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Triage during a mass disaster: The usual rules don't apply

Hard choices must be made, but establish ethical criteria ahead of time

A catastrophic disaster, either natural or manmade, that not only results in widespread casualties but also wipes out medical resources can force health care providers to abandon typical delivery of care and shift to a kind of battlefield medicine, where the sickest patients may not be treated so that care can be delivered to more.

That's the kind of decisions physicians were forced to make when they were trapped in hospitals in New Orleans after Hurricane Katrina with very sick, frail patients, no electricity, and few medical supplies.

"Doctors and nurses who stayed behind were scrambling to find drugs for their critically ill patients," says **Joseph L. Cappiello**, vice president for accreditation field operations at the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the nation's major hospital accrediting body, who toured New Orleans in the wake of Hurricane Katrina. "[Health care providers in New Orleans] had to make choices that we ordinarily don't make in America, to help those with the greatest chance of survival."

Triage in a typical U.S. hospital on an average, non-disasterous day typically consists of identifying the sickest or most critically injured patients and getting them appropriate care as quickly as possible, perhaps temporarily bypassing patients who are less sick or injured.

That kind of triage has to fall by the wayside to some extent when casualties are many and supplies and physicians are few, according to bioethicist **John Moskop**, PhD, professor of medical humanities and director of the Bioethics Center of University Health Systems of Eastern Carolina in Greenville, NC.

"There's a whole spectrum of situations that involve what we call triage, and it goes from the sort of routine triage that would happen in any busy emergency department, where we determine how quickly patients need to be treated, whether they can wait or have an urgent need for treatment. At the other end of the spectrum," he explains, "would be a massive disaster, [such as] a nuclear attack, in which many people say triage would be useless, because so many resources would

have been destroyed and so many thousands of serious injuries that you couldn't do anything."

But in between are disaster scenarios ranging from multivehicle car crashes that tax hospital emergency departments, plane crashes with hundreds of casualties, battlefield triage during war, or natural disasters like the tsunami that hit Sri Lanka or the hurricanes that hit the Gulf Coast in late summer.

"Each one is different; each has different criteria and difficulties for the triage officers, and there are underlying moral criteria involved. These are not typical situations, so there are some departures and some differences from the choices we might make outside a disaster situation," Moskop says.

Outside a disaster situation, when a patient presents to an emergency department with serious injuries, the medical staff does what it can to save him or her. In a large-scale disaster, that person might not be treated — and might die — since diverting the resources and manpower and time necessary to treat him or her might cost the lives or functionality of several more patients who could have been helped in the meantime and who might be more apt to survive.

"It's not an easy thing for people to do, because we don't want to feel like we're leaving someone to die," says Moskop. "One way to defend it would be to say 'This is an extraordinary circumstance, and look at the number we can save, and we're going to save as many people as possible.' And if that means setting another [less salvageable patient] aside, that's justifiable in these situations."

Cappiello, in comments made to the media during and after his visit to New Orleans after Hurricane Katrina, recounted harrowing details of how doctors and nurses felt compelled to ignore the fundamentals of their training and make triage-style choices to aid some patients at the expense of others.

Howard R. Epstein, MD, medical director of care management and palliative care at Regions Hospital in St. Paul, MN, has studied the ethics of triage, and says disasters such as the recent hurricanes, bioterrorist attacks, and the Sept. 11, 2001, terrorist attacks have caused physicians to give thought to situations many never thought they would experience.

He says large-scale disasters creating multitudes of casualties require physicians to treat patients based on the concept of medical utility rather than how they treat patients under normal circumstances.

Epstein says hospitalists and emergency medicine physicians who train for disasters should not concern themselves just with the medical aspects of such a frightful scenario.

"We must also prepare ourselves for the real and significant ethical and moral dilemmas we will encounter," when and if they are forced to deliver care primarily to those who benefit most from the fewest resources, he cautions.

Jeffrey Orledge, MD, is an emergency medicine physician at the Medical College of Georgia in Augusta, and is a member of the Georgia-4 Disaster Medical Assistance team that went to Louisiana to assist after Hurricane Katrina. He says even though he has trained in and taught lifesaving and mass casualty triage, and was part of

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the 9/11 medical response to New York, the situation demanded he adapt to what he found.

"I was doing triage the first day at the [New Orleans International] airport, and even though I teach BDLS/ADLS and have done the MASS triage station and helped teach that station, I still had to change because of the circumstances," he says. "There were tough questions — chest pain in a patient with a history of cardiac disease having the same type of chest pain, who after one nitro is pain-free, is he a red or green patient?"

In some ways, Orledge says, his decisions may have been easier than those made by hospital-based physicians in a disaster, because what he could offer patients was limited.

"At least we were part of a DMAT team, and we truly did not have enough resources there to do what is normally done, which is 'everything for everybody,'" he says. "That made it easier for me, because we knew our limited resources. I think it would be more difficult in a hospital setting."

"We need to have a conversation about what we would do if, like the doctors at Charity [Hospital in New Orleans], we are put into a situational ethics situation and have to decide what's right and wrong," says Epstein. "We need to give doctors and hospitals more of an ethical framework, to say that when we impose our hospital's disaster alert, what our medical response is going to be and what our ethical response is going to be."

By and large, Epstein says, physicians are not prepared to make those decisions without some authority from their states or communities that gives them permission to "change the paradigm."

No room for patient autonomy

A prize cornerstone of American health care, patient autonomy, by necessity, falls victim to the pursuit of the greater good when disasters strike, Epstein and Moskop point out.

"Patient autonomy kind of disappears in a triage situation," Moskop says. "That's another way our moral priorities shift."

Epstein says that in a disaster, doing what's best for the individual patient is supplanted by "society's competing interest."

"We are used to our paradigm, but what we're talking about is giving up patient autonomy and saying society has a competing interest," he says. "In a disaster with mass casualties, the balance shifts from individual autonomy to the greater good."

Key to making that shift, Epstein says, is hammering out a framework long before disasters strike, so that the medical staff, support staff, and the community know what health care will look like in a disaster.

"You need to have community support ahead of time, because you don't have the luxury of time to get everyone around a table [during a mass casualty incident]," he says. "You need to prepare in advance and have a plan that's transparent to the community, because if you're going to say 'I'm going to treat this person and not your grandmother,' you need to have already had that discussion and know, as a community, how you're going to handle it."

Moskop says physicians have to realize that even with a plan and set criteria in hand, the disaster and its scope will dictate many of the decisions that must be made.

"Each triage officer has to make tough judgments, such as whether or not a person's injuries justify priority for lifesaving intervention or should be passed over to give the time and resources to someone with a better chance at survival," he says.

Criteria have been developed for triaging patients in a disaster, in an effort to make as many decisions as routine as possible. Those are somewhat successful, Moskop continues, but don't remove all discretion and responsibility from the person making triage decisions.

"And in a situation like Katrina, other choices, like who to transport or not, don't come into play because you're stuck, at least temporarily, with limited resources — the hospitals were not functioning well, were low on supplies, no electricity," he says. "Physicians had to make do with what they had, and there's no way you can plan in that kind of detail."

But ethical issues probably should not arise during the application of disaster triage criteria, Moskop says; ideally, at that point, the physician should be trained and know the criteria, and thus be able to apply them "and not stew over the ethical issues."

"The ethical issues are more in how to design the criteria and deciding who do we give priority to," he explains.

This can include deciding priority — which can mean giving first priority to immediate lifesaving, second priority to those needing urgent but not lifesaving care, then those with minor injuries, and last, those who are so severely injured that they stand little chance of survival. That last group of patients, many say bluntly, may have to be considered a waste of scarce resources.

SOURCES

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"Not everyone agrees with that," Moskop points out. "Some people say you should try to give everyone an equal chance to survive, and then, even if most of them die, you can say, 'At least they had the chance.' But I think the majority reject that, and say that in extraordinary circumstances, you have to adopt a different moral perspective given the huge need that we have and the limited resources we have to address that need."

There is another priority advocated by some, taken from the military medicine practice of treating those lightly wounded in battle first, so they can return to the fight. In the case of a disaster in which medical personnel are among those injured, Moskop says an argument can be made to treat them first, so they can then assist in treating the rest of the sick and injured.

Epstein says that even physicians trained in disaster response and mass casualty triage can feel the effects of their decisions long after the disaster has passed.

"We're used to making the best decisions for our own patients and being the best advocates for those patients, regardless of what's going on, but in a triage situation like that, you have to treat those who have the most chance of survival," he says. "I don't think most health care providers are equipped emotionally and ethically, when they're put in a difficult situation, to avoid having ramifications down the road.

"I mean, how much more can you play God than when you say, 'I'm not going to feed this patient so I can feed that one,' or 'I am taking the ventilator off this patient so that I can put it on that patient'?"

Part of an institution's plan for coping with disasters should be provisions for debriefing and psychological counseling, he says.

"Especially if they inflict death on people who haven't asked them to do that," he says. "How do you make that decision at the point of care? There has to be some support [for the practitioner]."

Despite the daunting example provided by Hurricane Katrina and its effects on hospitals in New Orleans, Epstein says he has heard very little discussion among his colleagues at Regions Hospital about how they might respond if put in a similar situation.

"We have medical triage, but there's no way [in place] to make decisions in any fashion other than what we have now, which is the sickest get help first," he says.

Additional reading

• Epstein, H. Bioterrorism: Ethical issues for hospitalists. *The Hospitalist* 2002; 6:24-27. Available on-line at www.hospitalmedicine.org (accessed 9/24/05). ■

Medical ethics pioneer discusses advances

Cranford played critical role in Schiavo case

When **Ron Cranford** became a doctor in the 1960s, hospitals didn't have ethics committees. There were no ethics consultants, not even any case law addressing such issues as physician-assisted suicide. "Persistent vegetative state" hadn't been coined, and Terri Schiavo was just a toddler.

Cranford, a longtime editorial advisor to *Medical Ethics Advisor*, recently retired as senior physician and assistant chief of neurology at Hennepin County Medical Center in Minneapolis. Among those involved in end-of-life research and care, he is considered one of the foremost experts in the field, admired and reviled, depending on who is asked.

When Cranford was a young physician just out of the Air Force, the idea of patients being in a persistent vegetative state (PVS) was first described. At Hennepin, Cranford was a member of what is considered one of the nation's first ethics committees — the "thanatology committee" — and began fielding inquiries from people wanting to know just how prevalent PVS was.

"So, I sat down and gave it some thought, and

came up with the figure of 5,000 to 10,000," he says. "In a way, I just made it up, even though I tried to be accurate. But the media doesn't like ranges like that, so they just said '10,000,' and I started being quoted as saying there were 10,000 people in a vegetative state, and that became the standard.

"But we really didn't know then how many people were in a vegetative state, and we really don't know now, either. We just try to make good estimates."

While estimating PVS numbers is still apparently a specialty in progress, the field of medical ethics, particularly end-of-life ethics, has made incredible strides during Cranford's career.

"One thing people don't understand — even people on ethics committees — is how much progress we've made since the 1970s," he says. "We still have a long way to go. The next 20 to 30 years will be much more difficult and complex than the last 30, I think. We're just in the early stages of coping with end of life in a meaningful way."

Making end-of-life decisions in the early 1970s, when cases like Karen Ann Quinlan's were only beginning to come to public notice, was uncharted territory, Cranford says.

"We had no training, no law to back us, no ethics guidelines. We were just winging it by the seat of our pants," he says.

Hennepin's thanatology committee "didn't know what it was doing, but nobody else did, either. If you had an ethical dilemma, you had nowhere to turn."

The growth, both in number and in scope, of hospital ethics committees has been a tremendous advance in health care in the United States, Cranford believes.

"Ethics committees are not perfect, but they do serve a purpose, and now people can turn to an ethics committee to help when there is a dilemma. The importance is that they grow from a standpoint of need and vary from hospital to hospital and locality to locality, so they address the needs of the individual hospital and are locally driven, not federally driven, and that's really important," he says.

Even people who know little of end-of-life issues, palliative care, terminal sedation, and ethics committees got to know Cranford early in 2005, when the debate over the life of Terri Schiavo spread from within her family to the floor of Congress.

Cranford examined Terri Schiavo, served as an expert in the case, and was a staunch supporter of Michael Schiavo's quest to carry out what he insisted was his wife's desire to not be kept alive in a persistent vegetative state. His role in the Schiavo case won accolades from many, and generated scorn and threats from those who saw him as a proponent of euthanasia.

Cranford says the Schiavo case is not really all that different from many others in the United States, except that the state of Florida, Congress, and the president got involved.

"There are hundreds and hundreds of Schiavo cases out there, where families disagree. Stopping the feeding tube is a very common practice in the United States, notwithstanding all the controversy," he says.

"The state and federal governments made fools of themselves by intervening in Schiavo. Some decisions [to withdraw food and water from patients in PVS] are made at the state level, but most are made at the local and community levels, by families," Cranford adds. "In a lot of states — Minnesota, Washington, Colorado, Oregon — there are very few court decisions because these things are handled collegially. But some have crazy decisions, one after another, and only in a state like California or Florida would you have some of the insanity that you saw in the Schiavo case."

A case like Schiavo's would not have been handled well in the 1970s either, he says. "We wouldn't have thought of stopping feeding in the 70s, and stopping a respirator would have been huge back then."

Strides in aggressive palliative care

An area of advancement that Cranford believes may do away with disputes over many end-of-life cases is aggressive palliative care. When families see that their loved one is not in pain at the end of life, discussions of physician-assisted suicide and withdrawal of food and water don't arise as often.

"In the 70s and 80s, physicians were fearful of giving too much [pain-relieving] medicine because of legal liability, but doctors now are less concerned with legal liability and more concerned with doing the right thing," he says. Aggressive palliative care, hospice, and terminal sedation are much more accepted practices, relieving patient pain at the end of life and easing families' pain, as well.

"Medicine has become less paternalistic and more patient-driven. Families' rights have become more important, too, and that's one of the most important shifts I've seen, is to realize that families suffer sometimes as much as the patient does

and should be as much of a concern to the physician as the patient, and that's as it should be."

Expected faster progress

Though happy with the progress he's seen, Cranford says that he is surprised that American medicine hasn't moved forward more quickly.

"I underestimated how long it takes to educate people in these areas," he says. "I would have thought that brain death would be better accepted. I didn't think 30 years ago that DNR would be controversial. It was called 'playing God' in the 70s, and that charge is still there, but it's not nearly as controversial as it was."

Cranford sees dementia in the elderly as a much greater ethical challenge for physicians in coming years than cases like Schiavo's.

"The vegetative state is relatively simple and pretty straightforward," he says, though not always entirely predictable.

Cranford gained some notoriety in the early 1980s when he determined that a Minneapolis police officer, David Mack, who had been shot in the late 1970s, was in a persistent vegetative state. For reasons Cranford says he has never determined, Mack woke up 22 months later, and though gravely disabled, lived until 1986.

"In the elderly, dementia is more common than the vegetative state. What are we going to do with humane care for the elderly? One-third to one-half of people over the age of 80 will have some form of dementia. The neurological dilemmas will be far more common and far more complex."

Cranford was diagnosed with liver cancer two years ago and underwent surgery, but shunned chemotherapy. He says he feels great now, and plans to spend the rest of his life teaching, lecturing, and educating his colleagues and the public on end-of-life issues.

In September, hundreds of Cranford's friends and colleagues celebrated his career with an international conference on some of the most notable brain death and right-to-die cases that arose during his career.

"Schiavo was kind of the culmination of my career, but I will continue to work. There are enormous changes in the area of medical futility, and hundreds of families out there who can't accept the reality of medical futility. There's nothing wrong with that, because the idea of futility runs against the grain with patients and families. So it's a good thing to work on." ■

Build ethical practice into clinical study design

Public trust eroded by reports of ethical conflicts

Public trust in clinical trial research was damaged in the past year because of conflict-of-interest issues that arose with the National Institutes of Health (NIH) and by front-page media reports about drugs that had been studied and approved yet were found later to result in deaths among some people who used them.

"What people don't often realize is that virtually every decision we make has an ethical component to it," says **Evan G. DeRenzo**, PhD, bioethicist at the Center for Ethics at Washington (DC) Hospital Center and an adjunct faculty member in the graduate program in biotechnology at Johns Hopkins University in Baltimore. "We live in a world where we compartmentalize things. [Researchers] think of it as science, and then they think about ethics after thinking about science, and that's not the way it works."

Many researchers often fail to understand the ethical components of their decisions, including their ties to industry that could be construed as conflicts of interest, several ethical experts say.

Likewise, most researchers will think of conflicts of interest with regard to financial matters, but there also are other types, including process conflicts, says **Edward Fuchs**, PA-C, MBA, a research associate on the faculty at Johns Hopkins University School of Medicine. Fuchs also is the associate director of the Johns Hopkins drug development unit.

"Investigators, in order to get promoted, need to publish and get data, and in some ways, that poses as great a conflict as financial conflict," he says. "Also, in clinical practice, there is this issue of conflict that exists between the investigator role and the patient-subject role."

Because of these ethical challenges, the NIH director's Council of Public Representatives (COPR) held a workshop in Bethesda, MD, last fall — "Inviting Public Participation in Clinical Research: Building Trust through Partnerships."

More than 80 participants discussed issues related to public participation and trust and developed a set of recommendations designed to enhance and improve the state of clinical research and build trust. (**See recommendations, p. 127.)**

Regulatory guidelines, recommendations, and

an institution's own policies regarding conflict of interest and ethical responsibility all are part of the foundation for the house of ethical decision making, notes **Linda Strause**, PhD, executive director of global site development at CancerVax Corp. in Carlsbad, CA. Strause also is the chair of the IRB for San Diego Hospice and Palliative Care.

The regulations never were intended to be black and white, she says. "Each situation may be different, and we need to address that and balance it with educating the public."

Strause, Fuchs, and DeRenzo discuss some of the chief ethical issues the clinical trial industry faces today:

• **Address challenge inherent in physician-investigator roles.** "Possibly, the most inherently conflicted person is the physician, who is also the investigator," Strause says.

"I believe physicians make decisions based on what's best for the patient," she says. "However, that decision may be conflicted when the physician is also the investigator and the patient is also the research subject."

In this case, the physician has agreed to follow a protocol and comply with good clinical practices, Strause says.

Part of the challenge is the traditional relationship between doctors and patients in which patients ask their doctors to tell them what to do, Strause explains. In the case of a physician serving in the role of investigator, the doctor cannot make this decision and cannot apply any influence over the patient/research subject's decision-making process, she notes.

"This is potentially coercive and may put undue influence on the potential subject," Strause says. "Some subjects are more vulnerable than others, such as children, individuals with life-threatening illness, or those facing end-of-life care."

So the answer resides in better education for both physician investigators and potential research subjects, she adds.

• **Be aware of changes in ethical perceptions.** Research in recent decades has relied on an ethical model based on the Belmont Report, focusing on issues of respect, beneficence, and justice, Fuchs says. "We may be in a period where we're looking at something beyond the Belmont Report. In some cases, it's described as a relationships model."

According to the relationships model, there is a relationship established between the investigator and community and the investigator and research subjects, and this relationship begins before the trial and should continue after the trial has ended,

COPR Recommendations for Building Public Trust

The NIH director's Council of Public Representatives (COPR) held a workshop Oct. 26, 2004, "Inviting Public Participation in Clinical Research: Building Trust through Partnerships," in Bethesda, MD, for the purpose of learning more about strategies to build trust and partnerships in clinical trial research. Here are COPR's recommendations for improving and enhancing the state of clinical research in the United States:

- ✔ Incorporate into the NIH mission and philosophy that it values the involvement of the community in research and create language that expresses this value.
- ✔ Encourage change in the culture of the scientific community to ensure that medical research is viewed in the context of a long-term commitment to the community, not a one-time research study.
- ✔ Investigate ways to provide mechanisms that allow for follow-up health care when a clinical trial or treatment ends.
- ✔ Educate and re-orient the current research community to the importance of treating the public as a partner in the research process.
- ✔ Set the expectation across the entire research community, NIH-funded research, and beyond that study results and outcomes should be shared with research participants and the larger community promptly and consistently. This will ensure that the research conducted in communities promotes translational research.
- ✔ Take action to interest community providers in clinical research and maintain their involvement.
- ✔ Provide incentives (not just financial) for primary health care providers and community specialists to play a role in clinical trials.
- ✔ Engage researchers, educators, and academic institutions in incorporating the public's perspective consistently at every level of training and in both the conduct of clinical research and the publication of findings from that research.
- ✔ Continue to develop and fund efforts to build a national identity for the NIH based on what the NIH does best, research and education, as a basis for enhancing public trust in clinical research.
- ✔ Review the role and impact of institutional review boards and other patient protections in the clinical research process because the public views these protections as less effective than they should be.
- ✔ Document and publish best practices from efforts to re-engineer the clinical research enterprise as soon as the NIH begins to see results, so that progress in improving public trust in medical research grows rapidly and steadily.

he explains. "There are issues that may not be what one considers directly relevant to the trial, but they play a role in issues of trust and perception."

For example, although HIV investigators visited sites in the developing world and tried to do everything they could to protect subjects, the communities haven't always felt enough was done, Fuchs notes.

"There was a perception in the community that not enough was done for those individuals," he says. "The community wondered whether the subjects would receive the standard of care that the individual with HIV in the United States would have and, if so, whether they would get access to those medications once the study was concluded."

That disconnect between investigators' ethical perceptions and the community's ethical perceptions resulted in some trials being closed briefly until investigators met with local leaders to discuss and define the investigators' obligations to the community, Fuchs explains.

• **Learn an ethical process or analysis.** DeRenzo has been working on an ethical process model that would apply to whatever issue arises, and the result is an 11-step approach to decision making. **(See ethics analysis, at right.)**

Using an ethical process model in making decisions is one way of making the process more neutral, she says.

"When you're talking about making ethical decisions on what to do in a protocol, whether to involve older adults who might be depressed and in a nursing home or older adults in a community population, you don't want a specific perspective," DeRenzo says. "You want a full-blown, expanded neutral ethics analysis."

Also, the use of an ethical model provides guidance that is not persuaded by personal relationships and opinions.

"Part of the problem with ethics is it's really not quite like other fields," DeRenzo says. "It's the art of justification." For example, it doesn't provide clear-cut answers, only an opportunity to choose between a weak ethical argument and a strong ethical argument, she says.

For instance, no one would consider asking a nonmedical family member or friend for a cardiology consultation, but everyone naturally seeks moral guidance from their family and friends, DeRenzo notes.

"You can see this qualitative difference about moral analysis and decision making," she says. "Most people think, and rightly so, of themselves as well-intentioned, decent people."

Ethics Analysis and Thinking Through Issues

Titled "Thinking through the issue/problem case: Applying a systematic approach to ethics analysis," this concise process for ethical analysis was developed by Evan G. DeRenzo, PhD, a bioethicist at the Center for Ethics at Washington (DC) Hospital Center and an adjunct faculty member at Johns Hopkins University in Baltimore.

- Who are all the possible interested parties? Think broadly — include not only persons and categories of persons, but institutions/organizations/professions/communities.
- What are the full range of duties and obligations of each potentially interested party, or at least the primarily interested parties? Think of parties as not only individuals, but institutions and groups, also.
- How might various duties and obligations clash/conflict?
- What might be short/long-term consequences of each possible course of action? How confident are you of your predictive accuracy?
- What ethical principles are at stake? In tension?
- What might be the intentions of the various players? Evaluate the praiseworthiness, or lack thereof, of persons/organizations/institutions' motives.
- What appear to be the full range of the possible courses of action?
- Weed out those possible courses of action that appear not to be justifiable based on potentially bad consequences, inability to meet duties and obligations, and/or the ethical soundness of intentions.
- With the possible courses of action that are left, make explicit — either to oneself or with colleagues/friends/family whenever possible — the justifications for taking each. Then vigorously scrutinize whether those justifications are ethically robust.
- Act with moral courage.
- Reflect on outcomes.

• **Incorporate ethics into the entire research process.** Ethical decision making should be a part of the thought process from the time a study is imagined, DeRenzo says.

For example, suppose an investigator wanted to study depression in the elderly and believed that enrollment could be achieved by using nursing home residents as subjects, she says. The investigator should be following an ethical analysis model before even deciding between the nursing home

population and a community population, DeRenzo notes.

"If I don't stop and think at that point about what are the ethical issues raised by contemplating doing a study of depressed nursing home residents, then I'm already going down the wrong path," she explains.

Ethical questions to consider for the previously mentioned scenario include:

— Could an investigator study late-life depression without studying nursing home residents?

— How would the nursing home residents' constraints on their liberty and rights affect the study?

— Is there something about depressed nursing home residents that would be more complex? ■

Strengthen stem cell research ethics now

Protect safety of clinical trial participants

The possibility of using embryonic stem cells to treat disease, a strategy known as regenerative medicine, is not yet being explored in clinical trials, but current ethical practices need to be strengthened — now — in preparation for this possibility, according to an advisory committee at the University of California at San Francisco (UCSF).

UCSF's Campus Advisory Committee on Human Gamete, Embryo, and Stem Cell Research reports that current practices must be amended to promote both the safety and well-being of the patients who would participate in clinical trials and the confidentiality of people who donate the embryos, oocytes, and sperm that contribute to the development of embryonic stem cells.

The recommendations address issues not examined by the National Academy of Sciences, which issued guidelines in May 2005, and go substantially beyond those addressed by the U.S. Food and Drug Administration in its May 2005 report.

"The potential use of embryonic stem cells as medical therapies presents unique ethical challenges that must be addressed before clinical trials begin," says **Bernard Lo**, MD, UCSF professor of medicine and director of the UCSF Program in Medical Ethics, who was lead author of a paper on the committee's findings. "Lack of attention to these concerns could lead to delays of clinical trials in some cases and inappropriate clinical practices in others. Such developments, in turn, could undermine or delay progress toward stem cell therapies."

The recommendations of the team, which includes leading stem cell scientists, are aimed at ensuring the safety of biological materials being donated for the development of human embryonic stem cell lines, protecting the privacy of the people who donate biomaterials, and promoting effective communication between clinician–researchers and patients about the nature of early stage, or Phase I, clinical trials.

Addressing these issues would require:

- seeking consent from donors of biological materials to allow scientists to recontact them over the years to update their medical records and rescreen them;
- implementing stringent measures to secure donors' confidentiality;
- enhancing communication with prospective patients about the ethical decision of participating in a clinical trial involving the use of embryonic stem cells and the unlikelihood of receiving clinical benefit from participation in Phase I clinical trials, which focus on safety of the therapy and drug dosage.

Donated biological materials hold the key to enabling scientists to develop human embryonic stem cell (hESC) lines. However, transplanted hESCs and the proteins they produce could carry infectious diseases, such as Creutzfeldt–Jakob disease, and genetic-based diseases such as cancer, Parkinson's, and amyotrophic lateral sclerosis (Lou Gehrig's disease).

The FDA issued regulations in May 2005 for screening and testing for communicable diseases at the time of donation and for tracking transplanted materials back to the original donors. However, the UCSF team says that these regulations are insufficient.

It is critical, they say, that the consent process include asking prospective donors of biological materials to agree to be recontacted in the months or years following their donations, to provide updates on their medical history and participate, as deemed necessary, in further screenings.

Reestablishing contact is necessary, the team says, for determining if diseases that could have been latent at the time of donation subsequently emerged. The process would allow scientists to determine if a donor, or a number of members of the donor's family, has developed a disease with a strong genetic component that could affect the safety of transplanted cells.

These measures are necessary because there

could be a gap of years between the time biological material is donated for embryonic stem cell studies and the time embryonic stem cells or their proteins would be used for transplantation.

Notably, one embryonic stem cell line could be used to treat hundreds or thousands of patients. Thus, one cell line containing a pathogen or disease-causing genetic mutation could affect many patients.

Without permission to recontact and possibly rescreen donors, the advisory team writes, scientists would be invading donors' privacy by recontacting them. In such circumstances, the donors might refuse to reveal their updated medical information, which would disqualify the cells for transplantation.

It is equally critical, the UCSF team writes, that stringent measures be implemented to ensure that donors' medical records are secured. The authors advocate steps ranging from having computer files locked in a secure room and password-protected, with access limited to a minimum number of individuals on a strict "need-to-know" basis; to having files with identifiers copy-protected and double-encrypted with one of the keys held by a high-ranking institutional official who is not involved in stem cell research; to having the records protected from subpoena by having the scientists who receive the donated biomaterial obtain a federal Certificate of Confidentiality.

Finally, clinician–researchers should ensure that patients who are considering participation in Phase I clinical trials of hESC transplantation are fully counseled and able to give a truly informed consent.

Because of the ethical issues regarding the use of human embryonic stem cells, informed consent would include researchers making clear to prospective patients that their therapy would involve the use of cells obtained from embryos.

Clinician/researchers also must make clear to prospective patients that Phase I clinical trials are intended to begin the process of determining the safety of a given therapy and the appropriate dosage; such trials rarely lead to improvement in the patient's condition.

"The crucial ethical issue about informed consent is not what researchers disclose in consent forms or discussions, but rather what the participants in clinical trials understand," the UCSF team writes.

Because consensus on informed-consent practices needs to be in place by the time Phase I clinical trials are proposed, meetings to develop such guidelines should be convened now, the team says.

A chain of events — including funding, basic science, and clinical trials — must take place for the potential of human embryonic stem cells to be fully explored, the team concludes. The ethical issues of embryonic stem cell research form another important link, they write, adding, "a chain is only as strong as its weakest link."

The UCSF advisory committee's recommendation report, "A new era in the ethics of human embryonic stem cell research," is available in the Sept. 15, 2005, issue of the on-line journal *Stem Cell*s, at www.stemcells.alphamedpress.org. ■

FDA delays OTC status for 'morning after' pill

Advocates want pill sold to those older than 16

The U.S. Food and Drug Administration (FDA) might have avoided one kind of controversy over the so-called "morning-after" contraceptive, but it created another by indefinitely delaying approval for the pill known as Plan B to be sold over the counter (OTC).

The FDA's decision to withhold approval came more than two years after an FDA advisory panel first overwhelmingly approved OTC status for Plan B.

Lester Crawford, DVM, PhD, acting commissioner of the FDA, announced in September that the novelty of the drug manufacturer's application, which would make Plan B (Barr Pharmaceuticals Inc.) available OTC to girls and women older than 16 but prescription-only for girls younger than 16, posed regulatory and policy questions that the FDA felt necessary to resolve before approving OTC status for the drug.

In delaying its decision on whether to approve

OTC status for the emergency oral contraceptive, the FDA overruled a recommendation by one of its own advisory bodies, the Center for Drug Evaluation and Research, which voted in August that Plan B be made available OTC for women 17 and older and by prescription to girls younger than 17.

It also apparently resulted in the departure of one of the FDA's senior women's health officials, the FDA's assistant commissioner for women's health, Susan Wood, PhD, who resigned following the announcement to delay OTC status, to protest the agency's overruling staff scientists and refusing to approve OTC sales of Plan B. The indefinite delay by the FDA, she said, "is contrary to my core commitment to improving and advancing women's health."

The decision by the FDA to delay approval for OTC status for Plan B while it works on what it says are regulatory obstacles is the latest holdup in the manufacturer's two-year battle to gain OTC approval. But many states already have passed laws pertaining to emergency contraception (EC).

EC supporters say easier access to the drug is needed to make sure women get the pills in time. Emergency contraceptive pills are concentrated doses of the hormones found in regular oral contraceptives, and should be taken within 72 hours of unprotected intercourse to be effective, most experts say.

Opponents, who include some conservative lawmakers and advocacy groups, say wider availability could increase promiscuity and sexually transmitted diseases, especially among minors. Some Democrats and women's groups have charged the FDA with letting conservative politics interfere with scientific data.

The Alan Guttmacher Institute (www.agi-usa.org), a not-for-profit organization conducting sexual and reproductive health research, policy analysis, and public education, finds that state-level lawmakers nationwide have addressed EC from two approaches — writing laws requiring hospitals to make EC available to victims of sexual assault, or letting pharmacies provide EC without prescriptions under collaborative practice agreements with physicians or in accordance with other state protocols.

Three states have adopted restrictions on EC ranging from excluding EC from Medicaid coverage to excluding EC from mandates that compel coverage for contraception.

Eight states require hospitals to provide EC-related services to victims of sexual assault. Seven states require hospital emergency departments to provide information about EC, and one state requires health care providers who personally object to EC to refer patients to other providers. Six states require emergency departments to dispense EC upon request by victims of sexual assault.

Seven states already allow pharmacists to dispense EC without a doctor's prescription, under certain conditions, five states let pharmacists distribute EC under collaborative practice agreements with physicians, and three permit pharmacists to distribute EC under state-approved protocols.

Medical associations are divided over EC, particularly for minors. The American Association of

CME Questions

17. Which of the following best describes what many experts feel is the predominant objective in disaster triage?
    A. patient autonomy
    B. treating lethally injured patients first
    C. saving the most lives possible
    D. treating the least-injured patients first

18. DeRenzo's model for ethical process includes which of the following as part of its 11-step approach to decision making?
    A. identifying the interested parties
    B. establishing what duties and obligations of the parties might clash
    C. determining what ethical principles are at stake
    D. reflecting on outcomes
    E. all of the above

19. According to a University of California at San Francisco advisory committee, current stem cell clinical trial practices adequately provide for future contact and follow-up with trial participants.
    A. True
    B. False

20. In delaying action on an application to make Plan B emergency contraceptive available over the counter to women older than 16 and by prescription to girls 16 and younger, the FDA:
    A. overruled recommendations by its own advisory panels
    B. affirmed the recommendation of its advisory panel
    C. set a six-month deadline to reach a decision
    D. prohibits Plan B from being dispensed by prescription to anyone

Answers: 17. C; 18. E; 19. B; 20. A

Pro-Life Obstetricians and Gynecologists praised the FDA for delaying OTC approval of Plan B; in a statement at the time of the decision, the organization stated that EC obtained over the counter not only could encourage unprotected sex, but also would keep girls from seeking physician care.

The American Medical Association, on the other hand, condemned the FDA more than a year ago for not approving OTC status for Plan B.

Those on both sides of the OTC argument agree, however, that the FDA's decision to delay approval of OTC status for Plan B likely means the drug will be prescription-only indefinitely. ■

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