# PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Rethinking rehabilitation after percutaneous coronary intervention – a protocol of a multicentre cohort study on continuity of care, health literacy, adherence and costs at all care levels (the CONCARDPCI) |
| **AUTHORS** | Norekvål, Tone; Allore, Heather G; Bendz, Bjorn; Bjorvatn, Cathrine; Borregaard, Britt; Brørs, Gunhild; Deaton, Christi; Fålun, Nina; Hadjistavropoulos, H; Hansen, Tina; Igland, Stig; Larsen, Alf Inge; Palm, Pernille; Pettersen, Trond; Rasmussen, Trine; Schjøtt, Jan; Søgaard, Rikke; Valaker, Irene; Zwisler, Ann Dorthe; Rotevatn, Svein |

## VERSION 1 – REVIEW

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| **REVIEWER** | Shun Kohsaka<br>Keio University Department of Cardiology |
| **REVIEW RETURNED** | 30-Jul-2019 |

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| **GENERAL COMMENTS** | I appreciate the opportunity to review the work from Norekval et al . This is a design paper of a study (CORCORD PCI) that aimed to identify 'patient journey' from a patient perspective. They plan to collect patient information including PROs (accessed 3 times during the first year?), and 10-year follow up through access to their national registries. The study will involve 7 large PCI centers based in Denmark and Norway. The recruiting centers are high-volume centers, and perform 900-2000 PCIs annually.<br><br>Their strength is participation of the representative PCI centers wihin their nation, intensive screening procedures, and access to national centers and registries (to ensure the occurence/non-occurence of follow-up events),<br><br>Introduction: There is a substantial overlap in information provided in their Introduction section. The contents in the 1st and 3rd paragraph should be integrated. Most of the information provided in the 4th paragraph should probably be described in eithor Methods or Discussion section. Part of the information provided in the final paragraph (eg. sentence regarding the statements from European leaders) should be integrated in the 1st paragraph.<br><br>Methods: Brief summary of the inclusion and exclusion criteria should be provided. It was unlcear to me whether<br><br>It seems also essential to evaluate patient's nutritional status or overall frailty. How do the investigators plan to assess these condtion? Are they inlcuded in the baseline self-repot questionnaires (T0) or perhaps eHEALS or HCCQ? I am also concerned that patient that undergo theshttps://www.expedia.co.jp/e re-testing on eHEALS or HCCQ might be too small (100 out of 3000). |

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| | Page 7 line 51-52: statement on 'study nurse (reviewing the medical records for screening purposed)' overlaps with the statement on line 19-20 on the same page.<br>Page 10: Would be helpful to have more detailed description on the validation process.<br>Results and Discussions seem to be well written and reviewer has not additional comments. |

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| **REVIEWER** | Darshini Ayton<br>Monash University, Australia |
| **REVIEW RETURNED** | 07-Oct-2019 |

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| **GENERAL COMMENTS** | This is an important study and a well written protocol. Some minor comments/suggestions below.<br>Introduction:<br>Line 26: Define diverse support<br>Define what you mean by continuity of care<br>Methods:<br>Would be good to provide a rationale for why self report questionnaires were chosen. There are many cardiac PROMs so justifying these is important.<br>Figure 2 is helpful<br>Process for consent is unclear. Please explain this more.<br>Table 3 would be easier to read if divided into domains associated with the research aims. Measures related to continuity of care; measures related to health literacy and self management; measures related to adherance to treatment and measures related to healthcare utilisation and costs of care. |

## VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Shun Kohsaka
Institution and Country: Keio University Department of Cardiology
Please state any competing interests or state ‘None declared’: None

I appreciate the opportunity to review the work from Norekval et al. This is a design paper of a study (CORCORD PCI) that aimed to identify 'patient journey' from a patient perspective. They plan to collect patient information including PROs (accessed 3 times during the first year?), and 10-year follow up through access to their national registries. The study will involve 7 large PCI centers based in Denmark and Norway. The recruiting centers are high-volume centers, and perform 900-2000 PCIs annually.

Their strength is participation of the representative PCI centers wihin their nation, intensive screening procedures, and access to national centers and registries (to ensure the occurence/non-occurence of follow-up events),

1. Introduction: There is a substantial overlap in information provided in their Introduction section. The contents in the 1st and 3rd paragraph should be integrated. Most of the information provided in the 4th paragraph should probably be described in eithor Methods or Discussion section. Part of the

information provided in the final paragraph (eg. sentence regarding the statements from European leaders) should be integrated in the 1st paragraph.
Authors' response: Thank you. The Introduction has been edited following your suggestions. We integrated the 1st and 3rd paragraph on page 4. Some of the information provided in the 4th paragraph has been moved to the 1st paragraph and overlap deleted. The sentence regarding the statement from European leaders in the final paragraph has been moved to the 1st paragraph, where it fit with the sentence on the AHA health literacy paper (page 4).

2. Methods: Brief summary of the inclusion and exclusion criteria should be provided. It was unclear to me whether
Authors' response: The inclusion and exclusion criteria are provided in Table 2.
Unfortunately, the next sentence in your comment is not complete in the version we received.

3. It seems also essential to evaluate patient's nutritional status or overall frailty. How do the investigators plan to assess these condition? Are they included in the baseline self-report questionnaires (T0) or perhaps eHEALS or HCCQ?
Authors' response: Nutritional status is evaluated by patient self-report, and waist and arm circumference and BMI gathered at baseline (Clinical characteristics in Table 3). Detailed questions on diet including frequency and amount of intake of different foods, variety of beverages, supplements and number of meals per day are included at baseline (Life style in Table 3). Regarding frailty, this is evaluated by using the SOF Index (Table 3), including a question on weight loss measured at baseline and after one year. Detailed questions on physical activity at baseline and at all follow-up measuring points are included (Table 3).

4. I am also concerned that patient that undergo the shttps://www.expedia.co.jp/e re-testing on eHEALS or HCCQ might be too small (100 out of 3000).
Authors' response: The re-testing of eHEALS and HCCQ is done for methodological purposes only to test the psychometric properties (stability specifically) of the instruments. For this purpose, 100 patients will be included in the test-retest reliability evaluated by intraclass correlation (ICC) coefficients of patients' results obtained at a 2-week retest interval. The ICC for agreement is used to get the absolute agreement between repeated measurements between repeated measurements. For patient evaluation and clinical purposes, the eHEALS measurement is repeated at one year (T3) in the full cohort (N=3000).

5. Page 7 line 51-52: statement on 'study nurse (reviewing the medical records for screening purposed)' overlaps with the statement on line 19-20 on the same page.
Authors' response: Thank you. The statement on page 7 line 51-52 is deleted.

6. Page 10: Would be helpful to have more detailed description on the validation process.
Authors' response: The structural, discriminant and convergent validity, and reliability of the scales are evaluated. For internal consistency, Cronbach's alpha is used. Test-retest reliability is evaluated by using intraclass correlation (ICC) coefficients of patients' results obtained at a 2-week retest interval. The ICC for agreement is used to get the absolute agreement between repeated measurements. Confirmatory factor analysis (CFA) is used for evaluating the three-factor structure of the original HCCQ instrument and one-factor structure of the eHEALS. The following fit indices are used: (a) the root mean squared error of approximation (RMSEA) (preferably < 0.06); (b) Tucker-Lewis index (TLI) (preferably > 0.95); and (c) comparative fit index (CFI) (preferably > 0.95). In the manuscript, we added concise information on the validation process of instruments (page 9-10).

7. Results and Discussions seem to be well written and reviewer has not additional comments.
Authors' response: Thank you.

Reviewer: 2
Reviewer Name: Darshini Ayton
Institution and Country: Monash University, Australia
Please state any competing interests or state ‘None declared’: None

This is an important study and a well written protocol. Some minor comments/suggestions below.
1.Introduction:
Line 26: Define diverse support
Authors’ response: While the hospital stay is short, the patients need to gain access to, understand, and use health information, adjust their lifestyle, incorporate new medication, and acquire new support. This new support could be additional services, and an expanded care team. The study intends to map out these many sources of “diverse” support. We revised to “additional sources of support” to clarify (page 4).

2. Define what you mean by continuity of care
Authors’ response: In CONCARD, we avail to Haggerty’s description of continuity of care. In a literature review, Haggerty et al. [BMJ. 2003;327(7425):1219–21.] identified three types of continuity: informational, relational, and management continuity. Informational continuity refers to the use of information from previous events to provide adequate care to the patient. Relational continuity is described as the ongoing relationship between a patient and one or more healthcare providers. Management continuity is viewed as the provision of complementary healthcare services with shared management. The HCCQ was the first to measure multiple dimensions of continuity of care specifically among cardiac patients. It also corresponds well to the three aspects of continuity of care that Haggerty et al. identified. We have added the following reference in the Introduction: Haggerty R, Freeman GK, Starfield BH, Adair CE, McKendry R. Continuity of care: a multidisciplinary review. BMJ. 2003;327(7425):1219–21.

3. Methods:
Would be good to provide a rationale for why self report questionnaires were chosen. There are many cardiac PROMs so justifying these is important.
Authors’ response: Thank you. When determining which PRO questionnaire to use, several considerations are appropriate. Disease-specific measures may be more sensitive to specific symptoms experienced by patients and to challenges related to a particular disease. Considerations of the purpose of collecting PRO data and which type of PRO data is feasible for improving care for a particular patient (or group of patients) are paramount, along with a consideration of the psychometric properties (validity, reliability, responsiveness, sensitivity) of the instrument. We have chosen validated questionnaires on a global, generic and disease specific level, which allow us to evaluate patient-reported outcomes in a comprehensive manner. In case of the questionnaires not being available in Norwegian, we perform translation and validation in a Norwegian context. Regarding the disease-specific questionnaires (cardiac PROMS), we chose the SAQ, MIDAS and HeartQol. All are established questionnaires, although the SAQ is the most used. Still, the SAQ lacks important clinical aspects that are included in the MIDAS. The HeartQol is a promising instrument from the European Society of Cardiology. The HCCQ is also a disease specific (PREM) instrument, and was the first to measure multiple dimensions of continuity of care specifically among cardiac patients. Patient representatives participating in planning of CONCARDPCI ensured relevance of the questionnaires. Albeit, we believe these instruments cover the clinical symptoms, function and concerns of this patient group well. We have added briefly in the Discussion section on page 13 that we evaluate patient-reported outcomes comprehensively by use of measures at different levels.

4. Figure 2 is helpful. Process for consent is unclear. Please explain this more.
Authors’ response: During the in-hospital assessment, participants provide informed consent. Trained CONCARDPCI study nurses explain the study to the patients, including that participation includes

responding to questionnaires at 2, 6 and 12 months post discharge. It is stressed that participation or non-participation has no consequences for future healthcare services provided to them, and that all data will be stored securely according to regulations and treated with care to preserve confidentiality. Patients also receive this information in writing. At each follow-up measurement, patients receive written information on the study and information on their right to withdraw at any point in time. Patients providing informed consent at inclusion is mentioned in the Methods section (page 7). However, in the section on Ethics approval and consent to participate (page 10), we more thoroughly describe that at inclusion, a detailed letter informing the potential participant of the study, and the right to withdraw from the study at any time without any reason is underlined. The identifying key is kept in a separate file from the data, and the data are kept in strict confidence in locked files at research servers to protect the participants' privacy.

5. Table 3 would be easier to read if divided into domains associated with the research aims. Measures related to continuity of care; measures related to health literacy and self management; measures related to adherence to treatment and measures related to healthcare utilisation and costs of care.
Authors' response: Thank you. Several of the instruments are related directly to the research aims. Examples can be seen in Table 4 on outcomes. However, some of the instruments will be used in several of the projects (overview of projects in Figure 1). We have included a new column in Table 3 (headline Projects) which gives information on which project will make use of which measure. We hope this clarifies use of the instruments related to research aims.

## VERSION 2 – REVIEW

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| **REVIEWER** | Shun Kohsaka<br>Keio University Department of Cardiology, Tokyo, Japan |
| **REVIEW RETURNED** | 28-Oct-2019 |

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| **GENERAL COMMENTS** | I appreciate the detailed response from the authors to my previous comments. Most of the concerns have been addressed, only a few minor points to be considered.<br><br>1. Page 4 (Introduction 1st paragraph): Needs some minor editing. For instance, there are two sentences that starts with 'Therefore' (would omit the first sentence since it is fairly obvious that 'more people need to manage life with CAD as a chronic disease.' Would also consider taking out the prior sentence as well ('Although CAD is the<br>single most common cause of death in Europe as around 20% of the population die from the disease, there has been an encouraging decrease in mortality ascribed to improvements in risk-factor management, pharmacological treatment, and revascularization techniques; coronary artery bypass grafting and percutaneous coronary intervention.'), so that the paragarph is more focused on the objective of the study.<br><br>2. Page 5: First half of the 2nd paragraph (discussion on 'Uptake of cardiac rehab') should also be removed, and the latter should be integrated with the following paragraph. |

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| **REVIEWER** | Darshini Rebecca Ayton<br>Monash University |
| **REVIEW RETURNED** | 20-Nov-2019 |

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| **GENERAL COMMENTS** | This is an important study in the age where more and more people |

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| | are surviving cardiovascular events and the need for secondary prevention.<br>Some comments below.<br>1. The first sentence doesn't fit with the rest of the introduction - how is health literacy important to involve patients in planning and service development? This either needs to be expanded on or refined.<br>2. List the four thematic projects in line 56 on page 5.<br>3. It would be helpful to organise page 9 measurement and data collection section by the four thematic projects. It would be helpful to detail the aim, objectives and data collection for each of the thematic projects. At this stage it is unclear how they are four projects instead of just one?<br>4. Data analysis could also be organised under the 4 project headings.<br>Discussion is sensible |

## VERSION 2 – AUTHOR RESPONSE

Reviewer: 1 Reviewer Name: Shun Kohsaka Institution and Country: Keio University Department of Cardiology
I appreciate the detailed response from the authors to my previous comments. Most of the concerns have been addressed, only a few minor points to be considered.

1. Page 4 (Introduction 1st paragraph): Needs some minor editing. For instance, there are two sentences that starts with 'Therefore' (would omit the first sentence since it is fairly obvious that 'more people need to manage life with CAD as a chronic disease.' Would also consider taking out the prior sentence as well ('Although CAD is the single most common cause of death in Europe as around 20% of the population die from the disease, there has been an encouraging decrease in mortality ascribed to improvements in risk-factor management, pharmacological treatment, and revascularization techniques; coronary artery bypass grafting and percutaneous coronary intervention.'), so that the paragraph is more focused on the objective of the study.

Authors' response: Thank you. The first sentence with 'therefore' including 'more people need to manage life with CAD as a chronic disease' has been shortened and collapsed with the next sentence. Further, the following sentence on page 4: 'Although CAD is the single most common cause of death in Europe…' has been shortened and rephrased into: Although CAD is the single most common cause of death in Europe, there has been an encouraging decrease in mortality ascribed to improvements in risk-factor management, pharmacological treatment, and revascularization techniques.

2. Page 5: First half of the 2nd paragraph (discussion on 'Uptake of cardiac rehab') should also be removed, and the latter should be integrated with the following paragraph.

Authors' response: The first part of the 2nd paragraph on page 5 (except for the first five words) has been removed as suggested and the latter integrated accordingly.
We agree that the suggested edits have made the Introduction better and easier to read, and hope it is performed satisfactorily.

Reviewer: 2
Reviewer Name: Darshini Ayton
Institution and Country: Monash University, Australia

This is an important study in the age where more and more people are surviving cardiovascular events and the need for secondary prevention.

Some comments below.
1. The first sentence doesn't fit with the rest of the introduction - how is health literacy important to involve patients in planning and service development? This either needs to be expanded on or refined.

Authors' response: Thank you, we believe that the ability to access, process and comprehend health information and services is of importance for patients to be actively involved in service development, as well as their own care. Health literacy, can be used to complement many fields - from individual patient care to community-level development. Understanding the varying health literacy strengths and limitations of patients, particularly those who experience poor access and outcomes, is thereby pivotal when identifying particular areas of care-planning and intervention development in healthcare service. We have added a reference discussing this issue in depth: Batterham RW, Hawkins M, Collins PA, Buchbinder R, Osborne RH. Health literacy: applying current concepts to improve health services and reduce health inequalities. Public Health. 2016 Mar;132:3-12.
Further, the start of the Introduction has been expanded and refined as suggested, and now reads as follows: 'Health literacy, as the ability to access, process and comprehend health information and services, can be used to complement both individual patient care and community-level development. Understanding the varying health literacy of patients, particularly in those who experience poor access and outcomes, is thereby pivotal.'

2. List the four thematic projects in line 56 on page 5.

Authors' response: Thank you. The four thematic projects have been listed on page 5 as suggested.

3. It would be helpful to organise page 9 measurement and data collection section by the four thematic projects. It would be helpful to detail the aim, objectives and data collection for each of the thematic projects. At this stage it is unclear how they are four projects instead of just one?

Authors' response: The measurement, data collection and analysis in the four thematic projects are the same; therefore, described as one project. These projects are not separate when it comes to design and methods, but rather thematic projects (or work packages within the larger project) as shown in Figure 1. In order to clarify the variables measured related to each project, a separate column in Table 3 is dedicated to Projects and in the footnote each project is stated.

4. Data analysis could also be organised under the 4 project headings.

Authors' response: We have tried to be parsimonious as Reviewer 1 has generally suggested succinct text. The data analysis strategy is similar across the thematic projects, except some aspects of the project concerning 'Health care use and costs'. Therefore, the text would become repetitive were we to describe the analysis strategy for each thematic project. For example, for psychometric evaluation of translated instruments the analysis strategy is the same, but the instruments belong to different thematic projects. Therefore, we have described the analysis that are common for all thematic projects, and then specified if any particular analysis strategy belongs to separate project(s) only.

Discussion is sensible

## VERSION 3 – REVIEW

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| **REVIEWER** | Shun Kohsaka<br>Keio University Department of Cardiology |
| **REVIEW RETURNED** | 08-Dec-2019 |

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| **GENERAL COMMENTS** | I have no additional comments. |