

# Systematic reviews and retractions

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### NASEM panel

Lisa Bero, PhD  
Professor, Medicine and Public Health  
Chief Scientist, Center for Bioethics and Humanities  
[lisa.bero@cuanschutz.edu](mailto:lisa.bero@cuanschutz.edu)

Senior Research Integrity Editor, Cochrane



University of Colorado  
Anschutz Medical Campus

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Trusted evidence.  
Informed decisions.  
Better health.

Title Abstract Keyword

Browse

Advanced search

Journal for trials

Clinical Answers

About

Help

About Cochrane

Cochrane Handbook for

Systematic Reviews



Trusted evidence.  
Informed decisions.  
Better health.

Cochrane Database of Systematic Reviews

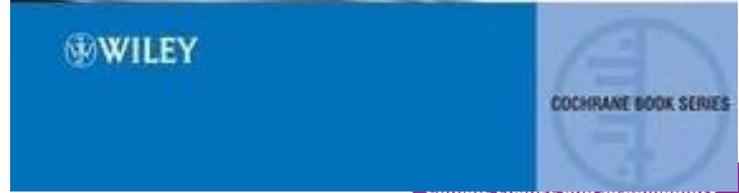
EDITORIAL

# When beauty is but skin deep: dealing with problematic studies in systematic reviews

Stephanie L Boughton, Jack Wilkinson, Lisa Bero

Study or Subgroup	Events	Total	Events	Total	Weight
Abrahamson 1997	2	49	12	38	2
Black 1997	36	532	40	538	48.1
Chen 1999	1	81	11	81	3.21
Chen 1999	14	81	20	107	16.47
Springer 1979	3	121	7	75	3.15
Wu 1979	1	71	1	71	0.47
Wu 1979	8	98	10	71	8.47
Total	70	1007	102	1007	100.0%

OR, Chi<sup>2</sup> = 8.20, df = 7, P = 0.29, I<sup>2</sup> = 24%  
 Hetero: I<sup>2</sup> = 4.50, P = 0.0001



Infectious diseases



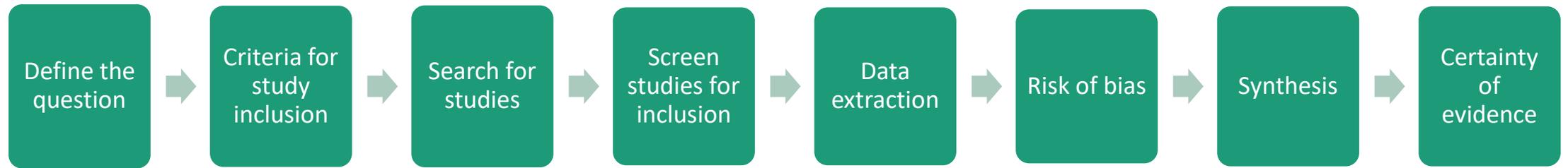
Maternal, newborn and child health



Multiple chronic conditions



# Steps in a Cochrane review



Protocols required since 1998

Published online only

Updating required

# Conducting a review

## Policy

- Identify retraction and expressions of concern
- DO NOT include retracted studies in the review

## Implementation challenge

### Identifying retractions

- Guidance in Cochrane Handbook, Problematic studies implementation guide, Retracted studies implementation guide. technological solutions

# What happens when a paper is retracted AFTER a Cochrane review is published?

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- Editorial note
- Update review
- Retract review

**COPE Guidance:** editors should retract a systematic review publication if they no longer have confidence in the results and conclusions due to retracted or corrected included studies.



# Decision Flowchart

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Is the study/studies with an associated retraction an included study?

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Do any other included studies have an associated retraction (or Expression of Concern)?

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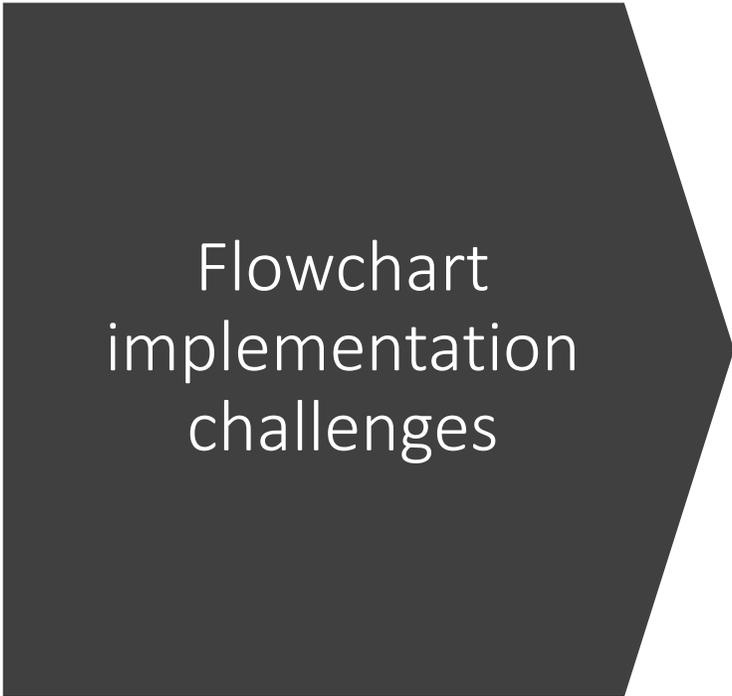
What is the scale of contribution of the study/studies with an associated retraction?

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Is the study/studies with an associated retraction included in quantitative analysis? Which ones? Qualitative analysis? Redo analysis. Effect on results?

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Redo certainty of the evidence assessment without the study/studies with an associated retraction. Effect on Certainty?



Flowchart  
implementation  
challenges

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Author resources and willingness to apply framework –  
Cochrane does not publish updates without a new search or  
using outdated methods

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Does not distinguish between reasons for retractions

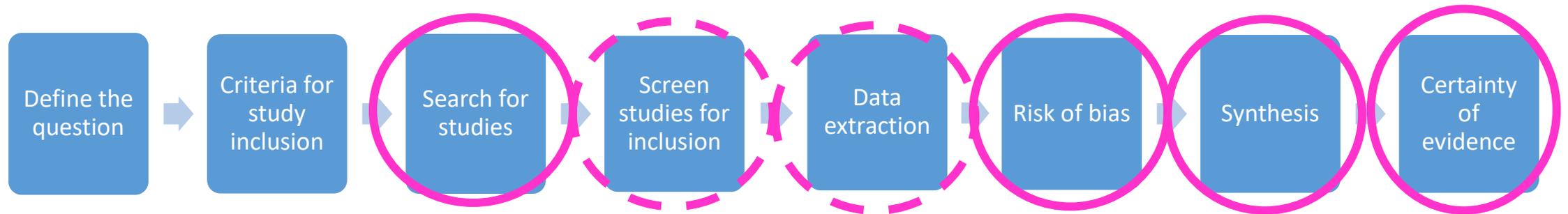
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Specific thresholds will be contested [proportion of retracted  
data contributing to analysis, “confidence changing” effect  
estimates (*direction, magnitude, certainty?*), qualitative  
synthesis, GRADE?]

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Developing way to publish editorial notes as citable items

# When a retracted study is detected after review is published...

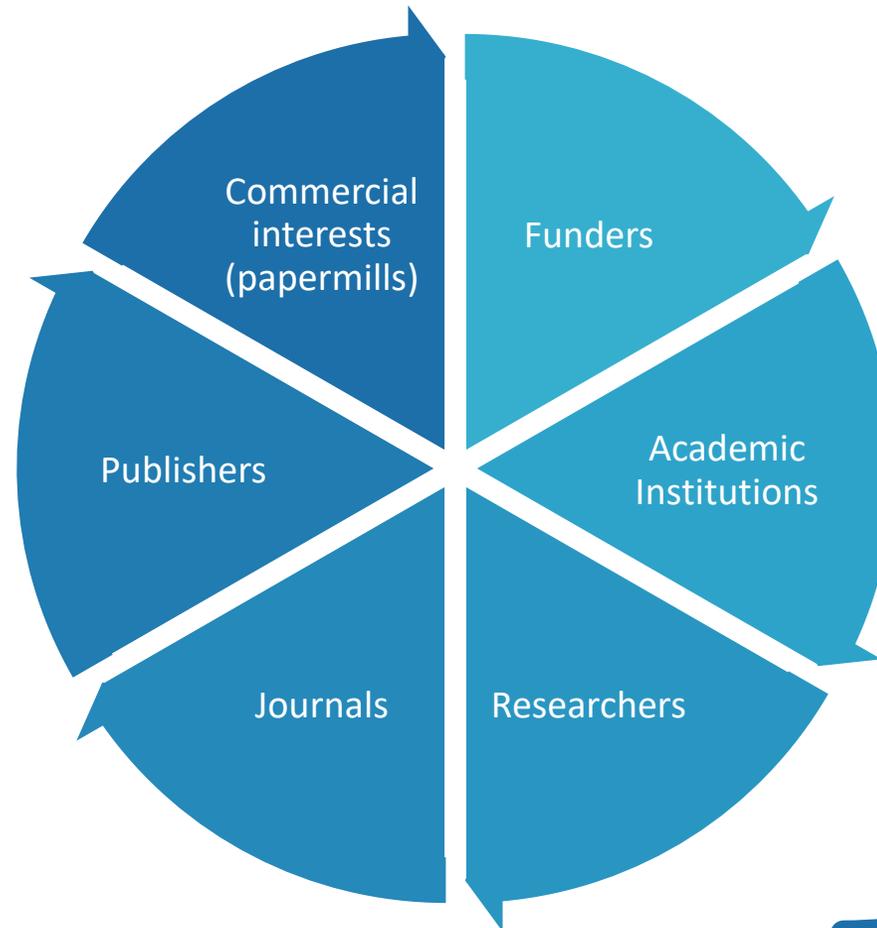


# What is the real problem? Defining a problematic study

- **“Any published or unpublished study where there are serious questions about the trustworthiness of the data or findings, regardless of whether the study has been formally retracted” (Cochrane)**
- Does not consider intent
- Focus is on problematic studies, not researchers
- Includes different manifestations of problematic studies, including fabrication, falsification, image manipulation, research misconduct, ethics misconduct, detrimental or questionable research practices, plagiarism, duplicate publication and author misconduct

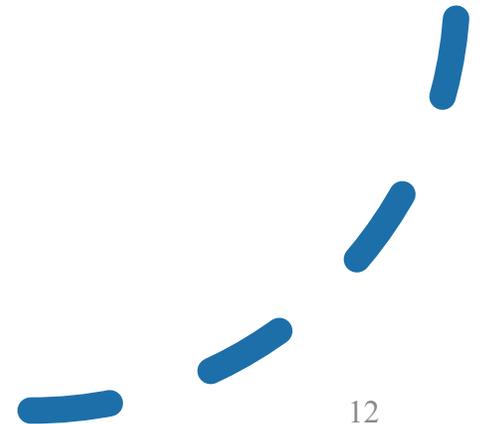
Whose  
problem is  
it?

- It's everybody's problem
- Prevention is the solution ..But.. In the meantime, the literature is populated with problematic studies



# Role of Systematic Reviewers

- Look across an entire body of evidence
- Have the resources to apply research integrity assessment tools
- “Signaling” problematic studies can improve the literature



## How do we identify problematic studies?



*“When we discovered those two [fraudulent papers] ...it just opened up the whole can of worms, because it was the first time I allowed myself to think that somebody might actually make up data.” [P27, researcher]*

Parker L, Boughton S, Lawrence R, Bero L.  
*J Clin Epidemiol.* 151:1-17; 2022



INveStigating ProblEmatic Clinical Trials in Systematic Reviews



Open access

Protocol

# BMJ Open Protocol for the development of a tool (INSPECT-SR) to identify problematic randomised controlled trials in systematic reviews of health interventions

Jack Wilkinson ,<sup>1</sup> Calvin Heal,<sup>1</sup> George A Antoniou,<sup>2,3</sup> Ella Fleming,<sup>4</sup> Zarko Alfirevic,<sup>5</sup> Alison Avenell ,<sup>6</sup> Ginny Barbour,<sup>7</sup> Nicholas J L Brown,<sup>8</sup> John Carlisle,<sup>9</sup> Mike Clarke ,<sup>10</sup> Patrick Dicker,<sup>11</sup> Jo C Dumville,<sup>12,13</sup> Andrew Grey ,<sup>14</sup> Steph Grohmann,<sup>4</sup> Lyle Gurrin,<sup>15</sup> Jill Alison Hayden ,<sup>16,17</sup> James Heathers,<sup>18</sup> Kylie Elizabeth Hunter ,<sup>19</sup> Toby Lasserson,<sup>4</sup> Emily Lam,<sup>20</sup> Sarah Lensen ,<sup>21</sup> Tianjing Li,<sup>22</sup> Wentao Li ,<sup>23</sup> Elizabeth Loder,<sup>24,25</sup> Andreas Lundh,<sup>26,27</sup> Gideon Meyerowitz-Katz,<sup>28</sup> Ben W Mol ,<sup>29</sup> Neil E O'Connell,<sup>30,31</sup> Lisa Parker ,<sup>32</sup> Barbara K Redman,<sup>33</sup> Lene Seidler,<sup>19</sup> Kyle A Sheldrick,<sup>34</sup> Emma Sydenham ,<sup>35</sup> David Torgerson,<sup>36</sup> Madelon van Wely,<sup>37,38</sup> Rui Wang ,<sup>29</sup> Lisa Bero ,<sup>39</sup> Jamie J Kirkham <sup>1</sup>

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LB and JJK are joint senior authors.

## ABSTRACT

**Introduction** Randomised controlled trials (RCTs) inform healthcare decisions. It is now apparent that some published RCTs contain false data and some appear to have been entirely fabricated. Systematic reviews are performed to identify and synthesise all RCTs that have been conducted on a given topic. While it is usual to assess methodological features of the RCTs in the process of undertaking a systematic review, it is not usual to consider whether the RCTs contain false data. Studies containing false data therefore go unnoticed and contribute to systematic review conclusions. The INveStigating ProblEmatic Clinical Trials in Systematic Reviews (INSPECT-SR) project will develop a tool to assess the trustworthiness of RCTs in systematic reviews of healthcare-related interventions.

**Methods and analysis** The INSPECT-SR tool will be developed using expert consensus in combination with

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The tool is being developed using empirical evidence and a large-scale international consensus process.
- ⇒ Key stakeholders will be involved in the development and dissemination of the tool.
- ⇒ There is no gold-standard test for inauthentic studies, and so the tool will not be a diagnostic test for fraud; rather, it will help the researcher to make a judgement about trustworthiness.

that ethical approval was not required for this project (30 September 2022), which incorporates secondary research and surveys of professionals about subjects relating to their expertise. Informed consent will be obtained from all survey participants. All results will be published as open-