A practical guide:

Data Extraction for Intervention Systematic Reviews

covidence

Introduction

Welcome to this practical guide to data extraction for intervention systematic reviews.

Whether you're a seasoned researcher or just starting out, this guide can help streamline your data extraction processes, avoid unnecessary work, and deliver high-quality outcomes, regardless of which data extraction tool you are using.

Shaped by insights from hundreds of researchers, this guide aims to distil the collective wisdom and best practices of the global systematic review community. It offers definitions, practical advice, links to the Cochrane Handbook, downloadable templates, and real-world examples from studies.

We hope this guide becomes an invaluable companion in your research journey.

About the author

We are Covidence. Launched in 2014, Covidence is a not-for-profit world leading Software as a Service (SaaS) platform. Our platform enables health and science research teams to rapidly synthesise and uncover actionable insights from the mountains of research produced around the world. Leading institutions worldwide use Covidence to create the knowledge that shapes our society.

If you find this guide helpful, please share it with your community so everyone can benefit. Feel free to use the pictures and drawings in your own content. We'd appreciate it if you could include a shout-out: 'Diagrams and illustrations courtesy of Covidence,' along with a hyperlink to the eBook whenever you can. Thanks for spreading the word!

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Data extraction for intervention systematic reviews

Systematic reviews

Systematic reviews are often referred to as the gold standard of research methodology. Systematic reviews strive to be the most thorough and rigorous type of review, to reduce the amount of bias. They apply pre-specified scientific methods to find, synthesise and appraise all the information on a given research question. The methodology is clear, transparent and reproducible.

> “Systematic reviews seek to collate evidence that fits pre-specified eligibility criteria in order to answer a specific research question. They aim to minimise bias by using explicit, systematic methods documented in advance with a protocol.”
>
> - Cochrane Handbook 1.1

Alternative ways of bringing together evidence

Systematic reviews are the gold standard for finding, appraising and synthesising studies, but sometimes a different approach is more suited to a research question. Some alternatives are given below, with explanations of why they might be used instead of a systematic review:

- **Scoping reviews** identify and map/summarise the amount and nature of evidence on a topic using predefined methods. Sometimes they are used to inform future research, determine if a systematic review is worthwhile, or to define the best way of defining the question for a systematic review. Search criteria and inclusion criteria are generally broader than a systematic review, meaning that more studies will be included. Data extraction is sometimes called “data charting” in scoping reviews.

- **Literature/Narrative reviews** describe the amount and nature of evidence on a topic, without formal appraisal or synthesis. Accuracy and replicability are not the focus of literature reviews. The author can introduce their own understanding and so the write-up can be biased. The conclusion is often in words rather than using statistical methods. Literature reviews can also be called narrative reviews.

- **Rapid reviews** are streamlined systematic reviews that use abbreviated methods to meet the urgent needs of decision-makers (e.g. narrower scope, limited search, fewer outcomes). Their goal is to produce more timely information for decision making compared with standard systematic reviews.

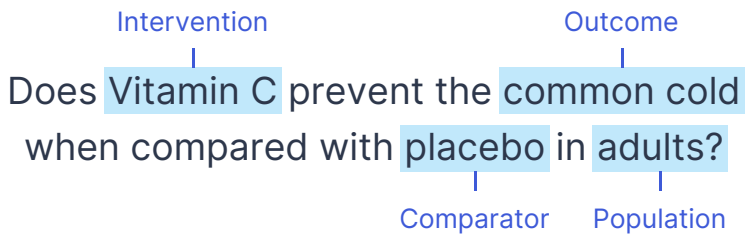
- **Overview/Umbrella reviews** are reviews of existing systematic reviews to compare and contrast results and examine the overall body of evidence. The wide picture obtainable from the conduct of an umbrella review can show if the evidence base around a topic or question is consistent or if contradictory or discrepant findings exist, and in exploring and detailing the reasons why.

Intervention systematic reviews

An intervention systematic review seeks to understand the effect of a drug or treatment (intervention) compared with a control or an alternative treatment, by collecting, assessing and combining the available evidence. Interventions might be different types or doses of drugs, therapies, vaccines, medical devices, procedures or public health policies.

Intervention systematic reviews often use the PICO framework in their protocol to define the review question, and structure the review team's approach to data extraction, analysis and write-up:

- **Population:** The population or patients of interest.
- **Intervention:** The drug or treatment being evaluated.
- **Comparator:** The comparison drug or treatment, no treatment, or placebo.
- **Outcomes:** The expected benefits and harms.



Other types of systematic reviews

Intervention reviews are the most common type of systematic review, but others exist to address different types of questions. Each uses its own question framework and methods for finding, assessing and bringing together relevant studies:

- **Reviews of observational studies** to answer questions about exposures (e.g. asbestos) that you cannot test in a randomised control trial.
- **Diagnostic test accuracy reviews** assess how well a diagnostic test performs in diagnosing and detecting a particular disease.
- **Methodology reviews** identify issues relevant to how systematic reviews and clinical trials are conducted and reported.
- **Qualitative reviews** synthesise qualitative evidence. These may be about effectiveness but often focus more on barriers, enablers, values, preferences and other experiences.
- **Prognosis reviews** address the probable course or future outcome(s) of people with a health problem.

Data extraction

Data extraction is a process within a review workflow in which review teams collect relevant information from included studies, and organise it in a way that enables them to make use of the data in future stages.

1	2	3	4	5	6	7	8
Set up	Search	Screen	**Extract**	Transform	Analyse	Interpret	Publish

Review workflow

Why is this important to review teams?

This process allows the review team to collect relevant data from all included studies in a consistent and useful way. Studies report information in a variety of different formats and are often unstructured. Without data extraction it would be impossible to make sense of the data within studies and to determine findings for the review question.

Unstructured Structured

The goal of data extraction is to produce an output in a format that allows the review team to analyse and compare data across multiple included studies.

Data extraction for systematic reviews

To ensure the review is thorough and reliable, the data extraction process should be:

- rigorous, transparent and reproducible
- guided by a predefined protocol
- piloted in advance
- done in a way that reduces errors and bias, such as blinding and duplication
- documented clearly

Producing an output that supports analysis and comparison of extracted data requires the completion of:

- standardised data extraction for each study
- quality assessment (risk of bias) for each study

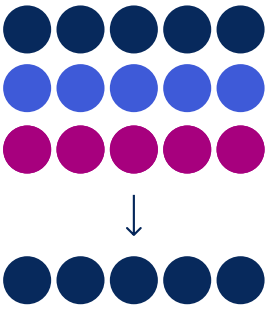
Quality assessment

Quality assessment (risk of bias) and data extraction are related but distinct processes in the review workflow.

Data extraction

Data extraction is the process of collecting and gathering data from various sources. It identifies relevant information and extracts it from documents, databases, or other sources.

Data extraction focuses on obtaining the necessary data that will be used for subsequent analysis, synthesis or evaluation in your review. The quality of data extraction can impact the accuracy and reliability of the data collected. Errors or omissions during this phase can lead to critical issues and erroneous conclusions.



Extracting relevant information

Quality assessment (risk of bias)

Risk of bias assessment, on the other hand, is the process of evaluating the quality and reliability of individual studies included in the systematic review. It identifies potential sources of bias or systematic errors in the design, conduct, or analysis of each study. It is useful to include information to support quality assessment decisions when extracting data, such as methods for randomising, and allocation concealment (who was blinded to the intervention and how).

Evaluating the quality of individual studies (as high, low or unclear)

The goal of risk of bias assessment is to determine how well each study's results can be trusted. This assessment often involves evaluating the study's methodology, such as randomisation, blinding, handling of missing data, and other factors that could impact the validity of the results.

Common tools for risk of bias assessment include:

- Cochrane Risk of Bias Tool (RoB 2 and RoB 1) for intervention studies.
- ROBINS-I for non-randomised studies of interventions.
- Newcastle-Ottawa Scale for observational studies.
- Critical Appraisal Skills Program (CASP) checklist.

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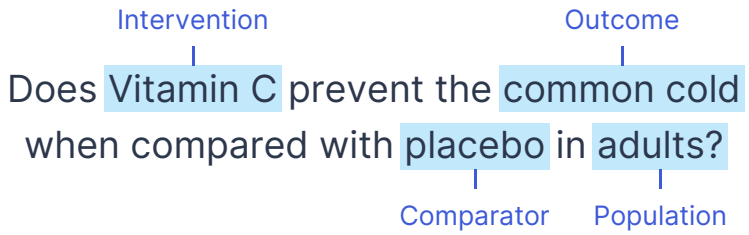
Use of PICO to guide Data Extraction

PICO(T)

The development of the data extraction template is guided by the protocol for the review.

A critical part of the protocol for a review is the PICO(T). “P” for population, “I” for intervention, “C” for comparison, “O” for outcome and “(T)” for timepoints. The PICO(T) components are often prespecified in the review protocol.

- **Population**: The specific population or group that you want to study. This should include characteristics such as age, gender, medical condition/disease, or any other relevant factors.
- **Intervention**: The treatment, exposure, or intervention you are investigating.
- **Comparison**: The comparison group or alternative intervention you are investigating. This can be a placebo, another treatment, standard care, or the absence of the intervention.
- **Outcomes**: The outcomes you are interested in measuring or evaluating. These can be clinical outcomes, patient-reported outcomes, adverse events, or any relevant endpoints. Consider including outcomes that matter to the end users of the review.
- **Timepoints**: Some reviews include timepoints as part of the PICO(T) framework. You might be interested in collecting data only at specific timepoints.
- **Other**: Includes other essential eligibility criteria for your review such as study design.



P	I	C	O	T
Population	**Intervention**	**Comparison**	**Outcomes**	**Timepoints**
Adults 18 years and older	Vitamin C	Placebo	No. of common colds Duration of symptoms Severity of cold	End of treatment

PICO(T) and your data extraction template

Using the protocol and the PICO(T) to guide data extraction ensures that the research question is clearly defined, and the data you collect are relevant and structured to answer that question. This approach helps maintain the rigour and consistency of your research.

You can use PICO(T) to:

- **Create a data extraction template:** Design a structured template to record the information for each included study in your review. Your template should include fields for the PICO(T) elements and any additional information you plan to extract for example characteristics of the population.
- **Define extraction criteria:** Clearly define the criteria for extracting data. For example, specify which data you will extract and any specific details you need to collect for each PICO(T) element.

Useful resources

Your protocol and your PICO(T) should guide the data you intend to collect. PRISMA-p is a useful reporting tool for protocols.

Population characteristics

Also known as: Participant characteristics, patient characteristics

Population characteristics in a systematic review are the key baseline demographic and clinical attributes of the individuals, or groups of individuals, who are the participants in the included studies.

P	I	C	O	T
Population	**Intervention**	**Comparison**	**Outcomes**	**Timepoints**
Adults 18 years and older	Vitamin C	Placebo	No. of common colds Duration of symptoms Severity of cold	End of treatment

Example of population characteristics

This is an example baseline characteristics table which you might find in a study. Characteristics might also be reported in the text of the study and not in a table.

Table 1. Baseline characteristics by group

Characteristic	Vitamin C (mean ± SD)	Placebo (mean ± SD)
Age (year)	24.1 ± 3.0	23.8 ± 4.1
Weight (kg)	82.0 ± 9.2	81.7 ± 10.2
BMI (kg/m^2)	24.4 ± 3.8	25.0 ± 3.7
Body fat (%)	17.7 ± 6.2	25.0 ± 3.7
Dietary vitamin C (mg/day)	93 ± 53	104 ± 45

Including a clear description of the population characteristics in a systematic review is essential for transparency, reproducibility, and for assessing the applicability of the review's findings to different populations or settings. It helps readers judge the relevance and external validity of the included studies.

Common population characteristics

The following information is usually included in the population characteristics:

- **Geographic location:** The geographic location of the study populations can be important for understanding regional variations and potential geographic bias.
- **Eligibility criteria (inclusion and exclusion criteria):** A list of criteria used to define who was eligible for the study. These criteria define the specific population that the study focused on.
- **Setting:** The setting where the study was conducted, which could be a specific healthcare facility, community, or geographic region. This is important for understanding potential contextual factors.
- **Demographics:** Information about the age, gender, race or ethnicity, and socioeconomic status of the study participants. This helps in assessing the diversity and representativeness of the population.
- **Health status:** Clinical characteristics related to the health status of the population, such as the presence or absence of specific medical conditions, disease severity, comorbidities, co-treatment and other relevant health factors.
- **Sample size:** The number of participants in each intervention and comparison group, which can affect the precision and generalisability of the findings.

How to collect population characteristics from a study?

In the study, characteristics might be reported across all of the population, separated by group, or both. Characteristics across studies will vary and you should define in your protocol and on your data extraction template which characteristics are the most important to extract for each study. This ensures that enough data is collected without wasting time on unnecessary data collection.

Intervention and comparison groups

Also known as: intervention/comparator groups, intervention/comparison groups, intervention/control groups, study arms, arms, groups, cohorts

In an intervention review, the research question investigates how a particular drug or treatment (intervention) performs against another drug or treatment (comparison). The intervention and comparison groups describe the groups of participants given a particular drug or treatment during a study.

Example intervention/comparison groups

This example study shows vitamin C given to one group or participants and a placebo given to another group.

> This randomised, double-blinded, placebo-controlled study followed a parallel arm design and lasted eight weeks.
>
> Participants were instructed to ingest two tablets daily in a divided dose. Vitamin C tablets (500mg vitamin C per tablet) were of the same size, shape and appearance to the placebo tablets that contained white flour.

Multiple intervention groups

Many studies have one intervention group and one comparison group. However, it can get more complex. As an example imagine a study where the investigators want to know about different variations of an intervention. In that case you will have multiple intervention groups. In your protocol it is critical to describe the intervention in sufficient detail to guide data extraction. For example, are you only interested in specific doses of vitamin C?

Example of multiple intervention groups

In this example vitamin C is given to three groups of participants at different doses.

> Participants were individually randomised into 1 of 4 groups:
>
> - **Group 1:** 1g/daily of ascorbic acid (vitamin C)
> - **Group 2:** 2g/daily of ascorbic acid (vitamin C)
> - **Group 3:** 3g/daily of ascorbic acid (vitamin C)
> - **Group 4:** 1 placebo tablet daily. Placebo tablets were of the same size, shape, appearance and taste as the ascorbic acid (vitamin C) tablets
>
> Duration of the intervention - 10 weeks

Common descriptors of interventions and comparators

In your protocol and data extraction template, specify the key descriptors of interventions and comparators to capture for each study.

In the example data extraction template, we suggest some descriptors to capture per intervention and comparator group included in the study. The Cochrane Handbook - Table 5.3.a also includes example descriptors.

How to collect intervention and comparison group data?

When extracting the intervention and comparison group characteristics, from a study, it's important to capture details that will help you compare studies in the analysis stage. For example, can you compare different doses? Capturing this data in a consistent way across studies will help you understand what can be analysed without needing to revisit the studies later.

For example, these two studies have extracted data for vitamin C and placebo groups. However the dose of vitamin C differs between groups. In your review protocol you should define what can and can't be grouped together for comparison.

Study ID	Group name	Dose	Frequency	Method
Study 1	Vitamin C	500mg	Daily	Oral tablet
Study 1	Placebo	0mg	Daily	Oral tablet
Study 2	Vitamin C	1000mg	Daily	Oral tablet
Study 2	Placebo	0mg	Daily	Oral tablet

Outcomes

In an intervention review, the research question investigates how a particular drug, exposure, or treatment (intervention) performs against another drug, exposure treatment/no treatment (comparison) in relation to specific outcomes.

P	I	C	O	T
Population	**Intervention**	**Comparison**	**Outcomes**	**Timepoints**
Adults 18 years and older	Vitamin C	Placebo	No. of common colds Duration of symptoms Severity of cold	End of treatment

Example of outcomes

This example study has multiple outcomes shown in one table.

Cold outcomes in participants ingesting 1000 mg vitamin C versus placebo daily for 8 weeks*

	n	Participants with colds	Cold duration, days (mean ± SD)
Vitamin C	16	8	3.2 ± 1.5
Placebo	15	12	5.6 ± 3.2
RR or change (95% CI)		0.63[a] (0.36, 1.08)	-2.4[b] (-4.18, -0.62)

* [a] Risk ratio; [b] treatment effect

Capture the characteristics of each outcome you extract from a study such as the scale or specific measurement, the metric (e.g. change from baseline or end point), method of aggregation, and the exact timepoint at which the outcome was recorded. This will help you compare and analyse outcomes across studies.

Primary vs secondary outcomes

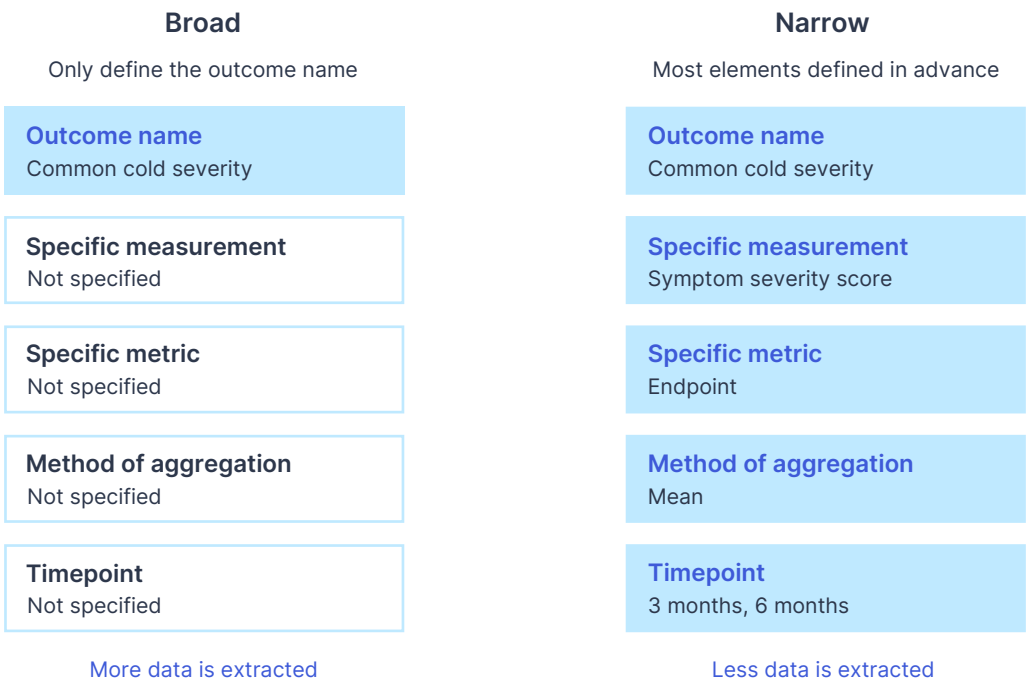
Most systematic reviews include outcomes that are critical or important to decision making. These are important when evaluating the overall impact and effectiveness of the intervention.

- **Critical or Primary outcome/s** are the most important and relevant outcomes for the review. They are usually chosen as the main measures of effectiveness for the intervention and they are often the outcomes used to power or determine the sample size of the population in the included studies. In our example review of vitamin C for preventing the common cold, the critical outcome is the total number of colds.
- **Important or Secondary outcome/s** provide additional information about the effectiveness of an intervention and often about the harms, quality of life, or cost-effectiveness. In our example review, the important outcomes are disease severity and days off work.

Broad vs narrow outcomes

The breadth of the outcome is dependent on the review question. The key is to find a balance by planning ahead and involving experts.

- **Broad outcome:** A lot of outcome data will be extracted from studies. The more data you extract, the more heterogeneity you're likely to encounter, which can affect your analyses and interpretations. Some data you extract might not be relevant to the review question.
- **Narrow outcome:** Fewer outcome data will be extracted across studies as it is recognised that only some of it is relevant to the review question. This will minimise variation, but give you a lot less information.



How to collect outcome data from studies?

Each study has its own objectives, which aren't necessarily aligned with your review question. So when extracting outcomes from a study, decide which outcomes are relevant to your review.

If you wanted to collect characteristics for the outcome "Total number of colds at 8 weeks" you would extract the information below.

Outcome	Specific measurement (scale or unit)	Metric	Method of aggregation	Timepoint
Total number of colds	Events	Endpoint	n, N	8 weeks

After completing extraction across all studies, you could pool similar outcomes for analysis. This information will help you decide what can and can't be pooled together. For example you might not compare results of an outcome which was reported at 8 weeks to an outcome reported at 1 year.

It is important to extract the unit of measurement. In the example above, it would be inappropriate to compare an outcome measuring number of events with an outcome measuring number of participants.

Timepoints

In an intervention review, the research question can investigate how a particular drug or treatment (intervention) performs against another drug or treatment (comparison) in relation to outcomes at a specific timepoint/s. Outcomes reported in studies will always relate to a specific time period or timepoint. When developing your protocol and extracting your data you should keep in mind which periods of time or timepoints are relevant to your review.

P	I	C	O	T
Population	**Intervention**	**Comparison**	**Outcomes**	**Timepoints**
Adults 18 years and older	Vitamin C	Placebo	No. of common colds Duration of symptoms Severity of cold	End of treatment

Example of timepoints

This example study has the timepoint shown in a table but it might also be reported in the text or in a chart.

Cold outcomes in participants ingesting 1000 mg vitamin C versus placebo daily for 8 weeks*

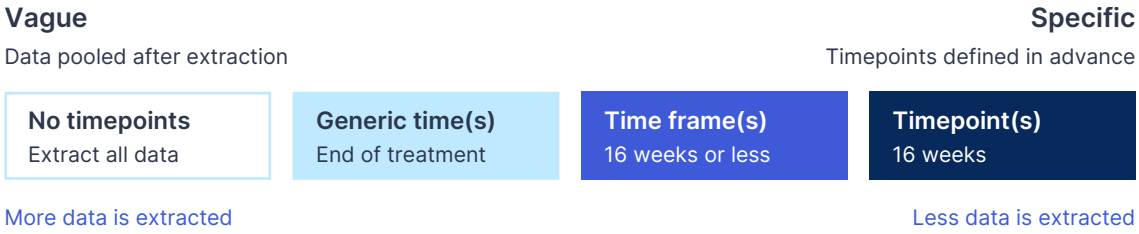
	n	Participants with colds	Cold duration, days (mean ± SD)
Vitamin C	16	8	3.2 ± 1.5
Placebo	15	12	5.6 ± 3.2
RR or change (95% CI)		0.63[a] (0.36, 1.08)	-2.4[b] (-4.18, -0.62)

* [a] Risk ratio; [b] treatment effect

Vague vs specific

The timepoints of interest can differ between outcomes in a review. For example an outcome of “quality of life” might have a timepoint of 28 weeks or less, whereas an outcome of “adverse events” might have a timepoint of “Last follow up”.

Timepoints can be defined as vague or specific depending on the review and the outcome.



For example, a specific timepoint could be “16 weeks” for a particular outcome. This would mean extracting only the outcome data at 16 weeks from the studies.

Another timepoint could be “end of treatment”. In examples like this, it’s useful to capture when exactly “end of treatment” was, as this can vary between studies.

How to collect timepoint data from studies?

It is important to provide guidance to extractors when extracting timepoints to reduce over extracting. You are trying to strike a balance between collecting all relevant data for your review without spending too much time extracting data that is not going to be relevant for analysis.

For example, if you are looking to collect data at an 28 week timepoint, are you only looking to collect the exact time point “28 weeks “ or is it “28 weeks or the closest time point” or “28 weeks or less”?

It might also be important to collect the exact timepoint as reported in the study, this will allow you to understand if you can compare studies.

For example if your looking to extract an outcome at the timepoint “End of treatment” you’ll need to know if the end of treatment is 28 weeks or 1 year. If a study has a follow up period, then make sure to capture the exact timepoint the treatment ended and the “last follow up” period.

Result data

Result data are the numerical data associated with an outcome in a study, which will be analysed and synthesised in your review.

When collecting numerical data for an outcome it's important to consider the different types of data.

Dichotomous data

Dichotomous (or binary) data only has two possibilities e.g. Yes or No. An example of a dichotomous outcome might be "Number of participants with a cold", where the participant either had a cold or didn't. Typically this data will be reported as an aggregate per group in a study. The study might report measures of a dichotomous outcome as a number or as a percentage along with the total number of participants in a group.

Continuous data

Continuous data occurs along a spectrum, with any point on the spectrum being valid. An example of a continuous outcome might be "Duration of a cold". Typically this data will be reported as an aggregate per group in a study, reporting the average, the measure of uncertainty and total number of participants in each group. Averages could be the mean or median whilst the measure of uncertainty could be reported as standard deviation (SD), standard error (SE), confidence intervals (95% CI), interquartile range (IQR).

Count data

Count data can only be integers which arise from counting {0,1,2,3,...}. Outcomes may be reported as count data where participants may experience an event on more than one occasion. An example of a count outcome might be "Total number of colds", where the participants might have a cold multiple times during the study. Make sure you don't treat count data as dichotomous data.

Example of dichotomous, continuous and count result data

This example study has vitamin C and placebo groups, showing dichotomous data for "Participants with colds", continuous data for "Cold duration, days" and count data for "Total number of colds".

Cold outcomes in participants ingesting 1000 mg vitamin C versus placebo daily for 8 weeks

	n	Participants with colds	Total number of colds	Cold duration, days (mean ± SD)
Vitamin C	16	8	13	3.2 ± 1.5
Placebo	15	12	18	5.6 ± 3.2

Effect estimate data

In some cases, studies will report effect measures. Effect measures can be used in two different ways. One way is to compare the intervention group with the comparison group to report the estimated difference of effect between them in relation to an outcome.

The other way is to compare a specific timepoint to baseline data for each group in the study, e.g. the change in cold severity score at 8 weeks compared with baseline for a vitamin C group and a placebo group.

Effect measures for dichotomous outcomes are typically ratios (risk ratio, odds ratio, etc). Effect measures for continuous outcomes are typically difference measures (mean difference, standardised mean difference) between the intervention group and the comparison group.

As the effects of a drug or treatment are estimated with effect measures, it's important to collect the variance which captures the degree of uncertainty around the estimate (95% CI, SD, SE, etc).

You can find more information on effect measures in chapter 6 of the Cochrane Handbook.

Example of effect estimate result data

This example study has vitamin C vs placebo for "Participants with colds", showing effect measures (RR, 95% CI) as well as vitamin C vs placebo for "Cold duration, days" showing effect measures (MD, 95% CI).

Cold outcomes in participants ingesting 1000 mg vitamin C versus placebo daily for 8 weeks*

	n	Participants with colds	Cold duration, days (mean ± SD)
Vitamin C	16	8	3.2 ± 1.5
Placebo	15	12	5.6 ± 3.2
RR or change (95% CI)		0.63[a] (0.36, 1.08)	-2.4[b] (-4.18, -0.62)

* [a] Risk ratio; [b] treatment effect

How to collect result data from studies?

It's not always necessary to capture all result data that's been reported in the study. When extracting result data for a study, it's important to follow guidance that's been defined for your review. For example:

- Outcomes of interest should be defined in advance, this means that you might not need to extract data for every outcome (and results) reported in the study.
- The same is true of the timepoints reported in the study. Not every timepoint will be relevant for your review.
- If effect estimates are reported as well as group data, it might not be necessary to capture both.

If you want to collect result data for the outcome "Number of participants with colds at 8 weeks" and you want to capture group data for vitamin C and placebo as well as the effect estimate you might extract:

Number of participants with colds at 8 weeks

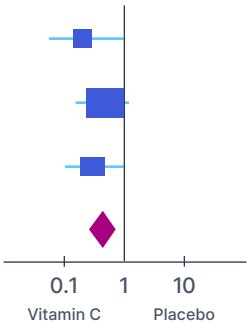
Vitamin C		Placebo		Vitamin C vs Placebo	
n	N	n	N	RR	95% CI
8	16	12	15	0.63	(0.36, 1.08)

When analysing the result data for this outcome across all studies, you might decide to pool similar data for similar populations and treatments. For example a forest plot in your review could look like this:

Forest plot

Study	Vitamin C n / N	Placebo n / N	Weight	Risk Ratio 95% CI
Study 1	8 / 16	12 / 15	20.4%	0.63 (0.36, 1.08)
Study 2	20 / 35	30 / 40	54.3%	0.76 (0.54, 1.07)
Study 3	10 / 20	15 / 19	25.2%	0.63 (0.39, 1.04)
Total	**38 / 71**	**57 / 74**	**100%**	**0.70 (0.54, 0.90)**

Heterogeneity: Chi² = 0.56, df = 2 (P = 0.76); I² = 0%
Test for overall effect: Z = 2.82 (P = 0.005)



Scenarios to be aware of when extracting result data

- **Unclear measure of uncertainty:** Do not assume result data is reported as standard deviation (SD), as it could be standard error (SE). Standard errors are often smaller and confusing the two can result in an inaccurate measure of uncertainty, making it appear more precise than it actually is.

- **Direction of the scales when using standarised mean difference (SMD):** Remember to note down if the direction of the scale is "lower is better" or "higher is better".

- **Extracting time-to-event outcomes:** Time-to-event outcomes focus on the time taken for an event to occur. For example, time-to-death (survival data) in cancer studies. Extracting these types of data can be tricky. We would recommend seeking statistical advice if you plan on including them in your analysis.

- **Don't treat count outcomes as dichotomous outcomes:** Count outcomes can have more events to participants in a group, for example in the outcome "Total number of colds" every participant could have more than one cold. Treating them as dichotomous will lead to analysis errors. Look for rates or consider if you could use another measure for your outcome. For example:
    - **Rates:** Total number of colds in relation to the total amount of person-years in each group
    - **Dichotomous measures:** The number of patients which experienced at least one cold in each group.
    - **Continuous measures:** The mean number of colds per person-year in each group.
    - Cochrane handbook section 6.7 provides more detail on extracting count and rate data.

- **Extracting ordinal outcomes:** Ordinal outcomes are categorical and have natural ordering or ranking, for example when level of disease severity can be categorised as mild, moderate or severe. When analysing these outcomes, you might make them dichotomous (cut points should be prespecified), continuous or analyse them as ordinal outcomes. The way you intend to analyse these outcomes might impact what data you extract from a study. Alternatively, you may decide to extract all data as reported and then analyse based on the most commonly reported form(s) across studies.
    - Cochrane handbook section 6.6 provides more detail on extracting ordinal outcomes.

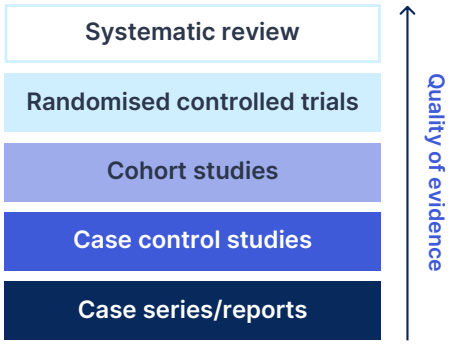
Study design and data extraction

In your review protocol you need to describe the details of the study designs you want to include. Study design plays a key role in data extraction for a systematic review because it can directly influence the quality and reliability of the evidence being synthesised.

The study design(s) you intend to include in your review should align with your research question. Some questions are best answered through experimental designs (e.g. RCTs), while others may require observational or qualitative approaches.

Here are some key issues to consider when choosing which study designs to include in your review. The selection of study designs depends on the question you are trying to answer in your review.

- **Internal validity:** Different study designs have varying levels of internal validity, i.e. how accurately a study measures what it intends to measure. Well-designed randomised controlled trials (RCTs), are considered to have higher internal validity than observational studies, with regards to intervention studies.



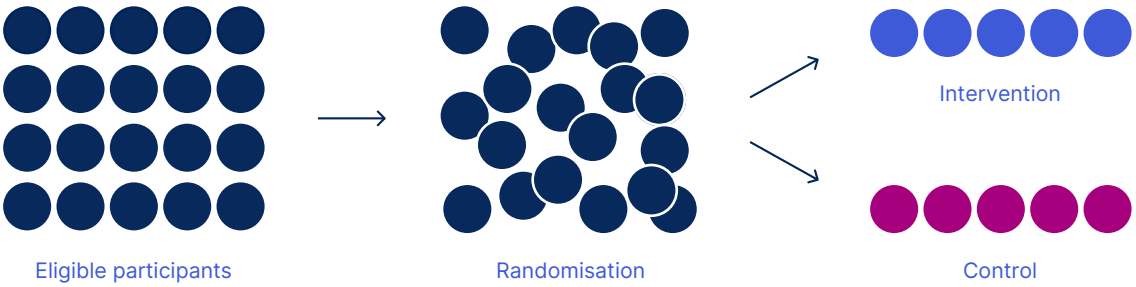
- **Risk of bias:** The risk of bias varies across study designs. Systematic reviews aim to minimise bias, and the inclusion of studies with strong methodologies helps achieve this goal. Certain study designs, such as RCTs, are designed to minimise confounding factors and reduce bias. Risk of bias is likely to increase toward the lower end of the evidence hierarchy.
- **Generalisability:** The generalisability of study findings to broader populations can be influenced by study design. RCTs are typically conducted under controlled conditions, and their findings may not always be directly applicable to real-world settings. This is why it's important to record details about the population demographics and study settings.
- **Precision and accuracy:** Studies with rigorous methodologies tend to provide more reliable and precise data, which is crucial for drawing meaningful conclusions in a systematic review. Well-designed, high-quality observational studies may be appropriate designs for some systematic reviews.
- **Comparability:** Using studies with similar designs enhances the comparability of the evidence which allows for a more straightforward synthesis of findings. You can include mixed-methods in your review but clearly document the study designs and avoid combining the data from mixed-methods in the analysis as this can introduce heterogeneity. Misinterpretation of data may result from mixing the evidence from RCTs with observational studies.

Study designs

There are many study designs used in research and each has benefits and limitations for answering different types of questions. Here are some of the more common study designs you might come across with examples in healthcare and education.

Randomised Controlled Trial (RCT)

A randomised controlled trial (RCT), is a robust scientific experiment designed to test the effectiveness of a particular intervention, treatment, or intervention under controlled conditions. Participants are randomly assigned to different groups, with at least one group receiving the treatment (intervention), while another group (the control group) does not receive the treatment. The random assignment (e.g. computer generated, coin toss, block randomisation) ensures that the groups are comparable, and any observed differences in outcomes can be attributed to the treatment rather than other confounding factors.



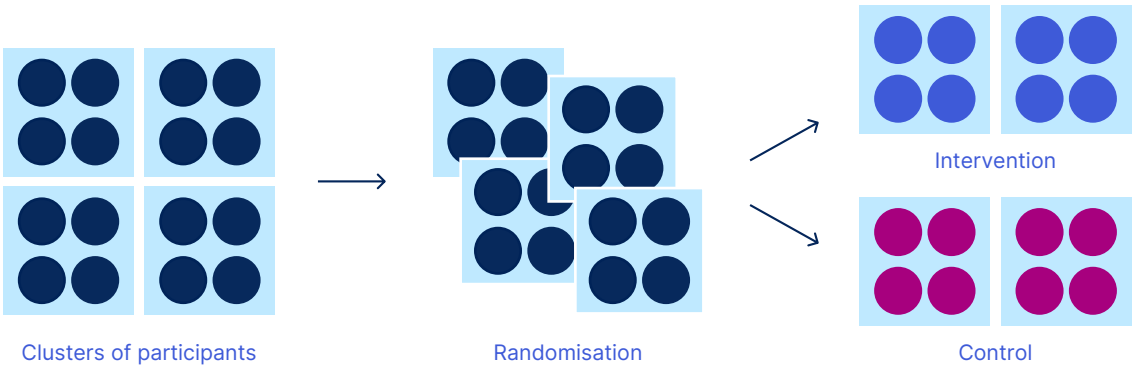
Example randomised controlled trials

Healthcare: Pharmaceutical companies conduct RCTs to test the effectiveness and safety of new drugs. Participants are randomly assigned to receive the experimental drug or other drugs, combinations of drugs, different doses of the same drug and/or placebo. The outcomes, such as symptom improvement or side effects, are compared.

Education: A study might investigate the impact of a new teaching method on student learning outcomes. Students are randomly assigned to different classes, with some using the new method and others using traditional teaching. Test scores or other educational measures are compared.

Cluster randomised controlled trial

In a cluster randomised trial, the unit of randomisation and analysis are groups or clusters of participants. Clusters can be schools, communities, hospitals, or any group of individuals that share certain characteristics or geographical proximity. Cluster randomised trials are particularly useful when it is logistically, or ethically, challenging to randomise individuals, and when the intervention is better suited for group-level implementation.



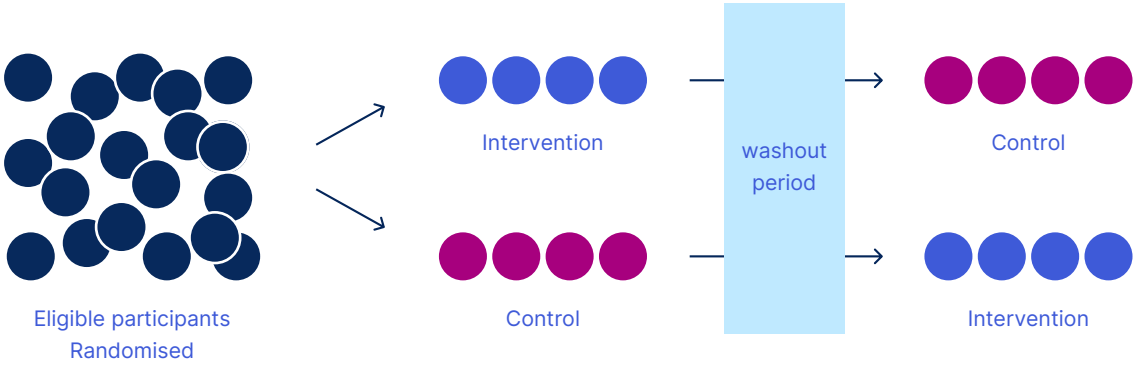
Example cluster randomised controlled trials

Healthcare: A study investigating the effectiveness of an infection control protocol in reducing hospital-acquired infections. Hospitals or hospital wards may be randomised to implement the new protocol or continue with standard procedures. Infection rates are measured for the entire hospital or unit.

Education: A study evaluating the effectiveness of a new teaching method to improve student performance in mathematics. Schools are randomly assigned to either implement the new teaching method or continue with the existing one. Student test scores are assessed at the end of the study, and the impact of the intervention is determined at the school level.

Cross-over randomised trial

In a cross-over randomised trial, participants receive interventions or control in a specific sequence, with each participant serving as their own control which minimises variability between participants. The key feature of a crossover design is that each participant undergoes all treatment conditions, and the order in which the treatments are administered is randomised.



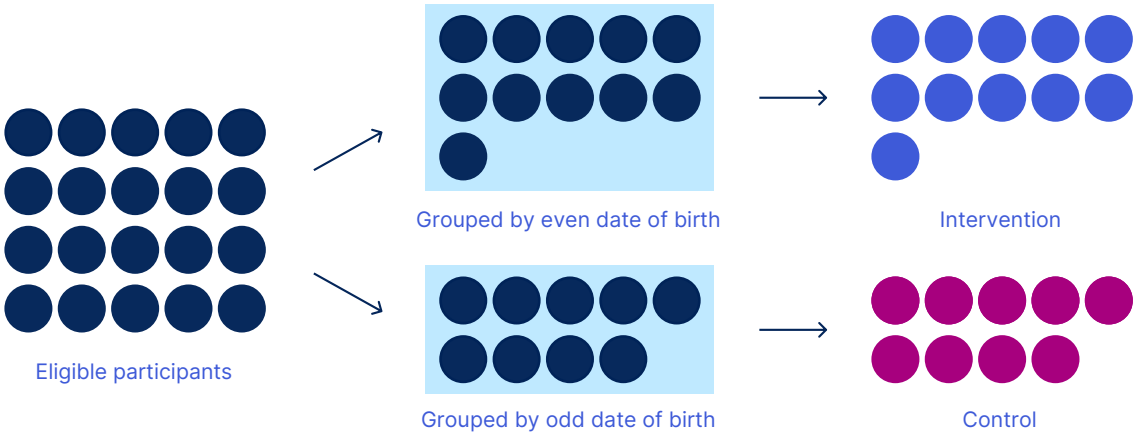
Example cross-over randomised trials

Healthcare: A study evaluating the effectiveness of two different types of insulin in managing blood sugar levels in individuals with diabetes. Participants could be randomly assigned to receive insulin A for 4 weeks, followed by a washout period where they go back to their usual treatment. After that, they would switch to insulin B for 4 weeks.

Education: Students could be randomly assigned to receive one teaching method for 6 weeks, followed by a washout period. Then, they would switch to the other teaching method for another 6 weeks.

Quasi-randomised trial

Quasi-randomised trials allocate participants to different treatment or control groups. However the allocation process is not technically random (e.g. alternate allocation, date of birth, even versus odd medical number). In these types of trials, the number of participants in each group may be unequal and there may be differences between groups for confounding variables.



Example quasi-randomised trials

Healthcare: A study in an emergency department setting might allocate participants arriving during even hours to one intervention and those arriving during odd hours to the alternate intervention.

Education: Students in a school might be assigned to a teaching intervention based on whether their class schedule was in the morning or the afternoon.

Case-control study

Case-control studies compare a group of individuals with a disease or exposure (cases) to a group without the disease/exposure (controls). By analysing their past exposures and characteristics, researchers can identify potential risk factors. Case-control studies are subject to recall bias (participants may not accurately remember past exposures) and selection bias (cases and controls are not well matched). Case-control studies are generally seen as having a lower quality of evidence compared with cohort studies and randomised control trials.

Example case-control studies

Healthcare: A study might compare a group of individuals with lung cancer (cases) to a group without lung cancer (controls). Researchers could collect data on smoking history to investigate the risk for developing lung cancer.

Environmental exposure: Researchers could compare individuals diagnosed with mesothelioma (cases) with those without the disease (controls). Data on occupational exposures to asbestos could be collected to determine the association between asbestos exposure and the development of mesothelioma.

Other common study designs

Here are some other common designs for non-randomised studies of interventions (NRSI), comparative or non-comparative studies. These designs do not always have a control group so they may not fit neatly into the framework of an intervention review.

- **Cross-sectional study:** In a cross-sectional study, researchers aim to examine a specific characteristic, variable, or condition and its prevalence within a population or subgroup. This design allows researchers to gain a snapshot of the population at a particular moment, without following individuals over time.
- **Cohort study:** A cohort study is a type of observational epidemiological study that investigates a group of individuals who share a common characteristic, or experience, and are followed over a period of time to assess specific outcomes. Cohort studies are valuable for assessing the relationships between potential risk factors and the development of diseases or outcomes and can collect data prospectively or retrospectively.
- **Controlled interrupted time series:** A controlled interrupted time series study evaluates the impact of an intervention or treatment by observing changes in a specific outcome variable over time. Data are collected at multiple timepoints, before and after the intervention, and compared with a control group that did not receive the intervention. This design allows researchers to assess whether any observed changes are attributable to the intervention rather than external factors.
- **Historically controlled trial:** An historically controlled study uses data from historical, or previously conducted, studies as the control group (no treatment) to evaluate the outcomes of a new intervention or treatment. The design is useful where it is challenging, or unethical, to have a concurrent control group but is associated with potential biases due to changes over time, differences in populations, and variations in methodology between the past and present.
- **Qualitative study:** Qualitative studies focus on exploring and understanding the nuances, meanings, and contexts of human experiences, behaviours, and social phenomena. They typically involve analysing non-numerical data, such as text, audio, or visual materials to uncover patterns, themes, and insights. These studies allow researchers to gain a deeper understanding of people's perspectives, motivations, and the social or cultural context in which a phenomenon occurs.

Cochrane Handbook

For further information on randomised and non-randomised studies refer to Chapter 23 of the Cochrane Handbook, Including variants on randomised trials.

03

Data extraction template

Components of a good template

A good data extraction template means that you should not have to go back to the original source. You will have recorded everything you need for subsequent analysis or synthesis and interpretation. You may want to consider any planned subgroup analysis (e.g. sex, dosage, mode of administration) as you design the sub-sections of the template.

Cochrane Handbook

Cochrane Handbook section 5.4.1 Rationale for data collection forms goes into detail about the importance of a good data extraction form and its design.

We've provided some examples of key components of a good template. They might not all be relevant for your review but they may be a useful starting point to help you develop your own template and save you time.

For each data item you can use different options to record data such as single or multiple choice lists (controlled lists), or free text.

- Controlled lists are easy to use but may need to be updated if the list expands. You will need an option for 'other' where data do not easily fit the list and this field will then need further sorting during data cleaning prior to analysis. Controlled lists are useful when documenting options like study design or country where the study was conducted.

- Free text allows you to capture the data as reported in the study but may require additional cleaning and categorising prior to analysis. If you're running a dual extraction process then there's an increased chance that reviewers could enter different free text, requiring a judgement to reach a final consensus. Free text is useful when documenting eligibility criteria.

Cochrane Handbook

The Cochrane Handbook sections 5.3.2 considerations in selecting data collection tools and 5.4.3 design of a data collection form go into detail on tools you can use and the optimal way to frame data items.

Example template

General guidance

Guidance for extractors

It's useful to add guidance that will help during extraction. For example:

- Record who has completed data extraction for each study.
- Use quotation marks if you copy and paste text directly from the study.
- No blank fields, enter "Not applicable", "Not reported", "Unclear" or "Missing".
- Contact study authors to obtain missing, not reported or unclear data.
- Note anything which didn't fit into the template and discuss it with the team.
- Enter dates in the format "DD/MM/YYYY" or "MM/DD/YYYY".

Study details

Study details are a good way to start your template. Use this section to collect information about the reference/citation, where the study was conducted and the study setting. Record the contact author details in case you need more information. You could also include trial registration numbers and trial start and end dates. This information is also useful if you are trying to link publications of the same study together.

Guidance for extractors

If you're planning a subgroup analysis by a study characteristic(s), then you may want to highlight this and provide any additional guidance on how to collect this data. For example if you intend to subgroup by geographic location.

Study ID

This is usually a unique number and/or name that identifies the study and prevents confusion when there are multiple publications by authors with the same name or by authors in the same year.

Example

#123 or Warren 2023

Reference/citation

Example

Warren F et a`l. Vitamin C versus placebo for the treatment of the common cold. 2023. J Covid. 2(1): 23-27.

Contact author details

This should include the contact authors' name, institution, email and or address. This can be used to contact the study team if further information or clarification is needed.

Example

Dr Frank Warren, Covidence, FrankWarren@covidence.org

Country study was conducted in

Record where the study was conducted and consider the geographic spread and applicability of included studies.

Example

New Zealand

Study setting/s

Note the type of place or environment the study was conducted in, such as hospital, outpatient clinics, workplace or schools.

Example

At participants' home

Trial registration number

Trial registration numbers are a good way to double check if multiple publications are reporting on the same study. Some registers also enable teams to add in trial data and so can be good sources for cross-referencing and checking for missing information (e.g. www.clinicaltrials.gov ; ICTRP).

Example

NCT1111111111

Trial start and end dates

Trial start and end dates are often given as standard information in trial registries. This information is useful to establish if a trial is completed and again to establish if there are multiple publications of data from the same study.

Example

16th January 2021 - 18th January 2022

Sponsorship/funding source (if any)

Use this to record how the study was funded. This can be important in identifying conflicts of interest and potential biases and may influence how results are interpreted.

Example

University grant to support staff

Other

Having an ‘other’ option is useful to capture any additional information.

Example

The original protocol specified that participants would remain in the study for a 6-month period. This was extended to 12 months.

Study methods

Use the study methods section to record details on the study aims/objectives, recruitment, design, timepoints, blinding, context and unit of analysis.

Guidance for extractors

Capturing study methods might be useful for assessing risk of bias.

Study aim/objective

Record the purpose of the study.

Example

This study aims to evaluate the effectiveness of daily vitamin C for the prevention of the common cold in healthy adults

Study design

It is important to record the study design as you may not be able to combine all study designs in your analysis. Consider documenting additional information about the study design such as whether it was prospective or retrospective, or whether the design was parallel or cross-over. Mixed study designs often result in heterogeneity and you may need to conduct sensitivity analysis based on study design.

If the study is a randomised controlled trial, you should record the method of randomisation that was used for the purposes of assessing risk of bias.

Example

Randomised controlled trial, used random number generator

Method of recruitment

The method of recruitment may be important in considering whether the population is representative. Common methods of recruitment are advertisements, via clinics, random selection from a list.

Example

Volunteers identified via newspaper advertisement

Timepoints and duration of follow-up

Note any timepoints that data were reported on in the study, the study endpoint and any follow-up timepoints. This will be important when you come to extracting result data on outcomes.

Example

Baseline, 12 weeks, (24 weeks), last follow up (28 weeks)

Blinding

Blinding is used to hide the allocation of an intervention or comparison group from the participant, clinician, outcome assessor, outcome adjudicators and/or data analysts. It is important to record who was blinded or if it was unclear who was blinded if you plan to assess risk of bias.

Example

Double blind, participants, researchers

Setting

Context may be important to consider when interpreting the applicability of the results.

Example

Healthy adults dwelling in the community

Unit of analysis

It may be important to identify the unit of analysis used in the study to prevent double counting of participants during analysis. Units of analysis may include participants, centres (e.g. schools or clinics), or parts of the body (e.g. eyes or joints).

Example

Participant

Other

Having an 'other' option is useful to capture any additional information.

Example

Study was ended early because of good effect of the drug

Study population

Use this section to collect important information on the population of the study and the flow of participants. This can be important information for assessing applicability, generalisability and risk of bias.

Guidance for extractors

- Population characteristics might be reported for each intervention or comparison group and/or the overall population. Where necessary, complete the following table for each group and for the overall population.
- If you're planning a subgroup analysis based on a population characteristic(s), provide guidance on how to collect this data. For example, if you intend to subgroup by age, you might want to collect data for each subgroup separately.

Total sample size

How many participants were included in the study.

Example
100

Inclusion criteria

Record the criteria used to define who was eligible for the study.

Example
Healthy adults (>/= 18 years)
No known comorbidities
Able to provide informed consent

Exclusion criteria

Record the criteria used to define who was not eligible for the study.

Example
Children
Known respiratory conditions or disease
Known allergies to components of intervention or comparison

Withdrawal from study

It is important to record the number, reason and timing of withdrawals from the study. If a large number of participants fail to complete the study this is potentially a source of bias and can influence the interpretation of the results. Recording the reasons for withdrawal is also important. For example, withdrawal due to study participant moving out of area may not affect the interpretation of the results or the risk of bias, whereas withdrawal due to adverse events may do so. Where possible record when the withdrawals happened e.g. prior to group allocation, during the study, or during follow-up.

Study details	Examples	
Withdrawal	**Intervention**	**Comparison**
Number of withdrawals	0	1
Reason for withdrawals	N/A	Moved out of area
Timing of withdrawals	N/A	Week 26

Baseline characteristics

The baseline characteristics that you record are dependent on the review question. We suggest recording mean age, sex and ethnicity to ensure that the data are generalisable and applicable. Other data might include comorbidities, co-treatment, disease severity.

Study details	Examples	
Baseline characteristics	**Intervention**	**Comparison**
Sex	Male: 23 Female: 27	Male: 21 Female: 29
Mean age (years) ± SD	40.1 ± 2.3 years	39.5 ± 1.9 years
Ethnicity	White 90% Asian 10%	White 80% Asian 20%
Other relevant characteristic	N/A	N/A
Group differences at baseline	None relevant	None relevant

Group differences at baseline

It is important to record any differences in baseline characteristics between groups as this can indicate a problem with the randomisation process.

Example	
Intervention	**Comparison**
None relevant	None relevant

Other

Having an ‘other’ option is useful to capture any additional information.

Example

Baseline characteristics were documented per group, not for the overall population

Study interventions

Use this section to record information on the intervention and comparison groups.

Guidance for extractors

- Where necessary, complete the following table for each intervention/comparison group.
- If you're planning a subgroup analysis based on an intervention characteristic(s), provide guidance on how to collect this data. For example, if you intend to subgroup by dose, you might want to collect data for each subgroup separately.

Intervention/comparison

Define the intervention and comparison as described in the study. Detail any active components.

For the comparison group it is important to record if the comparison was inert or included any active ingredients.

Example

Vitamin C	**Placebo (inactive)** matching size and colour of intervention

Number allocated to intervention/comparison group

Record the number of participants who were allocated or randomised to the intervention and comparison group.

Example

Vitamin C	Placebo (inactive)
50	50

Dose

Example

Vitamin C	Placebo (inactive)
1000mg buffered with sodium ascorbate	N/A

Frequency

Example

Vitamin C	Placebo (inactive)
Once daily in the morning	Once daily in the morning

Mode/route of administration

Example

Vitamin C	Placebo (inactive)
Oral tablet	Oral tablet

Duration of intervention

Record the duration of treatment for the intervention and comparison groups as your analysis may need to reflect if included studies had different durations of treatment.

Example

Vitamin C	Placebo (inactive)
24 weeks treatment	24 weeks treatment

Duration of follow-up

Once treatment has ended, there may be a period of follow-up observation. Record the duration of the follow-up.

Example

Vitamin C	Placebo (inactive)
28 weeks (24 weeks treatment plus 4 weeks follow-up)	28 weeks (24 weeks treatment plus 4 weeks follow-up)

Other

Having an ‘other’ option is useful to capture any additional information.

Example

No co-treatment was given to either group

Study outcomes

Use this section to record outcome data. This information will be needed to create tables. These are the data that will be used in your analysis and/or synthesis.

Guidance for extractors

- Provide guidance on what outcomes, timepoints and measures to collect, it can help to think about the tables and figures you intend to create after data extraction to define this. This will help reduce the risk of over-extracting. Clear definitions will also reduce the risk that data is missed and reduces the risk of conflicts.
- Collect result data for each intervention and comparison group for each outcome. Do not calculate data during data extraction, if needed this should be done in a later step.
- If you're planning a subgroup analysis, then you might collect result data for each subgroup separately.

Outcome

The name of the outcome (as defined in your protocol/PICO).

Example

Severity of cold	Duration of cold (days)

Type of outcome and default measures

Report whether the outcome is a continuous or dichotomous variable and how it is reported for each group (e.g. Mean, SD, N). If a treatment comparison (vitamin C vs placebo) or timepoint comparison (8 weeks vs baseline) is reported in the study you will need to record a treatment effect/effect estimate (e.g. RR, 95% CI).

Example

Severity of cold	Duration of cold (days)
Continuous, Mean, Standard Deviation (SD), N	Continuous, Mean, Standard Deviation (SD), N

Timepoints

The timepoints of interest to the review.

Example

Severity of cold	Duration of cold (days)
Baseline, 12 weeks, 24 weeks	End of follow-up

Scale

Details of the name of the scale used to measure the outcome.

Example

Severity of cold	Duration of cold (days)
Wisconsin Upper Respiratory Symptom Survey-21: Severity score: daily average total symptom score	N/A

Range

The upper and lower limits of the scale.

Example

Severity of cold	Duration of cold (days)
0-70	N/A

Unit of measurement

Such as days, unit, litres.

Example

Severity of cold	Duration of cold (days)
Score	Days

Direction

Whether higher or lower scores represent improvement.

Example

Severity of cold	Duration of cold (days)
0 = least severe 70 = most severe	Lower is better

Metric

Whether the data measure the change from baseline or endpoint values.

Example

Severity of cold	Duration of cold (days)
Endpoint values	Endpoint values

Other

It's always useful to have an 'other' section available in your template to be able to record information that you think is important but does not readily fit elsewhere. You could have this as a separate section or add it to the end of each of the sections suggested above.

Other

Having an 'other' option is useful to capture any additional information.

Example

The outcome "Severity of cold" also reported an 8 week timepoint but it is not relevant to this review.

04

Extracting the right amount of data

Finding the balance

Extracting the right amount of data in a systematic review is crucial for several reasons. It is important to collect enough information to be able to complete the analysis without having to keep going back to original sources because you didn't extract the data you need. You also don't want to waste time by extracting data that is not useful to your review or not needed in the analysis or synthesis. If you have a protocol, you should follow it. You can always make changes to the protocol as long as these are documented and explained for transparency.

Too few data

Biased or incomplete conclusions that don't reflect the overall evidence.

Example
In the study, the participants receiving vitamin C also received antibiotics as a co-treatment, however I do not extract this information.

Possible problem
Recommendations that are not based on a comprehensive understanding of the topic.

Too much data

Vast amounts of data that are difficult to manage and may be irrelevant.

Example
Symptoms are not an outcome of my review, but I included data on all the symptoms experienced during a cold from a study on the effectiveness of vitamin C for the prevention of the common cold.

Possible problem
Time-consuming and less focused review process.

> "Collecting too much information can lead to forms that are longer than original study reports, and can be very wasteful of time. Collection of too little information, or omission of key data, can lead to the need to return to study reports later in the review process."
>
> - Cochrane Handbook 5.4.3

Why is it important to extract the right amount of data?

- **Precise and robust conclusions:** Focusing on the key information that is relevant to the research question or objective of the systematic review. This precision helps ensure that the findings and conclusions drawn from the review are accurate and directly related to the research question, without including irrelevant or extraneous data. This is important for researchers and policymakers who rely on systematic reviews to make informed decisions.
- **Minimising bias (cherry-picking):** Careful selection and extraction of data minimises the risk of introducing bias into the systematic review. If you extract too much data, including irrelevant information, it can lead to the incorporation of biased or low quality data that could distort the review's findings. On the other hand, extracting too few data might result in an incomplete or skewed picture of the existing evidence. It's important to get the balance right.
- **Transparency and reproducibility:** Researchers should provide detailed descriptions of their data extraction process, including how and what data were collected.
- **Validity and reliability:** Ensuring the right amount of data are extracted helps maintain the validity and reliability of the systematic review. The review's findings and conclusions should be based on the best available evidence, and extracting an appropriate amount of data is essential for this purpose.
- **Efficient use of resources:** Strike the right balance. Extracting too much data can be time-consuming as well as resource-intensive, leading to inefficiency in the review process. Extracting too few data might necessitate additional searches or rework.
- **Organisation:** Systematic reviews aim to provide a structured and organised summary of the evidence. Extracting the right amount of data ensures that the review remains focused, well-organised, and easy to understand, which benefits both researchers and readers.

Summary

Extracting the right amount of data in a systematic review is essential to ensure the review's accuracy, relevance, and quality. It minimises the risk of bias, promotes transparency, optimises resource utilisation and helps maintain the validity and reliability of the review's findings. Below are sections to help you determine how to extract the right amount of data:

- Planning checklist (page 44)
- Importance of piloting (page 48)
- Communicating regularly (page 49)
- Keep a log (page 50)
- Data doesn't fit into the template (page 66)

05

Organise your team

Planning checklist

Plan approach

Planning a well-defined data extraction approach before starting the extraction process is crucial. This will minimise the need for rework, mitigate unforeseen circumstances, and address uncertainties.

During data extraction, if your methods, template or protocol change you can update your checklist to reflect this. Keeping a log of when and why your methods have changed will allow you to document a transparent and reproducible process.

About the checklist

We have created a data extraction planning checklist based on the PRISMA checklist items. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. It consists of a 27-item checklist and a flow diagram. Using the PRISMA checklist helps maintain a high standard of transparency and rigour for your review. You can use this empty planning checklist for your review.

If you complete this checklist before you begin data extraction it will allow you to think about the methods you intend to use. Going through these items in advance will help make sure your template is comprehensive and will also assist when preparing a manuscript, if that is the intention of your review team.

Checklist

Items 1-8 skipped in this document but will need to be completed in the final PRISMA checklist.

Data collection process

PRISMA item #9
Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.

In more detail	Things to consider
Which tool(s) will you use?	• Decide if you will use paper templates, electronic templates or systematic review software to collect data.
Who will be involved in extracting?	• You can decide to run a single or dual reviewer process or a combination. If you run a dual reviewer process then you'll also need to decide who will compare extraction templates and come to a final consensus. ***Note:*** *Where you intend to publish your review might impact what methods you decide to use.* • You can split extraction evenly across team members, or match content experts with more junior/inexperienced extractors.
What's the process for contacting authors?	• Define in what scenarios extractors should contact authors for example: Missing, unclear or not reported data. • Decide how extractors should contact authors and how many attempts should be given to obtain the data.
How often will you discuss progress and raise questions as a team?	• Decide how and how often your team will catch up. • If changes need to be made to your protocol and or template, decide how you will make these changes and how to record them for transparency.

Data items

PRISMA item #10a
List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, timepoints, analyses), and if not, the methods used to decide which results to collect.

In more detail	Things to consider
Which outcomes, timepoints and measures do you intend to collect?	• Your protocol should guide the outcomes, timepoints and measures, including effect measures, to collect. • Guidance should be provided. A good template will guide extractors to choose the relevant outcomes and timepoints from a study, and help them record anything that doesn't match the protocol exactly (such as how the outcome is defined, or the timing of when it was measured).

PRISMA item #10b

List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.

In more detail	Things to consider
What data items will you collect?	• Your protocol should guide the data items to collect for study details, methods, populations, interventions, outcomes and timepoint characteristics. • You can edit a template you've used before as a starting point, or the Covidence example or the Cochrane example.
What should the structure of the extraction form (often called a template) be?	• It's useful to think about the order in which to collect data. It helps if the template follows the flow of a publication. This means the extractors do not have to keep navigating to different sections of the PDF. • You should also consider how you intend to compare data so you can group it together for synthesis. It can help to think about what output you are looking to create and then work backwards.

What are the processes for handling and reporting missing or unclear data?	• This includes:
	  • Data which are missing, unclear or not reported.
	  • Studies which are awaiting classification or ongoing.
	• It is useful to standardise the terminology you intend to use during data extraction for consistent data collection.

What are the processes for handling a study which doesn't neatly fit into a template?	• Define a process to follow when a data doesn't neatly fit into the data extraction template. • Decide how notes or comments will be collected consistently across studies and how to discuss this with your team.

Study risk of bias assessment

PRISMA item #11

Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.

In more detail	Things to consider
Which tool(s) will be used?	• ***Note:*** *We don't discuss quality assessment in detail in this document (common quality assessment tools and advice from Cochrane).*
Who will be involved in assessing the risk of bias?	• You can decide to run a single or dual reviewer process or a combination. If you run a dual reviewer process then you'll also need to decide who will compare forms and come to a final consensus. • You can split quality assessment evenly across team members, or match content experts with more junior/ inexperienced extractors.

Effect measures

PRISMA item #12

Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.

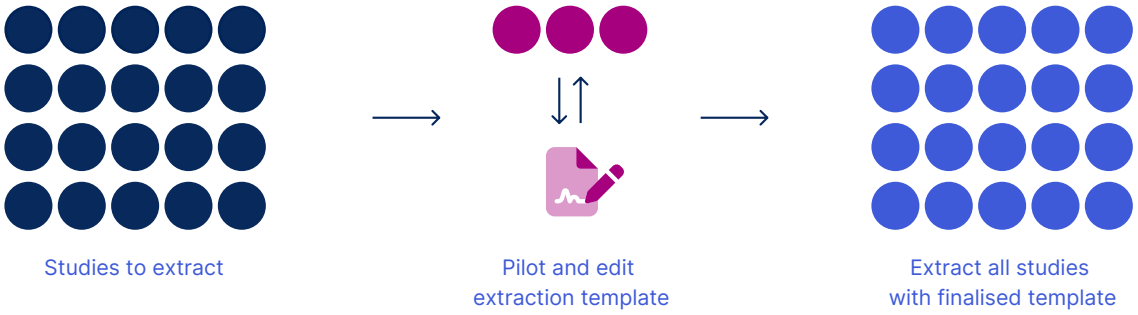
In more detail	Things to consider
Which effect measures will be collected and/or calculated?	• You should define on your template if you intend to collect effect measures and specify which ones. • Guidance for extractors should be clear about whether they are expected to calculate data when extracting. If data are calculated when extracting, then it's important to note that it's been calculated rather than extracted from the study.

Items 13-27 skipped in this document but will need to be completed in the final PRISMA checklist.

Importance of piloting

Why piloting is important

Piloting is the process of completing data extraction for a select number of studies so you can evaluate the process before extraction starts across all studies.



The objective is to assess the effectiveness of the extraction template that has been developed, to ensure that:

- The template's layout and sequence are logically organised.
- Any missed or irrelevant data points are identified early.
- The guidance and/or instructions for extractors are as comprehensive as possible.
- Extractors have had enough training to perform extraction effectively.
- The anticipated output will enable you to compare and group studies so you can analyse results for your review.

Piloting will reduce the risk that you need to:

- Edit the template during extraction.
- Go back to sources after extraction to extract more data.
- Spend a lot of time cleaning data or making sense of the data after data extraction.

Things to consider

You should consider who will be involved in the piloting process, for example do you want all extractors to pilot the extraction template so you can be sure the guidance and training is understood by everyone?

If you plan to analyse the results for each outcome, then it's worth thinking about how you will group the data for the later stages in your review process.

Example pilot process

The steps below are an example process of piloting the data extraction template:

Step	Action
1	Randomly select X studies.
2	Each extractor completes extraction for a study.
3	Each extractor raises any issues they found with the template: 1. Data points need to be added. 2. The format could be improved. 3. Scenarios appear that need to be catered for. 4. Lack of clarity regarding instructions/definitions.
4	The output is checked by the lead reviewer and/or the review team.
5	Feedback is provided to extractors if needed.
6	Changes are made to: 1. The extraction template. 2. The guidance and/or instructions. 3. Processes outside the template e.g. contacting authors for more information.
7	Document all changes made appropriately for transparency.

Communicate regularly

When planning your data extraction approach, we recommend that you establish a process for discussing progress and addressing any issues that arise. This can be done in person, virtually, or asynchronously. Effective communication during the data extraction process will enhance team efficiency and increase the likelihood of consistent data collection across studies. Early identification of any issues with the data extraction template or protocol is facilitated through communicating regularly.

However you decide to communicate with your team, you can use this agenda template to aid these discussions.

Example agenda

Date	
Attendees	

Agenda	1. Progress update.
	2. Discussion of any issues or questions.
	3. From point 2, is there a need to amend the data extraction approach (including data extraction template fields, guidance, instructions)?
	4. From point 2, is there a need to amend the protocol?
	5. If yes to 3 or 4, then decide:
	  a. Do you need to log this change for transparency purposes?
	  b. Who will be responsible for making the change?

Keep a log

A systematic review aims to be a thorough and rigorous type of literature review. The methods should be transparent and reproducible. All efforts should be made to define exactly how you intend to capture data consistently and accurately across studies. This means defining your approach, data extraction template, and processes before beginning data extraction.

During the process of data extraction you may need to amend these processes as you find scenarios which you hadn't anticipated. An example might be extracting data for a study and finding that the data you want to collect doesn't fit neatly into the data extraction template.

We have discussed the importance of regular communication. It's this discussion with your team which will help you decide if a change is needed. For example, do you need to add data item(s) to the data extraction template and revisit studies whose data you've already extracted to collect this data, or is it sufficient to add this data into a notes field for that one study?

If changes are made, then we recommend you keep a log of the change to aid with transparency.

Example change log

Date	Change	Why the change was needed?	Who made the change?
17/11/23	Added "Field X" to the data extraction template and we will revisit all studies to determine if it's relevant for all studies.	Study reported "Field X" and we discussed this as an important data item to capture across all studies.	Reviewer A.

Training extractors

Who should be a data extractor?

Data extractors in a systematic review should be individuals with the necessary expertise, skills, and training to accurately and consistently extract data from the included studies. Data extraction can be undertaken by all review team members or specific members, based on knowledge and experience. Who undertakes data extraction is dependent on the scope of the review, the complexity of the research question, and the available resources (time and people).

Here are some considerations for selecting data extractors:

- **Content knowledge:** Data extractors should have a good understanding of the subject matter which will enable them to identify and extract relevant data accurately.
- **Methodological expertise:** Having a team member/s who are familiar with the methods and techniques (use of data extraction templates and guidelines) used in systematic reviews is important.
- **Experience:** Experienced researchers, systematic reviewers, or subject-matter experts are often preferred as data extractors, as they are more likely to have the necessary skills and judgement to assess the quality of studies and extract data accurately. There are also opportunities for less experienced or knowledgeable members of the team to gain valuable skills.
- **Independence and objectivity:** Data extractors should be unbiased and objective in their approach. They should not have conflicts of interest that could affect their ability to impartially assess and extract data.
- **Resource efficiency and utilisation:** Consider the availability of individuals who can dedicate the required time and effort to the data extraction process. Adequate resources, including personnel, are crucial for conducting a systematic review effectively.

Why train data extractors?

Training data extractors in a systematic review is a crucial step to ensure that data extraction is consistent, accurate, and in line with the review aims and objectives. The process involves preparing individuals or a team to systematically and accurately collect and record relevant data from the included studies. Even experienced individuals should undergo training for the specific systematic review to ensure they are familiar with the review's objectives, inclusion/exclusion criteria, and data extraction procedures.

Here's why you should train data extractors:

- **Minimise bias:** Trained extractors are more likely to follow a standardised process, minimising the introduction of subjective judgement into data collection.
- **Consistency:** Training ensures that all data extractors use the same approach, making it easier to compare and combine data from different studies.
- **Accuracy:** Through training, extractors learn how to identify and record the relevant information and understand the nuances of the data to be collected. A well-trained team is less likely to make errors during the data extraction process, such as transcription errors, data entry mistakes, or misinterpretations of study findings.

Tips on how to train data extractors

- **Preparation:** Use a team meeting to provide data extractors with a clear understanding of the review's research question, objectives, and eligibility criteria. Make sure they have a good grasp of the specific data elements to be extracted.
- **Detailed instructions:** Create comprehensive data extraction guidelines or templates that detail what data to extract and how to record it. It's useful to include examples and definitions to clarify any potential ambiguities.
- **Piloting exercises:** Conduct some pilot extractions on a couple of included studies to ensure that the data extractors understand the process and can follow the guidelines and template effectively. You may need to modify the template and instructions based on this task.
- **Regular meetings:** Maintain regular communication with data extractors through meetings or discussions to address any issues, provide clarifications, and ensure consistency throughout the review process. This is particularly important if you have junior researchers on your extraction team.
- **Quality control:** Implement quality control checks, such as double-checking extracted data (sometimes referred to as consensus review), to identify and rectify any discrepancies or errors. These checks may look at all studies or a random sample.
- **Feedback and ongoing training:** It's important to provide regular feedback to data extractors and offer additional training if necessary. Don't leave it to the last minute if they are making consistent errors. Keep the team updated on any changes or refinements in the data extraction process.

Running dual extraction process

You may have a large team of reviewers undertaking data extraction and the whole team can be involved in the process. How many extractors work on each study can be subject to time and resources.

Cochrane has the following guidance on the number of extractors for intervention systematic reviews.

> Use (at least) two people working independently to extract outcome data from reports of each study, and define in advance the process for resolving disagreements.
> - Cochrane Handbook 5.5.2

Why have two data extractors?

It is common practice to have a minimum of two extractors for each included study in a systematic review in order to:

- **Minimise bias:** Having at least two data extractors independently extract data from the included studies helps minimise the risk of bias. If only one person is responsible for data extraction, there is a higher probability of subjective interpretation or transcription errors. When multiple extractors are involved, any discrepancies in their findings can be discussed and resolved through consensus, reducing the impact of individual bias. Blinding data extraction further minimises the risk of bias.
- **Improve reliability:** Multiple extractors can provide a more reliable and robust data extraction process. By comparing their results and reaching a consensus, you can be more confident in the accuracy of the extracted data.
- **Cross-check for errors:** Data extraction is a meticulous task, and mistakes can easily occur. Having two or more data extractors helps identify transcription errors or omissions, improving the overall quality of the data extraction process.
- **Adhere to guidelines:** Many systematic review guidelines and standards, such as the Cochrane Handbook and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, recommend the use of at least two independent data extractors to ensure the quality and reliability of the review.

Are there any challenges to having two extractors?

The main challenges to having two extractors are around time and resource utilisation.

- **Time, cost and resource utilisation:** Having two data extractors can increase the workload and time required for the data extraction process. This may be challenging in situations where resources and time are limited.
- **Attaining consensus:** Reaching a consensus between two data extractors can sometimes be difficult, particularly when they have differing interpretations of the data, personal biases, or when there is incomplete or ambiguous information in the included studies. Resolving discrepancies may require additional time and effort or an independent third party.
- **Training and expertise:** Training, including content knowledge is an important component of data extraction. If either extractor lacks the required skills, it can affect the quality of the data extraction and result in the generation of conflicts that will need resolution.

Is it okay to extract data with just one extractor?

Using one data extractor might be of value in situations where there are a lack of resources or where data are required urgently (rapid reviews), but there are inherent risks to this approach.

- **Risk of bias:** With a single data extractor, there's a higher risk of introducing bias into the review. The extractor's subjective judgement and potential transcription errors may go unchecked, which can affect the accuracy, objectivity, consistency and reliability of the data extraction process.
- **Reduced confidence in results:** Systematic reviews aim to provide the highest level of evidence by systematically gathering and synthesising research findings. With a single data extractor, the credibility and trustworthiness of the review's results may be compromised, as there is less assurance of the data's accuracy and completeness.
- **Quality and transparency:** Using a single extractor can make it more difficult to adhere to established quality and transparency standards for systematic reviews, such as those outlined in MECIR (Methodological Expectations of Cochrane Intervention Reviews). These standards often recommend multiple, independent data extractors to enhance the quality and rigour of the review.

Inconsistencies, errors, or misinterpretations in the data may go unnoticed with one extractor, potentially leading to flawed findings in the systematic review. If you decide to use just one extractor, it's recommended to check data (or a subset) after data extraction.

Cochrane Rapid Reviews Methods Group

The Cochrane Rapid Reviews Methods Group has published the following guidance around rapid reviews in relation to data extraction:

- Use a single reviewer to extract data using a piloted template. Use a second reviewer to check for correctness and completeness of extracted data. (R16)
- Limit data extraction to a minimal set of required data items. (R17)
- Consider using data from existing SRs to reduce time spent on data extraction. (R18)

Source: https://methods.cochrane.org/rapidreviews/cochrane-rr-methods

Is a proportional approach a compromise?

In those circumstances that are constrained by time or resource factors, a proportional approach to data extraction may be a compromise. This approach involves using independent extraction with two reviewers for a proportion (e.g. 20%) of the included studies. If the team is happy that there are minimal discrepancies or errors, then single reviewer data extraction can be used for the rest of the included studies. The team should note all decisions that are made for the purposes of transparency and we suggest using a simple checking procedure to ensure that no data have been omitted and that there are no obvious transcription errors.

Disagreements during consensus

What is consensus and why is it important?

Consensus is an important part of your systematic review. The use of consensus minimises bias and ensures the integrity of the review by providing reliable data. These data are the basis for transparent and valid conclusions made using the synthesised evidence from the included studies.

Consensus refers to the agreement among the members of the review team regarding the inclusion and interpretation of studies, data extraction and the overall conclusions drawn from the collated evidence. Two or more reviewers are required for consensus.

Here are some reasons to consider using consensus in your review:

- **Minimising bias:** Achieving consensus between team members involved in the review reduces the risk of bias during study selection and data extraction. If multiple reviewers independently assess and extract data from included studies and subsequently reach consensus on any disagreements, it reduces the risk of selective inclusion or extraction of data that could skew the review findings.
- **Transparency:** The processes involved in consensus provide transparency for your review. Any disagreements between reviewers must be resolved. Transparency is important for readers and peer reviewers to understand the methodology and how conclusions were reached.
- **Improved validity:** Consensus will ensure that the selection criteria for including studies are applied consistently which will enhance the robustness and trustworthiness of your review methodology.
- **Improved reliability:** Review reliability is increased by using multiple reviewers to reach consensus. The conclusions become less dependent on the views and preferences of a single reviewer and are more representative of the collective expertise of the review team.
- **Reduced subjectivity:** Subjectivity, which can be introduced with a single reviewer, can be reduced through the consensus process by using mechanisms such as discussion, arbitration and use of predefined eligibility criteria. This will minimise individual biases and preferences.
- **Quality control:** The processes of consensus also act as a form of quality control. Consensus can help identify and correct any errors or discrepancies that have occurred during data extraction and improves the overall quality of your review.

Example consensus

Here is an example where the consensus reviewer has checked extracted data and made a final decision:

	Final decision	Reviewer 1	Reviewer 2
Days off work	7.2	7	7.2
Number of colds	2		2

Who should be involved in achieving consensus?

The consensus process can be achieved in a number of ways depending on your review and review team.

The most common processes include:

- discussion between reviewers
- arbitration with a third reviewer
- reference to clear predefined eligibility criteria and/or review protocol

Consensus meetings, when required, can occur in person or via email.

Those involved in consensus are often senior members of the team based on their methodological and/or content expertise/knowledge. However, involvement in the consensus process, even in an observer role, is a valuable experience for junior team members.

Remember to document whichever process you have chosen.

Example of consensus process

Who	Scenario
Two reviewers	No conflicts occurred, all data extraction is in agreement.
Two reviewers	The original two reviewers can look at the data that are in conflict and try to come to an agreement on the final data decision.
One of the two reviewers	One of the original two reviewers can make the final decision if they can see that the second reviewer was correct.

Third reviewer when resolution cannot be reached	A third reviewer can be introduced in an arbitration role if consensus resolution cannot be met by the original two reviewers. The consensus reviewer does not have to agree with Reviewer 1 or Reviewer 2 and can enter their own interpretation into the final decision, but should discuss this with the two reviews for the purposes of transparency.
Third reviewer independent, senior team member	A third reviewer may be asked to undertake all conflict resolution. This may be a senior team member. The consensus reviewer does not have to agree with Reviewer 1 or Reviewer 2 and can enter their own interpretation into the final decision, but should discuss this with the two reviews for the purposes of transparency.

06

Overcoming common dilemmas in data extraction

Data doesn't fit into the template

As you start your data extraction journey, you may find that not all of the data fits neatly into the data extraction template. If this happens, it's important to accurately record data as they were reported in the study, and highlight any missing or ambiguous data that need attention before the data can be synthesised in the review.

Common reasons why study data do not fit the extraction template

You might come across a study where:

- Data are missing, unclear, or not reported.
- The investigation is ongoing and you need to monitor the literature for a publication.
- Data are reported in a format that the extractors did not anticipate.

How to handle data that do not fit the extraction template

When you come across data that are missing, unclear, or don't fit the format you expected there are several options. The choice depends on what is reported and what you need. It's always a good idea to plan for these scenarios at the beginning of the data extraction process. You could consider the following:

- **Review the data extraction template:** If you or the team find that a lot of the data you are collecting does not fit easily into the data extraction template then you could review the template. Check that it is designed correctly and includes all the relevant fields for the information you want to collect from the included studies. You may need to make changes and re-pilot the template to assess if the changes are effective.
- **Make a note of the data which does not fit:** When designing your template, it's a good idea to include a place for notes or comments, so that when extracting data from a study you can collect all relevant data. If needed, you can discuss these comments with your team without the need to revisit the study to find the problematic data.
- **Review the study:** Look at the study itself and determine why it doesn't fit. Is it an issue with the design or the population? You may discover that the study is ineligible. Is it the data presentation that does not fit? Maybe the data are in a different format to the way you had set up the template. For example, you may have set up the template for duration of cold to be Mean days, SD, N yet the study provides data for Median days, IQR, N. In these circumstances, you may want to adapt your template. It is useful to have a section for 'Other' where these alternate data can be recorded for completeness. When it comes to data analysis, you may be able to transform or calculate some of the data to add to your analysis or include as part of the narrative summary.
- **Consider sensitivity analysis:** You may want to consider sensitivity analysis as part of the statistical analysis for your review both including and excluding data that does not fit your template. Seek appropriate advice when undertaking and interpreting such analyses.

- **Contact study authors:** If the data in the study don't fit your template you could consider contacting the study authors to request the data that you need.
- **Ask topic experts for advice:** Experts in your field are likely to have seen examples of missing or unclear data before and could help you with how best to approach a particular study.
- **Discuss with the review team:** It is worth discussing studies that have data that do not fit the review template with the review team. Regular communication and meetings during data extraction with the team or with the lead reviewer may help with any problems that might arise.
- **Calculate the missing data:** If data are missing or unclear, and you intend to include the study in your analysis, it may be possible to calculate the data from other data points reported in the study. Follow your team's process on when, or if to do this and always make a note if data has been calculated rather than extracted directly from a study.

Missing, unclear or not reported data

Reporting missing, unclear, or unreported data is a crucial aspect of a systematic review, as it helps maintain the integrity of your research and provides readers with a clear understanding of the limitations and potential biases in the available evidence. Missing data may be an indicator of risk of bias.

The PRISMA checklist (Preferred Reporting Items for Systematic Reviews and Meta Analyses) is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. It consists of a 27-item checklist and a flow diagram. Using the PRISMA checklist helps maintain a high standard of transparency and rigour for your review. Learn more about PRISMA in Chapter 5, Planning checklist.

The PRISMA checklist requires you to document “Any processes for obtaining or confirming data from study investigators” (item 9) and “Describe any assumptions made about any missing or unclear information” (item 10b).

Examples of missing, unclear or not reported data

The outcomes for your systematic review are: Severity of disease, number of colds, use of over-the-counter medication reported at the following timepoints 3, 6, 12, and 15 weeks.

Missing data
The methods section of study X reports that they collected data for:

- severity of disease
- number of colds
- use of over-the-counter medication

The results section of the study only reports data for:

- severity of cold
- use of over-the-counter medication

Problem	Action
This may be an omission, it may be publication bias, or the data may be published elsewhere.	Check if there are other reports of the same study, including data repositories (e.g. clinicaltrials.org). Contact the authors for clarification or further information. If all reasonable attempts to obtain the data are made, and the data cannot be found, then follow your team's process to report them as missing.

Unclear data

The methods section of study Y reports that the study investigators collected data for:

- severity of disease
- number of colds
- use of over-the-counter medication

The results section of the publication has data for all these outcomes, but the severity of disease data is in a graph and it is not possible to accurately calculate the data for your review timepoints.

Problem	Action
The data are in study but not in a format that you can use for your review.	Contact the authors and request raw data. If all reasonable attempts to obtain the data are made, and the data cannot be found, then speak to your team or with experts to discuss if you can reasonably estimate the data values. Ensure you follow your team's process to report this as unclear and report the data as estimated.

Not reported data

Study Z reports the following outcomes:

- severity of cold
- use of over-the-counter medication

Problem	Action
The number of colds is not reported in this study.	Refer to the trial protocol or registration, if available, to cross-check. Once it's confirmed the data were not reported then follow your team's process to report that 'Number of colds' was not reported.

Conduct a thorough search to ensure that you haven't overlooked any reported data in the included studies.

Try and get the data

It is important to demonstrate that you have made all possible efforts to locate or clarify missing or unclear data.

- **Contact study authors:** If you suspect that a study has relevant data but did not report it, consider contacting the authors. This can be done through email, correspondence via academic institutions, or social media (e.g. ResearchGate).
- **Check study protocols and supplementary materials:** Try to locate the study protocol, or trial registration. Look carefully for supplementary materials, or appendices, as sometimes data may be mentioned there but not in the main body of the article.
- **Check for other publications related to the study:** Some studies may have more than one publication. It may be useful to check for other publications to see if they contain the missing data that you are looking for.
- **Document your efforts:** In your systematic review, it is useful to provide details of how you attempted to retrieve missing data. Mention the steps you took, the individuals or institutions you contacted, and the responses (or lack thereof) you received. Transparency in reporting your attempts is essential.

Steps to take if you cannot locate or clarify missing or unclear data

As well as documenting all your efforts you could also:

- **Discuss the implications:** In the discussion section of your systematic review, discuss the implications of missing or unclear data. Address the potential impact of missing or unclear data on the overall findings and the robustness of your conclusions. You may identify an evidence gap that requires new research.
- **Evaluate the risk of bias/study quality:** Evaluate the risk of bias for each included study, considering the presence of missing or unreported data. ROB-ME (Risk Of Bias due to Missing Evidence) is a tool to help identify if the missing data might result in a high risk of bias so you can interpret results appropriately.
- **Address possible publication bias:** If it seems that studies with certain results are more likely to report their data, use methods like funnel plots or statistical tests to assess and report on potential publication bias. We recommend you seek statistical advice to undertake publication bias assessments.
- **Follow reporting guidelines:** We recommend that your systematic review follows established reporting guidelines such as PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) to maintain a high standard of transparency in your reporting. Following reporting guidelines is a prerequisite for publication in some journals.
- **Calculate data:** If data are missing or unclear and you intend to include the study in your analysis, it may be possible to calculate the data.

Awaiting classification and ongoing studies

Studies 'awaiting classification'

Studies 'awaiting classification' includes potentially eligible studies that cannot be assessed for inclusion or exclusion in a systematic review due to insufficient or ambiguous information. These studies may impact your review findings and should not be included or excluded without further investigation.

Examples of studies 'awaiting classification'

Missing methods information on the study design.

Example	Implication for the review
"we divided into two groups."	It is not possible to determine if this is a randomised controlled trial. Including the wrong study design may influence the review findings. Contact authors for clarification.

Publication in foreign language.

Example	Implication for the review
Publication in Chinese.	If you have not restricted your review by publication language, all attempts should be made to translate the paper via translation services, online translation tools or contacting the authors for further clarification/data.

How to handle studies 'awaiting classification'

Cochrane Handbook

Chapter 4 of the Cochrane Handbook recommends that all reasonable attempts to obtain information must be made before studies are definitively categorised as 'awaiting classification'.

Covidence's example email can be adapted to request additional information from the contact author of the publication.

It is good practice to describe the study details in the 'Characteristics of studies awaiting classification' table, and to mention those that have the potential to influence the results.

Example table of 'Characteristics of studies awaiting classification'

Study ID	#123 or Warren 2023
Methods	Randomised (no details) Blinding (no details) Parallel design
Participants	Adults and children Healthy No documented asthma, chronic obstructive pulmonary disease, or bronchitis
Interventions	Vitamin C 1000mg Placebo
Outcomes	• Severity of cold (scale 0-10) • Number of colds • Use of over-the-counter medication
Notes	Study authors contacted by <Reviewer name> on 15th May 2023 for the following information: 1. Details of randomisation process 2. Details on whether there was any blinding and if so who was blinded 3. Is it possible to provide separate data for adults >/= 18 years on our outcomes of interest and demographics (Age, sex, ethnicity)

Ongoing studies

It is important to identify ongoing studies, so that when a review is updated these can be assessed for possible inclusion. Even when studies are completed, some are never published which can increase the risk of bias in your review. There is no easy and reliable single way to obtain information about studies that have been completed but never published.

There are several sources that you can search to locate ongoing studies, other than the main bibliographic databases and journals that include:

- Trial registries e.g. ClinicalTrials.gov, International Clinical Trials Registry Platform.
- Regulatory agency sources e.g. U.S. Food and Drug Administration, European Medicines Agency.
- Clinical study reports which are the very detailed reports prepared by industry for regulatory approval.

How to handle ongoing studies

Where possible, you should contact relevant individuals and organisations for additional information about unpublished or ongoing studies if needed. Make sure to note down all attempts at contacting these sources.

Information about possibly relevant ongoing studies should be included in the review in the 'Characteristics of ongoing studies' table.

Examples table of 'characteristics of ongoing studies'

Study name	A randomised trial of the effectiveness of high-dose vitamin C for the prevention of the common cold
Trial registry number	NCT 111111111
Methods	Randomised controlled trial Double-blinded
Participants	Adults over 18 years No known co-morbidities No cold within previous 4 weeks
Interventions	Vitamin C 1000mg daily orally Placebo
Outcomes	• Severity of cold (scale 0-10) • Number of colds • Use of over-the-counter medication • Symptoms • Severity of symptoms
Estimated sample size	500
Start date	1 October 2023
Anticipated end date	31st March 2024
Authors contact information	Dr F Warren (FrankWarren@covidence.org)
Notes	

Document these studies in the PRISMA figure

You should identify studies that are awaiting classification or ongoing and add details to your PRISMA flow diagram. This is important for transparency as the data may influence the findings of your review.

Contacting authors

Dealing with missing or unclear data in a systematic review is a common challenge. Missing or unclear data may affect your final data and lead to misinterpretation as it's challenging to draw meaningful conclusions or incorporate them into the review.

When you encounter this issue, it's essential to make efforts to obtain the missing data to ensure the completeness and accuracy of your review.

Tips on when to contact study authors

- Wait until you have completed data extraction for a study so that you can include a list of questions in the same email. This might include questions about how the study was conducted (e.g. method of randomisation), how an outcome was measured (e.g. what scale was used if it isn't clear), details about the population (e.g. a baseline characteristic you need for a subgroup analysis), or missing or unclear numerical data you need for analysis.
- Be as clear and concise as possible, acknowledging that it may have been a long time since the study was done and the authors may not have easy access to the information you need.
- Include a clear but reasonable deadline when contacting authors for this information.
- If you're finding it hard to locate the contact details of the authors, you can try:
  - Searching online using sites such as ResearchGate or LinkedIn.
  - If the publication isn't recent the author may have moved institutions, so you can try searching for recent publications where they are the corresponding author.
- Decide in advance what you'll do if you don't get a reply, these options could include:
  - Trying to contact the author again.
  - Setting a study as awaiting classification.
  - Excluding the study from the analysis.
  - Imputing missing data.

Here is an example of an email that can be adapted to request additional information from the contact author of the publication.

Example of email requesting information

To	
Cc	
Bcc	
Subject	Request for information

Dear [Author's or Source's Name],

I hope this email finds you well. My name is [Your Name], and I am currently conducting a systematic review on [Brief Description of Your Review Topic], and your study titled "[Title of the Study]" published in [Journal Name], [Year], has been identified as a valuable source of information for our review.

As part of our systematic review process, we are attempting to obtain all relevant data and information from the selected studies to ensure the completeness and accuracy of our review. However, during our data extraction process, we have encountered some missing data or data that require clarification from your study.

Specifically, we are in need of the following data or information from your study:

[Specify the exact data or information you need]
[If applicable, mention any specific subgroups or timepoints for which data is missing]

If it is possible to provide the missing data or clarify the ambiguous information, it would greatly contribute to the quality of our systematic review. We assure you that all data received will be handled with the utmost confidentiality and used solely for research purposes.

In the event that you do not have the data or are unable to provide it, kindly inform us of any constraints or reasons for not sharing the information. Your response will help us assess the completeness of the review.

Your contribution to our research is highly regarded, and we look forward to your response by [Specify a reasonable deadline for their response], if possible.

Sincerely,

[Your Name]
[Your Affiliation]
[Your Contact Information]

Unit of analysis issues

A unit of analysis issue can arise in a systematic review because of errors that are made in the definition of the “who” or “what” that are being analysed. It is important to specify the unit of analysis in your review as this will influence the analysis and interpretation of the data.

In a randomised trial, the unit of analysis is usually the same as the unit for randomisation and is most frequently a person/participant. However, in some studies the unit of analysis could be a limb, a lesion, or an eye and one participant could therefore be randomised multiple times. In cluster-randomised studies, the unit of analysis could be the cluster (school, hospital, city, household).

Avoiding unit of analysis problems in a systematic review is crucial to ensure the accuracy and reliability of your findings. Here are some steps to help you avoid these issues:

- **Clearly define your research question:** Define your research question in a way that explicitly states what the unit of analysis should be. Clarify whether you are interested in individuals, studies, groups, or some other entity.
- **Specify eligibility criteria:** Define the eligibility criteria for your systematic review. These criteria should be based on your research question and the appropriate unit of analysis.
- **Select appropriate study designs:** Choose study designs that match your research question and the unit of analysis. For example, if your question is about the effectiveness of an intervention in individual patients, select randomised controlled trials (RCTs) rather than aggregate data from group-level studies where the unit of analysis is a group of study subjects aggregated within geographic regions and/or temporal intervals.
- **Carefully screen and select studies:** When conducting your systematic review, carefully screen and select studies based on your inclusion and exclusion criteria. Pay close attention to the unit of analysis to ensure it aligns with your research question.
- **Extract data correctly:** Ensure that data extraction is performed accurately and consistently, taking into account the unit of analysis specified in your research question. For example, if you are interested in individual patient outcomes, extract data at the individual level, not group or aggregate data. Be aware of the potential for individuals being randomised more than once.
- **Address missing or incomplete data:** Be aware of potential issues with missing or incomplete data, and consider how they might affect the unit of analysis. For example, if some studies do not report individual-level data, you may need to make decisions on how to handle this in your analysis.

- **Document your methods:** Clearly document the methods you used in your systematic review, including how you handled the unit of analysis. Transparent reporting helps readers and reviewers assess the validity of your approach.

By following these steps and paying close attention to the alignment of the unit of analysis with your research question, you can minimise unit of analysis problems in your systematic review and enhance the validity of your findings.

Extract data from multiple publications of the same study

Reporting of multiple publications from the same study in a systematic review is a common scenario, especially when dealing with multiple papers or publications in different formats over time.

It is important to maintain the rigour of your review and to be transparent about how you handle these studies to avoid duplication of data and/or double counting of participants. Avoid discarding any publication of an included study, since it may contain valuable information not included in the primary report.

Identify publications relating to the same study

Make sure that you identify all publications relating to the same study. These could be primary research papers, conference abstracts, posters, personal correspondence or supplementary materials for example.

You can check for:

- trial registration numbers
- study sponsors or Ethics Committee numbers
- location/s of where the study was conducted
- start date and duration of the study
- number of participants recruited and baseline characteristics
- author names

If you are unsure if publications are linked to a specific study, contact the primary authors for more information.

Decide which is going to be the primary reference

You will need to make a decision about which of the publications or data repository will be the primary source. This is usually the most recent or most comprehensive and would typically be the publication from a peer-reviewed journal rather than a conference abstract/poster. In the reference list, the secondary publications are often indented from the primary reference or listed underneath the primary reference, indicating that they are associated but not contributing to the total publications in the review. Sometimes the data reported can be different between different sources. This should be noted and the authors contacted for clarification.

Reporting using PRISMA flow chart

If you're following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, you can include these multiple publications in your PRISMA flowchart, showing the screening and selection process. The flow diagram should indicate the total number of studies and the number of associated publications e.g. 20 studies/reports (25 publications).

Handling data and outcomes

If you're including data from these multiple publications, make it clear which publication provided which data or outcomes. If data are redundant or overlapping, consider using data from the primary source or the most comprehensive publication.

Check reporting guidelines or journal guidelines

Check if there are specific reporting guidelines for your systematic review topic (e.g. PRISMA for systematic reviews, PRISMA-P for systematic review protocols). These guidelines may provide additional recommendations for handling multiple publications from the same study. You could also check the author guidelines for any journals you plan to publish in regarding key information that is required when publishing a systematic review.

Remember that the goal is to ensure transparency, avoid duplication of data, and clearly communicate to readers that these publications are related to the same study. Consider consulting a librarian or a systematic review expert for guidance, especially if you're dealing with a complex set of related publications.

Calculating missing data

If your review requires certain data points for synthesis, and they are missing, then it might be possible to calculate the data you need from other values reported.

Example of calculating data from other values reported

Calculating standard deviation from standard error values reported in the study.

Cold duration (days)

	Mean	Standard error	N
Vitamin C	2.2	0.35	15
Placebo	5.4	1.4	13

If you need the value for standard deviation (SD) and you have the standard error (SE) and the sample size (N) then you can use the following calculation:

SE x √N = **SD**

Then in this example, the standard deviation of the vitamin C group can be calculated by:

0.35 x √15 = **1.36**

And the standard deviation of the placebo group can be calculated by:

1.4 x √13 = **5.05**

Tips on calculating missing data

- Always make a note of any data which have been calculated, rather than extracted directly from a study, and include a footnote in the analysis created as appropriate.
- Be sure to follow your review team's process on when, or if, to do this. Some teams might want to report that these data are missing during extraction and calculate data points after data extraction.

Common scenarios in relation to how you might calculate missing data

Standard deviation is missing or unclear
First, check if the study reports other variations such as the standard error or confidence intervals, these can be used to calculate the standard deviation.

If other variations aren't reported and the standard deviation can't be calculated, then contact the study author for the data.

Change from baseline values are not reported (change scores)
First, check if the study reports baseline and end value data points, ensuring the number of participants are the same at both timepoints. These can be used to calculate the change from baseline values, especially for the mean change. We suggest you seek statistical advice if you are planning to make these calculations.

Calculating the standard deviation can be tricky for change from baseline values and the Cochrane Handbook section 6.5.2.8 provides advice on this.

Imputing unclear data

If the data in the study are unclear, all reasonable attempts to clarify the data from authors should be made. If that is not possible, in certain cases, assumptions can be made to fill in (impute) missing data after data extraction. For example, you might consider imputing data when it is unclear if the variation is reported as standard deviation (SD) or standard error (SE).

Caution should always be taken with this approach as you are making assumptions of the data. When imputing data, we recommend that you:

- Always make a note of any data which have been imputed rather than extracted directly from a study.
- Include a footnote in the analysis, as appropriate.
- Speak to your review team, topic experts, statisticians before imputing data.
- Follow your review team's process on when or if to do this.

Useful resources

We don't discuss how to calculate data in detail in this document, you can find a lot more information in the Cochrane Handbook section 6.5.2.

The RevMan calculator is a helpful tool for calculating missing data.

07

Top 5 tips for intervention data extraction

Key takeaways

Throughout this document we have shared the knowledge we have gained through our internal systematic review experts, our community of users, best practice content from Cochrane and PRISMA and these are our top 5 tips to take away for intervention data extraction.

Top 5 tips for intervention data extraction

1. **Follow a framework**, such as PICO(T), for a systematic and organised approach that enhances the reliability, transparency, and efficiency of the systematic review process. Frameworks support the validity and credibility of the review's findings.
2. **Plan your approach** to data extraction prior to commencing the extraction process. Planning ahead will minimise the need for rework, mitigate unforeseen circumstances, and address uncertainties.
3. **Pilot the template** to save time, ensure the team is familiar with template components, reduce the likelihood of template edits during extraction and reduce the time spent re-extracting studies or cleaning data.
4. **Extract the right amount of data** to complete your analysis without having to keep going back to original sources. Effective extraction involves extracting all relevant data while avoiding extracting data that is not useful to your review or not needed in the analysis or synthesis.
5. **Communicate regularly and keep a log** communication between the team during data extraction is essential to ensure that everyone understands the processes required and allows for early identification of issues that may need a protocol or template amendment. Keep a log of communication, decisions and processes during data extraction to aid in completing checklists. These checklists are required by some journals during manuscript submission.

Did you know that we have other resources available on our website?

Visit our blog page for insights, announcements, and product updates: www.covidence.com/blog

Already working on a review using Covidence?

Visit our Knowledge Base for a step by step guide on extracting data within the Covidence platform: https://support.covidence.org/help/data-extraction-1-overview

Connect with us

Find out more about how we are helping institutions worldwide empower their researchers. Visit www.covidence.org and join our growing social media community.

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