Author's response to reviews

Title: Retrospective record review in proactive patient safety work - identification of no-harm incidents

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Author's response to reviews: see over
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To:
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On behalf of our research group I am pleased to resubmit the manuscript, entitled “Retrospective record review in proactive patient safety work – identification of no-harm incidents” by Kristina Schildmeijer, Maria Unbeck, Olav Muren, Joep Perk, Karin Pukk Härenstam, and Lena Nilsson, to be considered for publication in BMC Health Services Research.

We are deeply grateful for the positive response from you and the reviewers. We find the associate editor’s and reviewers’ considerations and comments wise, constructive and appropriate. Our responses to the associate editor’s and reviewers’ comments point-by-point are presented below in “Response to Reviewer Comments”. We have carefully considered and answered all items and clearly described how we have dealt with the questions.

At first, as requested by the associate editor, we want to clarify the connection between the present article and the previously published article “Is detection of adverse events affected by record review methodology? An evaluation of the “Harvard Medical Practice Study” and the “Global Trigger Tool” by Unbeck M, Schildmeijer K, Henriksson P, Jürgensen U, Muren O, Nilsson L, Pukk Härenstam K in Patient Safety in Surgery 2013;7(1):10. The two studies were performed with the same patient material, i.e. 350 patient records, but as the aims and hypothesis, respectively, for the two studies differ we find it appropriate to present the results as two separate publications. We have also clearly written in the present article that the study is based on the same material as the former study and given the full reference to that publication.
The previously published study is an evaluation of two retrospective record review methods and compares their feasibility and capability to identify adverse events that result in patient harm from the same sample of patient records. In that study, two different teams reviewed the patient records; one team used the Global Trigger Tool method and the other the Harvard Medical Practice Study method. In all, 160 different adverse events were identified in 105 (30.0%) of the 350 records with both methods combined. The Harvard Medical Practice Study method identified 155 of the 160 (96.9%) adverse events in 104 (29.7%) records compared with 137 (85.6%) adverse events in 98 (28.0%) records using the Global Trigger Tool. Adverse events “causing harm without permanent disability” accounted for most of the observed differences.

In the present study the focus is on no-harm incidents, i.e. events that reach but do not harm patients. Our aim was to evaluate retrospective record review for the detection of no-harm incidents and compare the findings with conventional incident reporting. We hypothesized that retrospective record review could be a valuable tool to identify and classify no-harm incidents.

The team that evaluated the records for adverse events using the Harvard Medical Practice Study method in the previously published study also evaluated the same set of records for no-harm incidents. Apart from the same set of records and a common database, the two datasets have been handled completely differently. In the present study, we have also made a comparison between retrospective record review and other traditional incident reporting systems. We truly hope that this has clarified the differences between the two studies.

Sincerely yours

Kristina Schildmeijer
Response to Reviewer Comments point-by-point

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<th>Reviewer's comments</th>
<th>Author’s response/solution.</th>
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<td>1) First of all I urge you to explain the context of this manuscript in the context of the project and your recent publications. This can be done in the cover letter for now and I will decide if some of this information needs to be incorporated in the manuscript. If you already wish to do so yourself, this is fine as well.</td>
<td>We have clarified this in the cover letter and added some information in the article. If the associate editor wants us to add more information in the article, we have no objection.</td>
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<td>2) Please be very clear about the terminology concerning no-harm incidents, incidents and adverse events and then use this terminology consistently. Especially when referring to all of these in one sentence or referring to other industries in the current manuscript is a bit confusing.</td>
<td>We have clarified the terminology and now use it consistently.</td>
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<td>3) Please reconsider the use of the term &quot;high reliability industries&quot;. I would prefer safety critical industries because, as pointed out by one reviewer, the conceptual space needs to be established more fully based on the pertinent literature and the links to your work are not crystal clear.</td>
<td>We agree and have changed accordingly.</td>
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4) I agree with both reviewers that your second goal of analysing the causes of the no-harm incidents identified has not been fulfilled to a satisfactory level. You provide characterizations of the no-harm incidents that could be used to expand the criteria for RRR aimed at identifying and and potentially analysing their causes. However, limiting the analysis to one main cause per no-harm incidents you have created a huge barrier to achieve what you are demanding and this will never be a solid basis for proactive safety management (e.g. on page 11 "failure to provide prophylactic treatment" is listed as a main cause but it is only another layer highlighting and error of omission of which we need to understand the causes. With your suggestion that "Working in a proactive way, this should be possible to avoid." you are blaming the individual defeating the purpose.)

We agree with the associate editor that our aim can be criticised. We find the expression “causes” that we used unsuitable, as our only information source was the patient record reviewed retrospectively, and nothing close to a root cause analysis could be performed. We have reclassified according to a scale by Vincent et al., who made a classification for contributory influencing factors. In the new Table 4 we have included more than one contributing factor for each no-harm incident. Our findings should primarily be seen as indications of a number of areas needing more work to increase patient safety. We have also added a discussion paragraph about the difficulties of this kind of analysis, including promoting a system view instead of blaming individuals.
5) There are numerous limitations related to the very limited data on inter-rater agreement (which is particularly worrying since the two physicians have very different expertise) and the identification of no-harm incidents? which is generating the data for you key results? has been done only by the RN and no data on reliability are reported. Please elaborate on these aspects.

In our study, we had two validation stages to assess the reliability of the nurse review process. The physicians had the possibility to include findings not identified by the RN when they reviewed the records, but they found no no-harm incident to include. Neither did the physician find any missed no-harm incidents when reviewing every tenth records not containing any potential no-harm incident. Eleven charts were reviewed by both physicians and they were coherent in all of the cases concerning healthcare causation and preventability.

We have tried to clarify this in the record review section.

We agree that this is a limitation and have added this under limitations.
6) Please explain in more detail how RRR can be seen as part of a proactive safety management strategy. The statements referring to this aspect of your work are scattered across the paper, redundant and rather general. I think you should discuss this in more detail and also reflect on the fact that no-harm incidents are not necessarily precursors of AEs. I am also unsure about your statements regarding the use of analysing no-harm incidents to prevent harm. It seems to me that the preventability ratings point to the fact that the no-harm incidents themselves could be reduced and that this should be the actual goal.

Thank you for this important comment. We have now concentrated our discussion. We believe that working with no-harm incidents is an important task because incidents that do not harm patients in one instance might be a sentinel of serious defects that could result in major harm in the next case. If a patient is harmed or not in a fall is just a matter of chance and has the same contributing factor. This is the same for e.g. not receiving prophylaxis. As you correctly pointed out, the aim is also to decrease the number of no-harm incidents themselves because these affect e.g. the patients, their trust for healthcare, and the staff's work environment. RRR, if used to identify both no-harm incidents and AEs, may give a clearer and broader picture of the no-harm incidents that occur in healthcare, pointing out patient safety problems that should be given priority for improving patient safety.

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<th>7) Please carefully review the literature on RRR again. As pointed out by one reviewer, important references have been omitted and I would like to suggest to include the work of M Woloshynowych and S Taylor-Adams.</th>
<th>We are grateful for the suggestions and have added the work of M Woloshynowych and S Taylor-Adams in our background.</th>
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| 8) Please explain how you were able to link the 350 admissions in the RRR with the IRS data. Normally, IRS are confidential and not linked to patient data. If the situation in Sweden is different this needs to be pointed out to the readers. | An important point, thank you. We have clarified the situation for Swedish conditions in the last part of the methods section. |
9) Please explicitly state the basis for the criteria and categorizations in the tables. | We have added the sources for Tables 2, 3 and 4. We have clarified this in the Method section.

10) Please explain what you mean by "healthcare causation". | Healthcare causation implies the actions of individual healthcare workers, and also the systems and care processes used in delivering healthcare rather than the patient’s underlying disease. It includes both acts of omission (for example, failure to diagnose or treat) and acts of commission (for example, incorrect diagnosis or treatment, or poor performance). We have clarified this in the review process Stage 2.

11) You mention on page 8 that most no-harm incidents were related to inpatient care. How was the distribution of in- vs outpatient care in your sample? | All reviews were based on randomly chosen inpatient care episodes. Besides reviewing the hospital stay, a review was made in the outpatient notes looking for no-harm incidents connected to the inpatient stay. We have tried to clarify this in the Method section.

12) The manuscript needs careful editing for typos and some language issues. | The revised manuscript has been carefully edited and has undergone language editing by a new native English speaking proof reader.

**Referee 1:**

1) The second aim of the study is not thoroughly enough worked with in the study; therefore there are some work to be done explaining this part of the study more in dept throughout the paper. | We agree and have expanded on the second aim, both in the result part but also in the discussion part of the article.
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<th>2) Page 3, the first time references [3] is used; I’m not sure that “Global Trigger Tool” are to be considered, as written, as a “well-developed system to monitor patient safety within the healthcare system”. (Jf. fx. Dan Med Bull. 2011 Nov;58(11):A4337. Uncertain added value of Global Trigger Tool for monitoring of patient safety in cancer care).</th>
<th>We agree and have removed the sentence.</th>
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<td>3) Page 11 section 2, the sentence “Although several studies…..the underlying causes to no-harm incidents”, should be moved to the beginning of the article.</td>
<td>Thank you for drawing our attention to this. According to the points from the editor, we have made extensive changes in this part of the article.</td>
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<td>4) At page 4 you explain, that this study is one part of a study design – perhaps you could elaborate a little bit more about the other part.</td>
<td>We agree and as suggested by the associate editor have clarified this in the accompanying letter and added information in the revised text.</td>
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<td>5) Page 8, line 7-8 from the bottom: I’m not sure that I understand “…0,34 no-harm incidents per admission (range 0-3).”</td>
<td>We agree that this can be unclear and have changed to only present the range 0-3 no-harm incidents per admission.</td>
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<td>6) Page 8, line 4 from the bottom: “almost all” – I suggest you to use percentages instead.</td>
<td>We agree and have changed accordingly.</td>
</tr>
<tr>
<td>7) Page 9 section “Place of occurrence of no-harm incidents”: the percentages should be included after all the numbers mentioned.</td>
<td>We agree and have changed accordingly.</td>
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<tr>
<td>8) Page 12, line 8 and 11 from the bottom: I’m not sure that I understand “…level A-D…”, and “…(level C-D)…”.</td>
<td>We have clarified this.</td>
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Referee 2
Another paper was published 15 April as provisional PDF in Patient Safety in Surgery (PSS), written by the authors of the present paper plus an additional author. Available as: doi: 10.1186/1754-9493-7-10 http://www.pssjournal.com/content/7/1/10/abstract. In both papers the authors report the analysis of a random sample of 350 admissions of a Swedish university hospital. The PSS paper reports a study involving two teams each with a protocol. One of the teams is identical with that of the present study and the protocols are almost the same. For many reasons, including publication ethics, it is necessary that the authors explain the overlap and differences in objectives between the papers.

We agree and as suggested by the associate editor has clarified this in the accompanying letter. We have also tried to be slightly more detailed regarding this connection in the revised version, and have added the reference as the article has been published.

2. The very first sentence of the paper raises concerns: The authors say that “in contrast to other high reliability organizations” healthcare is still lagging behind in terms of monitoring safety. But “other” HROs? The authors will probably not wish to argue that healthcare is a high reliability industry. But if they do, this needs justification. Otherwise, please rephrase.

Thank you. We have removed “other” i.e we are not including healthcare in high reliability organizations. We have also changed high reliability organizations to safety critical organizations.
3 The meaning of the term “high reliability organizations” is reasonably precise, if not entirely so, in the safety management literature and has been established in seminal papers (from 1993 and later) by Weick, Roberts and Rochlin and others; but the term does not mean the same as the much more widely applicable and much looser term “safety critical organizations [industries]”. The authors’ should consider if they really wish to use the more technically precise term “high reliability organizations” [HROs]; if they do so, they need to add at least a short characterization of the concept accompanied by citations of standard references. It is not sufficient to cite the technical report by Oedewald and Reiman (though the reference is relevant, it should be supplied with its proper URL: http://www.vtt.fi/inf/pdf/publications/2007/P633.pdf).

See our response above. We have rewritten this part and also included references by e.g. Hollnagel, Bird, Runciman and Woloshynowych.

Thank you very much; we have changed to the proper URL.

| 4. page 3. The authors define a no-harm incident as “an event that reaches the patient but results in no discernible harm”. Then they go on to claim that “no-harm incidents are a valuable source of information in many high reliability industries…” | We are grateful for the suggestions and have added the work of Phimister et al. We have also tried to clarify no-harm incidents (defined by WHO).

But the definition the authors use for “no-harm” incidents has no clear meaning in other industries - unless, of course, they are characterized as “near-miss” incidents. This is probably what the authors have in mind; if so, they need to clarify this; similarly, a reference or two would then be appropriate (see for instance: Near-Miss Incident Management in the Chemical Process Industry: J R Phimister et al. Risk Analysis, 23, 3, 445-459, 2003. DOI: 10.1111/1539-6924.00326. The authors might also refer to the well-known Aviation Safety Reporting System (ASRS) |

As the referee points out we made the connection between safety critical organization’s “near miss” and the healthcare system’s no-harm incidents. Near miss is also used in healthcare, and according to the WHO a near miss is an incident that does not reach the patient. In an RRR study these events are difficult to find because they are seldom documented, and were therefore not included in the study. |
5. page 6, line 4. “Each physician reviewed every second record”. It is unclear what is meant by this clause. Did each of the two physicians review half of the records? In the “overlapping” paper (doi:10.1186/1754-9493-7-10) by the same authors they describe this step differently (“Each physician …...reviewed half of the records forwarded by the RN”).

We agree that it is unclear and have changed to the same writing as suggested by the referee.

6. page 11 “this is the first study to our knowledge that has studied the underlying causes to [sic] no-harm incidents” [better: causes of…]. This claim is surprising. The authors’ classification and application of screening criteria do not constitute a taxonomy of “causes”; rather, they are “incident types” – in the terminology of Runciman et al [authors’ Ref 1]; in contrast, a study such as Zwaan et al 2010 (‘Patient Record Review of the Incidence, Consequences, and Causes of Diagnostic Adverse Events. doi:10.1001/archinternmed.2010.146) that also uses the HMPs review method, does in fact classify records in terms of a model of causes.

Thank you. Many studies have reported on underlying causes/contributing factors related to no-harm incidents/AEs. Please see response #4 to the associate editor.

7. The authors’ practice of providing URLs is inconsistent: Ref. 15 has an URL, but Refs 2 and 16 do not.

We had missed this and consequently added a URL to all web references.