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Bioethics programs called to address "new normal" under health care reform

But some are facing fiscal threats

In the eyes of cost-cutting hospital administrators, bioethics programs are sometimes perceived as a luxury rather than a necessity. "During periods of austerity, bioethics programs are often the first to not receive funding or not be maintained," says **Joseph J. Fins**, MD, MACP, the E. William Davis, Jr. Professor of Medical Ethics and chief of the Division of Medical Ethics at Weill Cornell Medical College, and director of medical ethics and attending physician at New York Presbyterian Hospital-Weill Cornell Medical Center in New York City. "A number of programs have recently come under threat."

"I do fear that some programs may be facing budget cuts. These are difficult times for institutions to take care of all of their needs. On the other hand, I also believe that there are some programs that seem to be expanding and doing well," says **Ruth L. Fischbach**, PhD, MPE, director of the Center for Bioethics at Columbia University in New York, NY.

Bioethics programs often lack departmental standing or the historical funding lines of mainstream departments, putting them at a disadvantage compared with more traditional lines of study, notes Fins. "It may be a secondary position for faculty members — their home program is O.K., but the secondary program is put at risk," he says.

If bioethics faculty have tenure in a home department, that department

EXECUTIVE SUMMARY

Bioethicists are needed to preserve the integrity of health care systems as they begin to implement the Patient Protection and Affordable Care Act, but some programs are facing loss of funding.

- Bioethics programs often lack departmental standing and historical funding lines.
- There are few tenured spots in the relatively young discipline of bioethics.
- Bioethicists need expertise in the specific clinical areas in which they work.

would need to be eliminated in order to cut their position, but this isn't necessarily true of the tenured faculty member's secondary department, he explains. "Faculty may have tenure in the Department of Medicine, and they might keep the faculty but take them out of the bioethics program. There are very few tenured spots in bioethics because the discipline is still relatively young," says Fins.

Various divisions and centers in bioethics programs have different political standings within the institution, making them vulnerable in a way that established departments aren't, says Fins. "If our core mission is our patients, and the integrity of the workforce is central to the service we provide to our patients or the science we produce, I think bioethics is our core mission," he says. "You only appreciate the centrality of the work after there is a problem."

Another challenge involves the interdisciplinary status of bioethics programs, which might bring their scholarly legitimacy into question. "In fact, interdisciplinary programs are just as relevant and often more relevant then a single discipline operating in a silo," argues Fins. "The most challenging problems involve at least two disciplines, and often more."

Fins says that bioethics is perhaps the most successful example of a discipline that brings scholars together from different parts of the academic spectrum to work collaboratively on truly complicated questions. "It's important to cultivate relationships," stresses Fins. "We are still struggling with the scholarly legitimacy of what we do, and we may not have as many allies as we would like."

Current need is great

"Bioethics programs should be supported, as they provide essential information and encourage thoughtful consideration of burgeoning advances in biomedical technology," says Fischbach. "We must always keep in mind the bioethics mantra — it's not what can be done; rather, it's what should be done."

While bioethics programs are at risk when budget cuts are being considered, the programs are especially important at this time to ensure that ethical choices are made, emphasizes Fins, and will be needed to preserve the integrity of health care systems as they begin to implement the Patient Protection and Affordable Care Act. "This will alter the way services are provided. We are going to have a different structure where the old norms could conceivably change," he says. "It's important to have somebody out there stressing that there are certain ethical principles that need to be adhered to in whatever system that is created."

Fins points to a 2011 report from the Presidential Bioethics Commission that recommends that bioethics explain the "why" of regulations to investigators.[1] "A lot of us are beginning to see that a regulatory approach is insufficient. The regulatory scheme of the [Institutional Review Board] isn't equipped to explain the ethics underlying their work," he says.

If cuts made to bioethics programs render them less effective, fundamental questions of patients' rights and training the next generation of providers is at risk, warns Fins. "In times of change, people need to know what those principles are and how to adapt them to the new normal, because there is going to be a new normal," he says. Here are changes that Fins says need to occur:

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Senior Vice President/Group Publisher: **Donald R. Johnston**.
Managing Editor: **Leslie Hamlin** (404) 262-5416 (leslie.hamlin@ahcmedia.com)
Executive Editor: **Shelly Morrow Mark** (352) 351-2587 (shelly.mark@ahcmedia.com).

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EDITORIAL QUESTIONS

Questions or comments? Call Leslie Hamlin at (404) 262-5416.

• Most people doing clinical ethics consults aren't being compensated for those activities currently, which calls for bioethicists to work with organizations such as The Joint Commission to develop standards for these consults.

"We need to further professionalize that activity. Hospitals need to be accountable for the quality of the consultation work that they do and have a revenue stream attached to that functionality," he says. "We need to minimize the variance so patients are better served. Nowhere else in the health care system do we tolerate that variance."

• Medical informatics, electronic decision aids, and care provided via email will need to blend with continued responsibility of the individual.

"These are ethical questions that require individuals well versed in informatics and ethics to sort out," says Fins.

• Bioethicists will need to work closely with clinicians and scientists to address new ethical questions posed by the reconfiguration of the health care system, such as medical homes, new organizational structures, providers working more closely with other disciplines, and doctors sharing clinical space with nurses and other colleagues.

"We will need to figure out who is responsible for what, when it's a team effort more than an individual effort," says Fins. "If you don't adequately fund the medical ethics infrastructure, there are not going to be people to answer these questions with the degree of sophistication required."

• The bioethics community has to secure a reliable funding stream, either through the National Institutes of Health, an extramural grant program that has yet to be fully articulated, or through some type of indirect cost recovery through research grants on the research side, and on the clinical side, by developing expertise in the area the bioethicist works in.

"In academic medical centers, the era of the generalist ethicist has passed. People who are going to work in cardiology, neurology, or psychiatry will need to know issues specific to that space," says Fins. "That will be very important for you to remain relevant with your investigator colleagues." ■

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• **Joseph J. Fins**, MD, MACP, Chief, Division of Medical Ethics, Weill Cornell Medical College, New York City. Phone: (212) 746-4246. E-mail: jjfins@med.cornell.edu.
• **Ruth L. Fischbach**, PhD, MPE, Professor of Bioethics, Director of the Center for Bioethics, Columbia University, New York, NY. Phone: (212) 305-8387. E-mail: rf416@columbia.edu.

ACA to address "ethically unacceptable" overtreatment

Rationing of care is issue

Because overtreatment imposes unnecessary harms upon a patient, it violates the normative rules of beneficence and nonmaleficence that pervade medical ethics, argues **Erin Fuse Brown**, JD, MPH, assistant professor of Law at Georgia State University College of law in Atlanta and former Visiting Fellow in Ethics and Health Policy with the Lincoln Center for Applied Ethics at Arizona State University's Sandra Day O'Connor College of Law.

"This is treatment that is more harmful than good, either in terms of medical risks, emotional harms, costs, or all of the above," says Fuse Brown. "From a utilitarian perspective, even if the incremental risk of harm or cost is fairly small on an individual basis, it adds up to a lot of wasted resources and excess morbidity when measured across the population."

When limited health care resources are expended on overtreatment, fewer resources are available to provide necessary treatment to others, she explains. If the provider is overtreating in order to practice defensive medicine or to satisfy an uninformed and unreasonable demand by the patient, the provider is elevating his or her own interests in avoiding liability or time-consuming patient education over the patient's well-being, says Fuse Brown. If the benefits clearly outweigh the risks or

EXECUTIVE SUMMARY

There is a continuing focus on the ethical concerns raised by the problem of overtreatment, which imposes unnecessary harms on patients and wastes limited health care resources. Overtreatment is expected to be diminished due to the implementation of these aspects of health care reform:
• Patient decision aids will be mandated for certain categories of care.
• Payment innovations will blunt financial incentives created by fee-for-service reimbursement.
• Comparative effectiveness research will be funded that might support less expensive alternatives.

costs to the patient, then it is not overtreatment, it is appropriate treatment. "There are almost no reasons to overtreat that can justify the harms to the patient inherent in overtreatment," she concludes.

Ethical obligation

Unintentional overtreatment that occurs due to the lack of coordination in the health care system, such as duplicative tests, are no less problematic in terms of the harm to the patient and the cost to the system just because it lacks nefarious intent, says Fuse Brown. "Providers have an ethical obligation to coordinate care to eliminate excess and unnecessary treatment," she underscores.

Overtreatment accounts for as much as 30% of the U.S. health care budget, according to some estimates.[1] "With zero expected benefit, there is no justification to expose patients to a risk of harm," warns **Howard Brody**, MD, PhD, John P. McGovern Centennial Chair in Family Medicine and director of the Institute for the Medical Humanities at the University of Texas Medical Branch at Galveston.

By 2025, the cost of insuring the average U.S. family will rise to the level of expected income of the average U.S. family, according to a September 2009 report from the Social Security Advisory Board. "We know that the rise in health care costs in the U.S. are unsustainable," says Brody. "The usual answer is that somehow or other we will need to 'ration' care."

Brody says that to most people, rationing implies that providers are depriving someone of a possibly beneficial treatment because the treatment is expensive. "If any sort of rationing is to be implemented — which is an ethical issue that would require separate discussion — then before any possibly beneficial treatment is denied, it only makes sense first to deny access to all non-beneficial interventions," he says. "Of course, what's non-beneficial can be controversial, especially when the whole idea of overtreatment is so new to both physicians and the public."

Fewer incentives to overtreat

The Patient Protection and Affordable Care Act (PPACA) addresses the problem of overtreatment in a number of ways, says Fuse Brown, as follows:

- The PPACA mandates the development and use of patient decision aids for certain categories of "preference-sensitive care," in which the medical evidence does not clearly support one treatment over another but instead depends on the preferences and values of the patient, such as certain treatments for early-stage breast cancer.

"The use of decision aids is aimed at reducing unnecessary treatment by presenting current clinical evidence, risks, and benefits in an age- and culturally appropriate manner," Fuse Brown says.

- The PPACA includes a variety of Medicare payment innovations designed to blunt the financial incentives for overtreatment created by fee-for-service reimbursement, including bundled payments, value-based purchasing, and the formation of accountable care organizations.
- The PPACA provides funding for comparative effectiveness research, which attempts to provide empirical evidence to guide and optimize treatment decisions.

"Comparative effectiveness research may, for example, supply empirical evidence to adopt a treatment protocol that is more effective than a more expensive or invasive alternative," says Fuse Brown.

Difficult conversations

"Each patient and doctor must decide together which treatment is best for the situation based on guidelines as well as the individual patient's circumstances and preferences," says **William A. Zoghbi**, MD, FACC, president of the American College of Cardiology (ACC) and professor of medicine at The Methodist DeBakey Heart and Vascular Center, both in Houston.

With the many resources now available on the Internet, patients often have treatment options in mind before they even set foot in a doctor's office. "These treatments may not be medically justified," says Zoghbi. "In many cases, it may be easier — and even financially beneficial — for the physician to provide the treatment that the patient expects, despite not being necessary."

This is where it is important for physicians to involve patients in the decision-making process, taking the time to explain that not everything that can be done should be done, that more is not necessarily better, and identifying which specific therapies are most likely to be beneficial, advises Zoghbi. "Conversations about appropriate care can be time-consuming and difficult, especially when patients are influenced by unreliable but ubiquitous outside sources," he adds.

The "Choosing Wisely" campaign provides reliable information about commonly overused procedures in terms patients can understand, says Zoghbi, and helps start the conversation between the patient and physician. ***(For more information on this topic, see "'Rationing' vs. defensive medicine? New approach is neither of the two,"* Medical Ethics Advisor, *July 2012, p. 73.)***

In 2012, the ACC developed a list of five tests or procedures in cardiology that patients and physicians should question and discuss, to spark discussion about the lack of need for these tests or treatments. "Sorting through all of the evidence surrounding treatments can be a confus-

ing and daunting task for physicians and particularly for patients," acknowledges Zoghbi.

The Choosing Wisely campaign promotes a shared decision-making approach, as opposed to focusing on administrative rules to deny access, says Brody, with this overall message: "Before you have this intervention, you and your doctor really need to talk about it. Here's some information that you can use to inform that discussion." "This maximally respects patients' rights and physicians' judgment, while starting us on a pathway to limit harmful, non-beneficial overtreatment," says Brody. ■

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• **Erin Fuse Brown**, JD, Assistant Professor of Law, Georgia State University College of Law, Atlanta, GA. Phone: (404) 413-9180. E-mail: efusebrown@gsu.edu.
• **William A. Zoghbi**, MD, FACC, President, American College of Cardiology, Houston, TX. Phone: (713) 441-4342. E-mail: wzoghbi@acc.org.

Reuse of devices in the developing world

Some bioethicists argue that it is not ethically justifiable to offer reused pacemakers overseas since these are not approved for use in the United States, but "this goes on every day in the developing world," says **James N. Kirkpatrick**, MD, an assistant professor of medicine at the Hospital of the University of Pennsylvania. Of 334 autopsies preformed between February 2009 and July 2011, 27 pacemakers and implantable cardioverter defibrillators were recovered, according to a study from the University of Pennsylvania. Of those, eight devices had at least four years of battery life remaining, and all but two of 40 patients who received used pacemakers reported improved health.[1]

"Reused devices may not be up to the standards we have set for ourselves in the United States in 2012, but they are up to the standards that Sweden set for itself in the 1990s, when they implanted reused devices in up to 14% of their primary implants," notes Kirkpatrick, adding that most of the studies done on reuse have shown no significant differences in infection risk, although there have been differences in device failure.[2]

"These differences are small and still amount to a very low risk of malfunction, which should be even less for newer devices," says Kirkpatrick. "It would be a different story if there was a large, demonstrated quality gap between new and reused devices. As always, we have to balance risk versus benefit. The data, so far, seem to indicate that the risk is small."

In most cases, pacemakers and defibrillators are implanted either to dramatically improve quality of life or to save lives, notes Kirkpatrick. "We're not talking about a brand name medication to treat upset stomach when a generic is available in the developing country, or cosmetic Botox injections," he says.

Cardiology and electrophysiology professional societies stated in a 2002 guideline, "reuse of explanted pacemakers, not currently performed to any extent in the United States, may eventually add significantly to the cost-effectiveness of cardiac pacing."[3] "It may not be too long before we in the United States are considering 'second-best' treatments in order to save money," says Kirkpatrick.

Double standard?

"In every country, there are clearly people who will die without a device. For that reason, even if one or two devices make it into such a country every year, ethically it makes sense to try and help," says **David L. Hayes**, MD, professor of medicine in the Division of Cardiovascular Disease at Mayo Clinic College of Medicine in Rochester, MN.

U.S. government agencies have been opposed to sending these devices out of country, and some other countries don't want cast-offs, notes Hayes. "However, those countries that self-identify as being open to whatever guidelines are established for the reuse of devices

EXECUTIVE SUMMARY

Ethical debates continue over whether reused pacemakers unapproved for use in the U.S. should be offered to the developing world, and new research indicates there is no significant difference in infection risk, but there is an increased risk of device failure. Bioethicists argue that:
• Devices that become contaminated but are non-infected could and should be resterilized and used.
• The Food and Drug Administration might have an ethical obligation to ensure safety of devices exported from U.S. companies.
• The ethical principle of egalitarianism supports the concept of pacemaker reuse by emphasizing the equality of health outcomes.

should be considered, and then available devices distributed by need and/or normalized to the population," he says. *(See story on a program working to export devices for clinical trials, p. 6.)*

If the devices have been removed because they are infected, even though there are good data to demonstrate they can be safely and completely sterilized and could serve another patient for years, most countries would likely balk at the reuse of such devices, says Hayes. Devices that become contaminated but are non-infected could and should be resterilized and used, he says.

"Devices in the U.S. have a 'use by' date, but are still fine for use after that date," says Hayes. "From a supply chain standpoint, most hospitals are very vigilant about not allowing outdating of a device because they don't implant by a certain date. However, I believe the manufacturers would have such devices that could and should be used."

The Food and Drug Administration (FDA) has a responsibility to make sure that devices are safe when used in the United States, and the argument can be made that it has a moral responsibility to make sure devices coming from the United States are safe for overseas use as well, says Kirkpatrick. "If there is to be large numbers of devices exported en mass from U.S. companies which are responsible for the quality and sterility of devices, the FDA should play a role," he says. "It is less clear what oversight it should have over small numbers of devices carried overseas by private parties to be sterilized overseas prior to implant."

Scarce resources

Understandably, lower-middle income countries have not allocated scarce resources to expensive pacemakers and defibrillators for their populations, notes Kirkpatrick. "Their health care budgets are much more wisely spent on prevention, since their primary duty is to the health of the population," he says. That is why the need that exists in these countries for these devices cannot and should not be met by the governments purchasing new devices, says Kirkpatrick, and can only be met by donation of expired new devices or reused devices.

"The cost of implanting these devices, although far below the cost of a new device, is not trivial," he adds. "There is a valid argument that this money could be better allocated to preventative measures."

When the issue is examined not from a population perspective but an individual perspective, the donation and implantation of a used device can make a large difference for the individual and, perhaps, the individual's family, argues Kirkpatrick. "In the United States, of course, we routinely make health care decisions that favor the individual over society," he says. "One could argue that we can afford to do so, at least right now, whereas lower-middle income countries cannot, but we still have to acknowledge the double standard."

Pacemaker implantation has effects beyond the health and well being of an individual, adds Kirkpatrick, because cardiovascular disease strikes patients much earlier in the developing world and keeps young people from being productive members of society. "A pacemaker can dramatically improve the quality of life of these patients, allowing them to return to work and contribute to their families, instead of being a burden," he says. "Defibrillators, of course, save lives — important for young patients in southeast Asia, where sudden unexplained death syndrome is the number one cause of death of young, otherwise healthy men." ■

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• **Thomas Crawford**, MD, Assistant Professor of Medicine, Cardiovascular Center, University of Michigan School of Medicine, Ann Arbor, MI. Phone: (734) 936-6859. E-mail: thomcraw@med.umich.edu.
• **David L. Hayes**, MD, Professor of Medicine, Division of Cardiovascular Disease, Mayo Clinic College of Medicine, Rochester, MN. E-mail: dhayes@mayo.edu.
• **James N. Kirkpatrick**, MD, Assistant Professor of Medicine at the Hospital of the University of Pennsylvania. Phone: (215) 662-7726. E-mail: James.Kirkpatrick@uphs.upenn.edu.

FDA: Pacemaker reuse "objectionable practice"

Devices could be exported for clinical trial

By refurbishing and repackaging pacemakers, "we are de facto creating a new product, which no longer adheres to the original specifications," says **Thomas Crawford**, MD, an assistant professor

of medicine in the Cardiovascular Division at the University of Michigan School of Medicine in Ann Arbor and co-chair of Project My Heart Your Heart, a program which collects used devices from patients and funeral directors to be someday donated to developing countries. So far, the project has collected more than 10,000 devices, and about 20% of them have more than four years of remaining battery life.

It is against Food and Drug Administration (FDA) regulations to ship adulterated medical devices across state lines and abroad. "We are working with the FDA to allow exportation of a limited number of devices for a clinical trial," Crawford reports.

My Heart Your Heart's survey of funeral homes in the Ann Arbor area found that only 4% returned devices to the manufacturers, which is currently recommended for quality improvement (QI). "The vast majority of pacemakers are never returned to the manufacturers, and end up buried with the deceased or fill the landfills," he says. "It is possible to create a system where a certain number of devices are randomly selected and returned to the device manufacturers to allow for ongoing QI."

The FDA considers pacemakers as class III devices, which are of "substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury." "This designation requires the highest standard of safety," says Crawford. "Many other medical devices, including catheters, are categorized as class II and do not require premarket approval."

The FDA regulations do allow reprocessing of most catheters under strict protocols, says Crawford, noting that although technically possible, pacemaker reuse is specifically called "an objectionable practice" by the FDA compliance manual. "Currently, there are no developed standards for safe pacemaker re-implantation," he says. The mission of My Heart Your Heart is to address this deficiency and to develop device evaluation protocols in terms of its functionality and sterility with appropriate validation, says Crawford.

A meta-analysis of data from 18 studies suggests that the risks of infection with pacemaker re-implantation are similar to the risks with brand new devices, although the risk of mechanical failure rate is six-fold higher with reused devices.[1] "We believe this may be an acceptable level of risk, given that many patients in the low- and middle-income countries have no alternative way of receiving this potentially life-saving therapy," says Crawford.

The World Health Organization's Medical Device Regulations, which emphasize that the quality of devices should be equal, appeal to egalitarian principles, while the use of refurbished devices aims to improve equality of access and equality of health outcomes for people in low- and middle-income countries, notes Crawford.

"Refurbished pacemakers, we believe, are a reasonable response to a dramatic disparity in access to this therapy between the advanced economies and the low and middle-income counties," says Crawford.

Cardiovascular disease remains a number one killer around the world, with the exception of sub-Saharan Africa, where acquired immunodeficiency syndrome and other communicable diseases claim more lives, notes Crawford. "It is estimated that one million people die each year because of lack of access to pacemakers, mostly due to economic constraints," he says. "We agree that it would be inappropriate to 'dump' unwanted and unreliable devices for use in patients in low- and middle-income countries."

However, the ethical principle of egalitarianism supports the concept of pacemaker reuse by emphasizing the equality of health outcomes, as without the donated pacemakers many deaths are likely to ensue, Crawford says. "Utilitarian conceptions of justice support reuse of pacemakers, provided that resources needed for such efforts were not better used elsewhere," he says. ■

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Medical futility debate has been largely "neglected"

More evidence-based information needed

The debate over medical futility has in large part been neglected, and should be expanded beyond "pull the plug" decisions to include doctors' involvement in the details of end-of-life care, argues **Lawrence J. Schneiderman**, MD, founding co-chair of the University of California, San Diego Medical Center Ethics Committee. "Patients and families who demand that 'everything be done' may well be expressing a subtext: 'Do not abandon me,'" says Schneiderman. "Physicians should see it as their obligation to pursue comfort care with the same skills and dedication as they applied to aggressive life-sustaining treatments. I cringe whenever I hear the phrase 'futile care.' A treatment may be futile. Care is never futile."

Pursuing a clear-cut concept of medical futility will encourage a more aggressive search for evidence-based

information from clinical trials that report not only on successful treatments but also treatments that are unsuccessful, says Schneiderman. "Both kinds of data are important to the practice of medicine. Both provide guidelines for physician choice," he explains.

Empirical studies and consensus agreements form the basis for establishing standards of practice, and these should be declared openly as policies by medical centers and organizations of medicine for the information of the public and as guidelines to the courts, argues Schneiderman. Many patients and patients' families have been forced to endure and pay for inhumane, unwanted care either because of an individual physician's misguided notions of medical duty or because of hospital administrators' fears of inflammatory media coverage, according to Schneiderman.

"As a consequence, many physicians practice defensive medicine, fearing that anything less than mindless continuation of aggressive treatments would make them legally vulnerable," he says.

It is up to hospitals to establish policies that record their professional stand on medical futility and end-of-life care, says Schneiderman. "These policies should provide specific definitions and a well-described dispute resolution process that will bear scrutiny by outside, impartial observers," he says. "Hospitals are likely to find the legal system willing to defer to well-defined and procedurally scrupulous processes for internal resolutions of futility disputes."

Outdated approach

Despite evidence showing that some interventions done with the intent to prolong life may actually shorten life, and definitely impair the quality of life, medicine is still operating from the priority to keep patients alive as the primary goal, and considering quality of life second, says **Nancy E. Havas**, MD, FAAFP, associate professor at the Center for Bioethics and Medical Humanities at The Medical College of Wisconsin in Milwaukee.

"This was generally a good approach to care at a time when most people died of infections and curable problems," she says. "But it is not necessarily a good approach when the major causes of death in the United States are chronic, progressive diseases that are ultimately fatal." Most people with these diseases experience multiple hospitalizations for their illnesses, including recurrent infections, episodes of heart failure or respiratory illness, delirium, anemia, or kidney failure, notes Havas, and often have severe, critical illnesses that they recover from temporarily, but are recurrent in nature.

"After multiple hospitalizations, usually accompanying an overall decline in overall health and quality of life, it is hard to define the point at which medical treatment becomes 'futile,' as some people recover, even when we do not expect them to," she says. "In most of these cases, the very aggressive [intensive care unit] level interventions people often are provided simply serve to prolong the dying process, rather than providing for additional living."

If families are unable or unwilling to recognize a futile condition, the health care team might need to remove the burden of decision making from the family and take leadership in supporting the family while simultaneously defining clear limits to a plan for appropriate care options and interventions. "This is where we struggle as health care providers," says Havas. "We are taught that paternalism is bad, and that patients and families should be the decision makers, but are never taught an alternative to this approach when people are unable or unwilling to engage in difficult decisions."

Schneiderman says he defines medical futility as the unacceptable likelihood of achieving an *effect* that the patient has the capacity to appreciate as a *benefit*. "A patient is neither a collection of organs, nor merely an individual with desires. Rather, a patient is a person who seeks the healing powers of the physician," he says. "The relationship between the two is central to the healing process and the goals of medicine."

Medicine today has the capacity to achieve a multitude of effects — raising and lowering blood pressure, speeding, slowing, and even removing and replacing the heart, to name a few, says Schneiderman. "But none of these effects is a benefit unless the patient has at the very least the capacity to appreciate it," he says. ■

EXECUTIVE SUMMARY

Medical futility discussions should be expanded to address physician involvement in the details of end-of-life care, including comfort care, argue bioethicists.

- Hospitals should establish policies recording their professional stand on medical futility and end-of-life care.
- Families might be unable or unwilling to recognize a futile condition.
- The health care team might need to remove the burden of decision making from the family.

SOURCES

- **Nancy E. Havas**, MD, FAAFP, Associate Professor, Department of Family and Community Medicine/Associate Professor, Institute for Heath and Society, Bioethics and Medical Humanities, Medical College of Wisconsin, Milwaukee. Phone: (414) 456-4318. E-mail: nhavas@mcw.edu.
- **Lawrence J. Schneiderman**, MD, Founding Co-Chair, Ethics Committee, University of California, San Diego Medical Center. E-mail: ljschneiderman@ucsd.edu.

Children on psych meds raise these ethical concerns

Desire for "quick fix"

It is vital for providers caring for pediatric patients not to jump to a diagnosis just because it is in the *Diagnostic and Statistical Manual of Mental Disorders (DSM)V*, argues **Harold J. Bursztajn**, MD, associate clinical professor of psychiatry at Harvard Medical School in Cambridge and co-founder of the Program in Psychiatry and the Law at Beth Israel Deaconess Medical Center. Bursztajn is president of the American Unit of the United Nations Educational, Scientific and Cultural Organization Bioethics Chair.

"The differential diagnosis needs to includes psychosocial or situational difficulties, rather than simply what is only in the main sections of the DSM," says Bursztajn. "There is also the problem of false positives, due to the search for a quick fix promoted by some pharmaceutical companies aimed at vulnerable families and clinicians desperate for help, and the problem of false negatives due to denial of major mental illness."

Providers should not overlook the possibility of Munchhausen syndrome or shared paranoid disorder in formulating the differential diagnosis, adds Bursztajn. "One needs to respect family values, as well as consider such fundamental values as maintaining children's autonomy and authenticity — and the cumulative effects of both suffering from an illness and the increasing risk burden of many psychotropic medications when used chronically," he underscores.

Lack of appropriate workups

For children and their families, the ethical considerations in psychiatry should be no different than those that apply to other fields of medicine, according to **Grace E. Jackson**, MD, a Wilmington, NC-based psychiatrist, and the same principles of patient autonomy, beneficence, and non-maleficence should be foremost.

"There is always a risk versus benefit calculation in all medical treatment decisions," says Jackson, author of *Rethinking Psychiatric Drugs: A Guide to Informed Consent*. "However, the stakes of this calculation are necessarily higher when speaking about child psychiatry." This is due to the frequent lack of appropriate medical workups and diagnoses, the deflection away from resolving root causes of mental suffering, and the application of psychologically and physically harmful drugs, she says.

"One of the problems in psychiatry today — especially as it pertains to children — is that many patients are not receiving appropriate physical or diagnostic exams — tests, brain scans, electroencephalograms — prior to the application of psychiatric diagnostic labels," says Jackson. "Even in the absence of a confirmed biological condition as the cause of problem behaviors or emotional distress, psychiatric labels are often applied to patients based upon an *assumption* of faulty brain function."

Even after a medical clearance comes back "normal," patients are led to believe that they have a "mystery" defect which awaits medical correction, says Jackson. "This assumption leads to aggressive interventions with pills or other technologies," she says. "This emphasis on 'pretend' pathology commonly precludes interventions in other domains."

Opponents point to risks

Jackson says the primary ethical concern with the labeling of healthy children is the fact that American psychiatry "now attaches an absolute priority" to the use of medications. "Although psychiatric drugs are frequently successful in quieting or restraining youngsters in a classroom, it should not surprise our society to see that these same children grow into teenagers and adults who have never practiced or mastered the capacity for law-abiding behaviors or self control," she says.

Jackson says that on a physical level, the pills present "devastating risks" for children in terms of maturation and survival. "Because of the fact that most psychiatric drugs are "endocrine disruptors" and mitochondrial toxins, they exert particularly damaging effects upon the central nervous system," she says. "A significant number of children die each year because of the physical and psychological adverse effects of these drugs."

EXECUTIVE SUMMARY

Increasing numbers of children on psychotropic medications are raising ethical concerns, including physical and psychological adverse effects, inadequate medical workups, overly aggressive interventions, and failure to address root causes of mental suffering. Bioethicists argue that:

- The provider's differential diagnosis needs to include psychosocial or situational difficulties.
- Providers must consider family values and children's autonomy.
- Risks of chronic use must be considered.

Randy L. Cima, PhD, was the CEO of several mental health agencies for children in California. He is now a board member of the International Society for Ethical Psychology and Psychiatry, an organization founded by doctors, psychologists, therapists, social workers, and psychiatric survivors opposed to the medical model. "From our perspective, the model is scientifically unethical and pragmatically ineffective," says Cima.

In the 1970s, about 200,000 children were taking psychotropic medications, and the number is now at 10 to 12 million, according to Cima. "In the 1980s, these chemicals were sold as miracle drugs. Now, all therapists at the masters or doctorate level are schooled on pharmacology," he says. "The pharmaceutical industry has been marketing these toxic chemicals for the last 25 years."

Cima says that increasingly, the idea of medication is first initiated in school settings. "When kids act up in the classroom, teachers and school psychologists are trained to suggest chemicals to help with their child management problems. That, too, is, in our view, unethical and unwise." Children often require additional medications for side effects such as upset stomach or trouble sleeping, notes Cima.

"I had many parents in my office who had children on medication for years. They all complained things were worse, not better," Cima said. "You won't find legitimate science to support the miraculous claims made by pharmaceutical companies, other than their own self-financed 'studies' designed to support their advertising departments." ■

SOURCES

- **Harold J. Bursztajn**, MD, Associate Clinical Professor of Psychiatry, Harvard Medical School. Phone: (617) 492-8366. E-mail: harold_bursztajn@hms.harvard.edu.
- **Randy L. Cima**, PhD, Riverside, CA. E-mail: randycima@yahoo.com.
- **Grace E. Jackson**, MD, Wilmington, NC. Phone: (910) 520-4162. E-mail: grace.e.jackson@att.net.

Some find donor protocols "extremely troubling"

Expanding pool ethically is issue

While Americans typically support organ donation, data show the number of actual donations is actually quite low and cannot keep up with demand, says **Leslie M. Whetstine**, PhD, an assistant professor of philosophy at Walsh University in North Canton, OH. "The fear that patients may not be given optimal care if they are organ donors, or that organs will be removed before one is actually dead, remain pervasive," she adds. "It is difficult to dispel these concerns when Uncontrolled Donation after Circulatory Determination of Death [UDCD] protocols give credence to what were once merely urban legends."

UDCD is a method of organ procurement used when death is unanticipated, says Whetstine. For example, a patient in cardiac arrest arrives in the ED and, after resuscitation fails, death is declared based on the irreversible cessation of circulation. A waiting period of two to five minutes elapses before organs are removed.

"The reason there is any waiting period at all after a declaration of death is to rule out autoresuscitation (AR). If a person were to autoresuscitate, then they were clearly not irreversibly dead, and removal of organs would be akin to homicide," she says. "If the procurement process is initiated during the time in which AR is possible, then a dying patient may be mistaken for a dead one."

Whetstine says the ethical question is whether providers can rely on the circulatory criterion required by donation after cardiac death (DCD) to determine death when the need for speed is paramount and still maintain the integrity of the Dead Donor Rule. A 2010 study surveyed the existing literature on AR and reiterated the need for prospective studies, and a 2007 study concluded that patients should be passively monitored for at least 10 minutes after the cessation of cardiopulmonary resuscitation before confirming death.[1,2]

"DCD conflates a prognosis of death with a diagnosis of death to the extent that imminently dying patients may be treated as dead, which violates the Dead Donor Rule," says Whetstine. "We obviously know that lack of circulation doesn't make one instantly dead. Resuscitation is premised on the fact

EXECUTIVE SUMMARY

Ethical concerns over Uncontrolled Donation after Circulatory Determination of Death (UDCD) protocols include the possibility that patients won't be given optimal care if they are organ donors, or that organs will be removed before a patient is actually dead. To address concerns, protocols should:

- Ensure patients receive aggressive resuscitation measures that meet or exceed current accepted medical standards.
- Require that the death declaration follow accepted medical and defined legal standards.
- Ensure the declaring physician is not associated with the donation or subsequent transplantation of donated organs.

that such cessation is not always irreversible."

DCD focuses on a criterion of death that claims cessation of the organism as a whole can be determined by loss of circulatory function only, independent of brain status, which is "simply erroneous," says Whetstine. "It is disingenuous at best, and potentially lethal at worst, to claim that we know the precise moment of death after cessation of circulation."

Patient "dying but not dead"

Whetstine says that some new UDCD protocols that initiate chest compression and artificial ventilation after a declaration of death in order to circulate preservatives that extend organ viability throughout the body are "extremely troubling. To prevent the possibility of return of consciousness, such UDCD protocols have instituted highly contentious and creative techniques."

In order to avoid cardiac or brain perfusion, such protocols implement a balloon catheter to occlude the thoracic aorta. This is a serious ethical dilemma, according to Whetstine, because the transplant team clearly understands that circulatory function has not been irreversibly lost, and brain perfusion and subsequent reanimation would be possible, which means the patient is dying but not dead.

There are some unique ethical considerations with UDCD because the patient's death is unanticipated, unlike DCD, in which there is a planned withdrawal of support expected to result in the patient's death, says **Alexandra K. Glazier**, Esq., vice president and general counsel at New England Organ Bank in Waltham, MA, and chair of the OPTN-UNOS Ethics Committee. For example, there is an ethical concern that UDCD could conflict with, or undermine, the priority that patients receive all possible life-saving measures before organ donation is considered.

Because the declaration of death in UDCD circumstances will be based on the irreversible absence of circulation, there has also been ethical debate regarding protocol measures that artificially restore circulation in the donor after death has been declared, says Glazier. For example, under some UDCD protocols, after the patient is declared, extracorporeal membrane oxygenation is instituted to perfuse the organs in an effort to improve transplant outcomes. "The ethical question is whether such measures negate the validity of the death declaration in the first instance," says Glazier.

Glazier gives these recommendations to address ethical concerns with UDCD:

• UDCD protocols should ensure that the patient receives aggressive resuscitation measures that meet or exceed current accepted medical standards and legal requirements before death is declared.

"All resuscitation efforts must be exhausted so that it is clinically clear the patient will not and cannot recover," says Glazier.

• UDCD protocols should require that the death declaration follow accepted medical and defined legal standards.

This addresses ethical concerns regarding death declaration, given the rapid nature of UDCD, says Glazier.

• As with DCD, the declaring physician must not be associated with the donation or subsequent transplantation of donated organs.

"This separation of duties helps to reduce any potential conflict or the appearance of a conflict," says Glazier.

DCD is a widely accepted practice endorsed by the Institute of Medicine, says Glazier, noting that last year 13% of all organ donations in the United States were DCD, and this number has steadily increased over time. "Many of the initial ethical concerns surrounding DCD have been resolved," she says. "Donation is not discussed as an option until the family and the health care team agree that further measures are futile, and the decision to withdraw support has been made." ■

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SOURCES

• **Alexandra K. Glazier**, Esq., Vice President/General Counsel, New England Organ Bank, Waltham, MA. Phone: (617) 244-8000. E-mail: Alexandra_Glazier@neob.org.

• **Leslie M. Whetstine**, PhD, Assistant Professor, Philosophy, Walsh University, North Canton, OH. Phone: (330) 244-4697. E-mail: lwhetstine@walsh.edu.

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.

CME QUESTIONS

1. Which is true regarding ethical considerations involving overtreatment, according to **Erin Fuse Brown**, JD?
   A. Because overtreatment imposes unnecessary harms upon a patient, it violates the normative rules of beneficence and nonmaleficence that pervade medical ethics.
   B. There are many reasons to overtreat that can justify the harms to the patient inherent in overtreatment.
   C. Unintentional overtreatment that occurs due to the lack of coordination in the health care system is not ethically problematic in terms of the harms to the patient because it lacks nefarious intent.
   D. Providers have no ethical obligation to coordinate care to eliminate excess and unnecessary treatment.

2. Which is true regarding ethical concerns with reuse of devices in the developing world, according to **Thomas Crawford**, MD?
   A. It is never ethically justifiable to offer reused pacemakers overseas because these are not approved for use in the United States.
   B. Most of the studies done on reuse have shown significant differences in infection risk, demonstrating a large quality gap between new and reused devices.
   C. The vast majority of funeral homes consistently return devices to the manufacturers, which is currently recommended for quality improvement.
   D. The ethical principle of egalitarianism supports the concept of pacemaker reuse by emphasizing the equality of health outcomes, as without the donated pacemakers many deaths are likely to ensue.

3. Which is true regarding medical futility, according to **Nancy E. Havas**, MD, FAAFP?
   A. The role of the health care team is to provide leadership in care of the patient, with clear limits and a plan for appropriate interventions, while simultaneously supporting the family.
   B. Discussions of medical futility should not address doctors' involvement in the details of end-of-life care, such as comfort care.
   C. Physicians have no obligation to pursue comfort care with the same skills and dedication as they apply to aggressive life-sustaining treatments.
   D. It is not advisable for hospitals to establish policies that record their professional stand on medical futility and end-of-life care.

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.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

COMING IN FUTURE MONTHS

- New high-tech, high-cost interventions
- Informed consent and health care reform
- Newly available data and COI
- Concerns of physicians selling products