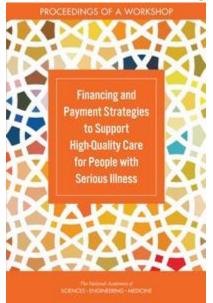
<u>Patient Safety America Newsletter</u> http://PatientSafetyAmerica.com August 2018 John T. James, Ph.D.

<u>*Question*</u>: In 2017, how much did the Department of Justice recover as a result of its healthcare fraud investigations? A) \$500 million B) \$1 billion C) \$1.5 billion D) \$2 billion E) \$2.5 billion F) \$3 billion

Book Review: Financing and Payment Strategies to Support High-Quality Care for People with Serious Illnesses. National Academy of Medicine

The battles over how to deal with Americans that need long-term care continue to rage. The Affordable Care Act blocked insurance companies from charging a



premium or denying health coverage for Americans with serious preexisting conditions, but that rule is under attack current by the administration. The NAM convened the third in a series of workshops to find ideas for financing and improving the quality of care for people with serious illnesses. This book and others like it are

available for free download from the National Academy Press.

Books from the NAM are targeted to experts in the field, so the casual reader will find them less than exciting. However, valuable insights can be gleaned from the summaries presented in this book. I'd suggest the reader scroll to pages 4-7 and read the suggestions made by experts. Below I'll mention those suggestions made by three or more of the experts:

- Adopt financial plans that incorporate social services and improve integration of the patient's physical, psychological and spiritual needs.
- Change Medicare's piecemeal approach to care by financing integration of care.

- Impel state and local entities to develop programs that are innovative, and improve quality, accessibility, and affordability of care beyond services paid for by Medicare and Medicaid.
- Develop quality measures that are not burdensome to providers, but hold providers accountable for care of the seriously ill.

I think there are some things missing from the list presented by the experts. For one, teams of experts should visit the health-care systems in other developed countries to learn how care is done there and how it is financed. We do not have to reinvent the wheel. Another thing missing is to incentivize young doctors and nurses to specialize in geriatrics. This would include lessons in what has been called "<u>caring science</u>." One thing I liked about the book was that the workshop was started by listening to patient stories. 4 stars.

Depression by Prescription

I have a collection of books by MDs that are critical of the way care is delivered in the U.S. One is called *Death by Prescription* and another is *The Truth about Drug Companies - How They Deceive Us and What to do about It.* In the wake of the high-profile suicides of Anthony Bourdain and Kate Spade, there is growing concern about the causes of such tragic events. The <u>CDC reports</u> that between 1999 and 2016 the suicide rate rose in all but one state. In half the states the rates went up 30% or more, and more than half the people committing suicide had no known mental illness. The number of deaths due to suicides was almost 45,000 in 2016. Obviously, it is important to understand the causes of suicide.

With that goal in mind, a team of 3 investigators set out to determine the prevalence of <u>depression</u> associated with the use of prescription medications. Their population included more than 26,000 people of average age 46 years. The prevalence in use of medications with depression as an adverse effect increased slightly from 35% in the 2005-6 period to 38% in the 2013-4 period. The prevalence of depression estimated in those using 3 or more medications with depression as a side effect was 15%, whereas those not using any such medications was 5%. The prevalence of persons using 3 or more depression-associated medications increased from 7% in the 2005-6 period to 10% in the 2013-4 period. The most commonly used medications that have depression as a potential adverse effect were blood pressure medications, proton-pump-inhibitors, analgesics, and hormonal contraceptives.



Current recommendations call for clinicians to screen adults for depression and follow up with needed services if it is found. The study may have underestimated the prevalence of use of medications with depression as a side effect because some of these are available over-the-counter, hence no prescription would be recorded in the database. Patients must know if depression is a side effect of any of their medications. As for depression screening if you or someone you are caring for may be depressed, <u>tools</u> are available for selfscreening for depression.

Who Does Your Informed Consent?

The Supreme Court of Pennsylvania just handed down a ruling that only the physician doing an invasive procedure may provide the information to the patient to elicit the patient's informed consent. Three <u>experts</u> writing in the *New England Journal of Medicine* took exception to this ruling, arguing that well trained subordinates should be allowed to provide detailed information to the patient after the clinician generally describes the patient's options and makes a preliminary recommendation. The physician should later ensure that all the patient's questions have been answered and that the patient is secure about the decision. The idea is to reduce the time that a busy clinician must devote to delivering information to the patient.

Given the well-known abuses of informed consent in hospitals, I am going to side with the Pennsylvania Supreme Court. If the law gives physicians any wiggle room for abuse of informed consent, then that wiggle room may be exploited. For example, who is going to decide that a subordinate is qualified to discuss informed consent with a given patient. Some patients will want little or no information, whereas, others will insist on complete information on their options. I just returned from a meeting where a physician friend told me that his surgeon proposed robotic surgery for prostate removal, but there seemed to be a high incidence of side-effects with this procedure. So the wise physician checked around, finding that a new laser procedure was available that was much better than robotic surgery. When the doctor-patient asked his laser surgeon why he was not informed of that option by his local urologists, his surgeon replied it's not done in many places. My friend had not been given sufficient information to make an informed decision. His research saved him from risk of permanent complications.

The authors of this article did note that the doctor performing the invasive procedure should retain ultimate responsibility that informed consent be properly done. The authors did not mention decision aids for patients. This could save much of the doctor's time by orienting the patient before discussions begin in which the doctor elicits the patient's preferences, and then asks for the patient's decision without any preconceived recommendation from the doctor. Of course, if the best procedure is not performed by the doctor, then he has a perverse incentive not to reveal that information

Until informed-consent laws thoroughly protect the autonomy of patients to control what happens to their bodies, patients must do all they can to inform themselves of their options, along with the risks and benefits of each.

Cancer Screening and Over-Diagnosis Harm

The concept of over-diagnosis is complicated, but I offer here a relatively simple explanation that patients should understand before they agree to cancer screening of any kind. This understanding is essential to protecting yourself from harm caused by over-diagnosis. I base my discussion on a "special article" appearing in *The Annals of Internal Medicine*. A team of authors set out to explain <u>over diagnosis</u> to clinicians, but their description is adaptable for understanding by nonmedical folks.

Their definition is as follows: "We advocate defining over-diagnosis as the detection of a (histologically confirmed) cancer through screening that would not otherwise have been diagnosed in a person's lifetime had screening not been done." "Histologically

confirmed" means that a pathologist has diagnosed the cancer from properly sampled tissue and microscopic inspection of stained tissue slices. The definition of "over-diagnosis" means that the screening has disclosed a cancer, but the patient is likely to die of another cause before the cancer would have become clinically detectable.



The authors use an extreme example of a 115year-old man PSA-screened for prostate cancer. He has his cancer confirmed by biopsy and the pathologist estimates that it would be clinically apparent in 6 years (lead time). The chances the man will live that long are virtually zero, so the screening led to over-diagnosis and did not contribute to the man's health. The authors point out that many factors affect lead time, including age of the patient, health status of the patient, and sensitivity of the screening test. They advocate use of decision aids and shared-decision making facilitate to patient understanding of when to be screened.

Do You need an Electrocardiogram (ECG)?

Some years ago it was common practice to use a resting ECG on older adults as a screen for heart disease. More recently, this practice was discounted during the "Choosing Wisely" campaign. The US Preventive Services Task Force has just released guidelines that you should know about if you are considering ECG screening. If you have a low risk of a cardiovascular event and no symptoms of possible heart disease (less than 10% in the next 10 years), then screening with an ECG is not recommended. It is very unlikely that any result from the ECG will lead to a change in your treatment. If you are at intermediate or high risk of a cardiovascular event, then the benefits vs. the risks of screening cannot be determined from the data available. It's not clear whether a single, random ECG in low-risk, middle-aged adults would be useful as a baseline ECG against which changes may be identified. One might suppose that the prevalence of heart disease and the widespread use of ECGs would have led to a conclusion about folks in the higher-risk groups. It hasn't. If you want to know your risk of a cardiovascular event in the next 10 years, you may use this site: <u>Risk</u>.

Overuse of Antibiotics and Surgery for Sinus Conditions

A group of investigators looked at sample records representative of roughly 3,700,000 outpatient visits during 2016 in which antibiotics were prescribed for sinusitis. Guidelines from The Infectious Disease Society of America recommend only 5-7 days of treatment for ordinary bacterial sinusitis; however, 70% of the prescriptions for this disease were for 10 days or longer. The authors note that these deviations from guidelines represent an opportunity to improve antibiotic stewardship. The message to patients is to ask "why" if your prescription specifies more than 7 days when being treated for acute sinusitis.

There are some new insights into the overuse of invasive procedures into your sinuses from Art Curtis, MD that you should read if endoscopic sinus surgery is recommended for your treatment: <u>Right Care Alliance</u>. Dr. Curtis generalizes his observation to suggest widespread overuse of invasive procedures.

Fecal Microbiota Treatment for C. diff.

Infection with *C diff* is a major health problem; according to the CDC, it kills about 29,000 people per year in the U.S. Something more than a dozen experts wrote "correspondence" to the New England Journal of Medicine in which they compared their results in treating C diff infections using two treatments: fecal microbiota transplantation and oral metronaidazole. Twenty adult patients were in the trial, 11 in the drug group and 9 in the microbiota group. The drug was given 3 times per day for 10 days, whereas the microbiota was given once by 60 ml enema. Both treatments worked to some extent; however, the microbiota treatment clearly worked better. Seventy days after treatments, the full cure for the drug treatment was about 45%, whereas the microbiota treatment had an 80% cure rate. Note that this is no more than a pilot study because of the small number of subjects. The authors report that a "Phase 3" trial is now underway.

Department of Justice (DOJ) Investigations of Hospital Compliance

In 2010 the DOJ began an investigation of hospitals' primary use of Implantable Cardioverter-Defibrillators (ICDs) that did not meet the standards of

the Centers for Medicare and Medicaid Services (CMS). This was initiated by a whistleblower. In 2007 the portion of inappropriate use of ICDs was about 24%. During the study period, which extended to 2015, there was a 14% absolute decrease in ICD implants. Hospitals that settled with the DOJ showed a slightly larger absolute decrease in non-evidence-based implants.

In perspective, it is clear that the fear of accountability for overuse of ICDs impelled the decrease in overuse. The 500 hospitals that settled with the DOJ parted with \$280 million. In 2018 the guidelines were updated by an expert panel. These included a requirement for shared-decision making. Such happenings underscore the need for patients to ask if their care is following a medical guideline. According to the American Heart Association, the cost of an ICD implant is about \$40,000. In my opinion, this is a lot of temptation to overuse of these devices.

Screening for Osteoporosis

guideline for А osteoporosis screening announces the importance of this illness by estimating that 12 million Americans over 50 years old will suffer from this disease by 2020. Osteoporosis increases the risk of hip fractures and may cause chronic pain and disability. Personally, I know several women with this illness. The goal of the guideline is to prevent fractures due to osteoporosis.

After careful examination of the accumulated data and studies, the US Preventive Task Force made the following recommendations:

- Perform bone measurement screening in all women over 65
- Perform bone measurement screening in women over 50 who are at risk for osteoporosis
- In men there is insufficient evidence to make a • recommendation for screening

The guideline reports that the risks of harm from medications to limit osteoporosis are small. A decision aid is available from the Mayo Clinic for dealing with osteoporosis risks, broken down by categories as follows: low, elevated, and high risk. Of course, such an aid does not substitute for a conversation with your physician about your risk and appropriate screening. The National Institute of Health has a page to help patients understand the meaning of bone density testing.

Health Effects of Environmental Guidelines

As a professional toxicologist specializing in the harm from air pollution, I am well aware of the health risks that come to people living in areas with high air pollution. Two experts ventured to estimate the number of deaths that may accrue over 10 years if current proposals to relax environmental guidelines are enacted. Apparently, the current administration favors industry. The key point writers make is that the harm will result in 80,000 premature deaths while the gain will be limited to very few industries.

For example, the plan is to repeal the Clean Power Plant rule, which allows states to choose how they constrain the emissions from their power plants to achieve goals to limit climate change. A state may choose to switch from coal to natural gas power generation or adopt renewable energy sources. Another part of the plan is to reduce restrictions on emissions from glider (rebuilt) trucks that fail current standards.

Coupled with an attack on these environmental rules, the administration is mounting an attack on the science behind the rules that predicts the number of lives saved. Basically, they wish to disregard observational studies as part of the science that supports the rules unless individual health records are released. This would be impossible given the confidentiality required to protect health records from being disclosed. Fortunately, it seems, the rules could not be changed until there is another administration in place. One would hope that that administration will support public health over the special interests.

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Answer to question: (E) \$2.6 billion, reference: https://jamanetwork.com/journals/jama/article-abstract/2686773