HAUTE AUTORITÉ DE SANTÉ

METHODOLOGICAL GUIDE

Accelerated Guidelines

April 2016

Summary

1 Introduction

The purpose of this guide is to describe the method used to produce accelerated guidelines (AG).

This guide is directed toward professionals who want to know the method used by the Haute Autorité de Santé (HAS) or who want to develop accelerated guidelines according to this method.

This guide will be adapted to best meet the demands and needs of the actors involved.

1.1 Accelerated guidelines

Among its missions, HAS is charged with "*producing 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) (1).

The method proposed allows the following to be produced within a short time (about 6 months) and in a short format (double-sided sheet).

These AG are part of an objective of improving the quality and safety of care.

They must be produced methodically and transparently and have the goal of assisting the practitioner and the patient in finding the most appropriate care in given clinical circumstances.

They have the objective of making recommendations based on data from science, professional experience and patient preferences available to the various actors in the healthcare system (professionals, patients and users, decision-makers), in order to:

- help with decision-making in choice of care;
- standardise practices;
- reduce useless or risky treatments and procedures;
- promote suitable procedures not carried out.

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

The develoment of these AG should not be an objective in itself, but should be part of a good practice programme, ranging from the identification of needs to the evaluation of this programme (2). A good practice programme can be part of continuing professional development.

These AG can also be used:

- to produce indicators for improving the quality and safety of care (3,4) or clinical practice indicators (5);
- as part of initial training.

The AG 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 their own findings and the patients' preferences.

1.2 AG method

A rigorous and clearly defined approach must be applied for the development of these AG.

The objective of these AG is to offer a small number of key recommendations or messages that are concise, unambiguous and, if possible, ranked.

The method is based on:

- the participation of professionals and representatives of patients and users affected by the topic of the AG;
- transparency, with provision of:
  - critical analysis of the literature,
  - essential points from debates and decisions made by members of the working group,
  - opinions of the stakeholders,
  - the list of all participants who contributed to the work;
- independence:
  - independence related to the status of HAS, as an independent public scientific authority (Law of 13 August 2007 on health insurance, Title II, Chapter I bis, Article L. 161-37) (1),
  - financial independence; public financing in the context of the AG developed by the HAS;
- 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" (6).

2 Registration of the request and project outline step

HAS, as a public and independent sponsor, ensures funding for the AG that it produces and distributes. It takes the initiative to develop an AG (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 of patients or users of the healthcare system.

After registering the topic in the HAS programme, an initial project outline phase is implemented. This step makes it possible to decide which method to use: good practice guideline or accelerated guideline.

The criteria favouring the development of an AG are:

- the existence of recent data about the topic, preferably from French and foreign GPGs and well-conducted meta-analyses;
- the lack of major controversy about the topic.

The progress of an AG, from outlining to distribution of 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;
- ensuring coordination and organising the project logistics.

The project manager participates in all meetings.

3 The actors

The AG method can involve two types of actors:

- the working group, which may be optional depending on the method chosen (see Chapter 4);
- the stakeholders.

The composition of the working group and the stakeholders are determined in advance, during outlining of the topic.

The members of the working group, 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[1], patient or user associations, institutions;
- based on the responses obtained in case of 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 development of the AG and, in case of changes, send it to the HAS project manager (6).

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 Social Security Code. In particular, they agree to:

- not communicate about the subject;
- 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 mission is to discuss the key recommendations or messages of the AG, after hearing or reading:

[1] Organisations for the defence of professional interests (trade unions) are not generally called on in the context of the development of the AG.

- the bibliographic data available, summarised by one or more project leaders in the development report;
- the opinions of the stakeholders.

Ideally, the working group includes about ten professionals and representatives of patients or users of the healthcare system.
One or more project leaders may be recruited to identify, select, analyse and draft a critical synthesis of the literature (development report), as well as to draft the initial and final texts of the AG.

The healthcare professionals of this group must have a good knowledge of professional practice in the field corresponding to the topic of the AG.

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;
- 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 is in accordance with that determined in the project outline. As the working group for AG is intended to be limited, one or two experts per professional organisation and association of patients or users concerned by the topic will be recruited.

If it wishes, the working group may interview experts on the topic who have a conflict of interest. Before interviewing such an expert, the working group will be notified of the declared interests. This participation will be mentioned in the development report (6).

3.2 Stakeholders

The stakeholders (professional organisations and associations of patients or users, institutions, etc.) concerned by the topic are determined in advance in the project outline.

A questionnaire about the AG and the development report are 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 development report.

4 Procedure of the method

The procedure of the method can be split into 3 or 4 phases depending on the chosen method:
- method A (no working group):
  - drafting of the development report and the first version of the AG,
  - request for opinion from stakeholders,
  - analysis of the opinions of the stakeholders and elaboration of the final version;

- method B (with working group):
  - drafting of the development report and the first version of the AG,
  - discussion of the first version by the working group,
  - request for opinion from stakeholders,
  - analysis of the opinions of the stakeholders by the working group and elaboration of the final version.

The guiding criteria for choosing between the 2 methods are:
- method A: numerous and recent data that do not require contextualisation for the French healthcare system and for which the request for opinion from stakeholders seems sufficient given the topic of the AG (general topic, no controversy, etc.);
- method B: less numerous or less recent data that may require contextualisation for the French healthcare system, topic with non-major controversy. In these situations, it may be necessary to establish a working group.

4.1 Drafting of the development report and the first version of the AG

This phase concerns methods A and B.

It can be carried out by an HAS project manager or by one or more project leaders under the supervision of the project manager.

The goal of 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 a development report;
- propose an initial version of AG.

► Critical analysis of the literature

The drafting of the development report and the first version of the AG 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 (7). Appendix 3 presents the levels of evidence and corresponding grades.

The bibliographic search is limited to French and international recommendations, meta-analyses and reviews of the literature (for example, Cochrane-type systematic reviews). Bibliographic updating will be carried out until publication of the AG.

► Drafting the development report

The development report includes the following elements:
- working method;
- document search and criteria for selection of articles;
- introduction presenting the topic and the context for developing the AG;
- a concise and hierarchical critical synthesis of the literature retained, including a referenced text and, if necessary, summary tables with mention of the levels of evidence;
- the opinion of the working group, if one was established, including decisions made, minority positions and points of difference or divergence from practice;
- opinions of the stakeholders with mentions of proposals retained;
- bibliographic references;
- list of participants.

► Drafting of the first version of the AG

The first version of the AG is produced during the drafting of the development report. If a working group is established, the development report and the first version of the AG will be sent at least 10 days before the first meeting.

4.2 Discussion of the first version by the working group

This phase concerns only method B.

The members of the working group meet once, or more if necessary, to discuss the key recommendations or messages proposed in the first version of the AG, as well as the development report.

The working group meetings are led and moderated by the HAS project manager.

4.3 Request for opinion from stakeholders

This phase concerns methods A and B.

The project manager sends the stakeholders the development report and the AG as well as the questionnaire in Word format with the content of the AG divided into chapters and paragraphs. The stakeholders are given a period of 3 weeks, or 15 days when the AG is developed within a very tight deadline, to complete the questionnaire.

The opinions of the stakeholders are compiled by chapter and/or by paragraph and inserted into the development report.

A sample questionnaire is provided in Appendix 1.

4.4 Analysis of the opinions of the stakeholders and elaboration of the final version

The responses are analysed either by the project manager with the project leaders in method A, or by the working group in method B (meeting, teleconference, email, etc.).

Regardless of the method used, the changes and decisions made following the analysis of the responses of the stakeholders must be mentioned and, if possible, explained in the development report.

The documents produced during this stakeholder analysis are the final versions of the AG and the development report.

► Validation

The AG and the development report are submitted to the committee concerned for opinion and to the HAS Board for adoption, thus authorising their distribution. 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 AG and the development 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 development 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, stakeholders, persons interviewed by the working group);
- the number and names of participants who do not wish to endorse the documents produced;
- the funding sources of the project (including distribution).

► Updating

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

Appendix 1. Sample stakeholder questionnaire

READING GRID

ACCELERATED 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: ----------

ACCELERATED GUIDELINE - TITLE

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

Appendix 2. Literature search

The project manager and the project leader(s) participate in the development of the document search strategy carried out by a documentalist.

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.

This search makes it possible to initially identify the French and international recommendations and evidence reports produced by governmental agencies, independent evaluation agencies and learned societies.

French and international biomedical databases and, depending on the work topic, specific databases will be queried.

This search is updated until publication of the AG.

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

The document 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.

Appendix 3. Grading of recommendations

Level of scientific evidence provided by the literature (therapeutic studies)	Grade of recommendations
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	
Level 4 • Comparative studies with major biases • Retrospective studies • Case series	**C** Low level of evidence

References

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Information sheet

Title	**Accelerated Guidelines**
Document type	Methodological guide
Date of publication:	Only available in electronic format: www.has-sante.fr
Objective(s)	To present the process for developing memo AG and relevance AG at the Haute Autorité de Santé
Professional(s) involved	Organisations and professional groups wishing to produce memo AG (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 Michel Laurence, Head of the Department for Good Professional Practice Secretary: Ms Laetitia Gourbail
Conflicts of interest	No conflicts of interest
Literature search	This method was carried out based on the ten or so experiments conducted at the Department for Good Professional Practice
Authors	Department for Good Professional Practice
Validation	Validation by the HAS Board in April 2016
Updating	This methodological guide will be updated based on new data and needs identified after the publication of this guide.
Accompanying documents	Documents related to the development of the project outline can be downloaded from www.has-sante.fr