

R30: Trial Steering Committees for Randomised Controlled Trials: Updating and Redeveloping Guidance and Terms of Reference, Informed By Current Practice and Experience

Summary/list of the original objectives:

1. Development of a comprehensive Terms of Reference document which will be submitted for publication.
 - a. Survey of registered CTUs to establish current practice and identify areas of MRC Terms of Reference that require updating and development.
 - b. Examining reporting of TSC activity in RCT journal publications.
 - c. Meeting of an expert panel to consider guidance development.
2. Dissemination
 - a. Submit an abstract for an oral presentation and/or workshop to be delivered at the MRC Trials Methodology
 - b. Circulation to UKCRN registered Clinical Trials Units
 - c. Circulate the Terms of Reference document to key funders.
 - d. Request the paper be tabled at a meeting of the UKCRN CTU Directors and at the UKCRN CTU statistician meetings.
 - e. Make recommendations to the CONSORT group on whether and how to incorporate reports of TSC activity in publications of RCTs.

What was actually achieved:

1. Development of the ToR
 - a. A survey of the registered CTUs was undertaken. An 81% (38/47) response rate was achieved. This survey was extended from its original objectives to include a request that CTUs provide a recent copy of a TSC terms of reference template or trial specific document. The text of these documents were analysed in NVivo. This has been written up as a paper and submitted to Clinical Trials where its status is waiting editorial decision.
 - b. TSC activity in journal reports of RCTs. Three journals were included for this objective (Lancet, NEJM, BMJ) for the time period been 1st July-31st Dec 2012. Additionally all HTA monographs were considered for inclusion. 415 potentially eligible reports/monographs were identified of which 264 (127 from HTA monographs) were eligible for inclusion. Codes were developed to summarise reporting of TSC role and activities across main trial publications and supplementary material. A draft manuscript is scheduled for circulation across co-authors by the end of Feb and the aim is to submit to Clinical Trials or Trials.
 - c. The expert panel was convened and comprised members identified and agreed by the co-applicants on the Hub network funded project. The panel consisted of a number of members who were also contributors to DAMOCLES. A set of questions were developed for the expert panel to consider during a full days meeting, however at their request this was extended by the addition of a further face to face meeting

and email correspondence. The transcripts of those two full day meetings have been summarised and supportive quotes from the meetings extracted. Following agreement by the expert panel this will be written up as a paper and will inform the development of the Terms of Reference document.

Additional

- d. The above components are all required to generate the revised Terms of Reference. However, given the engagement with the registered CTUs we have decided that prior to finalising the key guidance document we would like to pilot it across a number of volunteer CTUs. Therefore due to the time to pilot and revise as necessary this is expected to be completed and submitted for publication by July.
2. Dissemination
 - a. An abstract will be submitted to the 2015 HTMR conference in Glasgow.
 - b. The registered CTUs have been engaged with this project from the start. The project protocol and results of the survey have been presented at two network meetings of the UKCRC registered CTU Statistics Operational Group. This has led to the identification of volunteers to pilot the guidance. Following the pilot the finalised version will be discussed at a further meeting of the UKCRC registered CTU Statistics Operational Group.
 - c. During the course of the project there has been engagement with the funders. At the time of piloting the ToR will also be sent to the funders for their input and to initiate discussions around adoption of the guidance document.
 - d. Following the piloting a request will be made to the Executive committee of the UKCRC CTU Directors to table the ToR at an upcoming meeting.
 - e. The paper currently in draft for objective 1b will be sent to the CONSORT group and a request for the paper to be included as a reference on their website. The paper includes suggestions on the information that should be reported within a RCT journal publication and details of what should be included within supplementary material. Members of the expert panel are authors of the CONSORT guidelines and we will use this route to encourage consideration of these aspects in a subsequent CONSORT revision.
- Additional*
- f. A webinar is planned for the outputs of this project for the HTMR Trial Conduct Working Group. The webinar will take place on the 7th July 2015.

Summary of activity over next 12 months:

- Publication of work related to 1a and 1b, with finalised ToR as a further publication which will include expert committee considerations.
- Work with the UKCRC registered CTUs to pilot the ToR and then disseminate across the network
- Engagement with funders (NIHR, MRC, Wellcome Trust) and CONSORT group to gain endorsement/adoption
- Webinar for the HTMR Trial Conduct Working Group.
- Widespread circulation across journals to encourage improved reporting standards for oversight committees