PSA

Patient Safety America Newsletter

January 2013 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: According to the Institute of Medicine, how much money is misspent on administrative costs in the American medical system? a) $9 billion b) $18 billion c) $90 billion d) $180 billion e) $900 billion*

Fair Healthcare

A few years ago a young woman from a disadvantaged ethnic group fainted while working in my laboratory. She was taken to a nearby clinic by a coworker, and then, after a brief examination, on to a hospital. There it was discovered that her hemoglobin was 1/3 what it should have been. She received a transfusion and therapy and returned to work in a few days. It seems that she had kept her persistent bleeding a secret from her parents for many months because she knew her parents had no health insurance, even though her father worked. She was afraid of the cost uninsured care.

Two experts writing in a commentary in the *Archives of Internal Medicine* describe medical discrimination and propose ways to break down the barriers in our discriminatory medical care system.[1]

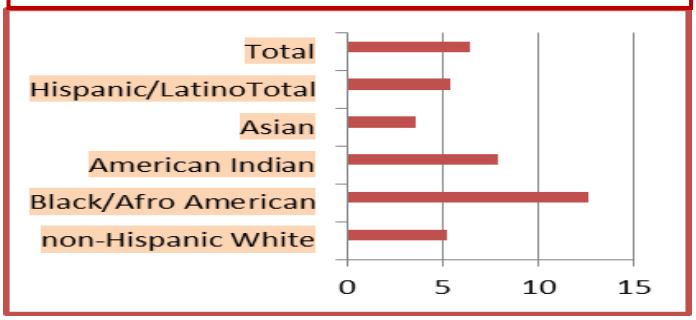
> Our nation lags behind many other industrialized countries in population health, in large part because of inequities of opportunity. Inequality itself is making our society sicker. Moreover, health disparities embody a staggering toll of suffering and loss of human potential.
> *Lisa Cooper, MD and Dawn Brown, PhD.*[1]

Perhaps the largest barrier they see is the stereotyping of disadvantaged people by professionals outside their ethnic group as mistrustful of medical professionals, poor communicators, little motivated to engage in healthy behaviors, and lacking the will to adhere to recommended treatments. Any change that reduces stereotyping and improves physician-patient communication would reduce ethnic disparities.

Research has shown that ethnic bias is associated with poorer communication between physician and patient. One recent study showed that some improvement in physician listening (i.e. patient sharing of information) occurs when the physician is trained to affirm the patient's values across the ethnic divide. The environment in which the patient is seen can also affect communication. For example, any institutional bias needs to be addressed by creation of a diversity climate within the setting where patients are seen. Beyond this, the authors call for physicians to advocate for fair distribution of healthcare resources.

The authors missed an important point. Being poor limits the options that foster quality medical care. Access may be limited for many reasons ranging from no way to pay to no way to get to where quality care is provided. Being poor in a country where capitalist principles dominate healthcare care is to be separated from that care. The graph shows the racial/ethnic disparity in infant mortality in our country, which on average ranks below 40th among nations of the world.

Infant Mortality in 2009 in the US per 1000 Live Births



Spendthrift Medicare

In doing research for my book several years ago I was shocked at the widespread practice of medical testing and intervention when neither is warranted by medical evidence. The law states that for Medicare "No payment may be made…for any expenses incurred for items or services, which…are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve functioning of a malformed body member." In my book, published in 2007, I used credible data to estimate that $25 billion per year are misspent on unneeded coronary artery stents in patients with stable heart disease. A large portion of the misspending is done by Medicare, which is wasting your tax dollars.

Two experts writing in the *New England Journal* note that The Centers for Medicare and Medicaid Services (CMS) has tried to deny payment for unnecessary services, but political pressure has thwarted the attempts.[2] One might suppose that the CMS would use scientific evidence in making their decisions; however, political pressure often seems to prevail. One example the writers use is the attempts in 2008 to deny payment for CT angiography in the face of evidence that the benefits of this imaging procedure were uncertain. Political pressure blocked the adoption of this evidence-based recommendation.

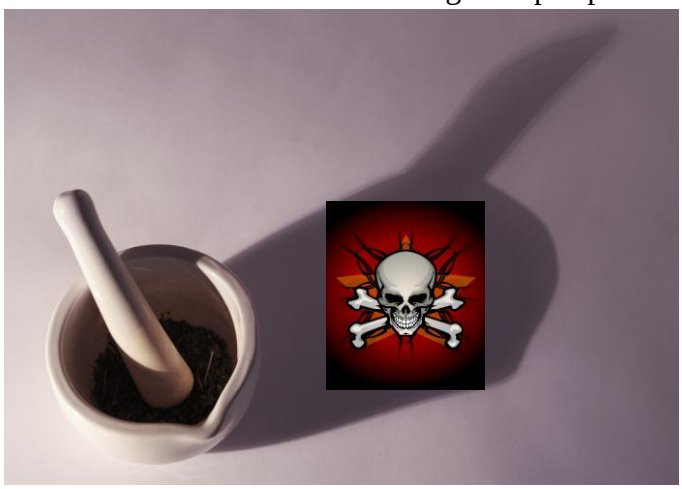
One of the problems with the idea of "reasonable and necessary" is the meaning that this phrase imparts. The writers point out that in 1989 CMS tried to define this phrase further as "safe, effective, non-investigational, appropriate, and cost effective." The idea that something had to be cost effective inflamed parts of the medical industry, thus cost-effective care was dropped. The writers go on to describe how political and industrial factions have blocked CMS's attempts to apply the "reasonable and necessary" clause.

One possible way to constrain medical care to "reasonable and necessary" is to force patients to always pay a portion of their care, hoping that they will then question whether the recommended care is in fact "reasonable, necessary and cost effective." It is unlikely that patients who pay nothing for their care are going to question whether that care fits this test. Finally, the writers note that medical technology marches on, determined to create new and expensive tests and procedures that are going to drain Medicare funds if something is not done to force your federal government to pay only for those interventions that are reasonable, necessary, and cost effective.

My fear in all this is that the medical industry has so effectively bought all necessary parts of our government that we ordinary citizens who pay taxes are going to continue to be victims of this industry. On a per person basis, we already have by far the most expensive medical care in the world; do we mean to make the industry even less accountable to the public for reasonable care.

Unregulated Compounding Pharmacies

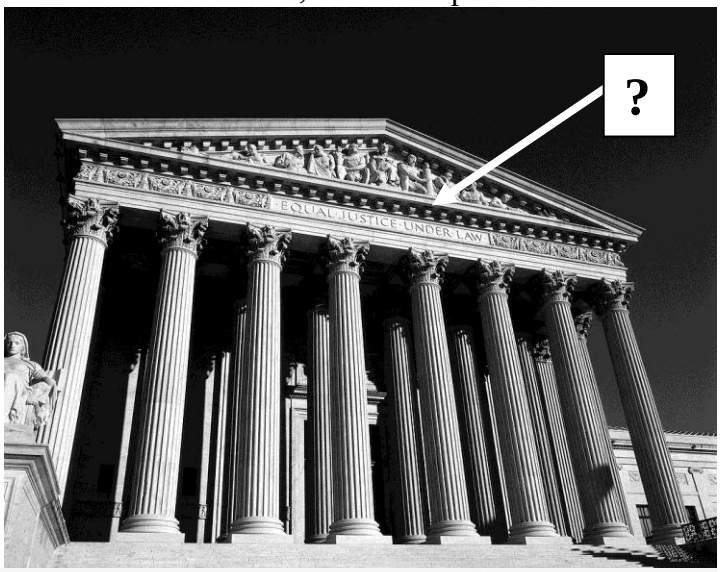
Besides the unspeakable tragedy of gun violence that unfolded in Newtown, Connecticut recently, one must note the earlier tragedy of 29 deaths and the sickening of 400 persons caused by fungal contamination of an injectable drug to treat back and joint pain.[3] The tragedy happened because the New England Compounding Center (NECC) produced several batches of the injection material that were contaminated. According to a perspective



article in the *New England Journal*, this happened because regulation of these compounding companies is lax. The federal government has left it to the states to regulate compounding companies, which historically have filled a gap for individual patients by performing small-scale operations to provide an

unusual drug formulation that was not commercially available from large-scale manufacturers.

Over the years, compounding companies have grown their business and were able to block a law in 2002 that forbade them from advertising, thanks to the Supreme Court, which viewed the law as blocking free speech. None the less, the FDA issued a 'compliance guide' for these companies, but as the perspective writer notes, NECC generally ignored compliance guidelines and state laws. For example, NECC did not have valid prescriptions for all the drugs it was compounding. It also skirted the law because the drug that caused all the deaths was available from Pfizer, but with a preservative.



The writer postulates that if the Supreme Court had not rejected key parts of the 2002 law that the FDA wanted, these people would not have been harmed and killed by contaminated drugs. Most recently federal courts have upheld the right of large drug manufacturers to advertise their drugs for off-label purposes – that is for purposes not approved by the FDA – under the guise of free speech.[4] I'm all for free speech, but when it leads to harm and death, then those involved must be held individually accountable.

The writer places some blame on doctors. He notes that high-quality evidence for use of such drugs as the NECC was compounding for joint pain is absent. Why were patients even being prescribed this drug in the first place? **As an empowered and cautious patient, you must thoroughly ask about the efficacy of any procedure or drug that involves invasion of your body.**

Over-diagnosis of Breast Cancer

To be an effective screening program for cancer that program must increase the detection of cancer at an earlier stage *AND* it must decrease the number of cancers detected at a later, life-threatening stage. Two MDs writing in the *New England Journal* deduce that breast cancer screening has increased the number of early-stage cancers detected, but has only 'marginally' reduced the rate at which women are found with advanced cancer.[5]

In women over 40 years of age, the incidence of early stage breast cancer in 1976 before widespread screening was performed was about 120/100,000 women, but this doubled to about 230/100,000 women in 2008 due to screening. During the same period the incidence of late-stage cancer detected was almost constant at about 100/100,000 women, with perhaps a drop of about 8/100,000 women from 1976 to 2008. If the early detection of cancer involved a substantial number of early-stage cancers that were going to develop into life-threatening, late stage cancers, then the incidence of late stage cancers would have also dropped much more.

The annual rate of death from breast cancer has dropped from 71 to 51 deaths per 100,000 women over the measurement period, but the authors make the case that very little of this decrease has been due to screening. They argue that improved treatment for a form of late-stage cancer called 'regional-disease (node-positive) breast cancer' has improved a lot during that period. At best, they argue, mammography screening has had a small effect on decreasing the death rate from breast cancer, whereas it contributed to about 70,000 over-diagnosed cases of breast cancer in 2008. This means that many women were treated for "breast cancer" that never would have harmed them.

The authors acknowledge that the situation is far from simple. Their goal is to point out that the value of mammography screening is questionable and that the harm from over-diagnosis is substantial. They end with the conclusion that for an individual woman the question of whether to be screened by mammography may have an uncertain answer. I am disappointed that with all the resources available to oncologists, they have not found a way to provide a clearer answer for women debating whether to be screened by mammography. In the meantime oncologists make a lot of money treating women who apparently do not need any treatment.

Painkillers Can Kill More Than Pain

I have two friends who in the past few years have lost young-adult children to accidental overdoses of opioid pain killers. One young adult received his prescription from a physician and the other received hers from a dentist. The fact is that each year about 16,000 Americans die of opioid overdoses.

Three experts wrote a viewpoint article in the *JAMA* entitled "Prevention of fatal opiod overdoses."[6] They point out that opiods cause respiratory depression, but that a dose of naloxone administered before death is inevitable can save the person's life. Apparently, there have been about 10,000 such rescues in the U.S. as of 2010. These authors are critical of the prescribers for their lack of willingness "to facilitate overdose prevention education and naloxone access." They provide a table listing the barriers to these undertakings and show which government agency should be responsible for removing the barrier. For example, one of these barriers is lack of public awareness of the risks of these drugs and the symptoms associated with an overdose. In their opinion, The Centers for Disease Control and The Food and Drug Administration should conduct a campaign to improve public awareness.

Discontinued Medications in Out-patients

A research article in the *Archives of Internal Medicine* by two MDs disclosed that in 84,000 records of medication-discontinuation, about 1.5% of the medications that had been discontinued by doctor's orders were still dispensed to patients.[7] About 1/3 of these were deemed to be high risk for patient harm. The authors note that better communication is needed between doctors and pharmacies where medications are dispensed. **Obviously, patients should be vigilant in understanding when a medication has been discontinued.**

References

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Answer to question this month: d) $180 billion (reference 8)