

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey
AUTHORS	Geraedts, Max; Krause, Svenja; Schneider, Michael; Ortwein, Annette; Leinert, Johannes; de Cruppé, Werner

VERSION 1 – REVIEW

REVIEWER	Marcial Velasco Garrido Institute for Occupational and Maritime Medicine (ZfAM), University Medical Center Hamburg-Eppendorf, Hamburg, Germany
REVIEW RETURNED	15-Oct-2019

GENERAL COMMENTS	<p>The authors address a very relevant issue of health care with appropriate methods. Due to the large representative sample, the findings provide sound evidence on the topic which is very relevant for both clinicians and health policy makers. The paper is clearly written, easy to read and includes well done tables. The conclusions are fully based on the presented findings and not speculative. In my view the paper deserves publication after minor improvements.</p> <ol style="list-style-type: none"> 1. In my view the authors should provide the full questionnaire as supplemental material in order to improve reproducibility of the research. In the methods section they should also state whether the questions were open or had predetermined answers options. In the first case, the authors should provide information on the method used to build categories. 2. Please provide some explanation what is meant with “temporal” harms (I guess you mean something like time-lost for example waiting..., but one could understand “temporary”). 3. In the results sections the authors should provide additional information relevant for assessing the representativeness of the sample. I recommend to report all socioeconomic variables (i.e. household size, income, education, citizenship, etc.) in addition to the ones already reported (gender, age, health status and prevalence of chronic illness); at best in a table including a column with, if available, population based data for the sake of comparison. 4. I also miss the average number of ambulatory doctor visits in the sample. In the methods section the authors discuss estimations of the average number of doctor visits ranging from 6 to 17 and choose an estimate of 10-20 to assess the proportion of visits with PSI. Why do not they report the number of visits in their own sample and assess the proportion of visits with PSI based on real data instead of a vague estimate of 10-20? The former would provide more sound evidence...
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	<p>5. The distribution of visits among specialities in the authors' sample needs to be reported too. This is of particular importance since the authors report the distribution of PSI by speciality (Suppl Tab 1). This is better interpretable if one knows the distribution of visits per speciality in the sample. The authors could also report the proportion of visits with PSI per speciality, which is of relevancy for example for identifying "problematic" specialities and targeting interventions to them.</p> <p>6. Line 237. Please provide a source for the data on hospital stays in which the extrapolation is based.</p> <p>7. Line 261. This line seems wrong.</p> <p>8. Lines 267-272 are very redundant with the lines 204-207 and 236-237. Perhaps you can take this information away from the results section and leave them only in the discussion section.</p> <p>9. Lines 292-296. A discussion of the proportion of visits with PSI per speciality would be more informative (see above).</p>
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REVIEWER	<p>Charles Vincent University of Oxford, Experimental Psychology I gave some early suggestions on the development of the PREOS methodology some years ago. I had no involvement at all in subsequent research.</p>
REVIEW RETURNED	17-Nov-2019

GENERAL COMMENTS	<p>This paper reports a large telephone survey of patients in Germany to assess their experience and perceptions of errors in their healthcare in the preceding twelve months. As the authors rightly say, comparatively little is known about safety errors and incidents in the ambulatory setting and patient reports could be an important source of data. The study is conducted with an established methodology, the methods are clearly reported and the overall approach appears to be sound. The response rate is low but consistent with similar surveys. The paper is potentially a valuable addition to the literature on safety in ambulatory care.</p> <p>While I think the paper is useful, there are a number of important points that need to be addressed. These concerns the rather loose use of terms and concepts, the extrapolation and interpretation of the findings.</p> <p>Definitions</p> <p>Throughout the manuscript the term patient safety incidents is used to describe the findings. However, the PREOS description makes it clear that patients are being asked about errors. While the definition of these terms is problematic they are certainly not equivalent and, to my mind, the loose use of the term PSI distorts the findings. A typical definition of a PSI is as follows:</p> <p>Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare. Reporting them supports the NHS to learn from mistakes and to take action to keep patients safe.</p> <p>The term incident usually implies more than a single error, but the more important point is that the incident must at least have the potential to cause harm. Looking at the list of errors suggests to me that many are likely to have been inconsequential and cannot necessarily be classed as incidents, with the implied much greater severity. The overall effect is to make the findings appear more</p>
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	<p>serious than they actually are (which is not to say that they are not very concerning).</p> <p>I suggest that if patients are asked about errors, then that is what should be reported. I agree that errors with clear consequences (or possible consequences) could be classed as incidents.</p> <p>Extrapolation to German population</p> <p>The authors argue that the patients in their survey are demographically equivalent to the general population and that therefore their findings based on a 10% sample can be extrapolated. They say (without explaining) that 'decisive aspects suggest that there is no significant selection bias'. I find this unconvincing. It seems quite possible that patients who agree to be interviewed are (a) more likely to have a health problem (b) more likely to be receiving regular healthcare and (c) more likely to have had errors in their care – if they agree to take part in a survey on error. The authors need to be very much more cautious about any extrapolations, if they continue to include them, and to discuss these various issues rather more objectively.</p> <p>Defence of methodology and patient reports</p> <p>At various points in the manuscript, particularly in the Discussion, the authors defend the use of patient reports in strong words. I felt that they were anticipating criticism and felt the need to defend the importance of patient accounts. I understand this anxiety but, at this point in the evolution of patient safety, I feel that it is not necessary to mount such a defence and that actually it detracts from the paper.</p> <p>I would suggest instead that the authors should assume the importance of the patient perspective and discuss how these findings relate to other sources of information about error and harm and how they might be most effectively used to improve safety. What would they recommend, for instance, that healthcare organisations do to capture this information routinely? Would that be a good idea? If so, how might the information be best used? I think this adjustment would require a substantial rewriting of the discussion but be much more useful to the reader.</p> <p>Overview</p> <p>The core of the paper is sound and a valuable addition to the literature. However, the definitions, extrapolation and interpretation of findings need further reflection and adjustment. The Introduction and Discussion in particular require substantial adjustment to respond to the points made above.</p>
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VERSION 1 – AUTHOR RESPONSE

REVIEWER 1

Comment 1: In my view the authors should provide the full questionnaire as supplemental material in order to improve reproducibility of the research. In the methods section they should also state whether the questions were open or had predetermined answers options. In the first case, the authors should provide information on the method used to build categories.

Authors: *Please find a translated version of all questionnaire items for the PSP-12-months-Incidence as supplementary file 1.*

Comment 2: Please provide some explanation what is meant with “temporal” harms (I guess you mean something like time-lost for example waiting..., but one could understand “temporary”).

Authors: *We added examples in table 3.*

Comment 3: In the results sections the authors should provide additional information relevant for assessing the representativeness of the sample. I recommend to report all socioeconomic variables (i.e. household size, income, education, citizenship, etc.) in addition to the ones already reported (gender, age, health status and prevalence of chronic illness); at best in a table including a column with, if available, population based data for the sake of comparison.

Authors:

We added a comparison of all collected socio-demographic and socio-economic parameters of the weighted study population with a population survey conducted as part of Germany's 2014 health monitoring as supplementary table 1.

Comment 4: I also miss the average number of ambulatory doctor visits in the sample. In the methods section the authors discuss estimations of the average number of doctor visits ranging from 6 to 17 and choose an estimate of 10-20 to assess the proportion of visits with PSI. Why do not they report the number of visits in their own sample and assess the proportion of visits with PSI based on real data instead of a vague estimate of 10-20? The former would provide more sound evidence...

Authors:

Because we only asked the participants whether the last visit to a GP or specialist took place within the last 12 months, we are not able to provide the number of visits in our sample. We have changed the wording in the manuscript (methods) to clarify this misunderstanding about the questions we asked in relation to the doctor's visits.

Comment 5: The distribution of visits among specialities in the authors' sample needs to be reported too. This is of particular importance since the authors report the distribution of PSI by speciality (Suppl Tab 1). This is better interpretable if one knows the distribution of visits per speciality in the sample. The authors could also report the proportion of visits with PSI per speciality, which is of relevancy for example for identifying “problematic” specialities and targeting interventions to them.

Authors:

Since we only asked for the specialist discipline in which a PSP reported by the patient occurred, we are unfortunately unable to provide this data.

Comment 6: Line 237. Please provide a source for the data on hospital stays in which the extrapolation is based.

Authors:

We deleted the sentence according to reviewer 2. We added the source in the discussion section.

Comment 7: Line 261. This line seems wrong.

Authors: *Thank you. We deleted line 261.*

Comment 8: Lines 267-272 are very redundant with the lines 204-207 and 236-237. Perhaps you can take this information away from the results section and leave them only in the discussion section.

Authors:

As recommended, we present the results of a cautious extrapolation only in the discussion section.

Comment 9: Lines 292-296. A discussion of the proportion of visits with PSI per speciality would be more informative (see above).

Authors:

Unfortunately not possible: see answer to comment #5.

REVIEWER 2

Comment 1: Definitions

Throughout the manuscript the term patient safety incidents is used to describe the findings. However, the PREOS description makes it clear that patients are being asked about errors. While the definition of these terms is problematic they are certainly not equivalent and, to my mind, the loose use of the term PSI distorts the findings. A typical definition of a PSI is as follows:

Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare. Reporting them supports the NHS to learn from mistakes and to take action to keep patients safe.

The term incident usually implies more than a single error, but the more important point is that the incident must at least have the potential to cause harm. Looking at the list of errors suggests to me that

many are likely to have been inconsequential and cannot necessarily be classed as incidents, with the implied much greater severity. The overall effect is to make the findings appear more serious than they actually are (which is not to say that they are not very concerning).

I suggest that if patients are asked about errors, then that is what should be reported. I agree that errors with clear consequences (or possible consequences) could be classed as incidents.

Authors:

Thank you for the detailed explanation of the actual use of the term "incident". For our study, we considered the term "patient safety incident" in the WHO sense (a PSI is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient) to be a very appropriate generic term, covering both errors and incidents that did not necessarily have harmful consequences for the patient. In our understanding, such an event or circumstance (with or without harm) can either be perceived either directly by the patient or subsequently by a physician continuing the treatment who informs the patient about the error or incident (e.g. examinations that should have been performed or questions that should have been asked during the anamnesis). With this interpretation of the term incident we were obviously wrong.

The use of the term "error" in the introductory part of our interviews results from the fact that patients in Germany associate the term "patient safety incident" less strongly with errors / incidents in the health care system than with protective measures, e.g. against theft during a hospital stay. So we were not interested in asking patients about "errors" per se, but to capture all forms of safety-related health care problems and to avoid misunderstandings during the interviews with the term.

In order to avoid the misuse of the term "PSI" in the article, we have now decided to use the term "patient safety problem" (PSP) as a suitable generic term to cover all errors and incidents reported by respondents. We know that the term "PSP" is not exactly defined by the WHO, but the term "patient safety event" has already been defined differently by the WHO.

We hope that this has solved the problem of the often difficult, ambiguous translatability of technical terms.

Comment 2: Extrapolation to German population

The authors argue that the patients in their survey are demographically equivalent to the general population and that therefore their findings based on a 10% sample can be extrapolated. They say (without explaining) that 'decisive aspects suggest that there is no significant selection bias'. I find this unconvincing. It seems quite possible that patients who agree to be interviewed are (a) more likely to have a health problem (b) more likely to be receiving regular healthcare and (c) more likely to have had errors in their care – if they agree to take part in a survey on error. The authors need to be very much more cautious about any extrapolations, if they continue to include them, and to discuss these various issues rather more objectively.

Authors:

Of course, it is true that patients who are chronically ill and therefore more often go to the doctor are more likely to experience a patient safety problem (PSP). Further analyses of our study data also show that the risk of PSPs increases with the presence of a chronic disease. We still believe that our study data allow extrapolation to the entire population at risk. In the article, we argue that the composition of the sample is consistent with the population as a whole in terms of socio-demographic and socio-economic characteristics, and moreover in terms of the frequency of visits to the doctor and the

presence of chronic diseases. To substantiate this argument, we have, as recommended by reviewer 1, included supplementary table 1 where we present a comparison of all socio-demographic and socio-economic variables collected by us with a population survey as part of Germany's health reporting.

Nevertheless, as recommended by the reviewer, we have decided to interpret our study results even more cautiously and conservatively. The extrapolation and its results is therefore only mentioned in the discussion section. We have deleted the extrapolation from the results section and tables as well as from the abstract. We have also deleted the estimate of the frequency of visits to the doctor from the participants section.

Comment 3: Defence of methodology and patient reports

At various points in the manuscript, particularly in the Discussion, the authors defend the use of patient reports in strong words. I felt that they were anticipating criticism and felt the need to defend the importance of patient accounts. I understand this anxiety but, at this point in the evolution of patient safety, I feel that it is not necessary to mount such a defence and that actually it detracts from the paper.

I would suggest instead that the authors should assume the importance of the patient perspective and discuss how these findings relate to other sources of information about error and harm and how they might be most effectively used to improve safety. What would they recommend, for instance, that healthcare organisations do to capture this information routinely? Would that be a good idea? If so, how might the information be best used? I think this adjustment would require a substantial rewriting of the discussion but be much more useful to the reader.

Authors:

We followed the reviewer's recommendation and rewrote the discussion substantially: In particular, we no longer defend the use of reports and make recommendations on how patient safety could be improved using patient reports.

VERSION 2 – REVIEW

REVIEWER	Charles Vincent University of Oxford, Experimental Psychology
REVIEW RETURNED	04-Jan-2020
GENERAL COMMENTS	The authors have responded very comprehensively and thoughtful to previous reviews. My concerns about definitions and about extrapolation of findings have been fully addressed. I am particularly glad to see that the authors have felt able to take a more confident approach to presenting the findings and to rewrite the discussion to provide valuable ideas and insights about the implications of the findings for both future research and clinical practice.