Author’s response to reviews

Title: Rationale and Design of the Brigham Cohort for Psoriasis and Psoriatic Arthritis Registry (COPPAR)

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Rationale and Design of the Brigham Cohort for Psoriasis and Psoriatic Arthritis Registry (COPPAR)

Maria Schneeweiss; Joseph F. Merola; Elizabeth W. Karlson; Daniel H. Solomon

Dear Prof. Tu,

Thank you for your kind invitation to resubmit our article for your section on Study Protocols. We have now reformatted the article and abstract according to the guidelines for Study Protocol. All previous changes in response to reviewer comments are included as well.
The manuscript is not submitted or under review elsewhere. The funding sources and potential conflicts are disclosed at the appropriate places on your webpage and the manuscript.

Please do not hesitate to contact me for any questions.

Sincerely,

Maria Schneeweiss

Reviewer #1 (Remarks to the Author):

This is a well written paper addressing the design and initial implementation of the COPPAR registry. I have no comments.

Response: Thank you for your kind words!

Reviewer #2 (Remarks to the Author):

I agree with the authors that developing a longitudinal cohort to study psoriasis and psoriatic arthritis over time is important and will allow the authors to better understand many aspects of these chronic diseases. Overall, the paper was clear and well written;

Response: Thank you for your kind words!
However I would recommend the following clarifications prior to publication:

- Please clarify if the registry study visits will be completely separate from clinic care or if follow up information will be collected during routine dermatology/rheumatology visits.

  Response: It is a mix. We now expanded this point on page 8 under registry procedures.

- Do you have a plan for total enrollment past 1000 per group? Have you performed any sample size calculations to determine the appropriate sample size for the outcomes you discussed, specifically in regards to biomarkers?

  Response: The plan is an ongoing open enrollment into COPPAR (see page 12 last sentence). There is no upper limit targeted at this point. As in almost all registries there is no sample size calculation because at the time of setting up the registry not all study questions are known. In fact most questions are not know.

- Please clarify if you will continue to collect clinical information and/or biomarkers after the initial two years discussed in the manuscript. I think analysis of long term (> 5 years) follow-up is very important/useful, especially given the goals outlined in the introduction.

  Response: This is an important question, which we have clarified in the manuscript on page 12, last sentence. The plan is to have long-term follow-up.

- Missing reference, page 4, line 56

  Response: We apologize for this omission. Reference 7 is now listed.
- Add a reference to Table 2 within the body of the manuscript

Response: We have now added a reference to Table 2.

Editor's comments:

Thank you for your revision work, however, before we can proceed on the peer-review process of your Database article, please read the following criteria carefully (which has been clearly stated in submission guideline, http://bmcemergmed.biomedcentral.com/submission-guidelines/preparing-your-manuscript/database-article).

Database articles should describe a novel biomedical database likely to be of broad utility. The database must be readily accessible and data within the database should be attributed to a source.

An article describing a database but also including research that merits publication in its own right should either be submitted as a research article or should be split into a research article and a separate database article.

The database described in the manuscript must be available for testing by reviewers in a way that preserves their anonymity. If published, the described databases must be accessible by any researcher wishing to use them for non-commercial purposes, without restrictions such as the need for a material transfer agreement. We may require an archive copy of the database to be held by BioMed Central as a safeguard.

If this database is accessible, please include a link of the database in your main manuscript. In addition, the "Availability of data and materials" section must be modified to reflect that fact.

Response by the authors: Thank you very much for this comment. We mistakenly thought we had addressed this point already with our declaration, which stated: “Availability of data and
materials: The datasets used and/or analyzed during the current study can be inspected jointly with the corresponding author on reasonable request. Individual-level data cannot be shared beyond the premises of the Brigham and Women’s Hospital.”

We have now added such text in the main manuscript:

“The registry described in the current study can be inspected jointly with the corresponding author on reasonable request. Individual-level data cannot be shared beyond the premises of the Brigham and Women’s Hospital at this point.”

Please also include this version of response to reviewers comments in your revision work.

Response by the authors: We have done so.