

# Patient Safety America Newsletter

October 2018

<http://PatientSafetyAmerica.com>

John T. James, Ph.D.

**Question: How many doses of hydrocodone did Phama ship to a single pharmacy in a town of 400 people?**  
a) 100,000    b) 1 million    c) 10 million    d) 100 million

## Book Review: **Dopesick – Dealers, Doctors, and The Drug Company That Addicted America**

Author: Beth Macy

Ms. Macy weaves a troubling tale of the seepage of opioid addiction into the Shenandoah Valley, starting with areas near her home – Roanoke, Virginia. The recipe for disaster that she describes requires several ingredients to become a poisonous soufflé. The ingredients include a vulnerable population, a drug company determined to market their dangerous product, doctors’ misplaced trust of marketing data, cellphones for business, interstate highways for access to big cities, clueless politicians, and government agencies and investigators that looked the other way for too long.

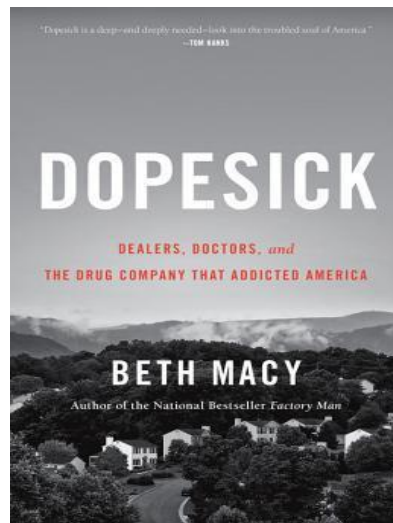
I have sat with parents of two young adults that died from accidental overdose of opioids. In a sense, Ms. Macy told their stories. One died of pain-mill overprescribing following a car accident, and the other died because a dentist prescribed opioids for pain after a tooth extraction, not knowing that the young woman who just had a tooth extraction had a history of opioid addiction. There are many ways that such drugs can seep into the fabric of our lives, tearing seams and burning irreparable holes.

Ms. Macy climbs into the fabric of this tragedy, finding heroes, victims, and villains galore. She traces their pathways from the hills of western Virginia through the small towns of the Shenandoah Valley, and then over to the big cities – New York, Philadelphia, and especially Baltimore, where the

“big operators” find endless supplies of heroin, a cheap, deadly substitute for prescription opioids that start many on the path to heroin addiction. Networks of suppliers, movers, dealers, buyers, user-dealers and plain-users function like a neural network, carrying the pain of those at the end upward through channels where big money is made. The top guys are guaranteed customers because the users are afraid of becoming “dopesick” through withdrawal symptoms. The parents of the young experience pain when the day comes that they realize their child is a drug addict, and then years of expensive detox attempts follow.

The answers to this stain on our fabric are not simple. We are not following science, which shows that drugs that stop cravings for addictive drugs have proven effective in “medication-assisted therapies.” Many would claim that putting users and low-level dealers in jail is not going to shrink the demand. There is hard data for this. Heroics of a few dedicated cops

have stalled a few operations, but there are always others willing to fill the void. Ms. Macy asks the reader to ponder many “why” questions for which there are no simple answers. For some the opioid epidemic has come to an end; they are dead. Their survivors champion smart changes, but their pleas are heard slowly if at all. Ms. Macy’s writing and story-telling are excellent. She does not go easy on those who are to blame and have refused to acknowledge the epidemic. She is critical of doctors who overreact to the management of pain, leaving patients to bear the unbearable. 5+ Stars.



## *Alternatives to Opioids*

In what can only be described as fortunate coincidence, I was sent an info-graphic called “Managing Pain with Alternative Therapies.” It was prepared by the non-profit RAND Corporation and appears to be well referenced and simple to decipher. Have a look: [RAND Corporation](#).

## *Shared Decision-Making Required by Medicare*

Shared-decision making (SDM) is the process by which the patient is given all options and their risks and benefits while engaging in a discussion about her preferences with the clinician. Medicare has required this in the case of lung cancer screening with low-dose CT scans and for left atrial appendage closure in the face of atrial fibrillation. Now, Medicare has required SDM when a patient is considering an implantable cardioverter defibrillator (ICD) as a primary prevention for sudden cardiac death. [Three experts](#) express their view in the *JAMA* that requiring SDM in the case of ICD implantation may take SDM into “uncharted territory.”

The experts point out that SDM can often reduce costs and lead to better patient satisfaction, especially when clinicians have a financial incentive to perform more expensive procedures (usually more invasive). Decision aids may be used in the SDM process, but some argue that these are not sufficiently mature in many cases. Subtle changes in the way information is presented may have a strong effect on patient preferences. The authors contend that the Centers for Medicare and Medicaid Services (CMS) should develop principles for whether to require SDM or not. The writers note that SDM may cause a burden for clinicians and hospitals.

In my opinion, ethical principles centered on patient autonomy, dictate that patients be given balanced SDM for cases where there are significant risks and benefits for the various options. For example, a procedure that offers clear benefits and little risk does not need SDM. This might include cardiac ultra sound, an exercise stress test, or drugs for hypothyroidism. Prescribing potentially dangerous drugs, such as fluoroquinolone antibiotics, should require a SDM process. **As a patient, if you are uneasy about where your treatment may be going, you should ask for formal SDM.**

## *Clinical Practice Guidelines*

According to the Institute of Medicine (now the National Academy of Medicine), clinical practice guidelines are “statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.” [An expert](#) traces the recent history of such guidelines and suggests future changes for the better. He notes that in 2018, using the definition above, The National Guideline Clearing House reduced to 1440 the number of guidelines, removing those that were not based on a systematic literature review. A pressing issue is that free access to the National Guideline Clearing House database can no longer be offered because it lacks funding. This is a serious barrier to the 2.6 million visitors to the site each year.



Other issues that need addressing include trustworthiness of each guideline. Are they biased by special interests, and when are they too old? In my opinion, versions of the guidelines should be adopted for reading by patients. We can get very smart when our lives are on the line – if we are given the chance to read trustworthy material about our care going forward. This, of course, may be captured in decision aids. A key point is that the clinical practice guidelines should guide decision aids for patients. **A smart patient will ask what guidelines apply to his medical care, and then do all he can to understand these.**

## *Aspirin Alone or with Clopidogrel (Plavix)?*

Speaking of [systematic reviews](#), an interesting one was published this month in the *JAMA*. Let’s suppose you are a patient with significant risk of heart disease or a history of

cardiovascular disease, but have no stent. Guidelines call for use of low-dose aspirin to reduce the risk ischemic events (reduced blood flow to tissue due to obstruction in an artery). Should the anti-platelet-aggregation drug clopidogrel be added to your drug regimen? The clear answer is “maybe.” Here are the data, expressed as the risk of an event per 1,000 patients:

Adverse Event	Aspirin + clopidogrel	Aspirin alone
Cardiovascular death	37	37
Heart Attack	45	58
Ischemic stroke	63	86
Major bleeding	30	21

The data came from 15 randomized trials, involving all most 34,000 hospitalized patients treated since 1998 in a variety of countries. The mean age was 64 years and a variety of ethnicities were represented. The authors note that a collection of guidelines now recommend up to several months of clopidogrel + aspirin rather than aspirin alone following a cardiovascular event. They note that patients with a history of bleeding problems were excluded from the trials.

The warning here for patients is to make sure that if you are prescribed clopidogrel, you know when to discontinue its use. The late Barbara Starfield, MD, a champion of patient safety, was left on clopidogrel too long and, and according to her physician husband, may have died as a result of this [oversight](#).

### *Save a \$Billion on Drugs*

[Four experts](#) wrote about the estimated savings Medicare could realize by requiring that generic components that are in brand-named combination drugs be prescribed rather than prescribing the brand-named drugs themselves. The investigators looked at 1500 drugs, finding 29 that were branded combinations. Of the 29 combinations analyzed from 2016 data, 20 were available as identical-dose generic components, 3 were available at different generic doses, and 6 were available as generic equivalents. The respective savings were as follows: \$235 million, \$219 million, and \$471 million. This comes to \$925 million. This is not quite a billion dollars, but it is close. **Always ask your doctor if you are prescribed a branded drug whether some combination of generic drugs is**

**available as an equivalent substitute.** Drug companies already get too much of your money.

### *Healthcare Waste in Washington State*

In what I would call a daring investigation, two experts decided to estimate the amount of waste in healthcare in Washington State from July 2015 to June 2016 using an “all payer” database and search tool capable of identifying low-value care. The authors define this as follows: “Low-value services are defined as medical tests and procedures that have been shown to provide little clinical benefit and have the potential to cause harm.” The procedures and expenditures were broken into necessary (\$503 million), likely wasteful (\$24 million), and wasteful (\$258 million).

The [unnecessary tests](#) were characterized as follows: “Almost all of the wasted expenditure was driven by 11 of the 47 low-value care practices identified: Frequent cervical cancer screening, preoperative baseline laboratory studies prior to low-risk surgery, unnecessary imaging for eye disease, annual electrocardiograms or cardiac screening in low-risk asymptomatic individuals, prescribing antibiotics for acute upper respiratory tract and ear infections, prostate-specific antigen screening, population-based screening for 25-hydroxyvitamin D deficiency, imaging for uncomplicated low back pain in the first 6 weeks, preoperative electrocardiograms, chest x-ray and pulmonary function testing prior to low-risk surgery, cardiac stress testing and imaging for uncomplicated headache.”

There is a message for patients, although it may be difficult to implement. Ask about the need for any of these procedures when you are about to be subjected to one of them. The authors opine that these procedures are deeply ingrained in current practice. It may be challenging to discard long-standing practices. If one were to do a rough calculation, noting that Washington State has about 2.3% of the U.S. population of 325 million, then the estimate for the nation in terms of wasted cost would be \$258 million X 100/2.3 = \$11 billion.

### *Diagnosis and Treatment of C diff*

*C diff* is a potentially lethal bacterium that has damaging effects on the GI tract. New guidelines from two [respected expert groups](#) chart the pathway from symptoms (watery diarrhea)

through diagnosis and treatment options. There is a weak recommendation based on low-quality evidence to do testing to confirm suspected *C diff* infection. If I were a clinician, I'm uncertain what I'd do with that recommendation. Depending on whether the illness is fulminant or not, the treatment should involve antibiotics (vancomycin, fidaxomicin, metronidazol) alone or in combination in routes of administration that depend on the conditions of the patient. For a recurrence, another round of antibiotics may be used (weak recommendation, low quality evidence); however, if these fail, then a strong recommendation based on moderate-quality evidence was given for use of fecal-microbiota transplantation.

I had two purposes in summarizing this *JAMA* guideline synopsis. One is to inform readers that there are guidelines for *C diff* diagnosis and treatment. The second is to underscore the difficulty clinicians must experience when trying to apply such guidelines to specific patients.

### *Hiding Unique Device Identifiers*

A [team of experts](#) wrote about the core problem of unique device identifiers (UDIs) that were mandated by the FDA in 2013. The idea is that if a device is creating a problem, then a UDI can quickly point to the specific devices creating the problem. Issue solved, right? Wrong. The UDI is not present in electronic health records nor in administrative claims data. This substantially impedes the ability of the FDA to discover ongoing harm. Between 2005 and 2014 seven devices were delayed in recall by the FDA, costing Medicare \$1.5 billion. Since 2015, meaningful-use requirements have stipulated recording of the UDI in electronic records, but apparently that is not enforced. The space for the UDI is often blank.

These shortcomings have obvious, important consequences for patients. Current data on a specific device may be unavailable, making comparisons by patients difficult. If a device has been recalled, it will not be easy to identify if it is

in your body. **Patients should insist that the UDI of any device put in their body be recorded in their electronic medical record.**

### *Pass the Pot and Small Bottle*

For those readers who [drink coffee](#) in just about any form, be rest assured. A recent study shows that the risk of death is inversely related to coffee consumption up to 8 cups per day. A half million coffee drinkers of average age 57 years in the U.K were surveyed and their mortality followed for 10 years. Compared to those who drank no coffee, the reduced mortality in those drinking 1 to 8 cups per day ranged from 8% to 16%.

A study published in *Lancet* reported that worldwide the health [effects of alcohol](#) are such that best health is achieved if no alcohol is consumed. In my opinion, the authors misinterpreted their data, which I asked for directly from the corresponding author. At an average of 1 drink per day, the average increased mortality risk compared to no drinking was +0.6 percent, but the uncertainty was **-2.5%** to +3.9 percent. At 2 drinks per day the increased mortality averaged +7.1% with an uncertainty range of +3.4 to +11.4 percent. I interpret this to mean that the study did not demonstrate an adverse effect at 1 drink per day, but did at 2 drinks per day.

#### **Patient Pages**

[Scabies](#)

[Cervical cancer screening](#)

[Injury around the eye](#)



NATIONAL  
QUALITY FORUM  
MEMBER

Find past newsletters:

<http://patientsafetyamerica.com/e-newsletter/>

Answer to question: best answer is (c) 10 million, actual number was 9 million, Page 169 in Dopesick