

How to Write a Paper

Methods

Global MECOR Course
Kenya, 2011

Objectives

- To allow the reviewer/editor/reader to assess the validity of the research.
- To allow replication of the study.
- To provide adequate information for those attempting to review the literature/ undertake meta-analyses.

Key elements

- Study design
- Populations and sampling
 - Inclusions
 - Exclusions
- (Interventions)
- Measurements
- Analysis: Statistical methods
- Ethical review

Study Design

- **Experimental study:**
 - randomised clinical trial
- **Observational study:**
 - Cross-sectional survey
 - Case Control Study
 - Cohort study

Trial Registration

- **CONSORT statement:**
 - Is the trial registered?

Population and Sampling

- **Population**: what was the source of the population studied?
- **Dates of Data Collection**: give the period over which data were collected.

Population and Sampling

- **Selection**: How were individuals selected into the study?
 - Inclusion criteria
 - Exclusion criteria

Population and Sampling

- **Assignment**: how were patients allocated in a trial –
 - Randomly? Systematically?
- Who did the allocation?
- What was the source of random numbers?
- Was minimisation used?
 - Blocking / stratification
- CONSORT statement

Failures to report important features of trials in 519 RCTs published in December 2000

from: *Chan and Altman. Lancet 2005; 365:1159-62*

Method of random sequence generation		N	%
Reported		109	21
	Computer	66	61
	Random number table	33	30
	Coin toss	5	5
	Other	5	5
Not reported		410	79

Failures to report method of allocation concealment in 519 RCTs published in December 2000

from: *Chan and Altman. Lancet 2005; 365:1159-62*

Method of allocation concealment		N	%
Reported		94	18
	<i>Envelopes</i>	<i>48</i>	<i>51</i>
	<i>Central</i>	<i>25</i>	<i>27</i>
	<i>Pharmacy</i>	<i>15</i>	<i>16</i>
	<i>Other</i>	<i>6</i>	<i>6</i>
Not reported		425	82

Population and Sampling

- **Sample size**: Why did you decide to study this number of people?
- In a trial this will normally be based on the primary outcome of interest as defined by the study.

published in December 2000

from: *Chan and Altman. Lancet 2005; 365:1159-62*

Power calculation	
Stated	142 (27%)
Not stated	377 (73%)
Total	519 (100%)

Main variables

- Outcome variables:
 - Dependent variables
 - In observational studies: what you are trying to predict
 - In trials: endpoints:
 - Primary
 - Secondary
- Exposure Variables
 - Main exposures of interest
 - Confounders/Effect modifiers

Failures to report primary outcome in 519 RCTs published in

December 2000

from: *Chan and Altman. Lancet 2005; 365:1159-62*

Primary outcome

	N	%
Defined	232	45
Not defined	287	55

Main Variables

- Operational definition of variables
- Transformation of variables
- Creation of categorical variables
 - Why?
 - Number of levels?
 - Predefined levels or quantiles?

Measurements

- Who made the measurements?
- What qualification did they have for the job?
 - What training was undertaken?
- Were they and/or the patients masked (blinded)?

Failures to report blinding in 519 RCTs published in December 2000

from: *Chan and Altman. Lancet 2005; 365:1159-62*

Blinding	N	%
Any blinding	309	60
<i>Details provided</i>	<i>148</i>	<i>48</i>
<i>No details provided</i>	<i>161</i>	<i>52</i>
Unblinded	166	32
Unclear	44	8

Measurements

- Conditions of measurement
 - Sitting, standing,... after 10 minutes rest, ...
- Instrumentation
 - Including model, source and supplier of instruments
- Precision of measurements
- Source of consumables

Interventions

- What were the alternative treatments in the trial?

Statistical Analysis

- What comparisons were made?
 - In trials was the comparison by “intention to treat” or “per protocol”?
- Using what technique?
- What software was used and (where relevant) which programs?
- (What p-values were taken to be significant)

Statistical Analysis

- Justify any sub-group analyses:
 - Were they in the original protocol?
 - Why were they done?
 - Were they post-hoc, because you didn't find what you originally expected?

Ethical Review

- Was the study approved by an Ethics Committee (Institutional Review Board) – which and when?
- Was informed consent obtained from adults and how? Written?
- Was assent obtained from children and how?

Which tense to use in the Methods section

- Use past tense throughout:
 - *“We recruited 143 patients with moderate persistent asthma”*