16th Annual Meeting of UK and Ireland-based Contributors to The Cochrane Collaboration

HOW TO INCLUDE ECONOMICS IN COCHRANE REVIEW PROTOCOLS

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

PART TWO: 11.00-12.30 Tomorrow

Campbell & Cochrane Economics Methods Group

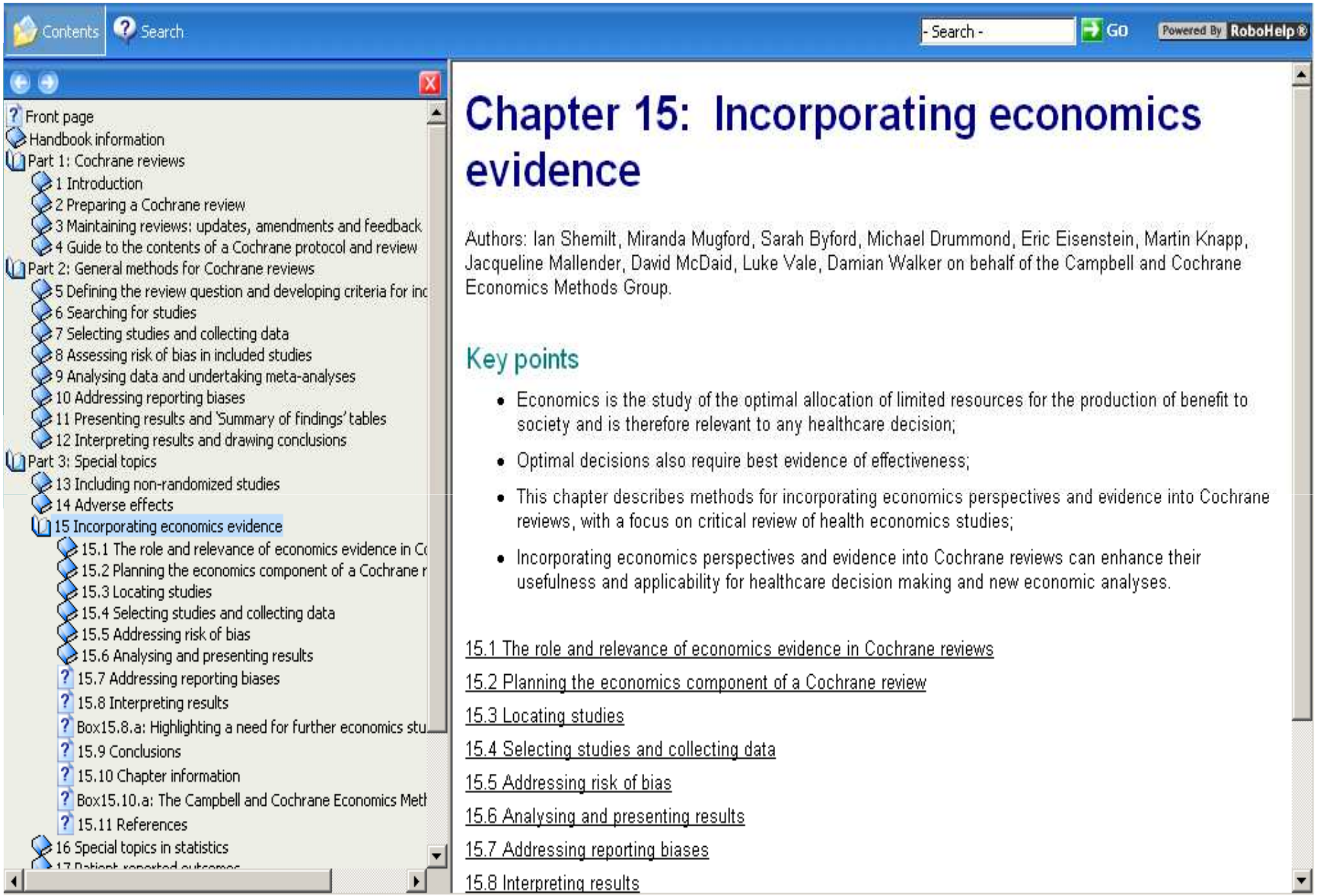
www.c-cemg.org

Learning objectives

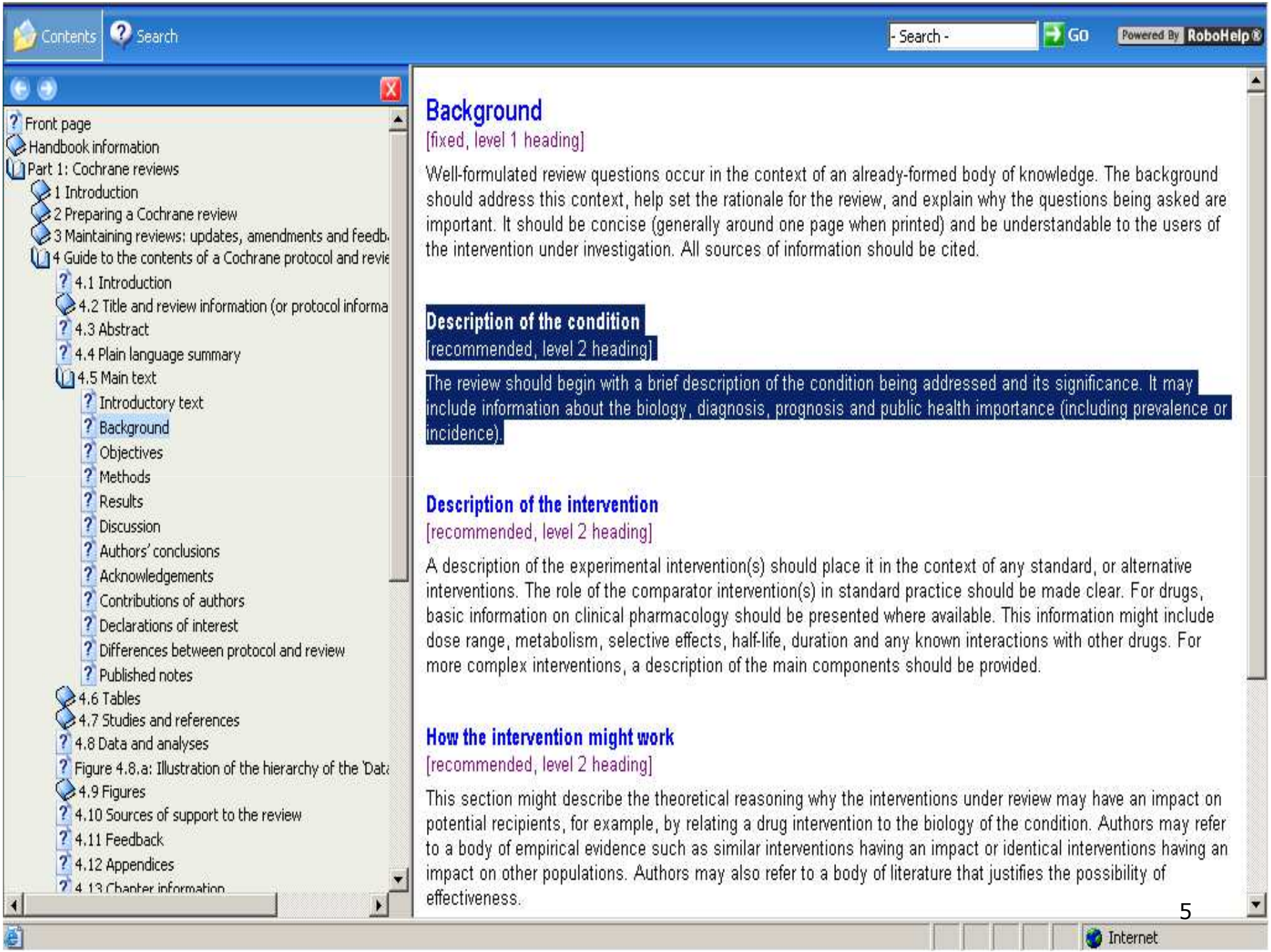
- Incorporate economic perspectives into 'Background'
- Formulate an 'Objective' for a critical review of health economic studies
- Identify measures of resource use, costs and cost-effectiveness to be included in 'Types of outcome measures'
- Identify types of health economic studies to be included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

Preliminary points

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



http://www.cochrane-handbook.org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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.
Internet

Background: Describe economic burden of condition

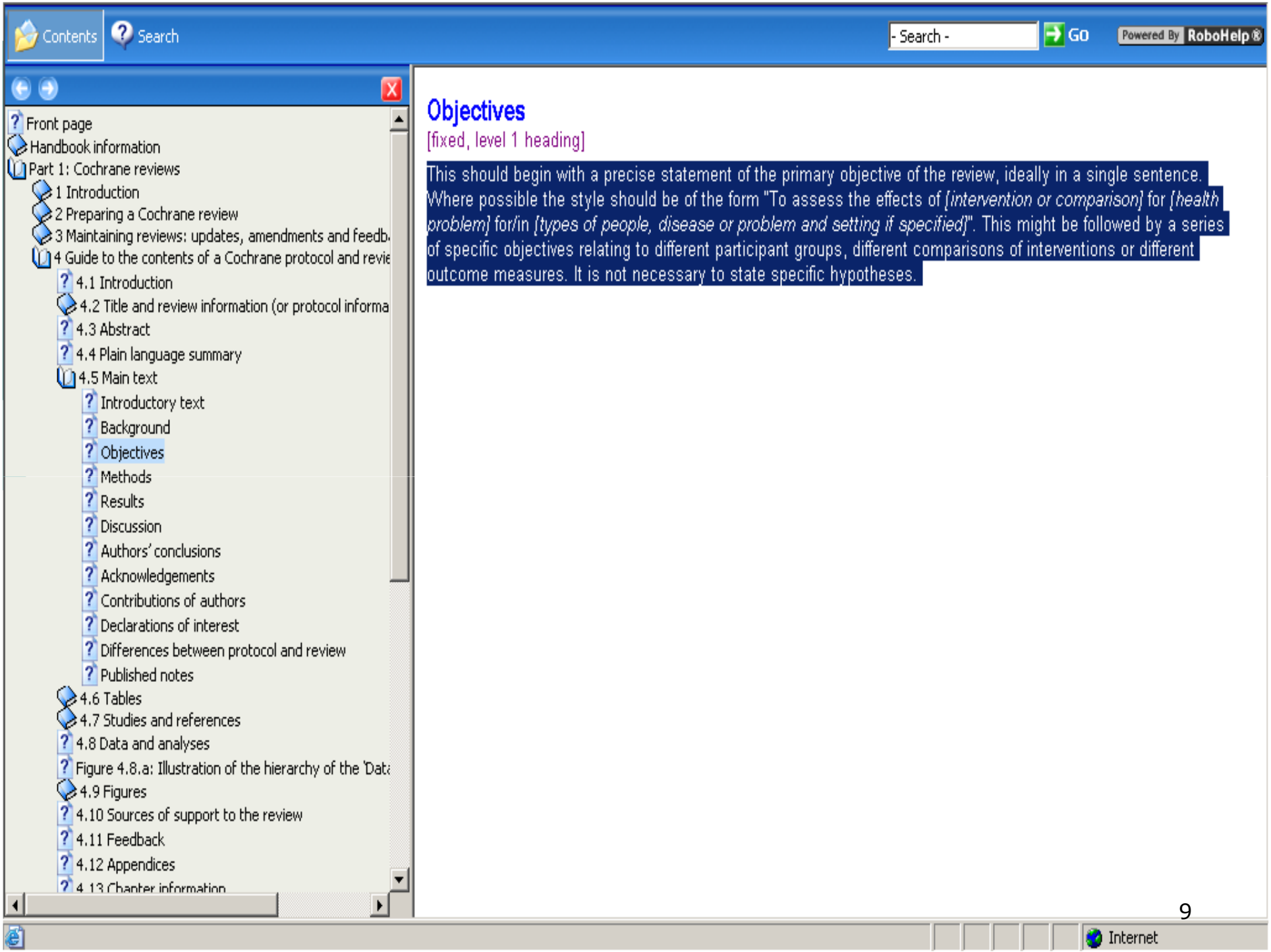
Faecal incontinence…can be a debilitating problem with medical, social and economic implications... In the United States more than $400 million is spent each year on a range of both urinary and faecal incontinence products... During 1991 the direct costs of pads, appliances and other prescription items 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

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.
Internet

Objectives: Clinical effects

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

Objectives: Economics

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

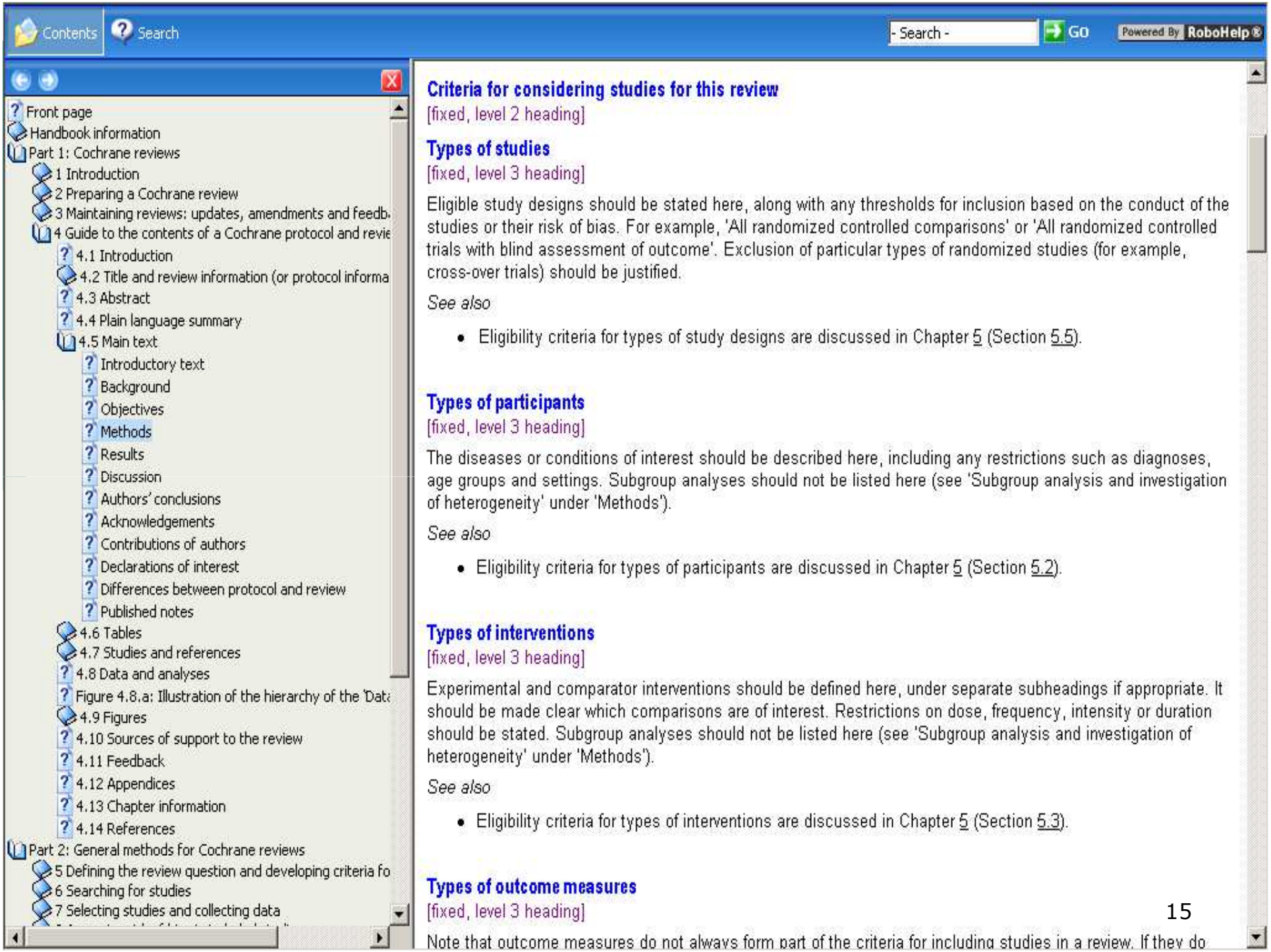
To critically appraise and summarise current evidence on the (incremental) resource use, costs and cost-effectiveness of Bone Morphogenetic Protein for fracture healing in skeletally mature adults, compared to current standard treatments

Objectives: Economics

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’

Event Pathway	Example
Clinical event	Stroke
↓	↓
Clinical event management + subsequent clinical events	Acute care and rehabilitation + sequelae and complications of treatment
↓	↓
Resources used to manage clinical event and subsequent clinical events	Length of hospital stay, pharmaceuticals, intensity of rehabilitation therapy, management of bleeding from secondary prophylaxis, follow-up outpatient visits, follow-up home nursing and social care
↓	↓
Cost of resources used to manage clinical event and subsequent clinical events	Valuation of resources using healthcare (and other) pay and prices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5 Defining the review question and developing criteria fo
6 Searching for studies
7 Selecting studies and collecting data
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

- 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

- 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)

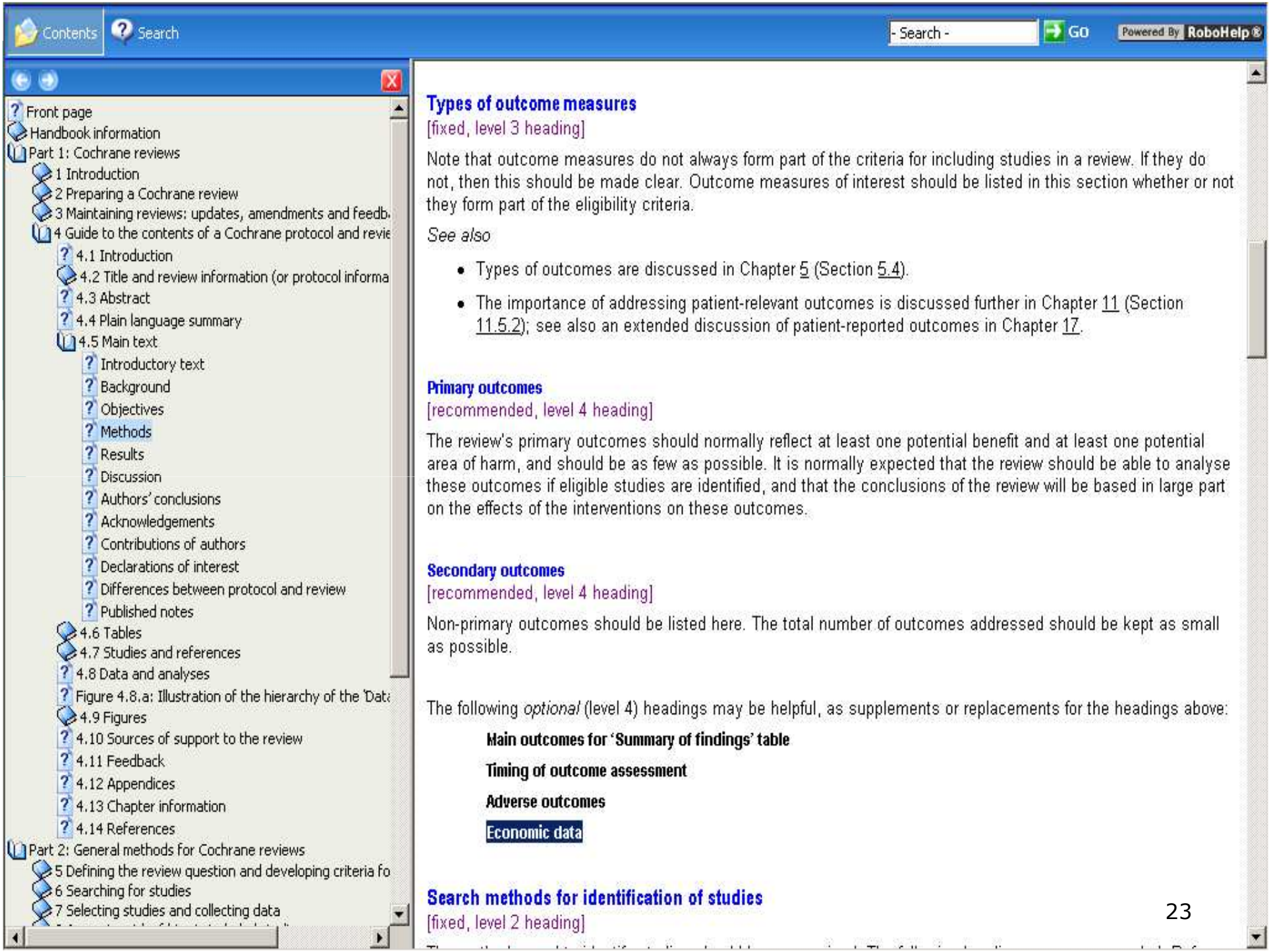
      - Average (mean) cost of 'X' per patient
    - Total direct medical costs per patient

      - Average (mean) total direct medical costs per patient
    - Total mon-medical costs per patient

      - Average (mean) total non-medical costs per patient

Types of outcome measures: economic outcomes

- 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
		Examines only consequences	*Examines only costs*	
	No	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

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
	Examines only consequences	*Examines only costs*	
No	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

- 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

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

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

- 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

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

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

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

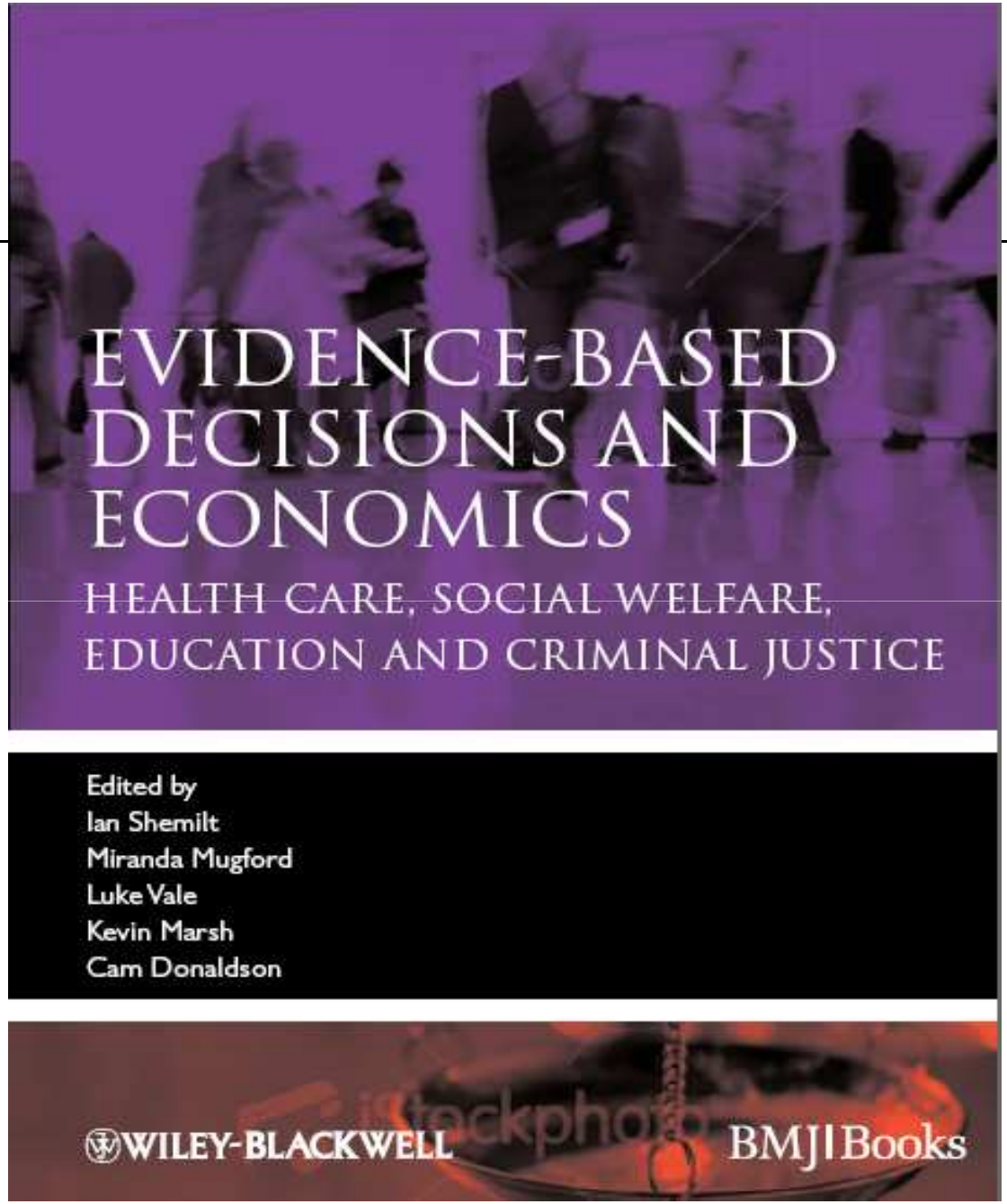
Option 3

Include all health economics studies meeting eligibility criteria re. 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

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.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