2019

Regulation of APCP Publications

ASSOCIATION OF PAEDIATRIC CHARTERED PHYSIOTHERAPISTS | apcp.csp.org.uk

REGULATION OF APCP PUBLICATIONS

The Association of Paediatric Chartered Physiotherapists' (APCP) publications include leaflets for care-givers and professionals, clinical guidelines for professionals, as well as information posters to display in health care environments. The aim of this document is to provide a rigorous, standardised process to regulate the information that is included in each of these publications- using evidence-based medicine.

Evidence-based medicine has been defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research [1].

NICE state that 'Clinical guidelines recommend how healthcare professionals should care for people with specific conditions. They can cover any aspect of a condition and may include recommendations about providing information and advice, prevention, diagnosis, treatment and longer-term management' [2].

This document is to be used as a working template for creating or reviewing publications. Once the publication is successfully reviewed/ created- a copy of this completed literature review and PRISMA flow diagram are to be sent to the APCP Publications Officer (office@apcp.org.uk) for storing until the publication is to be reviewed again. The parent leaflets will then be reviewed by three separate parents/ carers who have consented to assist APCP in this process.

It is suggested that first time users of this template read the previously published document by Robinson et al *Guidance for Clinical Guidance* published in the APCP Journal in March 1998 [3].

Please refer to the University of Oxford's Centre for Evidence Based Medicine (CEBM) website http://www.cebm.net for further information/ tutorials on finding evidence and critically appraising evidence [4].

PRODUCING A NEW OR REVIEWING AN EXISTING PUBLICATION

The steps in creating or reviewing a publication are so similar they are outlined together in this document.

Firstly a topic must be clearly defined and based on a clinical need for a publication.

Secondly a working party with the relevant expertise must be formed.

Thirdly the information gathering stage including thorough literature searches must be performed.

Fourthly the evidence must be critically appraised.

Finally the publication can be written/ reviewed based on the evidence available. Below, each of these steps has been expanded to ensure a standardised process is followed.

STEP 1: DEFINE A TOPIC (write on line below)

_____

1. Has the disorder to which these guidelines refer been clearly defined? Y / N

2. Has the level or levels of severity of the disorder to which these guidelines refer been clearly defined? Y / N

3. Has the age range of the child or children to which these guidelines refer been clearly defined? Y / N

4. Is there a clinical need to have a guideline on this population/ will it be transferrable to similar children in the UK? Y / N

If all of these answers are YES – proceed to Step 2

STEP 2: CREATE A WORKING GROUP

A working group should be kept small – a maximum of 3-4 people is recommended.

- 1-2 clinical expert(s) in the field (who has at least 5 years of clinical experience with this population or has done formal research of the population)
- 1 skilled researcher/ proficient in literature searches and analysing the literature
- 1 APCP member keen to learn the skills involved in creating publications

Members of the group: 1: 3:

2: 4:

STEP 3: INFORMATION GATHERING/ FINDING THE EVIDENCE

1. Did the developers carry out a comprehensive, reproducible literature review within the past 12 months? Y / N

2. Were appropriate search terms used? Consider alternative words relevant to the search topic (i.e./ adolescent, young person, teenager)

P – (patient/ problem/ population)	
I – Intervention	
C – (comparison/ control)	
O – (outcome)	

3. Was the search strategy appropriate? Y / N
(Refer to http://www.cebm.net/searching-exercise-warm/ for assistance)

Question part	Question term	Synonyms	
Population	(	OR	) AND
Intervention or indicator	(	OR	) AND
Comparator	(	OR	) AND
Outcome	(	OR	) AND

NOTE: **'*'** is a truncation symbol that means further letters can be added (*child** rather than *children)*
OR finds studies containing either of the specified words/phrases, and broadens your search
AND finds studies containing both specified words/phrases, and narrows your search

Before you search, you should do three things:

- Underline the key terms – those most specific to your question

- Number the PICO elements in order of importance from 1-4
- Think of alternate spellings, synonyms and truncations

http://www.cebm.net/finding-the-evidence/

4. What secondary sources were used? (examples below)
    - NICE
    - U.K.-National Library for Health
    - U.S.-National Guidelines Clearinghouse
    - Canadian Medical Association
    - New Zealand Guidelines Group
    - Structured Abstracts: EBM Online, ACP Journal Club
    - Systematic Reviews: Cochrane Library
    - To search several of the databases simultaneously you can use: www.tripdatabase.com

    Others:
    -
    -
    -
    -

    *It is suggested that both the words Physiotherapy and Physical Therapy are used

5. What primary sources were used?

    - PEDro
    - PubMed
    - OVID MEDLINE
    - CINHAL

    Others:
    -
    -

    *Use methodological filters to target the right type of study.
    For instance PubMED filters for: therapy, diagnosis, prognosis, aetiology.

    http://www.cebm.net/finding-the-evidence/

6. Create a reference list to critically appraise

STEP 4: CRITICALLY APPRAISING THE EVIDENCE

Critical appraisal is the systematic evaluation of clinical research in order to establish:
1. Does the study address a clearly focused question?
2. Does the study use valid methods to address this question?
3. Are the valid results of this study important?
4. Are these valid, important results applicable to my patient or population?

Firstly, rank each paper identified in the literature review according to the Oxford Centre for Evidence-based Medicine 2011 Levels of Evidence Question "Does this intervention help?" [5] http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf

Level 1 Evidence: Either N-of-1 randomised trial OR systematic review of randomized trials

Level 2 Evidence: Either randomised trial OR observational study with dramatic effect

Level 3 Evidence: Non randomized controlled cohort follow-up study

Level 4 Evidence: Either case series OR case control studies OR historical controlled studies

Level 5 Evidence: Mechanism based reasoning

*A Systematic Review is generally better than an individual study. Levels may be graded up if there is a very large effect size [impact] or down if there is a small effect size [impact].

Secondly, review each of the papers ranked using either:

- CEBM Critical Appraisal of therapy articles (Appendix 1)
- CEBM Critical Appraisal of systematic reviews (Appendix 2)

Reference: http://www.cebm.net/critical-appraisal/ accessed on 19.06.2017

Lastly, use the PRISMA 2009 Flow Diagram [6] to summarise the literature review process:

http://prisma-statement.org/PRISMAStatement/FlowDiagram.aspx (Appendix 3)

STEP 5: CREATE THE PUBLICATION

Publications are best in a user-friendly format. Please consider the following:

- Lay vocabulary
- Flow charts
- Bullet points & summaries to highlight important information
- All publications will be available electronically to print from the APCP website
- Leaflets and posters - a full reference list should be provided on the website- but 1-2 representative references can included in the PDF to be printed if required
- Clinical guidelines – full referencing throughout document and reference list are required. Recommendations must be referenced including the level of evidence it's based on.
- The publication does not need to be formatted at this point as the administrator will assist with layout and corporate colours/ fonts

STEP 6: REPORT BACK TO EVIDENCE-BASED OFFICER

Once the publication is successfully reviewed/ created, please email the following documents to research@apcp.org.uk:

- This completed template including the PICO search
- All of the CEBM critical appraisal forms for the included papers
- Completed PRISMA flow diagram

STEP 7: PARENT/ CARER FEEDBACK

- Once the leaflet review process has been successfully reviewed by the Publications Officer, and the revised leaflet has been formatted by APCP Administrator, the working party needs to provide three parent/ carers reviews of the content/ wording of the revised leaflet prior to publication on website - please see **Appendix 4** for the standardised questions
- This information needs to be reviewed by APCP Administrator for any potential actions needed on layout

STEP 8: STORING OF THE INFORMATION

- The revised leaflet will be published on the APCP website including the reference list used in the review process

- The APCP Administrator will store the review file so it is available to the next working party to review the leaflet

REFERENCES

[1] Sackett D.L., Straus S.E., Richardson W.S., Rosenberg W., Haynes R.B., Evidence based medicine: How to practice and teach E.B.M. 2nd edition Churchill Livingstone London, 2000 page 246.
[2] National Institute for Health and Care Excellence https://www.nice.org.uk/about/what-we-do/ourprogrammes/nice-guidance/nice-guidelines/types-of-guideline accessed 7.05.2017
[3] Robinson T., Kinley E., Jackson C., Poutney T. Guidelines for Clinical Guidelines. APCP Journal.1998
[4] University of Oxford's Centre for Evidence Based Medicine (CEBM) website, Nuffield Department of Primary Care Health Sciences: http://www.cebm.net accessed 19.06.2017
[5] Levels of Evidence Working Group: Howick J., Chalmers I., Glasziou P., Greenhalg T., Heneghan C., Liberati A., Moschetti I., Phillips B., Thornton H., Goddard O., Hodgkinson M. The Oxford Levels of Evidence 2. EBM.http:/www.cebm.net/index.aspx?0=5653
[6] Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses:
The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

APPENDIX 1: CEBM CRITICAL APPRAISAL OF THERAPY ARTICLES [4]
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THERAPY STUDY: Are the results of the trial valid? (Internal Validity)

What question did the study ask?

Patients –

Intervention -

Comparison -

Outcome(s) –

1a. R- Was the assignment of patients to treatments <u>randomised</u>?	
What is best?	Where do I find the information?
Centralised computer randomisation is ideal and often used in multi-centred trials. Smaller trials may use an *independent* person (e.g, the hospital pharmacy) to "police" the randomization.	The ***Methods*** should tell you how patients were allocated to groups and whether or not randomisation was concealed.
This paper: Yes □ No □ Unclear □ Comment:	
1b. R- Were the groups <u>similar</u> at the start of the trial?	
What is best?	Where do I find the information?
If the randomisation process worked (that is, achieved comparable groups) the groups should be similar. The more similar the groups the better it is. There should be some indication of whether differences between groups are statistically significant (ie. p values).	The ***Results*** should have a table of "Baseline Characteristics" comparing the randomized groups on a number of variables that could affect the outcome (ie. age, risk factors etc). If not, there may be a description of group similarity in the first paragraphs of the ***Results*** section.
This paper: Yes □ No □ Unclear □ Comment:	
2a. A – Aside from the allocated treatment, were groups treated equally?	
What is best?	Where do I find the information?

Apart from the intervention the patients in the different groups should be treated the same, e.g. additional treatments or tests.	Look in the ***Methods*** section for the follow-up schedule, and permitted additional treatments, etc. and in ***Results*** for actual use.
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	
2b. A – Were all patients who entered the trial accounted for? – And were they analysed in the groups to which they were randomised?	
What is best?	Where do I find the information?
Losses to follow-up should be minimal – preferably less than 20%. However, if few patients have the outcome of interest, then even small losses to follow-up can bias the results. Patients should also be analysed in the groups to which they were randomised – '*intention-to-treat analysis'*.	The ***Results*** section should say how many patients were randomised (e.g. Baseline Characteristics table) and how many patients were actually included in the analysis. You will need to read the results section to clarify the number and reason for losses to follow-up.
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	
3. M - Were measures <u>objective</u> or were the patients and clinicians kept "<u>blind</u>" to which treatment was being received?	
What is best?	Where do I find the information?
It is ideal if the study is 'double-blinded' – that is, both patients and investigators are unaware of treatment allocation. If the outcome is *objective* (e.g. death) then blinding is less critical. If the outcome is *subjective* (e.g. symptoms or function) then blinding of the outcome assessor is critical.	First, look in the ***Methods*** section to see if there is some mention of masking of treatments, e.g. placebos with the same appearance or sham therapy. Second, the ***Methods*** section should describe how the outcome was assessed and whether the assessor/s were aware of the patients' treatment.
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	

What were the results?

1. How large was the treatment effect?	
Most often results are presented as dichotomous outcomes (yes or no outcomes that happen or don't happen) and can include such outcomes as cancer recurrence, myocardial infarction and death. Consider a study in which 15% (0.15) of the control group died and 10% (0.10) of the treatment group died after 2 years of treatment. The results can be expressed in many ways as shown below.	
What is the measure?	**What does it mean?**
Relative Risk (RR) = risk of the outcome in the treatment group / risk of the outcome in the control group. In our example, the RR = 0.10/0.15 = 0.67	The relative risk tells us **how many times more likely** it is that an event will occur in the treatment group relative to the control group. An **RR** of **1** means that there is no difference between the two groups thus, the treatment had **no effect**. An RR < 1 means that the treatment decreases the risk of the outcome. An RR > 1 means that the treatment increased the risk of the outcome. Since the RR < 1, the treatment decreases the risk of death.
Absolute Risk Reduction (ARR) = risk of the outcome in the control group - risk of the outcome in the treatment group. This is also known as the **absolute risk difference.** In our example, the ARR = 0.15 - 0.10 = 0.05 or 5%	The absolute risk reduction tells us the absolute difference in the rates of events between the two groups and gives an indication of the baseline risk and treatment effect. An **ARR** of **0** means that there is no difference between the two groups thus, the treatment had **no effect**. The absolute benefit of treatment is a 5% reduction in the death rate.
Relative Risk Reduction (RRR) = absolute risk reduction / risk of the outcome in the control group. An alternative way to calculate the RRR is to subtract the RR from 1 (eg. RRR = 1 - RR) In our example, the RRR = 0.05/0.15 = 0.33 or 33% Or RRR = 1 - 0.67 = 0.33 or 33%	The relative risk reduction is the complement of the RR and is probably the most commonly reported measure of treatment effects. It tells us the reduction in the rate of the outcome in the treatment group relative to that in the control group. The treatment reduced the risk of death by 33% relative to that occurring in the control group.

Number Needed to Treat (NNT) = inverse of the ARR and is calculated as 1 / ARR.	The number needed to treat represents the number of patients we need to treat with the experimental therapy in order to prevent 1 bad outcome and incorporates the duration of treatment. Clinical significance can be determined to some extent by looking at the NNTs, but also by weighing the NNTs against any harms or adverse effects (NNHs) of therapy.
In our example, the NNT = 1/ 0.05 = 20	We would need to treat 20 people for 2 years in order to prevent 1 death.

2. How precise was the estimate of the treatment effect?

The true risk of the outcome in the population is not known and the best we can do is estimate the true risk based on the sample of patients in the trial. This estimate is called the **point estimate**. We can gauge how close this estimate is to the true value by looking at the confidence intervals (CI) for each estimate. If the confidence interval is fairly narrow then we can be confident that our point estimate is a precise reflection of the population value. The confidence interval also provides us with information about the statistical significance of the result. If the value corresponding to **no effect** falls outside the 95% confidence interval then the result is statistically significant at the 0.05 level. If the confidence interval includes the value corresponding to **no effect** then the results are not statistically significant.

Will the results help me in caring for my patient? (External Validity/Applicability)

The questions that you should ask before you decide to apply the results of the study to your patient are:

- Is my patient so different to those in the study that the results cannot apply?
- Is the treatment feasible in my setting?
- Will the potential benefits of treatment outweigh the potential harms of treatment for my patient?

APPENDIX 2: CEBM CRITICAL APPRAISAL OF SYSTEMATIC REVIEWS [4]

SYSTEMATIC REVIEW: Are the results of the review valid?

What question (PICO) did the systematic review address?	
What is best?	Where do I find the information?
The main question being addressed should be clearly stated. The exposure, such as a therapy or diagnostic test, and the outcome(s) of interest will often be expressed in terms of a simple relationship.	The ***Title, Abstract*** *or final paragraph of the* ***Introduction*** should clearly state the question. If you still cannot ascertain what the focused question is after reading these sections, search for another paper!
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	
F - Is it unlikely that important, relevant studies were missed?	
What is best?	Where do I find the information?
The starting point for comprehensive search for all relevant studies is the major bibliographic databases (e.g., Medline, Cochrane, EMBASE, etc) but should also include a search of reference lists from relevant studies, and contact with experts, particularly to inquire about unpublished studies. The search should not be limited to English language only. The search strategy should include both MESH terms and text words.	The ***Methods*** section should describe the search strategy, including the terms used, in some detail. The ***Results*** section will outline the number of titles and abstracts reviewed, the number of full-text studies retrieved, and the number of studies excluded together with the reasons for exclusion. This information may be presented in a figure or flow chart.
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	

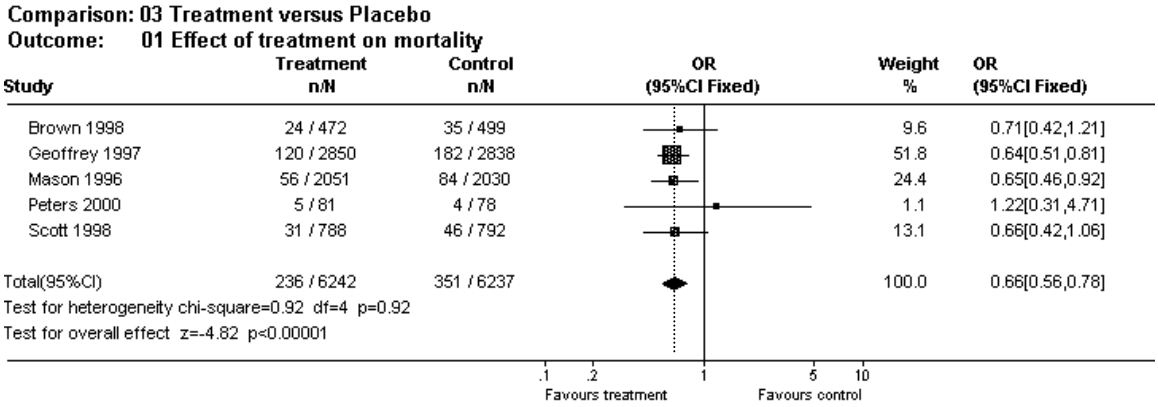
A - Were the criteria used to select articles for inclusion appropriate?	
What is best?	Where do I find the information?
The inclusion or exclusion of studies in a systematic review should be clearly defined a priori. The eligibility criteria used should specify the patients, interventions or exposures and outcomes of interest. In many cases the type of study design will also be a key component of the eligibility criteria.	The ***Methods*** section should describe in detail the inclusion and exclusion criteria. Normally, this will include the study design.
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	

A - Were the included studies sufficiently valid for the type of question asked?	
What is best?	Where do I find the information?
The article should describe how the quality of each study was assessed using predetermined quality criteria appropriate to the type of clinical question (e.g., randomization, blinding and completeness of follow-up)	The ***Methods*** section should describe the assessment of quality and the criteria used. The ***Results*** section should provide information on the quality of the individual studies.
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	

T - Were the results similar from study to study?	
What is best?	Where do I find the information?
Ideally, the results of the different studies should be similar or homogeneous. If heterogeneity exists the authors may estimate whether the differences are significant (chi-square test). Possible reasons for the heterogeneity should be explored.	The ***Results*** section should state whether the results are heterogeneous and discuss possible reasons. The forest plot should show the results of the chi-square test for heterogeneity and if discuss reasons for heterogeneity, if present.
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	

How are the results presented?

A systematic review provides a summary of the data from the results of a number of individual studies. If the results of the individual studies are similar, a statistical method (called meta-analysis) is used to combine the results from the individual studies and an overall summary estimate is calculated. The meta-analysis gives weighted values to each of the individual studies according to their size. The individual results of the studies need to be expressed in a standard way, such as relative risk, odds ratio or mean difference between the groups. Results are traditionally displayed in a figure, like the one below, called a **forest plot.**



The forest plot depicted above represents a meta-analysis of 5 trials that assessed the effects of a hypothetical treatment on mortality. Individual studies are represented by a black square and a horizontal line, which corresponds to the point estimate and 95% confidence interval of the odds ratio. The size of the black square reflects the weight of the study in the meta-analysis. The solid vertical line corresponds to 'no effect' of treatment - an odds ratio of 1.0. When the confidence interval includes 1 it indicates that the result is not significant at conventional levels (P>0.05).

The diamond at the bottom represents the combined or pooled odds ratio of all 5 trials with its 95% confidence interval. In this case, it shows that the treatment reduces mortality by 34% (OR 0.66 95% CI 0.56 to 0.78). Notice that the diamond does not overlap the 'no effect' line (the confidence interval doesn't include 1) so we can be assured that the pooled OR is statistically significant. The test for overall effect also indicates statistical significance (p<0.0001).

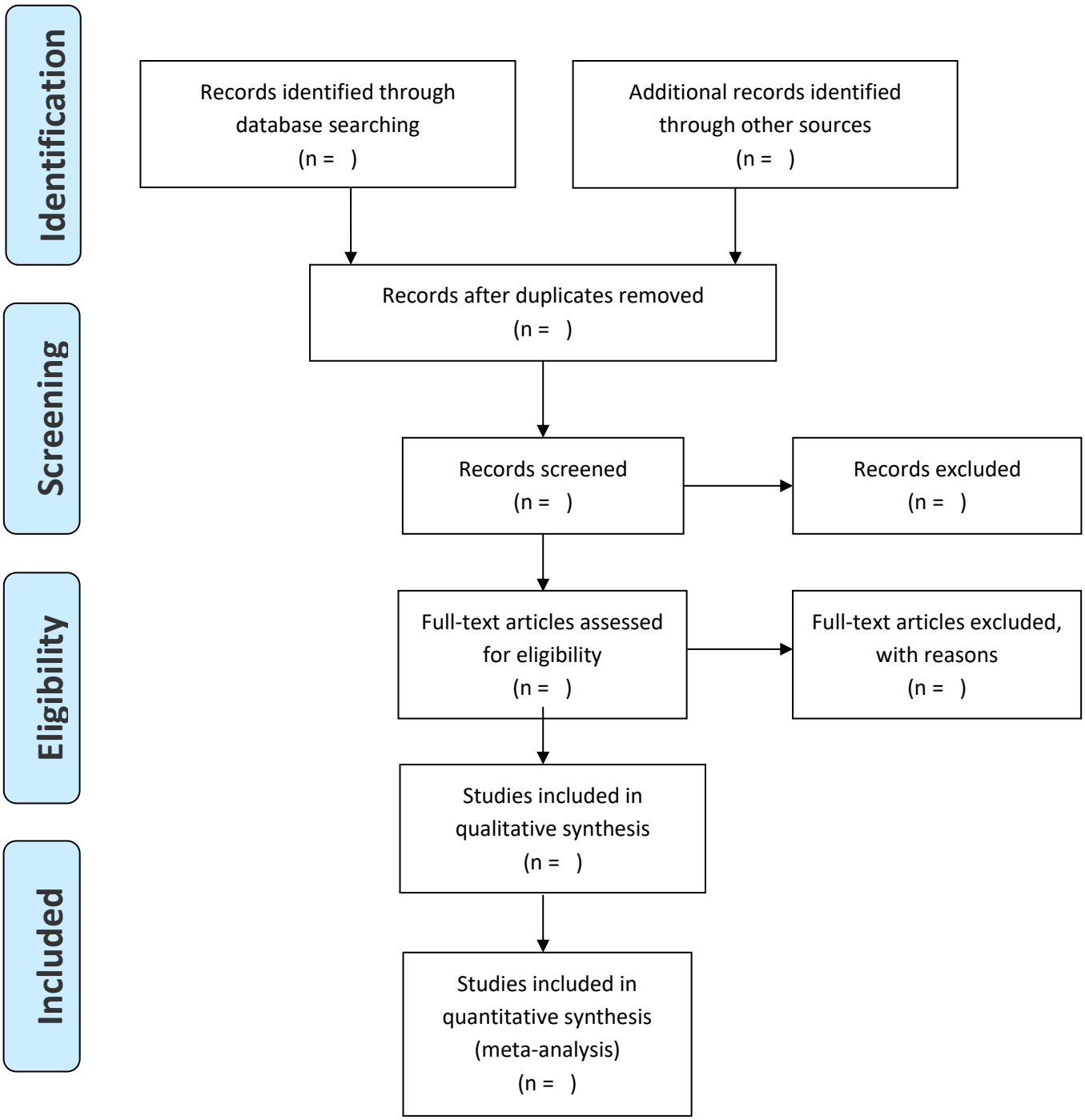
Exploring heterogeneity

Heterogeneity can be assessed using the "eyeball" test or more formally with statistical tests, such as the Cochran Q test. With the "eyeball" test one looks for overlap of the confidence intervals of the trials with the summary estimate. In the example above note that the dotted line running vertically through the combined odds ratio crosses the horizontal lines of all the individual studies indicating that the studies are homogenous. Heterogeneity can also be assessed using the Cochran chi-square (Cochran Q). If Cochran Q is statistically significant there is definite heterogeneity. If Cochran Q is not statistically significant but the ratio of Cochran Q and the degrees of freedom (Q/df) is > 1 there is possible heterogeneity. If Cochran Q is not statistically significant and Q/df is < 1 then heterogeneity is very unlikely. In the example above Q/df is <1 (0.92/4= 0.23) and the p-value is not significant (0.92) indicating no heterogeneity.

Note: The level of significance for Cochran Q is often set at 0.1 due to the low power of the test to detect heterogeneity.

APPENDIX 3: PRISMA 2009 Flow Diagram [6]

PRISMA 2009 Flow Diagram



Reference: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

APPENDIX 4: PARENT/ CARER FEEDBACK QUESTIONS

Name of Leaflet:

Date:

Name of Parent/ Carer:

Question 1:
This leaflet includes relevant and appropriate information for the audience

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

Question 2:
The leaflet uses language that is easy to read and understand by the audience

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

Question 3:
Do you have any additional comments regarding the leaflet?

Acknowledgements

The Association of Paediatric Physiotherapists would like to thank Jennifer McCahill for her work on producing these guidelines.