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Team considerations, study selection, data extraction, risk of bias assessment

December 12th 2023 Barbara Nussbaumer-Streit

Cochrane Rapid Reviews Methods Group

Cochrane Rapid Review

Definition:

'A type of evidence synthesis that brings together and summarises information from different research studies to produce evidence for people such as the public, healthcare providers, researchers, policymakers, and funders in a systematic, resource-efficient manner. This is done by **speeding up the ways** we **plan**, **do** and/or **share the results** of conventional structured (systematic) reviews, by **simplifying or omitting** a variety of methods that should be **clearly defined** by the authors.'

*Builds upon our original definition endorsed in the interim guidance^{1,2}. Definition has since been modified following the input of patient and public partners as part of a collaborative Priority Setting Partnership on rapid reviews³

1 Garritty C, Gartlehner G, Nussbaumer-Streit B, et al. Cochrane Rapid Reviews Methods Group offers evidence-informed guidance to conduct rapid reviews. J Clin Epidemiol 2021;130:13–22. doi:10.1016/j.jclinepi.2020.10.007

³ Beecher C, Toomey E, Maeso B, et al. Priority III: Top 10 rapid review methodology research priorities identified using a James Lind Alliance Priority Setting Partnership. J Clin Epidemiol 2022;0. doi:10.1016/j.jclinepi.2022.08.002



² Hamel C, Michaud A, Thuku M, et al. Defining Rapid Reviews: a systematic scoping review and thematic analysis of definitions and defining characteristics of rapid reviews. J Clin Epidemiol 2020;0. doi:10.1016/j.jclinepi.2020.09.041

Why focus on these steps?

- Very resource-intensive steps of a review¹
- Error prone and subjective
- In systematic reviews (SR) best practice that two people independently do these steps^{2,3}
- Accelerated methods can increase efficiency but also have negative impact







Recommendations based on

Research methods and reporting

OPEN ACCESS

Rapid reviews methods series: Guidance on team considerations, study selection, data extraction and risk of bias assessment

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Nussbaumer-Streit B, Sommer I, Hamel C On behalf of the Cochrane Rapid Reviews Methods Group, et al. Rapid reviews methods series: Guidance on team considerations, study selection, data extraction and risk of bias assessment *BMJ Evidence-Based Medicine* 2023;28:418-423.



- Updated Cochrane Rapid Reviews Methods Guidance (Garritty et al. submitted to BMJ)
- Interim Guidance: Garritty C, Gartlehner G, Nussbaumer-Streit B, et al. Cochrane Rapid Reviews Methods Group offers evidenceinformed guidance to conduct rapid reviews. J Clin Epidemiol 2021



Team considerations

- Experienced review team
- Team size (ideally 3-5 people) depending on the task
- Use collaborative platforms or SRtailored software
- Parallelisation of tasks
- Do data extraction and RoB assessment by same people in one step
- Direct line of communication







Gartlehner G, Nussbaumer-Streit B. Learning from emergency trauma teams: an organizational approach for conducting (very) rapid reviews. In: Collaborating in response to COVID-19: editorial and methods initiatives across Cochrane. Cochrane Database of Systematic Reviews 2020;(12 Suppl 1):[41-42]. https://doi.org/10.1002/14651858.CD202002



Piloting

Employ a piloting exercise for study selection, data extraction, and risk of bias assessment to allow team members to test this task on a small proportion of records to ensure that all team members perform it consistently and correctly



Allows team to test tools and processes on a small proportion of records



Ensures common understanding and reduces errors



Saves time later in the process



Example study selection form

Example of an Abstract Review Form on Novel Coronavirus and Quarantine (February 2020)

Is the study a research article? Note: We exclude books, letters to the editors, commentaries and editorials.	Yes	No STOP!
Is the study population of interest for the review? Healthy individuals from countries with an epidemic outbreak of nCoV, SARS or MERS Healthy individuals* who were in contact with a confirmed or probable case of nCoV, SARS or MERS 	Yes	No STOP !
*excludes health personnel		
Note: We are not interested in the isolation of sick individuals.		
Does the study assess the effectiveness of quarantine?	Yes	No
Note:		STOP !
1) We are interested in any form of quarantine (mandatory and voluntary, e.g. voluntary self-isolation); we are not interested in isolation or social distancing.		
2) Sometimes quarantine is part of the umbrella term 'physical intervention.'		
Is the study design eligible for the review? Note: We include all designs except case reports.	Yes	No STOP !
Should the study be included? (If you have checked "No" for any of the questions, abstract should be excluded.)	Yes	No

Abbreviations: MERS= Middle East respiratory syndrome, nCoV=novel coronavirus, SARS=severe acute respiratory syndrome

Definitions

Quarantine: Quarantine separates and restricts the movement of people who have been exposed to a contagious disease to see if they become sick. It lasts long enough to ensure the person has not contracted an infectious disease.

Isolation: Isolation prevents the spread of an infectious disease by separating people who are sick from those who are not. It lasts as long as the disease is contagious.

Social distancing: Social distancing is a way to keep people from interacting closely or frequently enough to spread an infectious disease. Schools and other gathering places such as movie theatres may close, and sports events and religious services may be cancelled.



Study selection

- Reduced number of human judgements involved
- Supportive software
- Crowdsourcing





Reduce the number of human judgement involved

- Our recommendation

- Screen only a proportion (e.g., 20%) of records dually, if good agreement (kappa 0.8 or higher) continue with single screening
- · If search yields small number of records consider dual, independent screening
- Same approach for abstract and full text screening

- Other approaches:

- Exclude obvious abstracts (e.g., wrong population) by one person screen rest dually
- Single screening of all abstract, let a second person screen excludes (does not really save time!)
- We don't recommend only single screening of abstracts!



Use supportive software

- Wide range of software exists (www.systematicreviewtools.com)
- Several applications have artificial intelligence incorporated (e.g., Abstrackr, DistillerSR, Eppi-Reviewer, Pico Portal, Rayyan, RobotAnalyst, SWIFTActive Screener, etc.)
 - Use the ranking
 - Apply stopping rules
- Semi-automation can be implemented in RRs
- Full-automation is not working well yet





Crowdsourcing

= outsourcing tasks to a large community of people

- Cochrane Crowd / Screen4Me service
 - performed well: sensitivity of 94-100% and completed abstract screening in 48-53 hours¹
 - currently only Cochrane authors have access
 - Other crowd services e.g., Amazon Mechanical Turk – but managing, training, and motivation of Crowd is a big challenge

1 Noel-Storr A, Gartlehner G, Dooley G, et al. Crowdsourcing the identification of studies for COVID-19-related Cochrane rapid reviews. Res Synth Methods 2022;13:585–94.





Common pitfalls

- Study selection (i.e., Screening)
 - Teams move on to single screening while not having enough agreement –
 risk of missing relevant studies (or overinclusiveness)
 - Machine learning does not yet work that well with complex topics
 - Crowdsourcing requires experience and talent in crowd management



Data extraction

- Reduced number of human judgements involved
- Supportive software





Reducing the number of human judgements involved

- One person extracts data, one person checks key data
- Highlight extracted data in papers
- Limit data fields for extraction
- Build on data from systematic reviews or dat repositories
- We don't recommend single data extraction without verification for key data (definition of outcomes, outcome data)!



Data fields commonly extracted

- Study level characteristics
 - Author name, year of publication
 - Country/countries of study conduct
 - Study design
 - Study duration
 - Funding
 - Participant demographics
 - Sex/gender
 - Age (e.g., mean (SD), Median (Range)
 - Ethnicity
 - Co-morbidities
 - Outcome data
 - Outcome 1 (definition, measurement): specific result (time point)
 - ...



Common pitfalls

- Data extraction
 - Data extraction form is not standardized across reviewers inconsistencies if multiple data extractors
 - Second person "verifying" data extraction just checks data that was extracted, but does not extract relevant data that was missed by the first extractor



Supporting software

- Wide range of software exists (www.systematicreviewtools.com)
- Most helpful tools allow data sharing accross the review process
- Tools assist review teams (detects, highlights data items)
- Full automation does not exist yet
 - promising proof-of-concept study¹

1 G Gartlehner, L Kahwati, R Hilscher, et al. Data Extraction for Evidence Synthesis Using a Large Language Model: A Proof-of-Concept Study. medRxiv 2023.10.02.23296415; doi: https://doi.org/10.1101/2023.10.02.23296415





Risk of bias assessment

- Reduced number of human judgements involved
- Supportive software





Reduce the number of human judgement involved

- Use a study design specific Risk of Bias (RoB) tool
- Use less complex tools (e.g. Cochrane RoB 1.0 instead of 2.0)
- Limit the number of outcomes for outcome level specific RoB assessment
- Let one person assess RoB and a second person check
- We do not recommend omission of RoB assessment!



RoB tools recommended by Cochrane

Study design	RoB tool
Randomised controlled trials	Cochrane RoB 2.0 ¹
Non-randomised studies of interventions	ROBINS-I ²
Non-randomised studies of exposures	ROBINS-E ³
Diagnostic studies	QUADAS 2 ⁴
Prognostic studies	PROBAST ⁵
Systematic reviews	ROBIS ⁶
PROBAST, Prediction model Risk Of Bias Assessment Tool; QUADAS, Quality Assessment of Diagnostic Accuracy Studies; RoB, risk of bias; ROBINS-E, Risk of Bias in Non-randomized Studies–of Exposures; ROBINS-I, Risk of Bias in Non-randomized Studies–of Interventions; ROBIS, Risk of Bias in Systematic Reviews.	

1 Sterne JAC, Savović J, Page MJ, et al. Rob 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019;366:I4898.

2 Sterne JA, Hernán MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. Bmj 2016;355:i4919.

3 Higgins JM, Rooney A, Taylor K, et al. Risk of bias in non-randomized studies - of exposure (ROBINS-E).

2022. Available: www.riskofbias.info/ welcome/robins-e-tool

4 Whiting PF, Rutjes AWS, Westwood ME, et al. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med 2011;155:529–36. 5 Wolff RF, Moons KGM, Riley RD, et al. PROBAST: a tool to assess the risk of bias and applicability of prediction model studies. Ann Intern Med

2019;170:51-8.

6 Whiting P, Savović J, Higgins JPT, et al. ROBIS: a new tool to assess risk of bias in systematic reviews was developed. J Clin Epidemiol 2016;69:225–34.



Supporting software

- Wide range of software exists (www.systematicreviewtools.com)
- Machine learning tools available (e.g., www.robotreviewer.net)
- Full automation does not exist yet
 - Research on Large Language Models not very promising yet ¹



1 Tyler Pitre, Tanvir Jassal, Jhalok Ronjan Talukdar, et al. ChatGPT for assessing risk of bias of randomized trials using the RoB 2.0 tool: A methods study

medRxiv 2023.11.19.23298727; doi: https://doi.org/10.1101/2023.11.19.23298727



Take home message

- Teams need SR experience
- Piloting is essential if steps are done by one person
- Not necessary to employ shortcuts at all steps
- Don't be discouraged by increased workload when using supportive software for the first time – learning curve!



RR methods series in BMJ Evidence-based Medicine

Published

- Knowledge user involvement
- Literature search
- Team considerations, study selection, data extraction, risk of bias assessment
- Certainty of evidence rating

Comming soon

- Appropriateness
- Synthesis
- Supportive Software
- Reporting
- Rapid Scoping Reviews
- Rapid Qualitative Evidence Synthesis





Questions

