Tips for avoiding common errors in protocols for Cochrane Systematic Reviews (of Interventions)

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Overview

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Protocols and Cochrane Reviews

- Development of review protocols
  - Enhance research integrity
    - Minimize bias
    - Increase transparency of methods
  - Requires planning for critical aspects of the review
    - Consider potential methodological challenges
    - Key decisions made in advance
- Protocol publication = peer review

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Resources for Authors

- Cochrane Handbook for Systematic Reviews of Interventions:
  - Protocol Development
  - Reporting of protocols of new Cochrane Reviews
- PRISMA-P
- MECIR C1-23

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Intervention Review Template

Available in RevMan Knowledgebase

Review template

NEW! We have a **recommended template for intervention reviews** in the focused review format.

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Your copy of the template will be **available for 30 days**. Come back here at any time to recreate a copy!

The template will be continuously updated to reflect best practice. Always open the template as a practice review in RevMan to ensure you are always viewing the latest version.

Cochrane conduct standard: Setting eligibility criteria for including studies in the review [48]

Read, and cite when applicable, Chapter III of the *Cochrane Handbook for Systematic Reviews of Interventions* [10].

PRISMA 2020 guidance #24c: Describe and explain any amendments to information provided at registration, in the protocol or the last update. Note: (a) the amendment itself and (b) the reason for the amendment. This includes post-hoc decisions about eligibility criteria or the addition of subgroup analyses). Report aspects of the protocol that were not implemented (e.g. because no studies, or few studies, were found) [6]. If more than a few sentences are needed to detail the deviations, use an additional supplementary material. Alternatively, if there were no deviations to information provided at registration, in the protocol or the last update, please state this.

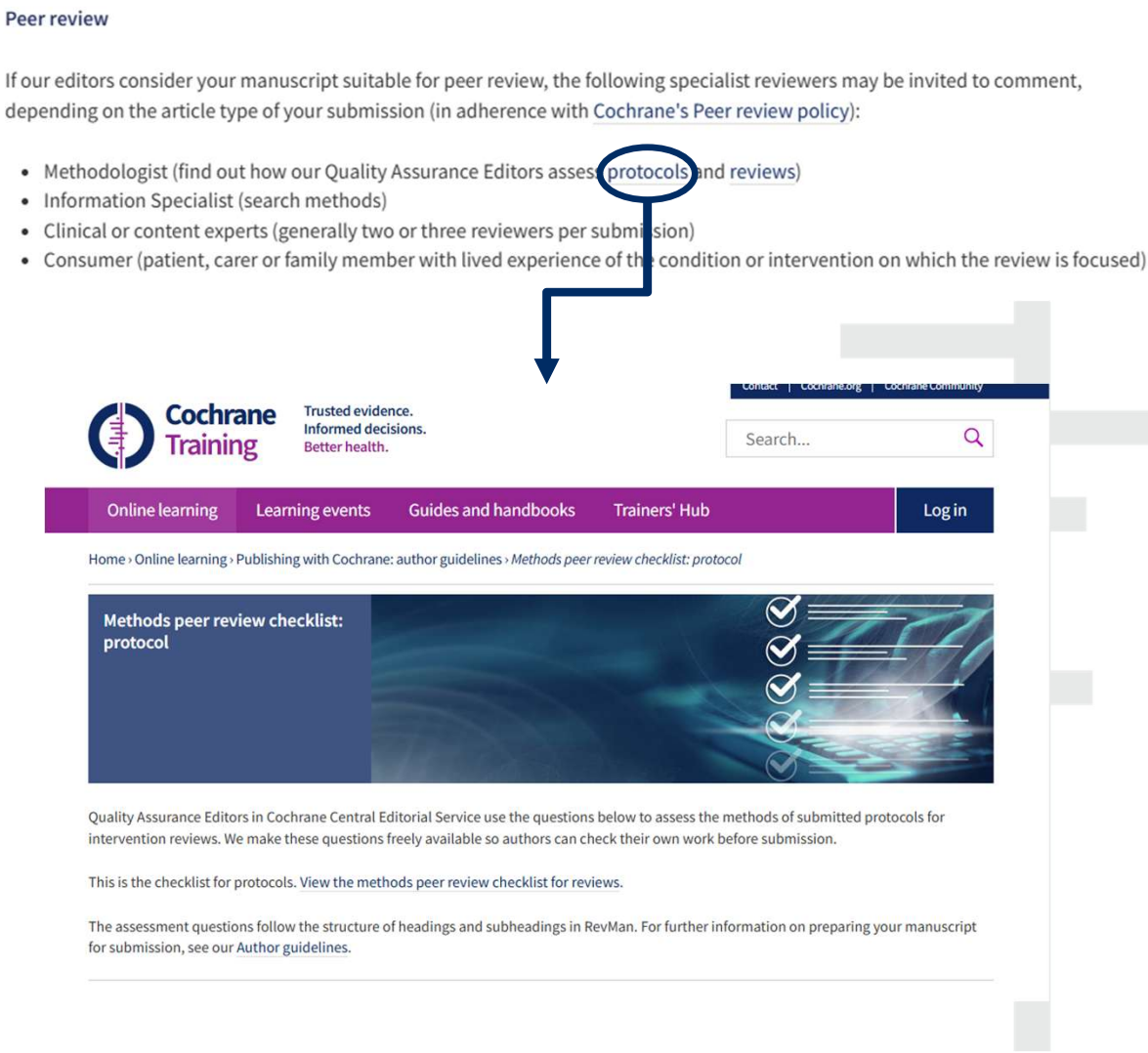
State which conduct and reporting guidelines were adhered to.

Example text:

Protocol: *We will follow the Methodological expectations for Cochrane intervention reviews (MECIR) when conducting the review [add citation for MECIR, see [48]], and PRISMA 2020 for the reporting [add citation for PRISMA, see [6]].*
Review: *We followed the Methodological expectations for Cochrane intervention reviews (MECIR) when conducting the review [add citation for MECIR, see [48]], and PRISMA 2020 for the reporting [add citation for PRISMA, see [6]].*

Did you know?

- Quality Assurance editorial checklists are available for both protocols and reviews!
  (can also access through ‘Publishing with Cochrane: author guidelines > scroll down to editorial process > peer review)



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Common Error #1: unclear descriptions of intervention/comparators

- MECIR C7: *Define in advance the eligible interventions and the interventions against which these can be compared in the included studies.*
- Are active and inactive comparators adequately described?
- Are dose, frequency, duration and other aspects of the intervention adequately described?
- Are co-interventions eligible?

Review template example

Table X. Intervention groupings with a description and eligible interventions

Intervention grouping	Description of intervention grouping	Eligibility criteria for interventions in the group
Counselling interventions	Interventions that provide motivation to quit, support to increase problem solving and coping skills (Ortendahl 2007c; Ortendahl 2008a; Ortendahl 2009b), and may incorporate 'transtheoretical' models of change (Prochaska 1992; Prochaska 2007)	• Motivational interviewing, cognitive behaviour therapy, psychotherapy, relaxation, problem-solving facilitation, and other strategies • Face-to-face, by telephone, via interactive computer programs, or using audiovisual equipment • May range from brief interventions (less than five minutes) to more intensive interventions, which can last for up to an hour and be repeated over multiple sessions. • Provided by a range of personnel, including pregnancy care providers, trained counsellors or others; on site or by referral to specialist stop-smoking services. • In this review, we included interventions that involved provision of videos with personal stories as counselling.

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Common Error #2: Unclear descriptions of outcomes

- Clarify and justify in advance if outcomes are to be used as criteria for including studies.

- Are the most important outcomes selected and categorized as critical and important? Do these outcomes include benefits and harms?

Common Error #2: Unclear descriptions of outcomes

- Are outcomes adequately described?
  - Outcome domain DEPRESSION (measured by Beck Depression Inventory, Hamilton Depression Scale, or other validated measures.
  - Timepoint of follow-up

- Is there a hierarchy of which scale will be extracted if a study measures more than one scale for a given outcome?

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Review template example

For each outcome, list the measurement tools (for example, 36-item Short Form (SF-36)) that you will use within each outcome domain (for example, quality of life). List a hierarchy of appropriate outcome measurements if you anticipate that studies may include more than one in each domain. List the time points that you will use, including your primary time point of interest. Provide the rationale for the labelling.

We will group outcomes into three sets of time points.

- T1: short term/immediate postintervention (defined as 0 to 1 month postintervention) to detect illness recovery/symptom reduction of the intervention.
- T2: intermediate term (defined as 1 to 6 months postintervention) to detect sustained illness recovery/symptom reduction
- T3: longer term (defined as 7 to 24 months postintervention) as a measure of medium- to long-term avoidance of recurrence and chronicity. We performed subgroup analyses for one- to two-year outcomes if available.

If an outcome is reported more than once during any of the above time points, we will use the latest time point within that category (e.g. if there is a measure at three months and at six months, we will use the results at six months for T2) or the time point that correlated best with other studies compared within each outcome.

Example modified from van Ginneken N, Chin WY, Lim YC, Ussif A, Singh R, Shahmalak U, et al. Primary-level worker interventions for the care of people living with mental disorders and distress in low- and middle-income countries. Cochrane Database of Systematic Reviews 2021, Issue 8. Art. No.: CD009149. DOI: 10.1002/14651858.CD009149.pub3

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Common Error #3: Reporting methods for assessing risk of bias

- **Who** is carrying out the assessment?
- **How** is it being carried out? Which tool?
- **What** are the ROB domains, outcome measures[1] and timepoints[1] ([1]where applicable).

-ROB1 – Adding or removing domains without clear justification. Assessing different outcomes (subjective versus objective measures).

-ROB2 – Confusion around it being a study-based, as opposed to outcome-based tool.

- If non-randomised studies are eligible for inclusion, have all ROBINS-I (or similar tool for NRSI studies) guidance points been adhered to?

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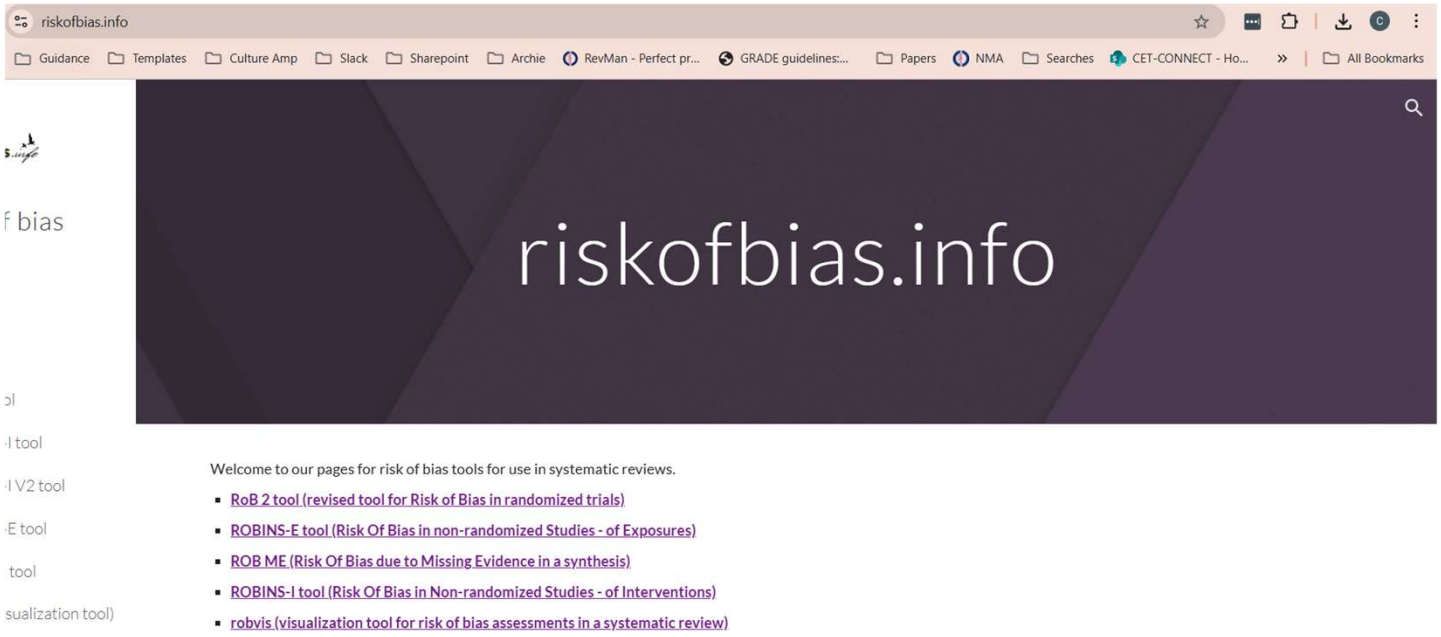
Resources to help with ROB



Common Error #4: Prioritizing comparisons and outcomes for SoF tables

- No plan for SoF/GRADE assessment
- **Who** will assess GRADE?
- **How** is it being carried out?
- **What** comparisons, outcomes and timepoints/timeframes are being prioritised?

SoF table tutorial and Template

Received: 22 April 2024 | Accepted: 26 May 2024
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Cochrane Evidence Synthesis and Methods

TUTORIAL

How to present an informative summary of findings table for systematic reviews of interventions: A tutorial

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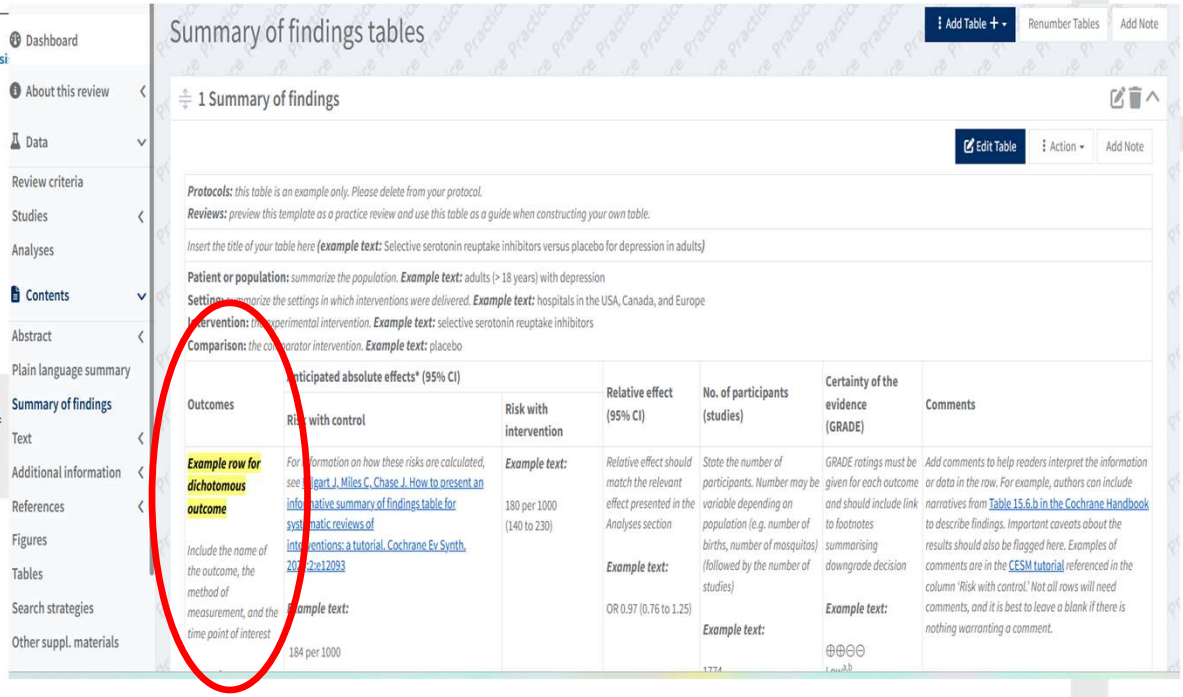
Abstract

This tutorial provides guidance on creating clear and informative summary of findings tables for systematic reviews of interventions.



Equity-related assessment & considerations

Equity-related assessment

Read, and cite when applicable, Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* [14].

State whether or not you will consider equity-related assessments. If the review will not consider health inequity, state "We will not investigate health inequity in this review" and explain why.

If the review will consider health inequity:

- define which populations experience it with respect to the condition, problem or intervention being assessed. A framework, such as PROGRESS-Plus [47], might help identify the populations to consider in a systematic way, as well as different settings like high-income, low- and middle-income countries. If appropriate, include a logic model as an additional supplementary material dedicated to equity methods;
- specify what methods will be used to identify and appraise evidence related to equity and specific populations. Define how you are going to extract information to inform the Characteristics of included studies and Results sections. In an additional supplementary material dedicated to equity methods, describe whether there are differences in the lived experiences of these populations (e.g. racism, ageism, stigma, acceptability, other underlying determinants of health); explain the rationale for methodological decisions related to specific populations (e.g. inclusion/exclusion criteria, subgroup analyses, choice of outcomes); and the choice of databases to locate studies including some of our populations of interest.
- if you are planning separate comparisons or want to assess different baseline risks for specific population characteristics, report how your will address this in the summary of findings table(s). For example, separate summary of findings tables for (needs justification) or separate rows for differences in risk of events.

The PRO EDI initiative provides guidance on equity, diversity and inclusion in evidence synthesis. Please note, PRO EDI is not formally endorsed by Cochrane yet as it is still in development but may be a helpful resource for authors; if you use it, please cite it.

MSU Webinar: Equity in all Cochrane reviews

Forthcoming tutorials in the Cochrane Evidence Synthesis and Methods journal

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Example 1

Equity-related assessment

We will explore health inequity through two characteristics defined by PROGRESS-Plus: gender/sex and socioeconomic status [43]. See Supplementary material 2 for additional details about study characteristics with equity-related implications.

The prevalence of stroke and its complications is higher in females, attributed to multiple factors including biologic, clinical, social, and healthcare system-related factors [2, 3, 5]. Consequently, we intend to conduct a subgroup analysis to assess whether the reviews consider the incorporation of different sexes.

Additionally, we will analyze the impact of residential location, as in 2019, the World Bank reported that low-income countries exhibited an age-standardized stroke-related mortality rate of 3.6 (95% uncertainty interval 3.5 to 3.8) times higher and an age- .5 to 3.9) times higher than those of high-income nic status based on residential location as a subgroup

ssment that considers the context in which the allow us to explore the implications of our findings across residential location disaggregated data. Where these data

ical outcomes (clinical function, health-related quality of ally, in the 'Equity-related implications for practice' and e will address the applicability of the results to different es and context-specific factors that may influence

Supplementary material 2 to: Blood pressure management in reperfused ischemic stroke

Varela LB, Díaz Menai S, Escobar Liquitay CM, Burgos MA, Ivaldi D, Garegnani L
https://doi.org/10.1002/14651858.CD016085

Summary of the characteristics of participants we should expect to see in the evidence and the actual participants' characteristics extracted from the included studies

Characteristics	Inclusion criteria of review (people we expect to see)	Represantation in included studies (people who took part)
Sex	Lifetime risk of stroke is 1 in 5 for females and ≈1 in 6 for males with a higher risk of complications [1]. Additionally, women have poorer functional recovery, higher mortality and lower quality of life than men after stroke[2].	
Residential location (country of data collection)	The highest stroke burden in 2021 is observed in east Asia, central Asia, and sub-Saharan regions, with the majority of the stroke burden in middle, high-middle, and low-middle sociodemographic regions[3].	

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2. Yoon CW, Bushnell CD. Stroke in women: a review focused on epidemiology, risk factors, and outcomes. Journal of Stroke 2023;25(1):2-15.
3. GBD 2021 Stroke Risk Factor Collaborators. Global, regional, and national burden of stroke and its risk factors, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021. Lancet Neurology 2024;23(10):973-1003.

Varela et al., 2025

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Example 2

Equity-related assessment

Rates of preterm births are higher in the lowest socio-economic groups [61]. Factors such as poverty and race can affect the risk of being born preterm [62]. Male preterm infants are known to have a poorer outcome than their female counterparts [63]; their neurodevelopment also seems to be more sensitive to poor postnatal growth [64].

We will report any relevant characteristics that are included in the acronym PROGRESS-Plus (place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socio-economic status, social capital, age, sexual orientation and disability) [65], given that the rate of preterm births is higher in lower socio-economic groups; and because we suspect differences may arise between high-, middle-, or low-income countries. We will assess this descriptively in our review. We will highlight and present in the summary of findings table any differences in baseline risks in our neonatal population that might result in disadvantages. If possible, we will conduct subgroup analyses based on income settings as defined by the World Health Organization [52], and sex.

Olsson et al., 2025

Consumer Involvement

Consumer involvement

State whether or not consumers or other people will be involved in the review. This may include researchers, patients and members of the public, or other professionals, such as policy makers or commissioners.

If consumers or others will be involved, review authors should report on their methods for involving them. This includes:

- the level of involvement of the people involved;
- the general approach to involvement;
- the roles of the people who will be involved;
- the stage in the review process at which they will be involved; and
- any formal research methods or techniques which are to be used.

A template supplementary material for reporting consumer involvement is available. See Supplementary material 3.

The ACTIVE framework provides guidance on consumer and stakeholder involvement in systematic reviews [49]: if you use it, please cite it.

If you will not involve consumers, state this with a rationale as to why, along with any details that may be relevant.

Example text:

We will not involve consumers in this review due to limited resources, although we will use core outcome sets for the review's outcomes, which have been developed with consumer involvement.

All protocols should include a section on consumer involvement

3 Template supplementary material: Consumer involvement

Title	Template supplementary material: Consumer involvement
Text	Example for a protocol:

Why are you involving people? The purpose / objectives.	
Who will be involved? For example, patients/public/carers, health professionals or other stakeholders, and provide numbers.	
What do you plan to do and when will you do it? Give a brief summary of what you will do, clearly stating when in the review process this will be (review planning and protocol development or during review conduct). If you plan to involve people during review publication and dissemination, also state this here.	

Example for a review:

Additional resources:

- ACTIVE Framework + paper
- Cochrane's Involving People resource
- GIN chapter on Involving People in a review

Example 1

Physical rehabilitation approaches for the recovery of function and mobility following stroke

Appendix 1. Stakeholder involvement in this review update

Aims of stakeholder involvement in this review

The pre-stated aims of the stakeholder group were to (i) clarify the focus of the review (including how physical rehabilitation was categorised within the review), (ii) inform decisions about subgroup analyses, and (iii) co-produce statements relating to key implications arising from the review. Members of the stakeholder group later clarified that their role was to:

- update and inform the description and categorisation of physical rehabilitation following stroke, and make it useful and accessible to all interested parties;
- ask the right questions in physical rehabilitation research, informing the structure and conduct of analyses and subgroup analyses within the Cochrane review of physical rehabilitation following stroke;
- consider implications for clinical practice arising from the results of the Cochrane review of physical rehabilitation following stroke;
- help shape plans for dissemination of the synthesised research evidence, so that it reaches – and is useful to - the right people/organisations.

[Todhunter-Brown, et al 2025]

Description of stakeholder involvement in this review

This description of stakeholder involvement in this review is structured using the ACTIVE framework (Pollock 2019), with an additional question about 'what changed'.

Who was involved?

A stakeholder group was formed. Members included four stroke survivors, four carers, and seven physiotherapists working in stroke care. Stakeholders were from England (n = 7), Scotland (n = 6), Wales (n = 1), and Ireland (n = 1). One stroke survivor and 1 physiotherapist dropped out of the group during the course of the review update.

How were stakeholders recruited?

An advert for stakeholder group members was circulated through local and national networks, via email, and through social media. Interested people contacted the research team, who provided a role description (including details of all planned meeting dates) and requested some personal/demographic details. Responses to personal/demographic details were collated anonymously and used to select a 'representative' sample. Representation considered: geographical location, time since stroke (stroke survivors and carers), years of experience, and area of work (physiotherapists).

What was the mode of involvement?

Stakeholder group members attended a series of online meetings (using Microsoft Teams). Five meetings of the stakeholder group were held between 25 November 2021 and 25 May 2023, supplemented with additional communication by email and individual telephone calls. In addition, two international webinars were held in order to gain wider perspectives on decisions around categorisation of physical rehabilitation within the review.

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Example 2

Patient and public involvement

We will use the ACTIVE framework to describe the nature of patient and public involvement undertaken during the development of this protocol and subsequent review (Pollock 2019). We involved clinicians, patients, patient representatives and other key stakeholders (e.g. representatives of key charitable bodies) in the development of this protocol. They were recruited by closed invitation through the Cochrane Incontinence consumer panel, with recruitment allowed to snowball. The mode of involvement from those engaged through recruitment has been through a single time point online survey, with no direct interaction.

Involvement has been at an influencing level, with outcomes for the interventions and potential adverse effects of interventions that respondents perceived as important to those with nocturia informing the selection of outcome measures listed in the Types of outcome measures. The online survey also requested feedback on the readability of the proposed review title and lay summary, and this feedback was used to revise these components in this protocol. We plan to administer a follow-up survey to the consumer panel to request assistance with interpreting the relevance of results and drawing conclusions, and providing feedback on the readability of the review.

Tanner et al., 2020

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Summary

- Access Cochrane's resources to develop the protocol (e.g., Handbook, Intervention review template, MECIR, QA checklists)
- Clearly describe interventions, comparators, and outcomes of interest
- Clearly describe assessment of risk of bias methods
- Prioritize comparisons and outcomes for SoF tables
- Be sure to include the sections on equity-related assessments and consumer involvement

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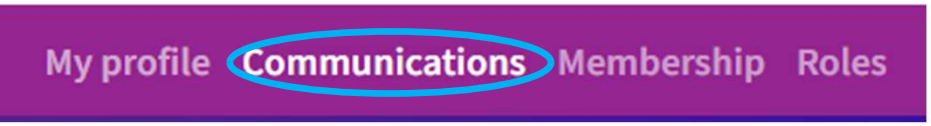

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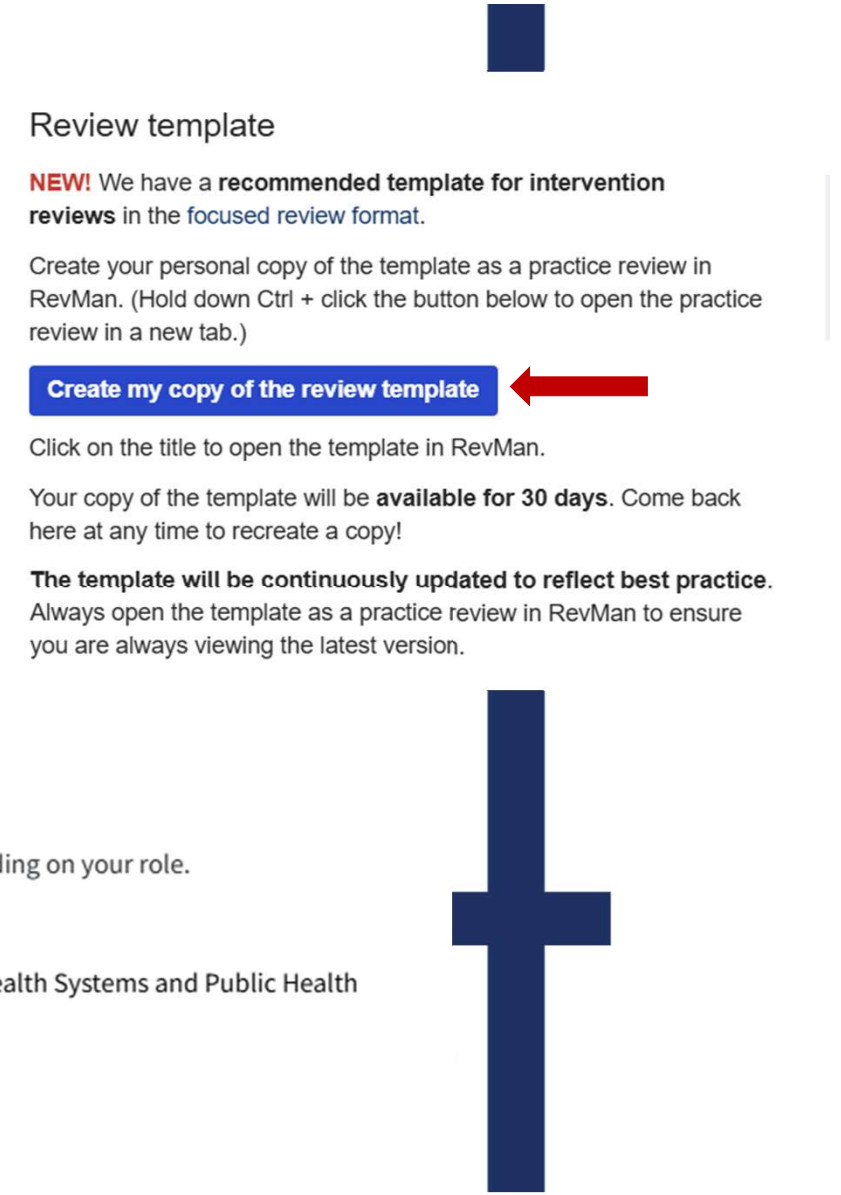

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