Subject: BMJ - Decision on Manuscript ID BMJ.2015.028378

Body: 27-Aug-2015

Dear Prof. Jena,

I am writing with information on your paper, Manuscript ID BMJ.2015.028378 entitled "Physician spending and subsequent risk of malpractice claims: an observational study"

First, thank you very much for sending this paper to The BMJ. We are keen to publish papers relevant to the US and were especially pleased to get a paper on such an interesting topic. We hope you are pleased with the timeliness and completeness of our peer review process. If you are, please tell your friends!

We would like to publish your paper but before making a final commitment we hope that you will be willing and able to revise it to address the comments and suggestions of external reviewers, editors and our statistician. These are summarised in the report from the manuscript committee meeting.

If you have any questions, please feel free to get in touch with me. I am one of the US-based BMJ editors and my clinical work is at the Brigham/Faulkner -- perhaps our paths will cross in person some day.

We look forward to seeing your revised article within a month and reaching a final decision.

** THE REPORT FROM THE MANUSCRIPT COMMITTEE MEETING, REVIEWERS' REPORTS, AND THE BMJ'S GENERAL REQUIREMENTS FOR RESEARCH PAPERS ARE AVAILABLE AT THE END OF THIS LETTER.**

Please remember these four important points about sending your revised paper back to us:

1. Deadline: Your revised manuscript should be returned within one month.

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If/when your article is accepted we will invite you to submit a video abstract, lasting no longer than 4 minutes , and based on the information in your paper's BMJ pico evidence abstract. The content and focus of the video must relate directly to the study that has been accepted for publication by The BMJ, and should not stray beyond the data.

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Very truly yours,

Elizabeth Loder, MD, MPH
BMJ Editorial Team

As well as submitting your revised manuscript, we also require a copy of the manuscript with changes highlighted. Please upload this as a supplemental file with file designation 'Revised Manuscript Marked copy'.

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INFORMATION ON REVISING THE CONTENT AND FORMAT OF YOUR ARTICLE

Report from The BMJ's manuscript committee meeting

Present: Elizabeth Loder (chair); Julie Morris (statistician); Wim Weber; Jose Merino; Tiago Villanueva; Rubin Minhas; Georg Roeggla; Kristina Fister

Decision: Request revisions prior to final acceptance

These comments are an attempt to summarise the discussions at the manuscript meeting. They are not an exact transcript. Please revise your paper to respond to all of the comments by the reviewers. Their reports are available at the end of this letter, below.

Please also respond to these additional comments by the committee:

* Along with one of the reviewers, we thought it would be useful for international readers if you could (briefly) discuss this from an international perspective. Not all of our international team of editors had a clear view of the malpractice situation in the US and we wondered how it compares to other places, particularly in relation to the leading causes of lawsuits. Perhaps a box or other brief discussion would suffice. This is also something an editorialist can comment on.

As an example of the discussion we had, our Austria-based editor commented that "it seems in the US that diagnostic errors are the leading cause of malpractice claims. This is entirely different in Austria: The leading cause for complaints at the patient ombudsman (the Austrian equivalent to malpractice claim) is insufficient counselling. That's why we tell our teams not to perform every possible procedure to avoid malpractice claims but to explain what we do to the patient in detail and document our thoughts in detail in the patients files."

* Did we understand correctly that results for family medicine were non-significant? If so, that is intriguing. Perhaps you could comment.

* Our UK doctor were interested in your comment that "Our findings focus on resource use and do not consider the relationship between avoidance medicine – that is, avoiding patients perceived to represent high liability risk, also called "negative defensive medicine" – with lower malpractice risk". They say this is very topical in the UK right now, as indemnity fees for family doctors are tremendous, so doctors are avoiding working out-of-hours work, which is considered high risk:
http://www.bmj.com/content/351/bmj.h4549

There is no need to comment on this but we thought you would be interested in this observation.

* We found ourselves wondering whether the highest test orderers had possibly been named in a malpractice suits BEFORE the study started.

* We wondered if you were able to account or control for teaching hospital status, where resource use is different and the probability of being sued might be different.

* One of our editors mentioned that "A cynical editorialist coud say: "So, if you spend twice the amount per patient, you decrease the risk of lawsuits fivefold. Very good ROI." Again, no need to respond directly to this comment but perhaps you might add a sentence or two to the discussion that anticipates or discusses that viewpoint.

* Our statistician thought your analysis was reasonable and noted that the modeling you used does take into account the fact that you have clustering within physicians. She did want to know more about why you used quintiles for the costing.

* She also wondered about the choice of lag time and whether you could do some sensitivity analyses that might shed light on whether the interval of a year really makes sense.

* As you obviously appreciate, based on the balanced discussion section of the paper, she felt that "The main point is whether patient case mix has been adequately adjusted for because that is very important in terms of looking at the resource use. Finally, whether or not the four years they have allowed for closure is sufficient." Can you do more to reassure us on those points? Specifically, she wondered whether it would be useful to do a sensitivity analysis looking at earlier discharges, perhaps in a period from 2003-2005, for example.

IMPORTANT
When you revise and return your manuscript, please take note of all the following points about revising your article. Even if an item, such as a competing interests statement, was present and correct in the original draft of your paper, please check that it has not slipped out during revision.

a. In your response to the reviewers and committee please provide, point by point, your replies to the comments made by the reviewers and the editors, and please explain how you have dealt with them in the paper. It may not be possible to respond in detail to all these points in the paper itself, so please do so in the box provided

b. If your article is accepted it will then be edited, proofed, and - after your approval - published on bmj.com with open access. This open access Online First article will not be a pre-print. It will represent the full, citable, publication of that article. The citation will be year, volume, elocator (a unique identifier for that article): eg BMJ 2008;337:a145 — and this is what will appear immediately in Medline, PubMed, and other bibliographical indexes. We will give this citation in print and online, and you will need to use it when you cite your article.

c. Please write an abridged version of the article for the print and iPad BMJ using the appropriate BMJ pico template for your study's design. Please be reassured that it doesn't take long to complete this. When your BMJ pico is ready please email it to papersadmin@bmjgroup.com.The templates for you to download are at http://resources.bmj.com/bmj/authors/bmj-pico

d. Please include these items in the revised manuscript to comply with BMJ style:

Title: this should include the study design eg "systematic review and meta-analysis”

Abstract
structured abstract including key summary statistics, as explained below (also see http://resources.bmj.com/bmj/authors/types-of-article/research)
for every clinical trial - and for any other registered study - the study registration number and name of register – in the last line of the structured abstract.

Introduction
this should cover no more than three paragraphs, focusing on the research question and your reasons for asking it now

Methods:
for an intervention study the manuscript should include enough information about the intervention(s) and comparator(s) (even if this was usual care) for reviewers and readers to understand fully what happened in the study. To enable readers to replicate your work or implement the interventions in their own practice please also provide (uploaded as one or more supplemental files, including video and audio files where appropriate) any relevant detailed descriptions and materials. Alternatively, please provide in the manuscript urls to openly accessible websites where these materials can be found
Results
please report statistical aspects of the study in line with the Statistical Analyses and Methods in the Published Literature (SAMPL) guidelines http://www.equator-network.org/reporting-guidelines/sampl/

summary statistics to clarify your message. Please include in the results section of your structured abstract (and, of course, in the article's results section) the following terms, as appropriate:

For a clinical trial:
• Absolute event rates among experimental and control groups
• RRR (relative risk reduction)
• NNT or NNH (number needed to treat or harm) and its 95% confidence interval (or, if the trial is of a public health intervention, number helped per 1000 or 100,000)

For a cohort study:
• Absolute event rates over time (eg 10 years) among exposed and non-exposed groups
• RRR (relative risk reduction)

For a case control study:
• OR (odds ratio) for strength of association between exposure and outcome

For a study of a diagnostic test:
• Sensitivity and specificity
• PPV and NPV (positive and negative predictive values)
one or more references for the statistical package(s) used to analyse the data, eg RevMan for a systematic review. There is no need to provide a formal reference for a very widely used package that will be very familiar to general readers eg STATA, but please say in the text which version you used
for articles that include explicit statements of the quality of evidence and strength of recommendations, we prefer reporting using the GRADE system
Discussion
please write the discussion section of your paper in a structured way, to minimise the risk of careful explanation giving way to polemic.Please follow this structure:
statement of principal findings of the study

strengths and weaknesses of the study
strengths and weaknesses in relation to other studies, discussing important differences in results and what your study adds. Whenever possible please discuss your study in the light of relevant systematic reviews and meta-analyses (eg Cochrane reviews)
meaning of the study: possible explanations and implications for clinicians and policymakers and other researchers; how your study could promote better decisions
unanswered questions and future research

Footnotes and statements

What this paper adds/what is already known box (as described at http://resources.bmj.com/bmj/authors/types-of-article/research)

ID of ethics committee approval and name of the ethics committee/IRB; or a statement that approval was not required (see http://resources.bmj.com/bmj/authors/editorial-policies/guidelines) and a statement that participants gave informed consent before taking part

a statement that any identifiable patients have provided their signed consent to publication. Please submit, as a supplemental file, the signed BMJ patient consent form giving consent to publication in The BMJ of any information about identifiable individual patients. Publication of any personal information about a patient in The BMJ, for example in a case report or clinical photograph, will normally require the signed consent of the patient.

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signed patient consent form(s), if the article gives enough personal information about any patient(s): this sometimes occurs even in research papers - for example in a table giving demographic and clinical information about a small subgroup in a trial or observational study, or in quotes/tables in a qualitative study - (see http://resources.bmj.com/bmj/authors/editorial-policies/copy_of_patient-confidentiality)

a data sharing statement declaring what further information and data you are willing to make available, over and above the results reported in the paper. Suggested wording: "Data sharing: technical appendix, statistical code, and dataset [state whether any patient level data have been anonymised] are available at this repository or website OR from the corresponding author at ". If there are no such further data available, please use this wording: "Data sharing: no additional data available". For papers reporting the main results of trials of drugs or devices we require that the authors state, at a minimum, that the relevant anonymised patient level data are available on reasonable request from the authors
The BMJ has partnered with the Dryad Digital Repository datadryad.org to make open deposition easy and to allow direct linkage by doi from the dataset to The BMJ article and back - we encourage authors to use this option
funding statement (see http://resources.bmj.com/bmj/authors/article-submission/article-requirements)
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a statement describing the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication
assurance, in the cover letter, that a clinical trial funded by a pharmaceutical or other commercial company follows the guidelines on good publication practice (see http://resources.bmj.com/bmj/authors/article-submission/article-requirements)
inclusion in the list of contributors the name(s) any professional medical writer(s), specifying in the formal funding statement for the article who paid the writer. Writers and authors must have access to relevant data while writing articles.

Patient centred research
for studies that are relevant to patients we expect authors to report in their articles the extent of their study's patient-centredness, as highlighted by these questions:
did you involve patients/service users/carers/lay people in the design of this study? Please state whether you did, and give details (Methods section)
was the development and/or selection of outcome measures informed by patients' priorities and experiences? Please give details (Methods section)
were patients/service users/carers/lay people involved in developing plans for participant recruitment and study conduct? If so, please specify how (Methods section)
have you planned to disseminate the results of the study to participants? If so how will this be done? (Describe in brief footnote)

are patients thanked in the contributorship statement or acknowledgements?
for articles reporting randomised controlled trials: did you assess the burden of the intervention on patients' quality of life and health? If so, what evaluation method did you use, and what did you find? (Methods and Results sections)

REFEREES COMMENTS

Reviewer: 1

Recommendation:

Comments:
Overview: in somewhat crude terms, defensive medicine captures the idea in which physicians may deliver more care (more tests, procedures, etc.) as a result of fears over liability. One of the conventional ways to shed light on the empirical relevance of this concept is to construct metrics capturing the extent of those liability fears (perhaps captured by the presence of a damages cap) and then to observe whether physicians deliver more care when such metrics suggest higher levels of malpractice pressure—i.e., more spending when the environment suggests stronger liability fears. In this traditional light, the causal direction of the analysis runs from the liability environment to the physician behavior. One thing is missing from these studies, however. Presumably, in response to stronger fears, one would exercise more care in order to stem future liability exposure. With this in mind, one might also want to investigate this latter channel—that is, does the exercise of more care in fact lead to a reduction in future liability. Stated differently, if physicians do practice defensively, do such measures work as they intend? As the authors suggest, there may be a number of mechanisms by which greater spending can achieve favorable liability outcomes looking forward (more potential 'errors' may be caught, patients (or jurors) may view their physician as having exhausted all resources, added care may improve the likelihood of winning a malpractice case if a patient is sued, etc). This question, in the opinion of this reviewer, has been substantially less studied in the literature. In fact, to my knowledge, I agree with the authors that they may be first to tackle this particular question. With this in mind, this submission was well received and provides a very welcome contribution to the literature in attempting to fill this gap. I believe it has the potential to motivate many additional papers on this question, with others attempting to follow the lead in linking rich administrative data on medical incidents to malpractice claims data on physicians.

Clearly, the fact that this relationship between spending and liability claims may potentially work in both directions creates the possibility for a reverse causality problem in any attempt to focus only on the spending-causing-few-claiming story. Appropriately, the authors attempt to address the reverse causality concern by carefully structuring the timing of the analysis—that is, by estimating the association between current spending and future med mal claiming against that physician—as captured by the incidence of an event leading to litigation that occurs the year after the observed spending level. I suppose one minor suggestion for the authors would be to alternatively try some kind of a distributed lag specification that builds even more forward-looking dynamics into this relationship.

Even with the timing structured so as to alleviate some reverse causality concerns, there naturally remains some omitted variables concerns that may limit the ability to make strong causal claims here—e.g., concerns over unobserved differences in patient mixes that may simultaneously drive spending and med mal outcomes (note the physician fixed effects specifications help resolve many concerns over unobserved physician heterogeneity). Nonetheless, the authors do much work to resolve patient mix concerns with careful comorbidity controls. In any event, the authors are clear to state this caveat for the reader (and are generally clear to address most other limitations that came to mind in reviewing the piece). They are also clear to suggest that any such bias here should work in the other direction (and thus not explain their findings). Given the novelty of their exercise and the care that went into looking rich inpatient claims data with the malpractice history of the associated attending physician, I do not view caveats of this nature as being detrimental to the paper. The contribution here is nonetheless powerful.

A few additional comments / questions:
(1) I might recommend that the authors cite one paper that comes close to the contribution they are making. See Greenberg, Michael D., Amelia M. Haviland, J. Scott Ashwood, and Regan Main. 2010. Is better patient safety associated with less malpractice activity? Evidence from California. Santa Monica: RAND Institute for Civil Justice. This paper likewise tries to approach the problem in reverse, though instead of focusing on spending / utilization measures, the paper asks whether a hospital's success at reducing patient safety incidents is associated with reductions in future med mal claiming. While the present paper attempts to illuminate the idea of defensive medicine, this Greenberg et al paper attempts to illuminate the notion of deterrence of medical errors, a related but distinct concept.

(2) The fact that greater spending is associated with reduced liability is consistent with the presence of defensive behavior. However, it doesn't necessarily prove the existence of defensive medicine. First, it bears mentioning that one could conceivably note such a relationship even if no physicians are prospectively acting defensively. It could that physicians are acting without liability in mind but happen to spend at different rates for idiosyncratic purposes. And, ex post, it happens to be that those who spend more have more favorable liability outcomes. Of course, with so much commentary suggesting the presence of defensive behavior ex ante, it is not unreasonable to think that physicians would anticipate such an outcome and alter their behaviors initially. Regardless, the fact that the authors observe this reverse finding is highly illuminating to the bigger defensive medicine debate and does complement those studies that attempt to look at this question more prospectively.

(3) Relatedly, it is important to note that defensive medicine does not necessarily follow from their findings if we thought that patient outcomes are actually more favorable with higher spending—that is, let's say the

mechanism at play here is higher spending leads to fewer medical errors, which in turn leads to less lawsuits. This may not be characteristic of "defensive medicine," which we typically think of as being wasteful medicine. Rather, this could be capturing favorable deterrence in action. The authors acknowledge this, but this is an important point that I think might deserve a tad more emphasis on revision. To be consistent with the law and economists' general approach here, I suppose my comment is that one should really reserve the label "defensive" for situations of wasteful spending or wasteful avoidance, as distinct from socially beneficial deterrence. In any event, regardless of the precise interpretation, the finding that higher spending is associated with lower lawsuits is still highly important and interesting.

(4) It helps that the sample was cutoff in 2009 to allow time for claims to be processed, which as the authors note take on average 4 years. The concern otherwise would be truncation at the end of the sample. Even stopping at 2009, I imagine there may still be some claims open at the time of data collection and thus not in the sample. Year fixed effects, which the authors use, should address this concern. However, the authors may, as a robustness check, also consider estimating the relationship between spending and the likelihood of an incident leading to a claim that closes within 4 (or 5) years throughout—i.e., even in the early years of the sample.

Additional Questions:
Please enter your name: Michael Frakes

Job Title: Associate Professor

Institution: Northwestern University School of Law

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: 2

Recommendation:

Comments:
I have reviewed the revised manuscript "Physician Spending and Subsequent Risk of Malpractice Claims: An Observational Study." I found it to be interesting, insightful, and important. The article explores a fundamental question in medical malpractice that, to my knowledge, has never been investigated: Does "defensive medicine" by physicians actually "defend" against malpractice claims? Much research has assumed that precautionary tests and procedures – dubbed as defensive medicine by some – ward off lawsuits, but I do not believe this basic assumption has ever been tested. The test of this assumption is important, because it is not obviously true. It could well be the case that malpractice liability stems primarily from issues of trust and communication between patient and physician – e.g., some have found that simply apologizing for errors reduces claims rates. In this case, healthcare utilization and clinical decision making actually has less to do with malpractice.

The authors find that healthcare utilization does in fact reduce malpractice liability. In other words, they report the first rigorous empirical evidence that defensive medicine actually works. This is a first-in-class finding likely to be widely cited in the voluminous literature on medical malpractice.
I do have a few relatively modest comments for improving the paper further.

1. BMJ has an international readership. As such, some context for defensive medicine in the U.S., as well as the U.S. malpractice system, would be useful. A short 'background' section would suffice. I would also encourage the authors to cite examples of defensive medicine outside of the U.S., although though I do not believe the issue has been extensively studied elsewhere.

2. The C-section example is very interesting. C-section rates are higher in the U.S. than in many countries

and have grown considerably, which many attribute to defensive medical behavior. I would recommend spending more time on the motivation and implications of the C-section example in order to provide this context for international readers.

3. One possible explanation for the findings is that greater healthcare spending is associated with better patient health outcomes; it could be these improvements in outcomes that reduce malpractice claims, since patients who get better have less reason to sue their physicians. There are a number of studies that now suggest this positive spending-outcomes association in the U.S. at the hospital-level, though none exist at the individual physician-level. For example, papers in the last several years in JAMA and Annals of Internal Medicine have shown that greater hospital spending is associated with better outcomes. The authors should discuss this as a possibility for why they find their estimated association between spending and malpractice claims, and what it means for clinical practice and public policy.

Additional Questions:
Please enter your name: Darius N. Lakdawalla

Job Title: Quintiles Chair in Pharmaceutical Development and Regulatory Innovation

Institution: University of Southern California

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: 3

Recommendation:

Comments:
This paper examines the correlation between (a) either individual physician health care spending or C-sections (for obstetricians) and (b) medical malpractice claim incidence. This sheds light on whether physicians' beliefs that greater expenditure or procedures reduces malpractice claim risk, a key step in the logic behind why malpractice law may induce defensive medicine.

I think this paper is an important contribution to the medical malpractice literature. If they had found the opposite, it may have changed physician behavior. Knowing that physician's beliefs are correct gives policymakers information that helps them formulate better policies to reduce the side effects of liability laws.

I would recommend publication with appropriate revisions.

If appropriate and there is space, I would recommend that the authors try some back of the envelope calculations to shed light one whether the care being provided is cost effective. This should be confined to their data and crude calculations, otherwise it will end up as a separate paper altogether (which should not discourage the publication of this paper). I tried to do this myself. Looking at Table 3, I see there is roughly a 2% reduction in claims (I assume this is per physician but equivalently per patient) from moving from the bottom to top quintile. From Table 2 I see that the gap between the top and bottom quintiles of spending is roughly $20,000 per patient. So long as the average medical claim is $1 million or less, then I would conclude that the spending is cost effective, at least from the physician's or liability insurer's personal perspective. If we are confident that the medical malpractice system works well, i.e., $1 million less damages means $1 million less injury, then we might say it is also cost-effective from the patient's perspective. Of course, these require additional assumptions – and also that I am correct that suits per patient fall by 2%. But if the numbers are not unreasonable, i.e., the rate of return to $1 of spending is roughly $1 of claims savings, then it would at least cast some doubt on whether the spending was clearly defensive, i.e., not cost effective.

SPECIFIC COMMENTS

I wonder whether the data are long enough to handle OB claims. I thought they had a longer lag than 4 years. So having data from 2013 may not tell one about claims except really early in the sample. If the

claims data have date of incidence, one way to show that your data are accurate is to show what fraction of claims filed in year t are from incidents in a year covered by the sample. This should be done in the appendix. I don't want to make too much about this because the authors do not find a zero result, which the long lag could explain.

I understand the authors regress incidents in year t that are the basis for a future claim on expenditures or procedures in year t-k, with k = 1. (If that is wrong, then the authors should explain what they actually do more clearly and explain why they don't do what I described.) That strategy makes sense for come treatments, but not others. E.g., for C-sections, k should surely be k=0 with little risk of reverse causality. But I can also imagine that for other treatments the lag is longer. Did the author's check whether longer lags are appropriate. Or even run a model with multiple years of lagged expenditures?

Do so few physicians have multiple claims that binary models are appropriate? If enough physicians have multiple claims, I would consider a zero-inflated Poisson (or just a Poisson) since it is not clear those models really give significantly different estimates.

Are you also clustering at the physician level?

Why do the authors group the treatment variable into quintiles? Why not just leave it a continuous variable? That would make interpretation easier. For sure there is more noise when you don't bin the treatment variable. But binning assumes you know what the relationship is supposed to look like and could hide valuable information. I would prefer a more flexible polynomial specification. At least the authors should verify to reviewers or show in the appendix that spending or C-sections have a positive effect even if left as a continuous variable.

Additional Questions:
Please enter your name: Anup Malani

Job Title: Lee and Brena Freeman Professor

Institution: University of Chicago

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?: Yes

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: I am an occasional consultant for Precision Health Economics, a health economics consulting firm.

END

Date Sent: 27-Aug-2015