Practical

What do we mean by poor reporting?

In brief

- **Key information is missing, incomplete or ambiguous**
- **Misleading interpretation**

A particular concern

- **Selective reporting of methods or findings**

- **Focus on checklists**
  - Checklists cover the main issues
  - Non-checklist items may also cause concern

CONSORT

PRISMA

STROBE

CONSORT checklist (22 items)

TITLE & ABSTRACT

INTRODUCTION

- Background

METHODS

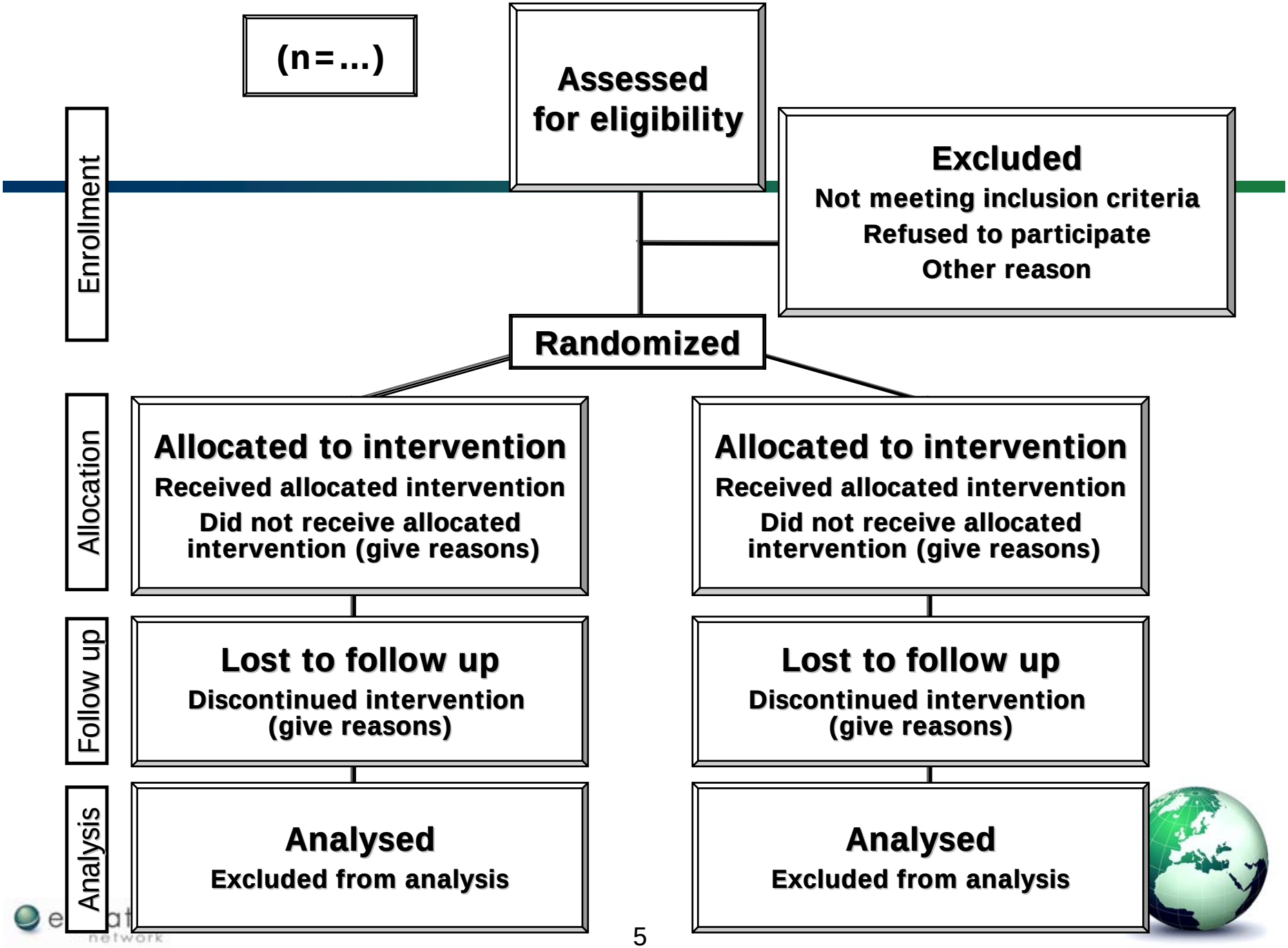
- Participants
- Interventions
- Objectives
- Outcomes
- Sample size
- Randomization
  - Sequence allocation
  - Allocation concealment
  - Implementation
- Blinding (Masking)
- Statistical methods

RESULTS

- Participant flow
- Recruitment
- Baseline data
- Numbers analyzed
- Outcomes and Estimation
- Ancillary analyses
- Adverse events

DISCUSSION

- Interpretation
- Generalisability
- Overall evidence


(n=…)
Assessed for eligibility
Excluded
Not meeting inclusion criteria
Refused to participate
Other reason
Enrollment
Randomized
Allocation
Allocated to intervention
Received allocated intervention
Did not receive allocated intervention (give reasons)
Allocated to intervention
Received allocated intervention
Did not receive allocated intervention (give reasons)
Follow up
Lost to follow up
Discontinued intervention (give reasons)
Lost to follow up
Discontinued intervention (give reasons)
Analysis
Analysed
Excluded from analysis
Analysed
Excluded from analysis

What do we need to know about treatment allocation?

- **Was the allocation sequence generated in an appropriately unpredictable way, e.g. by randomization ["Sequence generation"]**
  - How was the sequence determined?

- **Was the act of allocating a treatment to a patient done without any knowledge of what treatment they will get? ["Allocation concealment"]**
  - What was the mechanism of allocation?

Description of randomization in RCTs

So important that CONSORT checklist has 3 items:

Item 8. Method used to generate the random allocation sequence. Details of any restriction [of randomization] (e.g., blocking, stratification).

Item 9. Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.

Item 10. Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.

Good (clear) reporting

Sequence generation:

- "Independent pharmacists dispensed either active or placebo inhalers according to a computer generated randomization list."
- … The randomization code was developed using a computer random number generator to select random permuted blocks. The block lengths were 4, 8, and 10 varied randomly …"

Clear reporting?

“Patients were assigned to either the intervention or control group, by selection of a card from a pile of equal numbers of cards for each group.”

[*Lancet* 2002; 360: 1455–61.]

Clear reporting but poor methodology

“Randomization was alternated every 10 patients, such that the first 10 patients were assigned to early atropine and the next 10 to the regular protocol, etc. To avoid possible bias, the last 10 were also assigned to early atropine.”

[Lessick et al, *Eur J Echocardiography* 2000;1:257-62]

CONSORT 2010 is coming soon!