Of Note

New System for Patients to Report Medical Mistakes

Dr. Carolyn M. Clancy, director of the Agency for Healthcare Research and Quality, said, “Currently there is no mechanism for consumers to report information about patient safety events.” The Obama administration wants to begin a project that offers patients the opportunity to report medical mistakes or unsafe practices through a Web site and telephone interviews.

The project would ask the patient or family member “what happened; details of the event; when, where, whether there was harm; the type of harm; contributing factors; and whether the patient reported the event and to whom.” The government would inquire if the mistake involved incorrect medicine or amount of medicine; wrong test, procedure, or diagnosis; or infections or “unclean or unsanitary care.” All reporting would be confidential and voluntary.

Doctors and hospitals are open to the patient reporting system but have concerns about malpractice liability and penalties for poor performance. Robert Pear, “New System for Patients to Report Medical Mistakes,” *The New York Times*, Sept. 23, 2012.

Medicare Bills Rise as Records Turn Electronic

Although the goal of electronic records was to improve efficiency, patient safety and lower health care costs, electronic records may actually be contributing to higher costs because it is easier for hospitals and doctors to bill more for the services provided. There has been an increase in the number of highest-paying claims submitted for reimbursement in Medicare that corresponds with the hospital’s implementation of electronic records systems. The Office of Inspector General of the U.S. Department of Health and Human Services warns that coding has been “vulnerable to fraud and abuse.” The alleged abuse includes doctors cutting and pasting the same examination findings for multiple patients giving the appearance that the doctor conducted a more thorough exam than was actually completed.

Hospitals and doctors assert that fraud is not increasing the reimbursement rate but rather more accurate documentation. Dr. David J. Brailer, need title, organization, a proponent of digitizing records, said that many doctors and hospitals were underbilling before they started using electronic records but acknowledges that electronic records “makesit faster and easier to be fraudulent.” Reed Abelson, Julie Creswell and Griffin J. Palmer, “Medicare Bills Rise as Records Turn Electronic,” *The New York Times*, Sept. 22, 2012.

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Doctors Move Beyond Bionic Legs and Grow Ears, Bone, Muscle and Skin for Troops

The Armed Forces Institute of Regenerative Medicine(AFIRM) is helping veterans and wounded troops by advancing cell science and plastic surgery. Created by the federal government four years ago, AFIRM brought together top hospitals and universities to develop technologies that will aid the recovery of injured veterans.

The tissue engineering lab at Massachusetts General Hospital has grown anatomically correct human ears from cells and is seeking approval from the Food and Drug Administration to implant the ears into patients. At the University of Pittsburgh, Dr. Stephen Badylak is testing implants of "extracellular matrix," a connective tissue from pigs that holds cells together. Early testing shows improvement in muscle strength after treatment. In addition, a new method for making skin has been developed in which take a small piece of the patient's skin, process it in the lab and spray the new cells on burned or wounded areas. Estimates say that up to 200 troops might need a face transplant. Transplants can be high risk because drugs needed to prevent rejection raise the risk of cancer. Dr. W.P. Andrew Lee at Johns Hopkins University has found that giving recipients bone marrow taken from the donors helped patients better tolerate the new tissue. Increased acceptance of the new tissue allows patients to take less anti-rejection medicine. Associated Press, "AP IMPACT: "Doctors Move Beyond Bionic Legs and Grow Ears, Bone, Muscle and Skin for Troops," *The Washington Post*, Sept.10, 2012.

Kidney Transplant Committee Proposes Changes Aimed at Better Use of Donated Organs

The kidney transplantation committee of the United Network of Organ Sharing has developed a proposal to improve the use of needed organs through better evaluation of the quality of kidneys recovered from dead donors. Based on the new evaluation score, the top 20 percent of organs would be given to recipients who are expected to live the longest instead of a first-come-first-served basis. Dr. John J. Friedewald, the committee's chairman, stated "By providing long-lived organs to long-lived recipients, we prevent returns to the wait list, and by preventing returns to the wait list we actually make more organs available for other candidates." Another change states that patients will be added to the wait list when they start dialysis rather than when they are signed up for a transplant list. Changes were also proposed for donor matching. In the past patients who were the most difficult to match were given priority; now, however, points will be given on a sliding scale based on difficulty of finding a match. The new proposal is open for public comment until Dec. 14. Kevin Sack," Kidney Transplant Committee Proposes Changes Aimed at Better Use of Donated Organs," *The New York Times,* Sept. 21, 2012.

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Prenatal Genome Sequencing Expected to Pose Challenges to Doctors

Prenatal whole genome sequencing was recently completed by extracting fetal DNA from a pregnant woman's blood. Although not available in a clinical setting, experts predict doctors will soon be using this process to improve detection of serious genetic disorders before the child's birth. Bioethicists say that the medical community is not prepared to manage the clinical and ethical issues that will occur.

A report by Benjamin E. Berkman in *The Hastings Center Report*, calls for medical organizations to start educating physicians about whole genome sequencing and give guidance to physicians about what types of genetic findings to offer expectant parents. Whole genome sequencing offers more information than other prenatal genetic testing that focuses primarily on detecting cystic fibrosis and Down syndrome. This wealth of information needs to be handled with caution or it may cause expectant parents unnecessary anxiety. "We need to, as a society, think carefully about how to filter this massive amount of information," Berkman said. "And we need to articulate thoughtful [recommendations] about what findings we should or shouldn't return to people." Many are concerned that learning nonmedical traits of unborn children may lead parents to terminate a pregnancy if the traits are undesirable. At this time there is no official guidance on how to use prenatal whole genome sequencing in the clinical setting. Christine S. Moyer, "Prenatal Genome Sequencing Expected to Pose Challenges to Doctors," *American Medical News/ amednews.com*, Aug. 27, 2012.

Most Employers to Continue Offering Healthcare Plans in 2014: Survey

In 2014, the Patient Protection and Accountable Care Act will require employers with at least 50 employees to offer qualified coverage to full-time employees or pay a fee of $2,000 per full-time employee. In 2018, the health reform imposes a 40 percent excise tax on premium costs that exceed $10,200 for single coverage and $27,500 for family coverage.

A recent survey conducted by Towers Watson & Co found that 88 percent of employers do not plan to terminate health care coverage for full-time employees in 2014 or after. Only one percent said they planned to terminate coverage while 11 percent were unsure. These results are consistent with other surveys. Of those surveyed, 83 percent of employers are planning to take action to control costs to avoid the 40 percent excise tax in 2018. Another finding showed that 60 percent of employers offer account-based health care plans and it is expected that number will be 80 percent by 2018. Jerry Geisel, "Most Employers to Continue Offering Healthcare Plans in 2014: Survey," *Crain's Business Insurance*, Aug. 27, 2012.

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A student 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).

FDA Says Massachusetts Pharmacy Knew of Sterility Problems for Months

The Massachusetts pharmacy at the center of the national outbreak of fungal infections has been linked to outbreaks affecting 338 people in 18 states, and 25 deaths. A recent report detailed FDA inspections revealing that the New England Compounding Center had knowledge of multiple instances of bacterial and fungal contamination of two "clean rooms" at least nine months before the meningitis outbreak was linked to the company, yet the company took no documented corrective actions. A criminal investigation has ensued against the New England Compounding Center. In response to the seriousness of the results, the acting director of operations for the FDA's Office of Medical Products and Tobacco stated, "Manufacturers and compounding firms have the responsibility to manufacture quality drugs and ensure there is no breakdown in supplies or processes that would cause contamination." Here, however, the newly released federal inspection report revealed the extent of the contamination in vials of the steroid methylprednisolone acetate, much of which was visible to the naked eye. "FDA Says Massachusetts Pharmacy Knew of Sterility Problems for Months", Richard Knox, NPR, Oct. 26, 2012. http://www.npr.org/blogs/health/2012/10/26/163725906/fda-says-massachusetts-pharmacy-knew-of-sterility-problems-for-months

Are Social Factors Tied to Hospital Readmissions?

A study published in the *Journal of General Internal Medicine* provides a new look at a series of papers examining the reasons why heart and pneumonia patients died or were readmitted to the hospital, many of which may be non-medical factors outside of hospitals' control. This study found that social factors such as age, race, employment status, living situation, education and income levels, may indicate a high risk for readmission.

Although more research is needed regarding whether these risk factors actually cause, rather than simply correspond to, patient death or need for readmission, physicians can use this information to be preventative and proactive in patient care. In evaluating for hospitals for payment, the Centers for Medicare and Medicaid Services (CMS) started using readmission rates and patient outcomes, but CMS does not consider social factors. The researchers of the study believe that a consideration of the social factors, however, could make patient care assessments more accurate. "Are Social Factors Tied to Hospital Readmissions?" Andrew M. Seaman, Reuters Health, Oct. 19, 2012.

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http://www.reuters.com/article/2012/10/19/us-social-factors-idUSBRE89I1CQ20121019

Supreme Court Turns Down Appeal in Oklahoma 'Personhood' Case

Personhood has been a prevalent, yet stagnant, topic for states thus far. Today, personhood proposals attempt to redefine "life" under state laws and constitutions as beginning at the moment of conception. The effect of this determination would prohibit abortion, and could lead to the restriction of reproductive technology such as in vitro fertilization. Although this proposal made it to the ballot in Mississippi, voters rejected it. The Supreme Court of Oklahoma blocked a personhood amendment from the state's ballot because it would violate the Constitution.

Recently, the Supreme Court of the United States declined to hear an appeal of the case, thus leaving in place the lower court's finding of unconstitutionality. Because only four of the nine justices must agree for the Court to take a case, such a rejection could suggest that the conservative justices are not yet willing to dive into the divisive topic. "Supreme Court Turns Down Appeal in Oklahoma 'Personhood' Case", Sam Baker, The Hill's Healthcare Blog, Oct. 29, 2012.

http://thehill.com/blogs/healthwatch/abortion/264605-supreme-court-denies-appeal-in-abortion-case

'Drastic' Variations in Care Found at Top Academic Medical Centers

Recent findings regarding patient experience, patient safety and pneumonia-care quality comparisons, by the Dartmouth Atlas Project, challenge "the assumption that clinical science alone drives medical practice." In an effort to discern patterns of care among 23 of the top academic medical centers, the report used Medicare data and the HHS Hospital Compare website. Significant variations were found in intensity of end-of-life care, surgical procedure rates, patient reported experience, patient safety, and quality of care.

The drastic variations in care among institutions expose a significant gap in clinical science. Importantly, medical students should consider such variances when making career choices because they indicate a "hidden training curriculum" which can affect a lifetime of practice. "'Drastic' Variations in Care Found at Top Academic Medical Centers", Andis Robeznieks, *ModernHealthcare*.com, Oct. 30, 2012.
http://www.modernhealthcare.com/article/20121030/NEWS/310309958?AllowView=VW8xUmo5Q21TcWJOb1gzb0tNN3RLZ0h0MWg5SVgra3NZRzROR3l0WWRMVGFWUDRCRWxiNUtpQzMyWmFyNUh3WUpibXA=&utm_source=link-20121030-NEWS-310309958&utm_medium=email&utm_campaign=am

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