Ottawa Hospital
Research Institute
Institut de recherche
de l'Hôpital d'Ottawa

EQUATOR

David Moher, Senior Scientist

20 May 2015

Calgary, Alberta

COMET V

Competing interests

- Member of the EQUATOR Network steering committee
- Director of the Canadian EQUATOR Centre
- SPIRIT PRO member
- COS-STAR expert panel member

Professor Doug Altman receives BMJ Lifetime Achievement Award


EQUATOR Meeting - Wolfson College Oxford
30th May - 1st June 2006

EQUATOR Network launch meeting, 2008

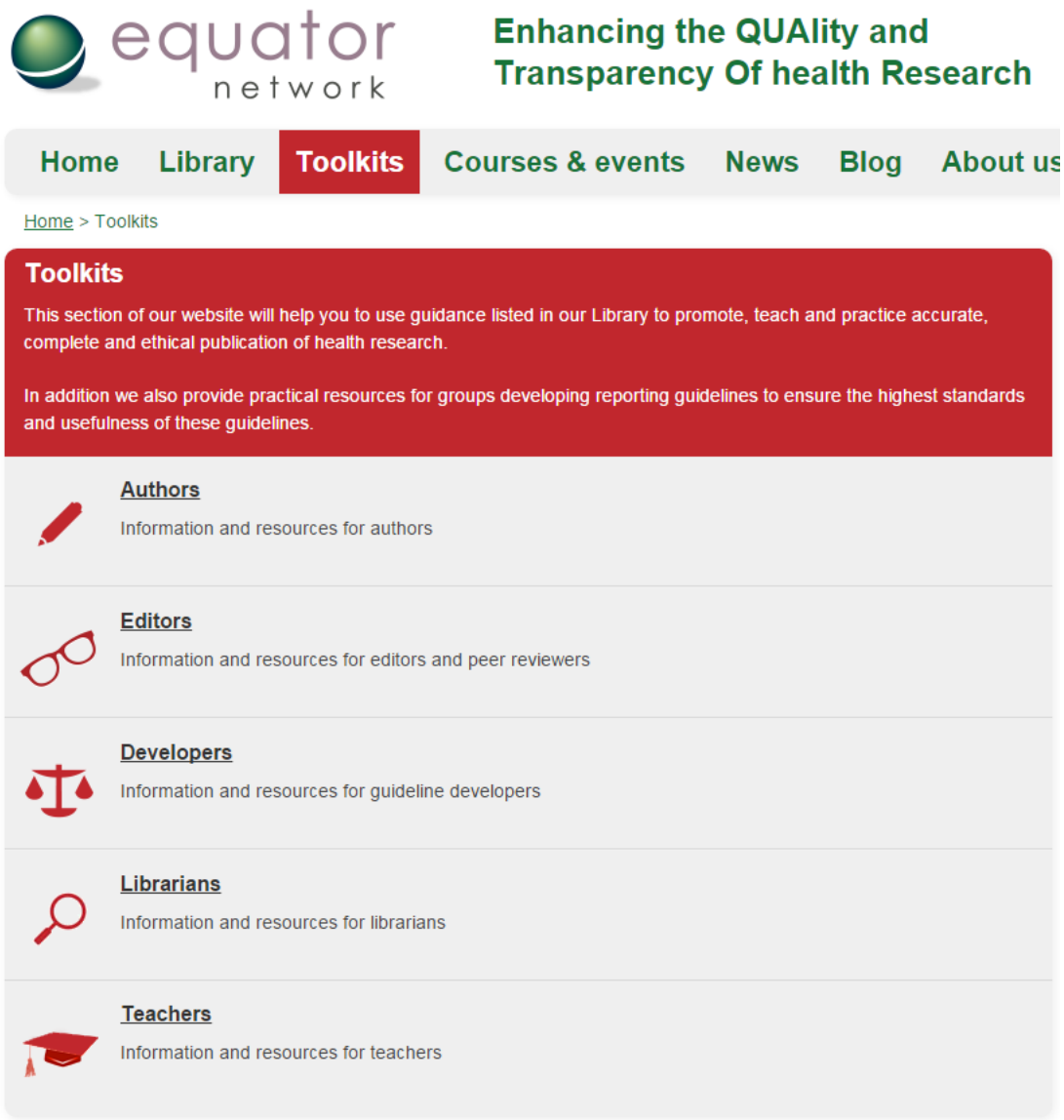
- Launched in June 2008
- Improve conduct and reporting
- Supports researchers, editors, peer reviewers (everyone involved in health research and its publication) in responsible publication of research
  - Promoting the use (and adherence to reporting guidelines)
  - Program focus is more on RG implementation (rather than their development)
- Limited attention to conduct, thus far
  - Watch this space in the coming years

EQUATOR Network goals

- Help maximize the value of research
  - Improve conduct and reporting
  - Toolkits
  - Library of reporting guidelines

http://www.equator-network.org/

Toolkits


equator network
Enhancing the QUAlity and Transparency Of health Research
Home
Library
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Toolkits
This section of our website will help you to use guidance listed in our Library to promote, teach and practice accurate, complete and ethical publication of health research.
In addition we also provide practical resources for groups developing reporting guidelines to ensure the highest standards and usefulness of these guidelines.
Authors
Information and resources for authors
Editors
Information and resources for editors and peer reviewers
Developers
Information and resources for guideline developers
Librarians
Information and resources for librarians
Teachers
Information and resources for teachers

Authors of research reports

The following resources will help you to produce high quality research publications:

- Planning and conducting your research
- Writing up your research
- Data sharing, reporting data
- Additional guidance for industry sponsored research
- Ethical guidelines and considerations
- Publishers' resources for authors
- Reviewing research articles
- Communicating research to media
- Other resources
- Training opportunities

- What can I do to support the EQUATOR Network's effort

Library of reporting guidelines

Enhancing the QUAlity and Transparency Of health Research

Visit the EQUATOR Spanish Website

Library for health research reporting

The Library for health research reporting provides an up-to-date collection of guidelines and policy documents related to health research reporting. These are aimed mainly at authors of research articles, journal editors, peer reviewers and reporting guideline developers.

Reporting guidelines for main study types

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

Translations

Some reporting guidelines are also available in languages other than English. Find out more in our Translations section.

About the Library

For information about Library scope and content, identification of reporting guidelines and inclusion/exclusion criteria please visit About the Library.

UK EQUATOR Centre – key focus

- EQUATOR website
  - Development and maintenance of online resources, including Library for Health research reporting and Toolkits
- Collaborative activities to raise reporting standards
  - UK Health Research Authority, Pan American Health Organisation, Global Health Network (focus on low and middle income countries)
- 'Research into oncology research'
  - Assessment of methodology issues and development of resources for researchers, editors and reviewers
- Education and training
  - Organising workshops, courses, seminars, conference for researchers, research students, editors and peer reviewers

(http://www.equator-network.org/category/events/all-past-events/)

UK EQUATOR Centre

Publication School

6-10 July 2015
St Anne's College, Oxford

The secrets of success in writing and publishing research articles

Week-long residential course in heart of beautiful and historic Oxford

Features lectures and many practical sessions including:

- Writing the key sections of your research article
- Effective use of Reporting Guidelines including, CONSORT, STROBE and PRISMA
- Targeting the right journal for your article
- Peer review
- Communication with the public and the media

Course tutors include:
Dr Elizabeth Wager, Dr Iveta Simera, and Professor Doug Altman

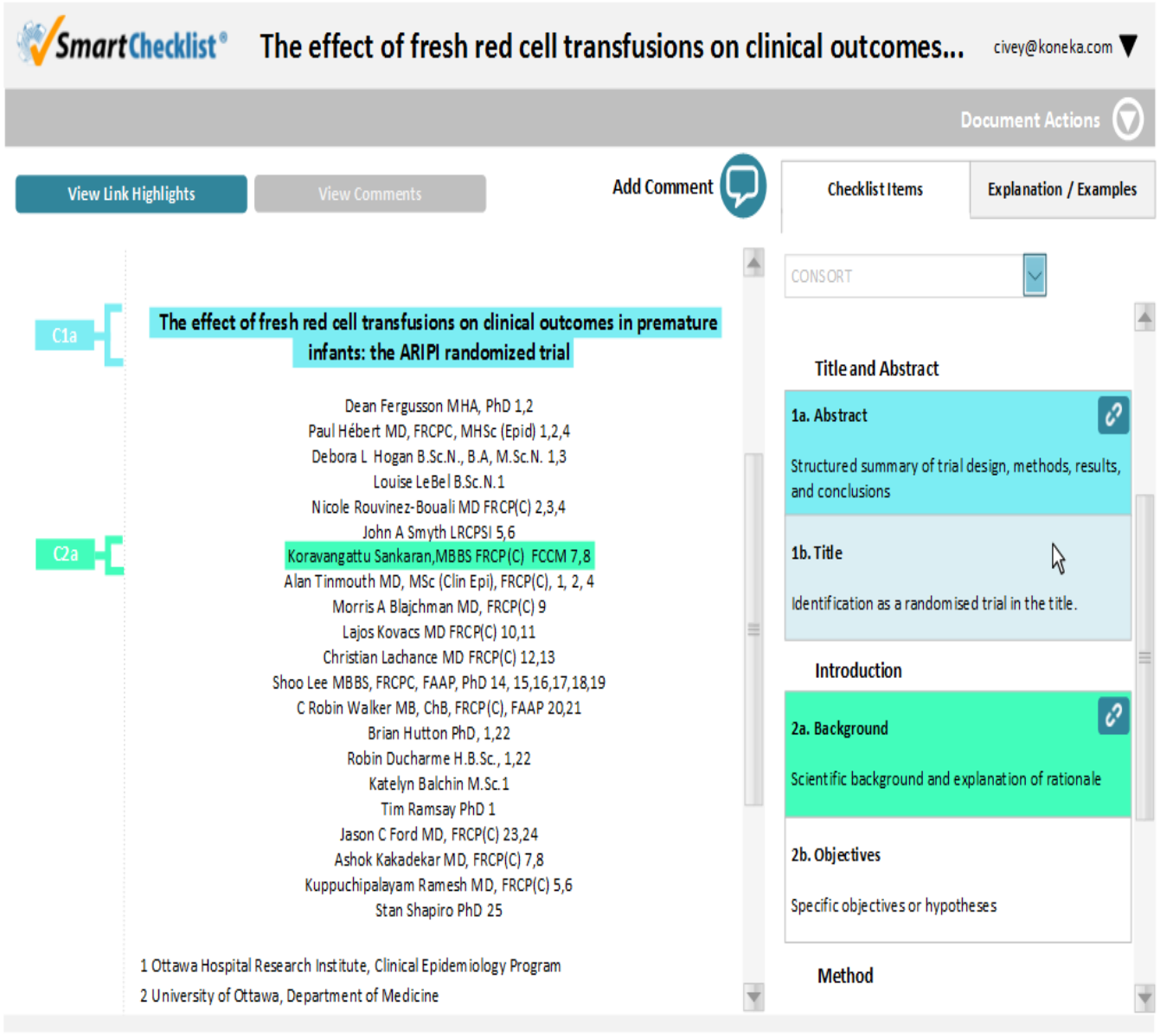
French EQUATOR Centre, key focus

- To develop interventions to improve the reporting of clinical studies
  - Tools combining the different guidelines and extension
    - Web CONSORT
  - Writing aid tools
- To develop interventions to improve the design and conduct of clinical studies
  - Trial design aid tool
- To perform interventional studies to evaluate these interventions

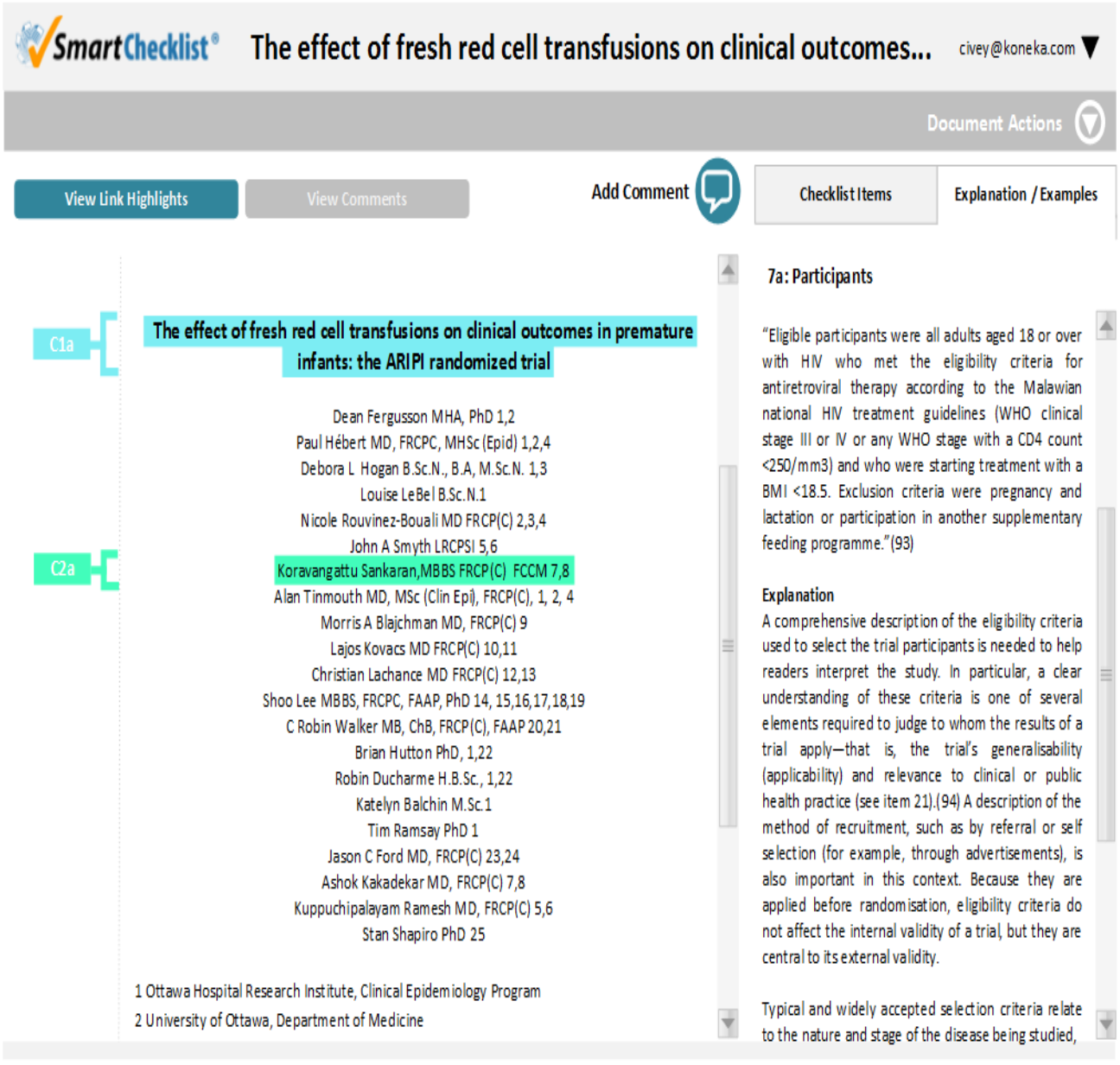
Canadian EQUATOR Centre, key focus

- Launched fall 2014
- Using technology to increase the uptake of reporting guidelines

Linking manuscript text to checklist items



Viewing Explanations & Examples for checklist items



Developing reporting guidelines

- Help develop reporting guidelines, particularly from those initiated in Canada:
  - STREGA
  - CONSORT-E
  - PRISMA-NMA
  - CONSORT-C
  - SPIRIT-C
- Looking to enhance collaboration across Canada

Introducing a publications officer

- Grants officers
- Tech transfer officers

- Little assistance at the back end – when the research in completed

- OHRI is piloting, testing, and evaluating

EQUATOR Network and Centres

TRYING TO IMPROVE THE COMPLETENESS OF THE PUBLISHED RECORD

Recent examples of poor reporting of RCTs

- 39% of 137 non-pharmacological interventions were adequately described
    - Hoffmann et al, *BMJ* 2013
- Of 164 breast cancer trials, 33% showed bias in reporting of the primary endpoint and 67% in the reporting of toxicity
    - Vera-Badillo et al, Ann Oncol 2013
- 319 RCTs in top-ranked anaesthesiology journals in 2011 satisfied a median of 60% of the CONSORT criteria
    - Münter et al, *Eur J Anaesthesiol* 2014


THE LANCET
Research: increasing value, reducing waste - January, 2014
www.thelancet.com
"By ensuring that efforts are infused with rigour from start to finish, the research community might protect itself from the sophistry of politicians, disentangle the conflicted motivations of capital and science, and secure real value for money for charitable givers and taxpayers through increased value and reduced waste."
Research: increasing value, reducing waste

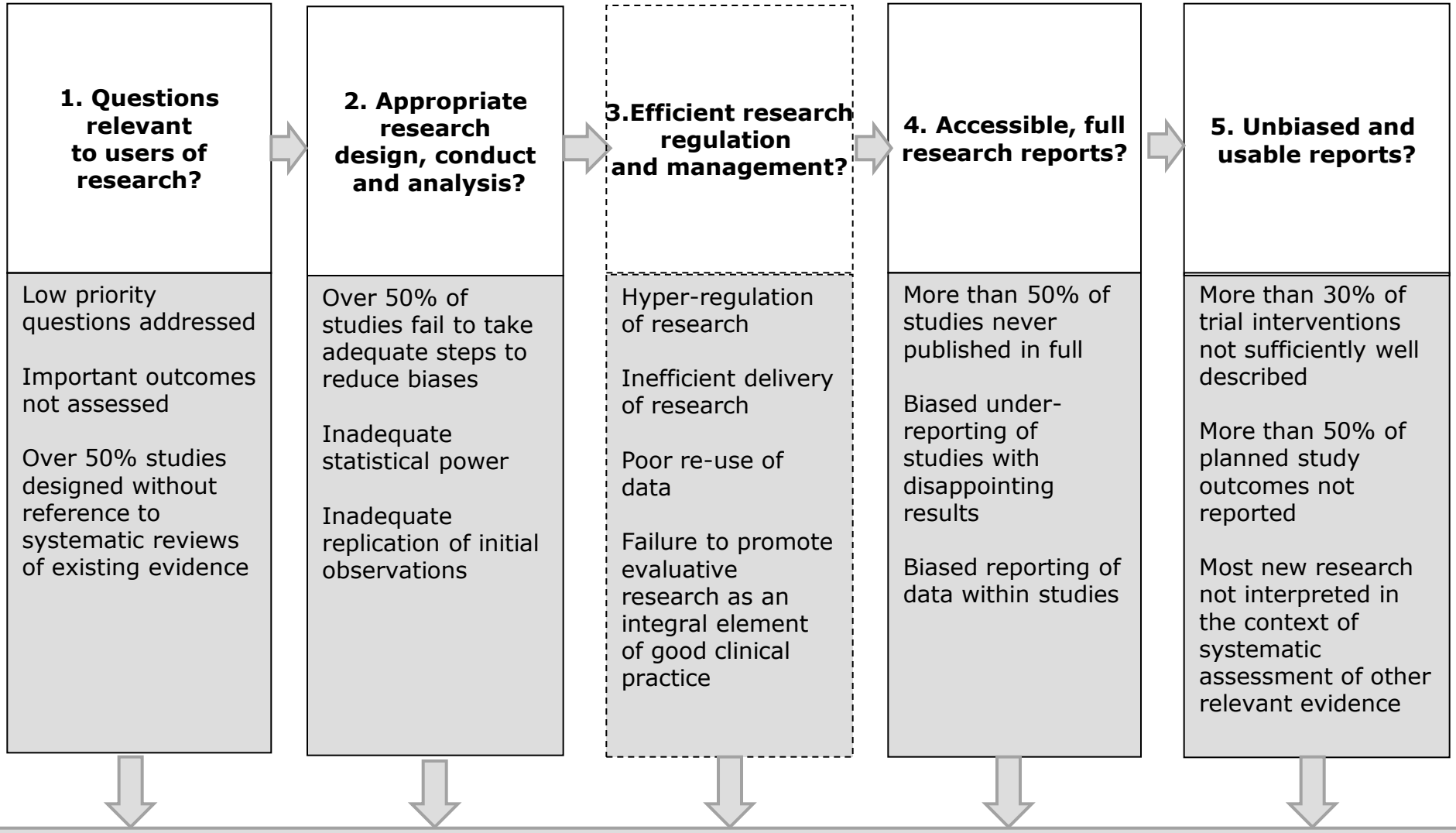
Research: increasing value, reducing waste 5

Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager

Research publication can both communicate and miscommunicate. Unless research is adequately reported, the time and resources invested in the conduct of research is wasted. Reporting guidelines such as CONSORT, STARD, PRISMA, and ARRIVE aim to improve the quality of research reports, but all are much less adopted and adhered to than they should be. Adequate reports of research should clearly describe which questions were addressed and why, what was done, what was shown, and what the findings mean. However, substantial failures occur in each of these elements. For example, studies of published trial reports showed that the poor description of interventions meant that 40–89% were non-replicable; comparisons of protocols with publications showed that most studies had at least one primary outcome changed, introduced, or omitted; and investigators of new trials rarely set their findings in the context of a systematic review, and cited a very small and biased selection of previous relevant trials. Although best documented in reports of controlled trials, inadequate reporting occurs in all types of studies—animal and other preclinical studies, diagnostic studies, epidemiological studies, clinical prediction research, surveys, and qualitative studies. In this report, and in the Series more generally, we point to a waste at all stages in medical research. Although a more nuanced understanding of the complex systems involved in the conduct, writing, and publication of research is desirable, some immediate action can be taken to improve the reporting of research. Evidence for some recommendations is clear: change the current system of research rewards and regulations to encourage better and more complete reporting, and fund the development and maintenance of infrastructure to support better reporting, linkage, and archiving of all elements of research. However, the high amount of waste also warrants future investment in the monitoring of and research into reporting of research, and active implementation of the findings to ensure that research reports better address the needs of the range of research users.

Five opportunities for waste and inefficiency, from question to report



Harm from poor reporting

- “The most dangerous risk associated with poor-quality reporting is an overestimate of the advantages of a given treatment …
- Whatever the outcome of a study, it is really hard for the average reader to interpret and verify the reliability of a poorly reported RCT …
- In turn, this problem could result in changes in clinical practice that are based on false evidence and that may harm patients.”

Zonta & De Martino. Standard requirements for randomized controlled trials in surgery. *Surgery* 2008 Nov;144(5):838-9.

What can be done to improve the situation?

- “It is the responsibility of everyone involved to ensure that the published record is an unbiased, accurate representation of research.”
    - PLoS Medicine Editors, *PLoS Med* 2009

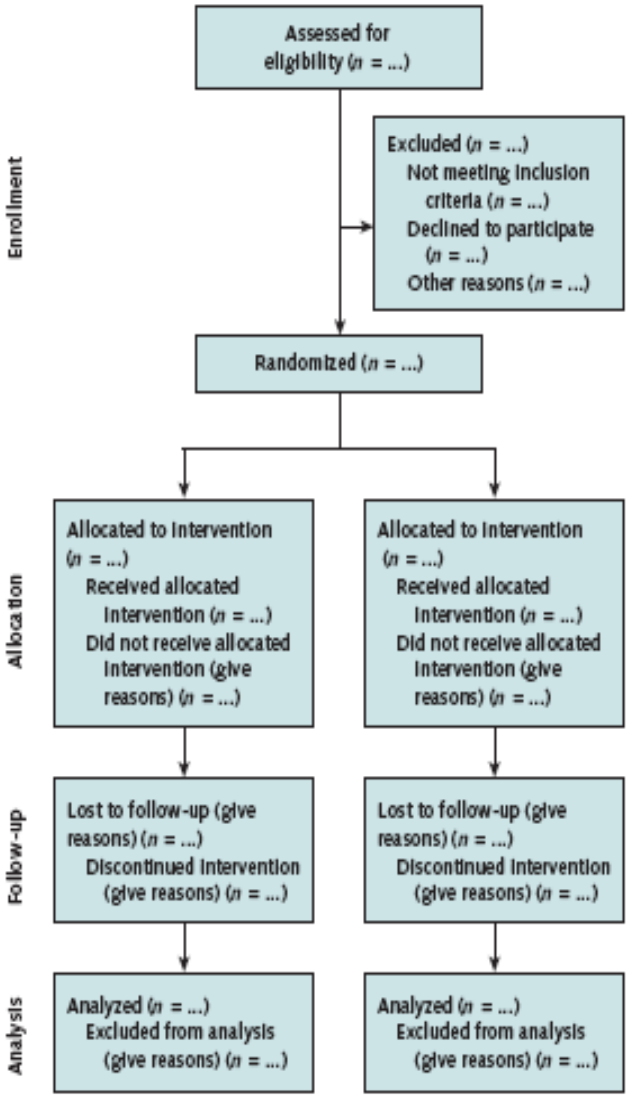
- “… how should the entire scientific enterprise change to produce reliable and accessible evidence that addresses the challenges faced by society and the individuals who make up those societies?”
    - Kleinert & Horton, *Lancet* 2014

USE REPORTING GUIDELINES

CONSORT Reporting guideline 2010

Table. CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial*

Section/Topic	Item Number	Checklist Item	Reported on Page Number
Title and abstract	1a	Identification as a randomized 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 prespecified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomization; 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	If relevant, description of the similarity of interventions	
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	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	
	13b	For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms [28])	
Discussion			
Limitations	20	Trial limitations; addressing sources of potential bias; imprecision; and, if relevant, multiplicity of analyses	
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other Information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	



Schulz KF, et al. BMJ 2010;340:c332; Moher D, et al. BMJ 2010;340:c869. www.consort-statement.org

Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide

Tammy C Hoffmann *associate professor of clinical epidemiology*[1], Paul P Glasziou *director and professor of evidence based medicine*[1], Isabelle Boutron *professor of epidemiology*[2], Ruairidh Milne *professorial fellow in public health and director*[3], Rafael Perera *university lecturer in medical statistics*[4], David Moher *senior scientist*[5], Douglas G Altman *professor of statistics in medicine*[6], Virginia Barbour *medicine editorial director, PLOS*[7], Helen Macdonald *assistant editor*[8], Marie Johnston *emeritus professor of health psychology*[9], Sarah E Lamb *Kadoorie professor of trauma rehabilitation and co-director of Oxford clinical trials research unit*[10], Mary Dixon-Woods *professor of medical sociology*[11], Peter McCulloch *clinical reader in surgery*[12], Jeremy C Wyatt *leadership chair of ehealth research*[13], An-Wen Chan *Phelan scientist*[14], Susan Michie *professor*[15]

BMJ. 2014 Mar 7;348:g1687. doi: 10.1136/bmj.g1687

Item No	Item
Brief name	
1	Provide the name or a phrase that describes the intervention
Why	
2	Describe any rationale, theory, or goal of the elements essential to the intervention
What	
3	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)
4	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities
Who provided	
5	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given
How	
6	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group
Where	
7	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features
When and How Much	
8	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose
Tailoring	
9	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how
Modifications	
10*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
How well	
11	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them
12*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

Reporting of Patient-Reported Outcomes in Randomized Trials

The CONSORT PRO Extension

Melanie Calvert, PhD
Jane Blazeby, MD
Douglas G. Altman, DSc
Dennis A. Revicki, PhD
David Moher, PhD
Michael D. Brundage, MD
for the CONSORT PRO Group

The CONSORT (Consolidated Standards of Reporting Trials) Statement aims to improve the reporting of randomized controlled trials (RCTs); however, it lacks guidance on the reporting of patient-reported outcomes (PROs), which are often inadequately reported in trials, thus limiting the value of these data. In this article, we describe the development of the CONSORT PRO extension based on the methodological framework for guideline development proposed by the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network. Five CONSORT PRO checklist items are recommended for RCTs in which PROs are primary or important secondary end points. These recommendations urge that the PROs be identified as a primary or secondary outcome in the abstract, that a description of the hypothesis of the PROs and relevant domains be provided (ie, if a multidimen-

THE CONSORT (CONSOLIdated Standards of Reporting Trials) Statement, first published in 1996 and most re-

JAMA. 2013 Feb 27;309(8):814-22. doi: 10.1001

Reporting on outcomes

- 6a Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed

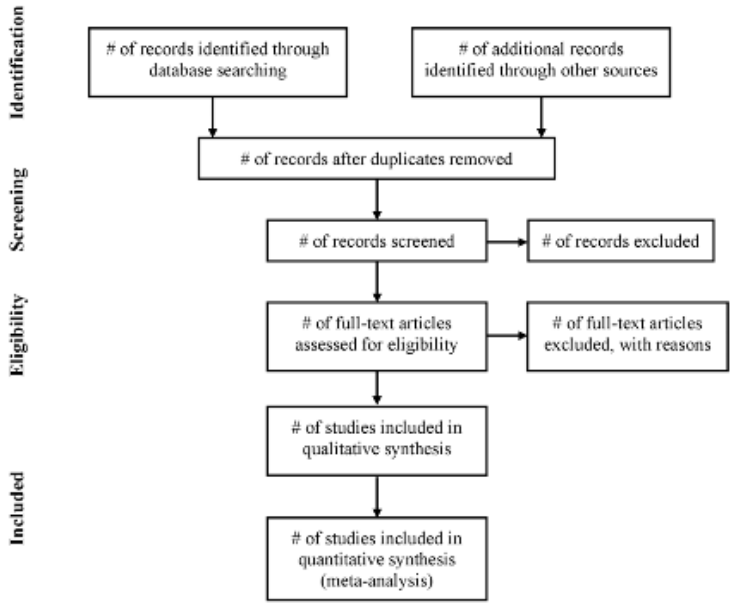
- P6a: Evidence of PRO instrument validity and reliability should be provided or cited if available including the person completing the PRO and methods of data collection (paper, telephone, electronic, other)

PRISMA: *p*referred *r*eporting *i*tems for systematic reviews and *m*eta-*a*nalyses

Section/Topic	#	Checklist Item	Reported on Page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

Moher D, Liberati A, Tetzlaff J, Altman DG, the PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA Statement.

- PLoS Med 2009; 6(6): e1000097
- Open Medicine 2009; 3:123-130
- Annals of Internal Medicine 2009;151:264-269
- BMJ 2009 ;339:332-336
- Journal of Clinical Epidemiology 2009; PMID: 19631508



www.prisma-statement.org

Liberati A, et al. The PRISMA explanation and elaboration

Guidelines for Reporting Health Research: A User's Manual

Edited by David Moher, Douglas Altman, Kenneth Schulz, Iveta Simera, Elizabeth Wager

- How to choose and correctly apply the appropriate guidelines
- Covers CONSORT, STROBE, PRISMA, STARD, and more
- Written by the authors of health research reporting guidelines, in association with the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network

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"My question is: Are we making an impact?"

Do reporting guidelines work?

Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals (Review)

Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Moher D

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2012, Issue 11

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Turner *et al. Systematic Reviews* 2012, **1**:60
http://www.systematicreviewsjournal.com/content/1/1/60

SYSTEMATIC REVIEWS

RESEARCH Open Access

Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review[a]

Lucy Turner[1], Larissa Shamseer[1], Douglas G Altman[2], Kenneth F Schulz[3] and David Moher[1,4*]

Abstract

Background: The Consolidated Standards of Reporting Trials (CONSORT) Statement is intended to facilitate better reporting of randomised clinical trials (RCTs). A systematic review recently published in the Cochrane Library assesses whether journal endorsement of CONSORT impacts the completeness of reporting of RCTs; those findings are summarised here.

Methods: Evaluations assessing the completeness of reporting of RCTs based on any of 27 outcomes formulated based on the 1996 or 2001 CONSORT checklists were included; two primary comparisons were evaluated. The 27 outcomes were: the 22 items of the 2001 CONSORT checklist, four sub-items describing blinding and a 'total summary score' of aggregate items, as reported. Relative risks (RR) and 99% confidence intervals were calculated to determine effect estimates for each outcome across evaluations.

Results: Fifty-three reports describing 50 evaluations of 16,604 RCTs were assessed for adherence to at least one of 27 outcomes. Sixty-nine of 81 meta-analyses show relative benefit from CONSORT endorsement on completeness of reporting. Between endorsing and non-endorsing journals, 25 outcomes are improved with CONSORT endorsement, five of these significantly ($\alpha = 0.01$). The number of evaluations per meta-analysis was often low with substantial heterogeneity; validity was assessed as low or unclear for many evaluations.

Conclusions: The results of this review suggest that journal endorsement of CONSORT may benefit the completeness of reporting of RCTs they publish. No evidence suggests that endorsement hinders the completeness of RCT reporting. However, despite relative improvements when CONSORT is endorsed by journals, the completeness of reporting of trials remains sub-optimal. Journals are not sending a clear message about endorsement to authors submitting manuscripts for publication. As such, fidelity of endorsement as an 'intervention' has been weak to date. Journals need to take further action regarding their endorsement and implementation of CONSORT to facilitate accurate, transparent and complete reporting of trials.

Keywords: CONSORT, Endorsement, Reporting guideline, Completeness of reporting

Cochrane Database Syst Rev. 2012 Nov 14;11:MR000030. doi: 10.1002/14651858.MR000030.pub2

- Objective: To compare the completeness of reporting between trials published in CONSORT endorsing vs. non-endorsing journals and pre-post CONSORT endorsement

- Included 50 evaluations of 16,000+ trials
  - assessed reporting of 27 CONSORT 2001 checklist items

- Main finding: significantly more complete reporting of at least 5 CONSORT checklist items in endorsing journals

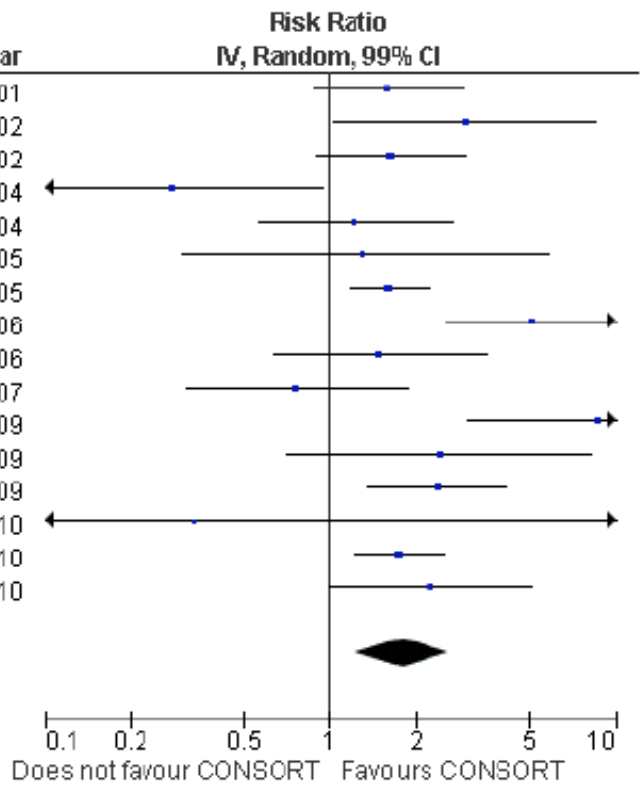
e.g. Allocation concealment

Figure 5. Forest plot of comparison: 1 CONSORT-endorsing journals versus CONSORT non-endorsing journals, outcome: 1.9 Allocation concealment.

Study or Subgroup	Endorsers Events	Endorsers Total	Non-Endorsers Events	Non-Endorsers Total	Weight	Risk Ratio IV, Random, 99% CI	Year
Moher 2001	47	77	14	37	7.8%	1.61 [0.89, 2.91]	2001
Hill 2002	4	8	19	113	5.4%	2.97 [1.03, 8.57]	2002
Devereaux 2002	28	49	17	49	7.8%	1.65 [0.91, 2.99]	2002
Llorca 2004	5	37	11	23	4.8%	0.28 [0.08, 0.95]	2004
Halpern 2004	4	6	51	94	6.8%	1.23 [0.56, 2.69]	2004
Greenfield 2005	5	98	7	182	3.8%	1.33 [0.30, 5.79]	2005
Hewitt 2005	138	166	35	68	9.1%	1.62 [1.18, 2.22]	2005
Kober 2006	7	7	12	67	7.2%	5.10 [2.54, 10.26]	2006
Dias 2006	9	19	13	41	6.4%	1.49 [0.63, 3.52]	2006
Lai 2007	17	51	7	16	6.2%	0.76 [0.31, 1.86]	2007
Wei 2009	13	35	8	188	5.4%	8.73 [3.04, 25.09]	2009
Uetani 2009	4	11	13	87	4.7%	2.43 [0.72, 8.25]	2009
Ethgen 2009	12	17	34	115	8.0%	2.39 [1.38, 4.13]	2009
Areia 2010	0	2	4	8	1.0%	0.33 [0.01, 10.34]	2010
Hopewell 2010	91	274	65	342	8.9%	1.75 [1.22, 2.51]	2010
Ladd 2010	9	19	19	90	6.6%	2.24 [0.99, 5.07]	2010
Total (99% CI)		**876**		**1520**	**100.0%**	**1.81 [1.25, 2.61]**	
Total events	393		329				

Heterogeneity: Tau² = 0.21; Chi² = 60.42, df = 15 (P < 0.00001); I² = 75%

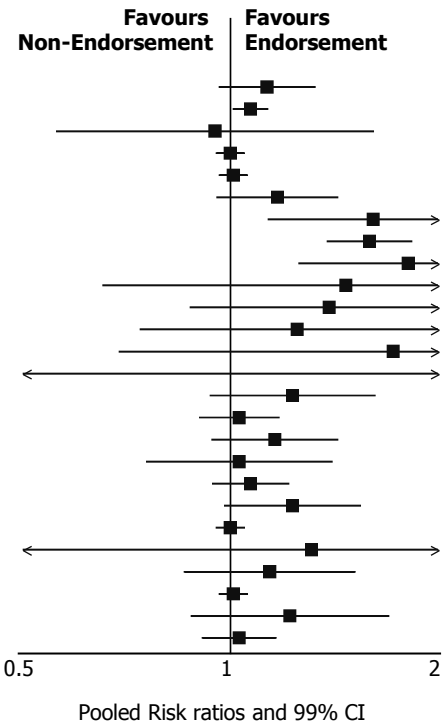
Test for overall effect: Z = 4.14 (P < 0.0001)



Relative vs. absolute? Only 393/867 (45%) completeness within endorsers

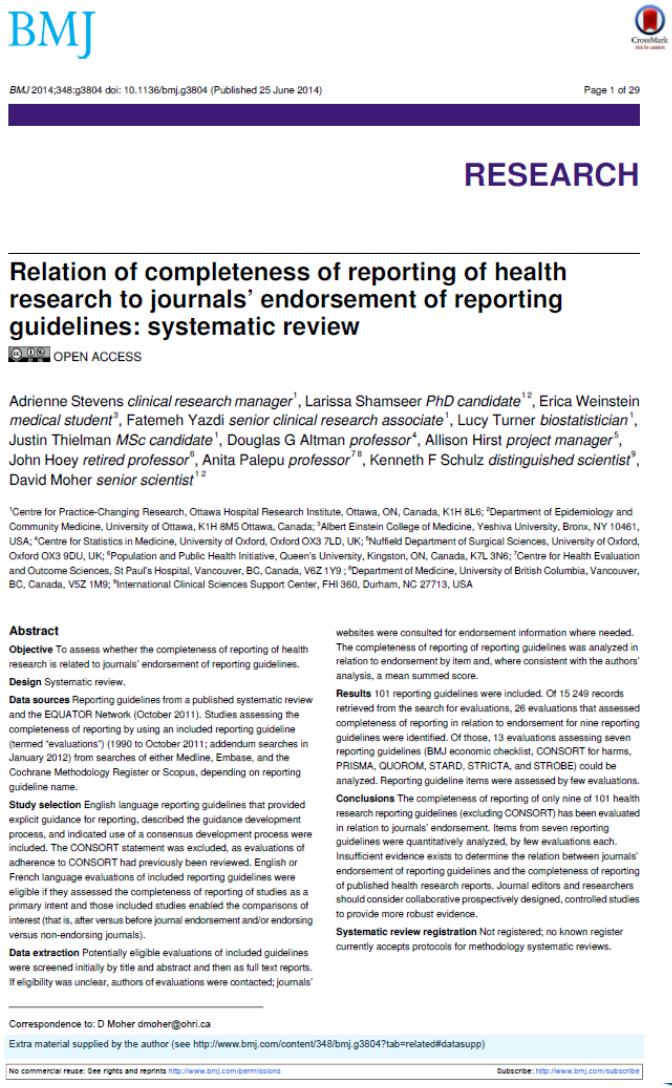
CONSORT impact

CONSORT Checklist Item	# of Evaluations	# of RCTs	RR	99% CI
Title and Abstract	7	1,233	1.13	(0.96, 1.33)
Introduction	5	513	1.07	(1.01, 1.14)
Participants	6	683	0.95	(0.56, 1.62)
Interventions	6	638	1.00	(0.95, 1.05)
Objectives	5	540	1.01	(0.96, 1.06)
Outcomes	8	1,302	1.17	(0.95, 1.44)
Sample Size	11	1,843	1.61	(1.13, 2.29)
Sequence Generation	14	2,231	1.59	(1.38, 1.84)
Allocation Concealment	16	2,396	1.81	(1.25, 2.62)
Implementation	5	498	1.47	(0.65, 3.32)
Blinding of Paticipants	5	711	1.39	(0.87, 2.22)
Blinding of Intervention	5	710	1.25	(0.74, 2.12)
Blinding of Outcome Assessor	5	719	1.72	(0.69, 4.30)
Blinding of Data Analyst	3	497	3.56	(0.40, 31.8)
Blinding Any description	8	1,851	1.23	(0.93, 1.62)
Statistical Methods	9	894	1.03	(0.90, 1.18)
Participant Flow	16	2,461	1.16	(0.94, 1.44)
Recruitment	6	959	1.03	(0.75, 1.41)
Baseline Data	5	529	1.07	(0.94, 1.22)
Numbers Analysed	13	2,145	1.23	(0.98, 1.55)
Outcomes and Estimation	6	617	1.00	(0.95, 1.05
Ancillary Analyses	4	378	1.31	(0.48, 3.58)
Adverse Events	8	911	1.14	(0.86, 1.52)
Interpretation	5	540	1.01	(0.96, 1.06)
Generalisability	5	540	1.22	(0.88, 1.70)
Overall Evidence	4	317	1.03	(0.91, 1.17)



Reporting guideline endorsement SR
Stevens et al. BMJ 2014; 348:g3804

- Objective: To compare the completeness of reporting between studies published in endorsing vs. non-endorsing journals and pre-post endorsement for each RG (non-CONSORT)
- Only 7 of 101 included RGs evaluated by a combined 26 studies
  - No clear effect of benefit or harm
    - very small sample (compared to CONSORT)
- PRISMA associated with more complete overall reporting in endorsing journals (n=3 studies incl 143 SRs)



BMJ

BMJ 2014;348:g3804 doi: 10.1136/bmj.g3804 (Published 25 June 2014)

RESEARCH

Relation of completeness of reporting of health research to journals' endorsement of reporting guidelines: systematic review

OPEN ACCESS

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Abstract

Objective To assess whether the completeness of reporting of health research is related to journals' endorsement of reporting guidelines.

Design Systematic review.

Data sources Reporting guidelines from a published systematic review and the EQUATOR Network (October 2011). Studies assessing the completeness of reporting by using an included reporting guideline (termed "evaluations") (1990 to October 2011; addendum searches in January 2012) from searches of either Medline, Embase, and the Cochrane Methodology Register or Scopus, depending on reporting guideline name.

Study selection English language reporting guidelines that provided explicit guidance for reporting, described the guidance development process, and indicated use of a consensus development process were included. The CONSORT statement was excluded, as evaluations of adherence to CONSORT had previously been reviewed. English or French language evaluations of included reporting guidelines were eligible if they assessed the completeness of reporting of studies as a primary intent and those included studies enabled the comparisons of interest (that is, after versus before journal endorsement and/or endorsing versus non-endorsing journals).

Data extraction Potentially eligible evaluations of included guidelines were screened initially by title and abstract and then as full text reports. If eligibility was unclear, authors of evaluations were contacted; journals' websites were consulted for endorsement information where needed. The completeness of reporting of reporting guidelines was analyzed in relation to endorsement by item and, where consistent with the authors' analysis, a mean summed score.

Results 101 reporting guidelines were included. Of 15 249 records retrieved from the search for evaluations, 26 evaluations that assessed completeness of reporting in relation to endorsement for nine reporting guidelines were identified. Of those, 13 evaluations assessing seven reporting guidelines (BMJ economic checklist, CONSORT for harms, PRISMA, QUOROM, STARD, STRICTA, and STROBE) could be analyzed. Reporting guideline items were assessed by few evaluations.

Conclusions The completeness of reporting of only nine of 101 health research reporting guidelines (excluding CONSORT) has been evaluated in relation to journals' endorsement. Items from seven reporting guidelines were quantitatively analyzed, by few evaluations each. Insufficient evidence exists to determine the relation between journals' endorsement of reporting guidelines and the completeness of reporting of published health research reports. Journal editors and researchers should consider collaborative prospectively designed, controlled studies to provide more robust evidence.

Systematic review registration Not registered; no known register currently accepts protocols for methodology systematic reviews.

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Extra material supplied by the author (see http://www.bmj.com/content/348/bmj.g3804?tab=related#datasupp)

- Reporting is late in the game
- If inadequate methods:
  - Can only work on getting the authors to be transparent about what they did and found
- Need to move up earlier in the food chain:
  - Methods

Remit of SPIRIT

- To improve content and quality of clinical trial protocols through evidence-based guidance

SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials

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High quality protocols facilitate proper conduct, reporting, and external review of clinical trials. However, the completeness of trial protocols is often inadequate. To help improve the content and quality of protocols, an international group of stakeholders developed the SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials). The SPIRIT Statement provides guidance in the form of a checklist of recommended items to include in a clinical trial protocol.

This SPIRIT 2013 Explanation and Elaboration paper provides important information to promote full understanding of the checklist recommendations. For each checklist item, we provide a rationale and detailed description; a model example from an actual protocol; and relevant references supporting its importance. We strongly recommend that this explanatory paper be used in conjunction with the SPIRIT Statement. A website of resources is also available (www.spirit-statement.org).

The SPIRIT 2013 Explanation and Elaboration paper, together with the Statement, should help with the drafting of trial protocols. Complete documentation of key trial elements can facilitate transparency and protocol review for the benefit of all stakeholders.

Every clinical trial should be based on a protocol—a document that details the study rationale, proposed methods, organisation, and ethical considerations.[1] Trial investigators and staff use protocols to document plans for study conduct at all stages from participant recruitment to results dissemination. Funding agencies, research ethics committees/institutional review boards, regulatory agencies, medical journals, systematic reviewers, and other groups rely on protocols to appraise the conduct and reporting of clinical trials.

To meet the needs of these diverse stakeholders, protocols should adequately address key trial elements. However, protocols often lack information on important concepts relating to study design and dissemination plans.[2-12] Guidelines for writing protocols can help improve their completeness, but existing guidelines vary extensively in their content and have limitations, including non-systematic methods of development, limited stakeholder involvement, and lack of citation of empirical evidence to support their recommendations.[13] As a result, there is also variation in the precise definition and scope of a trial protocol, particularly in terms of its relation to other documents such as procedure manuals.[14]

Given the importance of trial protocols, an international group of stakeholders launched the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Initiative in 2007 with the primary aim of improving the content of trial protocols. The main outputs are the SPIRIT 2013 Statement,[14] consisting of a 33 item checklist of minimum recommended protocol items (table 1) plus a diagram (fig 1); and this accompanying Explanation and Elaboration (E&E) paper. Additional information and resources are also available on the SPIRIT website (www.spirit-statement.org).

The SPIRIT 2013 Statement and E&E paper reflect the collaboration and input of 115 contributors, including trial investigators, healthcare professionals, methodologists, statisticians, trial coordinators, journal editors, as well as representatives from research ethics committees, industry and non-industry funders, and regulatory agencies. Details of the scope and methods have been published elsewhere.[13-15] Briefly, three complementary methods were specified beforehand, in line with current recommendations for development of reporting guidelines[16]: 1) a Delphi consensus survey[15]; 2) two systematic reviews to identify existing protocol guidelines and empirical evidence supporting the importance of specific checklist items; and 3) two face-to-face consensus meetings to finalise the SPIRIT 2013 checklist. Furthermore, the checklist was pilot tested by graduate course students, and an implementation strategy was developed at a stakeholder meeting.

The SPIRIT recommendations are intended as a guide for those preparing the full protocol for a clinical trial. A clinical trial is a prospective study in which one or more

SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials

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The protocol of a clinical trial serves as the foundation for study planning, conduct, reporting, and appraisal. However, trial protocols and existing protocol guidelines vary greatly in content and quality. This article describes the systematic development and scope of SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013, a guideline for the minimum content of a clinical trial protocol.

The 33-item SPIRIT checklist applies to protocols for all clinical trials and focuses on content rather than format. The checklist recommends a full description of what is planned; it does not prescribe how to design or conduct a trial. By providing guidance for key content, the SPIRIT recommendations aim to facilitate the drafting of high-quality protocols. Adherence to SPIRIT would also enhance the transparency and completeness of trial protocols for the benefit of investigators, trial participants, patients, sponsors, funders, research ethics committees or institutional review boards, peer reviewers, journals, trial registries, policymakers, regulators, and other key stakeholders.

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For author affiliations, see end of text.
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The protocol of a clinical trial plays a key role in study planning, conduct, interpretation, oversight, and external review by detailing the plans from ethics approval to dissemination of results. A well-written protocol facilitates an appropriate assessment of scientific, ethical, and safety issues before a trial begins; consistency and rigor of trial conduct; and full appraisal of the conduct and results after trial completion. The importance of protocols has been emphasized by journal editors (1–6), peer reviewers (7–10), researchers (11–15), and public advocates (16).

Despite the central role of protocols, a systematic review revealed that existing guidelines for protocol content vary greatly in their scope and recommendations, seldom describe how the guidelines were developed, and rarely cite broad stakeholder involvement or empirical evidence to support their recommendations (17). These limitations may partly explain why an opportunity exists to improve the quality of protocols. Many protocols for randomized trials do not adequately describe the primary outcomes (inadequate for 25% of trials) (18, 19), treatment allocation methods (inadequate for 54% to 79%) (20, 21), use of blinding (inadequate for 9% to 34%) (21, 22), methods for reporting adverse events (inadequate for 41%) (23), components of sample size calculations (inadequate for 4% to 40%) (21, 24), data analysis plans (inadequate for 20% to 77%) (21, 24–26), publication policies (inadequate for 7%) (27), and roles of sponsors and investigators in study design or data access (inadequate for 89% to 100%) (28, 29). The problems that underlie these protocol deficiencies may in turn lead to avoidable protocol amendments, poor trial conduct, and inadequate reporting in trial publications (15, 30).

In response to these gaps in protocol content and guidance, we launched the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) initiative in 2007. This international project aims to improve the completeness of trial protocols by producing evidence-based recommendations for a minimum set of items to be addressed in protocols. The SPIRIT 2013 Statement includes a 33-item checklist (**Table 1**) and diagram (**Figure**). An associated explanatory paper (SPIRIT 2013 Explanation and Elaboration) (31) details the rationale and supporting evidence for each checklist item, along with guidance and model examples from actual protocols.

Development of the SPIRIT 2013 Statement

The SPIRIT 2013 Statement was developed in broad consultation with 115 key stakeholders, including trial investigators ($n = 30$); health care professionals ($n = 31$); methodologists ($n = 34$); statisticians ($n = 16$); trial coordinators ($n = 14$); journal editors ($n = 15$); and representatives from the research ethics community ($n = 17$), industry and nonindustry funders ($n = 7$), and regulatory agencies ($n = 3$), whose roles are not mutually exclusive. As detailed later, the SPIRIT guideline was developed through 2 systematic reviews, a formal Delphi consensus process, 2 face-to-face consensus meetings, and pilot-testing (32).

The SPIRIT checklist evolved through several iterations. The process began with a preliminary checklist of 59 items derived from a systematic review of existing protocol guidelines (17). In 2007, 96 expert panelists from 17 low- ($n = 1$), middle- ($n = 6$), and high-income ($n = 10$) countries refined this initial checklist over 3 iterative Delphi consensus survey rounds by e-mail (33). Panelists rated each item on a scale of 1 (not important) to 10 (very important), suggested new items, and provided comments that were circulated in subsequent rounds. Items with a median score of 8 or higher in the final round were included, whereas those rated 5 or lower were excluded.

Developing SPIRIT

- 33 items in five categories
  1. Administrative information
     2a “Trial identifier and registry name. If not yet registered, name of intended registry”
  2. Introduction
     7 “Specific objectives or hypotheses”

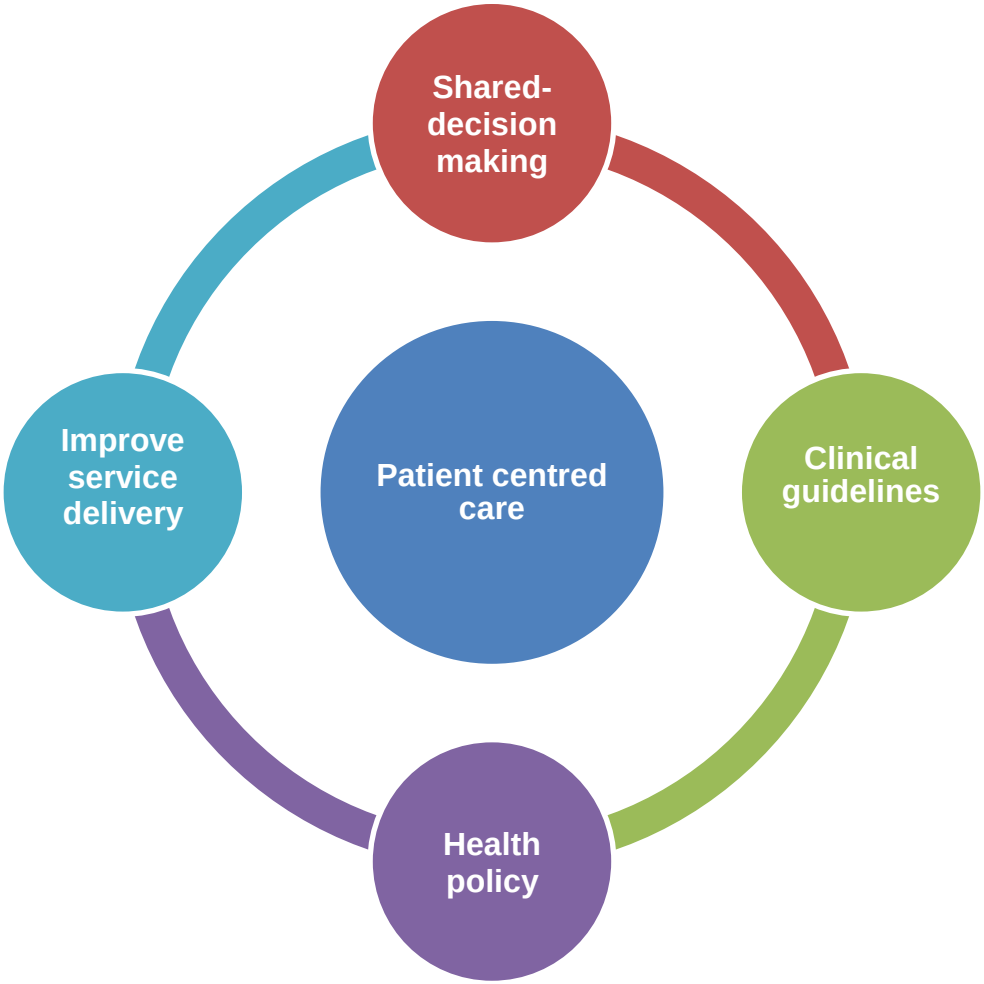
  Study methods

  14 “Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations”

  4. Ethical considerations and dissemination
     28 “Financial and other competing interests for principal investigators for the overall trial and each study site”
  5. Appendices
     28 “Model consent form and other related documentation given to participants and authorised surrogates”

Why are Patient-Reported Outcomes Important?

Making Patient-Centred Care a Reality.



M Calvert, PROs Research Group University of Birmingham, UK: m.calvert@bham.ac.uk

Challenge: Lack of consolidated guidance for protocol writers relating to PROs

Systematic Review

- Identified 54 publications
- Containing 162 unique recommendations!

OPEN ACCESS Freely available online

PLOS ONE

Patient-Reported Outcome (PRO) Assessment in Clinical Trials: A Systematic Review of Guidance for Trial Protocol Writers

Melanie Calvert[1,2*], Derek Kyte[1,3], Helen Duffy[1], Adrian Gheorghe[4], Rebecca Mercieca-Bebber[5], Jonathan Ives[6], Heather Draper[2,6], Michael Brundage[7], Jane Blazeby[8], Madeleine King[5]

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Citation: Calvert M, Kyte D, Duffy H, Gheorghe A, Mercieca-Bebber R, et al. (2014) Patient-Reported Outcome (PRO) Assessment in Clinical Trials: A Systematic Review of Guidance for Trial Protocol Writers. PLoS ONE 9(10): e110216. doi:10.1371/journal.pone.0110216

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PLOS ONE

Systematic Evaluation of the Patient-Reported Outcome (PRO) Content of Clinical Trial Protocols

Derek Kyte[1], Helen Duffy[1], Benjamin Fletcher[2], Adrian Gheorghe[3], Rebecca Mercieca-Bebber[4], Madeleine King[4], Heather Draper[5,8], Jonathan Ives[5], Michael Brundage[6], Jane Blazeby[7], Melanie Calvert[1,8]*

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Abstract

Background: Qualitative evidence suggests patient-reported outcome (PRO) information is frequently absent from clinical trial protocols, potentially leading to inconsistent PRO data collection and risking bias. Direct evidence regarding PRO trial protocol content is lacking. The aim of this study was to systematically evaluate the PRO-specific content of UK National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme trial protocols.

Methods and Findings: We conducted an electronic search of the NIHR HTA programme database (inception to August 2013) for protocols describing a randomised controlled trial including a primary/secondary PRO. Two investigators independently reviewed the content of each protocol, using a specially constructed PRO-specific protocol checklist, alongside the 'Standard Protocol Items: Recommendations for Interventional Trials' (SPIRIT) checklist. Disagreements were resolved through discussion with a third investigator. 75 trial protocols were included in the analysis. Protocols included a mean of 32/51 (63%) SPIRIT recommendations (range 16–41, SD 5.62) and 11/33 (33%) PRO-specific items (range 4–18, SD 3.56). Over half (61%) of the PRO items were incomplete. Protocols containing a primary PRO included slightly more PRO checklist items (mean 14/33 (43%)). PRO protocol content was not associated with general protocol completeness; thus, protocols judged as relatively 'complete' using SPIRIT were still likely to have omitted a large proportion of PRO checklist items.

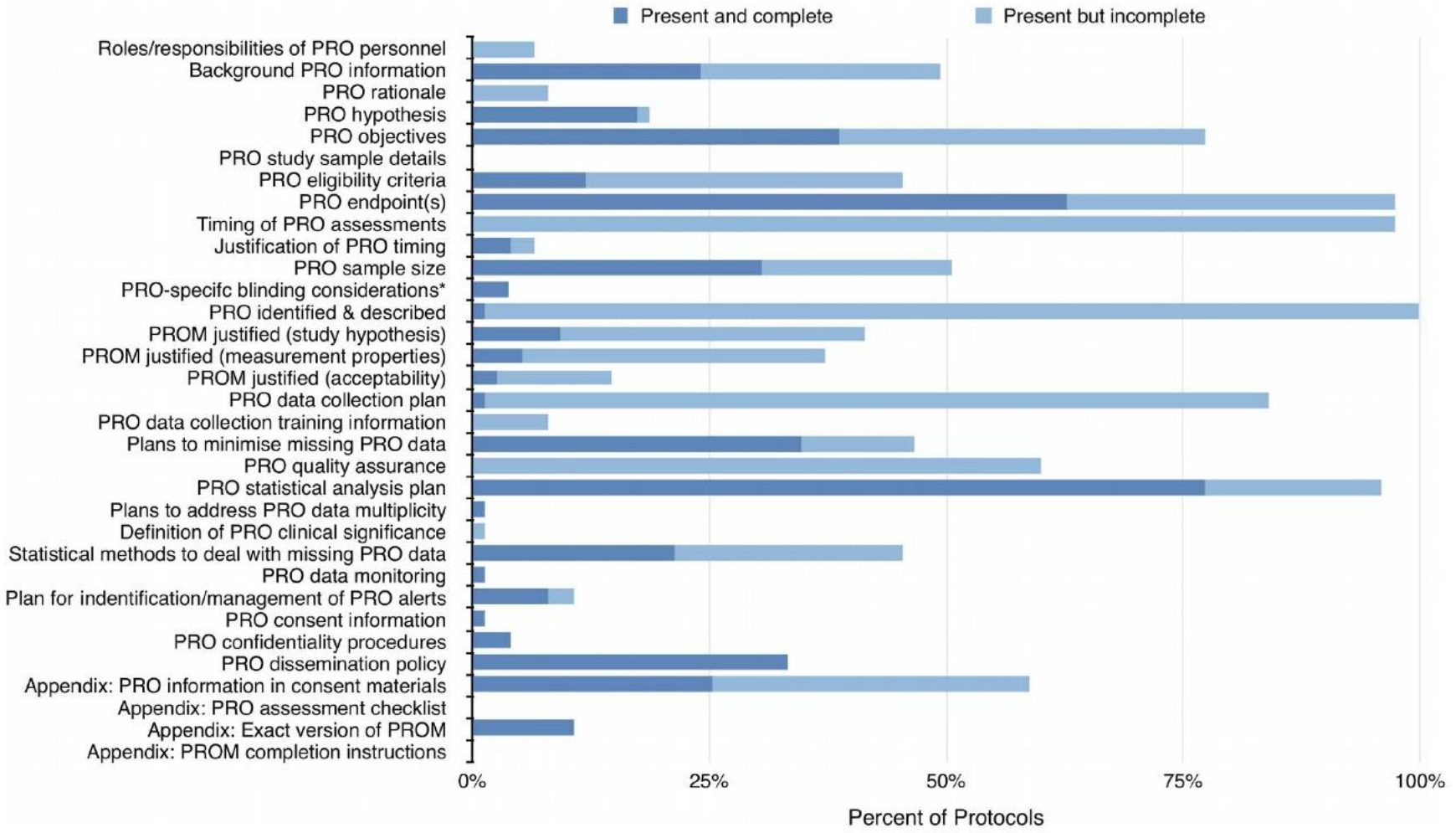

Figure 3. Protocol adherence to individual PRO items. *Denominator adjusted as n = 46 blinded trials included in sample.
doi:10.1371/journal.pone.0110229.g003

Summary

- PRO-specific information often absent from protocols
  - Even where the PRO is the primary outcome!
- Research waste and suboptimal patient care
- Do we need a SPIRIT PRO extension?

Opportunity: to improve trial design/protocols

THE LANCET

Volume 385, Issue 9973, 21–27 March 2015, Pages 1073–1074

Correspondence

Putting patients at the heart of health-care research

Melanie Calvert[a,], Derek Kyte[a], Maria von Hildebrand[b], Madeleine King[c], David Moher[d]

Show more

doi:10.1016/S0140-6736(15)60599-2

Williamson *et al. Trials* 2012, **13**:132
http://www.trialsjournal.com/content/13/1/132

COS-STAR

TRIALS

COMMENTARY Open Access

Developing core outcome sets for clinical trials: issues to consider

Paula R Williamson[1*], Douglas G Altman[2], Jane M Blazeby[3], Mike Clarke[4], Declan Devane[5], Elizabeth Gargon[1] and Peter Tugwell[6]

Abstract

The selection of appropriate outcomes or domains is crucial when designing clinical trials in order to compare directly the effects of different interventions in ways that minimize bias. If the findings are to influence policy and practice then the chosen outcomes need to be relevant and important to key stakeholders including patients and the public, health care professionals and others making decisions about health care. There is a growing recognition that insufficient attention has been paid to the outcomes measured in clinical trials. These issues could be addressed through the development and use of an agreed standardized collection of outcomes, known as a core outcome set, which should be measured and reported, as a minimum, in all trials for a specific clinical area. Accumulating work in this area has identified the need for general guidance on the development of core outcome sets. Key issues to consider in the development of a core outcome set include its scope, the stakeholder groups to involve, choice of consensus method and the achievement of a consensus.

Table 1 Checklist of the items that groups should consider when reporting the development of a COS of domain concepts (that is, 'what' to measure)

Section/topic	#	Checklist item
TITLE		
Title	1	Identify the report as a study to develop a COS.
ABSTRACT		
Structured summary	2	Provide a structured summary including, as applicable: background, objectives, data sources, participant eligibility criteria, study methods, results, limitations, conclusions, and implications of key findings.
INTRODUCTION		
Rationale	3	Describe the rationale for the development of a COS in the context of what is already known. This may include a review of outcomes in previous trials or systematic reviews.
Objectives	4	Provide an explicit statement of questions being addressed with reference, as applicable, to: health condition, population, and types of intervention(s).
METHODS		
Protocol and registration	5	Indicate if a study protocol exists, and where it can be accessed (for example, web address)
Eligibility criteria	6	Specify participant eligibility criteria, including stakeholder group, the rationale for involving them, and how participants were identified and sampled.
Information sources	7	Describe all information sources (for example, systematic review, databases with dates of coverage, contact with study authors) provided to participants before the start of and during the consensus process. If no information on previously measured outcomes is provided, this should be clearly stated together with details of the method for obtaining information on outcomes of importance from the participants.
Consensus process	8	Describe method to determine consensus and the rationale. A checklist for reporting Delphi methods applied to the development of COS has previously been recommended [29].
Outcome scoring	9	Describe how outcomes will be scored during the consensus exercise, and how scores will be summarized across participants during each stage of the consensus process.
Definition of consensus	10	Clearly describe any pre-determined definition of consensus. Describe procedure for determining how outcomes will be included or excluded from consideration at each stage of the consensus process.
RESULTS		
Participants	11	Give the total number of participants invited and the number involved in each aspect of the study. Give the proportion of each type of participant from the various stakeholder groups involved. Present any data collected on participant characteristics.
Results of the consensus process	12	As a minimum, provide a comprehensive list of all the outcomes that participants agreed should be included in the core set. Describe a measure of group response and distribution of response for each outcome considered during the process.
DISCUSSION		
Summary of evidence	13	Summarize the main findings regarding the level of consensus and the content of the COS. Consider its relevance to key groups e.g. patients and the public, healthcare providers, and policy makers, and any potential barriers to implementation.
Limitations	14	Discuss limitations in terms of stakeholder and geographical coverage. Describe methods used for assessing risk of bias, in relation to information provided to participants beforehand, attrition, any lack of anonymity, etc.
Conclusions	15	Provide a general interpretation of the results in the context of other evidence, and implications for future research.
Funding and editorial independence		
Funding	16	Describe sources of funding and the role of the funder in the study.
Conflicts of interest	17	Describe any conflicts of interest within the study team, for example researchers who have developed an outcome measurement instrument applicable to the scope of the COS.

Moher et al. Systematic Reviews 2015, 4:1
http://www.systematicreviewsjournal.com/content/4/1/1

SYSTEMATIC REVIEWS

RESEARCH Open Access

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement

David Moher[1*], Larissa Shamseer[1], Mike Clarke[2], Davina Ghersi[3], Alessandro Liberati[†], Mark Petticrew[4], Paul Shekelle[5], Lesley A Stewart[6] and PRISMA-P Group

Abstract

Systematic reviews should build on a protocol that describes the rationale, hypothesis, and planned methods of the review; few reviews report whether a protocol exists. Detailed, well-described protocols can facilitate the understanding and appraisal of the review methods, as well as the detection of modifications to methods and selective reporting in completed reviews. We describe the development of a reporting guideline, the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols 2015 (PRISMA-P 2015). PRISMA-P consists of a 17-item checklist intended to facilitate the preparation and reporting of a robust protocol for the systematic review. Funders and those commissioning reviews might consider mandating the use of the checklist to facilitate the submission of relevant protocol information in funding applications. Similarly, peer reviewers and editors can use the guidance to gauge the completeness and transparency of a systematic review protocol submitted for publication in a journal or other medium.

Background

Systematic reviews are the reference standard for synthesizing evidence in health care because of their methodological rigor. They are used to support the development of clinical practice guidelines and inform clinical decision-making. They are becoming increasingly common; in 2010, 11 new reviews were estimated to be published daily [1]. Ideally, systematic reviews are based on pre-defined eligibility criteria and conducted according to a pre-defined methodological approach as outlined in an associated protocol.

The preparation of a protocol is an essential component of the systematic review process; it ensures that a systematic review is carefully planned and that what is planned is explicitly documented before the review starts, thus promoting consistent conduct by the review team, accountability, research integrity, and transparency of the eventual completed review. A protocol may also reduce arbitrariness in decision-making when extracting and using data from primary research, since planning provides an opportunity for the review team to anticipate potential problems. When clearly reported protocols are made available, they enable readers to identify deviations from planned methods in completed reviews and whether they bias the interpretation of a review results and conclusions. Bias related to the selective reporting of outcomes has been characterized as a serious problem in clinical research, including systematic reviews [2-7].

Until recently, systematic review protocols were generally available only through select organizations, such as The Cochrane [8] and Campbell Collaborations and the Joanna Briggs Institute, for which the preparation of a protocol is mandatory. Outside of these organizations, the existence of a protocol is infrequently reported in completed reviews [9,10]. Fewer than half of 300 systematic reviews indexed on MEDLINE in November 2004 (most recent generalizable sample; 2014 update underway) report working from a protocol [10], 80% of which are non-Cochrane affiliated. Of the non-Cochrane therapeutic reviews, only 11% mentioned the existence of a protocol [10]. The majority of reviews in health care are

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RESEARCH METHODS & REPORTING

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation

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Dedication: The PRISMA-P 2015 initiative is dedicated to our colleague Alessandro Liberati (1954–2012), who passed away while PRISMA-P 2015 was under development and whose contributions to this work were invaluable.

Abstract

Protocols of systematic reviews and meta-analyses allow for planning and documentation of review methods, act as a guard against arbitrary decision making during review conduct, enable readers to assess for the presence of selective reporting against completed reviews, and, when made publicly available, reduce duplication of efforts and potentially prompt collaboration. Evidence documenting the existence of selective reporting and excessive duplication of reviews on the same or similar topics is accumulating and many calls have been made in support of the documentation and public availability of review protocols. Several efforts have emerged in recent years to rectify these problems, including development of an international register for prospective reviews (PROSPERO) and launch of the first open access journal dedicated to the exclusive publication of systematic review products, including protocols (BioMed Central's *Systematic Reviews*). Furthering these efforts and building on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines, an international group of experts has created a guideline to improve the transparency, accuracy, completeness, and frequency of documented systematic review and meta-analysis protocols—PRISMA-P (for protocols) 2015. The PRISMA-P checklist contains 17 items considered to be essential and minimum components of a systematic review or meta-analysis protocol.

This PRISMA-P 2015 Explanation and Elaboration paper provides readers with a full understanding of and evidence about the necessity of each item as well as a model example from an existing published protocol. This paper should be read together with the PRISMA-P 2015 statement. Systematic review authors and assessors are strongly encouraged to make use of PRISMA-P when drafting and appraising review protocols.

Introduction

Systematic reviews hold a unique place in healthcare. They help form the basis for developing practice guidelines and they provide information on gaps in knowledge, thus informing future research efforts. This information is relevant to stakeholders across the health system. The rigour and trustworthiness of systematic reviews is, in large part, based on the a priori planning and documentation of a methodical approach to conduct (that is, a protocol).

A systematic review protocol is important for several reasons: (1) it allows systematic reviewers to plan carefully and thereby anticipate potential problems; (2) it allows reviewers to explicitly document what is planned before they start their review, enabling others to compare the protocol and the completed review (that is, to identify selective reporting), to replicate review methods if desired, and to judge the validity of planned methods; (3) it prevents arbitrary decision making with respect to inclusion criteria and extraction of data; and (4) it may reduce duplication of efforts and enhance collaboration, when available.

Various international organizations such as the Cochrane and Campbell Collaborations and the Agency for Healthcare Research and Quality (AHRQ) regularly require and publish protocols. However, outside of such organizations, few protocols are published in traditional journals and most reports of completed reviews (89%) do not mention working from a protocol[1] (2014 update under way). Many experts have called for improved documentation and availability of review protocols. In response, experts (some of whom are authors on this document) launched an international, prospective register for systematic review protocols (PROSPERO, www.crd.york.ac.uk/prospero/) through the Centre for Reviews and Dissemination at the University of York (UK) in February 2011, in which more than 5000 systematic review protocols from 69 countries have been registered as of December 2014. In February 2012, the