Definizione del quesito clinico e degli outcome di interesse

Defining the review question

A clearly defined, focused review begins with a well framed question.

The review question should specify:

- types of population (participants),
- types of interventions (and comparisons),
- types of outcomes that are of interest.

These components of the question, with the additional specification of types of study that will be included, form the basis of the pre-specified eligibility criteria for the review.

Screening for prostate cancer (Review)
Ilic D, Neuberger MM, Djulbegovic M, Dahm P
Cochrane Database of Systematic Reviews 2013, Issue 1.

OBJECTIVES

The primary objective of this review was to determine the efficacy of screening men for prostate cancer in reducing prostate cancer-specific and all-cause mortality.

The secondary objectives of this review were to:

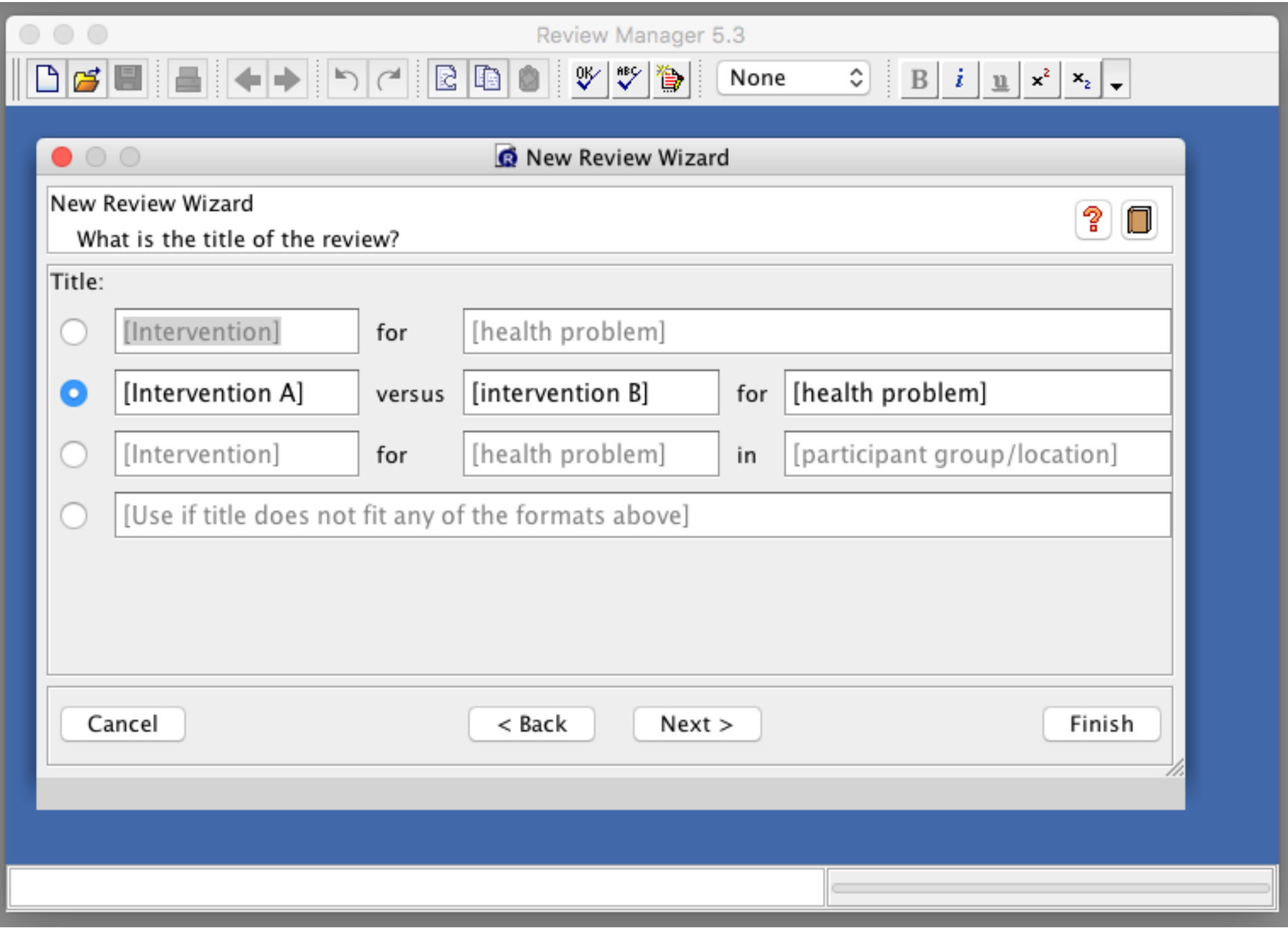
- determine the impact of prostate cancer screening on quality of life and adverse effects; and
- document the costs of screening for prostate cancer.

Defining the review question

A statement of the review's objectives should begin with a precise statement of the primary objective, ideally in a single sentence.

Where possible the style should be of the form:

'To assess the effects of [*intervention or comparison*] for [*health problem*] in [*types of people, disease or problem and setting if specified*]'.


Review Manager 5.3
None
New Review Wizard
New Review Wizard
What is the title of the review?
Title:
[Intervention]
for
[health problem]
[Intervention A]
versus
[intervention B]
for
[health problem]
[Intervention]
for
[health problem]
in
[participant group/location]
[Use if title does not fit any of the formats above]
Cancel
< Back
Next >
Finish

Defining the review question

A statement of the review's objectives should begin with a precise statement of the primary objective, ideally in a single sentence.

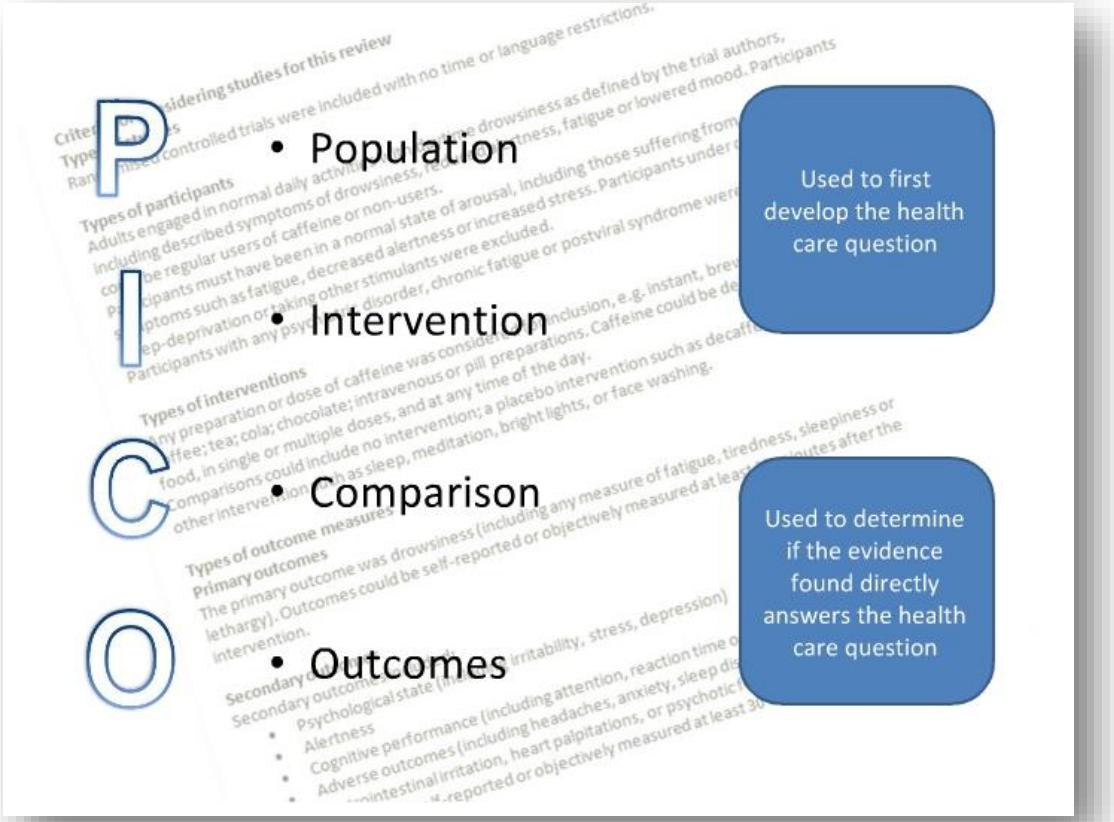
Where possible the style should be of the form:

'To assess the effects of [*intervention or comparison*] for [*health problem*] in [*types of people, disease or problem and setting if specified*]'.

This might be followed by one or more secondary objectives, for example relating to different participant groups, different comparisons of interventions or different outcome measures.

The ‘clinical question’ should specify the types of population (participants), types of interventions (and comparisons), and the types of outcomes that are of interest.

The acronym PICO (**P**articipants, **I**nterventions, **C**omparisons and **O**utcomes) helps to serve as a reminder of these.

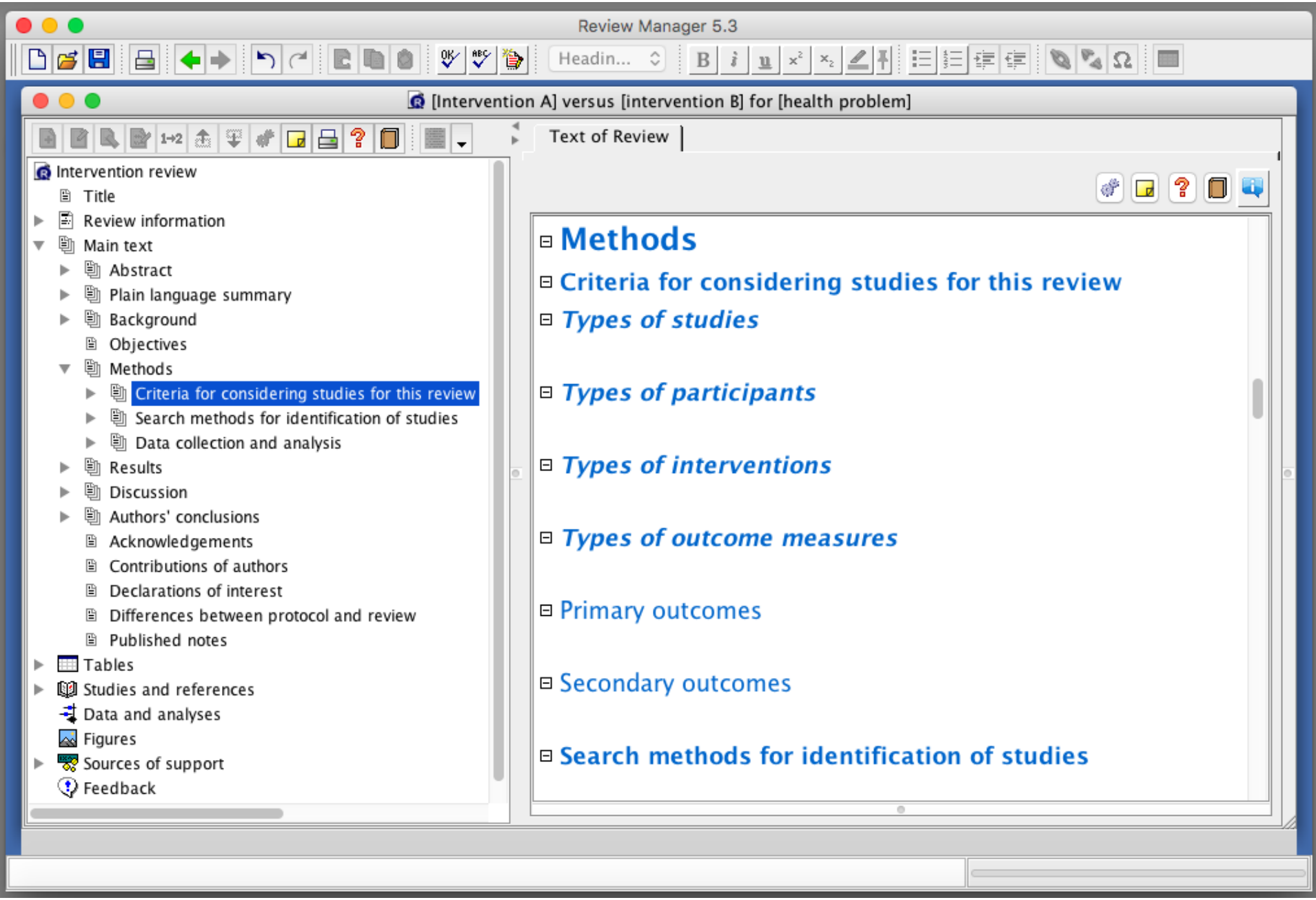


Eligibility Criteria

Eligibility criteria are a combination of aspects of the clinical question plus specification of the types of studies that have addressed these questions.

The **P**articipants, **I**nterventions and **C**omparisons in the clinical question usually translate directly into eligibility criteria for the review.

Outcomes usually are not part of the criteria for including studies, however, some reviews do legitimately restrict eligibility to specific outcomes.


Review Manager 5.3
[Intervention A] versus [intervention B] for [health problem]
Text of Review
Intervention review
Title
Review information
Main text
Abstract
Plain language summary
Background
Objectives
Methods
Criteria for considering studies for this review
Search methods for identification of studies
Data collection and analysis
Results
Discussion
Authors' conclusions
Acknowledgements
Contributions of authors
Declarations of interest
Differences between protocol and review
Published notes
Tables
Studies and references
Data and analyses
Figures
Sources of support
Feedback
Methods
Criteria for considering studies for this review
Types of studies
Types of participants
Types of interventions
Types of outcome measures
Primary outcomes
Secondary outcomes
Search methods for identification of studies

Which Populations?

The criteria for considering types of people included in studies in a review should be sufficiently broad to encompass the likely diversity of studies, but sufficiently narrow to ensure that a meaningful answer can be obtained when studies are considered in aggregate.

Which Populations?

The criteria for considering types of people included in studies in a review should be sufficiently broad to encompass the likely diversity of studies, but sufficiently narrow to ensure that a meaningful answer can be obtained when studies are considered in aggregate.

It is often helpful to define the types of people that are of interest in two steps:

- ✓ diseases or conditions of interest using explicit criteria for establishing their presence or not;
- ✓ the broad population and setting of interest

Factors to consider when developing criteria for 'Types of participants'

- ✓ How is the disease/condition defined?
- ✓ What are the most important characteristics that describe these people (participants)?
- ✓ Are there any relevant demographic factors (e.g. age, sex, ethnicity)?
- ✓ What is the setting (e.g. hospital, community etc)?
- ✓ Are there other types of people who should be excluded from the review (because they are likely to react to the intervention in a different way)?
- ✓ How will studies involving only a subset of relevant participants be handled?

Screening for prostate cancer (Review)
Ilic D, Neuberger MM, Djulbegovic M, Dahm P
Cochrane Database of Systematic Reviews 2013, Issue 1.

Types of participants

All men enrolled in studies of prostate cancer screening were eligible for this review, with no exclusions based on ethnicity, age, or presence of lower urinary tract symptoms. Studies including men with a previous diagnosis and treatment of prostate cancer were excluded.

Which comparisons to make?

The second key component of a well-formulated question is to specify the interventions of interest and the interventions against which these will be compared (comparisons).

- ✓ *Consider exactly what is delivered, at what intensity, how often it is delivered, who delivers it, etc.*
- ✓ *Are the interventions to be compared with an inactive control intervention (e.g. placebo, no treatment), or with an active control intervention (e.g. a different variant of the same intervention, a different drug, a different kind of therapy)?*

Factors to consider when developing criteria for 'Types of Interventions'

- ✓ Does the intervention have variations (e.g. dose/intensity, mode /frequency / duration / timing of delivery)?
- ✓ Are all variations to be included?
  (is there a critical dose below which the interv-ention may not be clinically appropriate?)
- ✓ How will trials including only part of the interv-ention be handled?
- ✓ How will trials including the intervention of interest combined with another intervention (co-intervention) be handled?

Screening for prostate cancer (Review)

Ilic D, Neuberger MM, Djulbegovic M, Dahm P

Cochrane Database of Systematic Reviews 2013, Issue 1.

Types of interventions

Studies that used any of the following screening procedures, individually or in combination, were included:

- digital rectal examination (DRE);
- prostate-specific antigen (PSA) test (including total, velocity, density, and percentage free and complex); and
- transrectal ultrasound (TRUS)-guided biopsy.

Which outcome measures are most important?

The third key component of a well-formulated question is the delineation of particular outcomes that are of interest.

Outcomes

Should be
importance driven
NOT
evidence driven

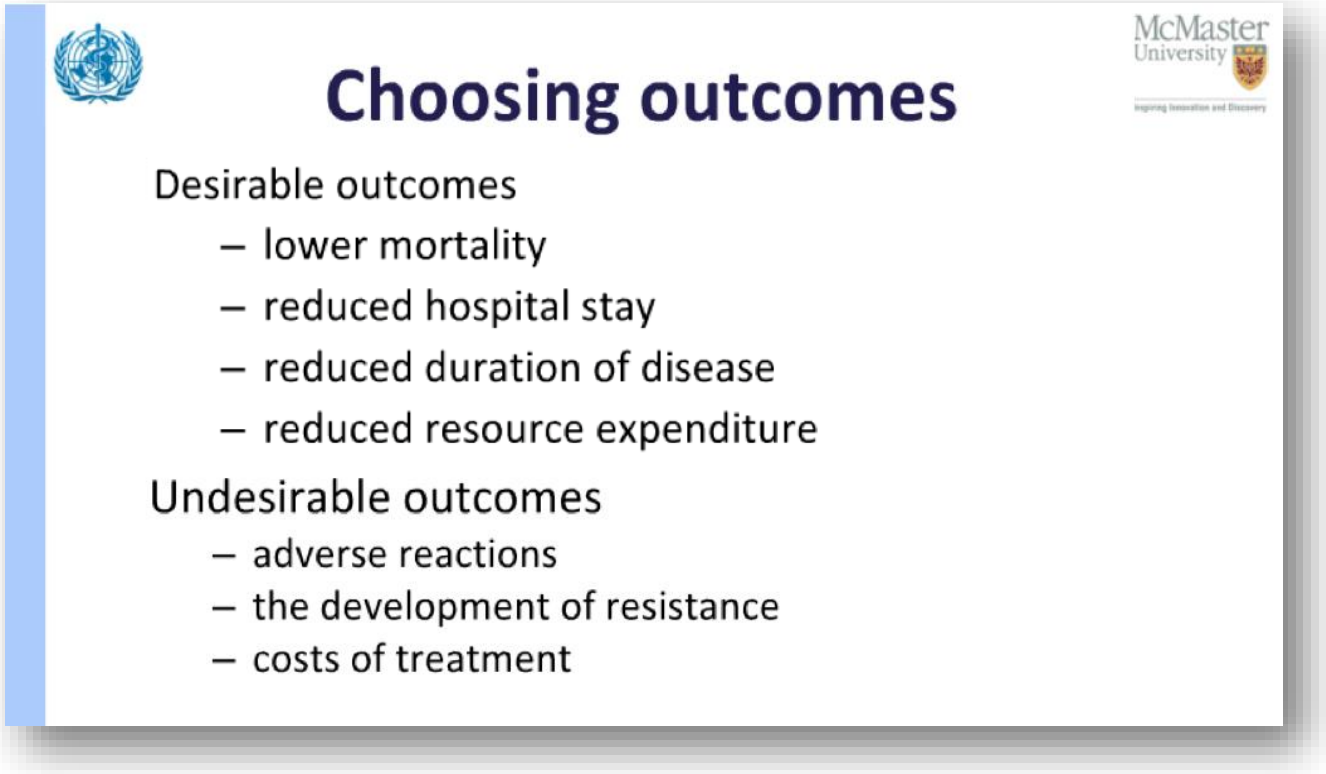
Which outcome measures are most important?

The third key component of a well-formulated question is the delineation of particular outcomes that are of interest.

- ✓ *Outcomes considered to be meaningful, and therefore addressed in a review, will not necessarily have been reported in individual studies.*
- ✓ *Including all important outcomes in a review will highlight gaps in the primary research and encourage researchers to address these gaps in future studies.*

Which outcome measures are most important?

It is critical that outcomes used to assess adverse effects as well as outcomes used to assess beneficial effects are among those addressed by a review



Screening for prostate cancer (Review)

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Cochrane Database of Systematic Reviews 2013, Issue 1.

Primary outcomes

Primary outcome measures for this review were prostate cancer-specific and all-cause mortality.

Secondary outcomes

Secondary outcome measures included:

- incident prostate cancers by stage and grade at diagnosis;
- metastatic disease at follow-up;
- quality of life;
- harms of screening (including both adverse outcomes from false-positive or false-negative results and their impact upon resulting treatment procedures); and
- costs associated with screening programs.

Factors to consider when developing criteria for 'Types of Outcomes'

- ✓ Main outcomes are those that are essential for decision-making.
- ✓ Primary outcomes are the two or three outcomes from among the main outcomes that the review would be likely to be able to address, in order to reach a conclusion about the effects (beneficial and adverse) of the intervention(s).
- ✓ Secondary outcomes include the remaining main outcomes plus additional outcomes useful for explaining effects.
- ✓ Consider outcomes relevant to all potential decision makers, including economic data.

Defining the scope of a review question (broad versus narrow)

The questions addressed by a review may be broad or narrow in scope.

- ✓ *A review might address a broad question regarding whether antiplatelet agents in general are effective in preventing all thrombotic events in humans .*
- ✓ *A review might address whether a particular antiplatelet agent, such as aspirin, is effective in decreasing the risks of a particular thrombotic event, stroke, in elderly persons with a previous history of stroke .*

Some advantages and disadvantages of Broad versus Narrow review questions

	Broad scope	**Narrow scope**
Choice of participants e.g. corticosteroid injection for shoulder tendonitis (narrow) or corticosteroid injection for any tendonitis	*Advantages*: Comprehensive summary of the evidence. Ability to assess generalizability of findings across types of participants.	*Advantages*: Manageability for review team. Ease of reading.
	Disadvantages: May be more appropriate to prepare an Overview of reviews (see Chapter 22). Searching, data collection, analysis and writing may require more resources. Risk of 'mixing apples and oranges' (heterogeneity); interpretation may be difficult.	*Disadvantages*: Evidence may be sparse. Findings may not be generalizable to other settings or populations. Scope could be chosen by review authors to produce a desired result.

Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0

Some advantages and disadvantages of Broad versus Narrow review questions

	Broad scope	**Narrow scope**
Definition of an intervention e.g. supervised running for depression (narrow) or any exercise for depression (broad)	*Advantages*: Comprehensive summary of the evidence. Ability to assess generalizability of findings across different implementations of the intervention. *Disadvantages*: Searching, data collection, analysis and writing may require more resources. Risk of 'mixing apples and oranges' (heterogeneity); interpretation may be difficult.	*Advantages*: Manageability for review team. Ease of reading. *Disadvantages*: Evidence may be sparse. Findings may not be generalizable to other formulations of the intervention. Scope could be chosen by review authors to produce a desired result.

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Some advantages and disadvantages of Broad versus Narrow review questions

	Broad scope	Narrow scope
Choice of interventions and comparisons e.g. alarms for preventing bed-wetting (narrow) or interventions for preventing bed-wetting (broad)	*Advantages*: Comprehensive summary of the evidence. *Disadvantages*: May be unwieldy, and more appropriate to present as an Overview of reviews (see Chapter 22). Searching, data collection, analysis and writing may require more resources.	*Advantages*: Manageability for review team. Clarity of objectives and ease of reading. *Disadvantages*: May have limited value when not included in an Overview.

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