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AHC Media

Sandy response points to possible bigger role for ethics during disasters

Ethics is central to disaster planning

There is nothing like a mandatory hospital evacuation to underscore the importance of including ethics in emergency preparedness, according to **Kenneth W. Goodman**, PhD, professor and director of the Bioethics Program at University of Miami (FL). "Indeed, the most difficult decisions might have less to do with transportation, logistics, or resources, but everything to do with ethics," he says. "This is applied ethics on steroids: Life and death in the balance, and no dithering permitted. This is why preparedness is so important. You don't want to have to make these calls on the fly."

Decisions range from "Who goes first?" to "Who doesn't get to go at all?"— questions which must be answered by focusing on ethics, evidence, and available resources, says Goodman. "The ethical foundations include saving as many lives as possible while not perpetuating disparities," he explains. "The evidence will tell us who is most likely to survive and who is not. Knowing what resources you have will provide the glue for linking the two."

Hospital evacuations confront the ethical challenge of balancing risk and uncertainty with the risk of physically moving patients balanced with the risk of staying in place, says **Amy Fairchild**, PhD, MPH, professor at the Center for the History and Ethics of Public Health at the Columbia University Mailman School of Public Health in New York, NY.

EXECUTIVE SUMMARY

Resource allocation and balancing risk and uncertainty were the central ethical issues for health care providers during Hurricane Sandy. Hospital evacuations underscore the importance of including ethics in emergency preparedness, according to bioethicists. They argue that:

- Ethicists should be involved in the decision-making process for hospital evacuations.
- Ethicists can be a source of moral support for healthcare professionals.
- Hospitals should consider having ethicists on-call for disasters.

"Moving a critically ill patient carries a health risk, and trying to move someone in the midst of a hurricane, of course, increases the risks," she says, noting that providers at NYU Langone Medical Center carried premature babies down nine flights of stairs while nurses hand-pumped oxygen. "Providers don't want to move such fragile infants dependent on respirators for survival until the risk of staying outweighs the risk of moving them. The same is also true of the frail or elderly."

There have been instances in which nursing home patients have been moved and suffered heart attacks, adds Fairchild. "We do have a special ethical duty to people made vulnerable by sickness or deteriorating health or cognition," she says. "There is little question that once the decision has been made to evacuate, patients have no choice in the matter."

Allocation of resources

The central ethical issue with providing care during a hurricane and other disasters is allocation of scarce resources, says **Gregory R. Moore**, MD, MPH, senior director of Stamps Health Services at Georgia Institute of Technology in Atlanta. "This is essentially triage, in which you assess the needs and the resources and then try to match them to provide the most benefit to the most people," he says. "In the most severe situations, it can come down to who lives and who dies."

Rationing of medical care occurs whenever resources aren't enough to serve medical needs, but what differs in emergency evacuations is that such decisions have to be made very unexpectedly and very quickly, says **H. Steven Moffic**, MD, author of *The Ethical Way: Challenges and Solutions for Managed Behavioral Healthcare* (Jossey-Bass, 1997), and former professor of psychiatry and family and community medicine at the Medical College of Wisconsin in Milwaukee.

For instance, a decision must be made as to who is to be evacuated first and last, and whether this should be based on the severity of illness, on the basis of those likely to recover from their illness, or the patient's age. "Apparently, at NYU Langone Medical Center, the youngest and sickest were evacuated first, including some 20 babies in neonatal intensive care," Moffic says.

While the most widely accepted bioethical principles are patient autonomy, non-maleficence, beneficence, and justice, these seem to be of limited usefulness in an emergency evacuation, says Moffic, as there may not be enough time for patients to understand their choices and everyone can't be taken care of in the same way at the same time. "Harm, to some degree, is a likely byproduct of the evacuation itself," he adds. "Justice will be influenced by chance and unexpected circumstances or consequences."

Natural disasters and public health emergencies transform not only the usual and customary approaches to patient care, but also the prevailing ethics of patient care, according to **Ben A. Rich**, JD, PhD, professor and School of Medicine Alumni Association Endowed Chair of Bioethics at University of California — Davis Health System.

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"The underlying presupposition is that the exigencies of the event do not permit all patients to receive the prevailing standard of care for their medical condition," he says. "Tough decisions must be made about how to allocate scarce human and material resources." Rich says the guiding principle should be: What would a reasonable institution or health care professional do under the circumstances to minimize risk to all of the patients under the circumstances as they appear at the critical point in time?

"This last point is important, since the key decision makers may have incomplete or perhaps even inaccurate information upon which they might have to base their decisions," says Rich.

Role of ethicists

Bioethicists have a clear role in contributing to the development of institutional policies and procedures to govern an institution's response to disasters and public health emergencies, as "in real time, there is less opportunity for 'stat' ethics consults," says Rich.

Ethicists should be involved in the decision-making process for hospital evacuations, as they can identify ethical trade-offs that might not otherwise be considered, argues Fairchild. "They can use ethical principles to answer the question: 'What would be the bigger ethical — as opposed to political — mistake?'" she says. "Is it creating hardship and potentially contributing to some casualties by [evacuating] or accepting the potential for misery and death by failing to take decisive steps?"

Individuals in various positions of power might have differing priorities that need to be reconciled by an ethicist, says Moffic. "Politicians will not want to be blamed for being ill-prepared, whereas administrators may tend to be more concerned with the entire hospital and institution, rather than the individual patient of most concern to the doctor and nurse," he says. Ethicists can also be a source of moral support for the healthcare professionals involved in a disaster, he adds.

"Most hospitals have an ethics committee that deliberates tough medical decisions, but these deliberations are usually not as time-sensitive," says Moffic. He argues that hospitals should consider having ethicists on-call for disasters, just like other medical and administrative personnel.

"For now, their role in such a crisis is both to review the emergency responsiveness after the fact, as well as to suggest ways to prepare better for the next," says Moffic. "It is to help share the God-like responsibility of deciding who may live and who may die when life-threatening choices need to be made." ■

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Medical students, residents want more ethics training

Real-time exposure to ethical dilemmas needed

Two-thirds of medical students and residents believe there is a need for more ethics training during their curricula and training programs, according to a survey of 129 medical students and 207 residents done in 2009 and 2010 at University of Maryland School of Medicine in Baltimore.

There is a general feeling among educators that

EXECUTIVE SUMMARY

Two-thirds of medical students and residents believe there is a need for more ethics training, according to a recent survey, but university officials might need additional evidence to be convinced of the need for additional ethics education. The study's findings suggest that:

- More formal instruction is needed within the context of real-time exposure to ethical dilemmas.
- Some formal instruction is better than none.
- Most students and residents are not comfortable with ethics issues they will commonly encounter in clinical practice.

medical students and residents haven't had sufficient ethics education to deal with medical ethics issues that they confront when they begin to practice, according to **Henry Silverman**, MD, the study's lead author and faculty in the Department of Medicine at University of Maryland.

"Nonetheless, such beliefs need to be confirmed and documented in order to convince top officials at universities to further enhance ethics education in the curriculum," says Silverman. "Having said this, the present study did document that medical students and residents do desire more ethics education in their curriculum."

Only eight of 35 scenarios covered in the survey resulted in more than 70% of respondents saying they felt comfortable. Physicians-in-training felt least comfortable when dealing with reporting medical errors, cultural issues, resolving disagreements between family members, talking with family members after a patient has died, and determining when it is appropriate to withhold life-sustaining treatments from patients.

"These results are very concerning. They indicate most students and residents surveyed are not comfortable dealing with ethics issues they will encounter on a regular basis in clinical practice," says **Marianne L. Burda**, MD, PhD, a Pittsburgh, PA-based ethics consultant and educator.

Physicians-in-training felt very comfortable with breaking bad news, discussing do-not-resuscitate orders, and obtaining informed consent, which probably reflects recent emphasis on these issues, says Silverman.

Only 13.4% of respondents reported receiving a formal course in ethics during medical school training. Having had any type of prior ethics education in medical school was not associated with being more comfortable dealing with clinical ethics dilemmas, notes Silverman. "This finding suggests that physicians-in-training are not receiving optimal training to deal with real-world clinical ethics dilemmas," he says. "To be sure, curricula that teach abstract ethical principles and even critical thinking skills do not go far enough to prepare students for the wards."

Residents felt more comfortable with many of the clinical ethics issues than medical students. "Essentially, physicians-in-training gain experience by actually confronting clinical ethics issues while on the wards, the so-called 'experiential' curriculum. However, much of this experience is unstructured and unfocused," says Silverman. "What they need is more formal instruction within the context of real-time exposure to ethical dilemmas." For instance, medical students could participate in weekly conferences to discuss ethics issues in a formal manner as they occur, instead of discussing hypothetical cases.

The authors conclude that the best approach to ethics training may be "experiential" training that exposes students and residents to ethical dilemmas in the actual clinical setting, with a structured format that develops ethical reasoning skills. One such approach is already in place at Drexel University College of Medicine, reports Burda. Third-year medical students participate in a class where they encounter patients or family members in a number of common clinical ethical dilemmas.

"Students have the opportunity to practice applying classroom ethics knowledge to clinical situations," she says. Other experiential approaches include observing and participating in clinical ethics case consultations and including clinical ethicists on teaching rounds to help train students and residents in identifying and resolving ethical issues, adds Burda.

Horace M. DeLisser, MD, associate professor of medicine at the University of Pennsylvania's Perelman School of Medicine, recommends an approach that covers all four years of medical school. "Our approach begins in year one with formal course work, instruction on ethical analysis, and discussion of classic cases. It continues through the clinical clerkships with frequent opportunities for students to discuss ethically challenging experiences with faculty and peers," he says. "It concludes in the fourth year, two months before graduation, with an intensive capstone bioethics course. That includes a lot of small group discussion." ■

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Surprising reasons for continuing futile treatment

Emotions run high on both sides

The reasons for providers continuing futile life-sustaining treatment are primarily emotional, such as guilt, grief, fear of legal consequences, and concerns about the family's reaction, according to a recent study which surveyed intensive care unit (ICU) and palliative care clinicians.[1] "The reasons and motives that the clinicians gave for performing futile treatment amazed us," says **Ralf J. Jox**, MD, PhD, the study's lead author and an assistant professor at the Institute for Ethics, History, and Theory of Medicine at the University of Munich in Germany. "We thought they would all highlight the unrealistic treatment wishes of patients and relatives. Instead, they presented a variety of very personal and emotional reasons."

If a certain treatment is ethically unjustified, even the strongest emotions shouldn't change a provider's ethical assessment, argues Jox. "On the other hand, these emotions should be taken very seriously. They show us how we could, and must, improve the provision of health care in hospitals," he says.

Patti White, PhD, Esq, a San Diego-based psychologist who has consulted on end-of-life hospice care, says providers should remember that nothing prepares a family member to make a life-ending decision for a loved one, and that providers themselves experience many of the same emotions. "The natural tendency for some is to delay making the decision; for others, to altogether refuse to make it," she says. "Guilt, grief, fear of legal consequences, or concerns about family reactions are to be expected, anticipated, and compassionately understood."

Jox notes that some ICU providers have started to use patient diaries, allowing clinicians to express their perceptions and experiences with a patient in a narrative style. "Such interventions may reduce the psychological burden on professional caregivers and, thereby, also help them to do what ethics and law require them to do," he says.

Be prepared for conflicts

While competent patients are generally entitled to make their own decisions, even if these conflict with those of the family or physician, decisions regarding medical futility often involve patients who are no longer competent or are only competent on an episodic basis, notes **Gary E. Jones**, PhD, JD, a professor in the Philosophy Department at University of San Diego (CA).

"In such cases, it is hoped that the patient executed an advanced directive while competent, especially a directive that is sufficiently specific in regard to the kind of treatment decisions at hand," he says.

Even if the patient has executed an advanced directive, the physician will often be interacting with the patient's adult family members and/or the patient's advocate as determined by a durable power of attorney or its equivalent. Jones says that physicians should emphasize that while certain courses of treatment may be futile, medical care is never futile.

"Physicians should allay fears that the patient will be abandoned," he says. "It should be emphasized that the patient will receive palliative care, pain control, and treatment that is respectful."

If physicians believe a certain treatment is futile, Jones says they must engage in an in-depth discussion of the relevant treatment options and indicate the reasons they feel that the treatment is futile, in terms of the likely outcome and the probable wishes of the patient. "In most cases, an agreement can be reached regarding the patient's probable wishes regarding treatment," he says.

In cases in which resolution is not possible, the physician should consider referring the case to the institution's ethics committee, consulting with other providers, or, in extremely difficult cases, transferring the patient to another facility. "This situation, however, poses a significant ethical problem," says Jones.

The family might be adamant that the patient receive all possible treatment, including treat-

EXECUTIVE SUMMARY

Providers continue futile life-sustaining treatment largely for a variety of personal and emotional reasons, according to a recent study. One ethical challenge is that there is no agreement among medical professionals or ethicists on how to define futility.

- Physicians should indicate the reasons they believe the treatment is futile.
- If resolution is not possible, physicians might refer the case to the institution's ethics committee, consult with other providers, or transfer the patient.
- Legal intervention might be required if the physician believes the treatment is not in the patient's best interest.

ment that is painful and will last over a protracted period of time, for example. If the physician believes that the treatment is not only futile but also not in the patient's best interest, he or she might conclude that legal intervention is required.

"The physician may reasonably conclude that merely allowing the family to attempt to find another physician who will agree with their opinions is insufficient," says Jones. "In such a case, the appointment of a legal guardian by the court may be the only manner in which to protect the interests of the patient." ■

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Medical futility policy should include these steps

Gary E. Jones, PhD, JD, professor in the Philosophy Department at University of San Diego (CA), says that all health care institutions, whether large or small, should adopt a policy on medical futility, and that policies on medical futility should follow a due process approach with these seven steps:

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

2. Joint decision-making should occur between patient or proxy and physician to the maximum extent possible;

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

4. Involvement of an institutional committee, such as the ethics committee, should be requested if disagreements are irresolvable;

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

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

7. If transfer is not possible, the intervention need not be offered. ■

What is futility? Definition unclear

There are many ethical challenges involving medical futility, but possibly the biggest one is a lack of agreement among medical professionals or among ethicists about how futility is defined, says **Cynthia Griggins**, PhD, an assistant professor of neurology at University Hospitals — Case Medical Center in Cleveland, OH.

"There have been attempts to quantify the definition such as defining a treatment as futile if it has not been successful in the last 100 patients. But for various reasons, this has not been accepted," says Griggins, nor has a more general definition been accepted, such as futility being defined as no reasonable chance that the treatment will improve the patient's condition.

"If the medical profession cannot even agree on a definition, then providers are going to be extremely reluctant to label something futile, especially in the face of disagreement from the family," says Griggins.

On the providers' side, obstacles to labeling a treatment futile include fear of being sued for not providing treatment, discomfort with conflict, the wish to preserve hope, and the provider's own discomfort with accepting death, says Griggins. Providers might believe that the patient and family always have a right to any treatment they request, that it is the provider's duty to "do everything" to preserve life, or that in the face of no definition of futility, then nothing is futile and every treatment is appropriate, she says.

"Because no one has agreed on a definition of futility, I think physicians are better off thinking of when they should not honor requests from the patient or

family," says Griggins. "They should always be weighing possible harms and burdens against possible benefits. If the harms seriously outweigh the benefits, then they should not be providing that treatment."

Physicians aren't necessarily supposed to provide a treatment just because a patient or surrogate for the patient requests it, she underscores. "We generally think of autonomy as a 'negative' right — 'Keep your hands off me unless I give permission' — and not a 'positive' right — 'You must give me whatever I request,'" says Griggins. "If it looks like the patient is going to be harmed with no chance of benefit, then the physician shouldn't be providing it, even if the patient or family insists."

Griggins notes that her institution defines futility in a very strict manner: That there is no reasonable chance that a proposed treatment will do what it is supposed to. "This is a medical call. For example, a family requests a particular antibiotic be given to a patient and we know that he has an infection that is resistant to that antibiotic. We know it won't work," she says. If the treatment will do what it is supposed to do, but not improve the patient's overall condition, then one has to ask if the overall condition is acceptable to the patient or family, says Griggins.

"This is a question of values, not medicine, and we usually let the family decide," she says. "So if a feeding tube will maintain a person in a persistent vegetative state, and that state is acceptable to the family, then generally we don't label the feeding tube as futile." ■

Increasing burden on family caregivers: Ethical concerns

Almost half of family caregivers perform nursing and medical tasks for family members with chronic physical and cognitive conditions, often without any training, in large part because hospitals are discharging very sick patients more quickly, according to a September 2012 report released by the AARP Public Policy Institute and the United Hospital Fund. (To view the report, *Home Alone: Family Caregivers Providing Complex Chronic Care*, go to http://www.uhfnyc.org/publications/880853.)

The survey of 1,677 family caregivers reports on the complexity of tasks that caregivers provide, and challenges the common perception of family caregiving as a set of personal care and household chores that most adults already do or can easily master. Three out of four caregivers surveyed provided medication management, including administering intravenous lines and injections, and more than one-third of those who provided medical and nursing tasks reported doing wound care. Other frequently provided tasks included operating specialized medical equipment and monitors.

Carol Levine, director of United Hospital Fund's Families and Health Care Project and an author of the report, says that while the report's findings didn't surprise her, many health care providers were probably unaware of what family caregivers do. "A lot of people live in a fanciful world where there is a home health care nurse that takes care of everything, and private insurance or Medicare pays for it, but that is not reality," she says.

Inadequate training

Family caregivers reported that they didn't get much training in the complex medical tasks they performed, despite the fact that their chronically ill family members were in and out of hospitals and emergency departments. However, the health care providers themselves would probably insist they had showed the family member all they needed to know, says Levine. "The lack of alignment between what health care providers think they are communicating and what family caregivers actually experience is very great. That, in itself, is an ethical issue," she says.

The question is whether providers have to provide training that caregivers can actually understand, or just "check it off their list," says Levine. "I think physicians have a responsibility, not necessarily to actually *do* the training, but to ensure

EXECUTIVE SUMMARY

Nearly half of family caregivers perform nursing and medical tasks for family members with chronic physical and cognitive conditions, including medication management, wound care, and operating specialized medical equipment, according to a recent survey.

- Providers often have misconceptions about what family caregivers do.
- Even if family caregivers receive training, they often feel unprepared.
- Electronic medical records often fail to identify the caregiver's name and contact information.

that this training is taking place. Right now, there is a lot of handing off — 'The social worker will take care of that,' 'The nurse will tell you about the medications,' 'The physical therapist will show you what to do with the equipment' — without any serious accountability that this is actually in place."

Everyone on the team should understand the importance of training the person who will be caring for the patient, emphasizes Levine. "Some professionals develop a kind of casual attitude because they have been doing these tasks for years," she says. "They don't understand that this is brand new for the family caregiver. It's different when you are doing it on a person you love, not on a volunteer or student, and without somebody watching over your shoulder making sure you don't make a mistake."

There is an individual ethical responsibility on the clinician's part to understand the gravity of what is being expected of caregivers, and a broader organizational responsibility to see that those needs are built into professional education and practice standards, says Levine. "The first rule of medical ethics is, 'Do no harm.' If you send somebody home with a feeding tube or on a ventilator or intravenous line, and the person taking him home doesn't know what she is doing, you are opening up the door to harming the patient," she says. Professionals might fail to warn caregivers performing wound care about the need to maintain a sterile field, for example.

In addition, untrained family caregivers might be terrified of making a mistake and harming the patient. "A lot of the things they are expected to do are painful or embarrassing, and potentially very disruptive to an intimate relationship," she says. "That may not equate with leaving a scalpel in somebody, but that is harm, in my view."

Misperceptions persist

Providers might assume that family caregivers are doing only basic tasks such as cooking and shopping, but that is not reality for many people. "It's not deliberate avoidance — it's just not in the framework in which most physicians work," says Levine. "A lot of this has to do with physicians being trained in hospital settings with relatively little opportunity to see what actually goes on in the home."

In the United Hospital Fund's Transitions in Care Quality Improvement Collaborative, hospital teams found that in many cases, the family caregiver wasn't even identified in the medical record. Some electronic medical records lacked a field for the individual's name. Even if there was a place to list the family caregiver, the information was often simply, 'the wife,' 'the daughter,' or 'next of kin,' instead of the person's name and contact information. "Even when professionals *do* identify the caregiver, there are all kinds of barriers — their availability or their understanding of how to recognize and respond to changes in the patient's condition," says Levine. "Those are real difficulties, but you have to start by at least knowing who the family caregiver is and how to reach that person. If the caregiver knows know how to reach someone who can help, you have a much better chance of getting a good outcome."

The importance of family caregiving is getting more attention, but at a time when resources are more constrained, notes Levine. "The population is aging, with many more people with multiple chronic conditions taking multiple medications," she says. "More responsibility is being pushed onto family caregivers. That is the world we are living in, and it is not going to go away." ■

SOURCE

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Act ethically when ending patient-physician relationship

Abandonment is central issue

Is a physician unable to exercise reasonable objectivity in providing care, or does the physician lack the requisite skill or training to help the patient? "Physicians can, and many would say *should*, terminate their relationship with patients when they can no longer help them," says **John Banja**, PhD, a medical ethicist at Emory University's Center for Ethics in Atlanta. "An important qualifier, however, is the phenomenon of abandonment."

Before a physician terminates a patient relationship, says Banja, he or she should give the patient adequate notice of that intention and provide the patient with names and contact information of health professionals who could see the patient, assuming the patient requires further treatment. A physician who terminates a relationship with a patient because the patient owes him or her money, or because the patient is rude, needs to make sure

that such termination would not amount to abandonment, he warns.

If, for example, the patient is unable to identify another physician for needed care and becomes worse, the physician has hardly acted in the patient's best interests and can be sued for intentional abandonment, Banja explains. "If the physician is the only health professional reasonably available who can competently treat that patient's condition, he or she might have to do so regardless of how distasteful the task may be," he says. "This rarely happens, though, and in any event, physicians ultimately retire so the obligation to treat doesn't last forever."

However, physicians should keep this in mind if they would like to terminate a relationship because they intensely dislike a patient, or the patient doesn't pay his or her bills, says Banja. "I think it's enough for physicians to remember that they can't leave patients in dire straits. Once a physician has undertaken a patient's treatment, he or she is contractually bound to advance the patient's welfare," he says.

Most of the time, physicians won't have any trouble terminating their relationships with patients because it will be easy to arrange for another professional to take over the patient's care, Banja adds, "but the most ethically compelling reasons for physicians doing so are reasons that advance the patient's interests." If the physician's course of therapy is going nowhere, or he or she finds it particularly difficult to communicate with the patient, or finds him- or herself experiencing feelings for the patient that disrupt clinical objectivity, it might well be better to refer the patient to someone else, he explains.

"But physicians who terminate the relationships with patients in a way that leaves patients badly off have probably capitulated to their urge just to be rid of this individual, which doesn't meet the ethical standard of due care," says Banja.

In any non-emergency situation, a physician or any health care professional can decline to provide care for anyone unless otherwise required by their employer, but "the issue of abandonment arises," says **Reed E. Pyeritz**, MD, PhD, director of the Center for the Integration of Genetic Healthcare Technologies and professor of medicine and genetics at the University of Pennsylvania. "Most states have laws that prohibit abandonment. Similarly, all codes of ethics of professional societies consider abandonment unethical."

In order to terminate a physician-patient relationship, the physician must give notice of the intent to terminate that provides sufficient time for the patient to arrange alternative care, and consider suggesting alternatives, says Pyeritz. "An example is a pediatrician who refuses to see children whose parents decline routine vaccinations," he says. "The pediatrician may feel that the parents are not acting in the best interests of the child. Additionally, the pediatrician may feel that an unvaccinated child poses a risk in the waiting room." *(For more information on termination due to vaccine refusal, see story on p. 142.)* ■

SOURCES

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IOM report makes major drug safety recommendation

Ongoing monitoring is needed

One of the biggest ethical challenges with drug safety is the need for patients and providers to understand that even after a drug is approved, there is still more to learn about its benefits and potential harms, according to **Ruth R. Faden**, PhD, MPH, Philip Franklin Wagley Professor of Biomedical Ethics and Director of the Johns Hopkins Berman Institute of Bioethics in Baltimore, MD.

"We can't know everything about a drug's safety after the drug is approved, even under the best circumstances," she says. "People need to come to understand that we are making a judgment that at this point in time, on balance, it is a good drug for patients to take. Information could change as we have more experience with the drug."

The Food and Drug Administration's (FDA) current approach to drug oversight in the post-market setting is not sufficiently systematic, and does not ensure that it assesses the benefits and risks of drugs consistently over the drug's life-cycle, according to a May 2012 report from the

Institute of Medicine (IOM).[1]

"We are now the second IOM committee to have promoted a full lifecycle approach to drug regulation, and the FDA has accepted it," says Faden, co-chair of the IOM committee that wrote the report. "People need to stop thinking that everything is uncertain only until the drug is approved, and of post-market as falling off a cliff."

There is just as intense an obligation to vigilantly monitor a drug's effectiveness after it enters the marketplace as there is before the drug is approved, says Faden. "Maybe with some additional understanding about the kind of provisional approvals that could be provided, we can make that artificial divide disappear," she adds. This approach would give more flexibility in allowing drugs to go forward when there are very pressing health care needs, but allow for careful monitoring as to whether the drug has an acceptable benefit-risk profile, Faden explains.

Both patients and providers might have difficulty accepting the fact that decisions are sometimes made about drug safety without complete scientific information. "We don't want to undermine people's confidence in their medical care unduly. We want people to have confidence that the clinician is making a recommendation based on the best available evidence," says Faden. "But they also need to understand that the evidence is not always very good, and that it is changing over time."

FDA's ethical challenges

The FDA has a "profound moral obligation" to promote the safety and effectiveness of the drug supply, which means requiring manufacturers to conduct both pre-market and post-market research to protect the public's health, according to Faden. "On the other hand, the FDA also has a moral obligation to people that participate in the research that it requires, to make sure that the research is ethically acceptable," she says. A related ethical challenge faced by the FDA is how to strike a balance between having enough good evidence to allow a drug to enter the marketplace and responding to pressing unmet health needs where new or better pharmaceuticals are desperately needed, says Faden.

The IOM report recommends adopting a regulatory framework that is standardized across all drugs, yet flexible enough to adapt to regulatory decisions of differing complexity, to make the agency's decision-making process more predictable, transparent, and proactive. "One issue is that recommendations to do non-required post-approval safety research often fall on deaf ears within pharmaceutical companies," says **Sean Hennessy**, PharmD, PhD, associate professor of epidemiology and of pharmacology at University of Pennsylvania's Perelman School of Medicine and director of the Center for Pharmacoepidemiology Research and Training.

"This is because those who control the money can be too concerned about short-term profits and not concerned enough about the company's long-term sustainability," says Hennessy. Another issue is that despite clinical trial registry requirements, not all studies involving human subjects are reported publicly. "This is because the companies who paid for these studies think of the resulting data as belonging to them and proprietary," he says. "However, research involving human subjects is ethical only if it advances science, which means that it needs to be published."

Institutional review boards should require as a condition of approval that any human subjects research be published or otherwise made available, argues Hennessy, who favors banning direct-to-consumer advertising of prescription drugs in the United States. "There are theoretical health benefits to allowing prescription drugs to be advertised, such as public awareness of treatable disease, but I haven't seen evidence that this theoretical benefit is realized," he says. "It certainly has unintended adverse consequences." ■

EXECUTIVE SUMMARY

A full "lifecycle" approach is needed for drug regulation, recommends an Institute of Medicine report, to ensure that the risks, benefits, and effectiveness of drugs are measured over time.

- There is a need for drugs to be monitored vigilantly post-market.
- Recommendations are sometimes made without adequate scientific evidence.
- Not all studies involving human subjects are reported publicly.

REFERENCE

1. Committee on Ethical and Scientific Issues in Studying the Safety of Approved Drugs, Institute of Medicine. Ethical and scientific issues in studying the safety of approved drugs. Washington, DC: National Academies Press, 2012 (http://www.iom.edu/Reports/2012/Ethical-and-Scientific-Issues-in-Studying-the-Safety-of-Aprroved-Drugs.aspx.)

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Is vaccine refusal reason to terminate relationship?

Provider autonomy must be considered

Refusing to have a child as a patient because of a decision made by the child's parent should always be a last resort, according to **Douglas S. Diekema**, MD, MPH, attending physician and director of education at the Treuman Katz Center for Pediatric Bioethics at Seattle (WA) Children's Hospital. "However, when a substantial level of distrust develops, significant differences in the philosophy of care emerge, or poor quality of communication persists, the pediatrician may encourage the family to find another physician or practice," he says.

In these situations, the parent would probably also be better served by another provider, as long as one is available in the community, adds Diekema, but in the event that a physician feels it is necessary to terminate a relationship with a patient and parent, the physician must give sufficient advance notice to allow the parent to secure another health care professional to assume the care of the child.

"However, when a parent has a good working relationship with the physician, I don't think physicians should discharge them from the practice simply because the parent refuses to vaccinate his or her child," he says. Families with concerns about immunization should still have access to good medical care, and maintaining the relationship in the face of disagreement conveys respect and, at the same time, allows the child access to medical care, explains Diekema. "Continuing the relationship also allows the provider to have future opportunities to discuss the issue of immunization over time," he adds.

Vaccine refusal is "a classic case of clashing between parental autonomy and beneficence," says **Daniel S. Kamin**, MD, director of the Gastroenterology Consultation Service and member of the Ethics Advisory Committee, both at Boston (MA) Children's Hospital. Physicians must consider the welfare of the child, the welfare of the community, physician integrity, physician-parent relationship, and parental autonomy to determine an ethical response to this disagreement, he says.

CME OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- Discuss new developments in regulation and health care system approaches to bioethical issues applicable to specific health care systems.
- Explain the implications for new developments in bioethics as it relates to all aspects of patient care and health care delivery in institutional settings.
- Discuss the effect of bioethics on patients, their families, physicians, and society.

"If a family were refusing to vaccinate a child bitten by a bat, in almost all circumstances the ethical response would be to seek a court order to compel vaccination, based on what we know about the risk and outcome of rabies infection, which often is death," he says. In contrast, if a family were refusing to vaccinate against human papillomavirus in a pre-teen, given that the risk is much lower for serious complications, that cancer can often be treated or avoided with good preventive care, and that the risk is way in the future, Kamin says that education would be an ethical response.

Some physicians feel very strongly that it is wrong not to vaccinate, and that they can't in good conscience continue to take care of children whose parents don't agree, however. "Physicians should not be forced to provide care they think is wrong," Kamin says. "Ethical responses include frank discussion and planned transition to a provider that is willing to consider not vaccinating."

Kamin says that unethical responses would include angry responses and refusals to continue caring for children, while missing the opportunity to understand the parent's position. "Parents are often super worried about terrible reactions," he explains. "They are perhaps mystified by misinformation, but are taken by the many compelling stories out there about bad responses." It is crucial for providers to understand that parents' greatest responsibility is to protect their children from harm, says Kamin. "Coercion by scaring parents or unnecessarily making it difficult to get care would also be questionable ethically," he says.

It is often reasonable policy, says Kamin, to both educate and use some coercion to increase vaccination rates, because of the interest in protecting the health of populations, especially children. "This is why mandatory school vaccination policies stand up to ethical scrutiny," he says. ■

CME QUESTIONS

1. Which is true regarding ethical practices involving providers continuing futile life-sustaining treatment, according to **Gary E. Jones**, PhD, JD?
   A. If physicians believe a certain treatment is futile, there is no ethical obligation to engage in an in-depth discussion of the relevant treatment options.
   B. It is unethical for intensive care unit providers to use patient diaries to express their perceptions and experiences with a patient in a narrative style.
   C. When interacting with the patient's adult family members and/or the patient's advocate, physicians should emphasize that the patient will receive palliative care, pain control, and treatment that is respectful.
   D. If physicians believe a treatment is not only futile but also not in the patient's best interest, he or she should simply allow the family to attempt to find another physician who will agree with their opinions.

2. Which is recommended regarding the Food and Drug Administration's (FDA) approach to post-market drug oversight, according to an Institute of Medicine report?
   A. The FDA has an ethical obligation to require manufacturers to conduct pre-market research, but there is no such ethical obligation to require post-market research.
   B. The FDA's current process does not ensure the benefits and risks of drugs are consistently assessed over the drug's lifecycle.
   C. There is less of an ethical obligation to vigilantly monitor a drug's effectiveness *after* it enters the marketplace than there is before the drug is approved.
   D. Provisional approvals are unethical even if there are pressing health care needs.

3. Which is true regarding ethics training in medical school, according to a study published in *Journal of Medical Ethics*?
   A. The vast majority of respondents received a formal course in ethics during medical school training.
   B. Prior ethics education in medical school was strongly associated with being more comfortable dealing with clinical ethics dilemmas.
   C. Residents felt more comfortable with many clinical ethics issues than medical students.
   D. Physicians-in-training felt most comfortable with reporting medical errors.

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.
1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice, or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
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