New SPIRIT & CONSORT Extensions to Trial Outcomes

DEVELOPMENT, IMPLEMENTATION,
& CHALLENGES FOR AUTHORS AND JOURNALS

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This session

1. Trial Reporting Standards
2. SPIRIT | CONSORT OUTCOMES Reporting Guidelines for Trial Outcomes
3. Outcome reporting in Neonatology RCTs
4. PRISMA - COSMIN OUTCOME Measurement Instruments
5. Discussion

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Poll

1. Who writes trial protocols and/or trial reports?
2. Who has heard of the equator network ?
3. Anyone in child health?
4. Who designs trials?
   - Specifically, the "trial primary outcome"?
   - Who has used PROMs for this?

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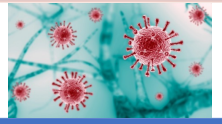
Credibility crisis in biomedical research

Journal Retractions (FFP)	Selection Bias - Information Bias
Vested Interests	Selective Outcome Reporting Bias
"Fake news"	False positive studies – irreplicable findings



"Can I **trust** this research?"

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Transparency

Indispensable for

- Usability of evidence
- Applicability of results

- Decision making
  - Implementation & de-implementation (of futile or harmful) interventions or policies to improve public health outcomes
  - Research agenda and grant resources ("building on results", replication)

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BMJ

BMJ 2013;347:f4796 doi: 10.1136/bmj.f4796 (Published 7 August 2013) Page 1 of 2

EDITORIALS

Declaration of transparency for each research article

OPEN ACCESS

An antidote to inadequate reporting of research

Douglas G Altman *director*[1], David Moher *senior scientist*[2]

[1]Centre for Statistics in Medicine, University of Oxford, Botnar Research Centre, Oxford, UK; [2]Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa Hospital - General Campus, Ottawa, ON K1H 8L6, Canada

"It is the responsibility of everyone involved to ensure that the published record is an unbiased, accurate representation of research."[3]

The research record is often manipulated for short term gain but at the risk of harm to patients. The medical research community needs to implement changes to ensure that readers obtain the truth about all research, especially reports of randomised trials, which hold a special place in answering what works best for patients.

Failure to publish the findings of all studies, especially randomised trials, seriously distorts the evidence base for clinical decision making. A recent systematic review of reboxetine for treating depression found that almost three quarters of included in relation to allocation. A 2006 study found that only a third of trial reports described how the randomisation sequence was generated and only a quarter described an adequate method of allocation concealment.[20] A review of 357 phase III oncology trials concluded that "numerous items remained unreported for many trials."[21] Harms too are poorly reported.[22 23]

The problems associated with publishing and reporting other types of research may be worse than for randomised trials. Although less intensively studied, similar concerns have been expressed in relation to epidemiology,[24 25] pharmacoepidemiology,[26] diagnosis research,[27] prognosis research,[28] and preclinical research.[29 30] Of course, good reporting is not the same as high quality research. But a full and clear report allows readers to judge a study's reliability and relevance.

Transparency declaration BMJ 2013

"The lead author* affirms that this manuscript is an **honest, accurate, and transparent** account of the study being reported; that **no important aspects** of the study have been **omitted**; and that any **discrepancies from the study as planned** (and, if relevant, registered) have been **explained**."

*The manuscript's guarantor.

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Why is reporting important?

"Complete, accurate and transparent reporting is an integral part of responsible research conduct."

Poor reporting has consequences for

- future research
- policy making
- clinical practice
- patients

Altman, D. G., & Moher, D. (2014). Importance of Transparent Reporting of Health Research. In Guidelines for Reporting Health Research: A User's Manual (pp. 1–13). John Wiley & Sons, Ltd. https://doi.org/10.1002/9781118715598.ch1

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Research Reporting Guidelines

- Evidence-based* checklists: what should be reported in a manuscript
  - **Minimum set** of information that should be reported
- *Specific* guidelines for *specific* study designs (& interventions, & populations)
  - **Clinical trial protocols**
    - Standard Protocol Items: Recommendations for Trials (SPIRIT 2013)
  - **Clinical trial reports**
    - Consolidated Standards of Reporting Trials (CONSORT 2010)

+ Various extensions *specific* to study sub-type or (para) medical field

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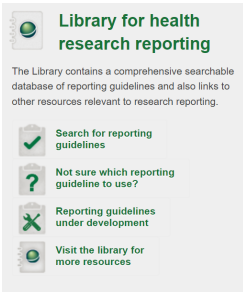
Where to find reporting guides?

equator network

Enhancing the QUAlity and Transparency Of health Research

"International initiative that seeks to improve the reliability and value of published health research literature by promoting **transparent and accurate reporting** and wider use of **robust reporting guidelines**."

https://www.equator-network.org/about-us



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Many reporting guidelines…!

https://www.equator-network.org

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	Extensions
Economic evaluations	CHEERS	

See all 553 reporting guidelines

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Benefits of using reporting guidelines

Accessible tools that can be used from trial design stages to ensure comprehensive reporting	Different reporting guidelines and extensions are available for different fields and study types	Though reporting is still suboptimal, there has been some improvement in reporting over time
• Better transparency, replicability, and usability of trial findings • "Upstream" improved design and conduct of studies • Reduce and minimize research waste	• Fit-for-purpose • Provides guidance to authors and trialists to ensure **essential elements** are incorporated in reporting	• Adherence higher in journals that endorse reporting guidelines • Articles that published more recently tend to adhere to reporting guidelines more

- Samaan Z, Mbuagbaw L, Kosa D, Debono VB, Dillenburg R, Zhang S, Fruci V, Dennis B, Bawor M, Thabane L. A systematic scoping review of adherence to reporting guidelines in health care literature. Journal of multidisciplinary healthcare. 2013 May 6:169-88.
- Jin Y, Sanger N, Shams I, Luo C, Shahid H, Li G, Bhatt M, Zielinski L, Bantoto B, Wang M, Abbade LP. Does the medical literature remain inadequately described despite having reporting guidelines for 21 years?–A systematic review of reviews: an update. Journal of multidisciplinary healthcare. 2018 Sep 27:495-510.
- Stevens A, Shamseer L, Weinstein E, Yazdi F, Turner L, Thielman J, Altman DG, Hirst A, Hoey J, Palepu A, Schulz KF. Relation of completeness of reporting of health research to journals' endorsement of reporting guidelines: systematic review. Bmj. 2014 Jun 25;348.

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BMJ Open

Effect of an editorial intervention to improve the completeness of reporting of randomised trials: a randomised controlled trial

BMC Medicine

RESEARCH ARTICLE Open Access

Impact of an online writing aid tool for writing a randomized trial report: the COBWEB (Consort-based WEB tool) randomized controlled trial

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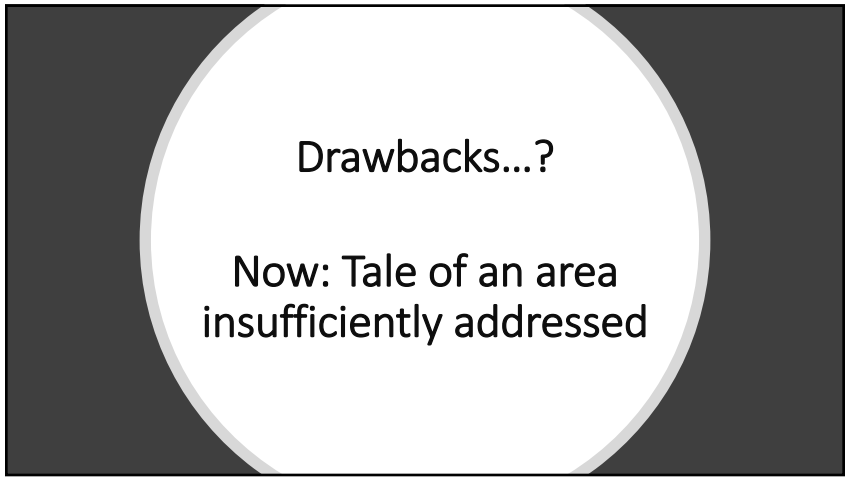

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SPIRIT-Outcomes 2022 & CONSORT-Outcomes 2022

Enhanced trial outcome transparency, quality, and utility to improve **health outcomes**

SPIRIT | CONSORT OUTCOMES
Reporting Guidelines for Trial Outcomes

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Large variability in outcome reporting

REVIEW Open Access

Outcome reporting in neonates experiencing withdrawal following opioid exposure in pregnancy: a systematic review

RESEARCH ARTICLE Open Access

Primary outcome reporting in adolescent depression clinical trials needs standardization

RESEARCH Open Access

COMPare: a prospective cohort study correcting and monitoring 58 misreported trials in real time

Research Letter

November 7, 2017

Association of Trial Registration With Reporting of Primary Outcomes in Protocols and Publications

ORIGINAL ARTICLE

High incidence of outcome switching observed in follow-up publications of randomized controlled trials: Meta-research study

A Core Outcome Set for Children With Feeding Tubes and Neurologic Impairment: A Systematic Review

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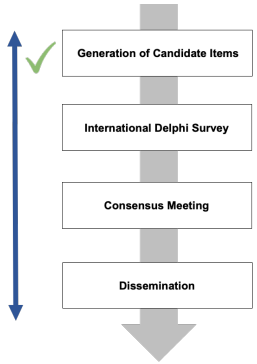
Scoping Review Results



- 132 candidate reporting items
- Majority not in SPIRIT (72%) or CONSORT (83%)

REVIEW Open Access

Outcome reporting recommendations for clinical trial protocols and reports: a scoping review

Nancy J. Butcher[1*], Emma J. Mew[1], Andrea Monsour[1], An-Wen Chan[2], David Moher[3,4] and Martin Offringa[1,5,6]

Butcher, N.J., Mew, E.J., Monsour, A. *et al.* Outcome reporting recommendations for clinical trial protocols and reports: a scoping review. *Trials* **21**, 620 (2020). https://doi.org/10.1186/s13063-020-04440-w

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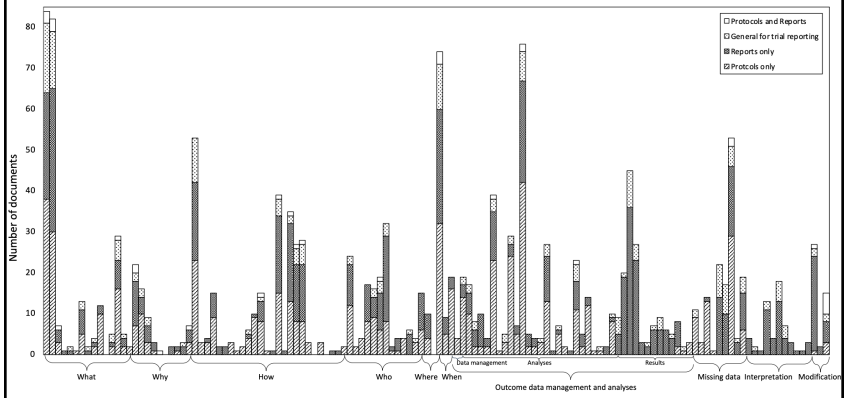

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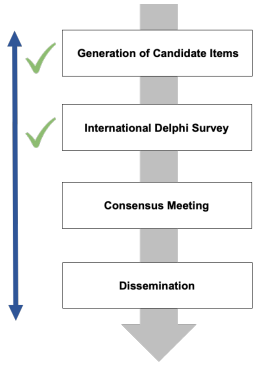
International three-round Delphi study



Assess the importance of candidate items
- Ranked on 9-point Likert scale to determine inclusion and exclusion of items

Identify additional candidate items
- 124 participants completed from 22 countries (79% retention)
- Stakeholders: systematic review/meta-analysis authors, trial report authors, trial protocol authors, epidemiologists, biostatisticians, clinicians, core outcome set developers, journal editors, reporting guideline developers, research ethics committee members, and more.

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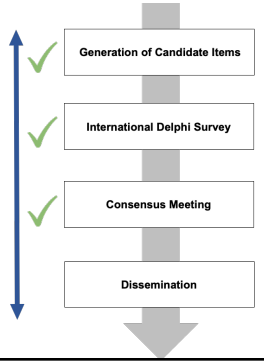
International consensus meeting



25 participants from 4 countries:
Trial Protocol and Report Authors, Clinical Trialists, Methodologists, Systematic Reviewers, Biostatisticians, Epidemiologists, Health Technology Assessors, Clinicians, Research ethics boards leadership, Research funders, **Patient & Public representatives**, Academic Journal Editors

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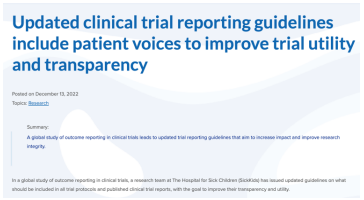
+ Patient and public involvement



Patient/public engagement in the Consensus Meeting using GRIPP 2-SF (Guidance for Reporting Involvement of Patients and the Public):[6]

Section and topic	Item
1: Aim Report the aim of the study	Patient and public partners are key knowledge users of trial results. Patient/public involvement (PPI) is not yet a formal part of EQUATOR reporting guideline methodology.[7] Our aim was to collaboratively engage with a patient partner and a member of the public, both with significant expertise in patient/public engagement methods as well as research methodology to (i) determine how engagement could be successfully conducted before the Consensus Meeting and (ii) facilitate active participation in the Consensus Meeting.
2: Methods Provide a clear description of the methods used for PPI in the study	The research team was committed to supporting the patient and public partners so that they could contribute meaningfully to the Consensus Meeting. One meeting was held each with a patient partner (Maureen Smith; MS) and a member of the public (Frank Gavin; FG) separately with the project Co-Chairs (Nancy Butcher; NB and Martin Offringa; MO) to provide an overview of project and Consensus Meeting goals to determine if and how engagement could be supported and facilitated. MS and FG also communicated directly with one another to discuss the project and their roles.

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Clinical Review & Education | *JAMA*. 2022;328(23):2345–2356. doi:10.1001/jama.2022.21243

JAMA | Special Communication

Guidelines for Reporting Outcomes in Trial Protocols
The SPIRIT-Outcomes 2022 Extension

Nancy J. Butcher, PhD; Andrea Monsour, MPH; Emma J. Mew, MPH, MPhil; An-Wen Chan, MD, DPhil; David Moher, PhD; Evan Mayo-Wilson, DPhil; Caroline B. Terwee, PhD; Alyssandra Chee-A-Tow, MPH; Ami Baba, MRes; Frank Gavin, MA; Jeremy M. Grimshaw, MBCHB, PhD; Lauren E. Kelly, PhD; Leena Saeed, BSc, BEd; Lehana Thabane, PhD; Lisa Askie, PhD; Maureen Smith, MEd; Mufiza Farid-Kapadia, MD, PhD; Paula R. Williamson, PhD; Peter Szatmari, MD; Peter Tugwell, MD; Robert M. Golub, MD; Suneeta Monga, MD; Sunita Vohra, MD; Susan Marlin, MSc; Wendy J. Ungar, PhD; Martin Offringa, MD, PhD

Clinical Review & Education | *JAMA*. 2022;328(22):2252–2264. doi:10.1001/jama.2022.21022

JAMA | Special Communication

Guidelines for Reporting Outcomes in Trial Reports
The CONSORT-Outcomes 2022 Extension

Nancy J. Butcher, PhD; Andrea Monsour, MPH; Emma J. Mew, MPH, MPhil; An-Wen Chan, MD, DPhil; David Moher, PhD; Evan Mayo-Wilson, DPhil; Caroline B. Terwee, PhD; Alyssandra Chee-A-Tow, MPH; Ami Baba, MRes; Frank Gavin, MA; Jeremy M. Grimshaw, MBCHB, PhD; Lauren E. Kelly, PhD; Leena Saeed, BSc, BEd; Lehana Thabane, PhD; Lisa Askie, PhD; Maureen Smith, MEd; Mufiza Farid-Kapadia, MD, PhD; Paula R. Williamson, PhD; Peter Szatmari, MD; Peter Tugwell, MD; Robert M. Golub, MD; Suneeta Monga, MD; Sunita Vohra, MD; Susan Marlin, MSc; Wendy J. Ungar, MSc, PhD; Martin Offringa, MD, PhD

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• Butcher NJ, Monsour A, Mew EJ, et al. Guidelines for Reporting Outcomes in Trial Reports: The CONSORT-Outcomes 2022 Extension. *JAMA*. 2022;328(22):2252–2264.

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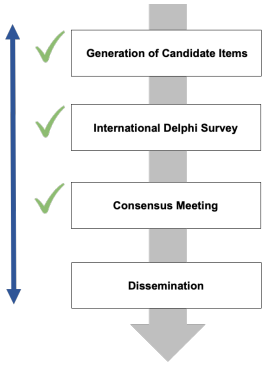
New outcome reporting items



SPIRIT-Outcomes:
9 new items

CONSORT-Outcomes:
17 new items
More (new items + harmonizes with SPIRIT 2013)

23

New items

Item	SPIRIT-Outcomes 2022	CONSORT-Outcomes 2022
Outcome definition	✓	✓
Rationale for outcome selection	✓	✓
Components of composite outcomes	✓	✓
Minimal important difference/change	✓	✓
Measurement properties of study instruments	✓	✓
Outcome assessors	✓	✓
Adjustments for multiplicity	In SPIRIT 2013	✓
Data quality processes	In SPIRIT 2013	✓
Missing outcome data	In SPIRIT 2013	✓
Definition of the analysis population	N/A	✓
Identifying outcomes that were not prespecified	N/A	✓
Prespecified and not prespecified outcome analyses	N/A	✓

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Glossary

Minimal important change

Minimal important difference

Box. Glossary of Terms Used in the CONSORT-Outcomes 2022 Extension

Composite outcome: A composite outcome consists of ≥2 component outcomes (eg, proportion of participants who died or experienced a nonfatal stroke). Participants who have experienced any of the events specified by the components are considered to have experienced the composite outcome.[17,43]

CONSORT 2010: Consolidated Standards of Reporting Trials (CONSORT) statement that was published in 2010.[2,3]

CONSORT-Outcomes 2022 extension: Additional essential checklist items describing outcome-related content that are not covered by the CONSORT 2010 statement.

Construct validity: The degree to which the scores reported in a trial are consistent with the hypotheses (eg, with regard to internal relationships, the relationships of the scores to other instruments, or relevant between-group differences) based on the assumption that the instrument validly measures the domain to be measured.[30]

Content validity: The degree to which the content of the study instrument is an adequate reflection of the domain to be measured.[30]

Criterion validity: The degree to which the scores of a study instrument are an adequate reflection of a gold standard.[30]

Cross-cultural validity: The degree to which the performance of the items on a translated or culturally adapted study instrument are an adequate reflection of the performance of the items using the original version of the instrument.[30]

Minimal important change: The smallest within-patient change that is considered important by patients, clinicians, or relevant others.[4,5] The change may be in a score or unit of measure (continuous or ordinal measurements) or in frequency (dichotomous outcomes). This term is often used interchangeably in health literature with the term *minimal important difference*. In the CONSORT-Outcomes 2022 extension, the minimal important change conceptually refers to important intrapatient change (item 6a.3) and the minimal important difference refers to the important between-group difference. Minor variants of the term, such as minimum instead of minimal, or the addition of the adjective clinically or clinical are common (eg, the minimum clinically important change).[23]

Minimal important difference: The smallest between-group difference that is considered important by patients, clinicians, or relevant others.[34-37] The difference may be in a score or unit of measure (continuous or ordinal measurements) or in frequency (dichotomous outcomes). Minor variants of the term, such as minimum instead of minimal, or the addition of the adjective clinically or clinical are common (eg, the minimum clinically important difference).[23]

Outcome: Refers to what is being assessed to examine the effect of exposure to a health intervention.[1] The 5 core elements of a defined outcome appear in Table 2.

Primary outcome: The planned outcome that is most directly related to the primary objective of the trial.[38] It is typically the outcome used in the sample size calculation for trials with the primary objective of assessing efficacy or effectiveness.[39] Many trials have 1 primary outcome, but some have >1. The term *primary end point* is sometimes used in the medical literature when referring to the primary outcome.[4]

Reliability: The degree to which the measurement is free from error. Specifically, the extent to which scores have not changed for participants and are the same for repeated measures under several conditions (eg, using different sets of items from the same rating scale for internal consistency; over time or test-retest; by different persons on the same occasion or interrater; or by the same persons, such as raters or responders, on different occasions or intrarater).[30]

Responsiveness: The ability of a study instrument to accurately detect and measure change in the outcome domain over time.[31,32] Distinct from an instrument's construct validity and criterion validity, which refer to the validity of a single score, responsiveness refers to the validity of a change score (ie, longitudinal validity).[30]

Secondary outcomes: The outcomes prespecified in the trial protocol to assess any additional effects of the intervention.[38]

Smallest worthwhile effect: The smallest beneficial effect of an intervention that justifies the costs, potential harms, and inconvenience of the interventions as determined by patients.[33]

SPIRIT 2013: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement that was published in 2013.[35,36]

SPIRIT-Outcomes 2022 extension: Additional essential checklist items describing outcome-related trial protocol content that are not covered by the SPIRIT 2013 statement.[17]

Structural validity: The degree to which the scores of a study instrument (eg, a patient questionnaire or a clinical rating scale) are an adequate reflection of the dimensionality of the domain to be measured.[30]

Study instrument: The scale or tool used to make an assessment. A study instrument may be a questionnaire, a clinical rating scale, a laboratory test, a score obtained through a physical examination or an observation of an image, or a response to a single question.[34]

Target difference: The value that is used in sample size calculations as the difference sought to be detected on the primary outcome between intervention groups and that should be considered realistic or important (such as the minimal important difference or the smallest worthwhile effect) by ≥1 key stakeholder groups.[17,18]

Validity: The degree to which a study instrument measures the domain it purports to measure.[30]

- Butcher NJ, Monsour A, Mew EJ, et al. Guidelines for Reporting Outcomes in Trial Protocols: The SPIRIT-Outcomes 2022 Extension. *JAMA*. 2022;328(23):2345-2356. doi:10.1001/jama.2022.21243
- Butcher NJ, Monsour A, Mew EJ, et al. Guidelines for Reporting Outcomes in Trial Reports: The CONSORT-Outcomes 2022 Extension. *JAMA*. 2022;328(22):2252-2264. doi:10.1001/jama.2022.21022

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Five core elements of a defined outcome

Table 2. The 5 Core Elements of a Defined Outcome[a]

Element No.	Element term	Definition used	Example 1	Example 2	Example 3
1	Domain[b]	Title or concept to describe ≥1 outcomes	Blood pressure	Depression	Death
2	Measurement variable or specific measurement	Corresponds to the data collected directly from trial participants; description includes the instrument used to assess the outcome domain			
		• Descriptive name	Systolic blood pressure measured with Omron upper arm blood pressure monitor	MADRS	All-cause mortality per hospital database
		• If applicable, the total score or the subscales that will be analyzed	Not applicable	MADRS total score	Not applicable
3	Specific metric	Participant-level unit of measurement (eg, change from baseline, final value or z value at a time point, time to event) for analysis	Value at a time point	Change from baseline	Time to event
4	Method of aggregation	The procedure for estimating the treatment effect			
		• If the outcome will be treated as a continuous, categorical, or time-to-event variable	Continuous variable	Binary variable	Time to event
		• For continuous variables, a measure of central tendency (eg, mean value); for categorical and time-to-event data variables, proportion with an event and, if relevant, the specific cutoff values or categories compared	Mean value	Proportion of participants with ≥50% decrease	Incidence density and between-group incidence density rate
5	Time point	The timing of follow-up measurements			
		• When outcome measurements will be obtained	2, 4, and 12 wk after randomization	2, 4, 6, and 8 wk after randomization	Daily
		• Which of the outcome measurements will be analyzed	12 wk after randomization	8 wk after randomization	End of follow-up

Abbreviation: MADRS, Montgomery-Åsberg Depression Rating Scale.

[a] Content adapted from Zarin et al,[38] Mayo-Wilson et al,[33] and Chan et al.[2]

[b] An explicit and specific description of the outcome domain should be provided in the trial protocol, as appropriate, when defining the trial outcome. If an outcome domain is broad, such as pain, a specific protocolized domain definition might be the daily average of the intensity of the sensation of pain expressed on a range from no pain to worst pain imaginable over a 24-hour window during an average day.[39]

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Checklists: SPIRIT and CONSORT-Outcomes 2022

SPIRIT | CONSORT OUTCOMES
Reporting Guidelines for Trial Outcomes

SPIRIT-Outcomes 2022 Extension items only (for separate completion of SPIRIT 2013 and SPIRIT-Outcomes 2022 items)[a]

Section	Item No.	SPIRIT-Outcomes 2022 item	Location Reported[b]
Methods: Participants, interventions, and outcomes			
Outcomes	12.1	Provide a rationale for the selection of the domain for the trial's primary outcome	Click to enter text
	12.2	If the analysis metric for the primary outcome represents within-participant change, define and justify the minimal important change in individuals	Click to enter text or specify not applicable
	12.3	If the outcome data collected are continuous but will be analyzed as categorical (method of aggregation), specify the cutoff values to be used	Click to enter text or specify not applicable
	12.4	If outcome assessments will be performed at several time points after randomization, state the time points that will be used for analysis	Click to enter text or specify not applicable
	12.5	If a composite outcome is used, define all individual components of the composite outcome	Click to enter text or specify not applicable
Sample size	14.1	Define and justify the target difference between treatment groups (eg, the minimal important difference)	Click to enter text
Methods: Data collection, management, and analysis			
Data collection methods	18a.1	Describe what is known about the responsiveness of the study instruments in a population similar to the study sample	Click to enter text or specify not applicable
	18a.2	Describe who will assess the outcome (eg, nurse, parent)	Click to enter text or specify not applicable
Statistical methods	20a.1	Describe any planned methods to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	Click to enter text or specify not applicable

[a] It is strongly recommended that this checklist be read in conjunction with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement paper for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license and is reproduced with permission.

[b] Indicates page numbers and/or manuscript location: to be completed by authors during trial protocol development.

CONSORT-Outcomes 2022 Extension items only (for separate completion of CONSORT 2010 and CONSORT-Outcomes 2022 items)

Section	Item No.	CONSORT-Outcomes item	Location Reported[a]
Methods			
Outcomes	6a.1	Provide a rationale for the selection of the domain for the trial's primary outcome	Click to enter text
	6a.2	Describe the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, mean, proportion), and the time point for each outcome	Click to enter text or specify not applicable
	6a.3	If the analysis metric for the primary outcome represents within-subject change, define and justify the minimal important change in individuals	Click to enter text or specify not applicable
	6a.4	If the outcome data were continuous, but were analyzed as categorical (method of aggregation), specify the cutoff values used	Click to enter text or specify not applicable
	6a.5	If outcome assessments were performed at several time points after randomization, state the time points used for analysis	Click to enter text or specify not applicable
	6a.6	If a composite outcome was used, define all individual components of the composite outcome	Click to enter text or specify not applicable
	6a.7	Identify any outcomes that were not prespecified in a trial registry or protocol	Click to enter text
	6a.8	Provide a description of the study instruments used to assess the outcome (eg, questionnaires, laboratory tests) along with reliability, validity, and responsiveness in a population similar to the study sample	Click to enter text or specify not applicable
	6a.9	Describe who assessed the outcome (eg, nurse, parent), and any qualifications or trial-specific training necessary to administer the study instruments to assess the outcome	Click to enter text or specify not applicable
	6a.10	Describe any processes used to promote outcome data quality during data collection (eg, duplicate measurements) and after data collection (eg, range checks of outcome data values), or state where details can be found	Click to enter text
Sample size	7a.1	Define and justify the target difference between treatment groups (eg, the minimal important difference)	Click to enter text
Statistical methods	12a.1	Describe any methods used to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of one outcome)	Click to enter text or specify not applicable
	12a.2	State and justify any criteria for excluding any outcome data from the analysis and reporting, or report that no outcome data were excluded	Click to enter text
	12a.3	Describe methods to assess patterns of missingness (eg, missing not at random), and describe the methods to handle missing outcome items or entire assessments	Click to enter text or specify not applicable
	12a.4	Provide definition of outcome analysis population relating to protocol nonadherence (eg, as randomized analysis)	Click to enter text
Results			
Outcomes and estimation	17a.1	Include results for all prespecified outcome analyses or state where results can be found if not in this report	Click to enter text
Ancillary analyses	18.1	If there were any analyses that were not prespecified, explain why they were performed	Click to enter text or specify not applicable

[a] It is strongly recommended that this checklist be read in conjunction with the CONSORT-Outcomes and CONSORT Statement papers for important clarification on the items. The CONSORT Statement checklist is distributed under the terms of the Creative Commons Attribution License. Indicates page numbers and/or manuscript location: to be completed by authors during trial report development.

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SPIRIT-Outcomes 12.1

Description of outcomes

Section	Item No.	Existing SPIRIT Item	SPIRIT-Outcomes 2022 Item
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended.	12.1. Provide a rationale for the selection of the domain for the trial's primary outcome

Extension of SPIRIT item 12:

- Providing the rationale for the selection of the outcome as it justifies the purpose of the trial. Critical aspects to address with the rationale include:
  - Importance of outcome domain to individuals involved in the trial
  - Expected effect of the intervention on the outcome domain
  - Ability to assess it accurately, safely, and feasibly
  - Whether the outcome is from a core outcome set

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SPIRIT-Outcomes 12.1

Reporting example

12.1. Provide a rationale for the selection of the domain for the trial's primary outcome

"We justify this endpoint for the following reasons: 1) Mortality is a clinically meaningful endpoint; 2) Our previous studies have shown 60-day mortality is influenced by amount of protein intake; and 3) Longer term outcomes and outcomes related to functional recovery are not practical given the nature of this protocol."

Heyland DK, Patel J, Bear D, Sacks G, Nixdorf H, Dolan J, Aloupis M, Licastro K, Jovanovic V, Rice TW, Compher C. The effect of higher protein dosing in critically ill patients: a multicenter registry-based randomized trial: the EFFORT trial. Journal of Parenteral and Enteral Nutrition. 2019 Mar;43(3):326-34.

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SPIRIT-Outcomes 18a.2

Data collection, management, and analysis

Section	Item No.	Existing SPIRIT Item	SPIRIT-Outcomes 2022 Item
Outcomes	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol.	18a.2 Describe who will assess the outcome (eg, nurse, parent)

Expands on SPIRIT-Outcomes 18a:

- Responses and trial results collected are affected by the outcome assessor, particularly for outcomes that are behavioral or psychological
- These differences may stem from variability in the outcome assessors' training, experience, perspectives, or even patient recall

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SPIRIT-Outcomes 18a.2

Data collection, management, and analysis

18a.2 Describe who will assess the primary outcome (eg, nurse, parent)

"Clinical and laboratory data will be extracted from hospital medical records by the research nurses. The data collected are reported in hospital medical records and do not require interpretation. Patient-reported outcome data will be collected through questionnaires self-completed by participants. Participant experience of the trial and intervention will be collected through qualitative interviews. Compliance with the intervention will be recorded by the intervention HCPs against a checklist."

Bailey PK, Caskey FJ, MacNeill S, Ashford R, Pryce L, Kayler L, Ben-Shlomo Y. Investigating strategies to improve AccesS to Kidney transplantation (the ASK trial): a protocol for a feasibility randomised controlled trial with parallel process evaluation. Pilot and Feasibility Studies. 2023 Dec;9(1):1-3.

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CONSORT-Outcomes 6a.2

Outcome definition

Section	Item No.	Existing CONSORT Item	CONSORT-Outcomes 2022 Item
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	6a.2. Describe the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, mean, proportion), and the time point for each outcome

Expands on CONSORT 6a, and harmonizes with existing SPIRIT item #12

- Impact: Reduces undetectable multiple testing, data cherry-picking, and selective non-reporting of outcomes' elements based on results
  - Selective reporting introduces bias to extent of "evidence of benefit" to "no evidence of benefit" in Cochrane review conclusions (Kirkham, 2010 BMJ)[1]

Kirkham JJ, Dwan KM, Altman DG, Gamble C, Dodd S, Smyth R, Williamson PR. The impact of outcome reporting bias in randomised controlled trials on a cohort of systematic reviews. Bmj. 2010 Feb 15;340.

32

CONSORT-Outcomes 6a.2

Outcome definition

6a.2. Describe the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, mean, proportion), and the time point for each outcome

"The primary outcome was all-cause mortality occurring before discharge from the hospital or 6 months' corrected age, whichever came first. We attempted to collect primary outcome data on infants transferred to other institutions. Trial infants who remained hospitalized at 6 months' corrected age were coded as being alive… Descriptive statistics were calculated for all variables of interest. Continuous measures were summarized via mean and SD, whereas categorical measures were summarized by the use of the count and percentage. The primary outcome of mortality was assessed between groups using a logistic model adjusting for the correlation among observations taken at the same site. Results were reported with OR and their associated 95% CI."

Reilly MC, Vohra S, Rac VE, Dunn M, Ferrelli K, Kiss A, Vincer M, Wimmer J, Zayack D, Soll RF, Prevention VO. Randomized trial of occlusive wrap for heat loss prevention in preterm infants. The Journal of pediatrics. 2015 Feb 1;166(2):262-8.

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CONSORT-Outcomes 6a.7

Outcome definition

Section	Item No.	Existing CONSORT Item	CONSORT-Outcomes 2022 Item
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	6a.7. Identify any outcomes that were not prespecified in a trial registry or trial protocol* *not just since the "trial commenced"

Extension of CONSORT 6a - definition:

- There can be good reasons to change study outcomes while a trial is ongoing, published manuscripts should disclose and explain these changes (CONSORT 6b).
- Fundamental changes to primary outcomes should be reported by investigators – such as the nature and timing, motivation, reason, and who proposed and approved changes
- In 67 trials published in 5 "high-impact" and CONSORT-endorsing journals, 365 outcomes added, mean of 5 undeclared outcomes per trial (Goldacre et al., 2019)

Goldacre B, Drysdale H, Dale A, Milosevic I, Slade E, Hartley P, Marston C, Powell-Smith A, Heneghan C, Mahtani KR. COMPare: a prospective cohort study correcting and monitoring 58 misreported trials in real time. Trials. 2019 Dec;20(1):1-6.

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CONSORT-Outcomes 6a.7

Outcome definition

6a.7. Identify any outcomes that were not prespecified in a trial registry or trial protocol

"When this trial was registered, the primary end point was a composite comprising clinically important upper gastrointestinal bleeding, Clostridioides difficile infections, and episodes of mechanical ventilation lasting longer than 10 days. It was changed in March 2017 to in-hospital mortality because it was determined that giving mortality primacy was preferable to combining components of a composite end point that were not necessarily equally important to patients and which might move in opposite directions. The change was made prior to any site completing recruitment and prior to reviewing any data."

Young PJ, Bagshaw SM, Forbes AB, Nichol AD, Wright SE, Bailey M, Bellomo R, Beasley R, Brickell K, Eastwood GM, Gattas DJ. Effect of stress ulcer prophylaxis with proton pump inhibitors vs histamine-2 receptor blockers on in-hospital mortality among ICU patients receiving invasive mechanical ventilation: the PEPTIC randomized clinical trial. JAMA. 2020 Feb 18;323(7):616-26.

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Uptake and implementation challenges

Time and resources:

- Extensions are not (yet) integrated in main SPIRIT and CONSORT checklists
  - Some authors and editors may consider finding and using multiple checklists as burdensome (Howick et al., 2021)

Inconsistencies in practice:

- While some journals endorse the use of reporting guidelines, not all of them do (Jin et al., 2022)
  - Inconsistent recommendations across journals on which guidelines are used and how to use them (Johansen et al., 2016)

- Howick J, Webster R, Knottnerus JA, Moher D. Do overly complex reporting guidelines remove the focus from good clinical trials?. bmj. 2021 Aug 16;374.
- Jin Y, Sanger N, Shams I, Luo C, Shahid H, Li G, Bhatt M, Zielinski L, Bantoto B, Wang M, Abbade LP. Does the medical literature remain inadequately described despite having reporting guidelines for 21 years?–A systematic review of reviews: an update. Journal of multidisciplinary healthcare. 2018 Sep 27:495-510.
- Johansen M, Thomsen SF. Guidelines for reporting medical research: a critical appraisal. International scholarly research notices. 2016.

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Uptake and implementation challenges (cont.)

Adherence:

- Authors may not be be adhering to a guideline or extension that is most appropriate for their study (Blanco et al., 2018) Inconsistencies in what is indicated as reported in the checklist and what is in the paper (Johansen et al., 2016)
  - Journal editors and peer reviewers do not want to be the ones to verify that the checklists are adhered to correctly (Johansen et al., 2016)
  - As of 2023, some journals have weaved in verification of consistency in reporting between submitted manuscripts and reporting checklists (e.g., *Trials* for protocol submissions)

- Blanco D, Biggane AM, Cobo E, Ahmed I, Attreau J, Doug Altman Lorenzo Bertizzolo Isabelle Boutron Efstathia Gkioni Ketevan Glonti Jamie Kirkham Camila Olarte Maria Olsen Cecilia Superchi. Are CONSORT checklists submitted by authors adequately reflecting what information is actually reported in published papers?. Trials. 2018 Dec;19:1-4.
- Johansen M, et al.. Guidelines for reporting medical research: a critical appraisal. International scholarly research notices. 2016.

37

Uptake and implementation challenges (cont.)

Training to improve knowledge:

- Understanding items – need for good reporting examples
  - Not all reporting guidelines have an explanation and elaboration document available (Schlussel et al., 2023)

Scientific reward system:

- Researchers are rewarded for quantity rather than quality and rigor of their research (Moher et al., 2018; Ioannidis et al., 2014)

- Schlussel MM, Sharp MK, de Beyer JA, Kirtley S, Logullo P, Dhiman P, MacCarthy A, Koroleva A, Speich B, Bullock GS, Moher D. Reporting guidelines used varying methodology to develop recommendations. Journal of Clinical Epidemiology. 2023 Mar 24.
- Moher D. Reporting guidelines: doing better for readers. BMC medicine. 2018 Dec 14;16(1):233.
- Ioannidis JP, Greenland S, Hlatky MA, Khoury MJ, Macleod MR, Moher D, Schulz KF, Tibshirani R. Increasing value and reducing waste in research design, conduct, and analysis. The Lancet. 2014 Jan 11;383(9912):166-75.

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Sharing results beyond RCT reports…

- Communicating and sharing trial results goes beyond reporting in trial protocols and reports
- Protocols and reports published in academic journals are often read and targeted for **those in academia**
  - Academic papers may not be accessible or understandable to **those who participated in these trials** and made these results possible

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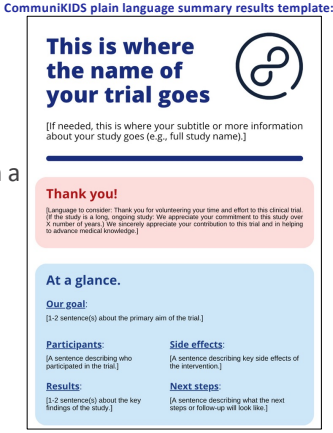
CommuniKIDS

- Youth and family caregivers have unique knowledge needs and preferences in receiving trial results after participating in a clinical trial
- Plain language summary results template was created in partnership with patient partners, youth, and parent advisors
  - Available as part of Clinical Trials Ontario's Participant Experience Toolkit
- Sharing results fosters transparency in research

CommuniKIDS plain language summary results template:



This is where the name of your trial goes

[If needed, this is where your subtitle or more information about your study goes (e.g., full study name).]

Thank you!

[Language to consider: Thank you for volunteering your time and effort to this clinical trial. (If the study is a long, ongoing study: We appreciate your commitment to this study over X number of years.) We sincerely appreciate your contribution to this trial and in helping to advance medical knowledge.]

At a glance.

Our goal:
[1-2 sentence(s) about the primary aim of the trial.]

Participants:
[A sentence describing who participated in the trial.]

Side effects:
[A sentence describing key side effects of the intervention.]

Results:
[1-2 sentence(s) about the key findings of the study.]

Next steps:
[A sentence describing what the next steps or follow-up will look like.]

https://www.ctontario.ca/patients-public/resources-for-engaging-patients/toolkit-to-improve-clinical-trial-participants-experiences/plain-language-result-summary-for-pediatric-clinical-trials/

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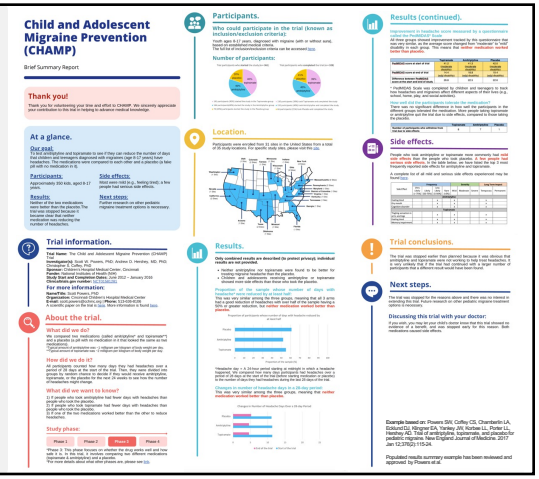
CommuniKIDS

Example



Child and Adolescent Migraine Prevention (CHAMP)

Brief Summary Report

Thank you!

At a glance.

Trial information.

About the trial.

Participants.

Location.

Results.

Results (continued).

Side effects.

Trial conclusions.

Next steps.

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Evaluating trial outcome reporting using CONSORT-Outcomes 2022

Neonatal medicine as an example

SPIRIT | CONSORT OUTCOMES Reporting Guidelines for Trial Outcomes

Prof Chris Gale, MBBS, MSc, PhD, FRCPCH
Neonatal Medicine, School of Public Health, Imperial College London
christopher.gale@imperial.ac.uk

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Aims of CORINT

Core Outcome Reporting in Neonatal Trials

Explore outcome reporting neonatal trials
- Large trials
- Recent trials
- Primary outcomes

Identify strengths and weaknesses – of outcome reporting

Develop examples of good outcome reporting
- Neonatal examples
- To support optimal outcome reporting

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Why neonatal medicine?

Core Outcomes In Neonatology

Original article

Inconsistent outcome reporting in large neonatal trials: a systematic review

James William Harrison Webbe,[1] Shohaib Ali,[2] Susanna Sakonidou,[1] Thomas Webbe,[3] James M N Duffy,[4] Ginny Brunton,[5] Neena Modi,[6] Chris Gale,[1] On behalf of the COIN Project Steering Committee

Cochrane Neonatal

Well-established Core Outcome Set Webbe et al., 2020	Systematic reporting review of neonatal trials Webbe et al., 2020	Well-developed trial methodology expertise
• Developed empirically • Consistency in neonatal outcome selection • Selection of outcomes for evaluation	• Existing, validated search strategy • Large neonatal trials	• Expert neonatal reviewers • Clinical trialists and methodologists • Experience appraising trials using reporting guidance

- Webbe JWH, Duffy JMN, Afonso E, Al-Muzaffar I, Brunton G, Greenough A, Hall NJ, Knight M, Latour JM, Lee-Davey C, Marlow N, Noakes L, Nycyk J, Richard-Löndt A, Wills-Eve B, Modi N, Gale C. Core outcomes in neonatology: development of a core outcome set for neonatal research. Arch Dis Child Fetal Neonatal Ed. 2020 Jul;105(4):425-431.
- Webbe JWH, Ali S, Sakonidou S, Webbe T, Duffy JMN, Brunton G, Modi N, Gale C; COIN Project Steering Committee. Inconsistent outcome reporting in large neonatal trials: a systematic review. Arch Dis Child Fetal Neonatal Ed. 2020 Jan;105(1):69-75.

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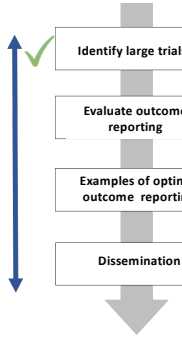
Systematic review of outcome reporting



- Neonatal trials, >100 babies per arm, 2015-2020
- Neonatal Core Outcome reported as primary outcome
- Outcome reporting assessed by 39 Cochrane reviewers

Clinical Review & Education

JAMA | Special Communication

Guidelines for Reporting Outcomes in Trial Reports
The CONSORT-Outcomes 2022 Extension

Nancy J. Butcher, PhD; Andrea Monsour, MPH; Emma J. Mew, MPH, MPhil; An-Wen Chan, MD, DPhil; David Moher, PhD; Evan Mayo-Wilson, DPhil; Caroline B. Terwee, PhD; Alyssandra Chee-A-Tow, MPH; Ami Baba, MRes; Frank Gavin, MA; Jeremy M. Grimshaw, MBCHB, PhD; Lauren E. Kelly, PhD; Leena Saeed, BSc, BEd; Lehana Thabane, PhD; Lisa Askie, PhD; Maureen Smith, MEd; Mufiza Farid-Kapadia, MD, PhD; Paula R. Williamson, PhD; Peter Szatmari, MD; Peter Tugwell, MD; Robert M. Golub, MD; Suneeta Monga, MD; Sunita Vohra, MD; Susan Marlin, MSc; Wendy J. Ungar, MSc, PhD; Martin Offringa, MD, PhD

Butcher NJ, Monsour A, Mew EJ, Chan AW, Moher D, Mayo-Wilson E, Terwee CB, Chee-A-Tow A, Baba A, Gavin F, Grimshaw JM, Kelly LE, Saeed L, Thabane L, Askie L, Smith M, Farid-Kapadia M, Williamson PR, Szatmari P, Tugwell P, Golub RM, Monga S, Vohra S, Marlin S, Ungar WJ, Offringa M. Guidelines for Reporting Outcomes in Trial Reports: The CONSORT-Outcomes 2022 Extension. JAMA. 2022 Dec 13;328(22):2252-2264

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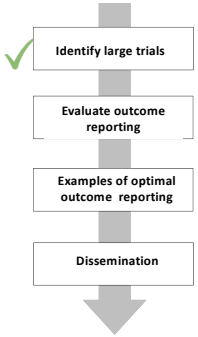
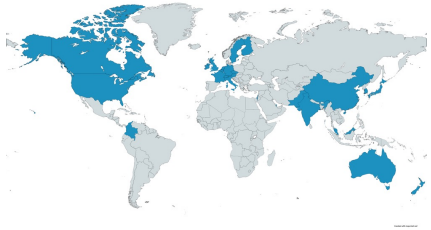
Systematic review of outcome reporting



- 36 neonatal trials, median sample size 456
- Primary outcome: 36% single, 56% composite, 8% multiple
- Survival most common: 64%



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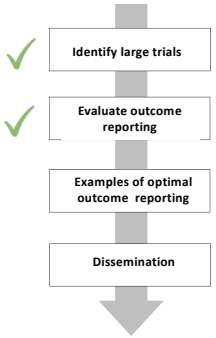
Assessment of outcome reporting



CONSORT:
13 items

CONSORT-Outcomes:
17 new items

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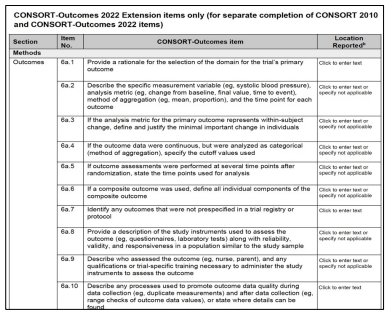
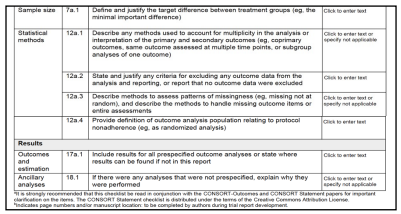
Checklists for **CONSORT** and **CONSORT-Outcomes 2022**



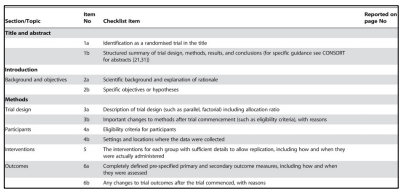
CONSORT-Outcomes 2022 Extension items only (for separate completion of CONSORT 2010 and CONSORT-Outcomes 2022 items)

Section	Item No.	CONSORT-Outcomes item	Location Reported[b]
Methods			
Outcomes	6a.1	Provide a rationale for the selection of the domain for the trial's primary outcome	Click to enter text
	6a.2	Describe the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, mean, proportion), and the time point for each outcome	Click to enter text or specify not applicable
	6a.3	If the analysis metric for the primary outcome represents within-subject change, define and justify the minimal important change in individuals	Click to enter text or specify not applicable
	6a.4	If the outcome data were continuous, but were analyzed as categorical (method of aggregation), specify the cutoff values used	Click to enter text or specify not applicable
	6a.5	If outcome assessments were performed at several time points after randomization, state the time points used for analysis	Click to enter text or specify not applicable
	6a.6	If a composite outcome was used, define all individual components of the composite outcome	Click to enter text or specify not applicable
	6a.7	Identify any outcomes that were not prespecified in a trial registry or protocol	Click to enter text
	6a.8	Provide a description of the study instruments used to assess the outcome (eg, questionnaires, laboratory tests) along with reliability, validity, and responsiveness in a population similar to the study sample	Click to enter text or specify not applicable
	6a.9	Describe who assessed the outcome (eg, nurse, parent), and any qualifications or trial-specific training necessary to administer the study instruments to assess the outcome	Click to enter text or specify not applicable
	6a.10	Describe any processes used to promote outcome data quality during data collection (eg, duplicate measurements) and after data collection (eg, range checks of outcome data values), or state where details can be found	Click to enter text



Sample size	7a.1	Define and justify the target difference between treatment groups (eg, the minimal important difference)	Click to enter text
Statistical methods	12a.1	Describe any methods used to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of one outcome)	Click to enter text or specify not applicable
	12a.2	State and justify any criteria for excluding any outcome data from the analysis and reporting, or report that no outcome data were excluded	Click to enter text
	12a.3	Describe methods to assess patterns of missingness (eg, missing not at random), and describe the methods to handle missing outcome items or entire assessments	Click to enter text or specify not applicable
	12a.4	Provide definition of outcome analysis population relating to protocol nonadherence (eg, as randomized analysis)	Click to enter text
Results			
Outcomes and estimation	17a.1	Include results for all prespecified outcome analyses or state where results can be found if not in this report	Click to enter text
Ancillary analyses	18.1	If there were any analyses that were not prespecified, explain why they were performed	Click to enter text or specify not applicable

[a] It is strongly recommended that this checklist be read in conjunction with the CONSORT-Outcomes and CONSORT Statement papers for important clarification on the items. The CONSORT Statement checklist is distributed under the terms of the Creative Commons Attribution License. [b] Indicates page numbers and/or manuscript location, to be completed by authors during trial report development.



Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts [21,31])	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	

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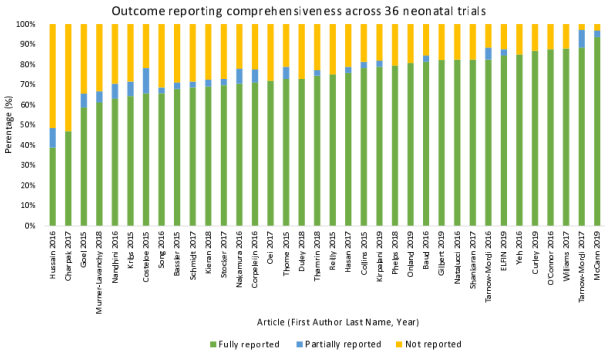
Completeness of outcome reporting by trial



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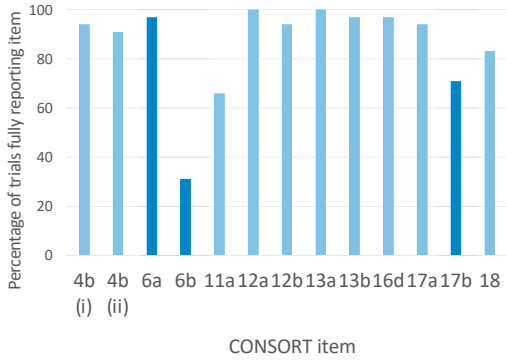
Completeness: CONSORT items



6b: Any changes to trial outcomes after the trial commenced, with reasons *(31%)*
11a: If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how *(66%)*
17b: For binary outcomes, presentation of both absolute and relative effect sizes is recommended *(71%)*

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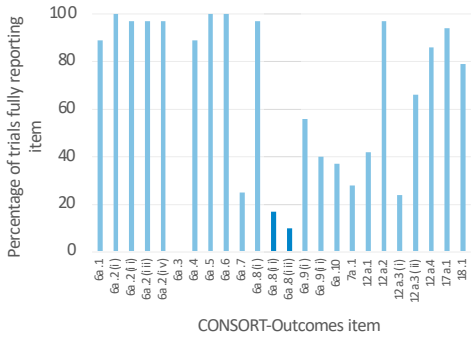
Completeness: CONSORT-Outcomes items



6a.3: If the analysis metric for the primary outcome represents within-subject change, define and justify the minimal important change in individuals *(0%)*
6a.8 (iii): Provide a description of the study instrument's validity in a population similar to the study sample *(10%)*
6a.8 (ii): Provide a description of the study instrument's reliability in a population similar to the study sample *(17%)*

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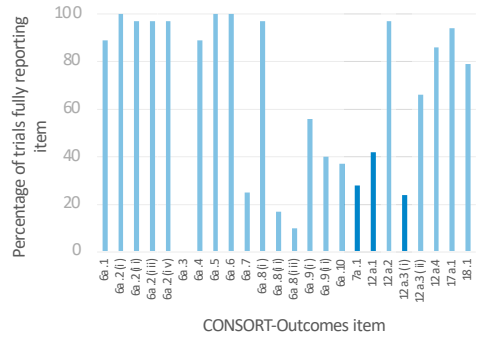
Completeness: CONSORT-Outcomes items



7a.1: Define and justify the target difference between treatment groups (eg, the minimal important difference (MID)) *(28%)*
12a.1: Describe any methods used to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes *(42%)*
12a.3 (i): Describe methods to assess patterns of missingness (eg, missing not at random) *(24%)*

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Implications for neonatal trials and trial reporting

Evidence of good reporting
- Pre-specified primary and secondary outcomes

Identification of suboptimal report
- Blinding of the outcome assessor
- Minimal important difference between treatment groups
- Outcome data missingness
- How outcome multiplicity was dealt with in the analysis

Examples of good practice
- Inform and improve neonatal trial reporting

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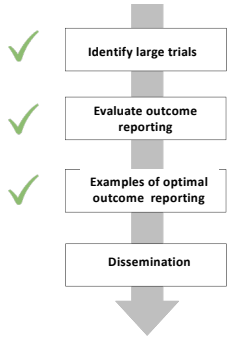
Examples of optimal reporting



Identified from included trials

Developed where no examples found

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CONSORT-Outcomes 6a.8 (iii)

Example reporting

6a.8 (iii): Provide a description of the study instrument's validity in a population similar to the study sample

"The primary outcome was necrotising enterocolitis, defined according to the gestational age-specific necrotising enterocolitis definition proposed by Battersby et al. This definition has been validated using population-level data from neonates admitted to neonatal units in the UK."

Battersby C, Longford N, Costeloe K, Modi N; UK Neonatal Collaborative Necrotising Enterocolitis Study Group. Development of a Gestational Age-Specific Case Definition for Neonatal Necrotizing Enterocolitis. JAMA Pediatr. 2017 Mar 1;171(3):256-263.

55

CONSORT-Outcomes 7a.1

Example reporting

7a.1: Define and justify the target difference between treatment groups (eg, minimal important difference (MID))

"A sample size of 176 infants in each treatment group was estimated to be sufficient to detect a 5-point difference in the Bayley-III cognitive composite score with 80% power (α=.05) and a standard deviation of 15. An effect size of 5 points was chosen because the literature suggests that this difference could translate into a reduction in the number of children born preterm requiring special education services (with associated costs) and an improvement in longer-term academic achievement. A meta-analysis completed prior to study initiation reported a difference of 5.18 in cognitive scores between infants born weighing less than 2500 g who were fed mother's milk vs formula, suggesting that this effect size was achievable." (O'Connor et al., 2016)

O'Connor DL, Gibbins S, Kiss A, Bando N, Brennan-Donnan J, Ng E, Campbell DM, Vaz S, Fusch C, Asztalos E, Church P, Kelly E, Ly L, Daneman A, Unger S; GTA DoMINO Feeding Group. Effect of Supplemental Donor Human Milk Compared With Preterm Formula on Neurodevelopment of Very Low-Birth-Weight Infants at 18 Months: A Randomized Clinical Trial. JAMA. 2016 Nov 8;316(18):1897-1905.

56

Uptake and implementation **challenges**

Size of the problem
- Review limited to largest neonatal trials
- Likely underestimate of true challenge
- Reporting in smaller trials may less optimal

Time and resources
- Multiple relevant extensions
  - Inconsistent recommendations across journals on which guidelines are used and how to use them (Johansen et al., 2016)
- Multiple related guidance documents
- Large volumes of text required
  - Limited word counts for most journals

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Uptake and implementation **challenges** (cont.)

Limitations inherent with existing outcomes
- Heterogeneity of outcome selection
- Even for core neonatal outcomes
  - Incompletely validated
  - Minimally Important Differences rarely established
  - Highly variable populations even within individual trials (gestation)

Awareness and expertise
- Inconsistency among expert reviews about CONSORT-Outcomes items
- Situation likely worse among less experienced/expert authors
- Greater training in outcome reporting

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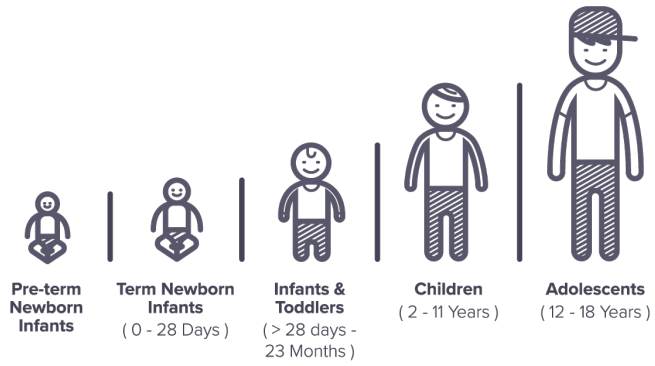
Pediatric trials…



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Pediatric trials…

…are SPIRIT and CONSORT not sufficient?

- Patients – age range 0-18 yrs
- Interventions
  - geared to age group ?
  - comparator: “standard of care” (?)
- **Outcomes…**

- Procedures
- PPI
- EDI
- Research Ethics

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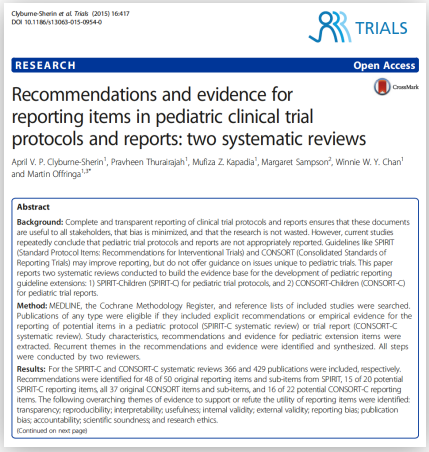

Clyburne-Sherin *et al. Trials* (2015) 16:417
DOI 10.1186/s13063-015-0954-0

TRIALS

RESEARCH Open Access

Recommendations and evidence for reporting items in pediatric clinical trial protocols and reports: two systematic reviews

April V. P. Clyburne-Sherin[1], Pravheen Thuraisingam[1], Mufiza Z. Kapadia[1], Margaret Sampson[2], Winnie W. Y. Chan[1] and Martin Offringa[1,3*]

Abstract

Background: Complete and transparent reporting of clinical trial protocols and reports ensures that these documents are useful to all stakeholders, that bias is minimized, and that the research is not wasted. However, current studies repeatedly conclude that pediatric trial protocols and reports are not appropriately reported. Guidelines like SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) and CONSORT (Consolidated Standards of Reporting Trials) may improve reporting, but do not offer guidance on issues unique to pediatric trials. This paper reports two systematic reviews conducted to build the evidence base for the development of pediatric reporting guideline extensions: 1) SPIRIT-Children (SPIRIT-C) for pediatric trial protocols, and 2) CONSORT-Children (CONSORT-C) for pediatric trial reports.

Method: MEDLINE, the Cochrane Methodology Register, and reference lists of included studies were searched. Publications of any type were eligible if they included explicit recommendations or empirical evidence for the reporting of potential items in a pediatric protocol (SPIRIT-C systematic review) or trial report (CONSORT-C systematic review). Study characteristics, recommendations and evidence for pediatric extension items were extracted. Recurrent themes in the recommendations and evidence were identified and synthesized. All steps were conducted by two reviewers.

Results: For the SPIRIT-C and CONSORT-C systematic reviews 366 and 429 publications were included, respectively. Recommendations were identified for 48 of 50 original reporting items and sub-items from SPIRIT. 15 of 20 potential SPIRIT-C reporting items, all 37 original CONSORT items and sub-items, and 16 of 22 potential CONSORT-C reporting items. The following overarching themes of evidence to support or refute the utility of reporting items were identified: transparency; reproducibility; interpretability; usefulness; internal validity; external validity; reporting bias; publication bias; accountability; scientific soundness; and research ethics.

(Continued on next page)

No,
SPIRIT and CONSORT are not sufficient

Conclusion: These systematic reviews provide useful and translatable evidence on which to build pediatric extensions to the SPIRIT and CONSORT reporting guidelines.

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ELSEVIER

Journal of Clinical Epidemiology ■ (2023) ■

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

Reporting standards for child health research were few and poorly implemented

Qinyuan Li[a,1], Qi Zhou[b,1], Ivan D. Florez[c,d,e], Joseph L. Mathew[f], Yasser Sami Amer[g,h,i], Janne Estill[j,k], Rosalind Louise Smyth[l], Enmei Liu[a], Yaolong Chen[b,m,n,*,*], Zhengxiu Luo[b,*], for the RESCUE Working Group

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[m]Chevidence Lab of Child and Adolescent Health, Children's Hospital of Chongqing Medical University, Chongqing 40001, China
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Accepted 21 March 2023; Published online xxxx

Abstract

Objectives: This study aims to identify existing reporting standards for child health research, assess the robustness of the standards development process, and evaluate the dissemination of these standards.

"There is a quantitative and qualitative paucity of well-developed reporting standards for child health research."

Li Q, et al. J Clin Epidemiol. 2023

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Reporting standard	Publication year	Published in multiple journals	Journal of checklist publication	Number of citations	Number of studies adhering to the standard	Journal endorsement
STROBE-NI [15]	2016	No	The Lancet Infectious Diseases	103	5	No
CREMAS [16]	2016	No	Journal of Medical Internet Research	111	17	No
C.A.R.E [17]	2018	No	Annals of the New York Academy of Sciences	36	4	No
RAPID [18]	2021	No	BMC Oral Health	1	0	No
CONSORT-C and SPIRIT-C [19]	NA	NA	NA	NA	NA	NA
PRISMA-C and PRISMA-P-C [20]	NA	NA	NA	NA	NA	NA

Abbreviations: STROBE-NI, Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection; CREMAS, Checklist for Reporting Ecological Momentary Assessments (EMA) Studies; C.A.R.E., Consolidated Advice for Reporting Early Childhood Development (ECD) implementation research; RAPID, Reporting stAndards for research in Pedlatric Dentistry; CONSORT-C, Consolidated Standards of Reporting Trials in children; SPIRIT-C, Standard Protocol Items: Recommendations for Interventional Trials in Children; PRISMA-C, Preferred Reporting Items in Systematic Review and MetaAnalysis in Children; PRISMA-P-C, Preferred Reporting Items in Systematic Review and MetaAnalysis Protocol in Children; WHO, World Health Organization; NIH, National Institutes of Health; ACS, American Cancer Society; UNICEF, United Nations International Children's Emergency Fund; RCT, randomized controlled trial; NA, not applicable, NR, not report.
[a] Development duration, the duration between commencement and publication.
[b] Items in the "General" theme.
[c] CONSORT-C has been indexed in EQUATOR, but SPIRIT-C has not.

Li Q, et al. J Clin Epidemiol. 2023

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SPIRIT | CONSORT
CHILDREN
Reporting Guidelines for Child Health Trials

Interested ? Scan the QR code & fill out the online interest form:

Or: 1) type in https://surveys.sickkids.ca/surveys/ in your browser
2) enter code **RNTR9NMF3**

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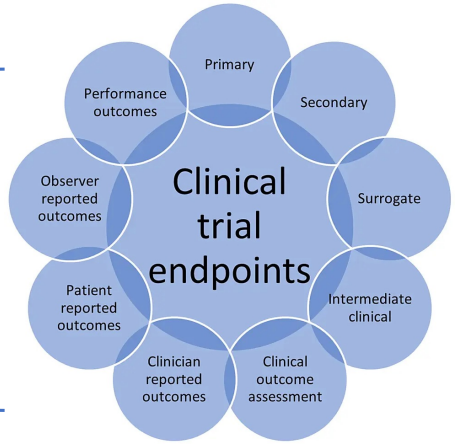
Scales…
Questionnaires…



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Primary trial outcome design

1. Select the outcome domain
2. **Consider a PROM / Scale**
3. Select specific metric
4. Choose method of aggregation
5. Choose time point

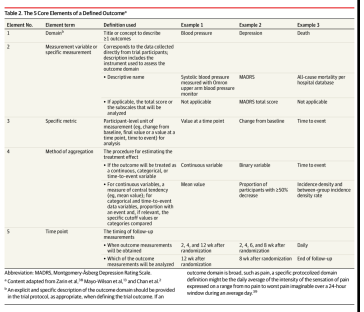

Table 2. The 5 Core Elements of a Defined Outcome[a]

Element No.	Element term	Definition used	Example 1	Example 2	Example 3
1	Domain[b]	Title or concept to describe 1	Blood pressure	Depression	Death
2	Measurement variable or specific measurement	Core keywords to the data collected directly from trial participants, the clinical sample, or instrument used to assess the outcome domain			
	• Descriptive name		Systolic blood pressure measured with Omron upper arm blood pressure monitor	MADRS	All-cause mortality per hospital database
	• If applicable, the total score or the subscales that will be analyzed		Not applicable	MADRS total score	Not applicable
3	Specific metric	Participant-level unit of measurement (eg, change from baseline, final value or z value at a time point, time to event) for analysis	Value at a time point	Change from baseline	Time to event
4	Method of aggregation	The procedure for estimating the treatment effect			
	• If the outcome will be treated as time-to-event, censored, or competing-risk variable		Continuous variable	Binary variable	Time to event
	• For continuous variables, a measure of central tendency (eg, mean value); for categorical and time-to-event data variables, proportion with the event; for ordinal, the specific cutoff values or categories compared		Mean value	Proportion of participants with ≥50% decrease	Incidence density and between-group incidence density rate
5	Time point	The timing of follow-up measurements			
	• When outcome measurements will be obtained		2, 4, and 12 wk after randomization	2, 4, 6, and 8 wk after randomization	Daily
	• Which of the outcome measurements will be analyzed		12 wk after randomization	8 wk after randomization	End of follow-up

Abbreviation: MADRS, Montgomery-Åsberg Depression Rating Scale.
[a] Content adapted from Zarin et al.[18] Mayo-Wilson et al,[19] and Chan et al.[2]
[b] An explicit and specific description of the outcome domain should be provided in the trial protocol, as appropriate, when defining the trial outcome. If an outcome domain is broad, such as pain, a specific protocolized domain definition might be the daily average of the intensity of the sensation of pain expressed on a range from no pain to worst pain imaginable over a 24-hour window during an average day.[20]

- Butcher NJ, Monsour A, Mew EJ, et al. Guidelines for Reporting Outcomes in Trial Protocols: The SPIRIT-Outcomes 2022 Extension. *JAMA*. 2022;328(23):2345–2356. doi:10.1001/jama.2022.21243

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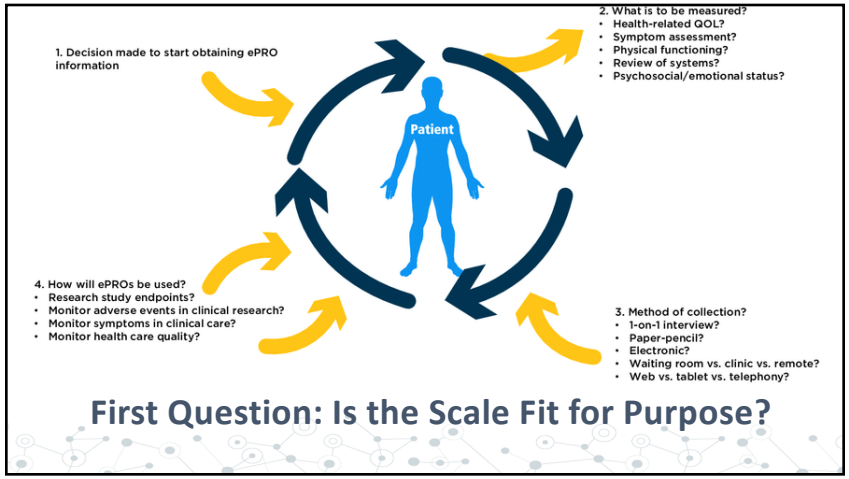

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REVIEW

Systematic Review: The Measurement Properties of the Children's Depression Rating Scale–Revised in Adolescents With Major Depressive Disorder

Emma Stallwood, BA, Andrea Monsour, MPH, Craig Rodrigues, BMSc, Suneeta Monga, MD, Caroline Terwee, PhD, Martin Offringa, MD, PhD, Nancy J. Butcher, PhD, MSc

Objective: To systematically appraise existing evidence of the measurement properties of the Children's Depression Rating Scale–Revised (CDRS-R) in adolescents with major depressive disorder (MDD). The CDRS-R is the most commonly used scale in adolescent depression research, yet was originally designed for use in children 6 to 12 years old.

Method: Seven databases were searched for studies that evaluated the measurement properties of the CDRS-R in adolescents (ages 12–18 years). Of 65 studies screened by full-text, 6 were included. Measurement properties were appraised using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines. The COSMIN minimum requirements for recommending the use of an outcome measurement instrument are (1) evidence for sufficient content validity (any level of evidence), and (2) at least low-quality evidence for sufficient internal consistency.

Results: Four studies assessed an English-language version of the CDRS-R; the other 2 assessed German and Korean versions, respectively. No study assessed content validity, cross-cultural validity/measurement invariance, or measurement error of the CDRS-R in adolescents with MDD. Low-quality evidence was found for sufficient construct validity (n = 4 studies) and responsiveness (n = 2 studies) assessed via comparator instruments. Very-low–quality evidence was found for sufficient interrater reliability (n = 2 studies). The results for structural validity (n = 3 studies) and internal consistency (n = 5 studies) were inconclusive.

Conclusion: It remains unclear whether the CDRS-R appropriately measures depressive symptom severity in adolescent MDD. Before use of the CDRS-R in adolescent MDD research can be recommended, evidence of sufficient psychometric properties in adolescents with MDD is needed.

Key words: major depressive disorder, adolescent, outcome measurement instruments, measurement properties, Children's Depression Rating Scale–Revised

J Am Acad Child Adolesc Psychiatry 2021;■(■):■–■.

- Most common rating scale used in adolescent Major Depressive Disorder (MDD) RCTs: clinician-rated Children's Depression Rating Scale-Revised (CDRS-R)
- Key measurement properties were either never assessed in adolescents, or only had low quality evidence or inconclusive results.
- The CDRS-R lacks sufficient evidence for use in adolescents with MDD.

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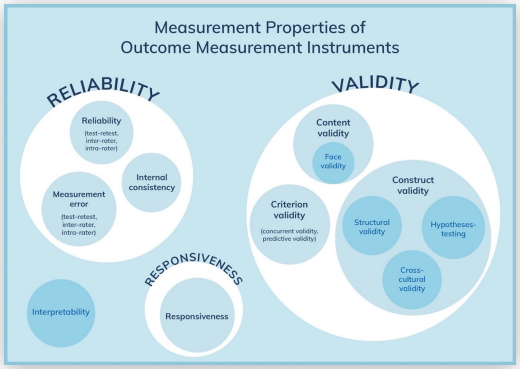
COSMIN

***CO**nsensus-based **S**tandards for the selection of health **M**easurement **IN**struments*

- Develops methodology and practical tools for selecting suitable outcome measurement instruments
- **COSMIN Guideline for Systematic Reviews of Outcome Measurement Instruments**



https://www.cosmin.nl

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Content validity	Not assessed
Cross-cultural validity / measurement invariance	Not assessed
Measurement error	Not assessed
Construct validity	Low quality evidence (n=4 studies)
Responsiveness	Low quality evidence (n=2 studies)
Reliability (inter-rater)	Very low quality evidence (n=2 studies)
Structural validity	Inconclusive (n=3 studies) ~ not unidimensional
Internal consistency	Inconclusive (n=5 studies)

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We used PRISMA to report this SR...

Preferred **R**eporting **I**tems for **S**ystematic reviews and **M**eta-**A**nalyses

- An evidence-based minimum set of items for reporting in systematic reviews and meta-analyses
- Focus on reporting of reviews evaluating the effects of interventions
- **Extensions**: facilitate the reporting of other types or particular aspects of systematic reviews

- PRISMA for Abstracts
- PRISMA for Acupuncture
- PRISMA for Diagnostic Test Accuracy
- PRISMA for EcoEvo
- PRISMA Equity
- PRISMA Harms (for reviews including Harm outcomes)
- PRISMA Individual Patient Data
- PRISMA for Network Meta-Analyses
- PRISMA for Protocols
- PRISMA for Scoping Reviews
- PRISMA for Searching
- Extensions in development

http://www.prisma-statement.org & http://www.prisma-statement.org/Extensions

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcc study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to c	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results	
Synthesis	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and	

Too general

Not applicable

Not applicable

Source: http://www.prisma-statement.org/documents/PRISMA_2020_checklist.pdf

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Needed: a "SR of OMI"- reporting guide…

Not all important information reported → Not possible to independently judge information → Less optimal outcome measurement instrument selected → Consequences for measurements and possibly treatment

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PRISMA - COSMIN OUTCOME Measurement Instruments

Reporting Guideline 2023 !

(in preparation)

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Elsman et al. Systematic Reviews (2022) 11:121
https://doi.org/10.1186/s13643-022-01994-5

Systematic Reviews

PROTOCOL Open Access

Study protocol for developing, piloting and disseminating the PRISMA-COSMIN guideline: a new reporting guideline for systematic reviews of outcome measurement instruments

Ellen B. M. Elsman[1,2*], Nancy J. Butcher[3,4], Lidwine B. Mokkink[1,5], Caroline B. Terwee[1,5], Andrea Tricco[6,7,8], Joel J. Gagnier[9,10,11,12], Olalekan Lee Aiyegbusi[13], Carolina Barnett[14], Maureen Smith[15], David Moher[16] and Martin Offringa[3,17,18]

Abstract

Background: Systematic reviews of outcome measurement instruments are important tools in the evidence-based selection of these instruments. COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) has developed a comprehensive and widespread guideline to conduct systematic reviews of outcome measurement instruments, but key information is often missing in published reviews. This hinders the appraisal of the quality of outcome measurement instruments, impacts the decisions of knowledge users regarding their appropriateness, and compromises reproducibility and interpretability of the reviews' findings. To facilitate sufficient, transparent, and consistent reporting of systematic reviews of outcome measurement instruments, an extension of the PRISMA (Preferred Reporting of Items for Systematic reviews and Meta-Analyses) 2020 guideline will be developed: the PRISMA-COSMIN guideline.

Methods: The PRISMA-COSMIN guideline will be developed in accordance with recommendations for reporting guideline development from the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network. First, a candidate reporting item list will be created through an environmental literature scan and expert consultations. Second, an international Delphi study will be conducted with systematic review authors, biostatisticians, epidemiologists, psychometricians/clinimetricians, reporting guideline developers, journal editors as well as patients, caregivers, and members of the public. Delphi panelists will rate candidate items for inclusion on a 5-point scale, suggest additional candidate items, and give feedback on item wording and comprehensibility. Third, the draft PRISMA-COSMIN guideline and user manual will be iteratively piloted by applying it to systematic reviews in several disease areas to assess its relevance, comprehensiveness, and comprehensibility, along with usability and user satisfaction. Fourth, a consensus meeting will be held to finalize the PRISMA-COSMIN guideline through roundtable discussions and voting. Last, a user manual will be developed and the final PRISMA-COSMIN guideline will be disseminated through

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Scope

PRISMA - COSMIN OUTCOME Measurement Instruments

Reporting systematic reviews of outcome measurement instruments, in which **at least one measurement property** of **at least one outcome measurement instrument** is rated, including **risk of bias assessment of studies**, **evidence synthesis**, and **certainty assessment** of the body of the evidence.

Not intended for reviews that provide an overview (characteristics) of the instruments used, or in which the results of measurement properties are listed, but not rated. These review types are more scoping in nature.

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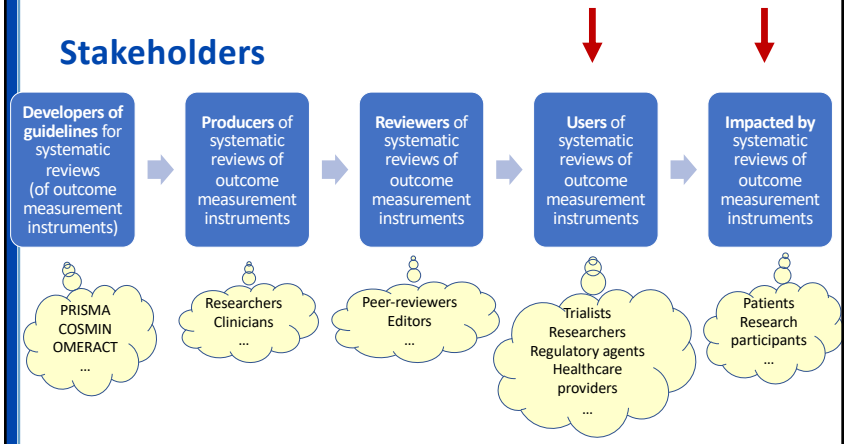
Stakeholders



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Why is a patient/public perspective essential in 2023?

- Patients are **partners** in designing trials and are **co-authors** on trial reports.
  - They are the **ultimate end-users** of the outcome measurement instruments that are chosen to monitor their health status and make decisions about their healthcare.
- Any SR reporting guideline that will enable trialists to have all the information they need to evaluate the outcome measurement instruments needs patient input on **what information is important to them**.
  - **People with lived experience** tell us what they think is important to report when SR information is gathered (e.g., the rationale or objective of the systematic review, or items about recommendations).
- Essential that **patient perspectives be considered** along with those of researchers, healthcare professionals and organizations, and journal editors.

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SELF-REPORTED CHARACTERISTIC	N (%)
Primary perspective	
Academia	94 (86)
Hospital	4 (4)
Industry	2 (2)
Government	1 (1)
Editor	1 (1)
Non-profit	1 (1)
Patient	4 (4)
Patient group representative	1 (1)
Public member	1 (1)
Country of workplace/living	
UK	28 (26)
Canada	27 (25)
USA	15 (14)
Australia	12 (11)
Spain	9 (8)
The Netherlands	5 (5)
Italy	3 (3)
Japan	2 (2)
Other*	8 (7)

*Belgium, China, South Korea, Singapore, France, South Africa, New Zealand, Switzerland (all n=1)

SELF-REPORTED CHARACTERISTIC	N (%)
Previously involved in research	
As participant	5 (83)
As patient/public research partner	6 (100)
Previously involved in methodological research	2 (33)
As participant	4 (67)
As patient/public research partner	
Previously involved in a Delphi study	4 (67)

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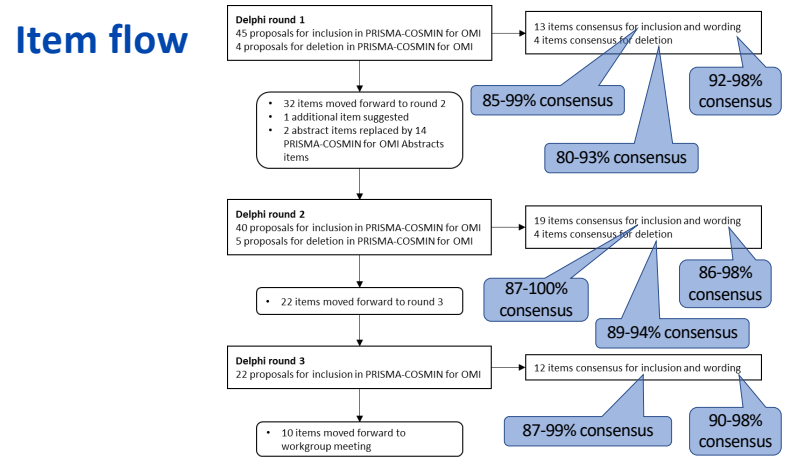
Item flow



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Item history

Section and topic	Item #	PRISMA 2020 item	Candidate PRISMA-COSMIN item Round 1	Revised candidate PRISMA-COSMIN item Round 2	Revised candidate PRISMA-COSMIN item Round 3	Revised candidate PRISMA-COSMIN item Workgroup meeting[a]
TITLE						
Title	1	Identify the report as a systematic review.	Identify the report as a systematic review and include ~~the construct~~ of interest, population of interest, ~~(type of)~~ outcome measurement instrument(s) of interest, measurement property(ies) of interest. **85% consensus for inclusion** **73% consensus for wording**	Identify the report as a systematic review and include as applicable the following (in any order): outcome of interest, population of interest, name/type of outcome measurement instrument(s) of interest, and measurement property(ies) of interest. **91% consensus for inclusion** **86% consensus for wording**	*Consensus on inclusion obtained in Round 2.*	

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A. Checklist for SR OMI Reports

PRISMA - COSMIN OUTCOME Measurement Instruments

41 reporting (sub)items

Compared to PRISMA 2020:

- 17 items are *original* PRISMA 2020 items – exactly the same items as in the PRISMA 2020 checklist
- 18 items are *modified* PRISMA 2020 items – included in PRISMA 2020, but content is modified
- 6 items are *new* – added to the PRISMA COSMIN checklist
- 7 original PRISMA 2020 items have been *deleted* – not present in the PRISMA-COSMIN checklist

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B. Checklist for SR OMI Abstracts

PRISMA - COSMIN OUTCOME Measurement Instruments

13 reporting items

Compared to PRISMA 2020 for Abstracts:

- 9 items are *original* PRISMA 2020 items – exactly the same items as in the PRISMA 2020 for Abstracts checklist
- 3 items are *modified* PRISMA 2020 items – included in PRISMA 2020 for Abstracts, but content is modified
- 1 item is *new* – added to the PRISMA COSMIN Abstracts checklist

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Wrapping up…

1. Trial Reporting Standards
2. SPIRIT | CONSORT OUTCOMES Reporting Guidelines for Trial Outcomes
3. Outcome reporting in Neonatology RCTs
4. SPIRIT | CONSORT CHILDREN Reporting Guidelines for Child Health Trials & PRISMA - COSMIN OUTCOME Measurement Instruments
5. Now: Q & A, Discussion

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