“You have to keep your nerve on a DMC.” Challenges for data monitoring committees in neonatal intensive care trials: qualitative accounts from the bracelet study

The Harvard community has made this article openly available. Please share how this access benefits you. Your story matters

| Citation       | Snowdon, Claire, Diana Elbourne, Peter Brocklehurst, Martin Ward Platt, and Robert Tasker. 2015. “You have to keep your nerve on a DMC.” Challenges for data monitoring committees in neonatal intensive care trials: qualitative accounts from the bracelet study.” Trials 16 (Suppl 2): 038. doi:10.1186/1745-6215-16-S2-038. http://dx.doi.org/10.1186/1745-6215-16-S2-038. |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Published Version | doi:10.1186/1745-6215-16-S2-038                                                                                                                                                                     |
| Citable link    | http://nrs.harvard.edu/urn-3:HUL.InstRepos:23845133                                                                                                                                                  |
| Terms of Use    | This article was downloaded from Harvard University’s DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA                                           |
“You have to keep your nerve on a DMC.”
Challenges for data monitoring committees in neonatal intensive care trials: qualitative accounts from the bracelet study

Claire Snowdon1,5*, Diana Elbourne1, Peter Brocklehurst2, Martin Ward Platt3, Robert Tasker4

From 3rd International Clinical Trials Methodology Conference
Glasgow, UK. 16-17 November 2015

Background
Data Monitoring Committees (DMCs) are essential to the good conduct of many trials. Typically they comprise a small expert group which monitors safety, efficacy, progress and early outcome data as trials recruit. DMCs can recommend protocol revisions and early stopping of a trial. As DMC meetings usually consider unblinded interim data confidentially, they are seldom exposed to research scrutiny. An important exception was case studies presented in the DAMOCLES project.

Methods
Using interviews with participants in the BRACELET Study on bereavement in neonatal intensive care trials, qualitative accounts of experiences of 18 DMC members were used to build on these earlier case studies.

Results
Interviewees considered the neonatal research populations especially vulnerable, and that outcomes that included both death and major disability were crucial for families. DMC members discussed particular difficulties of balancing the competing risks of these outcomes, especially when mortality data were available long before data on longer term disability could be collected. An additional consideration was the choice of age at which disability was assessed, as some manifestations would not become apparent in the short term. Interviewees commonly used the imagery of bravery, and described DMCs either holding or losing their nerve.

Conclusions
DMCs for trials in other fields may also face difficult ethical trade-offs in monitoring composite outcomes. The experience from this sample of DMC members suggest that, for neonatal trials, the combination of the importance of the timing of one component of the outcome assessment, alongside the vulnerability of the population, presented particular challenges.

Authors’ details
1London School of Hygiene and Tropical Medicine, University of London, London, UK. *University College London, London, UK. 2Royal Victoria Infirmary, Newcastle upon Tyne, UK. 3Harvard Medical School, Boston, MA, USA. 5London Hub for Trials Methodology Research, London, UK.

Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-O38

Cite this article as: Snowdon et al.: “You have to keep your nerve on a DMC.” Challenges for data monitoring committees in neonatal intensive care trials: qualitative accounts from the bracelet study. Trials 2015 16(Suppl 2):O38.