conditions must be chronic and persistent

The guideline is not meant to apply to any MCS or PVS patient. It specifically stipulates that the conditions must have persisted for three months for anoxic brain injuries or six months for traumatic brain injuries.

"We have been very careful to specify that the label 'persistent and chronic' is only applied after three months for someone with an anoxic injury, such as someone who went into cardiac arrest and was resuscitated but remains in a persistent vegetative or minimally conscious state. Then we have a threshold of six months for a brain injury due to trauma."

Prior to that point, clinicians and families may decide together to limit or refocus treatment that they believe is not in the best interest of the patient. But if the guideline is going to be used to substantiate the treatment decision, those are the thresholds that should be used.

Guideline reflects evidence base, consensus

The university's guideline was painstakingly developed by a subcommittee of the hospital ethics committee that thoroughly researched the literature to determine appropriate treatments for patients with these conditions, DeLisser notes.

In addition, the subcommittee sought input from the whole ethics committee, the hospital's medical board, other hospital staff (both clinical and non-clinical personnel), and experts with the University of Pennsylvania's Center for Bioethics, DeLisser adds.

"The process behind the guideline did not represent a secret conspiratorial process involving a couple of people trying to impose their prejudice and bias on the institution," he states. "It is more of a collective consensus."

To avoid any misunderstanding, hospital officials are making careful efforts to educate those most likely to be affected by the guideline, such as personnel at nursing homes and assisted living facilities who might send patients to the hospital, members of the public, and other health care providers at the hospital and beyond.

"Since the guideline has been on the books, I am not aware of any instance when it has been used, but we are working to get the word out to people about what is involved in the guidelines, their purpose and intent, and making sure people are educated," he notes.

Because the document is a guideline and not a policy, families who disagree with the care plan for their relatives under the guideline can appeal to the ethics committee, and physicians are not required to adhere to the guideline's recommendations if the families disagree.

AMA's ethics guideline on medical futility policies

Following is an excerpt from the ethics guidelines of the American Medical Association (AMA). The complete guideline can be found on the AMA's web site at www.ama-assn.org.

E-2.037 Medical Futility in End-of-Life Care

When further intervention to prolong the life of a patient becomes futile, physicians have an obligation to shift the intent of care toward comfort and closure. However, there are necessary value judgments involved in coming to the assessment of futility. These judgments must give consideration to patient or proxy assessments of worthwhile outcome. They should also take into account the physician or other provider's perception of intent in treatment, which should not be to prolong the dying process without benefit to the patient or to others with legitimate interests. They may also take into account community and institutional standards, which in turn may have used physiological or functional outcome measures.

Nevertheless, conflicts between the parties may persist in determining what is futility in the particular instance. This may interrupt satisfactory decision-making and adversely affect patient care, family satisfaction, and physician-clinical team functioning. To assist in fair and satisfactory decision-making about what constitutes futile intervention:

(1) All health care institutions, whether large or small, should adopt a policy on medical futility; and

(2) Policies on medical futility should follow a due process approach. The following seven steps should be included in such a due process approach to declaring futility in specific cases.

(a) Earnest attempts should be made in advance to deliberate over and negotiate prior understandings between patient, proxy and physician on what constitutes futile care for the patient, and what falls within acceptable limits for the physician, family, and possibly also the institution.

(b) Joint decision-making should occur between patient or proxy and physician to the maximum extent possible.

(c) Attempts should be made to negotiate disagreements if they arise, and to reach resolution within all parties' acceptable limits, with the assistance of consultants as appropriate.

(d) Involvement of an institutional committee such as the ethics committee should be requested if disagreements are irresolvable.

(e) If the institutional review supports the patient's position and the physician remains unpersuaded, transfer of care to another physician within the institution may be arranged.

(f) If the process supports the physician's position and the patient/proxy remains unpersuaded, transfer to another institution may be sought and, if done, should be supported by the transferring and receiving institutions.

(g) If transfer is not possible, the intervention need not be offered. (I, V)

Source: "Medical-Futility in End-of Life Care." Issued June 1997, based on the report adopted December 1996. Chicago; American Medical Association. ■

"In the end, because it is a guideline, physicians can just acquiesce to the wishes of family members [who want invasive therapies for MCS and PVS patients]. But we hope they will not do that but will instead make a real effort to talk to the families and follow through on the guideline," DeLisser says.

Invasive and intensive treatments have side effects of their own that will eventually cause health complications in these patients, he points out. Family members need to understand the true risks and benefits that "doing everything" will have for their loved ones, and health care professionals have a responsibility to take a role in helping families make such difficult decisions.

"We are trying to get away from just saying to families, 'Here is the situation, what do you want us to do?'" he says. "We know that something tragic has occurred; it is three months to six months to a year later, and their loved one

SOURCES

- **Horace DeLisser**, University of Pennsylvania Medical Center, Pulmonary, Allergy & Critical Care Division, Biomedical Research Building II/III, Rm. 806, 421 Curie Blvd., Philadelphia, PA 19104-6160.

is not going to recover. Given that, we need to emphasize that what we intend to do is focus our care on making sure the patients do not suffer in any way, and we do things that will affirm their dignity."

(Editor's note: The Hospital of the University of Pennsylvania has not yet published its guideline, "Care for Patients with Severe Impairments in Consciousness Following Acute Brain Injury," but the hospital will soon do so and will feature the guideline on its web site for other institutions to see. The web address is www.upenn.edu.) ■

Docs demanding reform as insurance crisis worsens

Physicians want limits on malpractice awards

According to a recent analysis by the Chicago-based American Medical Association (AMA), 18 states are experiencing a medical liability crisis, with residents unable to get needed medical care because physicians there cannot afford insurance premiums for medical malpractice coverage.

In a June 2002 report, the AMA indicated that 12 states — Florida, Georgia, Mississippi, New Jersey, Nevada, New York, Ohio, Oregon, Pennsylvania, Texas, Washington, and West Virginia — had reached a crisis stage in provider shortages due to liability insurance rates. On March 3, the association added six more states to the list: Arkansas, Kentucky, Connecticut, Illinois, Missouri, and North Carolina.

"There is something terribly wrong when dedicated professionals, who have trained for years, want to give up the work of a lifetime, move to another state, or stop offering high-risk procedures such as delivering babies," says AMA president **Yank D. Coble**, MD.

Among the findings in the AMA's analysis:

- More than 50% of Arkansas physicians report that they have been forced to reduce or discontinue one or more medical services in the last two years due to rapidly increasing medical liability premiums.
- In Connecticut, premiums for neurosurgeons and other high-risk specialists are more than $100,000 per year, and an increasing number of obstetricians in that state are refusing to deliver babies.
- High-risk specialists in Kentucky, including emergency room physicians and general surgeons, saw increases in their liability premiums of between 87% and 200% last year.
- North Carolina hospitals have seen professional liability insurance premium increases of 400% to 500%, with small rural hospitals experiencing the greatest increases.

The culprit in these skyrocketing insurance premiums, Coble says, is the current medical malpractice system, which has become a "lawsuit lottery" in which select patients and attorneys get astronomical awards while others are left out in the cold.

According to jury verdict research cited by the AMA, the median jury award increased 43% in the one-year period from 1999 to 2000, with more than half of all awards topping $1 million and the average award coming in at $3.5 million.

The AMA and others want to see a federal cap limiting non-economic damage awards to $250,000, similar to a California state law that already limits damage awards.

But others say high damage awards are not the real force behind the rising insurance premiums, and capping damage awards will only limit the ability of injured patients to get compensation for medical mistakes and encourage bad physicians to continue to practice.

"Doctors are falsely demonizing America's legal system rather than saving tens of thousands of lives and litigation costs by preventing careless or unnecessary medical errors, such as operating on the wrong part of the body," says **Joan Claybrook**, president of the consumer advocacy group Public Citizen. "Most injured people don't sue. They turn to the courts in egregious situations. Capping damages will only hurt those who have suffered the most."

Recent spikes in insurance premiums are the result of cyclical economic factors affecting the insurance companies and are not tied to substantial increases in jury malpractice awards, Claybrook claims.

The medical professional societies would better serve patients by better policing their own members, she adds. Studies conducted by Public Citizen and by independent research groups indicate that the majority of malpractice awards are paid by a minority of "repeat offender" physicians.

And contrary to popular opinion, insurance

premium rates have not kept pace with the skyrocketing cost of health care overall.

For example, West Virginia received national attention after doctors walked out of hospitals and refused to practice unless the state intervened to reduce malpractice insurance premiums.

Yet the median amount of malpractice awards in West Virginia remained steady at $145,000 from 1997 to 2002, the consumer group claims. Adjusting for inflation, the median amount actually represents a decrease.

A key factor in West Virginia's malpractice insurance crisis is the decision by a large insurance carrier — St. Paul Companies, which once covered one-third of the state's doctors — to stop offering medical malpractice insurance.

In New York, another crisis state, doctors' malpractice insurance premiums have remained nearly level for a decade, with the total amount doctors paid in premiums in 2001 at $873 million, compared to $821 million in 1992.

A Public Citizen analysis of information from the National Practitioner Databank indicates 7% of New York doctors are responsible for 68% of malpractice payouts in that state, with 80% of physicians there not paying a malpractice claim since 1990.

Doctors win most suits

Although capping damage awards is not the answer to solving the medical liability crisis, the current system does need reform, malpractice attorneys tell *Medical Ethics Advisor*.

"If you look at the statistics, about 62% to 67% of the cases that actually go to trial wind up with a defense verdict — the doctor wins. So, how is a cap going to help?" says **Brad Parker**, JD, a medical malpractice and personal injury lawyer practicing in Fort Worth, TX.

Many patients injured by medical mistakes are not even able to sue because most attorneys won't take cases if the expected payout isn't high enough to cover legal fees and still compensate the victim, he adds.

"Once we get to a point we think we might take a case, we also look at damages," he says. "The state of malpractice right now is such that unless I have a patient who has serious and permanent damages, I don't want the case. I am not even talking about a case where they had to go back in for a second surgery to correct what they goofed up the first time and the person missed an additional six weeks of work. From my perspective, that is not a case, because I am going to spend tens of thousands, if not hundreds of thousands, of dollars on the case, and what is six weeks of work and surgery really worth?"

Most malpractice attorneys turn away clients with valid claims all the time because the claims do not justify the economic expense of a lawsuit.

Some experts have proposed that the current tort structure for medical malpractice be replaced with an alternative system — possibly similar to worker's compensation — in which providers pay into a pool that would compensate patients injured by medical mistakes.

Last year, a report from a committee at the National Academy of Sciences' (NAS) Institute of Medicine called for a small number of states to develop injury compensation systems outside the courtroom that would be "patient-centered" and "focused on safety."[1]

The systems would be able to set reasonable payments for avoidable injuries; provide fair, timely compensation and apologies to a greater number of patients; and stabilize the malpractice insurance market by limiting providers' financial exposure, the report suggested.

"A lot of people recognizing that we do have a medical malpractice crisis focus solely on the size of the damage awards," says attorney **Mark Lamb**, JD, who practices health law with the firm Preston, Gates and Ellis in Seattle. "The NAS proposal says there are other problems as well: the length of time of litigation, delayed payments, and the fact that people with relatively minor medical mistakes don't really have access to the courts."

The current tort system also presents a number of "perverse incentives" that keep hospitals and

For More Information

• The **American Medical Association** has an information resource on medical liability reform issues. The resource can be accessed on the association's web site at: **www.ama-assn.org/ama/pub/category/7861.html**.

• The consumer group **Public Citizen** has published a number of research reports on the medical malpractice crisis, including state-by-state reports on malpractice insurance premium rates and the number of damage awards. The reports are available on the group's web site at: **www.citizen.org**.

SOURCES

- **Yank Coble**, MD, American Medical Association, 515 N. State St., Chicago, IL 60610.
- **Joan Claybrook**, Public Citizen, 1600 20th St. N.W., Washington, DC 20009.
- **Brad Parker**, Watson & Parker, 1701 River Run, Fort Worth, TX 76107.
- **Mark Lamb**, Preston, Gates and Ellis, 925 Fourth Ave., Suite 2900, Seattle, WA 98104-1158.

physicians from disclosing mistakes when they are made, he adds.

In order to keep premiums low, physicians have an incentive not to self-report medical errors, in addition to the natural inclination not to acknowledge mistakes.

"In the idea of a non-judicial system where you could honestly flag an mistake and already have a realistic sense of what the economic implication would be, you wouldn't be in danger of losing your entire practice over it and there would be some sort of certainty to the result, which would give some sense of rationality to the system as a whole," Lamb says.

Better reporting of medical errors would allow the health care industry to track physicians responsible for a larger percentage of them and institute some kind of intervention, he adds.

The report did not call for an immediate shift to non-judicial remedies, but asked that four or five states initiate pilot programs that would be evaluated at the end of a specific time.

"What I like about the proposal is that it takes a step back from the current wars over a damage cap and tries to think about what the goals of the system are, and one of the goals is to discover medical errors, as well as providing prompt payment to the injured," he says. "We do need a system that functions more rationally, where you don't have huge disparities in awards, with someone who gets the right jury gets enormous damages, whereas someone else with the same injury gets almost nothing. I don't think that benefits anyone."

Reference

1. Committee on Rapid Advance Demonstration Projects: Health Care Finance and Delivery Systems. "Fostering Rapid Advances in Health Care: Learning from System Demonstrations." National Academy of Sciences, Institute of Medicine; 2002. http://national-academies.org. ■

Organ transplant tragedy is focus of investigation

Family, health care community ask, 'How?'

The United Network for Organ Sharing (UNOS) is conducting a review of the circumstances leading to a transplant fatality, in which a recipient received a heart-lung transplant from a donor with an incompatible blood type, the network reports.

Jesica Santillan, a 17-year-old Mexican immigrant, died Feb. 22 of complications suffered when her body rejected the heart and lungs from a transplant performed at Duke University Hospital in Durham, NC. Doctors discovered shortly after surgery that the organ donor's blood type was different from Santillan's. A second heart-lung transplant was performed days later, but Santillan developed swelling in the brain due to the original rejection and died.

In its role as administrator of the national Organ Procurement and Transplantation Network (OPTN) for the U.S. Department of Health and Human Services, UNOS is reviewing all facts related to the patient's listing and the donated organs that were offered to her, the network said in a statement issued Feb 20.

"Ms. Santillan was registered on the national waiting list as a candidate for a heart-lung transplant," the statement indicated. "However, she did not appear on the 'match run' — a computer-generated list of potential recipients who were medically compatible with the donor — because her blood type did not match the donor's."

The UNOS/OPTN investigation is focusing on how the organ offer and acceptance occurred despite her absence on the specific list used for the match.

UNOS/OPTN policies have established a procedure for matching donors and recipients and require that detailed medical information about each donor, including blood type, be recorded and provided to the transplant center. If properly followed, these policies, in conjunction with the quality management procedures utilized by the state-level organ procurement organizations and transplant centers, should prevent erroneous blood-type mismatches.

The OPTN/UNOS Membership and Professional Standards Committee is spearheading the investigation for the network and also has

recommended certain immediate changes to prevent future recurrences, says UNOS spokeswoman **Ann Paschke**.

The committee is calling for all organ procurement organizations to ensure their staff members are thoroughly familiar with the most current information regarding existing network policies and procedures designed to ensure proper allocation of organs. Specifically, the committee requested that information be disseminated immediately regarding OPTN policies that require organs to be allocated only for patients who are included on the official network "match run."

The committee also has required that more detailed information be disseminated on the use of the UNOS computer system to facilitate running a donor/patient match.

Upon completion of its review, the committee will present its final recommendations to the OPTN/UNOS Board of Directors. In addition, a special subcommittee is being formed to conduct an in-depth review of OPTN policies and procedures to determine whether additional safeguards need to be implemented to protect against potential errors in the future.

Questions about citizenship status

Since the transplant tragedy, some experts also have questioned how Santillan was able to receive the transplant at Duke, given that she was an undocumented Mexican immigrant and U.S. transplant policies require non-citizen organ recipients to have legal status here.

UNOS policies do state that recipients must be in the country legally and do prohibit centers from performing more than 5% of their transplants on non-resident aliens, Paschke says. These regulations are stipulated in the federal law creating the OPTN. But, the network does not perform a policing function, she notes.

"Considerations about residency and immigration status do not come into play when deciding whether someone will be on the waiting list," she explains. "We do collect data about a recipient's residency status, but only to track how centers are adhering to the rules, after the fact. Her residency status would not have affected her ability to be matched. This is not a criterion that is even considered by the computer."

Decisions about who should be listed as a candidate for transplantation are made by transplant coordinators at each center, Paschke said. ■

VA mandates review of research programs

The U.S. Department of Veterans Affairs (VA) last month issued a nationwide ultimatum to its medical centers involved in research to shape up or else.

The department ordered a 90-day review in its 115 medical centers following a series of accidents, including the death of one patient at an undisclosed location. The review, outlined in a March 6 memo to VA research personnel, requires individuals who run and oversee medical research to update their training on patient protection.

VA studies have not been suspended during the review process. Stopping testing could do more harm to patients who need the procedures being offered without increasing the chance to prevent rare adverse incidents, said **Nelda Wray**, MD, the VA's chief research and development officer, in her memo.

Wray called the review a "stand down," a military term that means halting procedures to identify a problem. "The purpose of this stand down is to focus attention on proactively reviewing the human study program to ensure we are doing all that is possible to ensure the protection of human subjects and the ethical conduct of research," she wrote. The review will last until June 6.

The VA is responsible for more than 15,000 research studies involving around 150,000 patients each year, according to the agency. As a result of the review process, each hospital involved in research must confirm to VA headquarters that it ensures its ethics procedures and system for catching errors meet widely accepted human research standards.

Incidents cited, while not specific because of the ongoing investigation, include:

- falsified individual patient data that contributed to the death of one patient;
- a patient overdose in a drug study project at another center;

• an experimental procedure being conducted without the approval of the institutional review board (IRB);

• a drug study being conducted by a researcher who lacked the clinical privileges required to prescribe the study medication;

• failure of a review board to meet even minimally required standards.

The incidents are "exceptions in a VA program that is otherwise outstanding," Wray wrote. She did note that since taking her position eight weeks ago, she had learned of practices that "will not be tolerated," she said.

The medical director, chief of staff, or chief of staff for research will have to attest that the IRB and research and development committees are appropriately constituted and meet on a regular basis to provide timely review and oversight of new and continuing protocols and a review of adverse events and serious adverse events, according to the memo.

Investigators involved in human studies research will be notified that if they conduct research without IRB approval, it will affect their standing in the VA, warned Wray. ▼

Partial-birth abortion ban approved by Senate

A ban on a late-term abortion procedure known as "partial-birth" abortion overwhelmingly passed the U.S. Senate in March.

The 65-32 vote sent the legislation to the House of Representatives, where passage is expected this spring. The majority Republican Senate defeated several challenges to the bill banning the procedure on March 12, clearing the way for passage.

Congress has twice before passed legislation to impose a ban, but President Clinton vetoed both measures. A third attempt was sidetracked in 2000 when the Supreme Court invalidated a Nebraska state law that closely resembled the measure moving through the House and Senate. And a fourth attempt failed last year when Democrats, then in control of the Senate, refused to schedule a vote.

The current bill prohibits doctors from committing an "overt act" designed to kill a partially delivered fetus. "Partial birth" is described as a case in which the entire fetal head is outside the body of the mother, or, in the event of a breech delivery, if "any part of the fetal trunk past the navel is outside the body of the mother."

The legislation includes an exemption in cases in which the procedure is necessary to save the life of the mother.

If the bill becomes law, physicians performing procedures that fall under the ban would face either fines or a maximum jail term of two years.

The American College of Obstetricians and Gynecologists (ACOG) officially opposes all state and federal efforts to enact "partial birth abortion bans."

As indicated by a policy statement passed by its executive board in 1997, "ACOG continues to find it disturbing that legislators would take any action that would supersede the medical judgment of a trained physician, in consultation with a patient, as to what is the safest and most appropriate medical procedure for that particular patient."

And, although a panel convened by the college could cite no circumstances under which intact D&X would be the only option to protect the life or health of a woman, "intact D&X may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman, and only the doctor, in consultation with the patient, based upon the woman's particular circumstances, can make this decision," the statement concludes.

The House of Representatives is scheduled to consider its version of a "partial-birth" abortion ban in April. ■

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- ■ The 'medicalization' of female sexual dysfunction
- ■ Treatment obstacles for female heart patients
- ■ Selecting candidates for organ transplants

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13. According to our article, "futile" medical care is:
A. Care that is believed to be of no benefit to the patient
B. Care that, if delivered, would not substantially improve the patient's condition
C. Difficult to define
D. All of the above

14. The guideline established by the Hospital of the University of Pennsylvania in Philadelphia:
A. Covers patients who have suffered an acute brain injury and have been in a coma for six months
B. Covers patients who have suffered an acute brain injury and have been in a persistent vegetative state for a year
C. Covers patients who have suffered an acute brain injury and been in either a persistent vegetative state or minimally conscious state for three to six months, depending on the condition causing the injury
D. None of the above

15. According to the article, which factors have been cited as the cause of recent restrictions on access to medical care in 18 U.S. states?
A. Rising malpractice insurance premiums inducing physicians to limit or leave their practices
B. New federal laws establishing practice requirements
C. Reports of physician malpractice contained in the National Practitioner Databank
D. None of the above

16. According to policies administered by the United Network for Organ Sharing under federal law, organ transplants in this country can only be performed on what percentage of non-resident aliens (non-citizens)?
A. No more than 5% at each center
B. No more than 10% overall
C. Just under 20%
D. None of the above

Answers: 13-D; 14-C; 15-A; 16-A