Of Note

Study: Boost in Hospice Visits by Way of the ICU

A recent study published in the *Journal of the American Medical Association* found that more Medicare patients are using hospice care, from 22 percent in 2000 to 42 percent in 2009. Although this appears to be good news, the details of the research tell a different story. Researchers found that many patients were only in hospice for a few days and usually entered after stays in the ICU. The number of patients transferred from one setting to another in their last three days has increased as well. Study author Joan Teno said that moving patients near the end of life can cause agitation, disruption of vital pain medication, and additional stress on the family. Researchers concluded that, "Short lengths of stay raise concerns that hospice is an 'add-on' to a growing pattern of more utilization of intensive services at the end of life." The Institute of Medicine has formed a task force called Coalition to Transform Advanced Care (C-TAC) to examine end-of-life care in light of the aging population and 2010 national health care law. (Joanne Kenen, *Politico*, Feb. 6, 2013)

Assisted Suicide on Legal Agenda in Several States

Although a ballot initiative to allow physicians to help terminally ill patients die failed in Massachusetts, the conversation has spread across the country. State legislatures in Connecticut, New Jersey, New York, Vermont, Kansas, Arizona, Montana and Hawaii are all considering bills that would legalize assisted suicide. Connecticut legislature is set to hear at least two bills that could make it the first state legislature to legalize the practice. A bill allowing physicians to prescribe a lethal dose of medication has passed the New Jersey state Assembly and awaits voter approval. Although thirty-four states prohibit assisted suicide and seven have banned it, Montana's Supreme Court ruled that assisted suicide is medical treatment and Oregon and Washington passed right-to-die laws via voter referendum.

In Connecticut there are groups on both sides of the issue. Peter Wolfgang, directors of the Family Institute, believes that this is not the will of the people of Connecticut but out-of-state advocacy groups trying to influence Connecticut lawmakers. Dr. Gary Blick, a doctor who treats patients with HIV and AIDS, believes it is time for the state legislature to discuss this issue. "This is not for everybody. We realize there are people that do not believe in this for religious beliefs, and I respect that. But there are those subsets of people that do not want to go through the suffering that they have to go through." (Susan Haigh, Associated Press, Feb. 8, 2013)

Alzheimer's 'Epidemic' Now a Deadlier Threat to Elderly

Alzheimer's disease has become the sixth leading cause of death in the United States. Susan Mitchell, professor of medicine at Harvard, believes that the number of deaths caused by Alzheimer's may be much greater than recorded. She says that other medical problems are often listed as a cause of death when Alzheimer's is the actual cause. After conducting a study of patients with advanced dementia, Mitchell found that as the disease progresses it damages the brain in such a way that normal body functions are affected such as swallowing, balance and walking. Due to the disease's ability to diminish the body's defenses, the most common cause of death is infection. "The body is so debilitated, frail and weak at the end of dementia that some of the usual immunological and metabolic factors that can protect a healthy body from infections and fevers really become susceptible," Mitchell stated. These findings are important for families to know when making decisions regarding the care of their loved ones suffering from the later stages of dementia. (Jon Hamilton, *National Public Radio*, March 19, 2013)

New Data to Consider in D.N.R. Decisions

A recent study published in the *New England Journal of Medicine* looked at what happened to elderly patients who were discharged following an in-hospital cardiac arrest. Of those studied, 58.5 percent were still alive and 52 percent had moderate or severe neurological damage. After leaving the hospital, 60 percent went to nursing homes, rehabilitation facilities or hospice. Dr. Paul Chan, lead author of the study, believes there is hope for resuscitation survivors. Improvements in hospital resuscitation such as use of therapeutic hypothermia to reduce brain swelling, quicker response times, and advances in performing CPR can significantly change outcomes. The quality of health post-cardiac arrest was not explicitly measured in the study. Study authors encourage doctors to share these findings with patients when discussing medical plans concerning cardiac arrest and resuscitation. (Judith Graham, *New York Times*, March 14, 2013)

Should Family Members Watch as their Dying Loved Ones Get CPR?

Researchers theorized that family presence during resuscitation might have positive results. Witnessing CPR might allow the family to know that all possible efforts were implemented to try to save the life of the patient. Family witness could also give loved ones an opportunity to say goodbye. Lastly, witnessing CPR could eliminate unrealistic expectations and end suspicion surrounding closed-door efforts. The study, published in the *New England Journal of Medicine*, supported the researchers' theories. The study found that family members who did witness CPR were less likely to have post-traumatic stress disorder or symptoms of anxiety and depression. The medical teams were concerned that family witnesses would be

in the way or lead to more lawsuits but this was not the case. Only 3 percent of those who witnessed CPR said they regretted it and one witness wrote a thank-you letter to the medical team. (Karen Kaplan, *LA Times*, March 13, 2013)

Key Long-Term-Care Insurer to Raise Women's Premiums

Long-term care insurance is not subject to the provision in the Affordable Care Act which prohibits insurers from charging premiums based on gender. Starting this spring, Genworth Financial, the country's largest long-term care insurance provider, will increase premiums for women who buy new individual policies by 20 to 40 percent. An increase in premiums is not a surprise because two of every three insurance claim dollars go to a woman. Other factors play a role such as women live longer than men, women act as caregivers keeping men's health care costs lower, and a lack of family caregivers who take care of women. Although the Affordable Care Act does not apply to Genworth, Colorado and Montana have state laws that prohibit premium costs based on gender. Advocates see this as an opportunity to encourage other states to adopt similar laws. (Michelle Andrews, *Kaiser Health News*, Feb. 26, 2013)

Hospitals Clamp Down on Dangerous Early Elective Deliveries

Delivering babies before 39 weeks without a medical reason is dangerous for both baby and mother. Babies have a higher likelihood of breathing or feeding problems, infections and developmental problems later in life. Mothers who deliver early have higher rates of infection due to an increase in the occurrence of Caesarian sections. The Leapfrog Group, a group of the country's largest corporations that buy health care for employees, found that the national average of elective deliveries before 39 weeks decreased from 14 percent in 2011 to 11.2 percent in 2012. Although the decrease is promising there is still more to be done. Individual states have taken a role in lowering the number of early elective deliveries. The Midwest Business Group on Health has assisted Illinois lower the early deliver rate to 7 percent. South Carolina and Texas Medicaid stopped reimbursing for early elective delivers. (Phil Galewitz, *Kaiser Health News*, Feb. 21, 2013)

Cell Therapy Shows Promise for Acute Type of Leukemia

A study published in the journal *Science Translation Medicine* gives great hope for the use of T-cell therapy to treat adults suffering from acute lymphoblastic leukemia. The treatment consists of extracting patients' T-cells and genetically engineering the T-cells to recognize and kill all B-cells which carry the protein CD19. The side effect of destroying all B-cells, even those that make antibodies, is treatable. Of the five patients studied, three are in remission, one died in remission from a blood clot and the fifth patient died after relapsing. All four of the patients that went into remission also received a bone marrow transplant. It is

unclear if the bone marrow transplant was necessary or if the T-cells would have been enough. Since a bone marrow transplant is standard, withholding that treatment would have been unethical. Dr. Michel Sadelain, senior author of the study, said "We're creating living drugs. It's an exciting story that's just beginning." (Denise Grady, *The New York Times*, March 20, 2013)

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 students Srishti Miglani (JD/MPH anticipated '15) and Michael K. Morton (JD anticipated '14).

The following submissions are by Srishti Miglani

Robot Watson to Provide Health Care

IBM's Watson supercomputer is the next big IT breakthrough in health care delivery. It can process information and make recommendations much more quickly and intelligently than any machine that preceded it. It can make diagnoses and recommend treatments while giving a series of possibilities, each with its own level of confidence. Dr. Marty Kohn, the clinical leader of the IBM team training Watson for health care applications, said that in addition to primary care, Watson can help in specialized fields such as oncology. Unlike humans, Watson has the ability to process large amounts of information. Watson's abilities don't end at diagnosis and suggesting treatment options- it also has an application to submit treatment proposals to managed-care companies for instant approval, thereby reducing administrative time for getting payment authorizations.

There are, however, some areas in which Watson still needs work. Before it becomes an integral part of the health care system it has to learn to extract relevant information and relationships from cases, understand and analyze medical information, and understand the various terminologies used by different people in the medical field. Some people are afraid that Watson might increase the cost of health care because it would suggest multiple possible diagnoses per patient which the doctor would want to further investigate with additional medical tests. Watson is currently being tested and developed at Memorial Sloan-Kettering Cancer Center and the Cleveland Clinic. In addition, WellPoint has begun testing Watson as a support tool for nurses who make treatment-approval decisions. IBM is very optimistic about Watson's future prospects but it does not claim that Watson will replace doctors. Instead it sees Watson as a "clinical support tool rather than a decision-making tool." ("The Robot Will See You Now" Jonathan Cohn, *The Atlantic*, Feb. 20, 2013 http://www.theatlantic.com/magazine/archive/2013/03/the-robot-will-see-you-now/309216/)

Where the Sequestration Cuts Are in HHS

Since Congress and the White House failed to agree on targeted levels of deficit reduction, The Budget Control Act of 2011 put sequester into effect. Budget cuts resulting from the sequester went into effect on March 1, 2013. On March 4, 2013 its effects began to be felt when the program offices of Department of Health and Human Services (HHS) began their cuts. The Office of Management and Budget reported that HHS programs, large and small, will be subjected to a 5.1 percent spending cut in this fiscal year.

Medicare and Medicare are not subjected to the full budget cuts. Physician payments under Medicare were cut by 2 percent, while Medicaid did not suffer any budget cuts. On April 1, 2013 cuts in physician reimbursement went into effect resulting in $11 billion in lost revenues. But other programs under the Centers for Medicare and Medicaid Services (CMS) will be subjected to budget cuts related to the sequester.

Budgets of other agencies will also be reduced during this fiscal year. For example: The National Institutes of Health (NIH) by $1.5 billion, Centers for Disease Control and Prevention (CDC) by $289 million, the Office of the National Coordinator for Health Information Technology by $1 million, the Food and Drug Administration (FDA) by $209 million, the Substance Abuse and Mental Health Services Administration by $168 million, and the Indian Health Service by $198 million. ("HHS Officials Begin Implementing Cuts in Federal Health Programs Under Sequester" Ralph Lindeman, *BNA's Health Care Policy Report*, March 11, 2013 http://news.bna.com/hcln/HCLNWB/split_display.adp?fedfid=29966540&vname=hcpnotallissues&fcn=3&wsn=498759500&fn=29966540&split=0)

Drug Costs Are Down but Increases on the Horizon

In 2012, for the first time in over fifty years, spending on prescription drugs dropped 1 percent to $325.7 billion. Spending on commonly used medications, such as those used to control high blood pressure and high cholesterol, dropped by 1.5 percent. This drop has been attributed to the increasing use of generics. The use of generics was increased when dozens of brand name drugs, like Plavix and Lipitor, lost their patent protection.

The question is whether this drop in spending will continue; predictions say that it will not. Fewer drugs are set to lose their patent protection in the next several years. The use of generic drugs has been said to reach its saturation point at 84 percent and it is not estimated to go higher than 86 percent or 87 percent.

Despite the drop in the cost of traditional drugs, the spending on specialty drugs by commercially insured patients increased by 18.4 percent. These drugs tend to cost more than other prescription drugs and can cost up to $200,000 per patient. IMS Health has predicted that the spending on drugs will increase by 4 percent in 2014 because fewer brand name drugs will lose

their patent protection and health care utilization will increase under the Affordable Care Act. That increase will be followed by a small dip in spending in 2015, with a subsequent rise of 4 percent in 2016. Steps are being taken to reduce spending and insurance companies and drug-benefit managers are either recommending patients to try the less expensive treatments first or they are seeking prior approval for higher-priced drugs. In addition, biosimilars, which are considered the generic version of biologics and cost 30 percent to 50 percent less than biologics, might be available in the United States in the near future. ("U.S. Drug Costs Dropped in 2012, but Rises Loom" Katie Thomas, *The New York Times*, March 18, 2013 http://www.nytimes.com/2013/03/19/business/use-of-generics-produces-an-unusual-drop-in-drug-spending.html?pagewanted=all&_r=0)

The President's Brain Mapping Initiative

President Obama asked Congress to put $100 million next year towards the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative. This funding would support the research at the National Institutes of Health (NIH), the Defense Advanced Research Projects Agency (DARPA), and the National Science Foundation. President Obama also urged the private sector to get involved with government agencies to further this research.

Even though the specific goals of this project are unclear, the ultimate goal is to understand the workings of the brain by tracking the activity of the individual cells and the neuronal connections. This research will hopefully facilitate better understanding of neurological and psychiatric disorders such as autism. The BRAIN initiative is hoped to be a return on investment and a much needed effort to understand, treat, and cure various neurodegenerative and psychiatric diseases. ("Obama Proposes Brain Mapping Initiative"
Nedra Pickler & Malcolm Ritter, *Huffington Post*, April 2, 2013 http://www.huffingtonpost.com/2013/04/02/obama-brain-initative_n_2999027.html)

Hospitals May Be Making Money from Errors

A study reported in *The Journal of the American Medical Association* (JAMA) showed that hospitals profit from their own mistakes because insurers reimburse them more for longer hospitals stays and the extra services provided to patients to treat preventable surgical complications.

The study's conclusion was based on a survey of the medical records of 34,256 people who had surgery in 2010 at one of 12 Texas Health Resources hospitals. Of these patients, 1,820 had preventable complications resulting in longer hospital stays. That resulted in hospital revenue averaging $30,500 more for patients with complications than those without. Hospitals were reimbursed at a higher rate

by private insurers than by Medicare, Medicaid, or patients who paid for their bills out of pocket. The authors of this study used the contribution margin, a measure of a hospital's income and ability to cover its costs, to understand the relationship between services rendered and the resulting revenues. When complications arose, it tripled for patients with private insurance and doubled for Medicare patients.

The problem is the fee-for-service system which rewards quantity more than quality; the current payment system does not reward hospitals for performing better. To the contrary, it provides a disincentive for better training and improvements in hospital care because both cost money. The researchers not only urged for a quality-based payment system but for increased transparency in hospitals' reporting of their quality performance measures.

It should be noted that the study did not claim that the current payment system causes hospitals to deliberately cause complications in patients. Instead, it concluded that the payment system rewarded hospitals for the increased quantity of health care services provided as a result of complications when it should instead focus on rewarding hospitals that make improvements to reduce complications. ("Hospitals Profit From Surgical Errors, Study Finds" Denise Grady, *The New York Times*, April 16, 2013 http://www.nytimes.com/2013/04/17/health/hospitals-profit-from-surgical-errors-study-finds.html?emc=tnt&tntemail0=y&_r=0)

The following submissions are by Michael K. Morton

Stem Cell Breakthroughs May Revolutionize Heart Failure Therapy

Heart attacks and heart failure often turn the human body's most powerful muscle into an inefficient circulation tool. Millions of heart cells are lost during heart attacks and other failure due to heart disease. In the absence of those cells, dense, unworkable scar tissue forms. This extreme reduction in healthy heart cells and increase in scar tissue negatively affects the rate at which the heart can pump blood through the body. However, research breakthroughs regarding harvesting and utilizing a patient's own stem cells can reverse the damage done by heart failure.

Beginning in 2009, a research team at the University of Louisville, had successfully harvested and reproduced stem cells taken from patients' own hearts who have experienced heart failure. Stem cells are vital to the reproduction of heart cells after a heart attack or other type of heart failure; however, this process only takes place within the body for up to two weeks after an attack. That short time frame does not adequately make up for the damage done by the heart attack. The ability to harvest and reproduce the stem cells outside of the body has given the research team the opportunity to discover whether this recovery period within the heart can

be lengthened by additional stem cell infusions.

After reproduction, the native stem cells are then pumped back into a patient's coronary artery through a catheter. While the experimental community is small – this has only been attempted on 16 patients – the results are positive and the outlook on future implications on heart failure recovery are exceedingly bright. In the sixteen patients who received this experimental native stem cell treatment, an 8 percent increase was seen in the amount of blood that the heart was pumping through the body after four months. This was compared to a control group of patients, who had received the standard treatment for heart failure, consisting of primarily beta blocker injections, resulting in 0.1 percent increase in pumping efficiency. Impressively, analysis a year after this stem cell treatment revealed an average of a 30 percent reduction in scar tissue in the 16 patients receiving this breakthrough treatment. (A Change of Heart: Stem Cells May Transform Treatment for Heart Failure, Ferris Jabr, *Scientific American*, April 3, 2013 http://www.scientificamerican.com/article.cfm?id=change-heart-stem-cell-treatment-heart-failure)

Injecting Humanity into Medical Education

As medical schools hurry to keep up with the ever-changing world of medicine with additions to their required curricula, schools are also taking a step back to look at patient care from a more holistic perspective. To that end, many medical schools are beginning to "teach" compassion and empathy, by adding required courses in the arts and humanities to their grueling sets of medical science courses.

The University of Chicago Pritzker School of Medicine has added a creative writing course to its curriculum. At Northwestern University's Feinberg School of Medicine, students are required to take two courses from the University's Humanities and Bioethics program in order to graduate. According to research done by Penn State University's College of Medicine, every medical school in the United States requires some coursework in medical ethics, while almost half now push their students to delve into the world of art and humanities.

While the old guard of medical education looks down upon such deviation from the standard scientific medical education, both younger educators and current practitioners have endorsed this new portrait of medical education in the United States. (Teaching Compassion, Lisa Pevtzow, March 20, 2013, *Chicago Tribune* http://articles.chicagotribune.com/2013-03-20/health/ct-x-medical-school-arts-20130320_1_doctors-humanities-students)

Failure to Warn Regarding Premature Subjects Leads to Reprimand

Death of premature babies who had taken part in a large research study has led to the Office for Human Research Protections (OHRP), a federal agency, notifying over 20 research institutions that their informed consent procedures did not adequately warn infant subjects' parents of the dangers of this given study. The study – named Support – was established to analyze the optimal amount of oxygen that should be administered to infants born prematurely. Oxygen support is crucial to premature infants, as their lungs are not yet fully formed; however, unnecessarily high levels of oxygen support lead to blindness in these same patients. This research was charged to find at what exact level in the American Academy of Pediatrics' standard of 85 percent to 95 percent oxygen concentration was most advantageous for survival future health of premature babies.

Based on past scientific endeavors, it was known that higher concentration levels in oxygen would result in an eye disease in premature subjects often leading to blindness. For the study to work, some of the infants would necessarily need to be exposed to higher concentrations within the set standard. However, in the study's informed consent forms and procedures, parents were not notified that these higher levels of oxygen meant a greater possibility of eye troubles for their infants. Researchers argue that since even the highest oxygen levels to which any of their premature subject were exposed was in the set standard of care, the odds that blindness would occur in these subjects compared to premature babies outside of the study were just as severe. However, the OHRP argues that, although within the standard of care, it is known within this research community that any increased level of oxygen concentration leads to an increased possibility of eye disease; therefore, the parents should have been warned during the consent period.

Violations of OHRP informed consent policy can have serious consequences. Punishment can range from corrective actions being promulgated from the agency itself, to federal funding being pulled from the institutions at issue that conduct human subjects research. (Crucial Studies, Fragile Subjects, Sabrina Tavernise, April 16, 2013, *New York Times* http://www.nytimes.com/2013/04/16/health/balancing-risks-and-benefits-in-clinical-trials.html?pagewanted=1&_r=0&ref=ethics)

High-risk Insurance Pools Established by PPACA Already Drying Up

The Pre-Existing Condition Insurance Plan – an insurance pool for individuals with high-risk health conditions run by the federal government – has been forced to stop accepting applications due to lack of funding. Established by the Patient Protection and Affordable Care Act in 2010, this high-risk insurance plan was supposed to act as a bridge for historically sick individuals until the bulk of health

care reform took effect in 2014. However, the $5 billion that Congress appropriated to the high-risk plan is on the verge of being exhausted. About $2.3 billion of the original appropriation remains, which is only enough to cover the existing 100,000 individuals who have already enrolled in the high-risk plan. As of March 2, the federal government will be forced to reject any new application submitted by an individual.

The reason for the shortfall, according to individuals within the Department of Health and Human Services' Center for Consumer Information and Insurance Oversight, is that the majority of the 100,000 individuals that had originally enrolled in the Pre-Existing Condition Insurance Plan have proven to be more costly to insure than originally calculated. By extrapolating the numbers of applications that the federal government had received during the last few months – about 4,000 new applications per month – tens of thousands more Americans would have applied for coverage under this plan, had more funds been available. According to the Department of Health and Human Services, additional appropriations from Congress for this high-risk plan will not be sought. (Funds Run Low for Health Insurance in State "High-Risk Pools," N.C. Aizenman, Feb. 16, 2013, *Washington Post* http://www.washingtonpost.com/national/health-science/funding-is-running-low-for-health-insurance-in-state-high-risk-pools/2013/02/15/cb9d56ac-779c-11e2-8f84-3e4b513b1a13_story.html)