Reviewer's report

Title: Effectiveness of a novel and scalable clinical decision support intervention to improve venous thromboembolism prophylaxis: a longitudinal study.

Version: 1 Date: 23 March 2012

Reviewer: Ian H Jenkins

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Discretionary Revisions:
Suffice to say on page 5 that the iteration was launched in 4/08; on page 6, much space again expended clarifying the difference of one day, which the reader does not need to dwell on. No need to repeat the details about Sunrise.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
Page 2: consider: VTE causeS morbidity… systems to prevent IT
Page 3: spelling in the keyword “throbosis”

General: is the punctuation not before the reference #, like in this question? 1,2,3 This is how the format occurs on, say, page 11, but not on some earlier pages. Misplaced comma on page 11.

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)
Page 2:
Should there not be a comment on bleeding analysis in the methods if they are reported in the conclusions?
Recommended prophy went up about 7-8% and yet it also increased from 27 to 52%? This is confusing.

Page 3:
I would exclude the outdated discussion of asymptomatic VTE events and substitute some estimate of symptomatic VTE; note the movement away from surrogate endpoints in ACCP and ACP publications.
Might want to quote the primary source for material in paragraph 1; consider removing the 8th ACCP source now that the 9th is out (although there is less useful overview material).
Actually, reference 2 says in 2008 that CMS is considering adding DVT to its list for nonpayment, in 2009—and isn't it orthopedic post op DVT?
Missing from the list of published CDS efforts is a non-popup alert based effort which increased adequate prophy to > 95% with a reduction in overall VTE: J Hosp Med. 2010 Jan;5(1):10-8. Optimizing prevention of hospital-acquired
venous thromboembolism (VTE): prospective validation of a VTE risk assessment model. Maynard GA. This effort was since translated into Epic, a widely used commercial EMR. Or other successful projects; McKean J Hosp Med 2009 lists a few.

Page 6

Would list the exclusion criteria adjacent to the inclusion criteria, not separate them by the time periods.

Page 7

Duplication of prophyl advice—why not say we recommend x, y, or z on all patients except a, b, c on ortho trauma? Are there no other services, eg neuro? Would list definitions in the order they’re originally listed (any prophyl mentioned first and defined last) OR just list the terms once followed by definitions. The comment on creatinine clearance could be moved to the list of measured items as a parenthetical “a, b, c, creatinine clearance (measured by the C-G equation), etc etc” back on page 6; seems out of place at the end. Also, was pharm prophyl truly “recommended” for everyone, including patients with bleeding, or low risk? No contraindications are mentioned.

If only prophyl heparin doses count for the medicine services, what about those who arrived on therapeutic Coumadin?

Can the authors be certain that discharges with VTE as the primary dx are always POA VTE? What if PE became the primary problem, might a coder possibly end up listing that as a primary diagnosis even though it was a HA-VTE?

Following reference 16 for the AHRQ PSI subset is a frustrating experience. The website does not list the patient inclusion criteria for this subset in an easy to find manner. I tried a bunch of searches and still don’t know what subset we’re discussing. A direct link would be better. (I see the comments about surgery patients later on 12).

Page 8:

The bleeding analysis is fundamentally limited. It relies on a coder recognizing that a bleeding event was linked to a prophylactic dose of AC or physicians documenting the same. This is practically impossible since people bleed with and without VTE prophyl. A better measure would have been rates of overall bleeding, but even that is quite limited and one would need bleeding criteria as defined in major trials, measured via EMR or chart by chart—perhaps not feasible, but represents a limitation.

What other confounders did the statistics adjust for?

Here is a major discrepancy with the abstract and page 9. Abstract says pharm prophyl did not go up. Here it says it did. It is not clear how recommended prophyl (which was defined as UFH TID enox 40 or dalte 5000) went to 52%, while pharm prophyl went to 54% (was the difference just some UFH BID?). Most importantly seems that (again) the “recommended” prophyl takes no account of contraindications, which is an odd definition.
Any thoughts about why PE went up when DVT went down, since they are part of the same disease?

What about percent prophy in the AHRQ subset? If we are to focus on this subset (and why?) should we not hear how VTE prophy changed in this group? Otherwise, why assume the whole project would be worth duplicating? VTE could have fallen for other reasons, like it went up for other reasons overall.

I think the authors overcall their use of a default treatment. It’s not as if the prophy order was prechecked and users had to cancel it if not wanted; for the first section of the intervention, they had to go to another module to find the “default” order.

If the desirability of this product is its reach of all hospitalized patients, what are we to make of the lack of VTE impact except in a subset of the data? Note: other work HAS targeted whole hospital populations, and the authors should avoid implying their steps are groundbreaking in this way.

True that another limitation of the data is lack of information about whether any meaningful prophy occurred. Many sites struggle with prophy resumption after transfer or procedures. Here, a single dose counts as “sufficient” – I would mention this point in the limitations as well, also, you don’t need changes in the frequency of missed prophylaxis to account for unchanged VTE rates; they might not change because the prophy remained underdosed throughout.

I’m not sure refs 26 and 27, apply fully. The ACP review notes the risk benefit calculus, but you should be able to predict a reduction in VTE based on your N of patients and their VTE per 1000 patient data—the real point is benefits are small. And the mortality study is irrelevant to your DVT prevention study; mortality has never been reduced in a trial or a meta analysis nor did you assess it.

Was the subset analysis prespecified or posthoc?

Other limitations to consider mentioning:

Why even look at patients who had VTE present on admission? We are only interested in HA-VTE, UNLESS you were able to identify “POA” VTE as HA-VTE related to recent hospitalizations. But the methods makes it clear that you did not have POA data for earlier admissions. This is a significant limitation. Because period 2 started at 4/7/08 for PMC, and POA data was unavailable until 4/1/08 at PMC, for example, you missed an entire time period. A causal reader would not notice this.

The poor linkage of providers stating they would not use prophy but many going on to order it suggests “blow through” of the module—people zooming through it without using it properly because it felt intrusive into their work flow. The number of patients deemed a bleed risk seems low—I admit far more than 2% of patients
with severe ESLD or outright bleeding, never mind low platelets, PUD, or other issues.

The limitations discussion on admin data misses the fundamental point. It’s nice that VTE or bleeding codes have reasonable sensitivity or PPV—but if this were a robust method, you wouldn’t have had to do other analyses to show that VTE was stable not worse, and maybe went down in a subset, but some elements of the same disease were more frequent as others dropped.

The bleeding data performance measure I would most want would be sensitivity, which you do not mention. Maybe you caught only 10% of the bleeding events from your therapy, but those coded had high PPV—not that useful.

For conclusions:

Pharmacologic prophylaxis, or a measure of adequate prophy (pharm, or mech if pharm is contraindicated) would be the best measure to rate, since mech prophy is iffy. The issue with pharmacologic prophy (did it go up or not) is of major importance here as a result. The prespecified findings of the study should be the primary conclusion reported—if you searched for all VTE events, then your conclusion is that your efforts did not decrease all VTE (rather, it increased). You can mention a posthoc analysis on POA events and patient subsets AFTER that.

Some things worth considering that are not mentioned:

1) successful programs require multiple interventions, a lot of effort, education, and the transmission of quality culture. Look at Pronovost's work in Michigan's CLABSI data—they didn’t just put out an orderset, they had to change the way doctors and nurses spoke to each other. For a VTE example, look at the multimodal recommendations in AHRQ's guide to improvement, or the SHM VTE resource room. Throwing a protocol out there doesn’t work well, and the authors say not a word about how this change was announced or if anything else was done in their project—I assume not. 52% “recommended” prophylaxis is not sufficient, even if an improvement, and thus there should be some “lessons learned” rather than just the suggestion other sites can adopt this partially effective orderset.

2) Is the orderset available to other sunrise users, anyway? If not, then this is not any more scalable than ANY orderset someone would have to reprogram to their institution. If so, where do they get it?

**Level of interest**: An article whose findings are important to those with closely related research interests

**Quality of written English**: Acceptable

**Statistical review**: Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
I have no financial COI. I have worked on similar projects myself and have worked in SHM's VTE quality improvements mentorship program. We believe based on experience with > 100 hospitals that simply tossing an orderset out there without a QI framework and high reliability design measures is insufficient to expect such a project to achieve success.