Implementation of editorial interventions

Larissa Shamseer, PhD candidate School of Epidemiology & Public Health University of Ottawa

Declarations

- Clinical Epidemiologist/Journalologist/Methodologist
- Associate Edito 🛐 Systematic Reviews
- Reporting Guideline developer (PRISMA-P[rotocols], CONSORT extension for N-of-1 trials, 8 others)

"Implementation"

- ≠ dissemination
- ≠ endorsement
- Integrating knowledge (i.e., standards/guidelines/proce taking account of barriers



Guideline developers: Measuring uptake of reporting guidelines

- Typically..
 - # of citations to guidelines
 - # of journals endorsing guidelines or with certain policies

- ...but reporting is complex issue
 - What is "best practice"?
 - Adhering to effective guidelines and standards
 - How do we measure uptake/adherence to best practice?

The basic SR process



PRISMA-P: Preferred Reporting Items for Systematic Review and Meta-analysis Protocols; MECIR: Methodological Expectations of Cochrane Intervention Reviews; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses; OSF: Open Science Framework

PROSPERO https://www.crd.york.ac.uk/PROSPERO/



International prospective register of systematic reviews

PROSPERO Registration data set

23 required items, 18 optional items

Review title and timescale

- Review title *
- 2. Original language title
- 3. Anticipated or actual start date *
- 4. Anticipated completion date *
- 5. Stage of review at time of registration *

Review team details

- 6. Named contact *
- 7. Named contact email *
- 8. Named contact address
- 9. Named contact phone number
- 10. Review team members and their organisational affiliations
- 11. Organisational affiliation of the review *
- 12. Funding sources/ sponsors *
- 13. Conflicts of interest *
- Collaborators

* Mandatory items

Review methods

- 15. Review question(s) *
- 16. Searches *
- 17. URL to search strategy
- 18. Condition or domain being studied *
- 19. Participants/ population *
- 20. Intervention(s), exposure(s) *
- 21. Comparator(s)/ control *
- 22. Types of study to be included *
- 23. Context
- 24. Primary outcome(s) *
- 25. Secondary outcomes *
- 26. Data extraction (selection and coding)
- 27. Risk of bias (quality) assessment *
- 28. Strategy for data synthesis *
- 29. Analysis of subgroups or subsets *

PROSPERO Guidance

Review methods

15. Review	State the question(s) to be addressed / review objectives. Please complete a
question(s)*	separate box for each question.
16. Searches*	Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.
17. URL to search	If you have one, give the link to your search strategy here. Alternatively, upload
strategy	your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.
18. Condition or	Give a short description of the disease, condition or healthcare domain being
domain being studied*	studied. This could include health and wellbeing outcomes.
19. Participants/ population*	Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.
20. Intervention(s),	Give full and clear descriptions of the nature of the interventions or the exposures
exposure(s)*	to be reviewed. The preferred format includes details of both inclusion and exclusion criteria.
21. Comparator(s)/ control*	Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.
22. Types of study to	Give details of the study designs to be included in the review. If there are no

https://www.crd.york.ac.uk/prospero/aboutreg.php?reg=registrationdataset

PROSPERO Registration data set (cont'd)

General information

- 30. Type and method of review *
- 31. Language
- 32. Country
- 33. Other registration details
- 34. Reference and/or URL for published protocol
- 35. Dissemination plans
- 36. Keywords
- 37. Details of any existing review of the same topic by the same authors
- 38. Review status *
- 39. Any other information
- 40. Link to publication of final report

Why haven't we achieved best practice?



- Improving reporting = changing current practice
- Changing practice = changing behaviour of multiple people

What are the desired outcomes?

- Adherence to guidelines/standards/policies
- Behaviour Change
 - Use Psychological theory to develop an "implementation intervention" or knowledge translation strategy



Bonus: there is an established science on how to do this!

Designing implementation interventions

French et al. Implementation Science 2012, 7:38 http://www.implementationscience.com/content/7/1/38



METHODOLOGY

Open Access

Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework

Simon D French^{1,2*}, Sally E Green¹, Denise A O'Connor¹, Joanne E McKenzie¹, Jill J Francis³, Susan Michie⁴, Rachelle Buchbinder^{1,5,9}, Peter Schattner⁶, Neil Spike⁶ and Jeremy M Grimshaw^{7,8}

Abstract

Background: There is little systematic operational guidance about how best to develop complex interventions to reduce the gap between practice and evidence. This article is one in a Series of articles documenting the





The «Swiss Cheese » Model

 An organization's defenses against failure are modeled as a series of barriers, represented as slices of cheese

POOR Reporting

Authors

Reviewers

The system produces failures when a hole in each slice momentarily aligns

Funders/reg ulators/instit utions

Slide courtesy of Philippe Ravaud

Editors

• DIAGNOSE THE PROBLEM

- Identify barriers and facilitators to reproducible systematic reviews
- Interviews with representatives from target stakeholder groups
- Re: factors influencing the development/reporting/availability/assessment of systematic reviews

• USE PSYCHOLOGICAL THEORY to:

- understand potential mechanisms of change
- understand which behaviours are associated with each identified barrier

Theoretical Domains Framework (Michie 2005, Cane 2012)

- Knowledge
- Skills
- Social/professional role and identity
- Beliefs about capabilities
- Optimism
- Beliefs about consequences
- Reinforcement
- Intentions
- Goals
- Memory, attention and decision processes
- Environmental context and resources
- Social influences
- Emotion
- Behavioural regulation

E.g., Barriers/Facilitators to CONSORT

- Elicit thoughts, understanding, and use of CONSORT to identify barriers/facilitators
 - 1. Editor surveys (n=79)
 - 2. Editor interviews (6 endorsers, 1 non-endorser)
 - **3.** Author Interviews (n=10, CMAJ & Imp Sci)

Editor Survey Results – descriptive characteristics of journals

- 79 editors completed survey (response rate: 29.8%)
 - 76.7% Editor-in-Chief
 - 11.6% Managing Editors
 - 11.7% Other
- >50% of editors from US, followed by Europe, Canada
- ~50% of journals published ≥10 trials in 2009
- ≥50% journals with 3+ IF

Endorsement characteristics

- In endorsing journals (70%):
- 84.6% refer to CONSORT in ITA
- 62.3% do not require checklist prior to peer review
- 86.5% do not mandate use of CONSORT during peer review
- Only 35.3% considered CONSORT when making publication decision
- CONSORT adherence is responsibility of: editors (70%), authors (42%), editorial staff (38%) or someone else (60%).

Editors Survey Results

• What would (further) facilitate the endorsement of CONSORT in your journal? (select all that apply)

- Web-enabled applications (e.g., programs to connect CONSORT submission with other documents at peer-review): 81.0 %
- Links to educational tutorials about CONSORT items (e.g., webinars): 59.5 %
- Other (please specify) 14.3 %

Editors Survey Results

Which of the following, if any, do you feel are disadvantages to using the CONSORT statement within the editorial process? (select all that apply)

- Strict endorsement of CONSORT can lead to formulaic writing: 34.7%
- Strict endorsement of CONSORT can diminish the importance of clinical content: 18.4%
- I do not feel there are any drawbacks to using the CONSORT statement within the editorial process: 55.1%
- Other (please specify): 16.3%

Editor interviews

 "You know, we don't need that, we are so smart we know better"

• "Even though that's what you recommend, it's not all that practical for us, for our particular readers"

 "...we need submissions right now, we felt it may be a barrier...authors might submit it [manuscript] to a journal that doesn't require it [CONSORT]"

Editor Responses (cont'd)

- "In the past we've had discussion about, you know, requiring it at initial submission and holding it back if they don't have it at initial submission, but we've decided to keep it the way things are....it would be seen as too onerous"
- "Our instructions to authors does ask them to include a completed CONSORT checklist with the submitted manuscript....They [peer reviewers] would not see it... it slows down the review process"

Summary of Author Responses

- Non-authors (research associates or administrative assistants) submit manuscripts to journals, including completion of CONSORT
 - Journal submission is often first encounter with CONSORT
- Authors didn't recall or know how journals required its use or how its use was enforced
 - Not reading instructiosn to authors
 - Ambiguity and inconsistencies across journals

Which intervention components could overcome the modifiable barriers?

- Scheduled consequences
- Reward and threat
- Repetition and substitution
- Antecedents
- Associations
- Covert learning
- Natural consequences

- Health consequences
- Feedback and monitoring
- Goals and planning
- Social support
- Comparison of behaviour
- Self belief
- Comparison of outcomes
- Identity
- Shaping knowledge
- Regulation

Mapping behavior domains to appropriate interventions

Behaviour change technique	Social/ Professional role & identity	Knowledge	Skills	Beliefs about capabilities	Beliefs about consequences	Motivati on and goals	Memory, attention, decision processes	Environme ntal context and resources	Social influen
Goal/target specified:									
Monitoring									
Self-monitoring									
Contract									
Rewards;									
Graded task,									
Increasing skills:									
Stress management									
Coping skills									
Rehearsal of relevant skills									

agree use; agree don't use; disagreement; indefinite

Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From theory to intervention: mapping theoretically derived behavioural determinants to behaviour change techniques. Appl Psychol 2008;57(4):660-680

- Identify endpoints that are sensitive to change
 - Journal and other stakeholder endorsement/adoption of solutions (Preregistration, PROSPERO, PRISMA-P, PRISMA, Registered reports)
 - Registration and reporting quality of SRs (using relevant reporting guideline)

• Identify mediators/gatekeepers of behaviour

• i.e. policies from journals or funders

• Implement and study the effectiveness of strategies (e.g. randomized controlled trial, interrupted time series, before-after control study, stepped-wedge)

PRISMA-P Stakeholder table

Stakeholder	Proposed Action	Potential Benefits
Funders	Promote or mandate adherence to PRISMA-P or use PRISMA-P as a template for systematic review proposals for grant applications	Improved quality, completeness, and consistency of systematic review proposal submissions
		Standardized protocol content will improve peer review efficiency and investigator understanding of requirements
Systematic Reviewers/groups/organizations	Use/adhere to PRISMA-P during protocol development	Improved quality, completeness, and consistency of protocol content
		Enables reviewers to anticipate and avoid future changes to review methods (i.e. outcomes)
		Increased awareness of minimum content for protocol reporting
		Improved completeness of reporting of completed reviews
PROSPERO (and other review registries)	Encourage the development of PRISMA- P-based protocols	Improved quality of registry entries
		Improved consistency across registry entries, protocols, and systematic reviews
Practice Guideline Developers	Use PRISMA-P to gauge the completeness of protocols and facilitate detection of selective reporting when considering reviews for guideline	Enables easy comparison across protocols, registry entries, and completed systematic reviews

Stakeholder	Proposed Actions	Proposed benefits
Policymakers	Advocate use of PRISMA-P by those funding and carrying out systematic reviews	May yield better quality, more complete, and more consistent reviews to inform decision-making
Journal editors	Encourage compliance to PRISMA-P for authors submitting protocols for publication	Improved quality, completeness, and consistency of protocols over those published in journals not endorsing PRISMA-P
	Offer PRISMA-P as a template to assist in protocol writing for publication	Increased efficiency in protocol peer and author understanding of journal requirements
		Improved transparency, and interpretation of reviews by readers
Educators	Use PRISMA-P as a training tool Encourage adherence in students submitting protocols for coursework	Simplified teaching and grading of protocols
		Improved quality, completeness, and consistency of protocol content
Students	Develop protocols for coursework or research using PRISMA-P	Improved understanding of the minimum protocol content
		Well-trained systematic reviewer going into the workforce

Editors cannot fix reporting alone Upstream incentives can eliminate downstream barriers

Editorial Interventions

Different purposes:

- To improve peer review (e.g., recruitment, quality of review, time spent)
- To improve manuscript quality (e.g., adherence to standards, reporting transparency)
- To improve author experience (e.g., increase submissions, facilitate submission process)
- Others

Evaluating editorial interventions

RESEARCH ARTICLE

Designs of trials assessing interventions to improve the peer review process: a vignette-based survey

Amytis Heim^{1,2}, Philippe Ravaud^{1,2,3}, Gabriel Baron^{1,2,3} and Isabelle Boutron^{1,2,3*}

Abstract

Background: We aimed to determine the best study designs for assessing interventions to improve the peer review process according to experts' opinions. Furthermore, for interventions previously evaluated, we determined whether the study designs actually used were rated as the best study designs.

Methods: Study design: A series of six vignette-based surveys exploring the best study designs for six different interventions (training peer reviewers, adding an expert to the peer review process, use of reporting guidelines checklists, blinding peer reviewers to the results (i.e., results-free peer review), giving incentives to peer reviewers.

Heim et al. BMC Medicine (2018) 16:191 https://doi.org/10.1186/s12916-018-1167-7

Fig. 1 Interventions for peer review identified and classified. Interventions selected to be explored in the vignette-based survey are highlighted in a white box

Designs supported by expert methodologists

	Training peer reviewers (24 vignettes, 276 pairs)	Adding an expert to the peer review process (10 vignettes, 90 pairs*)	Use of reporting guidelines checklist (13 vignettes, 156 pairs*)	Results free peer review (24 vignettes, 276 pairs)	Using incentives (13 vignettes, 156 pairs*)	Post-publication peer review (10 vignettes, 90 pairs*)
	Estimate [95% Cl]	Estimate [95% CI]	Estimate [95% CI]	Estimate [95% CI]	Estimate [95% Cl]	Estimate [95% CI]
Study type						
RCT with randomization of manuscripts	0.92 [-0.50 ; 2.41]	2.03 [0.51 ; 3.49]	2.69 [1.39 ; 3.95]	2.53 [1.27 ; 3.76]	1.00 [-0.21 ; 2.16]	2.55 [1.13 ; 4.09]
RCT with randomization of peer reviewers	1.45 [0.14 ; 2.78]	N/A	1.99 [0.69 ; 3.37]	2.24 [0.98 ; 3.50]	2.25 [0.94 ; 3.49]	N/A
Cluster RCT with randomization of journals	0.30 [-1.12 ; 1.63]	0.76 [-0.90 ; 2.43]	0.34 [-1.25 ; 1.93]	0.63 [-0.56 ; 1.88]	-0.16 [-1.49 ; 1.18]	1.73 [0.13 ; 3.51]
Interrupted time series analysis	-0.10 [-1.48 ; 1.38]	-0.19 [-1.74; 1.39]	0.10 [-1.21 ; 1.44]	0.07 [-1.28 ; 1.40]	0.73 [-0.51 ; 2.02]	1.58 [0.13; 3.15]
Pairwise comparison	0.83 [-0.49 ; 2.18]	N/A	N/A	1.61 [0.35 ; 2.86]	N/A	N/A
Stepped wedge cluster RCT with randomization of iournals***	0.00 [-]	0.00 [-]	0.00 [-]	0.00 [-]	0.00 [-]	0.00 [-]

Interventions supported expert methodologists

Table 5 Ranking of the study designs of the RCTs identified in the methodological review of interventions to improve the peer review process according experts

	Studies	identified	Ranking according to experts*				
	No. of studies	Study type	Setting	Type of manuscript	Preference	Trust	Feasibility
Training	6	 - 5 randomized controlled trial of peer reviewers - 1 cross-sectional study 	Single journal	 Real manuscripts 1 RCT with fabricated manuscript 	8/24 (4 RCTs) 21/24 (1 RCT)	11/24 (4 RCTs) 22/24 (1 RCT)	9/24 (4 RCTs) 6/24 (1 RCT)
Use of reporting guidelines checklist	2	Randomized controlled trial of manuscripts	Single journal	Real manuscripts	5/13	5/13	2/13
Adding an expert	2	Randomized controlled trial of manuscripts	Single journal	Real manuscripts	8/10	8/10	1/10

*The cross-sectional design was not included in the vignette study

Heim et al. BMC Medicine (2018) 16:191 https://doi.org/10.1186/s12916-018-1167-7

Table 6 Notable characteristics of the preferred designs for each intervention							
Intervention	Comments on the best study design according to experts						
Training intervention	The design recommended by the experts was an RCT with randomization of peer reviewers, set in several biomedical journals from different publishers, using actual manuscripts submitted to the journal. The choice of an RCT with randomization of peer reviewers has the advantage of being close to the real-life procedures of the peer review process, with the benefit of using randomization. The issue with the training intervention is its length in time. This raises issues related to poor adherence and missing outcome when peer reviewers randomized never assess a manuscript. The pairwise comparison was the second-ranked design. This design has the advantage of addressing the issue of manuscript variability, thus increasing statistical power, and avoiding the loss to follow-up problem, because no long-term follow up is needed. Such design has never been used to our knowledge. The duster RCT and stepped wedge duster RCT were not often chosen by the participants because of the risk of contamination, because peers can review for more than one journal at a time.						
Addition of an expert (methodologist or statistician)	The addition of an expert to the peer review process was preferably assessed with an RCT of manuscripts, set in several journals from different publishers, using the actual manuscripts submitted to the journal. The cluster RCT was the second preferred design for all three of the outcomes. This design has the advantage of including a large variety of reviewers and manuscripts, and it is logistically easy for the editors who do not have to change process for each manuscript. It is nevertheless a difficult design to put in place, as shown by its systematically low score in the feasibility rankings, and a very large number of clusters would be needed to compensate for the high variability between journals (publisher, editorial policies, subject area, quality of reviewers etc.). The interrupted time series set in a single journal was the preferred design in terms of feasibility. This study type is not randomized, which could potentially create bias.						
Use of reporting guidelines checklist	The favored designs to assess the use of reporting guidelines checklist was an RCT of manuscripts, set in several biomedical journals from several or a single publisher, using actual manuscripts. The choice to randomize manuscripts rather than peer reviewers is interesting in terms of logistics, because manuscripts receiving the intervention can be						

Peer Review Interventions

RESEARCH ARTICLE

Impact of interventions to improve the quality of peer review of biomedical journals: a systematic review and meta-analysis

Rachel Bruce^{1,2,3†}, Anthony Chauvin^{2,3,4†}, Ludovic Trinquart^{2,3,5}, Philippe Ravaud^{1,2,3,5} and Isabelle Boutron^{2,3,5*}

Abstract

Background: The peer review process is a cornerstone of biomedical research. We aimed to evaluate the impact of interventions to improve the quality of peer review for biomedical publications.

Methods: We performed a systematic review and meta-analysis. We searched CENTRAL, MEDLINE (PubMed), Embase, Cochrane Database of Systematic Reviews, and WHO ICTRP databases, for all randomized controlled trials

> Bruce et al. BMC Medicine (2016) 14:85 DOI 10.1186/s12916-016-0631-5

Use of statistical reviewer

	Statistical	peer rev	view	Usua	l proce	SS	:	Std. Mean Difference	Std. Mean Difference	Risk of Blas
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl	ABCD
Arnau 2003	4.41	3.3	17	3.06	2.55	26	40.6%	0.46 [-0.16, 1.08]		
Cobo 2007	9.26	7.3	30	4.87	5.7	32	59.4%	0.66 [0.15, 1.18]		••?•
Total (95% CI)			47			58	100.0%	0.58 [0.19, 0.98]	•	
Heterogeneity: Tau ² =	0.00; Chi ² = 0	.24, df =	1 (P = 0).62); I ^z :	= 0%			-	-1 -0.5 0 0.5 1	

Risk of bias legend

(A) Random sequence generation (selection bias)

(B) Allocation concealment (selection bias)

(C) Blinding of outcome assessment (detection bias)

(D) Incomplete outcome data (attrition bias)

Fig. 3 Impact of adding a statistical peer review versus usual process: standardized mean difference (SMD) of the final manuscript quality

Statistical Reviewers Improve Reporting in Biomedical Articles: A Randomized Trial

Erik Cobo 🔟, Albert Selva-O'Callagham, Josep-Maria Ribera, Francesc Cardellach, Ruth Dominguez, Miquel Vilardell

Published: March 28, 2007 • https://doi.org/10.1371/journal.pone.0000332

Article	Authors	Metrics	Comments	Media Coverage						
*										
Abstract	Abstract									
Introduction	Background	Background								
Methods	2									
Results	Although peer re and improving th	Although peer review is widely considered to be the most credible way of selecting manuscripts and improving the quality of accepted papers in scientific journals, there is little evidence to support its use. Our aim was to estimate the effects on manuscript quality of either adding a								
Discussion	support its use.									
Supporting Information	statistical peer re clinical reviewers	eviewer or suggesting the us or both.	use of checklists such as C	ONSORT or STARD to						
	chilled feviewers	or boun.								

2x2 factorial design

E.g. Author-targeted writing tool

The writing tool prompted the writer to describe both the experimental and then control intervention separately. Below is an example of the writing aid for describing the experimental intervention for non pharmacological behavioral based interventions.

Interventions

The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

Please provide a detailed explanation of the experimental intervention, including:

- The type of intervention (rehabilitation, behavioral treatment, education, psychotherapy or other)
- The content of each session and the content of the information exchanged with participants
- · If the intervention was delivered to an individual or a group
- · Whether the treatment was supervised
- Any instruments used to provide information (computers, tablets, smartphones, other)
- The number and timing of sessions
- The duration of each session, and overall duration of the intervention
- Any procedures for tailoring the interventions to individual participants (to patients comorbid conditions, tolerance, clinical course, other)
- Any permitted or restricted co-interventions

The mean (SD) global score for completeness of reporting was higher with than without writing tool: mean difference (95 % Cl): 2.1 (1.5–2.7; P <0.01).

Legislation on registration

- Funders and journals can require registration
 - E.g. UK NIHR

All NIHR-funded projects that include a systematic review as part of their protocol (even if embedded within a trial) are required to register their protocols on the PROSPERO database (an international database of prospectively registered systematic reviews in health and social care). Registration advice is provided in the documentation supplied by your programme as part of the application, contracting and start-up processes.

• Journals

5

• E.g., protocols

Registration 2 If registered, provide the name of the registry (e.g., PROSPERO) and registration number

• E.g., complete SRs

Protocol and registration

Indicate if a review protocol exists, if and where it can be accessed (such as web address), and, if available, provide registration information including registration number

e.g., Clinical Trials

Annual numbers of registered clinical trials on the International Clinical Trials Registry Platform (ICTRP) and annual numbers of publications about clinical trials on PubMed from 1998 to 2013.

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Roderik F Viergever, and Keyang Li BMJ Open 2015;5:e008932

Meeting Outputs

- Collaborative paper
- What else?

Develop a systematic, purposeful implementation plan to improve reproducibility of SRs?

- Highest impact journals in field
- Funders
- Largest government/Regulators
- Academic institutions
- Societies
- What

How

Measuri

ng change

Who

- What are the barriers? What could help?
- Carry out surveys followed by interviews across relevant stakeholder groups
- Identify key behaviour domains
- What actions/interventions are appropriate?
- Match behaviour domains to agreed on intervention
- How should we evaluate/test what works?
 system of evaluation & monitoring for adherence/compliance to standards
 Automation (Statreviewer)