Instructions for completion of the C2010 evidence evaluation worksheet

Introduction
Welcome to the C2010 evidence evaluation process for the science related to resuscitation and emergency cardiovascular care. The process of evaluation of the resuscitation science for the C2010 has built on the strengths of the C2005 process. One major goal was to significantly simplify the worksheet, to minimise the amount of work required to be done by the literature reviewers (worksheet authors). The instructions for the worksheet now reside in this document (which can be updated as required) and associated appendices (which will be posted on the internet as they become available). The purpose of the instructions that follow is to maximise the quality of the literature review (http://www.cochrane.org; Scott 2006).

The type of information that should be provided in various sections (especially the Discussion, Conclusions and Citation list) can be found in the example worksheets that have been placed on the ILCOR worksheet management website (http://mc.manuscriptcentral.com/ilcor). To review it, please go to Instructions & Forms link on your right.

Getting started
The specific questions to be addressed are allocated to individual worksheet authors. The submission process will be entirely electronic, and instructions will be provided separately for that process.

The worksheet requires 9 separate sections to be completed:

- Basic demographics
- Clinical Question
- Declaration regarding conflict of interest
- Search strategy and results
- Summary of the evidence
- Reviewer’s final comments
- Conclusion
- Acknowledgements
- Citation list

Basic Demographics

We need a fair bit of information (eg. Name, contact addresses, resuscitation council etc), but most of this will be obtained as part of the electronic submission process. On the worksheet itself, we only request the author name(s) and the date that the worksheet was uploaded.

Please insert the worksheet author name(s), and the date that the worksheet was submitted for review, into the worksheet.
Clinical Question

The specific question that is being addressed needs to be in the standardised PICO format (Patient/population Intervention Comparison Outcome; http://www.cebm.net/index.aspx?o=1036), and may have been provided to you already. The generic format for question related to therapeutic interventions is:

In (P)atients does the (I)ntervention, when compared with (C)omparator, improve (O)utcome.

(In studies related to diagnosis or prediction the question would read:
In Patients does the Intervention, when compared with Comparator, improve the diagnosis/prediction of the Outcome (or clinical state etc.).)

The Comparator (or Control) is usually placebo or usual management. The Outcome should not be too restrictive as sometimes we don’t know what evidence is out there, and often specifying an outcome results in unrealistic expectations of what is required (ie. a change in guideline is based on many factors, not just a specific outcome benefit; also we need to be transparent about claiming short term benefit [which may be reasonable] but stating that no long term benefit was detected). The relevant outcomes may vary according to the specific intervention. Obviously for all interventions in cardiac arrests, an improvement in neurologically intact hospital discharge is the desired outcome. For most therapeutic interventions, the studies would include some form of survival data and this should be included. Some topics will have data limited to specific surrogate outcomes relevant to the intervention. These might include shock success or re-fibrillation rate (for defibrillation waveforms), improved quality of CPR (for feedback devices), or time taken to achieve target temperature (with cooling devices).

Please insert the specific clinical question that is being addressed into the worksheet.

The final question once accepted should not be altered without consultation with the Evidence Evaluation Expert (E3).

Please state the type of question that the worksheet is addressing (intervention/therapy, prognosis, diagnosis), as this will determine the definitions of the Levels of Evidence to be used.

Please also confirm whether this is a new topic, or a revision of a previous worksheet.

Declaration regarding Conflict of Interest

A specific conflict of interest form will need to be completed electronically, and updated on a regular basis, as part of the registration process. In addition to this, to facilitate the review process, a brief declaration regarding any relevant conflicts is required for each worksheet on behalf of all authors.

Search strategy and results

Two of the most important factors that are related to the final quality of a systematic literature review are:

- a clearly enunciated (and valid) search strategy, and
• clearly defined inclusion and exclusion criteria for the studies to be included the final evaluation phase.

This is effectively the “methodology section” of the worksheet based systematic review.

Searching for the relevant articles

<table>
<thead>
<tr>
<th>Search strategy (including electronic databases searched)</th>
</tr>
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<tbody>
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</tbody>
</table>

An initial search may have already been commenced for you, but you will be expected to explore various databases to detect all the appropriate publications.

Databases to be searched include:

- the Cochrane Library (for Systematic Reviews, DARE, and the Central register of Controlled Trials),
- Medline (eg. via PubMed, OVID or Scopus),
- Embase, and
- the AHA Endnote database.

The following is a brief description of the required process. A separate document to provide additional assistance in searching the literature is also available (see Search Strategies.doc). A copy of the Endnote software (eg. version X.1) will be made available to all worksheet reviewers.

Cochrane Library

The initial port of call should be the Cochrane Library (http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME?CRETRY=1&SRETRY=0). A quick search of the database of Systematic Reviews (using text words, or MeSH) will confirm the presence or absence of an existing Cochrane review. This does not obviate the requirement for further evaluation, but instead provides a great starting point for the location of relevant publications. At the same time the search can identify:

- abstracts of other systematic reviews (DARE: Database of Abstracts of Reviews of Effects), and
- Controlled Trials that have been included in the Cochrane Central Register of Controlled Trials (CENTRAL: over 415,000 reports included).

The results of all of these searches can be exported into a format that Endnote can import (see C2010Importing.doc). The searches can also be saved, and an email notification of new publications meeting search criteria can be created (see Search Strategies.doc). If you cannot get access to Cochrane Library, please contact us and we can facilitate a broad search for you.

Medline

The next port of call should be Medline. The most widely used mechanism to search the Medline database is PubMed (www.pubmed.org). On Pubmed the search can be performed using textwords or MeSH, but can also be narrowed down using the “filtering” search strategies provided using “Clinical Queries” (see Search Strategies.doc). The results of all of these searches can be exported into a format that Endnote can import using standard filters (see C2010Importing.doc). Searching can also be performed from within EndNote itself, with the results directly imported into your EndNote library. A facility known as “My NCBI” (National Centre for Biotechnology Information) can be set up to: save searches, and to set up e-mail alerts for new studies (see Search Strategies.doc).
Other search engines (which may require a subscription) have additional features that may be useful. One such feature is the “cited by” option used by Scopus, Google Scholar or Web of Science. These “cited by” searches offer a good initial approach to find literature on unusual topics or those that don’t have an intuitive search strategy. To use this approach, early relevant or “classic” papers are used as the starting point, and literature that cites those papers can be identified and then reviewed (for relevance, alternative search terms etc).

**Embase**

Embase is a separate database of the published literature that contains over 11 million records from 1974 to present (compared with around 7 million MEDLINE records from 1966 to present). It is particularly good for European journals, and drug research, and has been shown in a number of settings to access many articles that Medline did not. Searching can easily be performed by using keywords, which can also be linked to “subject headings” (see also Search Strategies.doc). The results of these searches can be directly exported (“direct export”) into an Endnote file (see C2010Importing.doc). A personal account can be set up to: save searches, and to set up e-mail alerts (“AutoAlert”) for new studies (see Search Strategies.doc).

If you do not have access to Embase (eg. via OVID) then a free trial of a combined database (Medline and Embase) appears to be available at [http://www.info.embase.com/embase_com/about/index.shtml](http://www.info.embase.com/embase_com/about/index.shtml). If you still cannot get access to Embase, please contact Tanya Semenko at tanya.semenko@heart.org and we can facilitate a broad search for you.

**AHA Endnote Database**

As part of the guideline development process, the AHA has continued to add the references found to a single Endnote database. This database can be easily searched (eg. using textwords or keywords). It can be downloaded by worksheet authors from the ILCOR worksheet management website ([http://mc.manuscriptcentral.com/ilcor](http://mc.manuscriptcentral.com/ilcor)). You need to login and go to the Author Center to download the Master library to your computer.

**Other strategies to complete the search**

In addition to the databases listed above, additional specific search strategies are required to ensure that all the relevant manuscripts are obtained. These include options such as:

- Review of references of articles (or reviews) of relevance
- Use of forward searching (eg. “cited by” in Scopus, Google Scholar or Web of Science)
- Hand searching (manual reviewing) of specific journals (eg. Resuscitation)

Please insert your “Search Strategy”, including the databases searched into the worksheet.

<table>
<thead>
<tr>
<th>Search strategy (including electronic databases searched):</th>
</tr>
</thead>
<tbody>
<tr>
<td>PubMed: “cardiac arrest” or “cardiopulmonary resuscitation” as MESH (headings) AND “Hyperthermia” keyword in abstract.</td>
</tr>
<tr>
<td>EMBASE search using text words (all fields) hyperthermia AND (cardiac arrest OR resuscitation)</td>
</tr>
<tr>
<td>AHA EndNote (Master library), Cochrane database for systematic reviews, Central Register of Controlled Trials, Review of references from articles. Forward search using SCOPUS and Google scholar.</td>
</tr>
</tbody>
</table>

**Retrieving the relevant articles**

A review of the title and abstract of each study identified will assist in identifying articles which need to be obtained for further review. Most of the articles that you find will be accessible in an electronic format (via either individual journal or institutional subscription). Articles that are not available electronically should be requested from your institution. If there are specific articles that
have been identified on your search, and confirmed to be important after review of the abstract, and you are not able to obtain them, then let us know and we will assist whenever possible.

**Selecting the articles**

A crucial part of the maintenance of the validity of the evidence-based review is a clear description of the inclusion and exclusion criteria for articles to be considered for further review. Some of these criteria are generic, and others are specific to the individual topic being reviewed. Some generic criteria for inclusion or exclusion relate to the study design (eg. randomised controlled trials, animal studies [included or excluded], population age ranges, exclusion of review articles etc.). As a rule only articles in the peer reviewed literature are included (no abstract only studies). There may also be a number of more specific exclusion criteria depending on the individual topic (eg. exclusion of studies using cardio-pulmonary bypass), or studies that do not specifically answer the question (eg. using a stroke model, or generic critically ill patients). These latter studies can either be excluded or listed as “Level 5” evidence (see below).

Please insert your inclusion and exclusion criteria into the worksheet.

<table>
<thead>
<tr>
<th></th>
<th>State inclusion and exclusion criteria</th>
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<tbody>
<tr>
<td></td>
<td>The following studies were excluded: Not true cardiac arrest models (eg. exanguinations, great vessel occlusion [5], carotid artery occlusion [7]), pre-arrest [6] or during arrest cooling [4], resuscitation with cardio-pulmonary bypass instead of CPR [9].</td>
</tr>
</tbody>
</table>

**Summarising the search results**

After your search (and the application of inclusion and exclusion criteria) has identified articles for further review, please submit your preliminary worksheet online (only “Search strategy”, “inclusion and exclusion criteria” and “Number of articles/sources meeting criteria for further review” fields completed) at http://mc.manuscriptcentral.com/ilcor . You are now ready to begin the detailed review of the individual studies as soon as you receive feedback regarding your preliminary submission from worksheet expert.

Please insert the number of studies that met criteria for further review into the worksheet.

<table>
<thead>
<tr>
<th></th>
<th>Number of articles/sources meeting criteria for further review</th>
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<tbody>
<tr>
<td></td>
<td>29 studies met criteria for further review. Of these six were LOE 1, one LOE 2, two LOE 3, nine LOE 4, and eleven LOE 5.</td>
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</tbody>
</table>

**Summary of the evidence**
Summary of evidence

Evidence Supporting Clinical Question

<table>
<thead>
<tr>
<th>Level of Evidence</th>
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<tbody>
<tr>
<td>Good</td>
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<tr>
<td>Fair</td>
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<td>Poor</td>
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<th>4</th>
<th>5</th>
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<tbody>
<tr>
<td>Level of evidence</td>
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</table>

Each individual study now needs to be reviewed in detail. The critical information to be obtained in this process includes:

- Level of Evidence
- Relevance to the question asked
- Methodological quality
- Outcome(s) assessed
- Magnitude of any observed effect
- Direction of support or otherwise for the question asked, according to the specific outcomes that have been assessed

This evidence is then represented graphically (according to the tables that represent the various directions of support), and in the text of the “Reviewer’s Final Comments” section. This is effectively the results section of the worksheet based systematic review.

**Level of Evidence**

The Level of Evidence for any study is allocated according to the type of study, and its inherent likelihood to exclude bias. The specific Levels of Evidence that are to be used vary according to the type of question being asked.

Levels of Evidence for therapeutic interventions are the most straightforward and are shown below:

<table>
<thead>
<tr>
<th>Levels of Evidence for Therapeutic Interventions</th>
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</thead>
<tbody>
<tr>
<td>LOE 1: Randomised Controlled Trials (or meta-analyses of RCTs)</td>
</tr>
<tr>
<td>LOE 2: Studies using concurrent controls without true randomisation (eg. “pseudo”-randomised) (or meta-analyses of such studies)</td>
</tr>
<tr>
<td>LOE 3: Studies using retrospective controls</td>
</tr>
<tr>
<td>LOE 4: Studies without a control group (eg. case series)</td>
</tr>
<tr>
<td>LOE 5: Studies not directly related to the specific patient/population (eg. different patient/population, animal models, mechanical models etc.)</td>
</tr>
</tbody>
</table>

For further explanation of Levels of Evidence, including Levels of Evidence for studies for diagnosis or prognosis please see separate document (Defining Levels of Evidence.doc).

**Methodological quality**

There is no uniformly agreed to way of defining methodological quality. A number of numerical systems have been proposed but all have their limitations. Instead of a strict criterion based assessment, we ask the worksheet reviewer to allocate the quality of each study into Good, Fair and Poor.
Good studies would be expected to have most/all of the quality items suggested to assess the type of study (see below).

Fair studies would be expected to have some of the quality items suggested to assess the type of study (see below).

Poor studies would be expected to have few of the quality items suggested to assess the type of study (see below), but to be of sufficient value to include for further review.

Specific quality items are listed below for each type of intervention study (http://www.cebm.net/index.aspx?o=1157). For further information, including quality for diagnosis and prognosis questions, see separate document: Defining Quality of Evidence.doc).

Meta-analysis (of LOE 1 or LOE 2 studies) [Scott 2006]

- Were specific objectives of the review stated (based on a specific clinical question in which patient, intervention, comparator, outcome (PICO) were identified)
- Was study design defined?
- Were selection criteria stated for studies to be included (based on trial design and methodological quality)?
- Were inclusive searches undertaken (using appropriately crafted search strategies)?
- Were characteristics and methodological quality of each trial identified?
- Were selection criteria applied and a log of excluded studies with reasons for exclusion reported?

Randomised Controlled Trials (LOE 1) (http://www.cebm.net/index.aspx?o=1157)

- Was the assignment of patients to treatment randomised?
- Was the randomisation list concealed?
- Were all patients who entered the trial accounted for at its conclusion?
- Were the patients analysed in the groups to which they were randomised?
- Were patients and clinicians "blinded" to which treatment was being received?
- Aside from the experimental treatment, were the groups treated equally?
- Were the groups similar at the start of the trial?

Studies using controls without randomisation (concurrent LOE 2, or retrospective LOE 3) (http://www.cebm.net/index.aspx?o=1157)

- Were comparison groups clearly defined?
- Were outcomes measured in the same (preferably blinded) objective way in both groups?
- Were known confounders identified and appropriately controlled for?
- Was follow-up of patients sufficiently long and complete?

Studies without controls (LOE 4)

- Were outcomes measured in an objective way?
- Were known confounders identified and appropriately controlled for?
- Was follow-up of patients sufficiently long and complete?

Studies not directly related to the specific patient/population (LOE 5)

Studies not directly related to the specific patient/population (eg. different patient/population, animal models, mechanical models etc.) should have their methodological quality allocated to the
type of study (ie. RCTs = good, studies without randomised controls = fair, and studies without controls = poor). Animal studies should also be designated using *italics*.

**Note:** The allocation of a grade for methodological quality helps graphical representation but is relatively simplistic. What is probably more important is the discussion of the relevant factors for the individual studies, which is expected in the “Reviewer’s Final Comments” section.

**Direction of support for the question asked**

**Evidence Supporting Clinical Question**

**Evidence Neutral to Clinical question**

**Evidence Opposing Clinical Question**

The outcomes of each study need to be classified according to their direction of support for the original question/hypothesis. Studies can be supportive, neutral (not supportive or opposing) or opposing for their various endpoints.

**Outcome(s) assessed**

<table>
<thead>
<tr>
<th>A = Return of spontaneous circulation</th>
<th>C = Survival to hospital discharge</th>
<th>E = Other endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>B = Survival of event</td>
<td>D = Intact neurological survival</td>
<td><em>italics = Animal studies</em></td>
</tr>
</tbody>
</table>

The relevant outcomes that were assessed by the studies should be designated in the table along with the study citation. The choice of outcome designations include:

- A = Return of spontaneous circulation
- B = Survival of event
- C = Survival to hospital discharge
- D = Intact neurological survival
- E = Other endpoint

These outcomes should be those that were decided on when the question was asked, though during the course of the literature review it may become apparent that other outcomes should be included (eg. decreased “hands-off” time with a new compression:ventilation ratio).

**Note:** Intact neurological survival may indicate a favourable Cerebral Performance Category (of 1 or 2), or a particular discharge destination (eg. home or rehabilitation facility).

The various qualities of the individual studies (LOE, Quality grade, Direction of Support, Outcome assessed) should be inserted into the relevant table of the worksheet, with appended outcome letters as appropriate.
Magnitude of any observed effect

The magnitude of the observed effect should be quantified for each study. Preferred representations of data include means (or medians if data not normally distributed) or proportions, both with 95% confidence intervals. Changes in proportions should be expressed as absolute risk reduction, and number needed to treat (or harm). Diagnostic or prognostic data should be converted into sensitivity, specificity, and positive/negative likelihood ratios (http://www.cebm.net/index.aspx?o=1157). A useful program (DAG_stat.xls) is available at http://www.mhri.edu.au/biostats/DAG_Stat/. (See also C2010Effects.doc)

This information can be included in the “Reviewers’ Final Comments” section, as well as in the notes for the individual studies (in the “Citation list”).

Reviewer’s Final Comments

This section is probably the most important part of the whole worksheet. This is where the author, who now has the most intricate understanding of the literature, can succinctly describe the results of their review (including reference to individual studies where relevant), and start to synthesize the information. The author can tease out the contradictions, make observations, and propose solutions. This is effectively the discussion section of the worksheet based systematic review.
CONCLUSION

This section represents the conclusion of the worksheet based systematic review.

**Conensus on Science statement**

In this section the author should try and create a summary statement that encompasses the body of evidence. The generic format for the Consensus on science statement is as follows:

Evidence from X\# type of study in adults [{insert study design and highest quality design}] and additional studies [{insert range of LOE}] document consistent improvement in [{insert relevant clinical outcome}] when [{insert treatment}] is administered by [{insert provider}] to patients with [{insert clinical condition}] in the [{insert prehospital, hospital, etc}] setting.

Two examples of these are included below from the 2005 CoSTR publication (hence they use the C2005 Levels of Evidence):

“Ten studies (LOE 2\(^{20,21}\); LOE 4\(^{22-26}\); LOE 5\(^{27}\); LOE 6\(^{28,29}\)) show that lay rescuers\(^{23,25,30}\) and healthcare providers\(^{20,21,24,26-29}\) are often unable to accurately determine the presence of a pulse within 10 seconds. Two studies in infants (LOE 5\(^{31,32}\)) reported that rescuers rapidly detected cardiac activity by direct chest auscultation but were biased because they knew that the infants were healthy.”

“One RCT (LOE 2)\(^{115}\), 1 prospective controlled cohort study (LOE 3)\(^{116}\), 2 cohort and case studies (LOE 4)\(^{117,118}\), supported by 27 cohort and case studies (LOE 5\(^{119-138}\); LOE 7\(^{139-145}\)) indicate hesitancy or unwillingness to perform CPR, particularly mouth-to-mouth ventilation, on adult patients in and out of hospital, even after CPR training. Reasons for the hesitancy or unwillingness to perform CPR include, but are not limited to, fear of contracting a disease while performing mouth-to-mouth ventilations, fear of performing the skills incorrectly, and fear of hurting the patient.”

**Treatment recommendation**

Whenever possible a treatment recommendation will be developed. Obviously a number of complex factors must be considered when finally creating a consensus statement. Some of these factors
include the magnitude of the effect, the outcome affected, the generalisability from the specific population studied, and the potential barriers to implementation (including cost, education, logistics etc). For these and many other reasons, the treatment recommendation suggested by the worksheet author may be significantly modified before final publication in a consensus document. The generic format for the treatment recommendation statement is as follows:

Therefore, administration of {{therapy}} for patients with {{condition, setting by personnel}} is recommended/should be considered.

Two of these are included below from the 2005 CoSTR publication:

“It is reasonable for laypeople and healthcare professionals to be taught to position the heel of their dominant hand in the center of the chest of an adult victim, with the nondominant hand on top.”

“Introduction of a MET system for adult hospital in-patients should be considered, with special attention to details of implementation (eg, composition and availability of the team, calling criteria, education and awareness of hospital staff, and method of activation of the team). Introduction of an EWS system for adult in-hospital patients may be considered.”

**Conclusion**

<table>
<thead>
<tr>
<th>CONSENSUS ON SCIENCE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence from one fair randomized trial (LOE 1) and supportive evidence from nine other studies (LOE 2 to 6) document consistent improvement in neurological outcome after discharge from hospital in patients who had experienced an out-of-hospital cardiac arrest where the initial rhythm was ventricular fibrillation and were still comatose, and who were cooled within minutes to hours after return of spontaneous circulation to 32-34°C for 12-24 hours.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>TREATMENT RECOMMENDATION:</th>
</tr>
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<tbody>
<tr>
<td>Unconscious adult patients with spontaneous circulation after out-of-hospital cardiac arrest should be cooled to 32-34°C for 12-24 hrs when the initial rhythm was ventricular fibrillation (VF) (Level 1).</td>
</tr>
<tr>
<td>Unconscious adult patients with spontaneous circulation after out-of-hospital cardiac arrest as a result of any other rhythm, or cardiac arrest in hospital, cooling to 32-34°C for 12-24 hrs may also be beneficial (Level 4).</td>
</tr>
<tr>
<td>Cooling should be started as soon as possible.</td>
</tr>
<tr>
<td>Rapid infusion of 30 ml kg⁻¹ of 4°C saline is a simple method of achieving a decrease in core temperature of approximately 1.5°C (Level 5).</td>
</tr>
</tbody>
</table>

**Acknowledgements**

As with any publication that undergoes peer review, the worksheet author(s) are required to acknowledge any significant contributions to their work.

Please insert any acknowledgements into the worksheet.

**Citation list**

The final part of the worksheet is also extremely important. In the section entitled “Citation list” we request the authors paste their references in alphabetical order. This can be easily done from the Endnote program, where the reviewed studies can be selected, and then pasted with accompanying details into the worksheet. Citations should be pasted after they have been copied formatted (command K). The easiest approach is to export the citations in a modified Vancouver style, with abstracts and notes fields included (see also C2010Endnote.doc). Before pasting, please put citations into alphabetical order. Please also include comments with each of the citations (these can be inserted into the notes field of the reference in Endnote):

- LOE,
• Quality,
• Supportive/Neutral/Opposing, and
• Brief summary statement(s), including comment about industry funding.

There is accumulating data that industry funding of RCTs and meta-analyses can result in an increased estimate of effect size, so some statement should be made for each study about industry funding or otherwise.

Please paste your citations, with accompanying abstract and notes/comments, into the worksheet.

Citation List

Level 3. Neutral/Unconvincing)
27 in-hospital arrests at Johns Hopkins University (Baltimore), excluded 2 failed resuscitations and 6 good neurological outcomes. 19 patients with neurological insult after successful resuscitation (internal cardiac massage) were either cooled or not. Concurrent controls. No randomisation. 12 cooled to 30-32°C within 1 to 6 hours (for 3hrs to 8 days). 7 not cooled. Survival in 1/7 vs 6/12 (FE, P=0.17). Included all four cases reported in Williams and Spencer Ann Surg 1958. No comment about industry funding.

Summary

You should now have completed your worksheet ready for submission. You should be proud of the work that you have done, but now the peer review process begins. As with any manuscript submission, a number of questions or suggestions may result from the review of your worksheet by the Evidence Experts or other leaders within the 2010 process. Please accept any feedback as constructive comments, which are provided to try and optimise the process.

Peter Morley
Evidence Evaluation Expert
C2010

References

http://www.cebm.net
http://www.cochrane.org