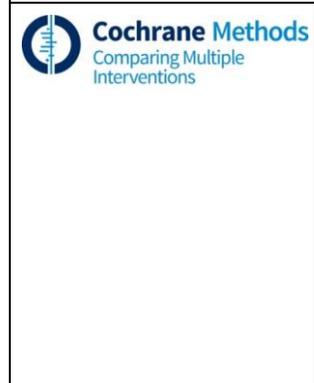


 <p>Cochrane Methods Adverse Effects</p>	<ul style="list-style-type: none"> We published evidence that reporting of harms is still sub-optimal. We are finishing the CONSORT Harms update and working with senior CONSORT Executive so that enhanced harms reporting is incorporated into the main checklist. <p>Publication:</p> <ul style="list-style-type: none"> Junqueira DR, Phillips R, Zorzela L, Golder S, Loke Y, Moher D, Ioannidis JPA, Vohra S. Time to improve the reporting of harms in randomized controlled trials. <i>J Clin Epidemiol.</i> 2021 May 10;136:216-220. doi: 10.1016/j.jclinepi.2021.04.020
 <p>Cochrane Methods Bias</p>	<p>Methodological projects initiated and led by the Bias Methods Group:</p> <ul style="list-style-type: none"> The Bias Methods Group actively participated in the implementation and rollout of the revised tool to assess risk of bias in randomized trials (RoB 2) in Cochrane. Funding source: Cochrane and other The Bias Methods Group led the work on developing a tool for assessing risk of bias due to missing evidence (ROB-ME). During the past year, a preliminary version of the tool has been made publicly available (https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.riskofbias.info%2Fwelcome%2Frob-me-tool&data=04%7C01%7Ceflemyn%40cochrane.org%7C79429522b75d4d5f67f008d95596b478%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C0%7C637634928038398876%7CUnknown%7CTWFpbGZsb3d8eyJWljoimC4wLjAwMDAilCjOljoiV2luMzliCjBTil6k1haWwIlCjXVCl6Mn0%3D%7C1000&data=x0Ro%2F8agkks5UJBBDurawynDjcmu7q5w%2EhFfkXTVuE4%3D&reserved=0) and the tool has been pilot tested. Funding source: other The Bias Methods Group led the work on developing a tool for addressing conflicts of interest in randomised trials (TACIT). A preliminary version of the tool has been developed and during the past year pilot and user testing has been initiated. Funding source: other <p>Methodological projects with participation from convenors of the Bias Methods Group:</p> <ul style="list-style-type: none"> Convenors of the Bias Methods Group have led the work on updating the reporting guideline for systematic reviews (PRISMA). The updated guideline was published in <i>BMJ</i> in 2021: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. <i>BMJ</i> 2021;372:n71. Funding source: other Convenors of the Bias Methods Group were involved in the process of updating reporting guidelines for protocols for randomised trials (SPIRIT) and randomised trials (CONSORT). The Bias Methods Group was involved in developing a database with literature relevant to SPIRIT or CONSORT (the SCIP database), conducting a scoping review on suggested changes for SPIRIT or CONSORT, and a conducting a systematic evaluation of CONSORT extensions. Funding source: other Convenors of the Bias Methods Group led the work on developing updated versions of RoB 2 for cluster-randomised and crossover trials. During the past year, test versions of both tools have been made publicly available (cluster-randomised trials: https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.riskofbias.info%2Fwelcome%2Frob-2-0-tool%2Frob-2-for-cluster-randomized-trials&data=04%7C01%7Ceflemyn%40cochrane.org%7C79429522b75d4d5f67f008d95596b478%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C0%7C637634928038398876%7CUnknown%7CTWFpbGZsb3d8eyJWljoimC4wLjAwMDAilCjOljoiV2luMzliCjBTil6k1haWwIlCjXVCl6Mn0%3D%7C1000&data=x0Ro%2F8agkks5UJBBDurawynDjcmu7q5w%2EhFfkXTVuE4%3D&reserved=0)

	<p>https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.riskofbias.info%2Fwelcome%2Frob-2-0-tool%2Frob-2-for-crossover-trials&data=04%7C01%7Ceflemyn%40cochrane.org%7C79429522b75d4d5f67f008d95596b478%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C0%7C637634928038398876%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLjBtIl6IklhaWwiLCJXVCI6Mn0%3D%7C1000&data=GSPicDu07HzW8ll3bVR0SgrREji01L%2FuQrznkxbOo%3D&reserved=0. Funding source: Cochrane and other</p> <ul style="list-style-type: none"> • Convenors of the Bias Methods Group led the work on developing version 2 of the Risk Of Bias In Non-randomized Studies – of Interventions Tool (ROBINS-I), which has variants in development for different study designs. Funding source: other • Convenors of the Bias Methods Group led a living network meta-analysis of interventions for COVID-19 (https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nma.com%2F&data=04%7C01%7Ceflemyn%40cochrane.org%7C79429522b75d4d5f67f008d95596b478%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C0%7C637634928038398876%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLjBtIl6IklhaWwiLCJXVCI6Mn0%3D%7C1000&data=9%2BdGCYlaI63kVzhfjrbJOhI0Wk2O0qi3NqwyiqiyeF%3D&reserved=0). The Bias Methods Group led a methodological project in which procedures for performing a quality control on the risk of bias assessments on included trials (done using RoB 2) has been developed. In addition, the Bias Methods Group led the work on assessing risk of bias (done using ROBINS-I) in included observational studies investigating vaccine effectiveness on COVID-19 variants (e.g. the delta variant). Funding source: other <p>Methods research and developments in the year ahead: In the year to come, the Bias Methods Group will continue the work on implementing and developing core tools to assist authors in conducting systematic reviews. The main priorities will be to participate in the rollout of RoB 2 including training activities related to the tool, and to continue the development of ROB-ME and TACIT.</p>
	<p>Network meta-analyses:</p> <ul style="list-style-type: none"> • A Markov chain approach for ranking treatments in network meta-analysis. A Chaimani, R Porcher, É Sbidian, D Mavridis. <i>Statistics in medicine</i> 40 (2), 451-464 • More than words: Novel visualizations for evidence synthesis. A Nikolakopoulou, A Chaimani. <i>Research Synthesis Methods</i> 12 (1), 2-3 • Visualizing the evolution of evidence: Cumulative network meta-analyses of new generation antidepressants in the last 40 years. Y Luo, A Chaimani, TA Furukawa, Y Kataoka, Y Ogawa, A Cipriani, ... <i>Research Synthesis Methods</i> 12 (1), 74-85 • Conduct and reporting of individual participant data network meta-analyses need improvement. A Chaimani. <i>BMC Medicine</i> 18 (1), 1-2 <p>Overviews:</p> <ul style="list-style-type: none"> • Our current efforts are focused on developing a reporting guideline for overviews (PRIOR). During the last year, we completed our second delphi survey and held a virtual consensus meeting. We are currently working on the manuscript and E&E document, and hope to have this completed and ready to submit for publication by the end of 2021.

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	<ul style="list-style-type: none"> Gates M, Gates A, Guitard S, Pollock M, Hartling L. Guidance for overviews of reviews continues to accumulate, but important challenges remain: a scoping review. <i>Syst Rev.</i> 2020 Nov 4;9(1):254.
 <p>Cochrane Methods Economics</p>	<i>Not reported.</i>
 <p>Cochrane Methods Equity</p>	<ul style="list-style-type: none"> In 2020, we published a framework for identifying and mitigating the equity harms of COVID-19 policy interventions. In 2021, we published a GRADE concept paper introducing the FACE (Feasibility, Acceptability, Cost, Equity) approach to guide implementation decisions for evidence-based guidelines. Pottie, K., Magwood, O., Rahman, P., Concannon, T., Alonso-Coello, P., Garcia, A. J., ... & Tugwell, P. (2021). GRADE Concept Paper 1: Validating the "FACE" instrument using stakeholder perceptions of feasibility, acceptability, cost, and equity in guideline implement. <i>Journal of Clinical Epidemiology</i>, 131, 133-140. We are co-investigators on an eCOVID grant in which a living map of COVID-19 recommendations is being developed. This project included developing methodological guidance to support the consideration of equity in reviews and decision making for COVID-19. We also developed a framework for classifying equity-related reviews and piloted this on studies included COVID-END inventory. In March 2021, we successfully applied for funding to develop guidance for multi-stakeholder engagement in systematic reviews. This project will begin in late 2021.
 <p>Cochrane Methods GRADEing</p>	<ul style="list-style-type: none"> Akl, E. A., R. L. Morgan, A. A. Rooney, B. Beverly, S. V. Katikireddi, A. Agarwal, B. S. Alper, C. Alva-Diaz, L. Amato, M. T. Ansari, J. Brozek, D. K. Chu, P. Dahm, A. J. Darzi, M. Falavigna, G. Gartlehner, H. Pardo-Hernandez, V. King, J. Klugarová, M. W. M. Langendam, C. Lockwood, M. Mammen, A. G. Mathioudakis, M. McCaul, J. J. Meerpohl, S. Minozzi, R. A. Mustafa, F. Nonino, T. Piggott, A. Qaseem, J. Riva, R. Rodin, N. Sekercioglu, N. Skoetz, G. Traversy, K. Thayer and H. Schünemann (2021). "Developing trustworthy recommendations as part of an urgent response (1-2 weeks): a GRADE concept paper." <i>J Clin Epidemiol</i> 129: 1-11. Brignardello-Petersen, R., I. D. Florez, A. Izcovich, N. Santesso, G. Hazlewood, W. Alhazanni, J. J. Yepes-Nuñez, G. Tomlinson, H. J. Schünemann and G. H. Guyatt (2020). "GRADE approach to drawing conclusions from a network meta-analysis using a minimally contextualised framework." <i>Bmj</i> 371: m3900. Brignardello-Petersen, R., G. H. Guyatt, R. A. Mustafa, D. K. Chu, M. Hultcrantz, H. J. Schünemann and G. Tomlinson (2021). "GRADE guidelines 33: Addressing imprecision in a network meta-analysis." <i>J Clin Epidemiol</i> 139: 49-56. Brignardello-Petersen, R., A. Izcovich, B. Rochweg, I. D. Florez, G. Hazlewood, W. Alhazanni, J. Yepes-Nuñez, N. Santesso, G. H. Guyatt and H. J. Schünemann (2020). "GRADE approach to drawing conclusions from a network meta-analysis using a partially contextualised framework." <i>Bmj</i> 371: m3907. Brozek, J. L., C. Canelo-Aybar, E. A. Akl, J. M. Bowen, J. Bucher, W. A. Chiu, M. Cronin, B. Djulbegovic, M. Falavigna, G. H. Guyatt, A. A. Gordon, M. Hilton Boon, R. C. W. Hutubessy, M. A. Joore, V. Katikireddi, J. LaKind, M. Langendam, V. Manja, K. Magnuson, A. G. Mathioudakis, J. Meerpohl, D. Mertz, R. Mezencev, R. Morgan, G. P. Morgano, R. Mustafa, M. O'Flaherty, G. Patlewicz, J. J. Riva, M. Posso, A. Rooney, P. M. Schlosser, L. Schwartz, I. Shemilt, J. E. Tarride, K. A. Thayer, K. Tsaion, L.

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Vale, J. Wambaugh, J. Wignall, A. Williams, F. Xie, Y. Zhang and H. J. Schünemann (2021). "GRADE Guidelines 30: the GRADE approach to assessing the certainty of modeled evidence-An overview in the context of health decision-making." *J Clin Epidemiol* 129: 138-150.

- Goldkuhle, M., R. Bender, E. A. Akl, E. C. van Dalen, S. Nevitt, R. A. Mustafa, G. H. Guyatt, M. Trivella, B. Djulbegovic, H. Schünemann, M. Cinquini, N. Kreuzberger and N. Skoetz (2021). "GRADE Guidelines: 29. Rating the certainty in time-to-event outcomes-Study limitations due to censoring of participants with missing data in intervention studies." *J Clin Epidemiol* 129: 126-137.
- McGowan, J., E. A. Akl, P. A. Coello, S. Brennan, P. Dahm, M. Davoli, S. Flottorp, G. Guyatt, M. Langendam, J. Meerpohl, R. Mustafa, M. X. Rojas, P. Tugwell and H. J. Schünemann (2021). "Update on the JCE GRADE series and other GRADE article types." *J Clin Epidemiol*.
- Mustafa, R. A., C. A. C. Garcia, M. Bhatt, J. J. Riva, S. Vesely, W. Wiercioch, R. Nieuwlaat, P. Patel, S. Hanson, F. Newall, J. Wiernikowski, P. Monagle and H. J. Schünemann (2021). "GRADE notes: How to use GRADE when there is "no" evidence? A case study of the expert evidence approach." *J Clin Epidemiol* 137: 231-235.
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- Pottie, K., O. Magwood, P. Rahman, T. Concannon, P. Alonso-Coello, A. Jaramillo Garcia, N. Santesso, B. Thombs, V. Welch, G. A. Wells, A. Saad, D. Archibald, R. Grad, A. Moore, M. Ximena Rojas, A. Iorio, N. Pinto, M. Doull, R. Morton, N. Santesso, E. A. Akl, H. J. Schünemann and P. Tugwell (2021). "GRADE Concept Paper 1: Validating the "F.A.C.E" instrument using stakeholder perceptions of feasibility, acceptability, cost, and equity in guideline implement." *J Clin Epidemiol* 131: 133-140.
- Santesso, N., W. Wiercioch, A. M. Barbara, H. Dietl and H. J. Schünemann (2021). "Focus groups and interviews with the public led to the development of a template for a GRADE plain language recommendation." *J Clin Epidemiol*.
- Schünemann, H. J., N. Santesso, G. E. Vist, C. Cuello, T. Lotfi, S. Flottorp, M. Davoli, R. Mustafa, J. J. Meerpohl, P. Alonso-Coello and E. A. Akl (2020). "Using GRADE in situations of emergencies and urgencies: certainty in evidence and recommendations matters during the COVID-19 pandemic, now more than ever and no matter what." *J Clin Epidemiol* 127: 202-207.
- Verbeek, J. H., P. Whaley, R. L. Morgan, K. W. Taylor, A. A. Rooney, L. Schwingshackl, J. L. Hoving, S. Vittal Katikireddi, B. Shea, R. A. Mustafa, M. H. Murad and H. J. Schünemann (2021). "An approach to quantifying the potential importance of residual confounding in systematic reviews of observational studies: A GRADE concept paper." *Environ Int* 157: 106868.
- Yang, B., R. A. Mustafa, P. M. Bossuyt, J. Brozek, M. Hultcrantz, M. M. G. Leeflang, H. J. Schünemann and M. W. Langendam (2021). "GRADE Guidance: 31. Assessing the certainty across a body of evidence for comparative test accuracy." *J Clin Epidemiol* 136: 146-156.
- Zeng, L., R. Brignardello-Petersen, M. Hultcrantz, R. A. C. Siemieniuk, N. Santesso, G. Traversy, A. Izcovich, B. Sadeghirad, P. E. Alexander, T. Devji, B. Rochwerf, M. H. Murad, R. Morgan, R. Christensen, H. J. Schünemann and G. H. Guyatt (2021). "GRADE guidelines 32: GRADE offers guidance on choosing targets of GRADE certainty of evidence ratings." *J Clin Epidemiol* 137: 163-175.

Completed:

- Based on a comparison of results based on IPD with those based on aggregate data, a decision tree was developed to help researchers to systematically determine when aggregate data MAs have enough information for robust clinical conclusions, and when the IPD approach might add considerable value
Tierney JF, Fisher DJ, Burdett S, Stewart LA, Parmar MKB. Comparison of aggregate and individual participant data approaches to meta-analysis of randomised trials: An observational study. PLoS Medicine. 2020;17(1):e1003019
- Based on IPD, determined that the association between blood pressure differences and stroke risk multiplication was not the same between individuals, as that within individuals; and within individuals, it was not the same when on diuretics as when on betablockers (*final analyses being conducted prior to submission*)
- Undertook pilot work exploring potential for developing topic-based IPD repositories (based on depositing data at the end of IPD projects)
Medley, N., Cuthbert, A., Crew, R., Stewart L., Tudur Smith C., Alfirevik Z. Developing a topic-based repository of clinical trial individual patient data: experiences and lessons learned from a pilot project. Syst Rev 10, 162 (2021). <https://doi.org/10.1186/s13643-021-01717-2>
- An IPD network meta-analysis, to examine the comparative efficacy / safety of cognitive enhancers by patient characteristics for managing Alzheimer's, showed that the choice among different cognitive enhancers may depend on patient's characteristics (submitted)
- An IPD network meta-analysis, to examine the comparative efficacy / safety of long- (determir or glargine) and intermediate-insulin (NPH) regimens for type-1 diabetes for different patient characteristics, showed that Long-acting insulins reduced A1c compared to intermediate-acting insulins and were associated with lower severe hypoglycaemia (submitted)
- Conducted a collaborative meta-analysis to investigate the long-term benefits and risks of adjuvant trastuzumab on breast cancer recurrence and cause-specific mortality, which showed that adding trastuzumab to chemotherapy for early-stage, HER2-positive breast cancer reduces recurrence of, and mortality from, breast cancer by a third, with worthwhile proportional reductions irrespective of recorded patient and tumour characteristics.
Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Trastuzumab for early-stage, HER2-positive breast cancer: a meta-analysis of 13 864 women in seven randomised trials. Lancet Oncol 2021;22(8): 1139-50

Planned:

- *Richard Riley, Jayne Tierney and Lesley Stewart:* Following on from the publication of a book on meta-analysis using IPD, a series of individual papers are planned to further expand on specific topics covered by the handbook e.g. embarking on an IPD project
- *Larysa Rydzewska, Jayne Tierney, Lesley Stewart and Mike Clarke:* Initiating a project, together with members of the Cochrane Prospective Meta-analysis Methods Group, to develop global standards for data sharing. Grant funding is currently being sought for this project
- *Sarah Burdett and Jayne Tierney:* Ongoing collaborative project, based on IPD collected from bladder cancer trials, to investigate potential surrogate outcomes for overall survival

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	<ul style="list-style-type: none"> • <i>Jayne Tierney and Larysa Rydzewska</i>: IPD collected from prostate cancer trials is being used to identify potential surrogate outcomes for overall survival (as part of the STOPCAP programme to speed up the evaluation of therapies for metastatic hormone-sensitive prostate cancer) • <i>David Fisher, Peter Godolphin and Jayne Tierney</i>: Building on a previous project (BMJ 2017), which provided guidance (and associated Stata programs) for estimating, reporting and plotting interactions between participant covariates and treatment effects in order to avoid aggregation bias. This work is being extended to estimate within-trials interactions for both aggregate data and for modelling continuous covariates and prognostic modelling in IPD meta-analysis • <i>Francois Gueyffier</i>: Using IPD to validate a new method (see above) to explore the relationship between blood pressure changes induced by treatment and the associated reduction in the risk of stroke • <i>Areti-Angeliki Veroniki</i>: Protocol in development for an IPD network meta-analysis compare the effect of prophylactic, intermediate, and therapeutic dose anticoagulation on 28-day all-cause mortality in hospitalized patients with Covid-19 • <i>Brooke Levis, Brett Thombs and Andrea Benedetti</i>: The DEPRESSD team (https://www.depressd.ca/) was awarded a 3-year grant by the Canadian Institutes of Health Research (CIHR) to develop and test statistical methods for individual participant data meta-analysis in diagnostic test accuracy
 <p>Cochrane Methods Information Retrieval</p>	<p>ISSG Search Filter Resource: https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsites.google.com%2Fa%2Fyork.ac.uk%2Fissg-search-filters-resource%2Fhome&data=04%7C01%7Ceflemyng%40cochrane.org%7C3f2a0857db954595a10d08d958e58ae8%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C1%7C637638565168687684%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAilCjQljoiv2luMzllLjBTll6lk1haWwiLCJXVCI6Mn0%3D%7C3000&sddata=p7%2BB7EqYV4OoGfdiVTI9953FOqziAMruUd318U7XoJl%3D&reserved=0</p> <p>Julie Glanville and Carol Lefebvre, together with Paul Manson, Sophie Robinson, and Naomi Shaw are the editorial team for the InterTASC Information Specialists' Sub-Group (ISSG) Search Filter Resource, which aims to identify, assess and test published and unpublished search filters designed to retrieve research by study design or focus. It also provides information and guidance on how to critically appraise search filters and provides independent appraisals for some of the filters and published reviews comparing filters.</p> <p>The site continues to be updated monthly. New features added during 2021 so far include links to launch filters in PubMed and the addition of comments, correspondence and errata to search filter records.</p> <p>SuRe Info web resource: https://eur01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fvortal.htai.org%2F%3Fq%3Dsure-info&data=04%7C01%7Ceflemyng%40cochrane.org%7C3f2a0857db954595a10d08d958e58ae8%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C1%7C637638565168687684%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAilCjQljoiv2luMzllLjBTll6lk1haWwiLCJXVCI6Mn0%3D%7C3000&sddata=scDsnSB7REosoz4cKczE3PKweqUGN8088hqTkmXOuk0%3D&reserved=0</p>

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	<p>Julie Glanville and Carol Lefebvre, together with other IRMG members and non-members, continue to maintain and develop the SuRe Info (Summarized Research in Information Retrieval) web site, providing updated research-based information relating to the information retrieval aspects of producing systematic reviews and health technology assessments. JG is the site lead, together with Jaana Isojarvi, and CL is on the Steering Group. Both CL and JG are also authors of specific sections on the site. The site continues to be updated every 6 months with the latest evidence in information retrieval in the field of evidence synthesis.</p>
	<p>The NRSIMG has continued to collaborate with the Bias Methods Group to develop / improve tools for assessing the risk of bias in primary studies.</p> <ul style="list-style-type: none"> • Convenors (HW and BR) are working on a risk of bias approach for the discontinuity design, an increasingly common approach in social science and public health. One of the Bias Methods Group convenors (Julian Higgins) is aware of this work, and is keen to incorporate the finished product as an extension to ROBINS-I. • The NRSIMG collaboration with Sandra Eldridge and colleagues on an extension of RoB v2 for cluster RCTs has been finalised (see URL below). • The NRSIMG has collaborated with Julian Higgins and Jonathan Sterne to develop a “version 2” of ROBINS-I for cohort studies, including algorithms to map responses to signalling questions to bias domain judgements (reported last year). This version will align ROBINS-I more closely with RoB v2 for RCTs, including algorithms to help users proceed from signalling questions answers to risk of bias judgements. • NRSIMG convenors (BS, PT, BR) have continued to collaborate with an OMERACT working group on a second paper to define contextual factors in rheumatology studies (two publications are listed below).
	<ul style="list-style-type: none"> • Patient Reported Outcomes Minimal Important Difference (PROMID) database in development but website is publicly accessible: the largest database of anchor-based MID estimates for PROs. By providing easy access to available MIDs, including ratings of their credibility, and thus by reducing the time, effort, and likelihood of error in MID estimate identification and selection, the inventory will close the gap between the estimation of MIDs and their subsequent application for facilitating the interpretation of PROs in clinical trials, systematic reviews, and clinical practice guidelines: https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpromid.mcmaster.ca%2F&data=04%7C01%7Ceflemyn%40cochrane.org%7Ce8d54c5036aa49e356d908d96381a053%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C1%7C637650230661337705%7CUnknown%7CTWFpbgZsb3d8eyJWljojMC4wLjAwMDAilCJQljoIV2luMzIiLjJBTiI6Ik1hYWwllCjXVCi6Mn0%3D%7C3000&data=uH3hZ%2BsljtOOoKfj7cN3d%2Bimedyl4r19PRKXgNK78q4%3D&reserved=0 • Development of a criterion to assess construct proximity, an alternative to the correlation between PROM and anchor when establishing the credibility of an anchor-based MID estimate • Development of principles for selection of an MID estimate for application in clinical trials, systematic review, and guidelines is currently underway. This guidance will help clinical trialists, systematic review authors and guideline developers select trustworthy applicable MIDs for interpretation of PRO data. • Development of a reporting guideline to improve the completeness and transparency of MID estimation studies and promote higher methodologic standards is in progress.

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	<ul style="list-style-type: none"> Wang Y, Devji T, Qasim A, et al. A systematic survey identified methodological issues relevant to conducting studies developing anchor-based minimal important differences in patient-reported outcomes. Manuscript submitted for publication. Journal of Clinical Epidemiology. 2021. Carrasco-Labra A, Devji T, Qasim A, et al. Serious issues of reporting exist in minimal important difference studies: Current state and suggestions for improvement. Manuscript submitted for publication. Journal of Clinical Epidemiology. 2021.
 <p>Cochrane Methods Priority Setting</p>	<ul style="list-style-type: none"> Sumanth Kumbargere is working on a PhD project on how to engage with different ethnicities in a research priority setting exercise - how it affects the process and how their priorities differ. We expect the initial results of the project will be available in 2022 and we can present in relevant Cochrane events We worked with the EU office of WHO on an overview of reviews on research priority setting. The overview is submitted for publications. Further development of a national evidence gap map for research priority setting: <ul style="list-style-type: none"> Moola S, Beri D, Salam A, Jagnoor J, Teja A, Bhaumik S. Leptospirosis prevalence and risk factors in India: Evidence gap maps. Trop Doct. 2021 Apr 9:494755211005203. doi: 10.1177/00494755211005203. Epub ahead of print. PMID: 33832378. Beri D, Moola S, Jagnoor J, Salam A, Bhaumik S. Prevention, control and management of leptospirosis in India: an evidence gap map. Trans R Soc Trop Med Hyg. 2021 Mar 9:trab036. doi: 10.1093/trstmh/trab036. Epub ahead of print. PMID: 33693843 Our priority is to develop better guidance how to develop a more inclusive approach to setting priorities for research.
 <p>Cochrane Methods Prognosis</p>	<ul style="list-style-type: none"> We are currently focusing on developing guidance for reporting and quality assessment of prediction models developed using Machine Learning techniques. We have published the first of a series of articles in which we appraise the methodological and reporting quality of studies developing prediction models using Machine Learning. This will result in TRIPOD-AI and PROBAST-AI. Delphi procedures to develop these tools have started or will start very soon and we will prioritise this the coming year. We've also coauthored many papers on reporting of and methods for primary and meta-prognosis studies, including guidance for sample size calculations for prediction model development and validation (see reference list in 'defining best practice'). Currently we focus, amongst others, on developing guidance for using GRADE in systematic reviews of prognosis studies. Guidance on GRADE for prognostic model studies has been approved by the GRADE working group and will be published in the coming year. <p>There is no funding for any of these projects.</p> <ul style="list-style-type: none"> Furthermore, we are developing a risk of bias tool for Overall Prognosis studies. A protocol for this is published on the Open Science Framework: https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fosf.io%2Fdfk2r&data=04%7C01%7Ceflemyn%40cochrane.org%7C04836c5a03a143eaa65308d952899e4c%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C1%7C637631573287888901%7CUnknown%7CTWFpbGZsb3d8eyJWljoicM4wLjAwMDAilCJQljoiv2luMzliLjBBIi6k1haWwvLjCJXVCl6Mn0%3D%7C3000&data=Kcf5WGtdlBsEWONJlaf%2BzaToVKknb9bn1kMZgxe7dnk%3D&reserved=0. This

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will be funded by the Federal Ministry of Education and Research, Germany (NaFoUniMedCovid19, funding number: 01KX2021; part of the project “CEOSys”).

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Methods / guidance papers:

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- Archer L, Snell KIE, Ensor J, Hudda MT, Collins GS, Riley RD. Minimum sample size for external validation of a clinical prediction model with a continuous outcome. *Stat Med*. 2021 Jan 15;40(1):133-146. doi: 10.1002/sim.8766. Epub 2020 Nov 4. PMID: 33150684.
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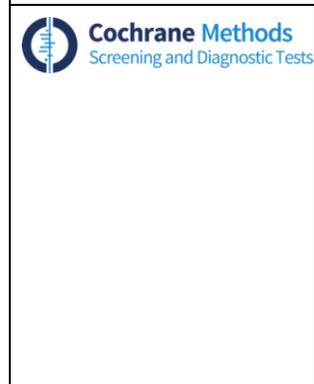
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	<p>KIE, Sperrin M, Spijker R, Steyerberg EW, Takada T, Tzoulaki I, van Kuijk SMJ, van Bussel B, van der Horst ICC, van Royen FS, Verbakel JY, Wallisch C, Wilkinson J, Wolff R, Hooft L, Moons KGM, van Smeden M. Prediction models for diagnosis and prognosis of covid-19: systematic review and critical appraisal. <i>BMJ</i>. 2020 Apr 7;369:m1328. doi: 10.1136/bmj.m1328. Update in: <i>BMJ</i>. 2021 Feb 3;372:n236. Erratum in: <i>BMJ</i>. 2020 Jun 3;369:m2204. PMID: 32265220; PMCID: PMC7222643.</p> <ul style="list-style-type: none"> Zamanipour Najafabadi AH, Ramspek CL, Dekker FW, Heus P, Hooft L, Moons KGM, Peul WC, Collins GS, Steyerberg EW, van Diepen M. TRIPOD statement: a preliminary pre-post analysis of reporting and methods of prediction models. <i>BMJ Open</i>. 2020 Sep 18;10(9):e041537. doi: 10.1136/bmjopen-2020-041537.
	<p>Publications:</p> <ul style="list-style-type: none"> Seidler AL, Hunter KE, Espinoza D, Mihrshahi S, Askie LM, on behalf of the EPOCH Collaboration: Quantifying the advantages of conducting a prospective meta-analysis (PMA): a case study of early childhood obesity prevention. <i>Trials</i> 2021, 22(1):78. Hunter KE, Johnson BJ, Askie L, Golley RK, Baur LA, et al. on behalf of the TOPCHILD Collaboration. Transforming Obesity Prevention for CHILDren (TOPCHILD) Collaboration: protocol for a systematic review with individual participant data meta-analysis of behavioural interventions for the prevention of early childhood obesity. medRxiv 2020.12.17.20248441; https://doi.org/10.1101/2020.12.17.20248441 (also under review at <i>BMJ Open</i>) Tan AC, Askie LM, Hunter KE, Barba A, Simes RJ, Seidler AL. Data sharing—trialists' plans at registration, attitudes, barriers and facilitators: A cohort study and cross-sectional survey. <i>Res Syn Meth</i>. 2021; 1-17. https://doi.org/10.1002/jrsm.1500 Seidler AL, Aberoumand M, Williams JG, Tan A, Hunter KE and Webster A. The landscape of COVID-19 trials in Australia. <i>Med J Aust</i>. 2021;215:58-61.e1. https://doi.org/10.5694/mja2.51148 Levett K, Lord S, Dahlen H, Smith C, Girosi F, Downe S, Finlayson K, Fleet J, Steen M, Davey M, Newnham E, Werner A, Arnott L, Sutcliffe K, Seidler AL, Hunter K, Askie L. The AEDUCATE Collaboration. Comprehensive antenatal education birth preparation programmes to reduce the rates of caesarean section in nulliparous women. Protocol for an individual participant data prospective meta-analysis. <i>BMJ Open</i> 2020;10:e037175. doi: 10.1136/bmjopen-2020-037175 Seidler AL*, Hunter KE*, Baur L, Espinoza D, Taylor RW, Wen LM, Hesketh KD, Campbell K, Daniels L, Mihrshahi S, Rissel C, Taylor B, Askie LM. Sustainability of effects of early childhood obesity prevention interventions: follow-up of the EPOCH individual participant data prospective meta-analysis. Submitted to <i>Pediatric Obesity</i> 2021 * Anna Lene Seidler and Kylie E Hunter contributed equally to this manuscript Brown V, Moodie M, Tran HNQ, Sultana M, Hunter KE, Byrne R, Zarnowiecki D, Seidler AL, Golley R, Taylor R, Hesketh KD, Matvienko-Sikar K. Protocol for the development of Core Outcome Sets for Early intervention trials to Prevent Obesity in Children (COS-EPOCH) <i>BMJ Open</i> 2021;11:e048104. doi: 10.1136/bmjopen-2020-048104 <p>Presentations:</p> <ul style="list-style-type: none"> Hunter KE, Understanding childhood obesity prevention interventions using NextGen evidence synthesis methodologies. Oral presentation (virtual), EPOCH Special Symposia at the Australian and New Zealand Obesity Society (ANZOS) Annual Meeting, July 2021. Hunter KE, Seidler AL, Baur L, Espinoza D, Taylor RQ, Wen LM, Hesketh K, Campbell K, Daniels L, Mihrshahi S, Rissel C, Taylor B, Askie L. Sustainability of effects of early childhood obesity prevention interventions: follow-up of an individual participant data prospective meta-analysis of four randomised controlled trials. Oral presentation (virtual) at the

	<p>Australian and New Zealand Obesity Society (ANZOS) Annual Meeting, July 2021. * Won Best ANZOS Early Career Researcher Oral Presentation Award, Public Health</p> <ul style="list-style-type: none"> Seidler AL, Hunter KE, Johnson BJ. Early prevention of childhood obesity - moving the field forward through collaboration. Webinar for the Centre of Research Excellence in the Early Prevention of Obesity in Childhood (CRE EPOCH), 17th December 2020 <p>Other:</p> <ul style="list-style-type: none"> Anna Lene Seidler was awarded a PhD for her thesis entitled, 'Next generation systematic review methodology' <p>Future plans:</p> <ul style="list-style-type: none"> Manuscript nearly ready for submission on how to search for planned, ongoing, and unpublished studies using trial registries, which is a key early step in building a PMA collaboration Methods projects focusing on data sharing standards, data integrity and processing <p>Funding:</p> <ul style="list-style-type: none"> The group's research is supported in-kind by each of the convenor's respective organisations. No other funding is provided.
 <p>Cochrane Methods Qualitative and Implementation</p>	<ul style="list-style-type: none"> GRADE CERQual - celebrates 10 years since publication of the first use and we have conducted a review of the application and fidelity of CERQual. This will be completed this year and submitted for publication. Sub group work continues on: (i) identifying dissemination bias in qualitative research(ii) further developing our understanding of methodological limitations in primary studies and development of the CAMELOT tool for use with CERQual and (iii) ongoing CERQual training activities. WHO is providing some support to develop the 10 year retrospective paper. Cochrane has previously provided a partially funded MIF grant to develop some of the stages of CAMELOT. Other work is undertaken at no cost to Cochrane. In the next year we focus on development of the Cochrane Campbell QES Handbook.
 <p>Cochrane Methods Rapid Reviews</p>	<p>As part of Cochrane's Content Strategy to 2020, the RRMG has been exploring the appropriateness of RRs as a formal Cochrane product. To inform this work, the RRMG conducted two formal scoping reviews that have been published within the last year:</p> <ul style="list-style-type: none"> Hamel C, Michaud A, Thuku M, Skidmore B, Stevens A, Nussbaumer-Streit B, Garritty C. Defining rapid reviews: a systematic scoping review and thematic analysis of definitions and defining characteristics of rapid reviews. J Clin Epi. 2020 Oct. 7. https://doi.org/10.1016/j.jclinepi.2020.09.041 (funding source: Cochrane) Hamel C, Michaud A, Thuku M, Affengruber L, Skidmore B, Nussbaumer-Streit B, Stevens A, Garritty C. (2020). Few evaluative studies exist examining rapid review methodology across stages of conduct: a systematic scoping review. Journal of Clinical Epidemiology, 126, October 2020, Pages 131-140. (funding source: Cochrane) <p>In addition, members of the RRMG published the following RR methods papers:</p> <ul style="list-style-type: none"> Garritty, C., Hamel, C., Hersi, M. et al. Assessing how information is packaged in rapid reviews for policy-makers and other stakeholders: a cross-sectional study. Health Res Policy Sys. 18, 112 (2020). https://doi.org/10.1186/s12961-020-00624-7

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	<p>searches led to identical or very similar effect estimates: meta-epidemiological study, Journal of Clinical Epidemiology, https://doi.org/10.1016/j.jclinepi.2020.08.002.</p> <ul style="list-style-type: none"> Nussbaumer-Streit B, Klerings I, Dobrescu AI, Persad E, Stevens A, Garrity C, Kamel C, Affengruber L, King VJ, Gartlehner G. Excluding non-English publications from evidence-syntheses did not change conclusions: a meta-epidemiological study. Journal of Clinical Epidemiology 2020;118:42-54. DOI: https://doi.org/10.1016/j.jclinepi.2019.10.011 <p>Ongoing Projects:</p> <ul style="list-style-type: none"> Systematic Prospective Assessment of Rapid Knowledge Synthesis SPARKS (Project Lead: A Tricco; A Stevens and C Garrity – co-investigators) (Funded by CIHR) Developing an extension to PRISMA for rapid reviews (Project Lead: A Stevens) (Funded by CIHR) Systematic review and methods study on falsely excluded studies in the literature screening process (Project Lead: L Affengruber) (Funded by NFB Science Call 2017) <p>Priority Methods Research and Development Planned for the Year Ahead:</p> <p>The Cochrane RRMG has outlined a specific preliminary workplan to establish RR as a new evidence format within Cochrane. Unfortunately, this workplan did not receive any funding from Cochrane. Nevertheless, we will pursue methods research in the area of RR in the year ahead. Specifically, we plan to:</p> <ul style="list-style-type: none"> Collaborate with Cochrane Crowd and validate the accuracy of the Screen4Me approach within RRs. To seek formal feedback and input from those research teams that have applied the interim Cochrane RR methods guidance as part of the response to COVID-19. Prepare a series of papers providing guidance on several steps and aspects of the RR process that will be published in the journal BMJ EBM. <p>Note: The RRMG is also in search of funding in order to develop guidance on when to do and when ‘not’ to do rapid reviews.</p>
	<ul style="list-style-type: none"> Development of QUADAS-C, extension to QUADAS-2 for appraising the risk of bias of comparative accuracy studies included in test accuracy reviews. Paper soon to be published. Related paper: <ul style="list-style-type: none"> Yang B, Vali Y, Dehmoobad Sharifabadi A, Harris IM, Beese S, Davenport C, Hyde C, Takwoingi Y, Whiting P, Langendam MW, Leeflang MMG. Risk of bias assessment of test comparisons was uncommon in comparative accuracy systematic reviews: an overview of reviews. J Clin Epidemiol. 2020 Nov;127:167-174. PRISMA-DTA for abstracts and the explanation and elaboration paper for PRISMA-DTA published. <ul style="list-style-type: none"> Cohen JF, Deeks JJ, Hooft L, Salameh JP, Korevaar DA, Gatsonis C, Hopewell S, Hunt HA, Hyde CJ, Leeflang MM, Macaskill P, McGrath TA, Moher D, Reitsma JB, Rutjes AWS, Takwoingi Y, Tonelli M, Whiting P, Willis BH, Thombs B, Bossuyt PM, McInnes MDF. Preferred reporting items for journal and conference abstracts of systematic reviews and meta-analyses of diagnostic test accuracy studies (PRISMA-DTA for Abstracts): checklist, explanation, and elaboration. BMJ. 2021 Mar 15;372:n265. Salameh JP, Bossuyt PM, McGrath TA, Thombs BD, Hyde CJ, Macaskill P, Deeks JJ, Leeflang M, Korevaar DA, Whiting P, Takwoingi Y, Reitsma JB, Cohen JF, Frank RA, Hunt HA, Hooft L, Rutjes AWS, Willis BH, Gatsonis C,

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	<p>Levis B, Moher D, McInnes MDF. Preferred reporting items for systematic review and meta-analysis of diagnostic test accuracy studies (PRISMA-DTA): explanation, elaboration, and checklist. <i>BMJ</i>. 2020 Aug 14;370:m2632. doi: 10.1136/bmj.m2632. PMID: 32816740.</p>
 <p>Cochrane Methods Statistics</p>	<p>An empirical study comparing the impact of using different statistical methods for random effects meta-analysis applied to meta-analyses in the Cochrane reviews is nearing completion. Specifically, we have examined the impact of using different heterogeneity variance estimators (Paule-Mandel, Restricted Maximum Likelihood, and DerSimonian and Laird) and different methods for confidence interval calculation for the summary effect estimate (Hartung-Knapp-Sidik-Jonkman (and variants), Wald-type). This study has informed recommendations for proposed additional random effects meta-analysis methods to be included in RevMan.</p>