



Perinatal Trials Toolkit

Establishing a data monitoring committee (DMC)

Primary role

The DMC monitors trial data to check that there are no clear reasons to change the trial protocol, or terminate recruitment early or extend recruitment to secure a larger sample size. A data monitoring committee may or may not have a separate Safety Monitoring Committee.

Data monitoring committees have to balance the competing interests of trial participants and potential future participants and society (or people that may benefit or be harmed by the intervention in the future)

- these interests don't always coincide
- trial participants' interests are served by closing recruitment as soon as a clear answer is available (so that all patients can receive the best treatment)
- society's interests are served by continuing recruitment until a clear answer is available so that results are sufficient to lead to a change in clinical management of future patients
- stopping the trial early may appear to confer benefits to trial participants but if sample is too small to detect a real difference then neither participants or society will benefit
- stopping a trial early for apparent benefit has ethical implications and may lead to biased results – inflating the size of the treatment effect, particularly if the event rate is low (Montori 2005, Mueller 2007)

What to consider when putting together a DMC

Number of members	usually 3 to 8 members
Independent	need to declare any competing/conflicting interests
Multidisciplinary	including at least one clinician and one statistician
Chair	should be experienced, understand statistics and clinical issues and take a facilitatory approach
Trial statistician	conducts the confidential analyses and attends closed sessions of the DMC but is not a member of the DMC
DMC statistician	provides statistical guidance to the DMC - trial statistician and DMC statistician need to agree on the analytical approach planned

Questions for the DMC to consider

The study should stop completely or partially

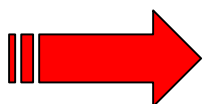
- Apparent strong benefit of active treatment on primary outcome
- Apparent strong benefit of control on primary outcome
- Safety concerns with secondary outcomes
- Small chance of eventually showing benefit
- Convincing evidence of equivalence or non-inferiority

Part of the study should stop?

- Stopping randomisation in a subgroup for one of the above reasons
- Stopping randomisation in one arm for one of the above
- External evidence
- Need to influence clinical opinion

The study should continue with modification?

- Additional interim analyses
- Extending recruitment or follow-up time



[See related toolkit - Statistical approaches to data monitoring](#)

SCENARIO ONE

You and your team have just been awarded a large grant to carry out a major perinatal trial and are recruiting participating centres.

A US trial of a similar intervention is closed down very early with *widespread publicity* on the grounds of a cluster of adverse outcomes.

What do you do? Would a functioning data monitoring committee make a difference to your options? Or to your actions?

SCENARIO TWO

Clinician/researcher A is carrying out a relatively small clinical trial in her/his own work setting. A's work includes: Recruitment of women or babies; information for potential participants; seeking informed consent from the women. There are no problems.

Clinician/researcher A decides this is a good time to update the systematic review (SR) of the intervention which was carried out before s/he began the current trial. The updated review shows strong but not conclusive evidence that the intervention is harmful.

What should A do? What are the consequences for the trial? What are the consequences for practice?

This toolkit was prepared by Caroline Crowther, Judith Lumley and Rebecca Tooher.

References:

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