**Updating your Cochrane review**

* **[IMP! 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.]**

**Things to do before writing your draft update – decide is it necessary to update at all?**

* Look at the updating classification guide (https://community.cochrane.org/editorial-and-publishing-policy-resource/cochrane-review-management/updating-classification-system-cochrane-reviews) and in particular the flow table on pages 5 to 7. Can the studies currently awaiting classification in your review be incorporated into the review? Have other new studies been published which can be incorporated into the review? And will the inclusion of these new studies change the conclusions of the review?
* If they won’t change the conclusion there is no desperate urgency to update

Go through the flow chart and the questions below before spending a great deal of time updating this review

* Please inform me if no new studies have been published that match the inclusion criteria of your review. Your review will then be marked as up to date; no new studies identified with search. (See page 5-7 in attached Updating Classification Guide) YOU DO NOT NEED TO UPDATE THE REVIEW AT THIS STAGE
* Please inform me if new studies have been published that match the inclusion criteria of your review and the review needs to be updated. Your review will then be marked as update pending (authors currently updating/studies awaiting assessment etc). (See page 5-7 in attached Updating Classification Guide) YOU THEN NEED TO ANSWER THE NEXT QUESTION
* Please inform me if you know that although new studies have been published they will not change the conclusions of your review. Your review will then be marked as up to date; new studies have been identified but unlikely to change review findings (See page 5-7 in attached Updating Classification Guide) YOU DO NOT NEED TO UPDATE THE REVIEW AT THIS STAGE
* Please inform me if you know already that the inclusion of these new identified studies will change the conclusions of the review? Your review will then be marked as update pending; (authors currently updating/studies awaiting assessment etc); (See page 5-7 in attached Updating Classification Guide). YOU NEED TO UPDATE THE REVIEW AND SHOULD WORK YOUR WAY THROUGH THE INSTRUCTIONS

**How to update your review. Please do through ALL sections**

* 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 (see page 3 RevMan userguide – open RevMan/click on help/choose userguide ).
* Be aware ALL Cochrane authors must make sure they use the MECIR standards for conducting, reporting and updating Cochrane reviews
* 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)
* OR - (please look at the pdf version) <http://methods.cochrane.org/sites/default/files/public/uploads/Cochrane%20MECIR_Standards%20FINAL%20booklet_web_version.pdf>)

**Training/useful resources available**

* 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 update the review, and 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. 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.]
* 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’)*
* 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 last published version?
* If it has changed make a note of the change in the section 'differences between protocol and review'
* If it has changed then make sure current 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 only be two entries in this section
* You should have two new events A) updated and B) new citation conclusions changed or not changed
* In the updated event description, you write when you ran the search to and how many new studies you found (included/excluded/ongoing/awaiting classification); so for example if you included 16 studies in the previous version and there are 22 studies included in the updated version; the there are six new included studies. You would cite the six new studies and link them
* In the new citation conclusions changed or not changed you state whether the conclusions are changed by the inclusion of the six new studies or not
* You also state which new authors have joined the team and which have left, since the review was last published.
* You state whether you have updated your methods (for example you state you have included full risk of bias tables and summary of findings tables)
* You move the any old events ‘history’ section

**Abstract**

* The abstract can between 700 and 1000 words in length

**Background**

* Check the background section is up to date (for example are the references still relevant)
* Add an additional final line to this section. State “This is an updated version of the review first published in 20\*\* ‘ and if previously updated write ‘(previous updates 200\*; 200\*).

**Objectives**

Please be aware that the abstract objectives should be identical to those of the main review -word for word.

**Search methods**

* 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

**Main results**

* This section will need to be redone.
* Be aware that: ALL updated reviews must contain summary of findings tables (see notes on that section). You should use the information in the SOF table(s) to write the abstract results and conclusions (PLS, Effects of interventions, Discussion (especially quality of evidence).)
* You must make it clear what the total number of studies and participants is; and how many studies and participants were included in the analysis.
* 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
* 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

**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**

* 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**

* This section needs to be totally updated.
* You need to look at the MECIR standards (see the pane in RevMan) and make sure your PLS complies with those standards (at present it does not).
* I have inserted the headings shown in the MECIR standards; you need to update your text and move the text around to fit those headings
* The title can be no more than 150 characters
* The text can be between 400 and 700 words in length
* 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 now 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

**Outcome Measures**

* I have reinserted the two predefined subheadings: primary and secondary outcomes
* You need to indicate which are your primary outcomes and which are your secondary outcomes
* (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))
* You need to 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.)

**Search methods for identification of studies**

**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**

* 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.

**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 now 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.

**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:\Users\JC0002\Desktop\Jane%20making%20it%20easy\Editing\chapter_11\11_presenting_results_and_summary_of_findings_tables.htm) and Chapter [12](file:///C:\Users\JC0002\Desktop\Jane%20making%20it%20easy\Editing\chapter_12\12_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
* (You should mention in the 'differences between protocol and review' section that you have included summary of findings tables in the updated review)

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. 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
* Can any of the previous studies awaiting classification and ongoing be included in this review?
* Have you stated the number of new included studies? The number of participants in those new studies?
* Have you stated the total number of included studies? The total number of participants in those studies?
* 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**

* Have you decided whether any of the studies that were awaiting classification in the last version can be included in this version?
* Please state the number of new studies currently awaiting classification
* Please state the total number of studies currently awaiting classification
* Cite the studies
* Provide a link to the characteristics of studies awaiting classification table

**Ongoing studies**

* Have any of the previous ongoing studies been published?
* If they have, have you decided whether they meet your inclusion criteria and can be included/excluded/ or should be awaiting classification
* Are any still ongoing and why?
* Please state the number of new ongoing studies
* Please state the total 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 included in the analysis
* 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
* 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 now 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 section should ‘Describe the relevance of the evidence to the review question. This should lead to an overall judgement of the external validity of the review. Are the studies identified sufficient to address all of the objectives of the review? Have all relevant types of participants, interventions and outcomes been investigated? Comments on how the results of the review fit into the context of current practice might be included here, although authors should bear in mind that current practice might vary internationally. ‘
* It is good practice to: To provide broad descriptive summary. Rather than repeating results, brief narration of headline findings:
* 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**

* Here you should ‘Describe the relevance of the evidence to the review question. This should lead to an overall judgement of the external validity of the review. Are the studies identified sufficient to address all of the objectives of the review? Have all relevant types of participants, interventions and outcomes been investigated? Comments on how the results of the review fit into the context of current practice might be included here, although authors should bear in mind that current practice might vary internationally. ‘

**Quality of the evidence**

* This section should answer the following question: ‘Does the body of evidence identified allow a robust conclusion regarding the objective(s) of the review?’
* You should summarize the amount of evidence that has been included (numbers of studies, numbers of participants), state key methodological limitations of the studies, and reiterate the consistency or inconsistency of their results. This should lead to a description of the overall judgement of the quality of a body of evidence contributing to the results of the review.
* The reasons or rationale for up- or downgrading the quality of a body of evidence in the ‘Summary of findings’ table (which should be described in the footnotes of that table) can be summarized and incorporated into this section.
* It is good practice to place emphasis on how risk of bias impacts on findings on key outcome results; using information about other possible impacts on quality of evidence (i.e. imprecision, inconsistency, indirectness & reporting bias); reference to and use of information contained in GRADE or SoF tables where applicable. For example: Although we judged the studies to be at varying risks of bias overall, the evidence for our main outcomes is drawn from studies at low risk of bias.... We downgraded the quality of evidence to moderate for the main outcomes, due mainly to inconsistency or imprecision. Subgroup analyses did not provide a convincing explanation for observed variation between the results of the studies.

**Potential biases in the review process**

* In this section you should state the strengths and limitations of the review with regard to preventing bias. These may be factors within, or outside, the control of the review authors.
* So, to remind you: A number of different issues can affect the implantation of protocol methods and these can be useful to draw on here. For example: Were any decisions made about the analysis or investigation of heterogeneity after seeing the data?
* Might assumptions made about class or intensity of intervention (e.g. dose of drug, classification of behavioural interventions) be contested?
* Were there any marginal decisions around the inclusion or exclusion of studies or use and analysis of data which could have impacted on the findings of the review, for example: clinical heterogeneity, variation in study design or delivery of intervention, prioritisation of data from multiple time-points, definition of subgroups, alternative definitions of outcome, use of adjusted as opposed to unadjusted data, outcome surrogacy?
* Consideration of specific ways in which the search process could have been limited, for example: challenges in optimising search terms/poor indexing of studies, limitations of databases used or grey literature sources accessed, restrictions on dates of search, and incomplete correspondence with study investigators or sponsors.
* Were any relevant departures from protocol a potential source 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**

* You need to update all this information
* 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. It should be 5.3
* Please state precisely which authors did what

**Declaration of interest**

* Since the last version of this review was published 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>

**Differences between protocol and review**

* It is good practice to note any differences between the protocol and the review in this section (for example the change to title)
* 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 (notes section of the table)
* 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

**Awaiting classification**

* Can any of the studies currently awaiting classification be included in the review?
* Are there any new studies awaiting classification?
* Complete the table
* Complete the acronyms in the footnotes of this study

**Ongoing**

* Have any of the ongoing studies been published and can they be included in the review/excluded or moved to awaiting classification?
* Are any new ongoing studies?
* 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.

**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

**References in general**

* 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

**Additional references**

* RevMan should be citing, and using, the latest version of RevMan which is: Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

**Sources of support**

* Are there any internal or external sources of support?

**Appendices**

* Provide your search terms for all the databases

Finally check your review against the attached triage tool

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ABSTRACT** | | **SUMMARY OF FINDINGS TABLE** | | **DATA AND ANALYSIS  (for Critical and Important outcomes in Main comparison)** | |
| **Item** | **Response** | **Item** | **Response** | **Item** | **Response** |
| Title reflects the review question |  | SoF table presents main outcomes (both benefits and adverse effects) for main comparison  *Look at methods section for consistency of SoF table outcomes; Assess methods for using GRADE* |  | Analyses match the plan specified in the methods section (e.g. MDs or SMDs; fixed or random effects meta-analysis)  *MDs or SMDs; fixed/random effects, subgroup analysis. Check differences between protocol & review to see what plans changed from protocol.* |  |
| Research question (PICO) is clear and the rationale for the review is well described |  | PICO (including Settings) presented and accurate |  | Data from non-standard designs (cluster, cross-over, etc.) appropriately incorporated where relevant (check ‘Unit of analysis issues’ in methods & footnotes in forest plots)  *Check ‘Unit of analysis issues’ in methods/footnotes in forest plots/sensitivity analyses. Study characteristics help to confirm unit of allocation & sample sizes if in doubt.* |  |
| Search date is less than 12 months from publication? |  | Outcomes fully defined (i.e. time of measurement, scale of measurement, range of scores specified) |  | Multiple measurements from multi-arm studies or subgroups handled appropriately (check for double counting of studies in Forest plot and adjustment of sample size in control groups)  *Check for double counting of studies in Forest plot & adjustment of events/sample size in control groups* |  |
| Direction, magnitude and confidence intervals of effects clearly described where appropriate |  | Assumed and Corresponding risks presented (where appropriate) |  | Outlying results acknowledged and explored appropriately  *Assess plausibility of direction/size of effect* |  |
| Findings for all important outcomes reported for the main comparison(s), including information about harm? (i.e. consistent with the outcomes reported in the SoF table)  *Check consistency with first SoF table & others as appropriate* |  | Clear and accurate summary of narrative results (where appropriate) |  | No unusually high or low mean/SD/count data  (look at comparability of SDs for studies using same scale; check that sample sizes for same studies are similar across key outcomes; look at weights of individual studies relative to sample size)  *Comparability of SDs for studies using same scale (end of treatment).*  *Weights of individual studies relative to sample size*  *Similar sample sizes across different outcomes for the same study (events not participants)* |  |
| There an estimation of the certainty (or quality) of the body of evidence using GRADE for each outcome reported in the abstract |  | Quality ratings presented for narrative results (where appropriate) |  |
| Absolute effects used to illustrate the relative effects where appropriate |  | GRADE ratings are clearly justified (supported by clear and appropriate quality assessment criteria in Footnotes) |  | Key findings consistent across the summary versions of the review (compare abstract, PLS, SoF table, Effects of interventions and Data tables) |  |
| Reporting of results avoids emphasizing statistical significance to determine presence or absence of an effect |  |  |
| Conclusions are an accurate reflection of the evidence presented in the GRADE SoF table(s) and do not make direct recommendations |  |  |