

GRADE



Writing, GRADEing and Using Systematic Reviews Symposium and Workshop

May 8-9, 2008
Rome, Italy



Data Collection



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- Overview
 - Building a team
 - Formulating a question
 - Developing the protocol
 - Searching for studies
 - Selecting studies
 - Assessing the quality
 - Data extraction
 - Meta-analysis
 - Heterogeneity, subgroup and sensitivity analyses
 - Evaluating & presenting and interpreting results
 - Interpreting results and drawing conclusions

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Outline

- Collecting data
- Data to collect
- Data collection form

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Collecting data



Collecting data

- Duplicate and independent collection
 - To minimize errors and potential biases
 - Preferably reviewers from complementary disciplines (methodologist, content expert)
 - Alternatives: serial or partial
- Appropriate training of data collectors
- Blinding of data collectors is not generally recommended

Collecting data

- Stepwise approach to resolve disagreement between data collectors:
 - Resolve by discussion; if unsuccessful:
 - 3rd reviewer arbitration; if unsuccessful:
 - Contact authors
- Record disagreements and their resolution


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Collecting data

- If agreement is assessed, this should be done only for the most important decisions/ data (e.g. Inclusion in the review, risk of bias assessment)

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Data to collect

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PHARMACY

WHAT IF THIS ISN'T THE RIGHT DRUG?

YOU WON'T BE BACK

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Data to collect

- Source
- Eligibility → 'Characteristics of excluded studies' table
- Methods and potential sources of bias → 'Characteristics of included studies' table; 'Risk of bias' table; GRADE Summary of Findings table
- Participants → 'Characteristics of included studies' table
- Interventions → 'Characteristics of included studies' table
- Control → 'Characteristics of included studies' table
- Outcomes → 'Characteristics of included studies' table
- Results → RevMan analysis
- Other

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Data to collect

- Source
 - Study ID (created by review author)
 - Report ID (created by review author)
 - Review author ID (created by review author)
 - Citation and contact details
- Eligibility
 - Confirm eligibility for review
 - Reason for exclusion

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Data to collect

- Methods
 - Parallel, crossover, factorial, cluster
 - Total study duration
- Potential sources of bias
 - Sequence generation *
 - Allocation sequence concealment *
 - Blinding (participants, providers, data collectors, outcome adjudicators, data analysts) *
 - Adherence to the intention to treat (ITT) principle
 - Incomplete outcome data
 - Selective outcome reporting
 - Other criteria(e.g. early stoppage of the trial;) *

*Full description required for standard items in the 'Risk of bias' tool

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Data to collect

- Participants
 - Total number
 - Characteristics that could be related to:
 - Age
 - Sex
 - Ethnicity
 - Socio-demographic characteristics
 - Diagnosis (diagnostic criteria)
 - Comorbidities
 - Setting (e.g. country, healthcare facility, year)

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Data to collect

- Interventions
 - Number of intervention groups
 - Specific intervention
 - Details of intervention (e.g. dose, frequency, duration, length of treatment)
- Control
 - No intervention vs. placebo vs. other intervention (provide details)
 - Co-interventions

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Data to collect

- Outcomes
 - Review outcomes evaluated by trial
 - Outcome definition, method of measurement (i.e. diagnostic criteria)
 - Time point collected
 - Percentage follow up for each outcome
 - Scale , unit of measurement (if applicable)

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Data to collect

- Results
 - Number of participants randomized
 - For a categorical outcome:
 - # of participants followed up for the outcome, by group
 - # of participants with event
 - For a continuous outcome:
 - # of participants followed up for the outcome, by group
 - Mean and standard deviation
 - For a time to event outcome:
 - HR and and it 95% CI , HR variance, log HR and it 95% CI, etc. (see attachment: Parmar methods)


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Data to collect

- Other
 - Funding source
 - Key conclusions of the study authors
 - Miscellaneous comments from the study authors
 - References to other relevant studies
 - Correspondence required
 - Miscellaneous comments by the review authors

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Data collection forms

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I'VE ALWAYS WONDERED
WHAT HAPPENED WHEN
YOU MISSED A DEADLINE

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Data collection forms

- Bridge between what is reported by the trial reports and what is reported by the review
- Functions:
 - Confirm eligibility (could be separate form)
 - Abstraction of relevant data (participants, intervention, control, outcomes)
 - Assess methodological quality of studies
 - Abstraction of statistical data
 - Historical record

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Data collection forms

- Ample time and thought needed for designing data collection form
- Consider how much information to collect:
 - All possibly relevant data (risk: overly collection) vs.
 - Feasible amount (risk: insufficiently detailed)

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Data collection forms

- Pilot testing
 - Of both data collection form and instructions
 - To check for clarity and completeness
 - Use a representative sample of the studies
 - Repeat pilot testing if major revisions
 - May need revisions after data extraction started

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Data collection forms

- Tips:
 - Include the title of the review (header)
 - Include a revision date or version number
 - Record the name (or ID) of the reviewer
 - Leave space for notes on the 1st page of the form
 - Record source of key information
 - Use tick boxes or coded responses to save time
 - With 'yes'/'no' options, include 'not reported' or 'Not clear' or 'probably yes'/'probably no' options

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Data collection forms

- More tips:
 - Have sections to match RevMan data tables
 - Collect outcome data in the format in which they were reported; transform, if needed, in a subsequent step
 - For each outcome, collect number of participants assessed in addition to number randomized
 - Leave plenty of space for notes

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Data collection forms

- Instructions for data collection form
 - Separate document vs. integrated in form
- Coding schemes:
 - Help with efficiency and systematic presentation
 - Should be simple

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Resources

- Cochrane Handbook, version 5.0.0
<http://www.cochrane-handbook.org/>

Chapter 7: Selecting studies and collecting data

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