Author's response to reviews

Title: Analysis and classification of oncology activities on the way to workflow based single source documentation in clinical information systems

Authors:

Stefan Wagner (stefan.wagner@fau.de)
Matthias W. Beckmann (fk-direktion@uk-erlangen.de)
Bernd Wullich (Bernd.Wullich@uk-erlangen.de)
Christof Seggewies (christof.seggewies@uk-erlangen.de)
Markus Ries (ries.markus@googlemail.com)
Thomas Bürkle (thomas.buerkle@bfh.ch)
Hans-Ulrich Prokosch (ulli.prokosch@imi.med.uni-erlangen.de)

Version: 5
Date: 31 October 2015

Author's response to reviews:

Resubmission of an revised article for “BMC Medical Informatics and Decision Making”

Dear Sir or Madam,
Dear Editors,
Dear Reviewers,

Thank you for your feedback, comments and helpful hints on our paper.

In the revised version the following changes have been made according to your hints and suggestions:

Changes regarding Reviewer: Brigitte Seroussi

“The sentences are very long which makes the article difficult to read. A lot of typos should be corrected.”:
Sentences have been shortened and typos have been corrected in the whole text (lines 64-453).

“In addition, if the article is structured according to the regular Background/Methods/Results/Discussion/Conclusion layout, the sections are not so clear. As far as I am concerned, if the Methods section describes the whole 14-step method, the Results section proposes a focus on the steps 12 and 13 which is also part of the Methods section. In addition, a similarity/conformity coefficient is introduced in the Results section and should clearly belong to the
Methods section.”: The mentioned coefficient has been removed because multiple interpretations would have been possible and it is not essential to explain our results and their contribution.

The Results section focuses on the steps 12 and 13 because all other steps are preparation steps for the final ones (12 + 13).

“Finally, the last paragraph of the Results section should be in the Discussion.”:
The position of the mentioned text was changed. The new position: lines 377-383.

“The method described is not new: compilation of documentation, first draft of workflows and pathways, semi-structured interviews with experts, completion of original workflows and pathways, last round with the experts, this is common. Then, a generalization process has been handled on the workflows to generalize the common steps and build branching derivations to take into account particular cases, to finally get 3 general classes. This is also very common. New contributions as far as the methods are concerned have not been described.”:
We cannot agree with this opinion. The parts of the combined method are not new alone, but the combination of process analysis, workflow modelling and the focus on a large number of cancer entities instead of single ones (lines 152-154 and 399-401). Especially the focus on a great number of 13 entities instead of single entities is a new contribution. Please refer to the literature in the introduction and discussion chapters for details.

“In addition, we don’t understand why the generalization stopped at the level of 3 classes. It would have been possible to generalize more and get only one class. It would have been possible to generalize more and get only one class.”:
This point is now explained/discussed in detail in the text (lines 274-278 and 355-360 and 409-411).

It was not possible to gain only one class for all entities because we realized that the prostate cancer workflow, for example, was not transferable to melanoma or breast cancer since the components of the process were too different to get only one group for all of them. For melanoma you have other tumour markers and incident light microscopy. For prostate you have a digital-rectal examination for example, but not for melanoma.

First of all we identified two main groups after finishing the classification process:
• solid and
• non-solid-entities (plasmocytoma and acute myeloid leukemia)

In a next step we realized that in early stages surgery may be the only therapeutic component of a process (see melanoma or kidney cancer patients) and if there were metastases we would have combinations of surgery, radio- and chemotherapy (see breast cancer or cervical cancer for example).
“The criterion used to stop the generalization is not explained. It is particularly important because, intuitively, one should have generalized the first two classes (« Solid entities with surgical therapy » and « Solid entities with surgical therapy and additional therapeutic activities ») and get only 2 classes: either “with and without surgery”, or similarly “solid and non-solid entities”.": refer to lines 274-284: In our previous version of the manuscript we did not mention this fact in detail. In the revised one it is included.

“Another issue concerning the work presented is the fact that it is justified by the need to have a documentation to manage cancer patients that seems to be customized to the practices of the EUH. In addition, clinicians are said to deploy great efforts in the “jungle of treatment” to access the information about the “right actions at the right time”. This should be argued since in the case of cancer management, the pace of information update is so fast that clinicians rather look for state of the art practices in Pubmed and ASCO publications instead of relying on a built-in documentation. Finally, if it is a jungle when considering all the sub-specialties of oncology, it is not the case for cancer specialists that follow the publication of successful protocols or the discovery of new markers or exams in their specialty.”: This fact is now argued as suggested (lines 416-423).

Thus we hope to be able to guide clinicians with restricted effort through the jungle of treatment and documentation and to promote the right documentation activities at the right time. Our workflow model will manage the appearance of electronic documentation forms in our CIS for all process steps of all patients at the EUH from initial diagnostics, treatment to follow-up. The developed workflow model takes care of changing and optimized or even new therapeutic standards in radio- or chemotherapy. We provide flexible structures for chemotherapy and radiotherapy schemes that adapt to the patient’s individual case/stage and focus on other conditions during treatment process. Therefore, it is easy to integrate new therapeutic knowledge within our workflow model.

“If their contribution concerns the results, they should evaluate the results and describe the impact of the solution developed on clinicians and/or patients and/or the hospital organization. The authors should more explain how their work is useful.”: New part of the results section with detail information (lines 335-350).

We implemented electronic documentation workflows and documentation forms for all steps of the diagnostic and therapeutic processes in our workflow engine of the CIS. After this important step we evaluated the effects on our hospital organization and the daily documentation workload of the doctors, compared to the mixed-up documentation structures before.
To sum up the main impacts of our workflow implementation we noticed a reduced documentation time, higher quality in the documented fields and its contents as well as a greater database for reuse of our clinical routine data in our cancer registry after export from the CIS.

In the fields of medical history and clinical examination data quality could be improved most by replacing all different sorts of paper forms through one single branched electronic version for all departments. The same effect applied to radio- and chemotherapy planning as well as the treatment cycles.

The documentation workload of our doctors could be reduced by nearly 25 per cent. Moreover, the satisfaction of our doctors regarding clinical documentation itself could be increased by our approach. But finally even the patients profit from the greater database of structured information at the EUH since we can easily reuse existing data for research or certification without additional efforts to provide the best treatment options.

"letters for affiliations are not in the right order of authors": was fixed (lines 4-35 and 490-495 and 498-508).

"some results given in the abstract are not found in the document ("130 figures, 94 tables and 23 tumour classifications, 12 follow-up tables")": was fixed (lines 297-301).

"in the Conclusions of the abstract, "of a comprehensive cancer" is not clear": was fixed (lines 58-60).

"lot of typos should be corrected": was fixed in the whole text (lines 64-453).

"authors should say if the experts consulted in the first and second rounds of interviews were the same": They were the same, now mentioned in the Methods section (lines 180-187).

"the 13 cancer entities should be labelled the same lg 130-131 and lg 190-191": was fixed (lines 232-234 and 137-139).

"the calculation of lg 200 is not clear"/"similarity/conformity coefficient should be normalised otherwise the absolute threshold at 6 does not work for long sequences the same applies when prostate, kidney and bladder are merged, and when mamma and cervix are merged - similarity/conformity coefficient should be normalised otherwise the absolute threshold at 6 does not work for long sequences": The coefficient was removed because multiple interpretations would have been possible. Moreover, it is not essential for the explanation of our results.

"The above identified three classes should be treated separately when implementing clinical documentation modules because they are so distinct in
their course and order of inpatient and outpatient episodes", lg 242-243 should be reworded to show moderation (otherwise, this has to be proven)”: The text was reworded in order to show moderation (lines 302-312).

Changes regarding Reviewer: Habib Pirnejad

1. “Introduction is too long and can safely be shorten by moving the context of the study into the Methods section”: Two paragraphs were moved to the Methods section from the Background section (lines 122-126 and 127-134). But I think you need some background information before we talk about the methods and the results in detail if you are not an expert in our topic. In addition, the structure of the Methods section was improved according to readability (compare lines 135-221).

2. “In the Methods section: no detailed information about the interview such as how many interviews have been performed. Why other role players in the workflow processes (for example nurses) were not interviewed?”: All suggestions are now integrated in the new Methods section which has been modified (lines 180-187 and 188-195). The two interview rounds are now mentioned and the answers provided in the chapter.

3. “In the result section line 207: what is similarity/conformity coefficient? The definition of the coefficient and the way it has to be interpreted were not presented in the methods section”: The coefficient is now removed from the whole text.

“Although presented in abbreviation list at the end of the manuscript, for the sake of readability, abbreviations should be defined at first place they appear in the text.”: was fixed in the whole text (lines 64-453).

4. “Answers to the research questions should typically be provided (clearly) at the first part of the Discussion section of the paper.”: was fixed (lines 354-376).

5. “In the reference section: the Vancouver style was not followed carefully in many references.”:
The literature of the whole text was modified according to the following EndNote style file from:
http://www.biomedcentral.com/download/endnote/SpringerVancouverNumber.ens

“Considerable part of the literature is not in English. As a result their meaning, relevancy, and etc. is not understandable for an international audience.”: Most of
the literature in German language has been removed as far as possible (lines 530-675). But the literature part dealing with the medical expert literature in German used for the analysis is necessary.

Further main changes of the content of the manuscript:

Explanations of the methods in greater detail, compare the part about process analysis:
lines 143-151.

Lines 156-169: improved readability through list structure.

Lines 175-179: improved readability through list structure, style improvements.

Lines 192-195: improved readability through list structure.

Lines 200-207: more detailed background information about the program solutions for workflow modelling.

Lines 212-214: improved readability through list structure.

Lines 218-221: improved readability through list structure.

Lines 279-284: new information about the two main classes used for our classification process before going on to the subclasses.

Yours faithfully

Stefan Wagner
(corresponding author)