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Contents

Int	roduction	3
Со	chrane Plain language summaries	4
Но	w to approach writing a Cochrane Plain language summary	6
Ge	neral advice on writing in plain language	8
Pla	ain language summary template	11
Th	e Cochrane Plain language summary, section by section	14
a.	The title	14
b.	Key messages	15
c.	Introduction to the review topic and review aims	17
d.	Brief mention of the methods	19
e.	Summary of results	21
f.	Main limitations of the evidence	26
g.	Reporting how current the evidence is	29
Re	ferences	30
Ap	pendix 1 Plain language alternatives to common terms	31
Ар	pendix 2 Resources for writing in plain language	33

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Introduction

What is the purpose of this guidance?

This guidance is designed to help you write a Cochrane Plain language summary. It:

- takes you through the steps of preparing a Cochrane Plain language summary;
- advises you how to write in plain language;
- includes a template that can be used for all types of Cochrane Reviews; and
- explains what to include in each section of the summary, with examples.

What is the guidance based on?

This guidance was prepared by 3 writers hired by Cochrane between May 2020 and May 2021 to improve Cochrane Plain language summaries. It builds on:

- existing work on writing Plain language summaries and disseminating Cochrane Reviews, in particular:
 - Cochrane Norway and Cochrane Effective Practice and Organisation of Care (EPOC)'s guidance: How to write a plain language summary of a Cochrane intervention review [1];
 - PLEACS: Standards for the reporting of Plain language summaries in new Cochrane intervention reviews [2];
 - The Cochrane Dissemination Checklist [3];
 - GRADE guidelines 26: informative statements to communicate the findings of systematic reviews of interventions [4].
- advice from people with plain language expertise within the Cochrane Community
- feedback from over 450 volunteers, gathered as part of the Cochrane Plain language summary project that ran between May 2020 and May 2021; and
- the writers' experience of writing more than 160 Cochrane Plain language summaries.

Cochrane Plain language summaries

What is a Cochrane Plain language summary?

A Cochrane Plain language summary is a stand-alone summary of a Cochrane Review written in plain English. It briefly describes the key question and findings of the review. It is clearly set out, uses words and sentence structures that are easy to understand and avoids technical terms and jargon.

A clear, simple summary written in plain language helps people to understand complex health evidence. Cochrane Plain language summaries are freely available on cochrane.org and in the Cochrane Library in a range of languages. The aim is that anyone looking for information about the key points of a Cochrane Review can read and understand them.

How do Cochrane Plain language summaries differ from Cochrane Abstracts?

Plain language summaries:

- use simpler, conversational-style language;
- do not report statistical data such as summary statistics and confidence intervals;
- do not follow the set structure of Cochrane abstracts;
- are shorter (850 words maximum, compared to 1000 words for abstracts);
- do not feature on PubMed.

Who are Cochrane Plain language summaries written for?

The Plain language summary is for anyone who needs brief, accurate, easy-to-read information to help them make a healthcare decision.

Each Cochrane Review has only one Plain language summary and it has a difficult job to do. It has to sum up the review, be accessible to a wide audience and it may form the basis of other, more targeted dissemination products. We aim to write the summary using words that can be understood by as many different people as possible. The people reading the summary might not have any specialist knowledge or be familiar with technical words and jargon.

It is difficult to suggest a target reading age for all Plain language summaries, because population reading age varies in different countries and amongst different audiences. In the UK, 84% of the population has a reading age of 11 years or older (2011 Skills for Life survey). So if you are writing for a UK audience or one with similar literacy levels, you could aim for a reading age of around 11 years old (similar to the target reading age of materials developed by the UK National Health Service, <u>service-manual.nhs.uk/content/how-we-write</u>; and UK newspapers, <u>www.see-a-voice.org/marketing-ad/effective-communication/readability/</u>).

Importantly, your readers might:

- not have any knowledge of systematic reviews, or of the subject matter of the review;
- not have English as their first language; or
- be reading the summary in a language other than English.

Therefore, we should write Cochrane Plain language summaries using language that is:

• easy to understand for non-experts;

- easy to read for non-native English speakers; and
- easy to translate into any of the <u>14 languages</u> in which Cochrane makes the summaries available.

What does a Cochrane Plain language summary include?

- 1. Title
- 2. Section that summarizes the key messages of the review
- 3. Brief explanation of the review topic and aims
- 4. Brief description of the review methods
- 5. Summary of the review results (whatever the strength of the evidence for them)
- 6. Summary of the limitations of the evidence
- 7. Statement about how current the evidence is

The key messages and findings of the summary must be the same as those in the review. Do not add any new information to the summary or include any results that cannot be found in the review.

How to approach writing a Cochrane Plain language summary

- 1. Before you start writing, we suggest that you read the following parts of the Cochrane review:
 - the Abstract;
 - the summary of findings tables;
 - the Background section; and
 - any other parts that might cover key information, such as the Discussion or Authors' conclusions.

This will help you get a sense (or remind you) of what the review is about, its main findings and their implications.

2. We then suggest that you identify:

- the main question that the review aimed to answer (that is, the question that the review set out to answer, rather than the one it might have ended up answering, for example if studies did not report results on everything you were interested in);
- background information that is key to understanding the review topic and findings; and
- the most important review findings and implications for people who will use this summary to make healthcare decisions. This will help you to work out what someone reading the review might want to know about it.

If possible, talk to the review authors and ask them to explain the main points to you in plain language.

3. Familiarize yourself with the template for a Plain language summary.

We developed a template that can be used for Cochrane Reviews.

4. Now you are ready to start writing.

You can write the summary in any order you like. For example:

- you might find it easier to write the key messages section once you have summarized the results; or
- you might want to complete the body of the summary before you finalize the title.

5. As you write ...

We recommend that you:

- read the guidance relevant to each section of the Plain language summary as you go along;
- follow the advice listed in the 'General advice on writing in plain language' section of this guidance; and

• note any questions you'd like to ask the review authors, Cochrane Review Group, or any consumers with whom you are collaborating on the summary.

6. Allow enough time to produce a first draft.

We found it took about 5 hours to familiarize ourselves with the review and to produce a first draft of the summary. It may take you more or less time depending on how familiar you are with the review topic, the number of findings and how easy they are to communicate in plain language, or how experienced you are at writing in plain language.

7. Once you have completed a first draft ...

Take a break! Returning to the summary with fresh eyes will help you to improve it. Another helpful step is to ask someone to read what you have written and to suggest improvements. This could be:

- a consumer who co-produced the review;
- someone with an interest in the review topic (a patient or carer, for example); or
- someone who doesn't know much about the topic.

General advice on writing in plain language

We encourage you to use this advice as a guide while you write $[\underline{1}, \underline{2}, \underline{3}]$. When you have written your summary, check it against the advice to make sure you have followed all the points, and make any changes you need to.

Language

- Use everyday language. For example, refer to 'people' instead of 'study participants'.
- Avoid (or, when this is not possible or desirable, explain):
 - o long words. For example, use 'blood thinners' as an alternative to 'anticoagulants'.
 - research jargon. Use:
 - 'study' rather than 'trial';
 - 'people with [condition]', 'women', 'children' etc. rather than 'participants';
 - the name of the intervention instead of 'intervention'
 - the name of the control or comparison instead of 'control' or 'comparison';
 - the name of the outcome instead of 'outcome'.
 - words or phrases with dual or nuanced meanings. For example, use 'medicines' instead of 'drugs'.

• Explain

- **'common' medical words**, for example:
 - 'acute condition': a condition or state that develops suddenly and lasts a short time;
 'chronic condition': a condition or state that lasts for a long time.
- **technical medical terms.** Plain language does not always mean 'lay language'. Your reader may know the topic via the technical term especially if they are a patient or carer, so it might be best to include the technical term and explain it.

For example, to explain the action of anticoagulants, you could write: 'Anticoagulants are medicines that stop harmful blood clots forming. However, these medicines may cause unwanted effects such as bleeding.' Or you could write the term in plain language followed by the technical term in brackets. For example, 'blood thinners (anticoagulants)'.

Ask one of your readers if you are unsure about using a particualr term.

- **Avoid acronyms and abbreviations.** If you cannot avoid them, make sure you define them when you first mention them.
 - For example, 'nicotine replacement therapy (NRT)'.
 - Use phrases like 'for example', 'such as', 'in other words', 'and so on' instead of 'e.g.', 'i.e.' or 'etc.', as they are not always understood if you are writing for a wide audience.
- Write for an international audience. Avoid regional words or terms; for example, use 'hospital emergency care' instead of 'Accident & Emergency (A&E)' (UK) or 'Emergency Room (ER)' (USA).

Tools and resources to help you with language

- We have put together:
 - a list of plain language alternatives to common medical terms (<u>Appendix 1</u>);
 - a list of resources about plain language (<u>Appendix 2</u>).
- We encourage you to look at definitions of conditions and treatments:
 - in other Cochrane Plain language summaries on the same topic;
 - on <u>nhs.uk/conditions/;</u>
 - o on patient organization websites; and
 - o in any other resources you trust that are aimed at non-specialists.
- You can use readability formulas to get a sense of how easy the language in your summary is to read. See the Readability Statistics in Word, or <u>readabilityformulas.com/free-readability-formula-tests.php</u>). These formulas generate a readability score that gives an indication of the reading age required to understand your text (the higher the score, the higher the reading age). **However**, readability formulas are not perfect; difficult but necessary words in your summary will drive up your test score.
- It can be tricky to decide if a word is easy enough for your readers to understand. If in doubt, we suggest that you:
 - \circ check patient organization websites, to see whether they use or explain the term; and
 - $\circ \quad$ ask non-experts in the field if they understand the word.
 - o ask one of your readers what they think.

Style

- Keep paragraphs and sentences short, but vary your sentence length occasionally to keep the readers' attention. Aim for an average of 20 words in a sentence. Break up longer sentences into shorter ones. For example, instead of 'Most people who smoke want to stop, however many find it difficult to do so, even though they may use medicines that are designed to help them stop', you could write 'Most people who smoke want to stop, but many find it difficult. People who smoke may use medicines to help them stop.'.
- **Use the active voice.** For example, write 'We compared and summarized the results of the studies' instead of 'The results of the studies were compared and summarized'.
- **Use pronouns.** Write in the first-person plural. For example, use 'we assessed' instead of 'the review authors assessed'. Address your reader using the second-person pronoun 'you'. For example, write 'A pedometer is a small, portable electronic device that counts the number of steps you take.'.
- **Use good verbs.** For example, say 'the students investigated' not 'the students conducted an investigation', or 'we analyzed the data' not 'we carried out an analysis of the data'.
- Write numbers as numerals (1, 2, 3...) rather than words. However, avoid starting a sentence with a numeral. If necessary, rewrite the sentence. For example, write 'The studies included 3260 people' instead of 'Three-thousand, two-hundred and sixty people took part in the studies'.
- **Be concise.** A Plain language summary can be up to 850 words long, but you do not have to fill the word limit. You should aim to keep it as short as possible while still including the most important information. Replace 'wordy' phrases with shorter alternatives:
 - use 'during' instead of 'during the course of';

- use 'often', instead of 'it was often the case that';
- o use 'some' or 'many', instead of 'a number of'; and
- o use 'because' instead of 'due to the fact that'.

Tools and resources to help you with style

You can use an average sentence length calculator (available under Readability Statistics in Word) to check the average sentence length in your summary.

Structure

- **Use subheadings** to guide the reader, break up the text and make it more readable. For example, 'What is a cataract?', 'How are cataracts treated?', 'What happens after cataract surgery?'. Whenever possible, we suggest that you phrase subheadings as questions. This gives a more conversational tone to your summary and will help to engage your readers.
- Use bullet points to break up lists. Review Manager (RevMan) formatting does not currently support this in Plain language summaries but you can use a dash or hyphen instead.

Treatments for boils include:

- antibiotics (medicines that fight bacterial infections);
- light therapy; and
- surgery.
- Alternatively, insert a bullet point symbol.
 - In Word, choose Symbol from the Insert menu, make sure Windgings 2 is selected in the Font dropdown and scroll down to select the bullet point, click Insert;
 - o In Windows, hold down Alt and x and type 8226 on the numeric keypad
 - On a Mac, hold down Alt and Shift and type 2022).

Use a numbered list if the rest of the review uses numbered lists but be careful not to start the point with a number, as this can be tricky to read. For example:

- 1.86 people died ...
- 2. 34 recovered ...
- Keep paragraphs short. Start a new paragraph when the theme or topic of a sentence does not directly follow from the sentence immediately before it.
- Leave plenty of white space in your summary. Dense text is hard to read. White space separates, and groups, elements of your text, which makes it easier for readers to find their way around.

Plain language summary template

This template:

- outlines the structure you should use for your Plain language summary;
- provides brief guidance on what each section should cover; and
- suggests text for you to use.

For more detailed guidance and examples, see links in each section.

Word limit: 400 to 850 words, including the title.

Title

Instructions: write the main review question in plain language.

Example of text you could use:

What are the benefits and risks of intervention for (treating) condition? Intervention a or intervention b: which works better to treat condition?

For more information and further examples, see full guidance below.

Key messages

Instructions: add at least 2 and no more than 3 bullet points that summarize the main findings and implications of the review, or separate the points as short paragraphs.

Explain any technical terms that appear in the key messages. The key messages will likely be read first and they might be the only part of the summary that some people read. Do not use any terms that your readers might not understand. Even if you explain those technical terms later in the summary, you should also explain them in the key messages.

For more information and further examples, see <u>full guidance</u> below.

Introduction to the review topic

Instructions: replace the heading for this section with heading(s) tailored to the review. Briefly explain what the review is about.

Make sure that you:

- avoid acronyms and abbreviations (or introduce and explain them if you need to use them); and
- define any technical terms you use.

Example of text you could use:

What is condition?

Condition is a [common/rare] condition that affects relevant part of the body. It is caused by brief explanation of cause. People with condition [can] experience symptoms.

How is condition treated?

Treatments for condition include:

- intervention a
- intervention b

For more information and further examples, see <u>full guidance</u> below.

What did we want to find out?

Instructions: briefly explain the review aims.

Example of text you could use:

We wanted to find out if intervention a was better than intervention b to improve:

- outcome 1
- outcome 2

We also wanted to find out if intervention a was associated with any unwanted or harmful effects.

For more information and further examples, see <u>full guidance</u> below.

What did we do?

Instructions: briefly mention the review methods (for example, that the review involved searching for studies with specific characteristics, summarising their results and evaluating the evidence).

Example of text you could use:

We searched for studies that looked at/investigated/examined intervention a compared with intervention b in population.

We compared and summarized the results of the studies and rated our confidence in the evidence, based on factors such as study methods and sizes.

For more information and further examples, see <u>full guidance</u> below.

What did we find?

Instructions: write about:

• the main characteristics of the studies that were included in the review.

Example of text you could use to report study characteristics:

We found number of studies that involved number of people with condition and lasted study duration.

• the main results of the review (those presented in the summary of findings table(s) and the Abstract when there are not too many, or those agreed with the review authors, consumers, or the Review Group when you need to select a subset of results). You could give this section a separate heading, 'Main results'.

Do not:

- o report summary statistics and confidence intervals; and
- o use 'low/moderate/high-certainty evidence'.

For more information and further examples, see <u>full guidance</u> below.

What are the limitations of the evidence?

Instructions: mention the main limitations of the evidence.

Do not use technical phrases like 'risk of bias', 'indirectness' or 'low-certainty evidence'. See <u>table</u> below for ways to express the limitations of the evidence in plain language.

Example of text you could use:

We have very little/little/moderate confidence in the evidence because ...

For more information and further examples, see <u>full guidance</u> below.

How up to date is this evidence?

Instructions: state the month and year studies were searched for.

Example of text you could use:

[This review updates our previous review.] The evidence is up to date to month and year of search. For more information and further examples, see <u>full guidance</u> below.

The Cochrane Plain language summary, section by section

a. The title

The title of a Plain language summary should convey the main review question in plain language. Try to use words in your title that readers are likely to search for, recognize, and find relevant (see item 3 in the Dissemination checklist) [3]. We recommend phrasing the title as a question whenever possible; this makes it clear that the purpose of a Cochrane Review is to answer a question. If you cannot avoid using a technical term in the title, include a brief explanation of it in the title.

Examples:

Type of review	Review title	Plain language summary title
Intervention review	Hydrosurgical debridement versus conventional surgical debridement for acute partial- thickness burns	Is surgery with a high-pressure water jet (hydrosurgery) better than conventional surgery for treating severe burns?
Intervention review – network meta-analysis Dipeptidyl peptidase-4 inhibitors, glucagon-like peptide 1 receptor agonists and sodium-glucose co- transporter-2 inhibitors for people with cardiovascular disease: a network meta-analysis		What are the benefits and risks of different antidiabetic medicines for treating cardiovascular disease?
Diagnostic test accuracy review	Thoracic imaging tests for the diagnosis of COVID-19	How accurate is chest imaging for diagnosing COVID-19?
Qualitative evidence synthesis	Barriers and facilitators to healthcare workers' adherence with infection prevention and control (IPC) guidelines for respiratory infectious diseases: a rapid qualitative evidence synthesis	What factors influence whether healthcare workers follow infection prevention and control guidelines for respiratory infectious diseases?

b. Key messages

You will find the relevant information to complete this section in the

- main results and conclusions section of the Abstract;
- the summary of findings table(s); and
- the 'Authors' conclusions' section of the review.

The key messages section should include at least 2 and no more than 3 bullet points or short paragraphs that summarize:

- the most important review findings, including any mention of unwanted or harmful effects. If harmful effects were not reported, say so.
- the main implications of these findings for practice (for example: does the treatment work?) or research (for example: do certain gaps in research need to be addressed in future?).

It might not be clear from the review what its most important findings are, or what they mean for practice and research. When deciding what to include in this section, we encourage you to:

- refer to the advice in Cochrane's Dissemination checklist (items 8, 11 and 12) [3]
- ask the review authors if they agree with your choice of key messages; and
- involve people who might want to use this summary to inform their decision-making what the key messages should be.

It might be helpful to structure your key messages as below:

- First key message. Aim to answer the review question asked in the title, and remember to include any unwanted or harmful effects, or state that they were not reported. If the review could not answer the question in the title, state this as your first key message, with the reason why (for example, no studies found). Remember to give a sense of the quality of the evidence and state to whom the results apply. See below for <u>suggested wording for narrative statements</u>.
- Second key message (optional). Include any other significant finding or important secondary objective.
- Final key message. State what should happen next. For example, future studies should measure the longer-term effects/last longer than 1 year. Mention key limitations and important unanswered questions here.

The key messages might be the only part of the summary that some people will read. Therefore, it is important that your key messages provide a reasonable representation of the evidence. Use neutral terms and take care to include any important nuances; for example, mention if a particular finding applies only to a subgroup of the population [3].

Explain any technical terms that might appear in your key messages. This can be tricky when writing about a technical topic. Even though you might explain technical terms later in the summary, the key messages will likely be read first. Therefore, do not use any terms that your readers might not understand.

Do not make any recommendations about whether a treatment should be used.

Type of review	Key messages in the Plain language summary
Intervention review Topic: comparison of different beds,	 Due to a lack of robust evidence, the benefits and risks of most types of beds, mattresses and mattress toppers for treating pressure ulcers are unclear.
mattresses and toppers for treating pressure ulcers	• Beds with an air-filled surface that applies constant pressure to the skin may be better than mattresses and toppers made of foam for ulcer healing, but may cost more.
	 Future research in this area should focus on options and effects that are important to decision-makers, such as: foam or air-filled surfaces that redistribute pressure under the body; and unwanted effects and costs.
Intervention review Topic: pharmacologic interventions for mydriasis in cataract surgery	 We did not find enough good-quality evidence about the best way to deliver medicines directly to the eye during cataract surgery. We found only one study that had enrolled a large enough number of people to give reliable results. Larger, well-designed studies are needed to give better estimates of the benefits and potential harms of the different ways of delivering these medicines.
Diagnostic test accuracy review Topic: antibody tests for COVID-19	Antibody tests may help to confirm COVID-19 infection in people with negative PCR (laboratory) test results but are not accurate enough to be the main test to identify COVID-19 in people with new symptoms.
Network meta- analysis	• After six months of treatment, medicines called 'biologics' seem to work best to clear patches of psoriasis on the skin.
Topic: pharmacological treatments for	• Longer studies are needed to assess the benefits and potential harms of longer treatment with medicines that are injected or taken by mouth to treat psoriasis.
chronic plaque psoriasis	• More studies are needed that compare these types of medicines directly against each other.
Living systematic review Topic: interleukin-6	• Treating COVID-19 with tocilizumab (a medicine that blocks interleukin-6) reduces the numbers of people who die within 28 days of treatment, and probably results in fewer serious unwanted effects than placebo treatment.
blocking agents for treating COVID-19	• Studies of other medicines that block interleukin-6 to treat COVID-19 are under way. We will update this review when results from them become available.

c. Introduction to the review topic and review aims

This corresponds to the:

- 'Background' and 'Objectives' sections of the review; and
- 'Introduction to the review topic' and 'What did we want to find out?' sections in the PLS template.

The PLS should include a brief explanation of the review topic. You should provide enough information for the reader to understand:

- what the review is about. For example, what is the condition of interest? How is it treated?
- what the review authors wanted to find out.

It can be helpful to break up this section into several short sections, with subheadings tailored to the topic.

Type of review	Background information in the Plain language summary	
Intervention review	What can people do to stop smoking?	
Topic: behavioural interventions for smoking cessation (overview of reviews and network meta- analysis)	Most people who smoke want to stop, but many find it difficult. People who smoke may use medicines to help them stop. Behavioural support provides an alternative – or additional – way to help people stop smoking. Sometimes behavioural support can be combined with nicotine replacement or other medicines to help people stop smoking. Types of behavioural support can include: advice and counselling on ways to make it easier to stop smoking; information about why or how to stop; or a combination. Behavioural support can be given in group sessions or one- to-one. What did we want to find out?	
	We wanted to find out:	
	• which types of behavioural support work best to help people stop smoking;	
	• the best ways to give behavioural support (including the best people to give it); and	
	• what aspects of behavioural support help someone to stop smoking.	
	We also wanted to know if behavioural support can cause any unwanted effects.	
Diagnostic test	What are routine laboratory tests?	
accuracy review Topic: routine laboratory testing to determine if a patient has COVID-19	Routine laboratory tests are blood tests that assess the health status of a patient. Tests include counts of different types of white blood cells (these help the body fight infection), and detection of markers (proteins) that show organ damage or general inflammation. These tests are widely available and in some places they may be the only tests available for diagnosis of COVID-19.	

What did we want to find out?
People with suspected COVID-19 need to know quickly whether they are infected so that they can self-isolate, receive treatment, and inform close contacts.
Currently, the standard test for COVID-19 is usually the RT-PCR test. In the RT-PCR, samples from the nose and throat are sent away for testing, usually to a large, central laboratory with specialised equipment. Other tests include imaging tests, like X-rays, which also require specialised equipment.
We wanted to know whether routine laboratory tests were sufficiently accurate to diagnose COVID-19 in people with suspected COVID-19. We also wanted to know whether they were accurate enough to prioritise patients for different levels of treatment.

d. Brief mention of the methods

This corresponds to the:

- 'Methods' section of the review; and
- 'What did we do?' section of the Plain language summary template.

The Plain language summary should explain the review methods **very briefly.** For example, that the review authors:

- searched for studies with specific characteristics (for example, about a specific population, treatment or comparison);
- summarized the evidence across studies; and
- evaluated the evidence.

Review topic	Explaining methods in the Plain language summary (technical terms in examples are explained earlier in the summary)	
Intervention review	What did we do?	
Topic: hair removal before	We searched for studies that compared:	
surgery to avoid infection	 hair removal against no removal; or different methods and times of hair removal. 	
	We compared and summarized their results, and rated our confidence in the evidence, based on factors such as study methods and sizes.	
DTA review What did we do?		
Topic: the accuracy of tests to diagnose extrapulmonary	We searched for studies that investigated the accuracy of the Xpert Ultra and Xpert MTB/RIF tests for detecting tuberculosis and rifampicin resistance.	
tuberculosis that is resistant to antibiotic	We combined the results of the studies to work out the best estimates of accuracy, in particular:	
rifampicin treatment	 sensitivity: how many people with tuberculosis, and rifampicin- resistant tuberculosis, were correctly diagnosed as having the disease; and 	
	• specificity: how many people without tuberculosis were correctly identified as not having the disease.	
	The closer sensitivity and specificity are to 100%, the better the test.	

A note about primary study designs

Unless you have a specific reason to do so, you should avoid including details about study design. If you do think it is important to mention study designs in your PLS, you will need to explain what they are.

Study design	Text in the Plain language summary
Randomized controlled trials	A study in which participants are assigned randomly to 2 or more treatment groups. This is the best way to ensure that groups of participants are similar, and that investigators and participants don't know who is in which group.
Retrospective studies	We included 7 non-randomised 'retrospective' studies that looked back at treatments given to number of people with condition.
Observational and modelling studies	Studies could be of any design including studies that used 'real-life' data (observational studies) or data generated by a computer based on a set of assumptions (modelling studies).

e. Summary of results

This corresponds to the:

- 'Results' section of the review; and
- 'What did we find?' section in the Plain language summary template.

This section should report:

- the main characteristics of the studies that were included in the review;
- the main results of the review (those presented in the summary of findings table(s) and the Abstract).

Reporting the main characteristics of included studies

The summary should include information that will help the reader put the findings into context. You should mention whether the number of studies and participants found was enough to answer the review questions. Give:

- the total number of included studies;
- the total number of people who took part in the studies;
- how long the studies lasted (for intervention reviews);
- overview of study funding sources;
- population characteristics (such as age, gender, severity of condition);
- study settings, such as the countries in which they took place;
- types of interventions and comparisons;
- if you found no studies on a particular intervention, outcome or population of interest.

Type of review	Describing the main characteristics of studies in the Plain language summary (technical terms in examples are explained earlier in the summary)	
Intervention review	What did we find?	
Topic: treatments for bladder pain syndrome	We found 81 studies that involved 4674 people with painful bladder. The biggest study was in 369 people and the smallest study was in 10 people. The studies were conducted in countries around the world; most were done in the USA (25). Most studies lasted for around 3 months; only 6 studies lasted for 12 months or more. Pharmaceutical companies funded 24 of the studies.	
Diagnostic test	What did we find?	
accuracy review Topic: tests for	We found 72 studies that involved a total of 6059 people. The studies investigated the ability of ferritin blood tests to diagnose:	
measuring the level of ferritin in the blood to diagnose iron deficiency and overload	 iron deficiency in people who sought medical care and whose doctor suspected iron deficiency (70 studies, 5709 people); iron deficiency in people without any sign of disease (5 studies, 350 people); and iron overload suspected by a doctor (36 studies, 1927 people). 	

The studies did not all use the same levels of ferritin in the blood to diagnose iron deficiency or overload. For example:	
 one study diagnosed iron deficiency if people had less than 12 micrograms of ferritin in 1 litre of blood; another study diagnosed iron deficiency if ferritin levels were below 200 micrograms in 1 litre of blood. 	

Reporting the main results of the review

The main review results are those that feature in the summary of findings tables and Abstract. Remember to include unwanted and harmful effects as well as positive effects.

Readers will find overly dense summaries difficult to read, so when there are many summary of findings tables or outcomes, you might need to identify those that are most important for the Plain language summary [3]. Focus on the comparison(s) that have the most clinical importance for decision makers, not the ones with the most data or the best results. To help you do this, we recommend that you involve:

- people who might use this summary to inform their decision-making; and
- the review authors.

Cochrane Norway have made 2 videos about selecting the most important results, which supplement the Dissemination checklist. See Ensuring a reasonable representation of the evidence <u>Part 1</u> and <u>Part 2</u>. See also <u>Reporting the effects of the intervention in systematic reviews</u> by Cochrane Sweden.

Do not:

- present only the most interesting results;
- include summary statistics and confidence intervals;
- refer to 'very low-/low-/moderate-/high-certainty evidence'. Readers have indicated in feedback to us that they do not find these terms easy to understand;
- use GRADE jargon such as 'indirectness' or 'imprecision'.

Instead, use narrative statements. The table below presents suggested wording for narrative statements, based on the suggestions in Chapter 15 of the *Cochrane Handbook for Systematic Reviews of Interventions* [5]. Note that you will need to amend the statements, for example:

- to fit your review type (for reviews other than intervention reviews); or
- to add 'compared with other intervention' when appropriate.

Level of certainty of the evidence					
Effect size	High certainty	Moderate certainty	Low certainty	Very low certainty OR when the point estimate indicates a large effect and the confidence interval also includes a large effect in the opposite direction or no effect	
Large effect	Intervention causes a large reduction/ increase in outcome.	Intervention probably causes a large reduction/increase in outcome.	Intervention may cause a large reduction/increase in outcome.	It is unclear if intervention has an effect on outcome. OR	
Moderate effect	Intervention reduces/ increases outcome.	Intervention probably reduces/increases outcome.	Intervention may reduce/increase outcome.	We do not know if intervention has an effect on outcome.	
Small important	Intervention reduces/ increases outcome slightly.	Intervention probably reduces/increases outcome slightly.	Intervention may reduce/increase outcome slightly.	OR Intervention may reduce/increase/have little to no effect on outcome but we are	
Trivial, small unimport- ant effect, or no effect	Intervention makes little to no difference to outcome.	Intervention probably makes little to no difference to outcome.	Intervention may make little to no difference to outcome.	very uncertain about the results.	
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Suggested wording for narrative statements [4]

We acknowledge that the modifying terms suggested (such as 'probably' or 'may') have different meanings to different people and that they can be difficult to translate into other languages. For example, 'probably' does not have a unique translation in Chinese, and 'may' can be translated in at least 3 different ways in French. Still, the general principle to note here is that **your statements should give your reader a sense of your confidence (or lack of confidence) in the evidence,** based on its GRADE rating. For more information about GRADE, see <u>training.cochrane.org/grade-approach</u>. If you use qualifiers other than 'probably' or 'may', you should use them consistently throughout your summary.

Examples of text used to report results in a Plain language summary:

Type of finding	Text in the Plain language summary (technical terms in examples are explained earlier in the summary)	
Low-certainty evidence Intervention review on antibiotics to prevent complications following tooth extractions	Antibiotics given just before or just after surgery may reduce the risk of infection and dry socket after wisdom teeth are removed by oral surgeons. However, they may cause more (generally brief and minor) unwanted effects for these patients.	
Moderate-certainty evidence Intervention review about rapid versus standard antimicrobial susceptibility testing for bloodstream infection	 Compared with standard tests, rapid susceptibility tests probably made little to no difference to: how many people died within 30 days (evidence from 6 studies in 1638 people); how long people stayed in hospital (4 studies in 1165 people); or how long it took for people to be given the right antibiotic to treat the infection (5 studies in 1493 people). Or but the effects of this treatment vary, so it is possible that it may make little or no difference. 	
No studies that met review eligibility criteria Intervention review about ear cleaning for chronic suppurative otitis media	The only study that looked at hearing did not present the results in a way that could tell us whether dry mopping affects hearing.	
No studies that report usable information	We found no studies to help us answer our question.	

Where possible, present the results as numbers as well as narrative statements. This way the reader can judge the results for themselves [3].

Presenting the results using numbers		
(technical terms in examples are explained earlier in the summary)		
(technical terms in examples are explained earlier in the summary)How accurate are routine laboratory tests for diagnosis of COVID-19?On average, in people with RT-PCR-confirmed COVID-19, antigen tests were better at diagnosing COVID-19 in people with symptoms (72% accurate), than in people without symptoms (58% accurate).		

	In people who did not have COVID-19, antigen tests correctly ruled out infection in 99.5% of people with symptoms and 98.9% of people without symptoms.
In IVF, does transferring the embryo in solutions containing high concentrations of hyaluronic acid result in more live births?	Embryo transfer using solutions with high concentrations of hyaluronic acid probably increases the number of live births compared with using solutions with low concentrations or no hyaluronic acid (10 studies). If transfer solutions with low concentrations or no hyaluronic acid have a 33% chance of resulting in a live birth, solutions with high concentrations increase the chance of a live birth to between 37% and 44%. There would probably be one additional live birth for every 14 embryos transferred in a high concentration hyaluronic acid solution.
Do electronic cigarettes help people to stop smoking, and do they have any unwanted effects?	Nicotine e-cigarettes may help more people to stop smoking than no support or behavioural support only (4 studies; 2312 people). For every 100 people using nicotine e-cigarettes to stop smoking, 10 might successfully stop, compared with only six of 100 people using nicotine-replacement therapy or nicotine-free e-cigarettes, or four of 100 people having no support or behavioural support only.

A note about findings that readers might find upsetting, controversial or disappointing

Some review findings might:

- be upsetting (for example, when they relate to events such as death or miscarriage);
- challenge people's beliefs (for example, when a treatment is thought to work but the evidence does not support this); or
- be disappointing (for example, when there is no information about treatments for a distressing condition).

When this is the case, we encourage you to follow the guidance about handling findings sensitively in the Dissemination checklist, item 15 [3].



f. Main limitations of the evidence

This corresponds to the:

- 'Quality of the evidence' section in the Discussion and the footnotes of the summary of findings tables in the review; and
- 'What are the limitations of the evidence?' section of the template.

The PLS should mention the main reasons for down-GRADEing the certainty of the evidence, using plain language.

Do not use GRADE jargon such as 'downgrading' or 'very low/low/moderate/high certainty evidence. Instead, here are examples of text you can use:

GRADE judgement	Explanation of limitations of the evidence
High certainty	'We are confident that'
Moderate certainty	'We are moderately confident in the evidence because' followed by the main reasons for downgrading the evidence (see table below).
	Our confidence in the evidence is only moderate because of concerns about
Low certainty	'We have little confidence in the evidence because' followed by the main reasons for downgrading the evidence (see table below).
Very low certainty	'We are not confident in the evidence because' followed by the main reasons for downgrading the evidence (see table below).

When reporting the reasons for the GRADE judgements, **do not** use technical terms such as 'risk of bias' or 'indirectness'. Instead, refer to these in plain language. The table below lists examples of how you might do this. Do not refer to evidence being 'downgraded', just explain why you are less than confident in the results (if you are). Focus on how the lack of confidence affects how you interpret the findings. You do not need to explain every reason for downgrading for every result in the summary of findings table, especially if there are multiple comparisons.

This section about the limitations of the evidence should be a concise paragraph, outlining the main reasons for any lowering of certainty. It will be unique to each review. See below for more examples.

Reason for down- or up-GRADEing	Plain language version
Study design (non-RCTs)	People in the studies were not randomly placed into the different treatment groups. This means that differences between the groups could be due to differences between people rather than between the treatments.
Risk of bias	It is possible that people in the studies were aware of what treatment they were getting. Not all of the studies provided data about everything that were interested in
Inconsistency	The studies were done in different types of people/assessed different ways of delivering an intervention

Suggested wording for GRADE criteria

Indirectness	The evidence does not cover all of the people/intervention/comparators/outcomes we were interested in. Or The evidence focused on specific population/intervention/comparators/outcomes whereas the question we wanted to answer was broader.
Imprecision	Studies were very small. Or The evidence is based on few cases of condition, or type of event. Or There are not enough studies to be certain about the results of our outcomes.
Publication bias	The studies that provide results for our review are likely to exaggerate the benefits of the intervention because they represent only a small set of the studies on intervention.
Large effect	The evidence showed that X had a large effect on Y.
Plausible confounding	The evidence suggests that intervention is beneficial/harmful even though some factors such as X might be interfering with its effect.
Dose-response gradient	The evidence shows that the benefits/harmful effects of the treatment increase with the number/length/strength of treatment.

Examples of text used in the Plain language summary:

Text in the Plain language summary

(technical terms in examples are explained earlier in the summary)

The studies either did not report information that we could use, or produced findings in which we have very little confidence. These studies were small, used methods likely to introduce errors in their results and focused on specific settings or populations. Their results are unlikely to reflect the results of all the studies that have been conducted in this area, some of which have not made their results public yet.

We are confident in our results for the seven biologic medicines that worked best to treat psoriasis. We are less confident in our results for serious unwanted effects, because of the low number of unwanted effects reported.

We are also less confident in the results for the non-biologic medicines because of concerns about how some of the studies were conducted. Further research is likely to change these results.

We did not find many studies for some of the 20 medicines included in our review. Participants in the studies often had severe psoriasis at the start of the study, so our results may not be useful for people

whose psoriasis is less severe. Our findings relate only to treatment with systemic medicines for up to six months at most.

Our confidence is limited because the results from the studies varied widely, and the studies involved only small numbers of people. Some studies did not clearly report how they were conducted, or whether the people taking part knew who had received which method of delivering the medicine, which could have affected the study's results. Further research is likely to change our results.

We are confident that tocilizumab reduced the number of deaths (from any cause) at 28 days. Our confidence in the other results for tocilizumab is moderate to low; further evidence may change our results. Our confidence in the results for sarilumab is low; further evidence is likely to change these results. Our confidence was lowered because some of the studies did not report all their results.

g. Reporting how current the evidence is

Readers should be able to tell from the Plain language summary how current the included evidence is. Therefore, you should mention the month and year that the review authors searched for studies.

Suggested text: [This review updates our previous review.] The evidence is up to date to month and year of search.

29

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- McIlwain C, Santesso N, Simi S, Napoli M, Lasserson T, Welsh E, et al. Standards for the reporting of Plain language summaries in new Cochrane intervention reviews Version 1. Cochrane: London. 2013. Available from: <u>training.cochrane.org/resource/cochrane-standards-preparing-plain-languagesummaries</u>
- 3. Glenton C, Rosenbaum S, Fønhus MS. Checklist and guidance for disseminating findings from Cochrane intervention reviews. Cochrane 2019. Available from: <u>training.cochrane.org/online-</u> <u>learning/knowledge-translation/how-share-cochrane-evidence/dissemination-essentials-checklist</u>
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- Schünemann HJ, Vist GE, Higgins JP, Santesso N, Deeks JJ, Glasziou P, et al. Chapter 15: Interpreting results and drawing conclusions. In: Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions. Version 6.2 (updated February 2021). Cochrane, 2021. Available from <u>www.training.cochrane.org/handbook</u>.

Appendix 1 Plain language alternatives to common terms

Term	Plain language alternatives and explanations	
Acute	Serious or severe; swift or sudden onset	
Adverse effects	Unwanted or harmful effects of a treatment	
Adverse events	An unwanted event that causes harm to the patient.	
Anaesthesia	Loss of feeling or sensation in a part or all of the body	
Anaesthetic	A medicine that prevents you/[people] feeling pain	
Analgesia/analgesic	A medicine to treat or lessen pain; pain relief; pain killer; pain-killing medicine	
Antibiotic	A medicine that kills bacteria and fungi (or stops bacteria growing)	
Anti-inflammatory	A medicine to treat or reduce inflammation (an over-response of the immune system)	
Chemotherapy	A treatment used to kill cancer cells	
Chronic	Long-lasting	
Control	[Use the name of the control]	
Cost-effective	The benefits are worth the money paid	
Cost-effectiveness	The balance between the cost of a [treatment/medicine] and how well it works	
Diagnosis	Identification of a health condition from its signs and symptoms or test results	
Diagnostic test	A medical test carried out to find out if a person has a particular disease or condition	
Exposure	Contact with something that causes a disease, so that someone is at risk of being infected	
Intervention	[Use the name of the intervention, such as a medicine or a programme]	
Nausea	Feeling sick	
Observational study	A type of study that investigates the effects of a treatment during usual care. The investigators do not allocate people to different groups to receive the treatment or not, or make any changes to their circumstances, they just monitor what happens.	
Oral	By mouth: for example, 'medicines taken by mouth (orally)'	
Oral medicine	Medicines that are taken by mouth (swallowed), usually in the form of a tablet, pill, lozenge, or liquid	

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Placebo	A 'dummy' treatment, or sham treatment, that does not contain any medicine but looks or tastes identical to the medicine being tested.
Quality of life	Well-being
Randomized controlled trial (RCT)	[Note: think carefully whether you need to mention randomized controlled trials. It might be enough to say 'studies'. If you do use the term 'randomized controlled trial' you will need to add a definition.]
	A study in which participants are assigned randomly to 2 or more treatment groups. This is the best way to ensure that groups of participants are similar, and that investigators and participants don't know who is in which group.
Risk factor	Something that makes a person more likely to get a particular disease or condition.
Topical	A medicine in the form of a cream, foam, gel, lotion or ointment that is put onto the surface of the skin.
Sensitivity (in diagnostic tests)	Sensitivity is the proportion of people with a disease or condition correctly detected by the test being investigated. The nearer sensitivity is to 100%, the better the test.
Specificity (in diagnostic tests)	Specificity is the proportion of people without a disease or condition who are correctly identified by the test being investigated. The nearer specificity is to 100%, the better the test.
Systemic	Something [medicine/disease] that affects the whole body
Vomiting	Being sick

Appendix 2 Resources for writing in plain language

Writing in plain English: general

- Plain English Campaign: <u>www.plainenglish.co.uk/free-guides.html</u>
- European Union, How to write clearly: op.europa.eu/s/piLJ
- National Council for Voluntary Organisations: <u>knowhow.ncvo.org.uk/how-to/how-to-write-</u> <u>clearly-using-plain-english#</u>
- US government: <u>www.plainlanguage.gov/guidelines/</u>
- Plain language Australia: plainlanguageaustralia.com/services-2/

Writing in plain English: medical

- NIHR Involve: https://www.invo.org.uk/resource-centre/plain-english-summaries/
- NHS Digital Service Manual Content Style Guide: <u>service-manual.nhs.uk/content/how-we-write</u>
- NHS guide to conditions, symptoms and treatments, in plain language: <u>www.nhs.uk/conditions</u>
- Plain English Campaign, *How to write medical information in plain English:* <u>www.plainenglish.co.uk/files/medicalguide.pdf</u>
- Plain language definitions of healthcare terms getitglossary.org/

Communicating risk

- Royal College of Anaesthetists guideline on communicating risk: <u>www.rcoa.ac.uk/patient-information/patient-information-resources/anaesthesia-risk/risk-explained</u>
- *Know your chances*, available free from US National Institutes of Health <u>https://www.ncbi.nlm.nih.gov/books/NBK115435/</u>

Writing for an international audience

• Word clashes in UK English, US English and German: <u>www.agcc.de/media/British-US.pdf</u>