



CONSORT: missing missing data guidelines, the effects on HTA monograph reporting

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NWORTH

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Our Questions

- Does the reporting of RCTs include information on missing data?
- How does the reporting of missing data compare to that of randomisation, blinding, and allocation concealment?
- Would extending CONSORT help?



CONSORT

- Reporting of RCTs has improved since the CONSORT statement was first published in 1996
- It facilitates critical appraisal and interpretation of RCTs by providing reporting standards for authors and journals
- Its current version consists of 4-stage flow diagram and 25 item check list



What does CONSORT say about reporting randomisation & blinding?

Methods: 2001 check list	Item no.	Descriptor
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding		
	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	How the success of blinding was evaluated



What does CONSORT say about reporting missing data?



What does CONSORT say about reporting missing data?

Methods: 2001 check list	Item no.	Descriptor
Statistical methods:		
	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses

Not explicitly stated !!!



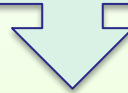
Why HTA?

- Transparency in reporting is crucial to identify bias and assess the validity of a study
- Word limitations on journal articles still preclude full description of methodology
- HTA monographs can be up to 200 pages (50,000 words + appendices) giving authors room to comprehensively report their methodology and findings



Methodology: Study selection

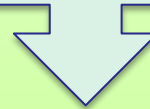
517 Monographs published in HTA up to February 2010



Narrowed to 119 using “primary research” as filter.



Screening using key words; “Randomised control trials” and “Randomised trials”. 26 Monographs excluded



93 Monographs included in the final study



Methodology: Data extraction

- Mini CONSORT check list including items relating to randomisation, allocation concealment and blinding i.e. Items 8a, 8b, 9, 10, 11a and 11b.
- Check list designed by the team to include 5 items related to missing data



Methodology: Data extraction

Topic	Item no.	Descriptor
CONSORT diagram	1	Flow diagram of the progress through the phases of a randomised trial (that is, enrolment, intervention allocation, follow-up, and data analysis).
Missing data	2	Monograph refers to missing data within the text
Quantifying missing data	3	Type of missing data reported; Participants, questionnaires and items
Method of Imputation	4	Monograph states a complete case analysis or a method of imputation used
Sensitivity analysis	5	Method of analysis performed to asses the effect of missing data imputation



Results: Good CONSORT Item adherence

Items	All Trials (n=93)	1998-2001 (n=10)	2002-2005 (n=35)	2006-2010 (n=48)
'Randomised' stated in title	75 (81%)	8 (80%)	28 (80%)	39 (81%)
Method of random sequence generation	81 (87%)	7 (70%)	30 (86%)	44 (92%)
Restriction to randomisation	82 (88%)	6 (60%)	30 (86%)	46 (96%)
Method of allocation concealment	77 (83%)	7 (70%)	27 (77%)	43 (90%)
Allocation sequence - executor separated from generator	65 (70%)	5 (50%)	21 (60%)	39 (81%)



Results: Poor CONSORT Item adherence

Blinded 33 (36%)

1998-2001	2002-2005	2006-2010
1 (10%)	12 (34%)	20 (42%)

Details reported 27(82%)

1998-2001	2002-2005	2006-2010
0%	10 (83%)	17 (85%)

Details not reported 6 (18%)

1998-2001	2002-2005	2006-2010
1 (100%)	2 (17%)	3 (15%)

Blinding assessed 9 (33%)

1998-2001	2002-2005	2006-2010
0%	4 (40%)	5 (29%)

Unblinded 43 (46%)
Not Reported 14 (15%)
Not clear 3 (3%)

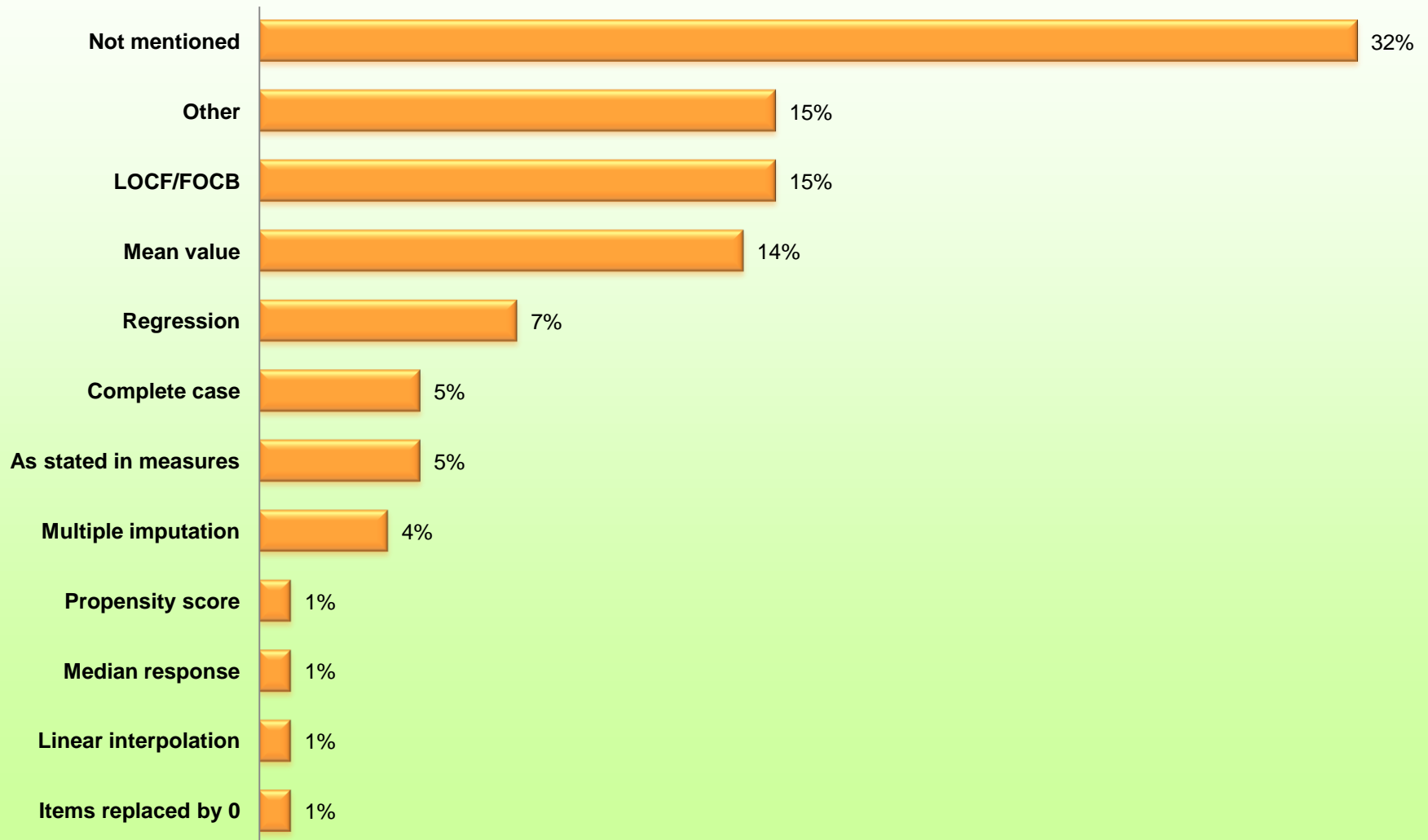


Results: Reporting of items related to missing data

Items	All Trials (n=93)	1998-2001 (n=10)	2002-2005 (n=35)	2006-2010 (n=48)
CONSORT diagram	90 (97%)	10 (100%)	32 (91%)	48 (100%)
Acknowledging missing data	86 (92%)	8 (80%)	34 (97%)	44 (92%)
Quantifying missing data	77 (83%)	7 (70%)	31 (89%)	39 (81%)
Method of imputation	59 (63%)	4 (40%)	21 (60%)	34 (71%)
Sensitivity analysis	25 (27%)	-	10 (29%)	15 (31%)



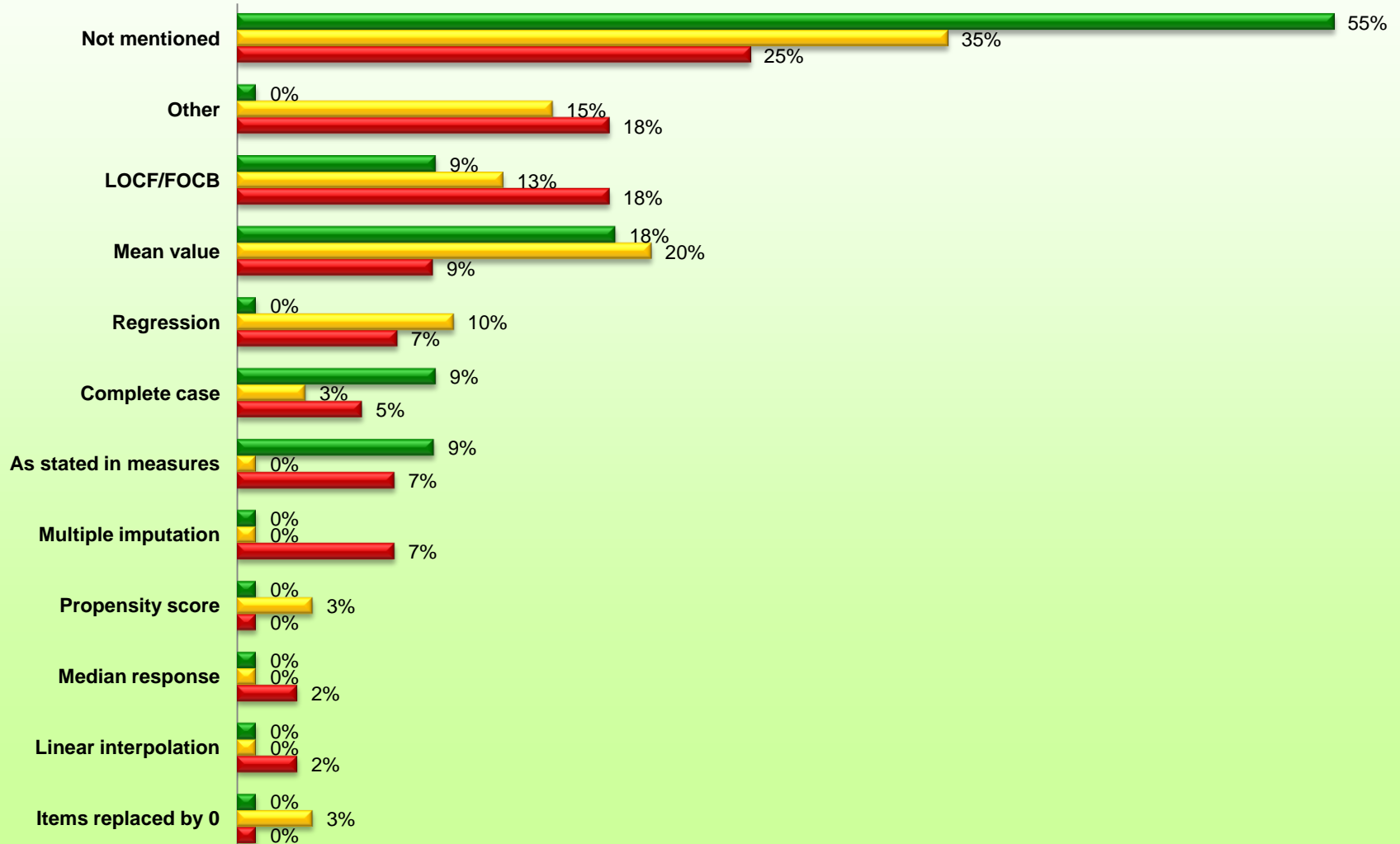
Results: Reporting of missing data imputation methods





Results: Reporting of missing data imputation methods by period

■ 1998-2001 ■ 2002-2005 ■ 2006-2010





Conclusion

- Reporting of randomisation, blinding and allocation concealment has improved with each revision of the CONSORT statement
- Almost 1/3 of the studies do not report a method for imputing missing data
- There is no consistency in the remaining 2/3 with a high proportion of the studies not giving any details on how imputations were performed



Thank you for listening

Questions?