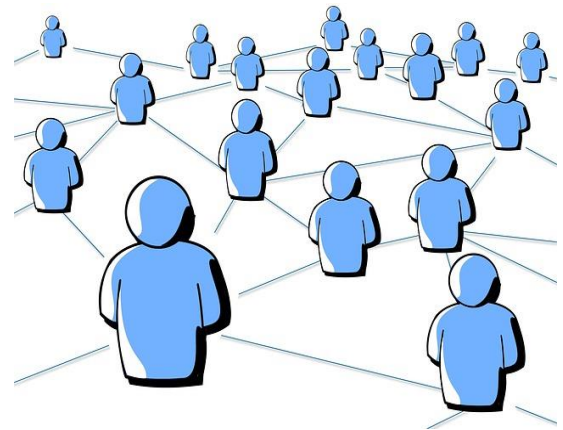


Research Summary

17 January 2018

Relationships in trial oversight and their impact

Trial oversight in the UK is informed by the Medical Research Council's (MRC) Guidelines for good clinical practice in clinical trials, published in 1998. These need updating to reflect advances in trial conduct. Clinical Trials Units (CTUs) now play an important oversight role, and recent evidence points to ambiguity and confusion regarding the roles of different stakeholder in trial oversight.



We examined how the oversight of clinical trials is implemented to inform future guidelines for those planning and conducting trials. We found that the relationships between stakeholders involved in trial oversight are central to the process and quality of that oversight. Effective oversight depends on clearly defined and collaborative relationships between Trial Management Group (TMG), Trial Steering Committee (TSC), Data Monitoring Committee (DMC), and trial funders and sponsors. Lack of clarity regarding responsibilities, accountability and lines of communication threatens trial oversight.

What we did

We conducted an ethnographic study to explore trial oversight in practice. Through observing and recording 14 TSC and TMG meetings associated with 8 clinical trials across a range of settings and topics, and interviewing 52 people involved in conducting, overseeing and funding trials, we built up a detailed picture of how trial oversight takes place.

What we found

- There was evidence of collaborative relationships, based on mutual respect, between CTUs, TMGs and TSCs, but also evidence of conflict.
- CTUs provided methodological and trial conduct expertise within the TMG, and could also act as arbiter between trial oversight committees in cases of conflict.
- Trial managers (TMs), usually employed by a CTU, were key in supporting trial Chief Investigators (CIs) by running day-to-day trial management.
- Relationships between trial oversight committees were influenced by stakeholders' priorities, both organisational and individual. For example, CIs were perceived as personally invested in the success of their trial, and CTU members as more objective and detached.
- Good communication following specific, recognised routes played a central role in ensuring that relationships were productive and trial oversight efficient.
- Participants described the possession of power over trials as a shifting political landscape, and there was lack of clarity regarding the roles and accountability of each oversight committee, the sponsor and funder.

- The appointment of independent TSC members by a funder, and the potential consequences of this for trial rigour, was a concern for some participants, who felt it compromised the independence of the TSC.
- Stakeholders' perceptions of their own power over a trial, and the power of others, influenced relationships between those involved in trial oversight. For example, fear of being called to a 'monitoring meeting' by a funder could lead CIs to put a favourable 'spin' on their progress reports, affecting the quality of trial oversight.

Ten recommendations to inform trial oversight

1.	Led by their Chair, trial oversight committees must foster a culture of openness and mutual respect, recognising and drawing upon the skills of all trial oversight committee members. To ensure optimal decision making and problem solving, committee conduct should be respectful of all voices and Chairs should actively seek opinions from all members.
2.	Recognise the partnership role of CTUs and TMs in managing a trial and supporting the CI in decision making, management, and achieving deliverables.
3.	The differing priorities of trial stakeholders in overseeing and delivering the trial should be explicitly stated, considered and, where necessary, realigned to the shared priority across stakeholder groups to produce a good quality trial that informs practice. Guidance and best practice on resolving differences should be shared and could be collated and hosted by CTUs and funders.
4.	Clear lines of communication between oversight groups should be established in advance of the trial starting, documented in the trial Charter, shared between stakeholders, and maintained. From the trial outset, the frequency of oversight meetings should be considered and agreed. The frequency should be regular enough to be responsive to challenges and implement trial oversight decisions promptly, while allowing for extraordinary meetings in the event of challenges.
5.	Ensure a primary, single point of contact for the trial, and coordinate communication with trial oversight stakeholders.
6.	Consider and agree before trial initiation who will act as arbiter if/when needed; the CTU may or may not play this role.
7.	Consult with stakeholders to determine the full implications of funders appointing independent TSC members to trials, and agree an approach to this issue.
8.	Clarify the roles and responsibilities of all those involved in trial oversight, and make stakeholders aware of these. This includes the different reasons for shutting down a trial, and which oversight bodies might do so in which circumstances. Each trial should consider these from the outset. Discuss before trial initiation the information needs of different stakeholders and communicate efficiently and in a timely manner as needed.
9.	Be aware of how the threat of monitoring meetings, or of closing trials, can negatively impact trial conduct and relationships, especially the way a CI or TMG might present the trial to the TSC. It might be of benefit to identify risks to the trial from the outset, and report on these at each meeting.
10.	Acknowledge how the close relationship between TSC and funder and the threat of the latter withdrawing funding is in tension with the role of the TSC in providing expert support to the TMG. Power hierarchies between committees can restrict the effectiveness of trial oversight, so efforts should be made to decentralise power.

Further information

Paper: Daykin A, Selman LE, Cramer H, McCann S, Shorter GW, Sydes MR, Gamble C, Macefield R, Lane JA, Shaw A. [‘We all want to succeed, but we’ve also got to be realistic about what is happening’: an ethnographic study of relationships in trial oversight and their impact](#). *Trials* 2017; 18:612.

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