PSA

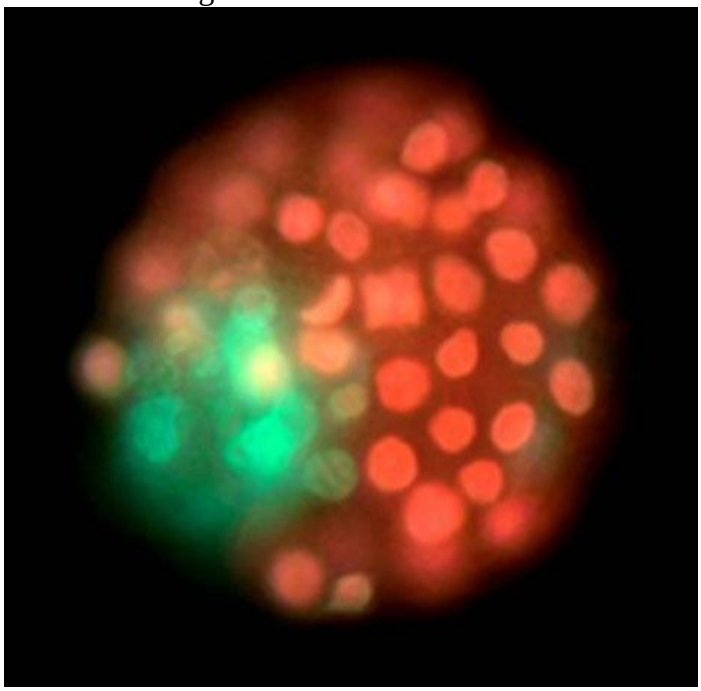
Patient Safety America Newsletter

December 2019 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: How many American adults have a friend or family member die in the last 5 years because they could not afford needed medical care? A) 1 million B) 5 million C) 15 million D) 25 million E) 35 million*

Stem Cell Therapies – Be careful

Three experts writing in the *JAMA* describe the problem of unethical marketing of some stem-cell therapies to hapless patients. The problem is that there are legitimate therapies and bogus therapies imbedded in this type of care. How does a wise patient distinguish whether a given treatment is effective? It seems that web-based attempts to disseminate information on which therapies are effective has not curtailed the fraud. Hundreds of unproven therapies are still being marketed. This is an area ripe for honest informed consent and shared-decision making.



Magnified image of a human blastocyst. Green area is the inner cell mass, the cluster of cells along the inner wall of the blastocyst that provide the embryonic stem cells. The red cells are trophectoderm. Photo courtesy of Gary Smith, University of Michigan.

In some states the standard for disclosure depends on what the reasonable patient wishes to know. In other states what is disclosed is up to the clinician; however, there is little to no enforcement of what should be communicated. Given the reality that patients are unlikely to know what to ask when considering stem-cell therapy, there is a need for rigorous guidelines centered on the patient's likely need to know. Enter the ISSCR (International Society for Stem Cell Research) to solve the problem of missing standards for informed consent outside clinical research – i.e. in clinical treatment. The article lists 13 topics that should be addressed to inform patients. In principle, the creation of such a standard will enable patients to file a malpractice action if they are not followed. Here is a link to the announcement from ISSCR. And here is the link to the 13 topics for clinicians to present to patients: ISSCR informed consent guidelines. A handbook for patients (decision aid if you will) that's a bit old (2008), but gives some important explanations is written at the patient level of understanding.

This all strikes me as an excellent example of how to deal with a controversial treatment. It would be a revolution if other medical disciplines followed this approach.

Surprise Medical Bills and Patient Harm

A viewpoint article captured in *JAMA Internal Medicine* from the New York Times and written by a Vox journalist describes the raw impact of out-of-network bills following an ER visit. She chronicles several stories of injured patients racking up bills reaching into the 10s of thousands of dollars. Perhaps the most troubling story is that of a mom whose daughter swallowed a potential poison. She was told by poison control to take her daughter

to the ER. She did not exactly do that. She took her daughter near the ER, and then engaged her in watching a movie in her vehicle until she determined if the little girl showed any signs of poisoning. It seems that she did not.

There are several states that have protected patients from surprise medical bills and there is some hope in Congress for a national bill. Here is a link to the bill that was introduced, then referred to various committees in the House in late June: HB 3502. It seems that for now no actions have been taken. The American Hospital Association is lobbying this bill and 2 like it in the Senate: S 1266 and S 1531. **You may want to lobby.**

In a comprehensive study of millions of privately insured patients experiencing an in-patient admission to a hospital or an ER admission from 2010 to 2016, four experts found that the percentages of out-of-network bills associated with admissions increased from 26% to 42% (in-patient admission) and from 32% to 43% (ER admission). The associated average patient responsibility for payments increased from $804 to $2000 (in-patient admissions) and $220 to $630 (ER visits). Clearly, this practice, at least as of 2016, was growing rapidly. The authors conclude that these increases are likely to place a financial strain on patients.

In a somewhat related survey by Gallup and West Health, it was estimated, based on nation-wide results, that 34 million Americans knew of someone, either a friend or family member, who died in the past 5 years because they could not afford medical care. The burden of unaffordable care was greatest for poor and non-white families.

Please write your Congress-person, appealing for changes in American healthcare that eliminate shocking medical bills and the causes that lead people to die when they are unable to afford medical care. We cannot claim to be one of the developed nations of the world until we do something about the way healthcare is delivered and paid for in this country.

Dangers of Blood Pressure Medications

A Veteran's Administration study of about 4,000 hospitalized men with high blood pressure of average age 77 years was conducted to determine if increasing antihypertensive (blood-pressure reducing) medications at discharge would be helpful to the patient. In general, even when the patients already had well-controlled blood pressure, more antihypertensive medications were prescribed. This is a common practice, but does it help the patient? Short term outcomes assessed were 30-day hospital readmission, serious adverse events and cardiovascular events. The long term outcome was systolic blood pressure reduction measured 1 year after discharge.

The investigators discovered that intensifying antihypertensive medications caused short-term harm, including hospital readmission and serious adverse events, and had no long term value, including no reduction in cardiovascular events. The possible reasons for this somewhat unexpected result are many, but the bottom line is that patients and those who advocate for them must ask the rationale for any additional medications that are prescribed when a patient is discharged. If the patient did not need it while hospitalized, then why should he need it after discharge?

Mistreatment of Surgical Residents

A large team studied the mistreatment of 7,400 surgical residents from 262 residency programs in the U.S., reporting their findings in the *NEJM*. They used a modified, standard instrument to assess 'burnout inventory.' Of the residents surveyed, 32% reported gender discrimination, 17 % reported racial discrimination, 30 % reported abusive behavior, and 10 % reported sexual harassment. Patients and family were the most frequent source of gender and racial discrimination, whereas attending physicians were the most common source of sexual harassment and abuse. Women were much more often the victims than men. Overall, 38% reported weekly burnout symptoms and 4% had suicidal thoughts. There was a large variation in mistreatment among the surgical programs (0 to 67%).

I returned to work after my father's death to find that nobody was willing to discuss his case with me…My grand rounds were cancelled out of fear of what I'd say, and I was advised to never speak of the circumstances of my father's death should I want reasonable career options in the city.
-Letter to me from a cardiology resident

I was surprised and a little disappointed that patients and family were most often behind gender and racial discrimination. It seems to me that surveys like the one reported should be mandatory for all surgical residencies and made available to the public and young doctors seeking a residency. I suspect that at least the attending physicians would clean up their act. I don't know how to get patients and families to behave respectfully.

A partial solution to physician burnout may lie in professional coaching. A team of 5 experts report in *JAMA Internal Medicine* that up to 6 coaching sessions resulted in reduced stress for a group of 88 doctors in the following specialties: medicine, family medicine, and pediatrics. The study was conducted at Mayo Clinics in various states.

Overall burnout after 5 months decreased by 20% in the intervention group and increased 10% in the non-intervention, control group. Since burnout is known to have adverse effects on patient safety, strategies to mitigate burnout must matter to patients. The coaching sessions began with a 1-hour session and these were followed by five 30-minute sessions every 2-3 weeks. All sessions were conducted by telephone and the total cost for each series of sessions was $1400. The fundamental question left unanswered is whether the positive effects of the coaching lasted or would have to be reinforced with additional coaching over the physician's years of practice. The investigators consider their study to be a pilot study.

Prevention of Venous Blood Clots

A new guideline has been published to improve prevention of venous thromboembolism (VT) in patients that are or have recently been hospitalized. About half of all VTs happen in association with hospitalization and 10% of these are pulmonary embolisms that may be fatal. A few of the overall recommendations may be of interest to patients:

- Prophylaxis of VT during hospitalization may be warranted, but not after discharge
- For pregnant women with acute VT two specific drugs were recommended
- There were several other complex recommendations

Bottom line is for patients to ask if a guideline is being followed to prevent having a clot during hospitalization. Apparently, this guideline differs from others already published. There are many patients that do not need precautionary treatment or testing, so the clinician must carefully decide who would benefit.

Forced Sexual Initiation and Women's Health

A group of investigators in Massachusetts studied the prevalence of forced sexual initiation (woman did not agree voluntarily to have intercourse) in a group of more than 13,300 US women aged 18 to 44 years old. Their goal was to determine if forced sexual initiation has an adverse effect on a woman's health. Of the surveyed women, 6.5 % reported forced sexual initiation. The investigators point out that if this incidence were extrapolated to the US population of women in this age group, it would come to 3.3 million women. Forced sexual initiation occurred at average age of 15 ½ years, whereas for unforced initiation, the average age was 2 years older.

Compared to voluntary sexual initiation, the women with forced initiation were more likely to experience the following adverse conditions: unwanted first pregnancy or abortion, endometriosis, pelvic inflammatory disease, illicit drug use and fair-to-poor health. Poor women were more often the target of unwanted first sexual encounters. Other studies have found higher rates of sexually transmitted diseases and HIV in women submitting involuntarily. The investigators suggest that there are no evidence-based approaches to solve this problem at the public health level.

The solution as my wife and I were rearing 3 children was to absolutely limit access to gatherings that could lead to unwanted sexual activity. Supervision by responsible parents was essential at any home our kids visited. At times we were not popular. When teenagers came to our house to swim, more than a few T-shirts were given to young ladies to wear over 'inappropriate' bikinis being worn by them. If there is no responsible parenting, then I am not sure what society might do to curtail sexual violence on young women.

FDA and Drug Safety Communications (DSCs)

Once a drug is approved by the FDA for marketing, that agency has the task of communicating subsequent, emerging information about safety concerns to doctors. In a research letter, investigators describe their findings regarding how the FDA comes to know that a DSC is warranted. The safety signal, of which there were 228, may come from the FDA's Adverse Event Reporting System (FAERS) (n=87), from results of randomized clinical trials (RCTs) (n=81), or observational studies (n=60). The study encompassed DSCs issued in the years 2010 through 2018. The average number of years between initial approval and issuance of a DSC was just over 12 years.

The researchers point out that the FDA relies heavily on the FAERS voluntary reporting system, which is well known to involve significant under-reporting of actual adverse events. Despite recent legislation suggesting replacing RCT data with real-world data, that does not seem to be happening, yet. Given that about 1/4th of approved drugs eventually have a DSC issued, and that the average time to issue such a warning is 12 years after first approval, one must surmise that millions of people may be exposed to potentially toxic drugs before a DSC is issued**. As a patient, it's never a bad idea to ask how long a drug prescribed to you has been on the market and whether a DSC has been issued. You are not a guinea pig.**

2019 Report on Medical Overuse

In the 'Less is More' section of *JAMA Internal Medicine*, researchers provide an annual report of those procedures that have been found to be overused in the U.S. healthcare industry. The investigators distilled 1500 candidate articles down to the best (n=117). Some of the identified overuse concerns were as follows: MRIs and CT scans continue to turn up incidentalomas (inconsequential findings leading to worthless evaluations) in 30% of the scans, 9% of women dying of stage 4 breast cancer are still getting mammography screens, and CT lung cancer screening of low risk patients leads to harm. Furthermore, urgent care clinics over-prescribe antibiotics, too many opioids are still being prescribed for non-cancer pain, and oxygen supplementation is being given to patients with normal oxygen saturation levels.

The investigators note that physicians are being handed more work, they may be influenced by various perverse incentives (drug company payments or fee-for-service) and burnout continues to be prevalent. They encourage a restructuring of medical delivery, allowing for doctors to spend more time with patients, thereby serving them better on many levels.

Colon Cancer (CC) Screening Guidelines

An MD reports that the American College of Physicians (ACP) has undertaken the task of reconciling CC screening guidelines. Guidelines were considered from Canada, the USPSTF (U.S Preventive Services Task Force), American Cancer Society, and other organizations. The major controversies seem to be the age at which screening should begin (45 to 60) and the frequency of stool testing (1-3 year intervals). The ACP recommends starting screening at 50 years of age and stool testing every 2 years, but they also recommend shared-decision making between clinician and patient, noting the importance of patient preferences.

Note that these guidelines apply to people at no increased risk for colon cancer. If your risk is above normal, then more frequent screening would be appropriate.

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Answer to question: Best answer (E), Gallup & West Health Survey, 2019