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Hub: ConDuCT-II Bristol	Host University: University of Bristol
Supervisor: Sara Brookes & Rob Hinchliffe (joint leads) Sara.T.Brookes@bristol.ac.uk	Co-supervisors: Joy Adamson, Paula Williamson
Is the project clinical or non-clinical?: Either	
Title of PhD project: Understanding the impact of feedback in Delphi consensus methodology: a case study nested within the development of a core outcome set (COS) for diabetic foot ulcer treatment	

Background to the project: Core Outcome Sets are an agreed set of outcomes recommended to use in all randomized controlled trials of a particular treatment, to improve data synthesis across trials, reduce research waste and limit outcome reporting bias. They require stakeholders to identify and agree the core set, prioritizing outcomes from a long list of potential items. An increasing number of COSs employ a Delphi survey as a method to obtain consensus amongst stakeholders. Participants rate the importance of different outcomes in a questionnaire; summarized responses are fed back in subsequent questionnaires or 'rounds' such that initial responses may be changed in light of this feedback. This is the only mechanism for gaining consensus within the Delphi. The exact methodology used varies and the most appropriate methods are unknown.¹ Previous work has demonstrated that feedback, and type of feedback, impacts on subsequent responses, but the rationale for such impact is not always clear.² Consensus is fundamental to the Delphi process and it is crucial to ensure it is not simply a result of participants 'conforming'. Qualitative work is now needed to gain further understanding of how participants respond to feedback and to what extent consensus is reached within a Delphi survey. This will inform optimal future development of COSs.

This methodological work will be embedded within the development of a new COS for diabetic foot ulcer treatment. Foot ulceration is a major cause of morbidity in people with diabetes. Delayed or inadequate treatment may result in leg amputation. There are around 100 amputations per week in the UK, with 85% preceded by a foot ulcer.³ The evidence base for relevant treatment is of poor quality and outcomes reported across trials are heterogeneous and poorly defined;⁴ hence treatment decisions are based on unfounded patient and clinician preferences. There is an urgent need for a minimum set of outcomes (a COS), agreed by key stakeholders, to be reported in all trials of treatment for diabetic foot ulcer.

What the studentship will encompass (including fieldwork):

- *Systematic review:* Identify methodological studies exploring consensus within Delphi surveys and the influence of providing feedback on subsequent decision-making.
- *The development of a COS for diabetic foot ulcer:* (i) Phase 1 - identification of a 'long list' of outcomes including a systematic review of treatments for foot ulcer and development of a survey questionnaire; (ii) Phase 2 - prioritization of outcomes by patients and clinicians using a 3 round Delphi survey, and; (iii) Phase 3 - consensus meeting to finalize COS.
- *Qualitative interviews:* Within Phase 2, qualitative interviews will explore how participants respond to feedback. Purposive samples of patients and clinicians (25-30) completing round 1 of the Delphi will be recruited. 'Think aloud'⁵ cognitive interviews will be conducted whilst participants complete rounds 2 and 3. Focus will be on how a respondent makes the decision to initially score an item and how they rescore that item based firstly on feedback from their own stakeholder group and then based on that of other stakeholder groups. Different styles of feedback will be considered (quantitative and qualitative data). Recommendations for conducting a Delphi process in COS development will be generated.

Supervision: Regular meetings with Professor Hinchliffe and Dr. Brookes. Professor Adamson will advise on qualitative aspects. Professor Hinchliffe is Professor of Vascular Surgery interested in clinical trials, Board member of the International Working Group of the Diabetic Foot and Editor of British Journal of Surgery. Dr. Brookes is joint lead of the ConDuCT-II Hub outcomes theme and has contributed substantially to the development of COSs. Professor Adamson is Professor of Applied Health Research and Ageing with extensive qualitative and mixed method expertise. Professor Williamson is experienced in COS development, she chairs the COMET Management Group and will help advise the overall design/conduct of the research.

¹ Sinha IP et al. PLoS Medicine 2011. 8(1) e1000393.

² Brookes ST et al. Trials 2016. 17(1):409

³ nice.org.uk/guidance/ng19

⁴ Lancet Diabetes Endocrinol. 2016 Sep;4(9):781-8

⁵ Willis, G. B. (2005) Sage

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Supplementary information

1. Describe the alignment of the project with the HTMR Network strategy

The proposal aligns well with the HTMR Network strategy. The collaborative supervision promotes high quality collaborative methodological research relevant to trials, both across Hubs (ConDuCT-II and North West Hubs) and with other groups (COMET Initiative, University of Newcastle) with collaborative supervision. The student will also liaise with two other PhD students in the North West Hub working in the area of core outcome sets. The work will help inform the clinical trials community of the most effective and appropriate methods with which to develop future core outcome sets for use in trials and will provide a COS for diabetic foot ulcer treatment to be used in all future randomized trials. The advisory group will also enable the work to be guided and influenced by different stakeholders.

2. Does this project align with the work of a HTMR Working Group; if so, which?

This project fits well with the HTMR Outcomes Working Group (OWG); OWGs themes include reporting of outcomes and core outcome sets. The successful candidate would become a member of the Outcomes Working Group and participate in meetings. The OWG includes members with experience of core outcome set development in institutions both within and outside of the Hubs and would offer a good networking opportunity for the student.

3. Describe how this project aligns with the host Hub strategy

Within the outcomes theme of ConDuCT-II, COSs are a major focus, so this work will be well positioned within the Hub.

4. Detail of any Project specific training offered in the studentship

The student will receive additional training in qualitative interviewing, including 'think aloud', and qualitative analysis and basic statistics if necessary. An advisory group will consist of a patient and public representative, a clinical expert and an experienced qualitative researcher with knowledge of the Delphi process. In addition, there are currently two ongoing PhDs in the North West Hub exploring patient involvement and participation in COS development. The PhD students will liaise as an additional learning opportunity.

5. Are there any prerequisite qualifications or experience for this studentship?

Candidates for an MRC-funded studentship must meet residence eligibility and hold qualifications in a relevant subject at the level of, or equivalent to, a good honours degree from a UK academic institution (see methodology website for more details- www.methodologyhubs.mrc.ac.uk).

For this project: Previous experience and interest in health services research. Knowledge of randomized controlled trials. Experience of using qualitative methods. Training in basic statistics will be offered if necessary so is not a pre-requisite.