

R34 An ethnographic study of group decision-making and member roles to understand and improve how Trial Steering Committees and Trial Management Groups contribute to trial conduct (QuANTOC study)

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Summary of the original objectives

1. To understand the roles and decision-making of Trial Steering Committees (TSCs) and Trial Management Groups (TMGs) and how they enhance trial conduct using ethnographic methods
2. To contribute to updates to the MRC Terms of Reference for TSCs and TMGs

What was actually achieved

1. A purposive sample of eight trials (case studies) across the UK who were facing 'challenging' decisions about trial conduct were successfully identified through close collaboration between: ConDuCT HTMR, North West HTMR, All-Ireland HTMR, the MRC Clinical Trials Unit, the Health Services Research Unit at the University of Aberdeen and with the help of a Funder.
2. Using ethnographic methods, non-participatory observation of TSC and TMG meetings was triangulated by follow-up interviews with committee members. We also had access to study documents such as minutes, reports and Charters if available (Table 1).

Table 1: Data collected

	TSC	TMG
Observed and Recorded Meetings	8	6*
Interviews**	37	22
Documents	12	8

* one TMG meeting was cancelled, one was not observed as it was embedded within an overseas conference

** 8 additional interviews with Funder, Sponsor and Chief Investigator representatives were also conducted

3. The data were fully transcribed, and coded and analysed thematically using methods of constant comparison, aided by the qualitative software NVivo. The project researcher (Anne Daykin) led the analysis, with support of the wider team.
4. Analysis focused on two broad areas, to address the first of our original research objectives: firstly, the role and value of TSCs and TGMs, and secondly, decision making and accomplishment of tasks within TSC/TMG meetings. Both these areas of analysis inform updates to the terms of reference for TSCs and TMGs (our second objective).
5. Alongside our qualitative study, we have collaborated with a parallel quantitative study on TSCs, led by Gamble (North West HTMR). Knowledge exchange between the two TSC studies has occurred through joint teleconference meetings and workshops, where the findings of the two studies have been discussed by expert consensus groups, to generate recommendations for the MRC Terms of Reference for TSCs.

6. Findings from the study have been successfully disseminated at a variety of conferences and workshops. These include: oral presentations at the MRC Trials Methodology Conference in Edinburgh (November 2013) and the South West Society for Academic Primary Care Conference in Bristol (March 2014). The study methods have been disseminated to the trials community through a *Qualitative Research in Trials* workshop at the University of Bristol (May 2013). A poster presentation was given at the Society for Clinical Trials in Philadelphia, USA (May 2014).

The next steps for the project

1. Two peer-reviewed publications are near to submission to peer reviewed journals relevant to the trials community.
 - 1a. The first paper focuses on the role and value of TSCs and makes a series of practical recommendations for updates to the MRC Terms of Reference for TSCs. This is shortly to be submitted to *Trials* following final review by all authors.
 - 1b. The second paper addresses types of decision making and accomplishment of tasks within TSCs and TMGs, and is aided by a recent collaboration with Professor Pat Hoddinott at the University of Stirling which arose from presentation of the study findings at a ConDuCT Hub meeting. This paper has taken a new direction through this collaboration and will be submitted to *Trials* or *Clinical Trials* early in 2015.
2. An abstract reporting some of the study findings has been submitted to the 2015 Society for Clinical Trials Conference in Virginia, USA. We hope that this will lead to an oral presentation at the conference.
3. Following joint workshops with the parallel quantitative TSC study led by Gamble, we hope to collaborate on a joint mixed methods paper reporting findings from both studies, leading to further integrated recommendations about updates to the MRC Terms of Reference for TSCs. The joint findings will benefit members of the trials community who design and conduct clinical trials along with those who oversee their conduct.
4. A summary of the study findings will be disseminated to the trial community via registered trials units.