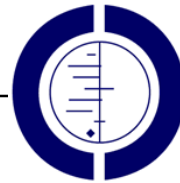


# HOW TO INCLUDE ECONOMICS IN COCHRANE REVIEW PROTOCOLS



## Part One: Background, objectives, outcome measures and types of studies

COI statement

*I have no actual or potential conflict of interest in relation to this presentation*

Campbell & Cochrane Economics Methods Group

<http://methods.cochrane.org/economics/>



# Learning objectives

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- Incorporate economic perspectives into 'Background'
- Formulate an 'Objective' for a critical review of health economic studies
- Identify measures of resource use, costs and cost-effectiveness to be included in 'Types of outcome measures'
- Identify types of health economic studies to be included in 'Types of studies'

# Preliminary points

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- Advisory support from a health economist useful
  - Check with CRG - health economist advisor?
  - Contact Economics Methods Group  
[janice.legge@newcastle.ac.uk](mailto:janice.legge@newcastle.ac.uk)
- Focus on how to prepare protocol for a critical review of health economics studies

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- Additional material

# Chapter 15: Incorporating economics evidence

Authors: Ian Shemilt, Miranda Mugford, Sarah Byford, Michael Drummond, Eric Eisenstein, Martin Knapp, Jacqueline Mallender, David McDaid, Luke Vale and Damian Walker on behalf of the Campbell and Cochrane Economics Methods Group.

## Key points

- Economics is the study of the optimal allocation of limited resources for the production of benefit to society and is therefore relevant to any healthcare decision.
- Optimal decisions also require best evidence of effectiveness.
- This chapter describes methods for incorporating economics perspectives and evidence into Cochrane reviews, with a focus on critical review of health economics studies.
- Incorporating economics perspectives and evidence into Cochrane reviews can enhance their usefulness and applicability for healthcare decision-making and new economic analyses.

- [15.1 The role and relevance of economics evidence in Cochrane reviews](#)
- [15.2 Planning the economics component of a Cochrane review](#)
- [15.3 Locating studies](#)
- [15.4 Selecting studies and collecting data](#)
- [15.5 Addressing risk of bias](#)
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## Background

[fixed, level 1 heading]

Well-formulated review questions occur in the context of an already-formed body of knowledge. The background should address this context, help set the rationale for the review, and explain why the questions being asked are important. It should be concise (generally around one page when printed) and be understandable to the users of the intervention under investigation. All sources of information should be cited.

### Description of the condition

[recommended, level 2 heading]

The review should begin with a brief description of the condition being addressed and its significance. It may include information about the biology, diagnosis, prognosis and public health importance (including prevalence or incidence).

### Description of the intervention

[recommended, level 2 heading]

A description of the experimental intervention(s) should place it in the context of any standard, or alternative interventions. The role of the comparator intervention(s) in standard practice should be made clear. For drugs, basic information on clinical pharmacology should be presented where available. This information might include dose range, metabolism, selective effects, half-life, duration and any known interactions with other drugs. For more complex interventions, a description of the main components should be provided.

### How the intervention might work

[recommended, level 2 heading]

This section might describe the theoretical reasoning why the interventions under review may have an impact on potential recipients, for example, by relating a drug intervention to the biology of the condition. Authors may refer to a body of empirical evidence such as similar interventions having an impact or identical interventions having an impact on other populations. Authors may also refer to a body of literature that justifies the possibility of effectiveness.

## Background: Describe economic burden of condition

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*Faecal incontinence...can be a debilitating problem with medical, social and economic implications... In the United States more than \$400 million is spent each year on a range of both urinary and faecal incontinence products... During 1991 the direct costs of pads, appliances and other prescription items throughout hospitals and long term care settings in the UK for incontinence in general was estimated at £68 million... With the rise in numbers of elderly people in the world, this condition will be an increasing challenge to both healthcare services and home carers.*

# Background: Describe potential impacts of intervention(s) on resource use (costs)

---

- 'Resource inputs' ('input costs')
  - e.g. staff time and skills, equipment, devices, drugs, hospital care, patient out-of-pocket expenses...
- 'Resource consequences' ('downstream costs')
  - e.g. health care and other resources used to manage sequelae and complications of treatment, time off work...

# Background: Highlight issue of cost-effectiveness

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*It is important to consider whether use of Bone Morphogenetic Protein is worthwhile...given the incremental costs (resource use) and benefits (effects) which may be associated with the intervention.*



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## Objectives

[fixed, level 1 heading]

This should begin with a precise statement of the primary objective of the review, 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]* for/in *[types of people, disease or problem and setting if specified]*". This might be followed by a series of specific objectives relating to different participant groups, different comparisons of interventions or different outcome measures. It is not necessary to state specific hypotheses.



# Objectives: Clinical effects

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*To assess the [clinical] effectiveness of Bone Morphogenetic Protein for fracture healing in skeletally mature adults, compared to current standard treatments*

# Objectives: Economics

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To critically appraise and summarise current evidence on the [*resource use/ costs/ and cost-effectiveness*] associated with [*intervention or comparison*] for [*health problem*] for/in [*types of people, disease or problem and setting if specified*]

# Objectives: Economics

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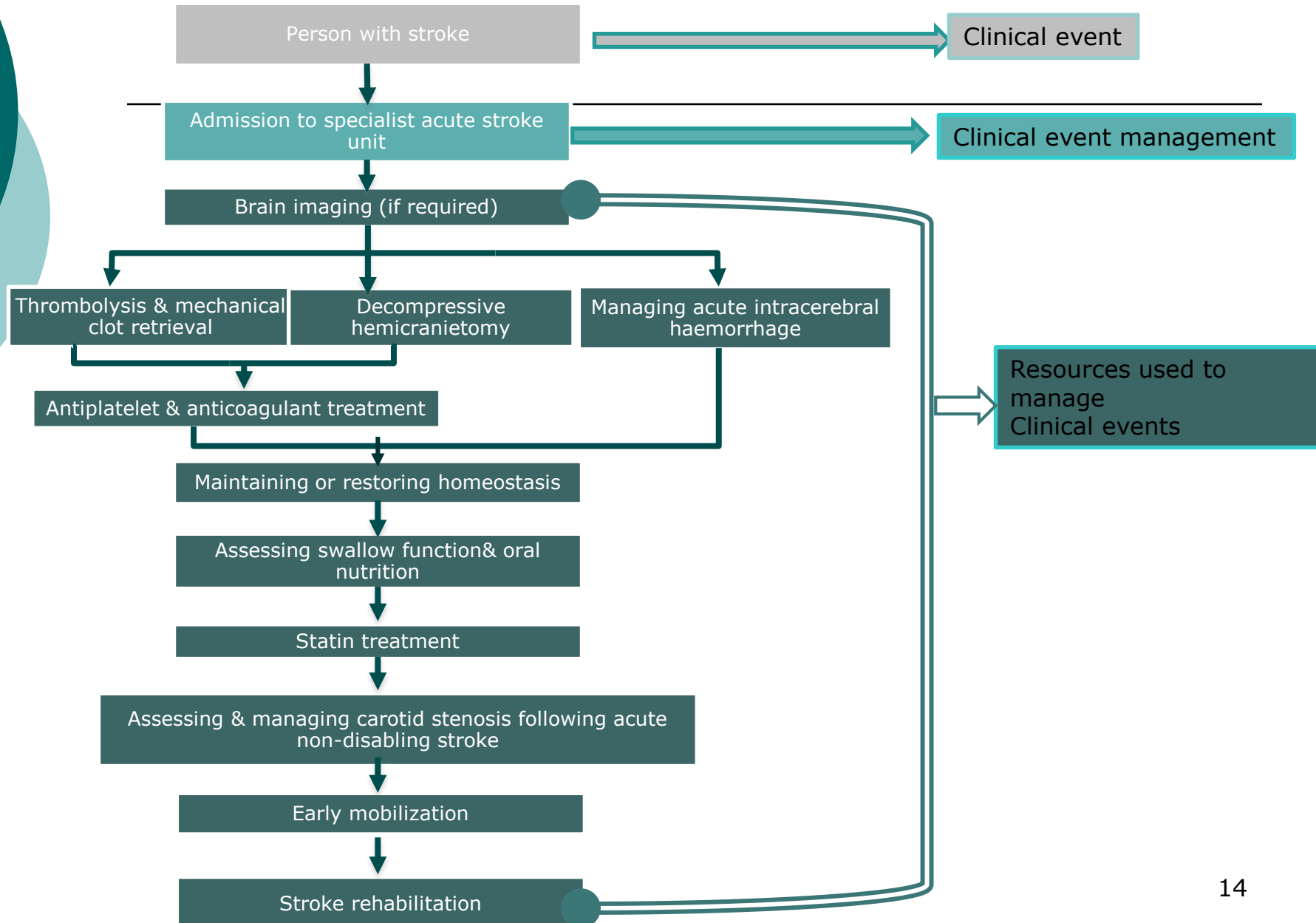
*To critically appraise and summarise current evidence on the (incremental) resource use, costs and cost-effectiveness of Bone Morphogenetic Protein for fracture healing in skeletally mature adults, compared to current standard treatments*

# Objectives: Economics

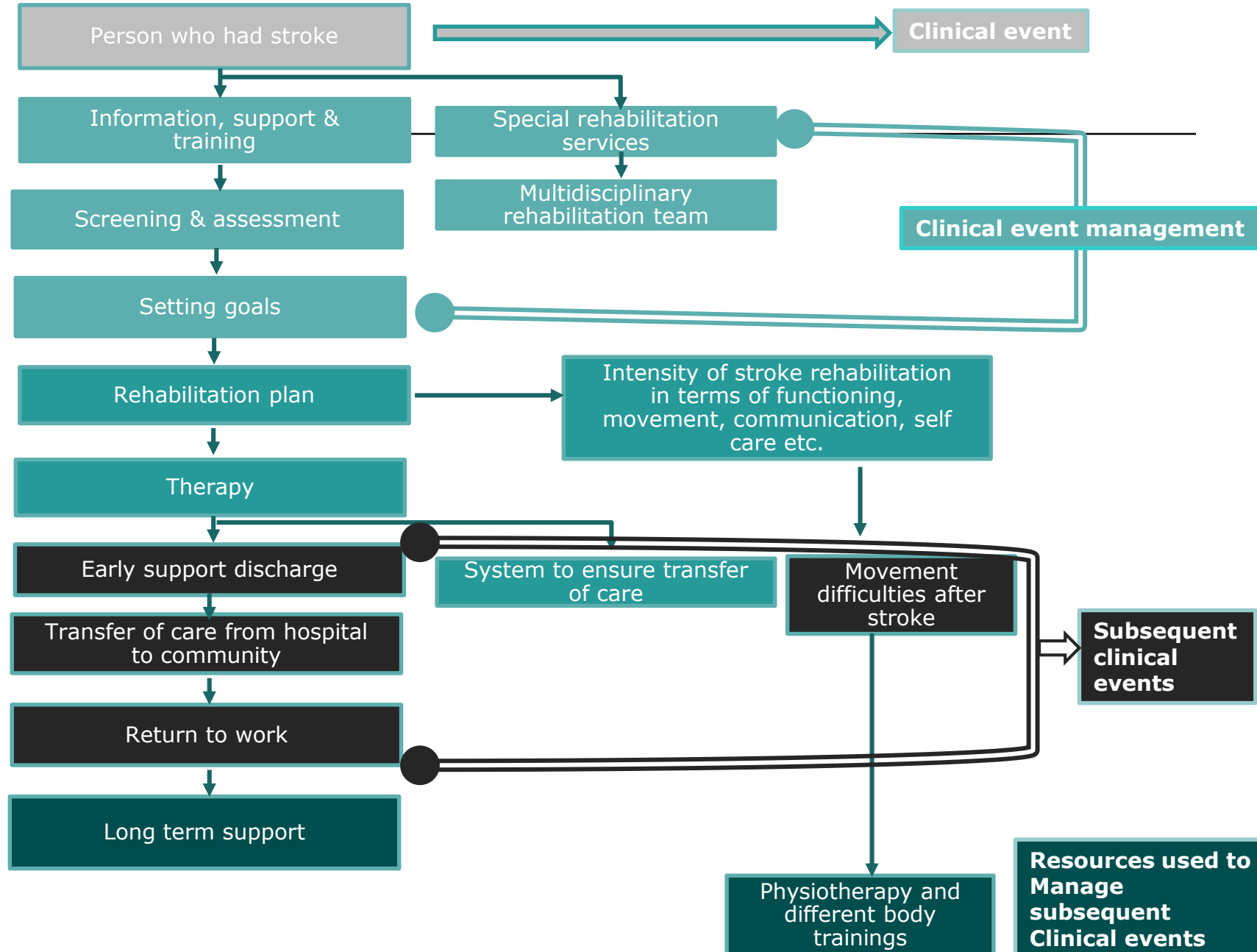
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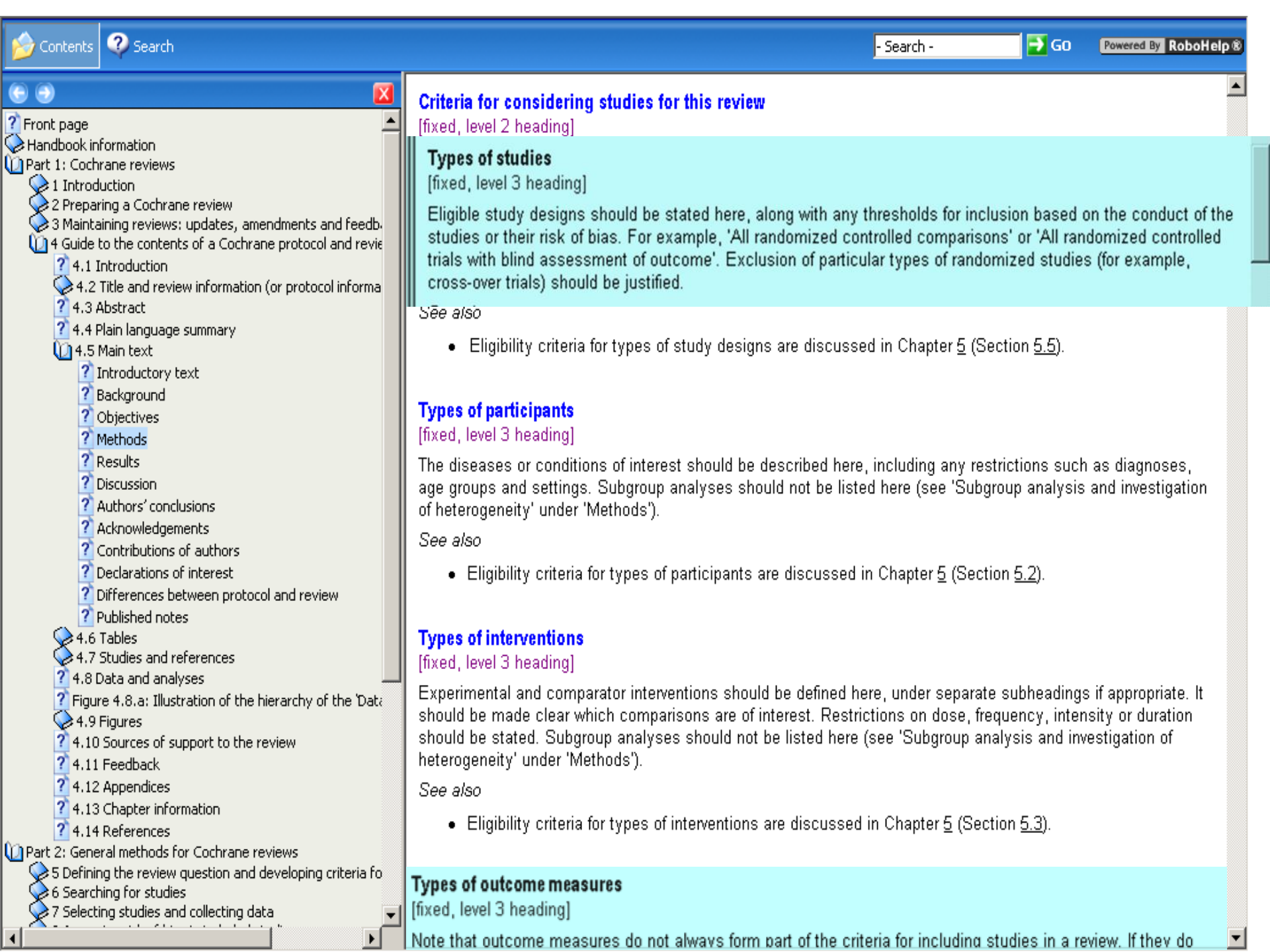
*To critically appraise and summarise current evidence on the (incremental) **resource use, costs and cost-effectiveness** of Bone Morphogenetic Protein for fracture healing in skeletally mature adults, compared to current standard treatments*

# Use of 'Clinical event pathway descriptions'



# Use of 'Clinical event pathway descriptions'





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## Criteria for considering studies for this review

[fixed, level 2 heading]

### Types of studies

[fixed, level 3 heading]

Eligible study designs should be stated here, along with any thresholds for inclusion based on the conduct of the studies or their risk of bias. For example, 'All randomized controlled comparisons' or 'All randomized controlled trials with blind assessment of outcome'. Exclusion of particular types of randomized studies (for example, cross-over trials) should be justified.

*See also*

- Eligibility criteria for types of study designs are discussed in Chapter 5 (Section 5.5).

### Types of participants

[fixed, level 3 heading]

The diseases or conditions of interest should be described here, including any restrictions such as diagnoses, age groups and settings. Subgroup analyses should not be listed here (see 'Subgroup analysis and investigation of heterogeneity' under 'Methods').

*See also*

- Eligibility criteria for types of participants are discussed in Chapter 5 (Section 5.2).

### Types of interventions

[fixed, level 3 heading]

Experimental and comparator interventions should be defined here, under separate subheadings if appropriate. It should be made clear which comparisons are of interest. Restrictions on dose, frequency, intensity or duration should be stated. Subgroup analyses should not be listed here (see 'Subgroup analysis and investigation of heterogeneity' under 'Methods').

*See also*

- Eligibility criteria for types of interventions are discussed in Chapter 5 (Section 5.3).

### Types of outcome measures

[fixed, level 3 heading]

Note that outcome measures do not always form part of the criteria for including studies in a review. If they do



# Types of outcome measures: economic outcomes

---

- Resource use
- Costs
- Cost-effectiveness
  
- Magnitude
- Time horizon
- Analytic perspective

# Magnitude and analytic perspective

---

## Bone Morphogenetic Protein for fracture healing

- Costs of acute treatment and care
- Costs of revisional procedures
- Costs of secondary interventions
- Cost of antibiotics
- Cost of outpatient visits
- Cost of travel to outpatient visits
- Cost of physiotherapy
- Cost of child care
- Lost wages
- Lost productivity (work output)
- Wages paid to temporary staff to cover absence

# Types of outcome measures: economic outcomes

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- Resource use

- Specific items of resource use

- Length of hospital stay (days)

- Duration of operation (minutes)

- Outpatient visits (number)

- Pharmaceuticals (treatment duration and dosage)

- Time to return to work (days)

# Types of outcome measures: economic outcomes

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- Resource use
  - Exceptions
    - Other direct resource use associated with complications of treatment

# Types of outcome measures: economic outcomes

---

## ○ Costs

- Specific cost items?
  - Cost of hospital stay
  - Cost of operation
  - Cost of outpatient visits
- Specific cost categories
  - Direct medical costs
  - Non-medical costs

# Types of outcome measures: economic outcomes

---

## ○ Costs

### ● Level

- Cost of 'X' per patient (specific cost items)
  - Average (mean) cost of 'X' per patient
- Total direct medical costs per patient
  - Average (mean) total direct medical costs per patient
- Total non-medical costs per patient
  - Average (mean) total non-medical costs per patient

# Types of outcome measures: economic outcomes

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## ○ Cost-effectiveness

- Incremental cost-effectiveness ratios (ICERs)
- Incremental cost per quality-adjusted life year (QALY)
- Incremental cost per disability-adjusted life year (DALY)
- Incremental cost-benefit ratios
- Net benefits

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### Types of outcome measures

[fixed, level 3 heading]

Note that outcome measures do not always form part of the criteria for including studies in a review. If they do not, then this should be made clear. Outcome measures of interest should be listed in this section whether or not they form part of the eligibility criteria.

See also

- Types of outcomes are discussed in Chapter 5 (Section 5.4).
- The importance of addressing patient-relevant outcomes is discussed further in Chapter 11 (Section 11.5.2); see also an extended discussion of patient-reported outcomes in Chapter 17.

### Primary outcomes

[recommended, level 4 heading]

The review's primary outcomes should normally reflect at least one potential benefit and at least one potential area of harm, and should be as few as possible. It is normally expected that the review should be able to analyse these outcomes if eligible studies are identified, and that the conclusions of the review will be based in large part on the effects of the interventions on these outcomes.

### Secondary outcomes

[recommended, level 4 heading]

Non-primary outcomes should be listed here. The total number of outcomes addressed should be kept as small as possible.

The following *optional* (level 4) headings may be helpful, as supplements or replacements for the headings above:

- Main outcomes for 'Summary of findings' table**
- Timing of outcome assessment**
- Adverse outcomes**
- Economic data**

### Search methods for identification of studies

[fixed, level 2 heading]



# Types of studies: Economic evaluation studies

Are both costs (inputs) and consequences (outputs) of the alternatives examined?

Is there comparison of two or more alternatives?

		No		Yes
No		<i>Examines only consequences</i>	<i>Examines only costs</i>	
		1A Partial evaluation	1B	2 Partial evaluation
		Outcome description	Cost description	Cost-outcome description
Yes		3A Partial evaluation	3B	4 Full economic evaluation
		Efficacy or effectiveness evaluation	Cost analysis	Cost-effectiveness analysis (CEA) Cost-utility analysis (CUA) Cost-benefit analysis (CBA)

# Bone Morphogenetic Protein (Example)

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## Objectives

To critically appraise and summarise current evidence on the (incremental) resource use, costs and cost-effectiveness of Bone Morphogenetic Protein for fracture healing in skeletally mature adults, **compared to current standard treatments**

## Types of intervention

BMP versus surgery alone

BMP versus surgery with or without bone graft

BMP and bone substitutes versus surgery and bone substitutes

# Types of studies: Economic evaluation studies

Are both costs (inputs) and consequences (outputs) of the alternatives examined?

Is there comparison of two or more alternatives?

		No		Yes
No		<i>Examines only consequences</i>	<i>Examines only costs</i>	
		1A Partial evaluation	1B	2 Partial evaluation
		Outcome description	Cost description	Cost-outcome description
Yes		3A Partial evaluation	3B	4 Full economic evaluation
		Efficacy or effectiveness evaluation	Cost analysis	Cost-effectiveness analysis (CEA) Cost-utility analysis (CUA) Cost-benefit analysis (CBA)

# Types of studies: Full economic evaluation studies

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- Cost-effectiveness analysis: cost per unit of effect (ICER)
- Cost utility analysis: cost per QALY/ cost per DALY (ICER)
- Cost-benefit analysis: cost-benefit ratio/ net benefit

# Types of studies: health economics studies

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## Comparative health economics studies

### *Resource utilisation studies*

'Comparative' resource utilisation studies  
(e.g. resource use measured within an RCT)

### *Partial economic evaluations*

Cost analyses

### *Full economic evaluations*

Cost-effectiveness analyses

Cost-utility analyses

Cost-benefit analyses



# Types of studies: health economics studies

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## Types of studies

Randomised controlled trials. Full economic evaluations (cost-effectiveness analyses, cost-utility analyses and cost-benefit analyses), cost analyses and comparative resource utilisation studies.

# Types of studies: the issue of scope

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- Full economic evaluations, cost analyses and comparative resource utilisation studies can *all* be conducted alongside an RCT
- Full economic evaluations can *also* be conducted as 'model-based economic evaluations'
- Cost analyses and comparative resource utilisation studies can *also* be conducted as 'stand-alone' studies



# Types of studies: the issue of scope

---

## Option 1

Include only 'empirical' health economics studies conducted alongside single, primary studies of effects which meet eligibility criteria for the review of intervention effects



# Types of studies: health economics studies

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## Types of studies (Option 1)

Randomised controlled trials. Full economic evaluations (cost-effectiveness analyses, cost-utility analyses and cost-benefit analyses), cost analyses and comparative resource utilisation studies **conducted alongside a randomised controlled trial.**

# Types of studies: the issue of scope

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## Option 2

Include 'empirical' health economics studies conducted alongside single, primary studies of effects which meet eligibility criteria for the review of intervention effects

AND

Health economics studies utilising effects data sourced from one or more single, primary studies meeting eligibility criteria for the review of intervention effects

# Types of studies: health economics studies

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## Types of studies (Option 2)

Randomised controlled trials. Full economic evaluations (cost-effectiveness analyses, cost-utility analyses and cost-benefit analyses) **conducted alongside a randomised controlled trial or those utilising effects data generated using either a meta-analysis of randomised controlled trials or a single randomised controlled trial.** Cost analyses and comparative resource utilisation studies **conducted alongside a randomised controlled trial.**

# Types of studies: the issue of scope

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## Option 3

Include all health economics studies meeting eligibility criteria, populations and comparisons, whether or not conducted alongside or utilising effects data sourced from studies which meet eligibility criteria for the review of intervention effects

# Types of studies: health economics studies

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## Types of studies (Option 3)

Randomised controlled trials. Full economic evaluations (cost-effectiveness analyses, cost-utility analyses and cost-benefit analyses), cost analyses and comparative resource utilisation studies – **any study design.**



The Campbell & Cochrane Economics Methods Group (CCEMG) is an international network of individuals with an interest and expertise in approaches to evidence synthesis that combine economics and systematic review methods. CCEMG strives to promote the inclusion of economic perspectives and evidence in systematic reviews of health care, social welfare, education and criminal justice interventions.

This is achieved through our development and provision of methods guidance, training, peer review and advisory support for economics components of reviews. CCEMG is a Methods Groups of Cochrane and a subgroup of The Campbell Collaboration Methods Coordinating Group.

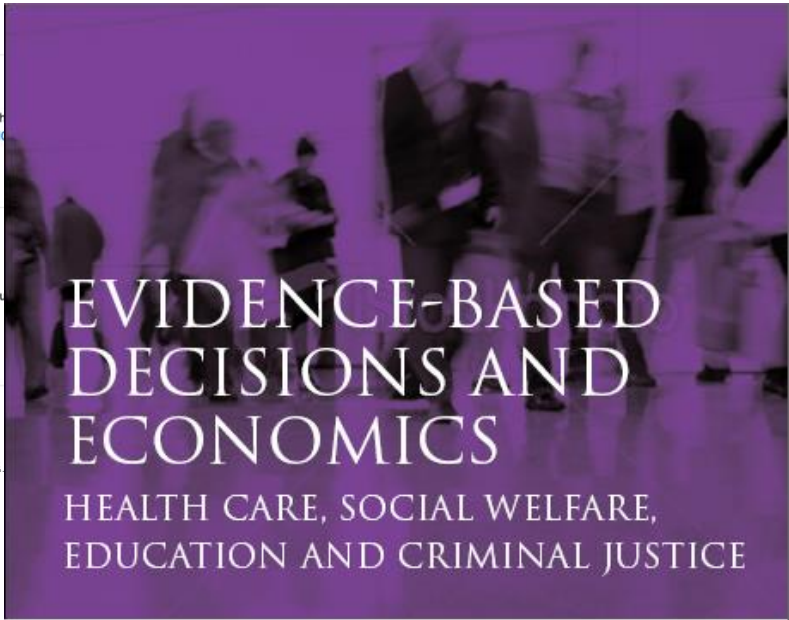
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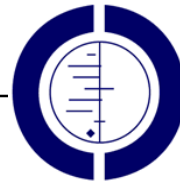


# EVIDENCE-BASED DECISIONS AND ECONOMICS

HEALTH CARE, SOCIAL WELFARE, EDUCATION AND CRIMINAL JUSTICE

Edited by  
Ian Shemilt  
Miranda Mugford  
Luke Vale  
Kevin Marsh  
Cam Donaldson

# HOW TO INCLUDE ECONOMICS IN COCHRANE REVIEW PROTOCOLS



## Part One: Background, objectives, outcome measures and types of studies

Campbell & Cochrane Economics Methods Group

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