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Pandemic influenza: The rules aren't the same as for typical flu season

Vaccine rationing shifts from protecting vulnerable to protecting masses

The Bush administration's projections of the potential impact of an avian flu pandemic expose the enormity of the ethical issues that come with any plan for rationing and distributing vaccine.

Basing a worst-case scenario on what the United States and the world learned during the three flu pandemics that struck in the 20th century — most notably the Spanish influenza pandemic of 1918 that felled as many as 50 million people worldwide — the federal government's pandemic response strategy, released May 3, cautions that a flu pandemic would cause massive disruptions lasting for months. Though the crisis would be nationwide, President Bush said, cities and states would have to deal with the local effects themselves, without guarantee of a federal rescue.

With current vaccine production capabilities using egg-based media for developing new vaccines, six months after a flu strain was identified, at full global production, perhaps 1 billion doses of vaccine would be available worldwide, experts predict. So the question is not whether vaccine would have to be rationed, but how.

"We have a responsibility to take this planning stage very seriously," says **Kathy Kinlaw**, MDiv, director of the Atlanta-based Emory University Center for Ethics. Kinlaw is a member of a panel of experts assembled to serve as an external advisory board to the Centers for Disease Control and Prevention (CDC) on the ethical issues related to rationing and prioritizing flu vaccine in a "normal" epidemic and in the event of a pandemic.

"The more we can do now to describe the scope of possibility and enhance our resources and readiness, the less we'll have to rely on allocation," Kinlaw says.

Most Americans have become familiar with flu vaccine rationing in the past three years, but rationing during normal flu seasons has as its primary objective protecting the most vulnerable — the sick, the elderly, and anyone in fragile health — and health care and emergency services workers who have direct patient contact or contact

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with many people.

“A pandemic is different from a shortfall in a regular flu season, because the basis for prioritization for a vaccine shortfall in a typical season is based squarely on minimizing serious complications,” she says. “If you move into pandemic flu concerns, you want to keep those criteria for vaccination for those at risk, but other factors come into play. The nature of a pandemic means large volumes of people are affected in a short period of time, in a short geographical area, and that brings another layer of complexity to the allocation question.”

While protection of the most frail is still a priority during a pandemic, distribution of limited

vaccine and antivirals where they will do the most good for the greatest number of people becomes the goal.

Good of the many vs. good of the few?

Confronted by the looming threat of a pandemic, America’s traditional commitment to the “equal moral worth” of each person would shift, according to **John D. Arras**, PhD, Porterfield professor of biomedical ethics and professor of philosophy at the University of Virginia in Charlottesville. “[That view] would predictably and justifiably yield to a social value perspective narrowly focused on survival and the minimization of social disruption.”

Arras, also a member of the CDC advisory committee focusing on the ethical issues related to a pandemic, writes on the ethics of allocating influenza vaccines in an article in progress for the *Yale Journal of Biology and Medicine*.

A pandemic on the scale of the 1918 disaster would cripple key social institutions, including schools, courts, prisons, and government. Commerce and domestic travel would be severely curtailed. In that situation, the traditional plan of protecting the most vulnerable — the old, the very young, and the very sick — would be weighed against plans that would protect and preserve life for millions more people.

Arras says that a pandemic would force the consideration of plans that give preference to public health and safety and crisis response workers; protect transportation, food production, utilities, and other key social functions — including companies that produce and transport vaccine; and even rationing by age, dropping elderly people down on the priority scale in favor of those who have yet to live long lives.

Notable is the fact that many of the goals to consider are incompatible with each other.

“When you look at quality of life vs. quality of the benefit, or protecting the most vulnerable vs. getting the greatest good for the greatest number of people affected, you have competing values,” says Kinlaw.

An example of how criteria shift is the reason health care workers would be considered high priority in a regular flu season or in a pandemic. During a regular shortfall, health care workers are considered at risk because of their patient contact. During a pandemic, they would be considered priority for vaccine allocation, because in a widespread infection the need for strong health

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Editorial Questions

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care providers would be critical.

"The ethical reasoning shifts a bit in a pandemic," Kinlaw says. "It's not just a risk of complications, but an issue of keeping strength in our medical system."

Discussion of allocation also has to address what or who constitutes an essential service; public safety, vaccine manufacturers, food processing, and primary government all bear important responsibility in times of crisis.

"What it takes to keep a society running is a whole host of people," says Kinlaw. "You need food, need waste removal — there are lots of potential people we would have to look at on this essential services list."

Regardless of what allocation plan might be adopted in anticipation of a pandemic, its ability to work will be doubtful if there is not widespread ownership of it, Kinlaw stresses.

"When we're talking about allocation, we need to talk about building public goodwill and trust, because when we get to the point of allocation, we need to have people with us and for them to understand how we got there," she says.

Kinlaw says there is a natural tendency for individuals to ignore the looming threat of a pandemic, or to lapse into denial that they will be affected.

"It is easy for the public to not keep this issue in front of them, and somewhere we have to move beyond that, being careful not to be alarmist and simply building fear," she explains. "Somewhere in the middle is where we as citizens and organizations can be persuaded to learn about influenza and take reasonable precautions and see ourselves as partners with local, state, and federal agencies."

Preparations can limit, contain damage

The federal pandemic response plan puts terrific emphasis on and support behind development of speedier, cell-based vaccine development. In addition to improving and streamlining the stockpiling and new production of vaccines and antivirals, the plan takes a cue from the handling of Hurricane Katrina to urge states, local governments, and businesses to do everything they can to prepare to continue functioning despite widespread infections and without guarantee of being rescued by the federal government.

Because 85% of systems that American society depends on are privately owned and operated, including medical services, financial institutions,

SOURCES/RESOURCES

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- **Kathy Kinlaw**, MDiv, director, Emory University Center for Ethics. Phone: (404) 727-4954. E-mail: kkinlaw@emory.edu.
- *Implementation Plan for the National Strategy for Pandemic Influenza*, Homeland Security Council, Washington, DC. Available on-line at http://www.whitehouse.gov/homeland/nspi_implementation.pdf.

and food and drug producers, the federal plan pushes businesses to prepare plans for keeping operations going.

Kinlaw says efforts to shorten the time it now takes between recognition of a new viral strain and intervention with a new vaccine "can change the picture" of a pandemic, possibly avoiding some of the ethical dilemmas posed by harsher allocation plans.

"If we can shorten that time, we would be shifting the allocation need, because one of the problems [contributing to a shortage] is that it takes so long to manufacture a vaccine after the virus strain is identified," she says.

Regardless, she admits, "we can come up with some wonderful plans, but if we don't have a system where people can partner with and trust the system, the system will break down."

This is particularly important when considering groups who already are marginalized in society, who already may have misgivings about the equity of the health care system.

Global prevention eyed

The federal pandemic response plan outlines international efforts to monitor and contain influenza outbreaks, but Arras says he wonders if individual nations can act globally enough.

"Ordinarily, when people speak about the moral necessity of global justice, they usually, but not always, assume that giving sufficient aid and support to the distant needy will only put a small dent in our national budgets," he says. "We can thus do good and do pretty darn well simultaneously. This is because the cause of global justice is largely a matter of money rather than scarce commodities."

A pandemic, he says, would pose a greater obstacle because the necessary commodities would be scarce. As for giving equal priority to frail elderly in a third-world country and frail elderly in the United States, Arras says, "it's hard for me to imagine the 'America first' ideology being compromised on a matter of life and death."

"No matter how blissful the state of international relations at the time, my hunch is that the strong wind of nationalism will just blow away any countervailing claims of global justice," he suggests.

Says Kinlaw, "From an ethical standpoint, we need to think globally not only because we need to see the trajectory [of the spread], but also we need to look out and say, 'Where can we be helpful?'" ■

Discussing brain death, organ/tissue donation

Program to assist doctors, boost organ donor rates

Doctors recognize the importance of delivering news of brain death as well as possible — thoroughly, taking as much time as necessary, conveying the information of irreversible loss of brain function clearly and at a level family members can absorb.

But because the delivery of bad news is not a subject that has been given great attention by medical schools, physicians perform this difficult task by feeling their way through the encounters, usually with mixed success.

"Brain death can be a difficult concept for families to grasp," says **June Hinkle**, RN, MSN, director of bereavement services at The Ohio State University Medical Center in Columbus. "The circumstances are often sudden and traumatic, and while they hear the words 'brain-dead,' they see a body that is pink, warm, and still [mechanically] breathing. It's a very difficult concept. It doesn't happen frequently, and residents don't get much experience [in delivering news of brain death]."

Compounding the damage inflicted when news of brain death is delivered incompletely or insensitively is the potential loss of donor tissue. Patients who suffer brain death are a major source of potential organ donors, even though only a small

percentage of all patient deaths are classified as "brain deaths." Before families can consider — much less consent to — organ and tissue donation, they first must have a clear understanding of brain death. The longer that process takes, the less viable the donor tissue becomes.

"Time is essential if you are going to pursue donation, because once the brain has died, the body follows suit," Hinkle points out. "There is a lot we can do to keep a body going" — measures medical staff would not take if the family is not going to agree to donate.

"It requires a lot of medication to keep the heart going, so it's sort of essential that we know how aggressive to be in maintaining a heartbeat, because you want to keep the body stable until it reaches the operating room."

If discussions between the physician and family regarding the patient's condition are incomplete or otherwise handled clumsily, they might not understand that their loved one is dead, and so any discussion about donating organs or tissues might strike the family as premature — making the potential for donation even bleaker.

Simulation program developed

Hinkle says the need for some sort of model that would give residents the opportunity to practice delivering news of brain death and experience simulated family responses led her to search the literature for models of testing that use simulations.

"Medical students are now required, as part of their boards, to go to a setting where they have to evaluate a simulated patient, and they in turn are evaluated by their instructors," she explains. "It allows them to see patients before they — the residents — get to clinical settings. They learn to use tools and take histories in a controlled environment. So they are used to that style of testing."

With a grant from the Ohio Department of Health Second Chance Trust Fund, which supports organ and tissue donation efforts, and

SOURCES/RESOURCES

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development assistance from LifeLine of Ohio, a federally appointed organ procurement organization, Hinkle created a monitored, simulated laboratory to give residents realistic rehearsals for delivering news of brain death.

The simulation takes place in a laboratory that recreates, as closely as possible, a hospital setting, complete with multiple exam rooms, albeit ones equipped with camera and one-way-window monitoring. Actors portray next of kin, who react as real families might when told that a relative or friend is dead.

Realism is crucial, says Hinkle, from the circumstances that render the “patients” brain-dead to the reactions of the actor-families to the news and how it is delivered.

“Unfortunately, [brain death] is usually a situation where the person was fine in the morning, and then you get called to the hospital and there’s been a motor vehicle accident or a bleed in the brain or a gunshot,” she explains. “It’s a sudden, traumatic change for the family, and it then becomes how well they understand the concept and how easily they can understand that the person is gone.”

The aim is not merely to present information to families in a way that pushes them to donate organs and tissue, Hinkle stresses.

“There are great benefits to the family. They can grasp the news faster, and that gives them time to say goodbye, to realize that this really is the end, without a period of confusion and not really knowing what’s going on,” she says.

Targets those most likely to need it

The Ohio State program is in its first year, and is tailored to the physician populations that are most likely to deliver news of brain death — surgical residents, pulmonary fellows, and emergency medicine residents. The training directors for each program added the simulation to their programs’ continuing education program.

A resident going through the simulation is provided with a patient history — gunshot wound, motor vehicle accident, or brain bleed — as well as diagnostic results (X-rays, etc.) and the patient’s current status. The physician also is shown how to do a proper coma exam, Hinkle says, so that the diagnosis of brain death can be confirmed.

The actors playing family members are trained to act like next of kin would in such a situation and learn the appropriate questions to ask.

“Then, we videotape the residents’ delivery; first, they deliver the news of injury and that the situation looks bad, and then they deliver the news of brain death,” explains Hinkle. “They get to see the videotape themselves, and they get feedback. We critique what we like and what we don’t like, behaviors that we like and behaviors we think they should think about.”

The “family” is involved in the feedback phase, submitting an evaluation of how well the doctor fared in terms of his or her composure, mannerisms, and communication of the necessary information about brain death. Their comments are used as coaching tools, Hinkle says, to help doctors recognize what they can improve on and what clues to look for in family members’ responses and behaviors that indicate they are not getting the message.

Residents have been very positive in their feedback about the program, Hinkle says, and Ohio State already has gotten inquiries from other hospitals about gaining access to the training.

“Our goal is to continue with new residents each year, and I think it will come down to cost- and time-effectiveness as to whether we bring in older residents,” she says. “It would be interesting to re-evaluate older residents [who went through the training early in their residencies] to see if they improve over time.” ■

Presuming consent to organ donation? Not yet

Recommendations for increasing organ donations

The United States is not ready to follow some European nations in presuming that deceased patients have consented to organ donation if they did not specifically opt out, according to the national Institute of Medicine (IOM). However, the need for donor organs calls for boosting efforts to increase donations, including using organs from patients whose deaths are determined by cardiac criteria.

The IOM released its recommendations in a report, *Organ Donation: Opportunities for Action*, in May (available for purchase on-line from National Academies Press at www.nap.edu).

Most organs transplanted in the United States come from deceased donors whose deaths have been determined by neurologic criteria based on

the irreversible loss of activity in the brain, including in the brain stem. According to the IOM and data from the United Network for Organ Sharing (UNOS), the administering agency of the national organ procurement program, there are at most about 16,000 eligible donors whose deaths are declared in this way each year in the United States.

But many more people are declared dead using circulatory criteria (irreversible loss of heart function and permanent cessation of circulation). The IOM estimates that at least 22,000 people who die of heart attacks outside of hospitals could be potential donors, provided certain ethical and practical issues can be resolved.

In its report, the IOM recommends that federal agencies work with states and cities that have extensive trauma centers and emergency response systems to develop demonstration projects that can determine the feasibility of increasing rates of donation after circulatory determination of death

Presumed consent rejected, for now

Right now, people in the United States must make a deliberate decision to donate their organs, or next of kin must make this choice after their deaths. Some groups have suggested enacting policies that would presume consent to donate unless a person explicitly opts out, as Spain and Italy have done. The IOM committee that prepared the recommendations examined several methods that could be pursued to increase organ donation, including the so-called “Spanish plan” of presumed consent.

“We believe that at this time the best approaches are to pursue ways to increase donations based on circulatory determination of death, to enhance public education about the value of organ donation, to increase opportunities for people to opt in, and to sustain quality improvements in the organ donation system,” the committee reported.

While supporting many of the principles underlying a presumed-consent approach, the IOM determined that now is not the time to replace the current legal framework requiring explicit consent. Without broad public support, such a shift would probably reduce rather than increase the supply of organs, the report says. However, the committee encouraged those with a stake in increasing donation rates to work to create the social support necessary to make this

change.

Organ donation in the United States has increased steadily over the last two decades, but the growth in donor tissues and organs is far outstripped by the increasing need. In early May, more than 92,100 people were waiting to receive organs.

Also rejected is the trend of offering financial incentives such as direct payments, coverage of funeral expenses, or contributions to the donor’s choice of charity as a means of encouraging donations. Individuals who are willing to be organ donors should not be given preferential status as recipients of organs, the report adds.

So-called living donors — those who donate organs and tissues while still alive and healthy — do save lives, but the risk to their own health is considerable, and the IOM recommends additional advocacy on behalf of those donors to make sure they are fully informed when they consent to living donations. Additional study of living donation and its risks to the donor is urged by the IOM.

For more information, visit the Institute of Medicine web site at www.iom.edu. ■

Spirituality and medical treatment go hand in hand

Schools offering more resources for physicians

The link between patients’ spirituality and their response to medical treatment is gaining more attention, and according to a recent study, more than nine out of 10 doctors surveyed believe it is appropriate to discuss spiritual or religious issues when a patient brings them up.

However, the same survey (published in the May issue of *Medical Care*) showed that if their patients do not bring up religion or spiritual beliefs, only half of the doctors inquire about their patients’ faith.

“Physicians should take a spiritual history for all new patients for whom they are doing a new physical history or who they are admitting,” says **Harold G. Koenig**, MD, professor of psychiatry and behavioral sciences and assistant professor of medicine at Duke University Medical Center in Durham, NC. “It should be a part of their social history, and if the patient is not competent, take [the spiritual history] from the guardian, next of

kin, or person acting as power of attorney.”

Koenig says although the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires that spiritual histories be taken for all patients admitted to accredited hospitals, many hospitals rely on a question on admittance forms that asks if the patient has any religious preference.

“The checkbox isn’t sufficient for JCAHO standards,” says Koenig. “It doesn’t provide the doctor with the kind of information he or she needs.”

Little data, so far

Koenig says there is not much data on the effects that taking a spiritual history can have on a patient’s care, but one study published on physician inquiry into patients’ spirituality, indicates the impact might be significant.

In the *International Journal of Psychiatry in Medicine* article, the authors report that in a study of 118 cancer patients whose physicians (Christian and non-Christian) did a brief spiritual history, 85% of the physicians felt comfortable administering the spiritual history, 70% of the patients felt the history was useful, and in follow-up, there was a greater reduction in depressive symptoms in those patients and an increase in functional well-being.¹

“I was amazed that with a couple of questions addressing this subject, there was a statistically significant impact on the patients’ coping and well-being,” says Koenig. “How many things do we do in health care that have that kind of effect?”

The positive effects might come even if the physician and patient never discuss religion or spiritual beliefs after the history is taken, Koenig says. The benefit may be in merely letting the patient know that if he or she ever wants or needs to talk about spiritual beliefs, the door is open. He adds that the spiritual history should elicit whether the patient is comfortable talking about his or her religious beliefs, or if such discussions make the patient uncomfortable. (See **sample**

SOURCES/RESOURCES

- **Harold G. Koenig, MD**, professor of psychiatry and behavioral sciences, Duke University Medical Center, Durham, NC. E-mail: koenig@geri.duke.edu.

A Brief Spiritual History

- Do your religious beliefs provide you comfort and support, or are they a source of stress?
- How would these beliefs influence your medical decisions if you became really sick?
- Do you have any beliefs that might interfere or conflict with your medical care?
- Are you a member of a religious community, and do you consider it supportive?
- Do you have any spiritual needs that you need to have addressed?

questions for a spiritual history.)

The study published in *Spiritual Care* found that 76% of the most religious doctors asked about their patients’ beliefs, compared to 23% of minimally religious physicians. Thirty-eight percent of physicians surveyed said they thought doctors spent too little time addressing spiritual needs.

The majority of medical schools in the United States offer courses in spirituality in medicine, but most are not required courses.

The Birmingham, AL-based Southern Medical Association has undertaken a project to study and provide resources on the overlapping worlds of spirituality and medicine. The Spirituality/Medicine Interface Project will provide educational activities, regular journal articles, and live conferences. An educational conference for physicians, physicians-in-training, chaplains, social workers, and nurses will be held Sept. 14-17 at the Emory Conference Center in Atlanta, addressing the medical-spiritual roles played in chronic illness, palliative care, substance abuse, cancer, depression, STDs, domestic violence, and catastrophes. For information about the Spirituality/Medicine Interface Project, visit the Southern Medical Association web site at www.sma.org/spirituality.

Resource

1. Kristeller JL, Rhodes M, Cripe LD, et al. Oncologist assisted spiritual intervention study (OASIS): Patient acceptability and initial evidence of effects. *Int J Psych Med* 2005; 35:329. ■

Growth in palliative care a response to EOL issues

Medical community welcomes growing field

Surveys of ethics committees have long shown that the greatest share (90%) of ethics committee consults in the United States pertain to end-of-life issues. But in one growing specialty, ethics consults are about almost nothing but end of life.

Sometimes called the “everything else doctors” — meaning everything but a cure — palliative care specialists are there to support patients facing life-threatening illnesses and to provide relief from the physical and emotional suffering the patients and their families are going through. A study by Mount Sinai Medical Center in New York and the Washington, DC-based American Hospital Association (AHA) found that the number of palliative care programs grew from 632 to 1,037 between 2000 and 2003.

Some 1,200 U.S. physicians have been certified as specialists in palliative care since 1996 by the American Board of Hospice and Palliative Medicine, and the field continues to grow, according to **Charlotte J. Williams, MD**, assistant professor at the University of Alabama at Birmingham, which has opened three palliative care units at the university and Veteran’s Health Administration (VHA) hospitals in the Birmingham area in recent years.

“Some [entering palliative care medicine] are residents who have expressed an interest in palliative care and found a mentor in our section, or had a patient experience that caused them to become interested in specializing in palliative care,” says Williams.

“Others are older physicians who maybe have become disillusioned and have chosen to re-train and improve their skills in the area. Many of us have had a family end-of-life experience and it feels like a mission to improve patient care at the end of life.”

Williams says the medical community is welcoming the expanding field, because access to palliative care was an ethical issue in the past.

“Withdrawing or withholding treatment, do-not-resuscitate orders, surrogate decision making — just like patients and family members— staff come in with diverse values and backgrounds, and people need to be educated about what America in general and people individually

believe about end-of-life issues,” she says.

An author of the Mount Sinai study writes that the growth of palliative care “is a win-win for both patients and hospitals,” because palliative care provides quality care to patients in a way that is efficient and cost-effective.

The study showed that while palliative care has grown as a field nationwide, larger medical centers and VHA hospitals are more likely to have palliative care programs than smaller institutions. Hospitals that have their own hospices are more likely to have palliative care programs, as are hospitals that have American College of Surgeons oncology programs.

The AHA reports 22.2% of all U.S. hospitals have palliative care programs.

Factors influencing the growth of palliative care programs include the rising cost of caring for chronically ill Medicare patients and data showing that historically pain symptoms have been treated inadequately. ■

Recipients of suspect tissue reporting adverse effects

CDC, tissue banks try to calm patients’ fears

In a case described by a prosecutor as resembling a horror movie, the U.S. Food and Drug Administration (FDA) has received reports of adverse effects in patients who received human tissue grafts that were allegedly harvested from bodies in funeral homes without consent of families and, possibly, without being tested for infectious diseases as required by federal law.

The scandal surfaced late in 2005 when the FDA shut down BioMedical Tissue Services (BTS), a Fort Lee, NJ-based company that prosecutors say made \$4.6 million by illegally harvesting human tissue from funeral homes and selling it for use in transplants and research. Four men, including the owner of the company, Michael Mastromarino, have been indicted by New York state prosecutors on more than 100 charges that they falsified records to conceal the source of the tissues they harvested and sold, as well as the age and health of the bodies they were taken from.

The case exposes the potential for fraud in the record keeping required for donor screening and processing. BTS is accused of falsifying details on

death certificate copies kept in its files, altering information regarding testing for communicable diseases, and falsifying details about the deceased and their next of kin. The altered and inaccurate records made it impossible for the tissue processing companies that bought the tissue from BTS to accurately verify the quality and safety of the tissue.

Relevant communicable diseases for which the donor tissue is tested are HIV-1 and -2, hepatitis B virus, hepatitis C virus, and syphilis.

The FDA initially issued an advisory in late 2005 revealing preliminary findings of its investigation into BTS record keeping; the details of the case were more chilling than simple records fraud, however. Prosecutors say Mastromarino, working with an embalmer and two other associates, surreptitiously stole tissue and bone from more than 1,000 corpses. The bodies were in funeral homes. The tissue extractions allegedly took place at the funeral homes without families' knowledge or consent; afterward, removed bones were replaced with plumbing pipes before the bodies were sutured and prepared for burial.

In March 2006, the FDA updated its initial advisory to recommend, along with the Centers for Disease Control and Prevention (CDC), that health care providers offer testing to their patients who received tissue grafts originally obtained through BTS. The FDA also issued a call to patients and physicians to report any adverse effects they suspect might have resulted from that tissue.

"FDA has received reports of adverse reactions following implantation of suspect tissue," FDA public affairs spokesman **Paul Richards** told *Medical Ethics Advisor* in early May. "However, at this time, it is unclear if exposure to recalled tissue resulted in adverse reactions or infectious disease transmission. We are currently investigating reports of potential disease transmission resulting from the transplant of suspect tissue."

Industry reassures public of safety

The national association of tissue banks is reeling from the allegations and extent of the BTS charges. The American Association of Tissue Banks (AATB), a not-for-profit peer group organization founded in 1976 to facilitate the provision of transplantable cells and tissue of uniform quality in quantities sufficient to meet national needs, reacted quickly to assure the public that the processing that donor tissue undergoes makes the

risk of transmission of communicable diseases — even when the tissue's origin is as clouded as that allegedly obtained by BTS — very low.

AATB publishes standards to help ensure that the tissue banking meets acceptable norms of technical and ethical performance, and provides technical information and describes procedures to foster responsible approaches to recovery, processing, preservation, and distribution of transplantable tissue.

According to AATB information, it maintains strict criteria for screening for HIV and hepatitis, selecting donors, testing and record keeping, and labeling and storage of tissues. The association inspects and accredits tissue banking organizations and certifies tissue bank personnel.

However, while some AATB-accredited tissue banks bought tissue from BTS, BTS itself was not accredited by the association.

"BioMedical Tissue Services is not now, nor has it ever been, accredited by the AATB," association CEO **P. Robert Rigney, Jr.**, JD, said in a statement released at the time charges were announced against the BTS principals. "In fact, BTS has never applied for AATB accreditation."

According to federal law, tissue for potential donations is removed by registered tissue recovery agencies, of which BTS was one. Tissue recovery agencies are subject to FDA regulations, the "Current Good Tissue Practices" rule. During an inspection of BTS late in 2005, the FDA uncovered deviations in record keeping that raised red flags about the safety of the tissue harvested by the company.

Rigney outlined the processing that donor tissue undergoes before being banked, emphasizing that the processing is conducted according to FDA regulations and AATB standards, resulting in "multiple layers of screening, testing, quality assurance, and quality control measures." When tissue is harvested and processed according to industry standards, the following sequence of steps occurs:

- Following recovery, tissue is quarantined until a donor suitability determination is made. The donor is tested for communicable diseases (HIV-1 and -2, hepatitis B, hepatitis C, human T-cell lymphotropic virus-I and -II, and syphilis), in some instances using multiple tests and methodologies; the FDA has said that because blood samples and records accompanying the donor tissue from BTS are suspect, it cannot be determined if the BTS tissue met this criteria;
- A medical doctor reviews available medical

records and donor medical and social histories, and makes the final determination on the donor's suitability;

- Once the donor is accepted, the tissue is processed in controlled environments to prevent contamination and cross-contamination. Processing methods are validated, as required by the FDA and AATB. Rigney says most musculoskeletal tissues are highly processed, cleaned, treated with antibacterial and virucidal agents, and subjected to gamma irradiation or another method of viral inactivation or sterilization.

"To the best of our knowledge and belief, this is the first time in the 29-year history of the AATB where allegations have been made of possible widespread falsification of donor consent forms and medical records," said Rigney.

CDC recommends testing

The CDC has posted information and advisories about the safety of donor tissues on its web site (www.cdc.gov/ncidod/dhqp/tissue-transplantsFAQ.html) and advises physicians about testing their patients should receive if they were recipients of donor tissue:

- Patients who received tissue implanted *more* than six months ago should be given the following tests: HIV antibody, antibody to hepatitis B core antigen, antibody to hepatitis C virus, non-treponemal syphilis test (e.g., RPR or VDRL), and treponemal syphilis test (TP-PA or ELISA). If all tests are negative, the patient is unlikely to contract any of the diseases from donor tissue, and follow-up testing is not necessary, the CDC advises;

- Patients who received donor tissue *less* than six months ago can be offered the same tests described above, but should be re-tested six months after the tissue was implanted.

Nucleic acid tests, such as PCR assays, should not be used in place of the antibody tests recommended, the CDC advises.

Adverse reactions should be reported to the bank from which the tissues were obtained, or to the FDA's MedWatch voluntary reporting program, or both, the CDC, FDA, and AATB recommend. MedWatch is accessible at www.fda.gov/Medwatch/report.htm, or by calling (800) FDA-1088.

Following the advisory issued by the FDA, all BTS tissue remaining in banks was quarantined, and any that had been distributed for transplant was recalled.

As of late April, dozens of class-action lawsuits involving hundreds of tissue recipients had been filed in state and federal courts; that number could grow exponentially as the number of individual grafts distributed numbered in the thousands, according to investigators.

[For more information:

U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Rockville, MD. Phone: (301) 827-2000.

American Association of Tissue Banks, 1320 Old Chain Bridge Rd., Suite 450, McLean, VA 22101. Phone: (703) 827-9582. Web site: www.aatb.org.] ■

NEWS BRIEFS

Off-label use common, not always backed by data

More than 20% of the prescriptions written for the 500 most commonly prescribed drugs in 2001 were for off-label uses, and almost three-quarters of those uses had no scientific support for the use, according to a survey of office-based physicians.

Researchers found that while most prescriptions are written for the use indicated by the Food and Drug Administration (FDA), one-fifth were for off-label uses. While some off-label use logically followed the indications for use, such as the use of asthma medications for other lung ailments, some uses lacked data to back them up — for example, the use of anticonvulsants to treat chronic pain.

The study, conducted by David C. Radley, MPH, Dartmouth Medical School, appears in *Archives of Internal Medicine* ("Off-label prescribing by office-based physicians," 2006; 166:1,021-1,026), raises questions about patient safety and health care costs, the authors conclude, since off-

CE/CME answers

21. D; 22. D; 23. B; 24. A.

label uses do not receive the same level of scientific scrutiny as approved uses. Cardiac medications (46%), anticonvulsants (46%), and medications used to treat asthma (42%) were the most likely to be prescribed off-label. Psychiatric drugs were highly likely to be prescribed off-label with limited or no scientific support (96% vs. 4% strong support), as were allergy medications (89% vs. 11% strong support).

Radley and his colleagues surveyed 3,500 physicians quarterly for one year, during which time the doctors reported on all patient interactions during two consecutive workdays. Diagnoses and prescriptions were indexed, and prescriptions were compared to the indications listed on the drug's package insert. Off-label prescriptions were further evaluated and classified as having strong scientific support if evidence from drug trials or clinical settings suggested the medication was effective for the condition it was prescribed to treat, or as having limited to no scientific support if such evidence did not exist. ▼

Study says fewer doctors providing charity care

Ten years ago, 76% of physicians in the United States reported providing charity care to the uninsured, but that figure has declined every year, with the latest figures, from 2004-2005, showing 68% of physicians donating their time and skill to charity medical care. The center for Studying Health System Change reports each year on charity care, and in its most recent report states that declines in charity care have been seen across most major specialties, practice types, practice income levels, and geographic regions.

Increasing financial pressures and changes in practice arrangements may account in part for the continuing decrease in physician charity care, the center's researchers conclude. Physicians at the

highest income levels continue to report the greatest provision of charity care, with 75.6% of physicians with practice incomes greater than \$250,000 providing charity care in 2004-05, compared with 66.4% of physicians earning less than \$120,000. The drop in physician charity care occurred as the number of uninsured Americans grew to 45.5 million in 2004, signaling growing stress on the health care safety net, according to a spokesman for the Center.

The Center for Studying Health System Change report is available at www.hschange.org/CONTENT/826/?topic=topic02. ▼

EDs report greater shortage on-call specialist coverage

Nearly three-quarters of emergency department medical directors reported inadequate on-call specialist coverage in 2005, leaving patients at risk of not getting the orthopedic, plastic surgery, neurosurgery, otolaryngology, and hand surgery care they need in an emergency.

The Irving, TX-based American College of Emergency Physicians (ACEP) reports the shortage is up from two-thirds of ED medical directors surveyed by ACEP in 2004. The share of hospitals paying stipends for on-call specialist coverage increased to 36% in 2005.

ACEP said the survey findings are evidence of further strain on an already frayed health care system, driven by reduced health insurance coverage and funding and ongoing medical liability concerns.

According to the study's authors, the Emergency Medical Treatment and Active Labor Act (EMTALA) created "an unfunded safety net program for everyone using the nation's emergency departments," fueling a demand for emergency care that increases by 5 million visits each year while capacity decreases. ■

COMING IN FUTURE MONTHS

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■ Training ethics committee members

■ Drug companies: Exaggerating claims?

■ Emergency medical records and privacy

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CME Questions

21. Among the issues to consider in devising a vaccine allocation plan for an influenza pandemic is/are:

- A. the availability of vaccine and antivirals;
- B. prioritizing who should be immunized in order to protect the largest segments of population and critical institutions;
- C. evaluating the importance of protecting those most vulnerable (i.e., the elderly, the chronically ill, and pregnant women);
- D. all of the above.

22. The Ohio State University developed a module to train residents on delivering news of brain death so:

- A. physicians could handle such conversations more adeptly;
- B. families could be prepared to make end-of-life decisions;
- C. organ donation opportunities would not be needlessly lost;
- D. all of the above.

23. Among the recommendations of the Institute of Medicine committee on organ donations is that the United States shift to a policy of presumed consent in deceased patients who have not indicated a desire to donate organs.

- A. True
- B. False

24. A patient's spiritual history should include:

- A. asking whether religious beliefs make him or her more or less comfortable;
- B. a description of the physicians' beliefs;
- C. assurances that religion will not enter into physician/patient discussions;
- D. all of the above.

CME instructions

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge.

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. **The semester ends with this activity.** You must complete the evaluation form provided and return it in the reply envelope provided to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE objectives

After reading each issue of *Medical Ethics Advisor*, you will be able to do the following:

- discuss new information about hospital-based approaches to bioethical issues and developments in the regulatory arena that apply to the hospital ethics committee;
- stay abreast of developments in bioethics and their implications on patient care, risk management, and liability;
- learn how bioethical issues specifically affect physicians, patients, and patients' families. ■

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The report examines salary trends and other compensation in the hospital, outpatient, and home health industries.

For access to your free 2006 on-line bonus report, visit www.ahcpub.com. ■