HAUTE AUTORITÉ DE SANTÉ

METHODOLOGICAL GUIDE

Development of good practice guidelines

“Clinical practice guidelines” Method

December 2010
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Summary

1 Introduction

The purpose of this guide is to describe the method for development of good practice guidelines according to the "Clinical practice guidelines" (CPG) method. It replaces the guide published by the National Health Accreditation and Assessment Agency (ANAES) in 1999 (1).

This guide is directed towards professionals who want to know the method used by the Haute Autorité de Santé (HAS) or who want to develop good practice guidelines (GPG) according to this method[1].

This guide will be updated after analysis:
- of the literature;
- of the opinions of methodologists and healthcare professionals outside of HAS;
- of discrepancies noted between the method published in 1999 and its implementation after survey of HAS project managers.

This guide will be adapted to best meet the demands and needs of the actors involved. Changes of the guide will be discussed and decided on with all of these actors.

1.1 Good practice guidelines

Among its responsibilities, HAS is charged with "creating good practice guides or **good practice guidelines**, distributing them and contributing to informing healthcare professionals and the public within these fields, without prejudice to measures taken by the French Healthcare Product Safety Agency (AFSSAPS) in the context of its health safety tasks" (Law of 13 August 2004 on health insurance, Title II, Chapter I bis, Article L. 161-37) (2).

The "good practice guidelines" are defined in the health field as "methodically developed proposals to assist the practitioner and the patient to find the most appropriate care in given clinical circumstances" (3).

These sheets are part of an objective of improving the quality and safety of care (4-6).

They are not intended to describe all of the management of a health condition or disease. They should be limited to points for improvement of this management, identified using studies of practices or, in the absence of such studies, using the opinions and experience of healthcare professionals concerned by the topic.

They have the objective of making available to the various actors in the healthcare system (professionals, patients and users, decision-makers), a rigorous synthesis of the latest developments and scientific data, in order to:
- help with decision-making in choice of care;
- standardise practices;
- reduce useless or risky treatments and procedures;
- reduce breaks in the care pathway.

The goal of the GPG is to improve patient management, and therefore the care provided to them.

The creation of a GPG should not be an objective in itself, but should be part of a good practice programme, ranging from the identification of points from improvement of management to the evaluation of this programme (7). A good practice programme can be part of continuing professional development.

[1] For sponsors outside of HAS, please refer also to the informational document "If you want to make a good practice guideline", available on www.has-sante.fr.

These GPGs can also be used:
- to create criteria for evaluation of professional practices (8), indicators for improving the quality and safety of care (9,10) or clinical practice indicators (11);
- as part of initial training.

The GPGs are rigorous summaries of the latest developments and scientific data at a given time. They do not exempt the healthcare professional from exercising discretion in the patient's treatment; this must be the treatment considered to be most appropriate depending on the professional's own findings and the patient's preferences.

1.2 "Clinical practice guidelines" method

A rigorous and clearly defined approach must be applied for the creation of valid and credible good practice guidelines.

The methods for development of good practice guidelines described by HAS are:
- the "Clinical practice guidelines" (CPG) method;
- the "Formalised consensus guidelines" (FCG) method (12).

The choice between these two methods is determined during the GPGs outline phase [2].

The CPG method is the preferred method for creating GPGs. However, the "Formalised consensus guidelines" method must be discussed if at least 2 of the following conditions are met:
- absence or insufficiency of literature with a high level of evidence, specifically addressing the questions raised;
- possibility of turning down the topic in easily identifiable clinical situations (lists of indications, of criteria, etc.);
- controversy, with the need for an independent group to identify and select among several alternatives the situations in which a practice is deemed appropriate.

The objective of the CPG method is to offer a small number of recommendations that are:
- concise;
- ranked, in accordance with the levels of evidence identified or, in the absence of scientific evidence, resulting from expert agreement;
- unambiguous;
- and respond to the questions raised.

The CPG method is a rigorous method for GPG creation, which is based on:
- the participation of professionals and representatives of patients and users affected by the topic of the GPG;
- transparency, with provision of:
  - critical analysis of the literature;
  - essential points from debates and decisions made by members of the working group;
  - ratings and comments of members of the reading group (version A) or comments of stakeholders (version B);
  - the list of all participants of the various groups.
- independent creation:
  - independence related to the status of HAS, as an independent public scientific authority (Law of 13 August 2004 on health insurance, Title II, Chapter I bis, Article L. 161-37) (2);
  - independence of the groups amongst each other; the working and reading groups each have a specific role that they accomplish independently of each other;

[2] Refer to the methodological guide "Development of good practice guidelines: Project outline" (13).

  - financial independence; public financing in the context of HAS GPGs;
- management of the interests declared by the experts of the working group, according to the procedure described in the HAS "Guide on the declaration of interests and management of conflicts of interest" (14).

2 General procedure for development of a good practice guideline

HAS, as a public and independent sponsor, ensures funding for the GPGs that it creates and distributes. It takes the initiative for creation of the GPG (on its own initiative) or responds to the request of another organisation, such as:

- a national professional speciality council, the Board of general medicine, a good practice board, a learned society or any other organisation of healthcare professionals;
- an institution, a health agency or a public health organisation;
- a health insurance organisation;
- an association representing users of the healthcare system.

After registering the topic of the guideline in the HAS programme, a project outline phase prior to the creation of any GPG is implemented. This step allows HAS, in collaboration with the requesting party, professionals and users involved, to select the GPG creation method (CPG or FCG) and to define the topic. In particular, this outlining phase makes it possible to specify the objective of the guidelines and the expected benefits in terms of quality and safety of care, the questions to address and the professionals and users affected by the guideline.
This outlining phase is described in a specific methodological guide available on the HAS website (13) (www.has-sante.fr).

The progress of a GPG, from outlining to distribution of the guidelines, is under the responsibility of an HAS project manager in charge of:

- ensuring the respect of the method and the quality of the synthesis of data from the literature;
- ensuring coordination and organising the project logistics.

The project manager participates in all meetings.

The chronological steps and the groups involved in the development of a good practice guideline according to the CPG method are shown in figure 1.

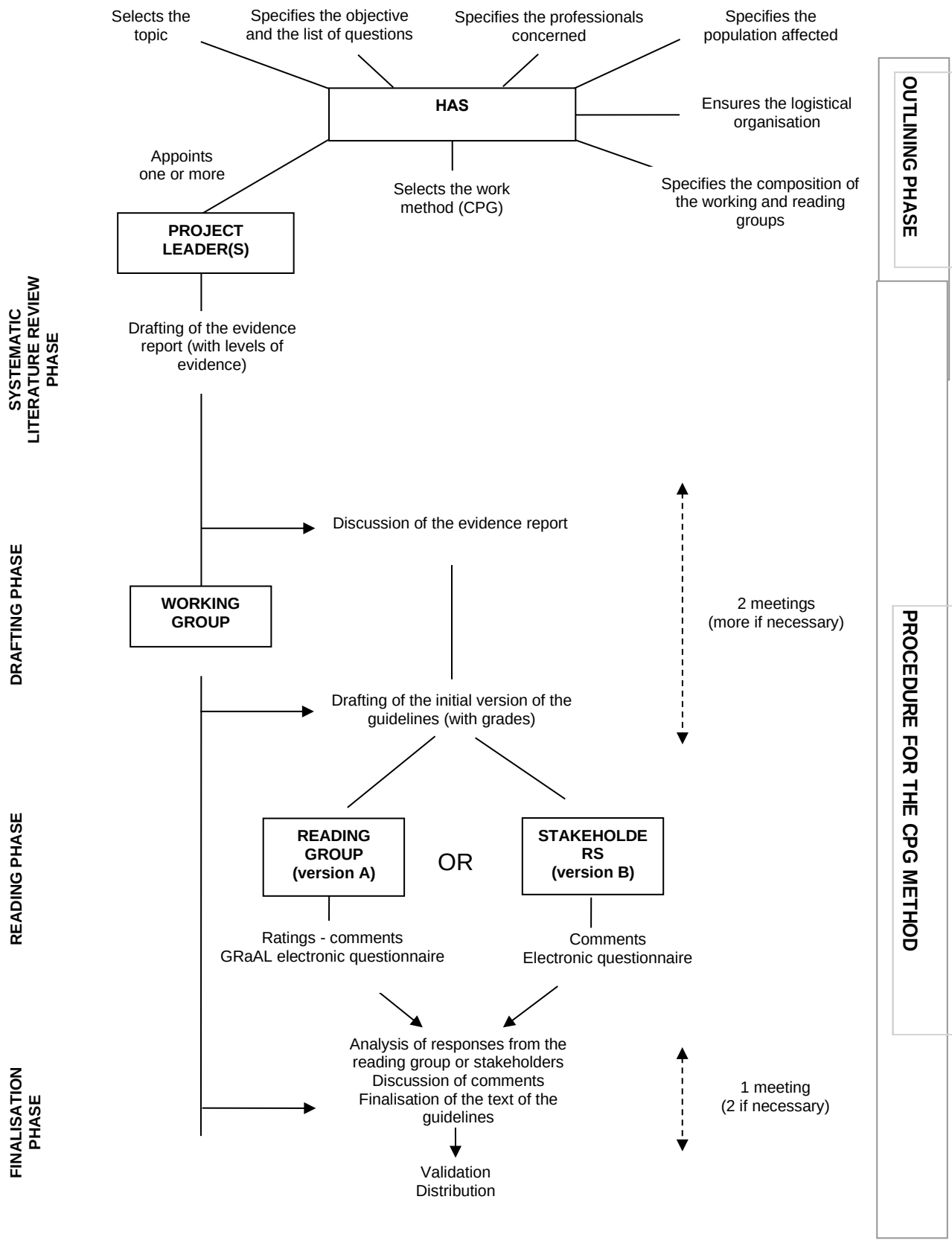

Figure 1. Development of a good practice guideline according to the CPG method.

3 Groups

Version A of the CPG method involves 2 groups: a working group and a reading group.

Version B involves only a working group.

The qualitative and quantitative composition of the different groups is determined in advance during outlining of the topic (see "Specific methodological guide" (13)).

The members of the working and reading groups, subject to their agreement, are appointed by HAS:

- on the proposal of the parties concerned by the topic: national professional speciality councils, the Board of general medicine, professional organisations[3], patient or user associations, institutions;
- based on the responses obtained to a call for candidates carried out in parallel on its website.

Moreover, HAS may directly ask independent persons known for their expertise.

The experts asked to participate in the working group must report their declaration of interests. They are analysed based on the topic by an entity dedicated to the management of conflicts of interest. The existence of major interests, as defined in the "Guide on the declaration of interests and management of conflicts of interest" available on the HAS website, justifies limiting or excluding the participation of an expert. The declarations of interests of the experts of the working group are published on the HAS website (www.has-sante.fr). The members of the working group must update their declaration of interests during the creation of the GPG and, in case of changes, send it to the HAS project manager (14). These experts express themselves as individuals, not as representatives of their professional organisation.

After having agreed to participate, all actors agree to respect the confidentiality rules in accordance with Articles R. 161-85 and R. 161-84 of the French Social Security Code. In particular, they agree to:

- not communicate about the subject by suggesting what might be or should be the conclusions of the guidelines;
- not distribute the content of debates, or the documents given to them.

At the end of the editorial work, all participants are cited in the documents distributed. Before publication and distribution, each participant has the option of indicating his or her dissent with the final version approved and endorsed by HAS.

3.1 Working group

The working group's task is to draft the guidelines, after hearing or reading:

- the bibliographic data available, summarised by one or more project leaders;
- the formalised opinion of the members of the reading group (ratings and comments) in version A or of the stakeholders (comments) in version B.

Ideally, the working group includes 15 to 20 professionals and representatives of patients or users, including:

[3] Organisations for the defence of professional interests (trade unions) are not generally called on in the context of the creation of good practice guidelines.

- a chair, in charge of coordinating all of the work with the HAS project manager.. Furthermore, it is recommended that this person:
  - be recognised for his/her scientific and human qualities;
  - have experience presiding over scientific meetings and the necessary skills to lead a group with sometimes divergent interests: authority, impartiality, moderation, and an ability to analyse, synthesise, judge and listen;
- one or more project leaders may be recruited to identify, select, analyse and draft a critical synthesis of the literature, as well as to assist in the drafting of the guidelines by writing preparatory texts and synthesising the proposals made by the members of the working group. The project leader(s) must not have any hierarchical relationship with the chair of the working group.

The healthcare professionals of this group must have a good knowledge of professional practice in the field corresponding to the topic of the study, and must be able to judge the relevance of the published studies and different clinical situations evaluated.

The working group must bring together people concerned by the topic under consideration. Depending on the topic, the members of the working group may be:
- physicians and non-physician healthcare professionals: nurses, physical therapists, speech therapists, etc.;
- researchers, epidemiologists, methodologists, etc.;
- members of associations of patients or users of the healthcare system;
- experts in non-medical fields: economists, legal experts, ethics specialists, sociologists, psychologists, etc.;
- representatives of public agencies, if necessary.

Representatives of the administration, health insurance or industry do not participate in the working group. However, the working group can consult them in order to ask them for information that the working group deems useful.

The project manager ensures that the composition of the group guarantees a balanced representation of:
- the main healthcare professions implementing the strategies evaluated, in accordance with the project outline;
- methods of practice (public, university-based or not, self-employed);
- different currents of opinion or schools of thought;
- the geographical origins of the stakeholders.

If it wishes, the working group may interview experts on the topic. Before interviewing such an expert, the working group will be notified of the declared interests. This participation will be mentioned in the evidence report.

Members of the working group must undertake to actively participate in the work for analysis and drafting of the guidelines. This imposes an availability, of which each member must be informed and aware of beforehand.

3.2 Reading group

The reading group gives a formalised opinion on the form and substance of the initial version of the guidelines, in particular on its applicability, its acceptability and its readability. The members give an advisory opinion, individually, and do not meet.

The reading group includes, depending on the topic, 30 to 50 people concerned by the topic under consideration, experts in the subject or not. Like the working group, this group is multidisciplinary and multi-professional, in order to reflect all professions, medical or not, implementing the strategies evaluated. It expands the range of participants in the work, bringing together representatives from medical specialities, healthcare professions or civil society not present in the working group.

In order to respect the independence of the groups, the members of the working group and the outlining meeting, as well as persons interviewed by the working group and those participating in the validation bodies, cannot be part of the reading group.

4 Procedure of the method

The procedure of the method is split into 4 phases:
- systematic review and synthesis of the literature;
- drafting of the initial version of the guidelines;
- reading;
- finalisation.

The main aspects related to coordination and logistics are specified in Appendix 1.

4.1 Systematic review and synthesis of the literature phase

The project leader(s) carry out this first step under the supervision of the project manager.

The tasks of the project leader(s) during this phase are to:
- conduct a systematic bibliographic search to identify and select references conforming to pre-established selection criteria;
- carry out a critical analysis and a synthesis of the literature retained in the form of an evidence report;
- propose a list of recommendations from the literature analysis conducted.

► Critical analysis of the literature

The drafting of the evidence report is preceded by a phase of document search and critical analysis of the literature. Appendix 2 presents the document search methods. For more details about the analysis and synthesis of the literature, refer to the specific methodological guide (15). Appendix 3 presents the levels of evidence and corresponding grades.

The bibliographic search is limited to French and international guidelines, from government or independent agencies, not funded by the industry, and to meta-analyses and systematic reviews (for example, *Cochrane*-type systematic reviews). Bibliographic updating of the documents retained will be carried out.

► Drafting the evidence report

The report includes the following elements:
- working method;
- document search and criteria for selection of articles;
- introduction presenting the topic and the context for creation of guidelines;
- one chapter per question including:
  - a critical, concise and hierarchical synthesis of the literature retained, including a referenced text and summary tables with mention of the levels of evidence;

  - the opinion of the working group including decisions made, minority positions and points of difference or divergence from practice;
  - a conclusion;
  - recommendations, graded and validated at the end of the finalisation phase;
- bibliographic references;
- list of participants;
- the annexed document made available on the website including the ratings and comments of the reading group for version A or the comments of the stakeholders for version B.

► Drafting proposals for recommendations

The proposals for recommendations graded and written based on the critical analysis of the literature by the project leader(s) are sent to the members of the working group at least 15 days before the first meeting.

4.2 Drafting of the initial version of the guidelines

The members of the working group meet twice, or more if necessary, to create, based on the evidence report and proposals for recommendations written by the project leader(s), the initial version of the guidelines that will be submitted to the reading group.

The chair of the working group and the project manager share the responsibility for leading and moderating the meetings of the working group.

During the meetings of the working group, the evidence report and the proposals for graded recommendations are discussed based on the data and existing practices. The levels of evidence and the grades assigned will be discussed based on any new data from the literature provided by the members of the working group.

In the absence of scientific evidence, a proposal for a recommendation will appear in the guidelines text subject to the opinion of the reading group if it is approved by at least 80% of the members of the working group. Ideally, this approval will be obtained using an electronic voting system (failing this, by show of hands) and will constitute an "expert agreement". If all of the members of the working group approval a proposal for a recommendation without the need to conduct a vote, this will be stated in the evidence report.

4.3 Reading phase

Two methods are proposed for the reading phase:

- version A: consultation of a reading group (field professionals);
- version B: consultation of stakeholders (professional organisations, patient or user associations, institutions, etc. affected by the topic)

The choice between version A and version B depends on the topic and the nature of the comments expected: experience of field professionals on medical management for version A, more global opinion with a professional component for version B. Consultation of stakeholders is preferred (version B) for a topic with an organisational component, while that of a reading group is more suitable for topics with a strong geographical disparity of practices (version A). The choice of the version selected will be noted and explained in the project outline.

The project manager, from the initial version of the guidelines, formats a questionnaire intended to collect the opinion and comments of the reading group or the comments of the stakeholders.

The initial version of the guidelines is sent for informational purposes to the members of the outlining meeting, to the requesting party and to institutions concerned.

In version A, the reading group gives a formalised opinion on the form and substance of the initial version of the guidelines, in particular on its acceptability, its applicability and its readability.

This step culminates in the production of an analysis report that collects all the ratings and comments, and presents the distribution of responses from members of the reading group.

In version B, an open questionnaire on the guidelines text and the evidence report is sent to each stakeholder. The response sent by each stakeholder represents the official opinion of the organisation, association or institution asked about the topic. The responses of the stakeholders are compiled in the evidence report.

► Collection of the opinion of the reading group (version A)

The project manager sends the members of the reading group the evidence report, the initial version of the guidelines and the questionnaire, with which each member gives an individual opinion electronically (using the GRaAL[4] computer tool, available on the HAS website www.has-sante.fr).

This questionnaire includes a discrete numerical scale, ranked from 1 to 9, and a free-text area for each recommendation made. It allows each member of the reading group to judge the form and substance, as well as the acceptability, applicability and readability, of each recommendation.

The rating ranges from 1 (total disagreement) to 9 (total agreement) and must be based on:
- the synthesis of data published in the literature (attached to the questionnaire in order to inform about the state of published knowledge);
- the readers experience in the field in question.

In order to improve the final text, any rating < 5 should be accompanied by a comment.

In case of criticism on the substance, the members of the reading group must send the working group the articles, or at least the specific references, which support their criticisms; failing that, these criticisms cannot be taken into account.

Members of the reading group may answer only those parts of the questionnaire that fall within their expertise. For this purpose, the scale must have a value of "I cannot answer". Thus, when interpreting the results, the following can be distinguished:
- missing values (no answer);
- values of 5 (reader undecided but has the expertise to answer);
- no position reported by the reader who feels that he/she does not have the expertise required to answer this question ("cannot answer").

Members of the reading group can also give their opinion on all or part of the evidence report.

[4] GRaAL: Gestion rationalisée des avis de lecture [Streamlined management of reading opinions].

► Collection of the opinion of the stakeholders (version B)

The project manager sends the stakeholders the initial version of the guidelines, the evidence report and a questionnaire so that each stakeholder can give a single opinion electronically.

The questionnaire in Word format contains the titles of the chapters and paragraphs of the guidelines text. Comments are requested for each part so identified. The stakeholders are given a period of 3 weeks to complete the questionnaire.

The opinions of the stakeholders are compiled by chapters and by paragraphs and inserted into the evidence report.

A sample questionnaire is provided in Appendix 4.

► Analysis of responses from the reading group (version A) or stakeholders (version B)

The project manager, in collaboration with the chair of the working group, is responsible for the analysis of the responses and their synthesis. The project leader critically analyses the articles submitted as supplements by the reading group or the stakeholders and, if necessary, supplements the evidence report.

For version A: The analysis conducted based on the number of questionnaires received. The response percentage by category of professionals or users may be analysed in order to identify any biases to be taken into account in the interpretation of the results.

An analysis report created by GRaAL, including all ratings and comments received, as well as the distribution of responses, is sent to the working group, highlighting recommendations that obtain less than 90% of responses within range [5-9].

In order to avoid any bias of the experts, the names of the members of the working group are not stated in the GRaAL analysis report submitted to the members of the working group.

The results of the reading phase (GRaAL analysis report) are attached to the evidence report.

For version B: The opinions of the stakeholders are compiled by chapters and by paragraphs and inserted into the evidence report.

4.4 Finalisation phase

This last step involves the working group and HAS validation bodies. It culminates in the production of the final versions of the evidence report, the recommendations and its synthesis, and then the distribution of the validated versions of these 3 documents.

► Drafting of the final version of the guidelines

The final version of the guidelines is written during a meeting of the working group (or two meetings, if necessary).

In order to facilitate the conduct of the meeting, the chair of the working group and the project manager may prepare the changes, in particular changes in form, prior to the meeting.

After analysis and discussion of ratings and comments of the reading group (version A) or comments of stakeholders (version B), the initial recommendations are modified according to the following rules:

- recommendations based on a high level of evidence (grade A or B):
  - consideration of relevant comments to improve the form;
  - changes of the substance, if any, based on data provided, changing the grade of the recommendation if necessary;
- recommendations based on a low level of evidence (grade C) or on an expert agreement (with no expression of ratings for version B):
  - when the reading group confirms the appropriate nature of the recommendation (≥ 90% of responses from the reading group within range [5 – 9]), the recommendation is retained and relevant comments are considered to improve the form;
  - when the reading group is more widely undecided or disagrees with the initial recommendation (< 90% of responses from the reading group within range [5 – 9]), the working group discusses the relevance of the comments and, if applicable, modifies the recommendation. If the debates in the meeting reveal divergent points of view, an in-session vote of the working group must confirm the withdrawal or the final wording of the modified recommendation.

One or more summary sheets, written by the project leader or the project manager, are offered to the working group based on the final version of the guidelines, in order to present the key points that should be widely distributed with a view to improving practices (1 to 2 page double-sided document).

► Validation

The GPG is submitted to the HAS Board for adoption. At the request of the HAS Board, the documents may be amended. The participants are then notified.

► Distribution

At the end of the process, HAS puts the summary sheet(s), the guidelines and the entirety of the evidence report online on its website (www.has-sante.fr), and sends them to the requesting party. The distribution may be supplemented by scientific publications and presentations at conferences in which members of the working group may participate.

The guidelines and evidence report distributed at the end of the process must indicate:
- the requesting party, any other sponsors and the stakeholders called upon;
- the list of names and capacities of all parties involved (work leader(s), working group, reading group, persons interviewed by the working group or during the outlining phase);
- the number and names of participants who are not in agreement with the final report;
- the funding sources of the project (including distribution).

A summary sheet with a list of guidelines, supplemented when possible with decision trees or diagrams that may be useful, is the main objective of the distribution. A double-sided presentation is recommended.

Preference should be given to electronic formats that take into account modern technological options. Access should be direct to the list and decision trees, with links for access to the reports and other documents. Compatibility with software used by professionals should be sought.

► Updating

Updating the guidelines must be considered depending on the data published in the scientific literature or significant practice modifications occurring since publication of the guidelines.

Appendix 1. Organisational aspects

Systematic literature review and drafting phase

► Before the first meeting of the working group

- Call upon learned societies, national professional speciality councils, the Board of general medicine, user associations, etc., at least 4 months before the first meeting of the working group, to collect the names of experts.
- Call upon the chair of the working group and the project leader(s); after receiving their agreement, analysis of their declarations of interests and examination of these by the competent HAS authority, confirm the appointment of the chair and start the procedure for recruitment of the project leader.
- The chair and the project leader(s) meet (1/2 day) in order to:
  - present the "Clinical practice guidelines" method, the topic, the context and the issues of the good practice guidelines;
  - determine the provisional calendar, choice of dates and places of meetings (2 to 3 meetings spaced 2 to 3 months apart);
  - determine the document strategy and the criteria for selection of articles.
- Call upon experts to participate in the working group at least 3 months before the first meeting; after receiving their agreement, analyse their declarations of interests and present them to the competent HAS authority.
- Notify the experts who were selected to participate in the working group and those who were not selected, confirm the meeting dates and explain their role and their responsibilities.
- Conduct the query of automated databases and other sources of information.
- Select, order, and analyse the articles selected.
- Plan a meeting (in-person or by phone) with the project leader(s) and the chair of the working group, within a period of 4 weeks before the 1st meeting of the working group, to review the evidence report and possibly discuss proposals for recommendations.
- Send the working group, within 15 days before the 1st meeting:
  - the first version of the evidence report with summary of the articles in the form of a table, with mention of the levels of evidence;
  - the proposals for graded recommendations.

► During the first meeting of the working group

- Present:
  - the interests declared by the members of the group and update them, if applicable; reiterate the commitment to confidentiality and the obligation for each participant to inform the public of any links with companies and establishments producing or distributing healthcare products, or advisory bodies when they speak about such products in the context of a public event or in print or broadcast media (16);
  - the topic of the guideline, the context, the issues, the questions and secondary questions;
  - the "Clinical practice guidelines" method;
  - the expected role of the working group;
  - the planned schedule and logistical organisation;
  - the document search conducted and the criteria for selection of articles selected;
- Analyse and discuss the relevance of articles selected;
- Discuss and draft recommendations based on the proposals of the project leader;
- Divide the work between the members of the working group.

► During the subsequent meetings of the working group

- Update the interests declared;
- Analyse and discuss the relevance of articles selected;
- Supplement the evidence report; summarise the group's discussions, taking into account minority opinions; propose one conclusion per question;
- Prepare the initial version of the guidelines to be submitted to the reading group in the form of a questionnaire.

Reading phase

► Before submission to the reading group

- Ask the members of the reading group at least 3 months before submission of the reading texts;
- In case of public consultation, notify the stakeholders by mail, electronically or through the press of the start date at least 2 months before the date thereof;
- Set the working group meeting date for finalisation 6 to 8 weeks after the planned submission to the reading group;
- Prepare the questionnaire (ratings and free-text comments) from the initial version of the guidelines.

► Before submission to stakeholders

- Set the working group meeting date for finalisation 6 to 8 weeks after the planned submission to stakeholders;
- Prepare the questionnaire (free-text comments) from the initial version of the guidelines.

► Submission to the reading group or stakeholders

- Send the evidence report, the initial version of the guidelines and the questionnaire to the reading group for opinion;
- For informational purposes, send the evidence report and the initial version of the recommendations to the working group to members interviewed during the outlining phase or by the working group.

► After submission to the reading group

- Monitor the return of feedback and follow up, if necessary, one week before the deadline for return set between 3 and 4 weeks after submission to the reading group;
- Analyse the results (ratings and free-text comments) and prepare the reading report, writing a summary of the free-text comments if necessary; allow 1 week;
- Analyse the articles submitted by the reading group and supplement the evidence report, if applicable.

► After submission to stakeholders

- Monitor the return of feedback and follow up, if necessary, one week before the deadline for return set between 3 and 4 weeks after submission to the reading group;
- Analyse the comments and compile the opinions in the evidence report; allow 1 week;
- Analyse the articles submitted by the reading group and supplement the evidence report, if applicable.

Finalisation and recommendation phase

► Before the finalisation meeting

- Send the results to the working group (GRaAL file for version A), evidence report and guidelines text for the purpose of the finalisation meeting 1 to 2 weeks beforehand;
- Prepare the finalisation meeting:
  - rank the recommendations to be discussed based on the results of the reading phase;
  - propose changes to the form and consider possible changes to the substance.

► During the finalisation meeting

- Update the interests declared;
- Discuss the points to be modified for each recommendation;
- If applicable, hold an in-session vote on questions of substance raised by the reading group or the stakeholders and for which the in-session debates reveal divergent points of view;
- Discuss the key points of the recommendations to appear in the summary sheet(s) of the guideline;
- Gather final remarks related to the evidence report;
- Discuss possible relays in terms of distribution.

► After the finalisation meeting

- Draft the final version of the evidence report and the guideline, integrating the changes accepted at the meeting;
- Draft one or more guideline summary sheets;
- Send the final report to the HAS validation bodies.

► After validation

- Integrate, after notifying the working group, the amendments requested by the validation bodies;
- Send the validated version of the report to all participants of the working group, in order to collect any refusals to endorse the final text;
- Prepare the distribution phase (formatting of bibliographical references, spelling and typographical corrections, publishing of texts, submission of abstracts or articles, press requests, etc.).

Appendix 2. Document search

The project manager, the chair of the working group and the project leader(s) participate in the creation of the document search strategy.

The document search must be systematic, hierarchical and structured. It is carried out over a period suitable for the topic. The languages retained will be at minimum English and French.

It cannot be limited to articles published and indexed in databases. For this, grey literature (all documents published outside the normal commercial publication channels) is found by consulting relevant sources. This search makes it possible to initially identify the French and international guidelines and evidence reports created by governmental agencies, independent evaluation agencies and learned societies.

French and international biomedical databases and, depending on the topic of the work, specific databases, are queried.

This search is updated until publication of the memo GPG.

It is supplemented by the bibliographic contribution of the experts of the working group and reading groups, and the references cited in the documents analysed.

The document search strategy must absolutely appear in the final document. It describes the key words used as well as the types of documents searched in the databases, specifying the results obtained, and also states the sources used for searching grey literature.

Appendix 3. Grading of recommendations

Level of scientific evidence provided by the literature (therapeutic studies)	Grades of guidelines
Level 1 • High-power randomised comparative studies. • Meta-analysis of randomised comparative studies. • Decision analysis based on well-conducted studies.	**A** Established scientific evidence.
Level 2 • Low-power randomised comparative studies. • Well-conducted non-randomised comparative studies. • Cohort studies.	**B** Scientific presumption.
Level 3 • Case-control studies.	**C** Low level of evidence.
Level 4 • Comparative studies with major biases. • Retrospective studies. • Case series.	

Appendix 4. Sample stakeholder questionnaire

READING GRID

GOOD PRACTICE GUIDELINE ON "Title"

Month Year

To be completed in Word format and emailed back to:
@has-sante.fr
by XX/XX/20XX

NAME OF THE ORGANISATION OR ASSOCIATION: ----------

GOOD PRACTICE GUIDELINES - TITLE

COMMENTS ON FORM	
(+) Elements	**(-) Elements**
"INTRODUCTION" COMMENTS	
Comments:	
"CHAPTER" COMMENTS	
"Title" Paragraph	
Comments:	
"Title" Paragraph	
Comments:	
"CHAPTER" COMMENTS	
"Title" Paragraph	
Comments:	
"Title" Paragraph	
Comments:	
Other comments	

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Information sheet

Title	**Development of good practice guidelines** **“Clinical practice guidelines” method**
Document type	Methodological guide.
Date of publication	Only available in electronic format: www.has-sante.fr.
Objective(s)	To present the process for creating good practice guidelines according to the “Clinical practice guidelines” method at the Haute Autorité de Santé.
Professional(s) involved	Organisations and professional groups wishing to create good practice guidelines (institutions, national professional speciality councils, board of general medicine, patient associations, learned societies, etc.).
Requesting party	Own initiative.
Sponsor	Haute Autorité de Santé.
Financing	Public funds.
Project steering	Coordination: Dr Pierre Gabach, Head of the Department for Good Professional Practice. Secretary: Ms Laetitia Gourbail. Document research: Ms Emmanuelle Blondet, with the assistance of Ms Sylvie Lascols, Public Documentation and Information Department (Department Head: Ms Frédérique Pagès).
Participants	See list of participants.
Conflicts of interest	No conflicts of interest.
Document search	The document search strategy consisted of the use of HAS document sources on methods for development of good practice guidelines, consultation of websites of French and international evaluation agencies, websites of French learned societies (2000-2010) and an update on the Medline and Emerald databases (2009-2010).
Authors	Mr Emmanuel Nouyrigat, project manager, and Dr Michel Laurence, Head of the HAS Department for Good Professional Practice until 2018.
Validation	Adoption by the HAS Board in December 2010, February 2015 and January 2020 for updates
Updating	This methodological guide will be updated based on new data and needs identified after the publication of this guide.
Other formats	Summary of the methodological guideline can be downloaded from www.has-sante.fr.
Accompanying documents	Documents related to the creation of the project outline and the “Formalised consensus guidelines” method can be downloaded from www.has-sante.fr.