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Election makes prenatal tests a massive campaign issue

Common tests spark controversy in presidential race

Republican presidential candidate Rick Santorum has attacked President Obama's healthcare law initiative, which intends to give free screenings for birth defects to all pregnant women by requiring insurers to cover the costs of the test. *(For a related story about the future of prenatal blood tests, see story, p. 39.)*

Santorum's young daughter was born with Trisomy 18, a genetic disorder in which a person has a third copy of material from chromosome 18, instead of the usual two copies. Symptoms of Trisomy 18 include clenched hands, feet with a rounded bottom, low birth weight, and mental deficiency. Santorum has said in interviews that he believes the law is a gateway to abortion, because it is a way to encourage more women to have abortions that will "cull the ranks of the disabled in our society."

Bernard W. Freedman, JD, MPH, clinical bioethicist and health law attorney at Clinical Bioethics Consults, Los Angeles, says, "Santorum's comments are ethical because he is running for office, and he has the right, and the electorate has the right to know his perspective on the subject of abortion. It is preferable that he does so than to have a hidden agenda."

While Santorum has connected common prenatal testing to abortion, **Bruce Jennings**, MA, director of bioethics, Center for Humans and Nature, Dobbs Ferry, NY, says, "The term 'gateway' is a derisive term in this context that does not further clarify thought or ethical action." However, prenatal testing does provide information guiding decisions concerning abortion, he explains.

EXECUTIVE SUMMARY

Republican presidential candidate Rick Santorum has a young daughter with a serious genetic disorder, and he believes the rules requiring insurers to cover prenatal tests are designed to encourage more women to have abortions. According to Santorum, those prenatal tests will "cull the ranks of the disabled in our society."

- President Obama's re-election campaign spokesperson called Santorum's remarks "misinformed and dangerous."
- Federal health officials and the nation's obstetricians recommend that all pregnant women be offered blood tests and an ultrasound exam that assess the risk of having a baby with various birth defects or genetic disorders.
- Studies show that in the vast majority of cases in which amniocentesis reveals Down syndrome, women decide on abortion.

Sometimes it is a factor leading to a decision to abort; sometimes it is a factor leading to a decision to carry the pregnancy to term. "The vast majority of abortions occurs in the first trimester and is largely influenced by considerations in the woman's life other than prenatal test results," Jennings says.

According to research[1] in the *Journal of the American Medical Association* (JAMA), the use of next-generation sequencing will enable the detection of a larger number of harmful genetic variants, thereby expanding the number of pediatric disorders evaluated without substantially increasing the costs of newborn screening.

Jennings says there are ethical implications pertinent to three dimensions of offering free prenatal screenings:

- making tests available: access and equity questions;
- providing information to the pregnant woman, and others, about the fetus before birth: the right to know, the obligation to know, the burden of knowledge;
- the decisions the pregnant woman makes concerning medical care as a result of this information: whether or not to terminate the pregnancy.

Personal medical information is just that: personal and intended for the sole use of the patient. Freedman says that you must ask what the reasoning is behind the screening.

"The intent of a provider of the screening should not make screening unethical unless there is a misuse of the results of the screening, which would include surreptitious efforts to influence or manipulate behavior or the free exercise of choice, such as to counsel for abortion. To do so is not ethical," he says. "Similarly, attempts to prevent screening for birth defects in order to withhold the free exercise of choice to prevent abortion, is not ethical."

Genetic testing to genetic intervention

Amniocenteses have been used for many years, but it might not have been equally available to marginalized populations. This figures in to the issue of ethnic, racial and socioeconomic disparities in care. Some might choose abortion, and others might benefit in preparing for a child with genetic predisposition to disease.

"From a medical ethics point of view, distributive justice protects autonomous decision-making and guards against governmental paternalism," says Freedman.

Not knowing something but fearing it can lead to abortion; in such cases tests can sometimes prevent abortions. Jennings says, "there are many times in which a woman or a couple may say they would terminate a pregnancy in the face of a positive test for some disability beforehand and in the abstract, but actually follow a different course in the context of the pregnancy and in the context of their own beliefs and feelings and the information they receive and the support that may be available to them."

As technology extends from genetic testing to genetic interventions and clinical uses, we will pass through many enhancements of therapy that should be the cause for ethical celebration, as in more effective treatments for cancer, for example, says Jennings. "But the fantasy that talks of perfect children is the same fantasy of control that talks of positive biological enhancement and a radical extension of the lifespan, even a technologically mediated form of deliberate biological evolution of human beings," says Jennings.

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SOURCES

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Is analysis of fetal DNA ethical?

A blood test that was created at Stanford (CA) University is said to be able to detect genetic defects, such as Down syndrome, very early in a woman's pregnancy and is a great deal less invasive, unlike amniocentesis. There are legal and ethical implications associated with this emerging technology.

The findings about the tests were reported[1] in the *Journal of the American Congress of Obstetrics and Gynecology*. The simple blood test carries a relatively low price tag at only $1,200 per kit, and it analyzes fetal DNA. The controversy begins with parents knowing soon after conception, everything about their child including any genetic defects, as well as gender and hair color.

"Prenatal testing has been described in that way as a tool for the production of perfect 'designer babies.' As such, biotechnology does little to advance human flourishing, but much to diminish our humanity and to commodify our children," says **Bruce Jennings**, MA, director of bioethics at Center for Humans and Nature, Dobbs Ferry, NY.

The tests that are on the market only seek major abnormalities on three chromosomes: 13, 18, and 21. They can also tell whether a fetus is a boy or girl.

The case study that was reported in the *Journal of the American Congress of Obstetrics and Gynecology* accurately detected all 89 cases of Down syndrome in 532 maternal blood samples. It also detected 35 of 36 cases of Edwards syndrome and 11 of 14 cases of Patau syndrome. The tests count the millions of DNA molecules from both the mother and baby and can detect excessive genetic material that signals a birth defect.

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Kidney transplant disparity reduced

According to a new study[1], kidney failure patients who take part in an education program are more likely to get evaluated for a kidney transplant. The study appears in the *Clinical Journal of the American Society Nephrology* (CJASN). The findings indicate that requiring a formal patient education class might help reduce inequities in kidney failure patients' access to kidney transplantation.

Kidney transplantation is the preferred treatment for kidney failure. Among kidney failure patients, blacks are less likely to receive kidney transplants than whites for reasons that are unclear. Few published studies have looked at interventions that might reduce such racial disparities in access to kidney transplantation.

In an attempt to educate patients about the transplant process, the kidney program at Emory Transplant Center, Emory Healthcare, Atlanta, implemented a required educational session in 2007 for each patient who was referred for a kidney transplant evaluation. The session consisted of a half-day class involving lectures and discussions from a transplant coordinator, financial coordinator, and social worker.

Rachel Patzer, PhD, assistant professor, Emory University, Atlanta, and her colleagues looked to see if this required patient education program helped reduce transplant-related disparities. The researchers retrospectively examined information from 1,126 kidney failure patients who were referred for kidney transplant evaluation between 2005 and 2008. Seventy-five percent of patients were referred before the program was implemented, while 25% were referred after. Among the major findings:

• After the education program was implemented, 80.4% of patients completed a kidney transplant evaluation within one year. Before the program, only 44.7% completed the evaluation during that time.

• The intervention particularly improved the likelihood that black patients and those patients living in poor neighborhoods would complete an evaluation.

The findings indicate that kidney failure patients who take part in an education program are more likely to get evaluated for a kidney transplant. Also, requiring a formal patient education class might help reduce disparities among patients.

"This study provides some evidence to test an intervention of a patient education program for potential transplant candidates in a randomized controlled study to examine whether this improves access to kidney transplantation for poor or minority patients," said

Patzer. "These results may also give other centers an idea of how to design and evaluate their own centers' educational programs by subgroups of race and socioeconomic status."

Patzer noted that current clinical guidelines do not provide recommendations on the most effective content and format for such educational programs.

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Abortion safer than giving birth

A study published in the journal *Obstetrics & Gynecology* suggests that getting a legal abortion is much safer than actually giving birth. Researchers found that women were about 14 times more likely to die during or after giving birth to a live baby than to die from complications of an abortion.

These findings seem to contradict some state laws that suggest abortions are high-risk procedures. In the report, the researchers write that the findings aren't surprising given that women are pregnant for a lot longer when they decide to have a baby and therefore have more time to develop complications.

The researchers combined government data on live births and pregnancy, and abortion-related deaths, with estimates on legal abortions performed in the United States from the Guttmacher Institute, with offices in New York and Washington, DC, and conducts sexual and reproductive health research and education.

An induced abortion, like any other medical procedure, requires obtaining informed consent from the woman, said **Bryna Harwood**, MD, an OB-GYN from the University of Illinois in Chicago, who didn't participate in the new research. That informed consent means women understand and acknowledge the risks of their different options.

What makes the issue complicated, Harwood added, is when the law interferes and requires doctors to state information that isn't always balanced or medically sound, usually exaggerating the risk of abortion.

Between 1998 and 2005, one woman died during childbirth for every 11,000 or so babies born, says the research from **Elizabeth Raymond**, MD, senior medical associate at Gynuity Health Projects, a research and technical assistance organization in New York City, and **David Grimes**, MD, scientist, of the University of North Carolina School of Medicine, Chapel Hill. That number compared to one woman of every 167,000 who died from a legal abortion.

The researchers also cited a study from the Centers for Disease Control and Prevention which found that, from 1998 to 2001, the most common complications associated with pregnancy, including high blood pressure, urinary tract infections, and mental health conditions, happened more often in women who had a live birth than those who had an abortion.

Harwood said previous studies have also shown the safety of legal abortions. Most abortions typically have been done surgically, she told Reuters Health[1]. But since the abortion drug mifepristone was approved for use in the United States in 2000, the number of medically-induced abortions has been on the rise. Both methods are now considered equally safe, she said, with the main risk, though very small, coming from medication- and procedure-related infections.

Depending on the state, however, doctors legally must go over the risks of abortion in language that might be misleading, with skewed lists of possible complications, researchers said. Others require a 24-hour waiting period between the counseling and the abortion.

Harwood said that laws regarding what's said between the doctor and a woman seeking an abortion often hamper doctors' attempts to inform patients in a balanced way.

"It is certainly an impediment to have the state dictate my informed consent process beyond the usual," Harwood told Reuters Health[1]. "Abortion care and pregnancy care should not really be any different than consenting people for any other procedure."

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Complex end-of-life care aims to provide comfort

Providing for fundamental human needs to people who are close to death is complex and sophisticated, but ultimately it involves the integration of physical, psychological, social, and spiritual elements, according to a study[1] published in *PLoS Medicine* by international researchers.

End-of-life care is a major public health issue, yet despite the inevitability of death, issues related to

death and dying are often taboo. This study involved identifying the variety of caregiving activities (other than provision of medication) performed by health workers in the last days and hours of life for patients with cancer in palliative care settings in nine countries: Germany, Italy, the Netherlands, Slovenia, Sweden, Switzerland, the United Kingdom, Argentina, and New Zealand.

The researchers found that the greatest number of activities involved caregiving for an individual carried out through contact with his or her body, such as attending to diverse bodily needs while maintaining comfort and dignity. Health workers also reported that important elements of caregiving close to death involved close communication with the individuals and their families, and also creating an attractive, safe, and pleasing environment. Professionals also reported that just being present was important, especially when the patient was close to death.

The researchers identified several areas needing further investigation, such as the ways in which a dying person's sensory and general environment can be improved. Developing a greater level of detail, such as improved terminology for end-of-life care, would enhance appreciation of the nuances and complexity in providing care during the last days of life, which should be also beneficial for clinical practice, teaching, and research, they say.

"In these data, an underlying feature of the pattern of palliative care practice appears to be an effort to provide personalized and compassionate end-of-life care by maintaining and supporting links with the individual's everyday life," the authors say. "This adaptation is accomplished by using knowledge about and respect for the person as an individual with a life history lived in a particular context, that is the person is not viewed only as a dying patient."

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End-of-life care with doc often occurs too late?

Incurable cancer patients deprived of opportunities

The vast majority of patients with incurable lung or colorectal cancer talk with a physician about their options for care at the end of life, but often not until late in the course of their illness, according to a new study[1] by Dana-Farber Cancer Institute, Boston, published in a recent issue of the *Annals of Internal Medicine*.

The researchers found that such belated conversations tend to occur under particularly stressful conditions, when patients have been admitted to a hospital for acute care. And the doctor who shares in the end-of-life (EOL) care talk is often a hospital physician, rather than an oncologist who has treated the patient for much of his or her illness.

Together, these circumstances might deprive patients of the opportunity for extended reflection and deliberation that would have been possible months earlier, when the conversation also could have occurred under less trying and hectic conditions, the authors suggest.

"Previous studies have shown that patients who discuss their end-of-life care preferences with a physician are more likely to choose palliative, comfort-focused care over aggressive measures, and receive hospice or other care consistent with their wishes," says the study's lead author, **Jennifer Mack**, MD, MPH, co-director, Pediatric Hematology/Oncology Fellowship Program, Dana-Farber/Children's Hospital Cancer Center. "But studies haven't looked at the timing of these discussions, or where and with whom they occur."

The study, which involved 2,155 patients with stage IV (highly advanced) lung or colorectal cancer, found that 73% percent of the patients had an EOL care talk with a physician, according to medical records or an interview with the patient or a companion. Among the nearly 1,000 patients who passed away and whose records document an EOL care discussion with a physician, the median time of those discussions was just 33 days before death.

Other findings pertain to the location of those discussions and the type of physician involved. Of the more than 1,000 EOL care discussions in medical records, 55% occurred in the hospital. Oncologists documented EOL care talks with only 27% of their terminally ill patients in the study.

Data for the study was provided by the Cancer Outcomes Research and Surveillance Consortium (CanCORS), a multi-region, population- and health system-based study of more than 10,000 patients with lung or colorectal cancer. Researchers interviewed patients at two time points and analyzed their medical records 15 months after diagnosis.

"It's encouraging to see such a high percentage of patients had end-of-life care conversations with a physician," Mack says. "There's a concern, though, that so many of these talks are taking place late in the trajectory of the disease."

Previous studies had estimated that fewer than 40%

of patients with advanced cancer had EOL care discussions. Mack theorizes that this lower figure might reflect that earlier studies didn't record EOL talks that took place shortly before patients' death.

Other research has suggested that physicians might delay EOL care discussions because of a natural reluctance to broach the subject or because it conflicts with physicians' problem-solving, hope-giving image. While such motivations are understandable, Mack says, they might work to patients' detriment if they postpone the conversations too long.

Mack and her colleagues are planning future studies to examine the quality and content of EOL care conversations, and then they plan to explore whether having such talks earlier in the course of illness can benefit patients.

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Although important, patients snub EOL plan

Survey: 76% neglect care planning

California HealthCare Foundation, Oakland, CA, commissioned a survey that would determine what percentage of patients actually has end-of-life (EOL) wishes in place. The survey unveiled that even though there was great interest in documenting their final wishes, patients are delaying these difficult talks.

According to the survey, more than 80% of patients believe it is important to have their EOL wishes in writing, yet less than a quarter of them have accomplished that planning. Furthermore, only about 40% said they had talked with a loved one about what medical treatments they would want at the end of life. The top reason for avoiding the talk, respondents said, was that they had "too many other things to worry about right now." About one-fourth of respondents said they did not want to talk about death or dying. Only 3% said they had not thought about the subject.

These statistics are not at all shocking, considering only 8% of the patients said they had ever been asked about EOL treatment wishes by a physician, the survey said.

Patients who were aged 65 and older were the likeliest to discuss EOL wishes with a loved one, with 71% having done so, the survey of California responders said. Surprisingly, less than 40% of those surveyed had heard of the term "advance directive," yet nearly three-quarters knew of hospice care. This difference comes as no surprise, considering the use of hospice has risen in recent years, according to The National Hospice and Palliative Care Organization's (NHPCO) annual report, *Facts and figures: Hospice care in America. (For more information see "New hospice facts and figures,"* Medical Ethics Advisor*, March 2012, p. 31.)*

The data gathered are expected to be reported publicly by the Centers for Medicare & Medicaid Services (CMS). ■

FDA details compliance for informed consent

The FDA issued a guidance detailing how to comply with the new regulation that informed consent documents include a specific statement that clinical trial information will be or has been submitted for inclusion in ClinicalTrials.gov's trial registry. The statement must be included in informed consent documents for "applicable" trials started on or after March 7, 2012.

"Applicable" trials "generally include controlled interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the United States, involves a drug, biologic, or device that is manufactured in the United States (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE). Trial sponsors and investigators have the responsibility of determining whether or not a trial is an 'applicable clinical trial,'" guidance said.

The agency noted that the rule "does not prevent investigators from voluntarily reporting data from clinical trials that do not meet the definition of an applicable clinical trial to ClinicalTrials.gov and sharing that information with participants."

The guidance answers 27 questions on the new requirement and "is intended to help sponsors, investigators and institutional review boards better understand" the new requirement in 21 C.F.R. §50.25(c).

Although "applicable" trials conducted outside the United States must comply with the notification regulation, the agency noted that "the mere fact that we accept data from a foreign clinical trial in connection with a marketing application does not make it an applicable clinical trial." In addition, the rule "does not preclude the inclusion of mandatory or recom-

mended language from non-U.S. governments, and it does not preclude reference to other clinical trial registries or regulatory bodies." ■

Study: How informed is too informed?

In a survey of more than 380 patients, nearly 80% said that they believe a surgeon's experience is essential information that patients need to make an informed decision about elective surgery.

The results of a survey that was presented at the 2011 Clinical Congress of the American College of Surgeons suggests that surgeons do have an ethical obligation to disclose information about their experience during informed consent discussions. The study authors have further supposed that disclosure one day might be legally mandated in some jurisdictions.

Lead author of the study, **Susan J. Lee Char**, MD, JD, a lawyer and general surgery resident at the University of California San Francisco, said that if patients think they need to know about a surgeon's volumes and outcomes, then surgeons need to provide them that information. "That information should include their own volumes and outcomes if accurate data are available, and whether it would be their first time performing the procedure," she said.

The study highlights the enduring debate in surgery about whether surgeons should be required to disclose their volumes and outcomes when obtaining informed consent.

In half of U.S. states, courts use a "reasonable physician standard" as the basis for their decisions on what type of disclosure is necessary, meaning that information should be included if a reasonable physician believes it is relevant for a patient deciding whether to have surgery. The other half of U.S. states uses a reasonable patient standard to determine what is relevant.

The investigators surveyed 383 patients and 85 surgeons from the University of California-San Francisco and affiliated hospitals. The patients, who had already undergone surgery at the university, were asked to answer two questions: What types of information about volumes and outcomes are essential to patients deciding whether to have surgery? How do patients and surgeons differ on what information is important during the informed consent process?

Results proved that the most important piece of information was if the surgeon would be performing the surgery for the first time. Eighty percent of patients considered this information essential to decision making.

The results also showed that surgeons thought that their volumes/outcomes and their previous number of cases were not as relevant to the informed consent process as discussion of risks and benefits. ■

Sex changing for kids, teens

A report[1] that appears in the medical journal *Pediatrics* reveals that sex-changing treatments are becoming more prevalent among teens and children who believe they were born the wrong sex. The report goes on to say that these youngsters are getting support from parents and doctors alike.

Ethically, it is an issue, considering experts in the field urge caution in treating children with puberty-blocking drugs and hormones. The report says that some of the kids are labeled with gender identity disorder, which is a psychiatric diagnosis, though research suggests they might have brain differences more similar to the opposite sex. According to the researchers, some estimates indicate that 1 in 10,000 children have the condition.

Guidelines from the Endocrine Society in Chevy Chase, MD, endorse transgender hormone treatment, but say it should not be given before puberty begins. At that point, the guidelines recommend puberty-blocking drugs until age 16, then lifelong sex-changing hormones with monitoring for potential health risks. Mental health professionals should be involved in the process, the guidelines say. The society's mission is to advance excellence in endocrinology and promote its role in scientific discovery, medical practice, and human health. The group's members are doctors who treat hormonal conditions.

Another study[2] by the Harvard School of Public Health, Boston, and also appearing in the journal *Pediatrics*, exposed that 39% of women facing gender uncertainty experienced some type of abuse when they were younger, as did 30% of men. Among children and teens evaluated for treatment, 44% have been given a psychiatric diagnosis (most often depression), and 21% reported self-mutilation.

RESOURCE

• Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline - http://bit.ly/wgFtzl.

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Empathy difficult for medical students

One year ago, a landmark study quantified a relationship between physicians' empathy and their patients' positive clinical outcomes and suggested that a physician's empathy is an important factor associated with clinical competence. The study[1] was led by **Mohammadreza Hojat**, PhD, research professor, Department of Psychiatry and Human Behavior at Thomas Jefferson University, Philadelphia, PA, and published in the journal *Academic Medicine*.

As a follow-up to that landmark study, Hojat asked if it were possible to improve or even maintain physicians' empathy as a way to further enhance patient care.

Hojat's team found that empathy can indeed be improved. In an article called, "Impact of a workshop about aging on the empathy scores of pharmacy and medical students,"[2] which was published in the *American Journal of Pharmaceutical Education*, Hojat and his team used the Jefferson Scale of Empathy with pharmacy and medical students at Midwestern University, Glendale, AZ, before and after a 40-minute workshop. During the workshop, students observed and discussed a theatrical performance about the challenges of aging. The results showed that the workshop increased empathy significantly from pre-test to post-test in both groups of students. However, empathy scores were not sustained.

"Our results from this study are encouraging," says Hojat, also the director of the Jefferson Longitudinal Study of Medical Education in the Center for Research in Medical Education and Healthcare at Jefferson Medical College "Given our previous finding that empathy tends to decline during the education of health professionals, we are excited to learn that with targeted educational activities, empathy scores can improve, and that can potentially lead to positive clinical outcomes."[3]

Participants in the empathy workshop study included 187 first-year students in the Chicago College of Pharmacy and 183 first-year students in the Chicago College of Osteopathic Medicine at Midwestern University. Before starting the workshop, the Jefferson Scale of Empathy (JSE) was administered. This instrument is validated for measuring empathy in the context of patient care. It has been translated into 42 languages, and it has been used in more than 60 countries. It includes 20 items answered on a 7-point Likert scale developed based on a definition of empathy as a predominantly cognitive attribute that involves an understanding of the patient's experiences, concerns, and perspectives, combined with a capacity to communicate this understanding and an intention to help.

After the students completed the JSE, a 10-minute performance began. One actor portrayed an elderly person who was being admitted to a long-term assisted-care living facility. The other actor portrayed the assistant manager of the facility. The actors (volunteer students) were coached to follow the script written by Hojat and given to them prior to the workshop. The actor who played the role of the elderly person wore eye goggles covered with petroleum jelly to simulate visual impairment, earplugs to simulate hearing problems, and a walker to simulate movement problems. The actor assumed a demanding personality, exhibiting impatient behavior and using a grumpy tone of voice. The actor asked questions about what to do in case of emergency, how food service was provided, what were schedules for taking their medicine, and other issues. The actor who played the assistant manager showed more concern about rules and regulations related to running the facility than about attempting to understand the elderly person's concerns.

After the performance was over and students discussed their observations, the JSE was administered to students (post-test one) and then again seven days later to pharmacy students and 26 days later to medical students (post-test two).

Empathy scores increased significantly among pharmacy and medical students between pretest and post-test one, but returned to the pretest level in post-test two.

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Kidney transplant chain is the world's longest

At Loyola University Medical Center in Maywood, IL, a patient has become the final link in the world's longest living-donor kidney transplant chain.

The chain involved 30 donors, 30 recipients, and

17 hospitals nationwide. The record-breaking chain is described in a recent front-page article in *The New York Times*[1], "Lives forever linked through kidney transplant chain 124."

Living-donor chains have the potential to dramatically reduce transplant waiting times for thousands of patients. Loyola has started 13 kidney transplant chains. That's second only to Cornell University, Ithaca, NY, which has started 17 chains, according to the National Kidney Registry, which coordinates kidney chains. In 2011, Loyola started more chains than any other center.

Patients typically must wait as long as 5-10 years to receive a kidney from a deceased donor. Having a living donor can eliminate the wait. But in one-third of such cases, a transplant can't be done because the immune systems of the patient and a willing donor don't match.

A kidney chain provides an innovative solution. Each chain begins when a good samaritan steps forward to donate a kidney, expecting nothing in return. For example, say the good samaritan donates a kidney to a patient we'll call John. John's wife, Mary, would have donated a kidney to her husband, but her kidney doesn't match. So instead of donating to John, Mary "pays it forward" by donating to a second patient, Bill. Bill's sister is willing to donate, but she doesn't match Bill. So she instead gives her kidney to a third patient, whom she does match.

The chain can go on indefinitely, moving from hospital to hospital across the country. It stops only when a recipient does not have a friend or family member who can keep the chain going. The previous record for the longest chain, set in 2010 by the National Kidney Registry, was 23 transplants.

The recent record-breaking chain began when a good samaritan donated a kidney at Riverside (CA) Community Hospital. His kidney was flown cross-country to a recipient at St. Barnabas Medical Center in Livingston, NJ. From there, the chain moved back and forth across the country, stopping at Loyola on the 12th link, and finishing at Loyola on the 30th link.

The last donor in the chain was a 59-year-old California woman. Her kidney was removed at UCLA and flown in the middle of the night to Loyola. The National Kidney Registry ended the chain at Loyola, rather than at another center, because Loyola had started so many previous chains with good samaritan donors. This effort made Loyola eligible based on the registry's chain-ending policy.

Thirteen chains have started at Loyola. So far, 11 chains have ended at Loyola, benefiting 11 patients who otherwise would have languished on the waiting list. Six other Loyola patients also have been involved in transplant chains, which brings the total to 17.

Of the 13 good samaritans who jump-started kidney transplant chains at Loyola, five are Loyola employees who donated kidneys to strangers. Two other Loyola employees have given kidneys to acquaintances. Collectively, they are known as the Seven Sisters of Loyola. Loyola is believed to be the only organization in the world in which seven employees have donated kidneys to non-relatives.

The National Kidney Registry has coordinated 77 transplant chains that have provided kidneys to 393 patients, but kidney chains have the potential to provide kidneys to as many as 20,000 patients immediately, and 3,000 patients per year thereafter.

REFERENCE

1. Sack K. 60 Lives, 30 Kidneys, All linked. *The New York Times*, Feb. 18, 2012: http://nyti.ms/xypHNU. ■

Harnessed stem cells bring hope for infertile

According to a report, the years-long belief that women are born with all their eggs is false.[1] Harvard scientists believe they've discovered the ovaries of women harbor rare stem cells that are able to create new eggs. Being able to harness those stem cells is good news for women who are infertile but wish to have children.

The research, led by **Jonathan Tilly**, PhD, chief, MGH Vincent Department of Obstetrics and Gynecology, Massachusetts General Hospital, Boston, MA, extracted human stem cells that could become immature eggs because all carry a unique protein called DDX4.

These spontaneously generated into immature eggs, called oocytes, in the laboratory. Using live ovarian tissue grafted into mice, these cells were made to mature into egg cells.

While the findings have yet to be applied to humans, it is believed that the study could represent a major breakthrough for fertility treatments. The results could be used to develop new therapies that might benefit older women or infertile women.

For technical, ethical, and legal reasons, the

researchers weren't able to test whether the human DDX-expressing cells could generate viable embryos. Nonetheless, they state, "we have established a consistent and close parallelism between human ovary-derived DDX4-positive cells and mouse OSCs in terms of strategy of purification, yield from adult ovary tissue, morphology, primitive germline gene expression profile, in vitro growth properties, mitotic activity, meiotic activity, and the ability to form oocytes in defined cultures in vitro and in injected ovary tissue in vivo.

"We feel it is reasonable to conclude that the rare cells with cell-surface expression of DDX4 that are present in the ovaries of reproductive-age women represent adult human OSCs," the authors conclude. "In addition to opening a new research field in human reproductive biology that was inconceivable less than 10 years ago, clear evidence for the existence of these cells in women may offer new opportunities to expand on and enhance current fertility-preservation strategies."

REFERENCE

1. Tilly J, White Y, Woods D, et al. Oocyte formation by mitotically active germ cells purified from ovaries of reproductive-age women. *Nature Medicine* 2012;18:413-421. ■

School vending machine offers morning after pill

Students at Shippensburg (PA) University can receive the Plan B One Step emergency contraceptive right out of a vending machine on campus. The vending machine also dispenses condoms, decongestants, and pregnancy tests.

After the vending machine made local news reports, federal authorities began investigating Shippensburg University's use of a vending machine to dispense morning-after pills to students.

The FDA's probe is to determine whether the school vending machine is in line with a federal requirement that any female under age 17 have a prescription for the drug, which is used after unprotected sex. Normally, Plan B emergency contraception is kept behind the counter so a pharmacist can check ID.

The decision to use a vending machine was made after school officials determined no one enrolled at Shippensburg is younger than 17, **Roger Serr**, PhD, vice president for student affairs, said in a statement. Serr also said the vending machine's presence on the campus is not a green light for sexual activity on campus.

An FDA spokeswoman said in a statement, "We are working to gather the facts now, including contacting Pennsylvania state authorities and the university." ■

Pope says IVF is unethical

Pope Benedict XVI's call for more research into ethical treatments for infertility as an alternative to in vitro fertilization (IVF) is being applauded by a leading Catholic bioethicist.

"The pope is quite right when he says that IVF is a profit-making business; they make a lot of money, and their success rates are not great," **Edward Furton**, PhD, editor with the National Catholic Bioethics Center, Philadelphia, PA, told the Catholic News Agency. "The profit motive here is not good," he said. "There are lesser known, more ethical, more effective methods which are being ignored because these labs are making money telling couples that IVF is the best or only option."

Pope Benedict made his remarks at a workshop hosted by the Pontifical Academy for Life to discuss ethically treating infertility. He said he is concerned that the field of human procreation seems to be dominated "by scientism and the logic of profit," which often "restricts many other areas of research."

The pope said that "research into diagnosis and therapy is the most scientifically correct approach to the question of infertility, as well as being the most respectful of the human condition of the people involved."

He also underscored the Catholic position that IVF is an unethical means of treating infertility and that "that community of love and life which is marriage, represents the only worthy 'place' for a new human being to be called into existence."

The Catholic Church also objects to the destruction of human embryos during IVF treatment. The pope called for treatments that are the "expression of the concrete possibility of fruitful dialogue between ethics and biomedical research." ■

Quality measures endorsed for EOL, palliative care

The National Quality Forum (NQF) is endorsing 14 quality measures on palliative and end-of-life (EOL) care focused on addressing care management concerns.

"As the number of palliative and end-of-life care programs continue to grow across the country, it's critical that providers have the right measurement tools to help

ensure patients receive safe, high-quality, and compassionate care," said **June Lunney**, PhD, RN, in a statement announcing the measures. Lunney serves as the director of research at the Hospice and Palliative Nurses Association and as co-chair of the Palliative Care and End-of-Life Care Endorsement Maintenance Steering Committee at NQF.

The endorsed measures include 12 new measures and two previously endorsed measures. The measures cover pain management, psychosocial needs, care transitions, and experiences of care.

"As the number of older adults in this country continues to grow, palliative and end-of-life care services are needed more than ever," said **Janet Corrigan**, PhD, president and CEO of NQF, in a statement. "This set of measures will help promote the type of high-quality care older people and acutely ill patients deserve." ■

Integrative medicine effective in treating illness

A survey of 29 integrative medicine centers around the United States found that 75% reported success using integrative practices to treat chronic pain and more than half reported positive results for gastrointestinal conditions, depression and anxiety, cancer, and chronic stress.

The results of the survey, *Integrative medicine in America: How integrative medicine is being practiced in clinical centers across the United States*, are being released by The Bravewell Collaborative in Minneapolis, which develops and manages strategic initiatives that support integrative approaches to healthcare.

"What we have seen in our clinics over the past 14 years is that more and more people are turning to integrative therapies to help them with health problems," says **William Stewart**, MD, the co-founder and medical director of California Pacific Medical Center's Institute for Health and Healing (IHH), San Francisco. "This survey shows that for many patients, particularly those with chronic health issues, the multidimensional team approach of integrative medicine works."

Donald Abrams, MD, co-author of the report and professor of clinical medicine at the University of California San Francisco, says, "With chronic health issues costing the U.S. economy more than $1 trillion a year, it's essential to find the most effective ways to treat and prevent the most prevalent conditions,"

Twenty-nine integrative medicine centers were surveyed by The Bravewell Collaborative. All participating centers were affiliated with hospitals, health systems, and/or medical and nursing schools. Patient services included adult care, geriatric care, adolescent care, OB-GYN care, pediatric care and end-of-life care. Findings from the report, which evaluated trends in prevention and wellness, patient outcomes, and emerging norms of care and reimbursement, suggest that the practice of integrative medicine offers promise for increasing the effectiveness of care and improving people's health.

The interventions prescribed most frequently by practitioners in the study, usually in combination, were: food/nutrition, supplements, yoga, meditation, traditional Chinese medicine/acupuncture, massage and pharmaceuticals.

"It's important to remember that these therapies are often used in conjunction with other medical

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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

- Spiritual therapy may help terminal patients
- Hospice in the continuum of care
- Ethical issues of genetic testing
- The ethics of H5N1 research

Continued from p. 47

approaches, such as chemotherapy and/or surgery," says Stewart. "At the IHH we work with each patient and their other caregivers to come up with an approach that is best suited for them. Our care integrates traditional and contemporary healing practices."

RESOURCE

• *Integrative medicine in America: How Integrative medicine is being practiced in clinical centers across the United States*. Web: http://bit.ly/yXpBHc. ■

CME QUESTIONS

1. According to research published in the *Journal of the American Medical Association (JAMA)*, the use of next-generation sequencing will enable the detection of what?
   A. A larger number of harmful genetic variants
   B. Ethical implications pertinent to three dimensions of offering free prenatal screenings
   C. The decisions the pregnant woman makes concerning medical care as a result of this information.
   D. None of the above

2. According to a study that appears in the *Clinical Journal of the American Society Nephrology* (CJASN), what do the authors claim can happen for kidney failure patients who take part in an education program?
   A. Patient is more likely to get evaluated for a kidney transplant.
   B. Might help reduce disparities among patients.
   C. Both A & B
   D. None of the above

3. True or False: According to a study published in the journal *Obstetrics & Gynecology*, women were about 14 times more likely to die during or after giving birth to a live baby than to die from complications of an abortion.
   A. True
   B. False

4. Guidelines from the Endocrine Society endorse transgender hormone treatment, but say it should not be given when?
   A. After puberty
   B. During puberty
   C. Before puberty begins
   D. None of the above

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