# DATA SYNTHESIS AND ANALYSIS

Consumers and Communication Review Group (CC&CRG) reviews often assess complex interventions.  Commonly, these reviews:

- cannot analyse data using meta-analysis;
- can only pool some of the included studies and/or data statistically;
- include data from different study designs that are not suitable for lumping all together in analysis; or
- may have captured a very wide range of interventions.

Therefore, other ways of expressing and synthesising the results of studies collected together for review are needed. We often describe these methods as 'narrative' analysis or synthesis. Additionally, even where meta-analysis is used, the results need to be described and integrated in the text of the review. A narrative synthesis can provide a first step in looking systematically at, and organising, the data.

Since narrative synthesis will be used to a greater or lesser extent in a review, the methods for performing the synthesis need to be described at protocol stage. Pre-specifying the approach to synthesis may also help to avoid emphasising some findings above others, even inadvertently, and so may reduce the potential for unsubstantiated claims to appear in the synthesis. At review stage, authors will make further decisions about how best to organise and present the data based on the actual review findings.  While it may be possible or necessary to make some changes to the synthesis approach after the protocol has been developed, thinking through and planning the approach at protocol stage is still very important, and changes made at later stages of the review may need to be justified in terms of a rationale for making changes.

This document aims to assist authors in planning their narrative analysis at protocol stage, and to highlight some issues for authors to consider at review stage. Narrative forms of synthesis are an area of emerging research, and so advice is likely to be adapted as methods develop. This document sits alongside the RevMan templates for protocols and reviews developed by the CC&CRG, as the examples of different approaches to analysis and synthesis in CC&CRG reviews, all available at http://cccrg.cochrane.org/author-resources

## STARTING A NARRATIVE SYNTHESIS

Synthesising narratively the results of different studies in a review is not simply describing or summarising the main features of each in turn, although doing this can be a starting point. For example, describing the included studies, and describing and commenting on the methodological quality (risk of bias) of each study can be used for authors to become familiar with the data, as a first step in the synthesis process.

An initial stage in any synthesis is to become familiar with the results of the included studies. This means assessing systematically and comprehensively the results of each study, highlighting important characteristics of the studies

where relevant, such as important similarities or differences (for example, in study design, populations, interventions or other elements).

## SUMMARISE AND SYNTHESISE DIFFERENT STUDY DESIGNS SEPARATELY

In those CC&CRG reviews which include studies of diverse designs, we suggest that these designs be dealt with separately in summaries and syntheses. This is because different study designs have fundamentally different methodological strengths and weaknesses, and should not be treated as though they are equivalent.

For example, if a review has included randomised controlled trials (RCTs) plus non-randomised studies, the synthesis of studies could be divided into RCTs, quasi-RCTs and so on. Authors should also:

- explore any potential heterogeneity in the results that might be due to differences in study designs (eg. RCTs and non-RCTs coming to different conclusions about the particular effects of an intervention);
- compare the results of RCTs with those of quasi-RCTs; and
- highlight any similarities or differences in the findings within the review.

## OVERVIEW OF DIFFERENT APPROACHES TO SYNTHESIS

There are different ways to approach narrative data synthesis. The approach you choose will be determined by the type of question your review is attempting to address. It will also be affected by the characteristics of the included studies.

The key to any rigorous synthesis of data, whether narrative or statistical, should be that the processes employed avoid bias. The process of narrative data synthesis must therefore itself be rigorous and transparent, ideally with methods specified in advance (ie. at protocol stage) - although this may not always be possible. These methods should be justified and followed systematically.

A narrative synthesis can be challenging, especially if: the review includes a large number of studies; the studies examine complex interventions and outcomes; or there is a lot of variation in the effects of the intervention. Patterns of effects, and similarities or differences between studies may not be immediately obvious, and so adopting a systematic approach to synthesis is key to making sense of the results.

We encourage authors to attempt a narrative synthesis that includes investigation of the similarities and the differences between the findings of different studies, as well as exploration of patterns in the data.[1] This might involve examining associations between study outcomes and any other factors related to the study design and conduct. For example, considering the results of studies of different design (eg. RCTs and non-RCTs), or with different forms of intervention implementation or delivery, could be ways to approach the synthesis. Reasons for both similarities and differences in the findings should also be explored systematically, with possible explanations for the pattern of results considered in a logical way for each of the included studies.

See the 'Examples of narrative synthesis' guide at http://cccrg.cochrane.org/author-resources

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[1] This compares with the approaches taken by meta-analysis, in which heterogeneity in study results is examined statistically.

## NARRATIVE SYNTHESIS GUIDELINES

Guidelines are available to help review authors to structure narrative syntheses of results in systematic reviews.[2] These outline several steps that can help review authors to systematically analyse and then integrate the results across studies, and so form conclusions based on the assembled body of evidence. Below we highlight the major points adapted from these guidelines, which CC&CRG authors should consider when conducting narrative syntheses. Please refer to the full guidelines for a detailed explanation of the methods.

The guidelines describe four major steps for narrative synthesis in reviews of effectiveness questions, as follows.

### 1. DEVELOPING A THEORY OF HOW THE INTERVENTION WORKS, WHY AND FOR WHOM

- Complex interventions are often developed in a theoretical context that helps to determine why or why not an intervention works. Consider the rationale for the intervention outlined in included studies: this may identify key theories or pathways whereby the intervention has its effects (and where, and in whom it has its effects).
- Consider the pathway whereby the intervention is thought to operate: are there outcomes directly influenced by the intervention? Are there intermediate outcomes that should be considered when systematically reviewing the evidence?

See 'Examples of theoretical models' in CC&CRG reviews at http://cccrg.cochrane.org/author-resources

### 2. DEVELOPING A PRELIMINARY SYNTHESIS OF THE FINDINGS OF INCLUDED STUDIES

- Consider how to examine systematically the results from included studies. This might mean considering how many studies you are dealing with, what their results are, and how best to describe the results so that both the direction of effects and their size will be identifiable and comparable across included studies.
- This preliminary synthesis is the first step in systematically analysing the results—but it is only a preliminary analysis (not the endpoint).
- Possible examples of ways to approach this step are:
  - Describe each of the included studies: summarising the same features for each study and in the same order).
  - Group the studies: for example, by intervention (eg by comparisons made, complexity, format, delivery); population groups; study design; setting; or by outcomes (eg type of outcome measure (primary, secondary, adverse events) or outcome measure).
  - Tabulate results in order to identify patterns across the included studies: for example, organising the studies by study design, risk of bias, or results. Additional information may also be helpful to include alongside this, to help to identify pattens, such as information on the participants, interventions or other factors.
  - Transform the data: for example, transforming data expressed in different ways into a common statistical or descriptive format.
  - Using vote counting: as a way of providing an initial description of results. Note however that vote counting is generally seen as an acceptable approach only as an interim step in assessing data.
  - Translating data: using thematic or content analysis to identify areas in common between studies.

See http://cccrg.cochrane.org/author-resources for selected examples of narrative data synthesis in CC&CRG reviews.

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[2] A copy of the guidelines (Popay et al (2006) *Guidance on the conduct of narrative synthesis in systematic reviews*) can be obtained from Libby Osborn via email at l.osborn@lancaster.ac.uk.

## 3. EXPLORING RELATIONSHIPS IN THE DATA WITHIN AND BETWEEN STUDIES

- Consider how to look systematically at the relationships both within and between included studies in order to explore reasons for differences in the direction and size of effects of interventions.
  - Within studies – for example, differential effects of an intervention in different settings or population groups
  - Between studies – for example, RCTs may not detect an effect of an intervention whereas lower quality studies (eg quasi-RCTs) may; patterns may also exist based on differences in population features (eg adult versus child), intervention characteristics (eg simple versus complex interventions) or other factors.
- Consider whether the following are likely to explain differences between and within studies:
  - Variability in outcomes;
  - Variability in study designs;
  - Variability in populations, interventions, settings;
  - 'Poor' outcome measures used.

Examining the effects of **heterogeneity** is also important in any synthesis. This means considering how the results of studies might be affected by factors such as methodological differences between studies, or variable characteristics of the populations studied or interventions investigated. In studies of complex interventions, such as many of those examined in CC&CRG reviews, this can form a very important part of the narrative synthesis of results.

**Note** that having a theoretical basis for the intervention and the way that it operates will also help at this stage to help to identify reasons for heterogeneity between and within studies, including identification of relationships to explore in subgroup analyses.

Different approaches can be used to explore the relationships between and within included studies,[3] including:

- Graphs and other plots: visual tools such as forest plots or graphs can be a helpful way to organise and present results. However, review authors should also provide a description and synthesis of the results, in addition to using graphs.
- Subgroup analysis: it can be very useful to explore the impact of potential effect modifiers on the effects of an intervention, to help to answer the bigger questions that a review is trying to address, such as 'What works? For whom? In what setting? What versions or with whom does the intervention work better or best?'
- Developing conceptual models: includes approaches such as ideas webbing, concept mapping and conceptual triangulation.

## 4. ASSESSING THE ROBUSTNESS OF THE SYNTHESIS

The robustness of the synthesis depends on:

- The amount and quality of the evidence (ie the included studies);
- The methods used to synthesise the evidence (ie how well the methods minimised bias).

Each of these components should be considered systematically as they will help with determining the overall strength of evidence on which conclusions are based.

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[3] See also Thomas J, Harden A, Newman M. 'Synthesis: Combining results systematically and appropriately.' In  Gough D, Oliver S,  Thomas J (authors) (2012). *An Introduction to Systematic Reviews.* Sage Publications: London.

Think through the points below to help to address these different components of the synthesis.

- Using the Cochrane Risk of bias tool to assess the methodological quality of the included studies will feed into a formal assessment of the quality of the evidence using the GRADE process. This will form the basis for commenting on the quality of the evidence in the review.
- The assessment of the quality of the evidence will be incorporated into the Effects of interventions and Discussion (Quality of the evidence) sections of the review. Consider whether the quality of the included studies is adequate to enable trust in the results: are there any specific and/or serious limitations in methodological quality?
- Critically reflect on the strengths and weaknesses of the synthesis methods you have used to narratively synthesise the results of the included studies. This might include:
  - In the Methods, under Data synthesis: describe the methods used to synthesise the results, including major features and any assumptions about the data or included studies, or about the approach used.
  - A clear rationale and discussion of the approach used and the assumptions made should also be included in the Discussion section.
  - It may also be appropriate in the Methods section (under 'Subgroup analysis and investigation of heterogeneity' subheading) to describe the moderator variables that have been used to explore relationships in the data. In narrative synthesis, subgroup analyses does not test statistically the influence of particular variables on the outcomes, but it is important to articulate the relationships that have been explored in synthesising the data.

In the 'Discussion' section, use the following subheadings to address aspects of the narrative synthesis:

- 'Overall completeness and applicability of evidence': comment on whether the included studies address sufficiently the objectives of the review; and whether all relevant participants, interventions and outcomes have been evaluated (highlighting any important gaps). Highlight the absence of data for any of the comparisons that had been planned. This may include highlighting any outcomes that were looked for but were not reported by included studies. This section should lead to an overall assessment of the generalisability of the results of the review.
- 'Quality of the evidence': consider how the risk of bias of the included studies might impact on the results of the review. Do the included studies address the review objectives according to the PICO question? Are the results consistent across studies? Are there enough participants or events in the studies? Is it possible that some studies are missing or were not published, in particular studies with negative or 'non-significant' results? This section should allow an overall assessment of the quality of the evidence reviewed.
- 'Potential biases in the review process': this should include a description and critical evaluation of the assumptions made when analysing the data/ conducting the review; acknowledgement of any limitations in the approaches used; and any effects that this may have had on the results. Discrepancies and/or uncertainties identified in the results of the included studies – such as how differences in findings between studies were dealt with or explored – should also be outlined here.

Overall, summaries of the quality of the evidence and of the synthesis will allow the review's readers to interpret its findings with any limitations in mind, including limitations associated with the generalisability of the results and with the methods of the review.

This does not have to be a major section of the review; however it should reflect a critical and fair assessment of the methods used, noting any particular strengths and/or weaknesses of the approach used, and commenting on how these may effects the results and the conclusions of the review.

See also our guide: 'Common mistakes in presenting results' at http://cccrg.cochrane.org/author-resources

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