DAMOCLES: Issues in data monitoring for RCTs & a Charter for DMCs

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MRC Clinical Trials Unit, London, UK

for the **DAMOCLES** study group

FAQs

1. What are DMCs?
2. What was the DAMOCLES project?
3. Why a Charter?
4. Why **this** Charter?
5. How and when should I use it?
6. What does the Charter look like?
7. How does it help with contentious issues?
8. Where do I get a copy of the Charter?

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Data Monitoring Committees

- A group responsible for reviewing accruing information from clinical trials
- Many names used for this committee
  - 46 names in 662 trials
- Recommend “DMC”
  - Standardisation helpful
  - Short
  - Doesn"t emphasise only some roles (eg safety)
  - ICH GCP

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Background

- Formal monitoring of trials becoming more common
- Monitoring function delivered mainly through DMCs
- Wide variation DMC structure / organisation
- Little guidance on how they should operate

The DAMOCLES study

- Commissioned by the HTA Programme
- Aims:
  - to investigate the processes of monitoring accumulating trial data
  - to identify ways of increasing the likelihood that DMCs make good decisions
- Underlying principle:
  - Examine DMC processes and identify how "right" decisions are made

DAMOCLES study group

BSU, Cambridge

David Spiegelhalter

CSM, Oxford

Doug Altman

CTU, London

Abdel Babiker

Janet Darbyshire

Mahesh Parmar

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HRSU, Aberdeen

Marion Campbell

Adrian Grant

Sharon McLeer

Anne Walker

Sheila Wallace

LSHTM, London

Felicity Clemens

Diana Elbourne

Stuart Pocock

DAMOCLES methodology

1 Systematic review of literature on DMCs

2 Systematic review of small group processes relevant to DMCs

3-6 Surveys:

- DMC use in published RCT reports
- DMC use in recent RCTs
- DMC use in ongoing RCTs
- DMC policies of relevant organisations

7 Case studies DMCs

8 Interviews with experienced DMC members

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23 questions about DMCs

- Role of DMC (5)
- Structure and organisation (5)
- Information available to DMC (3)
- Decision-making and reporting (10)

Example questions

4 Does the DMC have a role before the trial recruitment phase?

11 What material should be available to a DMC?

15 What decisions/recommendations should be open to the DMC?

16 How should the decision or recommendation be reached within the DMC?

Systematic review of literature on DMCs

Review - methods

• Keyword online search Of MEDLINE, PREMEDLINE, EMBASE, CINAHL and HealthSTAR	4007
• Removal of duplicates by hand Double review by group - grading into categories of interest	3525 (303)
• Articles relevant to DMCs Review by all group members as suitable for first collection	116
• Graded as worthy of retrieval	84
• Supplementary sources Library searches, books, references from other articles	16
• Total	100

Review – data collection

- All articles were obtained
- Coded in ATLAS.ti using 23 questions
- Variable amounts written for each question
  - 2124 quotes (range 8 – 305)
- Some easier to summarise than others

Review – selected results

- Q14: Is the DMC advisory or executive?
  - General agreement DMC is advisory
  - Advisory to Trial Steering Committee
  - DMC not organising the trial, so should limit to recommendations
  - DMC recommendations generally prevail

Review – selected results

- Q10: What training & preparation needed?

  Consensus of qualities needed:

  - Knowledge of disease area
  - Experience of clinical trials

Review - selected results

- Q3: **Primary** role of the DMC?
  - review interim analyses of outcome data
  - monitor trial for safety
  - monitor trial for early convincing benefit
  - protect the trial subjects
  - ensure patients risks are reasonable
  - participant safety and trial integrity
  - protect patients in the trial **and** other patients with the disease in question

Review - selected results

- Q3: Role of the DMC
  - Role may be reflected in names *(later)*
  - Role may differ according to the trial
  - DMCs do not specify analysis but may advise
  - DMCs do not assess treatment effects on individual patients
  - DMCs ensure credibility and integrity by allowing PI to remain free of knowledge

Review - selected results

- Q2: DMC responsible to who?
  - Patients in the trial
  - Future patients to be enrolled in the trial
  - Future patients in target population treated after the trial
  - Society in general
  - Principal investigators
  - Steering committee
  - Sponsor

Systematic review of small group processes relevant to DMCs

Background

- Decision-making process is considered to be one of the most important group tasks
- Current literature is not conclusive on how best to optimise performance
- Most based within cognitive, social & organisational psychology, sociology & management sciences

Aim & Methods

- To identify factors that make errors more or less likely in small decision-making groups
- Review focused primarily on reviews of empirical studies of small task-orientated decision making groups in:
  - (i) laboratory settings
  - (ii) naturally occurring groups (esp juries, political task-orientated decision-making groups)
- 9 electronic databases searched
- 3187 review abstracts identified & assessed
- 57 reviews included

Group size

- Group size may affect the quality of the decision-making process
- Smaller groups tend to make poorer quality decisions because the range of views expressed is limited
- In larger groups, members may be reluctant to express their views and bias may occur towards riskier decision making

Group roles

- A degree of diversity within the group membership tends to result in better quality decisions
- The Chair can have an important influence on decision-making process and outcome
- If large status differences among group members, decision tends to be the one preferred by more powerful members

Communication in groups

- Groups tend to be more efficient if there is active communication between members, preferably face-to-face
- Effects of telephone conferences on decision quality or outcome are not conclusive
- Effects of electronic communication in context of electronic decision support systems unclear
  - Work predates video conferencing, Webex, Adobe Connect, etc

Information given to groups

- The way in which information is framed can have a significant impact on decision outcomes

- Jury studies show that strength of evidence (quantity & quality) is a major determinant of decision outcome

Group decision-making

- Quality improved if range of opinions are expressed and all members have an opportunity to participate
- Jury studies: decision rule influences decision quality
  - i.e. unanimous decisions better quality
- Voting useful if it follows a full discussion of all views
- Formal methods of reaching decisions generally as good or better than informal methods
- Studies of decision support systems using electronic forms of communication inconclusive

Interviews and case studies

Interviews and case studies

- Qualitative methods used to explore working practices of DMCs
- Data derived from:
  - In-depth interviews with experienced DMC members across a range of trials
  - In-depth case studies of trials where decision-making had been "difficult"

Methods

- Purposive sample of DMC members and case studies
- 14 general interviews
  - Experiences of DMC decision-making across range of trials
- 4 in-depth case studies
  - "Difficult" DMC decision-making situations across different clinical areas
  - n=23 interviews
- Interviews in-person or by phone
  - Audio-recorded and transcribed verbatim

Size and composition of DMCs

- Consensus that between 3-6 members works well
- DMCs should be large enough to provide appropriate diversity of perspectives and experience
- Statistical and clinical expertise essential
- Strong views about selecting the "right people"
- Concerns about effect of a "maverick" member, especially on a small DMC

Size and composition of DMCs

- Mixed feelings about "consumer input" on DMCs - needs to be explored further
  - Consumer involvement in TMGs greater now
- Involvement of ethicists in some DMCs not seen as successful
- Chairperson crucial in influencing discussions and decision outcome
- Previous experience as chair (preferably of DMC) essential

Practical arrangements

- Not always enough time at the beginning of a trial for DMC to discuss issues such as terms of reference, reviewing the protocol etc
- Advantages of pre-trial meeting:
  - facilitate an easier atmosphere for members to get to know each other (must be face-to-face if possible)
  - enable discussion of hypothetical scenarios
- Preference for face-to-face meetings
- Teleconferences accepted but concerns about its impact on communication

Decision-making

- Agreement that decision-making process is neglected
- No experiences of DMCs with pre-agreed procedures, apart from stopping guidelines
- Favoured approach is for decisions to be reached by discussion leading to development of opinion and unanimous agreement
- Mixed feelings about voting or other formal decision-making methods being used

Training issues

- Concerns that increasing demand for DMCs has led to appointment of members with insufficient experience or expertise
- Lack of DMC background information and reading material for new members
- Unclear as to "what they are there to do"
- "Observer role" for new DMC members considered potentially helpful

Survey of published RCT reports

Survey - methods

- Eligible trials
  - Randomised controlled trial
  - Human subjects
  - Intention to evaluate therapeutic or preventive health care interventions
  - Main **published report** of trial results
- General *vs* specialist journals
- 1990 *vs* 2000

Survey - journals included

General medical journals

NEJM
JAMA
Lancet
Annals Internal Medicine
Archives Internal Medicine
British Medical Journal

Specialist - Cardiology

Circulation
Journal American College Cardiology
Stroke
European Heart Journal

Specialist - Infectious diseases

AIDS
Infection & Immunity

Specialist - Cancer

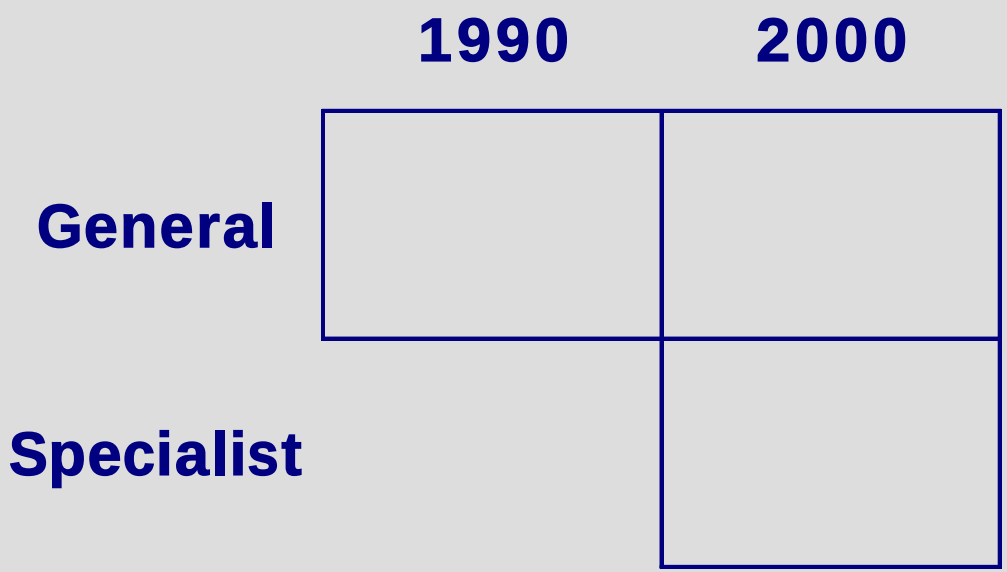
Journal National Cancer Institute
Journal Clinical Oncology
Cancer
Leukemia
British Journal of Cancer

Specialist - Psychiatry

Archives General Psychiatry
American Journal Psychiatry
Neuropsychopharmacology
Journal Clinical Psychiatry
British Journal Psychiatry

Journal Infectious Diseases
Journal Antimicrobial chemotherapy

Survey - comparisons



Survey - comparisons

	1990	2000
General	204	282
Specialist	x	x

Survey - comparisons

	1990	2000
General	x	282
Specialist	x	380

Survey - reported DMC use

	1990	2000
General	21 205 (10%)	70 282 (25%)
Specialist	x	x

Survey - reported DMC use

	1990	2000
General	x	70 282 (25%)
Specialist	x	50 380 (13%)

Reported DMC use…

… **more** likely if

- Multi-centre trial
- Larger planned sample size
- Drug company involvement
- Factorial design
- Vital status endpoint

… **less** likely if

- Cross-over design

Based on data for 2000

Stopping rules reported

Methodology for interim rule	1990 General		2000 General		2000 Special	
Frequentist (Group Sequential)	5	31%	12	34%	7	35%
Frequentist (Group Sequential) *and* Decision Theory	0	3%	1	3%	0	0%
Frequentist (Continuous)	5	31%	8	23%	6	30%
Likelihood (Haybittle-Peto)	4	25%	9	26%	3	15%
Bayesian	0	0%	0	0%	1	5%
Other	1	6%	1	3%	1	5%
None	1	6%	4	11%	2	10%
Missing	*12*	*43%*	*49*	*50%*	*45*	*69%*

Based on trials reporting DMC use or planned interim analyses

Survey - DMC nomenclature

- 44 different names for DMC role
- Most commonly used words in name:

1.	Monitoring	125	89%
2.	Safety	107	76%
3.	Data	104	74%
4.	Committee	75	53%
5.	Board	65	46%

No other word >4%

Percentage based on trials reporting DMC

A standard name?

Most common names:

- Data & Safety Monitoring Board/Committee 32%
- Data Monitoring Board/Committee 15%

- Data Monitoring Committee

Surveys of policy and practice

Surveys of policies & practice

- Survey of investigators" practice in recently completed RCTs
- Survey of investigators" practice in ongoing RCTs in UK
- Survey of policies of major organisations involved with RCTs

Recent practice: aim & methods

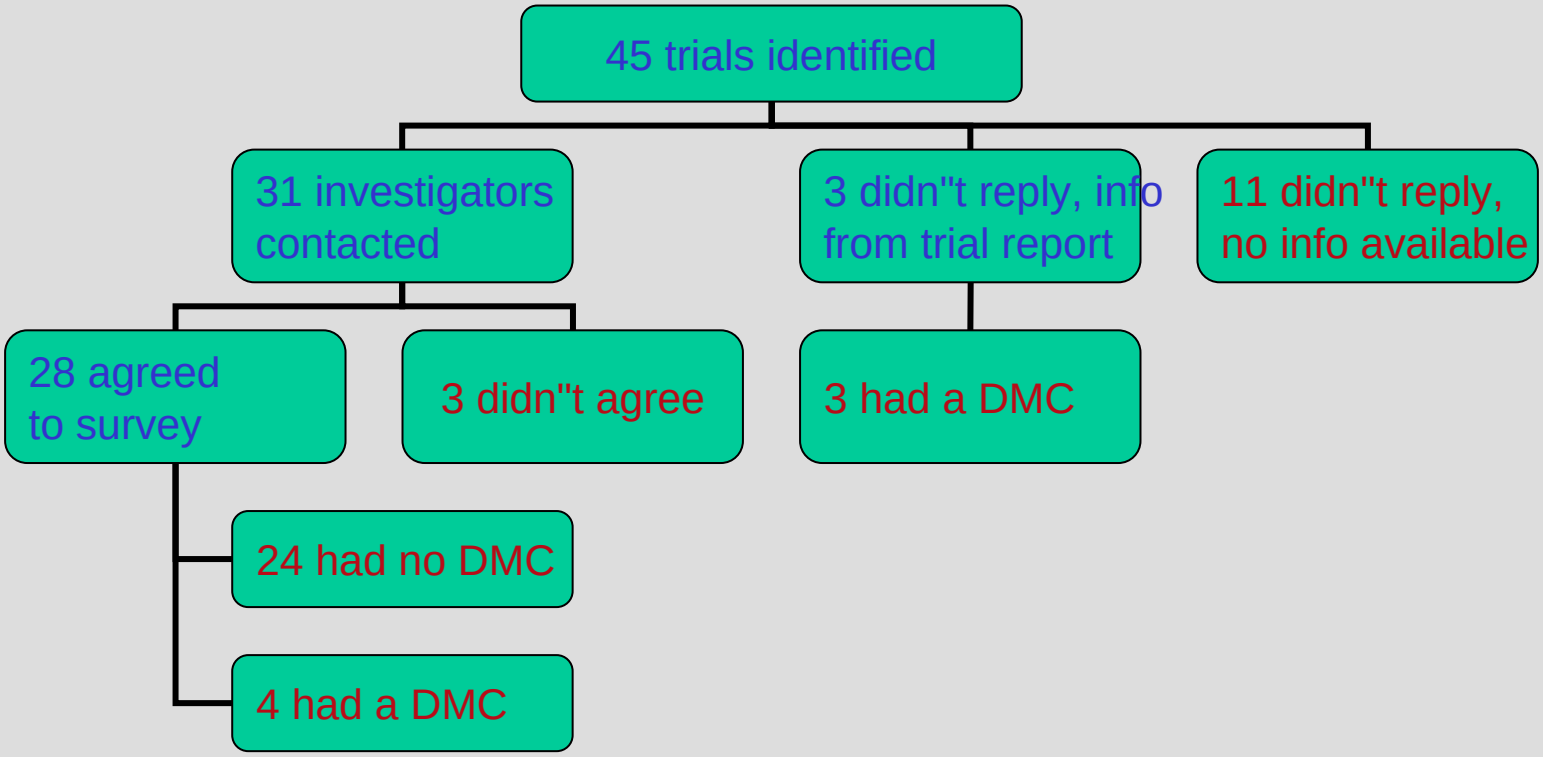
Aim

- To describe data monitoring practice in a sample of trials published in 2000

Methods

- 45 trials selected from database of trials published in 2000
- Contacted principal investigators
  - Failing that, contacted sponsors and colleagues

Recent practice: results



Recent practice: results

- Disappointing response rate (69%) reflected difficulty in contracting PIs for trials conducted several years previously
- Reasons given for not having DMC included
  - Trial not blinded, investigators monitoring
  - Low risk of adverse outcomes
  - Small number of patients
  - Short duration
  - Said would have had a DMC if starting now

Survey of current practice: training

- None of the 20 respondents provided training for the DMC members
- One investigator suggested a formal training programme

Current practice: aim & methods

Aim

- to describe data monitoring practice in a stratified sample of ongoing trials

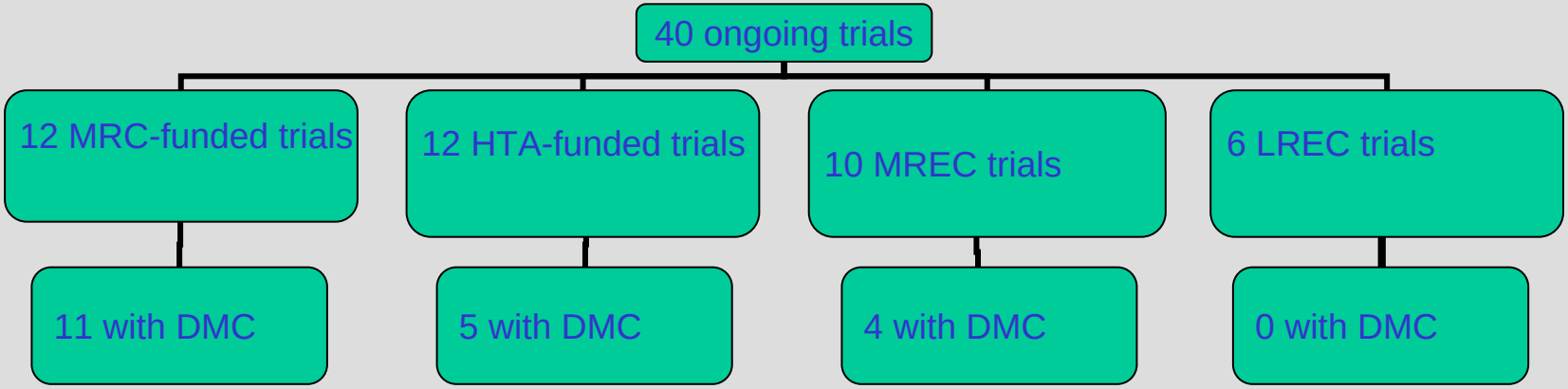
Methods

- 40 UK-based trials sampled from MRC, HTA, MREC and LREC registers
- Investigators interviewed by telephone

Survey of current practice: remarks

- Difficult to describe industry practice because only 4 trials gave information on data monitoring in industry trials
- Small pool of experts able to sit on a DMC
  - training may be necessary

Current practice: results



20 had DMC information available

Current practice: selected results

- 75% followed MRC guidelines
- 60% membership nominated by PIs or TSC
- All included a statistician or epidemiologist
- Trial statistician present at all or part of meetings
- General agreement that members should be "independent" but not defined and only one had policy for formal declaration of conflicts

Policies: aim & methods

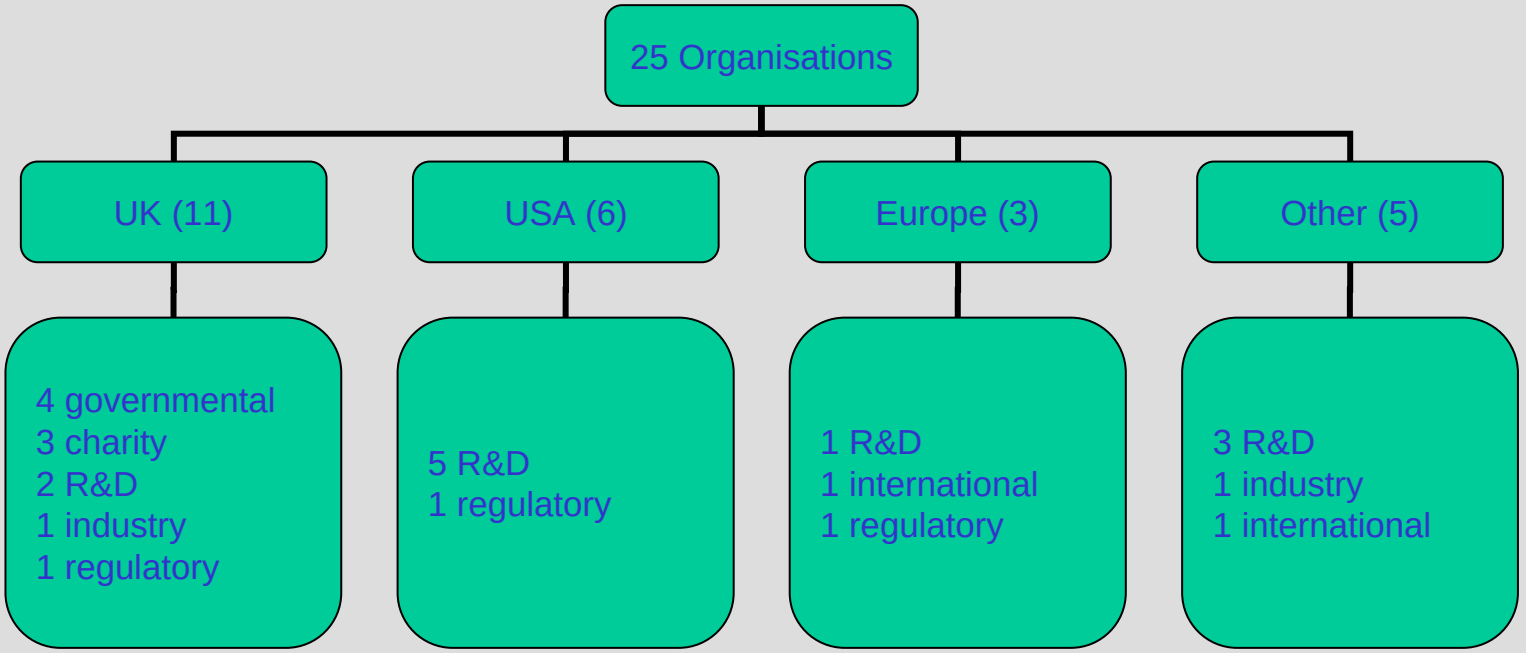
Aim

- to describe the data monitoring policies of some of the major organisations involved in RCTs

Methods

- 25 organisations involved with RCTs identified
- information sought from websites
- supplemented by personal contact

Policies: organisations involved



Policies: selected results

- 18/25 had formal policies for their DMCs
  - Many implemented only recently
  - Some less formal but *de facto*
  - Remainder were planning to review
- Half thought DMC as default for all trials
- 11 had policy of declaration of potential conflicts of interests
- 10 had policy about payment (expenses)

DAMOCLES publications

1. The DAMOCLES study group. Issues in data monitoring and interim analysis of trials. **Health Technology Assessment monograph series** 2005, 9(7)
2. The DAMOCLES study group. A proposed charter for clinical trial Data Monitoring Committees: helping them to do their job well. **Lancet** 2005, 365: 711-722
3. Sydes MR, Altman DG, Babiker AB, Parmar MKB, Spiegelhalter DJ, DAMOCLES Group. Reported use of data monitoring committees in the main published reports of randomised controlled trials: a cross-sectional study. **Clinical Trials**; 2004, 1(1): 48-59
4. Sydes MR, Spiegelhalter DJ, Altman DG, Babiker AB, Parmar MKB, DAMOCLES Group. Systematic qualitative review of the literature on data monitoring committees for randomized controlled trials. **Clinical Trials**; 2004, 1(1): 60-79
5. Walker AE, McLeer SK, DAMOCLES group. Small group processes relevant to data monitoring committees: an overview of reviews. **Clinical Trials**; 2004, 1(3): 282-296
6. Clemens F, Elbourne D, Darbyshire J, Pocock S, DAMOCLES group. Data monitoring in randomised controlled trials: surveys of recent practice and policies. **Clinical Trials** 2005; 2(1): 22-32

Guidance

- Consider all trials for DMC
- Not all need IDMC
  - Internal DMC may suffice
  - May not need any DMC
- Always report reasoning for choice
- Mention independence where relevant
  - IDMC

Which trials need IDMCs?

- Efficacy of a new intervention
- Efficacy in a new indication
- High-risk treatments
- Treatments with possible safety issues
- Long-term follow-up period

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Why any charters?

- Clarity from variety
- Increase in use of SOPs
- Process documentation

Why a DMC charter?

- Systematic and transparent approach
  - Structure
  - Operation
  - Policy
  - Process

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Why this Charter?

- Not original idea
- Little explicit guidance elsewhere
- Areas for consideration come from project
- Broad and comprehensive structure
  - Highlights areas not routinely considered
- Guidance based on multi-faceted project
- Flexibility
- Readily available

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Implementation

- Ideally before or at first DMC meeting
  - Can be set up once trial is under way
- Early agreement on potential difficult issues
- Should be drawn up with input from
  - Trial investigators (TMG)
  - DMC members
  - Sponsor, funder, executive body (TSC)
- All should agree on the Charter contents
- Iterative process – expect agreement on most areas

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CONTENT	COMMENTS FROM DAMOCLES AND ILLUSTRATIVE EXAMPLES
1. INTRODUCTION	
Name (and sponsor's ID) of trial plus ISRCTN and/or EUDRACT number	Insert name (and sponsor's ID) of trial and registration number (egISRCTN and/or EUDRACT number)
Objectives of trial, including interventions being investigated	Insert objectives of trial, including interventions being investigated from protocol. Suggest including a flow chart of the trial design (insert as Figure 1).
Outline of scope of charter	Summary of the purpose and content of this document. *Illustrative example:* *The purpose of this document is to describe the roles and responsibilities of the independent DMC for the ### #### trial, including the timing of meetings, methods of providing information to and from the DMC, frequency and format of meetings, statistical issues and relationships with other committees.*
2. ROLES AND RESPONSIBILITIES	
A broad statement of the aims of the committee	*Illustrative example:** *"To protect and serve [trial] patients (especially re: safety) and to assist and advise Principal Investigators so as to protect the validity and credibility of the trial."* *"To safeguard the interests of trial participants, assess the safety and efficacy of the interventions during the trial, and monitor the overall conduct of the clinical trial."*
Terms of reference	*Illustrative example:** *The DMC should receive and review the progress and accruing data of this trial and provide advice on the conduct of the trial to the Trial Steering Committee.* *The DMC should inform the Chair of the steering committee if, in their view:* *(i) the results are likely to convince a broad range of clinicians, including those supporting the trial and the general clinical community, that one trial arm is clearly indicated or contraindicated, and there was a reasonable expectation that this new evidence would materially influence patient management;* ***or*** *(ii) it becomes evident that no clear outcome would be obtained."*

DMC charte

CHARTER FOR TRIAL MANAGEMENT GROUP

CONTENT	DETAILS OF TMG
1. Introduction	
Name (& Sponsor's ID) of trial	RADICALS (MRC PR10/NCIC PR13)– Radiotherapy and Androgen Deprivation In Combination After Local Surgery (ISRCTN 40814031 EUDRACT 2006-000205-34)
Objectives of trial, including interventions being investigated	Although the number of radical prostatectomies being performed is increasing, there is considerable uncertainty over the optimal management strategy for patients that have had a prostatectomy. The two main management questions relate to the timing of radiotherapy and the use of hormone therapy with post-operative radiotherapy. RADICALS will address each of these questions. A study summary diagram is included in Figure 1 and 2.
Outline of scope of Charter	The purpose of this document is to describe the membership, terms of reference, roles, responsibilities, authority, decision-making and relationships of the Trial Management Group (TMG) for the this trial, including the timing of meetings, frequency and format of meetings and relationships with other trial committees.
2. Roles and responsibilities	
A broad statement of the aims of the TMG	To manage the trial, including the clinical and practical aspects.
Specific roles of TMG members	The specific roles of the TMG will be to: • attend TMG meetings and advise on availability for future TMG meetings • input into and comment on the protocol and case report forms • allow contact details to be included in the protocol • promote the trial • develop strategies to encourage recruitment and address any issues with recruitment at each trial centre • be involved in the day-to-day running of the trial by supporting the Chief Investigator and MRC CTU • provide clinical or other expert guidance to MRC CTU and participating sites on trial-based matters such as clinical and practical queries and interpretation of information recorded on CRFs • maintain confidentiality of any trial information that is not in the public domain • respond to trial correspondence and any questions in a timely fashion • encourage completion of case report forms (CRFs) and monitor reported CRF completion rates • input into the monitoring and classification of serious adverse events (SAEs) • input into the meetings of the Trial Steering Committee (TSC), if appropriate • input into the meetings of the Independent Data Monitoring Committee (IDMC), when appropriate (open sessions only) • provide responses to any issues or concerns raised by TSC • consider the implications of any recommendations made by the IDMC and accepted by the TSC

Roles & responsibilities

- Specific roles of DMC
  - Interim review of the trial"s progress including updated figures on recruitment, data quality, and main outcomes and safety data.
- Select specific aspects from following list:
  - assess data quality
  - monitor recruitment & loss to follow-up
  - monitor compliance
  - monitor trial conduct
  - monitor main efficacy outcome measures
  - monitor evidence for treatment harm

Roles & responsibilities

- Specific roles of DMC (cont)
  - recommendations on recruitment
  - suggest additional analyses
  - advise on protocol modifications
  - monitor planned sample size assumptions
  - monitor appropriateness of patient information
  - compliance with previous DMC recommendations
  - ethical implications of recommendations
  - assess impact & relevance of external evidence

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Contentious issues

- Composition
  - Membership
  - Independence of members
  - Decision-making
- Relationships
- Role of trial statistician
- Meeting format

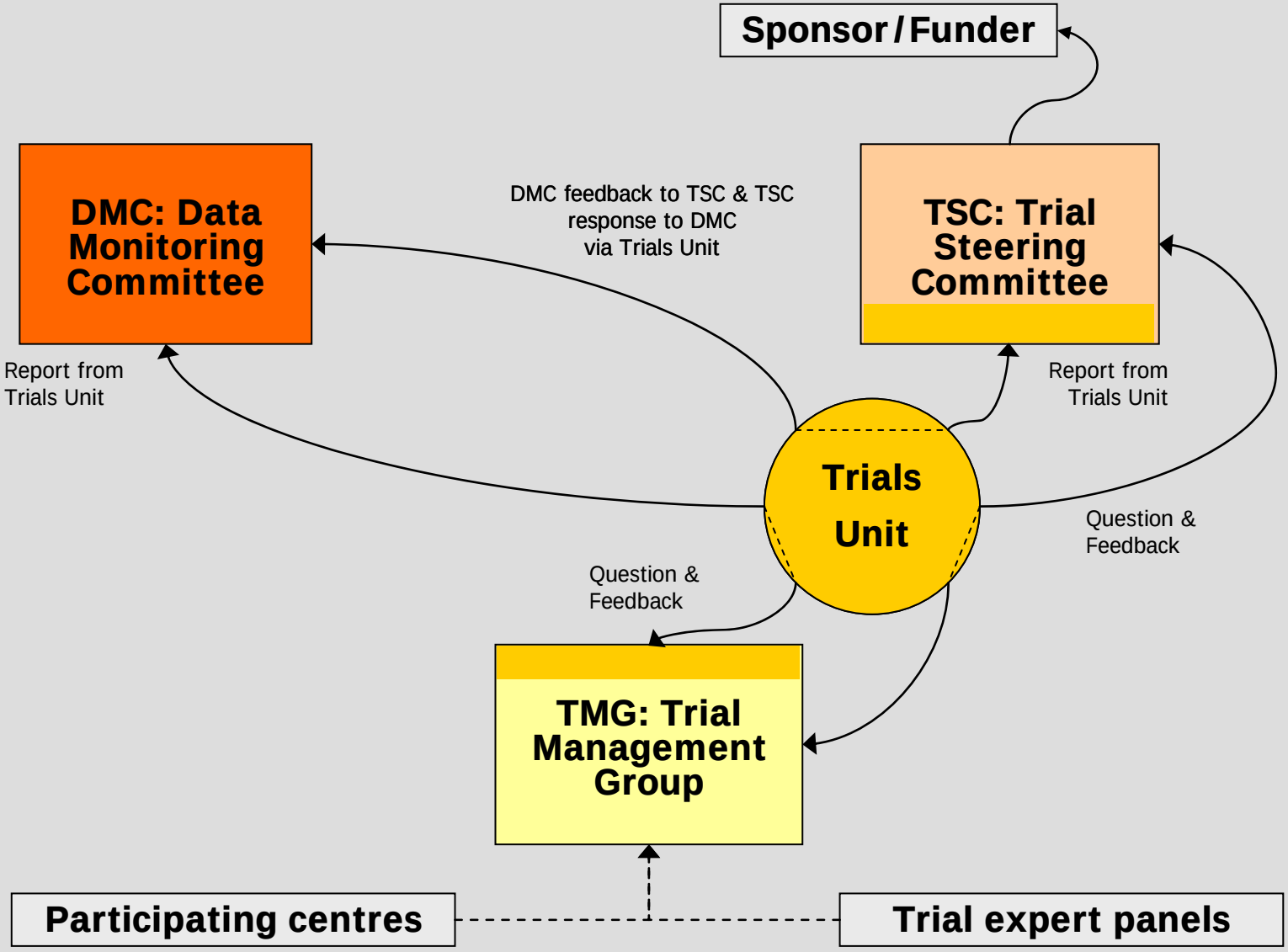
Composition

- Small number (3-6)
- 1+ clinician, 1+ statistician, consumers?
  - Balance full range of opinions with lack of suitable people
  - Practicalities and timings for when the trial needs review
  - Non-attendees (quoracy)
  - Lessen the impact of any one dud member!
- Independence (competing interest forms)
- Is an odd number necessary?

Decision-making

- How “decisions” are reached
  - Methods for guiding deliberations
  - Consensus preferable to voting
  - Role of Chair
- Role of formal statistical methods
  - Stopping rules vs stopping guidelines
- List of recommendations available to DMC
  - Recommendations not decisions

Relationships and reporting



Responsibilities & formatting

- Trial statistician
  - Produces report?
  - Attends meeting?
- Meeting organisation
  - Closed and open sessions?
  - Who should be present?
  - In person or teleconference?

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Clinical Trials

A proposed charter for clinical trial data monitoring committees: helping them to do their job well

DAMOCLES Study Group*

Lancet 2005; 365: 711–22

*Members listed at end of report

Correspondence to:
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Formal monitoring of data from randomised controlled trials (RCTs) is becoming more common. Wide variation exists in the structure and organisation of data monitoring committees (DMCs), with little guidance on how they should operate. We used various strategies to consider the behavioural, procedural, and organisational aspects of data monitoring in RCTs: systematic reviews of DMCs and small group processes in decision making; surveys of reports of RCTs, recently completed and ongoing RCTs, and the policies of major organisations connected with RCTs; detailed case studies of four DMCs that faced difficult decisions; and interviews with experienced DMC members. The findings aided the development of a template for a charter for DMCs. We summarise the findings and outline the key considerations at every stage of the data monitoring process. Widespread use of a charter for the structure and organisation of DMCs would promote a systematic and transparent approach, and enable them to operate more effectively and efficiently.

Examples in practice

- Asphyxial Encephalopathy – TOBY
- Bell"s palsy - BELLS
- Cognitive and retinal function - OPAL
- Colorectal cancer diagnosis - SIGGAR1
- Diabetes - DAPIT
- Hepatocellular carcinoma – TACE
- Neonatal cooling – NEST
- Osteosarcoma – EURAMOS 1
- Lung cancer - multi-trial IDMC
- Prostate cancer – STAMPEDE
- Renal cancer - RE04
- Respiratory failure - CESAR

Summary on Charter

- Provides consistent and transparent frame
- Includes aspects of data monitoring are not often addressed in existing DMC ToRs
- Can be customised.
  - Framework still useful even if not using DAMOCLES guidance!
- Use structure for all MRC CTU committees
  - TMG
  - TSC

Download the template Charter

Email to:

CTUEnquiries@ctu.mrc.ac.uk

Paper:

The DAMOCLES study group. A proposed charter for clinical trial Data Monitoring Committees: helping them to do their job well. **Lancet** 2005, 365: 711-722

Contact

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