Unit Four: Developing a Protocol

<u>Learning Objectives</u>

- *To understand the rationale for documenting the review plan in the form of a structured protocol*
- *To understand the importance of setting the appropriate scope for the review*

What is a protocol?

A protocol is the plan the reviewers wishes to follow to complete the systematic review. It allows thinking to be focused and allocation of tasks to be determined. Methods to be used in the systematic review process must be determined at the outset. The Cochrane Reviewers' Handbook[1] states that "the reviewer's knowledge of the results of the study may influence:

- The definition of the systematic review
- The criteria for study selection
- The comparisons for analyses
- The outcomes to be reported in the review."

Furthermore, spending time at this stage preparing a clear protocol will reduce time spent during the systematic review process.

Information to include in the protocol

Examples of protocols (of Cochrane systematic reviews) can be found in The Cochrane Library (http://www.thecochranelibrary.com).

1) Background

This section should address the importance of conducting the systematic review. This may include discussion of the importance or prevalence of the problem in the population and the results of any similar reviews conducted on the topic.

The background should also describe why, theoretically, the interventions under review might have an impact on potential recipients.
Reviewers may refer to a body of:

- empirical evidence such as similar interventions having an impact, or identical interventions having an impact on other populations.
- theoretical literature that justifies the possibility of effectiveness.

If reviewers choose to examine more proximal outcomes (knowledge and attitudes), theory should be used to explain the relationship to more distal outcomes (changes in behaviour).

2) Objectives

Reviewers will need to determine the scope of the review. The scope of a review refers to the type of question being asked and will affect the kind of studies that need to be reviewed, in terms of study topic, population and setting, and, of course, study design.[2]

The scope of the review should be based on how the results of the review will be used. It is useful to consult with the potential users of the review when determining the review's scope. For example, many health promotion practitioners and policy makers would find it more useful to have systematic

reviews of 'approaches' to health promotion (eg. community development or peer-delivered interventions), rather than topic-focused reviews (eg. healthy eating or accident prevention).

The scope is also likely to depend on how much time is available and the likely volume of research literature.

Lumping the review question, i.e. addressing a wide range of interventions (eg. prevention of injuries in children):
- likely to be time-consuming because of the searching and selecting processes
- will better inform decisions about which interventions to implement when there may be a range of options
- may be ultimately of more use to policy decisions

Splitting the review, i.e. addressing a narrow range of interventions, (eg. prevention of drowning in toddlers)
- may be less time-consuming
- will only inform decisions about whether or not to implement narrowly focused interventions
- may be more useful for practitioners

3) Pre-determined selection criteria

The selection criteria will be determined by the PICO(T) question, which is described in the following unit (Unit Five. Asking an Answerable Question). It is important to take an international perspective – do not restrict the inclusion criteria by nationality or language, if possible.[1]

4) Planned search strategy

List the databases that are to be searched and if possible, document the search strategy including subject headings and textwords. Methods to identify unpublished literature should also be described (eg. handsearching, contact with authors, scanning reference lists, internet searching).

5) Planned data extraction

Reviewers should describe whether they are going to extract process, outcome and contextual data and state how many reviewers will be involved in the extraction process. The quality assessment checklists to be used for appraising the individual studies should also be specified at this stage.

6) Proposed method of synthesis of findings

Describe the methods to be used to synthesise the data. For example, reviewers of health promotion and public health interventions often tabulate the included studies and perform a narrative synthesis due to expected heterogeneity. It is worthwhile at this stage to consider the likely reasons for heterogeneity in the systematic review.

Establish an Advisory Group

Systematic reviews are more likely to be relevant and of higher quality if they are informed by advice from people with a range of experiences, in terms of both the topic and the methodology.[2] Gaining significant input from the potential users of the review will help bring about a review that is more meaningful, generalisable and potentially more accessible.

Preferably, advisory groups should include persons with methodological and subject/topic area expertise in addition to potential review users.

- Establish an Advisory Group whose members are familiar with the topic and include policy, funders, practitioners and potential recipients/consumers perspectives. Also include methodologists to assist in methodological questions.

- The broader the review, the broader the experience required of Advisory Group members.

- To ensure international relevance consult health professionals in developing countries to identify priority topics/outcomes/interventions on which reviews should be conducted.

- The Effective Public Health Practice Project has found that six members on an Advisory Group can cover all areas and is manageable.

- Develop Terms of Reference for the Advisory Group to ensure there is clarity about the task(s) required. Tasks may include:
  - making and refining decisions about the interventions of interest, the populations to be included, priorities for outcomes and, possibly, sub-group analyses
  - providing or suggesting important background material that elucidates the issues from different perspectives
  - helping to interpret the findings of the review
  - designing a dissemination plan and assisting with dissemination to relevant groups

- Develop job descriptions and person specifications for consumers and other advisors to clarify expectations. Further information, including how to involve vulnerable and marginalised people in research, is also available at www.invo.org.uk.

An example of the benefits of using an Advisory Group in the planning process

A review of HIV prevention for men who have sex with men (MSM) (http://eppi.ioe.ac.uk/EPPIWebContent/hp/reports/MSM/MSMprotocol.pdf) employed explicit consensus methods to shape the review with the help of practitioners, commissioners and researchers.

An Advisory Group was convened of people from research/academic, policy and service organisations and representatives from charities and organisations that have emerged from and speak on behalf of people living with, or affected by, HIV/AIDS. The group met three times over the course of the review.

The group was presented with background information about the proposed review; its scope, conceptual basis, aims, research questions, stages, methods. Discussion focused on the policy relevance and political background/context to the review; the inclusion criteria for literature (interventions, outcomes, sub-groups of MSM); dissemination strategies; and timescales. Two rounds of voting identified and prioritised outcomes for analysis. Open discussion identified sub-groups of vulnerable MSM. A framework for characterising interventions of interest was refined through Advisory Group discussions.

The review followed this guidance by adopting the identified interventions, populations and outcomes to refine the inclusion criteria, performing a meta-analysis as well as sub-group analyses. The subsequent product included synthesised evidence directly related to health inequalities.

REFERENCES

1. Clarke M, Oxman AD, editors. Cochrane Reviewers' Handbook 4.2.0 [updated March 2003]. http://www.cochrane.org/resources/handbook/index.htm

2. Evidence for Policy and Practice Information and Co-ordinating Centre Review Group Manual. Version 1.1, Social Science Research Unit, Institute of Education, University of London, 2001.

ADDITIONAL READING

Silagy CA, Middleton P, Hopewell S. Publishing Protocols of Systematic Reviews: Comparing What Was Done to What Was Planned. JAMA 2002;287(21):2831-2834.

Hanley B, Bradburn J, Gorin S, et al. Involving Consumers in Research and Development in the NHS: briefing notes for researchers. Winchester: Help for Health Trust, 2000.

EXERCISE

1. Group exercise: Scenario: You wish to conduct a review on one of the following topics:
        "Interventions for preventing tobacco sales to minors"
        "Workplace interventions for smoking cessation"
        "Post-licence driver education for the prevention of road traffic crashes"
        "Primary prevention for alcohol misuse in young people"
        "Support for breastfeeding mothers"
        "Interventions aimed at improving immunisation rates"

Choose one review. Brainstorm, in small groups, who you might want to include in an Advisory Group for your chosen review. After brainstorming all potential members, try to restrict to 6-7 members. Remember to keep an international focus.

2. In your own time:

1. Search the Cochrane Library for protocols relevant to your area of interest.

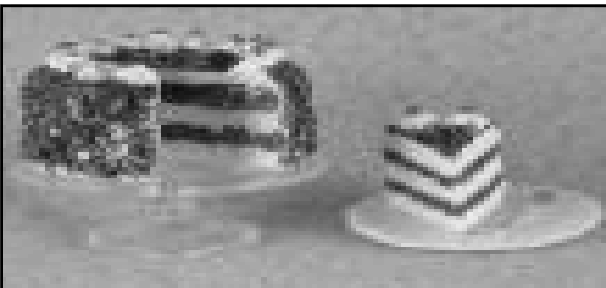2. Familiarise yourself with the essential components of a review protocol.

Setting the scope of your review

Advisory Groups

- Policy makers, funders, practitioners, recipients/consumers
  - Make or refine the review question
  - Provide background material
  - Help interpret the findings
  - Assist with dissemination
- Formal (role descriptions) or informal

LUMP

OR

SPLIT?

Lump or split?

- Users needs
  - Policy – broad reviews to answer questions when there is a range of options
  - Practitioners – more-specific interventions or approaches
- Lump – inform which interventions to implement, more time-consuming
- Split – Yes/No to implement, less time

Lumping or splitting

- Interventions to modify drug-related behaviours for preventing HIV infection in drug users
- Interventions to modify sexual risk behaviours for preventing HIV infection
- Interventions to modify sexual risk behaviours for preventing HIV infection in men who have sex with men.
- Interventions for preventing HIV infection in street youth
- Interventions for preventing HIV infection in young people in developing countries
- Counselling and testing for preventing HIV infection

Writing your protocol

1) Background
  - Why is it important?
  - How important is the problem?
  - Is there uncertainty?
  - What is the reasoning as to why the intervention(s) might work? (include theoretical frameworks)
  - Other similar reviews?

Writing your protocol

2) Objectives
- What are the questions/hypotheses?

3) Selection criteria
- PICO(T)
  - Population(s)
  - Intervention(s)
  - Comparison(s)
  - Outcomes (Primary / Secondary)
  - Types of studies

Writing your protocol

4) Planned search strategy
- Databases and terms

5) Planned data extraction
- Processes and outcomes?
- More than one reviewer?
- Planned quality appraisal (incl. checklists)

6) Method of synthesis
- Tabulate
- Narrative/qualitative synthesis or meta-analysis