PSA

Patient Safety America Newsletter

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Question: How many years of work did advocates need to get a new hospitalized-patient bill of right passed in Maryland? a) 1 b) 2 c) 3 d) 4 e) 5 f) never was passed

Victory for Patient Rights in Maryland

by Anna Palmisano, PhD

On April 30, 2019, Maryland Governor Larry Hogan signed into law the Hospital Patient's Bill of Rights, replacing a woefully outdated, totally ineffectual law from 1978. He is pictured along with Delegate Karen Lewis Young of Frederick, the lead bill sponsor, and me. The bill passed the Maryland General Assembly unanimously, both in the House of Delegates and the Senate. This bipartisan success was the result of four years of advocacy by Marylanders for Patient Rights—a coalition that has grown to 26 advocacy groups including AARP, NAACP, American Association of University Women, mental health and disability rights groups, Patient Safety America and many others. The only opponent to the bill was the Maryland Hospital Association, one of the richest and most powerful lobbies in the state.

A number of key ingredients contributed to this surprising success story. As a microbiologist by training, I had a very steep learning curve in the corridors of power in the state capitol, Annapolis. Early in the process, I was fortunate to find a key mentor—the Chief of Staff for my State Senator who helped draft legislation, focused my research, connected me with legislative sponsors, and answered many naïve questions. I conducted extensive research on how Maryland compared to other states in patient rights and safety. This research revealed that Maryland was among the worst in the USA in hospital patient satisfaction, hospital patient safety, and emergency room wait time.

Building relationships with strategic partners was critical. Engaging key stakeholders in the state such as AARP, NAACP and others helped to add strength and power to the coalition. Informed discussions with legislators from both parties were held and supporters identified. Working with the press through opinion articles, letters to the editor, and providing quotes to journalists on related issues helped to increase the visibility of the bill to Marylanders. Another key ingredient was perseverance. Many bills take years to pass state legislatures, so it was important to persist and be ready to dedicate a lot of time and effort to repeatedly briefing all state legislators on key committees and stakeholders.

The final key ingredient, over which we had no control, was luck. Maryland had several high profile scandals involving our major hospital system—University of Maryland Medical System—in the past two years including patient dumping and large payments to state and local politicians. Afterwards, legislators seemed less inclined to be seen as close with hospital donors. Moreover, in the last election, a Senate chair who had firmly opposed the Hospital Patient's Bill of Rights was voted out of office, despite aggressive campaigning by the Maryland Hospital Association in his district.

The next challenge will be ensuring implementation by the hospitals. The law will go

into effect October 1, 2019. Compliance will be the responsibility of the Maryland Department of Health which is tasked with a full report to the legislature in January, 2021. Marylanders for Patient Rights will work on a campaign of engagement and education of hospital patients so they know their lawful rights.

Louis Pasteur said "chance favors the prepared mind" true in politics as well as science. Prepare, engage, persevere…and hope for some good luck. Link to the bill: Bill of Rights.

Lessons on Drug Pricing from Canada

Our free-market drug pricing has allowed manufacturers of name-brand medications to gouge the public during the period of patent protection after FDA approval. We have the highest prices for such drugs in the world. Two experts wrote about how drug prices are controlled in Canada to prevent companies from abusing their monopoly. Since 1987 Canada has had a Patent Medicine Prices Review Board. To set prices, it uses approved indications, therapeutic efficacy, comparison to other competing medicines, and the price in 7 developed countries, including the U.S.

In preparation for the onslaught of new and extremely expensive medicines, Canada developed a plan in 2017 to protect the public from price gouging. The list of comparator countries was expanded and the U.S. price was dropped as a comparator. One facet of that plan is to determine if the medicine is being sold at an excessive price, based in part on the quality-adjusted life years it provides and incremental cost-effectiveness ratio (ICER). The authors write about a new drug to treat a rare form of childhood leukemia. The price of this drug in the U.S. is $475,000, but using the ICER, the price should be $61,000.

Among other changes is that the drug maker must report its development costs and discounted prices offered under 'product listing agreements.' The new law has not gone into effect yet. To me it is obvious that the proposed Canadian solution makes a great deal of sense, especially when compared to the free-market approach in the U.S. that allows direct marketing to the public and has a 'smoke-and-mirrors' approach to setting prices for drugs that are protected from competition after FDA approval.

One of the challenges of lowering U.S. drug prices is the contention that this will stifle development of new drugs. A summary opinion in the *JAMA* reflected on what might work to achieve sustainable costs without compromising new development. Unlike other developed countries, in the U.S. drug makers are allowed to set initial prices at the level the market will bear, reducing the costs gradually if negative publicity ensues. The writers point out that the U.S. essentially subsidizes drug research and development costs for other countries.

The writers succinctly capture what must be done to reach fair pricing, "The most effective ways to address pricing involve 4 categories: importation from other countries; reduction of bloated administrative and marketing activities; direct negotiations between federal payers and industry; and creation of a value based system." The writers do not favor the first option because of challenges with ensuring the quality of imported drugs (I'd disagree here). The writers attack the 'increasingly brazen use of the internet, social media and television for marketing based on marginal or unproven benefits." This is under the guise of free speech protections thanks to our Supreme Court (my observation).

Medicare negotiating of drug prices seems to be a non-starter because of the influence the drug industry has over Congress. The 4th option is probably the best. Set prices based on the risks of drug development and the performance in the real world. The writers call for more attention to compiling real world data to establish the value of drugs in terms of quality adjusted life years. Patients have a role in the latter approach. If you have taken a drug that caused serious side effects or simply did not work as advertised, you can report this to the FDA: FDA Drug Reporting. If your friends have complained to you about an adverse effect, then show them how to report this outcome. Share your report with the doctor who prescribed the medication.

Shared Decision Making

A series of articles on shared-decision making (SDM) appeared this past month in the journals I read. The process of SDM involves the clinician revealing all information a reasonable patient would want to know to participate in a discussion about options for dealing with their illness or disease, or the potential for detecting disease when considering screening. The clinician in turn respects the preferences of the fully-informed patient. The first SDM article dealt with aortic valve stenosis. The writer surveys current data showing that the best choice may depend on the age and gender of the patient. She considers a variety of factors, including severity of the stenosis and associated symptoms and the overall health of the patient. If the valve is to be replaced, should it be with a mechanical valve or bioprosthetic valve? If the latter is chosen, then there are options for how to perform the surgery. The physician writer laments the lack of updated, accessible and patient-centered information on the options. Clearly, SDM is not going to happen if the patient does not understand the options and uncertainties involved. It is complicated.

Four experts examine the level of compliance with SDM for lung cancer screening in older patients. The Centers for Medicare and Medicaid Services (CMS) mandated SDM in early 2015 before performing any CT screening for lung cancer in people 55-77 years old with 30+ pack-years of smoking history. The SDM included use of a decision aid and counseling on stopping smoking. The investigators asked how often the SDM mandate was being followed before the CT scan. The percentage of enrollees receiving SDM before CT screening was about 2 % in October 2015 and climbed to 10% by May of 2016 where it plateaued. Of those who received SDM, 60% decided against CT screening. The writers lament the 'unwillingness' of the clinical community to apply the SDM mandate, and the CMS' tendency to pay for the screening in the absence of SDM. My experience has been that there is nothing new about CMS making rules that they do not enforce.

Implementing SDM in the intensive care unit (ICU) is especially challenging because surrogate decision makers, usually the family, must make decisions for the incapacitated patient. A study of actual discussions between clinicians and the surrogates was conducted in 249 encounters occurring from 2009 to 2012. The patients studied were unable to communicate a decision, they had acute respiratory syndrome and had a 50% expected in-hospital mortality. About 1/4th of the discussions involved no discussion of patient preferences. Just under 50% of the discussions elicited patient preferences and showed how those apply to the clinical decision. Only 8 % of the time did clinicians make their decision based on expressed preferences. The study authors note that 'robust deliberations were particularly deficient.'

In an invited commentary, an MD made some observations about SDM in the ICU. The writer notes that the 'best scientific evidence available' must be part of the decision making. The study is the first to use actual encounters related to ICU care. The nature of the outcomes associated with each option must be carefully presented by the clinician. The paper described above reinforces a call to improve SDM in the ICU.

One thing I thought was missing during ICU SDM was the situation where the family members disagree on the patient's preferences. That is why, if possible, such discussions between the patient and her potential surrogate-decision makers must happen prior to the possibility of the patient ending up in the ICU. Most people fear the process of dying rather than death itself. As one of my older buddies once said, "I want to die young at an old age."

Bang, More Dead Again

An emergency department physician wrote in *JAMA Internal Medicine* about our nation becoming comfortable with gun related deaths. He travels the country eliciting discussions in physicians about gun issues. He noted our high number of deaths and the upward trajectory of those deaths. He notes that between 2009 and 2016 almost 100 million guns were added to the nation's collection, which is now estimated at about 350 million. In 2017 there were 40,000 firearm deaths, 8,000 of these in children. He notes the expiration of the Federal Assault Weapons Ban in 2004. He suggests 4 legislative measures to reduce gun deaths: 1) universal background checks, 2) prevention of child access to guns, 3) take guns away from violent people, and 4) remove guns from those with mental health issues. There is an interesting graphic in the article showing by age-group the portion of deaths due to homicide, suicide or accident.

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I would add to the good doctor's list of needed changes the recovery and ban of all assault weapons in the hands of the public. I'd also ban ammunition designed to slaughter any living flesh it encounters. In an example of utterly stupid legislation on guns, I noticed a story this morning (May 28) in the Houston Chronicle. The Houston Police Chief has come out against a law that has reached the Texas governor's desk for signature. It would allow open or concealed carry of pistols by ***anyone*** for a week after a natural disaster. The supposed reason is so that those with caches of weapons who must leave their homes in a disaster can pack along their guns. Looters can't get them! I can just imagine some dude being rescued from his flooded home in a boat while he carries 10 guns.

Opioid Epidemic Amends

Two MDs writing in the *JAMA* Forum describe how their professional community is making amends for the role of doctors in facilitating the opioid epidemic. They point to efforts to educate doctors on the use of opioids as painkillers and the use of drugs (methadone and buprenorphine) to manage opioid addiction. The latter is a hard-sell in some quarters. It's interesting that the FDA has an education model on medication assisted treatment of addiction. It seems to me that the old 'elephant in the room' when it comes to physician responsibility in the opioid epidemic is their failure to police their own. In 2018 the Department of Justice charged 162 doctors with illegal prescribing and so far this year, another 32 have been identified (Washington Post). The article is entitled "Doctors in 7 states charged with prescribing pain killers for cash, sex."

Many of us know doctors who claim to enjoy a career fixing the mistakes of other doctors. This cannot happen under a system where all physicians are required to report their dangerous colleagues. It is past time for the physician community to devise more effective ways to cull dangerous doctors from their ranks, simply to protect the public.

Cash for Improving Healthy Behaviors

In the past I have been a proponent of rewarding healthy behaviors, but doing this is complicated as 3 experts observed when they surveyed the possibilities in *JAMA*. They cite several studies on incentivizing compliance with medication use that did not work. Then they ask, "What is needed to make incentives work?' In a nutshell, these seem to

be as follows: avoid including only 'opt-in' patients (be more inclusive), time the incentive intelligently, offer immediate rewards, make sure the patients understand the incentive, and make the incentive sufficiently high to be enticing.

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Answer to question: best answer is (d) 4 years.