**Writing your Cochrane review**

**Things to do before writing up the draft review**

* If Janne (janne.vendt@regionh.dk) hasn't helped design your search strategy, then you should send the strategy to her for comments as soon as they have designed it – before you run the searches and especially before you start screening the references. It is often too late to make larger changes to a search strategy when Janne see it as a reviewer. If you have made minor mistakes it can usually easily be changed before publication, but if there are problems with the structure of the searches, you will need to rerun the searches and the screening, which is a huge task. Much better to eliminate errors early on in the process.
* Make sure you have updated your rm5 to RevMan 5.3.5 (http://tech.cochrane.org/revman/download)
* Once you do this, make sure that your version of RevMan (5.3.5) is displaying the MECIR standards pane - to do this go to the tool bar - click on 'view' - a drop down menu will appear. Make sure there is a tick bext to 'guidance box' . MECIR guidance will now appear in the right hand of your screen.
* You should check your review against the MECIR standards (you do this in RevMan by placing your cursor at the end of the relevant section (for example abstract objectives – the instructions for that section will appear in the pane on the right)
* If you still have problems please look at the pdf version <http://methods.cochrane.org/sites/default/files/public/uploads/Cochrane%20MECIR_Standards%20FINAL%20booklet_web_version.pdf>
* Be aware ALL Cochrane authors must make sure they use the MECIR standards for conducting, reporting and updating Cochrane reviews

**Training/useful resources**

* Online training is available at http://community.cochrane.org/news/connecting-online-training-cochranes-directions-systematic-reviews
* The online training offers Interactive learning courses for new and experienced systematic review authors http://training.cochrane.org/interactivelearning
* You can earn a certificate for each module successfully completed. We would like a copy of any certificates obtained for our records
* The online training offers a series of monthly webinars aimed at anyone interested in learning skills or gaining knowledge and experience relating to Cochrane activities. The series is managed by Cochrane’s Learning and Support Department. The webinars are open to anyone wanting to learn in the Cochrane environment, be they complete beginners or seasoned experts. http://training.cochrane.org/cochrane-learning-live-webinar-programme
* The online training offers a set of learning resources to help you understand GRADE http://training.cochrane.org/path/grade-approach-evaluating-quality-evidence-pathway
* Once you have your search results, you may proceed with study selection and data collection. We would recommend you to use Covidence http://community.cochrane.org/tools/review-production-tools/covidence for the next stage of review production. The Covidence tool assists authors screening the search results to identify the included studies, carry out risk of bias assessment and data extraction. The information and data collected can then be uploaded directly into your review via RevMan 5.
* You may also find it useful to use GRADEpro GDT https://gradepro.org/ to complete your GRADE assessments and Summary of Findings tables

**Your review**

* Make sure that you generate a summary of findings table BEFORE you write the review.
* Make sure that what is in your summary of findings table(s) accurately reflects what is in your review and that you use the summary of findings table to write the abstract, plain language summary and discussion.
* There should be one SOF table per clinically important comparison
* If an outcome is important enough to be in the abstract then it should be in the summary of findings table and vice versa.
* The primary outcome should always be in the summary of findings table (whether studies were found or not) [Abstract results: findings R12, Mandatory: Report findings for all primary outcomes, irrespective of the strength and direction of the result, and of the availability of data. Details Findings should typically include concise information about the quality of the body of evidence for the outcome (such as study limitations, consistency of effect, imprecision, indirectness and publication bias), for example using GRADE. Outcomes should not be selected solely on the basis of the findings. If no studies measured the primary outcomes, then a comment should be made to that effect.]
* Adverse events should be in the SOF table
* Make sure you have incorporated grade in your review (see sources of support (under summary of findings table section). In particular make sure you:
* *Have described the methods for assessing the quality of the evidence under the ‘Data collection & analysis’ section of protocols and full reviews.*
* *Explained decisions about the quality of the evidence in reporting of results.*
* *Incorporated information about the quality of evidence in the Discussion.*
* *Drawn on quality of evidence ratings when summarizing and interpreting the results e.g. abstracts, plain language summaries and implications for practice sections*
* *Make sure that you inform the reader if you downgraded an item. (If you do not understand what I mean by this then read the attached ‘Introduction to summary of findings’ and the SOF statistics documents.*
* Make sure to run a status report (instructions on how to run one on page 63 RevMan user guide). Check that the numbers in the status report match up with what you state in your text and search flow figure
* Create a preview publication pdf version, and check that what you state in the review is accurate. (To create such a pdf open the review in rm5.3.5 then go to tool bar – now click on file – a drop menu will appear – choose the option ‘published pdf preview’. It will take a few minutes to generate. Once you have created a pdf preview either print it off or perhaps send to an ipad or another device. Then check the pdf preview against the rm5 version.) The preview publication pdf mimics the published version. The tables and figures appear where they will be in the published pdf. So for example SOF table one appears under the abstract and plain language summary and the search flow diagram underneath the search results section. It makes it easy to check that you what you state in the text matches up with what you state in the tables and figures and vice versa. (It also makes it easier for a reader to spot where there are inconsistencies.)
* Check your review against the validation report (page 63 RevMan user guide).
* Do a spell check (page 78 RevMan userguide)
* Make sure that you double check the numbers of participants, search results etc
* Make sure you are referring to the latest version of RevMan and the Handbook and have referenced them
* Finally check your review against the attached review submission checklist
* **Now go through the instructions for each individual section of the review below**

**Title**

* Is the title still the same as in the published protocol?
* If it has changed make a note of the change in the section 'differences between protocol and review'
* Make sure the title matches the review’s PICOs.

**Dates**

* You need to update this section.
* The date of search should be the same as the assessed as up to date section
* Be aware that the date of search indicates how up to date the review is
* So, make sure the two entries have the same date

**What’s new**

* There should be no entries in this section
* If entries were published (ie we published an amended version of the protocol) then move them to ‘history’

**Abstract**

* The abstract can between 700 and 1000 words in length

**Background**

* R4, Mandatory Summarize the rationale and context of the review.

**Objectives**

* R5, Mandatory: State the main objective(s), preferably in a single concise sentence
* The objective(s) should be expressed in terms that relate to the population(s), intervention comparison(s) and, where appropriate, outcomes of interest.
* Please be aware that the abstract objectives should be identical to those of the main review -word for word.

**Search methods**

* Provide the date of the last search from which records were evaluated and any studies identified were incorporated into the review, and an indication of the databases and other sources searched.
* The date of the search indicates how up to date the review is.
* Ideally the search should be no older than six months old when the review is submitted for the editorial process
* State whether trial registries have been searched

**Selection criteria**

* R7, Mandatory: Summarize eligibility criteria of the review, including information on study design, population and comparison.
* Any extensions to eligibility criteria to address adverse effects, economic issues or qualitative research should be mentioned.

**Data collection and analysis**

* Summarize any noteworthy methods for selecting studies, collecting data, evaluating risk of bias and synthesizing findings. For many reviews it may be sufficient to state “We used Cochrane’s standard methodological procedures.”

**Main results**

* The total number of included studies should be stated. It might be appropriate to provide numbers of studies and participants for specific comparisons and main outcomes if the amount of evidence differs substantially from the total. Numbers of participants analysed should generally be presented in preference to numbers recruited (e.g. randomized); more important is to be clear which numbers are being reported. For some types of data there may be preferable alternatives to the number of participants (e.g. person-years of follow-up, number of limbs)
* Provide a brief description of key characteristics that will determine the applicability of the body of evidence (e.g. age, severity of condition, setting, study duration)
* Provide a comment on the findings of the bias assessment
* If an outcome is important enough to be in the abstract then it should be in the summary of findings table and vice versa.
* The primary outcome should always be in the summary of findings table and therefore the abstract, whether studies were found or not
* Adverse events should be in the abstract and SOF table. If adverse effects data were sought, but availability of data was limited, this should be reported
* You should state the number of participants, the number of studies and the quality of the evidence for each outcome in the abstract. See the example at end of this section
* It is good practice to place emphasis on magnitude and precision of the estimated effect.
* It is good practice to describe the quality of evidence as high/moderate/low/very low as indicated from GRADE rating
* Present summaries of statistical analyses in the same way as they are reported in the review and in a standard way, ensuring that readers will understand the direction of benefit and the measurement scale used, and that confidence intervals are included where appropriate

**Example**

“We included eight new studies (617 participants) in this updated review. In total we included 17 studies (1493 participants). A total of 15 trials provided data for the meta-analyses. We judged only two trials as low risk of bias. The majority of studies included participants undergoing cardiac surgery.

We found six ongoing trials but were unable to retrieve any data from them. Compared with transfusion guided by any method, TEG or ROTEM seemed to reduce overall mortality (7.4% versus 3.9%; risk ratio (RR) 0.52, 95% CI 0.28 to 0.95; I2 = 0%, 8 studies, 717 participants, low quality of evidence) but only eight trials provided data on mortality, and two were zero event trials. Our analyses demonstrated a statistically significant effect of TEG or ROTEM compared to any comparison on the proportion of participants transfused with pooled red blood cells (PRBCs) (RR 0.86, 95% CI 0.79 to 0.94; I2 = 0%, 10 studies, 832 participants, low quality of evidence), fresh frozen plasma (FFP) (RR 0.57, 95% CI 0.33 to 0.96; I2 = 86%, 8 studies, 761 participants, low quality of evidence), platelets (RR 0.73, 95% CI 0.60 to 0.88; I2 = 0%, 10 studies, 832 participants, low quality of evidence), and overall haemostatic transfusion with FFP or platelets (low quality of evidence). Meta-analyses also showed fewer participants with dialysis-dependent renal failure.”

**Authors’ conclusions**

* State key conclusions drawn
* Ensure that all three conclusions (abstract, PLS and main review) are consistent with one another
* This section must incorporate GRADE
* This is an example of what we are looking for

Example

“There is growing evidence that application of TEG- or ROTEM-guided transfusion strategies may reduce the need for blood products, and improve morbidity in patients with bleeding. However, these results are primarily based on trials of elective cardiac surgery involving cardiopulmonary bypass, and the level of evidence remains low. Further evaluation of TEG- or ROTEM-guided transfusion in acute settings and other patient categories in low risk of bias studies is needed.”

**Finally make sure you cover all of these points in your abstract**

☐ Does the title reflect the review question?

☐ Is the research question (PICO) clear and the rationale for the review well described?

☐ Is the search date less than 12 months from publication?

☐ Does the abstract indicate that trials registers were searched?

☐ Are the eligible study designs described in the abstract appropriate to the review question?

☐ Are the findings for all important outcomes reported for the main comparison(s), including information about adverse effects? (i.e. consistent with the outcomes reported in the SoF table)

☐ Is there an estimation of the certainty (or quality) of the body of evidence using GRADE for each outcome reported in the abstract?

☐ Are harms (or the absence of harms) reported?

☐ Are the direction, magnitude and confidence intervals of effects clearly described where appropriate?

☐ Does the reporting of results avoid reliance on emphasizing on statistical significance to determine presence or absence of an effect?

☐ Are the conclusions an accurate reflection of the evidence presented in the GRADE SoF table(s)?

☐ Do the authors avoid making recommendations?

**Plain language summary**

* You need to look at the MECIR standards (see the pane in RevMan) and make sure your PLS complies with those standards.
* The title can be no more than 150 characters
* The text can be between 400 and 700 words in length
* I have inserted the headings shown in the MECIR standards
* Make sure you state the total number of studies and participants, and the total included in the analysis
* State when the evidence is current (for example the evidence is current to July 2016)
* Make sure you incorporate grade in your PLS (state what the quality of the evidence is)
* Ensure that the key messages of the review are reported consistently between the plain language summary, the main text of the review including the abstract, ‘Summary of findings’ tables, and authors’ conclusions
* Make sure you use simple plain English

**Background**

* Update this section (make sure references are up to date).
* Be aware that there are four subheadings in the background section (description of the condition, description of the intervention; how the intervention might work; why it is important to do this review)
* Text must appear under those subheadings rather than under the main heading (background)

**Objectives**

* See notes on abstract objectives

**Methods section**

* General:
* Make sure you refer to the latest version of RevMan: Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.
* Make sure you change the text from the future tense to the past. (You are describing what you plan to do in a protocol and what you have done in the review)
* Make sure you note all changes to the published protocol in the ‘Differences between protocol and review’ section

**Types of studies, types of participants, types of intervention**

* Make sure you note all changes in the ‘Differences between protocol and review’ section

**Outcome Measures**

* (The primary outcomes must appear in the summary of findings table even if no studies report on them)
* Make sure you use the same terms for the outcomes throughout the review (abstract, PLS, tables (SOF and analysis))
* Make sure you define how you will measure your outcomes (Explain how multiple variants of outcome measures (e.g. definitions, assessors, scales, time points) are addressed. MECIR conduct standard 14 (Define in advance which outcomes are primary outcomes and which are secondary outcomes.) Also MECIR conduct standards 15 – 18.)
* Make sure you note all changes in the ‘Differences between protocol and review’ section

**Search methods for identification of studies**

**Electronic searches**

* You should list all sources searched, including: databases, trials registers, web sites and grey literature. Database names should include platform/provider name and dates of coverage; web sites should include full name and URL.
* You need to state that there are no language restrictions
* You need to provide a link to the search terms, for each of the databases you searched, which should be stored in the appendices
* Make sure you note all changes in the ‘Differences between protocol and review’ section
* We now have an information specialist (Janne Vendt: janne.vendt@regionh.dk). However, be aware that the Information Specialist's role has changed. Janne will not routinely design searches or search all databases for authors. Janne will facilitate and check that the searches are adequate. She will keep our clinical database up to date. She will only run a search for an author in an exceptional circumstance - for example if the database is not available in that person's country.

**The text below is a suggestion/checklist. Authors are welcome to change the wording or add extra information about handsearching, extra databases etc.**

**Electronic searches**

We searched for studies with systematic and sensitive search strategies as described in the Cochrane Handbook of Systematic reviews of Interventions Chapter 6 (Higgins 2011).
There were no language, publication year or publication status restrictions.

We searched the following databases:

* Cochrane Central Register of Controlled Trials (CENTRAL) (latest Issue)
* MEDLINE (Ovid SP, 1946-Date)
* EMBASE (Ovid SP, 1974-Date)
* Web of Science (1945-Date)
* And other relevant databases? CINAHL, PsycInfo, Biosis, Scopus, LILACS etc.

We developed a subject-specific search strategy in MEDLINE and modified it appropriately for the other databases.

Where appropriate, we used the highly sensitive search strategy designed by Cochrane for identifying RCTs and controlled clinical trials as described in the Cochrane Handbook for Systematic Reviews of Interventions Chapter 6 (Lefebvre 2011).

Search strategies can be found in Appendix 1 (LINK).
Searches were last run (STATE DATE)

 **Searching other resources**We checked the bibliographic references and citations of relevant studies and reviews for further references to trials.

We also searched ClinicalTrials.gov ([www.clinicaltrials.gov](http://www.clinicaltrials.gov/)), the World Health Organization International Clinical Trials Registry Platform ([apps.who.int/trialsearch/](http://apps.who.int/trialsearch/)) and ISRCTN (http://www.isrctn.com/) for unpublished and ongoing studies and Open Grey (http://opengrey.eu/) for grey literature. (STATE DATE).

We screened the first 200 references of a targeted search in Google Scholar as in our experience the yield after 200 hits is limited.

When necessary we contacted trial authors for additional information.
The search strategy was developed in consultation with the Information Specialist.

(Relevant references

Example: Higgins JP, Green S, editor(s). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.)

Reference type Other

Authors Higgins JP, Green S, editor(s)

English title Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011

Journal/book/source Available from handbook.cochrane.org

Example: Lefebvre C, Manheimer E, Glanville J. Chapter 6: Searching for studies. In: Higgins JP, Green S, editor(s). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Reference type Other

Authors Lefebvre C, Manheimer E, Glanville J

English title Chapter 6: Searching for studies. In: Higgins JP, Green S, editor(s). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011

Journal/book/source Available from handbook.cochrane.org

**Data collection and analysis**

* This section of the review contains 12 subheadings (Selection of studies; Data extraction and management ; Assessment of risk of bias in included studies; measures of treatment effect; unit of analysis issues; dealing with missing data; assessment of heterogeneity; assessment of reporting biases; data synthesis; subgroup and investigation of heterogeneity; sensitivity analysis and summary of findings and GRADE).
* Text must appear under each subheading. Please refer to the handbook (see instructions above on how to access handbook easily in RevMan) and the MECIR standards.
* Make sure you note all changes in the ‘Differences between protocol and review’ section

**Selection of studies**

* In brief this section should state the method used to apply the selection criteria. Whether they are applied independently by more than one author should be stated, along with how any disagreements are resolved.

**Data extraction and management**

* In brief this section should state the method used to extract or obtain data from published reports or from the original researchers (for example, using a data collection form). Whether data are extracted independently by more than one author should be stated, along with how any disagreements are resolved. If relevant, methods for processing data in preparation for analysis should be described.

**Assessment of risk of bias in included studies**

* In brief this section should state the method used to assess risk of bias (or methodological quality). Whether methods are applied independently by more than one author should be stated, along with how any disagreements are resolved. The tool(s) used should be described or referenced, with an indication of how the results are incorporated into the interpretation of the results
* It is good practice to acknowledge that for some interventions, performance bias is inevitable

**Measures of treatment effects**

* This section should state the effect measures used by the review authors to describe effect sizes (e.g. risk ratio, mean difference) in any included studies and/or meta-analyses.
* Be aware that Cochrane reviews no longer refer to relative risk but instead to risk ratio. Make this change throughout the review

**Unit of analysis issues**

* This section should detail special issues in the analysis of studies with non-standard designs, such as cross-over trials and cluster-randomized trials, should be described.

**Dealing with missing data**

* This section should explain how missing outcome data were handled. It should describe how assumptions are applied for missing data, e.g. last observation carried forward, or assumptions of particular values such as worst-case or best-case scenarios.

**Assessment of heterogeneity**

* Approaches to addressing clinical heterogeneity should be described, along with how the authors will determine whether a meta-analysis is considered appropriate. Methods for identifying statistical heterogeneity should be stated (e.g. visually, using I2, using a chi-squared test)

**Assessment of reporting biases**

* This section should describe how publication bias and other reporting biases are addressed (for example, funnel plots, statistical tests, imputation). Authors should remember that asymmetric funnel plots are not necessarily caused by publication bias (and that publication bias does not necessarily cause asymmetry in a funnel plot).

**Data synthesis**

* The choice of meta-analysis method should be stated, including whether a fixed-effect or a random-effects model is used. If meta-analyses are not undertaken, systematic approaches to synthesizing the findings of multiple studies should be described.

**Subgroup analysis and investigation of heterogeneity**

* All planned subgroup analyses should be listed (or independent variables for meta-regression). Any other methods for investigating heterogeneity of effects should be described.
* If subgroup analysis (or meta-regression) was performed, state the potential effect modifiers with rationale for each, stating whether each was defined a priori or post hoc. Details: MECIR conduct standard 22 (Pre-define potential effect modifiers (e.g. for subgroup analyses) at the protocol stage; restrict these in number; and provide rationale for each.) [PRISMA item 16]

Sensitivity analysis

* This section should describe analyses aimed at determining whether conclusions are robust to decisions made during the review process, such as inclusion/exclusion of particular studies from a meta-analysis, imputing missing data or choice of a method for analysis.

**Summary of findings table and GRADE**

* This section should describe the methods used to prepare any ‘Summary of findings’ tables. It should include information about (i) which populations (including  the specification of low, medium or high risk populations), interventions and comparisons are being addressed by one or more ‘Summary of findings’ tables, and why; (ii) the source of any external information used in the ‘Assumed risk’ column; (iii) a brief comment that the GRADE approach to assessing the quality of  the body of evidence is being used; and (iv) any departures from the standard methods described in Chapter [11](file:///C%3A%5CUsers%5CJCRA0002%5CDesktop%5CJane%20making%20it%20easy%5CEditing%5Cchapter_11%5C11_presenting_results_and_summary_of_findings_tables.htm) and Chapter [12](file:///C%3A%5CUsers%5CJCRA0002%5CDesktop%5CJane%20making%20it%20easy%5CEditing%5Cchapter_12%5C12_interpreting_results_and_drawing_conclusions.htm), along with a justification for such departures. The review’s main outcomes, i.e. those intended for inclusion in the ‘Summary of findings’ table, should have been listed under the section ‘Types of outcome measures’.
* Remember you can study no more than seven outcomes. You need to include the primary outcomes, any adverse outcomes and any outcomes of interest
* You should include a new summary of findings table for each comparison of interest (most important comparisons only)
* Look at the ‘create a SOF’ and ‘introduction to SOF tables’ documents which will help you generate such a table
* Make sure you note all changes in the ‘Differences between protocol and review’ section

Here is an example of what we expect to appear in this section

*We developed a 'Summary of findings' table highlighting the quality of evidence in six major outcomes, namely, clinically diagnosed sepsis, CRBSI, all-cause mortality, catheter colonization, catheter-related local infection and adverse effects (combined). We used the five GRADE criteria (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of evidence relating to the studies that contributed data to the meta-analyses for each of these six outcomes. When we identified an issue that we considered to be serious in each of the five GRADE criteria, we downgraded the quality of evidence by one level, and when we considered the issue to be very serious, we downgraded the quality of evidence by two levels. Whenever we decided to downgrade the quality of evidence from the default high quality, we justified our decisions and described the level of downgrade in the footnotes of the table. We developed the 'Summary of findings' table using a web-based version of the GRADEpro software (*[*http://www.guidelinedevelopment.org/*](http://www.guidelinedevelopment.org/)*), according to the methods and recommendations described in Section 8.5 and Chapter 12 of the Cochrane Handbook for Systematic Reviews of Interventions (*[*Higgins 2011*](https://archie.cochrane.org/sections/documents/view?version=z1603031414479382601553428717799&format=REVMAN_GRAPHS#REF-Higgins-2011)*). (Taken from Lai NM, Chaiyakunapruk N, Lai NA, O'Riordan E, Pau WS, Saint S. Catheter impregnation, coating or bonding for reducing central venous catheter-related infections in adults. Cochrane Database of Systematic Reviews 2016 , Issue 3 . Art. No.: CD007878. DOI: 10.1002/14651858.CD007878.pub3)*

**Results**

**Description of the studies**

* There should be no text under the headings ‘Results’ and ‘Description of the studies’

**Results of the search**

* Text should appear under this heading
* ACE expects authors to include in their draft review a figure explaining how your papers were found. It is possible to generate a flow diagram within RevMan (and we recommend that you do so as it is possible to edit this figure within Revman). That figure should be linked to this section

**Included studies**

* MECIR standard R61, Mandatory: Provide a brief narrative summary of any included studies. This should include the number of participants and a summary of the characteristics of the study populations and settings, interventions, comparators and funding sources. See Handbook 4.5
* We recommend that authors new headings to make this section easier to read. For example ‘source of funding,’ ‘participants’, ‘setting’ etc
* Provide a link to the Characteristics of included studies table

**Excluded studies**

* Please state the number of excluded studies
* Cite the excluded studies
* Provide brief reasons why they were excluded and then provide a link to the characteristics of excluded studies table

**Studies awaiting classification**

* Please state the number of studies awaiting classification
* Cite the studies
* Provide a link to the characteristics of studies awaiting classification table

**Ongoing studies**

* Please state the number of ongoing studies
* Cite the studies
* Provide a link to the characteristics of ongoing studies table

**Risk of bias in included studies**

* You should generate a risk of bias summary and a risk of bias graph. They should cited and appear under this heading. No other text need appear under this heading
* There are five predefined subheadings in your review (Allocation (selection bias); blinding (performance bias and detection bias); incomplete outcome data (attrition bias); selective reporting (reporting bias); Other potential sources of bias).
* Text must appear under each of those headings.
* (R73, Highly desirable) You should summarize the risk of bias across domains for each key outcome for each included study, and ensure that these are supported by the information presented in the ‘Risk of bias’ tables. You should provide a brief narrative summary of the risks of bias among the included studies. Details: It may be helpful to identify any studies considered to be at low risk of bias for particular key outcomes. [PRISMA items 22 and 25]

**Effects of interventions**

* Summarize the results in a structured way (e.g. organized by comparison and then outcome). For example: Intervention 1, primary outcome 1, 2 and then secondary outcomes, 1, 2 etc, subgroups and sensitivity analysis; then Intervention 2..
* Report the outcomes in the same order as listed in the ‘Types of outcome measures’ section, and make sure primary and secondary outcomes are identified
* Report the available results for each comparison, outcome and subgroup described in the Cochrane Protocol, including those for which no results were found and those that were not statistically significant
* Provide links to the relevant tables of data and analysis.
* An orphan study - a data and analysis with only one included study - should not be entered in a data and analysis table. Rather, the outcome could be placed in an additional table. An orphan study entered, as a subgroup single included study, would still be appropriate when associated with the other subgroups of the data and analysis table. Empty forest plots should not appear in any CARG review.
* Authors should NOT create RevMan Figures for all forest plots. This is effectively, a duplication of information that appears in the data and analysis section at the end of the full Review version
* It is good practice to place emphasis on size and precision of effect. Incorporation of GRADE ratings to contextualize the numerical results. For example: ‘The estimated risk ratio for [outcome] was 0.92 (95% CI 0.78 to 1.32), 12 studies, 1437 participants). We rated this as high quality evidence since the confidence intervals are within the minimum clinically important difference of X%.’ ‘Compared with control the difference in quality of life scores with intervention was 3.2 [units] higher with intervention (95% CI 1.2 to 5.2; 9 studies, 965 participants). We downgraded the quality of evidence from high to moderate due to inconsistency in the direction and magnitude of effect across the studies (I square 63%).’
* Make sure you cover all points mentioned in the MECIR standards
* You should state the number of studies in total and the total number of participants and cite them
* You should state the total of number of studies and participants contributing to the analysis of an outcome
* For each outcome you should state the number of studies and participants and state the quality of the evidence - whether it was downgraded and if downgraded by how many levels (The assessment of the evidence for each domain by outcome and the overall certainty of the evidence for each outcome
* If no studies looked at an outcome then state 'no study looked at this outcome' .
* Make sure you link the relevant analysis or forest plot to each outcome
* Remember no orphan studies in forest plots (no single study forest plots; place them instead in and additional table) and no empty forest plots
* (Downgrading information will be in the summary of findings table you are expected to generate)

**So for example**

“This review evaluated a total of 16,784 catheters in 57 studies. The total number of participants was unclear as some studies only specified the number of catheters and not the participants.

Comparison 1: Antimicrobial impregnation versus no impregnation

Primary outcomes

1. Clinically diagnosed sepsis

There was no difference between the impregnated group and the non-impregnated group (risk ratio (RR) 1.0, 95% confidence interval (CI) 0.88 to 1.13; 12 studies, 3686 catheters; I² = 19%;[Analysis 1.1](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#CMP-001.01); [Figure 4](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#FIG-04)). The funnel plot for this outcome (not shown) is asymmetrical, suggesting a possibility of publication bias, as smaller studies with outcomes that favour non-impregnated catheters appear to be lacking. As a result, we downgraded the overall quality of evidence for this outcome from high to moderate.

2. Catheter-related bloodstream infection (CRBSI)

CRBSI: there was a significant reduction in CRBSI in the impregnated group (absolute risk reduction (ARR) 2%, 95% CI 3% to 1%, number needed to treat for an additional beneficial outcome (NNTB) 50; RR 0.62, 95% CI 0.52 to 0.74; 42 studies, 10,405 catheters; I² statistic = 20%; [Analysis 1.2](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#CMP-001.02); [Figure 5](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#FIG-05)). There was no evidence of publication bias from the funnel plot and no other issues that affected the quality of evidence, so we rated this as high quality evidence in our 'Summary of findings' table.

CRBSI per 1000 catheter days: there was no difference between the impregnated group and the non-impregnated group (RR 0.75, 95% CI 0.51 to 1.11; 15 studies; I² statistic = 19%; [Analysis 1.3](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#CMP-001.03)).”

**Discussion**

* No text should appear under the main heading ‘Discussion’
* There are five subheadings (summary of main results; overall completeness and applicability of evidence; quality of the evidence; potential biases in the review process; agreements and disagreements with other studies or reviews)
* Text should appear under each of those subheadings

**Summary of main results**

* This should summarize the summary of findings takinto account both important benefits and harms, and focus on the most important outcomes as presented in the ‘Summary of findings’ tables. You do not need to repeat detailed numerical data here, but can draw overall conclusions about the effects, including harms of the intervention, in the context of your overall review question.
* When summarising the results, think about the certainty of the evidence. For example, you shouldn't say that an intervention is effective if the evidence is low or very low certainty.
* For example: ‘Evidence from 13 studies in 876 people contributing data to the primary outcomes of this review showed that [intervention] given for between 8 and 16 weeks reduced symptoms, physiological markers of disease and hospital admission. The impact on quality of life was less certain and we found moderate quality evidence of an increased risk of harms associated with treatment.’ This sets the context for the rest of the discussion section

**Overall completeness and applicability of evidence**

* In this section you should describe how well the evidence you have found answers your original review question. The questions you should ask yourself are: "Are the studies identified sufficient to address all of the objectives of the review?" or "Have all relevant types of settings, participants, interventions, comparators, and outcomes been investigated?". Another consideration might be the age of the included studies, especially if the intervention of interest has changed or evolved over time. These are the same issues that you should already have given some consideration to when assessing the indirectness of evidence using the GRADE approach.
* In this section, you may also discuss and provide an overall judgement of the external validity of the review, that is, if the results are applicable to other settings, etc.

**Quality of the evidence**

* A broad question you want to address here is: "Does the body of evidence identified allow a robust conclusion regarding the objectives of the review?". This is the place to discuss all the domains of your GRADE assessment and the certainty of the evidence supporting your conclusions, including the main reasons why the evidence may have been downgraded or upgraded, consistent with your 'Summary of findings' tables.
* A common error here is to repeat information about the risk of bias of the included studies. You should remember that the GRADE ratings reflect how risk of bias and other factors such as inconsistency, indirectness, imprecision, and publication bias, impact on your confidence in the results of the review.

**Potential biases in the review process**

* This subheading is sometimes a source of confusion. This is not the place to discuss the biases in the included studies, but to reflect on the strengths and limitations of your review process, and the assumptions and decisions you have made as the author.
* For example, it may be a limitation of the review if the search was not comprehensive enough to allow for detection of adverse effects. Decisions you have made about the inclusion of studies or the selection of statistical methods may have influenced your conclusions. There may be concerns about the completeness of data collection processes, or methods to account for missing data. If there are studies awaiting classification, you might want to consider the impact of not including these studies on the review findings. You may find it helpful to consult a tool designed for the assessment of reviews, such as ROBIS, to identify any additional risks of bias.

**Agreements and disagreements with other studies or reviews**

* Comments on how the included studies fit into the context of other evidence might be included here, stating clearly whether the other evidence was systematically reviewed.

For example

‘There have been several systematic reviews published since 1999 that assessed the effectiveness of CVC impregnations. Many reviews assessed chiefly C-SS and/or MR impregnation and found that impregnated CVCs significantly reduced CRBSI or catheter colonization, or both (Casey 2008; [Falagas 2007](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Falagas-2007); [Hockenhull 2008](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Hockenhull-2008); [Hockenhull 2009](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Hockenhull-2009); [Niel-Weise 2007](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Niel_x002d_Weise-2007); [Ramritu 2008](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Ramritu-2008); [Veenstra 1999a](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Veenstra-1999a)), and were estimated to be cost-effective ([Veenstra 1999b](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Veenstra-1999b)). However, other reviews found antimicrobial-impregnated CVCs to have no significant benefits ([Gilbert 2008](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Gilbert-2008); [McConnell 2003](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-McConnell-2003); [Niel-Weise 2008](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Niel_x002d_Weise-2008)). Notably, the authors in [Niel-Weise 2007](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Niel_x002d_Weise-2007) found substantial benefits of antimicrobial-impregnated CVCs in a meta-analysis of 21 trials conducted either in ICUs or other acute care settings, but found no benefits in a separate meta-analysis of nine trials assessing CVCs for TPN and chemotherapy, which agrees with our results ([Niel-Weise 2008](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Niel_x002d_Weise-2008)). The authors postulated that the difference in the duration of catheter placement between these reviews (mean of six to 12 days in the included studies in [Niel-Weise 2007](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Niel_x002d_Weise-2007) and 11 to 20 days in the included studies in [Niel-Weise 2008](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Niel_x002d_Weise-2008)), the small sample sizes and the methodological limitations of the included studies in [Niel-Weise 2008](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Niel_x002d_Weise-2008), were possible factors that could have influenced the findings. In [Niel-Weise 2007](https://archie.cochrane.org/sections/documents/view?version=z1604160510594336410212480819849&format=REVMAN_GRAPHS#REF-Niel_x002d_Weise-2007), the authors included a study that assessed haemodialysis catheters and a study on children.

The systematic reviews cited above vary in scope, and most evaluated only catheter-specific outcomes such as CRBSI and catheter colonization. There is no systematic review that incorporates non-catheter-specific critical outcomes such as clinical sepsis and mortality for a direct comparison with our findings.’

**Authors' conclusions**

**Implications for practice**

* It is good practice to place emphasis on evidence being supportive rather than directive:
* For example: There is high quality evidence that intervention reduces/improves [important outcome] The evidence in our review demonstrates that Rx reduces X.../challenges the current practice of... Use of intervention is given only limited support based on evidence from our review…
* It is good practice to place emphasis on how the findings of the review address the overall set of objectives: For example ‘We do not have sufficient evidence to determine the effects of…’
* It is good practice to acknowledge the limitations of the current state of the evidence and the clear avoidance of directing practice based on ineligible evidence of benefit or harm

**Implications for research**

* It is good practice to: Use key limitations described from Quality of evidence/Completeness & applicability into priorities for research; Go beyond simple study design labels (i.e. more RCTs) to include consideration of what aspects of study are important, for example standardized definition of outcomes, better information about the nature of the interventions delivered; Draw on any information already known about ongoing studies.

**Contribution of authors**

* Please make sure you are referencing the latest version of RevMan.
* Please state precisely which authors did what

**Declaration of interest**

* Cochrane has changed its conflicts of interest policy
* You need to look at that policy you will find it at: <http://community-archive.cochrane.org/editorial-and-publishing-policy-resource/conflicts-interest-and-cochrane-reviews>
* Authors often describe at great length potential conflicts of interest. We would prefer to see statements like these shown in this example:
* *Review: Examicin for globular poritis*
* *Comparators: Placebo or any other pharmaceutical product licensed for use in globular poritis.*
* *John Smith has received personal payments for consultancies and lecture fees from a variety of commercial companies, none of which are relevant to this review.*
* *Mike Jones has received personal payments for consultancies and lecture fees from a variety of commercial companies. Specifically he received personal payments in 2015 from PharmCo plc for consultancy and lectures on globular poritis. PharmCo plc manufactures miraculomab which is a potential comparator in this review*
* *Ann Baker gave a lecture for Medrug International which manufactures examicin. The honorarium was paid to her University directly and she did not benefit directly*

**Differences between protocol and review**

* It is good practice to note any differences between the protocol and the review in this section (for example change to title, outcomes etc)
* You should briefly describe what change was made and why
* You can also use the information in this section to help write the ‘potential biases in the review process’ section

**Characteristics of studies**

**Included**

* These tables must fully conform to the MECIR standards.
* Make sure to provide full demographics for each study (age, gender, etc); setting , country whether single or multi centre trial; declarations of interest funding, study period, inclusion/exclusion criteria, full list of outcomes in the study (and how measured - not just the ones of interest to you)
* See the MECIR standards for full details but in brief you need to report:
	+ 1. the sample size for each included study
		2. the basic study design or design features (e.g. parallel group randomized trial, cluster-randomized trial, controlled before and after study)
		3. sufficient information about the study populations to enable a user of the review to assess the applicability of the review’s findings to their own setting (for example country, setting)
		4. sufficient information to enable users of the review to assess the applicability of the intervention to their own setting, and if possible in a way that allows the intervention to be replicated
		5. clear and consistent information about outcomes measured (or reported), how they were measured and the times at which they were measured
		6. the dates when the study was conducted in the table of ‘Characteristics of included studies
		7. details of funding sources for the study, where available (notes section of the table)
		8. details of any declarations of interest among the primary researchers
* Complete a list of acronyms and abbreviations used in this table in the footnotes of this table

**Risk of bias tables**

* Make sure your risk of bias tables are up to date, refer to all the domains and that you have fully completed all of the description sections.
* You need to provide evidence/justification for judging some domains to be high risk, others low risk and some unclear

**Excluded**

* Do NOT exclude a study if it does not report the outcome of interest. You can exclude it if the study not measure it
* The list of excluded studies should be as brief as possible. It should not list all of the reports that were identified by a comprehensive search. It should not list studies that obviously do not fulfil the entry criteria for the review as listed under ‘Types of studies’, ‘Types of participants’, and ‘Types of interventions’, and in particular should not list studies that are obviously not randomized if the review includes only randomized trials. (We do understand that you may want to make your search as transparent as possible – one way to do this is to provide brief details (ie 5 studies excluded – editorials) in the search flow diagram. If you want to provide more detail then you can always provide it in an appendix.
* Complete the acronyms in the footnotes of this study

**Ongoing**

* Complete the table
* Complete the acronyms in the footnotes of this study

**Awaiting classification**

* Complete the table
* Complete the acronyms in the footnotes of this study

**Summary of findings tables**

* You need to generate a Summary of Findings table
* This table should be generated BEFORE you update the review
* You use the information in that table to write the abstract, results and conclusions of the review
* You need to make sure to provide the setting (country, location etc)
* You need to complete the footnotes and state whether you downgraded the evidence and if you did by how many levels and for what reasons (for example imprecision)

For example

###### **Footnotes**

1 Downgraded two levels due to serious concerns about study limitations and imprecision.

3Downgraded one level due to serious concerns about study limitations.

5Downgraded two levels due to serious concerns about inconsistency and imprecision.

6Downgraded three levels due to serious concerns about study limitations, inconsistency, imprecision and strongly suspected publication bias.

* Look at ‘create a summary of findings table’ and introduction to summary of findings tables’.
* Look at the following resources

<http://community.cochrane.org/news/screening-notes-planning-methods-using-grade-and-preparing-summary-findings-tables>

<http://community.cochrane.org/news/screening-notes-common-issues-summary-findings-tables-and-how-address-them>

<http://www.guidelinedevelopment.org>

[incorporating GRADE in to the text of the review](http://editorial-unit.cochrane.org/sites/editorial-unit.cochrane.org/files/uploads/Incorporating%20GRADE%20in%20Cochrane%20Reviews.docx)

Cochrane Handbook Chapter 11 (Presenting results and ‘Summary of findings’ tables): <http://handbook.cochrane.org/chapter_11/11_presenting_results_and_summary_of_findings_tables.htm>

A list of publications introducing GRADE: <http://www.gradeworkinggroup.org/publications/>

The 2011 series of articles about GRADE in the Journal of Clinical Epidemiology (free access): <http://www.gradeworkinggroup.org/publications/JCE_series.htm>

Schedule of webinars and workshops: <http://www.gradeworkinggroup.org/news.htm>

Software for generating GRADE Evidence Profiles and Summary of Findings tables:

<http://tech.cochrane.org/revman/gradepro>

**Tables of data and analysis**

* An orphan study - a data and analysis with only one included study - should not be entered in a data and analysis table. Rather, the outcome could be placed in an additional table. An orphan study entered, as a subgroup single included study, would still be appropriate when associated with the other subgroups of the data and analysis table. Empty forest plots should not appear in any ACE review.
* The tables of data and analysis are ordered in the same fashion as the Effects of intervention section. So for Analysis 1, the header or title is the comparison between interventions: For example: “The indirect videolaryngoscope versus the conventional laryngoscope for intubation of children”.
* The next level nested in the hierarchy is 1.1. This should be the outcome. So for example Intubation time (and so on)
* Make sure you clearly label the graph and state for example favours intervention (and if space what the intervention is) and favours control (and again if space what the control is)

**Figures**

* Authors should NOT create RevMan Figures for all forest plots. This is effectively, a duplication of information that appears in the data and analysis section at the end of the full Review version. To ensure the best presentation of the Figures in the published review (particularly in the PDF version), we recommend a maximum of six figures per review, but ideally between three and five
* You must generate a search flow figure and a risk of bias graph and risk of bias summary
* Some key points to remember are that for figures created outside of Revman you should:

•   Delete white space

•    use file format "PNG", not JPG

•    keep the size small (eg. <740 pixels)

**References in general**

* Follow the Cochrane style resource (http://community.cochrane.org/style-manual)
* The author line should be written as follows: first six authors and then et al. Authors last name and then initials – So Cracknell JP not J.P Cracknell
* Journal titles should be written out in full
* Please provide the PMIDS for included and excluded studies
* If there is a duplicate study – please enter it as a secondary reference rather than as a new reference (then indicate which is the primary reference)

 **Sources of support**

* Are there any internal or external sources of support?

**Appendices**

* Provide your search terms for all of the databases and link the appendices to the text