

Additional file 3. Detailed guidance

- 1. Clearly state the problem and the options (interventions) that you address, using language that is familiar to your target audience – so that people can determine if the information is relevant to them.**

When searching for or considering information about the effects of interventions, people must decide whether the information is relevant to them. This requires a clear statement of the questions that you address, including the problem that you address. Unless an intervention is compared to something else, it is not possible to know what would happen without the intervention, so it is difficult to attribute outcomes to the intervention. Consequently, it is essential to specify at least two options (the intervention and a comparison intervention, which may be simply not adding the intervention to whatever else is done) whenever presenting information about the effects of interventions. Ideally, you should consider all the relevant options, since people making choices want to know what their options are.

- 2. Present key messages up front, using language that is appropriate for your audience and make it easy for those who are interested to dig deeper and find information that is more detailed.**

Such a “layered” format is helpful to readers for several reasons:

- People tend to scan information first, to estimate its relevance and potential value, before deciding to read it. Short summaries can facilitate scanning.
- When people decide to start to read, many jump straight to the abstract and conclusions. Many people only read the abstract. Providing a short summary up front makes the parts readers are looking for easier to find.
- Different audiences have different needs regarding the amount of detail they want. When content is layered, readers can control the amount of detail presented to them according to their own needs, which may differ over time.
- A layered document structure encourages information providers to write clearly and succinctly, something they might not otherwise prioritize.

It is common to use three or four layers: the key messages, a brief summary, a full report, and appendices.

- 3. Report all potentially important benefits and harms, including outcomes for which no evidence was found – so that there is no ambiguity about what was found for each outcome that was considered.**

Information about the effects of treatments should include information about both desirable and undesirable effects. When reliable evidence for potentially important harms or benefits is not available, you should clearly report this, rather than saying nothing about those outcomes.

Both short and long-term outcomes should be reported. Whenever possible, surrogates for important outcomes should be avoided. When the best available evidence only reports surrogate outcomes (e.g. hypertension) and not important outcomes (e.g. myocardial infarction and stroke), this should be made clear.

In order not to overwhelm the target audience with information when there are many potentially important outcomes, it may be desirable to omit less important outcomes [1]. Alternatively, less important outcomes can be omitted from the top layer but included in other layers. Decisions regarding which outcomes are more important require judgment and should be informed by how much people affected by the intervention value the outcomes of interest [2].

4. Explicitly assess and report the certainty of the evidence.

The quality or certainty of the evidence (the extent to which research provides a good indication of the likely effects of interventions) can affect the healthcare decisions people make [3]. For example, someone might decide not to use or to pay for an intervention if the certainty of the evidence is low or very low. Information about the effects of interventions should include explicit judgements about the certainty of the evidence, based on the GRADE approach or similar approaches [4]. Consistent definitions of different levels of certainty should be used, such as those shown in Table 1. The definitions that are used should be easily accessible, for example using a pop-up or scroll-over for online information.

Table 1. Definitions of different levels of certainty of the evidence

| Assessment | Definition |
|------------------|--|
| ⊕⊕⊕⊕ High | This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different* is low. |
| ⊕⊕⊕○ Moderate | This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different* is moderate. |
| ⊕⊕○○ Low | This research provides some indication of the likely effect. However, the likelihood that it will be substantially different* is high. |
| ⊕○○○ Very low | This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different* is very high. |

* Substantially different = a large enough difference that it might affect a decision

5. Use language and numerical formats that are consistent and easy to understand.

The language that you use to report effects should reflect the importance of the effect and the certainty of the evidence, and it should be consistent. It is easy to cause confusion and misinterpretation by using words inconsistently or by using overly complicated phrases such as “a high likelihood of a somewhat small but possibly important effect”.

The importance of the effect depends on the size of the effect and how important the outcome is to people. For example, a small effect, say a difference of 5%, for an outcome that is not very important, such as mild discomfort, might be considered an unimportant effect. On the other hand, the same effect on an important outcome, such as strokes or death, is likely to be considered an important effect.

These can be difficult judgements to make. To help formulate clear, consistent expressions of the effects of interventions, we have developed standard expressions (Table 2) [3,5]. These describe effects in plain language, using similar words for similar combinations of importance and certainty.

Although these words can have different meanings to different people, consistent use of words such as these, and clear explanations of the meanings of the words that are used to express uncertainty, can reduce confusion, misunderstandings, and misleading presentations of how sure we can be about effects.

Table 2. Standard expressions for communicating effects

| | Important benefit/harm | Less important benefit/harm | No important benefit/harm |
|--|--|---|--|
| High quality / certainty ¹ evidence | [Intervention] improves/reduces [outcome] (high quality / certainty evidence) | [Intervention] slightly improves/reduces [outcome] (high quality / certainty evidence) | [Intervention] makes little or no difference to [outcome] (high quality / certainty evidence) |
| Moderate quality / certainty ¹ evidence | [Intervention] probably improves/reduces [outcome] (moderate quality / certainty evidence) | [Intervention] probably slightly improves/reduces / probably leads to slightly better/worse [outcome] (moderate quality / certainty evidence) | [Intervention] probably makes little or no difference to [outcome] (moderate quality / certainty evidence) |
| Low quality / certainty ¹ evidence | [Intervention] may improve/reduce [outcome] (low quality / certainty evidence) | [Intervention] may slightly improve/reduce [outcome] (low quality / certainty evidence) | [Intervention] may make little or no difference to [outcome] (low quality / certainty evidence) |
| Very low quality / certainty ¹ evidence | We / The review authors are uncertain whether [intervention] improves/reduces [outcome] as the quality / certainty of the evidence has been assessed as very low | | |
| No studies | None of the studies looked at [outcome] | | |

Using “plain language” means writing in a way that helps readers understand the content in a document the first time they read it. Although the use of plain language is commonly associated with information that is written for non-professionals, the principles underlying plain language [6] apply to any audience. This includes, for example, using:

- Words that are easily understood by the target audience
- Active verbs and personal pronouns
- Bullets, tables, and other design features that break up the text and add visual interest
- Short sentences and paragraphs

Terms that are unfamiliar to the target audience should be used only when necessary, and their meaning should be explained. Information about the effects of treatments should be as concise as possible. Extra or elaborate words reduce clarity and they should be avoided. Acronyms and abbreviations should also be avoided. Although they may be more concise, acronyms and abbreviations that are not familiar to the target audience make information more difficult to understand.

6. Present both numbers and words, and include summary of findings tables.

People's interpretations of the words used to describe treatment effects varies [7-9]. Patients' preferences for words, numbers, or both also vary [7]. More importantly, these different presentations can affect decisions. For example, women who received verbal information about disease-free survival for an experimental cancer treatment were more likely to select the treatment than those who received numerical information [7].

Words and numbers have different strengths and weaknesses for presenting the effects of interventions. The main argument for using numbers is that they are precise, whereas words can mean different things to different people. This can lead to misunderstanding. On the other hand, words are easier and more natural to use than numbers, allowing for fluidity in communication. They also may be easier to understand for people with poor numerical skills. In addition, words can quickly convey the "gist" of effects. This can be useful in situations where a precise understanding is not necessary and a rough understanding of the direction of effect is sufficient. Brief verbal summaries can also help people decide whether to continue on to more precise or detailed information [10]. Moreover, some people may not want numbers.

Because people have different preferences, and because numbers and words support different kinds of cognitive tasks (e.g. establishing gist, or determining precise effect differences), it is helpful to use both words and numbers to present the effects of interventions. The fact that some people may not be interested in numbers is not a reason not to provide them for those who can benefit from numerical information. This recommendation is supported by findings from user tests of various formats of Cochrane Review summaries using words, numbers, or both; which suggest that users prefer a combination [11]. Care must be taken to label numbers so that people can understand what they are referring to (e.g. "7 per 100 **adults**"). Standard expressions, such as those suggested above, presented alongside numerical results can help users feel more confident in their understanding of the numbers [3].

People's preference for words or numbers also depends on the way they are presented. For example, people may experience numbers inserted in text as off-putting and complicated, and therefore prefer numbers in tables. Summary of findings tables show size of the effect and the certainty of the evidence for each important outcome [10-14]. Other advantages of using summary of findings tables to present numerical information about the effects of treatments, include:

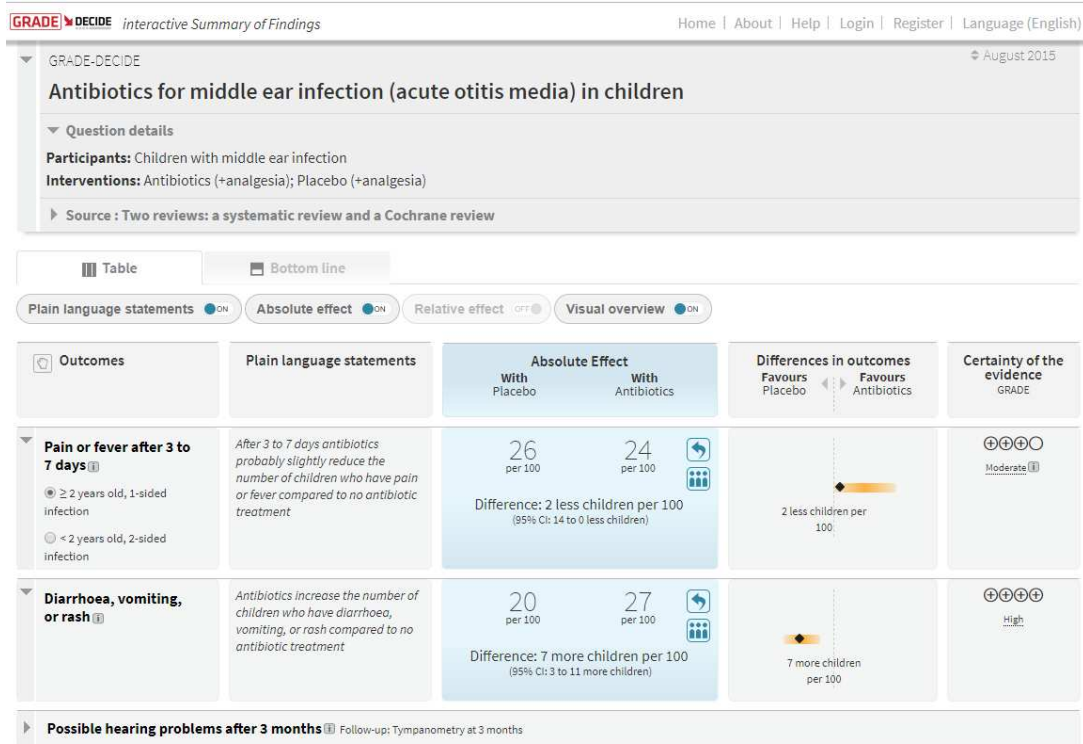
- Tables are more efficient for presenting numbers in the text, since the headings do not need to be repeated.
- Tables facilitate putting standard expressions alongside the numbers.
- People who are not interested or have difficulties with numbers can easily hop over tables or can just focus on selected information in tables, such as standard expressions.

Graphs or visual displays are appealing because they are visually interesting, and they take advantage of rapid visual perception skills. Visual displays of effects can help people to comprehend proportions and the size of effects. However, not all visual displays are more intuitive than text or numbers, some visual displays can be misleading, some may require explanation in order for people to understand them, and people tend to prefer simplicity and familiarity, which may not be associated with accurate quantitative judgements [8,9,15-17]. There is not sufficient evidence for us to recommend any specific visual display for presenting the effects of interventions, and people vary in their preferences. Thus, although well-designed visual displays can be used to supplement

numerical and verbal presentations of effects, they should not be considered as a substitute in most circumstances.

An illustration of these principles can be found in interactive Summary of Findings tables [18]. These tables enable the presentation of a visual display of effect sizes (Figure 1) and provide explanations of the visual displays, the size of the effects, and the confidence interval. Different columns in the tables can be turned on or off by the target audience, based on their needs.

Figure 1. Screen shot of an interactive Summary of Findings with a visual display of effects*



*[View an interactive version of this table](#)

7. Report absolute effects.

Three of the most used formats for presenting effects of interventions are relative risk reduction, absolute risk reduction and number needed to treat (NNT). The relative risk reduction is the risk in the intervention group relative to the risk in the control group. If the risk is 10% in the intervention group and 20% in the control group, the risk in the intervention group is halved, i.e. a 50% relative risk reduction. The absolute risk reduction is the difference in risk between the two groups, i.e. 10% (or 10 percentage points), using the same example. The NNT is the number of patients you need to treat in order to prevent one bad outcome. It corresponds to the inverse of the absolute risk reduction. With the same example, the NNT is 10 (1/0.1).

A relative effect may give readers the impression that a difference is more important than it is when the likelihood of the outcome is small to begin with [19,20]. On the other hand, the absolute effect of a treatment is likely to vary for people at different baseline risk. Therefore, when people with different baseline risks may make different decisions because of this, absolute effects should be

presented for people at different levels of risk. This should be done in such a way that the target audience can easily identify which information is relevant for them, either based on the description that is provided (see, for example, Figure 1), or by using a risk calculator.

Although it has been argued that natural frequencies (e.g. 26 per 100 or 3 per 1000) are preferable to percentages (26% or 0.3%), the evidence used to support this argument has come from studies of presenting information about diagnostic or screening tests [19]. Two randomised trials that compared using natural frequencies to percentages to present information about the effects of interventions found that understanding was slightly better when percentages were used for levels of risk that are high enough that whole numbers can be used when percentages are presented [20,21].

Considering this evidence, it may be appropriate to use either percentages or natural frequencies. When natural frequencies are used, the denominator should be kept constant across outcomes (typically per 1000) to avoid misleading numerators [16]. For very low levels of risk, natural frequencies may be preferable to percentages using decimal numbers (such as 0.26% or 0.026%).

The number needed to treat (NNT) is a popular alternative way of presenting absolute effects and is preferred over the risk difference by some health professionals. However, NNTs (and, for adverse effects, numbers needed to harm) are more difficult to understand than risk differences [19,22].

8. Avoid misleading presentations and interpretations of effects.

Three common mistakes in presenting and interpreting treatment effects are:

- Help your audience to avoid misinterpreting continuous outcome measures.
- Explicitly assess and report the credibility of subgroup effects.
- Avoid confusing “statistically significant” with “important”, or a “lack of evidence” with a “lack of effect”.

[Help your audience to avoid misinterpreting continuous outcome measures.](#)

Average effects do not apply to everyone. For outcomes that are assessed using scales (for example, measuring weight, or pain) the difference between the average among people in one treatment group and the average among those in a comparison group may not make it clear how many people experienced a big enough change for them to notice it, or that they would regard as important. Whenever possible, this information should be presented. When it is not possible, this should be explained.

In addition, many scales are difficult to interpret and are reported in ways that make them meaningless. This includes not reporting the lower and upper ‘anchor’, for example, if a scale goes from 1 to 10 or 1 to 100; whether higher numbers are good or bad; and whether someone experiencing an improvement of, say, 5 on the scale would barely notice the difference, would consider it a meaningful improvement, or would consider it a large improvement. It is also difficult to understand the meaning for standardised mean differences (the difference in standard deviations between two comparison groups) when these are reported. Several strategies have been suggested for helping people to understand differences on unfamiliar scales [23]. Because there are limitations for each alternative, we suggest using more than one presentation for these outcomes and providing comments to help with correct interpretation [23].

Explicitly assess and report the credibility of subgroup effects.

Estimates of effects from studies or systematic reviews do not apply to everyone. Comparisons of treatments often report results for selected groups of participants to assess whether the effect of a treatment is different for different types of people (e.g. men and women or different age groups). These analyses are often poorly planned and reported. Most differential effects suggested by these “subgroup results” are likely to be due to the play of chance and are unlikely to reflect true differences [24]. Judgements about the credibility of the size of an effect being different for a subgroup should be assessed using explicit criteria [25], and an explicit judgement should be made about how credible such a difference is [26].

Avoid confusing “statistically significant” with “important”, or a “lack of evidence” with a “lack of effect”.

“Statistically significant” is so commonly misreported and misinterpreted that we recommend avoiding terms such as “not significant”, “not statistically significant”, “significant”, “statistically significant”, “trend towards [an effect]”, and “borderline significant” [27,28]. These terms are based on an arbitrary cut-off for statistical significance (typically 0.05). ‘Statistical significance’ (a ‘positive’ study) is often confused with ‘clinical significance’ (importance), especially when ‘significant’ is used rather than ‘statistically significant’. People also often misinterpret it as meaning that the certainty of the evidence is high, when it might not be for other reasons, such as a high risk of bias. Conversely, ‘statistically non-significant’ is ambiguous. It is often misinterpreted as evidence of ‘no effect’ (a ‘negative’ study). However, results that are ‘not statistically significant’ can either be informative (if the confidence interval, and the certainty of the evidence, suggests that there is unlikely to be an important effect) or uninformative (inconclusive, if the confidence interval does not rule out an important effect). It is better to consider explicitly estimates of effect and confidence intervals, and to use plain language to describe effects based on the size of the effect and the certainty of the evidence, as suggested above.

Systematic reviews sometimes conclude that there is “no evidence of an effect” when there is uncertainty about the effect. This is often misinterpreted as meaning that there is “no effect” [29]. However, lack of evidence of an effect is not the same as evidence of “no effect”. When there is a lack of evidence or very low certainty of the evidence (Table 1), we recommend using expressions such as the ones suggested in Table 2.

Although confidence intervals are more informative than p-values, confidence intervals can also be misinterpreted [3,30]. There are pros and cons to reporting confidence intervals and little evidence to support a recommendation either to include them or exclude them, or how to present and explain them, if they are included. Deciding whether and how to report confidence intervals may depend on the target audience.

9. Provide relevant background information, help people weigh the advantages against the disadvantages of interventions, and provide a sufficient description of the interventions.

Information about the benefits and harms of interventions is essential but not sufficient for informed decisions. Decisions about whether or not to use an intervention depend on the balance between the potential benefits and the potential harms, costs, and other advantages and disadvantages of the intervention. This balance often depends on the baseline risk or severity of the symptoms. The balance between the advantages and disadvantages of a treatment is more likely to

favour the use of an intervention by people with a higher baseline risk, or more severe symptoms. The balance also depends on how much people value (how much weight they give to) the intervention's advantages and disadvantages. Different people may value outcomes differently and sometimes make different decisions because of this. In addition, people usually place more value on things that happen soon than on things that happen years into the future. In other words, the further into the future something is (for example, reducing the chance of heart disease or cancer after many years) the more people tend to "discount" its value or importance. The balance between the advantages and disadvantages of treatments may also depend on how much costs and events in the future are discounted.

If a recommendation is made, those making the recommendation should take all these factors into account. Ideally, the criteria that they use to make a decision should be explicit, the judgements that they made for each criterion should be explicit, the evidence to inform each judgement should be explicit, and the justification for the recommendation should be clearly spelled out. GRADE Evidence to Decision frameworks provide a tool for doing this [31]. When a recommendation is not made, Evidence to Decision frameworks can provide a useful framework for considering factors that may help your target audience to make a decision [32]. For difficult clinical or personal decisions, providing or linking to a decision aid can be helpful [33].

Interventions are frequently inadequately described in trial reports and in systematic reviews [34,35]. If a decision is made to use an intervention, decision-makers cannot implement it if it is not adequately described. Therefore, it is essential to provide a sufficient description of interventions.

Examples of other key types of information that can be helpful for patients and the public, health professionals, and policymakers are summarised in Table 3.

Table 3. Additional information that can be helpful to different target audiences

| Patients and the public | Health professionals | Policymakers |
|--|--|--|
| What is (are) the intervention(s)? | Indications and contraindications | What are the policy options? |
| Who can use the intervention(s)? | Delivery of the intervention(s) | Equity considerations |
| What other options are there? | Cautions | Economic considerations |
| How do people experience the intervention(s) | Counselling patients | Monitoring and evaluation considerations |
| Is there anything else that someone should know before using the intervention(s) | Anything else that health professionals should know before using the intervention(s) | Anything else that policymakers should know before deciding on one of the policy options |

10. Tell your audience how the information was prepared, what it is based on, the last search date, who prepared it and whether the people who prepared the information had conflicts of interest.

You should tell your audience when the information was last updated and when the last search for research evidence was done, so that they know how up-to-date the information is. If relevant, provide information about plans for updating the information.

Conflicts of interest are common, frequently are not disclosed, and can lead to biased reporting [36,37]. Therefore, it is important to tell your audience whether the people who prepared the information had conflicts of interest.

In order to earn their trust, and for transparency, you should tell them how the information was prepared, what evidence it is based on – and specifically whether the information about the effects of interventions is based on systematic reviews of fair comparisons. Lastly, you should tell them who prepared the information and who paid for it, disclose any conflicts of interest, and provide a contact address for feedback and questions. It is not necessary to repeat all of this information in each summary, but all of this information should be clearly identified in the summary as available elsewhere and easy to find via links or instructions. When we reviewed websites that provide information about the effects of treatments for patients and the public [38], we found that very few websites provided all of this information. It was frequently difficult to establish what information was available and seldom obvious where it was located.

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