PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for evaluating and implementing a pragmatic value based health care management model for patients with inflammatory arthritis: a Danish population-based regional cohort and qualitative implementation study
AUTHORS	Jørgensen, Tanja Schjødt; Lykkegaard, Jens Jørgen; Hansen, Annette; Schrøder, Heidi; Stampe, Betina; Sweeney, Anne-Marie; Appel Esbensen, Bente; Bech, Bianca; Christensen, Katja; Friis-Mikkelsen, Ellen; Røgind, Henrik; Lundbak, Tine; Taylor, Peter; Petersson, Ingemar; Wæhrens, Eva; Kjellberg, Jakob; Gudbergsen, Henrik; Kristensen, Lars Erik

VERSION 1 – REVIEW

REVIEWER	Dr Lindsay Bearne Department of Population health Sciences King's College London Guy's campus London SE1 1UL
REVIEW RETURNED	24-May-2018

GENERAL COMMENTS	I would suggest that the authors refer to STROBE checklist to guide reporting of the key aspects of this protocol - for example eligibility criteria/ method of participant recruitment needs to be included. In addition would suggest the following revisions: Please use consider using consistent terminology for the study population. At present the text refers to inflammatory arthritis, chronic arthritis, rheumatic diseases, chronic inflammatory arthritides. Please provide a definition of your study population. Consider using long-term or persistent rather than 'chronic' to describe the disease duration Abstract: Include key aspect - eligibility, recruitment method etc Line 25 - is the abbreviation NIS needed? Introduction P4 Line 11 - please define 'sufficient response' Methodology P8 Line 15 onwards. Please include eligibility criteria, identification, recruitment and consent strategies P8 Line 45 please provide full details of focus group methodology, including how the subsample of participants will be selected, anticipated duration of each focus group, facilitator, topic guide, detailed methods of data analysis (with justification/references). P8 Line 20 Please define 'DANBIO' P8 Line 32 who will identify, approach and consent participants? P9 Line 10 Please provide details of the health professionals who will interview participants - please clarify if this is a qualitative research interview and provide methodology details.

	P9 Line 14 Remove the final sentence of this paragraph as this information is duplication of Table 1 P9/10 Table 1 Please complete the table (complete boxes, add units etc) and define abbreviations used in the legend. e.g. What is cs/bDMARD, which swollen and tender joint count is being used - presumably 28 but please state this in full. P10 Line 56 - Is this part of the intervention development? - in which case please consider where best to report this information P12 Line 12 Please clarify data collection - what will be collected when and by whom? P12 Table 2 Title 'outcome measures assessed at follow up baseline' - please clarify at which timepoints these outcomes will be collected Table 2 Please define all abbreviations used (some are omitted from the legend). Which level of EQ-5D is being used? Analysis P13 Line41 Analysis of cost data is included in this section. Please add data collection of these variables to the methods section. Could the authors consider reporting study management and oversight details? Describe how these will be analysed

REVIEWER	Rubén Queiro Hospital Universitario Central de Asturias (HUCA Avda. de Roma s/n. 33011. Oviedo, Spain.
REVIEW RETURNED	31-Jul-2018

GENERAL COMMENTS	Introduction This study protocol undoubtedly tries to delve into a topic of current and future interest for health care systems worlwide. More in concrete, this refers to what is a health care intervention with added value for patients, doctors and society as a whole. The authors adequately define these three kinds of health values. Through this protocol, what is sought is to better identify what health value means for patients. They also aim to identify those factors associated with a poor prognosis in patients with chronic arthritis using the WHO ICF categories. The objectives of the protocol, its reasoning and methods, are well planned and discussed. Some questions however I think deserve a clarification or a deeper and more detailed discussion. - According to this protocol, should we assume that the health value for a patient with established disease of several years of evolution is the same as for a patient with recent onset arthritis ?. In other words, has it been taken into account that what a patient with a long-term disease evolution expects is certainly different from the expectations of a patient with a few months of evolution of his/her disease? - The authors argue in their protocol that an attempt will be made to compare a health intervention system of standard financing with another (the model they advocate) of a fixed budget. What does the latter mean ?. That beyond the pre-specified budget, no other interventions would be carried out even if the patient's health demanded it? - This last point directly relates to what a health intervention with value for a patient means. That is, to obtain an optimal result in the health of the patient at a reasonable cost, not at any cost. In this way, how will the costs of the interventions programmed in the

	protocol be analysed to achieve the health results that are intended to be achieved? - How will authors deal with the age factor in their final analysis? Is it foreseeable that a patient with spondylitis of 30 years of age will have the same beliefs, expectations or healthcare preferences as a 53-year-old woman with rheumatoid arthritis of recent diagnosis? - Why do the authors include three kinds of chronic arthritis as a single process? It is taken into account, for example, that what a patient with psoriatic arthritis (PsA) expects can be very different from the expectations of another patient who has ankylosing spondylitis or rheumatoid arthritis? In fact, to give an example that the authors cite in the references, the PsAID is a specific instrument to measure the impact that PsA generates in the lives of patients. However, this useful tool is not considered in the protocol. What reasons are there for it? - Have the authors planned in some way how to incorporate potential new tools to measure disease activity or therapeutic response in these processes? It would not be strange that within a few years there were significant changes in the therapeutic areas and general management of these diseases that could involve a radical change in the approach to these entities. General comment. In general, the protocol is well designed and reasoned, and attempts to answer a crucial question in patients with chronic arthritis. Basically, this question refers to how the health systems of the world are going to offer quality assistance at an affordable cost to the society of each country. The protocol has more pros than cons, but I think some of the issues raised above should be clarified.

VERSION 1 – AUTHOR RESPONSE

Peer Reviewer 1 (Dr Lindsay Bearne, Department of Population Health Sciences, King's College London, Guy's campus, London)

I would suggest that the authors refer to STROBE checklist to guide reporting of the key aspects of this protocol - for example eligibility criteria/ method of participant recruitment needs to be included.

In addition, I would suggest the following revisions:

Please consider using consistent terminology for the study population. At present the text refers to inflammatory arthritis, chronic arthritis, rheumatic diseases, chronic inflammatory arthritides. Please provide a definition of your study population.

Response: Thank you for raising this important question.

Action: We have chosen “inflammatory arthritis” and inserted were relevant throughout the manuscript

Consider using long-term or persistent rather than 'chronic' to describe the disease duration?

Response: Evaded because the word might be misleading in terms of disease duration, i.e. we also include early inflammatory arthritis

1. **Abstract**
   Include key aspect - eligibility, recruitment method etc Line 25 - is the abbreviation NIS needed

   Response: Thank you for this question.

   Action: We have added more information to the method taking into account the restriction on word count. In addition, we have deleted NIS.

2. **Introduction**

   P4 Line 11 - please define 'sufficient response'

   Response: We agree that this must be defined more clearly.

   Action: We have now clarified the term.

3. **Methodology**
   P8 Line 15 onwards. Please include eligibility criteria, identification, recruitment and consent strategies

   Response: We agree that this could have been better described.

   Action: Information about recruitment is describe in “Design” in the methods section page 8/9. Furthermore, we have added information to “Participants” in the Method section page 9

4. P8 line 45 please provide full details of focus group methodology, including how the subsample of participants will be selected, anticipated duration of each focus group, facilitator, topic guide, detailed methods of data analysis (with justification/references).

   Response: Again, thank you for a very relevant question.

   Action: We have added a section describing the focus group interview methodology at page 9/10.

5. P8 line 20 Please define 'DANBIO'

   Response: We agree that this needs to be defined.

   Action: We have now defined DANBIO at page 9.

6. P8 line 32 who will identify, approach and consent participants?

   Response: Thank you for highlighting the need for further elaboration on this.

   Action: We have added information to “Participants” in the Method section page 9.

7. P9 line 10 Please provide details of the health professionals who will interview participants - please clarify if this is a qualitative research interview and provide methodology details.

   Response: Thank you.

Action: We have added information to “Variables and outcome measures“ on page 10.

8. P9 line 14 Remove the final sentence of this paragraph as this information is duplication of Table 1

Response: Thank you for informing us about this duplication.

Action: We have removed the last sentence.

9. Page 9/10 Table 1 Please complete the table (complete boxes, add units etc) and define abbreviations used in the legend. e.g. What is cs/bDMARD, which swollen and tender joint count is being used - presumably 28 but please state this in full.

Response: Thank you for highlighting the importance of this.

Action: We have now added the relevant information to Table 1.

10. Page 10 line 56 - Is this part of the intervention development? - in which case please consider where best to report this information

Response: Thank you for raising this important question. The interventions have been defined a priori. The current outcomes are used to define the personalized target to treat and will then be allocated if necessary to pre-defined educational tools.

Action: We have added more information on this topic on page 12.

11. Page 12 line 12 Please clarify data collection - what will be collected when and by whom?

Response: Thank you for this question. Please see Table 1 for core set criteria collected by patients, doctors and nurses.

Action: None.

12. P12 Table 2 Title 'outcome measures assessed at follow up baseline' - please clarify at which timepoints these outcomes will be collected Table 2 Please define all abbreviations used (some are omitted from the legend). Which level of EQ-5D is being used?

Response: We agree with the reviewer, this needs to be clarified.

Action: Detailed information and missing abbreviations has been added to the Title in Table 2 page 13/14 and to the Method section on page 9.

13. P13 Line 41 Analysis of cost data is included in this section. Please add data collection of these variables to the methods section.

Response: Again, thank you raising this very important and relevant question.

Action: We have added information to this topic as a supplementary file 1.

Could the authors consider reporting study management and oversight details?
Describe how these will be analysed

Response: Thank you for asking.

Action: We have added information about the management team in the Method section page 7/8.

Peer Reviewer 2 (Rubén Queiro, Institution and Country: Hospital Universitario Central de Asturias (HUCA), Avda. de Roma s/n. 33011. Oviedo, Spain.)

This study protocol undoubtedly tries to delve into a topic of current and future interest for health care systems worldwide. More in concrete, this refers to what is a health care intervention with added value for patients, doctors and society as a whole. The authors adequately define these three kinds of health values. Through this protocol, what is sought is to better identify what health value means for patients. They also aim to identify those factors associated with a poor prognosis in patients with chronic arthritis using the WHO ICF categories.

The objectives of the protocol, its reasoning and methods, are well planned and discussed. Some questions however I think deserve a clarification or a deeper and more detailed discussion.

1. According to this protocol, should we assume that the health value for a patient with established disease of several years of evolution is the same as for a patient with recent onset arthritis? In other words, has it been taken into account that what a patient with a long-term disease evolution expects is certainly different from the expectations of a patient with a few months of evolution of his/her disease?

   Response: Thank you, very good point**.** Stratified analysis will be reported as part of objective

   Action: We have added the information to the "Analysis and statistics" section on page 15.

2. The authors argue in their protocol that an attempt will be made to compare a health intervention system of standard financing with another (the model they advocate) of a fixed budget. What does the latter mean? That beyond the pre-specified budget, no other interventions would be carried out even if the patient's health demanded it?

   Response: The latter is a lump-sum of the current budget given the previous 3 years and adjusted for inflation, without requiring certain amount of DAGs to earn the planned budget.

Action: This has been added to the Method section on page 7.

3. This last point directly relates to what a health intervention with value for a patient means. That is, to obtain an optimal result in the health of the patient at a reasonable cost, not at any cost. In this way, how will the costs of the interventions programmed in the protocol be analyzed to achieve the health results that are intended to be achieved?

   Response: The intervention will be payed for by redistributing resources (the lumb-sum) as the project is not accountable for certain amount of DAGs. Thus, the budget would equal to the "normal" budget and be compared to a standard of care setting both in terms of quantity and quality of patient care (objective 5).

   Action: We have added this information to the Method section page 8.

4. How will authors deal with the age factor in their final analysis? Is it foreseeable that a patient with spondylitis of 30 years of age will have the same beliefs, expectations or healthcare preferences as a 53-year-old woman with rheumatoid arthritis of recent diagnosis?

Response: Thank you for raising the question.

Action: This will be identified during the focus group interviews. For further information about the methodology please see question 4 raised by reviewer 1.

5. Why do the authors include three kinds of chronic arthritis as a single process? It is taken into account, for example, that what a patient with psoriatic arthritis (PsA) expects can be very different from the expectations of another patient who has ankylosing spondylitis or rheumatoid arthritis? In fact, to give an example that the authors cite in the references, the PsAID is a specific instrument to measure the impact that PsA generates in the lives of patients. However, this useful tool is not considered in the protocol. What reasons are there for it?

Response: Thank you for asking this question. We found more or less the same, but we want to use the same identification method across diseases and embedded in a Danish health care setting.

Action: None

6. Have the authors planned in some way how to incorporate potential new tools to measure disease activity or therapeutic response in these processes? It would not be strange that within a few years there were significant changes in the therapeutic areas and general management of these diseases that could involve a radical change in the approach to these entities.

Response: Disease activity tools and outcome measures will not be an aim for this study, however the data gathered could serve as a base for future development on such outcome criterias**.**

Action: None.

General comment:

In general, the protocol is well designed and reasoned, and attempts to answer a crucial question in patients with chronic arthritis. Basically, this question refers to how the health systems of the world are going to offer quality assistance at an affordable cost to the society of each country. The protocol has more pros than cons, but I think some of the issues raised above should be clarified.

Response: Thank you for raising this relevant question.

Action: We have now added more limitations to the Strength and Limitations section, making it more balanced.

VERSION 2 – REVIEW

REVIEWER	Rubén Queiro Rheumatology Division. Hospital Universitario Central de Asturias. Oviedo. Spain.
REVIEW RETURNED	17-Sep-2018

GENERAL COMMENTS	All comments and suggestions of this reviewer have been reasonably answered.