Of Note

The Benefits and Risks of Direct-To-Consumer Genetics Tests

Patients see potential benefits from direct-to-consumer genetic testing, but are also concerned about how the test results will be used, and are generally unwilling to pay more than $10 or $20 for them, according to focus groups conducted by researchers at Loyola University Chicago Stritch School of Medicine. Findings were published in the *American Journal of Bioethics Primary Research.*

More than a dozen companies test consumers' genomes for single-gene disorders such as cystic fibrosis as well as risks of disorders involving multiple genes such as cancer, heart disease and diabetes. Costs currently range from about $100 to $1,500. Consumers can order these tests directly and receive results without the involvement of a qualified health care professional, geneticist or genetic counselor.

Focus group participants expressed concerns about the accuracy of the tests, who interprets them and whether the information should be shared with physicians and entered into medical records. Additional concerns included ethical issues such as risks to privacy and confidentiality.
(Loyola University Health System, "The Benefits and Risks of Direct-To-Consumer Genetics Tests," *Medical News Today*. MediLexicon, Intl., June 11, 2012, http://www.medicalnewstoday.com/releases/245287.php)

Health Care Increasingly Out of Reach for Millions of Americans

Tens of millions of Americans under 65, including people with and without insurance, saw their access to health care dramatically worsen over the past decade, according to a study by researchers from the Urban Institute published in *Health Affairs.*

The findings suggest that more privately-insured Americans are delaying treatment due to rising out-of-pocket costs and that safety net programs for the poor and uninsured are failing to keep up with demand for care.

Overall, the study found that one in five American adults under 65 had an "unmet medical need" because of costs in 2010, compared to one in eight in 2000. They also had a harder time accessing dental care according to an analysis of data from annual federal surveys of adults. (Phil Galewitz, *Kaiser Health News*, May 7, 2012.)

Egg-Producing Human Ovarian Stem Cells Concern Ethicists

Human eggs apparently can now be produced in a lab dish from stem cells

derived from adult women's ovaries, according to research by Harvard Medical School professor Jonathan Tilly.

The finding raises possibilities such as a limitless supply of lab-grown human eggs for experimentation and fertilization from one woman, as well as some sort of embryonic stem cell-derived anti-aging elixir.

Tilly's research team at Massachusetts General Hospital's Vincent Center for Reproductive Biology published their findings – which turn a half century of embryology orthodoxy on its head – in the March issue of *Nature Medicine.* The dogma that women inherit a fixed "bank account" of irreplaceable eggs at birth that dwindles until it expires in menopause has apparently been rendered obsolete by the team's isolation of egg-producing stem cells from the ovarian tissue of adult women undergoing "sex change" operations in Japan.

British scientists intend to carry out the next step of research to create human embryos from eggs derived from those stem cells for experimentation, freezing and destruction. This type of research is banned from receiving federal funding in the U.S. Celeste McGovern, *National Catholic Register,* April 22, 2012.

Healthcare Costs to Rise 7.5 Percent in 2013: Report

The cost of healthcare services is expected to rise 7.5 percent in 2013, more than three times the projected rates for inflation and economic growth, according to a report published in May 2012 by the Health Research Institute of PricewaterhouseCoopers (PwC). However, premiums for large employer-sponsored health plans could increase by only 5.5 percent as a result of company wellness programs and a growing trend toward plans that impose higher insurance costs on workers.

Healthcare costs have long outstripped economic growth and inflation rates, driving up government spending on Medicare and Medicaid at a time when federal policymakers and lawmakers are wrangling over how to trim the budget deficit of $1 trillion a year. Health Research Institute Managing Director Ceci Connolly said health plans with higher deductibles and co-pays for workers tend to dissuade unnecessary purchases and offer lower premium costs for employers while successful wellness programs can reduce the need for medical services. The report said prospects for higher growth are also being held back by consolidation of hospitals and physician practices, insurance industry pressure on hospital expenses, and a growing variety of primary care options such as workplace and retail health clinics, price transparency and increasing use of generic drugs. (David Morgan, *Reuters,* May 31, 2012.)

Fetal Genome Deduced From Parental DNA

Heralding a future in which a child's genetic blueprint can be safely scanned for

traits and defects long before birth, researchers announced they have reconstructed the genome of a fetus using a blood sample from its mother and a saliva sample from its father. The work was published in *Science Translational Medicine* in June 2012.

A pregnant woman's blood contains DNA fragments from both her genome and that of her unborn child. Generally, around 13 percent of the DNA in her blood plasma – called 'cell-free DNA – comes from the fetus. Jay Shendure, a geneticist at University of Washington in Seattle, and his colleagues constructed the mother's genome by sequencing the DNA in her blood cells and then computationally predicted the ratios at which certain blocks of gene variants, or haplotypes, should appear as cell-free DNA in her blood. Where observed ratios diverged from predictions, researchers surmised they were reading some genetic material from the fetus. To work out the paternal contribution, researchers sequenced the father's genome using from his saliva. Variants of his that didn't turn up in the maternal blood were presumed not to have been inherited by the fetus; those that did were presumed to come from the fetus.

Wide-ranging, noninvasive screening could reach the clinic within a few years, says Shendure. But he warns that more needs to be done to refine the method and make results meaningful to patients. "The technical piece is not the only challenge," he said. (Alison Motluk, *Nature News,* June 6, 2012.)

Health Exchanges' Sharing Of Patient Data Heightens Privacy Concerns

Maine was one of the first states to set up a health information exchanges connecting disparate medical practices and hospitals to help doctors share patient files with the click of a mouse. Fueled by $548 million in federal grants as part of the Obama administration's health care overhaul, the exchanges represent a radical change in how patient records are handled and used in treatment, according to a report in Bloomberg.com.

The health information networks have stirred controversy because in some cases, they include data without patients' consent. Privacy advocates fret that some exchanges may lose or even sell personal information.

A gap in federal law lets states set their own rules about whether to tell patients their medical data are being shared with an exchange and whether to let people opt out. According to EHealth Initiative, a nonprofit organization that researches health-care technology, many exchanges in the U.S. give patients no choice about removing this information.

"The whole system could get torn apart by the privacy issues," said Mark Rothstein, director of the institute for Bioethics, Health Policy and Law at the University of Louisville's Medical School. He said if people were properly notified, most would approve of the exchanges. (Jordan Roberston, *Bloomberg Businessweek,* May 15, 2012.)

Students from the Center for Health Law Studies at Saint Louis University School of Law contributed the following items to this column. Amy N. Sanders, assistant director, Center for Health Law Studies, supervised the contributions of health law student Lindsey Weinberg (JD anticipated '13).

High Court Health Care Ruling Shifts Action to States

States now hold the burden of implementing the Affordable Care Act after the Supreme Court upheld the law. Alan Weil, executive director of the nonpartisan National Academy for State Health Policy, said, "There are many states that will look at this opinion and realize that if they do not build their own health insurance exchange or take other steps to implement the law, the federal government will come and do it for them." To avoid this federal action, states have until mid-November to decide whether to set up and run a health insurance exchange where individuals without insurance and small businesses will go to compare plans and buy coverage.

States must also decide whether to take part in the Medicaid expansion which "calls for states to extend the program to everyone with incomes under 133 percent of poverty, just under $15,000 a year. It's about 17 million more people." Medicaid expert and law professor at the George Washington University, Sara Rosenbaum, stated "unlike the rest of Medicaid, where the funding is shared, in this case the federal government is paying almost the whole bill." (*High Court Health Care Ruling Shifts Action To States*, Julie Rovner, NPR News, June 29, 2012) http://www.npr.org/blogs/health/2012/06/29/155959343/high-court-health-care-ruling-shifts-action-to-states

California Races to Enroll Uninsured

On Oct. 1, 2013, California plans to open its shopping portal into the online exchanges where individuals without employer coverage can determine eligibility for subsidies, comparison shop, and purchase a policy beginning Jan. 1, 2014. With almost one in five people currently uninsured in the state, California would like to make shopping for health insurance as easy "as buying a book on Amazon." The Bay Area Council Economic Institute projects that the health care law is going to bring California more than $3.4 billion a year in new health care spending. Russ Mitchell, *Kaiser Health News*, June 29, 2012) http://www.kaiserhealthnews.org/Stories/2012/June/29/California-races-to-enroll-uninsured.aspx

Know Your BMI: Docs Urged to Screen for Obesity

In the U.S., two thirds of adults are either overweight or obese, and 17 percent of children and teens are obese and at risk for disease. Body mass index is the signal for whether someone is overweight, obese or just right as compared to height; however,

many physicians neglect to check this crucial marker for obesity. Possible reasons stem from the fact that few doctors are trained to treat obesity and do not know what to advise in the face of yo-yo diets of today. In addition, overweight physicians are less likely to advise patients about weight loss, according to Johns Hopkins University researchers.

The U.S. Preventive Services Task Force has issued new guidelines urging physicians to screen patients for obesity during checkups by calculating BMI. For those patients who fall into the obese category with a BMI of 30 or above, physicians should refer these patients to intensive nutrition-and-fitness help rather than simply recommending dietary changes. (*Know Your BMI: Docs urged to screen for obesity*, Lauran Neergaard, Associated Press, June 26, 2012) http://news.yahoo.com/know-bmi-docs-urged-screen-obesity-213247409.html

New Rules Will Ban ER Debt Collections at Charitable Hospitals

Growing reports of aggressive hospital debt collection activities, including allowing debt collectors to pursue collections in emergency rooms, prompted the 2010 federal health law to direct the U.S. Treasury Department to formulate rules protecting patients from abusive debt collection practices at nonprofit hospitals. Three out of five hospitals in the country are nonprofit.

The health law requires charitable hospitals to clearly explain to patients their best financial options, afford them adequate time to apply for those options, and cap a patient's charges to that charged of insurers. Aggressive debt collections in ERs "jeopardize patient care, and [the] proposed rules will help ensure they don't happen in charitable hospitals." The American Hospital Association disapproves of the federal health law requirement because it "places too much blame on hospitals…for the activities of the 3rd party debt collectors that they employ."(Jenny Gold, *Kaiser Health News,* June 27, 2012, http://www.kaiserhealthnews.org/Stories/2012/June/27/ER-debt-charity-hospitals.aspx)