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Guidelines promote better communication, "preventive ethics"

"Real-world" resource for bioethics

The 2013 *Guidelines for Decisions on Life-Sustaining Treatment and Care Near the End of Life* were written with the nation's changing health care landscape and "the real world of clinical practice" in mind, says **Nancy Berlinger**, PhD, a research scholar at The Hastings Center in Garrison, NY. Berlinger is lead author of the new edition of the *Guidelines* and the director of the research project supporting the new edition.

The *Guidelines* are written for all professionals responsible for the care of patients who are facing decisions about life-sustaining treatment, or approaching the end of life, in any setting. "The book aims to be a resource to health care professionals who must think broadly about the safety of patients and the quality of care across a large system, as well as to professionals directly involved in patient care," Berlinger says.

The *Guidelines* come at a pivotal time for care near the end of life, according to **Bruce Jennings**, MA, director of bioethics at the Center for Humans and Nature in Dobbs Ferry, NY. "This is a real time of transition and consequences in the American health care system," he underscores. "The number of persons in the late stage of incurable chronic illness is growing, and end-of-life care decisions and the need for pallia-

EXECUTIVE SUMMARY

New bioethics guidelines aim to improve the quality of end-of-life care in the United States, with new sections on pediatric decision-making, advance care planning, and palliative care. The guidelines, which emphasize the communication process and opportunities for system-wide improvements, can be utilized in these ways:

- To help individual clinicians serve the needs of patients and families.
- To bring individuals who conduct ethics consultations up-to-date on the latest thinking in the field.
- To give health care administrators a way to support better outcomes for patients.
- To support institutional changes to improve care.

tive care are the realities of an aging society. Health care systems will need to meet these challenges."

When the 1987 edition of The Hastings Center's *Guidelines on the Termination of Life-Sustaining Treatment and the Care of the Dying* was published, the central issue in bioethics was to empower individuals to control their own care near the end of life and to establish the patient's right to refuse any and all medical treatment, notes Jennings, a co-author of both editions of the *Guidelines*.

"Historically, the late 1980s was also a time of transition and ethical turmoil in end-of-life care, although without as much focus on the cost of care as we have today," he says. *(See related story on ethical issues involving the cost of care, p. 87.)* At that point in time, it was important to compose a clear statement of patient rights and rules for good decision-making in accordance with the patient's wishes and values, says Jennings.

The 2013 *Guidelines* reflect the ethical and legal consensus that has evolved in the United States since the 1987 edition, including the U.S. Supreme Court's 1990 *Cruzan* decision, the Patient Self-Determination Act, the Patient Protection and Affordable Care Act, and statutes and case law concerning physician-assisted suicide.

Since then, ethical standards in end-of-life care decision making have become much more institutionalized, with ethics committees and consultations active in most hospitals and many nursing homes. "Laws exist in every state to permit proxy decision making when patients lose the capacity to make decisions directly for themselves. Quality standards, such as those of The Joint Commission, now require attention to the ethical aspects of treatment decision making and communication," adds Jennings. "Virtually every health care facility and system must take this seriously."

New approach taken

Beyond clinical ethics, the book describes how and why organizational systems — including quality improvement, patient safety, information technology, legal, and risk management — are part of efforts to improve care for seriously ill patients. It frames all issues in the context of a changing health care system, identifying new opportunities to improve care such as collaborations between hospitals and nursing homes in the same community or between oncologists and hospice programs.

Jennings says the authors felt it was necessary to take a new approach with the 2013 *Guidelines*, which cover the entire spectrum of medical care near the end of life, including end-of-life and palliative care for neonates, children, and adolescents. In addition to recognizing the unique challenges with different age groups and medical conditions, the new *Guidelines* focus on advance care treatment planning, including setting goals of care, addressing surrogate decision making, and providing good continuity of care in various settings and stages of illness.

"Ethical conflicts can be prevented by good communication before a crisis," says Jennings. "To respect a dying person's rights in practice, it is necessary to remember that the person is a part of a larger

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EDITORIAL QUESTIONS

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web of meanings, emotions, and relationships."

For this reason, the *Guidelines* place a lot of emphasis on the communication process, such as working with family members as surrogate decision makers, defining the goals of care and treatment options to meet those goals, and, if necessary, making available processes of conflict resolution. Ethically appropriate and respectful care planning and decision making is not only best for patients and families, it is also very much in the best interest of health care professionals and institutions, stresses Jennings.

"Poor decision making is extremely costly and disruptive for health care systems and the professionals involved," says Jennings. "In health care today, Benjamin Franklin rules: 'An ounce of prevention is worth a pound of cure.'"

The authors intend for clinicians to use the *Guidelines* to bring themselves up-to-date on the latest thinking in the field. "No matter where you look, there are individual nurses and physicians who are highly motivated to do their work in an ethical way, and want to take good care of patients as they are dying," Jennings says. "I do think this book will be helpful for some professionals who have an opportunity to play an institutional role in ethics and need a good overview of issues and information on best practices."

In virtually all hospitals, the expertise of individual practitioners concerning ethics varies, even within specialties like palliative care. "Therefore, institutional supports like ethics committees and palliative care consultation services are very important," Jennings says. "Where they are just getting organized or need to be developed further, the *Guidelines* can be an important resource for the interdisciplinary teams needed for those services."

Avoid miscommunication

The *Guidelines* provide guidance on avoiding confusion and conflict in commonly occurring scenarios, such as when a physician or nurse asks the family of a dying patient, "Do you want us to do everything?" The book explicitly states that professionals should not use the phrase "doing everything" to represent maximal treatment, and explains why this phrase is the source of many problems.

"The *Guidelines* offers better ways to communicate with families, and recommends that professionals clarify what patients or surrogates mean if they request that 'everything' be done," says Berlinger.

The book also addresses how to communicate with families concerning decisions about nutrition and hydration, when a patient nearing the end of life stops eating or begins choking on food. It clarifies the right to refuse medical treatment as it applies to artificial nutrition and hydration, discusses why this decision can be emotionally difficult for decision makers and for staff, and describes how to develop a care plan for a patient who has stopped eating as he or she nears the end of life.

"Most people rely on their local hospital for inpatient care and treatment decisions, and care near the end of life may also concern seriously ill patients who are not hospitalized," adds Berlinger. "The new *Guidelines* offer extensive practical guidance on the decision-making process, working with families and other loved ones, addressing conflict, and other topics of perennial ethical concern." ■

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Guidelines: Cost *is* an ethical concern

Begin difficult conversations

The 2013 Hastings Center *Guidelines for Decisions on Life-Sustaining Treatment and Care Near the End of Life* acknowledge cost as an ethical concern in health care. "As a nation, we've decided not to have a national conversation about how to rein in health care costs — at least not yet," says Mildred Z. Solomon, EdD, president of The Hastings Center and a member of the project working group, which developed the *Guidelines*.

This responsibility is falling instead on the shoulders of institutional leaders. "Chief medical officers,

vice presidents for safety and quality, as well as chief financial officers can all play a leadership role in ensuring better quality care at more reasonable costs," says Solomon.

A new section of The Hastings Center *Guidelines* provides health system leaders with specific strategies for beginning difficult conversations about costs of care within their own institutions. "This is particularly timely, given the move to accountable care organizations and enhanced opportunities to build in greater care coordination across settings," says Solomon. "This is an example of the kind of leadership the *Guidelines* hope to stimulate."

The ethical goal of treating all patients equitably requires health care institutions to grapple with the moral as well as fiscal dimensions of resource allocation and health care cost. The *Guidelines* include a guide for hospitals and other institutions, with six strategies to encourage productive discussions that can support the development and use of a transparent policy.

"This is not to say, though, that end-of-life care is the primary driver of health care costs, nor even that better palliative care will substantially reduce costs, though it may," says Solomon. The main drivers of costs are other factors, such as the aging of the baby boomer generation, the prevalence of chronic conditions, and the prices paid for drugs, devices, and procedures.

The main reason to ensure better palliative care is not to save money, but because access to pain relief, psychosocial support, and advance care planning is something every American should be able to count on, adds Solomon. "The new *Guidelines* summarize the state of the art in all these areas, for both adults and children," she says. "They are a resource for all clinicians, no matter whether they work in quaternary and tertiary health care organizations, primary care, or long-term care settings." ■

Patients taking pre-emptive action due to genetic results

Bioethicists have a crucial role to play

Angelina Jolie's widely publicized bilateral mastectomy brought a great deal of public attention to the issue of what to do in response to genetic testing results, but also raised some important ethical concerns, according to bioethicists interviewed by *Medical Ethics Advisor*.

"I think it is very helpful for a celebrity to be brave enough to step forward and talk about these issues, because it makes them more of an everyday conversation," says **Gail Jarvik**, MD, PhD, professor of medicine and genome sciences at University of Washington in Seattle. "But when she is speaking about it in a way that suggests it was her only option, we need to take a step back and remind patients of other options."

For instance, patients might opt for more intensive screenings or medications to reduce risks. In addition, the decision to immediately have a mastectomy and postpone removal of ovaries is not necessarily the order that some patients would choose, adds Jarvik, as screening and treatment options for ovarian cancer are very poor.

Jarvik notes that the ability of patients to take preventive action based on genetic test results is not new, and has been offered for more than a decade for *BRCA* 1/2.

"It's very powerful for women to have information with which to make decisions," she says. "Some are put in the position of having a strong family history where we do not know the genetic basis. Therefore, we have to make decisions just based on a statistical model."

If women know they have the mutation and a high risk of breast cancer, for example, screening can allow them to make a decision based on better data. "It's useful for people to be reminded to look at their family history of cancer and potential preventive measures, whether or not they have a genetic result," adds Jarvik. "Certainly, we hope that some people will come to medical geneticists who might not have thought of it before."

Lack of genetic counseling

Whoever orders genetic testing should provide appropriate pre-test counseling about the potential

EXECUTIVE SUMMARY

The widely publicized bilateral mastectomy of the actress Angelina Jolie brought a great deal of public attention to taking pre-emptive action in response to genetic testing results, but bioethicists say this could mislead patients about their options. Bioethicists can:

- Help guide clinicians in communicating to patients about options.
- Serve as resources to health professionals who face unfamiliar or complex genetic testing situations.
- Advise laboratories, professional organizations, insurers, and health professionals on new complexities in genetic testing.

implications of the results, underscores **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 in Philadelphia. "The results should be presented to the patient in a situation in which questions can be addressed, and the patient's potential responses to the results discussed," he says.

Some genetic testing can be arranged directly by lay people, however. Some of the laboratories offering such "direct-to-consumer" testing introduce barriers to access the results that require consumers to acknowledge they are about to receive potentially disturbing results, and some provide access to genetic counselors should the consumer wish to have results interpreted or potential actions discussed.

Charis Eng, MD, PhD, FACP, chair and director of the Cleveland Clinic's Genomic Medicine Institute in Cleveland, OH, says that the biggest current ethical issue she sees involves non-trained physicians drawing blood for *BRCA* 1/2 testing, when those may not be the correct genes to test for, as there are 10 different breast cancer predisposition genes. Many do not do counseling pre- or post-test, she adds.

"I'll tell you this is happening all over the country," says Eng. "In this situation, we are robbing the patient of proper information and limiting her autonomy, and decrementing beneficience."

Kenneth W. Goodman, PhD, professor and director of the Bioethics Program at University of Miami (FL), says, "One of the most interesting lessons we're learning from the genetic revolution relates to how people behave when confronted with probability data," he says. "Some will run the risk of surgery, in the often false belief that surgery always prevents some dreaded malady from occurring."

Health literacy in the 21st century needs to include statistics and probability, argues Goodman. "Anyone contemplating removing a healthy body part because a celebrity did so should take a deep breath and talk to a trusted physician," he says. "Pre-emptive amputations are, themselves, risky, and should be considered only with the greatest caution and deepest possible understanding."

One important role for the bioethics community is providing guidance to patients and providers about medical probability and risk reduction. "When risk and fear are closely related — and they often are — there is usually an ethical issue that requires discussion," says Goodman.

Bioethicists can help clinicians to communicate uncertain genetic information to patients and families, for instance. "As we are turning to genetic testing more often, we will find more variants of uncertain significance," says Jarvik. "It's certainly been our experience that patients assume the worst, but most of these variants turn out to be benign. It is very hard information for people to understand."

Risk reduction

Undoubtedly, people will be influenced by widely publicized cases involving taking pre-emptive action due to learning genetic results, such as prostate removal or mastectomy due to testing positive for the *BRCA* 1/2 genes. "Often this can be for the good. People who were in denial about familial risks or reluctant to seek testing will be motivated to act," says Goodman. "However, actions taken by celebrities may not be appropriate for everyone. The average consumer must have his or her results interpreted by a knowledgeable health professional." Goodman sees these roles for bioethicists:

- Advising direct-to-consumer companies on best practices.
- Serving as resources to health professionals who face unfamiliar or complex genetic testing situations.
- Advising laboratories, professional organizations, insurers, and health professionals as new complexities arise in genetic testing, such as the occurrence of incidental findings when whole exome or genome sequencing is employed.

Eng notes that *BRCA* 1/2 were discovered in 1995 and 1996, respectively, and bioethicists and clinical psychologists have already studied many questions to guide the practice of clinical cancer genetics. "After 18 years of robust research, the community actually knows a lot about clinical outcomes of carrying the mutation, how best to return results, and how to utilize gene mutations for medical management," she says.

Prophylactic mastectomy and oophorectomy have been studied and found to be efficacious in very high-risk situations, notes Eng, whereas *BRCA*-related prostate cancer risks occur at the usual age for routine screening in the general population, and management guidelines aren't changed from the general population's. "It would be very unusual — and I've never seen it in my patients — for patients, if properly counseled, to opt for prophylactic prostatectomy," she says. ■

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Hype is ethical concern with cognitive enhancers

"There is still a lot to be proven"

Recent trends demonstrate a widening use of drugs that can facilitate cognitive capability, both in patient and general-use populations, says **James Giordano**, PhD, chief of the Neuroethics Studies Program at Edmund D. Pellegrino Center for Clinical Bioethics at Georgetown University Medical Center in Washington, DC.

However, there is "much more hype than evidence" that medications used to treat Alzheimer's disease and other cognitive deficits also may improve cognition in healthy individuals, says **Jonathan D. Moreno**, PhD, David and Lyn Silfen University Professor of Ethics at University of Pennsylvania in Philadelphia.

"Color me a skeptic," he says. "There really aren't many better ways to enhance cognition than a good night's sleep, a healthy diet, and, for some people, a nice cup of coffee." Moreno says that for methyphenidate and amphetamine, there is "very mixed evidence about enhancement. It may be that it works better for people who are closer to a standard deviation rather than a real enhancement."

As for more radical methods of enhancement, such as transcranial magnetic stimulation, Moreno notes that there are safety concerns about repeat exposure. "Nor is there really good evidence that people are enhanced by these things," he says. "There is still a lot to be proven, and little evidence of efficacy, and ethical medicine requires more than a hunch. It probably requires more than a series of anecdotes that you accumulate in your practice."

Some physicians have strong feelings about one treatment or another, even though there is not a lot of data, but any off-label use must have some rational basis, adds Moreno. "There probably will be a time when some of this stuff will work, but people need to appreciate that we are really far from good evidence," he says. "We may find there are physiological limitations for how much you can enhance cognition."

Moreno says that while off-label use isn't necessarily unethical, caution is advisable. "For example, external neuromodulation is being employed on a 'do-it-yourself' basis as a matter of curiosity," he says. "Even if there are short-term enhancements — and it would be necessary to do carefully controlled studies to make sure — the long-term risks are still a question. If a physician prescribed that sort of treatment for enhancement outside of a clinical trial, I would be concerned."

Unfair advantage?

One ethical concern involves whether unique capacities or advantages are obtained by those who take these agents, and the equitable distribution of these drugs to various individuals and groups in society. "It's hard to make the justice argument for this when there are so many other inequalities — not everyone can afford math tutors for kids, for example," says Moreno. "In terms of applied ethics, it's hard to single out one advantage from another."

There is a more fundamental issue that arises from the use of cognitive enhancing drugs — namely, that there is still much that remains unknown about the neural mechanisms that function in cognition, says Giordano. This raises a number of ethical concerns, he says, including the fidelity of informed consent; what responsibilities for care of unexpected consequences of use should be borne by clinicians, healthcare institutions, and pharmaceutical companies; and whether adequate or sufficient guidelines, policies, and laws are needed to govern the right and good use of such interventions.

EXECUTIVE SUMMARY

Ethical concerns involving cognitive enhancers include lack of good evidence of efficacy, safety concerns, the fidelity of informed consent, and just distribution.
• The debate over whether use of cognitive enhancers is inherently unethical typically hinges on whether these drugs represent treatments or enhancements.
• Benefits, burdens, and risks need ongoing reassessment.
• Bioethical guidelines are needed to steer sound utilization in clinical practice.

The debate over whether use of cognitive enhancers is inherently unethical typically hinges on whether these drugs represent treatments or enhancements, says Giordano. "In many ways, this hinges upon the nature of the 'good' that is being sought through the use of such drugs," Giordano says.

This also raises the issue of how society views the use of various implements such as caffeinated beverages, dietary supplements, and pharmaceuticals in relation to cultural norms, he says. "While one possibility is that cognitive enhancers will create new norms of human cognitive capability, another is that the availability and use of these agents may only serve to widen the gap between the proverbial 'haves' and 'have nots' of society," adds Giordano.[1]

Guidelines needed

Long-term consequences of use and potential misuse of cognitive enhancers are as yet unknown, says Giordano.[2] "This certainly compels the need for additional research and prudence in their employment, so as to enable both ongoing reassessment of the benefits, burdens, and risks, and the development of iterative, well-informed bioethical guidelines to steer their sound utilization in clinical practice," he says.

The goal is not necessarily to be proscriptive, but to address how benefits might be maximized while reducing burdens and risks. "Key to this process is the identification and analysis of gaps in information and/or capability," says Giordano. "These must be addressed so as to plan — and be prepared — for the likely ethical, legal, and social contingencies that will arise." ■

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Some surrogates overriding organ donors' wishes

Hospitals sometimes "surrender" to family demands

Some countries, such as Australia, Spain, Norway, Italy, and Canada, allow next of kin to override the consent of registered organ donor candidates if they personally do not concur with the donation desire of their relative, but this form of surrogate decision-making represents a double standard in terms of the principle of substituted judgment, argues **Katrina A. Bramstedt**, PhD, a clinical ethicist and associate professor at Bond University School of Medicine in Australia, and former faculty in the Department of Bioethics at Cleveland (OH) Clinic Foundation.[1]

This is not legally permitted in the United States. "However, sometimes U.S. hospitals do 'cave in' to family demands if they have a fear of media reprisal spurred by the family," she says. "Hospitals don't want bad press. To avoid this, they will sometimes 'surrender' rather than hold firm and educate families on the law and ethics of the situation."

Reinforce ethical obligations

Bioethicists should take a proactive approach, Bramstedt urges, by offering educational sessions to hospital personnel that reinforce the legal and ethical obligations of honoring the expressed values of their patients.

Surrogates who want to give their loved one a chance at life sometimes view enrollment in a research study as a means toward that end. "In

EXECUTIVE SUMMARY

Families might demand clinical or even research interventions that deviate from a patient's end-of-life wishes in attempts to keep their loved one alive, and avoid the discussion of organ donation with procurement personnel.
• Study participation can potentially prevent organ donation after death.
• Clinicians should consult the patient's advance directive to see if there are any expressed preferences about research or specific technologies/interventions.
• Bioethicists can perform a capacity assessment on surrogates involved in the consent process.

the setting of end of life, when the patient's values are known, families might want to deviate from that. They demand clinical or even research interventions in attempts to keep their loved one alive, avoiding death, and avoiding the discussion of organ donation with procurement personnel," Bramstedt adds.

Surrogates sometimes pursue study enrollment as a delay tactic with the goal of "curing" their loved one, even if this is contrary to the patient's values and wishes at the end of life. "Study participation could potentially prevent organ donation after death, if the study exposed the patient to agents which were toxic or if the organs otherwise deteriorated as a result of the extended dying process," she says.

If a patient has an advance directive, this should be consulted to ascertain if there are any expressed preferences about research, heroics, or specific technologies or interventions, says Bramstedt. "Surrogates, either out of desperation, ignorance, or emotional entanglement might be caught up in 'therapeutic misconception'—believing study participation will be for the clinical benefit of their loved one rather than future patients," she explains.

A bioethicist with the research subject advocate role can perform a capacity assessment on surrogates involved in the consent process. In addition to therapeutic misconception, the bioethicist can also explore the situation for surrogate conflict of interest.

"Hopefully, there will be more involvement of research subject advocates in participating in the consent process, assessing the decisional capacity of surrogates, and looking after the welfare of the subjects who are enrolled in studies by way of surrogates," says Bramstedt. ■

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Living donor near-misses underreported

Consider individual donors' needs

Aborted hepatectomies and potentially life-threatening near-miss events — during which a donor's life may be in danger but after which there are no long-term sequelae — are rarely reported, according to a survey of 71 transplant programs that performed donor hepatectomy 11,553 times.[1] Here are key findings:

• The average donor morbidity rate was 24%, with five donors (0.04%) requiring transplantation.

• The donor mortality rate was 0.2%, with the majority of deaths occurring within 60 days, and all but four deaths related to the donation surgery.

• The incidences of near-miss events and aborted hepatectomies were 1.1% and 1.2%, respectively.

• Program experience did not affect the incidence of donor morbidity or mortality, but near-miss events and aborted hepatectomies were more likely in low-volume programs.

Potentially life-threatening near-miss events and aborted hepatectomies are underappreciated complications that must be discussed as part of the informed consent process with any potential living liver donor, write the researchers.

Typically, the core set of information that must, at minimum, be disclosed to patients as part of the informed consent process includes the rationale for the proposed treatment, the risks, benefits, alternatives, and the expected prognosis, notes **Leslie M. Whetstine**, PhD, an associate professor of philosophy at Walsh University in North Canton, OH.

EXECUTIVE SUMMARY

Aborted hepatectomies and potentially life-threatening near-miss events are rarely reported, according to a recent survey of transplant programs.

• Informed consent should empower patients to make decisions that are consistent with their values.

• The subjective standard requires that clinicians disclose all the information that a particular patient would need in order to make an informed decision.

• It is beneficial to collect these data and have a standardized system.

"Informed consent should ideally empower patients to make decisions that are consistent with their values, rather than simply serve as a legal protection for clinicians," she says. "In this tradition, all relevant information that a hypothetical 'reasonable person' would want to know is generally considered ethically appropriate."

For living donors, though, the consent process might need to be approached differently. This is because their choice to donate is entirely elective, and provides no direct medical benefit to them. "The argument could be made that by virtue of the unique situation of living donors, the subjective standard may be a more comprehensive ethical approach than the traditional reasonable person standard," says Whetstine.

The subjective standard essentially requires that clinicians disclose all the information that a particular patient would need in order to make an informed decision. "Unfortunately, this standard is logistically difficult to implement in practice, since it usually takes some time to establish this kind of deep interpersonal relationship," says Whetstine. "Given the nature of living donors, perhaps it is a model worth working toward."

Information regarding aborted hepatectomies as well as potentially life-threatening and/or near-miss events should be disclosed using the subjective standard so that individual donors' needs are considered, advises Whetstine. "While donors' needs may vary, it would be beneficial to collect these data and have a standardized system," she says. "Whether every living donor would want or need such information remains to be seen, but it seems to represent a positive step in enhancing their autonomy." ■

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Mind-body training increases MDs' compassion

Teaching medical students about mind-body approaches could help boost their compassion, according to a study from Boston (MA) University School of Medicine.[1] The study included 27 first- and second-year medical students who underwent an 11-week course. Researchers measured the study participants' self-compassion, self-regulation, self-criticism, and stress levels at the beginning and end of the study to ascertain differences in each. Participants had improved self-compassion, slight decreases in stress, and increases in empathy.

"We were pleased, but not surprised, to find that a mind-body practice boosted self-regulation and self-compassion. Related activities, such as mindfulness-based stress reduction, have been found to have similar effects," says **Allison R. Bond**, the study's lead author and a third-year medical student at Boston University.

Physicians and medical students who take time to recharge their minds and bodies are more apt to be empathetic — and thus perhaps more ethical — physicians, says Bond.

"It can seem selfish, or even unethical, for health care providers and students to set aside time for self-care," she says. "However, our research indicates that doing so may yield great returns by helping physicians and medical students be more effective, compassionate providers for their patients." ■

REFERENCES
1. Bond AR, Mason HF, Lemaster CM, et al. Embodied health: The effects of a mind–body course for medical students. *Med Educ Online*. 2013; 18: doi: 10.3402/meo.v18i0.20699.

SOURCE
• **Allison R. Bond**, Boston (MA) University School of Medicine. Email: bond@bu.edu.

Obesity isn't often considered with transplants

It's associated with worse outcomes

Obesity presents many ethical challenges for transplant practice, according to a review article that describes an approach for applying available data on the importance of body composition to the kidney transplant population.[1]

"Our article demonstrates that in most studies, markers of obesity are associated with worse post-transplant outcomes — delayed graft function, graft failure, cardiac disease, and high costs — compared with ideal body composition," says **Krista L. Lentine**, MD, MS, associate professor of medicine at Saint Louis (MO) University Center for Outcomes Research. However, current data have not identified limits of body composition that preclude clinical benefit from kidney transplant compared to continued waiting on dialysis, or proven that weight-loss interventions improve outcomes.

Data on outcomes differences in obese patients can be used to support body mass index (BMI) thresholds as one of the criteria for transplant listing, says Lentine. "The demand for donated kidneys outpaces supply, and choices are necessary," she adds. "Currently, BMI is not part of the criteria for organ allocation after listing, but candidacy criteria [utilized by centers] determine who gets to be on the waiting list for a transplant."

In determining transplant candidacy, the ongoing ethical challenge is to balance optimization of organ utility by considering outcomes in obese compared to normal weight patients, against the justice of offering organs to all patients who may benefit from a transplant compared with their own experience on dialysis, as well as physician autonomy in making clinical decisions for individual patients, says Lentine.

EXECUTIVE SUMMARY

Since markers of obesity are associated with worse post-transplant outcomes in most studies, obesity presents these ethical challenges for transplant practice:

- The need to optimize organ utility by considering outcomes in obese patients compared to normal weight patients.
- The justice of offering organs to all patients who may benefit from a transplant compared with their own experience on dialysis.
- Physician autonomy in making clinical decisions for individual patients.

Lentine emphasizes that the decision to transplant an obese patient is not solely an ethical or cost-effectiveness decision, but is first and foremost a medical/surgical decision. "Clinical judgment is needed to weigh factors that are not reflected in BMI, such as the surgeon's assessment of the safety and feasibility of a transplant operation based on the distribution of abdominal fat in a particular patient," she says.

Potentially modifiable

Since obesity is a potentially modifiable risk factor, shared responsibility agreements for patients to lose some weight before transplant listing seem appropriate in many cases, argues Lentine. "Just as patients with alcoholic liver disease are required to stop drinking prior to transplant, it may be reasonable to ask kidney transplant candidates to lose excess body fat and attempt to increase lean muscle mass by becoming more physically active and modifying their diet," she suggests.

However, the lack of prospective data on the impact of intentional weight loss complicates efforts to manage obesity among end-stage renal disease patients, says Lentine. Transplant centers, primary nephrologists, and patients often face limited resources to access and pay for modalities such as monitored dietary changes, exercise programs, and bariatric surgery.

"For these reasons, bioethical input on the appropriate balance of utility, justice, autonomy, and management considerations related to obesity among potential transplant candidates is vital," Lentine says, adding that bioethicists can help resolve current controversies by entering public discussions on these areas:

- The need for more public funding of prospective studies of the impact of intentional weight-loss efforts among obese end-stage renal disease patients, including dietary changes, monitored exercise programs, and bariatric surgery.
- The need to determine to what extent chronically ill, obese patients are responsible to attempt to optimize their own body composition prior to receiving a donated organ.
- The need for formal clinical and cost-effectiveness studies, including appropriate quality-of-life adjustments that capture impact of complications, to determine if payers and society should be compensating centers for clinical and financial risks of transplanting obese end-stage renal disease patients.

"Evidence-based reimbursement decisions, such as a modified [diagnosis-related group] payment to cover higher risk transplants if determined to be cost-effective, would certainly impact transplant practice," Lentine says.

Societal or individual level?

A key ethical issue is deciding whether responses to obesity should focus on the societal or individual level, or both, according to **Harald Schmidt**, PhD, a lecturer in the Department of Medical Ethics and Health Policy at University of Pennsylvania's Perelman School of Medicine in Philadelphia.

"Action on the societal level includes interventions such as regulating fat and sugar levels in foods and drinks. Here, the key opposition comes from industry and politics," he says. Other less controversial options at the societal level include providing affordable opportunities for exercise, such as free or subsidized gym memberships.

"Interventions that focus on the individual level are also becoming increasingly common, especially in the employment context," he notes. For example, some employers impose considerably higher insurance premiums on overweight and obese employees.

Such policies pose risks of "victim-blaming," in which people are held responsible for factors that are beyond their control. "At the same time, we need to recognize that individual behavior does play a key role in obesity prevention," says Schmidt. "We need action at both the social and individual level, but we must take care not to penalize people unduly." Employers who cover employees' health insurance are increasingly interested in having employees with normal BMIs, for instance, and new rules on wellness incentives will enable employers to penalize employees up to $1,500 per year if they don't meet health standards.

"But employers may also offer rewards up to this amount," says Schmidt. "Depending on how exactly incentives are implemented, they can promote or undermine autonomy." It makes no sense to set out responsibilities that people are unable to comply with or that are extremely challenging to achieve, he argues, and incentive programs need support structures to help people achieve health goals.

"At the societal level, politicians and policy makers must realize that *not* acting on evidence-based policies, or *not* trying out new policies and evaluating their effect, can have real cost in terms of lost human welfare," says Schmidt. "Doing nothing is not a neutral position. Given current levels of obesity, not intervening requires justification, too." ■

REFERENCE

1. Lentine KL, Santos RD, Axelrod D, et al. Obesity and kidney transplant candidates: How big is too big for transplantation? *Am J Nephrol* 2012;36:575-586.

SOURCES

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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.

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.

COMING IN FUTURE MONTHS

■ Whole genome sequencing raises concerns

■ The rise in ACOs comes with ethical challenges

■ Ethical issues of medical marijuana

■ Bioethicists' reporting of impaired clinicians

CME QUESTIONS

1. Which is true regarding patients taking pre-emptive action in response to genetic testing results, according to **Gail Jarvik**, MD, PhD?
   A. It's useful for people to be reminded to look at their family history of cancer and potential preventive measures, whether or not they have a genetic result.
   B. Pre-test counseling about the potential implications of the results is not advisable except under certain circumstances.
   C. Bioethicists should not play any role in advising direct-to-consumer companies on best practices.
   D. Early screening for breast cancer genes is always the best protection for patients.

2. Which is true regarding ethical concerns about cognitive enhancers, according to **James Giordano**, PhD?
   A. The debate over whether use of cognitive enhancers is inherently unethical typically hinges on whether these drugs represent treatments or enhancements.
   B. There is very clear, substantial evidence that medications used to treat Alzheimer's disease and other cognitive deficits also may improve cognition in healthy individuals.
   C. There are no safety concerns involving repeat exposure to transcranial magnetic stimulation.
   D. Recent trends demonstrate a significant decrease in use of drugs that can facilitate cognitive capability.

3. Which is true regarding informed consent process with any potential living liver donor, according to **Leslie M. Whetstine**, PhD?
   A. Potentially life-threatening near-miss events and aborted hepatectomies should not be discussed as part of the informed consent process.
   B. Information regarding aborted hepatectomies as well as potentially life-threatening and/or near-miss events should be disclosed using the subjective standard so that individual donors' needs are considered.
   C. It is not beneficial for transplant centers to collect data on potentially life-threatening near-miss events.
   D. It is inappropriate to disclose information to potential donors on aborted hepatectomies unless this is specifically requested by the donor.

4. Which is true regarding ethical challenges of obesity in the kidney transplant population, according to **Krista L. Lentine**, MD, MS?
   A. It is unethical to optimize organ utility by considering outcomes in obese patients compared to normal weight patients.
   B. Body mass index thresholds should not be used as one of the criteria for transplant listing under any circumstances.
   C. The surgeon's assessment of the safety and feasibility of a transplant operation based on the distribution of abdominal fat in a particular patient should not play any role in the decision to transplant an obese patient.
   D. Centers should consider that markers of obesity are associated with worse post-transplant outcomes in most studies.