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Is anthrax the culprit, or antibiotic used to fight it?

Are we on the cusp of an evolutionary experiment?

It seems the terrorists achieved their goal of creating fear. Americans are rushing to get their hands on ciprofloxacin as a precaution against the anthrax scare that emerged following the terrorist attacks on Sept. 11, 2001.

But ethicists can play a pivotal role in allaying the fears of patients by creating a sense of reassurance — first among health care providers and then within the community.

"We have to reinstill a sense of confidence for

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COMING IN FUTURE ISSUES

- In the wake of the anthrax exposures, are physicians prescribing antibiotics for the worried well?
- Should hospitals ration ciprofloxacin?
- Vaccines for smallpox and anthrax are in limited supply, who should be the first to receive them in the event of large-scale exposures? How are these decisions made?
- Developing bioethics resources in rural areas
- New concerns about funding end-of-life care

people who work in the health care system," emphasizes veteran epidemiologist **William Schaffner**, MD, chairman of preventive medicine at Vanderbilt University School of Medicine in Nashville, TN.

"Start with the doctors. They are the ones that are going to be more panicked than the nurses," he advises.

Hospitals at front lines of vigilance

Ethicists, hospital epidemiologists, and other key clinicians involved in health care bioterrorism readiness and response must set the tone for a panicky public and an uneasy health care work force, advises Schaffner.

And the government echoes that sentiment by calling for hospitals to be vigilant. Speaking during a White House news conference last month, U.S. Department of Health and Human Services Secretary **Tommy Thompson** called for the nation's hospitals to take a prominent role in assisting the government with vigilance against bioterrorism.

Thompson said hospitals needed to help because the Centers for Disease Control and Prevention (CDC) in Atlanta is "stretched."

Jeffrey Koplan, MD, director of the CDC, challenged health care providers to participate in "grass-roots, frontline vigilance." Koplan says it's up to physicians and emergency department (ED) personnel to stop outbreaks in their tracks through early diagnosis and astuteness.

These pleas for calm come as insurers and pharmacists report dramatic increases in prescriptions for the drug ciprofloxacin, manufactured under the brand name Cipro by West Haven, CT-based Bayer AG.

Many people are stockpiling the medication, but those who take it indiscriminately could create a far more serious situation than the anthrax it fights.

Despite anthrax outbreaks in New York City, Washington, DC, and Boca Raton, FL, as well as New Jersey, only one death is attributed conclusively to the condition at press time. The good news in all the anthrax hysteria is that it is treatable.

Physicians urged not to prescribe

The Chicago-based American Medical Association (AMA) urged its 300,000 members in middle October to resist prescribing ciprofloxacin to patients who are merely worried and have no

evidence of anthrax exposure. "We're getting reports from physicians and [EDs] that are being overwhelmed with anxious patients," says AMA president **Richard Corlin**. "In the majority of cases, these people should not be on antibiotics."

Indiscriminate use of ciprofloxacin could lead to the emergence of germ-resistant strains of bacteria, experts warn. Ciprofloxacin belongs to the fluoroquinolone class of antibiotics, and is among the last effective treatments for some serious infections. **(For a list of biological agents and treatments, see chart, p. 124.)**

Germs resistant to antibiotics cause or contribute to the deaths of 70,000 hospitalized patients in the United States every year, says **Stuart Levy**, head of the Center for Adaptation Genetics and Drug Resistance at Tufts University School of Medicine in Boston.

Furthermore, a sudden surge in patients using ciprofloxacin could worsen the problem by encouraging germ-resistant strains of bacteria to emerge, Levy suggests.

"You're going to see a huge change in the microbiology of the world in which we live, to the detriment of a drug that's important to many patients," he says. "It's an experiment in evolution that we're witnessing."

Pressure over profits

The demand for antibiotics has resulted in round-the-clock production of medicines to keep up with demands from consumers and the government. The attention the drug industry is getting is not without a price, however. Some critics argue that drug companies are unduly profiting from the unfortunate attacks against America.

Bayer, the manufacturer of ciprofloxacin — the only drug approved to treat inhaled anthrax by the U.S. Food and Drug Administration, is being pressured to release its patent on the drug to allow for generic production to meet the increased demand.

The issue of patents will likely face more scrutiny as the government pumps millions of dollars into pharmaceutical research and development. The need for new treatments and vaccines against biological agents will cause pharmaceutical companies to become defense contractors for the government.

The new relationship will test the existing patent system, and ultimately the pricing structure, due to an overly anxious public.

CME questions

17. Ethicists can play a role in educating providers and the community about bioterrorist events by:
    - A. conducting seminars.
    - B. allaying fears.
    - C. coordinating vaccine drives.
    - D. all of the above

18. According to a legal opinion issued by the Texas attorney general:
    - A. it is against federal law to provide any health care to undocumented immigrants.
    - B. it is against federal law to provide subsidized, nonemergency care to undocumented immigrants, unless a state legislature passes a law specifically allowing it.
    - C. federal law allows no exception for subsidized health care services that treat com municable illnesses or emergency medical conditions.
    - D. publicly funded hospitals cannot offer care to undocumented immigrants, even if they are able to pay the bill.

19. The American Nurses Association:
    - A. encourages nurses to strike for better pay and benefits.
    - B. provide guidance for nurses to use collective bargaining and collective actions to improve their workplace and patient care.
    - C. prohibits members of state nurses' associations from engaging in strikes.
    - D. none of the above.

20. Physicians who believe that a recently deceased patient is a potential organ donor:
    - A. should contact a representative of their area organ procurement organization, or a designated requeseor at their facility to discuss donation with the patient's family.
    - B. should immediately approach the patient's family about the possibility of organ donation.
    - C. should, under no circumstance, discuss donation with the patient's family.
    - D. all of the above

(Editor's note: Next month, Medical Ethics Advisor *will examine the ethics of distributing vaccines and treatments for bioterrorist events.)* ■

Treatment of Biological Agent Exposure

AGENT	CLINICAL SIGNS AND SYMPTOMS	TREATMENT	OTHER	SECONDARY TRANSMISSION
Anthrax (spore)	Fever, malaise, non-productive cough, progressing to dypsnea, stridor, shock. Incubation 1-6 days.	Prophylaxis/treatment: ciprofloxin, doxycycline, PCN licensed vaccine. IV therapy: ciprofloxin doxycycline, PCN licensed vaccine.	High mortality (>90%) even with treatment.	None except aerosolized body fluids.
Pneumonic Plague (bacteria)	High fever, chills, headache, hemophysis, toxemia, dyspnea, stridor, bleeding diathesis. Incubation 2-3 days.	Prophylaxis/treatment: vaccine, doxycycline, TMP/sulfamethoxazole. IV therapy: streptomycin (>1 yo), gentamicin, chloramphenicol.	Antibiotic treatment effective if begun early.	Strict isolation needed. Isolation mandatory for at least the first 48 hours of treatment.
Tularemia (bacteria)	Regional lymphademepathy, fever, chills, headache, malaise, cutaneous ulcers. Incubation 2-10 days.	Streptomycin, gentamicin. Adult prophylaxis: doxycycline.	Low mortality (about 5%).	Rare, body fluid precautions only.
Q Fever (bacteria)	Fever, cough, pleuritic chest pain. Incubation 10+ days.	Tetracycline, doxycycline.	Low mortality.	Does not require universal precautions.
Smallpox (virus)	Malaise, fever, rigors, vomiting, headache, backache; 2-3 days later lesions appear and quickly progress from macules to papules to pustular vesicles. Incubation 16-17 days.	Supportive — vaccine available from CDC. Immune globulin may be available from CDC. No antiviral medication available.	Supposed to be extinct (doubtful).	Highly contagious.
Viral Equine Encephalitis	Supportive. No antiviral medication exists.	Ribaviron, supportive care.	Isolate patients in single room with an adjoining anteroom stocked with PPE. Negative air pressure if possible.	Body fluids. Otherwise infectious by vector (mosquitoes).
Viral Hemorrhagic Fevers	Fever, malaise, myalgias, headache, vomiting, diarrhea, easy bleeding, petechiae, shock.	Ribaviron, intensive care, convalescent plasma (Argentine HF), vaccine (yellow fever), blood replacement products for DIC.	Decontaminate with hypochlorite or phenolic disinfectants.	Transmitted by bodily fluids. Strict barrier-nursing techniques. Limit patient transfers: may increase risk for secondary transmission.
Botulism (toxin)	Ptosis, weakness, dizziness, dry mouth, blurred vision, diplopia, descending paralysis. Incubation 24-36 hours.	Several antitoxins are available and effective if administered early. CDC vaccine good only for A and B.	Disinfect with hypochlorite and/or soap and water. Supportive long-term mechanical ventilation.	None.
Ricin (toxin)	Weakness, fever, cough, pulmonary edema, incubation 18-24 hours.	Supportive — oxygenation and hydration. No antitoxin or vaccine available.	Disinfect with hypochlorite and/or soap and water.	None. Derived from caster beans.
Staphylococcal Enterotoxin B (toxin)	Fever, headache, chills, myalgias, cough, nausea, vomiting, diarrhea. Incubation 3-12 hours.	Supportive — oxygenation and hydration. Ventilator support may be required.	Disinfect with hypochlorite. Most victims recover.	Use PPE.

Source: Robert Suter, DO, MHA, FACEP, Questcare Emergency Services, Plano, TX.

Texas physicians caught in cross-border battle

New rules would turn providers into 'INS agents'

Public hospitals in Texas are struggling to come to terms with a recent state attorney general's opinion that they should refuse to provide subsidized nonemergency health services to undocumented immigrants.

County public hospitals and clinics have for years treated low-income residents regardless of their immigration status. An estimated 1 million Texans do not have legal residency status. Restricting services now to only citizens and legally recognized residents would turn health care providers into "INS agents" and jeopardize the fragile solvency of the public health system, claims **Ron Anderson**, MD, president and CEO of Parkland Hospital and Health System, the public health care system serving Dallas County.

"We don't want our hospitals to become places that people are afraid to come to until they are critically ill," he says. "If you want to solve problems with immigration, it should be done at the border or in the workplace, not in the back of an ambulance or emergency room."

Feds make first ruling

According to a legal opinion issued by Texas Attorney General **John Cornyn** on July 10, the 1996 federal welfare reform act (officially known as the Personal Responsibility and Work Opportunity Reconciliation Act) made it illegal for publicly-funded health systems to provide nonemergency services to uninsured residents who are undocumented immigrants, unless the state specifically passes legislation allowing it.

The only exceptions are emergency services, immunizations, diagnosis and treatment of communicable diseases, disaster relief services, school lunch and breakfast, and programs necessary to protect life and safety (domestic violence shelters, homeless shelters, food banks, soup kitchens, emergency mental health, and substance abuse services).

These are protected under federal law for all residents and cannot be restricted, says **Anne Dunkelberg**, MPA, senior policy analyst with the Center for Public Policy Priorities in Austin.

Following the opinion, a group known as the Young Conservatives of Texas filed complaints with the district attorneys in Harris, Dallas, Bexar, and El Paso counties, alleging that the public hospital districts had misappropriated taxpayer funds by providing nonemergency services to illegal residents. And, three county health districts (Nueces, Montgomery, and Tarrant) announced that they would not provide subsidized nonemergency care to undocumented immigrants.

"Some counties have been scared into not providing care," says Anderson. This is unfortunate not only because these people will have no access to primary and preventive services, but because the health districts will still be responsible for caring for emergency medical situations that arise when chronic medical conditions go untreated. The cost of treating critical and acute medical conditions is much higher than the cost of providing free preventive care to the uninsured, undocumented residents, he says.

"For example, we have really strong data on our prenatal care system. We deliver 16,000 babies each year at Parkland," Anderson states. "We get prenatal care for 96% of those births. For the 4% who don't get prenatal care, they have an infant mortality rate that is four to six times higher. Considering the costs associated with low birth weight and other complications of no prenatal care, the health system will have to absorb that higher price and they have also ethically and morally compromised the life of those children forever."

Dialysis patients are another concern for the public hospitals and clinics, he adds.

Renal failure is a chronic medical condition that becomes acute intermittently. Patients from other countries, many times the parents of legal residents, come here on visitation visas, have an acute episode, and end up in hospital emergency departments requiring treatment.

"That is a pretty expensive circumstance, and it is a huge issue for us," Anderson acknowledges. "We have about 19 patients who are undocumented from different parts of the world. We can't get these patients into private dialysis units, so we have been carrying the burden for that care, and we've never billed for it."

Public opinion polls have shown that 52% of Texans support the attorney general's position and are in favor of restricting subsidized medical care to legal residents. However, most people are unaware that hospitals are required by federal law to treat all people who present to their facility with emergency medical conditions — a fact

For More Information

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that would likely change their opinion about providing primary and preventive care earlier, Anderson contends.

It would make more sense, he says, to proactively try to establish better guest worker programs and get some sort of limited health insurance for these residents, rather than just restrict care altogether, which has the opposite of the intended effect, he says.

"The politicians are looking at the polls. But, we believe if the questions had been asked correctly, we would have had a different result," he says. "Nobody is saying, 'We have to pay for these illnesses at a much more expensive stage downstream, what do you think about that?' Even people who don't care about the morality of it, wouldn't want to spend the additional money."

Regardless of public opinion, public hospitals are obligated to provide indigent care to legal and undocumented residents alike, Anderson adds. "I think the polls are flawed, but even if it [public opinion against providing care] was 75%, it does not relieve us of our responsibility from a moral point of view."

After consulting with the hospital system's board of directors and attorneys, and meeting with the Dallas County district attorney, Parkland has decided to continue providing subsidized services to county residents without asking about immigration status, says Anderson.

Hospital attorneys have reviewed the federal law and Cornyn's opinion, as well as a 1999 constitutional amendment and a separate law passed by the Texas Legislature that, they believe, specifically allows public funds to be used to provide health services to undocumented residents.

The 1999 law was a renewal of a 1985 law that defined the roles and responsibilities of hospital districts, says Anderson. "We went back and listened to the tape of the legislators in 1985 and it was clearly their intention to cover the undocumented. They had the opportunity to change that in 1999, and they didn't. We think their intention was to keep things the way they were."

In addition, the 1999 amendment to the state constitution stated that counties were to provide medical services for all needy "inhabitants" of the county, and did not distinguish between those with legal status and those without, he adds. Their attorneys believe these two statutes demonstrate that the state has passed legislation specifically permitting subsidized care to undocumented immigrants.

At this time, criminal investigations still are proceeding although the Dallas district attorney has assured Parkland officials that he has found no evidence of criminal intent, and that he would not pursue complaints based on past actions by the hospital to cover illegal immigrants.

"Right now, we are kind of in limbo," Anderson says. As for the counties who have stopped providing the subsidized care, he suspects that they also are continuing to treat these patients, but are just writing off unpaid charges as bad debt.

"I have talked to some of them privately and, although that is their political position, they do not turn people away," Anderson states. "What they do is charge them the full amount."

Parkland has a program that allows indigent patients to pay for services on a sliding scale according to their ability to pay. In admitting patients to the program, hospital staff ask the patient if he or she is a resident of the county or intends to be a resident of the county, but they don't ask about immigration status.

"They apparently are asking that question and denying them any sort of sliding scale opportunity to pay for their bill," adds Anderson. "I seriously doubt they have wholesale turned people away, even though that may be what their board and county commissioners have expected them to do."

SOURCES

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- **Anne Dunkelberg**, Center for Public Policy Priorities, 900 Lydia St., Austin, TX 78702.

It's important to understand that the attorney general's opinion does not carry the weight of law and is not an enforcement order, explains Dunkelberg. "It is not like a judge making a decision and directing the government to do something. It is just asking a person, who is an expert, for his opinion and he gives it."

On Aug. 30, **Michael A. Stafford**, the attorney for Harris County, released his own legal opinion on the matter, which differed from that of the state attorney general. Like the Parkland officials, Stafford concluded that the state Legislature had, in fact, taken action to specifically allow these services to continue to be provided to all residents, documented and undocumented.

"The Texas Department of Health has always construed the term 'resident' in a manner which does not condition residency on the legal status of the person," the opinion reads. "Furthermore, the Legislature has also provided the necessary legislative action after Aug. 22, 1996, to permit the District's continuation of health care assistance to all residents, regardless of legal status."

Stafford's opinion carries equal legal weight with the state attorney general's and it remains to be seen whether the complaints against the public hospital districts hold up in court, Dunkelberg says. In the meantime, undocumented immigrants are being denied needed care in some areas, and even in counties that are committed to continue serving them, many may be afraid to seek care at all.

"Some people may not realize that they can still use the emergency room," she says.

But, the real fear is that, unless Congress or the Legislature acts, efforts made by the Texas public health system to improve access to primary care and preventive medicine will be lost.

"The whole thrust of public health systems over the last 20 to 30 years has been for government entities that deliver care to the uninsured, have been trying to get primary and preventive care out there as a way to reduce both the need for emergency care and the use of the emergency room for non-emergent care," Dunkelberg explains. "A policy like what the attorney general is pointing to would really run counter to the whole direction of public health systems that have been underway for three decades."

Although the Harris and Dallas County hospital districts have not changed their policies, a number of the smaller counties, notably Nueces and Montgomery, have changed theirs, even though hospital officials have said they think it is a bad idea, she adds.

"Very publicly they said they thought it was a bad policy change and they were only doing it because they were afraid of being sued," she says. "They are so small and their resources so limited that they simply cannot afford to be dragged into court."

The policy change will likely mean that these small counties will end up spending more money on emergency care for conditions they could have treated early. "They have to suffer the fiscal consequences of it as well as the humanitarian consequences," she says.

The hospitals' only hope for a remedy now is for the state legislature to pass a law explicitly granting counties the right to decide for themselves what to do with public health care funds. However, she notes, the Texas Legislature only meets every other year and will not convene again until January 2003.

The alternative, she says, is for Congress to act and alter the parts of the welfare reform act that affect provision of health care to immigrants.

"This is putting health care providers in a terrible, ethical bind," she says. "The best outcome that could happen would be for this ill-conceived federal law to be changed." ■

Should strikes be an option for physicians and nurses?

Is collective bargaining a violation of ethics?

After unsuccessfully trying to negotiate a new contract for more than a year, registered nurses at Brockton (MA) Hospital walked off the job for more than two months this summer, primarily to protest the hospital's continued demands that the nurses be compelled to work extra shifts, sometimes tacked on to the end of scheduled shifts, despite concerns that such mandatory overtime

compromised patient care. The nurses returned to work in September after hospital officials agreed to end mandatory overtime after 18 months and severely restrict its use until then.

Frustrated by demands for mandatory overtime as well as their inability to have a say in staffing levels and patient care, nurses at two hospitals in the Minneapolis area also went on strike for a month this summer until hospital officials agreed to limits on mandatory overtime and let nurse managers close units to new patients when they felt staff ratios were too low to be safe.

Strikes becoming more common

Once considered unthinkable, strike actions by nurses and other health care providers are becoming more and more common across the country as hospitals institute severe cost-cutting measures in the face of declining reimbursements and higher rates of uncompensated care. In the past two years, nurses, nurse's aides, and other providers staged strikes at multiple hospitals and nursing homes in New York and California as well as Massachusetts and Minneapolis.

"When I graduated from nursing school in 1970, we viewed collective bargaining as not the sort of thing that professional people did — we were interested in establishing a professional role where the patient is front and center, which I would say is still the case, but you would never consider a strike," says **Gladys White**, RN, PhD, director of the Center for Ethics and Human Rights at the American Nurses Association (ANA) in Washington, DC. "The view now is that we cannot afford to use that strategy in certain situations."

The ANA's code of ethics for nurses with interpretive statements demands that nurses "address concerns about the healthcare environment through appropriate channels" and states that: "Toward this end, nurses may participate in collective actions, such as collective bargaining or workplace advocacy, preferably through a professional organization such as the state nurses' association in order to address terms and conditions of employment."

In the current health care environment, nurses may be placed in situations that may ethically require them to take collective action, and such action may lead to a strike.

For example, mandatory overtime currently is a serious problem for many hospital nurses, White says.

"In many situations, at the end of a 12-hour shift, nurses are pressured to work longer, and their own views about whether they can function effectively after 12 hours aren't taken into consideration," she explains. "In addition to concerns about appropriate patient load, patient acuity, what the appropriate nurse-patient ratio should be, mandatory overtime has been a really serious issue that nurses have been trying to deal with across the United States."

Few professions would require someone to work for 12 hours and then compel them to work additional hours despite their own professional judgment, White adds. On top of that, at many hospitals nurses have no say in how many patients a nurse might be required to care for at any given time, and may have no input into when a unit can be closed to new admissions because of low staffing or an already high number of new admissions.

"When nurses are put in a position where they cannot use their professional judgment about the delivery of care it compromises them morally and ethically," she notes. "They must exert their power collectively. We definitely support collective bargaining, and when necessary, strikes on the part of nurses, as needed."

The ANA's code of ethics for nurses emphasizes that patients cannot be abandoned in the middle of acute episodes and nurses make every effort to give the hospital appropriate advance notice of a planned strike, says White.

"They alert the hospital in advance, and make every attempt to have attending physicians not admit additional patients to get the census very low, to continue to cover the emergency areas and, if necessary, transfer patients to neighboring hospitals," she explains. "In that way, we attempt to ensure continuity of care."

In one recent strike action, some nurses made arrangements with their union to continue to work in the hospital's neonatal intensive care unit, continuing to care for two infants during the strike, because they felt transfer to another facility or to another provider would have compromised their care, she notes.

Not all health professionals, including nurses, support strikes by caregivers.

And, although the American Medical Association (AMA) two years ago decided to support collective bargaining on behalf of physicians, the organization still strongly opposes physician participation in strikes. According to AMA Policy E-9.025 (Collective Action and Patient Advocacy): "Strikes reduce access to care,

eliminate or delay necessary care, and interfere with continuity of care. Each of these is contrary to the physician's ethic. Physicians should refrain from the use of the strike as a bargaining tactic."

In the current health care environment, collective bargaining on behalf of physicians in negotiating contracts with managed care organizations and health care facilities is very important. But, changes can and should be brought about without resorting to work stoppages, says **Susan Adelman**, MD, a pediatric surgeon at the University of Michigan in Dearborn, president of the Physicians for Responsible Negotiation (PRN) the physician's union established by the AMA in 1999. As a requirement for membership, physicians must agree not to participate in strikes or withhold essential medical services.

"We are committed to not using strikes as a strategy because they compromise patient care and, in most situations, are not necessary and can even be counterproductive," Adelman says.

National labor laws prevent many private practice physicians from participating in collective bargaining because they are considered independent contractors. Physicians on staff at public hospitals, or in publicly funded residency programs have been allowed to collectively bargain in the past. And, recent decisions by the National Labor Relations Board have expanded the number of physicians allowed to unionize and collectively bargain in certain situations.

Physicians wield power

Physicians as a group can have enormous power to effect change at their respective facilities without engaging in work disruption, says Adelman. "If a hospital were to negotiate in bad faith with the physicians, this could hurt them when it came time to negotiate with managed health plans. And, conversely, managed health plans who refuse to engage in appropriate negotiations with physicians will get a bad reputation when it comes time to bargain with hospitals."

Most physicians are ethically opposed to participating in strikes and are relieved to be able to be a member in an organization that will negotiate on their behalf, but will not force them to engage in activities that will compromise care, she says. "In some situations, if other unionized groups at their hospital went on strike, reciprocal agreements would require the doctors to go to the picket line as well."

Although many physicians are opposed to engaging in strike actions, it is important not to rule out strike as an option, argues **Robert Weinmann**, MD, president of the Union of American Physicians and Dentists, a 41-year-old union that represents 5,000 physicians in the state of California. "As long as people believe that nurses and physicians cannot take the strike action, they can always refuse to negotiate," he says. "They know there are no real consequences. Organizations that enter into the negotiations have to understand that obstructing negotiations has its consequences."

It is important that any collective actions taken be structured so that they do not adversely effect patient care, and this can be done, he states. "The strike has to be against the employer, not against the patient. You have to figure out ways of going on strike but ensuring there is triage, so that people who need care can still get it."

An example of such an action, he says, would be physicians continuing to provide care but refusing to fill out the paperwork necessary for the hospital to bill for the service. "The patients are still getting the care, but the hospital cannot collect its fees."

However, PRN warns its members that such actions can be considered "partial strikes," which are illegal under many state labor laws.

No health care provider wants to go on strike at their workplace, White emphasizes.

If hospitals and other facilities would act proactively to include different groups of providers in organizational decisions, most of these problems could be averted.

"No. 1, there should be nursing representation on the ethics committee," she says. "And, the committee should be attentive to issues like staff turnover rates among nurses and other health care professionals. They should know something about the context in which care is being delivered: about the number of unfilled positions, patient-staff ratios, and the level of experience on different units. The hospital ethics committee can

SOURCES

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exert a lot of positive power by speaking about issues related to the workplace, have orientation sessions for new staff, those kinds of things."

A significant increase in the number of cases referred to the ethics committee should also be a red flag that there may be workplace and staffing issues at the core of the problem. "If the committee is seeing more and more cases, this is a symptom of workplace issues that at least ought to be known about, if not remedied." ■

Organ donor success hinges on family members

Info needed about why families refuse to donate

The number of people waiting for a kidney transplant in the United States has exceeded 50,000 for the first time, according to the United Network for Organ Sharing (UNOS), the Richmond, VA-based organization that maintains the Organ Procurement and Transplantation Network (OPTN).

As of Oct. 1, 2001, there were 78,350 people on the national organ transplant waiting list, with 50,004 of these persons waiting for a kidney. The total number of people awaiting organ transplant exceeded 50,000 only four years ago, in July 1997.

The situation underscores the need for more Americans to agree to become organ donors upon death, said UNOS President **Jeremiah G. Turcotte**, MD, in a statement released on Oct. 5. "The No. 1 problem facing the field of transplantation today is the lack of available organs. While we continue to meet the needs of patients as best we can, we must improve upon the public's willingness to make and share a commitment to donation."

While the numbers of people consenting to become living donors has jumped dramatically — 16% between 1999 and 2000 — these don't begin to provide enough organs to cover the shortage. And, transplants from cadaveric kidney donors increased only 0.7 percent in the same time period.

Increasing rates of cadaveric organ donation has been a top priority of U.S. Department of Health and Human Services (HHS) Secretary **Tommy Thompson**. In April, Thompson formally launched the "Gift of Life Donation Initiative" which includes:

- development of a model national donor card;
- creation of a national forum on donor registries to explore options and guidelines for registry development;
- support for the creation of a national medal to be given to donor families, and development of model curriculum on organ donation to be included in driver education classes.

The initiative also includes the "Workplace Partnership for Life" a cooperative arrangement between HHS and private corporations that encourages private employers to work together to develop pro-donation educational activities.

On Oct. 3, the Health Resources and Services Administration (HRSA) at HHS, which regulates organ donation and transplantation efforts across the country, announced grants totaling $10 million over three years to 12 different organizations who will study different strategies aimed at increasing organ donation.

In addition to focusing on educating the public, HRSA wants to find out which specific initiatives actually increase rates of donation, as opposed to simply increasing the number of people willing to sign donor cards, says **Jon Nelson**, director of the Office of Special Programs at HRSA.

Although educational initiatives might make people more receptive to the idea of organ donation, unless this translates to family members giving consent at the time of death, it doesn't mean much.

"We don't really know a lot about what works, in terms of getting people to donate," Nelson says. "There is a lot of anecdotal evidence out there and a lot of it depends on the kind of personal interaction that occurs during the consent process. But, we need to figure out what works and see if that can be replicated in other areas."

According to the National Organ Procurement Study, public opinion polls show that most people say they would donate an organ, but most families don't agree to donate organs when they are asked. Although 84% of health professionals correctly identify patients' eligibility to donate some organs, currently only 34% of approached families agree to donate something.[1]

Although many people think donation education activities are aimed at convincing individuals to become donors, a more effective approach might be to educate specific communities about the value of organ donation in order to remove barriers to procuring organs, says **Tom Beyersdorf**, executive director of the Gift of Life Agency in Ann Arbor, MI, the organ procurement agency for the state.

The agency was one of 12 recipients of one of the HRSA grants and will launch a three-year initiative

aimed at increasing rates of donation among the Arab-American community in the southeastern part of the state.

That area has one of the highest concentrations of Arab-Americans in the country, and historically, they have seen low rates of organ donation, notes Beyersdorf. Developing multilingual education materials and networking with business and community leaders are goals of the three-year initiative.

According to Beyersdorf, the key to increasing organ donation is not just in persuading people to become organ donors, but educating entire communities so that families will not object to organ donation, even if evidence indicates that is what the deceased person wanted.

"Even if the person wanted to be a donor, and indicated it on the driver's license, in the end, we often have the families say no," he says.

One of the main focus areas of study for the new grant recipients will also be to examine different methods used to approach families to get consent for organ donation, says Nelson.

"In some areas, they use family members of people who have been organ donors to approach families or potential donors; they have people who are on staff at a hospital and on call to go talk to the family," he says. "Some organ procurement organizations have 'hospital development programs' where they work very closely with the hospital to ensure that either the Organ Procurement Organization's (OPO) trained staff members or hospital staff that the OPO has trained, determine whether a person is an eligible donor and then initiate the initial discussions with the family."

It's essential that there be a clear separation between the personnel who ask the family to consent to donate and the hospital personnel who have been in charge of caring for the patient prior to death, Nelson emphasizes. "There has to be a definite separation between the people caring for the patient while he or she is alive and the people who are there after the patient dies and approach the family about donating, and coordinate the recovery of the organs."

Some physicians incorrectly feel that it is their responsibility to raise the issue of organ donation with a patient's family after the patient has died, adds Beyersdorf. But, data show that rates of consent for donation are drastically lower when physicians ask than when the family is approached by someone from the OPO or another trained person, he says.

"The family is not able to separate from that person as the caregiver for their family member, and to have this person then ask them about organ donation, is usually very confusing," Beyersdorf explains.

In fact, because studies of the consent process have found physician-requested consent rates to be very low (9% vs. 67% when OPO representatives ask) federal HHS regulations governing organ procurement require that the person approaching the family to request donation be an OPO representative or a trained "donation requester." Designated requesters are individuals who have completed a course approved by an OPO on how to approach potential donor families to request organ or tissue donation. [2]

But, even if a potential donor's physician is a trained requester, say Nelson and Beyersdorf, it would still be preferable for a clearly objective

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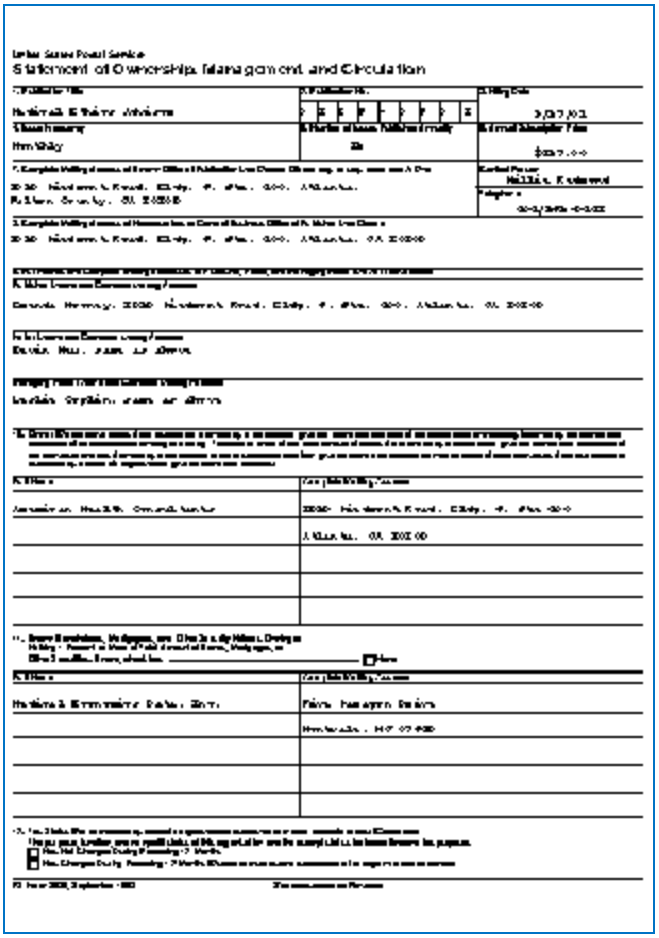

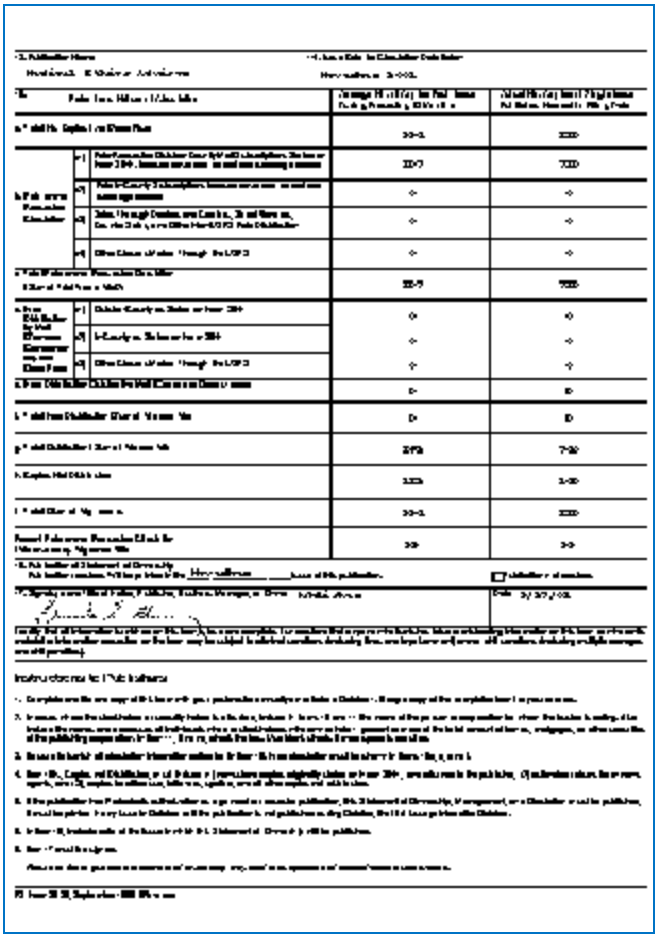

third person to be involved in approaching the patient's family.

In Beyersdorf's experience, consent rates are best when a team of people, led by an organ procurement representative from the agency, but including the patient's physician and other caregivers, approaches the family about donation.

"Many physicians feel it is their responsibility as a care provider to both the patient and the family to be the one to initiate the process — they feel that they have the history and background with the family and know how to approach them better," he explains. "But, the data show otherwise. We ask that the physicians, at the very least, invite us to join them for the initial discussion. And, if need be, step out of the picture, to avoid confusing the family."

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