



HAUTE AUTORITÉ DE SANTÉ

METHODOLOGICAL GUIDE

Development of Good Practice Guidelines

“Formal Consensus” Method

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1 Introduction

The purpose of this guide is to describe the method for developing good practice guidelines (GPG) according to the "Formal consensus" (FC) method. It replaces the guide published by Haute Autorité de Santé (HAS) in 2006 (1).

This guide is directed toward professionals who want to understand the method used by HAS or who want to develop good practice guidelines according to this method¹.

This guide will be updated after analysis:

- of the literature, in particular review of the methods used in the formal consensus published in France since 2000;
- of the opinions of methodologists and healthcare professionals outside of HAS;
- of discrepancies noted between the method published in 2006 (1) and its implementation after surveying HAS project managers.

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

1.1 Good practice guidelines

Among its missions, HAS is charged with "developing 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 missions" (Law of 13 August 2004 on health insurance, Title II, Chapter I bis, Article L. 161-37)(2).

The "good practice guidelines"² 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 guidelines 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 affected by the subject.

They have the objective of making available to the various parties 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; and
- reduce breaks in the care pathway.

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

The development 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

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

² This expression corresponds to the English terms "Practice guidelines" or "Clinical practice guidelines".

the evaluation of this programme (7). A good practice programme can be part of continuing professional development.

These GPG can also be used:

- to produce 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 GPG 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 Consensus methods

Four consensus methods are traditionally described in the literature (12): Delphi (13), nominal group (14), RAND/UCLA Appropriateness method (15), consensus conference (16,17).

The consensus methods are defined as a way to synthesise information and compare contradictory opinions, with the aim of defining the degree of agreement within a group of selected individuals (12,18). Their objectives and descriptions are briefly presented in Appendix 1.

Their benefit lies in the case where the opinion of professionals is not unanimous, due to the lack of data from the literature, data of a low level of evidence or contradictory data (19).

1.3 "Formal consensus" method

The "Formal consensus" method is a both a method for development of good practice guidelines and a consensus method³.

► Objectives

As a consensus method, its main objective is to formalise the degree of agreement among experts by identifying and selecting, through iterative ratings with feedback, the points on which experts agree and on which the recommendations are secondarily based, and the points on which experts disagree or are undecided, to provide professionals and patients with assistance in deciding on the most appropriate care in given clinical circumstances.

As a good practice guideline method, its objectives are to draft a small number of recommendations that are:

- concise;
- based on the formal agreement of experts or, according to the literature available, rated in accordance with the levels of evidence identified;
- unambiguous; and
- respond to the questions raised.

► Context of use

The methods for development of good practice guidelines described by HAS are:

³ As a consensus method, it can be used by HAS in the context of tasks other than the development of good practice documents. In particular, it can be used in the context of drafting opinions contributing "to the preparation of decisions relating to the registration, reimbursement and management by health insurance of health products, procedures or services, as well as to the special conditions for management of care provided to persons suffering from long-term conditions" (Law of 13 August 2004 on health insurance, Title II, Chapter I bis, Article L. 161-37) (2). In this case, the method may be adjusted according to the method described by RAND (15); in particular, the reading phase is optional.

- the "Clinical practice guidelines" (CPG) method (20); and
- the "Formal consensus" (FCG) method.

The choice between these two methods is determined during the GPG outline phase⁴.

Use of the "Formal consensus" method may be considered if at least two of the following conditions are met:

- absence or insufficiency of literature with a high level of evidence, specifically addressing the questions raised;
- possibility of applying the subject 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.

► Advantages and limitations

Its main advantages are:

- its ability to identify the degree of agreement or indecision among experts, by selecting from among several basic, complementary or even contradictory situations, those where the indication of a diagnostic test, a procedure, a device or a medical intervention is considered appropriate, inappropriate or uncertain;
- the strict independence of the steering group, which formulates the proposals to be submitted to a vote, and the rating group, which judges the proposals submitted to be appropriate or inappropriate, thus avoiding a single group being "judge and jury";
- the precise formalisation of the expert opinion, without seeking a convergence of opinions during the meetings of the steering group and rating group.

Its main limitation is the number of groups that should be established. This limitation is of particular importance to consider when dealing with subjects that encompass various areas of expertise and require the participation of a large number of disciplines and professions. The "Formal consensus" method requires the members of the rating group to vote on all proposals submitted to them, which may require formation of subgroups.

► Rigour of development

A rigorous and clearly defined approach must be applied for the development of valid and credible good practice guidelines. The methodological rigour and transparency of the GPG development process may be evaluated based on international criteria (22,23).

The "Formal consensus" method is a rigorous method for GPG development, which is based on:

- the participation of professionals and representatives of patients and users affected by the subject;
- use of a peer review phase;
- transparency, with provision of:
 - ▶ critical analysis of the literature,
 - ▶ essential points from debates during work meetings,
 - ▶ decisions made following analysis of the results of rating group votes,
 - ▶ opinions and comments from the review group,
 - ▶ the list of all participants of the various groups;
- independence:
 - ▶ 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 from each other; the steering, rating and review groups each have a specific role that they accomplish independently of each other,
 - ▶ financial independence; public funding in the context of HAS GPG;

⁴ Refer to the methodological guide "Development of good practice guidelines: Project outline" (21).

- management of the interests declared by the experts of the steering group and the rating group, according to the procedure described in the HAS “Guide on the declaration of interests and management of conflicts of interest” (24).

2 Overview of the “Formal consensus” method

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

- a national professional speciality council, the French College of General Practice, 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 subject of the guideline in the HAS programme, a project outline phase prior to the development of any GPG is implemented. This project outlining step allows HAS, in collaboration with the requesting party and stakeholders involved, to select the GPG development method (CPG or FCG) and to define the subject. 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 (21).

The progress of a GPG, from outlining to distribution of the recommendations, 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; and
- ensuring coordination and organising the project logistics.

The project manager participates in all meetings.

3 Groups

The "Formal consensus" method involves 3 groups:

- the steering group;
- the rating group; and
- the review group.

The members of these 3 groups, subject to their agreement, are appointed by HAS:

- on the proposal of the parties affected by the subject: national professional speciality councils, the French College of General Medicine, professional organisations⁵, 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 project manager ensures that the composition of the groups complies with what is defined in the project outline (21), and that all members appointed guarantee diversity and a balance of:

- the main professions, medical or not, implementing the strategies evaluated;
- different currents of opinion or schools of thought;
- methods of practice (public; university-based or not; private; self-employed; hospital, medico-social or educational establishments);
- the places of practice of the participants (geographical distribution).

Depending on the subject, the members of the groups may be:

- physician and non-physician healthcare professionals: nurses, physical therapists, speech therapists, etc.; these healthcare professionals must have a good knowledge of professional practice in the field corresponding to the subject of the study, and must be able to judge the relevance of the published studies and different clinical situations evaluated;
- researchers, epidemiologists, public healthcare physicians, 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, such as the ANSM in case of guidelines including a medication strategy.

The experts asked to participate in the drafting of the guidelines (steering group and rating group) must report their declaration of interests. They are analysed based on the subject by an entity dedicated to the management of conflicts of interest (24). 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 (www.has-sante.fr). The declarations of interests of the experts of the steering and rating groups are published on the HAS website. These experts must update their declaration of interests during the development of the GPG and, in case of changes, send it to the HAS project manager (24). These experts express themselves as individuals, not as representatives of their professional organisation.

After having agreed to participate, all parties 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; and
- not distribute the content of debates or the documents given to them.

⁵ Organisations for the defence of professional interests (trade unions) are not generally called on in the context of the development of good practice guidelines.

In addition, when they are asked to participate in the project, the members of the rating group are informed that they must agree to respond to both rounds of rating and to attend both meetings of this group.

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 Steering group

The mission of the steering group is to:

- draft the evidence report, after critical analysis and synthesis of the available literature data and relative discussion of existing practices;
- draft the proposals for submission to the rating group;
- draft, using the results of the rating, the initial version of the guidelines to be submitted to the reading group; and
- finalise the text of the guidelines, according to the procedure described paragraph 4.5, during the plenary meeting with the rating group after the reading phase.

The steering group includes:

- ideally, 6 to 8 professionals and representatives of patients or users, including a chair, in charge of coordinating all of the work with the project manager. It is recommended that this person, 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;
- possibly a project leader, recruited to identify, select, analyse and draft a critical synthesis of the literature, in close cooperation with the other members of the steering group. This project leader must not have any hierarchical relationship with the chair of the steering group.

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

The size of the steering group must be limited to increase the effectiveness of work meetings, including conference calls. This limitation may be difficult, especially for a subject involving many professions. This is why, for informational purposes and to enhance the relevance of proposals submitted for rating, the steering group may, if appropriate, consult as many people as necessary, depending on the fields covered and the currents of thought identified. Before consulting an expert, the working group will be informed of the interests declared. This consultation will be mentioned in the evidence report.

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

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

Members of the steering group must not be part of the rating group or the reading group.

3.2 Rating group

The mission of the rating group is to:

- select, in a vote conducted in two rounds, the proposals to be used for drafting the initial version of the guidelines, taking into account the literature available and the practical experience of its members; and
- finalise the text of the guideline, according to the procedure described paragraph 4.5, during the plenary meeting with the steering group after the review phase.

Ideally, the rating group includes 9 to 15 professionals who, in their daily practice, are directly involved with the people affected by the guideline subject.

This group is multidisciplinary and multiprofessional, to reflect all professions, medical or not, implementing the strategies evaluated. It includes representatives of users of the healthcare system, except if the proposals submitted for rating relate exclusively to the performance of technical procedures for which professional expertise is essential.

Representatives of the administration, health insurance or industry do not participate in the rating group.

The number of members may be expanded to increase the number of professions involved, especially in case of a subject requiring the intervention of many professions. However, the effectiveness of the rating group meeting and the plenary meeting must be preserved, bringing together the steering and rating groups after the review phase.

The members of the rating group practice one of the professions affected by the guideline. They must have a good knowledge of professional practice on all of the proposals they will rate. When the scope of the questions to which the recommendations respond does not allow each member to position themselves on all of the proposals submitted for rating, it is possible to divide the rating group into subgroups, depending on the subject matter and the required skills. Each subgroup must then include at least 9 members, in order to meet the validity criteria of the RAND/UCLA consensus method (15).

In order to respect the strict independence between the groups, members of the rating group cannot be part of the steering group or the reading group.

3.3 Reading group

The reading group gives a formal opinion on the content and form of the initial version of the guidelines, in particular its applicability, acceptability, and readability. The members offer an advisory opinion on an individual basis and do not meet together as a group.

Depending on the subject, the reading group includes 30 to 50 people affected by the subject, who may or not be experts therein. Like the steering and rating groups, this group is multidisciplinary and multiprofessional, to reflect all professions, medical or not, implementing the strategies evaluated. It allows the range of participants in the task to be widened, by bringing in representatives of medical specialities, non-medical professions or civil society not present in the steering and rating groups.

In order to respect the independence of the groups, members of the outlining meeting, the steering and rating groups, as well as people consulted by the steering group and those participating in validation bodies, cannot be part of the reading group.

When societal issues play a part in differences in practice or in differences of opinion regarding practice, HAS may also gather the opinion of concerned parties that it has not previously appointed or even identified. In this case, HAS can set up a public consultation, by making the initial version

of the guideline and a questionnaire available on its website. This aims to gather the collective advisory opinion of any organisation that considers itself affected by the subject.

4 Procedure of the method

The procedure of the "Formal consensus" method is split into 5 phases:

- systematic review and synthesis of the literature;
- rating;
- drafting of the initial version of the guidelines;
- reading; and
- finalisation.

The main aspects related to coordination and logistics of the project are specified in Appendix 2.

4.1 Systematic review and synthesis of the literature phase

The steering group carries out this first step. It culminates in the production of an evidence report and a list of proposals to submit to the rating group in the form of a questionnaire. When, due to the scope of the questions, the rating group is divided into several subgroups (cf. § 3.2), this list may be split into several questionnaires, different from one subgroup to another.

The mission of the steering group during this phase is 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; and
- draft a list of proposals to submit for rating based on the literature analysis conducted and the experience of its members in the field under consideration.

The fact that the limited amount of conclusive literature may be one of the criteria that led to the selection of this guidelines method does not exonerate the steering group from a rigorous search for available data, using an explicit search and selection strategy and study analysis grids (25).

To help the steering group in this task, HAS may be led to recruit a project leader in charge of the analysis and synthesis of the available literature, under the direction of the chair and the project manager. Depending on the number of questions to be handled and the scope of the subject, several project leaders may be appointed.

The project leader(s) draft the evidence report, in close collaboration with the steering group, under the supervision of the project manager.

► Critical analysis of the literature

The drafting of the evidence report is preceded by a phase of literature search and critical analysis of the literature.

For the literature search phase, the regular use of a documentalist very familiar with the procedures for querying databases and how to retrieve grey literature is necessary.

Appendix 3 presents the key points of the literature search and analysis and critical synthesis of the literature, according to the principles of medicine and evidence-based practice. For more details about the analysis and critical synthesis of the literature, as well as the levels of evidence of studies and the rating of recommendations, refer to the specific methodological guide (25).

► Drafting the evidence report

The evidence report includes the following elements:

- working method;
- literature search and criteria for selection of articles;
- introduction presenting the subject and the context for developing the guideline;
- one chapter per question including:
 - ▶ a critical and hierarchical synthesis of the literature selected, including a referenced text and summary tables with mention of the levels of evidence of the studies;
 - ▶ the opinion of the steering group including minority positions, as well as points of difference or divergence from practice; this opinion is then supplemented during the work by supplemental opinions from the rating group and the procedures for taking into account the ratings and comments of the reading group (cf. § 4.5);
 - ▶ a conclusion;
 - ▶ recommendations, graded and validated at the end of the finalisation phase;
- bibliographic references;
- list of participants; and
- the annexed document made available on the website including at minimum the rules for rating, analysis of the 1st and 2nd rounds of rating, as well as the ratings and comments collected during the reading phase.

► Drafting the list of proposals submitted for rating

The members of the steering group meet twice, or more if necessary, to discuss the evidence report, written by the project leader, and to prepare the list of proposals to be submitted to the rating group. Examples of proposals are described in Appendix 4.

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

First, the steering group drafts the proposals to submit for rating, based on the level of evidence of available studies (Appendix 3). Given the subjects for which the "Formal consensus" method is intended, recommendations based on a high level of evidence will be few. Nevertheless, for the sake of consistency across all work produced, all proposals, whether or not based on a high level of evidence, should be submitted to the rating group. In doing so, proposals based on the highest levels of evidence will be clearly differentiated from other proposals. They may be indicated as such by reference to a level of evidence adjacent to the conclusion of the literature.

Second, for questions where the literature is not very conclusive, the proposals submitted for rating are supplemented by the steering group, based on the clinical experience of its members or the people it has consulted. This consultation or the debates within the group aim to bring forth, from a precise line of questioning, the different points of view and the different practices that will make it possible to define the clinical situations for which the group wishes to know whether a healthcare procedure is considered appropriate. Each member of the group can make personal proposals. The moderator of the meeting verifies that everyone understands them in the same way and eliminates any redundancies.

At this stage, the proposals may be complementary or contradictory to each other, since they take into account all of the opinions of the members of the group brought forth during the work meetings. There is no search for consensus during these meetings, which differentiates the "Formal consensus" method from the "Clinical practice guidelines" method. The chair of the steering group and the project manager ensure that there is no pressure or censorship during the discussions.

The steering group can also propose that studies be carried out with the aim of advancing knowledge and improving the level of evidence on which future recommendations will be based.

The project manager, from the proposals formulated by the steering group, formats a questionnaire to be sent to the rating group.

4.2 Rating phase

The rating group is the main party in this second stage, in which the project manager, the chair of the steering group and the project leader will also participate. This phase, which takes place in 3 steps, identifies, by means of a vote conducted in two rounds and an interim feedback meeting, the points of agreement, disagreement and indecision among the members of the rating group. This phase culminates in the selection of the proposals on which there is a consensus within the rating group.

► First round of rating

During this first part, each member of the rating group receives, by post or electronically, the initial version of the evidence report and the list of proposals submitted for rating. Each rater has two weeks to read it. Then, individually and without prior contact with the other members of the group, he or she responds electronically to the questionnaire that was sent by the steering group (using the GRaAL⁶ computer tool, available on the HAS website www.has-sante.fr). This questionnaire includes a discrete numerical scale, running from 1 to 9, for each proposal formulated by the steering group during the preceding phase. This scale lets each member of the rating group give his or her opinion as to whether or not each of these proposals is appropriate. The questionnaire does not include comment sections, as comments will be expressed at the rating meeting.

At the end of the first round of rating, the project manager analyses the answers according to the rating rules described below, and prepares the rating group meeting, in collaboration with the chair of the steering group; this analysis makes it possible to determine the accepted proposals and the proposals that should be discussed with the rating group. Generally speaking, proposals that have obtained strong agreement during the 1st round are accepted as they stand: they are not discussed at the meeting or submitted to the second round of rating; other proposals, especially in case of uncertainty, are discussed and re-rated. Appendix 5 offers some examples of analysis of the results of the rating based on the rules described below.

The results of the 1st round of rating are annexed to the evidence report sent to the reading group.

► Rating group meeting

At the end of the 1st round of rating, the rating group meets in the presence of the chair of the steering group, the HAS project manager and the project leader.

The chair and the HAS project manager share the responsibility for leading and moderating the meeting.

This meeting aims to present the results of the 1st round and to discuss proposals deemed "uncertain", that is to say, those for which the rating group is undecided or for which there is not a consensus, as well as proposals that obtained a relative agreement (Appendix 5).

The presentation of the results allows each rater to see where he or she stands compared to the rest of the group: the results of the rating, aggregated⁷ and anonymised, are presented to the entire group; each member has access to his or her own response grid for his/her use only.

⁶ Streamlined management of reading opinions.

⁷ Aggregated results: lowest and highest ratings, median, number of responses per value 1 to 9.

The group is then invited to clarify the arguments behind the "for", "against" or "undecided" votes⁸, in order to share points of view. If applicable, the evidence report behind the proposals may be discussed and supplemented by studies provided by the rating group, when these studies meet the defined selection criteria. This discussion must allow each member to decide whether it seems appropriate to change his or her rating during the second round. This is why the absence of one of the members of the rating group at this meeting excludes that member from the second round of rating.

No proposal retained at the end of the rating phase should deviate from what has been explicitly demonstrated in the literature. Occasionally, there may be an apparent discrepancy between a high level of evidence and the chosen proposal, in particular because of an insufficient external validity of the study to extrapolate to the specific context studied. In this case, which should be exceptional, the chair of the steering group is responsible for discussing, in a meeting, this discrepancy with the rating group, to consider modification or withdrawal of the proposal and, if in the end the proposal is retained, to show the explicit justification in the evidence report.

Moderation of the meeting is essential: it must be characterised by its neutrality and ensure that members of the rating group are given equal time to speak, to prevent strong personalities from imposing their opinions. This provision is necessary so that each member can state his or her opinion without falling under the "group effect", that is to say, without feeling any constraint or pressure, even indirect, from other members present.

After debate in the rating group meeting, the proposals formulated by the steering group may be, as an exception, modified or amended for the second round of rating. This can be the case when:

- the wording proposed for rating was ambiguous;
- the proposal needed to be broken down into several sub-proposals or, conversely, to be grouped together with another proposal; or
- a relevant indication was left out.

To prevent the rating group from being judge and jury, after debate in meeting, these modifications are made by the chair of the steering group, in collaboration with the HAS project manager, and then put to the vote during the second round of rating.

► **Second round of rating**

At the end of the meeting, when the questionnaire has not been modified, or during the subsequent days if the questionnaire is modified, each member of the rating group who participated in the rating meeting will individually rate the submitted proposals a second time, electronically. Proposals accepted as they stand, because they obtained a strong agreement after the 1st round of rating, are not submitted to the second round of rating (Appendix 5).

At the end of this second round of rating, the HAS project manager analyses the answers according to the rating rules described below, and sends the results to the steering and rating groups, distinguishing the proposals that have been deemed appropriate from those that have not and those for which the rating group remains undecided (Appendix 5).

The results at the end of the second round of rating allow the steering group to prepare the peer review phase by an external group⁹, an essential step as part of the quality criteria for development of good practice guidelines (22).

The results of the 2nd round of rating are annexed to the evidence report sent to the reading group.

⁸ "For" votes correspond to values within the range [7-9], "against" votes to the range [1-3], and "undecided" votes to the range [4-6].

⁹ In the context of use of the "Formal consensus" method for producing lists of indications of medical procedures or devices, the results at the end of the second round of rating allow the steering group to finalise the ongoing evaluation without a reading phase, in accordance with the method described by the RAND (15).

► Rules for rating and analysis of responses

The rules for the rating and the analysis of the responses are defined *a priori* and communicated to the rating group, as appendix to the evidence report, before the 1st round of rating.

The rules below can be adapted by the steering group, especially when the rating group includes more than 15 members, on the express condition that this adaptation is carried out *a priori* and the rating group is notified before the first round of rating.

Rules for rating

Regardless of the round of rating, the members of the rating group (raters) must complete the questionnaires submitted to them in their entirety¹⁰, in order to limit missing values.

Members of the rating group who did not participate in the meeting between the two rounds are removed from the rating group: they do not participate in the second round of rating, or in subsequent meetings.

For each item on the questionnaire, there is a discrete numerical scale running from 1 to 9 (Figure 2):

- value 1 means that the rater considers the proposal "completely inappropriate" (or not indicated, or not acceptable);
- value 9 means that the rater considers the proposal "completely appropriate" (or indicated, or acceptable);
- values 2 to 8 refer to possible intermediate situations;
- value "5" means that the rater is undecided.

¹⁰ When, due to the scope of the questions (cf. § 3.2), the rating group is divided into several subgroups, the questionnaires may be different from one subgroup to another.

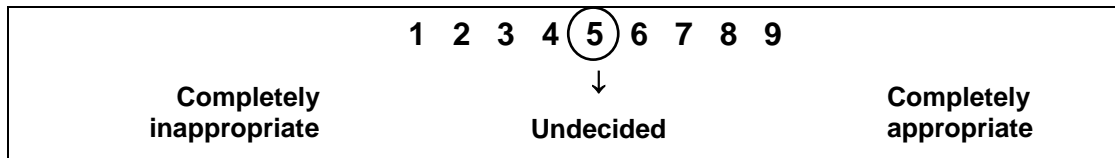


Figure 2. Meaning of the discrete numerical scale running from 1 to 9.

For each proposal listed, the rater must give a response by circling one of the numbers between 1 and 9. Responses located between 2 numbers are not accepted; if applicable, they are replaced by the immediately lower whole number. The rating must be based on:

- the synthesis of data published in the literature (evidence report attached to the questionnaire in order to inform about the state of published knowledge); and
- the rater's experience in the field in question.

Some proposals may be contradictory or complementary, to the extent that opposite or complementary points of view could respectively be issued within the steering group. However, all proposals must be assessed on their content and form, and rated independently from each other, whether or not they are acceptable.

Upon receipt of the questionnaires, the project manager verifies that there are no values missing on certain proposals. If there are missing values, the project manager actively and individually contacts the raters in question, to ask them to provide their position. Raters are reminded that in case of indecision, they must use the value 5.

Use of software offering the questionnaires online may facilitate collection of the responses by making their entry mandatory for each proposal submitted for rating.

Rules for analysis of responses

The project manager is responsible for analysis of responses and their synthesis, in close cooperation with the chair of the steering group.

Numerous definitions of expert agreement have been described in the literature (15). For the sake of simplification, the following rules are proposed and concrete examples of analysis are presented in Appendix 5.

The definition of expert agreement used by HAS is as follows: there is agreement when the ratings taken into account are all ≤ 5 or are all ≥ 5 .

The position of the median and the distribution of the responses on the scale of 1 to 9 make it possible to determine the appropriate or inappropriate nature of the proposal submitted to a vote, based on the degree of agreement among the members of the rating group (15).

A proposal is deemed:

- appropriate, when the median value is ≥ 7 **and** there is agreement among the members of the rating group;
- inappropriate, when the median value is ≤ 3.5 **and** there is agreement among the members of the rating group;
- uncertain, when the median value is between 4 and 6.5 (undecided) **or** when there is a lack of consensus among the members of the rating group.

Table 1 specifies the conditions for obtaining agreement and judgement at the end of the analysis process, in particular if the medians are not whole numbers. When the median is 3.5 or 6.5, the most conservative manner is to consider the proposal inappropriate if the median is 3.5 and uncertain if the median is 6.5. Other rules have been described (15).

Table 1. Conditions for obtaining an expert agreement and judgement, according to the median value and the distribution of ratings taken into account.

Proposal judged	Degree of agreement of the group	Conditions for obtaining	
		Median value	Distribution of ratings in the interval
Appropriate	Strong agreement	≥ 7	[7 – 9]
	Relative agreement	≥ 7	[5 – 9]
Inappropriate	Strong agreement	≤ 3	[1 – 3]
	Relative agreement	≤ 3.5	[1 – 5]
Uncertain	Undecided	$4 \leq \text{median} \leq 6.5$	[1 – 9]
	Lack of consensus	All other situations	

During analysis of the results of the 1st round of rating, all responses obtained are taken into account to determine the degree of agreement of the group. Taking all responses obtained into account makes it possible to discuss at the meeting all situations where there is even just one answer in opposition with those of the other members of the group, since in that case the proposal is not classified as strong agreement. If there is a missing value¹¹ despite the efforts made to avoid them, the proposal is considered "uncertain". This makes it possible to discuss at the meeting all proposals for which there is a missing value.

Proposals that have obtained strong agreement are accepted as they stand: they are not discussed at the meeting or submitted to the second round of rating.

During analysis of the results of the 2nd round of rating, a degree of tolerance in the definition of agreement and its strength is accepted as in the RAND/UCLA method (15). This tolerance has the advantage preventing a vote with systematic rejection of the proposals by a rater from blocking the proposals selection process. Thus, the responses taken into account for the analysis may, under certain conditions described below, exclude an extreme value.

The analysis in the 2nd round is carried out from questionnaires available from the members who participated in the meeting: non-return of the questionnaire by a member of the rating group means that he/she will be excluded from the group and the non-response will not be considered a missing value for each proposal. If there are still missing values despite effort to avoid them, the analysis is considered valid if at least 9 ratings are obtained for a proposal, for which reason the minimum number of participants must be 9 members (15). However, when the group is initially comprised of more than 10 people, it is necessary to collect at least 80% of responses.

If there is no missing value, one of the responses can be excluded from analysis of the degree of agreement according to the following rules:

- The lowest value is excluded if the median is strictly above 5; or
- the highest value is excluded if the median is less than or equal to 5.

When the rating group has 16 members or more, the rules may be adapted: it is proposed that at most one extreme value be excluded, in the absence of a missing value, for every 15 members. This corresponds to agreeing not to take into account:

- if 9 to 15 raters, one missing value or one excluded value (lowest value if median > 5 or highest value if median \leq 5); or

¹¹ A missing value is a non-response to one of the proposals when the rater filled out his or her questionnaire and handed it in.

- if 16 to 30 raters, 2 missing values, or 2 excluded values, or 1 missing value and 1 excluded value.

4.3 Drafting of the initial version of the guidelines phase

The chair of the steering group, the project manager and the project leader are the main parties of this phase.

The objective of this phase is to draft the first version of the guideline, which is then submitted to the reading group.

► Drafting of the initial version of the guideline

At the end of the analysis of the results of the 2nd round of rating, the chair of the steering group, in collaboration with the HAS project manager, drafts the initial version of the guideline based on the results obtained from the 2nd round of rating. If applicable, the project manager supplements the evidence report with the main points debated at the rating meeting and the studies corresponding to the selection criteria, submitted by the rating group.

The formulation of the guidelines varies according to the results obtained at the end of the rating process (Table 2).

Proposal judged		Possible formulation
Appropriate		- “It is recommended...”.
Uncertain	Undecided	- “The current state of knowledge does not allow a conclusion to be reached about...”.
	Lack of consensus	- Removal of the proposal if there is a suitable alternative proposal; - or “given the current state of knowledge and absence of consensus, it cannot be recommended...”; - or in the absence of an alternative proposal, and when it seems necessary to state an affirmative or negative decision, retention of the formulation of the proposals submitted for rating in order to obtain an advisory opinion from a wider panel of people. A third rating will then be proposed after the review phase to see if a consensus can be obtained.
Inappropriate		- “It is recommended to not...”; - or removal of the proposal if there is a suitable alternative proposal.

4.4 Reading phase

The project manager, from the initial version of the guidelines, formats a questionnaire intended to collect the opinions and comments of the review group, the main party of this phase.

The reading group and, if applicable, the participants in the public consultation give a formal opinion on the content and form of the initial version of the guidelines, in particular its acceptability, applicability and readability.

The initial version of the guidelines, as well as the results of the two rounds of rating, are sent for informational purposes to the members of the project outlining meeting and of the steering and rating groups.

This step culminates in the production of an analysis report that collates all the ratings and comments, and presents the distribution of responses from members of the reading group and, if applicable, participants in the public consultation.

► **Collection of opinions of the reading group**

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 computer tool, available on the HAS website).

This questionnaire includes a discrete numerical scale, running from 1 to 9, and a comments section for each recommendation formulated. It lets each member of the reading group judge the content and form, as well as the acceptability, applicability and readability of each of the recommendations.

The rating from 1 (complete disagreement) to 9 (complete agreement) 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); and
- the reader's experience in the field in question.

To improve the final text, any rating < 5 must be accompanied by a comment.

In case of criticism on the content, the members of the reading group must send the steering 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 respond only to 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 (lack of response);
- 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.

► **Analysis of responses of the reading group**

The project manager, in close collaboration with the chair of the steering 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 and, if necessary, supplements the evidence report.

The analysis is conducted based on the number of questionnaires received. The response rate 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 initial report produced by GRaAL, including all ratings and comments received, as well as the distribution of responses, is sent to the steering and rating groups, highlighting recommendations that obtain less than 90% of responses within the range [5-9].

In order to avoid any bias of the experts, the names of the members of the reading group are not stated in the analysis report submitted to the members of the steering and rating groups.

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

4.5 Finalisation phase

This last step involves the steering group, the rating group and HAS validation bodies. It culminates in the production of the final versions of the evidence report, the guidelines and its synthesis sheet, 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 guideline is written during a plenary meeting, combining the steering group and the rating group. The chair of the steering group and the HAS project manager share the responsibility for leading and moderating the meeting.

In order to facilitate the running of the meeting, the chair of the steering 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, 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 content, 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 agreement within the rating group:
 - ▶ when the reading group confirms the appropriate nature of the recommendation ($\geq 90\%$ of responses from the reading group within the 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 the range [5-9]), the steering group, after debate with the rating group, proposes possible modifications based on comments or the rejection of the recommendation.

If a change in the content is proposed, the steering group, after debate with the rating group, proposes maintaining or rejecting the initial recommendation or possible changes based on comments. A vote at a session of the rating group must confirm the final working of the recommendation or its rejection, after application of the rules defined for the rating phase. In the absence of final consensus, this must be specified in the final version of the guideline.

One or more summary sheets, written by the project leader(s) or the project manager, are proposed to the steering and rating groups based on the final version of the guideline, 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

After validation by the Board, 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 steering or rating groups 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 (steering group, rating group, reading group, persons consulted by the steering group);
- 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 recommendations, 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 directly to the list and decision trees, with links for access to the evidence 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 guideline.

Appendix 1. Consensus methods

	Delphi	Nominal group, base method	Rand/UCLA appropriateness rating method	Consensus conference method¹²
Objectives	Obtain a final, unique, convergent opinion of the group.	Classify, prioritise, rank questions, proposals, actions to carry out.	Initially to measure the over-use and under-use of a medical or surgical procedure. The appropriateness of performing a procedure is assessed by the benefit/risk ratio. Subsequently, this is extended to assessment of the need to perform a procedure.	Drafting of recommendations.
Brief description	Drafting of a questionnaire by the organiser. Anonymous individual iterative rating (by post). Feedback from the analysis of the group's responses to the previous round of rating to each participant. Finally, the group's response for each proposal is determined by applying pre-established rules.	2 individual rounds of rating during the group meeting, but in secret, separated by a discussion of the results of the 1 st rating. During the discussion, interactions are essentially between the coordinator and each of the members of the group, to avoid dominance phenomena.	Critical analysis and synthesis of the literature. Description of all clinical situations in which the procedure is possible. Drafting of a questionnaire by the organiser. 1 st round of anonymous individual rating (by post). Pre-established rules for analysis of ratings. Feedback. Discussion of the results of the 1 st rating during a single plenary meeting of the group. 2 nd round of individual rating by each participant at the end of the meeting.	Critical analysis of the literature on the issues of the conference (bibliographic group). Texts from experts gathering information (from their experience and literature) to answer a question from the conference. Public conference during which the experts present their works and formulate their interpretation based on their conviction. Discussion and debates on the most controversial points with members of the panel and the public. Deliberation of the panel behind closed doors for drafting of a consensual text, in the most independent and objective manner possible (conclusions and recommendations of the conference).

¹² This method is not used by Haute Autorité de Santé.

Appendix 2. Organisational aspects

Systematic literature review and drafting phase

► Before the first meeting of the steering group

- Call upon learned societies, national professional speciality councils, the French College of General Practice, user associations, etc., at least 4 months before the first meeting of the steering group, to collect the names of experts.
- Contact the chair of the steering 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 (24), confirm the appointment of the chair and start the procedure for recruitment of the project leader.
- The chair and the project leader meet (1/2 day) in order to:
 - present the "Formal consensus" method, the subject, the context and the issues of the good practice guideline;
 - determine the provisional calendar, choice of dates and places of meetings (2 to 3 meetings spaced one month apart); and
 - determine the document strategy and the criteria for selection of articles.
- Call upon experts to participate in the steering 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 steering group and those who were not selected, confirm the meeting dates and explain their roles and responsibilities.
- Search 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 steering 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 prior to 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.
- During the first meeting of the steering 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 involved in these products when they speak about such products in the context of a public event or in print or broadcast media (26);
 - the subject of the guideline, the context, the issues, the questions and secondary questions;
 - the "Formal consensus" method;
 - the expected role of the steering group;
 - the planned schedule and logistical organisation; and
 - the literature search conducted and the criteria for selection of articles selected.
- Analyse and discuss the relevance of articles selected.
- Discuss proposals to submit to rating.
- Divide the work among the members of the steering group.

► During subsequent meetings of the steering 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.
- Draft the list of proposals to submit to the rating group in the form of a questionnaire: each proposal (one idea per proposal) is accompanied by a discrete scale from 1 to 9.

Rating phase

► Before the meeting of the rating group

- Call upon the members of the rating group at least 3 months before the rating group meeting; after receiving their agreement, analyse their declarations of interests and present them to the competent HAS authority (24).
- Notify the experts who were selected to participate in the steering group and those who were not selected, confirm the meeting dates and explain their roles and responsibilities.
- Send the evidence report and the questionnaire made up of the list of proposals to the rating group, 3 to 4 weeks before the date of the rating group meeting. The deadline for receipt of the ratings is set at least 1 week before the meeting date.
- Check the completeness of the questionnaires received, and follow-up with members who have not completed their questionnaire at least one week before the deadline.
- Analyse the responses obtained.
- Prepare the rating meeting by ranking the proposals according to their degree of agreement.

► During the meeting of the rating 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 involved in these products when they speak about such products in the context of a public event or in print or broadcast media (26);
 - the subject of the guideline, the context, the issues, the questions and secondary questions;
 - the "Formal consensus" method;
 - the expected role of the rating group;
 - the planned schedule and logistical organisation.
- Lead debate from the presentation of the aggregated results.
- Note any modifications to be considered for the second round questionnaire; have them validated by the chair of the steering group before sending for the second round of rating.
- Proceed with the second round of rating if the questionnaire has not been modified.

► After the meeting of the rating group

- Modify the questionnaire, if applicable, and have it validated by the chair of the steering group before sending it to a second round of rating in the 3 days following the meeting on the questionnaire for the second round of rating; the deadline for return is between 3 and 7 days after the meeting.
- Follow-up on the return of questionnaires and verify their completeness; contact raters in case of delay or missing values.
- Analyse the results of the second round of rating.
- Address the results with the steering and rating groups.

Review phase

► Before submission to the review group

- Ask the members of the reading group at least 3 months before submission of the texts to review.
- In case of public consultation, notify the stakeholders by post, electronically or through the press of the start date at least 2 months before the date thereof.
- Set the date of the plenary meeting of the steering and rating groups 6 to 8 weeks after the planned submission to the reading group.
- Analyse the articles sent by the rating group, and supplement the evidence report, if necessary.

- Supplement the "opinion of the group members" section of the evidence report if new items were provided by the rating group.
- Draft the initial version of the guideline from the results of the second round of rating.
- Prepare the questionnaire (ratings and free-text comments) from the initial version of the guideline.

► **Submission to the reading group**

- Send the evidence report, the initial version of the guideline and the questionnaire to the reading group for opinion.
- Put the same documents and the questionnaire online for the public consultation, if applicable.
- For informational purposes, send the initial version of the guideline to the steering and rating groups, to members consulted during the outlining phase or upstream of the rating phase by the steering group.

► **After submission to the reading group**

- Monitor the return of feedback and follow up, if necessary, one week before the deadline set between 3 and 4 weeks after submission to reading.
- Analyse the results (ratings and free-text comments) and prepare the analysis report of the opinions (ratings and free-text comments) from the reading group and public consultation, writing a summary of the free-text comments if necessary; allow 2 to 3 weeks.
- Analyse the articles sent by the rating group, and supplement the evidence report, if necessary.

Guideline finalisation phase

► **Before the plenary meeting**

- Send the results (GRaAL file), the evidence report and the guideline to the steering and rating groups 1 to 2 weeks before the plenary meeting.
- Prepare the plenary 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 content.

► **During the plenary meeting**

- Update the interests declared.
- Discuss the points to be modified, recommendation by recommendation.
- If applicable, hold an in-session 3rd round of rating on recommendations whose content was modified as a result of the remarks made by the reading group.
- 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 plenary meeting**

- Draft the final version of the evidence report and the guideline, integrating the changes accepted at the plenary meeting.
- Draft one or more guideline summary sheets.
- Send the steering and rating groups the final report (final version of the evidence report, the guideline and the summary sheet), in order to ensure consistency of the whole and respect of the decisions made in plenary meeting (plan 1 to 2 weeks).
- Send the final report to the HAS validation bodies.

► **After validation**

- Integrate, after notifying the steering group, the amendments requested by the validation bodies.

- Send the validated version of the report to all participants, 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, HAS press department requests, etc.).

Appendix 3. Literature search and analysis of the literature

Even if a high level of proof can ultimately be attributed to only a few studies, literature search and analysis are essential in the process, if only to confirm the lack of available data and to identify existing consensus. This key step must be carried out with great methodological rigour, using an explicit search and selection strategy and study analysis grids. This work culminates in selecting or rejecting the studies and allows definition of the level of proof that can be deduced. Articles selected are grouped as much as possible and presented in summary tables.

Literature search

The project manager, the chair of the steering or working group and the project leader(s) participate in the literature search strategy, conducted by a documentalist.

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

It should not 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 produced by governmental agencies, independent evaluation agencies and learned societies.

French and international biomedical databases and, depending on the subject of the work, specific databases, are searched.

This search is updated until publication of the GPG.

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

The literature search strategy must 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.

Analysis of the literature

In practice, when a project leader is recruited, the bibliographical selection of references according to the defined selection criteria is carried out by the project leader, the project manager and the chair of the steering group in advance of the first meeting of the steering group.

Each article selected is analysed according to the principles of the critical reading of the literature, by focusing first on assessing the methodology used, and then the result, which may make it possible to assign to each study a level of scientific evidence (Table 3.1) (25).

Table 3.1. Level of scientific evidence and grading of guidelines.	
Level of scientific evidence provided by the literature (therapeutic studies)	Grades of guidelines
<p style="text-align: center;">Level 1</p> <ul style="list-style-type: none"> • High-power randomised comparative studies • Meta-analysis of randomised comparative studies • Decision analysis based on well-conducted studies 	<p>A</p> <p>Established scientific evidence</p>
<p style="text-align: center;">Level 2</p> <ul style="list-style-type: none"> • Low-power randomised comparative studies • Well-conducted non-randomised comparative studies • Cohort studies 	<p>B</p> <p>Scientific presumption</p>
<p style="text-align: center;">Level 3</p> <ul style="list-style-type: none"> • Case-control studies 	<p>C</p> <p>Low level of evidence</p>
<p style="text-align: center;">Level 4</p> <ul style="list-style-type: none"> • Comparative studies with major biases • Retrospective studies • Case series 	

In parallel to the analysis of medical and paramedical data, a critical analysis of legal or economic data¹³ available may be carried out in this step. In this case, it is preferable that this analysis be carried out by a legal expert or a health economist.

Data from the critical analysis and their synthesis are discussed in a meeting with the steering group and, if applicable, discussed with experts outside of the steering group.

¹³ if the efficacy and safety of the strategy are previously proven.

Appendix 4. Examples of proposals submitted to rating

► Choice between multiple definitions:

In the expression "persistent chronic pain", the term "persistent":

1. means that the chronic pain is difficult to evaluate;
2. means that the chronic pain is resistant to appropriate treatment;
3. means that the patient expresses feelings of anger and a need for change or, on the contrary, of resignation and helplessness, often accompanied by hostility towards caregivers;
4. is an ambiguous qualification, referencing numerous ideas such as the severity of the pain, difficulties in its evaluation or its treatment, a resistance to usual treatments, etc.

► Choice between multiple thresholds:

The treatment should be continued until:

1. the serum ferritin level returns to normal and is $\leq 300 \mu\text{g/L}$ for men and $\leq 200 \mu\text{g/L}$ for women;
2. the serum ferritin level is $\leq 50 \mu\text{g/L}$;
3. the serum ferritin level is $\leq 30 \mu\text{g/L}$ for men;
4. the serum ferritin level is $\leq 20 \mu\text{g/L}$ for women;
5. the serum ferritin level is $\leq 20 \mu\text{g/L}$ for men or women.

► Choice between multiple posology options:

During the first month after surgery, rehabilitation of uncomplicated total knee arthroplasty in a 75-year-old subject requires:

1. 2 sessions per day, 7 days a week;
2. 2 sessions per day for the first 7 days, then 1 session per day;
3. 2 sessions per day until recovery of an active knee flexion of 90° ;
4. 1 session per day.

► Choice between several basic clinical situations:

In consideration of the benefit/risk ratio on the acquisition of spoken language, cochlear implant is indicated in case of bilateral sensorineural hearing loss:

1. in children over 5 years of age;
2. in children between 2 and 5 years of age;
3. in children between 2 and 5 years of age with associated developmental disorders;
4. in children under 2 years of age.

Appendix 5. Rules for rating and analysis examples

The rules for analysis of responses making it possible to judge the appropriate or inappropriate nature of the proposals submitted to the vote of the rating group differ depending on whether it is the first round (Table 1) or the second round (Table 2). The first round is more conservative, in order to discuss at the meeting any situation where there is uncertainty or a missing value (Table 1). Analysis in the second round tolerates, for a group of 9 to 15 people, excluding a missing value or a value opposed to the majority of the group, with a view to judging the appropriate or inappropriate nature of the proposal submitted to the vote; the number of values excluded can be adjusted if the number of raters is > 15 (Table 2).

Concrete examples of analysis are presented (Table 3).

Proposal judged		Median value	Distribution of responses to 1 st round	Discussion at meeting of rating group	Submitted to second round of rating
Appropriate	strong agreement	≥ 7	All responses are between [7-9].	No, the recommendation is accepted as is. If one of the members present did not complete his/her questionnaire, make sure in the meeting that he/she also votes between [7-9].	No, the recommendation is accepted as is.
	relative agreement	≥ 7	All responses are between [5-9].	Yes	Yes
Inappropriate	strong agreement	≤ 3	All responses are between [1-3].	No, the recommendation is rejected as is. If one of the members present did not complete his/her questionnaire, make sure in the meeting that he/she also votes between [1-3].	No, the recommendation is rejected as is
	relative agreement	≤ 3.5	All responses are between [1-5].	Yes	Yes
Uncertain	undecided	between [4-6.5]	Whatever the distribution.	Yes, systematically.	Yes
	lack of consensus	≥ 7	At least one value < 5 or one missing value.	Yes, systematically.	Yes
		≤ 3.5	At least one value > 5 or one missing value.	Yes, systematically.	Yes

Table 2. Judgement retained at the end of the second round, based on the number of raters.				
Proposal judged		Median value	Distribution of responses to 2nd round (9 to 15 raters)	Distribution of responses to 2nd round (16 to 30 raters)
Appropriate	Strong agreement	≥ 7	All responses are between [7-9], except one, missing or < 7 .	All responses are between [7-9], except two, missing or < 7 .
	relative agreement	≥ 7	All responses are between [5-9], except one, missing or < 5 .	All responses are between [5-9], except two, missing or < 5 (two missing or two responses < 5 or one missing and one response < 5).
Inappropriate	strong agreement	≤ 3	All responses are between [1-3], except one, missing or > 3 .	All responses are between [1-3], except two, missing or > 3 .
	relative agreement	≤ 3.5	All responses are between [1-5], except one, missing or > 5 .	All responses are between [1-5], except two, missing or > 5 .
Uncertain	undecided	between [4 – 6.5]	Whatever the distribution of the responses.	Whatever the distribution of the responses.
	lack of consensus	≥ 7	At least two values < 5 or two missing (or at least one missing value and one value < 5).	At least three values < 5 or missing.
		≤ 3.5	At least two values > 5 or two missing (or at least one missing value and one value > 5).	At least three values > 5 or missing.

Table 3. Examples of analysis of responses based on the round of rating. Influence of the position of the median and the distribution of the responses.														
Proposal submitted for voting	Round of rating	Number of responses for value of 1 (completely inappropriate) to 9 (completely appropriate)									Number of raters	Number of missing values	Judgement retained	Remarks
		1	2	3	4	5	6	7	8	9				
Proposal A	1 st round							3	6	3	12	0	Appropriate with strong agreement	Median and all responses between [7-9]. Proposal accepted as is from the 1 st round; not discussed in meeting, not submitted to 2 nd round.
Proposal B	1 st round	6	3	3							12	0	Inappropriate with strong agreement	Median and all responses between [1-3]. Proposal rejected as is from the 1 st round; not discussed in meeting, not submitted to 2 nd round.
Proposal C	1 st round				2	6	4				12	0	Uncertain undecided	Median and all responses between [4-6]. Proposal discussed at the meeting.
	2 nd round				1	6	4	1			12	0	Uncertain undecided	One rater changes his/her response in the 2 nd round. The response "7" can be excluded in the 2 nd round, in the absence of a missing value; the median and all of the responses taken into account are between [4-6]. The rating group confirms its indecision: given the current state of knowledge, it cannot be decided whether or not the proposal is appropriate.
Proposal D	1 st round				1			8	1	2	12	0	Uncertain lack of consensus	While the median is located between [7-9], there is one response <5. This value cannot be excluded in the 1 st round, so that the rater can discuss his/her point of view at the meeting.
	2 nd round				1			8	1	2	12	0	Appropriate with strong agreement	The raters maintain their rating in the 2 nd round. The response < 5 can be excluded in the 2 nd round, in the absence of a missing value => median and all of the responses taken into account between [7-9].

Table 4. Examples of analysis of responses based on the round of rating. Influence of missing values.															
Proposal submitted for voting	Round of rating	Number of responses for value of 1 (completely inappropriate) to 9 (completely appropriate)									Number of raters	Number of missing values	Judgement retained	Remarks	
		1	2	3	4	5	6	7	8	9					
Proposal A Situation 1	1 st round								3	6	3	12	0	Appropriate with strong agreement	Median and all responses between [7-9] in the 1 st round. Proposal accepted as is from the 1 st round; not discussed in meeting, not submitted to 2 nd round.
Situation 2	1 st round								3	5	2	12	2	Uncertain missing value	Although the median and all responses are between [7-9] in the 1 st round, the presence of at least one missing value means that it must be ensured in the meeting that raters who forgot to respond are in agreement with the rest of the group.
Situation 2	2 nd round			1		1			3	5	2	12	0	Appropriate with relative agreement	The median is between [7-9]; the response "3" can be excluded in the 2 nd round; all of the responses taken into account are ≥ 5 .
Proposal B Situation 1	1 st round	3	1	3	1	2				1	1	12	0	Uncertain lack of consensus	In the 1 st round, median between [1-3]; distribution of responses on both sides of a value of 5. The lack of consensus requires discussion of the proposal at the meeting.
Situation 1	2 nd round	4	3	3							1	12	1	Uncertain lack of consensus	In the 2 nd round (situation 1), although the median and all of the responses, except one, are between [1-3], the response "9" cannot be excluded since there is a missing value.
Situation 2	2 nd round	4	3	3		1					1	12	0	Inappropriate with relative agreement	In the 2 nd round (situation 2), in the absence of a missing value, the response "9" can be excluded; the median is between [1-3] and all of the responses taken into account are ≤ 5 .

Table 5. Examples of analysis of responses based on the round of rating. Influence of the number of raters.														
Proposal submitted to vote	Round of rating	Number of responses for value of 1 (completely inappropriate) to 9 (completely appropriate)									Number of raters	Number of missing values	Judgement retained	Remarks
		1	2	3	4	5	6	7	8	9				
Proposal A Situation 1	1 st round			1	1	3	2	2		3	12	0	Uncertain lack of consensus	In the 1 st round (situation 1), median between [4-6]; distribution of responses on both sides of a value of 5; the proposal is discussed in the meeting.
	2 nd round				1	1	2	2	2	3	12	1	Uncertain lack of consensus	In the 2 nd round (situation 1), although the median and all of the responses, except one, are between [5-9], the response "4" cannot be excluded since there is a missing value (1 single missing or excluded value possible if $n \leq 15$ raters).
Situation 2	1 st round				4	4	3	3		4	18	0	Uncertain lack of consensus	In the 1 st round (situation 2), median between [4-6]; distribution of responses on both sides of a value of 5; the proposal is discussed in the meeting.
	2 nd round				1	1	4	6	1	4	18	1	Appropriate with relative agreement	In the 2 nd round (situation 2), median between [7-9]; the response "4" can be excluded (2 missing or excluded values tolerated if 16 to 30 raters); all of the responses taken into account are ≥ 5 .
Situation 2 bis	2 nd round				1	1	3	6	1	4	18	2	Uncertain lack of consensus	In the 2 nd round (situation 2 bis), median between [7-9]; the response "4" cannot be excluded (no more than 2 missing or excluded values if 16 to 30 raters).

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Participants

This guide was written by Ms Joëlle André-Vert and Dr Muriel Dhénain, under the responsibility of Dr Michel Laurence, Head of the HAS Department for Good Professional Practice.

The literature search was carried out by Ms Emmanuelle Blondet, with the assistance of Ms Sylvie Lascols, under the direction of Ms Frédérique Pagès, Head of the HAS Public Documentation and Information Department.

An initial version of this document was submitted to a reading group for opinion.

HAS would like to thank the participants of the following groups:

Simplification group

Prof. Jean-Pierre Boissel, clinical pharmacology, Lyon;
Dr Jean Brami, HAS, Saint-Denis;
Prof. Bernard Burnand, public health physician, Lausanne, Switzerland;
Prof. Charles Caulin, internist, Paris;
Prof. Jean-Michel Chabot, HAS, Saint-Denis;
Dr Pierre De Haas, general practitioner, Pont-d'Ain;
Dr Pierre Durieux, public health physician, Paris;

Prof. François Fourrier, anaesthetist and resuscitation specialist, Lille;
Dr Philippe Loirat, resuscitation specialist, Paris;
Dr Luc Martinez, general practitioner, Bois-d'Arcy;
Prof. Vincent Piriou, anaesthetist and resuscitation specialist, Lyon;
Dr Michel Serin, general practitioner, Saint-Amand-en-Puisaye.

Updating group

Dr Pascale Arnould, general practitioner, Villiers-Saint-Georges;
Dr Isabelle De Beco, general practitioner, Sainte-Geneviève-des-Bois;
Prof. Francis Bonnet, anaesthetist and resuscitation specialist, Paris;
Prof. Claude Jeandel, geriatrician, Montpellier;
Dr Philippe Loirat, resuscitation specialist, Paris;

Dr Gilles Morel, general practitioner, Dijon;
Prof. Philippe Orcel, rheumatologist, Paris;
Prof. Elisabeth Schouman-Clayes, radiologist, Paris;
Dr Jean-Pierre Vallée, general practitioner, Colleville-Montgoméry;
Dr Vincent Renard, general practitioner, Saint-Maur-des-Fossés.

Reading group

Dr Linda Banaei, HAS, Saint-Denis;
Dr Marie-Dominique Beaulieu, AETMIS, Montréal, Québec, Canada;
Dr Hervé Berche, general practitioner, Compiègne;
Dr Jacques Birgé, general practitioner, Boulay;
Ms Emmanuelle Blondet, documentalist, HAS, Saint-Denis;
Dr Jean Brami, HAS, Saint-Denis;
Dr Dominique Broclain, HAS, Saint-Denis;
Prof. Charles Caulin, internist, Paris;
Dr Corinne Collignon, HAS, Saint-Denis;
Dr Emmanuel Corbillon, HAS, Saint-Denis;
Dr Bachir Dahmani, HAS, Saint-Denis;

Dr Michel Delcey, doctor of physical and rehabilitation medicine, user representative, Paris;
Mr Dominique Delplanque, physiotherapist, Sartrouville;
Ms Agnès Dessaigne, HAS, Saint-Denis;
Dr Valérie Ertel-Pau, HAS, Saint-Denis;
Prof. François Fourrier, anaesthetist and resuscitation specialist, Lille;
Dr Gaétan Gentile, general practitioner, Marseille;
Ms Gersende Georg, HAS, Saint-Denis;
Dr Sylvie Gillier-Poirier, general practitioner, Sébastien-sur-Loire;

Dr Françoise Hamers, HAS, Saint-Denis;
Ms Vanessa Hernando, HAS, Saint-Denis;
Dr Grégoire Jeanblanc, HAS, Saint-Denis;
Ms Estelle Lavie, HAS, Saint-Denis;
Prof. Michel Leporrier, haematologist, Caen;
Dr Valérie Lindecker, HAS, Saint-Denis;
Dr Claudie Locquet, HAS, Saint-Denis;
Dr Luc Martinez, general practitioner, Bois-
d'Arcy
Dr Marina Martinowski, HAS, Saint-Denis;
Mr Hervé Nabarette, HAS, Saint-Denis;
Mr Emmanuel Nouyrigat, HAS, Saint-Denis;
Mr Cédric Paindavoine, HAS, Saint-Denis;

Ms Anne Françoise Pauchet Traversat, HAS,
Saint-Denis;
Ms Karine Petitprez, HAS, Saint-Denis;
Prof. Vincent Piriou, anaesthetist and
resuscitation specialist, Lyon;
Mr François Planchamp, INCa, Boulogne-
Billancourt;
Dr Nathalie Poutignat, HAS, Saint-Denis;
Ms Véronique Raimond, HAS, Saint-Denis;
Dr Christine Revel-Delhom, HAS, Saint-Denis;
Dr Olivier Scémama, HAS, Saint-Denis;
Dr Patrice Van Amerongen, psychiatrist, user
representative, Noisy-le-Roi;
Dr Olivier Wong, general practitioner, Paris.

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Mr Romain Aubourg, HAS, Saint-Denis;
Mr Alexandre Biosse-Duplan, HAS, Saint-
Denis;
Dr Philippe Blanchard, HAS, Saint-Denis;
Dr Lise Bosquet, INCa, Boulogne-Billancourt;
Mr Aurélien Dancoisne, HAS, Saint-Denis;
Prof. Laurent Degos, HAS, Saint-Denis;
Dr Roselyne Delaveyne, HAS, Saint-Denis;
Ms Christine Devaud, HAS, Saint-Denis;
Dr Patrice Dosquet, HAS, Saint-Denis;
Mr Michel Gedda, HAS, Saint-Denis;
Dr Cédric Grouchka, HAS, Saint-Denis;

Mr Raymond Le-Moign, HAS, Saint-Denis;
Dr Pierre Liot, HAS, Saint-Denis;
Dr Valérie Mazeau-Woynar, INCa, Boulogne-
Billancourt;
Ms Sandrine Morin, HAS, Saint-Denis;
Ms Frédérique Pagès, HAS, Saint-Denis;
Dr Sun-Hae Lee-Robin, HAS, Saint-Denis;
Mr François Romaneix, HAS, Saint-Denis;
Dr Dominique Tessier-Vetzel, HAS, Saint-
Denis;
Ms Caroline Tranche, HAS, Saint-Denis.

Information sheet

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Objective(s)	To present the process for developing good practice guidelines according to the “Formal consensus” method at the Haute Autorité de Santé.
Professional(s) involved	Organisations and professional groups wishing to produce good practice guidelines (institutions, national professional speciality councils, French College of General Practice, patient associations, learned societies, etc.).
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Project steering	Coordination: Dr Michel Laurence, Head of the Department for Good Professional Practice. Secretary: Ms Laetitia Gourbail. Literature search: 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.
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Literature search	The literature search strategy consisted of the use of HAS document sources on methods for the 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	Ms Joëlle André-Vert and Dr Muriel Dhénain, Project Managers, Department for Good Professional Practice.
Validation	Adoption by the HAS Board in in December 2010 and February 2015 for update.
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 guidelines can be downloaded from www.has-sante.fr .
Accompanying documents	Documents related to the development of the “project outline” and the “Clinical practice guidelines” method can be downloaded from www.has-sante.fr .