CAM Cancer | Complementary and Alternative Medicine for Cancer

METHODOLOGY

Manual for Writing and Reviewing CAM Cancer Summaries

Editorial Process

http://cam-cancer.org

Contents

1. Introduction

Complementary and Alternative Medicine (CAM) is frequently used by cancer patients in countries across the world. Reliable information about the safety, effectiveness and efficacy of CAM is therefore highly needed.

The CAM Cancer project was originally funded by the European Commission within the framework of the "Quality of Life and Management of Living Resources" program during its set-up phase October 2002 - September 2005).

Since September 2007, the National Research Center for Complementary and Alternative Medicine (NAFKAM) at the UiT The Arctic University of Norway has been managing the CAM Cancer project. The project is aimed at contributing to evidence-based cancer care by:

- Developing and sustaining a network of experts in the field of CAM and cancer research.
- Providing summarised and synthesized information about the efficacy and safety of CAM used in cancer. These 'CAM summaries' cover a wide range of topics
- Ensuring that the best available research evidence concerning CAM interventions is presented to healthcare professional in an accessible and easy-to-use way
- Ensuring that CAM summaries are written in an independent and non-judgemental way to maximise their use amongst health professionals
- Providing a freely available web resource hosting the various publications detailed above.

2. CAM summaries – definition and aims

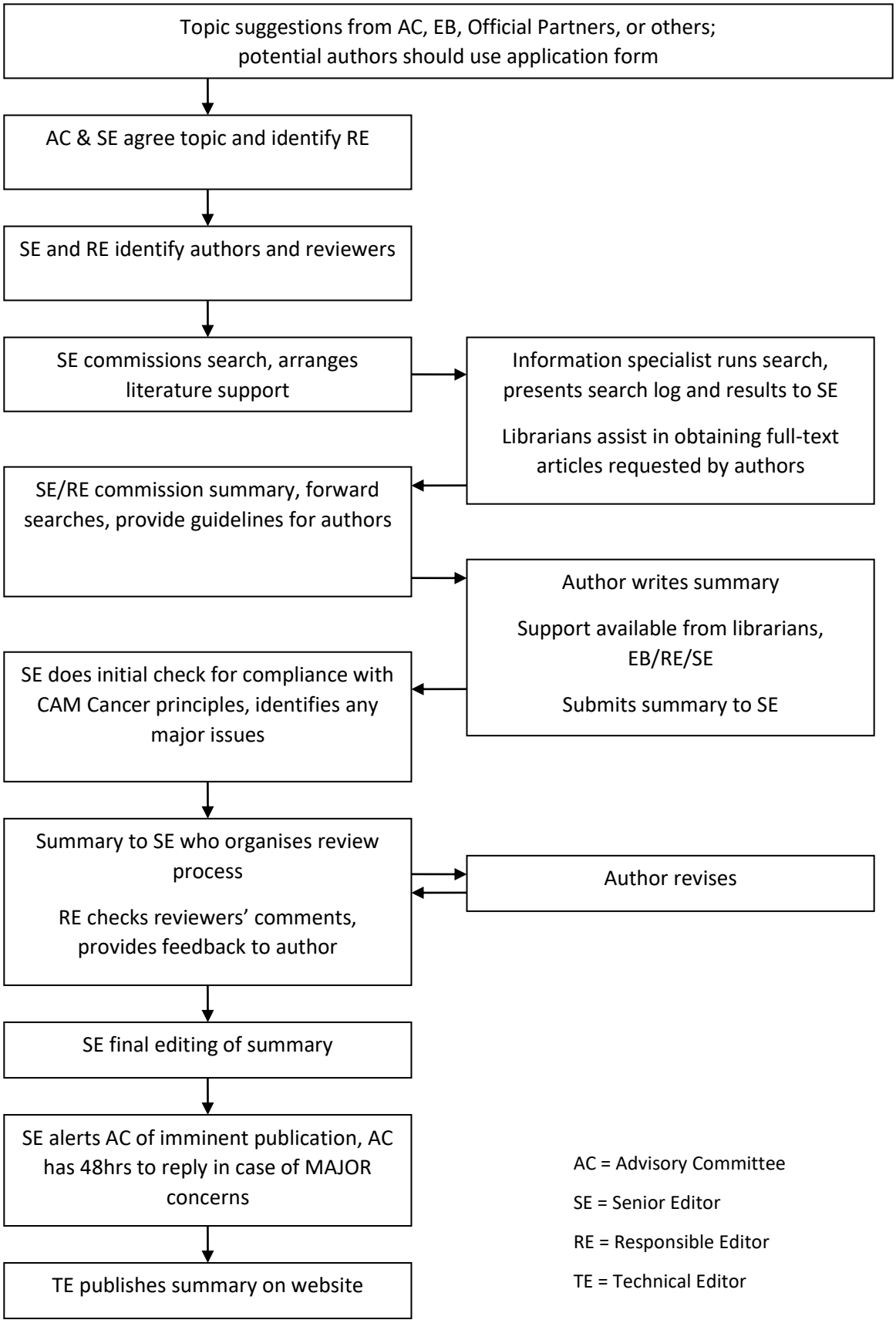
CAM summaries are evidence-based articles synthesizing the best available scientific information on CAM in cancer. They are aimed at summarising the existing evidence for or against CAM used in the prevention, treatment and palliative/supportive care of cancer patients. The selection criteria for CAM Cancer summary topics include 1) related safety issues 2) expressed patient interest and, if data are available, reported prevalence of use.

Although CAM summaries are NOT full systematic reviews they use systematic review methodology. For each CAM Cancer summary, background information on the intervention and evidence for or against its clinical effectiveness, efficacy and safety are systematically prepared. Both are presented in a standardized, clear and easily accessible format. CAM summaries are peer-reviewed and regularly updated. By providing clear statements they are aimed at assisting health professionals in making shared decisions with their patients.

Summaries produced to date can be found on the CAM Cancer website.

3. Authoring CAM summaries

Figure 1: CAM Cancer summary editorial process



3.1 Selecting topics and applying to write a CAM Cancer summary

The Advisory Committee advises on topics and Responsible Editors for new summaries. The respective Responsible Editor identifies together with the Senior Editor authors and reviewers for a topic.

If you wish to write a CAM-summary please contact the Scientific Coordinator Barbara Wider. Firstly, you should identify a CAM topic that has not yet been covered on the project website or is currently under development. The selection criteria include 1) the related safety issues 2) the expressed patient interest and the reported prevalence of use, if data are available.

Authors need to have experience in critical appraisal techniques and evidence synthesis. They should ideally be professionals working in the field of CAM and/or cancer, with experience of writing English language healthcare information. Authors are appointed on a case-by-case basis.

Once approved, authors should follow the instructions in Section 5 of this manual to produce the CAM Cancer summary using the CAM Cancer summary template.

3.2 Authorship and ownership

For each summary it is stated on the website that the summary is "written and reviewed by (author names) and the CAM Cancer Consortium". Readers will also be referred to a list of author and reviewer names posted on the project website. The ownership of the CAM Cancer summary and the related methodological documents will remain with the respective authors and the CAM Cancer Consortium.

4. Writing a CAM Cancer summary

The aim of a CAM Cancer summary is to synthesize and summarise the best available evidence about a specific intervention used in the prevention, treatment or management of cancer. This evidence can also be accessed according to symptoms/outcomes or cancer types. In order to maximise usability and reliability, the summaries need to follow the methods set out in this document.

4.1 General guidance for authors

CAM summaries are not full systematic reviews but follow systematic review methods to provide comprehensive summaries of the available evidence. The primary audience for CAM summaries are healthcare professionals and summaries need to be written with this readership in mind.

Please do not make any recommendations: Avoid wording the summary in a way which may be interpreted as making a recommendation. CAM summaries should summarise existing evidence in an unbiased way, but not provide advice.

4.2 Literature search

The CAM Cancer Scientific Co-ordinator provides authors with literature searches conducted by an experienced information specialist. The searches are all performed in Medline® and the Cochrane Library and are available in bibliographic software. They are fully documented (search terms, databases, interfaces, dates, filters, result log) in order to ensure they are systematic, transparent and reproducible. Full-text copies of key articles may be provided upon request by the Scientific Co-ordinator.

In addition, authors need to perform their own searches for general background information and general safety information. If an author's search does not provide any useful references, they can contact the Scientific Co-ordinator for assistance.

4.3 Guidelines and templates

Detailed guidelines and headings are provided in section 5. Please also refer to the template in appendix x. CAM summaries should be no longer than 3000 words with no more than 40 references, unless agreed otherwise with the Senior Editor.

5. CAM Cancer summary writing guidelines

5.1 Abstract

Leave the writing of the abstract to the end - it will be easier to summarise your work once you have gathered all information.

Summarise your findings in a way that will enable health care professionals to make unbiased and informed decisions. Although CAM summaries are written for professionals, do consider how the summary will be understood and interpreted by lay persons.

Structure the abstract as follows and summarise each point with 1-2 sentences:

- What is the commonly used name for the CAM modality you are describing (if it is a herbal remedy, please mention the *Latin* name, as well as any used common name where this is available) and what does the CAM method entail?
- What are the **claimed** effects of the therapy? Make sure to state that these claims are made by the provider and should not be taken at face value.
- What research evidence is available? Please copy over the summary bullet point list from the "Does it work section".
- What are the main safety issues?

5.2 What is it?

In this section, please provide a description of the CAM treatment covering the points listed below. Please use the appropriate headings for natural products (e.g. herbal/other supplements) and therapies. Please refer to monographs by EMA, ESCOP, WHO or Herbs at a Glance.
Please limit this section to a maximum of two pages. Please always reference your sources.

Natural products: (herbal) supplements, dietary approaches

Description and background

- Scientific name, known synonyms and common names
- Systematic classification into a plant family, genus and species; if necessary differentiate it from other related species
- Medicinally used plant parts
- Distribution and important cultivation areas
- Prevalence, if known

Word count: 200-300

Ingredients and quality issues

- Active ingredients/constituent groups
- Quality requirements/issues; if available include quality regulations (e.g. from a monograph such as Ph Eur)

Word count: 200-300

Alleged indication

- Use in traditional herbal medicine and/or rational phytotherapy
- Use in cancer-specific context

Word count: ~200

Application and dosage

- Different forms of administration (e.g. oral, intravenous; tablets, liquid)
- Recommended dosages (monographs of EMA, ESCOP or Commission E, if available)
- Other relevant information on use, onset of treatment effects, duration of use

Word count: ~200

Mechanism of action

- Describe how the intervention might work in relation to the alleged indications mentioned above.
- (Presumed) effects of ingredients or preparations in biological systems (e.g. cells, tissues, organs)
- If known, influence of dose-dependent and structure-dependent factors
- Pharmacological properties of the ingredients
- Mutagenic and teratogenic potential of the preparation

Word count: 200-300

Legal issues and costs

- Availability, legal provisions on pharmacy / prescription requirements as well as the approval status (drug, medicinal product, food supplement, food) classification of the EMA
- Estimated cost of a 1-month treatment course

Word count: 100-200

Therapies

Description

- Names, general description and definition
- Distinguish from other related therapies, if applicable

Word count: 200

Background and prevalence

- Brief history, who developed the therapy and further developments
- Prevalence data, if available

Word count: 100

Alleged indications

- General use / indications
- Use in cancer-specific context

Word count: ~200

Mechanisms of action

- Describe how the intervention might work in relation to the alleged indications mentioned above.
- If applicable, please describe the metaphysical/spiritual components of the effects
- Consider variations of the therapy and use for specific symptoms/indications

Word count 200-300

Application and providers

- Description of how the therapy is being used, components, techniques, setting, duration, frequency
- Description of provider: self-care technique, professional advice needed, monitoring of patient needed
- Required qualifications of providers

Word count: 200

Legal issues and costs

- Availability, legal provisions
- Estimated costs of a 1-month therapy course

Word count 100-200

5.3 Does it work?

In this section, please **critically appraise and summarise** the clinical evidence from the articles identified through the literature search.

The section consists of two main parts 1) a summary of the available evidence and 2) a description of included studies (see also template on page 3). Please start with the "**Description of included studies**" section following the guidelines below before writing the summary.

Summary

Once the "Description of included studies section" is completed, please provide a **summary** consisting of a brief description of the body of evidence available (how many SRs/RCTs are available; quality of this evidence) and a bullet point list summarizing the main findings per symptom/outcome (1-2 sentences per outcome). This summary will go at the beginning of the "Does it work" section and will also be copied into the abstract. Please see below for an example.

Description of included studies

Please use the main headings "Anticancer treatment", "Supportive care", "Prevention". Under these main headings, please start by summarizing the evidence according to symptoms/ indications/treatment outcomes using these outcomes as subheadings (e.g. Pain, Anxiety; see below, under "Template"). Start with systematic reviews/meta-analyses followed by clinical trials **not** included in the reviews. Please include PICO (participants, interventions, controls, outcomes) to describe the studies, a brief quality assessment and the main findings. If you include 5 or more studies, please also complete a table (see below Evidence tables).

Study types

Summarize evidence from the following study types:

- systematic reviews (SRs), meta-analyses
- controlled clinical trials

Only include the following study types if no systematic reviews or controlled clinical trials are available; please clearly describe them as such and discuss their limitations:

- narrative reviews (only if no SRs or RCTs are available)
- uncontrolled clinical trials – only if no or very few controlled trials are available
- case series/studies – only if no trials available.

Results of pre-clinical trials and basic research should be included under "Mechanisms of action".

There is no need to summarize individual trials if a systematic review is available. In such cases, only trials published after the SR or outside the scope of the SR should be added to the summarised results.

If several SRs are available please use the most recent authoritative SR, e.g. a Cochrane review as well as any subsequent SRs or SRs focussing on other outcomes/with a different scope. Consider including SRs published in the last 5 years only. If in doubt, please contact the Scientific Coordinator.

Methodological aspects

Evidence: What is the level of evidence?

- (Several, most rigorous etc) studies suggest (demonstrate, show etc) therapy x to be effective for condition y [the most positive result]
- No trial data are available [inconclusive because of lack of evidence]
- The data from the (most relevant, rigorous etc) trials are contradictory [inconclusive because of lack of agreement]
- The data from the (most relevant, rigorous etc) trials are of very low methodological quality [inconclusive because of lack of methodological rigour]
- Several, most rigorous etc studies suggest therapy x to be not effective (better than placebo) for condition y [the most negative result]

Quality/risk of bias:

- Please describe the quality/risk of bias/certainty of the evidence.
- What methodological limitations of the underlying clinical research might affect practical decisions about healthcare?
- Which other information should be considered by someone making a decision (current practice, compliance etc.)?

Evidence tables

Summaries including five or more SRs or RCTs/CCTs should present review/trial details in table format rather than describing them in full in the text. Please refer to the table templates in Section 5.6.

Please also include a paragraph in the text summarising the main conclusions of the trials (number of trials, indications, main results and conclusion) and reviews (number of studies and patients, type of studies, main outcomes, main results and conclusion). Readers should be able to understand this summary paragraph and get enough information without having to read the table.

Does it work? - Template

Antitumour therapy

General info, e.g. overview/number of systematic reviews and controlled clinical trials; have they looked at mainly one cancer type; if all/most studies suffer from methodological limitations please state this here so you don't have to include it for every single trial, which gets very repetitive.

- Survival: Summary of main findings, please summarize the main findings for each outcome, one bullet point with 1-2 sentence per outcome. Include number of studies, direction and quality/certainty of evidence
- Tumour progression: as above.

Description of included studies

Survival

Please describe and critically appraise the included systematic reviews and clinical trials using PICO: participants (including number of participants), interventions, comparison/control, outcomes. Please also include the study type (e.g. RCT, non-randomized controlled trial, etc) and a critical appraisal. Start with systematic reviews/meta-analyses followed by clinical trials **not** included in the reviews.

Tumour progression

As above under "Survival".

Supportive care

General info, see above under "Antitumour therapy".

- Summary of main findings (as above) for outcome 1
- Summary of main findings for outcome 2
- Summary of main findings for outcome 3, etc

Description of included studies

Pain

Please describe and critically appraise the included systematic reviews and clinical trials using PICO (see above under "Survival").

Fatigue

As above.

Depression and anxiety

As above.

Prevention

As above under "Antitumour therapy" and "Supportive care".

Sample summaries

https://cam-cancer.org/en/selenium; https://cam-cancer.org/en/music-therapy; https://cam-cancer.org/en/aloe-vera

5.4 Is it safe?

For this paragraph please summarise what you have found with regards to safety/applicability of the CAM modality. Please consider/include the following issues:

Adverse reactions/effects

- Frequency: common, occasionally, rare, very rare
- Dose-dependency
  Severity
- Reversibility
- Occurrence of severe AEs

Word count: 150

Contraindications

- To what extent should an administration be considered after carefully weighing up all advantages and disadvantages (relative contraindication) or should be rejected (absolute contraindication)

Word count: 100

Interactions

- Interactions with drugs or other therapies

Word count: 200

Warnings

Important procedures and precautionary measures with regard to the treatment of cancer patients are discussed (e.g. specialist medical clarification in advance of treatment, exclusion of interactions, communication on treatment-relevant diagnoses and complications)

Word count: 50

Please use the template provided *in appendix 1.* Please always reference your sources.

5.5 References

The summary should contain **a maximum of 40 references**. Please use the author date system.

5.6 Evidence tables

Table 1: Systematic reviews of xxx for xxx

Source:

Study year (ref)	**Design and methods**	**Inclusion criteria**	**Included studies and participants**	**Included interventions and outcomes**	**Main results/ Conclusions**	**Comments**
First author year (ref no)	Type of review: Search strategy: dates, databases, restrictions Quality assessment: Measure of treatment effect: Data synthesis: meta-analysis?	Studies: Participants: Interventions/ comparator: Outcomes:	Studies: n and design (e.g. RCT) Participants: n and diagnosis	Intervention: Control: Concurrent treatment: Outcome measures:	Results for outcome measures: Results quality assessment: Conclusions:	Review limitations: Any other comments:

Table 2: Controlled clinical trials of xxx for xxx

Source:

First author, year, (ref)	Study design	Participants (number, diagnosis)	Interventions (experimental treatments, control)	Main outcome measures	Main results	Comments (critical evaluation, weaknesses, etc)

6. Managing the production process

6.1 Submitting a CAM Cancer summary

After checking for compliance with the above guidelines, the author submits the CAM Cancer summary in electronic format to the Scientific Co-ordinator within the agreed deadlines. The Senior Editor and Responsible Editor then organise the peer review process.

6.2 Publishing a CAM Cancer summary

Following peer review and any necessary amendments the final CAM Cancer summary is published on the CAM Cancer website.

6.3 Updating CAM summaries

Summaries are updated on a regular basis. Updating should only be done in agreement with the Scientific Coordinator. Summaries over three years old and previous versions of summaries will be archived.

7. Reviewing a CAM Cancer summary

7.1 Task of scientific reviewers

The aim is to ensure that CAM summaries are prepared in accordance with the standards outlined in this manual.

7.2 Review process

- The Senior Editor checks the received CAM summary and forwards it to the respective Responsible Editor. If major issues are identified at this stage, the summary needs to be revised before peer review. Otherwise the summary is sent to the two appointed reviewers.
- The Responsible Editor checks the evaluation and recommendations provided by the two independent reviewers, and together with the Senior Editor prepares feedback for the author. Direct discussions between editors, reviewers and authors can take place.
- The author amends the summary; the modified version has to be approved by the reviewers and/or Responsible Editor.
- Once the document is considered as final by the reviewers and editors, it is sent to the Advisory Committee who can raise major concerns within 48 hours.
- After that, the document is published on the CAM Cancer website.

- For **updates**, minor updates are reviewed by the Responsible Editor and Senior Editor. Major updates are be fully peer reviewed.

7.3 Reviewing methods

Reviewer should assess the following four main quality criteria:

- completeness and comprehensiveness of the document,
- topicality,
- neutrality,
- user-friendliness.

A reviewer checklist is available upon request but reviewers can use free text or insert comments directly in the text.

The Responsible Editor ensures that there is consistency between reviewers' comments. In case of major disagreement between the author and the reviewers or between the reviewers themselves, the Responsible Editor will try to reach consensus. If no agreement can be found, the Senior Editor and/or the Advisory Committee shall make a decision.