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ACCREDITATION PROCEDURE FOR PRODUCERS OF EVIDENCE BASED PRACTICE SOURCES

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Table of contents

1. Introduction

Cebam, the Belgian Centre for Evidence Based Medicine, is an independent, multidisciplinary and inter-university medical scientific institute that focuses on healthcare providers, patients and healthy citizens. As host of Cochrane Belgium and member of GIN (Guidelines International Network), Cebam makes part of an international independent network of researchers, health care providers and patients who aim to promote and support health-related, evidence-based decision-making. In this context, one of the tasks of Cebam is the evaluation of clinical practice guidelines and evidence based practice (EBP) information for primary health care on scientific quality and reliability, following international standards. Cebam offers professional organizations all over the world the opportunity to have its guidelines validated and to have medical scientific information certified. Guideline organizations or producers of large quantities of guidelines or EBP-information can be accredited. This gives the care provider, the policymaker and the patient the guarantee that the guideline or the EBP-information is trustful and of methodologically good quality. A Cebam validation, certification and accreditation (*see glossary*) are considered as a quality label.[1]

Health care professionals routinely use clinical guidelines as reliable sources of information to support their clinical decision-making. However, for many clinical problems or health care professions there are no or limited guidelines available. In that case, one depends on other EBP-sources. Identification of the most relevant information and assessment of its quality and transparency is indispensable when used in clinical practice. Furthermore, the reliability of the information and the associated methodological process must be clear. For this purpose, the procedure for certification of EBP-sources was developed by Cebam. The procedure for certification of EBP-sources differs from the procedure for guideline validation, where AGREE II is applied. The accreditation of a producer of EBP-sources applies to producers that make a large amount of information available that is frequently updated. The basic principles and criteria used for this procedure are further explained in this document.

[1] In Belgium, only guidelines and EBP-information with this quality label are published on Ebpracticenet, which is the reference platform for point-of-care information, financed by the Belgian government, for evidence based practice for first line healthcare professionals. In this way, every healthcare professional has easy access to high-quality, reliable information.

2. Glossary

The procedures for EBP-source certification, guideline validation and accreditation of a producer are developed and are carried out by Cebam. What we understand by each of these procedures and to what information they can be applied, is clarified in this glossary:

- **Guidelines:** Clinical practice guidelines are statements that include recommendations intended to optimize patient care, which are informed by a systematic review of scientific evidence and an assessment of the benefits and harms of alternative care options (Graham et al. 2011). Guidelines are based on concrete clinical questions and are developed according to a strict methodology. This methodology meets all criteria of the international evaluation tool AGREE II (AGREE Next Steps Consortium 2009).

- **Recommendation**: recommendations are statements for or against an action and are intended to improve patient care and are based on the systematic assessment of scientific evidence, on the assessment of the benefits and harms of the different care options, and on a report of other consideration that play a role in translating the evidence to the recommendation(Graham et al. 2011). Recommendation are ideally developed within the framework of guidelines. Recommendations developed in the context of EBP-sources, do not always have the same rigor of development as recommendations developed in the context of guidelines. To make a clear distinction between the underlying methodological process, we will use:
    - Guideline recommendations: i.e. recommendations developed within the framework of guidelines.
    - EBP-source recommendations: i.e. recommendations developed within the framework of EBP-sources.

- **Guideline validation**: The assessment of a guideline and the methodological development process on quality and transparency, on the basis of internationally established criteria according to AGREE II (AGREE Next Steps Consortium 2009)**.**

- **EBP-sources:** "Evidence Based Practice sources". These are for example summaries, critical reviews, tools, care trajectories,… based on the best available scientific evidence. In the evaluation of EBP-sources, Cebam distinguishes between EBP-sources that include recommendations (also called 'hybrid sources') and EBP-sources that not include

recommendations. EBP-sources that include recommendations must meet additional evaluation criteria. Further explanation of these additional evaluation criteria can be found in the Cebam memorandum “Recommendation in EBP-sources”, see appendix).

- **EBP-source certification**: Assessing an EBP-source (except guidelines) and the associated methodological process, based on predefined criteria. The objectivity, validity and reliability of the EBP-source are evaluated. Certification applies to one product with a limited number of items. If new information is added, it must again be certified. The CAPOCI-tool (Lenaerts et al. 2021) was developed by Cebam for certification of EBP-sources.

- **Accreditation of a producer:** Assessing the methodology and transparency and execution of the methodological development process as applied by the independent producer, based on predetermined criteria. This procedure is used when an independent producer makes a large amount of information available that is frequently updated and complemented, which makes it impossible to systematically apply the previous procedures. An accreditation can apply to both a producer of guidelines and a producer of EBP-sources. There is a procedure for the accreditation of producers of EBP-sources, and a procedure for the accreditation of producers of guidelines (obtainable from Cebam). Accreditation is principally valid for 5 years. (In some circumstances, Cebam can decide to accredit for periods shorter than 5 years.) If new information is added during this 5-year period, this information is automatically accredited.

3. Basic principles and procedure for the accreditation of a producer of a specific EBP-source

Basic Principles

1. The procedure of accreditation of a producer of EBP-sources applies to organizations that produce a large amount of EBP-information, with regular updates. The methodological process, used for the development of a specific EBP-sources will be subjected to the accreditation procedure.

2. The accreditation procedure applies to EBP-sources and the associated developmental process. The producer can be accredited for the development of one specific EBP-source for which the same development process is always used.

3. Before to start the accreditation process, Cebam will preliminary check the following points:

1. The **purpose** of the information is clearly described.
2. It is clear **for whom** the EBP-source is intended.
3. It is clear **who manages** the EBP-source**.**
4. It is clear **who finances** the EBP-source.
5. There is a clear reference to the **initial source**.
6. The EBP-source is **independent**, i.e. the financier has no influence on the content of the EBP-source.
7. The medical or health-information is given based on **expertise,** from (para)medics or scientist, qualified and experienced in a specific domain.
8. The EBP-source is the result of a scientific, methodological process, this process can be explained at the request of Cebam.

4. Cebam guarantees the confidential treatment of all documents that are made available to Cebam by the producer for the accreditation procedure.

5. An accreditation is principally valid for 5 years starting on the date on which accreditation is granted.

<u>Procedure</u>

1. An application for accreditation is made in writing to Cebam.

2. The necessary information about the methodological process and independence of the producer (cf. Basic Principles, point 2) is transferred in a digital format to Cebam.

3. The eligibility of the application is investigated by Cebam (cf. Basic Principles, point 3).

4. The producer is informed about the formal acceptance or non-acceptance of the accreditation procedure.

5. Cebam has the right to visit the organization, when there is insufficient clarity about the development and execution of the methodological process, based on the transferred information. This visitation consists of

a. an interview with at least 3 key persons of the organization (for example a manager, information manager and coordinator the methodological process);

b. any observation of the different processes and methods that the producer applies to create the EBP-source.

6. A contract is made upon acceptance.

7. The producer makes the EBP-source and methodological handbook digitally available to Cebam.

8. An accreditation committee is composed of a chair (Cebam) and minimal 2 reviewers (Cebam). The reviewers must have a broad research experience, namely in the possession of a PhD or must be able to demonstrate more than 5 years of research experience. They must also be experienced in evidence-based methodology, that is, have demonstrable experience with validation (guideline validation, validation studies, writing systematic reviews, etc.). The review panel consults experts, experienced in the specific domain described in the EBP-source, where necessary. The producer of the EBP-source has the right to disapprove one expert in the content prior to the start of the accreditation process.

9. Cebam will take up the task of administrative support. This includes registration of the application, correspondence with the applicant, searching for and correspondence with experts, possible organization of the visit, etc. .....

10. The criteria for accreditation of a producer for a specific EBP-source, are based on the CAPOCI- tool developed by Cebam (*Lenaerts et al. 2021)*) and explained hereunder (cf. *4. Accreditation of EBP-sources using the CAPOCI-tool*). Cebam will evaluate whether the methodological handbook used to develop the EBP-source meets the CAPOCI-criteria and subsequently whether the described methodological process has been carried out correctly and transparently. Therefore, Cebam will also evaluate whether a sample of the EBP-products meets the CAPOCI-criteria. Therefore, each reviewer will evaluate a different sample, next the results for each criterion are compared and discussed, to come to a consensus for one final results for each criterion.

11. Cebam provides all members of the accreditation committee with the EBP-information to be examined, the CAPOCI-criteria and an evaluation form to be completed.

12. The members of the accreditation committee are given 6 weeks to carry out the evaluation. In the meantime, a date has been set for the meeting of the accreditation committee (preferably within 8 weeks after application). This timing can be extended in function of any local visit. This is done in consultation with the applicant.

13. In addition to the members of the accreditation committee, a representation (1 to 2 people maximum) of the producer is invited without obligation to the meeting of the accreditation committee.

14. At the start of the meeting, the members of the accreditation committee fill in a document "Declaration of conflicts of interest" to declare any conflicts of interest.
15. The meeting takes place in three phases; a report is made by someone from the accreditation committee:

a. Closed discussion of the accreditation committee: discussion of the completed evaluation form (reviewed per item). The chairman lists items that are still unclear.

b. The representatives of the producer are then called in by the chairman; they were asked to explain the observations made by the chairman.

c. Private deliberation by the accreditation committee. The final decision on accreditation is communicated.

16. Cebam may at any time request additional information that deems necessary to complete the accreditation procedure.
17. A report is sent (preferably within a week after the meeting of the accreditation committee) to the applicant. The report repeats the comments of the accreditation committee, even though they were explained by the applicant during the accreditation meeting. There are two possible final decisions:

- The methodological process for the development of a specific EBP-source is accredited by Cebam.
- The methodological process for the development of a specific EBP-source is not accredited by Cebam.

18. If the methodological process for the development of the EBP-source has not been accredited, this will be argued. The producer has 1 year to prove that he does meet the accreditation criteria. The producer is then reassessed on these points.

4. Accreditation of EBP-sources using the CAPOCI-tool

EBP-sources will be subject to an accreditation procedure according to the criteria described below.
Cebam conducted a systematic review for the development of a tool to assess the trustworthiness of EBP-information (Lenaerts et al. 2020). The scientific literature and relevant websites were systematically screened to find pre-existing tools, criteria and scoring systems that evaluate the objectivity, validity and reliability of EBP-sources. Based on the tools and criteria described in the included articles, the CAPOCI-tool, was developed. This new tool was piloted

several times during the development process on a few EBP-sources, and then discussed and refined by the various authors of this procedure. The tool was subsequently validated using an RAND modified Delphi method by an international panel of methodologists (*Lenaerts et al. 2021*). The CAPOCI-tool consists of 10 criteria, however, when an EBP-source contains recommendations (also called "hybrid source"), it is tested against the 10 criteria of the CAPOCI-tool, and three additional criteria, as stated below. For more information on the use of recommendations in EBP-sources, we refer to the Cebam memorandum on the use of recommendations in EBP-sources (see appendix).

Criterion 1: Authorship.

The authors must be referenced on the website, but not needed to be identified for each individual topic (clicking and searching may be necessary).

Criterion 2: Expertise of the authors

The author team is qualified in the specific domain and can demonstrate their expertise at the request of Cebam.

Criterion 3a: Literature search and surveillance

A systematic search strategy was used to search for source information.

Criterion 3b: Literature search and surveillance

Systematic methods were used for selection of the evidence from the search.

Criterium 4: Critical appraisal of the evidence

A critical appraisal has been implemented to assess the validity of the evidence used. The critical appraisal has to be scientifically robust and transparent. The critical appraisal assessment has informed the interpretation of the evidence.

Criterion for hybrid sources 1: Summary of the scientific evidence

The scientific evidence is summarized, including a description of the strengths and limitations of this evidence.

Criterion for hybrid sources 2: Description of the 'Evidence to Decision' (EtD)

The balance between the benefits and harms of the recommended intervention is reported, including other considerations (for example: costs, patient preferences, side effects,

feasibility of applying the recommendation) that were taken into account in formulating the recommendation.

Criterion for hybrid sources 3: Relationship between the recommendations and the evidence base

There is an explicit link between the recommendations and the underlying evidence.

Criterium 5: Use of the best available evidence

The content of the EBP-source should be based on the best available evidence, specific to the clinical question. Well-designed and conducted evidence synthesis documents, when available, are preferred above primary studies.

Criterion 6: Citation of expert opinions

When expert opinions are cited, this must be clearly indicated in order to distinguish it from empirical evidence. Experts should be listed along with their professional designation, organization g and a conflicts of interest statement.

Criterion 7: Review process

The scientific quality and the clinical applicability of the EBP-source is assessed by peer reviewers.

Criterion 8: Timeliness & updating

The frequency of updates is determined by the speed of developments in the field and is documented in the methodology. The content of the EBP-source is checked and updated when new information is available. The date of first publication, the date of the last update and data on the next planned update are clearly displayed in the EBP-source.

Criterion 9: Conflict of interest

There is a formal policy on declaring and managing financial and non-financial conflicts of interest of the authors and other stakeholders. Possible conflicts of interest are reported.

Criterion 10: Commercial support

It is clearly described to what extent commercial support was accepted for developing the content of the EBP-source. The financier has no substantive input and therefore no influence on the result or the content of the EBP-source. When advertisements on websites are a source of income, this must be clearly stated on the site. A short description of the advertising policy is

published on the site. Advertisements and other promotional material must be presented in such a way that visitors can clearly distinguish between editorial content.

5. Scoring system

A scoring system was developed based on the data from the systematic review conducted by Cebam (Lenaerts et al. 2019). Previous studies that assess the quality of EBP-sources use a scoring system to quantify the quality of different sources and thus be able to compare (Banzi et al. 2010; Kwag et al. 2016).

A system with the formulation of minor and major comments was opted for the CAPOCI-criteria used, analogous to the guideline validation process of Cebam. The EBP-sources are evaluated by two independent reviewers. Each reviewer will evaluate a different sample of items of the EBPs-source. Next, the results for each criterion are compared and discussed, to come to a consensus for one final results for each criterion. If necessary, a third reviewer is consulted.

Criterion 1: Authorship

- **Accepted**: name and affiliations of all authors are mentioned. Note: An affiliation with a particular institution is not necessary. Titles (such as, MD, PhD, Cardiologist…) are sufficient. Job title abbreviations must be explained if they are not standard in Belgium.
- **Minor remark**: only a general description is available (e.g. of the editorial board).
- **Major remark**: there is no information available on the authors.

Criterium 2: Expertise of the authors

- **Accepted**: the expertise of the author team is demonstrated. It does not need to be explicitly stated in the source. If necessary, this information will be requested.
- **Minor remark**: the expertise of the author team is unclear.
- **Major remark**: there is no information available on the expertise of the author team.

Criterion 3a: Literature search and surveillance.

- **Accepted**: A systematic search strategy has been used to search for source information. This search strategy is described in detail, stating the databases searched, the search terms used and the date of the last search.
- **Minor remark**: The description is not sufficiently detailed to be able to assess, there are inaccuracies in the methodological process.

- **Major remark**: Literature search seems to be implemented, but there is no description of the process; or, there is no information on how the literature search was done.

Criterion 3b: Literature search and surveillance

- **Accepted**: systematic methods has been used to select the evidence from the results of the literature search. These methods are described in detail, specifying the inclusion and exclusion criteria used to select the source information.
- **Minor remark**: The description is not sufficiently detailed to be able to assess, there are inaccuracies in the methodological process
- **Major remark**: A systematic selection process seems implemented, but there is no description of the process; or, there is no information on how this selection was done.

Criterion 4: Critical appraisal of the evidence

- **Accepted**: An adequate critical assessment of the scientific evidence has been carried out, the procedure has been described in a transparent way. This description mentions the tools and checklists used for the critical appraisal and its result; or, a full narrative description of the process. The critical assessment serves as a basis for the interpretation of the evidence.
- **Minor remark**: The description is not sufficiently detailed to be able to assess, there are inaccuracies in the methodological process.
- **Major remark**: It is unclear whether a critical assessment of study data has taken place.

Criterion for hybrid sources 1: Summary of the scientific evidence

- **Accepted**: The summary of scientific evidence contains statements about:
    - The studies with their respective study designs on which a recommendation is based;
    - The methodological quality of these studies, based on an assessment with a valid instrument;
    - The benefits and harms of the action, based on the results of these studies.
- **Minor remark**: The summary is incomplete; it lacks elements to reflect the strengths and limitations of the evidence.

- **Major remark**: There is no summary of the scientific evidence describing the strengths and limitations of this evidence.

Criterion for hybrid sources 2: Description of the 'Evidence to Decision' (EtD) –

- **Accepted**: The balance between the benefits and harms of the recommended intervention has been explicitly described; other considerations (costs, patient preferences, side effects, feasibility of applying the recommendation) are reported.
- **Minor remark**: The report of the balance between the benefits and harms of the recommended intervention contains inaccuracies or is incomplete. Other considerations were insufficiently described, so that the recommendation does not follow logically from the summary of the evidence.
- **Major remark**: There is no record of the balance between the benefits and harms of the recommended intervention.

- **Criterion for hybrid sources 3: Relationship between the recommendations and the evidence base.**
- **Accepted**: The relationship between the scientific evidence and the recommendations is clear: the references are anchored in the text and it is clear which scientific evidence supports the recommendation.
- **Minor remark**: The relationship between the scientific evidence and the recommendations is not sufficiently clear: e.g. the references are anchored in the text, but it is not clear which scientific evidence supports the recommendation.
- **Major remark**: The relationship between the scientific evidence and the recommendations can not be assessed.

Criterion 5: Use of the best available evidence

- **Accepted**: The content of the EBP-source is based on the best available evidence, specific to the clinical question. If available, well-designed and conducted evidence synthesis documents are preferred over primary studies.
- **Minor remark**: The description is not sufficiently detailed to be able to assess, there are inaccuracies in the methodological process.
- **Major remark**: It is unclear whether the authors prioritize evidence synthesis documents over primary studies.

Criterion 6: Citation of expert opinions.

- **Accepted**: It is clearly stated when expert opinions are cited, in order to distinguish it from empirical evidence. There is a description of the expertise of the experts, along with their professional affiliations, including a declaration of possible conflicts of interest.
- **Minor remark**: The description is not sufficiently detailed to be able to assess. The expertise of the experts is unclear. Or, the affiliations and declaration of conflicts of interest are lacking.
- **Major remark**: It is unclear whether expert opinions are cited. Or, the distinction between expert opinion and empirical evidence is unclear.

Criterion 7: Review process.

- **Accepted**: There is a detailed description of the review process of the scientific quality and the clinical applicability of the EBP-source. Note: Only a process description is sufficient, no details are expected about the comments that were made and how they were implemented in the EBP-source.
- **Minor remark**: Only a general description of the review process is available (e.g. "information was reviewed by external reviewer").
- **Major remark**: there is no information available about the review process.

Criterion 8: Timeliness & updating.

- **Accepted**: The EBP-source is frequently updated, in accordance with the developments in the field. The frequency of the updates is documented in the methodology. The date of first publication and last update can be found in the source, as well as information on the next planned update.
- **Minor remark**: Updates are performed, but not sufficiently frequently, which means that the content may be out of date.
- **Major remark**: No information about updates, date of last update not displayed.

Criterion 9: Conflict of interests.

- **Accepted**: Procedure for conflicts of interest has been implemented and documented (conflicts of interest should not be explicitly stated on the website, but the information must be able to be submitted to CEBAM).
- **Minor remark**: Conflict of interest procedure seems implemented, but not reported.
- **Major remark**: No information about conflict of interest procedure available (conflicts of interest are not checked or reported).

Criterion 10: Commercial support.

- **Accepted**: If commercial support is accepted, this is clearly and publicly announced and there is no influence of the financier on the content or the result of the EBP-source.
- **Minor remark**: not applicable.
- **Major remark:** There is insufficient information to judge.

6. Appendix

Attached document: Cebam memorandum on the use of recommendations in EBP-sources.pdf

7. References

AGREE Next Steps Consortium. 2009. 'Appraisal of Guidelines for Research & Evaluation (AGREE) II Instrument'. https://www.agreetrust.org/.

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