

MISRep: Managing the Incidence of Selective Reporting Bias - Survey of the Cochrane Collaboration

Emma Reid, B.Sc.(Pharm); Aaron M Tejani, B.Sc.(Pharm), PharmD; L. Nichoe Huan, B.Sc.(Pharm), ACPR; Gregory Egan, B.Sc.(Pharm), ACPR, PharmD; Cait O'Sullivan, B.A., B.Sc.(Pharm), PharmD; Kendra Lawrence, BSN

Background

- **Selective reporting bias (SRB):** Incomplete publication of original trial analyses, including outcome data
 - Impacts up to 62% of randomized controlled trials (RCTs), affecting systematic reviews & meta-analyses
 - Misrepresentation of treatment efficacy and harms in literature, widely influencing clinical decisions
- **Cochrane Collaboration:** Cochrane Handbook outlines *recommendations* for assessing SRB in trials as a component of the Cochrane Risk of Bias Tool
 - Expectations and verification process by Cochrane review groups (CRGs) may vary

Objectives

- To determine the methodology CRG editors and authors use to perform and verify assessments of SRB in their systematic reviews (SRs)
- To propose strategies to eliminate SRB from Cochrane reviews

Methods

- 21-question survey tool developed using FluidSurveys®

- Questions in 7 themes:

1	Instruction provided to authors
2	SRB considerations in SR protocol
3	Assessment of SRB within the RCTs in SR
4	Assessment of SRB on SR level
5	Assessment of risk of SRB in SR updates
6	Importance of SRB to review authors
7	General

- Distributed electronically, December 2013-March 2014
- All 52 CRGs publishing systematic reviews of clinical interventions
 - Contacts: Coordinating Editor(s) and Managing Editor(s)
 - Consultation among group members encouraged; one response per CRG

Results

CRGs that responded to survey	81% (42/52)
CRGs that refer their authors to the Cochrane Handbook for instruction	86% (36/42)

Predominant Survey Themes

Completeness of SRB Assessments

- 14% of CRGs require their review authors to create a **matrix of trial outcomes**
- 57% of CRGs **do not** require their review authors to seek out **trial protocols**
- 31% of CRGs **do not** require their review authors to **contact trial authors**

Appreciation for Implications

- 45% of CRGs require review authors to **incorporate the SRB assessment** into the **Results/Discussion** section of systematic review

Capability versus Responsibility

24% of CRGs consider their authors to be **moderately or largely capable** of SRB assessments → 48% of CRGs **always verify SRB assessments** before publication

Re protocol searching:
“...need to assess trade-offs with other tasks - authors already find Cochrane reviews too much work - so need to give up something else if we do this”

Re author contact:
“Most of the time it is a useless effort”

“[Yes] If bias is identified, not if no bias is identified”

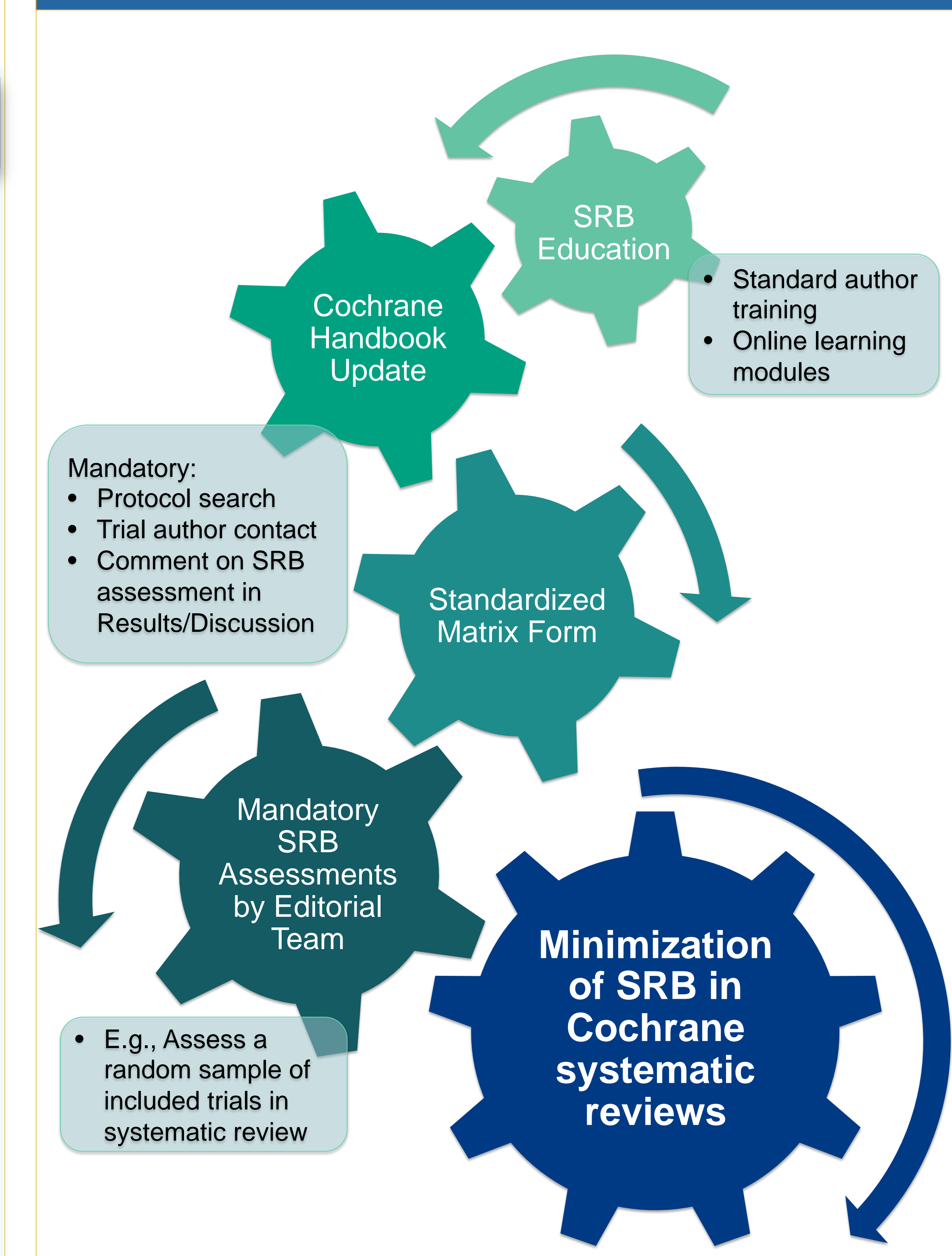
“We recently had a review which said 'low risk of bias' for every selective outcome reporting domain by study and the support for the judgment said 'All important outcomes were reported', but there was no indication that the study protocol had been sought.”

Fig. 2: Proposed Cochrane Standardized Matrix Form

Trial ID	Outcomes of Interest				Protocol	Trial author contact	Contact record	
	A	B	C	Other			Date	
Jones, 2014	✓	✓	✓		<input checked="" type="checkbox"/> Retrieved <input type="checkbox"/> Information from trials registry <input type="checkbox"/> Not retrieved	<input type="checkbox"/> Contacted <input type="checkbox"/> Additional outcome data <input type="checkbox"/> No additional data <input type="checkbox"/> Attempted, no response <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Email <input type="checkbox"/> Phone	
Wong, 2011	○	✓	✓	Outcome D	<input checked="" type="checkbox"/> Retrieved <input type="checkbox"/> Information from trials registry <input type="checkbox"/> Not retrieved	<input checked="" type="checkbox"/> Contacted <input checked="" type="checkbox"/> Additional outcome data <input type="checkbox"/> No additional data <input type="checkbox"/> Attempted, no response <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Email <input type="checkbox"/> Phone	Sept 14, 2013
Simpson, 2004	✓	✗	○		<input type="checkbox"/> Retrieved <input type="checkbox"/> Information from trials registry <input checked="" type="checkbox"/> Not retrieved	<input type="checkbox"/> Contacted <input type="checkbox"/> Additional outcome data <input type="checkbox"/> No additional data <input checked="" type="checkbox"/> Attempted, no response <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Email <input type="checkbox"/> Phone <input type="checkbox"/> N/A	Sept 14, 2013 Sept 28, 2013 Oct 7, 2013

Reporting of outcome:
 ✓ Full
 ✗ No
 ○ Partial

Fig. 1: Proposed Approach to SRB Minimization in Cochrane Reviews



Conclusions

- Recommendations in Cochrane Handbook for assessing SRB are variably enforced by CRGs
- Implications of SRB are inadequately incorporated into the results of systematic reviews
- The majority of CRGs do not consider their review authors sufficiently competent to assess for SRB yet risk of bias assessments are not consistently verified by editors before publication
- Incorporating a multi-faceted SRB minimization approach would help resolve identified issues