Preclinical Systematic Review Wiki

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Contents

Chapter 1

Welcome

Hello, Systematic Reviewers!

Welcome to the CAMARADES Preclinical Systematic Review & Meta-Analysis Wiki.

Find information, links, articles, and useful tools to guide you through your review.

Navigate through the sections to find out more about what a preclinical systematic review is, what the steps are, and how to complete them.

Use the table of contents bar on the left side of the screen to navigate along the steps of a systematic review.

If you have questions about the resources, or would like to ask a question about your specific review, please get in touch: Email us here

Chapter 2

Preclinical Systematic Reviews

2.1 What is a systematic review?

A systematic review (SR) is a literature review that involves systematically locating, appraising, and synthesising evidence from scientific studies to answer a defined research question based on pre-specified criteria.

The methods of a systematic review (and meta-analysis) should be transparent and reproducible. This means that the methods are planned, conducted, and reported in a way that can be repeated by other research groups.

2.2 What is a meta-analysis?

A meta-analysis is a method of combining quantitative results from individual studies identified through systematic review in an overall statistical analysis.

2.3 Clinical & preclinical reviews

There are many differences between preclinical and clinical systematic reviews, which is why we developed this Wiki, specific to preclinical systematic review methodology.

	Preclinical	Clinical
# of included studies	High	Low
Sample size within studies	Low	High
Experimental design	Variable	Consistent
Uses	Investigate translational failure – Explore differences between studies (heterogeneity) e.g. internal & external validity – Inform future preclinical studies e.g. model selection – Inform early phase clinical trials – Explain discrepancies in preclinical vs. clinical trial results – Inform 3Rs decisions	Explore heterogeneity e.g. clinical populations – Inform later phase clinical studies – Inform clinical practice and guidelines

2.4 Why perform preclinical SRs?

There are many reasons to perform preclinical systematic reviews:

- To summarise evidence from multiple similar studies to allow for more accurate estimates of effect
- The methods used to find and select studies are transparent and reproducible, reducing bias and increasing the likeliness of producing reliable and accurate conclusions.
- Summarise findings from all available studies making information easier for the end-user to read and understand
- Analyse individual study quality to inform confidence in the results
- Quantitative synthesis of results (meta-analysis)
- Allow for evidence-based inferences

The results of preclinical systematic reviews can:

- Provide evidence to change research practice by identifying risks of bias in preclinical experiments
- Influence development of reporting guidelines and editorial policies
- Provide evidence to support reporting of positive, negative and neutral results through detection of publication bias
- Identify study design features that compromise potential clinical application
- Contribute to evidence-based clinical trial design

Chapter 3

Systematic Reviews & 3Rs

The principles of the 3Rs (Replacement, Reduction, and Refinement) are a framework for humane animal research. Systematic review is a valuable tool for advancing the 3Rs, primarily through the reduction and refinement of animal use in research. Using existing animal data, systematic reviews can contribute to improvements in animal studies including:

- Providing reliable data to support sample size calculations for various experimental outcomes
- Allowing comparison of the statistical performance of different experimental outcome measures
- Characterising the extent to which subjecting animals to multiple tests contributes to additional knowledge
- Assessing whether the same information can be provided by less invasive tests

For more examples of systematic reviews which implement 3Rs and animal welfare, please see Ritskes-Hoitinga & van Luijk, 2019.

The Guidelines for Reporting Primary Animal Research are: ARRIVE 2.0

Chapter 4

Before You Start

There are a couple of things to check before you start your SR. Read more below.

4.1 Is it necessary?

Consider the following before starting your SR:

- Does the question have contemporary relevance?
- Does the question have clinical importance or importance to informing animal experiment design?
- Is there currently variation in practice?
- Is there uncertainty and debate in the field?
- Informing design of definitive animal experiment trial

4.2 Has it been done before?

Do a quick search on PubMed or the most commonly used bibliographic database in your field to check for published systematic reviews. We may also check preprint archives such as bioRxiv, medRxiv or OSF, to see if a systematic review has been published as a preprint. Check for ongoing systematic reviews on PROSPERO.

Questions to ask regarding existing systematic reviews in the field include:

- Has the research question been adequately addressed?
- Is the systematic review methodology used in the review of sound quality?

- Is the research question specific or broad enough for your aim?
- How recently was the systematic review carried out?

There is no need to start a systematic review if a recent, existing, high-quality SR answers your research question. If there is a relevant SR that is not up-to-date, consider contacting the original author team to discuss their plans for updating the review or a potential collaboration.

For additional reading on how to assess the quality of a published systematic review, see the PRISMA guidelines and other appropriate guidelines on the EQUATOR web-page.

4.3 Is one already in progress?

Before you start, check that the review question you are interested in answering is not already being investigated by another research group.

Where can I find this information? Check places where a systematic review protocol may be preregistered or published, e.g. PROSPERO, OSF, SyRF, preprint servers in your field e.g. bioRxiv or medRxiv. See more below: Register Your Protocol.

If you don't find anything, go ahead and start your SR.

If you find someone is working on the same or a similar question, contact the team. Ask about their aims, methods, and at what stage of the SR they are, and if you can collaborate to achieve the common aim.

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4.4 Build your systematic review team

A systematic review can take a long time, so ensure you have the adequate expertise and funding to complete the review. Get your colleagues to help out! And reach out to people outside of your immediate team for expert advice.

Librarians and information specialists can help with refining your search strategy. They will have insights into which bibliographic databases contain the literature on the fields and topics you are interested in. Librarians can support you to identify sources for grey literature (e.g. thesis documents, technical reports, etc), and they will be able to support you to find full text versions of articles you want to include in your review, especially if they are not available with your institutional subscription.

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- **Systematic Review Methodologists:** If you are new to the systematic review process, a methodologist will be able to help you plan and organise your review, give recommendations for software and tools, as well as meta-analysis support.
- **Statistician** You may require additional advice from a statistician if you plan to conduct a meta-analysis. If this is the case, it's good to get them involved as early on in the review process as possible.
- **Topic Experts:** Ensure you have researchers and other stakeholders with adequate topic knowledge in your team.
- **Project Managers:** Undertaking a systematic review requires effective project management. Ensure there is a clear and dedicated project leader who will be overseeing the project for the entire process. The project lead maintains the overview, which stage is the review at, and invites different members onto the team when necessary.

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4.4.1 Collborating with your team

Early on in the review process, decide a naming convention for documents and decide a place for storing all documents related to the review in shared location. You may need to go back to any stage in the review and revisit decisions or find information, so keep good records. Take thorough notes of decisions made along the SR process, any deviations from the protocol. Not only is this good practice and increases transparency, it can help to make sure all team members are on the same page.

Chapter 5

Research Question

All systematic reviews start with a strong, concise research question. This serves as the back-bone for a good search strategy, as it determines the structure and sequence for your literature searches.

Commonly preclinical SR research questions follow a PICO or PECO stucture:

- **(P)opulation, (P)articipants, or (P)roblem:** What are the characteristics of the population or participants (species, sex, developmental stage, risk factors, or for human participants demographics, pre-existing conditions, etc)? What is the condition or disease of interest?
- **(I)ntervention or (E)xposure:** What is the intervention or exposure under consideration for this population?
- **(C)omparison:** What is the alternative to the intervention (e.g. placebo, different drug, surgery)?
- **(O)utcome:** What are the relevant outcomes (e.g. quality of life, change in clinical status, morbidity, adverse effects, complications)?

There are other research question structures depending on your area or topic of interest, for example, diagnostic test reviews, and prognostic reviews. For more information, see this article on Formulating Review Questions.

5.1 Stakeholders

It is important that you engage stakeholders early on in the review phase to ensure the research question and findings from the review are relevant. Consider the following: - Who will use the results of your systematic review? - From their perspective, what are the relevant questions to ask?

5.2 Preclinical examples

For reference, see examples of research questions for published reviews.

"What is the effect of antidepressants compared to vehicle or no treatment on infarct volume in animal models of ischaemic stroke?"

- **P** - Animal models of ischaemic stroke

- **I** - Antidepressants
- **C** - Vehicle or no treatment
- **O** - Infarct volume

Chapter 6

Protocol

6.1 What is a protocol and why have one?

A systematic review protocol outlines why and how you are going to conduct your systematic review. It should include your: - research question - background to your review - the methods that will be used, including: - search strategy - inclusion criteria - data extraction - quality assessment - data synthesis - statistical analysis plan

A systematic review protocol outlines why and how you are going to conduct your systematic review. It should include your research question, background and the systematic review methods that will be used, including plans for:

- search strategy
- inclusion and criteria
- data extraction
- quality assessment
- data synthesis strategy
- quantitative meta-analysis strategy (where applicable)

Having a pre-specified protocol improves the methodological transparency of your systematic review and reduces the risk of introducing bias. Publishing your protocol allows others to locate reviews in progress and enables future replication. The process of putting together your protocol often involves communication between a number of key stakeholders, you may want to discuss it with an advisory group, external experts, or your funders.

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6.2 Protocol templates

We strongly recommend using a protocol template to ensure you have covered all the important information in your protocol.

SYRCLE (SYstematic Review Centre for Laboratory animal Experimentation) have developed a protocol template tailored to the preparation, registration and publication of systematic reviews of animal intervention studies. See the template and publication here.

It may also be useful to look through examples of previously published protocols from PROSPERO for Animals while you formulate your protocol. You can also use PROSPERO to check that no systematic reviews on your research question are currently underway.

It may also be useful to look through examples from the SyRF Protocol Registry while you formulate your protocol. Look at the Protocol Registry to check that no systematic reviews on your research question are currently underway. **Please not that the SyRF Protocol Registry is no longer accepting new protocol submissions.**

6.3 Register your protocol

Making the protocol for your systematic review available to the community has a number of benefits:

- it provides evidence that prespecified analyses were indeed prespecified;

- allows others to comment on your approach; provides examples for others planning such reviews;
- and can help you identify if other reviews in similar areas are already in progress.

PROSPERO: The Centre for Reviews and Dissemination at University of York now publish Preclinical Systematic Review Protocols. You can search published protocols by title, date, contact person or institution. For more information on registering at PROSPERO, see their website here.

OSF: You can preregister your systematic review project on the Open Science Framework here.

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You can choose to register your systematic review protocol via: - PROSPERO - Open Science Framework(OSF)

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6.4.1 Your protocol & 3Rs

We recommend that you include a statement in your protocol outlining how your research will impact the 3Rs (Replacement, Reduction and Refinement) in animal use in research.

Chapter 7

Systematic Search

To identify relevant studies to include in your SR, you need to perform a comprehensive literature search based on a well-designed search strategy.

7.1 Selecting databases

Bibliographic databases differ in their coverage of journals and indexing of articles, so to ensure your research is systematic, you will have to search multiple databases.

Which databases you search will depend on your research area and question. For preclinical research, typical databases include: - PubMed - Embase - Web of Science

A librarian or an expert in bibliographic databases will be able to help you identify other potential databases and construct database-specific search terms.

On top of electronic databases, you might want to use other methods to find relevant papers such as: scanning reference lists of relevant studies (both primary studies and reviews), hand searching key journals, contacting experts in the field, and searching additional relevant internet resources. Keep a record of alternative methods used and the data collected in a structured format.

7.1.1 PubMed

PubMed is a bibliographic database comprising of more than 30 million citations for biomedical literature from MEDLINE, life science journals, and online books.

It is a free resource that supports the search and retrieval of biomedical and life sciences literature with the aim of improving health, and is maintained by

the National Center for Biotechnology Information (NCBI) at the US National Library of Medicine.

Links & Resources: - The PubMed Advanced Search Builder is a useful tool to build your search query. - Information on MeSH Headings.

7.1.2 Embase

Embase is a biomedical research database covering literature from 1947 to present day. It indexes over 32 million records, including MEDLINE titles, as well as articles from 2,900 journals unique to Embase.

You may access Embase directly or through Ovid depending on your library subscription.

Links & Resources: - Embase indexing and EmTree Headings

7.1.3 Web of Science

Web of Science is a publisher-independent citation database. The Web of Science Core Collection indexes scholarly journals, books, and proceedings in the sciences, social sciences, and arts and humanities and can be used to navigate the full citation network.

Web of Science can also be used to search other databases including SciELO, KCI-Korean Journal Database and Zoological Record.

7.1.4 Other sources & grey literature

Other bibliographic databases include:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- Google Scholar
- Scopus
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- PsycINFO

Access may vary depending on institutional access. Document your search strategy so it is sufficiently reproducible.

7.2 Search strategy development

Select your search terms based around each of the PICO (or equivalent) concepts in your research question.

7.2.1 Step 1: Find keywords and synonyms for each element

A good exercise is to think of as many synonyms as possible for each of your main concepts or PICO elements.

For example:

If your research question is: *What is the effect of antidepressants compared to vehicle or no treatment on infarct volume in animal models of stroke?*

- **(P)opulation:** Stroke. Synonyms might include: cerebral ischaemia, cerebrovascular accident.
- **(I)ntervention:** Antidepressants. Synonyms might include: fluoxetine, SSRIs

7.2.2 Step 2: Index/subject terms (database-specific)

Each core database has their own system for indexing terms, topics, and subjects. Check what subject headings and indexing terms the databases you are interested in searching before you start.

- MeSH terms (PubMed)
- Emtree terms (Embase)
- (See more information about MeSH and EMTREE above Selecting Databases)

Why use both keywords and indexed terms in your search strategy?

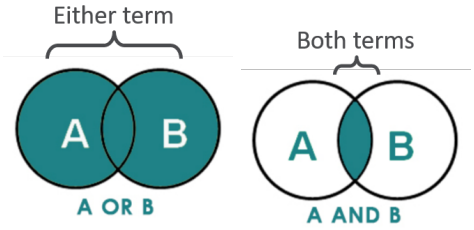
Articles in PubMed are manually indexed but there is usually a slight delay. To capture all articles that use non-standard language, including recently published ones, you might miss some by using only a keyword search.

7.2.3 Step 3: Combining search terms using Boolean operators

Boolean operators include: - AND - OR - NOT

The **OR** operator is used to connect two or more similar concepts (synonyms). It is used to broaden the results by telling the database that at least one of the search terms must be present in the results.

The **AND** operator is used to narrow the results. It is used to tell the database that all search terms must be present in each result.



7.2.4 Precision & sensitivity

A good search strategy aims to to **maximise sensitivity** while attempting to **maximise precision**.

- **Precision** is the ability of search strategy to exclude irrelevant articles.
- **Sensitivity** is the ability of a search strategy to identify all relevant articles.

7.2.5 Tips & tricks

- Consider differences in spelling (e.g. US vs UK English)
- Consider using other PubMed fields e.g. MeSH SubHeadings [SH], or Pharmacological Action [PA]. Find more information here: PubMed Search Tags
- When using the NOT Boolean Operator, consider what relevant literature you might be excluding
- Consider truncation symbols or "wildcards" for your search (e.g. ischem* for ischemia and ischemic, etc). Check all bibliographic databases allow this before adding to your search
- The Polyglot Search Translator is a tool that will assist you in translating the syntax of your search string across various databases. For more information of the Polyglot Search Translator see here

7.3 Combine search results

Once you have run your searches across multiple databases, you can combine your search results in a reference manager software, such as EndNote or Zotero.

To more easily find full text pdfs, remember to add you library subscription information into the settings or preferences of the reference manager, e.g. EzProxy information or OpenURL information.

7.3.1 Does the import order matter? YES!

The order that you import your references into Endnote or another reference manager matters. Different bibliographic databases have different quality or completeness of the references you are interested in, and reference managers use this information to deduplicate the results (the next step).

The recommended order is:

1. Medline
2. Embase
3. Medline in process (if included)
4. Other databases from OvidSP (PsycInfo, EconLit etc)
5. PubMed
6. Cinahl Plus
7. Other databases from Ebsco
8. Web of Science databases
9. Scopus
10. ProQuest databases
11. Cochrane databases
12. CRD databases
13. Any other databases
14. Clinical Trials websites

7.4 Deduplication

As you have searched several different databases and other sources, there are likely duplicates or overlap. Time spent deduplicating your reference library will ensure you have accurate numbers (total records/included/excluded) to report and don't waste your time screening duplicates.

Tools to help remove duplicate references include:

- Endnote can be used to find and remove duplicate records. See this resource.
- Stand-alone tools such as the SR-Accelerator Tool and the ASySD tool for preclinical reviews.

7.5 Searching tools

7.6 Updating your search & searching tools

SyRF Systematic Review Facility has a built-in function that can automatically retrieve new records that meet your search string from PubMed. For more

information, see the SyRF Help Guide here.

The Polyglot Search Translator is a tool that will assist you in translating the syntax of your search string across various databases. For more information of the Polyglot Search Translator see here.

7.7 Find & retrieve full texts

Once you have your library of unique references you can find and retrieve the full texts.

1. Use your reference manager. Guides for retrieving from Endnote and Zotero can be found at the respective links.
2. Search Online: Google search, GoogleScholar, ResearchGate, etc.
3. Contact corresponding authors directly via email or Twitter.
4. Last resort: ask your librarian to assist with inter-library loans. (NB: these can be very costly!)

7.7.1 Tips & tricks for full text retrieval

- Add your Institutional Log-in information to the settings or preferences of the reference manager, e.g. EzProxy information or OpenURL information, so you can more easily find the full texts that your institutional library has access to.
- Be careful using custom scripts or other programs to bulk download as this can result in your institutional IP address being blocked
- If your search strategy has retrieved a lot of potentially relevant results, you may want to consider waiting to find the full texts until after you have carried out titles and abstract screening (see below). This will greatly reduce the number of full text records you need to find, and you will not waste time trying to find articles that are not relevant to your research question.

Chapter 8

Study Selection

Once you have found articles that may be potentially relevant to your research question, you now need to assess each article for relevance against predefined criteria.

If applicable, you may consider doing this in two stages:

1. Title or Title & Abstract Screening
2. Full text Screening

8.1 Inclusion & exclusion criteria

Defining the inclusion and exclusion criteria sets the boundaries for your review.

- Inclusion criteria refer to everything a study must have to be included in your review.
- Exclusion criteria refer to factors that make a study ineligible for inclusion.

It is important the criteria are predefined, *a priori*, and applied consistently across all studies considered for the review. To ensure this, it is common to do citation screening in duplicate, two independent reviews, with discussion or a third independent reviewer to reconcile any discrepancies.

Commonly your inclusion and exclusion criteria are defined around:

«««< HEAD * Type of study or study design * Type of population (e.g. age, sex, disease model) * Type of intervention (e.g. dosage, timing of intervention, frequency) * Type of Outcome Measures (e.g. parameters related to method of assessment or apparatus) ======= - Type of study or study design - Type of population (e.g. age, sex, disease model) - Type of intervention

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Additional factors you may want to consider:

««««< HEAD * Language restrictions * Publication date restrictions * Type of publication (e.g. conference abstracts, peer-reviewed) ======= - Language restrictions (what languages can your review team translate?) - Publication date restrictions - Type of publication (e.g. conference abstracts, peer-reviewed) ««««< HEAD »»»»> 7787d8c099c1a44224dc8f74d2ff96147b136ed3 ======= »»»»> 7787d8c099c1a44224dc8f74d2ff96147b136ed3

You may consider prioritising your inclusion and exclusion criteria based on what criteria you are likely to apply at title and abstract stage, and what criteria you can only apply after having read the full-text.

8.2 Apply your criteria

Is a study included or excluded in your review? Is a study relevant, or not relevant, to your research question based on your pre-defined criteria?

To ensure your inclusion and exclusion criteria are applied in a unbiased, uniform fashion, it is good practice to have at least 2 independent screeners apply the criteria. If there are discrepancies in your decisions, you may discuss the discrepancies until you reach consensus or invite a 3rd independent reviewer to reconcile any differences.

8.3 Tools for screening

««««< HEAD You can complete title and abstract screening & full text screening in SyRF the Systematic Review Facility which is a free-to-use online platform to support your preclinical systematic review. ======= You can complete title and abstract screening & full text screening in SyRF the Systematic Review Facility which is a free-to-use online platform to support your preclinical systematic review. »»»»> 7787d8c099c1a44224dc8f74d2ff96147b136ed3

SyRF randomly presents the order of articles to screeners and by default requires a consensus between multiple screeners.

Other free-to-use platforms to perform citation screening include Rayyan and SysRev.

Chapter 9

Data Extraction

Extract relevant data as predefined in your protocol.

It is best practice for two reviewers to extract data independently to prevent errors. Any discrepancies can be resolved by a third independent reviewer or by discussion.

The data you extract from each included study should be pre-specificed in your systematic review protocol. It is best practice to extract data in duplicate, two independent reviewers, to prevent errors.

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9.1 Study characteristics

Study characteristics to extract from included articles may include:

- PICO information (e.g. age and sex of population, species and strain of animal, dose and timing of intervention, type and time of outcome assessment)
- Study Design information
- Study Quality information (see below)
- Additional information (e.g. time between intervention and outcome assessment, any comorbidity information)

9.2 Quantitative data

Extracting quantitative and numerical data from included studies is necessary to perform meta-analysis to pool the effect sizes from.

Your outcomes of interest may be:

- **Dichotomous** (e.g. mortality, tumour presence)

	Number in group	Number a
Treatment	N_a	N_b
Control	N_c	N_d

- **Continuous** (e.g. blood pressure, or weight loss)

	Treatment	Control
Mean	X_1	X_2
SD	SD_1	SD_2
N	N_1	N_2

- **Count Data** (e.g. number of events)

Data about your outcomes may be provided in various formats including:

- In tables
- In text
- In graphs

You may need to use tools such as Adobe desktop ruler or WebPlotDigitizer to extract numerical values (e.g. means and standard deviations (SD) or standard error of the mean (SEM) from graphs). Some studies may report values on a different scale. Be aware, you may need to convert these to a scale that is common across all studies (e.g. log scale conversion).

9.3 Data extraction software

As you are extracting these pieces of information you will want to store them in the same place for easier, later synthesis and analysis.

We recommend using SyRF the Systematic Review Facility to extract and store your data. It is a free-to-use online platform where you can create custom data extraction forms for your review. Flexible questions types and question settings, as well as online format allow for easy data extraction for you and your review team to simultaneous extract data from included papers. For more information

see the SyRF Website and the SyRF Help Guide to set up your free review project.

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Chapter 10

Quality Assessment

10.1 Why assess study quality?

Low methodological quality can affect internal validity and introduce bias into the results of primary studies. Internal validity refers to the extent to which study results reflect the true cause-effect of an intervention. Different types of bias can influence internal validity (e.g. selection, performance, detection, and attrition biases).

It is not impact. It is not novelty.

Bias in primary studies can lead to an over- or under-estimation of the true intervention effect in both primary studies and systematic reviews. It is important to consider the implications of study quality and validity for interpreting the results from your systematic review and it is often a good idea to incorporate a quality assessment section into your final report.

«««< HEAD «««< HEAD Study quality characteristics which have been shown to impact the results of preclinical studies include whether animals were randomised to control or treatment groups, and if researchers were blinded to intervention allocation or exposure when assessing outcomes. Read more about allocation and blinding on the NC3Rs Experimental Design Assistant website.

Chapter 11

Reporting

Study quality characteristics which have been shown to impact the results of preclinical studies include whether animals were randomised to control or treatment groups, and if researchers were blinded to animal group when assessing outcomes.

11.1 Reporting quality