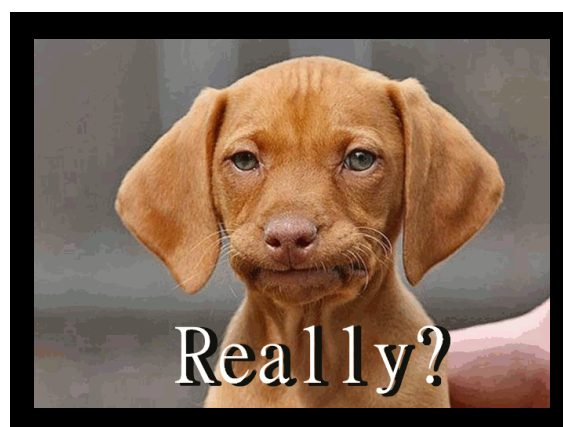


Should CONSORT do more to improve the quality of missing data reporting?



Dr. Jamilla Hussain @JamillaHussain1
NIHR Doctoral Research Fellow

Co-authors: Martin Bland, Dean Langan, Miriam Johnson,
David Currow, Ian R White



Questions

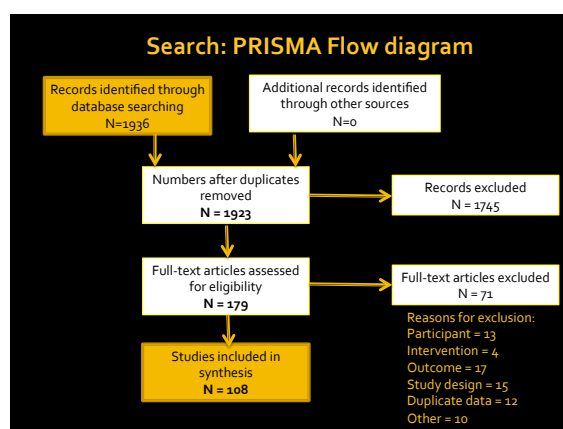
1. To what extent are missing data reported in accordance with current reporting guidance?
2. Does the quality of reporting differ between missing data reporting criteria specified by CONSORT vs. those not specified by CONSORT?
3. Are journal impact factor and CONSORT endorsement status associated with the quality of missing data reporting?

Method: Systematic review

- P= advanced life-limiting disease
- I = palliative
- C= palliative / usual care / placebo
- O = Patient reported / dependent
- S = RCTs
- Information specialist searched: CENTRAL, OVID Medline, EMBASE (Jan 2009-April 2014)
- Random selection / no language restrictions / double screening, selection, extraction

Method: Reporting criteria

1. Proportion of missing data
2. Reasons for missing data
3. Minimising missing data
4. Risk of bias posed by missing data
5. Justification of missing data analytical approach
6. Statistical methods to handle missing data
7. Impact of missing data on trial findings



Q1. To what extent are missing data reported in accordance with current reporting guidance?

1. Proportion of missing data

Missing data reporting criterion	Proportion of trials reporting the criterion
Account for all participants who enter the study	69% (75/108)
Report number of participants not included in the primary outcome analysis	94% (101/108)
Report number of participants with missing data in each arm in the primary outcome analysis (non-crossover trials)	87% (85/98)
Report amount of item-level missing data in the primary outcome analysis (if primary outcome was a scale summary)	10% (5/50)
Report missing data trend over time for primary outcomes measured repeatedly	All time points: 7% (5/69) Some time-points: 48% (33/69)
Report amount of missing data for secondary outcomes if measured	For all: 9% (9/99) For some: 18% (18/99)

2. Reason for missing data

Missing data reporting criterion	Proportion of trials reporting the criterion
Report reason for missing data	71% (66/93) ¹
Report amount of missing data due to death	65% (60/93)
Report amount of missing data due to illness/disease progression	46% (43/93)

¹ Fifteen trials reported no missing data

For 53% of participants with missing data the reason was described as 'LTFU' or 'withdrawal' only

3. Minimising & 4. Risk of bias

Missing data reporting criterion	Proportion of trials reporting the criterion
Report plans to minimise missing data	27% (29/108)
Report comparison of baseline characteristics of those with observed data	6% (6/93)
Report comparison of baseline characteristics of those with missing data	0%

5. Justification of missing data analytical approach

Missing data reporting criterion	Proportion of trials reporting the criterion
Report assumed mechanism of missing data	3% (3/108)
Report criteria for missing not at random (informative missing data)	1% (1/108)
Report pattern of missingness	0%
Compare baseline characteristics of those with and without missing data	13% (12/93)

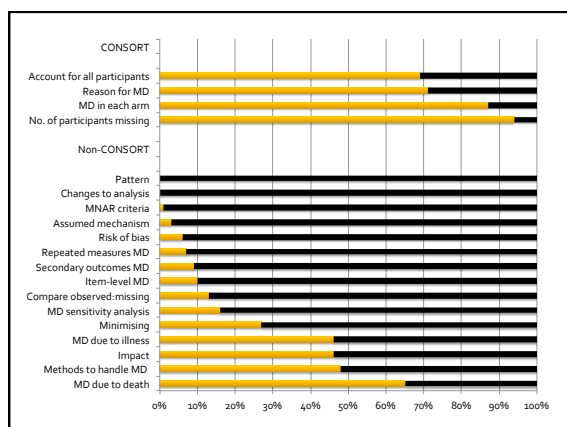
6. Statistical methods to handle missing data

Missing data reporting criterion	Proportion of trials reporting the criterion
Report methods used to handle missing data	48% (45/93)
Report missing data sensitivity analyses	16% (15/93)
Report any changes to the planned missing data analysis	0%

7. Impact of missing data on the trial findings

- 46% (43/93)
- Limitations section
- 13 discussed potential for missing data to bias the treatment effect estimate

Q2. Does the quality of reporting differ between criteria specified by CONSORT vs. those not specified by CONSORT?



Q3. Are journal impact factor and CONSORT endorsement status associated with the quality of missing data reporting?

Reporting criterion	Journal impact factor (Median 2.8, 0-56)		CONSORT endorsement status	
	Odds ratio per JIF doubling	95% CI	Odds ratio	95% CI
Account for all participants*	1.54	1.20, 1.97	2.46	0.73, 8.23
No. of participants not included in the primary outcome analysis*	1.39	1.15, 1.69	1.20	0.31, 4.70
Reasons for MD*	0.88	0.63, 1.23	0.65	0.20, 2.17
Plans to minimise MD	1.16	0.94, 1.42	1.00	0.40, 2.49
Compare baseline characteristics of those with and without MD	1.50	1.20, 1.87	1.11	0.42, 2.92
Methods to handle MD	1.40	1.13, 1.73	2.53	1.08, 5.94
MD sensitivity analyses	1.20	0.81, 1.80	3.48	1.15, 10.50
Impact on findings	1.14	0.93, 1.41	1.85	0.85, 4.04

So what?

- Q1. The reporting of missing data in palliative care trials does not comply fully with current reporting guidance
- Q2. Criteria specified by CONSORT were better reported
- Q3. The odds of reporting the majority of the MD criteria increased as journal impact factor increased and in journals that endorsed the CONSORT statement

**Methods section:**

1. Report the justification of the missing data analytical approach including all of the following:
 - a. Any assumptions about the missing data mechanism³ with justification.
 - b. What analyses will be performed to support assumptions about the missingness mechanism. For example, comparison of variables according to whether the partially observed variable of interest was missing may shed light on the credibility of the MAR assumption.
 - c. ⁴How the assumed missingness mechanism and any relevant features of the data such as pattern of missingness would influence the choice of method(s) to handle missing data and missing data sensitivity analyses.
 - d. Details of the statistical methods used to handle missing data.
 - e. How truncated data due to death will be handled and justification of method(s) (if applicable)⁷.

Results section:

2. Report the following measures of amount of missing data:
 - a. For each outcome: number of participants in each arm with missing data (unit-level missing data).
 - b. For outcomes that are scale summaries: amount of item-level missing data, for example the number of participants in each arm with some items reported and some items missing, and/or the proportion of item-level missing data.
 - c. For repeated outcomes: number of participants in each arm with missing data at each time-point.
3. Reasons for missing data in each arm, with enough detail that the reported reason can be used to reduce the uncertainty about the potential underlying mechanism of missing data—although this will not be verifiable using the partially observed data. If terms such as lost to follow up or withdrawal are used, these must be defined.
4. Comparison of the baseline characteristics of those included in the analysis (if participants are excluded from the analysis post-randomisation).
5. ⁵Results of investigations of the missingness mechanism and/or pattern, and whether these led to changes to the choice of the primary method³ to handle missing data.
6. ⁶Missing data sensitivity analyses results including analyses based on plausible missing not at random assumptions if appropriate.

Discussion section:

7. Impact of missing data on the interpretation of findings, including effect on validity and generalisability.