



review title

Written information about individual medicines for consumers

(Nicolson et al. 2009)

focus of the review

The aim of this Cochrane review was to examine the effects of providing written information about individual prescribed and over-the-counter medicines in terms of consumer outcomes such as:

- Knowledge about medicines;
- Attitudes towards taking medicines;
- Medicine-taking behaviours;
- Health outcomes (including physiological markers); and
- Adverse effects and/or symptoms.

key results of the review

What this review shows about providing written medicines information (WMI) to consumers:

Compared with no WMI, providing WMI:

- May improve medicines-related knowledge and recall, and recall of medication side effects, and may increase the reporting of medication side effects by consumers.
- May also improve ratings of satisfaction with information; and clarity, usefulness and adequacy of information provided; and may also decrease medicine-related worry.

When comparing different forms of WMI:

- Certain formats may improve medicines understanding and estimation of risk, but results were based on single studies and no clear differences between WMI forms were found.
- Certain formats may be more likely to affect the decision to take medicines, ratings of treatment, satisfaction, ratings of length, complexity, readability and/or understandability of information. Results were typically based on single studies with no clear differences between WMI forms.

What this review does not show about providing WMI to consumers:

The effects of WMI, compared with none, on outcomes such as:

- Compliance or continuation with medication instructions, correct application of medication information, numbers of people reporting health problems, self-care skills, costs or service use.

The effects of different forms of WMI on outcomes such as:

- Medicines-related knowledge, correct application of medication information, proportion of people reading the WMI thoroughly, health outcomes, or costs or service use.

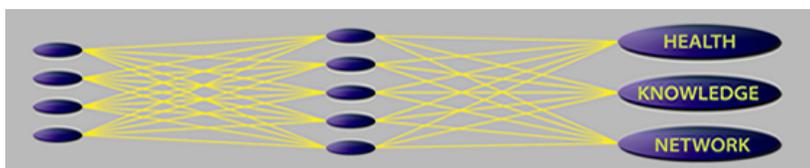
This Evidence bulletin is produced by the Centre for Health Communication and Participation, for Health Knowledge Network, with funding from Statewide Quality Branch, Department of Human Services, Victoria, Australia.

This bulletin summarises a recently published Cochrane systematic review

This page highlights key aspects of the review

Pages 2-5 summarise the review

The Evidence table on pages 6-10 contains more detail of the review



Background to the review

Medicines are a key intervention in health care. For medicines to be used effectively and safely people need enough information to assist them to make informed decisions about taking them, and to be informed of potential benefits and harms.

Around half of all patients do not take medicines as prescribed. There are complex factors underlying the way people use medicines. Patients are increasingly empowered and active participants in, and managers of their own health care. They are “demanding and using health information on an unprecedented scale” (EU Commission statement 2003); and make reasoned decisions about taking medicines in accordance with life’s “wider goals and aspirations”.

In a concordance model of health care the aim is for shared understanding and decision making between patient and health care provider. In this model providing good quality information is a key to active patient involvement in managing health and treatment.

EU legislation introduced in the 1990s requires that medicine packages should contain comprehensible information leaflets for patients. These leaflets are produced by the manufacturer and included with medicines as a package insert. They are a folded leaflet containing dense information about the product, including warnings and precautions. It has been shown that leaflets in medicine packages do not meet patients’ needs - that patients do not read them after the first time, and that information about risks may be ineffective (eg. warnings fail to inform users adequately).

In Australia leaflets are produced on a computer by the pharmacy and can consist of as many as five pages. In the US leaflets are computer-generated and shorter - about one page. Computer-generated information can be easily updated and customised to individual patient’s needs. The Internet also provides new access for patients - medicine leaflets can be viewed online; and patients have access to both official and unofficial health information.

This review aimed to include research on all

sources of written information about medicines including information in the legislated format, additional written information from health professionals, and information accessed by patients themselves including the Internet. Any type of electronically-generated information was also to be included in this review.

Other reviews have focused on particular aspects of providing written medicines information (WMI) (eg. role, value and effectiveness, adherence in a wide context, information design, or professional perspectives). This review aimed to encompass a broad range of elements (eg. consumers receiving written information about prescriptions or over-the-counter medicines, first time users of a medicine or not, single or multiple medicines, consumers with acute or chronic illness, inpatients or outpatients, or consumers receiving medicines from sources other than a pharmacy, such as via the Internet). This would enable authors to draw conclusions on the effectiveness of written medicines information that would be generalisable to a broad audience.

Trials included in the review

The review included 25 randomised controlled trials (RCTs); involving 4,788 participants.

Interventions in included trials were directed to consumers taking medicines, in various settings including hospital (including psychiatric) inpatient, outpatient clinics (including those for diabetes, rheumatology, and cardiac rehabilitation programs), community settings (including pharmacy, general practice, university clinic) and nursing home for respiratory illnesses.

Nineteen included trials involved WMI for chronic conditions (including 5 for NSAIDs and 10 for cardiovascular medicines); 5 used WMI for acute conditions. Also included were WMI provided for mental health problems (4 studies); antibiotics (3 studies); information on more than one medicine (5 studies); or other classes of medicines (4 studies). Overall, 11 studies used WMI for multiple medications, and 13 studies for single medications.

Trials were undertaken in Belgium (2), Canada (2), and one each in Finland, France, Hong Kong, Switzerland and Turkey.

Summary of
the review
continued...

Description of interventions

Review authors included any intervention providing written information about an individual medicine, such as:

- Information provided in a medicine package insert or a supplementary leaflet intended for the medicine; and,
- Non-print written information about an individual medicine, such as that provided on websites on the Internet.

Information on dosage and warnings that normally appear on medicine labels and which are often mandatory for provision with the medicine were not the focus of the review.

'Medicines information' was defined as fulfilling at least one of the five following categories, as providing information on:

- What the medicine is and how it works;
- Contraindications and precautions before taking the medicine;
- How to take the medicine;
- Possible side effects; or,
- How to store the medicine.

Information could be provided to consumers alone or as part of a more complex intervention.

Trials found, that were to be included in the review, were more limited. Content analysis was undertaken on the 18, of 25 included, trials which published a partial or full copy of the WMI intervention. Most interventions included information on what the medicine is and what it is used for (19 trials), and possible side effects (19 trials). Six trials contained information on the five EU categories.

Description of outcomes

The primary outcome of interest to review authors was:

- Consumer knowledge about medicines.

Secondary outcomes were:

- Change in consumers' attitudes towards taking the medicine;
- Changes to medicine-taking behaviours; and,

- Changes to health outcomes (including physiological markers, such as change in blood pressure; as well as less direct indicators such as number of hospital admissions).

Adverse events were also sought as WMI may influence recognition of adverse effects and/or symptoms and this may have an effect on symptom recognition and reporting by consumers.

Summary of key findings

What the review shows:

Written medicines information versus no written information

Primary outcomes:

There is some evidence from trials that compared with people receiving no written information those receiving WMI:

- May have significantly higher medicine-related **knowledge** levels (6 studies of 12; and in 2 further studies improved some measures of knowledge).
- May have significantly higher levels of **medicine-related recall** (2 of 4 studies, and in the other 2 studies improved approximately half of assessed measures) and recall of medication side effects (3 of 6 studies).

Other outcomes:

There is some evidence from trials that compared with people receiving no written information, those receiving WMI:

- May rate the information received higher on measures of **clarity, usefulness, understanding and adequacy**, and may report significantly reduced **worry** about medicines use (1 trial, 125 participants).
- Report higher **satisfaction** levels (2 of 2 studies).

Harms/adverse effects:

There is some evidence from trials that people receiving WMI may significantly more frequently **report side effects** of medications compared with those receiving no written information, (1 trial, 40 participants).

Summary of
the review
continued...

One type of written medicines information versus another

Primary outcomes:

There is some evidence from trials that:

- People receiving programmed instruction WMI may have significantly higher **understanding** of the use of the drug compared with those receiving a standard WMI booklet (1 trial, 45 participants).
- People receiving WMI with numerical descriptions of risk may have significantly more correct **estimations of risk** compared with those receiving a WMI with verbal risk information about side effects, (1 trial, 120 participants).

Other outcomes:

There is some evidence from trials that compared with people receiving WMI with numerical risk estimates of side effects:

- People receiving verbal descriptions of risk were significantly more likely to acknowledge it would affect their **decision to take the medicine** for one side effect (constipation) but not for the other (pancreatitis) (1 trial, 120 participants).
- People receiving WMI with verbal descriptions of risk were significantly less **satisfied** with the information for one side effect (pancreatitis) but not for the other (constipation) (1 trial, 120 participants).

There is some evidence from trials that:

- Compared with people receiving WMI presenting medication risk information before the benefits of taking the medication, those receiving WMI with risk information presented after benefits rated the **favourability** of treatment significantly lower (1 trial, 217 participants).
- Compared with people receiving WMI with information specifically worded for patients or professionals, those receiving WMI with 'normal' wording were significantly more likely to judge the information as appropriate in **length and complexity**, but there was **insufficient evidence** to decide between WMIs in terms of ratings of **emotional responses** or **evaluations** of the WMI (1 trial, 150 participants).

- Compared with people receiving experimental WMI, compared with the manufacturer's leaflet, people were significantly more likely to report that the text was **easy to understand**, that it was complete, and that it contained a lot of new information but there was **insufficient evidence** to decide between WMIs in terms of ratings of the WMI being **interesting** or **easy to read** (1 trial, 268 participants).

What the review does not show:

Written medicines information versus no written information

Other outcomes:

There is insufficient evidence from trials to decide between WMI and no written information, in terms of **compliance** or **continuation** with medication instructions, **correct** application of medication information or numbers **reporting** health problems.

There is insufficient evidence from trials to decide between WMI and no information in terms of effects on **health outcomes** (either direct or indirect measures).

One type of written medicines information versus another

Primary outcomes:

There is insufficient evidence from trials to decide between structured and easy-to-read WMI formats (1 study); evidence-based and standard leaflets (1 study); or experimental and manufacturer's leaflets (1 study) for **knowledge** (correct responses), although a trend towards improved knowledge was seen in most studies.

Other outcomes:

There is insufficient evidence from trials:

- To decide between structured and easy-to-read WMI formats for **correct application** of the WMI information.
- To decide between a leaflet with improved readability and a traditional leaflet in terms of the proportion of **people reading** the leaflet thoroughly.

Summary of
the review
continued...

See the
Evidence table
and
key to results
on pages 6-10

Forwarding
bulletins

Bulletins
available
online

Funding

In relation to different WMI formats none of the studies assessed:

- **Compliance** or **continuation** with medication instructions, or effects on **health outcomes** (either direct or indirect measures) in relation to different WMI formats; or,
- Effects on **health outcomes** (either direct or indirect measures).

Harms/adverse effects

None of the studies assessed adverse effects or reporting of medication side effects.

Conclusions

Authors conclude that written medicines information should be available as there is some evidence that they may improve knowledge of medicines and there are no adverse effects. Authors state that trials were conducted poorly—perhaps because they were conducted prior to the CONSORT statement, when less was known about best practice in conducting and reporting trials, consequently review results are inconclusive.

Recommendations from authors

Authors recommend that further high-quality research into the effects of WMI be undertaken to assess effects on a range of consumer outcomes, including knowledge, attitudes and behaviours in relation to medicines use.

Forwarding

You are welcome to forward this bulletin on to any interested colleagues—individuals, organisations or networks.

Contacting us

Health Knowledge Network,
Centre for Health Communication and
Participation,
La Trobe University, Bundoora, VIC 3078
Helen Dilkes, Research Officer
Ph: 03 9479 5730
hkn@latrobe.edu.au

Evaluation of outcomes in future research should aim to clarify the links between these different outcomes; should attempt to use standardised, validated outcome measures; and to assess effects in the longer term as well as immediately after WMI provision.

Authors note that future trials should aim to explicitly assess both potential positive and negative effects of WMI, for example, in recognition that informed decision making about medicines may include the decision not to take the medicine as directed.

Authors also indicate that future trials should follow best practice in the design of WMI materials. In particular, attention should be paid to the degree to which the information presented in WMIs is understandable. Qualitative research on the role of WMI may also be useful to assess the degree to which consumers value WMIs.

Finally, authors recommend that trials are needed to assess the effects of Internet-based WMIs. Future research should also take account of the regulatory context in which the provision of WMI occurs; should aim to identify those components of WMI that are most effective for changing consumers' outcomes in relation to medicines use; and should attempt to study the effects of WMI in those populations which represent the greatest users of WMI, such as the elderly or those following complex medication regimens.

Bulletins on the Health Knowledge Network website:

www.latrobe.edu.au/chcp/hkn/index.html

Funding

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Full citation for the review:

Nicolson D, Knapp P, Raynor DK, Spoor P. Written information about individual medicines for consumers. *Cochrane Database of Systematic Reviews* 2009, Issue 2. Art. No.: CD002104. DOI: 10.1002/14651858.CD002104.pub3. Link to review in The Cochrane Library: www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD002104/frame.html

This table is part of an overview of the review created by Dr Rebecca Ryan, at The Consumers & Communication Review Group, La Trobe University. It contains detailed data extracted from the review. The summary on the previous pages of this EVIDENCE bulletin draws on content from both this table and the review. This table uses standardised wording developed by the Review Group. A key to this wording follows the table and should be used to interpret the data.

Review title: Written information about individual medicines for consumers

Authors: Nicolson D, Knapp P, Raynor DK, Spoor P.

Description of main features

Aim: To assess the effects of providing written information about individual prescribed and over-the-counter medicines in terms of relevant patient outcomes such as knowledge, attitudes, behaviours and health outcomes.

Trial design: RCT.

Participants:

Included: Consumers of any age receiving written information about prescription or over-the-counter medicines, whether or not they were first time users of the medicine. Consumers could be in- or out-patients, those receiving their prescriptions in primary care, or those receiving medicines from sources other than a pharmacy (such as via the Internet).

Interventions:

Included: Any intervention providing written information about an individual medicine, such as: information provided in a medicine pack insert or a supplementary leaflet intended for the medicine; and non-print written information about an individual medicine, such as that provided on websites. However, information on dosage and warnings that normally appear on medicine labels and which are often mandatory for provision with the medicine were not the focus of the review. 'Medicines information' was defined as fulfilling at least one of the five following categories, as providing information on: what the medicine is and how it works; contraindications and precautions before taking the medicine; how to take the medicine; possible side effects; or how to store the medicine. Information could be provided to consumers alone or as part of a more complex intervention.

Excluded: Interventions where providing medicines information was not the main focus; information provided to consumers and aiming to assist in them in making a decision between (two or more) medicines; consumer information provided as part of an individualised illness management plan; and information aiming to assist doctors or others to prescribe medicines.

Comparison arms:

- Written medicines information (WMI) versus no WMI (including no WMI or spoken information).
- One WMI versus another (including comparisons of one versus another, and one way of describing risk compared with another).

Outcomes:

Included and specified in advance:

Consumer knowledge about medicines (primary outcome). Secondary outcomes: change in consumers' attitudes towards taking the medicine; changes to medicine-taking behaviours; and changes to health outcomes (including physiological markers as well as less direct indicators such as service use). Adverse events were also sought as WMI may influence recognition of adverse effects and/or symptoms and this may affect reporting by consumers.

Number of trials included: 25 (4 further studies await assessment)

Types of trials included: RCT

Number of participants included: 4,788

Meta-analysis performed: No, data described narratively due to extensive heterogeneity in design and conduct of included trials, including reported outcomes.

Review methods:

Standard Cochrane Collaboration review methods were used, including the following: *a priori* research design provided; extensive searching; selection criteria were specified in advance and applied; list of included and excluded studies provided; quality criteria for assessment of included studies were reported and applied; methods of analysis were reported; conflict of interest stated.

Quality:

Included trials:

Rated using several criteria including: adequacy of randomisation sequence and allocation concealment, blinding of outcome assessment, loss to follow-up and withdrawals from the study.

Review AMSTAR rating (out of possible 11): 9 - high quality review.

Comments: The review methods adequately met all items of the AMSTAR checklist with the exception of the items evaluating assessment of publication bias (ie the likelihood of publication bias was not explicitly addressed by this review); and that assessing whether the search included explicit searching for unpublished materials (not stated by the authors).

Setting: *Country:*

USA (8 studies), UK (8), Belgium (2), Canada (2), one each in Finland, France, Hong Kong, Switzerland, Turkey. *Intervention:* hospital (including psychiatric) inpatient, outpatient clinics (including those for diabetes, rheumatology, and cardiac rehabilitation programs), community settings (including pharmacy, general practice, university clinic) and nursing home for respiratory illnesses.

Recipient: Consumers taking medicines. Nineteen included studies involved WMI for chronic conditions (including 5 for NSAIDs and 10 for cardiovascular medicines); 5 used WMI for acute conditions. Also included were WMI provided for mental health problems (4 studies); antibiotics (3 studies); information on more than one medicine (5 studies); or other classes of medicines (4 studies). Overall, 11 studies used WMI for multiple medications, and 13 studies for single medications (unclear in 1 study).

Provider: Variable: In the majority of studies provider of the WMI was not reported; however in 7 studies the intervention was delivered by clinicians (GPs, pharmacists, nurse or unspecified clinician).

Format: All information was written, with or without accompanying spoken instruction, but varied in specific format and included: patient information leaflets, patient information wallet, brochure, programmed instruction booklet, information package with manufacturer's instructions, leaflet, one or two page information sheet, written statements or electronically produced WMI. 18 trials published a copy of the WMI intervention, or provided one on request. Different types of WMI included: varying the reading level of the provided information, using different wording, presenting the information in different text or in shaded panels, or comparing experimental patient information leaflets with those produced by the manufacturers. Information content was highly variable: few details were provided in 7 studies; most provided information about what the medicine was and what it was used for (19 trials); and possible side effects (19 trials); and 6 gave information covering all 5 medicines information categories.

*Full text of paper about AMSTAR: http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=17302989&ordinalpos=2&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

| Intervention | Results of review |
|--|---|
| <p>Written medicines information (WMI) versus none (no written information, written plus spoken information versus spoken information)</p> | <p><u>Primary outcome:</u></p> <p>Some evidence from trials: compared with people receiving no written information, those receiving WMI may have significantly higher medicine-related knowledge levels (6 studies of 12; and in 2 further studies improved some measures of knowledge).</p> <p>Some evidence from trials: compared with people receiving no written information, those receiving WMI may have significantly higher levels of medicine-related recall (2 of 4 studies, and in the other 2 studies improved approximately half of assessed measures) and recall of medication side effects (3 of 6 studies).</p> <p><u>Other outcomes:</u></p> <p>Some evidence from trials: compared with people receiving no written information, those receiving WMI may rate the information received higher on measures of clarity, usefulness, understanding and adequacy, and may report significantly reduced worry about medicines use (1 trial, 125 participants).</p> <p>Some evidence from trials: compared with people receiving no written information, those receiving WMI report higher satisfaction levels (2 of 2 studies).</p> <p>Insufficient evidence from trials to decide between WMI and no written information, in terms of compliance or continuation with medication instructions, correct application of medication information or numbers reporting health problems.</p> <p>Insufficient evidence in relation to measurement to decide between WMI and no information in terms of effects on health outcomes (either direct or indirect measures).</p> <p><u>Harms/ adverse effects:</u></p> <p>Some evidence from trials: compared with people receiving no written information, those receiving WMI may significantly more frequently report side effects of medications (1 trial, 40 participants).</p> |

| Intervention | Results of review |
|---|--|
| <p>One type of written medicines information versus another</p> | <p><u>Primary outcome:</u> Some evidence from trials: compared with people receiving a standard WMI booklet, those receiving programmed instruction WMI may have significantly higher understanding of the use of the drug (1 trial, 45 participants). Some evidence from trials: compared with people receiving a WMI with verbal risk information about side effects, those receiving WMI with numerical descriptions of risk may have significantly more correct estimations of risk (1 trial, 120 participants). Insufficient evidence from trials: to decide between structured and easy-to-read WMI formats (1 study); evidence-based and standard leaflets (1 study); or experimental and manufacturer’s leaflets (1 study) for knowledge (correct responses), although a trend towards improved knowledge was seen in most studies.</p> <p><u>Other outcomes:</u> Some evidence from trials: compared with people receiving WMI with numerical risk estimates of side effects, those receiving verbal descriptions of risk were significantly more likely to acknowledge it would affect their decision to take the medicine for one side effect (constipation) but not for the other (pancreatitis) (1 trial, 120 participants). Some evidence from trials: compared with people receiving WMI presenting medication risk information before the benefits of taking the medication, those receiving WMI with risk information presented after benefits rated the favourability of treatment significantly lower (1 trial, 217 participants). Some evidence from trials: compared with people receiving WMI with numerical risk estimates of side effects, those receiving WMI with verbal descriptions of risk were significantly less satisfied with the information for one side effect (pancreatitis) but not for the other (constipation) (1 trial, 120 participants). Some evidence from trials: compared with people receiving WMI with information specifically worded for patients or professionals, those receiving WMI with ‘normal’ wording were significantly more likely to judge the information as appropriate in length and complexity, but there was insufficient evidence to decide between WMIs in terms of ratings of emotional responses or evaluations of the WMI (1 trial, 150 participants). Some evidence from trials: compared with people receiving experimental WMI, compared with the manufacturer’s leaflet, people were significantly more likely to report that the text was easy to understand, that it was complete, and that it contained a lot of new information but there was insufficient evidence to decide between WMIs in terms of ratings of the WMI being interesting or easy to read (1 trial, 268 participants). Insufficient evidence from trials to decide between structured and easy-to-read WMI formats for correct application of the WMI information. Insufficient evidence from trials to decide between a leaflet with improved readability and a traditional leaflet in terms of the proportion of people reading the leaflet thoroughly. Insufficient evidence in relation to measurement to decide between different WMI formats in terms of compliance or continuation with medication instructions. Insufficient evidence in relation to measurement to decide between different WMI formats in terms of effects on health outcomes (either direct or indirect measures).</p> <p><u>Harms and adverse effects:</u> Insufficient evidence in relation to measurement to decide between different WMI formats in terms of side effects or reporting of medication side effects.</p> |

The table on this page presents the standardised wording that should be used to interpret the data in the results section of the EVIDENCE table on the previous pages.

| SUMMARY STATEMENT | TRANSLATION |
|---|---|
| <i>Sufficient evidence from trials</i> | <p>Evidence to support conclusions about the effect of the intervention(s) in relation to a specific outcome(s). This includes evidence of an effect in terms of:</p> <ul style="list-style-type: none"> • benefit or • harm. <p>Statistically significant results are considered to represent sufficient evidence to support conclusions, but a judgement of 'sufficient evidence' is also based on the number of trials/ participants included in the analysis for a particular outcome.</p> <p>A grading of 'sufficient evidence' is often based on meta-analysis producing a statistically significant pooled result that is based on a large number of included trials/ participants.</p> <p>This judgement may also be made based on the number of trials and/or trial participants showing a statistically significant result - for example (in a narrative synthesis) a result where 12 trials of a total of 14 for a specific outcome showed a statistically significant effect of an intervention would be considered to represent 'sufficient evidence.'</p> |
| <i>Some evidence from trials</i> | <p>Less conclusive evidence to make a decision about the effects of a particular intervention(s) in relation to a specific outcome(s).</p> <p>This may be based on narrative syntheses of review results. In this case, the result is qualified according to the findings of the review - for example, 'some evidence (5 trials of 9) reported a positive effect of'</p> <p>{This would be based on a more equivocal set of results than those obtained for 'sufficient evidence' above. For example, while 12/14 statistically significant trials would be classed as 'sufficient evidence', 5/9 statistically significant trials is more equivocal and would be classes as 'some evidence.'}</p> <p>This may also be based on a statistically significant result obtained in a small number of trials; or a statistically significant result obtained from trials with a small number of participants.</p> |
| <i>Insufficient evidence from trials</i> | <p>Not enough evidence to support conclusions about the effects of the intervention(s) on the basis of the included trials. This should be interpreted as 'no evidence of effect', rather than 'evidence of no effect'.</p> <p>Statistically non-significant results are considered to represent insufficient evidence.</p> <p>Where the number of trials is small, and/or the number of participants included in the trials is small, 'insufficient evidence' might reflect underpowering of the included trials to be able to detect an effect of the intervention.</p> <p>Where the number of trials is large, and/or the number of participants included in these trials is large, 'insufficient evidence' may reflect underlying ineffectiveness of the intervention to affect the outcomes being examined.</p> |
| <i>Insufficient evidence in relation to measurement</i> | <p>Not enough evidence to support conclusions about the effects of the intervention due to a lack of reporting on the specified outcomes.</p> <p>This can be the result of :</p> <p>(i) the review electing not to report on a particular outcome, or set of outcomes, despite being reported by the included trials; or</p> <p>(ii) the review was not able to report on the outcome, as data for the outcome was not reported by the included trials. Note: used for reporting against outcomes only.</p> |
| N/A | <p>Not applicable to the outcome category of interest. Note: used for reporting against outcomes only.</p> |