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PaPaS

THE COCHRANE COLLABORATION®

Summary of Findings tables

for the Pain, Palliative, and Supportive Care (PaPaS) Review Group

A 'Summary of findings' (SoF) table is intended to provide key information concerning the quality of evidence, the magnitude of effect of interventions examined, and the sum of available data on all the important outcomes for a given comparison in a Cochrane (or other) review.

SoF tables are typically constructed to satisfy interventions with a limited effect in a large population, predominantly in prophylactic therapy settings in which there is a generalised initial risk for the population, but whereby no means all would suffer without treatment (aspirin or statin to prevent heart attack would be examples).

Pain, palliative, and supportive care are different, because in almost all circumstances every single patient has a problem initially (pain, for example), and therapy removes or at least decreases the pain in some who are treated; the initial risk is one in one, or 100%. Moreover, developments in understanding what patients want from treatment, and what clinical trials tell us, has moved decisively towards a description of response – where response is variably described, but usually a major change in an outcome like pain brings with it concomitant improvements in other areas, like sleep, fatigue, depression, functioning, and quality of life.

The handbook advises that we consider the GRADE system, and GRADEpro for the production of Summary of Findings Tables. We are working with the GRADE working Group on an innovations fund project in 2012 to 2013 to consider how GRADE can evolve to take account of many of the issues pertinent to PaPaS reviews.

We recognize that the Methodological expectations of *Cochrane* Intervention Reviews (MECIR) process is also reviewing all aspects of methods guidance, and is likely to influence future PaPaS standards.

In the meantime, we recognize the importance of SoF and have developed outline tables that capture the essence of communicating complex results readily by focussing on the important outcomes of benefit and harm.

Version Control

This is version 1.0 of this document and was agreed as correct on September 1st 2011. It is scheduled for review in August 2012.

Summary of findings table - proforma

Patients or population:_____

Setting:_____

Intervention:_____

Comparison:_____

Outcome	Probable outcome with intervention	Probable outcome with comparator	NNT and/or relative effect	Number of participants and events	Quality of the evidence	Comments
At least 50% reduction in pain						
At least 30% reduction in pain						
Proportion below 30/100 mm on VAS						
Patient global impression very good						
Quality of life measure						
Adverse event withdrawals						
Serious adverse events						
Death						

Note that not all these outcomes may be available in every review. For some reviews, where an intervention may have been tested in different painful conditions, it may be appropriate for one or more efficacy outcomes to be presented for each condition.

Assessing the quality of evidence across studies for an outcome (notes)

Systematic reviews typically assess quality and validity according to individual studies. For the summary of findings table, an assessment of overall quality is required for each outcome chosen for inclusion in the summary of findings table. This aide memoir is designed to help in making those assessments. The table is limited to seven outcomes for one comparison, but can be changed in terms of the number of outcomes and the number of comparisons, consistent with requirements of the Cochrane Review Group (CRG). The following notes are intended to help guide the completion of the form.

Notes:

1. Number of studies and participants: the number reporting particular outcomes is likely to vary. Results from only a limited number of studies and participants might tend to be more subject to bias.

2. Number of events: an event is a beneficial or harmful outcome in one patient; with fewer than 50 events, random-effects can be very high, and with over 200 events random-effects will be limited.

3. Quality score: studies with an Oxford Quality Score of 3/5 or above have been shown to be unbiased. The score includes items describing randomisation, blinding and withdrawal, and their appropriateness. Where all studies with the outcome have scores of three or more, the likelihood of bias is minimal.

4. Appropriate study duration: chronic pain studies are known to demonstrate less efficacy over longer periods. Studies with the outcome of two weeks or less are likely to confer bias; this will be less in those of two to six weeks, and minimal in those of eight weeks or more. In other circumstances authors will need to be sure that outcomes are reported appropriately – for acute migraine, for example, are adverse events collected over 10 days for an acute attack relevant and appropriate?

5. Imputation method appropriate: this section includes issues over intention to treat (ITT), and how missing data points are dealt with. Completer analyses are not ITT, and tend to overestimate treatment effects. Last observation carried forward (LOCF) produces more favourable results than baseline observation carried forward (BOCF). Might these be factors for any outcome?

6. Potential threat from publication bias: this is a function of size and magnitude of the result for any outcome. Have you performed a publication bias threat for the outcome (see Guidelines on Reviews in Pain document)?

7. Other limitations: are there any other limitations affecting the evidence for the outcome?

8. Overall assessment of the quality of evidence: here you have to make an overall assessment, based on the questions already answered. For simplicity please use high, medium, or low.

Assessing the quality of evidence across studies for an outcome (table)

Comparison: _____

Quality assessment (please complete for each individual outcome)

Number of studies and participants	Number of events	Quality score (3/5 or more on Oxford Scale)	Appropriate study duration	Imputation methods appropriate	Potential threat from publication bias	Other limitations	Overall assessment of quality of evidence
Outcome:							
Outcome:							
Outcome:							
Outcome:							
Outcome:							
Outcome:							
Outcome:							

Summary of findings table – pregabalin chronic pain example

Patients or population: Postherpetic neuralgia – moderate or severe pain

Setting: Outpatient

Intervention: Pregabalin 600 mg daily

Comparison: placebo

Outcome	Probable outcome with intervention	Probable outcome with comparator	NNT and/or relative effect	Number of participants and events	Quality of the evidence	Comments
At least 50% reduction in pain	410 in 1000	150 in 1000	NNT 3.9 (3.1 to 5.1)	732 participants 220 events	High	Note LOCF imputation method probably overestimates efficacy
At least 30% reduction in pain	620 in 1000	240 in 1000	NNT 2.7 (2.2 to 3.2)	537 participants 210 events	High	Note LOCF imputation method probably overestimates efficacy
Proportion below 30/100 mm on VAS	No data					
Patient global impression much or very much improved	Inadequate data					
Quality of life measure	No data					
Adverse event withdrawals	190 in 1000	50 in 1000	Risk ratio 3.7 (2.3 to 6.0)	732 participants 37 events	High	
Serious adverse events	37 in 1000	32 in 1000	Risk ratio 1.2 (0.7 to 1.8)	2101 participants 70 events	High	All conditions combined
Death	No data for deaths					

Note that not all these outcomes may be available in every review. For some reviews, where an intervention may have been tested in different painful conditions, it may be appropriate for one or more efficacy outcomes to be presented for each condition.

Summary of findings table – aspirin for acute migraine example

Patients or population: Migraine (IHS), moderate to severe pain intensity, adults

Setting: Outpatient

Intervention: Aspirin 900/1000 mg

Comparison: Placebo

Outcome	Probable outcome with intervention	Probable outcome with comparator	NNT and/or relative effect	Number of participants and events	Quality of the evidence	Comments
Pain-free at 2 h	240 in 1000	110 in 1000	NNT 8.1 (6.4 to 11)	6 studies, 2027 participants 357 events	Good	Standard tablet and soluble formulations
Headache relief at 2 h	520 in 1000	320 in 1000	4.9 (4.1 to 6.2)	6 studies, 2027 participants 848 events	Good	Standard tablet and soluble formulations
Sustained pain-free at 24 h	No data					
Sustained headache relief at 24 h	390 in 1000	240 in 1000	NNT 6.6 (4.9 to 10)	3 studies, 1142 participants 361 events	Good	Standard tablet and soluble formulations
Relief of associated symptoms at 2 h (nausea)	560 in 1000	440 in 1000	NNT 9.0 (5.6 to 22)	4 studies, 878 participants 439 events	Good	Standard tablet and soluble formulations
Use of rescue medication within 24 h	420 in 1000	630 in 1000	NNTp 4.8 (3.9 to 6.0)	5 studies, 1881 participants 991 events	Good	Standard tablet and soluble formulations
At least one AE	120 in 1000	90 in 1000	NNH 34 (18 to 340)	5 studies, 1892 participants 206 events	Moderate?	Standard tablet and soluble formulations
AE withdrawals	Insufficient data - uncommon					

Summary of findings table – ibuprofen in acute pain example

Patients or population: Acute postoperative pain

Setting: In patient/out patient

Intervention: Ibuprofen 400 mg, oral

Comparison: Placebo

Outcome	Probable outcome with intervention	Probable outcome with comparator	NNT and/or relative effect	Number of participants and events	Quality of the evidence	Comments
At least 50% reduction in pain over 4 to 6 h	540 in 1000	140 in 1000	NNT 2.5 (2.4 to 2.6)	61 studies, 6475 participants 2388 events	High	Mixed conditions and formulations. NNTs significantly better for dental pain and soluble formulations
Use of rescue medication within 6 h	42 in 1000	79 in 1000	NNTp 2.7 (2.5 to 3.0)	28 studies, 2983 participants 1712 events	High	Mixed conditions and formulations. NNT significantly better for soluble formulations
Median time to use of rescue medication (h)	5.6	1.9	Not calculated	31 studies, 3548 participants	High	Mixed conditions and formulations
Adverse events	170 in 1000	160 in 1000	RR 0.92 (0.82 to 1.04)	40 studies, 48767 participants	Moderate	Mixed conditions and formulations. Data mostly over 4 to 8 h
Adverse event withdrawals	Inadequate data - uncommon					
Serious adverse events	Inadequate data - uncommon					
Death	None					

Note that not all these outcomes may be available in every review. For some reviews, where an intervention may have been tested in different painful conditions, it may be appropriate for one or more efficacy outcomes to be presented for each condition.