Author’s response to reviews

Title: Which patient reported outcome domains are important to the rheumatologists while assessing patients with rheumatoid arthritis?

Authors:
Apragjita Jagpal (ajagpal@uabmc.edu)
Ronan O'Brien (ronan@uab.edu)
Melanie Morris (mmoris8@uab.edu)
Bernadette Johnson (bajohnson@uabmc.edu)
James Willig (jwillig@uab.edu)
Huifeng Yun (yunn@uab.edu)
Andrea Cherrington (acherrington@uabmc.edu)
Liana Fraenkel (liana.fraenkel@yale.edu)
Jeffrey Curtis (jrcurtis@uabmc.edu)
Monika Safford (mms9024@med.cornell.edu)
Iris Navarro-Millan (yin9003@med.cornell.edu)

Version: 1 Date: 29 May 2019

Author’s response to reviews:

Dear Editor,

Thank you for consideration of our manuscript “Which patient reported outcome domains are important to the rheumatologists while assessing patients with rheumatoid arthritis?” (BRHM-D-19-00003). We have carefully considered all suggestions and comments by the reviewers and editor and made changes accordingly. The way that we have presented the data in the manuscript with Table 1 and the figures was what we thought to be the most clear for the audience of the journal. We would like to mention though that the request from reviewer 2 in the comment # 5 is not clear to us, we will be happy to oblige to the reviewer’s comment, but would need more specific details regarding the request. We hope that with these modifications, the manuscript will be now suitable for publication in BMC Rheumatology.
Thank you for reconsidering our work.

Sincerely,

Iris Navarro-Millán, MD MSPH
Assistant Professor of Medicine
Division of General Internal Medicine
Weill Cornell Medicine
Division of Rheumatology - Hospital for Special Surgery
420 E 70th St., LH-363
New York, NY 10021
Phone: 646-962-5896
E-mail: yin9003@med.cornell.edu

Editor Comments:

#1 In the second sentence in Discussion, the authors wrote that "observable information such as physical findings, inflammatory markers, and radiographic changes were also important for these physicians". However, I don't find any data to support this statement.

R: We have defined in the text what we meant by “objective information”. This refers to signs (“physical findings” topic), tests such as inflammatory markers, and X rays changes (“Tests” topic). All of these are considered objective information as opposed to subjective information.

#2 The number of participants in each group should be shown in figure 2 or in the figure legend.

R: The number of participants in each group have been added in the figure legend.
Reviewer #1 Comments:

Takahisa Gono (Reviewer 1): Aprajita Jagpal et al have conducted a research regarding the PRO for evaluation of patients with RA. This study is unique and interesting. The most important point of this study is to identify which factor rheumatologists consider to make a treatment-decision for patients with RA in daily practice. There, however, are several issues which the authors should clarify in this study.

#1 How did the authors nominate physicians who were invited by emails to participate in this research? How many physicians were invited in total?

R: Thank you for the comment. We sent email invitations to 325 rheumatologists who were members of the American College of Rheumatology (ACR). These members of the ACR are part of a manually curated list maintained by one of the authors. Invitees registered themselves to join the discussion. The investigators did not have a role in the selection of the participants for each group once the invitations were sent as invitees self-enrolled based on their availability and willingness to join the discussion. The maximum number of participants allowed to enroll per group were 12. We have added these details to the manuscript as well (under study participants).

Given the limited time that physicians have and the time commitment for this activity, 90 minutes, we invited a significantly higher number of possible participants so that we can recruit physicians. The goal was not to recruit a large number of doctors but that we identify consistencies in the topics the emerged across nominal groups. After conducting four nominal groups, the topics that emerged were consistent across groups therefore we did not need to recruit more physicians for additional nominal groups.

#2 In 25 rheumatologists who participated in this research, 76% practiced in private practice. The remaining 24% practiced in tertiary referral hospitals, such as university hospital, didn't they?

R: Yes, the remaining participants were working in academic medical centers. We clarified this in the manuscript.

#3 As shown in Figure 2, the distribution of the voted topics was different in each group. What factor influenced the difference of this distribution? Did a distribution of physicians depend on the distribution of the voted topics?
R: This is a great point made by the reviewer. The distribution of physicians (and their preferences) could affected the distribution of the topics. In the nominal group session, the participants enrolled themselves in each group based on their own availability, and willingness to participate. The characteristics of physicians were not identified until they had completed the session. We cannot determine if either an academic physician, a private practice doctor, early career, or senior career doctor made particular statements. We cannot ascertain what factors could have influenced the voted topics as it is beyond the scope of nominal group session. The purpose of showing the distribution of topics per group is to show that the same topics emerged and were discussed across groups. This distribution also showed the percentage votes that each topic obtain, but even though some topics did not obtain a vote in some groups or no votes at all, the topics were discussed in all sessions in one way or another.

#4 Minor issues:

In the result section, "adherence" was voted in only 4%" was described. In the Figure 1, "adherence" was 5%. Which was correct? There were little a bit of difference between Table 1 and Figure 1 in some technical terms, such as physical signs and physical finding, response to treatment and response, and so on. The terminology might want to be consistent in the manuscript.

R: The correct answer for adherence was 4% of the votes. We modified the results section to be consistent with the results reported in Figure 1. We reviewed the text in the manuscript, tables, and figures to make sure that the corresponding results are reported consistently throughout the manuscript.

Reviewer #2 Comments:

Kenji Oku (Reviewer 2): This manuscript discusses the importance of the patient reported outcome (PRO) domains from the aspect of the physicians. The paper arouses some interests but needs some modification before considered for the publication. First of all, the significance or the impact of the study is difficult to recognize. We know that the PRO is important for the daily practices as well as for the clinical researches. We also agree with that there should be physician's opinions included in the PRO. Also, we understand that the nominal group consideration is successfully performed in this study, a good precedent for the time-and-human-consuming procedure. However, this study proposes only the rough domains of the PROs that each item was not surprising and not unexpected. Followings are the points to be modified.
Please introduce some of the existing PROs for RA by indicating their shortcomings and also describe how this study can contribute for the overcoming of those shortage points.

R: This is a very important point. We agree that extensive data on PROs already exist in rheumatoid arthritis and their utilization and value have been documented for the most part from clinical trials and registries, but to lesser degree from clinical practices. Several shortcomings include logistic reasons such as lack of time and tools for collection of PROs, and lack of standardization and validation in RA specific population, particularly for PROMIS. Another shortcoming is that there is limited understanding among clinicians on the scoring and changes in scores of PROs. This study was the first step to identify the data most relevant to the physicians, so that we can identify a series of PROs that are in line with these priorities and build them into an electronic data collection tool. This study, alongside our previous work with patients, serve as formative work towards the development of a tool to collect PROs by identifying where physicians and patients interest and priorities overlap so that we can maximize the opportunity for data collection. We acknowledge that this needs further validation with a larger sample of physicians, which will be the next step in our project that will include a large-scale survey once physicians and patients have had the opportunity to interact with the tool that we are developing.

We have made changes to the discussion and introduced text in the manuscript to discuss some PROs and shortcomings.

Nominal group consideration allows re-ranking for participants as to deepen the discussion. However, I could not find the description showing that the study group having those opportunities. Did I only missed the description or did authors excluded this procedure due to their lack of time?

R: Thank you for the comment. We highly appreciate your input. We did not consider the need for re-ranking. This was because there was a high degree of agreement on responses from the different groups in our study, which met our research needs. While re-ranking can add value to the discussion, published literature in nominal group studies do not always utilize re-ranking step on mandatory basis. [1-3]


#3 It is better to validate the study by collecting external evaluation from the new group of physicians.

R: We agree with the reviewer that a validation process must be done with a different group of physicians. However, the intent is to first identify the kind of subjective data that matters most to the physicians which they will act on that information once available so that we can pair that with the respective PRO (e.g. pain, depression, function, sleep etc.). We will investigate how physicians are collecting PROs once the tool is deployed (e.g. frequency of collection of PROs, the type of PRO), which will be in a different group of physicians, as suggested by the reviewer. We will use this information to validate what we identified in this study. We did not investigate if physicians are indeed willing to collect the data or not, which is beyond the scope of this study, but will be within the development and deployment of the PRO data collection tool as we mentioned in the response to the first comment of this reviewer.

#4 As the participant of this study is not open-recruited. Authors need to show how they recruited them more clearly. Did authors recruited physicians randomly? Or is there any risks of selection bias? How many physicians have the authors contact for the recruitment?

R: Thank you for the comment. We sent email invitations to 325 rheumatologists who were members of the American College of Rheumatology (ACR). These members of the ACR are part of a manually curated list maintained by one of the authors. We have added this to the manuscript as well (under study participants). This was a self-selected sample but we invited rheumatologists across the U.S. from both academic and private practices. This is a semi-quantitative study design, which unlike hypothesis testing studies, is used to generate hypothesis or as a way of informing interventions based on the audience priorities. The risk of selection bias is more of a concern for hypothesis testing studies. Given the study design and goals, to inform an electronic PRO data collection tool for patients with RA and rheumatologists, selection bias is a lesser concern. We will test the PRO collection tool later where we have to take into consideration the risk of bias as part of the hypothesis testing process. It is then, when the selection of participants will be a random sample.

#5 Please show the votes results into the details by aggregating the data by rank order. For instance, in each domain, show the numbers of the votes that selected as most important, second
most important and the third most important. Were there fine accordance among the participants on the rank orders?

R: Thank you for the comment. The data in Table 1 already shows the aggregated votes per each topic and lists out the statements that received maximum to minimum votes. We felt that it was the most clear and concise way of representing the data. The figures show the votes per topic and per group. We would like to receive further clarification of this comment if there was anything else the reviewer would like to do, we would be happy to oblige.