Reviewer’s report

Title: A qualitative study of design stakeholders’ views of developing and implementing a registry-based learning health system

Version: 0 Date: 13 Nov 2019

Reviewer: Holger Pfaff

Reviewer's report:

Thank you very much for the opportunity to review this manuscript. This is an excellent article on an important topic written by highly qualified scientists. The article is well written and very informative. Nevertheless, this article raises some questions and comments which could be addressed in a revised version of the article. First, I will discuss some problems and questions; afterwards, I will make some suggestions.

Problems and questions:

1. Does the title really reflect fully the content of the article?

2. Is the main focus

   - on evaluating a learning system (as proposed in the abstract) or
   - on evaluating a co-production concept (as part of a learning system approach) or
   - on the implementation process?

3. In my opinion the article is more about the core of the intervention (program theory) and less about the implementation process. This is not a problem but it should be mentioned and discussed because this is an article for the journal "Implementation Science".

4. Within this context the reader may ask himself the following question: Why was it necessary to make a second round of interviews two years later? The reader misses a systematic endeavor to work out the differences between the two rounds. There are only a few sentences in the text on the differences between first and second round of interviews (see p. 19 and 20)

5. Is the result that all program stakeholders share a common vision and purpose with regard to the program in part due to the selection and recruiting method ("RCLS-CF program director invited 20 purposively selected program personnel to take part in a confidential interview" p. 5)?

6. How can the reader be sure that the quotations mentioned reflect the true content of the data gathered? What about conflicting results?
7. To perform interviews with stakeholders who are committed to the program by their official role elicits - not surprisingly - positive statements about the program and the common vision. It could be helpful to discuss the problems connected to this "friends of program approach" like "window dressing" or - more theoretically bound - keeping up an official "façade" (Meyer/Rowan; Nystrom/Starbuck)

Here are some suggestions for the authors:

1. It could be helpful for the reader to get the propositions on page 7 systematically explained afterwards (e.g. by specific headers). There is no direct fit or link between the following headers and the four propositions.

2. The four key propositions are of varying qualities (e.g. hypotheses vs. statements). Would it be helpful to harmonize them?

3. There is no clear distinction between the result and the discussion section. The discussion section contains results which have not been part of the result section (see p. 19 and 20). The suggestion is to report all results first in the result section and to discuss them in the discussion section later.

4. The authors could discuss the problem of selection bias more systematically (recruiting bias in the first round and the "panel mortality" in the second round)

5. It was sometimes unclear if the quotations were taken from the first or the second round of the interviews. I would ask the authors to work out the assignment more precisely please.

6. Because patients have not been part of the study the term stakeholder is not quite correct. For example, care delivery stakeholder may be a better term.

7. Interestingly, modern topics which could be positively or negatively connected to the topic co-production like guidelines, evidence-based medicine, individualized medicine and precision medicine are not discussed in great detail in this article. Probably, they are not part of the program theory of the stakeholders. But the concept of co-production could solve the conflict between individualization and the guideline-based standardization of medicine. This and other issues could be discussed more in-depth.

8. It may be helpful for the reader to have an overview over the content of the semi-structured interview guide.

9. Furthermore, it could be helpful for the reader if the authors could analyze and explain the character of the program theory they found (e.g. outcome-oriented or implementation-oriented program theory?)

10. Authors may include a chapter on limitations in their manuscripts
All in all, this already very good article may gain further if some of the above-mentioned points would be addressed.

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An article of importance in its field

**Quality of written English**
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