



AWMF Guidance Manual and Rules for Guideline Development

*Preliminary English version
of the original document:
Das AWMF-Regelwerk Leitlinien.*

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Preface

This AWMF Guidance Manual is designed to provide a tool for the scientific medical societies to create and publish up-to-date and high-quality guidelines in the AWMF Guideline Register. It is therefore divided into two parts:

Guideline development

Guideline register

The first part - with its workflow charts, aids and tools - supports the guideline developer. The objective of this part is to create guidelines for medical societies according to a reproducible procedure with the highest possible scientific standards, whilst making the development process transparent. This includes, among others, assigning responsibility for guideline development, convening the guideline development group, the use of sound methods for evidence synthesis and structured consensus development; additionally, it helps identify and manage conflicts of interest. The first part also aims to facilitate compliance with the quality criteria described in the German Instrument for Methodological Guideline Appraisal (DELBI). It thus serves to illustrate and assure the quality of the individual guidelines in the AWMF Register.

The second part describes the procedures used by the AWMF within the scope of internal quality management to keep the AWMF Guideline Register up-to-date and to maintain its high level of quality overall. These include the review of registered guideline projects in conjunction with already-published guidelines, their classification into "S" classes, the management of conflicts of interest and checking how current each individual guideline is. Thus the aim of the second part is to assure guideline register quality.

Overall, this Guidance Manual forms the basis for the further and continuing education of guideline consultants, coordinators and developers.

The AWMF Guidance Manual will be updated as required. Changes will be disclosed via the newsletter and the AWMF's guideline RSS feed (subscribe at www.awmf.org/service-navigation/rss.html). The publishers are responsible for making updates.

The currently valid version of the AWMF Guidance Manual is available online at <http://www.awmf.org/leitlinien/awmf-regelwerk.html>.

Text underlined in colour is actively linked in the document and is meant to facilitate finding specific chapters and thus working with the guidance.

Introduction: What are guidelines?

Guidelines are systematically developed statements reflecting the current state of knowledge and meant to support doctors and patients in making decisions concerning appropriate care for specific health problems.

Guidelines are important and effective instruments for quality development in health care. Their primary objective is to improve medical care by disseminating current knowledge.

Guidelines differ from other sources of "processed" knowledge (evidence reports, systematic reviews, health technology assessments with or without meta-analyses) in that they formulate clear recommendations for treatment backed up by a clinical weighting of the power and applicability of the study results.

Guidelines can be understood as "treatment and decision corridors" which can or should be deviated from in justified cases. The applicability of a guideline or individual guideline recommendations should be examined in individual situations and in the individual encounter according to the principles of shared decision-making.

Further reading:

AGREE Next Steps Consortium (2009) *The AGREE II Instrument* [Electronic version]. Current version available at www.agreetrust.org (Accessed on: 20 January 2013).

Brouwers M, Kho ME, Brouman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L for the AGREE Next Steps Consortium (2010) AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J.* 182:E839-842; doi:10.1503/090449.

Bundesärztekammer (BÄK), Kassenärztliche Bundesvereinigung (KBV), Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF) (2010). Programm für Nationale VersorgungsLeitlinien. Methoden-Report. 4. Auflage. Current version available at: www.versorgungsleitlinien.de/methodik/reports (Accessed on: 20 January 2013).

DELBI – Current version at www.delbi.de (Accessed on: 20 January 2013).

Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, Whitty P, Eccles MP, Matowe L, Shirran L, Wensing M, Dijkstra R, Donaldson C (2004) Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess.* 8(6):iii-iv, 1-72.

Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, Norris S, Falck-Ytter Y, Glasziou P, deBeer H, Jaeschke R, Rind D, Meerpohl J, Dahm P, Schuenemann HJ (2011) GRADE guidelines: 1. Introduction GRADE evidence profiles and summary of findings tables. *Journal of Clinical Epidemiology* 64; 383-394.

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (Accessed on: 20 January 2013).

Kopp I (2010) Perspektiven der Leitlinienentwicklung und -implementation aus der Sicht der AWMF. *Z Rheumatol* 69:298–304.

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med.* 156(7):525-531.

Objectives and structure of the AWMF Guidance Manual

This AWMF Guidance Manual is designed to provide a tool for the scientific medical societies to create and publish up-to-date and high-quality guidelines in the AWMF Guideline Register. Its objective is to assure and describe the quality of both the individual guidelines and that of the AWMF Guideline Register.

The AWMF Guidance Manual is primarily aimed at the professional societies in the AWMF that develop guidelines for the health care system. Furthermore, this Guidance Manual is designed for anyone interested in the methodology, traceability of quality and the development and implementation of guidelines in general.

This AWMF Guidance Manual is based on internationally accepted quality criteria and methodological guideline standards. The practical instructions provided supplement DELBI, The German Instrument for Methodological Guideline Appraisal. DELBI is an adoption of the international instrument "Appraisal of Guidelines for Research and Evaluation" (AGREE II).

The description follows the "life phases" of a guideline – from planning to updating. Every phase is described, including an introduction, reference to the AWMF's internal quality management (Guideline Register Rules) and the domains and criteria of DELBI and AGREE II. Resources and tips, practical examples and references for further reading are also provided.

Supplementation and updating should be continuous processes. Comments and suggestions are therefore explicitly encouraged and can be addressed to: imwi@awmf.org.

Planning and organisation

Rationale for guideline topic selection
Goal orientation of the guideline
Classification: S-Classes (S1, S2e, S2k, S3)
Constitution of the guideline development group: stakeholder involvement
Developing a Project plan and schedule
Establishing a Funding strategy
Formulating clinically relevant key questions
Disclosing and managing conflicts of interest

Registration

Registering with the AWMF Guideline Register

Guideline development

Constitutive meetings
Systematic review of the evidence: Introduction
Search, selection and methodological appraisal of guidelines and their synthesis
Search, selection, methodological appraisal of the literature and its synthesis
Structured consensus development
Grade of recommendations

Editing

Clarity and presentation
External review
Global adoption and authorisation
Long version, short version, patient version, guideline report

Implementation and evaluation

Preparing for implementation
Preparing the evaluation

Continuous updating

Planning supplements and updates

Publication

Submitting guidelines for publication with the AWMF

Planning and organisation

Rationale for guideline topic selection

For selecting the subject and scope for a new or revisable guideline, the first question to ask is: what are the perceived health issue(s) the guideline needs to address. Ideally, specific areas for potential improvement ought to be identified and scientifically verifiable.

For a guideline to be accepted into practice, it is helpful to provide plausible explanations as to why the subject was selected. Information on the prevalence of the aspect of care in question, current developments and specific areas where care can be potentially improved all serve this purpose. The [Goal orientation of the guideline](#) is deduced from this information as well.

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

Domain 1: Scope and purpose

Criterion 1: Specific Description of the overall objective(s) of the guideline

Resources and tips:

Think about why you selected this guideline subject.

Possible criteria for the selection of a guideline subject may include:

- Prevalence of that aspect of care
- Potential for optimisation and/or improvement of the quality of care
- Differences in care
- Burden of disease
- Economic relevance
- Ethical and social aspects
- Need for information relating to new technologies
- Need for coordination (interdisciplinary, interprofessional)

Further reading:

DELBI – Current version at www.delbi.de (*Domain 1: Scope and purpose*) (accessed: 20 January 2013).

AGREE II – Current version at www.agreetrust.org (Domain 1. Scope and purpose) (accessed: 20 January 2013).

Goal orientation of the guideline

Guidelines are not meant to replace textbooks. Their use can impact the health state of particular patient groups or large parts of the population. Therefore, it is important that the guideline's objectives be precisely defined against the backdrop of whom the dissemination and implementation of the guidelines aim to reach and why. The starting point is describing the [Rationale for guideline topic selection](#). A clear scope and clearly worded objectives will facilitate the [Formulating clinically relevant key questions](#) to be covered by the guideline. It should also assist evaluation of the guideline's impact on healthcare and its use as a tool for quality management. Therefore, it makes sense to describe as specifically as possible measurable objectives (see [Preparing the evaluation](#)).

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

Domain 1: Scope and purpose

Criterion 1: Specific Description of the overall objective(s) of the guideline

Resources and tips:

Example of how to word a simple general objective:

To disseminate evidence-based recommendations which help put healthcare decision-making on a more objective basis. The intention is to improve the structure, process and outcome quality of care and strengthen patients' position.

Example of how to word a specific objective:

To lower the rate of secondary vascular complications in patients after acute ischemic attacks.

Further reading

DELBI – Current version at www.delbi.de (*Domain 1: Scope and purpose*) (accessed: 20 January 2013).

AGREE II – Current version at www.agreetrust.org (*Domain 1. Scope and purpose*) (accessed: 20 January 2013).

Classification: S-Classes

During project planning, a decision ought to be made as early as possible about the planned "S class" as defined in the AWMF Guidance Manual. The AWMF classification grid is used to differentiate between the S1 expert recommendations and S2e, S2k and S3 guidelines. Every class stands for a specific methodological concept that ought to be described plausibly for the user (see [Long version](#), [short version](#), [patient version](#), [guideline report](#), [Submitting guidelines for publication with the AWMF](#)). S-Classes are meant to indicate the degree to which a guideline development process was systematic. The class is selected depending on how much effort is suitable and implementable. When answering this question, the need to legitimate the implementation of the guideline is to be considered (convincing the target group).

AWMF Guideline Register Rule:

S1, S2, S3 classification (for more details, see "AWMF Rules for the Guidelines Register", page 84).

www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-stufenklassifikation/klassifikation-s1.html

www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-stufenklassifikation/klassifikation-s2e-und-s2k.html

www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-stufenklassifikation/klassifikation-s3.html

Reference to the DELBI Instrument and AGREE II:

None

Resources and tips:

S-Classification according to the AWMF Guidance Manual

S-classification

S3	Evidence- and consensus-based guideline	Representative committee, Systematic review and Synthesis of the evidence, structured consensus development	<p>Degree of systematic development</p>
S2k	Evidence-based guideline	Systematic review and Synthesis of the evidence	
S2e	Consensus-based guideline	Representative committee, structured consensus development	
S1	Recommendations by expert groups	Consensus development in an informal procedure	

Further reading

Muche-Borowski C, Kopp I (2011) Wie eine Leitlinie entsteht. Z Herz-Thorax-Gefäßchir. 25:217-223.

Constitution of the guideline development group: stakeholder involvement

The guideline development group lays the groundwork for the subject-related appropriateness of the guideline's content which sensibly represents experienced users and patients. Balancing the composition of the guideline development group will lay the proper groundwork for comprehensively identifying potential clinical problems and foster critical appraisal of all relevant evidence. This will help to prevent the process from being impacted by potential biases arising from special interests. There is no set minimum number of participating medical societies, professional associations or organisations. Their number depends on the subject, the [Goal orientation of the guideline](#) and the user and patient target population of the respective guideline. Members of the guideline group should represent the professional and scientific expertise as well as patient experience in the guideline's subject area. It is additionally recommended to include at an early stage persons experienced in guideline development methodology and evidence-based medicine. The more complete the guideline development group, the greater is the probability that the guideline will be accepted and applied.

AWMF Guideline Register Rule:

The guideline development group ought to be representative of the target group. Representatives of target users (professional groups who shall implement the recommendations) and the patient target population (persons for whom the guideline is being developed and should apply to) should be included in the guideline development at an early stage.

Adherence to this rule is mandatory in order to classify a guideline as S2k or S3 (for more details, see "AWMF Rules for the Guidelines Register", page 84).

www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-stufenklassifikation/klassifikation-s2e-und-s2k.html

www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-stufenklassifikation/klassifikation-s3.html

Reference to the DELBI Instrument and AGREE II:

Domain 1: Scope and purpose

Criterion 3: Definition of the target population covered by the guideline (patients, public etc.)

Domain 2: Stakeholder involvement

Criterion 4: Involvement of all relevant professional groups

Criterion 5: Identification of views and preferences of the target population

Criterion 6: Definition of the target users of the guideline

Resources and tips:

As a rule, the initiator/coordinator of the guideline project informs the relevant medical societies and organisations about the planned project and invites them to participate. Each medical society or organisation ought to have its own standard procedure in place for nominating representatives and clarify the nominees' status, role and responsibilities.

Letter template "Nominating representatives"

(see [Appendix 1](#))

Briefentwurf - Einladung zur Mitwirkung an einem Leitlinienprojekt
Anwendungshinweise:
Bitte grün markierte oder durch / getrennte, alternative Formulierungsvorschläge auswählen,
graue Markierungen individuell ausfüllen.
Es handelt sich um ein Rohmuster-Text bitte individuell bearbeiten und ergänzen!

Absender
[Leitlinien-Koordinator/in, Titel der einladenden, federführenden Fachgesellschaft/
Organisation]

Anschrift
[persönliche/r Ansprechpartner/in, Titel der einzuladenden Fachgesellschaft/ Organisation,
Geschäftsstelle]

**Betr.: Einladung zur Mitwirkung an einem Leitlinienprojekt
und Bitte um Benennung eines Mandatsträgers**

Sehr geehrte/r [Titel, Name persönliche/r Ansprechpartner/in]

Falls die Leitlinie bereits angemeldet ist
es freut mich, Ihnen mitteilen zu können, dass die Anmeldung der [S2k/S3] Leitlinie [Titel
der Leitlinie, AWMF-Reg Nr.] in das Register der Arbeitsgemeinschaft der
Wissenschaftlichen Fachgesellschaften e.V. (AWMF) aufgenommen

The representative, with his or her specialised area of expertise, acts as a proxy for the medical society/organisation. Experience in writing and implementing guidelines is desirable.

The following 3 questions always apply when forming a guideline development group:

- Who should we include?
- Who is affected by our recommendations?
- Who could contribute to the success of the project (clinical, personal, methodological perspectives and experience)?

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 1. Scope and purpose, Domain 2. Stakeholder Involvement*) (accessed: 20 January 2013).

DELBI – Current version at www.delbi.de (*Domain 1: Scope and purpose; Domain 2: Stakeholder involvement*) (Accessed: 20 January 2013).

Hutchings A, Raine R. (2006) A systematic review of factors affecting the judgments produced by formal consensus development methods in health care. *J Health Serv Res Policy*. 11(3):172-9.

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 2. Background and Key Stakeholders in Guidelines Development and Use*) (Accessed on: 20 January 2013).

Kopp IB, Selbmann HK, Koller M (2007) [Consensus development in evidence-based guidelines: from myths to rational strategies]. *Z Arztl Fortbild Qualitatssich*. 101(2):89-95.

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) *Guidelines International Network: Toward International Standards for Clinical Practice Guidelines*. *Ann Intern Med*. 156(7):525-531.

Project plan and schedule

A project plan that defines timelines, activities and responsibilities will facilitate project management and financial planning. It also helps ensure that the tasks necessary for achieving a certain S class (see [Classification: S-Classes](#)) are completed and the publication is submitted by the planned date. The project plan is best individualised and adapted to the options available to the guideline development group.

Implementation, class projects	Responsible Function within guideline group(s) e.g. coordinator, steering committee, guideline group, topic-related work group, methodologists, guideline secretary	Tasks	Timeline
Planning and organisation			
<div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">S1</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">S2</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">S3</div>		<ul style="list-style-type: none"> • Selecting the guideline topic • Establishing the intended class (S1, S2e, S2k, S3) • Guideline development group composition: <ul style="list-style-type: none"> ○ Involving the guideline users (target group) and patient target population ○ Forming a guideline steering committee, as appropriate • Inviting medical societies / organisations and requesting them to nominate representatives or proxies • Preparing a project schedule • Establishing a funding strategy • Drafting key questions the guideline aims to address (if available in collaboration with the guideline steering committee) • Obtaining disclosures of (potential) conflicts of interest 	
		<ul style="list-style-type: none"> • Registering the guideline with the AWMF 	
Guideline development			
Constitutive meetings <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-top: 5px;">S1</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-top: 5px;">S2</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-top: 5px;">S3</div>		<ul style="list-style-type: none"> • Discussion and conclusion of the planning phase • Determining if the guideline development group is balanced, post-nominate as appropriate • Presenting and finalising the methodological concept (DELBI, project plan) • Revising and approving the key questions and establishing the process strategy • Forming topic-related work groups, as appropriate • Discussion of (potential) conflicts of interest 	

Implementation, class projects	Responsible Function within guideline group(s) e.g. coordinator, steering committee, guideline group, topic-related work group, methodologists, guideline secretary	Tasks	Timeline
Systematic review of the evidence S2e S3		<ul style="list-style-type: none"> • Search, selection, methodological critical appraisal of existing guidelines on the topic and their synthesis <ul style="list-style-type: none"> ○ Documentation of a reproducible search for guidelines ○ Establishing inclusion and exclusion criteria ○ Critical appraisal of the methodological quality (DELBI) ○ Tabular comparison of the clinical questions adopted as a result of the first consensus development that includes the contents of the selected guidelines and the literature they are based upon ○ A guideline synopsis (if applicable) 	
Writing draft versions S1 S2 S3		<ul style="list-style-type: none"> • Search, selection, methodological critical appraisal of the literature <ul style="list-style-type: none"> • Establishing the search strategy • Establishing inclusion and exclusion criteria <ul style="list-style-type: none"> ○ Recording the selection ○ critical appraisal of the methodological quality ○ Creating evidence tables • Content-related work (in small groups as appropriate) • Preparation of recommendations and draft texts based on the guideline synopsis (if applicable) and primary literature 	
Structured consensus development S2k S3		<ul style="list-style-type: none"> • Preparation • Selecting the technique • Discussion, considered judgment, grading of recommendations, adoption of recommendations 	
Editorial Office			
External review and overall adoption S1 S2 S3		<ul style="list-style-type: none"> • Review procedure • Final voting in the guideline development group by E-Mail written resolution procedure • Formal adoption by the chairpersons of the participating medical societies / organisations 	
Guideline documents		<ul style="list-style-type: none"> • Long Version • Short Version • Patients' version 	

Implementation, class projects	Responsible Function within guideline group(s) e.g. coordinator, steering committee, guideline group, topic-related work group, methodologists, guideline secretary	Tasks	Timeline
S1 S2 S3		<ul style="list-style-type: none"> • Guideline report • Supplemental document, if applicable (e.g. evidence reports, evidence tables) • Algorithms and practical aids, if applicable 	
Implementation and evaluation			
Preparation S1 S2 S3		<ul style="list-style-type: none"> • Identifying potential organisational, structural, financial or staff-related barriers • Description of solution strategies and targeted activities for promoting guideline implementation • Formulating quality indicators, if applicable 	
Continuous supplementation and updating			
Planning S1 S2 S3		<ul style="list-style-type: none"> • Notation of date (validity) and responsibilities • Establishing a procedure for the status and needs analysis to identify topic areas that are to be revised 	
Publication			
S1 S2 S3		<ul style="list-style-type: none"> • Securing the guideline report is complete according to the S-class and conflicts of interest are disclosed • Securing the societies and organisations involved have formally adopted the guideline • Submitting the guideline documents to the AWMF 	

Funding strategy

A funding strategy serves in planning and estimating the costs the guideline will incur. Most members of the guideline development group do their work on an honorary basis, exceptions might be external moderators or methodologists. The costs for a guideline may vary, depending on the topic to be addressed and the class intended. For this reason, it is worth preparing a rough financial framework in advance. The AWMF supports the guideline development groups with basic advice free-of-charge and provides informational materials along with all aids and tools described in the AWMF Guidance Manual.

AWMF Guideline Register Rule:

Prior to publication within the AWMF, the guidelines are reviewed with respect to funding information. The AWMF will not accept finalized guidelines for publication if they have funding issues that might lead to conflicts of interest or the conflicts of interest of the individual participants are not transparently disclosed. (see [Disclosing and managing conflicts of interest](#)).

Guidelines funded by third parties that have a direct influence on content will be rejected for publication in the AWMF Register; this is in accordance with internationally recognised and practiced policy.

Reference to the DELBI Instrument and AGREE II:

Domain 6: Editorial independence

Criterion 22: Naming the funding body and securing that views of the funding body have not influenced the content of the guideline

Resources and tips:

The sequential process to be addressed by funding

- Planning and organisation
- Guideline development
- Editing and dissemination
- Implementation
- Evaluating and planning updates

Variables necessary for estimating the time and costs required in relation to the specific project plan

- Number of key questions (PICO, s. [Formulating clinically relevant key questions](#))
- Literature searches and critical appraisals of the evidence
 - Databases (sometimes pay-for-use)
 - Purchasing literature (sometimes pay-for-use)

- Inclusion and exclusion criteria (sensitivity/specificity), scope of the need to search for and appraise the evidence (abstract/full text)
- Volume of text/guideline structure
- Costs for staff (secretaries, guideline infrastructure, moderators, methodologists etc.)
- Costs for materials (office, communication technologies, supplies)
- Travel expenses for consensus conferences and working sessions
- Facility and, if needed, TED costs at conferences
- Review / consultation procedures
- Adoption by the boards and/or representatives of the medical societies
- Publication, layout, translation
- Preparing implementation (quality indicators, patient guidelines etc.)
- Planned commitment and time resources to be allocated by the coordinators, experts and patients

Examples of funding grants to guideline projects

- "Proprietary contributions" by active guideline development group members
- Scientific medical societies
- Professional associations
- Independent funding institutions (foundations)
- Employers
- Guideline programs (German Program for National Clinical Practice Guidelines (NVL Program), Guideline Program in Oncology (OL program))
- BMBF Competence Networks (BMBF, German Federal Ministry of Education and Research)
- BMBF/BMG Individual Grants (BMG, German Federal Ministry of Health)
- Others
 - Patient organisations (leagues, professional self-help associations)
 - Topic-related working groups/task forces – associations
 - Funding associations of charitable foundations
 - Self-regulatory bodies
 - Funding institutions / purchasers of healthcare

Summary: Medical societies and authors make the greatest contribution to upholding editorial independence. It can always be assumed that funding will come from mixed sources.

Further reading:

AGREE II – Current version at www.agreetrust.org (*Domain 6. Editorial Independence*) (Accessed on: 20 January 2013).

DELBI – Current version at www.delbi.de (*Domain 6: Editorial Independence*) (Accessed on: 20 January 2013).

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 3. Trustworthy Clinical Practice Guidelines: Challenges and Potential*) (Accessed on: 20 January 2013).

Forms for completing a main application in the German Guideline Program in Oncology application procedure. <http://leitlinienprogramm-onkologie.de/Antragstellung.4.0.html> (Accessed on: 20 January 2013).

Formulating clinically relevant key questions

When planning of literature searches, it is essential to formulate clinically relevant key questions at an early stage. This will also make the guideline more attractive by keeping its substantive content within sensible and manageable limits. Here, a decision should be made as to which questions or recommendations should or will be in focus with a view to the [Goal orientation of the guideline](#). At the same time, the methodological strategy for answering the question should be established. Possible strategies include:

- Structured consensus development (see [Classification: S-Classes](#) (Criteria S2k and S3), [Structured consensus development](#)):
Grade of Recommendation: Expert consensus (no additional information on evidence or grade of recommendation)
- Use/adaptation of existing guidelines (see [Classification: S-Classes](#) (Criteria S2e and S3), [Systematic review of the evidence](#): Introduction).
Content and grading of the evidence will be accepted unaltered! Deviations from the grade of recommendation are only allowed when an appropriate note and justification are contained in the background text
- Systematic literature search (see. [Classification: S-Classes](#) (Criteria S2e and S3), [Systematic review of the evidence](#): Introduction).
Systematic search, selection, critical appraisal, summary in evidence tables

Especially when planning a systematic literature search, it makes sense to more precisely formulate the clinically relevant key questions. This will enable identification of the truly relevant literature based on a logical selection and linking of search terms. A precise formulation also helps prepare for the critical appraisal of the literature for formulations of recommendations.

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

Domain 1: Scope and purpose

Criterion 2: Specific description of the health question(s) covered by the guideline

Resources and tips:

It makes sense for the entire guideline development group to discuss and agree on the clinically relevant key questions at its first consensus meeting in order to delineate its working scope. Not every question can and must be founded on the group's own systematic literature

searches. During this first meeting, reasons for prioritising the development strategy ought to be discussed and recorded.

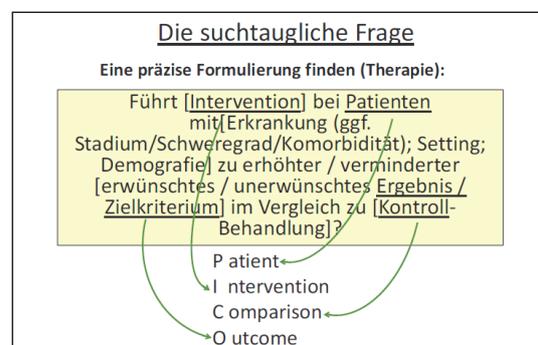
The PICO method has proved helpful for precisely formulating key questions.

Patient

Intervention

Comparison

Outcome



When deciding on the outcomes (endpoints of trials) to be considered, it is important to only use end points or validated surrogate parameters that are relevant to the patients. A consensus on the relevance of pertinent end points ought to be reached early, ideally at the first meeting of the guideline development group (see [Constitutive meetings](#)).

Example of a clinically relevant key question:

What are the merits of pharmacotherapy for secondary prevention of acute stroke?

Example of how to derive a searchable key question:

In patients with acute ischemic stroke, is the use of clopidogrel more effective than ASA for preventing future strokes?

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 1: Scope and purpose*) (Accessed on: 20 January 2013).

DELBI – Current version at www.delbi.de (*Domain 1: Scope and purpose*) (Accessed on: 20 January 2013).

Guyatt GH, Oxman AD, Kunz R, Atkins D, Brozek J, Vist G, Alderson P, Glasziou P, Falck-Ytter Y, Schünemann HJ (2011) GRADE guidelines: 2. Framing the question and deciding on important outcomes. *J Clin Epidemiol* 64(4):395-400.

Disclosing and managing conflicts of interest

All parties involved in writing the guideline shall disclose their conflicts of interest at an early stage and a procedure for managing conflicts of interest shall be put in place. Ensuring transparency in collecting and recording conflicts of interest builds trust and protects the group from any charges of bias or impartiality which may entail protracted clarification processes. This process is mandatory for S1 recommendations for action and class S2 and S3 guidelines.

AWMF Guideline Register Rule:

As a general rule, conflicts of interest are disclosed in writing on a standard form that covers material and immaterial interests.

Written disclosures of conflicts of interest by the steering committee members, coordinators and work groups leaders should be submitted before starting work on the guideline.

The boards of the delegating medical societies acknowledge the conflicts of interest disclosed by members of the steering committees and critically appraised in terms of their impartiality. The steering committee and coordinators shall appraise the written conflicts of interest disclosures from all other participants.

The conflicts of interest disclosures of all participants should be detailed in the guidelines report (e.g. in tabular form). The long version of the guideline must describe the procedure for recording and appraising conflicts of interest with reference to the guidelines report.

Finalized guidelines will not be accepted into the AWMF Register if their funding has conflicts of interest issues or individual participants have not transparently disclosed their conflicts of interest.

See also further explanations on managing conflicts of interest under “Rules for the AWMF Guideline Register”, page 87)

<http://www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-interessenkonflikte/interessenskonflikte.html>

Using a [Sample form for disclosure of conflicts of interest](#), obtain disclosure from all participants.
(see [Appendix 2](#))

1

Erklärung über Interessenkonflikte

(Titel, AWMF-Registernummer)

zu Händen

(Leitlinienkoordinator)

Vorbemerkung

Die Entwicklung von Leitlinien für die medizinische Versorgung verlangt über die fachliche Expertise hinaus eine Vermeidung kommerzieller Abhängigkeiten oder anderer Interessenkonflikte, die die Leitlinieninhalte beeinflussen. Es gibt eine Vielzahl von materiellen (z.B. finanzielle oder kommerzielle) und immateriellen (z.B. politische, akademische oder persönliche) Beziehungen, deren Ausprägungsgrade und Bedeutungen variieren können. Interessenkonflikte sind somit zumeist unvermeidbar, aber nicht

Reference to the DELBI Instrument and AGREE II:

Domain 6: Editorial independence

Criterion 23: Recording and addressing conflicts of interest/competing interests

Resources and tips:

[Examples of how to disclose potential conflicts of interest](#) in the guideline report (see [Appendix 3](#))

Anhang

3. Beispiele für Darlegungen von Interessenkonflikterklärungen

Leitlinienkoordinator:
Leitlinie:
Registernr.:

	Name des Autors*	Name des Autors*	Name des Autors*	Name des Autors*	Name des Autors*
1	Berater- bzw. Gutachterföigkeit oder bezahlte Mitarbeit in einem wissenschaftlichen Beirat eines Unternehmens der Gesundheitswirtschaft (z.B. Arzneimittelindustrie, Medizingrundindustrie), eines kommerziell orientierten Auftragsinstituts oder einer Versicherung				
2	Honorare für Vortrags- und Schulungstätigkeiten oder bezahlte Autoren- oder Co-Autorenschaften im Auftrag eines Unternehmens der Gesundheitswirtschaft, eines kommerziell orientierten Auftragsinstituts oder einer Versicherung				
3	Finanzielle Zuwendungen (Drittmittel) für Forschungsvorhaben oder direkte Finanzierung von Mitarbeitern der Einrichtung von Seiten				

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 6. Editorial Independence*) (Accessed on: 20 January 2013).

AWMF-Regelwerk:

http://www.awmf.org/fileadmin/user_upload/Leitlinien/Werkzeuge/empf-coi.pdf

<http://www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-interessenkonflikte/interessenskonflikte.html>

DELBI – Current version at www.delbi.de (*Domain 6: Editorial independence*) (Accessed on: 20 January 2013).

IOM (Institute of Medicine) (2011) Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 4. Current best Practices and Proposed Standards for Development of Trustworthy CPGs: Part I, Getting Started*) (Accessed on: 20 January 2013).

Deutsches Netzwerk Evidenzbasierte Medizin (Ed.) Strech D, Klemperer D et al. Interessenkonfliktregulierung: Internationale Entwicklungen und offene Fragen. <http://www.ebm-netzwerk.de/was-wir-tun/pdf/interessenkonfliktregulierung-2011.pdf/view> (Accessed on: 20 January 2013).

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med.* 156(7):525-531.

Registering with the AWMF Guideline Register

Guideline projects must be registered with the AWMF before the guideline can be published on the AWMF website. The registration of guideline projects promotes interdisciplinary collaboration in the guideline development community and helps avoid unresolved contradictions among the various guidelines on related subjects. Details about registered projects on the AWMF-website and newsletters keep other interested medical societies/professional associations/organisations informed and allow them to apply to the guideline coordinator if they want to contribute. The AWMF reviews all registrations as part of its maintenance and management of its Guideline Register.

AWMF Guideline Register Rule:

Registration procedure for guidelines in planning and development (for more details: see "AWMF Rules for the Guideline Register", page 86).

<http://www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-02-anmeldeverfahren.html>

Registration Form (see [Appendix 4](#))

Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.		Association of the Scientific Medical Societies in Germany			
Anmeldeformular Leitlinienprojekt <small>Fassung vom 15. Oktober 2010</small>					
Titel der Leitlinie:					
Art der Anmeldung: <input type="checkbox"/> neue Leitlinie <input type="checkbox"/> Upgrade oder <input type="checkbox"/> Update von AWMF-Register-Nr.:					
Geplante Klasse: <input type="checkbox"/> S1 <input type="checkbox"/> S2e <input type="checkbox"/> S2k <input type="checkbox"/> S3					
Anmeldedatum:					
Geplante Fertigstellung (Monat/Jahr):					
Gründe für die Themenwahl:					
Zielorientierung der Leitlinie:					

Reference to the DELBI Instrument and AGREE II:

None

Resources and tips:

Individual persons (e.g. initiator/lead author/guidelines coordinator) may submit the registration. The party registering the guideline notifies the guideline delegates and/or the guideline secretary of the medical society accordingly.

Aid for completing this Registration Form

(see [Appendix 5](#))

Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.		Association of the Scientific Medical Societies in Germany		
Ausfüllhilfe für Anmeldeformular Leitlinienprojekt Fassung vom 15. Oktober 2010				
Titel der Leitlinie: Bitte wählen Sie einen aussagefähigen, aber möglichst kurzen Titelvorschlag für Ihre Leitlinie				
Art der Anmeldung: <input type="checkbox"/> neue Leitlinie <input type="checkbox"/> Upgrade oder <input type="checkbox"/> Update von AWMF-Register-Nr.:				
Geplante Klasse: S1, S2e, S2k, S3, bitte konkret angeben. Eine Entscheidungshilfe für die Wahl der Klasse finden Sie unter http://www.awmf-leitlinien.de Rubrik LL-Regelwerk → LL-Register, Klassifikation der Entwicklungsstufen				
Anmeldedatum: Tag/Monat/Jahr				
Geplante Fertigstellung (Monat/Jahr): Bitte geben Sie an, wann die Leitlinie voraussichtlich fertig sein soll. Bitte beachten Sie: Nach Ablauf dieses Datums werden Sie von der AWMF um Auskunft zum Projektstand gebittet.				

Forgot anything?

- Have you filled in the Registration Form **completely**?
- Registering medical society(ies): is at least one an AWMF member society?
- Do target users and participating medical societies match?
- Did you consider the involvement of patient representatives?
- Does the intended class match the planned methodology?
- Are the connections to other guidelines checked and specified in order to avoid contextual contradictions?
- Submit the registration to anmeldung@leitlinien.net

Guideline development

Constitutive meetings

The purpose of the first joint meeting of all medical societies, associations and/or organisations involved in developing the guideline is first to allow everybody to get to know each other. The methodological procedure of guideline development according to the AWMF Guidance Manual is introduced; there is time allotted for discussion; the tasks from the planning phase are completed, whereupon the scientific and content guideline development phase commences. This process is also used to determine whether the guideline development group is complete, or whether additional medical societies/ associations/organisations should become involved. The guideline development group also discusses the pre-formulated clinically relevant key questions, approves them by consensus and devises their search strategy. It is helpful to determine whether each clinically relevant key question should be answered by adapting existing guidelines, by searching the primary literature or within an expert consensus procedure (see [Formulating clinically relevant key questions](#)). At this first meeting, the organisational structure, timeline and activities plan are agreed and the responsibilities within the guideline development group are defined (see [Project plan and schedule](#)). Depending on the planned scope of the guideline, a guideline steering committee can be assembled. It may make sense to form topic-related work groups to process the clinically relevant key questions/problem areas. At the end of this meeting, every participant takes home information about what the contents of the guideline should look like and who has been assigned which tasks.

Another purpose of this first meeting is to discuss and manage conflicts of interest according to the AWMF Guidance Manual (see [Disclosing and managing conflicts of interest](#)).

The first meeting is organised and conducted when the guideline development starts, usually after the guideline project has been registered. This meeting is recommended for all guidelines classes. For S2e guidelines, the completeness of the guideline development group is not a mandatory requirement.

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

Domain 1: Scope and purpose

Criterion 3: Definition of the target population covered by the guideline (patients, public etc.)

Domain 2: Stakeholder involvement

Criterion 4: Involvement of all relevant professional groups

Criterion 5: Identification of views and preferences of the target population

Criterion 6: Definition of the target users of the guideline

Resources and tips:

- Think about whether the meeting should be moderated by an external AWMF guideline consultant
- Schedule the time, date and place at an early stage
- Organise rooms, catering, media for the consensus conference (e.g. laptop, beamer, or TED system for voting among larger groups)
- The medical societies ought to have nominated their representatives/proxies by this time.
- Send out timely invitations and documents for the meeting to all members of the guideline development group and, if envisaged, external moderators and any other participants as appropriate (observers, external experts)

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 1. Scope and purpose; Domain 2. Stakeholder Involvement*) (Accessed on: 20 January 2013).

German Medical Association (BÄK), National Association of Statutory Health Insurance Physicians (KBV), Association of the Scientific Medical Societies (AWMF) (2010) National Programme for Disease Management Guidelines. Method Report. 4th Edition. [cited: 30 July 2010]. Available at: www.versorgungsleitlinien.de/methodik/reports (Accessed on: 20 January 2013).

DELBI – Current version at www.delbi.de (*Domain 1: Scope and purpose; Domain 2: Stakeholder involvement*) (Accessed on: 20 January 2013).

IOM (Institute of Medicine) (2011) Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 2. Background and Key Stakeholders in Guidelines Development and Use*) (Accessed on: 20 January 2013).

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med.* 156(7):525-531.

Systematic review of the evidence: Introduction

The term “evidence based” refers to the methods used for systematically searching, selecting, critically appraising and reviewing the available evidence for [Formulating clinically relevant key questions](#). These were formulated in advance by the guideline development group and should be answered with recommendations.

AWMF Guideline Register Rule:

For the classifications S2e and S3, this includes:

- A systematic search for guidelines on the same topic and assess whether individual recommendations therefrom can be used and/or adapted (DELBI Domain 8, criteria 30-34).
- A proprietary literature search using a systematic methodology. It is important to describe the search strategy in detail and list the applied search terms, sources (electronic databases, databases systematic reviews, handsearched journals, conference reports, other guidelines) and search results (DELBI Domain 3, criterion 9).
- Explicitly specify the evidence selection criteria, particularly the exclusion criteria (DELBI Domain 3, Criterion 8).
- Critical appraisal of the evidence researched and selected according to criteria defined a priori with regard to their methodological quality and synthesize the results in evidence tables
- Rating the quality of the evidence ("grade of evidence" or "level of evidence").

Reference to the DELBI and AGREE II Instrument:

DELBI	AGREE II
<p>Domain 8: Methodological rigour of the guideline development using existing guidelines</p> <p>Criterion 30: Search for existing guidelines</p> <p>Criterion 31: Selection as source of evidence</p> <p>Criterion 32: Reviewing the quality</p> <p>Criterion 33: Update searches of source guidelines</p> <p>Criterion 34: Description and justification of modifications to the recommendations of the source guideline(s)</p> <p>Domain 3: Methodological rigour of development</p> <p>Criterion 8: Use of systematic methods to search for evidence</p> <p>Criterion 9: Clear description of criteria for selecting the evidence</p> <p>Criterion in development: Methodological appraisal of the identified evidence</p> <p>Criterion 12: Explicit link between the recommendations and the supporting evidence.</p>	<p>Domain 3: Rigour of Development</p> <p>Criterion 7. Use of systematic methods to search for evidence.</p> <p>Criterion 8. Clear description of criteria for selecting the evidence</p> <p>Criterion 9. Clear description of the strengths and limitations of the body of evidence</p> <p>Criterion 12. Explicit link between the recommendations and the supporting evidence.</p>

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*) (Accessed on: 20 January 2013).

Balshem H, Helfand M, Schuenemann HJ, Oxman AD, Kunz R, Brozek J, Vist GE, Falck-Ytter Y, Meerpohl J, Norris S, Guyatt GH (2011) GRADE guidelines: 3. Rating the quality of evidence. *Journal of Clinical Epidemiology* 64; 401-406.

DELBI – Current version at www.delbi.de (*Domain 3: Methodological rigour of the guideline development; Domain 8: Methodological rigour of guideline development using existing guidelines*) (Accessed on: 20 January 2013).

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 3. Trustworthy Clinical Practice Guidelines: Challenges and Potential; Chapter 4. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part I, Getting Started; Chapter 5. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part II, Traversing the Process*) (Accessed on: 20 January 2013).

Quaseem A, Snow V, Owens DK, Shekelle P (2010) The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. *Ann Intern Med* 153(3):194-9.

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med.* 156(7):525-531.

Search, selection and methodological appraisal of guidelines and their synthesis

To limit the effort required for literature searches, it makes sense to start by searching for national and international guidelines relating to the subject in question. A targeted search in the AWMF Guideline Register will additionally help prevent unresolved contradictions in various guidelines on related subjects. One or several guidelines are selected as source guidelines based on their subject-related appropriateness, currency and transferability to the German health care system and on their quality after critical appraisal using DELBI. The relevant recommendations to be adopted from the primary guidelines are recorded appropriately.

AWMF Guideline Register Rule:

For the classifications S2e and S3, this includes:

- A systematic search for guidelines on the same topic and assessment whether individual recommendations therefrom can be used and/or adapted (DELBI Domain 8, criteria 30-34).

Reference to the DELBI Instrument and AGREE II:

DELBI	AGREE
<p>Domain 8: Methodological rigour of the guideline development using existing guidelines</p> <p>Criterion 30: Search for existing guidelines</p> <p>Criterion 31: Selection as source of evidence</p> <p>Criterion 32: Reviewing the quality</p> <p>Criterion 33: Update searches of source guidelines</p> <p>Criterion 34: Description and justification of modifications to the recommendations of the source guideline(s)</p>	<p>Domain 3: Rigour of Development</p>

Resources and tips:

Useful databases for the guideline search may include, but are not limited to:

- AWMF
- ÄZQ
- Websites of the German medical societies / organisations
- Guideline International Network (GIN)
- National Guideline Clearinghouse (NGC)

- Websites of international medical societies / organisations
- Medline (PubMed)

As a rule, the search is conducted in the databases using individual key words that describe the clinical picture, since the search results will then mostly be manageable and can be handsearched.

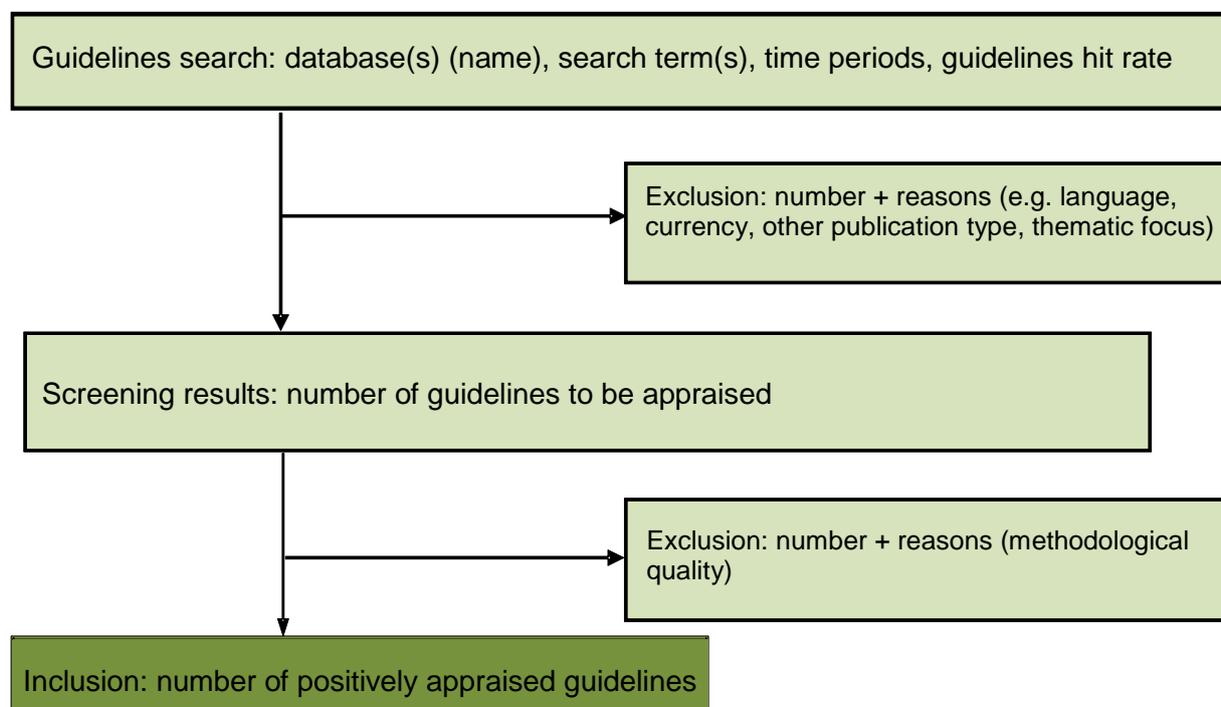
The selection and/or screening are conducted according to the previously defined inclusion and exclusion criteria.

A helpful hint for searching for guidelines in PubMed: use a search filter (logical link of characteristic key words) to limit the search results whenever the initial search produces a high hit rate, e.g.

guideline*[TI] OR recommendation*[TI] OR consensus[TI] OR
 standard*[TI] OR "position paper" [TI] OR "clinical pathway*" [TI]
 OR "clinical protocol*" [TI] OR "good clinical practice" [TI]

Don't forget to record the search strategy!

Example of how to record a guidelines search:



After reviewing the source guideline(s), it is recommended to plan a meeting of the entire guideline development group to discuss content, determine any need for supplementary lit-

erature searches and to devise a search strategy. If the guideline coordinators and/or the steering committee have already searched and selected source guidelines prior to the first meeting of the entire guideline development group (see [Constitutive meetings](#)), this information can be utilised effectively for reaching a consensus on the relevant key questions. That leaves time during the constitutive meeting to plan further literature searches.

In the next step, the contents of the selected source guidelines can be assigned to individual key questions (see [Formulating clinically relevant key questions](#)) and synthesised into a guideline synopsis. Various forms of presentation are possible.

Example 1 - Guideline synopsis: Regular retinopathy screening in patients with type-2 diabetes mellitus?

AAO 2003	DDG 2000	NICE 2002	SIGN 2001	CDA 2003
Yes	Yes	Yes	Yes	Yes
A II	A IB	D	A	A 1A
Klein R, Klein BE, Moss SE et al. Arch Ophthalmol 1984; 102: 527-32	UKPDS 33 Lancet 1998;352 (9131):837-53.	Consensus of the panel	Kohner EM, Aldington SJ, Stratton IM, et al. UKPDS 30 Arch Ophthalmol 1998;116:297-303.	Klein R, Klein BEK, Moss SE, et al. The Wisconsin Arch Ophthalmol. 1989;107: 244-249.

Source: M. Lelgemann for the National Disease Management Guideline Diabetes Typ-2-Retinopathy, 2005

Example 2 - Guideline synopsis: Neoadjuvant chemotherapy for stomach cancer

Quelle	Fazit/Empfehlung	Empfehlungsgrad	Evidenzgraduierung	Literaturbelege
FNCLCC, 2004 [1]	<p>Neoadjuvante Chemotherapie beim potentiell resektablen Magenkarzinom:</p> <p>Schlussfolgerung: Die verfügbaren Ergebnisse ermöglichen es nicht, den Stellenwert der neoadjuvanten Chemotherapie bei potentiell resektablen Tumoren zu etablieren (Evidenzlevel C). Entsprechende Studien werden zurzeit in Europa durchgeführt.</p> <p>Option: Keine.</p> <p>Empfehlung: Es wird empfohlen, weitere klinische Studien durchzuführen, in denen die neoadjuvante Chemotherapie mit der primären Chirurgie verglichen wird.</p>	Nicht angegeben	C	Allum, 1989 Allum, 2003 Fujji, 1999 Kang, 1996 Songun, 1999
SIGN, 2006 [2]	<p>Neoadjuvante (perioperative) Behandlung des Magenkarzinoms:</p> <p>Empfehlung: Der neoadjuvante Einsatz einer Chemo- oder Radiotherapie bei Patienten mit Magenkarzinom wird außerhalb von klinischen Studien nicht empfohlen.</p>	A	1+	Earle, 2003 Janunger, 2002

Source: Evidence report, S3 Guidelines on Stomach Cancer, 2012, AWMF Register No. 032/009OL

The guideline synopsis is used to answer the specific key question:

- Adapt the guideline recommendation (use the content, indicated level of evidence and grade of recommendation)
- Use the evidence synthesised in the guideline (e.g. evidence tables)
- Consider the recommendations as background information and establish the need for further literature searches
- Not applicable, key question not (adequately) addressed

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*) (Accessed on: 20 January 2013).

DELBI – Current version at www.delbi.de (*Domain 8: Methodological rigour of guideline development using existing guidelines*) (Accessed on: 20 January 2013).

IOM (Institute of Medicine) (2011) Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 3. Trustworthy Clinical Practice Guidelines: Challenges and Potential; Chapter 4. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part I, Getting Started; Chapter 5. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part II, Traversing the Process*) (Accessed on: 20 January 2013).

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med.* 156(7):525-531.

Search, selection, methodological appraisal of the literature and its synthesis

In principle, an iterative hierarchical search process is recommendable (search for 1. Guidelines, 2. Aggregate evidence, 3. Primary literature). Once the search for existing guidelines on the topic is concluded and the results have been gathered to answer specific clinically relevant key questions, the systematic literature search can begin. With a view to individual key questions, the search can be completely generated de-novo or continued as an updating search of a source guidelines by applying the strategy used on the source guideline.

Searching on the level of aggregate evidence

For pragmatic reasons, it is recommended to start by searching for systematic reviews with or without meta-analyses). This will produce a good summary of the literature. A critical appraisal of the quality of the aggregate evidence is indicated here.

Search for primary literature

If the above searches do not adequately answer the key question, now the search continues on the individual study level. Here, the work might be reduced by limiting study design of first choice for the respective key question (e.g. randomised controlled trials (RCT) on the question of the efficacy of therapeutic and diagnostic interventions or cohort studies on the question of the accuracy of diagnostic tests). However, these limitations will not always be appropriate.

AWMF Rule for the Guideline Registry:

For the classifications S2e and S3, this includes:

- The guidelines development group's own systematic literature search, i.e. it is important to describe the search strategy in detail and list the applied search terms, sources (electronic databases, databases systematic reviews, handsearched journals, conference reports, other guidelines) and search results (DELBI Domain 3, criterion 8).

Reference to the DELBI Instrument and AGREE II:

DELBI	AGREE
Domain 3: Methodological Rigour of development Criterion 8: Use of systematic methods to search for evidence	Domain 3: Rigour of Development Criterion 7: Use of systematic methods to search for evidence

Resources and tips:

For more detailed information on planning and implementing search strategies read the complimentary documents “Systematic search of the literature for the development of guidelines” provided by the German Cochrane Centre, the Agency for Quality in Medicine (ÄZQ) and the AWMF-Insitute for Medical knowledge Management (AWMF-IMWi) (see Further reading:).

Databases for literature searches include, but are not limited to:

- Cochrane Library
- Medline (PubMed)
- Embase (pay-for-use)
- topic-related databases (e.g. PsycLit, CINAHL, PEDRO)
- Other resources(IQWiG, DIMDI)

In addition to the identification of databases, search terms (MeSH, free text), search period and possible delineators (e.g. children or adults, investigations on humans) should be defined. It is helpful to agree the search strategy with the steering committee or, at best, with the entire guideline development group (e.g. by e-mail procedure). This will help ensure that all relevant search terms have been considered.

Don't forget to record the search strategy!

Example: Recording a specific / delimiting search strategy

Search	Query	Items found
#1	Search ("depression" [Mesh] OR "depressive disorder" [Mesh] OR "affective disorders, psychotic" [Mesh])	159930
#2	Search („hypericum [Mesh] OR "St John`s wort" [all fields])	2081
#3	Search (#1) AND (#2)	457
#4	Search (#3) AND (((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading]))	418
#5	Search (#3) AND (randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract]))	63
#6	Search (#5) Filters: published in the last 5 years	15

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*) (Accessed on: 20 January 2013).

DELBI – Current version at www.delbi.de (*Domain 3: Methodological rigour of guideline development*) (Accessed on: 20 January 2013).

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 3. Trustworthy Clinical Practice Guidelines: Challenges and Potential*) (Accessed on: 20 January 2013).

Quaseem A, Snow V, Owens DK, Shekelle P (2010) The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. *Ann Intern Med* 153(3):194-9.

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) *Guidelines International Network: Toward International Standards for Clinical Practice Guidelines*. *Ann Intern Med*. 156(7):525-531.

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Selection and critical appraisal of the literature

Using the pre-determined inclusion and exclusion criteria, the tasked members of the guideline development group read through the literature and sift out the papers relevant to the guideline. This selection process traditionally has 2 steps and, ideally, is conducted by 2 independent persons (clinically and methodologically experienced experts):

1. by title and abstract
2. by full text

Next, the guideline-relevant literature is critically appraised in a structured fashion based on pre-determined quality criteria on study design, implementation and analysis. In addition, it is indispensable to address clinical aspects of study quality, such as study population characteristics (external validity?), appropriateness of the comparator intervention (unbiased comparison?), follow-up period, relevance of the target variables (outcomes) and effect sizes. This applies to individual primary studies as well as to those included in systematic reviews or meta-analyses. The use of checklists is recommended (e.g. SIGN (Scottish Intercollegiate Guidelines Network, Cochrane Risk of Bias Tool)). Finally, the quality of the evidence is synthesised in a classification grid (grade of evidence, level of evidence, quality of the aggregate evidence relating to a key question).

AWMF Guideline Register Rule:

For the classifications S2e and S3, this includes:

- Explicit specification of the evidence selection criteria, particularly the exclusion criteria (DELBI Domain 3, Criterion 8).
- Critical appraisal of the evidence researched and selected according to criteria defined a priori with regard to their methodological quality and synthesize the results in evidence tables
- Identify the strength of the evidence ("grade of evidence" or "level of evidence").

Reference to the DELBI Instrument and AGREE II:

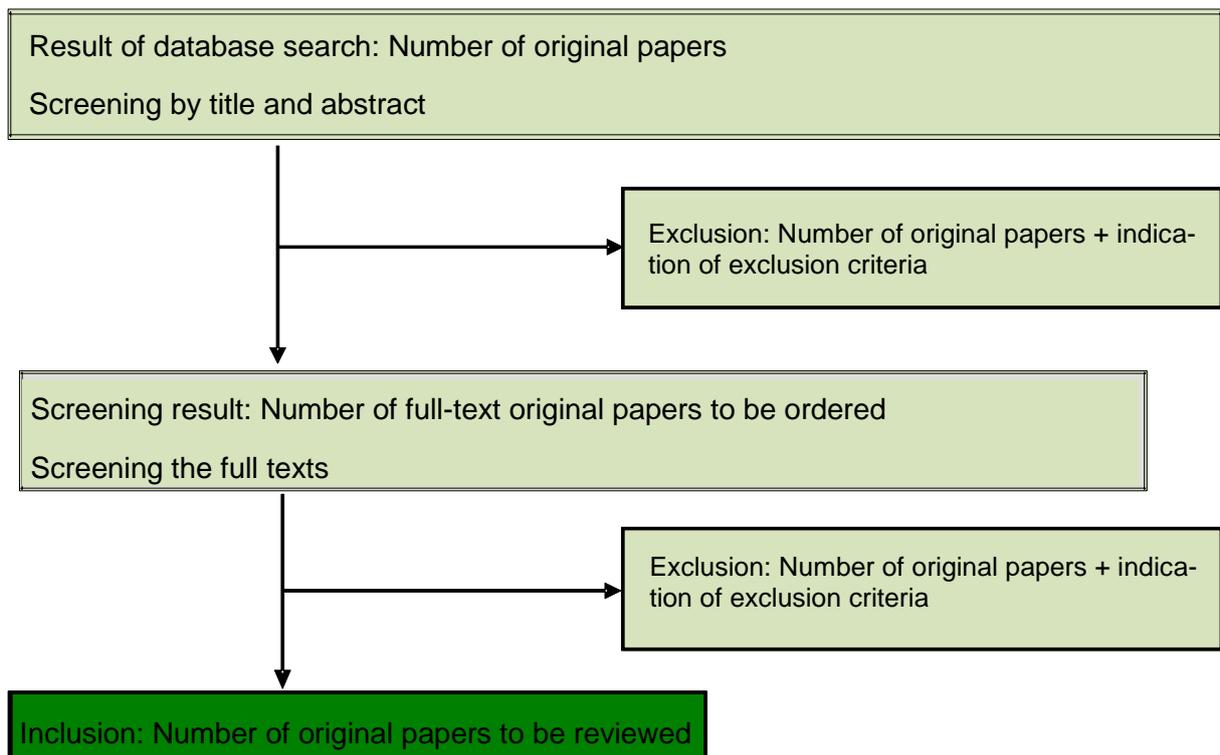
DELBI	AGREE
<p>Domain 3: Methodological Rigour of development Criterion 9: Clear description of criteria for selecting the evidence</p>	<p>Domain 3: Rigour of Development Criterion 8: Clear description of criteria for selecting the evidence Criterion 9: Clear description of the strengths and limitations of the body of evidence</p>

Resources and tips:

Inclusion and exclusion criteria may include, but are not limited to:

- Persons with a certain age, gender, disease status or co-morbidities
- Type of study
- Reference/comparator group
- Drug dosages
- Follow-up periods

Example: Record the search results and select original papers



The checklists and instructions for completing forms of the Scottish Intercollegiate Guideline Network (SIGN) are available at www.sign.ac.uk/guidelines/fulltext/50/index.html.



Ideally, an expert in methodology and an expert with clinical experience work in close collaboration to critically appraise the studies. The critical appraisal can be conducted centrally by

a defined team or decentrally by work group members. If the critical appraisal is very comprehensive, it forms a good basis for generating evidence tables.

A variety of classification systems are available for assigning grades of evidence.

Example:

Oxford

www.cebm.net/index.aspx?o=1025

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with > 80% follow-up; CDR† validated in a single population	Validating* cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic reviews) of the evidence; and including multi-way sensitivity analyses
1c	All or none‡	All or none case-series	Absolute SpPins and SnNus†††	All or none case-series or none-value analyses ††††	Absolute better-value or none-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level 2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level 2 economic studies
2b	Individual cohort study (including low quality RCT, e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample‡‡‡ or databases	Exploratory** cohort study with good†††† reference standards; CDR† after derivation, or validated only on split-sample‡‡‡ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited reviews) of the evidence, or single studies, and including multi-way

SIGN

www.sign.ac.uk/guidelines/fulltext/59/evidence.html

1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

GRADE

www.gradeworkinggroup.org/intro.htm



Quality of the evidence definitions

High quality— Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality— Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality— Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality— Any estimate of effect is very uncertain

The Oxford and SIGN classification systems focus on the quality of the individual studies. The GRADE approach views the available evidence from the outcome perspective (critical appraisal of the "body of evidence" from the studies for each relevant end point).

Guidelines ought to use a uniform system. The guideline development group ought to decide which grid system to use and record this in the guideline report. The selection should consider whether existing guidelines can be used sources of evidence on a broader scale (see [Systematic review of the evidence](#): , guideline adaptation) and which grid/which systems were used therein. If the source guidelines used apply different systems, it is important to verify whether transfer into a uniform grid is possible based on the critical appraisal of individual studies.

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*) (Accessed on: 20 January 2013).

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Guyatt GH, Oxman AD, Montori V, Vist G, Kunz R, Brozek J, Alonso-Coello P, Djulbegovic P, Atkins D, Falck-Ytter Y, Williams Jr. JW, Meerpohl J, Norris SL, Akl EA, Schuenemann HJ (2011) GRADE guidelines: 5. Rating the quality of evidence - publication bias. *Journal of Clinical Epidemiology* 64; 1277-1282.

Guyatt GH, Oxman AD, Kunz R, Brozek J, Alonso-Coello P, Rind D, Devereaux PJ, Montori VM, Freyschuss B, Vist G, Jaeschke R, Williams Jr. JW, Murad MH, Sinclair D, Falck-Ytter Y, Meerpohl J, Whittington C, Thorlund K, Andrews J, Schuenemann HJ (2011) GRADE guidelines 6. Rating the quality of evidence - imprecision. *Journal of Clinical Epidemiology* 64;1283-1293.

Guyatt GH, Oxman AD, Kunz R, Woodcock J, Brozek J, Helfand M, Alonso-Coello P, Glasziou P, Jaeschke R, Akl EA, Norris S, Vist G, Dahm P, Shukla VK, Higgins J, Falck-Ytter Y, Schuenemann HJ, The GRADE Working Group (2011) GRADE guidelines: 7. Rating the quality of evidence – inconsistency. *Journal of Clinical Epidemiology* 64;1294-1302.

Guyatt GH, Oxman AD, Kunz R, Woodcock J, Brozek J, Helfand M, Alonso-Coello P, Falck-Ytter Y, Jaeschke R, Vist G, Akl EA, Post PN, Norris S, Meerpohl J, Shukla VK, Nasser M, Schuenemann HJ, The GRADE Working Group (2011) GRADE guidelines: 8. Rating the quality of evidence – indirectness. *Journal of Clinical Epidemiology* 64;1303-1310.

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Guyatt G, Gutterman D, Baumann MH, Addrizzo-Harris D, Hylek EM, Phillips B, et al. (2006) Grading strength of recommendations and quality of evidence in clinical guidelines: report from an american college of chest physicians task force. *Chest*. 129(1):174-81.

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 3. Trustworthy Clinical Practice Guidelines: Challenges and Potential; Chapter 4. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part I, Getting Started; Chapter 5. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part II, Traversing the Process*) (Accessed on: 20 January 2013).

Kunz R, Burnand B, Schuenemann HJ (2008) [The GRADE System. An international approach to standardize the graduation of evidence and recommendations in guidelines]. *Der Internist*. 49(6):673-80. Das GRADE-System. Ein internationaler Ansatz zur Vereinheitlichung der Graduierung von Evidenz und Empfehlungen in Leitlinien.

Meerpohl JJ, Langer G, Perleth M, Gartlehner G, Kaminski-Hartenthaler A, Schuenemann H (2012) GRADE-Leitlinien: 3. Bewertung der Qualität der Evidenz (Vertrauen in die Effektschätzer). *Z. Evid. Fortbild. Qual. Gesundh. wesen (ZEFQ)*. 106:449-456.

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med*. 156(7):525-531.

Synthesising - creating evidence tables

Evidence tables compile the studies relating to a clinically relevant key question / subject area being considered for formulating the recommendation. This promotes transparency, improves analysis and ensures traceability, in turn, accelerating acceptance and implementation of the recommendations.

AWMF Guideline Register Rule:

For the classifications S2e and S3, this includes:

- Critical appraisal of the evidence researched and selected according to criteria defined a priori with regard to their methodological quality and synthesizing the results in evidence tables

Reference to the DELBI Instrument and AGREE II:

None

Resources and tips:

Example evidence table with the minimum criteria that guideline development groups can modify according to subject area and requirements (see **Appendix 6**)

Ziel der Evidenztabelle:
Einschätzung der gegenwärtigen Evidenzlage zum Thema als Informationsgrundlage zur Formulierung und Gradierung von Empfehlungen

Beispiel für Evidenztabelle:
Wir bitten, dieses Muster einer Evidenztabelle als Beispiel zu verstehen, dass nach der jeweiligen Thematik der Leitlinie modifiziert werden sollte.

Referenz	Studientyp	Teilnehmer (Anzahl und Charakteristika)		Drop out Rate	Intervention	Kontrolle	Zielgröße(n)	Haupt-ergebnis	Bemerkung
Autor und Jahr (RfZ Nr.) oder Link zur Publikation	Spezifikation der Studie: RCT, Fall-Kontroll-Studie, etc.	Anzahl aller Patienten in der Studie (EIn- und Auschlusskriterien, Unterstudie erziehen den Studien- und ausgewertete Gruppen; Anzahl rekrutierter (abrunder ausgewerteter) Patienten (pro Gruppe oder ITT)		Angabe insgesamt (und/oder pro Gruppe (abrunder abrunder Prozent) angebe	Details der Intervention für jede Gruppe (Dosis, Zeitraum, etc.)	Details der Kontrollgruppe (Dosis, Zeitraum, etc.)	Angabe der primären Zielgröße (gewöhnlich die auf die die Fallzahlkalkulation basiert) und sekundäre Zielgrößen (vom Autor angegeben)	Ergebnisse der primären Zielgröße (Ergebnisse und Präzisionsmaßstab) und sekundäre Zielgrößen (vom Autor angegeben)	Angaben aufzulager (positiver und/oder negativer) Aspekte hinsichtlich Studiendesign, Qualität und Auswertung (z.B. Konfidenzintervalle) Verbindung der RCT mit qualitative evidenzbasierte Verfahren (evidenzbasierte Verfahren) (evidenzbasierte Verfahren) (evidenzbasierte Verfahren)
		Pro Arm							
		Anzahl der Patienten in der Interventionsgruppe	Anzahl der Patienten in der Kontrollgruppe						

Zusammenfassende Beurteilung:
- Evidenzsynthesen der Autoren der Studie
- klinische Aussagekraft der Studie

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*) (Accessed on: 20 January 2013).

Bundesärztekammer (BÄK), Kassenärztliche Bundesvereinigung (KBV), Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF) (2010) Program for national clinical practice guidelines. Methoden-Report. 4th Edition. [cited: 30 July 2010]. Available from: www.versorgungsleitlinien.de/methodik/reports (Accessed on: 20 January 2013).

Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, Norris S, Falck-Ytter Y, Glasziou P, deBeer H, Jaeschke R, Rind D, Meerpohl J, Dahm P, Schuenemann HJ (2011) GRADE guidelines: 1. Introduction - GRADE evidence profiles and summary of findings tables. Journal of Clinical Epidemiology 64:383-394.

Mlika-Cabanne N, Harbour R, de Beer H, Laurence M, Cook R, Twaddle S, on behalf of the Guidelines International Network (GIN) Working Group on Evidence Tables (2011) Sharing hard labour: developing a standard template for data summaries in guideline development. BMJ Qual Saf;20:141e145. doi:10.1136/bmjqs.2010.040923.

Wienke A (2011) Medizinische Leitlinien sind wettbewerbsrechtlich nicht justiziabel. GMS Mitt AWMF. 8:Doc30. DOI: 10.3205/awmf000246, URN: urn:nbn:de:0183-awmf0002467.

Structured consensus development

Structured consensus development is aimed at discussing and adopting the recommendations and, thus, at answering the clinically relevant key questions.

Guideline development ought to be based on scientifically sound formal consensus methods like the nominal group process, the structured consensus conference and the Delphi Technique (see [Appendix 8](#)). The main rationale for using formal procedures is that decision-making by individuals and groups is susceptible to adverse impacts and biases and that formal procedures are superior to informal ones in terms of representativeness, efficiency, reproducibility and acceptance of the results. Selection of a suitable method ought to consider intervention-specific characteristics, size and heterogeneity of the group, complexity of the topic and the key question posed to the participating experts alongside existing resources (see [Appendix 8](#)). Often, a combination of various methods proves most effective. These include the written Delphi technique for gathering initial trends on group projections, the nominal group process for discussing complex topics and formulation and grading of recommendations and the structured consensus conference for final adoption of recommendations in a large committee.

Outcome quality essentially depends on how the procedure is prepared and implemented. For this reason, the participants should be provided with the approved written materials, including sufficient background information, in a timely manner. The objectives and pending tasks should be implemented into the consensus process by presenting the previously accomplished preliminary work.

During the implementation phase, it is advisable to engage an external, independent moderator trained in structured consensus development methods who can help identify and prevent sources of systematic bias (e.g. an AWMF guideline advisor). The procedure and results are to be recorded in the guideline report.

AWMF Guideline Register Rule:

When developing a class S2k or S3 guideline, each of the following criteria should be applied:

- Clearly describe the methods for formulating recommendations; this requires formal, structured consensus techniques (e.g. consensus conference, nominal group process or Delphi technique) (DELBI Domain 3, Criterion 10)
- Discuss and vote on each recommendation within the structured consensus process with a neutral moderator whose objective is to resolve still open decision-making issues, finalize the critical appraisal of the recommendations and measure the strength of the consensus.

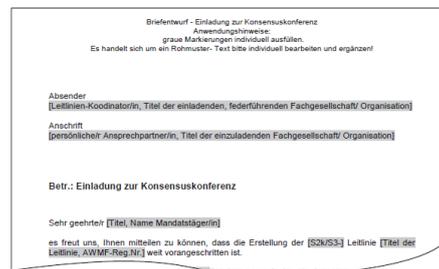
Reference to the DELBI and AGREE II Instrument:

DELBI- Domain 3: Methodological Rigour of development

Criterion 10: Description of the methods used for formulating the recommendations

Resources and tips:

- Schedule the time, date and place at an early stage
- Organise rooms, catering, media for the consensus conference (e.g. laptop, beamer, or TED system for larger groups)
- Send out timely invitations to the guideline development group (moderators, work group, participants, representatives)
- [Letter template “Invitation to the consensus conference”](#) (see [Appendix 7](#))



- Send out materials and information to the participants in a timely manner so that they can prepare for the conference
 - Draft versions of: Long version and guideline report
 - Voting proposal for recommendations and statements
(word processing format; do not use a presentation format!)

Establishing the strength of consensus

Classification of the strength of consensus	
Strong consensus	Agreement of > 95% of the participants
Consensus	Agreement of > 75 - 95% of the participants
Majority agreement	Agreement of > 50 - 75 % of the participants
No consensus	Agreement of < 50 % of the participants

Managing justified dissent:

If consensus is not reached, the result is likewise recorded in the guideline at the appropriate place and in the guideline report. In principle, two options are available in such cases:

1. The medical society petitions to have a special vote or the reasons for dissent noted along with the statements that cannot be supported. The medical society itself formulates this special vote as a concrete alternative proposal, including its justification, and includes it in the guideline.
2. The medical society petitions that the guideline report clarify that it was involved in the development process, but does not support the final wording of the guideline. Version of the guideline text approved by consensus of the members of the guideline development group and adopted by the other medical societies is not revised.
3. The medical society withdraws its participation and is no longer mentioned as a participant. The guideline text remains unchanged as is the case under 2.
4. The other medical societies involved decide about continuing the negotiations or publication of the guideline without the involvement of the dissenting medical society.

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*) (Accessed on: 20 January 2013).

Bundesärztekammer (BÄK), Kassenärztliche Bundesvereinigung (KBV), Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF) (2010) Programm für Nationale VersorgungsLeitlinien. Methoden-Report. 4th Edition. [cited: 30 July 2010]. Available from: www.versorgungsleitlinien.de/methodik/reports (Accessed on: 20 January 2013).

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Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CFB, Askham J, Marteau T. (1998) Consensus Development methods and their use in clinical guideline development. *Health Techn Assess.* 2(3):i-iv,1-88.

Grade of recommendation

The recommendations are graded on the basis of the identified evidence, clinical expertise and patient preferences. Hence, the grade also explicitly encompasses subjectively judged elements.

In the case of S3 guidelines, the formal consensus development process for adopting recommendations focuses on clinical aspects to judge the methodologically synthesised evidence. The recommendations are then discussed on this basis. Next, the strength of the recommendations is determined and a grade of recommendation assigned. Besides the underlying evidence, this discussion and assignment of grades of recommendation ought to give concrete consideration to the following criteria:

- Consistency of study results
- Clinical relevance of the endpoints and effect sizes
- Benefit-risk ratio
- Ethical, legal, economic considerations
- Patient preferences
- Applicability to the patient target population and the German health care system
- Practicality of routine use / in different areas of care

The quality of the evidence (strength of the evidence) is indicated to express the robustness of the study results and thus the degree of certainty / uncertainty of the knowledge, whilst the grade of recommendation reflects the results of weighing the desirable / undesirable consequences of alternative interventions. Hence, the strength of evidence and the strength of recommendation may deviate from one another in justified cases. A justification based on the aforementioned appraisal criteria should be recorded in a comment or in the background text to the recommendation.

By additionally indicating the strength of consensus for each recommendation, the guideline user is given an impression of the extent to which all participants were in agreement.

For consensus-based guidelines (S2k), the strength of recommendations are identified and adopted during the formal consensus process, although an indication of grades of recommendation (or levels of evidence) is not included because recommendations are not based on a systematic review of the evidence. Here, the strength of a recommendation is expressed in words only. Additionally, the strength of consensus (percentage of agreement within the guideline development group) can be indicated for each recommendation.

In evidence-based guidelines (S2e), the strength of the recommendations is determined and adopted during the informal consensus process. During the discussion and assignment of grades of recommendation, the methodological critical appraisal of the underlying evidence

should be complemented by a clinical appraisal applied analogous to the S3 guideline procedure.

AWMF Guideline Register Rule:

When developing a class S2k or S3 guideline, each of the following criteria should be applied:

- Clearly describe the methods for formulating recommendations: this requires formal, structured consensus techniques (e.g. consensus conference, nominal group process or Delphi technique) (DELBI Domain 3, Criterion 10)
- Discuss and vote on each recommendation within the structured consensus process with a neutral moderator whose objective it is to resolve pending decision-making issues, finalise the critical appraisal of the recommendations and measure the strength of the consensus.

Reference to the DELBI Instrument and AGREE II:

Domain 3: Rigour of Development

Criterion 11: Consideration of health benefits, side effects, and risks

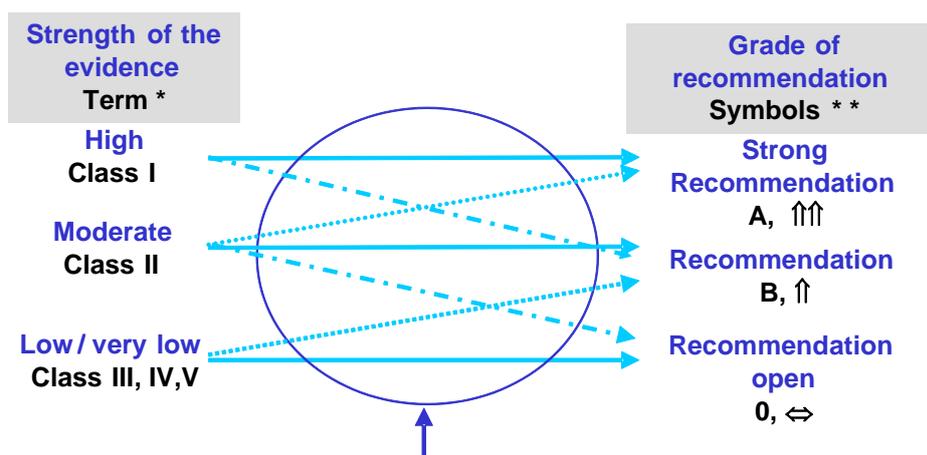
Criterion 12: Explicit link between the recommendations and the supporting evidence

Resources and tips:

Grid for grading recommendations

Grade of recommendation	Description	Syntax
A	Strong recommendation	should / should not
B	Recommendation	ought to / ought not to
0	Open recommendation	may be considered / no specific recommendation

Going from evidence to recommendations: Visualisation of considered judgmentl as a process of criteria-based consensus decision-making



Criteria for grading (aspects of consensus):

- Consistency of study results
- Clinical relevance of the outcomes and effect sizes
- Balance of benefit and harm
- Ethical, legal, economic considerations
- Patient preferences
- Applicability, Implementability

* Terminology according to GRADE [Critical appraisal of the overall evidence (blue)] and Oxford Centre of Evidence based Medicine [Critical appraisal of individual studies (black)]

** Grading of recommendations in the program for National Disease Management Guidelines

If possible, word the recommendation analogously:

Strong recommendation: "Should"; (weak) recommendation: "ought to";

Negative recommendations are expressed either using words only ("don't") and corresponding symbols or using words, additionally with downward arrows;

Open recommendations express a decision under uncertainty ("may be considered / "unclear- no specific recommendation can be made").

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*) (Accessed on: 20 January 2013).

Akl EA, Guyatt GH, Irani J, Feldstein D, Wasi P, Shaw E, Shaneyfelt T, Levine M, Schuenemann HJ (2012) "Might" or "suggest"? No wording approach was clearly superior in conveying the strength of recommendation. *Journal of Clinical Epidemiology* 65;268-275.

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Editing

Clarity and presentation

The way its recommendations are formulated and embedded into the context of the overall guideline plays a pivotal role in a guideline's acceptance and applicability. Recommendations ought to be clearly formulated, attractively presented and easily identifiable for the guideline's users. These are some editorial aspects to consider:

- Compare the semantics and grade of recommendation (e.g. "should" for a strong recommendation, "ought to" for a (weaker) recommendation)
- Use of the conditional (if....then...)- algorithmic logic
- Cite the sources which directly support the recommendation
- For S2e and S3 guidelines: Specify grade of evidence and recommendation
- For S2k and S3 guidelines: Specify the strength of consensus within the guideline development group
- Highlight the recommendations against the background text, e.g. in text boxes
- Orientation on the care procedure.

It is important to differentiate between statements (e.g. XY is effective/ineffective) and course of action recommendations (XY should be used/not be used) or "guidance" recommendations. One essential characteristic of guidelines is the wording of their recommendations for action; these explicitly account for the clinical weighting of the power (relevance) and the applicability of study results and weigh the potential benefits against the harms of the target intervention. A guideline's wording sets it apart from other sources of synthesised knowledge, such as evidence reports, systematic reviews or health technology assessments with or without meta-analyses (see [Grade of recommendation](#)). The wording gives the user the orientation needed in terms of any uncertainties remaining against the backdrop of the identified evidence. Conversely, statements can also be understood as assertions of fact that are potentially litigable. Therefore, substantiation by citing the source (literature) and/or a well-documented evidence synthesis are indispensable; this particularly applies as a basis for statements, whenever required (see [Systematic review of the evidence](#): and [Synthesising - creating evidence tables](#)).

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

DELBI	AGREE
<p>DELBI Domain 7: Applicability to the German health care system</p> <p>Criterion 24: Recommendations for measures for different areas of care (e.g. prevention, diagnosis, therapy, rehabilitation)</p> <p>Criterion 25: Information as on which interventions seem to be unsuitable, redundant or outdated</p> <p>Criterion 26: Organising the information: Clinical Algorithm</p>	<p>Domain 4: Clarity of presentation</p> <p>Criterion 15: Specific and unambiguous formulation of recommendations</p> <p>Criterion 16: Clear presentation of the different options for management of the condition or health issue</p> <p>Criterion 17: Key recommendations are clearly identifiable</p>

Resources and tips:

Example 1: Presentation of recommendations:

11. Medikamentöse Therapie		
Empfehlungen/Statements	Empfehlungsgrad	
	positiv	negativ
Prognoseverbessernde Therapie		
Thrombozytenaggregationshemmer		
11-1 Alle Patientinnen/Patienten mit stabiler KHK sollen 100 mg Acetylsalicylsäure (ASS) pro Tag erhalten.	↑↑	
11-2		

Background and Evidence

....According to a meta-analysis investigating the efficacy of ASA (75 – 100 mg/day) for the prevention of vascular diseases, therapy with ASA achieved an absolute risk reduction of 1.5% per year for the occurrence of serious vascular events compared with placebo

Overall, the benefit-harm ratio for prevention in patients after myocardial infarction (6 studies) and stroke or transitory ischemic attacks (10 studies) was rated as positive....

According to the: National Clinical Practice Guideline "Chronic CHD", Chapter 11 (Drug Management Module), AWMF Register No. nvl/004 (Status: 01 March 2011)

Example 2: Presentation of recommendations:

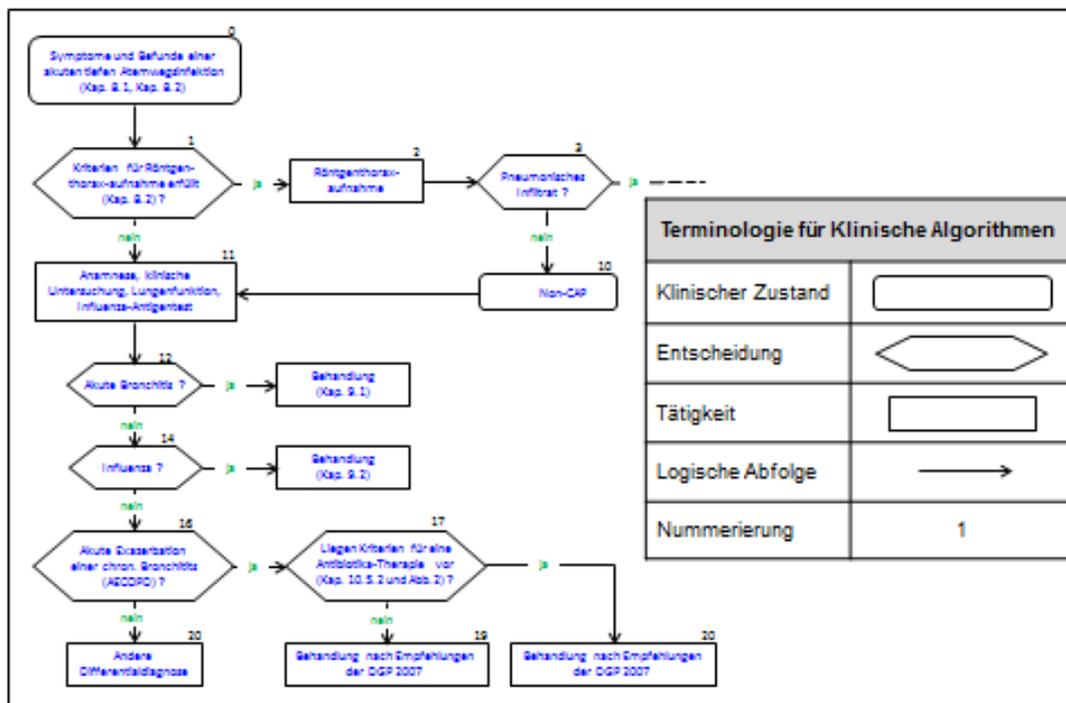
Patients who improve on aerobic endurance training should continue this long term.

EL1a, Strong recommendation, strong consensus.

Commentary: Only for aerobic training was it shown through RCTs that the positive effects at the initiation of training disappear after some time, yet persist with continuous exercise (35,36).

S3 Guideline "Fibromyalgia syndrome", AWMF Register No. 041-004 (Status: 01 April 2012)

Example: Orientation on the care procedure: Clinical algorithm



Algorithm for differentiating acute lower respiratory tract infections (acute bronchitis, acute exacerbation of chronic bronchitis, influenza infection, community-acquired pneumonia, S3 guidelines AWMF Register No. 082/001 (Status: 01 July 2009)

Further reading:

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development; Domain 4. Clarity of presentation*).

DELBI – Current version at www.delbi.de (*Domain 4: Clarity and presentation; Domain 7: Applicability to the German healthcare system*).

IOM (Institute of Medicine) (2011) Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 5. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part II, Traversing the Process*).

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med.* 156(7):525-531.

External review

A review process prior to publication of a guideline allows any uncertainties or missing areas to be identified. This is conducted by persons who were not involved in developing the guideline. The group of reviewers should be made up of experts in the medical field, methodologists and, if appropriate, patient advocates or representatives.

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

Domain 3: Rigour of development

Criterion 13: Externally reviewed by experts

Resources and tips:

There are a variety of external review options, e.g.

- A public consultation phase (in this case, the guideline can be posted on the Internet for a certain period of time, e.g. 6 weeks at a specific location (domain) and open for public comment)
- A peer consultation phase (e.g. during the adoption phase by chairpersons of the medical societies or by external experts)
- Publication in a peer-reviewed journal

Don't forget: The guideline report should record how commentaries are managed

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*).

DELBI – Current version at www.delbi.de (*Domain 3: Methodological rigour of guideline development*).

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 5. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part II, Traversing the Process*).

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) *Guidelines International Network: Toward International Standards for Clinical Practice Guidelines*. *Ann Intern Med.* 156(7):525-531.

Global adoption

After the structured consensus development process is completed, including any external review and final editing by the coordinators, the overall guideline is adopted by all members of the guideline development group, usually in an e-mail resolution procedure. The next step is formal adoption by the boards of the participating medical societies. This ensures that all parties involved in developing the guideline and the co-editing medical societies bear mutual responsibility for the contents. Any changes desired by the medical societies to passages requiring consensus approval must be re-approved by consensus within the guideline development group and re-submitted to the chairpersons of the other participating medical societies.

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

None

Resources and tips:

The representative of the medical society supports the formal adoption of the guideline before the board of the medical society he or she represents.

It should be determined in advance whether there are any and, if so, what rules apply to the authorisation of their representative and the internal adoption procedure of each medical society. Options include, but are not limited to:

- The representative is empowered by his or her medical society (if he or she agrees, the medical society has essentially agreed automatically)
- The board of the medical society itself authorises the content of the finalized guideline, above and beyond the approval of the representative
- The medical society has set up a guidelines commission which drafts a resolution for the board.

It is recommendable to obtain written feedback from the medical society; this can follow an informal procedure (e.g. by e-mail).

Don't forget: The guideline report should record how amendments are managed

Long version, short version, patient version, guideline report

User versions are a good way to disseminate and promote implementation of the guidelines. This includes a long version with background information, evidence tables (see [Appendix 6](#)) and a guideline report aimed at convincing the critical reader. A short version containing a summary of the recommendations and/or understandable flowcharts depicting the optimal care procedure (clinical algorithm) are helpful to provide quick information in practical settings. Additionally, reprints in medical journals, practical guides for implementing the recommendations, pocket guides, continuing educational materials like overhead transparencies and CME articles or apps / mobile websites are likewise helpful. Patient versions are highly recommended.

Given that the members of the guideline development group mutually hold the copyrights to a guideline, a mutual decision should also be made about its dissemination. Depending on the envisaged form of publication, it may be necessary to obtain permissions (see also [Preparing for implementation](#)).

AWMF Guideline Register Rule:

For S2e, S2k and S3 classifications, this includes:

- Description in a guideline report of the methods used (DELBI Domain 7, Criterion 29).

Reference to the DELBI Instrument and AGREE II:

DELBI	AGREE II
<p>Domain 4: Clarity and presentation Criterion 18: Providing tools and/or materials for application Domain 7: Applicability to the German health care system Criterion 26: Organising the information: Clinical Algorithm Criterion 29: Description of the methods used (guideline report)</p>	<p>Domain 5: Applicability Criterion 19: Providing advice and/or tools on how the recommendations can be put into practice</p>

Resources and tips:

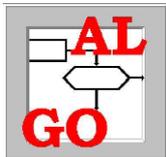
[Guide to writing the guideline report](#)

(see [Appendix 9](#))

**Leitfaden zur Erstellung des Leitlinienreports
für Autoren von S2k, S2e und S3-Leitlinien**

Dieser Leitfaden soll als Orientierungshilfe für die Dokumentation Ihrer methodischen Vorgehensweise bei der Entwicklung Ihrer Leitlinie dienen. Bitte berücksichtigen Sie die aufgeführten Aspekte bereits bei der Planung des Leitlinienprojekts und versuchen Sie, so detailliert wie möglich zu berichten. Dies dient der Transparenz, der Qualität und der Akzeptanz Ihrer Leitlinie. Der Leitfaden bildet vor allem die Kriterien des Deutschen Leitlinien-Bewertungs- Instruments *DELBI* ab (www.delbi.de oder www.awmf-leitlinien.de, Regelwerk). Aus diesem Grund wird die Nutzung der Langfassung von *DELBI* zusätzlich als Informationsgrundlage empfohlen. Bitte beachten Sie besonders die Kriterien, die bei Einreichung aller Leitlinien zur Publikation bei der AWMF geprüft und für die Begründung der Klassifikation als S2e-, S2k- oder S3-Leitlinie herangezogen werden (siehe Markierungen). Aus dem ... gehen, dass die Antwortkategorien 3 oder 4 auf der ...

"ALGO" software for generating a clinical algorithm



Available from Dr. Helmut Sitter, University Lecturer

Institute for Surgical Research

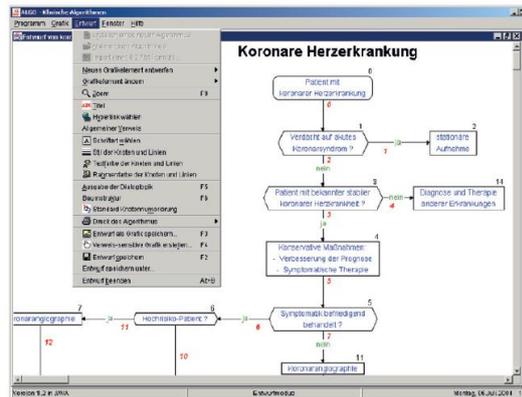
Philipps University of Marburg

Baldingerstrasse

35033 Marburg

E-mail: sitter@mail.uni-marburg.de

Website: staff-www.uni-marburg.de/~sitter



Each guideline version of a guideline can be accessed on the AWMF website under its register number

AWMF online
Das Portal der wissenschaftlichen Medizin

Registernummer **nl - 005** Klassifikation **S3**

Stand: 31.08.2011, gültig bis 28.05.2013

Basissdaten Herausgeber & Autoren

Verfügbare Dokumente

Kurzfassung der Leitlinie "Nationale VersorgungsLeitlinie Unipolare Depression"	Download PDF 0,83 MB
Langfassung der Leitlinie "Nationale VersorgungsLeitlinie Unipolare Depression"	Download PDF 2,18 MB
Patientenleitlinie "Nationale VersorgungsLeitlinie Unipolare Depression"	Download PDF 4,36 MB
Unipolare Depression - Short Version	Download PDF 0,73 MB

Federführende Fachgesellschaft
NVL-Programm von BÄK, KBV, AWMF → [Visitenkarte](#)

Further reading:

AGREE II – Current version at www.agreetrust.org (*Domain 5: Applicability*).

DELBI – Current version at www.delbi.de (*Domain 4: Clarity and Presentation; Domain 7: Applicability to the German health care system*).

Implementation and evaluation

Preparing for implementation

The benefit of a guideline is not revealed until it is applied to routine clinical practice. Implementation is the difficult task of translating recommendations for action into actions by individuals. High methodological and medical quality and effective dissemination of guidelines are usually not sufficient to change clinical behaviour. The classic topic of "hand hygiene in hospitals" succinctly illustrates the barriers that can exist to implementation of guideline recommendations, despite any degree of recognition and acceptance.

The first step is to identify potential organisational, structural, financial and human resources-related barriers and propose solutions to them. The second step should address which implementation strategies the guideline development group can actively support. The guideline or the guideline report should describe the results of these two steps.

The guideline development group ought to think about utilisation and copyrights before disseminating the guideline. The members of the guideline development group hold mutually the copyrights. Permission from the co-ownership community is required to publish the guidelines in various forms (e.g. reprints or modern dissemination forms like apps etc.) or to grant utilisation rights to third-parties (e.g. for joint ventures with publishing houses). Such permission can be obtained by guideline development group voting, for example, within the scope of consensus conferences (see [Structured consensus development](#)) and then taken down for the record.

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

DELBI	AGREE II
Domain 5: Applicability Criterion 19: Describing facilitators and barriers to its application Criterion 20: Considering potential resource implications of applying the recommendations Domain 7: Applicability to the German health care system Criterion 27: Concept for easy accessibility and dissemination of the guideline Criterion 28: Concept for implementing the guideline	Domain 5: Applicability Criterion 18: Describing facilitators and barriers to its application Criterion 20: Considering potential resource implications of applying the recommendations

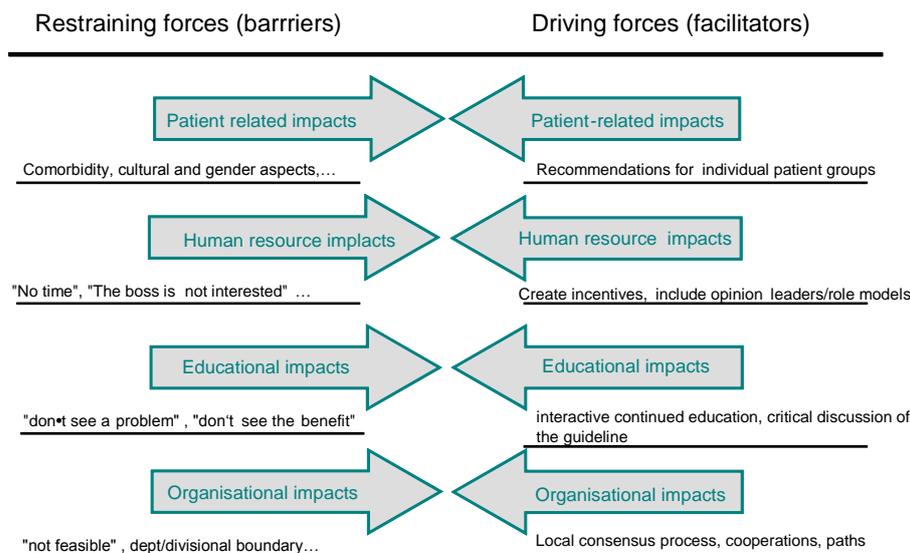
Resources and tips:

Recommendable implementation strategies include, but are not limited to:

- Obtain feedback from patients, nursing staff, physicians
- Local consensus groups for applying and/or modifying the guideline
- Interactive educational workshops on the guidelines
- Discussion of the guideline in quality circles

The guideline development group itself can best prepare for implementation by applying "Good Guideline Development Practice", editorial and dissemination work alongside public relations. It is recommended that members of the guideline development group also get actively involved in conducting the implementation strategies.

Example: Force field analysis



Tip: Vary the thickness of the arrows to reflect how strong you believe user group behaviour will be impacted .

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 5. Applicability*).

Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PAC, Rubin HR (1999) Why don't physicians follow clinical practice guidelines? A framework for improvement. *Journal of the American Medical Association* 282:1458-65.

DELBI – Current version at www.delbi.de (*Domain 5: General Applicability; Domain 7: Applicability to the German health care system*).

French SD, Green SE, O'Connor DA, McKenzie JE, Francis JJ, Michie S, Buchbinder R, Schattner P, Spike N, Grimshaw JM. (2012) Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. *Implement Sci.* 24(7):38.

Grimshaw JM et al. (2004) Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess* 8:1-72.

Gross PA, Pujat D (2001) Implementing practice guidelines for appropriate antimicrobial usage: a systematic review. *Med Care* 39(8 Suppl 2):II55-69.

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 6. Promoting Adoption of Clinical Practice Guidelines*).

Margolis CZ, Cretin S (1999) *Implementing Clinical Practice Guidelines*. Washington DC: AHA Press

Rogers E M. (2003) *Diffusion of Innovations*. New York, Free Press.

Selbmann H-K, Kopp I (2005) Implementierung von Leitlinien in den Versorgungsalltag. *Die Psychiatrie* 1(2):33-8.

Wienke A, Nölling T (2012) Urheberrechte an medizinisch-wissenschaftlichen Leitlinien: Rechteinhaber, Rechteverwertung und Rechteübertragung. *GMS Mitteilungen aus der AWMF* 2012, Vol. 9, ISSN 1860-4269. available at: <http://www.egms.de/static/pdf/journals/awmf/2012-9/awmf000265.pdf>.

Preparing the evaluation

Guidelines serve to improve knowledge transfer and the quality of care. A guideline does not become relevant or sensible until it is accepted and applied; but also when benefit is reaped from it. Therefore, it is advisable for implementation to be complemented by an evaluation aligned along the specific objectives of the guideline (see [Goal orientation of the guideline](#)). This can be anchored in health care research projects, internal institutional quality management projects, voluntary quality initiatives (e.g. peer review procedures, see [Preparing for implementation](#)) and/or conducted within the scope of external, comparative quality assurance.

The guideline's implementation and implications on health care can be examined by applying clinical review criteria, performance measures and quality indicators derived from the guidelines recommendations that address specific objectives.

In an effort to save data and avoid misguidance the standards placed on methods for identifying, selecting and critically appraising clinical review criteria, performance measures and quality indicators should be equally as high as for the guidelines themselves. Therefore, a consultation on methodological strategy, e.g. with an AWMF guideline advisor is advisable.

AWMF Guideline Register Rule:

None

Reference to the DELBI Instrument and AGREE II:

DELBI	AGREE II
<p>Domain 5: Applicability</p> <p>Criterion 19: Describing facilitators and barriers to its application</p> <p>Criterion 20: Considering potential resource implications of applying the recommendations</p> <p>Criterion 21: Presenting monitoring and/or auditing criteria</p> <p>Domain 7: Applicability to the German health care system</p>	<p>Domain 5: Applicability</p> <p>Criterion 18: Describing facilitators and barriers to its application</p> <p>Criterion 20: Considering potential resource implications of applying the recommendations</p> <p>Criterion 21: Presenting monitoring and/or auditing criteria</p>

Resources and tips:

Consider which key aspects you can use to evaluate the guideline's implementation and its implications on health care. Preliminary to formulating the clinical criteria and quality indicators, the following questions need to be answered:

- What is the health care objective?
- How well substantiated is the guideline recommendation that reflects this objective (strength of recommendation, consensus strength)?
- Is implementation of this recommendation measurable?
- Is there unequivocal evidence that a potential for improvement exists?

Further reading

DELBI – Current version at www.delbi.de (*Domain 5: General Applicability; Domain 7: Applicability to the German health care system*).

Kopp I, Geraedts M, Jäckel WH, Altenhofen L, Thomeczek C, Ollenschläger G (2007) Nationale VersorgungsLeitlinien - Evaluation durch Qualitätsindikatoren. Med Klinik 102(8):678-682.

Programm für Nationale VersorgungsLeitlinien von BÄK, KBV und AWMF (2009) Qualitätsindikatoren - Manual für Autoren. Berlin: Ärztliches Zentrum für Qualität in der Medizin, äzq Schriftenreihe; Volume 36. www.aezq.de/mdb/edocs/pdf/schriftenreihe/schriftenreihe36.pdf.

Reiter A, Fischer B, Kötting J, Geraedts M, Jäckel WH, Döbler K (2007) QUALIFY: Ein Instrument zur Bewertung von Qualitätsindikatoren. Z Arztl Fortbild Qualitatssich 101(10):683-8.

Planning supplements and updates

The quality of a guideline primarily depends on whether the recommendations are updated at regular intervals. The guideline document should indicate a specific date and statements on additional periodic updating that include who has been assigned these responsibilities.

The need for continuous supplementation and updating of a guideline is not only a function of the availability of new and emerging scientific knowledge, but also depends on the results obtained from an analysis of the guideline's previous application. The latter helps identify potentials for improvement.

A status and needs analysis forms the starting point for identifying subject areas in need of revision. The methodological requirements are specified in the DELBI instrument and the guideline requirements described in the AWMF Guidance Manual.

AWMF Guideline Register Rule:

The standing AWMF Guidelines Commission has adopted a policy that the AWMF shall no longer publish guidelines on the Internet once their validity has expired. The expiration date is the date indicated by the medical society(ies) when the guideline should be re-subjected to regular review – if not indicated by the medical society(ies), the AWMF will classify the guidelines as "out-of-date" at the latest 5 years after issue and remove the guideline from AWMF's publication system.

(see also "Deleting out-of-date guidelines posted by the AWMF", "AWMF Guideline Register Rules", page 89)

http://www.awmf.org/fileadmin/user_upload/Leitlinien/Werkzeuge/awmf000165.pdf

Reference to the DELBI Instrument:

DELBI	AGREE II
Domain 3: Methodological rigour of development Criterion 14: Updating the guideline	Domain 3: Rigour of development Criterion 14: Updating the guideline

Resources and tips:

Current research results may mandate faster-track updating of a valid guideline. Furthermore, the public can be notified quickly by means of an addendum on the AWMF website.

The easiest way to ensure continuous updating is for the original guideline to have been systematically developed. Literature searches and strategies for answering clinically relevant questions can be saved and reused when necessary. When updating a guideline version, the searches should cover only the period after publication of the earlier guideline version.

The extent of revision (complete, modular or limited to individual key questions) depends on whether there has been any recent updating, on the results of any updated guidelines searches, on the results of current, relevant research findings from the systematic literature search and on the judgment of the experts in the guideline development group.

In addition to obtaining targeted feedback from the field on the successes / problems associated with implementing the guideline, status analyses, needs analyses and prioritising are indispensable. In this context, the following key questions need to be answered:

- Who shall be responsible for monitoring and initiating the update of our guideline?
- What impact has our guideline had?
- Which new key questions have emerged?
- Has new scientific knowledge emerged that makes it necessary to change our recommendations?
- Do other guidelines (national, international) have recommendations with related contents that can be reviewed and adapted?
- Are there key questions requiring systematic search of the literature and synthesising of the evidence?
- Which updating resources are available to guideline development group?

These questions ought to always be re-appraised whenever a guideline needs updating.

Quality management for guidelines

- concept for updates, upgrades, supplements, amendments -

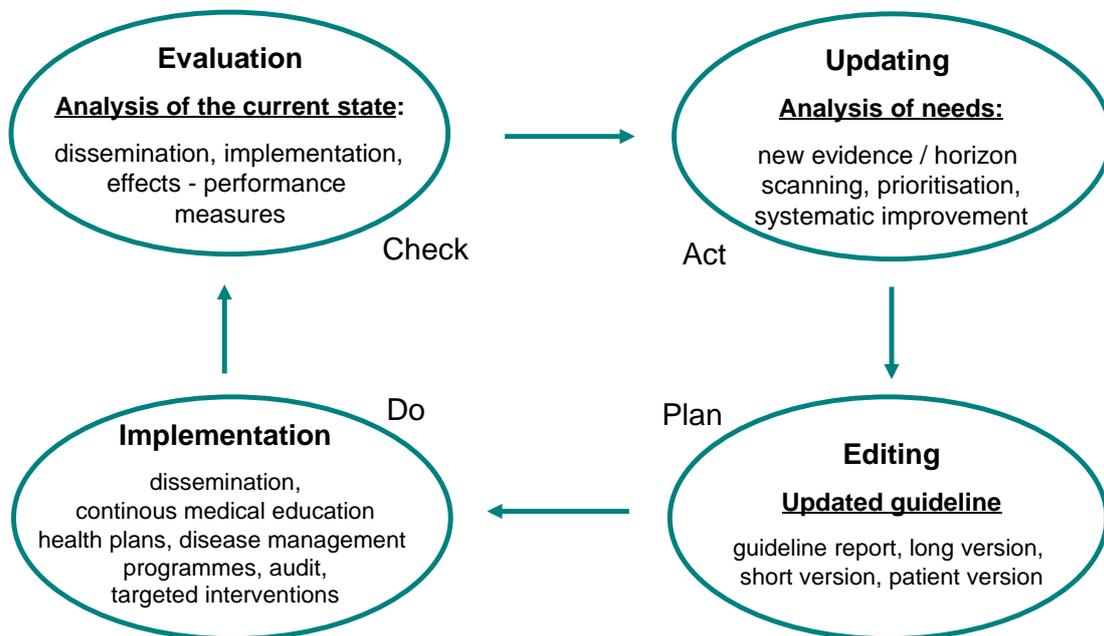


Fig. modified after Albert et al. 2008. The guideline "Early detection of breast cancer in Germany – methodology for updating S3 guidelines" [in German]

Further reading

AGREE II – Current version at www.agreetrust.org (*Domain 3. Rigour of Development*).

Albert U-S, Schulz K-D, Kopp I (2008) Die Leitlinie „Brustkrebsfrüherkennung in Deutschland“ – Methodik der S3-Leitlinien-Aktualisierung. *Präv Gesundheitsf.* DOI 10.1007/s11553-008-0123-3.

AQUA — Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen GmbH. Qualitätsreport 2009.

www.sgg.de/sgg/upload/CONTENT/Qualitaetsberichte/2009/AQUA-Qualitaetsreport-2009.pdf

Bundesärztekammer (BÄK), Kassenärztliche Bundesvereinigung (KBV), Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF) (2010) Programm für Nationale VersorgungsLeitlinien. Methoden-Report. 4. Auflage. [cited: 30 July 2010]. Available from: www.versorgungsleitlinien.de/methodik/reports.

DELBI – Current version at www.delbi.de (*Domain 3: Methodological rigour of guideline development*).

IOM (Institute of Medicine) (2011) *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press. www.iom.edu (*Chapter 5. Current Best Practices and Proposed Standards for Development of Trustworthy CPGs: Part II, Traversing the Process*).

Müller W (2008) Nicht aktualisierte Leitlinien werden von der AWMF nicht mehr publiziert. *GMS Mitt AWMF* 5:Doc22.

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P; for the Board of Trustees of the Guidelines International Network (2012) Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med.* 156(7):525-531.

Publication with the AWMF

Submitting guidelines for publication with the AWMF

Guidelines Conference of 4 October 1995, the AWMF shall publish the guidelines developed and adopted by the AWMF member societies (see [Global adoption](#)) on the "AWMF online" information system. Submission of guidelines to the AWMF automatically grants the AWMF the right to post and present the submitted texts in the electronic medium of the World Wide Web.

AWMF Guideline Register Rule:

Submission for publication with the AWMF: Guidelines of the AWMF for Guideline Publication (further reading: see "AWMF Guideline Register Rules", page 87).

www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-07-publikation/einreichung-zur-publikation-bei-der-awmf.html

Reference to the DELBI Instrument and AGREE II:

None

Resources and tips:

Prior to submission of your guideline for publication with the AWMF, your guideline documents should have received final approval and the guidelines officer and/or the guidelines secretary of the lead medical society(ies) should be informed thereof.

Checklist for publication with the AWMF

(s. [Appendix 10](#))

Checkliste	
	
Um Nachfragen der AWMF und damit unnötige Verzögerungen bei der Publikation Ihrer Leitlinie zu vermeiden, prüfen Sie bitte alle folgenden Punkte vor der Einreichung der Leitlinie bei der AWMF (eMail: imwi@awmf.org):	
Titel der Leitlinie: _____	
AWMF-Register Nr. ____/____	
<input type="checkbox"/> Der Leitlinientext ist vollständig korrigiert	<input type="checkbox"/>
<input type="checkbox"/> Leitlinientext ist in Kapitel unterteilt und diese sind konsistent nummeriert	<input type="checkbox"/>
<input type="checkbox"/> Leitlinientext enthält - wo möglich - die zugehörigen ICD-10-Codes	<input type="checkbox"/>
Die Titelseite der Leitlinie (auch bei Print-Publikationen !) enthält deutlich sichtbar	
<input type="checkbox"/> - die AWMF-Register Nr. der Leitlinie	<input type="checkbox"/>
der LL (S1, S2e, S2k oder S3)	

Further reading

Wienke A, Nölling T (2012) Urheberrechte an medizinisch-wissenschaftlichen Leitlinien: Rechteinhaber, Rechteverwertung und Rechteübertragung. GMS Mitteilungen aus der AWMF 2012, Vol. 9, ISSN 1860-4269. <http://www.egms.de/static/pdf/journals/awmf/2012-9/awmf000265.pdf>.

The AWMF Guideline Seal of Approval

Since August 2004, the "AWMF-certified" seal of approval can be issued for class S3 guidelines, provided they are of the appropriate quality. The guideline coordinators can submit an informal application for certification by e-mail to the AWMF Institute for Medical Knowledge Management (AWMF-IMWi): imwi@awmf.org

Entry requirements for the certification procedure are fulfilment of the quality criteria set forth in the AWMF Guidance Manual:

- Submission of the publication to the AWMF
- S3 class guideline

The certification procedure shall be initiated once the entry requirements have been fulfilled.

This encompasses:

- Critical appraisal of the methodological quality of the guideline based on DELBI by two independent reviewers
- Estimation of the anticipated impact of the guideline on health care in its scope by an external reviewer (clinical expert review)
- Approval by the AWMF (resolution)

Selection criteria for the reviewers include disclosure of any conflicts of interest (AWMF standard form), no involvement in the development of the guidelines, but experience in the application of DELBI (reviewer with methodological expertise) or scientific and clinical experience in one of the fields relevant to the expert appraisal (expert reviewer). If the certification is successful, the guideline shall be published on the AWMF website as an "AWMF Guideline" with its seal of approval; the printed version of the guideline may bear this seal of approval until any content changes are made thereto.

AWMF Guideline Register Rule:

Requirements for S3 guidelines according to DELBI

Reference to the DELBI Instrument and AGREE II:

All DELBI domains have been rated with a score of 3 or 4

Appendix

1. [Letter template “Nominating representatives”](#)
2. [Sample form for disclosure of conflicts of interest](#)
3. [Examples of how to disclose potential conflicts of interest](#)
4. [Registration Form](#)
5. [Aid for completing this Registration Form](#)
6. [Example evidence table](#)
7. [Letter template “Invitation to the consensus conference”](#)
8. [Formal consensus development techniques](#)
9. [Guide to writing the guideline report](#)
10. [Checklist for publication with the AWMF](#)

1. Letter template “Nominating representatives”

Letter template - Invitation to participate in a guideline project

Instructions:

Please select from the alternative wording proposals highlighted in green or separated by "/"; grey-highlighted fields fill out separately.

This is a rough template. Please complete the form and add text as appropriate!

Sender

[Guidelines coordinator, title of the lead medical society/organisation sending out the invitation]

Direct

[Personal contact person, title of the medical society/organisation to be invited, administrative office]

Re: Invitation to participate in a guideline project and request for the nomination of a representative

Dear [Title, name of personal contact person]

If the guideline has already been registered

I am pleased to inform you that the [S2k/S3] guideline [title of the guideline, AWMF Reg. No.] has been entered in the register of the Association of the Scientific Medical Societies in Germany (AWMF).

If the guideline has not yet been registered

I am pleased to inform you about the planning of a [S2k/S3] guideline [title of the guideline].

I have been commissioned by [title of the lead medical society] to coordinate the guideline project and take the first steps by approaching the medical societies and organisations concerned with this topic, with the objective of putting together a representative panel of experts for the target users of the guideline.

The guideline is being created based on the methodological requirements of the German Instrument for Methodological Guideline Appraisal *DELBI* and should be supervised by a representative of the AWMF.

If the medical society/organisation to be invited has already developed a related guideline

Because the medical society/organisation you represent is involved with the thematically related [S2k/S3-] guideline [title of the guideline, AWMF Reg. No.] / has published the thematically related [S2k/S3] guideline [title of the guideline, AWMF Reg. No.], I would like to invite you to participate in our guideline project and to contribute your expertise.

If the medical society/organisation to be invited has not yet developed a related guideline

The experience and perspectives your medical society/organisation has to offer are crucial to the success of this interdisciplinary project. I would therefore like to invite you to participate in our guideline project and contribute your expertise.

Would you, please appoint a representative as a contact person whom I can get in touch with concerning guideline matters and whom I can invite to working group meetings and guideline conferences.

In addition to contributing their scientific and personal experience to the project, this representative should represent the interests of your medical society/organisation in our guideline development group. This is meant to ensure that the content of the guideline can be officially supported by your medical society/organisation after conclusion of the development process.

By virtue of his/her scientific reputation/experience in the field of our guideline topic, I would like to propose Mr. / Ms. [title, name] for this office. Of course, I am also open to an alternative nomination on your part.

I would therefore ask you to complete and return the enclosed reply form by [Date].

If your medical society/organisation cannot participate in our project or does not see the necessity in doing so, I would be very grateful for a short reply specifying your reasons.

For any further questions, please do not hesitate to contact me by phone. I look forward to working with you.

Yours sincerely,

Reply to:

[Guidelines coordinator, title of the lead medical society/organisation sending out the invitation]

[FAX number]

Guideline Project

[Title, AWMF Reg. No.]

Medical society / organisation:.....

[Title of the medical society / organisation invited]

We would gladly like to participate in your guideline project and nominate the following

Representative:

Title, first name, last name:

Institute/Hospital:

Address

Postal code, city:

Email address:

Phone:

Fax:

Proxy of the representative:

Title, first name, last name:

Institute/Hospital:

Address

Postal code, city:

Email address:

Phone:

Fax:

Date, signature, stamp:

2. Sample form for disclosure of conflicts of interest



Disclosure of Conflicts of Interest

(Title, AWMF Reg. No.)

Attn.:

(Guidelines Coordinator)

Preliminary remarks

Above and beyond professional expertise, the development of clinical practice guidelines requires avoiding commercial dependencies or other conflicts of interest that affect the guideline's content. There are numerous material (e.g. financial or commercial) and immaterial (e.g. political, academic or personal) relationships which can vary in their magnitude and scope. Conflicts of interest are thus mostly unavoidable, but not necessarily problematic in terms of influencing the content of the guidelines.

Disclosure of the relationships and any resulting conflicts of interest held by the authors of the guidelines and the participants in the consensus process is crucial for judging the guideline quality, but also for its overall legitimacy and credibility in the mind of the public and politicians.

Disclosures are made to the guidelines coordinator at the beginning of the guideline project. Long-term projects may require that an additional disclosure be submitted. Depending on the individual's disclosure, the guideline development group should discuss and appraise whether there are any doubts about the necessary level of neutrality in their involvement in the guideline development process or areas in which the professional judgment of an expert may be inappropriately influenced by the interests of third parties.

The content of the disclosures and the results of the discussion on managing conflicts of interest should be openly presented in the guidelines report. The long version of the guidelines should refer to the collection method and appraisal of the disclosures.

Please fill out and sign the disclosure below.

Disclosure

This disclosure applies to financial and commercial (material), as well as psychological and social (immaterial), aspects and interests of the members themselves and/or their personal/professional partners within **the last 3 years**. Please give **specific details with regards to the following points**:

1. You were a consultant or reviewer or paid collaborator on the scientific advise board of a company in the health care sector industry (e.g. pharmaceutical industry, medical industry), a commercially oriented institution or an insurance company

- No
- Yes

If yes, please specify:

2. You received honoraria for lectures and training activities or were a paid author or co-author sponsored by a company in the health care sector, a commercially oriented institution or an insurance company

- No
- Yes

If yes, please specify:

3. You received financial (third-party) assistance for research or the institution's staff was directly funded by a company in the health care industry, a commercially oriented institution or an insurance company

- No
- Yes

If yes, please specify:

4. You have a proprietary interest in specific pharmaceuticals/medical devices (e.g. patent, copyright, retail license)

- No
- Yes

If yes, please specify:

5. You own shares, stocks, or funds with shares in companies in the health care industry

- No
- Yes

If yes, please specify:

Appendix

6. You have a personal relationship to an authorised representative of a company in the health care industry

- No
 Yes

If yes, please specify:

7. You are a member of a medical society/professional association relevantly associated with guideline development, or are a representative associated with guideline development

- No
 Yes

If yes, please specify:

8. You have political, academic (e.g. you subscribe to a certain "school of thought"), scientific or personal interests that might lead to potential conflicts

- No
 Yes

If yes, please specify:

9. Your current employer, relevant former employers in the past 3 years

Appraisal

In your opinion, are there any significant conflicts of interest for you or the whole guideline development group resulting from any of the above-mentioned items/aspects?

- No
 Yes

If yes, please make a proposal for discussion within the guideline development group (e.g. abstention on specific questions):

Place, date

Name (please print)

Signature

Address (institution, street, city, e-mail address)

3. Examples of how to disclose potential conflicts of interest

Guidelines Coordinator: Guideline: Register No.:					
		[Author's name]	[Author's name]	[Author's name]	[Author's name]
1	You were a consultant or reviewer or paid collaborator on the scientific advise board of a company in the health care sector industry (e.g. pharmaceutical industry, medical industry), a commercially oriented institution or an insurance company				
2	You received honoraria for lectures and training activities or were a paid author or co-author sponsored by a company in the health care sector, a commercially oriented institution or an insurance company				
3	You received financial (third-party) assistance for research or the institution's staff was directly funded by a company in the health care industry, a commercially oriented institution or an insurance company				
4	You have a proprietary interest in specific pharmaceuticals/medical devices (e.g. patent, copyright, retail license)				
5	You own shares, stocks, or funds in companies in the health care industry				
6	You have a personal relationship to an authorised representative of a company in the health care industry				
7	You are a member of a medical society/professional association relevantly associated with guideline development, or are a representative associated with guideline development				
8	You have political, academic (e.g. you subscribe to a certain "school of thought"), scientific or personal interests that might lead to potential conflicts				
9	Your current employer, relevant former employers in the past 3 years				

The authors and all participants actively involved in the consensus process have filled out the forms on potential conflicts of interest according to the AWMF specifications. The boards of the respective medical societies and the authors group have conducted an appraisal. Representatives of the pharmaceutical industry are not involved in the consensus process.

Appendix

Alternatively, conflicts of interest can be presented in text form, taking into account all the above criteria.

Wording example for criterion 1:

The following participants in the consensus process declare that no connections or conflicts of interest, financial or otherwise, exist with third parties potentially interested in the contents of the guideline: *names of the relevant guideline members*

The following participants in the consensus process declare that they were consultants, experts, lecturers, collaborators on a scientific advisory board or participated in studies for industrial companies or received grants to conduct research projects for industrial companies: *Names of the relevant guideline group members (financial aspects, can be listed with or without details on sponsors, e.g. companies)*

4. Registration Form

Arbeitsgemeinschaft der
Wissenschaftlichen
Medizinischen
Fachgesellschaften e.V.

*Association of the
Scientific
Medical
Societies in Germany*



Guideline Project Registration Form

Version of 15 October 2010

Title of the guideline:	
Type of registration:	<input type="checkbox"/> Guideline <input type="checkbox"/> Upgrade or <input type="checkbox"/> Update of AWMF Reg. No.:
Intended class	<input type="checkbox"/> S1 <input type="checkbox"/> S2e <input type="checkbox"/> S2k <input type="checkbox"/> S3 S1: expert recommendation S2e: evidence-based guideline S2k: consensus-based guideline S3: evidence- and consensus-based guideline
Registration date	
Planned completion date (month/year)	
Reasons for the topic selection	
Goal orientation of the guideline	
Relation to existing guidelines	Enter AWMF Register No.:
Registering person	
Registering medical society(ies)	
Involvement of other AWMF member societies	
Involvement of other medical societies and/or organisations	
Contact person (guideline's administrative office)	
Guideline coordination (name/s)	
Area of health care	
Patient target population	
Guideline target users	
Planned methodology (process for evidence review and synthesis, consensus development techniques)	
Supplemental information on the project (available yes/no, if yes: where?)	

Please complete, re-save as an RTF file and email as a separate file (as an email attachment, do not include in the text area of the email!) to:

anmeldung@awmf-leitlinien.de

5. Aid for completing this Registration Form

Arbeitsgemeinschaft der
Wissenschaftlichen
Medizinischen
Fachgesellschaften e.V.

Association of the
Scientific
Medical
Societies in Germany



Guide to completing the "Guideline Project" Registration Form

Version of 15 October

Title of the guideline:	Please propose a powerful title for your guideline, but keep as short as possible
Type of registration:	<input type="checkbox"/> New guideline <input type="checkbox"/> Upgrade or <input type="checkbox"/> Update of AWMF Register No.:
Intended class:	S1, S2e, S2k, S3, please specify. For help in deciding on which class you should select, please visit http://www.awmf.org/leitlinien/awmf-regelwerk/II-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-stufenklassifikation.html
Registration date:	day/month/year
Planned completion date (month/year):	Please indicate by when the guideline is expected to be completed. Please note: after this date expires you will be asked by the administrative offices of the AWMF for information on your project's status. If this information is not provided, your application will be removed from the register.
Reasons for the topic selection	Please state why you selected this guideline topic. The justification should contain data on the prevalence of the aspect of care and potentials for improvement.
Goal orientation of the guideline:	Please specifically indicate the objectives to be addressed in the guideline and achieved by its dissemination and implementation.
Relation to existing guidelines:	Please indicate whether content overlap with existing guidelines or registered guideline projects is possible, e.g. which guidelines have already dealt with specific subject areas in your guideline or (to some extent) have already made recommendations on these. The search function on the AWMF homepage can be used for this purpose. Please specify the AWMF register numbers of these guidelines.
Registering person:	Please specify who is registering the guideline; this need not be the coordinator.
Registering medical society(ies):	Please specify the medical society(ies) registering the guideline (must include at least one member society of the AWMF).
Involvement of other AWMF medical societies:	Please indicate which AWMF medical societies have been invited to cooperate in your guideline. Please note: In their own interest, the advocates/representatives of all target users of the guideline mentioned below should be involved in its development.
Involvement of other medical societies or organisations:	Please indicate which organisations have been asked to cooperate in your guideline (e.g., patient organisations, professional associations; please also include medical societies outside the AWMF). Please note: In their own interest, the advocates/representatives of all target users of the guideline mentioned below should be involved in its development.

Appendix

Contact person (Guideline's administrative office):	Please enter the address at which interested parties can contact the individuals responsible for registration / the guideline project (this need not be identical to the coordinator's address)
Guideline coordination (Name):	Please indicate which person(s) is/are responsible for coordinating the guideline development process
Area of care:	Please state the health care sector/s, segments and •levels for which the guideline is being developed, e.g. <ul style="list-style-type: none"> - Outpatient/inpatient/semi-inpatient - Prevention, early detection, diagnostics, therapy, rehabilitation - Primary/specialized care
Patient target population:	Please state <u>the target population of persons</u> for whom the guideline is being developed (e.g. infants / small children / children / adolescents / adults / pregnant women / nursing women / the elderly / men / women; classification / stage of the disease; co-morbidity(ies))
Target users:	Please state who should use this guideline and to whom the guideline information is directed. For example, these may be physicians in a specific field, patients or other professional groups.
Planned methodology (process for evidence review and synthesis, consensus development techniques):	If the objective of your guideline is one of the classes S2e, S2k or S3, please indicate, <ol style="list-style-type: none"> 1. How the literature was searched, selected and critically appraised (S2e, S3) 2. Which of the formal consensus techniques (nominal group process, consensus conference, Delphi method) will be applied during voting on the recommendations (S2k, S3).
Supplemental information on the project (available yes/no, if yes: where?):	If additional information is available on your guideline project, please state where this to be found (e.g. through the guidelines office) and/or list it here (e.g. regarding the existence of international guidelines, the sponsorship of guideline projects), where applicable as links.

Please load the file "II-anmeldung.rtf" from the AWMF guidelines website onto your computer (save to the hard drive!), fill out according to the example given above, save it as an RTF file on your hard drive and then send it by e-mail as a separate file (as an email attachment; Please do not copy it into the text area of the email!) to:

anmeldung@awmf-leitlinien.de

6. Example evidence table

Appendix

Objective of the evidence table:

Present the current body of evidence as a data basis for the wording and grading of recommendations

Example of an evidence table:

Please note that this is merely a sample evidence table. Modify yours according to your particular guideline topic.

Reference	Type of study	Participants (number and characteristics)		Drop-out rate	Intervention	Control	Target variable(s)	Primary outcome	Notes
		Overall							
Author and year (ref. no.) Link to publication (if available)	Specification of the study: RCT, cohort study, case-control study, etc.	Number of patients in the study (inclusion and exclusion criteria, differences between groups (e.g. included and evaluated group), number of recruited and/or of evaluated patients (per group or ITT))		Overall data and / or per group (absolute numbers and / or in %)	Details on the intervention for each group (dosage, time period, etc.)	Details on the control group (dosage, time period, etc.)	Specification of the primary target variable (usually based on the sample size calculation) and secondary target variable(s) (specified by the author)	Results of the <u>primary</u> and <u>secondary</u> target variables: Effect size and precision (absolute numbers, mean value or percentage data, p-value, confidence intervals)	Specification of abnormal positive and / or negative aspects related to study design, conduct and evaluation (e.g. inappropriate hypothesis, lack of blinding in RCTs, inadequate statistical methods and the clinical power of the study)
		Per arm							
		Number of patients in the intervention group	Number of patients in the control group					Specification of <u>adverse events</u> overall and/or per group	
Summary evaluation									
<ul style="list-style-type: none"> - Conclusions of the authors of the study - Conclusion of the assessor: Methodological quality and clinical relevance of the study 									

Modified from: Guidelines International Network - Evidence Tables Working Group. English original available under <http://www.g-i-n.net/document-store/working-groups-documents/etwg-documents/template-evidence-summary-intervention-studies>. (Status: July 20, 2011)

Appendix

7. Letter template “Invitation to the consensus conference”

Instructions:

Fill in each field highlighted in grey with your specific information.
This is a rough sample. Please complete the form and add text as appropriate!

Sender:

[Guidelines coordinator, title of the lead medical society/organisation sending out the invitation]

Address

[Personal contact person, title of the medical society/organisation to be invited]

Re.: Invitation to a consensus conference

Dear [Title, name of representative]

We are pleased to inform you that great progress has been made in the creation of the [S2k/S3] guideline [title of the guideline, AWMF Reg. No.].

The draft recommendations must receive formal approval by consensus for them to be accepted into the developmental stage [S2k or S3].

Because the medical society/organisation [title of the medical society/ organisation] you represent is a stakeholder in the guideline [title of the guideline], we wish to give you the opportunity to participate in the process for adopting the recommendations of this interdisciplinary guideline.

We would therefore like to cordially invite you

on [date]
at [time]
to [location and conference venue].

The formal consensus approval by procedure [nominal group process, structured consensus conference] will be moderated by Mr./Ms. [name] from the AWMF. You will be introduced to the procedure and the techniques at the venue.

In the attachment, you will find documents that will help prepare for the conference, including:

- The draft guidelines (full text including the guideline report)
- A summary of the recommendations to be approved by consensus

Would you please fill out and return the enclosed reply form to us by (date).

[FAX number]

[Your medical society's address]

We look forward to successful cooperation with you!
Best regards,

**Participation in the consensus conference on [S2k/S3] guideline
[title, AWMF Reg. No.]**

Medical society / organisation:.....

Representative / proxy:

Title, first name, last name:

Institute/Hospital:

Address

Postal code, city:

I will attend: () yes
 () no, but will be represented by

Title, first name, last name:

Date, signature, stamp:

8. Formal consensus development techniques

The **objective** is to achieve manipulation-free and reproducible results through structured interaction within which individual contributions of the participants are systematically collected, made transparent and synthesized.

Involvement in the consensus process:

- Experts, users and patients
- Interdisciplinary and multi-professional composition, where necessary
- Independence or plurality of dependencies

Consensus development methodology:

- Nominal group process (ca. 15 – 20 participants)
- Structured consensus conference (30 – 60 participants)
- Delphi Technique (50 – 200 participants)

Nominal group process

In advance:

Define goals, procedure, voting procedure, venue

Invite all consensus participants

Independent moderator

Hand-outs: Guidelines manuscript, recommendations

Procedure:

- Present the statements / recommendations to be approved
- Silent generation of ideas: Which recommendation/grade of recommendation do you not agree to? Supplement, alternative?
- Round robin: moderator records the positions in the written resolution procedure and summarizes comments
- Pre-vote by discussing the individual comments – Create a ranking list
- Debate / discuss points of discussion
- Final voting on every recommendation and all alternatives
- Steps are repeated for each recommendation

Appendix

Advantages	Disadvantages	Potential danger of bias
More group dynamics	Less anonymous contributions	Selection of participants
Strong group interaction	Longer duration (several days)	Majority and minority influences
Greater feeling of ownership	Usually only one opportunity to give feedback	Social laziness
More clarification options	Limited number of participants	"Groupthink"
Relatively little organisational effort		Brainstorming:
		Presentation of the information

Structured consensus conference

Procedure

In the first part of the conference

- Participants gather in small, topic-related groups
- Elaboration of common positions

In the second part of the conference

- Present results from the small group discussions to the plenum
- Positions are put to vote
- Independent moderators support small groups and plenary meeting
- The results are recorded at the end of the conference.

Appendix

Advantages	Disadvantages	Potential risk of bias
Suitable for over 100 participants	Little opportunity to interact	Selection of participants
Anonymous electronic voting systems possible	Little opportunity to structure the group discussion	Presentation of the information
Plenum is suitable for advanced external auditing, promotes acceptance		Majority and minority influences
		"Groupthink"
		Social laziness
		Brainstorming:

Delphi Technique

This is a multi-stage survey method that is carried out in writing by experts from various disciplines. It attempts to give group members the opportunity to review and/or compare their statements by means of a feedback process whereby participants are informed about the group's (summarised) response.

Procedure

- Solicit anonymous written contributions using structured questionnaires
- Summarize contributions and give feedback to the group
- Continue the questioning rounds until a group response is reached (consensus or justified dissent)

Advantages	Disadvantages	Potential danger of bias
Suitable for large numbers of participants	No direct exchange of ideas	Selection of participants
Anonymisation protects individual contributions and helps contributors focus on content	Large amount of organisational effort	Presentation of the information
Feedback / positions recorded on a pre-printed form	Pressure to conform during feedback phase	

9. Guide to writing the guideline report

This guide is designed to help you document your methodical approach to developing your guideline. Please consider the issues listed during the planning stage of your guideline project and try to report in as much detail as possible. This will ensure the transparency, quality and acceptance of your guideline. This guide specifically lists the criteria of the German Instrument for Methodological Guideline Appraisal (*DELBI*, www.delbi.de or www.awmf-leitlinien.de, AWMF Guideline Guidance Manual). For this reason, the full version of *DELBI* is also recommended as a basis for information. Please take special note of the criteria reviewed for all guidelines submitted for publication to the AWMF and used to justify the classification of each guideline as S2e, S2k or S3 (see highlighting). The description must state that the Response categories 3 or 4 were rated on the *DELBI* four-point scale (www.awmf-leitlinien.de, AWMF Guideline Guidance Manual).

1. Scope and purpose

- **Justification for guideline topic selection**
(see DELBI Criterion 1)
- **Goal orientation of the guideline**
(see DELBI Criterion 1)
- **Patient target population**
(see DELBI Criterion 3)
- **Area of care**
(see DELBI Criterion 3)
- **Target users/target group**
(see DELBI Criterion 6)

2. Guideline development group composition: Stakeholder involvement

- **Representativeness of the guideline development group: Participating professional groups**
(see DELBI Criterion 4) **S2k S3**
- **Representativeness of the guideline development group: Patient involvement**
(see DELBI Criterion 5) **S2k S3**

3. Methodological rigour

Search, selection and critical appraisal of scientific evidence

- **Formulation of key questions**
(see DELBI Criterion 2)
- **Using existing guidelines on the topic**
(see DELBI Criteria 30-34) **S2e S3**
- **Systematic literature search**
(see DELBI Criterion 8) **S2e S3**
- **Selection of evidence**
(see DELBI Criterion 9) **S2e S3**
- **Critical appraisal of the evidence** (using structured checklists, e.g. SIGN)
- **Creating evidence tables** **S2e S3**

Formulation of recommendations and structured consensus development techniques

Appendix

- **Formal consensus development techniques: Procedure and implementation**
(see DELBI Criterion 10) **S2k S3**
- **Consideration of benefits, side-effects-relevant outcomes**
(see DELBI Criterion 11)
- **Formulation of recommendations and assignment of levels of evidence and/or grades of recommendation**
(see DELBI Criterion 12) **S2e S3**

4. External review and adoption

- **Piloting**
(see DELBI Criterion 7)
- **External review**
(see DELBI Criterion 13)
- **Adoption by the chairpersons of the publishing medical societies / organisations** **S2k**
S2e S3

5. Editorial independence

- **Financing the guidelines**
(see DELBI Criterion 22) **S2k S2e S3**
- **Description and management of potential conflicts of interest**
(see DELBI Criterion 23) **S2k S2e S3**
see also www.awmf-leitlinien.de, "Managing conflict of interest disclosures"

6. Dissemination and implementation

- **Concept for dissemination and implementation**
(see DELBI Criterion 27, 28)
- **Supporting materials for guideline application**
(see DELBI Criterion 18)
- **Discussion of possible organisational and/or financial barriers to the use of the guideline recommendations**
(see DELBI Criterion 19, 20)
- **Monitoring criteria: quality objectives, quality indicators**
(see DELBI Criterion 21)

7. Period of validity and procedure for updating the guideline

- **Date of the last content change and status** (valid until...date)
- **Procedure for updating the guideline**
(see DELBI Criterion 14)

10. Checklist for publication with the AWMF

Checklist



To avoid inquiries from the AWMF and thus unnecessary delays in the publication of your guideline, please check all of the following points before submitting the guideline to the AWMF (email: imwi@awmf.org):

Title of the guideline: _____

AWMF Register No. ____/____

The **guidelines text** has been **fully proofread**

The text of the guideline has been divided into **chapters** and these have been **numbered consistently**:

The text of the guideline contains - where possible - the appropriate **ICD-10 Codes**..

The **title page of the guideline** (*also for print publications!*)

clearly and visibly contains

- the **AWMF Register No.** of the guideline

- the **methodological classification** of the guideline (S1, S2e, S2k or S3)

- the lead and participating **medical society(ies)**

For S2e, S2k and S3 guidelines: The **guideline report** is attached.....

For all guidelines: The **table containing the conflict of interest disclosures** from the guideline development group has been attached.....

If the guideline is also being published in a journal: The **publisher has been informed that the rights to electronic publication have been given to the AWMF**

The entries for **reasons for the topic selection, goal orientation of the guideline, links to related guidelines, participating medical societies / organisations, area of care, patient target population, target users**

can be found in the guideline text/guideline report **or**

should be transferred unchanged by the AWMF from the guideline registration to the guideline data sheet

Please provide us with **five key words from the guideline text** that we can use to improve the search function on our website.

You also have the option to provide five key words from the title to facilitate searches for your guideline (title synonyms).

AWMF Rules for the Guideline Register

I. Classification S1, S2, S3 (Status: April 29, 2010)

Classification S1 Recommendations for action

A representative group of experts from the medical society(ies) develops a recommendation based on informal consensus which is adopted by the board of the medical society(ies).

Classification S2 guidelines

Since 2004, division into the classes **S2e** (evidence-based) and **S2k** (consensus-based) with the applicable definitions:

If it is an **S2k guideline**,

- The guideline development group should be representative of the target users and representatives of the medical society(ies) and/or organisation(s) which should participate should be involved early in the development of guidelines (see DELBI Criteria 4 and 5, response category at least 3 or 4)
- The methods for formulating the recommendations are clearly described, in addition to which formal consensus techniques are needed (e.g., consensus conference, nominal group process or Delphi method (see DELBI Criterion 10, response category at least 3 or 4)
- Every recommendation is discussed and voted on as part of a structured consensus development with a neutral moderator; the objectives are to find a solution to pending decision-making issues, arrive at a conclusive appraisal of the recommendations and measure the strength of consensus.
- The guideline contains a description of the methodological procedure (guidelines report) (see DELBI Criterion 29, Response category at least 3 or 4) Note: Recommendations from S2k guidelines do not specify grades of evidence recommendations, because the evidence has not been systematically processed.

If it is an **S2e guideline**,

- A systematic search, selection and critical appraisal of scientific evidence for the relevant clinical issues are required.
- The first thing to be done is a systematic search for guidelines on the same topic to assess whether individual recommendations can be used and/or adapted (see DELBI Criteria 30-34, response category at least 3 or 4).
- This is followed by a separate literature search for a largely standardized methodology (see DELBI Criterion 8, Response category at least 3 or 4).
- Systematic methods are used to search for the evidence, i.e. the search strategy should be described in detail with a list of search terms and sources used (electronic databases, databases of systematic reviews, manually searched journals, conference proceedings and other guidelines) (see DELBI Criterion 8, Response category at least 3 or 4).
- The selection criteria for the 'evidence' are presented explicitly, especially the exclusion criteria (see DELBI Criterion 9, Response category at least 3 or 4).

- The evidence searched and selected according to criteria established a priori is critically appraised with respect to its methodological quality and the results are summarized in an Evidence Table.
- The critical appraisal establishes the strength of the evidence ("grade of evidence").
- The guideline contains a description of the methodological procedure (guidelines report) (see DELBI Criterion 29, Response category at least 3 or 4).

Classification S3 Guidelines

Guideline with all elements of systematic development

If it is an **S3 guideline**:

- The guideline development group should be representative of the target users, representatives of the medical society(ies) and/or organisation(s) should be involved early in the development of guidelines (see DELBI criteria 4 and 5, Response category at least 3 or 4)
- A systematic search, selection and critical appraisal scientific evidence to the relevant clinical questions is necessary.
- Thereby the first thing to be done is a systematic search for guidelines on the same topic to assess whether individual recommendations can be used and/or adapted (see Criteria DELBI 30-34, Response category at least 3 or 4).
- This is followed by a separate literature search for a largely standardised methodology (see DELBI Criterion 8, Response category at least 3 or 4).
- Systematic methods are used to search for the evidence, i.e. the search strategy should be described in detail with a list of search terms and sources used (electronic databases, databases of systematic reviews, manually-searched journals, conference proceedings and other guidelines) (see DELBI Criterion 8, Response category at least 3 or 4).
- The selection criteria for the evidence are presented explicitly, especially the exclusion criteria (see DELBI Criterion 9, Response category at least 3 or 4).
- The evidence researched and selected according to criteria established a priori is assessed with respect to its methodological quality and the results are summarised in an evidence table.
- The result of the appraisal allows the strength of the evidence ("grade of evidence") to be established.
- The methods for formulating recommendations are clearly described. This requires formal consensus techniques (e.g. consensus conference, nominal group process or Delphi method) (see DELBI Criterion 10, Response category at least 3 or 4)
- Every recommendation is discussed and voted on as part of a structured consensus development with a neutral moderator whose objectives are to find a solution to pending decision-making issues, a conclusive appraisal of the recommendations and measure the strength of consensus.
- The result of the structured consensus development establishes the grade of recommendation A (strong recommendation), B (recommendation) or 0 (open recommendation),
- The finalized guideline indicates level of evidence and grade of recommendation for each recommendation (see DELBI Criterion 12, Response category at least 3 bzw.4).
- A description of the methodological strategy (guideline report) is attached to the guideline (see DELBI Criterion 29, Response category at least 3 bzw.4)

IDA = interdisciplinary development: Is labelled by the supplement to the developmental stage "+IDA" (= interdisciplinary comparison)

DELBI = German Instrument for Methodological Guideline Appraisal

II. Registration procedure for guidelines under planning and development (Status: May/28/2009)

Guidelines projects are registered with the AWMF according to the following schedule:

1. The guideline project proposed by the respective medical societies is registered with the AWMF administrative office (email address only please: anmeldung(at)leitlinien.net).
2. The AWMF administrative office checks the completeness of the registration form (use the current version in each case!). All questions must be answered, incomplete forms will be returned with a request for completion.
3. Every two weeks, the AWMF administrative office sends the completed registrations received to the two chairmen of the guidelines commission (Professor Kreienberg, Professor Kopp). The chairmen and the administrative office consult on the registrations every 14 days during a conference call.

In particular, special attention is paid to the responses to the question about possible thematic overlaps or duplications in the registration form. Different guidelines for the same care setting (illness / symptom or intervention) and the same target users (speciality/field etc.) are not included in the AWMF Guideline Register. Different guidelines for the same treatment situation can be temporarily created for different target users. However, these need to be consistent and in the continuity of care they recommend.

4. The registering medical societies receive an official letter from the administrative office in which they are informed about the outcome of the consultation. If the decision is positive, the entry of the guideline project in the register will be announced along with the following requests:
 1. Prompt notification of any changes to the registrations (e.g. concerning the cooperating medical societies) so that these can be entered into the register, and
 2. After 1 year, a report on the progress of the guideline project and, where applicable, any longer delays or problems.

If there are any uncertainties, the application will be returned with the request for clarification, then the procedure will continue according to step 1.

5. Three months after the completion date specified in the registration, the registering medical societies will receive a letter with the request for information on the progress of the project and the expected definitive completion date. If there is no response the next two months, the guideline project will be removed from the register.
6. If requests for extensions of the completion date are timely and justified, the procedure will continue according to step 5.

III. Disclosure and management of conflicts of interest in guidelines projects (Status: June/9/2010)

The funding strategy for a guideline project must be disclosed by the lead medical societies at the time of its registration with the AWMF. Funding by a third-party with direct influence will lead to rejection of the registration, as is both recommended and practiced internationally.

Conflicts of interest are generally disclosed in writing using a standard form (attachment, RTF file) including both material and immaterial interests. Where applicable, immaterial interests include the individual's mandating organisation (e.g. medical society), their employer and their scientific focus.

Written disclosures of conflicts of interest by the steering committee members, coordinators and work groups leaders need to be submitted before starting work on the guideline. **The coordinators are responsible for requesting and compiling the conflicts of interest disclosures of any late-joining members of the work groups and the approval committee along with others.**

The boards of the delegating medical societies acknowledge the conflicts of interest disclosed by members of the steering committees and critically appraised with regard to their impartiality. **The steering committee and coordinators appraise the written conflicts of interest disclosures from all other participants.** An intention exists to develop an impartiality scale, together with the AWMF Guidelines Commission to ensure reproducible appraisals.

Participants with conflicts of interest whose impartiality is questioned by the medical societies and/or other organisations or by the steering committee should not be involved in the critical appraisal of evidence and consensus development (Recommendation IOM 4.1). If their expertise is indispensable, then they have the status of external experts. Efforts should be made to keep the authors' conflicts of interest at a minimum.

The conflicts of interest disclosures of all participants have to be detailed in the guidelines report (e.g. in tabular form). The long version of the guideline needs to describe the procedure for recording and appraising conflicts of interest with reference to the guidelines report. Finalized guidelines will not be accepted into the AWMF Register if their funding has conflicts of interest issues or individual participants have not transparently disclosed their conflicts of interest. The state of affairs will be examined by the head of the AWMF Guidelines Commission, and by the AWMF Board of Directors in contentious cases.

The procedure for recording and management of conflicts of interest is an integral part of the AWMF Guidance Manual, which is compiled, implemented and maintained by the Guidelines Commission of the AWMF

IV. Submission for publication with AWMF: AWMF policies for guideline publication (Status: September/24/2010)

The AWMF publishes the guidelines on diagnosis and treatment drawn up and approved by the member societies of the AWMF in their information system "AWMF online." The following rules apply:

1. Only those guidelines will be published that are registered with the AWMF and have thus received a registration number from the AWMF. The medical societies are encouraged to make the AWMF registration number and the class (S1, S2e, S2k or S3) clearly visible on the title page of the guideline.

2. Before publication, the AWMF will review the guidelines, including:
 - a. Details on funding and on managing conflicts of interest. Finalized guidelines for which conflicts of interest may arise from their funding or the conflicts of interest of individual contributors are not transparent will not be included in the AWMF publication (see instructions on "Disclosure of conflicts of interest in guidelines projects").
 - b. Details on methodological strategy and the classifications S1, S2k, S2e, and S3. If the description of the methodological strategy as part of guideline development (guideline report) does not demonstrate that the criteria for the specified classification have been fulfilled, the classification will be corrected, where applicable (see instructions on "Classification of the developmental stage").

If the information is incomplete, the guideline coordinators will receive a letter requesting clarification within 14 days.

3. The copyrights for the guidelines belong exclusively to the author(s)(groups) from the medical societies. This includes the right to change, supplement or delete the text.
4. Upon submission of the guidelines by the medical society, the AWMF shall automatically receive the right for the electronic publication in the Internet-based information system "AWMF online". It can make copies of these files available to individual hospitals for use in an "intranet", given that they commit to the AWMF's requirement that the guidelines be updated at regular intervals and be used exclusively in-house. The copyrights of the author(s)(groups) in the medical societies are marked by a copyright notice © for each guideline.
5. If necessary, the AWMF shall undertake to convert the medical societies' submitted guidelines to PDF format for publication on the AWMF website. The greatest care is taken to ensure error-free transfer/conversion. The medical societies must submit their texts electronically (diskette, CD-ROM, e-mail attachment etc.). Submission in a universally usable word processing format (RTF) is strongly recommended; word-processing formats from widespread manufacturers (e.g. WORD ®) are also possible. The texts will be used within any changes to their content. The AWMF only reserves the right to correct obvious spelling errors.
6. Within its technical possibilities, the AWMF secures files for electronic publication against loss or alteration by third parties.
7. If the author(s)(groups) from the medical society decide to change or supplement the guidelines, the AWMF shall endeavour to transfer these changes to the electronic publication as soon as possible. If the medical society resolves to cancel a guideline entirely, the AWMF will immediately delete the related file from the electronic publications. The AWMF will document the time and nature of the change.
8. The AWMF prohibits all users of their information system from any commercial use of the guidelines without the express written agreement of the author(s) (within the medical society).
9. For printed publication of the guidelines, the AWMF strongly recommends that all medical societies establish contracts with publishers wherein the publisher is only given a precisely described right of use to the (unique) copy of the guidelines, and is not granted arbitrary, un-

restricted use of the texts. Only in this way can the medical society as author control any further use of the work and prevent parts of it from being published in another context.

10. If the period of validity of the guideline (maximum: 5 years) has been exceeded and the medical society has not announced any updates to the guideline, the guideline will be completely deleted from the AWMF publication system.

Therefore, the medical societies are advised to ensure always that their guidelines are archived. **The AWMF does not provide long-term archiving of old versions.**

V. AWMF deletion of guidelines that have not been updated (Status: September 23, 2008)

According to the decision of the AWMF Standing Guidelines Commission, guidelines which have expired will no longer be published online by the AWMF in future. The specification from the medical society(ies) as to when the guideline should receive a scheduled review is considered to be the guideline's expiration date - if the medical society(ies) has made no such specification, guidelines are classified at the latest within 5 years after their creation as "non-updated" and removed from the publishing system by the AWMF.

Until now, these "non-updated" guidelines were labelled with a red mark, moved to a separate directory called "non-updated guidelines" and no longer accounted for in the internal keyword search system for AWMF guidelines. However, they were still available over the Internet and could be found using external search engines (Google, etc.). As of October 2008, this directory will be completely deleted.

The professional associations are encouraged to uphold their update deadlines and to register these update cycles with the AWMF. The AWMF administrative offices will notify the medical societies of the impending expiry of the guidelines with a form letter about 6 months before the expiration date. If the medical society has not registered any updates or submitted any updated guidelines for publication, the previous guideline file will be deleted after the deadline has expired.

We would like to note that it is incumbent upon the medical societies, as authors and publishers of the guidelines, to also save and archive their non-updated versions for documentation purposes. The AWMF only publishes the respectively current guidelines and always directs queries on formerly valid guidelines to the medical societies that published those guidelines.

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