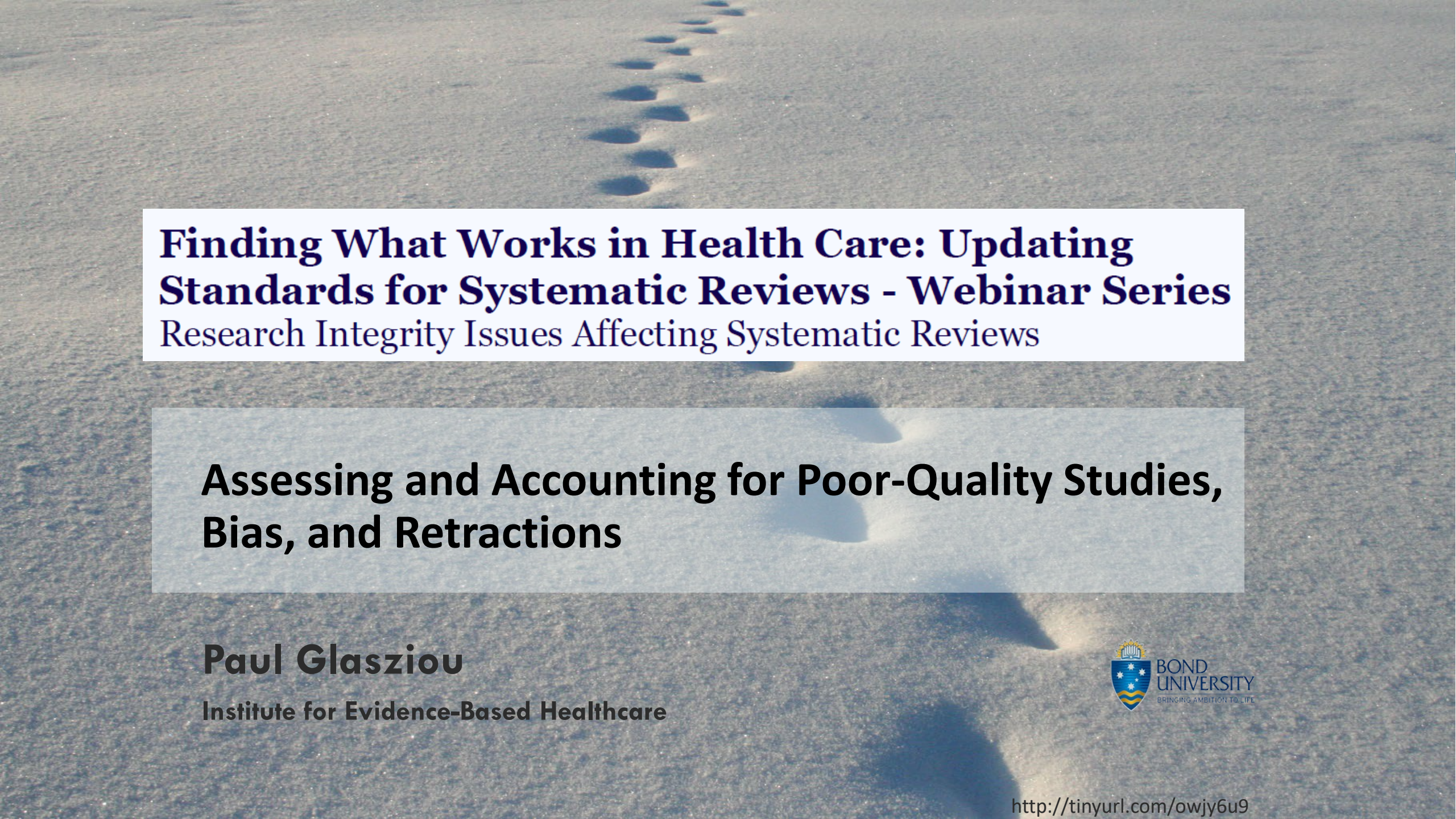


Finding What Works in Health Care: Updating Standards for Systematic Reviews - Webinar Series

Research Integrity Issues Affecting Systematic Reviews

Assessing and Accounting for Poor-Quality Studies, Bias, and Retractions

Paul Glasziou

Institute for Evidence-Based Healthcare

BOND UNIVERSITY
BRINGING AMBITION TO LIFE

http://tinyurl.com/owjy6u9

Summary

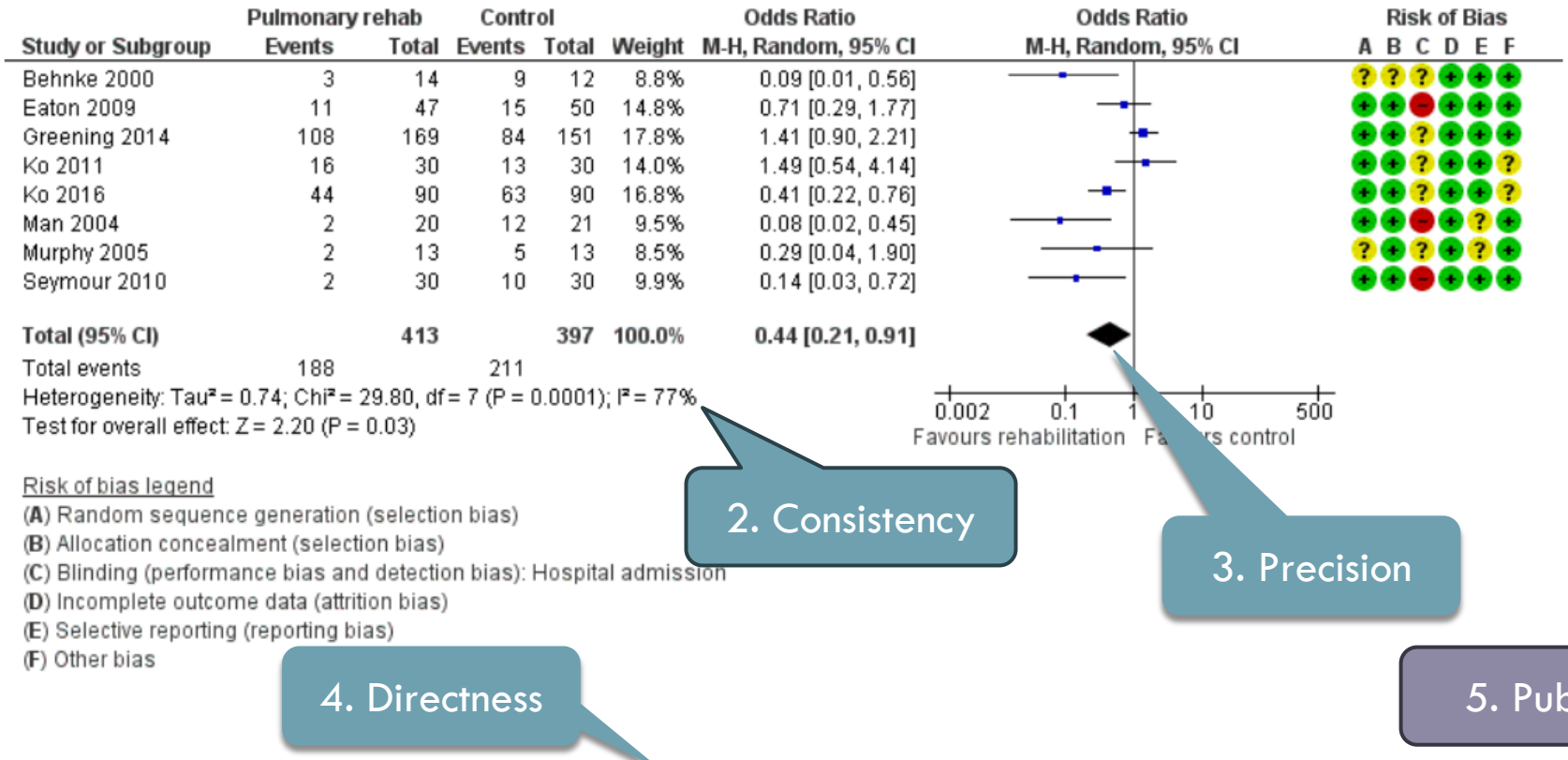
1. Use simplified RoB assessment: ROBUST-RCT
2. Search and Report on registered studies +/- subgroup analysis
3. Automation tools for flagging of possibly fraudulent studies
4. Automation for better (abstract) communication, eg PRISMA4Abstracts

GRADE: Quality of Evidence – Is bias < effect size?

Cochrane Database of Systematic Reviews | Review - Intervention

Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease

Milo A Puhan, Elena Gimeno-Santos, Christopher J Cates, Thierry Troosters Authors' declarations of interest



Study or Subgroup	Pulmonary rehab Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Behnke 2000	3	14	9	12	8.8%	0.09 [0.01, 0.56]
Eaton 2009	11	47	15	50	14.8%	0.71 [0.29, 1.77]
Greening 2014	108	169	84	151	17.8%	1.41 [0.90, 2.21]
Ko 2011	16	30	13	30	14.0%	1.49 [0.54, 4.14]
Ko 2016	44	90	63	90	16.8%	0.41 [0.22, 0.76]
Man 2004	2	20	12	21	9.5%	0.08 [0.02, 0.45]
Murphy 2005	2	13	5	13	8.5%	0.29 [0.04, 1.90]
Seymour 2010	2	30	10	30	9.9%	0.14 [0.03, 0.72]
Total (95% CI)		**413**		**397**	**100.0%**	**0.44 [0.21, 0.91]**
Total events	188		211			

Heterogeneity: Tau² = 0.74; Chi² = 29.80, df = 7 (P = 0.0001); I² = 77%
Test for overall effect: Z = 2.20 (P = 0.03)

Odds Ratio M-H, Random, 95% CI

0.002 0.1 1 10 500
Favours rehabilitation Favours control

Risk of Bias A B C D E F

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias): Hospital admission
(D) Incomplete outcome data (attrition bias)
(E) Selective reporting (reporting bias)
(F) Other bias

1. Risk of Bias

2. Consistency

3. Precision

4. Directness

5. Publication & Reporting Bias

Figure 3 Forest plot of comparison: 1 Rehabilitation versus control, outcome: 1.1 Hospital readmission (to end of follow-up).

Development of ROBUST-RCT: Risk Of Bias instrument for Use in SysTematic reviews-for Randomised Controlled Trials

1. Risk of Bias

Ying Wang,[1,2] Sheri Keitz,[3] Matthias Briel,[2,4] Paul Glasziou,[5] Romina Brignardello-Petersen,[2] Reed A C Siemieniuk,[2] Dena Zeraatkar,[2,6] Elie A Akl,[2,7] Susan Armijo-Olivo,[8,9] Dirk Bassler,[10] Carrol Gamble,[11] Lise Lotte Gluud,[12] Jane Luise Hutton,[13] Luz M Letelier,[14] Philippe Ravaud,[15] Kenneth F Schulz,[16] David J Torgerson,[17] Gordon H Guyatt[2,18,19]

Table 2 | ROBUST-RCT core items and two step approach

Core items and response options	Step 1 Evaluate what happened
Core items:	
Item 1 Random sequence generation	Was the allocation sequence adequately generated?
Item 2 Allocation concealment	Was the allocation adequately concealed?
Item 3 Blinding of participants	Were participants blinded?
Item 4 Blinding of healthcare providers	Were healthcare providers blinded?
Item 5 Blinding of outcome assessors	Were outcome assessors blinded?
Item 6 Outcome data not included in analysis	Extract the number of participants who were not included in analysis in each group
Response options	Definitely yes, probably yes, probably no, definitely no (except for item 6)

ROBUST-RCT=Risk Of Bias instrument for Use in SysTematic reviews-for Randomised Controlled Trials.

<= Intention-to-Treat "omitted"

(RAMbo – Randomized? Attrition? (Outcome) Measurements – blinded OR Objective)

Wang et al. *BMJ* 2025;388:e081199 http://dx.doi.org/10.1136/ bmj-2024-081199

Supported by Wang Y, …, Guyatt GH. Compelling evidence from meta-epidemiological studies demonstrates overestimation of effects in randomized trials that fail to optimize randomization and blind patients and outcome assessors. J Clin Epidemiol. 2024 Jan;165:111211.

Analysis by Registered vs Published Studies

Question: Ovarian Cancer chemotherapy: single v combined

5. Publication Bias

	Published	Registered
No. studies	16	13
Survival ratio	1.16	1.05
95% CI	1.06-1.27	0.98-1.12
P-Value	0.02	0.25

Simes RJ. Publication bias: The case for an international registry of clinical trials. J Clin Oncol. 1986:1529-41

Publication bias: some options

5. Publication Bias

☑ Search and report on registered studies – eg number unpublished

? Do a sub-group analysis of registered versus unregistered studies

X Do only an analysis of registered studies

Standard 3.2 Take action to address potentially biased reporting of research results

Required elements:

3.2.1 Search grey-literature databases, clinical trial registries, and other sources of unpublished information about studies

And report on …

“Problematic” studies

INSPECT-SR –Uses 21 structured checks across four domains:

1. post-publication notices
2. study conduct, governance and transparency
3. text and figures
4. study results

Cochrane

About us | Our evidence | Get involved | Learn | Products and services | For authors

What we do | Who we are | Our impact | Our story | News | Jobs | Events

New tool detects problematic trials before they distort evidence

A new tool has been developed to help researchers detect problematic clinical trials before including them in systematic reviews.

Friday, September 5, 2025 • By Mia Parkinson

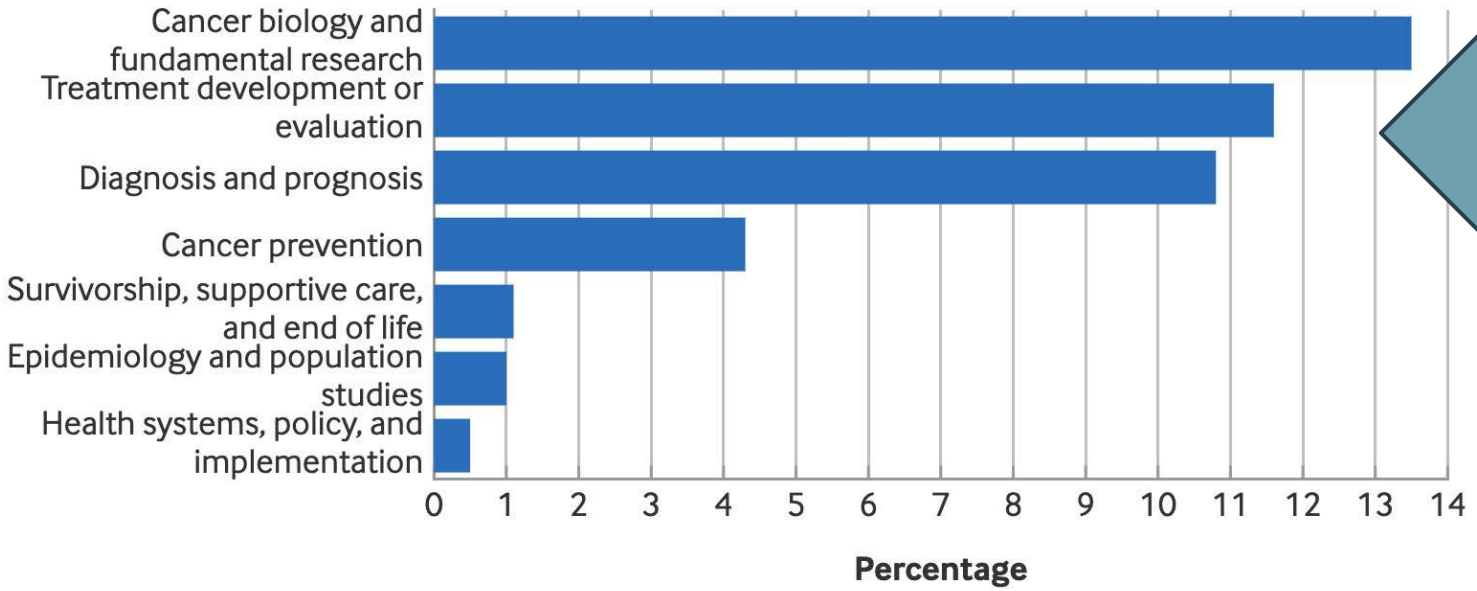
Automated Flagging of potentially fraudulent papers: (Model trained on Retraction Watch).

1. Risk of Bias/Fraud

Percentage of flagged papers within each research area of cancer research corpus*

Research areas determined by AI labelling. Each paper could be assigned to multiple research areas

*Flagged papers are textually similar to retracted paper mill papers



11% FLAGGED
= higher than other estimates

Article DOI: 10.1136/bmj-2025-087581 • Download data

Baptiste Scancar et al. BMJ 2026;392:bmj-2025-087581

Make Abstracts interpretable (eg direction & size of effects)

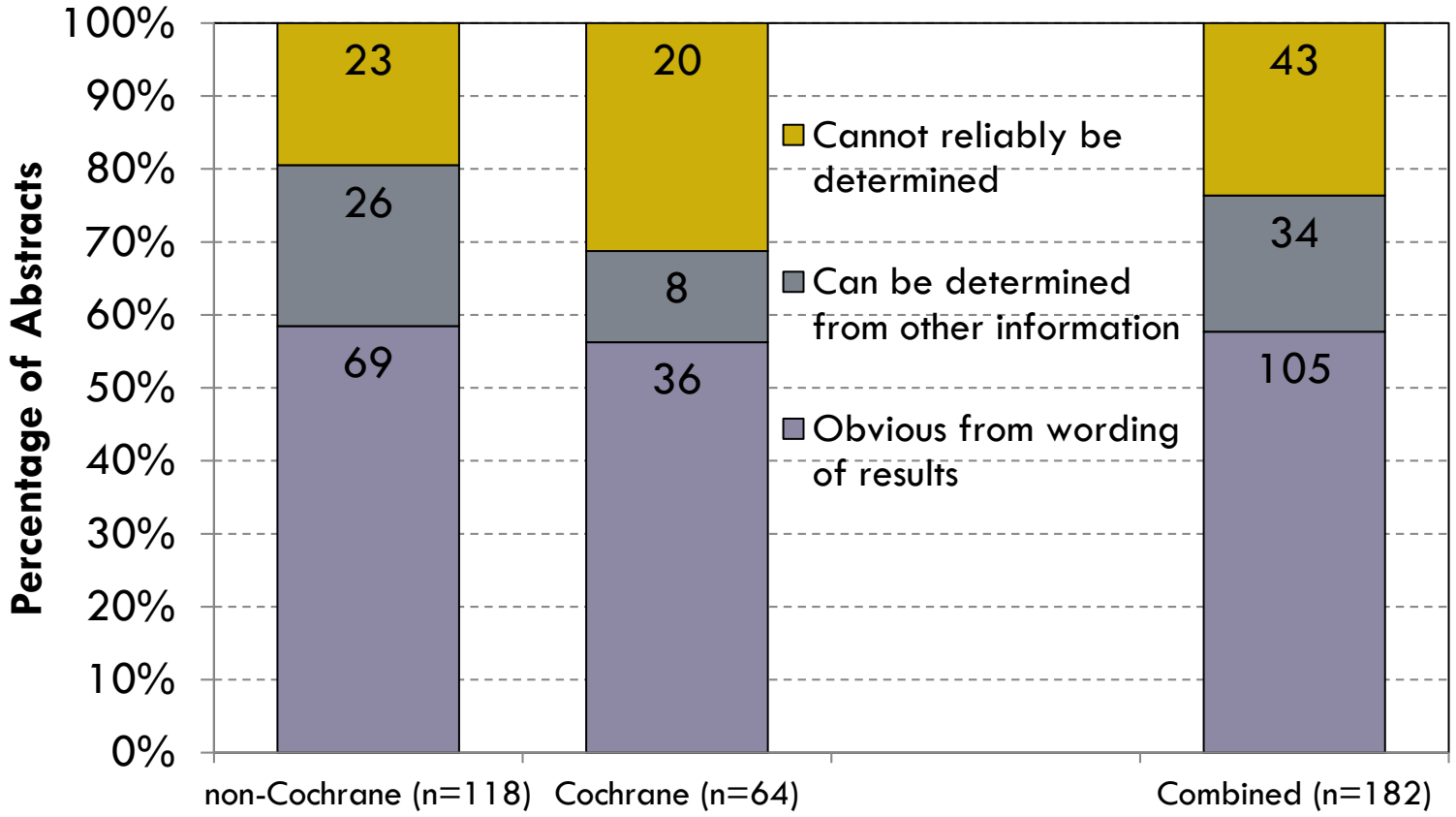
Interpreting Cochrane systematic reviews: can we do without authors' conclusions?

Nai Ming Lai[1], Cheong Lieng Teng[2], Cheong Wooi Cheah[1], Ming Lee Lee[3]

[1]*Department of Paediatrics, International Medical University, Malaysia;*

"Overall, 62% correctly identified the direction of effect"

Poor reporting of effect direction in abstracts

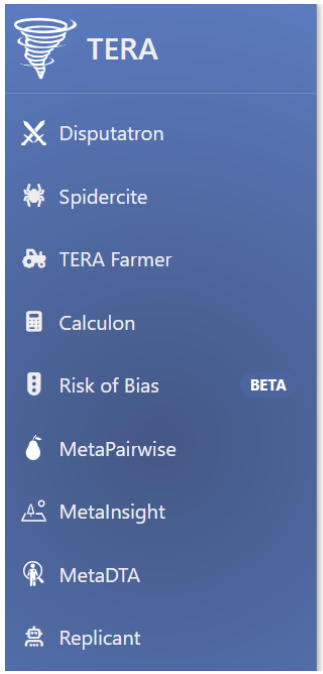


Beller EM, Glasziou PP, Hopewell S, Altman DG. Reporting of effect direction and size in abstracts of systematic reviews. *JAMA* 2011.

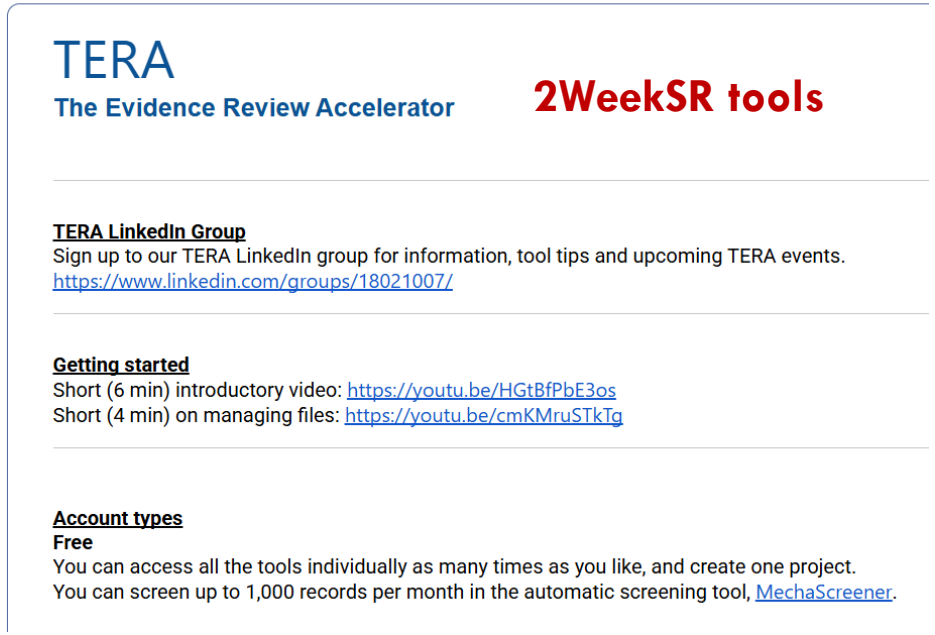
RevMan HAL: Computer-assisted writing

http://szg.cochrane.org/revman-hal

- Writes draft of the "Effects of intervention" section of a review automatically using the rm5 file.
- Combines pre-formed template sentence with results (NOT AI)



RevmanHal



https://tera-tools.com/

Summary

1. Use simplified RoB assessment: ROBUST-RCT

> uncertainty
> 4.4.4 Assess the sensitivity of conclusions to changes in the protocol, assumptions, and study selection (sensitivity analysis)

2. Search and Report on registered studies +/- subgroup analysis

> **Standard 3.2 Take action to address potentially biased reporting of research results**
> Required elements:
> 3.2.1 Search grey-literature databases, clinical trial registries, and other sources of unpublished information about studies

3. Automation tools for flagging of possibly fraudulent studies
   - New Item – minimum check RetractionWatch
4. Automation for better (abstract) communication, eg PRISMA4Abstracts