



Patient Safety America Newsletter

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John T. James, Ph.D.

Question: The DISCOUNTED price for Advair in the US is \$155. What is the price in France?

- a) \$35
- b) \$55
- c) \$75
- d) \$95
- e) \$115

Will Multi-Drug-Resistant Bacteria Win?

First, Multi-Drug Resistant Organisms (MDROs) are those strains of bacteria and fungi that have adapted to being attacked by common antibiotics to the point where those weapons against them are ineffective. Make no mistake, we are in a war with these microscopic threats. We cannot win the war using weapons of the past any more than modern wars can be won with muskets and cannon fire. Thus, the question on the table is what new weapons have been developed recently to fight the war against MDROs. The answer is not encouraging.

Four investigators asked what new antibiotics were approved by the FDA in the years from 2010 through 2015 to augment our armaments against bacteria.¹ They note that many large drug companies have not pursued development of new antibiotics because of anticipated poor return on investment and the technical challenges of developing new antibiotics. During the years in question, eight new antibiotics were FDA approved. This might seem like good news until one looks, as the authors did, at the impact these have had on improving patient care.

Seven of the 8 drugs were approved based generally on the demonstration of non-inferiority to the comparator drug, ideally the standard-of-care antibiotic. Non-inferiority means that the tested drug is as good as the standard drug or better within some predetermined margin of difference, say 10 percent. The authors pointed out that none of the drugs were tested for the most relevant endpoints: mortality and disability. In fact, some of the endpoints were subjective, based only on clinician judgment.

So, what's the problem with drug companies creating "me-too" drugs that are not demonstrably better than existing drugs? Money, dirty, rotten money.



The cost ratios for the new drug vs. the standard drug, with one exception, were from 2 to 6,000 times the standard antibiotic cost. The costs for a new treatment protocol ranged from a few thousand to a few tens-of-thousands of dollars. Apparently, none of these drugs have sold well. The authors suggest this may be due to the "poor clinical evidence supporting their use."

The authors conclude that the *quantity* of new antibiotics developed and approved is "impressive," yet the *quality* of said antibiotics "does not constitute a substantial improvement in terms of *quality in clinical practice or patient outcomes.*" It's unlikely that you'll be

prescribed one of these hyper-expensive, marginally effective antibiotics. **As an empowered patient, it never hurts to ask about the cost, side effects, and effectiveness of any antibiotic that has been prescribed to you so you can win the war going on in your**

body with the best weapon.

Nursing Homes: Resident-to-Resident Harm

It has been known for some time that a few nursing-home staff mistreat elderly residents, sometimes to better manage disruptive behavior. However, this is not the only source of mistreatment in such facilities. A large team of scientists set out to determine the prevalence of resident-to-resident harm, both physical and psychological, in nursing homes.² The investigation spanned a period of one month and included just over 2000 residents living in one of ten randomly selected nursing homes in New York State, half urban and half suburban.

The prevalence of harm, at 20%, was astonishing to me, considering that the study spanned only one month. The most common forms of harm were as follows: verbal (9%), physical (5%), and invasion of privacy or menacing gestures (5%). Sexual abuse was less than 1%. Typical verbal abuse was screaming or use of foul language. The most common physical abuses were hitting or pushing.

Residents with mild to moderate cognitive impairments were more likely to be involved with mistreatment than those with more severe cognitive impairment. In addition, facilities where the caseload of caregivers was higher experienced more resident-to-resident harm. The authors note that other studies have discovered an underreporting of resident-to-resident harm. They speculate that this sort of harm is so prevalent in nursing homes that it may be deemed part of the culture.

If these results are typical of nursing homes, then resident-to-resident harm is a major harm in nursing homes nationwide. If one were to consider all residents as equally likely to be targets of harmful behavior, then a stay of one year in a nursing home is almost certain to involve one or more instances of physical or psychological mistreatment from other residents.

If you have a family member in a nursing home, it might be wise to ask that resident, assuming their cognition is suitable, if they have experienced any events that they might consider troubling or personally harmful because of the actions of other residents. Make sure the caregivers in the nursing home know you are asking this question.



Disclosure of Potentially Harmful Medical Errors

In one sense there are two types of medical error – those that cause outright harm and those that have the *potential* to cause harm. This is where preventable adverse events are distinguished from medical errors. Many medical errors cause no adverse event, at least not one that is readily apparent. A team of three MDs discussed the way physicians should deal with a medical error that has the *potential* to cause harm.³ The story the authors used as a basis for discussion was an experience one of them had as a dermatologist taking skin biopsies. He realized that the biopsy tools had not been sterilized. Further, he found that none of the trays in holding had been sterilized. The question is how this mistake should be disclosed to those on whom unsterilized tools may have been used. The risk of infection is low but not negligible.

Guidelines exist for such an error. The first step is to make a full disclosure to the patient in language she can understand. The second is to disclose necessary medical care that should happen (in this case infection

monitoring). Third, should be a sincere apology for the mistake and a commitment to prevent this type of mistake in the future.

There are other actions to be taken, but according to the authors, these do not involve patients. One thing I did not think was right is that there was no indication that the affected patients should be invited to participate in the investigation and resolution of the mistake. I think this is essential because it is only the affected patients that can convey the emotional impact of the error on their life.

This was a very easy case for two reasons. First, the physician was not the root cause of the error, and the error caused no direct, immediate harm. In my opinion, if the physician had caused the error and the harm to the patient was serious, permanent and immediately obvious, the disclosure paradigm would be much different. Most likely the response would have been to “deny and defend.”

A Case for an Empowered Patient

A PhD environmental scientist and his primary-care physician wrote an interesting article in the “Less is More” section of *JAMA Internal Medicine*.⁴ Their title was “A grateful but not passive patient.” The lead author, a 75-year-old man familiar with risk assessments, experienced a heart attack and subsequently received a couple of stents in his coronary arteries. He states that he was grateful for his lifesaving medical intervention, but frustrated because his preferences were ignored. First off, he was frustrated by the variety of professional opinions about his subsequent care – does he really need bypass surgery, another stent, or just medical intervention? After a brief episode of atrial fibrillation – does he really need warfarin to reduce the risk of stroke? Once he was discharged on medications alone, were all these really necessary?



His primary care doctor took him off all medications but clopidogrel, which is an antiplatelet drug, to inhibit clots on the stents. After 3 months this drug was de-prescribed, so the lead author/patient is only on a low-dose statin and aspirin, and he claims to feel great. The authors lament the lack of any attempt at shared-decision making throughout the days of the patient’s hospitalization. The lesson here for empowered patients is obvious. **You must insist on knowing the risks and benefits of any invasive procedure recommended to you, and you must know all reasonable options including their risks and benefits. In some cases, this information may simply be unknown.**

Electronic Medical Records: Pain or Promise

Three experts lament the manifold shortcomings of current medical record systems.⁵ They begin their viewpoint article with a quote from Frances Peabody to the effect that “the secret of the care of the patient is to care for the patient.” (emphasis mine). The authors assert that every additional click while using the electronic record erodes the physician’s morale. This is due in part to the failure of electronic records to keep pace with modern technology. The records are bloated and devoid of personal information that could improve care. This gets in the way of “situational awareness” on the part of the physician, and by extension her ability to care for the patient.

The authors note what I have heard often from doctors – the electronic records are designed to maximize billing, not ease of use by doctors and nurses. I would argue further that if doctors and nurses struggle to use electronic records, then where does that leave the untrained patient?

An article in the *New England Journal of Medicine*, seemingly taking a cue from the article above, asserts that changes need to be made in the medical record systems.⁶ They note perverse incentives that reward quantity of services rather than quality of services. They suggest that the software creators have failed to engage users during development. I was pleased to note that the team that should be assembled to fix such problems included patients. They suggest that major innovations will be needed rather than simply refining what already exists – “paving the cow path” is not going to fix anything. They propose a “forum” for innovation.



My opinion is much more jaded than these writers. Because so much of medicine is driven by money, there is little motivation to transform electronic systems focused on billing. Only when the voices of frustrated doctors, nurses, and patients are heard will change happen. If you are one of these, and you have a specific story involving electronic medical records, then write to the Medicare administrator with copies of your letter sent to your congresspersons.

There was a report of what I would call “meaningful use” of medical records by medical students to follow the outcome of patients they had helped.⁷ Almost all the 103 fourth-year medical students that responded to the survey reported that they had tracked former patients after their care ended. The main reasons given were to know if a diagnosis was correct, follow the patient’s progress, or simple curiosity about the patient’s wellbeing. Obviously, this may be a valuable learning tool, but there is a critical issue. It may be construed as unethical to track former patients because of privacy laws. According to the study authors, this is something that needs exploring so students can track records for their education but not simply for curiosity’s sake.

This study brought a question to my mind: How often do practicing clinicians find the time to follow patients after their care ended. I suspect this is rare unless the patient returns to the same clinician. To me this is where the patient comes in. **Give feedback to your doctor.** If she got it right, thank her. If she got it wrong, say a wrong diagnosis, tell her that her diagnosis was in error and what the right diagnosis was. If the medication she prescribed did not work or made you ill, communicate that to her even if you go to another doctor.

High Drug Prices in the U.S.

Many of us experience sticker shock when we receive a new prescription for some medication. Recently someone I care for was given a prescription for skin ointment to treat a rash. A tiny tube of this stuff cost \$450. A tube might have covered one or two applications. A much cheaper ointment was identified and seems to have had some success. Two MDs and a lawyer wrote a “special communication” to the *JAMA* on how we arrived where we are and what should be done to solve the problem of inordinate drug costs.⁸

The first page of their article has an interesting graphic based on OECD data showing how the U.S. protrudes well above other countries in per capita spending on drugs. We spend about \$860 per capita, whereas the next highest countries, Japan and Canada, spend about \$650 per capita. All other OECD countries are below this level. The average spending was \$400 per capita. May I offer a quick, arm-chair estimate? There are about 325 million people living in the U.S. If we could get our costs down to the average of other OECD countries, we would spend $\$460 \times 325,000,000 = \$150,000,000,000$, or \$150 billion, less each year on medications than we do now.

The authors note that one reason for high drug prices is the protection offered by government agencies for brand named drugs. Brand-name drugs comprise only 10% of prescriptions, but they consume 72% of the total dollars spent on drugs. Between 2008 and 2015 the consumer price index increased 12%, but the cost of

commonly used, name-brand drugs increased 164%. Some specialty drugs cost a quarter of a million dollars per year. Some older generic drugs (e.g. Daraprim for toxoplasmosis) have had staggering price increases (5,500%) because only a single company is licensed to market the drug in the U.S.

The basic reason for the high prices in the U.S. is that drug manufacturers can set whatever price for their drugs that they please. Other developed countries with a national health system negotiate with drug companies for a price that reflects the value of the drug. Not in the U.S. By law, drug companies are allowed to manipulate the situation to maintain a monopoly, something that in most industries is considered anathema to free-market principles. The authors point out that the separation of doctor, patient, pharmacy, and payer is in part to blame for an environment where drug companies can maintain high prices.

Games can also be played by companies when exclusivity is about to expire. An example the writers gave involved the drug Nexium, which was nothing more than a reformulated version of a generic drug that was much cheaper.

Thanks to Congress, Medicare, which spends almost 30% of all dollars on prescription drugs in the U.S., is not allowed to negotiate lower drug prices, yet it is required to cover drugs that treat a great many illnesses. The Veterans Administration does have the power to negotiate for lower drug prices.

Drug companies argue that the high prices are justified by the cost to develop new drugs. The authors argue against this assertion, noting that more than half of

all transformative drugs developed in the last 25 years were developed in academic institutions with public funds. One study found that almost 1/4th of people surveyed said that they or a family member did not fill a prescription because of cost. There are clear clinical ramifications, harm if you will, from the inordinate cost of drugs in the U.S.

The approaches to fixing this broken drug-pricing paradigm fall into three broad categories – increase competition, government changes in the laws, and physicians and patients working together. I'll deal here only with government changes. Medicare could adopt the approach to drug pricing that the VA uses. Government could disseminate information on the comparative effectiveness and cost-effectiveness of each drug. Of course, one must have data to do this. Originally, the Patient Centered Outcome Research Institute (PCORI) was going to fund comparisons of drug-effectiveness, but here again, *your* Congress directed against this intelligent pathway.

If you are the victim of inordinate prescription drug costs, write your congress-person making it clear that you are highly dissatisfied with the way Congress has allowed drug companies to get away with bilking the American public.



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Answer to question this month: a) \$35, reference 8

¹ Deak D, Outterson K, Powers JH, Kesselheim AS. Progress in the fight against multi-drug resistant bacteria? A review of U.S. Food and Drug Administration-approved antibiotics, 2010-2015. *Ann Intern Med* 2016; 165:363-72

² Lachs MS, Teresi JA, Ramirez M, et al. The prevalence of resident-to-resident elder mistreatment in nursing homes. *Ann Intern Med* 2106; 165:229-36

³ Levinson W, Yeung W, Ginsburg S. Disclosure of medical error. *JAMA* 2016; 316:764-5

⁴ Rifkin E, Lazris A. A grateful but not passive patient. *JAMA Intern Med* 2016; 176:1248-9

⁵ Zulman DM, Shah NH, Verghese A. Evolutionary pressures on the electronic health record – caring for complexity. *JAMA* 2016; 316:923-4

⁶ Rudin RS, Bates DW, MacRae C. Accelerating innovation in health IT. *N Engl J Med* 2016: 375:815-7

⁷ Brisson GE, Tyler PD. Medical student use of electronic health records to track former patients. *JAMA Intern Med* 2016; 176:1395-7

⁸ Kesselheim AS, Avron J, Sarpatwari A. The high cost of prescription drugs in the United States – Origins and prospects for reform. *JAMA* 2016; 316:858-71