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Workshop outline

- **Issues about inadequate reporting (DGA)**
- **Interactive session (DM)**
 - experiences of inadequate reporting of primary studies during the conduct of a systematic review
- **CONSORT and reporting randomized trials (DM)**
- **Interactive session (DGA)**
 - Reporting randomized trial
- **The EQUATOR Network (DGA)**
- **Reporting systematic reviews (DM)**





Sharing experiences about how inadequate reporting of primary studies has affected the conduct of your systematic review(s)

- **Descriptive characteristics of trials**
- **Description of intervention(s)**
- **Risk of bias (quality) assessments**
- **Reporting of outcome effectiveness**



What can systematic reviewers do to improve the quality of reporting of primary research:

- **Use (and encourage others) CONSORT to report results of RCTs**
- **Enquire as to whether journal(s) in your content area have endorsed CONSORT?**
- **Find out whether the journal(s) has published research/editorial/commentary about quality of reporting of reports (and/or CONSORT) in their journal?**
- **Is journal aware of EQUATOR network?**





The CONSORT Statement



Lots of evidence that quality of reporting is inadequate

- **Pocock and colleagues, 1987**
- **Examined reports of 45 RCTs in the 'usual' five journals**
 - the analysis of multiple end points, the analysis of repeated measurements over time, subgroup analyses, trials of multiple treatments, and the overall number of significance tests in a trial report
- **Their results**
 - summaries or abstracts of trials tend to emphasize the more statistically significant end points.
 - overall, the reporting of clinical trials appears to be biased toward an exaggeration of treatment differences



What are the fundamental problems with inadequate reporting of research (I)

- **Inadequate reporting can lead to biased estimates of an interventions effectiveness**
 - Schulz, 1995
 - Pildal, 2007



What are the fundamental problems with inadequate reporting of research (II)

- **Readers cannot make judgments (critically appraise) about the usefulness of the intervention(s) they're reading**



In an attempt to overcome these problems we set out to develop a reporting guideline to help clinical trialists improve their trial reports

- By reporting guideline we mean “a reporting guideline is defined as the development of a checklist, flow diagram, or explicit text produced to guide authors reporting a specific type of research, using explicit methodology”
- A minimal guidance
- This systematic approach needs to be differentiated from other efforts even if a checklist is produced, such as the recent efforts to improve the design and conduct of self-administered surveys. This definition would also exclude formatting guidance for reporting health research, such as some journals ‘Instructions to Authors’



Ottawa 1993



Published in JAMA – 1996

- **Checklist, flow diagram, and descriptive text**
- **Evidence-based, whenever possible**
- **Transparent**



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- **Continually being revisited for improvements**
 - **Appears to be continually been evaluated**
 - does CONSORT improve the quality of reports of RCTs?
 - **CONSORT 2001 – published simultaneously in Annals of Internal Medicine, JAMA, and Lancet**
 - **Important addition – development of CONSORT explanatory document**



Does the intervention work?

- **105 reports of RCTs published in 26 journals of which 10 explicitly endorsed CONSORT and 16 did not**
- **time-frame: 1997 (median)**
- **used an 11-item checklist adapted from the 1996 CONSORT checklist**
- **trained assessors to complete checklist 'typical' evaluation**



Results

- **6 (of 11) methodological items were reported <50% of the time**
- **the number of items reported was statistically greater in CONSORT adopters than corresponding control journals**



Evaluating CONSORT

- **Systematic review of CONSORT evaluations – 2006**
- **8 studies published between 2001 - 2005**
 - CONSORT adopters before and after CONSORT publication
- **Primary result**
 - Use of CONSORT was associated improved reporting
 - There is still lots of room for improvement
- **Currently updating systematic review – at least another 10 studies to include**
 - Encouraging signs



Endorsement

- **2003, 22% (36/166) high impact factor journals provided any mention of CONSORT**
- **2008, 38% (62/165) of high impact factor journals**
 - 73% relative improvement
- **Same (121) journals in both years**
 - 26% in 2003 and 39% in 2008



Adherence

- **CONSORT was a requirement**
 - ‘Instructions to authors’, 23 journals
 - Authors must conform to the CONSORT Statement
- **Remaining journals were less clear in the recommendations**
 - Authors “should consult the CONSORT guidelines”
 - “we encourage authors to follow the CONSORT Statement”
- **Very few journals provided any mention of CONSORT extension papers**
 - Cluster (n=5)
 - Harms (n=3)
 - Herbals (n=2)
 - Non-inferiority and equivalence (n=1)



CONSORT 2009



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- Item 4, "Interventions," we encourage greater specificity by stating that descriptions of interventions should include "sufficient details to allow replication"
 - Item 6, "Outcomes," we added a sub-item on identifying any changes to the primary and secondary outcome (endpoint) measures after the trial commenced. This followed from empirical evidence that authors frequently provide analyses of outcomes in their published papers that were not the pre-specified primary and secondary outcomes in their protocols (i.e., selective outcome reporting bias)
 - Item 15, "Baseline data," we added "In a table" to clarify that baseline and clinical characteristics of each group are most clearly expressed in a table.



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- Item 23, “Registration,” we added an entirely new item. Empirical evidence supports the need for trial registration and recent advances by journal editors have fostered compliance. (26)
 - Item 24, “Protocol,” we added an entirely new item on availability of the trial protocol. Empirical evidence suggests that published papers often ignore or change that which was stated in the protocol.(20;27) Hence, availability of the protocol can instigate adherence to the protocol before publication and facilitate assessment of adherence after publication.





Moher and colleagues

- **Searched Medline, November 2004**
- **Included 300 reports of systematic reviews**
 - 129 were Cochrane reviews



Results I

- **most (91%) reports of systematic reviews are published in small specialty journals**
 - published in 132 journals
- **49.5% used the term 'systematic review' or 'meta-analysis' in the title or abstract**
- **46.8% reported the use of a protocol**



Results II

- **compared to non-Cochrane reviews, Cochrane reviews were more likely to:**

- report using a protocol (97.6% vs. 11.4%)
- reported being an update of a previous review (37.6% vs 2.3%)
- have no language restrictions (0.8% vs. 30.7%)
- searching twice as many bibliographic databases
- assess risk of bias in included studies (100% vs. 49.4%)
- assessed likely publication bias (32% vs. 18.4%)
- reporting funding sources (80.8% vs. 50%)



Wen and colleagues

- **Random sample of 161 meta-analyses (Medline)**
- **Published between 2000 and 2005**
- **QUOROM Statement**
 - Maximum score 18.0
- **Overall: rise in score from 2000 to 2005 (10.5 → 13.0)**
- **Cochrane reviews better than non-Cochrane reviews (14.2 vs. 11.7)**
- **“Room still exists for improvements in the reporting quality of both Cochrane and paper-based articles”**



Poor reporting is a serious problem for systematic reviews and clinical guidelines

- **“The biggest problem was the quality of reporting, which did not allow us to judge the important methodological items ...”**
- **“Data reporting was poor. 15 trials met the inclusion criteria for this review but only 4 could be included as data were impossible to use in the other 11.”**

(Reviews on *Cochrane Library*, accessed on 18 Sept 07)



Reviewers are often critical of how authors of primary studies are reported their studies

They need to be equally conscience of how their own systematic reviews are reported

Preferred Reporting Items for Systematic reviews and Meta- analyses (PRISMA)

**QUality Of Reporting Of Meta-
analyses (QUOROM)
1996**

PRISMA

- **Completing a systematic review is an iterative process**
- **Conduct and reporting research are distinct concepts**
- **Study-level versus outcome-level assessment of risk of bias**
- **Importance of reporting biases**



PRISMA



- **Objective (item 4)**

- addresses the explicit question the review addresses using the PICO reporting system (which describes the Participants, Interventions, Comparisons, Outcome(s) of the systematic review), together with the specification of the type of study design (PICOS)

- **Protocol (item 5)**

- This new item asks authors to report whether the review has a protocol and if so how it can be accessed

- **Assessment of bias (item 15)**

- This new item asks authors to describe any assessments of bias in the review, such as selective reporting within the included studies



What are the implications for Cochrane reviewers?

- **Expect poor reporting of study methods to be common**
- **Risk of bias cannot be assessed if methods are not reported fully**
 - e.g. allocation concealment, blinding, ...
- **Expect poor reporting of results to be common**
 - Cannot include some studies in meta-analysis
- **Be alert for selective reporting**
- **Ensure that your review is reported well**
 - PRISMA



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EQUATOR workshop Halifax, March 2009

Enabling systematic reviews: reporting research with clarity, accuracy, and transparency

Facilitators: David Moher, Doug Altman

We hope you have found the EQUATOR workshop useful and stimulating.

In order to make further workshops and EQUATOR work even more relevant to our users' needs we would like to ask you to share with us your ideas, suggestions or problems you have relating to the reporting of health research studies, reporting guidelines or to this workshop.

Please hand the completed form to the workshop facilitators or email Iveta Simera from the EQUATOR Network at iveta.simera@csm.ox.ac.uk

Feedback on this workshop (11th March 2009) (For example, content, timing, discussion time)

Suggestions for future workshops (scope, presentation, examples, etc.):

Suggestions for the EQUATOR Network:

Many thanks for your help!
EQUATOR Network team

