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AHC Media

Hospitals grapple with ethics of donation after cardiocirculatory death

In recent years, there has been a push for hospitals to receive organs from donors who are not technically brain dead. The issue of donation after cardiocirculatory death (DCD) is the focus of a recent study that appears in the journal Philosophy, Ethics and Humanities in Medicine, which points out the ethical problems of DCD.[1] The researchers argue that DCD donors might not be dead yet, and therefore, DCD might violate the generally accepted dead donor rule, which simply states that patients must be declared dead before the removal of any vital organs for transplantation.

An individual can be declared dead if he or she has sustained irreversible cessation of circulatory and respiratory function, or irreversible cessation of all functions of the entire brain, including the brain stem. "The first definition refers to circulatory death, if irreversible is understood as 'will not resume spontaneously' after a given period of time and will not be restarted on morally justified grounds," says **Melissa Kurtz**, MSN, MA, RN, bioethics consultant at The Montefiore-Einstein Center for Bioethics, Bronx, NY. "[For that reason] I do not think donation after circulatory death violates the dead donor rule."

This question of when a patient is dead hinges on two points, but both are simply one's own philosophy. First, it is relevant if one believes a patient who is dependent on life support is, in fact, alive.

EXECUTIVE SUMMARY

Ethical issues are linked with donation after cardiocirculatory death (DCD), according to a recent study in the journal Philosophy, Ethics and Humanities in Medicine. The researchers argue that DCD donors might not be dead yet and, therefore, DCD might violate the dead donor rule.

- An individual can be declared dead if he or she has sustained irreversible cessation of circulatory and respiratory function, or irreversible cessation of all functions of the entire brain, including the brain stem.
- A surrogate must make the decision to discontinue life support independent of a decision to donate organs.
- One of the primary concerns with DCD is that there must be a clear separation between the decision to withdraw life support and the decision to donate organs.

Some believe the criteria for death is brain death, which is not necessarily the case in patients who are ventilator/life support-dependent. Others have a different idea of what "life" is. **Brianna Soper**, MA, hospital ethics consultant in Boston, says, "personally, I believe life requires consciousness and the possibility, if not likelihood, that a patient will be able maintain cardiac function independent of life support. This is not true in cases of potential DCD since, by definition, the action of donation is to take place after cardiac death."

Second, under the dead donor rule, a surrogate must make the decision to discontinue life support independent of a decision to donate organs. If the surrogate does make this decision, he or she would believe the patient is no longer experiencing life as the patient would have wanted. "My analysis is based on my own ideals and philosophy, and my preferences are not held by everyone. I do not believe that the dead donor rule is violated, provided the surrogate makes the decision to discontinue life support independently of the decision to donate organs," says Soper.

Carol Bayley, PhD, vice president of Ethics and Justice Education at Dignity Health, San Francisco, says, "I think it's possible that DCD violates the dead donor rule, mostly because we don't have a really stable notion of what we mean by 'dead.'"

Trust also can be an issue. "There is a subset of the American population who already believes that such things as the withdrawing or withholding of treatment or even encouragement to create an advance directive are based more on their (low) socio-economic status than anything else," says Bayley. She is concerned that the great strides that have been made in organ donation of the usual type could be undermined by DCD, especially in this population. "Additionally, I'm not sure it's cost effective," Bayley says. "One gets fewer organs from DCD than from a traditionally dead donor, and the staff time it takes is great."

Soper's only concern is a surrogate being misinformed of the prognosis of the patient. "If there is a chance that the patient's condition could improve and he or she could come off life support and regain cardiac function, it is imperative that the surrogate be informed of this," she says.

One of the primary concerns with DCD is that there is a clear separation between the decision to withdraw life support and the decision to donate organs. Kurtz says, "the option of organ donation should be posed after the decision to withdraw life support, so that there is not an inappropriate hastening to withdraw treatment. Once the decision to withdraw treatment is made, the hospital will contact the appropriate organ procurement organization [OPO], and representatives from the organization will assess whether donation after cardiac death is possible." *(For a related story about the role of an ethics committee, see p. 51.)*

The researchers believe these points have not been fully disclosed to the public and incorporated fully into informed consent. While this step is a huge undertaking, the writers of the paper

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believe this issue requires a public debate.

"We have no evidence of a consensus, or even public awareness of DCD, much less a public conviction about it," says Bayley.[2]

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The ethics committee plays role in DCD

An ethics committee plays several key roles when it comes to organ donation after cardiocirculatory death (DCD).

"One role of a hospital ethics committee is to help develop or revise policies pertaining to clinical ethics. Therefore, one role that ethics committees can play in the issue of DCD is to be involved in developing or revising policies pertaining to organ procurement, especially when donation after cardiac death is involved," says **Melissa Kurtz**, MSN, MA, RN, bioethics consultant at The Montefiore-Einstein Center for Bioethics, Bronx, NY. Such policies ideally would promote the rights of patients, as well as maximize the likelihood of achieving good patient outcomes, Kurtz says.

The primary role of members of the ethics committee should be to examine the proposed policy rather than just accept an organ procurement organization's (OPO) suggestion that "everyone else is doing it," says **Carol Bayley**, PhD, vice president of ethics and justice education at Dignity Health, San Francisco.

The understanding of the general public (in hospitals) about such a radical change in organ donation criteria should be part of their concern. "The effect of a DCD policy on the hospital's efforts in palliative care and the pursuit of a peaceful death for their dying patients should be another concern," Bayley says. "They should also ask whether their hospital has sufficient resources to spend on DCD and how they will be sure any policy is carefully followed in each case."

The ethics committee is helpful in determining whether it is ethically justifiable to disconnect life support. **Brianna Soper**, MA, hospital ethics consultant, Boston, says, "The ethics committee must make their recommendations based solely on the patient and not on the resource of organs." It is the committee's duty to honor what the patient would have wanted and determine whether discontinuation of life support respects the patient's and surrogate's wishes.

"The ethics committee ought not to make this decision based on the benefit of the patient's organs to other patients," Soper says. "While organs are a scarce resource, it is ethically problematic to discontinue life support if it is against the patient's wishes or the patient's best interest."

The ethics committee does have a responsibility to look at other benefits and harms that might occur including financial costs when the medical team believes there is no possibility of the patient regaining consciousness, according to Soper.

DCD case study

An incident regarding DCD occurred recently and involved a hospital's ethics committee.

"A young man tried to commit suicide by hanging himself. He was brought to the hospital, and the OPO [Organ Procurement Organization] suggested DCD, in spite of the fact that the hospital had not adopted a policy. The OPO helpfully supplied one," explains Bayley.

The policy required that all medications be stopped, which in this case, because the man had sustained a terrible brain injury, included antiseizure medication. "It was stopped, and the man seized all the way to asystole for the requisite number of minutes. The distress of the caregivers was horrible, and they all wondered what in the world they had done," says Bayley.

Staff at the hospital involved in the case were so traumatized that they put a moratorium on DCD until the ethics committee could thoroughly study it and make a recommendation to the medical staff about policy, says Bayley. "The committee, who started out evenly split pro and con for DCD, studied the issues for a year and finally recommended that a policy allowing DCD not be developed for the time being. It was a horrible case, but that ethics committee subsequently really did its homework," says Bayley.

SOURCES

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Study suggests clarity in informed consent

High-risk population targeted

Researchers and review boards should pay close attention to informed consent comprehension among all research participants, but this attentiveness is especially needed for people from a high-risk population.

A study recently featured at the Public Responsibility in Medicine and Research (PRIM&R) 2011 conference found that a significant number of participants from a high-risk minority population had no knowledge about specific potential risks and/or benefits of the study in which they were enrolled.[1] The study also recommends that investigators and study coordinators use culturally appropriate strategies to improve participants' knowledge of risks and benefits.[1]

"Most of the time, if you asked participants if they understood some of the adverse things that could happen to them in a clinical trial, they would say 'yes,'" says **Jane Otado**, PhD, research participant advocate at Howard University College of Medicine, Georgetown — Howard Universities Center for Clinical & Translational Science in Washington, DC. "However, when asked an open-ended question about what they understood, the majority did not answer the question. It could be that some studies are of minimal risk, and they might not think there are any risks."

When participants were asked about the benefits of participating in the study, they generally had an answer, which mostly involved wanting to help with research, she says.

Based on her study's findings, Otado suggests some ways investigators and review boards can improve the informed consent process:

• Provide clear and simple definitions of the medical concepts.

During the consent process, educate participants on the related disease and why the study is so important, as well as what the research process will involve, Otado suggests. She has found that research participants needed simple and clear definitions (i.e., using layman language) from research staff.

"You have to give them a definition first," she explains. "So if you're conducting an Alzheimer's study, then tell them what Alzheimer's disease is, what the disease process is, and make them understand the condition before you tell them about the research."

Researchers also might need to define research and explain how a clinical trial works and why it's important, Otado says.

Defining the disease and explanation of the study should be initiated with participants at the start of the informed consent process, she says. Researchers also could make educational materials that are handed to participants, although these materials should not be the sole means of educating them about the study.

"At the follow-up visits, you can go over the informed consent form," Otado says.

• Repeat and reinforce study procedures at study visits.

Researchers should reinforce the study procedures and informed consent periodically at follow-up visits, Otado says. As a research participant advocate, Otado at times observes the informed consent interviews.

"At the end of the interview, I would ask a participant, 'Can you tell me in your own words what the study is all about?'" she says.

Other questions to ask participants are these:

— Do you know how many times you'll be here? What procedures are done to you? Why is the study important?

— Do you know that you can stop participation at any time?

"The majority of people do not tell you they don't understand it, so ask them to tell you in their own words," Otado says. "They don't want to come across looking stupid."

Study coordinators could reassure participants that it's OK to ask questions.

• Use true/false questions to assess comprehension.

In some high-risk studies, it might be helpful to assess participants' understanding of each study risk and detail through a brief true-false quiz. For example, during a recent study of cocaine use, researchers asked participants about some main parts of the informed consent document with true-and-false questions, including these:

— Drugs used in this study are approved by the FDA. True or false?

— There are no possible risks or discomforts associated with my participation in this stud. True or false?

— I will receive individual counseling once a week.

True or false?

• **Observe and improve informed consent process.**

Otado sometimes observes research coordinators as they conduct informed consent, and this strategy is another good one for improving the process.

For example, if Otado observes a research coordinator using words or acronyms such as DNA or cell line, she will note later that many lay people are unclear about what these terms mean and that they should be defined or broken down into simpler language.

"If someone says, 'We're looking for biomarkers,' what does that mean?" Otado says. "Make them understand and give examples, explaining your words."

An example might be to explain a genetic or biomarker test this way: "Everyone has a different genetic or biologic makeup, and we're interested in seeing how your specific makeup will influence a clinical outcome," Otado says.

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Researchers weigh in on H5N1 research

In a commentary on the biosecurity controversy surrounding publication of bird flu research details, a bioethicist and a vaccine expert at Johns Hopkins reaffirm that "all scientists have an affirmative ethical obligation to avoid contributing to the advancement of biowarfare and bioterrorism," but that there are not sufficient structures in place to evaluate potential societal risks.[1]

The commentary, titled "The Obligation to Prevent the Next Dual-Use Controversy" appears in the online "Policy Forum" of the journal *Science*. Adequate assessment of those risks requires "prospective review by an international body with a range of expertise, including in this case influenza virology and biosecurity," said athors **Ruth R. Faden**, PhD, director of the Johns Hopkins Berman Institute of Bioethics, and **Ruth A. Karron**, MD, director of the Center for Immunization Research and the Johns Hopkins Vaccine Initiative at the Johns Hopkins University Bloomberg School of Public Health, both in Baltimore, MD.

International prospective review of so-called dual-use research will help to mitigate future dilemmas over how to balance global security, academic freedom, and public health threats, the authors say. "There is no doubt that there are formidable obstacles to developing such a global oversight body. But that the challenge is hard is no excuse," Faden and Karron conclude.

Faden says, "When you take the perspective that both science and security experts are trying to prevent a global lethal pandemic, the problem becomes one of benefit-risk assessment and risk management."

She draws on her experience as a member of the Fink Committee convened by the National Research Council in 2001 to create a roadmap for evaluating biosecurity risks. The Fink Committee's recommendations led to the creation of the National Science Advisory Board for Biosecurity (NSABB), which touched off the current controversy over H5N1 (popularly known as "bird flu") research by calling for the redaction of details explaining how a version of the virus that is readily transmissible in ferrets was produced. The NSABB cited concerns that such details could help terrorists weaponize the flu virus.

Faden and Karron write, "The challenge is to implement effective practices to properly assess and manage these risks that allow for the vigilant stewardship of both the institution of science and public safety."

The Hopkins co-authors highlight key ethical dimensions of this challenge, including "a moral obligation to ensure that the results of that research are used to help reduce risks to global health," the prospect of which must be the ethical justification for undertaking the risk of dual-use research at all.

In 2006, the authors worked with other international experts at a meeting in Bellagio, Italy, to address the disproportionate impact global efforts to prevent a lethal influenza pandemic would have on the world's disadvantaged. The meeting, organized by the Johns Hopkins Berman Institute of Bioethics, included leaders in bioethics, public health, animal health, virology, medicine, public policy, economics, law and human rights. In their Statement of Principles, members of the group agreed that "developing as well as developed countries should have access to the best available scientific and socio-economic data and analyses to inform avian and pandemic influenza planning and response."

The editors of *Science* were pleased by the

recent backing from the U.S. government's biosecurity advisors who support publishing research studies showing how scientists made easy-to-spread forms of bird flu because the studies, now revised, don't reveal details that bioterrorists could use.

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Bioethicists contribute to consensus opinion

Bioethicists at the Johns Hopkins Berman Institute of Bioethics, Baltimore, MD, are co-authors on a consensus article[1] placing "significant responsibility" on biobanks to report individual research results (IRRs) and incidental findings (IFs) to the contributors of genetic material.

"The biobank should set the rules for the overall process of recognizing (and subsequently analyzing and returning) IFs and IRRs," the authors write in *Genetics in Medicine*. Biobanks should define and manage a system by which "findings that are analytically valid, reveal an established and substantial risk of a serious health condition, and are clinically actionable should generally be offered to consenting contributors," the authors write.

Jeffery Kahn, PhD, MPH, was co-investigator on the study and is deputy director for policy and administration at the Berman Institute. Co-author **Joan Scott**, MS, CGC, is a faculty member at the Berman Institute and executive director of the National Coalition for Health Professional Education in Genetics, Lutherville, MD. Kahn and Scott were joined by 24 colleagues on the consensus report of a two-year study funded by the National Institutes of Health (NIH).

"This discussion of the ethical duty to research patients is extremely important and a preview of the questions we will face as genomic technologies such as whole genome sequencing move from the research setting to clinical care, and patients and providers are faced with an increasing amount of genomic information," Scott says.

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Presidential commission promotes reforms

Panel takes up human subjects protections

Add another voice to the national conversation on improving protection of research participants: The Presidential Commission for the Study of Bioethical Issues, which recently released its recommendations for reforming federal oversight of human subjects' research.

The commission was charged more than a year ago by President Obama with investigating allegations of unethical research in Guatemala in the 1940s and determining whether current regulations adequately protect participants.

In its first report, the commission concluded that the Guatemala experiments, in which vulnerable populations were deliberately exposed to sexually transmitted diseases (STDs), represented "unconscionable basic violations of ethics."

In the report, "Moral Science: Protecting Participants in Human Subjects Research," the commission concludes that while modern regulations would not permit similar abuses to occur today, there is still more the federal government can do to protect current research subjects. Included were 14 recommendations for action, including steps to improve accountability, which would ensure that communities in which research occurs are protected and those who are injured by research are compensated. *(To view the recommendations, see related story, p. 56.)*

"The commission's report is thoughtful and thorough," says **Heather Pierce**, JD, MPH, senior director for science policy and regulatory counsel for the Association of American Medical Colleges (AAMC) in Washington, DC. "It took pains to assess the current state [of research protections] and incorporate that into the recommendations."

Pierce says the recommendations also recognize the resource constraints faced by institutions and regulators. "They seem to have an awareness that the protection of human subjects is of utmost importance and, therefore, we need to use our resources wisely, strategically, and effectively, as opposed to a recommendation that would represent some ideal scenario that could absolutely not be implemented,"

she says. "I think that gives it some additional potential for implementation."

At several points in the commission's report, it notes that previous similar reviews and recommendations have gone unanswered, and the group calls on regulators to enact these reforms or explain why they won't do so. "The public should know whether the federal government intends to move forward, and if so, in what way, with any or all of these recommendations," the commission wrote in its report.

The Department of Health and Human Services (HHS) released a statement thanking the commission for its work and pledging to "review its recommendation for strengthening these safeguards."

Accountability, ANPRM

Pierce notes that a recent HHS announcement might point to a response to one of the commission's concerns.

The department announced in January that it would commit $775,000 to health initiatives combating STDs in Guatemala and $1 million to evaluate whether proposed revisions to the human subjects protection regulations improve protections for research participants. While the commission's recommendations were not referenced in this announcement, one recommendation involved research into the effectiveness of human subjects' regulations as a way of improving accountability.

"It seems like it is certainly an issue that is being taken seriously, and it doesn't seem like a commission that is going to be entirely ignored," Pierce says.

The recommendations come as HHS is considering responses to its 2011 advance notice of proposed rule-making (ANPRM), a proposed revision of the Common Rule.

In its report, the commission generally praises the ANPRM proposals, particularly those that would better calibrate the level of oversight to the level of risk involved in a study and steps that would reduce unnecessary duplicated IRB reviews of multisite studies. The commission also supports a plan to create standardized consent forms with more understandable language and proposed harmonization of regulatory requirements across federal agencies.

"It will be interesting to see how the commission's recommendations are taken up while the agency is going through the comments to the ANPRM, and how that comes out in the next iteration of either proposed rules or some additional questions," Pierce says.

Compensating for injury

Two of the recommendations concern subjects who are harmed by research. The commission calls for the federal government to move "expeditiously" to study the scope of research-related injuries and to determine whether there needs to be a national compensation program. If there is found to be a need, it calls on HHS to work on a pilot study to determine the proper mechanism for doing that.

Other panels have made similar recommendations over the past several decades, says **Larry D. Scott**, MD, MA, a professor of medicine at The University of Texas Medical School at Houston who has written on the topic of research-related injury. "It's never gotten off the ground, and I don't know that it's any more likely to happen this time around," Scott says. "What has changed is the complexity of research over the past 20 years. We're getting into some pretty high-profile kinds of interventions with added risks," pointing to gene transfer trials as an example.

The commission notes these previous efforts and asks either HHS or the Office of Science and Technology Policy to issue an official reply to this point, explaining why the current system should be changed or maintained.

The commission outlines several approaches to compensation currently in use, including policies of the National Institutes of Health, the Medicare program, and the University of Washington, which has a long-standing self-insured compensation policy.

Standard of care

The commission also delved into a thorny issue in international research: Is it ethical to provide either placebo or a treatment that is not considered the best proven intervention for the control arm of a clinical trial, particularly in developing countries where the standard of care may not be as high as it is in the West?

The commission proposes a set of requirements for when these types of interventions are appropriate — when the intervention is known not to be the best for the study population (for genetic reasons or because of lack of

infrastructure, for example); when the scientific and ethical justifications have been properly reviewed; and when safeguards have been enacted, including monitoring subjects and providing rescue measures when necessary.

Pierce says the issue is a tricky one, requiring that reviewers look not just at the type of trial proposed, but the circumstances. "In some cases, a very well-designed placebo-controlled trial may in fact be the right answer," she says. "It's certainly an issue that we'll need to continue to address and both educate on a national scale and an international scale, teaching ethics boards how to evaluate not simply the type of trial that it is, but how does that relate to the situation, to assess whether it's the right approach."

RESOURCE

• To read the report "Moral Science: Protecting Participants in Human Subjects Research," visit the website of the Presidential Commission for the Study of Bioethical Issues. Web: http://bioethics.gov. ■

Recommendations for review boards

The Presidential Commission for the Study of Bioethical Issues offered 14 recommendations for improving oversight of human subjects' research:

• **Improve access.** Every federal agency or department that sponsors human subjects' research should make information available about all studies — including title, investigator, location, and funding. This information should be collected in some centralized way, through a comprehensive federal database or through links to various agency systems.

• **Investigate effectiveness.** Conduct research into whether existing human subjects' protections are, in fact, effective at protecting subjects.

• **Study compensation.** The government should move "expeditiously" to study the scope of such injuries and determine whether there should be a national system for compensating subjects. If it's determined that there should be, the Department of Health and Human Services (HHS) should work on a pilot study to determine the proper mechanism for that system.

• **Provide response.** Because previous calls for compensation systems have gone unanswered, the commission asks for an official reply, saying why the current system should be changed or retained.

• **Highlight ethics.** Make the ethical underpinnings of regulations more explicit. This recommendation addresses a common complaint that oversight focuses more process than actual protection. The regulations should explicitly state the ethical reasons for the regulations. This statement should be given by HHS or the Office of Science and Technology Policy.

• **Detail responsibilities.** Amend Common Rule to address investigator responsibilities. This change would put the Common Rule in sync with FDA regulations and international standards.

• **Educate about ethics.** Review boards and other institutional officials, professional societies, licensing bodies, and journals should work to improve the conversation about researchers' responsibilities. Institutions should provide more rigorous education about ethics and human subjects research at undergraduate, graduate, and professional levels.

• **Promote equivalence.** The Office for Human Research Protection (OHRP) should adopt or revise the 2003 Health and Human Services Equivalent Protections Working Group's recommendations to determine when a country's protections are equivalent to those of the United States and allow research to go forward without unnecessarily requiring that the letter of all U.S. regulations be followed.

• **Engage community.** OHRP should look to the Joint UN Programme on HIV/AIDS and the AVAC Good Participatory Practice Guidelines to provide standardized guidance on effective community engagement standards in research. After this guidance is developed, studies should be conducted to evaluate its effectiveness.

• **Ensure capacity.** Funding agencies should ensure that the sites being chosen for research can adequately protect subjects, whether that capacity exists already or is built up to carry out studies.

• **Select sites ethically.** OHRP and federal funding agencies should develop a plan for how to ethically select research sites, and they should take into account how the proposed study meets the needs of the local community. OHRP should develop guidance based on this plan.

• **Ensure ethical design.** In dealing with the question of whether it is ethical to allow placebo

or a treatment that is below the "best proven intervention" in a control arm, the commission says that it is permissible in limited circumstances: The intervention is not known to be best for the study populations for various reasons (genetic, infrastructure, etc.); and the scientific and ethical case has been reviewed carefully (elements of this review include limiting duration of the placebo or comparator, carefully monitoring subjects, and making sure there are rescue measures if serious symptoms develop and withdrawal criteria for people who have adverse events).

• **Promote reform.** The commission endorses certain elements of the advanced notice of proposed rulemaking (ANPRM), including calibrating level of oversight to level of risk, eliminating continuing review for some low-risk studies, reducing unnecessary or duplicative review board review in multisite studies, creating standardized consent forms with understandable language, seeking harmonization of regulations among all federal agencies, and working toward developing a federal government-wide data collection system for adverse event reporting.

• **Respond (or justify status quo).** Because previous sets of recommendations have been passed by previous boards with no real response by the federal government, the commission recommends that the Office of Science and Technology Policy or other federal entity respond to these recommendations with plans for changes or with an argument for retaining the status quo. Other agencies, including OHRP, might be a part of this response. ■

Request for comments on genome data

On Nov. 24, 2009, President Obama established The Presidential Commission for the Study of Bioethical Issues to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology.

The commission is examining issues of privacy and access as pertains to large-scale human genome sequence data, including whole exome and whole genome data. As a result of the tremendous technological advances that have dramatically reduced the cost of sequencing, the science is at a point where relatively inexpensive, rapid sequencing of whole human genomes appears not only likely, but imminent.

This prospect raises many questions for the ethics, scientific, medical, and patient communities related to how this information can and ought be collected, used, and governed. At the February 2012 meeting, the commission decided to focus specifically on those questions related to privacy and data access and the balancing of individual and societal interests. The commission will spend the next few months soliciting additional input from the ethics, scientific, and patient communities.

The commission is particularly interested in policies, practices, research, and perspectives on issues of privacy and data access as they relate to the integration of large-scale human genome sequencing into research and clinical care. To this end, the commission is inviting interested parties to provide input and advice through written comments. Among other issues, the commission is interested in receiving comments on the implications of large-scale human genome sequencing for the privacy of individuals, research subjects, patients, and their families; the views of those groups and medical professional communities about privacy, both as regards genomic information and evolving notions of privacy, as evidenced and influenced by social media; and models and mechanisms for protecting privacy, in genetic/genomic databases and biobanks, but also in large databases of sensitive information.

The commission is further interested in receiving comments on issues related to balancing individual and societal interests with regard to the sharing of and access to large-scale human genomic data; the views of patients and other stakeholders on who should have access to these data and who should control access; models and mechanisms for governing access to genomic information; the role of health information technology in providing and governing access to genomic data; and access to genetic/genomic information by law enforcement entities.

RESOURCE

• Address comments by email to info@bioethics.gov, or by mail to the following address: Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW, Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. ■

Organizations end myths about organ donation

Donor Alliance, a Denver-based federally designated non-profit organ procurement organization, and American Association of Tissue Banks (AATB), a McLean, VA-based accredited tissue bank, have announced results from an initiative designed to study the public's perception of organ, eye, and tissue donation.

The two-part survey aimed to increase knowledge and overall awareness about reasons people don't register to be organ, eye, and tissue donors in the state. The study results were released as part of National Donate Life Month, which honors the generosity of organ, eye, and tissue donors and their families and commemorates all transplant recipients in the United States.

Results showed that targeted education and awareness-building activities led to increased registration of organ, eye, and tissue donors by 4% overall. The survey also showed that many people continue to believe myths surrounding organ, eye, and tissue donation.

"This research gave us valuable data about the public's perception of organ, eye and tissue donation that we can use to refine our public outreach programs and continue to encourage higher rates of donor designation," said **Sue Dunn**, MBA, president and CEO of Donor Alliance.

Two surveys were conducted independently by Corona Insights and issued to separate households in the targeted areas over a seven-month period. Key findings included:

- Donor registration increased by 4% overall.
- Overall, 5% more residents shared their donation wishes with their families following the campaign.
- Myths about donation still persist. Forty-five percent of respondents do not know if their religion supports donation, 32% do not know if they can be a donor in spite of existing health conditions, and 21% don't know if being a donor would cost their family money.
- There are changes in reasons for not becoming donors. Prior to the community campaign, age and health were the primary reasons cited for choosing not to be a donor (42%), followed closely by respondents stating they hadn't considered the topic (36%). In the post-survey, respondents citing age and health reasons dropped (32%), and respondents claiming not to have thought about becoming donors dropped as well, but became the most cited reason (35%). ■

Human gene patents rejected by high court

The U.S. Supreme Court has recently thrown out a lower court ruling that allows human genes to be patented. This topic is of great importance to cancer researchers, patients, and drug-makers.

The court overturned patents on two genes that were linked to increased risk of breast and ovarian cancer. The American Civil Liberties Union had argued that genes couldn't be patented, and that position was shared by a district court judge but overturned on appeal.

This decision will send the case back down for a continuation of the battle between the scientists at Myriad Genetics of Salt Lake City, UT, who believe that genes should not be exploited for commercial gain, and companies which argue that a patent is a reward for years of expensive research that moves science forward.

In 2010, a federal judge ruled that genes cannot be patented. U.S. District Judge **Robert Sweet** said he invalidated the patents because DNA's existence in an isolated form does not alter the fundamental quality of DNA as it exists in neither the body nor the information it encodes. But last year, a divided panel of the federal appeals court that handles patent cases reversed the judge's ruling. The appeals court said genes can be patented because the isolated DNA has a "markedly different chemical structure" from DNA within the body.

The Supreme Court threw out that decision and sent the case back to the lower courts for rehearing. The high court said it sent the case back for

rehearing because of its decision in another case saying that the laws of nature are not patentable.

The U.S. Patent and Trademark Office have been awarding patents on human genes for almost 30 years. ■

Ex-VP given transplant — older than most recipients

Former vice president Dick Cheney has received a heart transplant at Inova Fairfax Hospital in Falls Church, VA, the same hospital where he received an implanted heart pump in July 2010. At the age of 71, he is older than most organ transplant recipients. Fortunately for Cheney, advances in healthcare have made it possible for older patients to be viable transplant candidates.

Over the last 35 years, Cheney has suffered from five heart attacks, the first occurring when he was 37 years old. Physicians have indicated that Cheney must have been in excellent health to have survived that number of attacks and still be eligible for a heart transplant.

The age of 55 has traditionally been the accepted upper limit beyond which heart transplantation should not be considered.[1] But older patients increasingly are receiving them, and there is no absolute cut-off age. The key seems to be comorbidities. If other chronic conditions are absent, it greatly increases the health of the transplant recipient.

To qualify for a heart transplant, patients must have end-stage heart failure but be otherwise healthy enough to undergo heart transplant surgery. In the surgery, a donor heart is implanted into the patient to replace a heart that has become so diseased it is no longer able to pump enough blood to keep organs working properly.

Cheney had been on a waiting list for a heart transplant for 20 months, which is longer than the average wait time of six months to a year.

RESOURCE

• Hospital Report – To not grow old is to die young: Kidney donor pool expands. http://bit.ly/HebF8g.
For further analysis and discussion of topics important to hospital professionals, check out Hospital Report, AHC Media's new free blog at www.hospitalreport.blogs.ahcmedia.com. *Medical Ethics Advisor*'s managing editor Felicia Willis contributes.

REFERENCE

1. Costanzo M, Augustine S, Bourge R, et al. Selection and treatment of candidates for heart transplantation. *Circulation* 1995;92:3593-3612. ■

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

- ■ How ethical is complementary medicine?
- ■ Are anti-aging drugs ethical?
- ■ Ethical issues of palliative sedation
- ■ Care of illegal immigrants

CME QUESTIONS

1. What is a role of an ethics committee regarding donation after cardiocirculatory death (DCD)?
   A. Develop or revise policies pertaining to organ procurement.
   B. Look at benefits and harms of DCD that might occur, including financial costs.
   C. Examine the proposed policy rather than just accept an organ procurement organizations' (OPO) suggestion that "everyone else is doing it."
   D. All of the above

2. True or False: The dead donor rule states that patients must be declared dead before the removal of any vital organs for transplantation.
   A. True
   B. False

3. Based on the findings of Jane Otado, PhD, research participant advocate at Howard University College of Medicine, Georgetown-Howard Universities Center for Clinical & Translational Science, a way that investigators and review boards can improve the informed consent process is to:
   A. Repeat and reinforce study procedures at study visits.
   B. Provide clear and simple definitions of the medical concepts.
   C. Both A&B
   D. None of the above

4. The Presidential Commission for the Study of Bioethical Issues offered 14 recommendations for improving oversight of human subjects research. These recommendations include:
   A. Improve access, investigate effectiveness, study compensation, and provide response.
   B. Highlight ethics, detail responsibilities, educate about ethics, promote equivalence, and engage community.
   C. Ensure capacity, select sites ethically, ensure ethical design, promote reform, and respond or justify status quo.
   D. All of the above