PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A Protocol to Develop a Core Outcome Set in Incisional Hernia Surgery – The HarMoNY Project
AUTHORS	Harji, Deena; Thomas, Christophe; Antoniou, Stavros; Chandraratan, Harsha; Griffiths, Ben; Heniford, Todd; Horgan, Liam; Koeckerling, Ferdinand; Lopez-Cano, Manuel; Massey, Lisa; Miserez, Marc; Montgomery, Agneta; Muysoms, Filip; Poulose, Benjamin; Reinpold, Wolfgang; Smart, Neil

VERSION 1 – REVIEW

REVIEWER	Alkhaffaf, Bilal Salford Royal NHS Foundation Trust, Department of Oesophago-Gastric Surgery
REVIEW RETURNED	07-Sep-2018

GENERAL COMMENTS	Well written article. Clear and to the point. The study will attempt to answer some very important questions. The methodology is rigorous and based on several other COS projects. Some queries for the author as follows: 1. Have the authors undertaken a 'rapid review' of literature over the last 12 months to demonstrate heterogeneity of outcome reporting in this field? This would be a more objective reason to explore this area further. 2. Please could the authors provide justification for which subjects they will interview? Especially with respect to nurses, radiologists, physiotherapists. If this is a patient-centred COS, what will these other interviews add that the team will not gain through the Delphi? 3. The authors state that 'Relevant outcomes will be identified and appropriately coded from the transcripts using a provisional coding framework based on the outcomes extracted from the systematic review'. How will authors identify outcomes not previously reported in the literature and that do not fit within the framework? 4. The outcomes identified in Phase I and II will be combined, developed into a long-list of items and categorised into broad domains. How do the authors plan to categorise the outcome domains? Are they using a validated system or one devised by themselves? 5.What methodology will be used to translate the survey? This is a huge undertaking that requires cultural adaptation and needs more detail. 6. How many stakeholder groups will participate in the Delphi? Will all healthcare professionals be part of one group or will each stakeholder group score outcomes within the Delphi? 7. What is the justification for the Delphi inclusion/exclusion criteria? The exclusion criteria are unlikely to be reached.

	8. If the Delphi has sufficient participation, would it not be far better use of resource if the consensus meeting simply discussed outcomes where consensus was not reached in the Delphi? A further meeting seems an inefficient use of resources, particularly given the international nature of the study.

REVIEWER	Pinkney, Tom University of Birmingham School of Clinical and Experimental Medicine, Surgery
REVIEW RETURNED	09-Oct-2018

GENERAL COMMENTS	This is a well-written protocol for an important and necessary piece of work. The team is well balanced and are a good mix of experts who know their onions, and trainees who are keen and capable. The protocol is clear and easy to follow. The study has been registered with the relevant systems/bodies - PROSPERO and COMET. There is no doubt in my mind that it should be accepted for publication. All of my comments are minor: Minor points: 1. Authorship - corporate authorship is perfect for this kind of project. A corresponding author is necessary, but why are the other co-authors all shown here in the corresponding author section? I would expect them to be at the bottom of the paper in a 'collaborators' or 'co-investigators' section 2. "The adoption of this COS into clinical and academic practice has been endorsed by the American, British and European Hernia Societies." This is rather strange, given that you haven't produced it yet. Suggest reword slightly. 3. It is commendable and appropriate that the researchers wish to interact with stakeholders that are not adequately represented within the current literature i.e. nurses, radiologists, physiotherapists - but how will these be approached and obtained - it states in the following paragraph that "All members of the American Hernia Society, the British Hernia Society and the European Hernia Society will be contacted and invited to participate" - but is is highly likely that the aforementioned groups will not be members of such societies 4. In patient eligibility criteria - one of the exclusions is "Breach of inclusion criteria". Which is just unnecessary.

VERSION 1 – AUTHOR RESPONSE

Response to BMJOpen Comments for Harmony Protocol

Dear Reviewers,

Many thanks for your comments on our paper ‘A Protocol to Develop a Core Outcome Set in Incisional Hernia Surgery – The HarMoNY Project’.
We have made the appropriate amendments and responded to the comments below.

Reviewer 1:

1. A systematic review was undertaken by Parker et al examining outcome reporting for randomised controlled trials for ventral hernias including incisional hernia. This group of

authors revealed marked heterogeneity in outcome reporting of clinical endpoints related to hernia recurrence in this cohort of patients. Following this work we felt it was important to explore outcome reporting across all studies reporting outcomes for incisional hernia.

2. We feel it is important to represent all stakeholders equally when developing a COS. Healthcare professionals such as nurses and physiotherapists provide unique insights into aspects of patient care that may not be reported in the literature. By including all stakeholders we hope to increase the potential future clinical and academic utility of our COS, as it will reflect the consensus opinion of all stakeholders, which in turn will standardise outcome reporting and improve patient care.

3. We have employed an inductive-deductive approach to highlighting reported outcomes. Our inductive phase is Phase I and will focus on outcomes reported in the current literature. Identified outcomes will be categorised using the principles of content analysis and will inform a provisional coding framework.

Our deductive phase is Phase II which will highlight qualitative data from stakeholder interviews. All interviews will be analysed using the principles of content analysis. Emerging themes will be categorised in accordance with the provisional coding framework. Any new themes arising will be identified as being new and will be categorised accordingly. This approach will enable structured data collection combined with an explicit analytical procedure which is informed by a priori reasoning based on the current literature and will extend this framework based on new and emerging qualitative data.

4. We will use the principles of forward-backward translation for translating the Delphi questionnaire into a variety of languages. This is a recognised method of translation and is advocated by the European Organisation of Research and Treatment of Cancer. The aim of translation is to achieve different language versions of the original Delphi questionnaire. The linguistic and translation process should ensure that the translated version of the Delphi are conceptual, semantic and pragmatic equivalents of the original questionnaire, whilst ensuring it is culturally appropriate, relevant and meaningful to the target countries.

The translation process should ensure conceptual equivalence in each target country (i.e. answers to the same questions in all language versions should reflect the same concepts), item equivalence (i.e. the semantic equivalence of each question survives translation across languages), and that each language version remains culturally relevant, acceptable and understandable. The original Delphi questionnaire (English) will be used as the standard from which all other translations are made.

Forward translation will be undertaken by two healthcare professionals with an understanding of incisional hernia. The translators will be bilingual with their primary language being that of the target country. They will perform a detailed review of the Delphi questionnaire and translate the questionnaire appropriately. Two independent translations will be prepared; these will be reviewed and compared to achieve a consensus version. Any discrepancies between the translated version and the original Delphi questionnaire will be discussed with the steering committee.

The final agreed translated version will be translated back into English (backward translation). This will be done by a native English speaker who is also proficient in the target language. The original Delphi questionnaire will be compared to the backward translation version and reviewed to ensure consistency. The aim is to ensure linguistic and conceptual equivalence between the original and translated versions of the Delphi. Any discrepancies will be discussed and resolved with the steering commitee and the bilingual translators who undertook the forward translation. If equivalent versions have not been created further translational work may be required. This may include additional forward

translations and/or the addition of further items/questions and will be repeated as many times as necessary to achieve a satisfactory translated version.

The final phase of forward-backward translation is pre-testing. The translated questionnaire will be pre-tested in patients from each participating country. Cognitive interviews will be used to determine comprehension and acceptability of the questionnaire. A sample size of 10-15 patients will be required for this phase. The results from the pre-testing will inform the finalised version of the translated questionnaire.

5. There will 6 broad categories for stakeholders including patients, general surgeons, plastic surgeons, radiologists, specialists nurses/physiotherapists and industry partners. Scores for each stakeholder group will be reported separately within the Delphi.

6. The eligibility criteria has been chosen to include only patients with incisional hernia. We have chosen to include patients with an existing incisional hernia or an incisional hernia which has been repaired within the last 12 months. The justification for this criteria is to minimise patient recall bias when discussing the impact of their hernia of their quality of life and daily activities.

7. The consensus meeting is a key part of the Core Outcome Measurement in Effectiveness Trials (COMET) methodology. Phase IV will be undertaken at the European Hernia Society meeting. This meeting will agree on the final COS. To do this it is essential to review all outcomes that have been included and excluded through the Delphi process to ensure appropriate items have been included and no important items have been excluded. The main focus of this meeting will be to discuss those items which did not achieve consensus during the Delphi process for inclusion/exclusion from the final COS.

Reviewer 2

1. We would be happy to publish this piece of work under the NoSTRA HarMoNY Collaborative. This was our intention, however, the submission process did not allow us to submit easily under the corporate authorship.
2. We have amended this sentence appropriately.
3. We recruit specialist nurses, radiologists and physiotherapists through surgeons participating in the project. All team members at participating hospital sites involved in managing patients with incisional hernia will be invited to participate in project.
4. We have removed this sentence.

VERSION 2 – REVIEW

REVIEWER	Alkhaffaf, Bilal Salford Royal NHS Foundation Trust, Department of Oesophago-Gastric Surgery
REVIEW RETURNED	19-Dec-2018

GENERAL COMMENTS	Dear Editor The team have answered the majority of questions satisfactorily. There are two questions from the original review which require further clarification: 4. The outcomes identified in Phase I and II will be combined, developed into a long-list of items and categorised into broad domains. How do the authors plan to categorise the outcome

	domains? Are they using a validated system or one devised by themselves? From personal experience in this field, it is important to ensure that outcomes are categorized. This is helpful for the study team (as the initial long-list will likely identify hundreds of outcomes), the study participants and for COS developer who are developing methodoligcal approaches in this new field. How will the team plan to organise their outcomes? There is a validated system already published; some COS developers have decided to use their own system. 7. What is the justification for the Delphi inclusion/exclusion criteria? The exclusion criteria are unlikely to be reached. I think I was not clear enough in my question. How has the study team reached their criteria for including or excluding outcomes scored during the Delphi survey?

VERSION 2 – AUTHOR RESPONSE

Dear Reviewer,

Many thanks for your comments on our paper 'A Protocol to Develop a Core Outcome Set in Incisional Hernia Surgery – The HarMoNY Project'.

We have made the appropriate amendments and responded to the comments below.

1. We will use the principles of thematic content analysis to categorise the outcomes into broad domains. This is a recognised qualitative methodology which employs an inductive approach to categorising outcomes.

2. The criteria for the inclusion/exclusion criteria were based upon the criteria employed for previous Delphi studies which have been successfully completed and were felt to be appropriate by the steering committee.