

# Patient Safety America Newsletter

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<http://PatientSafetyAmerica.com>

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**Question:** The prevalence of diabetes in women in England in the 50-64 year age range is 4.7%. What is the prevalence in American women of the same age?

- a) 3.4%
- b) 5.4%
- c) 7.4 %
- d) 9.4%
- e) 11.4%

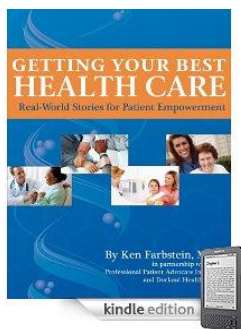
Book Review:

## Getting Your Best Health Care - Real-World Stories for Patient Empowerment

By Ken Farbstein

This timely book provides an interesting and broadly-cast view for empowerment of patients to protect themselves from dangerous healthcare. Mr. Farbstein shares many stories of those who have been harmed by healthcare gone wrong, relying especially on stories involving well-known personalities. He does a capable job of surveying all the ways healthcare can endanger or harm patients including unnecessary surgery, lack of informed consent, excess radiation, specimen mix ups, overuse of antipsychotic drugs, and refusal to acknowledge and apologize for errors. Some of the perverse incentives for NOT providing the best-possible care are thoughtfully documented. Mr. Farbstein takes a courageous and wise look at how to deal with a grave illness, which is likely to be the life-ending experience for most of us. We are all likely to deal with a chronic illness, either in our own life or in the life of someone we care about. The author gives some good recommendations for doing this, especially by admonishing us that we must assume a key role in understanding and managing chronic illness.

One chapter is devoted to finding and working with a professional patient advocate. Indeed, many chapters conclude with a small section entitled: ‘your professional patient advocate can.’ I’m personally a little annoyed at this apparent



salesmanship; however, I am much more saddened that we patients even have to consider that we might need a professional patient advocate. Is our healthcare industry so broken that we have to have a *professional* patient advocate present to protect us? In many situations this is precisely what we need, yet we are best off if we can be our own advocates, knowing of course when we may be in over our heads. That is the story of ‘Patient Empowerment’ that Mr. Farbstein promulgates: Protect yourself first, and then know when you need professional advocacy.



An unnamed relative in Mr. Farbstein’s family was a victim of medical error and through his book he has done an admirable job of responding to that outcome. He has been inducted into the small army of those of us who have been harmed by medical error and will fight like the rebels in Libya to overcome an entrenched, callous, and inefficient enemy – our healthcare industry. I highly recommend this book as a primer to patient safety as it applies to your personal healthcare journey. **4½ stars. Kindle \$19.99, Amazon Paperback \$27.99**

## Off-Label Use of a Coagulant Factor

When your blood clots it does so through a series of biochemical steps involving factors,

typically numbered with Roman numerals. Factor VIIa can be purchased and has been FDA approved since 1999 for use in certain hemophiliacs (people with defective or missing clotting factors) if they bleed spontaneously or during surgery. FDA approval requires that evidence of efficacy for the specific application be demonstrated by the manufacturer. Generally, off-label use of a drug can be much riskier for the patient; however, once a drug is approved for a specific application, physicians can prescribe it for any condition. From 2000 to 2008 the off-label use of factor VIIa increased 140-fold to the point where 97% of its use is off-label.<sup>1</sup>

Three MDs set out to determine if the off-label use actually benefited the patients or was harmful to them.<sup>1</sup> They examined records of 12,600 hospitalized patients that had received this drug from 2000 through 2008. The authors conclude that extensive off-label use raises concern about the application to conditions for which there is not strong supporting evidence.

In another study, a multi-disciplinary team looked at the five most common off-label uses of factor VIIa in hospitals as reported in major medical databases.<sup>2</sup> The conditions of use were intracranial hemorrhage, cardiac surgery, trauma, liver transplants, and prostatectomy. They concluded that, although the evidence was limited, there was no reduction in mortality when this factor was used; however, there was evidence that when used for intracranial hemorrhage or cardiac surgery there was an increase in thromboembolism (blood clots).

Two MDs commenting on these studies gave rather penetrating comments.<sup>3</sup> They noted that other studies from as early as 2007 had results compatible with those reported by Yank et al.<sup>2</sup> One estimate reported a cost of \$10,000 per dose, although an on-line source reports a cost of \$4,500.<sup>4</sup> The commentators<sup>3</sup> wrote that “Allowing physician autonomy to choose medications is appealing, but not when it results in unhelpful, dangerous, and costly decisions...Although off-label prescribing by physicians is not illegal, physicians who persist in such use in the face of clear evidence on inutility and harm could be subject to civil action by the affected patients or their heirs.”

We could do a little math here to estimate the misspent amount of money on use of factor VIIa. Since more than one dose is often required, we can make an assumption that at least \$10,000 was spent

per patient. We know that the first study did not include all who received this drug, but at least 17,800 uses were off-label in 2008. This means the amount misspent on factor VIIa was at or above \$178,000,000 in 2008. At this point there is no evidence that the drug manufacturer, located in Denmark, has engaged in off label promotion, but investigations are underway.<sup>3</sup> Maybe we should just chalk this up to foreign aid to Denmark.

Dr. Oz and friends on why you better be careful with drugs. Note his last comment to patients on the video:

<http://www.youtube.com/watch?v=Jody-ysyVE&feature=related>

## *Quest for a Cause of Unhealthy Americans*

Three investigators attempted to discern why American health is worse than British health across our life spans. From childhood until very late in life



**England Swings!**

Americans have higher mortality than the British, despite the fact that we spend more than twice as much per person on healthcare.<sup>5</sup> The authors note that Americans have a much higher obesity rate, but

they were unable to clearly associate this with the poorer health seen in Americans. They note that the British receive much more preventive care than Americans and that Americans receive twice as many coronary-artery bypass surgeries and four times as many angioplasties per capita as the British.

A commentary on this situation,<sup>6</sup> citing a study from the National Academies, points out that the higher rate of smoking in the US might explain some of the differences, but this seems to fail upon more detailed inspection. The commentators point out that “life in the United States can be distinguished from that of the rest of [Western European countries] in terms of the weakness of its social safety nets, the magnitude of social

inequalities, and the harshness of poverty.” Childhood poverty in 2005 affected 21% of US children, whereas in the UK this was 10%, in France it was 8%, and in Sweden only 4%.

In my opinion, these factors can be related based on my non-scientific personal observations and reports of others. I have observed that poor people tend to be overweight and more often smoke than their middle class counterparts. These personal observations are supported by many surveys. In fact, some have speculated that obesity and poverty are mutually self causing.<sup>7</sup> Americans below the poverty line have a 30% prevalence of smoking, whereas, the prevalence in those above the poverty level is 21 %.<sup>8</sup> It may simply be that the harshness of poverty in the US drives people to unhealthy personal habits that tend to keep them poor, and that the lack of preventive care in the US does not encouraged poor people to discard these unhealthy habits. Despite all the research, perhaps a dose of common sense will lead us to true causes.

### *Evidence-based Guidelines and You as an Individual*

Medical guidelines abound for various illnesses and disease-prevention strategies. This month I would like to reinforce earlier reports I have given about the life-saving importance of guidelines for heart attacks. Following this I will discuss the value of individually-tailored guidelines for those whose blood pressure may require careful management.

A team of Swedish investigators examined the records of 61,000 patients treated in Sweden between 1996 and 2007 with STEMI (ST-elevation myocardial infarction).<sup>9</sup> These are patients who have just had a heart attack and have reduced oxygen available to the heart muscle due to blockage of a coronary artery. This condition is suggested by an elevated line from the “S” position to the “T” wave on their electrocardiogram. The treatment for such heart attacks generally includes clot busters and placement of stents in the blocked arteries.

The investigators looked at mortality during hospitalization, 30 days later, and 1 year after the heart attack. Over the 11 years of medical record many strategies were developed that were complicit with guidelines and led to reduced mortality. For example, stent placement increased from 12% to 61% and many medications greatly increased in use.

The in-hospital mortality dropped from 12 to 7 %, the 30-day mortality from 15 to 9%, and the 1-year mortality from 21 to 13 %. The authors conclude that evidence-based care greatly increased during the study period and that this was associated with much improved survival rates. Evidence-based guidelines matter.

If you are a person at risk for a heart attack you’ll want to manage your personal risk factors; however, if you have a choice in hospitals in your area, then contact each hospital periodically to determine if they are following guidelines for care of patients that are brought to them with a heart attack. There can be considerable variability in compliance with evidence-based guidelines, and this could determine whether you survive a heart attack.

A second team of investigators set out to determine whether tailoring guidelines for management of elevated blood pressure to the health status of a patient improves outcomes in that patient. Unmanaged high blood pressure increases the risk of heart attack and stroke. They examined the course of approximately 2700 patients given one of three treatments: no prioritization according to health status, following the most recent ‘global’ guidelines, or following guidelines for conditions each individual may have.

The investigators found that compared to no prioritization in patients, those given treatment according to their personal illnesses could have prevented the same number of heart attacks and strokes as the ‘global’ guidelines at a cost savings of 67% over application of the ‘global’ guidelines. Contra wise, use of the individualized guidelines could have prevented 43% more heart attacks and strokes for the same cost as ‘global’ guidelines. I know these are complex conclusions. Basically, tailoring treatment to each patient’s specific needs can save much money and/or reduce heart attacks and strokes.

An editorial on this study concluded that “The individualized guidelines performed better because they more accurately stratified patients into high-and low-risk groups than the JNC 7 [global] guidelines.” **So, here is the bottom line for patients: If you are going to be treated for a**





**common condition such as high blood pressure and have other health issues such as diabetes, risky family history, or smoking, then ask your doctor if he has considered these factors in your treatment plan. Do not settle for a vague answer.**

### *Accidental Death from Opioid Overdose*

The rapid increase in deaths from accidental overdose of prescribed opioids was investigated by two research teams this past month. These pain killers are highly effective when used carefully; however, I can personally recall two young adults whose deaths were brought about by accidental overdose of prescribed opioids. The new studies highlight the association of deaths with higher prescribed doses of these powerful drugs.

One study involved the opioid-related deaths of 500 Canadians given prescriptions for opioids from 1997 to 2006.<sup>11</sup> Patients prescribed 200 mg/day or more of morphine, or its equivalent, were almost 3 times as likely to die of drug overdose as those prescribed only 20 mg/day or less. Doses in between these were associated with intermediate risk of death. This seems to me like common sense, but there is an important, two-part message for patients: first, never take more pain killers than you absolutely must have, and two, insist that the root cause of your pain be determined and mitigated if at all possible.



In a second study researchers determined the prescribed doses for patients that had been treated by the Veterans Health Administration from 2004 to 2008.<sup>12</sup> The investigators compared the risk of death from

opioid overdose in patients prescribed more than 100 mg/day to those prescribed less than 20 mg/day. Depending on the condition for which the patient was receiving pain medication, the higher dosages increased risk of death from 4 to 7 times, except for those receiving the medication for control of cancer pain, which was increased 12-fold.

In a commentary on the above study two experts point out that guidelines were promulgated by the American Academy of Pain Medicine in 2009 to guide prescribing and monitoring practices.<sup>13</sup> At

the end of their commentary the writers state that physicians, nurses, dentists, and pharmacists need better training in many aspects of the management of pain. If you or someone you care about has been prescribed opioids, then make certain that their care is being carefully managed by the caregiver. There are far too many unintended deaths to do otherwise.

### References

- 1) Logan, AC, V Yank, RS Stafford. Off-label use of recombinant factor VIIa in U.S. hospitals: Analysis of hospital records. *Ann Intern Med* 154:516-522, 2011
- 2) Yank, V, CV Touhy, AC Logan, et al. Systematic review: Benefits and harms of in-hospital use of recombinant factor VIIa for off-label indications. *Ann Intern Med* 154:529-540, 2011
- 3) Avorn, K. A hemorrhage of off-label use. *Ann Intern Med* 154:566-567, 2011
- 4) [http://www.medscape.com/viewarticle/503052\\_4](http://www.medscape.com/viewarticle/503052_4)
- 5) Martinson, ML, JO Teitler, and NE Reichman. Health across the life span in the United States and England. *Am J Epidemiol* 173:858-865, 2011
- 6) Avendano, M and I Kawachi. Invited commentary: The search for explanations of the American health disadvantage relative to the English. *Am J Epidemiol* 173:866-869, 2011
- 7) <http://www.slate.com/id/2229523/>
- 8) <http://nikoroosevelt.blogspot.com/2007/07/poverty-and-smoking.html>
- 9) Eddy, DM, J Adler, B Patterson, et al. Individualized guidelines: The potential for increasing quality and reducing costs. *Ann Intern Med* 154:627-634, 2011
- 10) Owens, DK. Improving practice guidelines with patient-specific recommendations. *Ann Intern Med* 154:638-639, 2011
- 11) Gomes, T, MM Mandani, IA Dhalla, et al. Opioid dose and drug-related mortality in patients with non-malignant pain. *Arch Intern Med* 171:686-691, 2011
- 12) Bohnert, ASB, M Valenstein, MJ Blair, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA* 305:1315-1321, 2011
- 13) Volkow, ND and TA McLellan. Curtailing diversion and abuse of opioid analgesics without jeopardizing pain treatment. *JAMA* 305:1346-1347, 2011

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**Answer to question this month:** d) 9.4%, which is twice the diabetes rate in the British women<sup>5</sup>