Subject: BMJ - Decision on Manuscript ID BMJ.2016.032144

Body: 20-Apr-2016

Dear Prof. Jena

Manuscript ID BMJ.2016.032144 entitled "Adverse outcomes during the transition to a new electronic health record"

Thank you for sending us your paper. We sent it for external peer review and discussed it at our manuscript committee meeting. We recognise its potential importance and relevance to general medical readers, but I am afraid that we have not yet been able to reach a final decision on it because several important aspects of the work still need clarifying.

The comments of the reviewers are not supportive and they raise many important points. We would like to see how you respond to these points (and revise the manuscript accordingly) before making a final decision on the manuscript. We encourage you to revise the paper but we will have to be convinced that you address these comments appropriately before proceeding with the process.

We hope very much that you will be willing and able to revise your paper as explained below so that we will be in a better position to understand your study and decide whether the BMJ is the right journal for it. We are looking forward to reading the revised version and, we hope, reaching a decision.

Jose Merino
jmerino@bmj.com

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Comments from Reviewers

Reviewer: 1

This large scale observational study uses a robust diff-in-diff analysis to determine the effect of EHR implementation "go live" on adverse outcomes including mortality, readmission, and adverse safety events across 17 hospitals and 399 control hospitals in the same referral region as the intervention hospitals. This study is original, well-written, the background is well-researched and up-to-date, and the methods rigorous to answer an important question regarding the safety of EHR implementation. The large scale and appropriate use of diff-in-diff analysis make the results more reliable and credible. I found the following major issues in my review:

1. Selection bias: the 17 intervention hospitals with eligible go-live dates were selected from 71 potentially eligible hospitals whose hospital IT leadership responded to emails regarding go-live date that were sent to 171 potentially eligible hospitals. The authors should compare outcomes between randomly selected hospitals that were responders and non-responders to mitigate the possibility of selection bias. This should also be mentioned in the Limitations portion of the discussion.

2. Length of follow-up: the authors state in the limitations that the "analysis focused on the short-term impact of EHR implementation and should not be interpreted as assessing its long-term impact." They also did not explore implementation strategies immediately following go-live, stating that "advanced planning among hospitals undergoing EHR implementation" may have contribute to the lack of difference in outcomes pre- and post-implementation. This combination limits interpretation of the analysis as during the study period, many hospitals were incorporating a "staffing up" model in the weeks immediately following go-live. If this were the case, adverse events and unintended consequences might be most amplified in the 30-90 day range. This should be mentioned in the limitations as well as a call for future work for analyses extending farther into both the short and long term effects of EHR implementation to see if this effect is sustained or changes. Furthermore, this calls into question its relevancy/relationship to past studies, e.g., Han 2005 followed 18-months post-implementation.
3. Sample size power: seems adequate. However, power calculations do not appear to have been done a priori. This should be discussed in the limitations

Other issues:
-introduction does not mention HITECH act and its effect on EHR adoption
-intro paragraph 2, sentence 2: should mention the broad concept of unintended consequences and could address usability challenges as well
-limitations should mention that hospitals adopting their first EHR in 2011-2012 could be considered majority adopters in the Diffusion of Innovation model [Rogers 1962] and, therefore, would be more likely to benefit from the experiences of innovators and early adopters
-falsification tests should be explained
-ethics statement should be extended to explain IRB exemption. e.g., all data de-identified?
-Table 1 would be more valuable if it included columns on adjusted outcome rates at the control sites as well. This would allow the reader to quickly calculate their own diff-in-diff.

Additional Questions:
Please enter your name: Edward R. Melnick

Job Title: Assistant Professor

Institution: Yale School of Medicine

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: Yes

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper?: No

If you have any competing interests (please see BMJ policy) please declare them here: Dr. Melnick is supported by grant number K08HS021271 from the Agency for Healthcare Research and Quality. The content of this review is solely the responsibility of Dr. Melnick and does not necessarily represent the official views of the Agency for Healthcare
Research and Quality.

Reviewer: 2

Comments:
This seems very relevant to patients and caregivers. We hear all the time about the implementation of EHRs and this is a valid question - whether the "focus" of caregivers is diverted and that patients can suffer adverse outcomes. Great concept.

Caveat: this is my first peer review so the below are largely my thoughts. This seems to be a well designed study so I'm not sure how I can be helpful; these were just questions that came up for me.

The July effect and the weekend effect are mentioned - does their study correct for these effects? One hospital reported a more than doubling of mortality in the five months after implementing an EHR. (Citation 17) Their evidence seems to show that it may not have been due to the implementation of the EHR, but the introduction of this single case doesn't fit with the overall findings of the paper, and these effects aren't discussed. Maybe outside the scope of this paper, but these notes do seem to run counter to the findings of their study and further explanation of "why" would be interesting. These are noted more in the discussion I see.

I see they identified hospitals in subgroup analyses, but are there different results between their two criteria: hospitals which implemented EHRs and hospitals which switched to a new one? As a patient, am I better off seeking treatment at a hospital that has just implemented an EHR, or one that has just switched vendors?

Might these results be different for different demographic patient populations? They used medicare data, but in facilities that see largely privately insured patients, would the hospital be more or less equipped to manage their patients and the EHR implementation? Possibly another study.

Also possibly another study, but their results beg the question of whether Epic systems are simply easier to implement. If the 14 epic sites were implementing product from a different vendor, would the results change? Maybe that's for marketing folks to figure out, but as a patient, I think it would be relevant to me to know if I'm admitted to a hospital that is implementing an Epic EHR I have less to worry about statistically than if I'm admitted to one implementing an EHR from Cerner.

Further discussion of advanced planning and clinical resiliency would be beneficial to readers planning to implement.

I may have missed a note on geographical distribution of the hospital regions that were studied, but this may bear mentioning in the limitation if the sites were geographically localized.

I think the first word in this sentence of the abstract should be "The": This purpose of this study was to assess the short-term impact of inpatient EHR implementation on patient outcomes of mortality, readmissions and adverse safety events.

Additional Questions:
Please enter your name: Dana E. Connors

Job Title: Project Manager

Institution: AcademyHealth

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

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Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper?: No

If you have any competing interests (please see BMJ policy) please declare them here: No competing interests

Reviewer: 3

This work presents an original and timely study on the short-term impact of EHRs implementation across multiple sites. The findings are indicating no negative effects on short-term mortality, adverse safety events and readmissions, as I can read from the authors.

Two main aspects are reproducibility of the study, and generalizability.

Reproducibility: the control group is constructed on the basis of HRR (hospital referral region), which makes the study very localized. The outcomes of interests are mainly two: 30-day mortality and re-admissions, plus adverse events.

This is reasonable and probably questionable without running a bit of sensitivity analysis around it, considering that it is more critical approaching the startup period than moving on with time. In a scenario of achieved stabilization, say, the expectation is probably different from the one which may present under shorter time-frames, and this would also be dependent on the conditions taken into consideration.

Chronic conditions and diagnostic categories are necessarily selected, and thus results hold conditioned to the choice that was made.

Logistic regression as a model is an acceptable choice as a baseline. Something more sophisticated to treat the covariates structure is not presented.

Generalizability: specific organization details were not investigated in their correlation with outcomes (and this is an important aspect for policy makers, as given the hospital dimension taken into consideration (>150 beds) it would be extremely important to infer about the most efficient conditions under which the translation occurs smoothly).

At the territory level, heterogeneity is mitigated by the choice of hospital size, but this leads to an important consideration. Patients' conditions may require a more or less specialized health facility or structure, and relatively large size of the hospital is probably not the only parameter needed.
Thus, an accurate choice of covariates is required for generalizability to be safely considered.

I would like the authors can clarify on the above points, which suggest limitations of the study which I have not read about.

Additional Questions:
Please enter your name: Enrico Capobianco

Job Title: Lead Scientist

Institution: University of Miami, Miller School of Medicine, Center for Computational Science

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

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Reviewer: 4

The chief concern with the manuscript is the lack of underlying theory and motivation for the analysis. The authors note, "Not surprisingly, many have raised concerns that EHR implementation may adversely impact patient safety and efficiency in the weeks to months following transition." It is not clear that unspecified and unfocused concern is an adequate motivation to conduct a study without a strong theoretical model that links a change in the process of communicating and documenting to demonstrable changes in patient outcomes. The authors note, "One hospital reported a more than doubling of mortality in the five months after implementing an EHR". In fact, this paper did not report on an EHR but rather a computerized physician order entry system. Moreover, the authors of that paper note that a different group of investigators within their hospital noted improvement in mortality during that same time period raising issues about the veracity of their claim. The authors do not make a strong case for a mechanism underlying changes in documentation leading causally to a change in undifferentiated mortality, undifferentiated readmissions, and hospital complications such as the development of decubitus ulcers.

Although the authors have utilized robust methods, the underlying theory and causal pathways are insufficiently developed to warrant an analysis of the type provided.

Additional Questions:
Please enter your name: Laurence McMahon

Job Title: Professor

Institution: University of Michigan

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper?: No

If you have any competing interests (please see BMJ policy) please declare them here:

Reviewer: 5

Recommendation:

Comments:
General

This paper reports a before-after study of potential adverse outcomes associated with the transition (either initial installation, or migration to a new) EHR, as assessed by 30-day all cause mortality, readmissions and PSI events. The design is strengthened by the use of non-changing hospitals as comparators in a difference-in-differences scheme, which removes many of the concerns of a simple before-after design.

Major comments

1. Given that the majority of care delivery organisations have already installed EHRs, (the great majority, at least in the US, anew), is this study even needed now? The horse is out of the barn. The notion that we may have dodged the bullet is reassuring, but does anyone care now? This comment does not reflect on the validity of the paper, but rather on its interest for readers.

2. The outcomes in this study are very distal, and may not be sensitive to disruptions in care processes

which are potentially hazardous but are compensated for by greater effort from the care delivery organisations and front-line providers. The PSI measure in particular has been criticized as insensitive [1].

3. Hospitals typically anticipate and attempt to compensate for the disruptions occasioned by the deployment of a new EHR. That they are successful in this is laudable, but is not necessarily an endorsement of the EHR; they could presumably similarly compensate for hurricanes or other anticipated stressors. Similarly, front-line providers are sensitive and responsive to disruptions in care trajectories, and often able to compensate for them [2]. Successful compensation tends to remove the evidence of potential harm; the paper should acknowledge this problem. One can imagine an edict that caregivers must always stand on one leg – doubtless mortality would not increase, but that would not be evidence that two legs are important.

4. The paper compares admissions in the target hospitals to previous periods at the same hospitals, but pointedly avoids comparison to the control hospitals, in contrast to the other comparisons in the study. Since hospitals commonly reduce clinic visits, elective procedures, etc, in anticipation of a "big bang" go-live, this comparison would be important. This shift in comparator tends to give the sense the authors are favourably biased towards the notion of EMR installation as being a non-event; this may not at all be true, but the paper should try to avoid giving that impression.

5. The detail in the appendices is a delight to reviewers – the authors should be commended for this additional effort. It only adds to the credibility of the work.

References

1. Classen DC, Resar R, Griffin F, Federico F, Frankel T, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Aff 2011;30(4):581-589.
2. Smith MW, Giardina TD, Murphy DR, Laxmisan A, Singh H. Resilient actions in the diagnostic process and system performance BMJ Quality & Safety 2013;22(12):1005 - 1012.

Additional Questions:
Please enter your name: Robert L Wears

Job Title: Professor

Institution: University of Florida / Imperial College London

Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: Yes

Funds for a member of staff?: No

Fees for consulting?: No

Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: No

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g. Footnotes and statements

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END

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