Author’s response to reviews

Title: Validating a transnational fracture treatment registry using a standardized method

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Author’s response to reviews:

Dear Mrs. Ojeda,

thank you very much for your feedback to the submission. Please find the answers in the following paragraphs:

Using translation software, and the German roots are clearly visible (i.e Line 119, "fracture page, number of side illnesses," from the German "Frakturseite, Nebenerkrankungen").
- Answer: Changed “fracture page” to “fracture side” and “side- illnesses” to” comorbidities” (lines 217 and 158)

ABSTRACT: Is it "adaptive monitoring" or "applied monitoring"? Both terms are used in the abstract. Length is adequate.
- Answer: It is solely “adaptive monitoring” – the spelling mistake was corrected in line 37

BACKGROUND: It is very short, and the method of the registry belongs to the "Methods" section. The question of why it is important to analyse data quality is not quite clear and should be explained better to catch the interest of readers.
- Answer: the registry part has been moved to the methods section. The importance of data-quality has been added with two additional sources in line 56.

METHOD:
It is now clear how data for the registry was collected (it is hinted at in the previous section). However, there are serious issues with the data collection software, as can be deduced by the discussion. Inclusion and exclusion criteria should be explained better.
- Answer: Inclusion criteria and data capture are now detailed further in lines 66-69. The issue of data collection has been further explained in the Conclusion section in lines 335-341
The search methodology should be better explained, including a flowchart with the results of your searches.
- Answer: In fact, a rather extensive Excel File is existing, which details Parameters investigated, Methods and Results from various publications on data quality of registries as well as complications. Unfortunately, I do not see a way to derive a systematic from it to represented in a flowchart. But I explained the approach in more detail in line 314-316. The excel file is any time available to be inspected, but I doubt it will positively contribute to the publication, but rather confuse the reader.

The section could be better structured with subheadings, to make it easier to follow for non-expert readers.

- Answer: The following subheadings were added:
  o Setting and Data Capture in line 64
  o Finding a method for data quality assessment in line 81
  o Scoring data quality and conducting a source data verification in line 101

A final paragraph should state all the software used for analysis, as some of the software is mentioned in the results section.

- Answer: The registry software is added to the “Setting and Data Capture” paragraph in line 75 and the statistical software is added to the “Scoring data quality[…]” paragraph in line 119-120

RESULTS: Line 116: "A random sample of patients equivalent to the size of was drawn from the registry...": What size was the random sample? What was the value of n? We finally find out several pages later, in line 183: In total, 73 patients were randomly sampled from the registry". Most readers will have gotten lost by this point, please try to structure the section in a clearer fashion. Again, large parts of this section belong to the "methods" section (Line 122. "A frequently used tool was the package ggplot2 and its geom_count and geom_density function in R...", for example).

- Answer: the text has been rearranged in order to clarify how sample size and data quality are connected. The statistical example was moved to the “methods” section in line 148-155

DISCUSSION: I could not find this heading in the manuscript. I understand it is included in the

- Answer: Now both are separate sections Starting in line 265 and in line 305.

CONCLUSIONS section.

Please follow the journal guidelines for structuring the manuscript.

- Answer: section now available.

There is no explanation on how outliers were managed.

- Answer: Outlier- management now explained in line 293-297

Also, there are serious issues with the date format in the registry's software which were only superficially addressed.

- Answer: Date format issue now explained in line 293-297

How did this data monitoring change your registry's practice? Were datasets adapted or modified in view of the results? Are there other methods of data quality monitoring? This is the first published application of adaptive monitoring, I'm missing a comparison to other more established methods. Weaknesses and strengths of your study are insufficiently highlighted.
Dear Mr. Stausberg:

Thank you very much for your detailed feedback to the manuscript. It was extraordinarily interesting to read the two publications of the colleagues Jacke et al. about their application of the method. It has been implemented into this work now.

1. There was previous work applying the standardized method of Nonnemacher et al. by Jacke CO:


This work could be included.

- Answer: both articles are now included in the discussion section in line 265
2. The flow of presentation is not always clear. The first two paragraphs of the result section should be moved to the method section. It should be clearly and unambiguously defined, what procedures were derived from the standardized method and what procedures were independently applied (SDV of complications?). It would be helpful for the readers to introduce some subheadings.
- Answer: sections have been moved and the two parts separated in paragraphs.

3. From the reviewer's point of view, the change of the registries' data quality from moderate to good seems to be questionable. Missing values in the registry remain a problem, even if the values are missing in the source data. This point should be explicitly discussed in the conclusions.
- Answer: Discussed in the discussion section in line 279-287. The optional element of “height and weight” is not recommended for scoring data quality.

4. Height and weight are used as a single item. It should be described, how the authors proceed if only one of the two variables were missing.
- Answer: The BMI is calculated, as the two items should be captured together. When one of the two items is missing, the BMI cannot be calculated and hence there is a missing in the source data. (explained in line 106-108).

5. The validation of complications remains unclear and should be described in more detail. Following the explanation in lines 134 to 137, only complications in the registry are validated giving a positive predictive value. However, figure 4 implies a search for complications in the source data that were not recorded in the registry (for example to calculate sensitivity).
- Answer: Thank you very much for this crucial remark. Both, sensitivity and specificity, and positive predictive value with a confidence interval of 0,95 had already been calculated but simply forgotten to add. It was of course aim of the source data verification to evaluate these values (lines 261-263)

6. The parts related to the score on the one hand and to the assessment of complications on the other hand should be separated using subheadings.
- Answer: separate headings are now used: lines 165, 256

7. As far as the reviewer understands the authors correctly, the SDV leads to changes in the documentation protocol for some items, e.g. the enabling of the recording of a combination of succession of methods. This consequence of an SDV is an important methodological finding about the power of SDV that should be highlighted in the conclusions.
- Answer: has been highlighted in lines 288-291 and 298-300

8. Again, the retrospective change of a threshold (line 242) is not sound from the reviewer's point of view.
- Answer: the sentence has been rephrased and put into context with Jacke et al.’s work. in line 279-287
9. Table 2 could be renamed to „Delta value in relation to score result and data quality“.  
- Answer: Table has been renamed accordingly

10. Figure 1 should be renamed to make clear that this figure provides an arbitrary example  
- Answer: Table has been renamed accordingly

11. Table 1 and table 3: The specific weights and the thresholds were defined by the authors. They differ from the values that were recommended in the standardized method. This is acceptable. However, it should be mentioned that the presented values are local ones.  
- Answer: now indicated in the Table- title.

12. The authors included two items in the calculation of one quality indicator („compliance with procedural rules“). Herewith, the authors suggest a way to handle a gap in the standardized method. The reviewer suggests highlighting this extension in the conclusions.  
- Answer: The choice for this splitting up of Individual weights has now been explained in the conclusions

13. The image of figure 7 includes the legend „SDV Reduction“. But, this figure does not describe a reduction of SDV, it describes a result concerning the „method of fracture reduction“. The legend should be corrected.  
- Answer: Legend has been corrected accordingly

14. In the PDF-file, tables and figures are not in the correct order.  
- Answer: will be diligently checked on readmission

15. It would be worthwhile to add a paragraph describing the plans for the future with regard to data quality.  
- Answer: “An outlook to monitoring data quality in the future” is now following the “conclusions” chapter

16. Conclusions could be split up in a longer part "discussion" and a shorter part „conclusion “  
- Answer: has been split up.