Unit Five: Asking an Answerable Question

Learning Objectives

- *To understand the importance of formulating an answerable question*
- *To be able to formulate an answerable question*

Reviewers should seek to answer two questions within their review:

1. Does the intervention work (not work)?
2. How does the intervention work?

Importance of getting the question right

A clearly framed question will guide:

- the reader
  - in their initial assessment of relevance
- the reviewer on how to
  - collect studies
  - check whether studies are eligible
  - conduct the analysis.

Therefore, it is important that the question is formulated before beginning the review. *Post-hoc* questions are also more susceptible to bias than those questions determined *a priori*. Although changes to the review question may be required, the reasons for making the changes should be clearly documented in the completed review.

Components of an answerable question (PICO)

The formula to creating an answerable question is following PICO; Population, Intervention, Comparison, Outcome. It is also worthwhile at this stage to determine the types of study designs to include in the review; PICOT.

Qualitative research can contribute to framing the review question (eg. selecting interventions and outcomes of interest to participants). The Advisory Group can also provide valuable assistance with this task.

Population(s)

In health promotion and public health this may include populations, communities or individuals. Consider whether there is value in limiting the population (eg. street youth, problem drinkers). These groups are often under-studied and may be different in all sorts of important respects from study populations usually included in health promotion and public health reviews.

Reviews may also be limited to the effects of the interventions on disadvantaged populations in order to investigate the effect of the interventions on reducing inequalities. Further information on reviews addressing inequalities is provided below.

Intervention(s)
As described earlier, reviewers may choose to lump similar interventions in a review, or split the review by addressing a specific intervention. Reviewers may also consider 'approaches' to health promotion rather than topic-driven interventions, for example, peer-led strategies for changing behaviour. In addition, reviewers may want to limit the review by focusing on the effectiveness of a particular type of theory-based intervention (eg. Transtheoretical model) for achieving certain health outcomes (eg. smoking cessation).

Comparison(s)
It is important to specify the comparison intervention for the review. Comparison interventions may be no intervention, another intervention or standard care/practice. The choice of comparison or control has large implications for the interpretation of results. A question addressing one intervention versus no intervention is a different question than one comparing one intervention versus standard care/practice.

Example: DiCenso A, Guyatt G, Willan A, Griffith L. Interventions to reduce unintended pregnancies among adolescents: systematic review of randomised controlled trials. BMJ 2002;324:1426-34.
The majority of the studies included in this review address primary prevention of unintended pregnancy versus standard care/practice. Therefore, this review is not addressing whether primary prevention is effective, it is simply investigating the effect of specific interventions compared to standard practice. This is a much smaller gap to investigate an effect, as it is usually easier to find a difference when comparing one intervention versus no intervention.

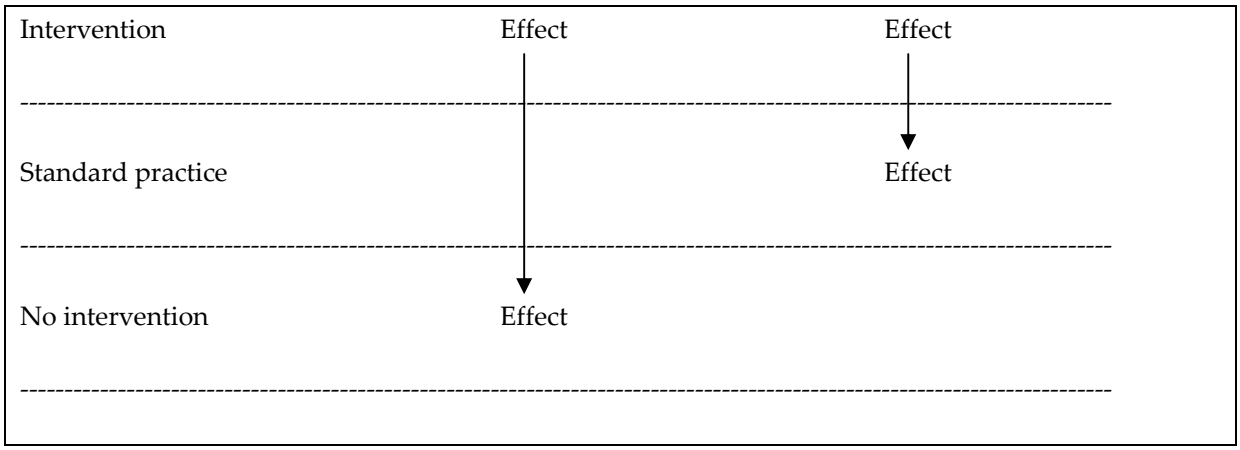

Figure Two. The difference between comparing the effect of one intervention versus no intervention and one intervention versus standard practice.

For example, many of the school-based interventions in the review are compared to normal sexual education in the schools, and are shown to be ineffective for reducing unintended pregnancies. Yet the interpretation of the results read "primary prevention strategies do not delay the initiation of sexual intercourse or improve the use of birth control among young men and women". This reads that the review question has sought to address primary prevention versus no intervention. Rather, the review addressed whether theory-led interventions are more effective than standard care/practice.

Outcome(s)
The outcome(s) chosen for the review must be meaningful to the users of the review. The discrepancy between the outcomes and interventions that reviewers choose to include in the review and the outcomes and interventions that lay people prefer to be included has been well-described.[1]

To investigate both the implementation of the intervention and its effects reviewers will need to include both process indicators as well as outcome measures. Unanticipated (side-effects) as well as anticipated effects should be investigated in addition to cost-effectiveness, where appropriate.

Reviewers will also need to decide if proximal/immediate, intermediate or distal outcomes are to be assessed. If only intermediate outcomes are measured (eg. blood sugar levels in persons with diabetes, change in knowledge and attitudes) reviewers need to determine how strong the linkage is to more distal outcomes (eg. cardiovascular disease, behaviour change). The use of theory can assist with determining this relationship. In addition, reviewers should decide if only objective measures are to be included (eg. one objective measure of smoking status is saliva thiocyanate or alveolar carbon monoxide) or subjective measures (eg. self-reported smoking status), or a combination of both (discussing the implications of this decision).

Examples of review questions

Poorly designed questions:

1. Are condoms effective in preventing HIV?
2. Which interventions reduce health inequalities among people with HIV?

Answerable questions:

1. In men who have sex with men, does condom use reduce the risk of HIV transmission?
2. In women with HIV, do peer-based interventions reduce health inequalities?

Are mass media interventions effective in preventing smoking in young people?

Problem, population	Intervention	Comparison	Outcome	Types of studies
Young people, under 25 years of age	1. Television 2. Radio 3. Newspapers 4. Billboards 5. Posters 6. Leaflets 7. Booklets	No intervention	1. objective measures of smoking 2. self-reported smoking behaviour 3. Intermediate measures (intentions, attitudes, knowledge) 4. Process measures (eg. media reach)	1. RCT (and quasi-RCT) 2. Controlled before and after studies 3. Time series designs

Types of study designs to include

The decisions about which type(s) of study design to include will influence subsequent phases of the review, particularly the search strategies, choice of quality assessment criteria, and the analysis stage (especially if a statistical meta-analysis is to be performed).

The decision regarding which study designs to include in the review should be dictated by the intervention (the review question) or methodological appropriateness, and not vice versa.[2,3] If the review question has been clearly formulated then knowledge of the types of study designs needed to

answer it should automatically follow.[3] If different types of study designs are to included in the same review the reasons for this should be made explicit.

Effectiveness studies
Where RCTs are lacking, or for issues relating to feasibility and ethics are not conducted, other study designs such as non-randomised controlled trials, before and after studies, and interrupted time series designs should also be considered for inclusion in the review.

Comparisons with historical controls or national trends may be included when this is the **only** type of evidence that is available, for example, in reviews investigating the effectiveness of policies, and should be accompanied by an acknowledgement that the evidence of evidence is necessarily weaker.

Randomised controlled trial

Subjects are randomly allocated to groups either for the intervention being studied or the control (using a random mechanism, such as coin toss, random number table, or computer-generated random numbers) and the outcomes are compared.[1]
Each participant or group has the same chance of receiving each intervention and the investigators cannot predict which intervention is next.

Quasi-randomised controlled trial / pseudo-randomised controlled trial

Subjects are allocated to groups for intervention or control using a non-random method (such as alternate allocation, allocation of days of the week, or odd-even study numbers) and the outcomes are compared.[1]

Controlled before and after study / cohort analytic

Outcomes are compared for a group receiving the intervention being studied, concurrently with control subjects receiving the comparison intervention (eg, usual or no care/intervention).[1]

Uncontrolled before and after study / cohort study

The same group is pre-tested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pre-test, act as their own control group.[2]

Interrupted time series

A time series consists of multiple observations over time. Observations can be on the same units (eg. individuals over time) or on different but similar units (eg. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.[2] These designs are commonly used to evaluate mass media campaigns.

Qualitative research

Qualitative research explores the subjective world. It attempts to understand why people behave the way they do and what meaning experiences have for people. Qualitative research relevant to effectiveness reviews may include the following:

Qualitative studies of experience: these studies may use a range of methods, but frequently rely on in-depth tape-recorded interviews and non-participant observational studies to explore the experience of people receiving an intervention.

Process evaluations: these studies can be included within the context of the effectiveness studies. These evaluations use a mixture of methods to identify and describe the factors that promote and/or impede the implementation of innovation in services.[3]

References:

1. NHMRC (2000). How to review the evidence: systematic identification and review of the scientific literature. Canberra: NHMRC.
2. Thomas H. Quality assessment tool for quantitative studies. Effective Public Health Practice Project. McMaster University, Toronto, Canada.
3. Undertaking Systematic Reviews of Research on Effectiveness. CRD's Guidance for those Carrying Out or Commissioning Reviews. CRD Report Number 4 (2nd Edition). NHS Centre for Reviews and Dissemination, University of York. March 2001. http://www.york.ac.uk/inst/crd/report4.htm

Cluster-RCTs and cluster non-randomised studies

Allocation of the intervention by group or cluster is being increasingly adopted within the field of public health because of administrative efficiency, lessened risk of experimental contamination and likely enhancement of subject compliance.[4] Some studies, for example a class-based nutrition intervention, dictate its application at the cluster level.

Interventions allocated at the cluster (eg. school, class, worksite, community, geographical area) level have particular problems with selection bias where groups are formed not at random but rather through some physical, social, geographic, or other connection among their members.[5,6] Cluster trials also require a larger sample size than would be required in similar, individually allocated trials because the correlation between cluster members reduces the overall power of the study.[5] Other methodological problems with cluster-based studies include the level of intervention differing from the level of evaluation (analysis) and the often small number of clusters in the study.[7] Issues surrounding cluster trials have been well described in a Health Technology Assessment report[7], which should be read for further information if cluster designs are to be included in a systematic review.

The role of qualitative research within effectiveness reviews

- to "provide an in-depth understanding of people's experiences, perspectives and histories in the context of their personal circumstances and settings"[8]

Qualitative studies can contribute to reviews of effectiveness in a number of ways including[9]:

- Helping to frame the review question (eg. selecting interventions and outcomes of interest to participants).
- Identifying factors that enable/impede the implementation of the intervention (eg. human factors, contextual factors)
- Describing the experience of the participants receiving the intervention
- Providing participants' subjective evaluations of outcomes
- Helping to understand the diversity of effects across studies, settings and groups
- Providing a means of exploring the 'fit' between subjective needs and evaluated interventions to inform the development of new interventions or refinement of existing ones.

Methods commonly used in qualitative studies may include one or a number of the following; interviews (structured around respondents priorities/interests), focus groups, participant and/or non participant observation, conversation (discourse and narrative analysis), and documentary and video analysis. The unit of analysis within qualitative studies is not necessarily individuals or single cases; communities, populations or organisations may also be investigated. Anthropological research,

which may involve some or all of these methods in the context of wide ranging 'fieldwork' can also be a valuable source of evidence, although may be difficult to subject to many aspects of the systematic review process.

Health inequalities

Health inequalities are defined as "the gap in health status, and in access to health services, between different social classes and ethnic groups and between populations in different geographical areas."[10]

There is a need for systematic reviews to consider health inequalities in the assessment of effectiveness of interventions. This is because it is thought that many interventions may not be equally effective for all population subgroups. The effectiveness for the disadvantaged may be substantially lower.

Evans and Brown (2003)[11] suggest that there are a number of factors that may be used in classifying health inequalities (captured by the acronym PROGRESS):

- **P**lace of residence
- **R**ace/ethnicity
- **O**ccupation
- **G**ender
- **R**eligion
- **E**ducation
- **S**ocio-economic status
- **S**ocial capital

Therefore, it may be useful for a review of public health interventions to measure the effect across different subgroups (as defined by any of the PROGRESS factors).

Example of a review addressing inequalities: Kristjansson E, Robinson VA, MacDonald B, Krasevec J, Greenhalgh T, McGowan J, Francis D, Tugwell P, Petticrew M, Shea B, Wells G. School feeding for improving the physical and psychosocial health of disadvantaged elementary school children (Protocol for a Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd. Disadvantage in this review is defined by income (SES status).

Data required for reviews addressing inequalities:

- A valid measure of health status (or change in health status)
- A measure of disadvantage (i.e., define socio-economic position)
- A statistical measure for summarising the differential effectiveness.

The above review chose to define interventions effective in reducing inequalities as interventions which were more effective for people in lower SES. A potentially effective intervention was one which was:

  - equally effective across the socioeconomic spectrum (potentially reducing health inequalities due to the higher prevalence of health problems among the disadvantaged).
  - targeted only at disadvantaged groups and was effective.

REFERENCES

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2. Nutbeam D, Harris E. (2004). Theory in a Nutshell. A practical guide to health promotion theories. Sydney, Australia: McGraw-Hill Australia Pty Ltd, vii-9.

3. Petticrew M, Roberts H. (2003). Evidence, hierarchies, and typologies: horses for courses. J Epidemiol Community Health, 57, 527-9.

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5. Torgerson DJ. Contamination in trials: is cluster randomisation the answer? BMJ. 2001 Feb 10;322(7282):355-7.

6. Murray DM, Varnell SP, Blitstein JL. Design and analysis of group-randomized trials: a review of recent methodological developments. Am J Public Health. 2004 Mar;94(3):423-32.

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8. Spencer L, Ritchie J, Lewis J, Dillon L. Quality in Qualitative Evaluation: A framework for assessing research evidence. Government Chief Social Researcher's Office. Crown Copyright, 2003.

9. Centre for Reviews and Dissemination (Undertaking Systematic Reviews of Research on Effectiveness. CRD's Guidance for those Carrying Out or Commissioning Reviews. CRD Report Number 4 (2nd Edition) March 2001), at http://www.york.ac.uk/inst/crd/report4.htm

10. Public Health Electronic Library. http://www.phel.gov.uk/glossary/glossaryAZ.asp?getletter=H. Accessed June 29, 2004

11. Evans T, Brown H. Road traffic crashes: operationalizing equity in the context of health sector reform. Injury Control and Safety Promotion 2003;10(2):11-12.

ADDITIONAL READING

Richardson WS, Wilson MC, Nishikawa J, Hayward RSA. The well-built clinical question: a key to evidence-based decisions [Editorial]. ACP J Club 1995;123(3):A12-3.

Richardson WS. Ask, and ye shall retrieve [EBM Note]. Evidence Based Medicine 1998;3:100-1.

EXERCISE

1. Write an answerable review question (will be used in a later exercise)

P = ……

I = ……..……..…..

C = ……

O = ……

Q……...
……

The effectiveness of (I) versus (C) for (0) in (P)

2. What type(s) of study design(s) should be included to investigate the effectiveness of the intervention?

❒ Randomised controlled trial / cluster randomised controlled trial

❒ Quasi-randomised controlled trial/pseudo-randomised trial

❒ Controlled before and after study/cohort analytic/concurrently controlled comparative study

❒ Uncontrolled before and after study/cohort study

❒ Interrupted time series designs

❒ Qualitative research

Asking an answerable question

Importance

A clearly framed question will guide:

- the reader
  - in their initial assessment of relevance
- the reviewer
  - on how to collect studies
  - on how to check whether studies are eligible
  - on how to conduct the analysis

Questions of interest

Effectiveness:

- Does the intervention work/not work?
- Who does it work/not work for?

Other important questions:

- How does the intervention work?
- Is the intervention appropriate?
- Is the intervention feasible?
- Is the intervention and comparison relevant?

Answerable questions

EFFECTIVENESS

A description of the populations **P**

An identified intervention **I**

An explicit comparison **C**

Relevant outcomes **O**

A PICO question

Time-consuming question:

What is the best strategy to prevent smoking in young people?

An answerable question

Q. Are mass media *(or school-based or community-based)* interventions effective in preventing smoking in young people?

Choose to look at mass media interventions .....

The PICO(T) chart

Problem, population	Intervention	Comparison	Outcome	Types of studies
Young people under 25 years of age	a) Television b) Radio c) Newspapers d) Bill boards e) Posters f) Leaflets g) Booklets	a) School-based interventions b) No intervention	a) objective measures of smoking (saliva thiocyanate levels, alveolar CO) b) self-reported smoking behaviour c) Intermediate measures (intentions, attitude, knowledge, skills) d) Media reach	a) RCT b) Controlled before and after studies c) Time series designs

Types of study designs

- Randomised controlled trial
- Quasi-randomised/pseudo-randomised controlled trial/controlled clinical trial
- Controlled before and after study/cohort analytic (pre and post-test)/concurrently controlled comparative study
- Uncontrolled before and after study/cohort study
- Interrupted time series
- Qualitative research

See handbook

Inequalities as an outcome

Health inequalities

- "the gap in health status, and in access to health services, between different social classes and ethnic groups and between populations in different geographical areas."[1]
- Other factors used in classifying health inequalities[2]
  - **P**lace of residence
  - **R**ace/ethnicity
  - **O**ccupation
  - **G**ender
  - **R**eligion
  - **E**ducation
  - **S**ocio-economic status
  - **S**ocial capital

PROGRESS

1 Public Health Electronic Library. http://www.phel.gov.uk/glossary/glossaryAZ.asp?getletter=H.
2 Evans T, Brown H. Injury Control and Safety Promotion 2003;10(2):11-12.

Inequalities reviews

- First Cochrane review

  Effectiveness of school feeding programs for improving the physical, psychological, and social health of disadvantaged children and for reducing socio-economic inequalities in health
- Defining effectiveness:
  - More effective for disadvantaged than advantaged
  - Potentially effective:
    - Equally effective for both groups (prevalence of health problems greater in disadvantaged groups)
    - If intervention is only allocated to disadvantaged and is effective

Incorporating inequalities into a review

- Reviews rarely present information on differential effects of interventions
- Systematic review methods for distilling and using information on relative effectiveness are underdeveloped.
  - Difficult to locate studies – need broad search
  - Need original data from authors
  - Low power to detect subgroup differences
  - Complexity and variety of study designs