Reviewer’s report

Title: Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table

Version: 0 Date: 04 Jun 2019

Reviewer: Patricia Logullo

Reviewer's report:

Overall

This manuscript is hard to read and understand. The objectives are not clear, and they seem to change all the way from the abstract to the conclusions section. The reader cannot understand what the aims are, what is the study design, what the authors did and what results they got, the reader can only infer some of it by navigating through confusing text and more confusing tables. Tables are not clear, and unfortunately, we end the reading without knowing what this paper adds to the literature.

Title

The term "review" is not precise in the title. The title does not make it very clear if the paper is a critical review of a published template or if it adds a literature review. The "by the developers" part of the title does not make clear if the developers did the review (and why to cite this in the title?) or if they built the template (and, again, why mention here?).

Abstract

1) The abstract needs improvements for clarity. The reader cannot have a clear or complete idea of what they are going to find in the full text by reading the abstract as it is now. The reader cannot understand what are the aims of the manuscript by reading the abstract.

2) In the background section, it is not clear what "requires minimum redaction and modification": the CORE guideline? The CSRs? This part of the abstract, from "requiring..." to "disclosure" could be deleted without any significant loss.

3) The sentence "Although independent..." is also not clear and useful. The Background could begin with the definition of CORE ("CORE is a complete...") and end in "development". Or the authors could explain better why the aims of CORE are important here.

4) In the Methods section of the abstract, you declare that the CORE authors reviewed the template. However, you did not tell your readers first that you developed the template (when and how, and maybe why). There is no chronological sequence.
5) In the Results section, what are "template findings"? It is tough to get an idea of what you are presenting in the Results section of the paper, according to this description. What did the study find? What were the results?

6) In the Conclusions section, the authors state that the publication intends to do something. Such a comment is not proper to a Conclusions section, but rather to the Objectives/Aims section. I also don't see how a template can allow "common interpretations". I believe "warmly welcome" is an expression not supported by anything else in the abstract text, because the reader, at this point, did not understand why we need a template, what it is built for, and why it is innovative or useful.

7) The last section of the abstract highlights so many limitations of the template that the reader is hardly convinced to read further.

8) The authors state that the CORE Reference is registered on the EQUATOR website. OK, but it seems, by reading the abstract, that the paper is not about CORE, but about a new template. Was the template registered anywhere? Please clarify.

9) We suggest that the authors use reporting guidelines to plan and write their abstract. The STROBE Statement is a basic start.

Introduction

1) The Introduction section draws a nice historical description of the CSR scenario, up to line 120. Then suddenly the authors present "a first version of CSR template" by something called TransCelerate… something that the reader is not familiar with at this point of the text. There is no introduction or presentation of what TransCelerate is (an organisation? A document?), why it was created and when. All we can learn is that in November 2018 a template was released, but we have no clue about how it began. So, the history goes well until line 120. From that point on… the reader gets lost.

2) In line 127, the authors state that the CORE Reference had 18K downloads "at the date of publication of this paper". The authors do not know if this paper will be accepted, nor when it will be published. Therefore, the sentence must be changed to "at the date of the writing of this paper". The authors should also comment on why they think 18K downloads mean "global recognition" (did the visitors come from all parts of the world?).

3) At the end of the Introduction, the authors should make it clear:
   a) what is the aim of this paper;
   b) who created the template;
   c) who reviewed it.
   It seems that the information is currently presented in a disorganised, not chronological way. Maybe, the authors could develop using this sequence, if it is right:
   i. Someone (who?) developed a template based on previous work from the BWG (the CORE)
   ii. The BWG reviewed the template (how? Critically? Delphi involved?)
   iii. The aim of this paper is to present… (what? The critical review? The template reviewed?).
   The authors should make sure that readers can understand what this paper is about, at this point of the Introduction, without the need of reading the whole methods section. What is the question this paper tries to answer?
Methods

1) I don't understand why the methods section should begin with the (incomplete) description of a review team — even before the reader is told this is a review paper. The Methods section should start with a declaration of the study design: a narrative review? A critical evaluation of a "template"? A systematic review? An observational study? What is it?

2) The second block of the Methods section (lines 153-159) state that "the team reviewed the TransCelerate template. But again: what is the template reviewed? Where? When was it created?

3) There seems to be a mixture of results and methods in the Methods section. We suggest that the authors critically review this. Outputs (from line 153 to 166) are probably results, not methods.

3) The authors do not describe (and they should) in the Methods section:
- what were the techniques to build the template and to review it
- what were the tools used (for instance, software)
- who did the evaluations and how (there is some mention of "statistics" in the "team" block above, but what statistical analysis was undertaken?)
- when these evaluations happened and where

4) There is no declaration of ethics approval or waiver anywhere in the Methods section, where it would be appropriate.

Results

1) Are the authors sure that the journal prints in colour (so that they can "pink highlight" something)?

2) "Word file" is entirely unnecessary in the results section (line 170). "Text file" is enough. The journal reader will probably not be able to see "formatting marks" or "hidden text" either (line 175). The authors should write their paper in the format that it would appear in the published version of the RIPR journal.

3) The authors mention "these are our key recommendations for consideration in further development of the template"... Well, from the "developing a template" and "reviewing a template" sentences, now the reader begins to think that the manuscript's objective was to build recommendations....!

4) I could not understand Table 1. I could not get what it is presenting, what are the "page numbers" in the second column and would probably understand it better if the authors explained the basis for it (i.e., what they are criticising) in the text and/or in the Table title. I could not find anything marked in pink as they stated - and marking in pink might not be a good idea considering the journal graphic style.

5) Table 2 seems to have been already published elsewhere. Do the authors have permission for reproduction? Also: is this what Table 1 was criticising? (question above)

6) Page 33 of this pdf shows a "confidential" table with a lot of comments. I do not think this is proper for publication. And I do not believe the reader should be made to go through all these comments to
Discussion

1) In the first line of the Discussion section, TransCelerate is described as an alliance. Not a template for writing, as suggested in the other sections of the paper. This highlights the need for adequately presenting what you are doing in a logical, chronological, and clear way to your reader, especially regarding aims and methods.

2) The authors wrote the whole Discussion section citing only one reference (no. 12). This is odd. The purpose of a discussion section is to comment and argue one's results with those from others. There are many sentences in the Discussion section that lack supporting, and therefore look opinative. Also, from lines 196 to 199, and again 245 to 247, the authors use quotation marks for sentences, suggesting that they took those sentences from a text published elsewhere. But where? Please, cite references!

3) "The BWG views the TransCelerate CSR template endeavour as a valuable addition…" (line 202). This seems to be the opinion of BWG. Was this published/endorsed by BWG? Is this a result of your study? (if so, please report it in the Results section).

4) Lines 210 to 211 cite something as "Level 1" and "Level 2", but the reader, at this point of the text, may have no idea about what it is. The whole paragraph from line 207 to 215 is unclear.

5) The authors jump from discussing the availability of their template, from lines 217 to 235, to "primary and secondary endpoints" in the next paragraph, starting on line 237, without any linkage between the two. It is an abrupt, unjustified change of subject. The same applies to the jumping from this paragraph to the one starting on line 254. Indeed, there is little or no connection between paragraphs in this paper, which reduces readability.

6) The paragraph starting on line 237 is difficult to understand. The authors seem to require the reader to have gone through additional material to know what they are talking about.

7) The paragraph starting on line 276 seems to be a critic of the TransCelerate template. Is that it? What is the connection between this and the other paragraphs?

Conclusions

In the Conclusion section, the reader is presented with a new, different, aim of the paper: to differentiate between CORE Reference and the TransCelerate. Some problems:
1) this had not been done before in the article, and if it is true, this should be pasted into the Objectives section in the Introduction;
2) the conclusion is usually not the right place to declare aims;
3) the results of this paper did not present such differences;
4) the methods as described in this paper did not show how the authors would detect and explain the differences;
5) the authors state that they have shown that the application of CORE provides additional instructional
value for users of the template. I am sorry, but they did not. They did not show anything like that throughout the paper.

6) Again, the "warmly welcomed" expression might be out of place.

In the declarations section, the authors state that the TransCelerate has already been disseminated to the press, by a press release. The editors should think about originality and embargo issues. Also, it seems that authors are republishing original material published elsewhere (Table 2).

References

The references are not cited properly, especially in the discussion section.

Level of interest

Please indicate how interesting you found the manuscript:

An article of limited interest

Quality of written English

Please indicate the quality of language in the manuscript:

Not suitable for publication unless extensively edited

Declaration of competing interests

Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?
If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.


I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal