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Updated core competencies for consults are important milestone for bioethics

Field is at pivotal juncture

While the field of bioethics has traditionally embraced a diversity of approaches to clinical ethics consultations, there is now a general consensus for the need to agree of some basic standards in order to evaluate the quality and impact of the service.

"We are certainly in a state of transition. The train to professionalize health care ethics consultants has left the station," says **Anita J. Tarzian**, PhD, RN, program coordinator at the Maryland Healthcare Ethics Committee Network in Baltimore. Tarzian chaired the task force to update the American Society for Bioethics and Humanities' Core Competencies for Health Care Ethics Consultation report, and is lead author of a manuscript summarizing that report *(To view the manuscript, go to: http://bit.ly/15W0jy1)*.

The original 1998 Core Competencies report discouraged any move toward certifying individual ethics consultants. The 2013 report recognizes the value in having individuals functioning as expert ethics consultants who are held accountable to quality standards, though it doesn't endorse any particular approach.

The second edition of the Core Competencies clarifies various concepts described in the first edition, reframes the distinction between clinical and organizational ethics, expands on how to evaluate ethics consultation ser-

EXECUTIVE SUMMARY

There is a general consensus that basic standards are needed to evaluate the quality and impact of clinical ethics consultations. The American Society for Bioethics and Humanities' Core Competencies for Health Care Ethics Consultation 2013 report recognizes the value in holding individuals functioning as expert ethics consultants accountable to quality standards. The report:

- contains criteria for the evaluation and assessment of ethics consultations.
- emphasizes quality improvement processes and establishing research priorities.
- acknowledges that some degree of standardization is needed across facilities.

vices, and introduces "process standards" for how to perform ethics consultation. "The ethics consultation knowledge and skills tables are essentially the same, but additional skills were added," says Tarzian. These include quality improvement and evaluative skills; the ability to communicate and collaborate effectively with other responsible individuals, departments, or divisions within the institution; the ability to access relevant ethics literature, policies, and guidelines; and the ability for at least one member of an ethics consultation service to effectively run the service.

"The bottom line is that if someone has an ethics question or concern and calls for an ethics consultant's help, the person responding should actually be able to help, and we should know how to evaluate whether that happens," says Tarzian.

Pressure toward professionalization

Some bioethicists have post-graduate degrees in ethics and health policy, while others have only brief exposure obtained at a week-long ethics seminar. "There is also now a willingness, at least, to consider the certification of individuals who regularly perform ethics consultation. This is a contentious issue. Even the existence of 'ethics expertise' is a hotly debated topic," says **David M. Adams**, PhD, MLS, a clinical ethicist at Pomona (CA) Valley Hospital Medical Center.

The latest Core Competencies report contains a new section devoted entirely to criteria for the evaluation and assessment of ethics consultation, including proper documentation and follow-up. Some have expressed concern that the additional standards may be overly burdensome for smaller hospitals without the same level of resources.

"In academic centers, we have access to a lot of people with formal ethics training. Community hospitals might not have access to people with the same level of training or expertise, but who are still making valuable recommendations," says **Keith M. Swetz**, MD, MA, assistant professor of medicine at Mayo Clinic in Rochester, MN.

The creation of competencies and core requirements could exclude individuals with a wealth of clinical and ethical experience, but who don't meet a certain certification standard. On the other hand, if certification criteria do not ensure that consultants have sufficient knowledge of clinical day-to-day realities confronting clinicians who request an ethics consultation, then certification would fail. "The new guidelines do a nice job of not necessarily mandating, but suggesting and being somewhat flexible in terms of what ethics teams and consults can actually look like," says Swetz.

The field of bioethics is grappling with how to retain its historic roots in a plurality of disciplines. **Stuart G. Finder**, PhD, director of the Center for Healthcare Ethics at Cedars-Sinai Medical Center in Los Angeles, CA, notes that the original Core Competencies took the approach of an agreed-upon consensus at a time when the field of bioethics was in an earlier stage of its evolution. "It was not initially pursued to created standards that would be imposed on other people. But once it was done and put out there, some people viewed it that way," he says.

The 2013 Core Competencies seek to identify "emerging standards" as opposed to a definitive set of standards. "This is an important document that helps further that effort in a field that draws from many

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EDITORIAL QUESTIONS

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different disciplines," says Finder. "But by definition, once you create the standards, you are going to cut someone out."

The challenge is how to create standards that are inclusive but also create some sense of boundary, says Finder. "I believe the value is to help us continue to ask important questions, and to provide a means for being accountable for the kinds of skills and judgments that we who do this kind of work hold as crucial," he says.

Andrew Courtwright, MD, PhD, a physician at Massachusetts General Hospital's Institute for Patient Care in Boston, MA, says what is most notable about the core competencies report is what is *not* included. Namely, there is no call for formal Health Care Ethics Consultation (HCEC) accreditation to ensure that the consultation competencies are actually being met.

"The 'professionalization' of HCEC has been a longstanding controversy in bioethics. The fact that the task force did not recommend formal credentialing or accreditation means that this will remain an active debate," says Courtwright.

As the role of HCEC services is increasingly formalized in official hospital policy and state law, particularly in areas such as unilateral medical futility decisions, there will be increasing external pressure toward professionalization in a manner similar to other ancillary clinical hospital services, predicts Courtwright. "As this happens, I expect that hospital administrators and legislators will use the task force core competencies as a template for accreditation and credentialing expectations, if not adopt them outright," he says.

Lack of outcomes data

Looking forward, the task force's emphasis on quality improvement processes and establishing research priorities could have the most long-term impact on bioethics as a field. "There remains a significant dearth of empirical data on the practice of ethics consultation and its impact on patient care," Courtwright says. "The task force's call for better understanding of the current state of HCEC will help improve these services."

As bioethics in general, and clinical ethics consultation in particular, become more established, the imposition of standards for education and practice of clinical ethics is inevitable, says **Stuart J. Youngner**, MD, Susan E. Watson Professor and Chair in the Department of Bioethics at Case Western Reserve University in Cleveland, OH.

"On the one hand, no robust method for determining how to measure outcome exists. On the other hand, clinical ethics consultants have a very real effect on the lives of patients, families, and health professionals," says Youngner. "As bioethics enters deeper into the real world of clinical medicine, it is encountering a host of real-world dilemmas."

The bottom line, says Tarzian, is that the practice of each ethics consultant doing it his or her own way needs to be replaced with a more standardized approach. This will allow for better internal quality improvement evaluation and research across practice settings. "We are in dire need of research to identify what types of outcomes are most valued and how they are best achieved," she says. "We need to agree that some level of standardization is needed across facilities in order to compare apples to apples." ■

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Patients in MCS: Misdiagnosis is ethical issue

Patients in a minimally conscious state (MCS) demonstrate behaviors suggestive of consciousness episodically and intermittently, and because these behavioral signs are not reproducible, diagnostic errors can be quite high, says **Joseph J. Fins,** MD, MACP, the E. William Davis, Jr., MD, Professor of

Medical Ethics and chief of the Division of Medical Ethics at Weill Cornell Medical College. Fins is director of medical ethics at New York-Presbyterian Hospital/Weill Cornell Medical Center in New York City.

"MCS patients are often disregarded and mistakenly diagnosed as vegetative because they look vegetative when they are not demonstrating these behaviors," says Fins. "Some of the diagnostic error rates are quite staggering. There are cases of people who have been misdiagnosed and mischaracterized for decades."

Of MCS patients with a traumatic brain injury (TBI) who were diagnosed as vegetative in nursing homes, 20% to 40% are, in fact, minimally conscious.[1,2] "So the first major ethical problem is a proper diagnosis, to distinguish those who are conscious from those who are not," says Fins. "I think we owe something more to a conscious entity than we owe to people who are permanently unconscious. That is an important distinction and a diagnostic imperative."

MCS individuals may have a higher level of integrative cognitive function than they are able to manifest behaviorally. "And we have a moral obligation to identify these people," says Fins.

Diagnosis could change

Patients who are vegetative can move into a minimally conscious state due to recovery of higher cortical function. "Most clinicians are still unaware of this, so it goes unrecognized and undiagnosed," says Fins. According to prevailing guidelines, the persistent vegetative states become permanent three months after an anoxic brain injury and 12 months after a TBI, notes Fins. In the period before permanence sets in, patients who are vegetative often get transferred to nursing home facilities because they are not demonstrating any improvement, and at a later point in time, some of these patients become minimally conscious.

"A patient may be properly diagnosed as vegetative initially, but the diagnosis then changes to MCS and goes unrecognized," says Fins. "It's unlikely the nursing home director will challenge the diagnosis that came from the academic medical center, even as behaviors evolve."

The "minimally conscious state" category came into the literature formally in 2002. "Before that, we didn't have a category for this patient population, but, of course, it did exist biologically," says Fins. Fins' upcoming book, *Rights Come to Mind: Brain Injury, Ethics and the Struggle for Consciousness* (Cambridge Press) tells the story of some 40 patients seen at Cornell Medical Center for multimodal assessment of their disorder, and family de-briefings about their challenge to find care for their loved ones.

A related ethical issue involves the diagnostic and therapeutic imperative, as more is learned about how patients recover and how to maximize any residual cognitive capability, says Fins. A number of studies have shown that certain drugs can either accelerate recovery or can actually improve a patient's level of consciousness.[3-5]

Patients are also subject to reimbursement strategies that do not adequately cover their needs. "We have a kind of somatic-based reimbursement structure. The patient's brain may recover long before their body manifests that they are getting better, and we are paid based on those manifestations," says Fins. "These people are subject to the malignant bureaucratic machinations of what is called medical necessity — if you don't demonstrate behavior, then we're not going to pay for it. That is something that needs to be changed."[6]

Range of recovery

The right to die movement got started in the context of severe brain injury, but some misconceptions exist due to it being over-generalized to a patient population who may actually improve.[7] "Not all brain injuries are invariably catastrophic," Fins underscores.

It's important to realize that there is a continuing range of recovery that can occur, from being vegetative all the way to full recovery, says Fins. "We would rather look for the happy ending than the more complex, intermediate ending, because it absolves us of our guilt," he explains. "Though nobody would choose to be in this brain state, there are people for whom heroic measures did bring a great curative result. We have to distinguish between what we would hope prospectively and what we have to do for the patient population that currently exists."

EXECUTIVE SUMMARY

Misdiagnosis is a major ethical concern involving patients in the minimally conscious state who demonstrate behaviors suggestive of consciousness episodically and intermittently.

- Minimally conscious individuals may have a higher level of integrative cognitive function than they are able to manifest behaviorally.
- Patients who are vegetative can move into a minimally conscious state due to recovery of higher cortical function.
- Patients are subject to reimbursement strategies that do not adequately cover their needs.

The level of scientific excitement that currently exists is "totally unmatched" by the level of care that the average American receives if he or she has severe brain injury, however, says Fins. "What happens in chronic care is really a national tragedy. It is something we really need to do a lot more about, both for the civilian and the military population," he argues. "It should be a golden opportunity to improve quality care, but it still hasn't been a priority."

Patients in chronic brain states can, in fact, get better over time, and there may be ways to facilitate those recoveries, but this area of research is "woefully underfunded," according to Fins. "That is where the action should be, but it's hard work, and there is a low number of programs that work in this area," he says. ■

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Ethics of functional neuroimaging at bedside

Can functional neuroimaging, which is currently used largely in the research setting, be used as a clinically actionable tool for disorders of consciousness? "This is an important and a loaded topic," says **Judy Illes**, PhD, FRSC, FCAHS, Canada Research Chair in Neuroethics and professor of neurology at the University of British Columbia in Vancouver, Canada.

Illes and colleagues received a grant from the Canadian Institutes of Health Research specifically to explore the issues around neuroimaging and loss of consciousness. The team developed a framework for how to address the ethical issues involved.[1]

"We looked at what variables we need to think about to ensure the ethical translation of the technology, and what we might learn from the research even if it doesn't prove to have clinical utility," says Illes. "Our whole approach is a very rigorous systematic analysis that is very solution-oriented. We are always looking for solutions, even as we identify challenges and risk." As for what it would take for functional neuroimaging to be clinically actionable, Illes says these are three questions to consider:

1. What is the technical feasibility?

Magnetic resonance imaging scans are widely available in the United States, less so in Canada, and extremely limited in under-resourced parts of the world. "Colleagues are trying to develop an EEG-based technology, which has been around since the 1920s. It is very portable and could conceivably be available in the home, if we ever get to that point," Illes says.

2. If it's technically feasible, will it result in a significant change in outcome?

"The question turns on how if, in fact, we were able to reliably and reproducibly elicit signals from individuals in a disordered state of consciousness, how we would act on this," says Illes. Patients could communicate about levels of pain, preferences for food and music, and life decision-making, for instance.

EXECUTIVE SUMMARY

Functional neuroimaging is currently used largely in the research setting, but there is potential for it to be used as a clinically actionable tool for disorders of consciousness. Some ethical considerations:

- Availability of magnetic resonance imaging scans varies widely.
- Patients in a disordered state of consciousness could potentially communicate their preferences.
- The general public may be unaware of the limitations and risks involved.

3. If it will result in a significant change in outcome, can it be incorporated into the clinical environment ethically, socially, legally, and in an economically feasible way?

The question is to what extent complex communications might be enabled between people who have lost that ability with the outside world, a family member, health care provider, or even a lawyer looking after the person's affairs. "Here, it becomes very complicated. These are complex phenomena and we are looking at them in detail," she says.

The researchers interviewed experts in the areas of disorders of consciousness, physicians in direct contact with individuals in a disordered state of consciousness, ethicists and lawyers with expertise in this area, and researchers, to learn their major ethical concerns.

"We just completed this analysis, and the problem is not as binary as we had envisioned it," says Illes. "The problem is really a continuum of phenomena. The solutions are not black and white with one side 'yes' and one side 'no.'"

Bioethicists can play a role in ensuring that the public, while attuned to advances in technology, is also aware of the limitations and risks involved. "When a topic is very hot, the level of caution needs to escalate proportionately to the level of interest," Illes underscores. "When there are enormous tensions between clinical potential and research desires, it's important for bioethicists to be unafraid to be open and transparent with patients and families about the state of the art."

This is the case whether bioethicists are discussing neuroimaging technology for level of consciousness, liberation therapy for multiple sclerosis, or supplements for children with neurodevelopmental disorders. "It's a daily challenge for bioethicists that we appreciate immensely," says Illes. "The best we can do is bring really good empirical data so that bioethicists can operate in an evidence-informed way." ■

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Consent, safety of human egg donors is unclear

Compensation is another ethical concern

The primary ethical concern with human egg donation is that there are no long-term studies on the safety of this practice, according to **Jennifer Lahl**, president of The Center for Bioethics and Culture Network in Pleasant Hill, CA.

"If this was a classic IRB [Institutional Review Board] that was going to be started at Stanford or [University of California — Los Angeles], there would be so many safety hurdles just to move it into clinical trials," she says. "We don't have one long-term, peer-reviewed major study on what happens to these young women, short-term or long-term, who donate or sell eggs."

Lahl says it's not possible to obtain informed consent in this scenario. "How can you give informed consent on something you have never studied?" she asks. "I understand you can't know everything about something to give informed consent, but the first step should be that we've done the studies to know this is safe, or not safe."

Ethicists are concerned about what protections are in place to make sure egg donors aren't exploited, coerced, or harmed, and how restitution would be provided if the donor is harmed. "We are all busy talking about informed content, how much money the egg donors should be paid, and if they should be paid. Nobody is saying, 'We have to first answer the question: is this safe?'" says Lahl.

The major ethical concern is the lack of federal or systematic oversight, argues **Lisa Campo-Engelstein**, PhD, an assistant professor in the Alden March Bioethics Institute and the Department of Obstetrics

EXECUTIVE SUMMARY

Ethical concerns involving human egg donation include lack of long-term studies on the safety of this practice, the corruption of informed consent due to compensation, and lack of protections to ensure donors aren't exploited, coerced, or harmed. In addition, inadequate screening of donors could:

- enable women to donate at multiple centers.
- result in donors being untruthful about their personal and medical information.
- affect intended parents, in the case of egg donation for assisted reproductive technologies.

and Gynecology at Albany (NY) Medical College. The UK's Human Fertilisation and Embryology Authority regulates the use of gametes and embryos for fertility treatment and research. "In contrast, the U.S. is the Wild West when it comes to reproductive medicine," says Campo-Engelstein. "We lack any real regulation in this field. There are soft policy guidelines from various medical and scientific organizations, but these don't have teeth."

While informed consent is always necessary to perform any type of medical procedure, there is a concern that without oversight, some clinics may not ensure that informed consent guidelines are being met. One way this could happen is if clinics minimize the medical and psychological risks because they are eager to obtain specific types of egg donors.

"There isn't clear or conclusive research on all the medical and psychological risks associated with egg donation, in part because this is a neglected research area," says Campo-Engelstein. "This may allow clinics to downplay or omit some of the very real risks associated with egg donation."

High compensation

Some view the high compensation that is associated with egg donation as coercive, especially toward economically disadvantaged groups, such as recent college graduates with high student debt. "If you are going to be in a clinical trial, you might make $50 or $100. These women are making thousands of dollars," Lahl says. "Poor women in financial need will be the ones lining up to do this. It's not going to be wealthy women." A bill in California would make $10,000 the maximum amount that can be paid for one ovulation cycle.

"Women will take a lot of risk if they are going to be compensated a lot of money," says Lahl. "As bioethicists, we need to be the ones standing in that gap and demanding that the studies be done and that the safety hurdles be met, and that we really need to back off from this compensation model."

Lahl points out that organ donation wasn't done until studies showed that people could live a long and healthy life with one kidney. "We don't allow compensation for organ donation because we know that compensation corrupts," she says. "Who would be selling their kidneys? It would be poor people and people who don't have adequate health coverage, should they have complications."

Lahl says that in contrast, egg donation is operating more like an industry than medicine, as it doesn't ensure that subjects are protected and that everything possible has been done to ensure they aren't harmed, or that the amount of money paid isn't incentivizing people to do things that probably aren't in their best interest.

"There is nothing in place for that. This is not how medicine operates," she says, noting that organ transplant teams have a firewall in place, with the donor and recipients each having a separate medical team caring for them.

"The role of the bioethicist is not to be a rubber stamp for industry stakeholders, but to be an impartial spokesperson on the ethics of the matter," says Lahl. "Unfortunately, some bioethicists are attached to major universities that have a vested interest in getting eggs to advance their science policy, or they may have fertility services. But our obligation is to people, and not our organization affiliations."

Screening of donors

"Another big problem has to do with screening of donors," says Campo-Engelstein. "Without any regulations, women can donate at multiple centers without any of the other centers knowing. This could be detrimental to women's health and could lead to less diversity in the research sample." A related concern is that without screening, donors may not be truthful about their personal and medical information.

In the case of egg donation for assisted reproductive technologies, inadequate screening also affects the intended parents. "If fertility clinics do not adequately screen their donors, then people who purchase an egg may not get what they signed up for. For example, a donor may lie about information or omit certain information, such as being a carrier for a particular disease," says Campo-Engelstein.

One significant development is the American Society for Reproductive Medicine's 2012 recategorization of egg freezing as established technology; it was previously considered an experimental technology. "It is becoming increasingly common, though it's still quite rare, for young women to freeze their eggs as an insurance policy against age-related infertility," says Campo-Engelstein. "If this trend continues, then it's possible that egg donation may not be as common in the future as it is today, at least for age-related infertility." ■

SOURCES

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Many med students biased against obese or thin patients

More than one-third of 310 medical students surveyed had a moderate to strong bias against obese people, according to a recent study.[1] Researchers gave third-year medical students Harvard's Implicit Association Test on weight, which measures how long it takes for people to associate a positive word with an image of a person who is either thin or obese. Overall, 39% of medical students had a moderate to strong unconscious anti-fat bias. Less than 25% of students were aware of their biases.

In addition, 17% had a moderate to strong anti-thin bias. "We were surprised that none of these students recognized their preference for obese individuals," says **David P. Miller**, MD, MS, the study's lead author and an associate professor of internal medicine at Wake Forest School of Medicine in Winston-Salem, NC.

"Just like the students with an anti-obesity bias, they thought they, too, were either neutral or preferred thin people," says Miller. "It made us wonder if anti-obesity bias has become so common in our society, that even students who prefer obese people to thin people have a hard time believing it."

Physicians strive to treat all patients equally, deliver the best care possible, and treat everyone with respect, and bias or prejudice interferes with the ability to accomplish those goals, says Miller. "This is why it is critical for medical schools to teach their students about bias and strategies for minimizing its impact on patient care," he urges.

The study's findings are consistent with other studies that have examined physicians' weight-related attitudes and preferences. Other studies have found that many physicians assume obese patients are unlikely to follow healthy lifestyle recommendations or adhere to medical treatments.[2-4]

"Another study using the same bias test we used found a high rate of anti-obesity bias among practicing physicians. In that study, even obese physicians showed a bias against obese individuals," says Miller.[5]

Research has shown that bias affects the diagnoses doctors make and the treatments they recommend.[6] "Bias can also harm trust," says Miller. "People tend to notice if someone has an initial negative reaction to them. Patients who sense this bias will be less likely to trust their doctors or confide in them."

Addressing bias in medical care has proven difficult, however. "One strategy that some experts recommend is reframing the medical encounter as a chance to practice egalitarian goals," says Miller. "Bioethicists could help teach students these principles and strategies for putting them into practice." ■

EXECUTIVE SUMMARY

More than one-third of medical students surveyed had a moderate to strong bias against obese people, according to a recent study. To address this, bioethicists can:

- teach students about bias.
- develop strategies to minimize the impact of bias on care.
- reframe the medical encounter as a chance to practice egalitarian goals.

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Stem cell research is ethical balancing act

Balancing the therapeutic needs of very sick patients with the demands of rigorous scientific research is a major ethical challenge in stem cell research, according to **Mary Devereaux**, PhD, director of the biomedical ethics seminars and assistant director of the Research Ethics Program at the University of California, San Diego (UCSD).

"As we develop greater expertise in stem cell research and begin moving into early clinical trials, patients and families naturally want access to experimental therapies for degenerative diseases, such as

ALS [amyotrophic lateral sclerosis]," she says.

Patient groups have generated a lot of discussion about ways to move the research forward more quickly, including giving patients a larger role in determining what risks they are willing to take. **Duane Roth**, of The California Institute for Regenerative Medicine, argues that patients and patient advocates should, through carefully selected representatives, have "a seat at the regulatory approval table."[1]

"How you would involve patient representatives in the [Food and Drug Administration] process, or decide which patient groups would get a seat at the table, raises complicated issues," Devereaux says. "Certainly in California, patients and their families do have a key role to play in the stem cell research initiative." At UCSD, the local community is updated with an annual presentation of stem cell research by area investigators. "A recent national conference on ALS held in La Jolla included patient advocacy groups, as well as a presentation by a patient and his family," adds Devereaux.

Proceed with caution

On the other hand, researchers and clinicians involved in stem cell trials have voiced concerns about the need to proceed with enough caution, including adequately informing and protecting human subjects. "There isn't a whole lot that many of these patients can do, in terms of standard medicine, for some of these diseases. The pressure to do something experimental is very, very strong," says Devereaux. "If you are cutting corners on the science, oftentimes you lose time anyway, because others can't replicate it. The only ethical or responsible path is to do the absolute best science that you can."

A related issue is the challenge of creating effective informed consent procedures in highly experimental areas like stem cells. "One of the things we talk about continually is that stem cell biology is a new and complex field," says Devereaux. "You want people who are deciding to enroll in a clinical trial to have a really clear picture of what they are taking on."

If an intervention is offered in the earliest stage, in a Phase I trial, it's extremely unlikely that an individual patient will gain personal benefit, even if the patient is in the active wing of the trial, for example. "One of the things we always talk about as ethicists is the therapeutic misconception; that is, the false belief that the primary aim of a clinical trial is the benefit of the individual subject rather than generalized knowledge," says Devereaux. Whatever patients are told about the risks of experimentation, what they tend to hear is that this is one thing that they can do that offers some hope, she explains.

"Our challenge consists in explaining these complicated scientific protocols so that patients know enough about what could happen that they can give thoughtful consideration to the risks and benefits for them," says Devereaux.

The possibility of hope makes it difficult for most people to stop and think about what a clinical trial means in their own particular case. "One thing I tell trainees and students all the time is that they should not assume that because somebody has a degenerative disease or is dying of metastatic cancer, that they can't make them worse," says Devereaux. "If somebody has three months to live and we make them sicker, or we turn three months into two months, that is harm — a real loss for the patient."

Patients often also don't understand the time required to translate research into something that can actually help individual patients. "Regenerative medicine offers enormous possibilities, but it's not going to be realized in the next three years," says Devereaux. "The normal scientific trajectory from 'bench to bedside,' to get things to market that are safe and effective, is a pretty slow process. It's tragically too slow if you've got a neurodegenerative disease and need a treatment today."

Managing expectations

At one point in time, stem cell research had to fight against opponents simply in order to continue. "Back in the Bush era, when some people wanted to make this whole field just go away, the emphasis then was either 'yea' or 'nay,'" Devereaux says. "There was, at that time, a lot of hype — on the part of scientists and funders — and hope, on the part of patients and patient advocates."

In California, there was a citizen mandate to go forward with stem cell research, reflecting acceptance and financial commitment from the general public. "Once we decided we were going to go down this

EXECUTIVE SUMMARY

The therapeutic needs of very sick patients must be balanced with ensuring rigorous scientific standards and effective informed consent procedures with stem cell research. Some ethical concerns:

- Patients and families want access to experimental therapies for degenerative diseases.
- If an intervention is offered at the very earliest stage, it's extremely unlikely that an individual patient will gain personal benefit.
- Patients might have unrealistic expectations for what a clinical trial means in their own particular case.

road in California, then other states followed," she says. "Now we have a different administration, and polls show that a majority in the U.S. do support stem cell research, embryonic as well as non-embryonic strategies."

More public education is needed on how clinical trials are run, and more generally on the process of scientific discovery. "Only then will patients and providers have a better understanding of what we can realistically expect of stem cell research," argues Devereaux. "The field is moving very fast, but we've got a lot to do in terms of science education. We're talking about a very steep learning curve here." ■

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SOURCE

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Call to revamp ethical framework on human research

Move is toward integrated health care learning systems

The longstanding ethical framework for protecting human volunteers in medical research needs to be replaced because it is outdated and can impede efforts to improve health care quality, according to a *Hastings Center Report* special report, "Ethical Oversight of Learning Health Care Systems.[1]

Ruth R. Faden, PhD, MPH, Philip Franklin Wagley Professor of Biomedical Ethics and director of the Johns Hopkins Berman Institute of Bioethics in Baltimore, says a lot of effort is spent determining whether quality improvement (QI) initiatives should be considered as research or practice.

"It is work that is sometimes called research and sometimes called practice. But if you scratch the labels off them, they look exactly the same," says Faden. "Conscientious stakeholders across all fronts want to get the work done and don't want to be unnecessarily held back."

Moving toward truly integrated health care learning systems is "morally important," adds Faden. "And the traditional way of thinking about clinical research and clinical practice as sharply distinguished from one another is antithetical to what a learning health system calls for."

In a 2012 report, The Institute of Medicine called on health care organizations to become learning health care systems.[2] Faden describes this as the complete integration, on a daily, continuous level, of the generation of new knowledge with the delivery of high-quality care.

"If you are continuously adding new knowledge in the process of delivering care, and then using new knowledge to improve the delivery of that care, that is a complete integration of research with practice," says Faden. "But to get there in the context of the old way of thinking, which puts a sharp line between the two, is very difficult."

EXECUTIVE SUMMARY

The longstanding ethical framework for protecting human volunteers in medical research is hindering efforts to move toward truly integrated health care learning, according to a recent report. Bioethicists argue that:
• Too much effort is currently spent on determining whether quality improvement initiatives should be considered as research or practice.
• Regulatory burden should be minimized for low-risk activities, while activities that pose substantial risk should be closely scrutinized.
• Organizations should identify the kinds of activities that can go forward without elaborate prospective ethics review.

Overly protective

At one end of the spectrum are activities that have immediate benefits for patients and pose minimal risk. "Such activities should have local institutional oversight, minimizing regulatory burden so that they can move ahead expeditiously," says **Steven Joffe**, MD, MPH, associate professor of pediatrics and global health and social medicine at Harvard Medical School and hospital ethicist at Dana-Farber Cancer Institute in Boston, MA.

At the other end of the spectrum are activities that impose substantial risks on individuals, with benefits that are speculative and only occur down the line. These activities should have prospective scrutiny by a group that's accountable to the public through a regulatory body, he argues.

In addition, activities closer to the latter type should essentially always require individual informed consent, whereas those at the former end may require only disclosure within the context of other routine health system disclosures, says Joffe.

"The current system is overly protective and burdensome. I think we have to get away from asking

whether or not these activities are research or not," says Joffe. "We need to focus on the nature of various types of activities and the risks that they pose, and adapt our oversight to that nature."

Massive amounts of information are being gathered through electronic health systems and billing records, which permit relatively low-cost analyses looking for patterns of relationships and events across huge numbers of people. "There are problems of data standardization, quality, and cleanliness that need to be solved, as well as regulatory barriers, but the promise is there," says Joffe. "If we go this route, every time a person touches the health care system, he or she will leave tracks that can be used to improve that system."

Joffe argues that "absolutist" positions that value potential health and quality benefits over privacy, or vice versa, threaten the ability to achieve these improvements. "Among other things, we need patient and family engagement in oversight and governance mechanisms," he says. "At their best, bioethicists can help stakeholders weigh and balance the relevant values, and can promote healthy dialogue and debate among all the stakeholder groups."

The authors of the framework used the term "learning activity" instead of the terms "research" and "practice." "Instead of putting a lot of energy trying to figure out what goes in each bucket, which has caused so much confusion, we used the best term we could come up with at the moment,'" Faden explains. "What we are trying to do is say, 'Stop worrying about whether something is QI practice or QI research.' If you are trying to improve quality in a way that is systematic, then you are going to be generating new knowledge."

What to do now

Faden recommends that institutions begin working with various stakeholders to identify the kinds of activities that really should be able to go forward without too much in the way of elaborate prospective ethics review.

"Now is the time to start working with patients and families and advocacy groups and health care professionals, to think through the kinds of designs that people feel comfortable with, and don't feel comfortable with, and what sorts of things require a higher degree of commitment to careful solicitation of consent," she says.

The team conducted focus groups with researchers in patient safety and comparative effectiveness to learn their concerns. "We heard from a number of folks that they take pains to describe what they are doing as not research, and they don't publish what they learn, to avoid the resources that are necessary for going through an IRB [Institutional Review Board] system," says Faden. "This is really unfortunate for several reasons."

Researchers might be using suboptimal designs to identify whether their QI project is effective, in order to avoid the appearance of employing the trappings of research. Also, if something valuable is learned, it's not shared, so efforts have to be duplicated.

"Another problem is that IRB systems are often overworked and inadequately staffed," says Faden. "They are caught up having to spend their limited resources in reviewing projects that are really unproblematic. That causes them not to have sufficient resources to review carefully those activities that are very high stakes and really should be carefully scrutinized." ■

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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.

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■ Helping physicians manage conflicts

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■ What must be disclosed to any living liver donor

CME QUESTIONS

1. Which is true regarding a 2013 report on updated core competencies for clinical ethics consultations?
   A. The report mandates a specific approach for holding individuals who perform ethics consults accountable to quality standards.
   B. The report discourages routine evaluation and assessment of ethics consultations.
   C. There is a strong emphasis against any standardization of ethics consultations.
   D. The report recognizes the value in having individuals functioning as expert ethics consultants held accountable to quality standards.

2. Which is true regarding patients in the minimally conscious state, according to **Joseph J. Fins,** MD, MACP?
   A. Misdiagnosis is virtually unheard of in this patient population.
   B. Minimally conscious individuals may have a higher level of integrative cognitive function than they are able to manifest behaviorally.
   C. It is not possible for patients who are initially diagnosed as vegetative to be subsequently diagnosed as minimally conscious due to recovery of higher cortical function.
   D. Persistent vegetative states always become permanent three months after traumatic brain injury.

3. Which is true regarding medical students' bias toward obese patients, according to a recent study published in *Academic Medicine*?
   A. More students had an anti-thin bias than had a bias against obese people.
   B. None of the students had an anti-thin bias.
   C. Of the students who had an anti-thin bias, none recognized their preference for obese individuals.
   D. All students with an anti-thin bias recognized their preference for obese individuals.

4. Which is true regarding the longstanding ethical framework for protecting human volunteers in medical research, according to **Ruth R. Faden**, PhD, MPH?
   A. More effort should be spent determining whether quality improvement initiatives should be considered as research or practice.
   B. The traditional way of thinking about clinical research and clinical practice as sharply distinguished from one another is antithetical to what a learning health system calls for.
   C. Even activities that have immediate benefits for patients and pose minimal risk should essentially always require individual informed consent.
   D. In most cases, even activities that impose substantial risks on individuals should have local institutional oversight in order to minimize regulatory burden.

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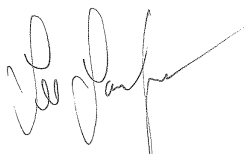

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