



Association of the  
Scientific Medical Societies  
in Germany



Agency for Quality in Medicine

# German Instrument for Methodological Guideline Appraisal

Deutsches Instrument zur methodischen  
Leitlinien-Bewertung (DELBI)

Version: 2005/2006 + Domain 8 (2008)

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The **German Instrument for Methodological Guideline Appraisal (DELBI)** is a generic tool for providing assistance to the developers and users of clinical guidelines in appraising their methodological quality. **The instrument is not suitable for assessing the appropriateness of the content of guideline recommendations.**

Editors and authors accept no responsibility for the improper use of the **DELBI** instrument.

## PERIOD OF VALIDITY AND UPDATING

The **German Instrument for Methodological Guideline Appraisal** was published June 7, 2005 and amended on September 22, 2008 (version 2005/2006 + Domain 8). It remains valid until the next revision will be published or no later than the middle of 2013, respectively. Accordingly, an updating process has been initiated. After review by the editors the period of validity was extended until middle of 2015.

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The continuous supplementation, updating und publication are the common responsibility of the Agency for Quality in Medicine (AQuMed) and the AWMF guideline commission.

Additions and modifications of **DELBI** are accessible through the website [www.english.delbi.de](http://www.english.delbi.de).

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## Foreword

In summer 1999 the self-governing bodies of the German healthcare system (German Medical Association, National Association of Statutory Health Insurance Physicians, German Hospital Federation, Federal Association of the Statutory Sickness Funds) and the Association of the Scientific Medical Societies in Germany (AWMF) have agreed on a common programme for the enhancement of the quality of guidelines for medicine. This programme is based on the recommendations of the European Council for the methodology for drawing up guidelines [1], the first edition of the checklist “Methodological Quality of Clinical Practice Guidelines” developed by AQuMed and AWMF [2], and the quality requirements of the partners of the Guideline Clearinghouse of the self-governing bodies in the German healthcare system [3].

In addition to these basic principles, the present new version of the guideline checklist ([German Instrument for Methodological Guideline Appraisal, DELBI](#)) reflects the international movement towards standardising the documentation of the development process and the appraisal of the methodological quality of guidelines.

Thus, the fundamental quality requirements of [DELBI \(DELBI Domains 1-6\)](#) correspond to those of the AGREE instrument developed and validated by an international working group with German participation (Appraisal of Guidelines for Research and Evaluation 2001 [4-6]). These requirements have been complemented by detailed questions about the presentation of methodology, content and implementation strategies that the editors regard as highly relevant for both the acceptance and implementation of guidelines within the German healthcare system ([DELBI Domain 7](#)).

The instrument was developed by a multidisciplinary group of recognised experts in the field of guidelines and presented for public discussion in spring 2005 as part of an open consultation process on the Internet. We would like to thank all the authors and commentators of the DELBI instrument.

The [German Instrument for Methodological Guideline Appraisal \(DELBI\)](#) is meant to assist guideline users and other interested parties with subjecting guidelines to methodological evaluation. Guideline authors are recommended to consider the 29 DELBI criteria when developing their guidelines.

**Duesseldorf and Berlin, June 2005**

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## Introduction

### Purpose of DELBI

The purpose of the [Deutsche Instrument zur methodischen Leitlinien-Bewertung \(DELBI\)](#), i.e., the [German Instrument for the Methodological Appraisal of Guidelines \(DELBI\)](#) is to enable the appraisal of the methodological quality of clinical practice guidelines. Between 2003 and 2005 it was developed by the experts mentioned in the masthead and piloted by 15 guidelines experts.

**Since existing guidelines are increasingly being used as a source of evidence for the development of new guidelines, a multi-disciplinary expert group collaborated during the years 2007 and 2008 to set up Domain 8 as an addendum to the 2005/2006 version of the DELBI instrument on the basis of both international and national manuals for guideline adaptation [7; 8].**

DELBI constitutes a refinement of the checklist “Methodological Quality of Guidelines” [2] incorporating the experiences that AWMF, AQuMed, and their partners [9-14], the AGREE Collaboration [15-19] and the International Guideline Network G-I-N [20] have accumulated in the field of clinical guidelines.

### Definitions

By **guidelines** we mean “systematically developed statements to assist physicians and, if necessary, other healthcare professionals and patients with decisions about appropriate health care in specific clinical circumstances.”

They are meant to facilitate orientation in the sense of “treatment and decision corridors,” from which deviation is not only allowed but even recommended in certain duly justified cases.

The primary aim of clinical practice guidelines is to enhance good clinical practice including the consideration of available resources and to inform the public.

Guidelines are an essential component of quality management in healthcare [1].

Guidelines are intended to assess the comprehensive knowledge (scientific evidence and clinical experience) about problems of care, to reconcile opposite views and to define current optimal practice by trading off benefits and harms.

Guidelines are not intended as guidance towards so-called “cookbook medicine”; neither do they reflect the opinions of individual experts in the field. Guidelines represent a consensus reached by a multidisciplinary panel of experts according to well-defined and transparent methods. This consensus is based upon a systematic search and appraisal of the existing literature.

Guidelines differ from systematic reviews and HTA (Health Technology Assessment) Reports by their primary objective, which is to provide explicitly formulated and specific decision aids. Guidelines can assist in decision making on appropriate and effective



healthcare, especially in areas with significant variation in healthcare routines or healthcare quality.

Meanwhile the favorable impact of guidelines on the quality of both processes and outcomes in healthcare has been scientifically proven [21]. Guidelines, though, can begin to take effect only if the guideline recommendations are applied in the care of individual patients. This is why supraregional (national or international) guidelines must be assessed according to their applicability on a regional or local level and adjusted if necessary. However, the effectiveness of guidelines depends on their acceptance and the reliability of their recommendations, both being subject to numerous factors [22].

The essential factors include the following:

- systematic search for and appraisal of the evidence
- structured consensus finding techniques
- orientation towards patient outcomes (“outcome appraisal”)
- trade-off between benefit and harm (“decision analysis”)
- reproducibility of care processes (“algorithmic logic”) [1, 10].

By the **quality of clinical guidelines** we mean

- that these factors have been appropriately taken into account during guideline development (internal validity),
  - that the recommendations are practically feasible, and
  - that they can favourably influence healthcare delivery processes (external validity)
- (modified acc. to AGREE [4, 5]).

### Which guidelines can be appraised with DELBI?

**DELBI** represents the consensus about quality criteria for “good guidelines for the German healthcare system.” It allows for evaluation of the internal validity and a prospective estimation of the guideline’s potential in reaching its objectives. The checklist cannot reflect its actual influence on healthcare delivery (external validity).

**DELBI** has been designed for the appraisal of guidelines developed by local, regional, national or international working groups.

These include:

1. new guidelines
2. existing guidelines
3. updates of existing guidelines.

**DELBI** is generic and can thus be applied to guidelines for any clinical areas and any areas of care (diagnosis, prevention and health promotion, treatment or interventions) (modified acc. to AGREE [4, 5]).

### Who can use DELBI?

**DELBI** is intended to be used by the following groups:

- by *guideline developers* to follow a structured and rigorous development methodology and use it as a self-assessment tool – to ensure that their guidelines comply with international standards;

- by *physicians and other healthcare providers* who wish to perform their own appraisal before adopting guideline recommendations;
- by *educators or teachers* to help them enhance the critical appraisal skills among physicians and other health professionals;
- by healthcare policy makers to help them decide which guidelines should be recommended for use in practice. In such instances, **DELBI** should be part of a formal assessment process.

(modified acc. to AGREE [4, 5])

## Instructions for Use

**Please read the following instructions carefully before using the DELBI instrument.**

Before applying the checklist appraisers should try to identify all information available about the guideline development process.

This information may be part of the guideline document itself or a supplementary publication (guideline report, accompanying documentation).

The assessment, though, should only be based on publicly available information whose existence is pointed out in the guideline document and which can unambiguously be attributed to the guideline subject to assessment (modified acc. to AGREE [4, 5]).

### 1. Structure and Content of the DELBI Instrument

DELBI contains 34 criteria for the methodological quality and practicability of a guideline. These criteria are organised in 8 domains, with domains 1-6 corresponding to those of the validated AGREE instrument [4, 6]. Domain 7 describes the special requirements for German guidelines and incorporates the experiences of AWMF [12] and the German Guideline Clearinghouse [23]. Domain 8 describes the specific requirements that need to be met by guidelines which have been developed on the basis of already existing guidelines. Each domain covers a separate dimension of guideline quality.

The domain **“Scope and Purpose”** (Criteria 1-3) is concerned with the overall aim of a guideline, the specific clinical questions / problems and the target patient population.

The domain **“Stakeholder Involvement”** (Criteria 4-7) focuses on the extent to which the guideline reflects the views of its intended users and affected patients.

The domain **“Methodological Rigour of Development”** (Criteria 8-14) relates to the process used to gather and synthesise the evidence and the methods used to formulate, review and update the recommendations.

The domain **“Clarity and Presentation”** (Criteria 15-18) deals with the comprehensibility of the language and the format of the guideline.

The domain **“Applicability”** (Criteria 19-21) pertains to the likely organisational, behavioural and cost implications of applying the guideline.

The domain **“Editorial Independence”** (Criteria 22-23) is concerned with the independence of the recommendations and the acknowledgement of possible conflict of interest from the guideline development group.

The domain **“Applicability to the German Healthcare System”** (Criteria 24-29) describes additional quality criteria for a guideline to be applied within the German healthcare system.

The domain “**Methodological Rigour of Development when Using Existing Guidelines**” (Criteria 30-34) relates to the process used to gather, appraise and synthesise existing guidelines in order to include them in the formulation of recommendations.

## 2. Number of Appraisers

Each guideline should be assessed by at least 2 appraisers, preferably by 4 appraisers, as this will increase the reliability of the assessment [6].

## 3. Response Scale

Each item (criterion) is rated on a 4-point scale ranging from 1 = “Strongly Disagree” to 4 = “Strongly Agree” with two mid points: 3 = “Agree” and 2 = “Disagree.” The scale measures the extent to which a criterion has been fulfilled.

- If you are confident that the criterion has been fully met you should answer “*Strongly Agree.*”
- If you are confident that the criterion has not been fully met or if there is no information available then you should answer “*Strongly Disagree.*”

## 4. User Guide

Additional information is provided for each item of the DELBI instrument. It is intended to help you understand the issues and concepts addressed by these items. It is completed by specific references to the requirements that must be fulfilled for individual response categories (1-4) and practice examples. Please read this guidance carefully before giving your answers.

## 5. Assessment of Individual Domains

The Agree Collaboration has agreed on how to calculate domain scores that can be used, for example, for international comparison [6].

From a methodological perspective it must be noted that due to the heterogeneity of the criteria a comparison of the total domain scores is only partly conclusive. Also note that it is not permissible to set thresholds for the domain scores in order to mark guidelines as more or less ‘good’ or ‘bad’.

We leave the decision whether to make use of the method for calculating standardised domain scores set out by the Agree Collaboration to the user.

Note that the 7 domain scores are independent of each other and should not be aggregated into a single “quality score.”

Domain scores can be calculated by summing up all the scores of all the individual items in a domain and by standardising the total as the percentage of the maximum possible score for this domain.

### Example

If 4 appraisers give the following scores to Domain 1 (Scope and Purpose):

Maximum possible score = 4 (Strongly Agree) x 3 (Items) x 4 (Appraisers) = 48  
Minimum possible score = 1 (Strongly Disagree) x 3 (Items) x 4 (Appraisers) = 12

	Item 1	Item 2	Item 3	Total
Appraiser 1	2	3	3	8
Appraiser 2	3	3	4	10
Appraiser 3	2	4	3	9
Appraiser 4	2	3	4	9
Total	9	13	14	36

#### Standardised Domain Score:

$(\text{obtained score} - \text{minimum possible score}) / (\text{maximum possible score} - \text{minimum possible score}) = (36 - 12) / (48 - 12) = 24 / 36 = 0.67$

## Domain 1: Scope and Purpose

### 1. The overall objective of the guideline is specifically described.

Strongly Disagree

1	2	3	4
---	---	---	---

Strongly Agree

Guidelines have an impact on the health state of specific patient groups or larger parts of the population. Therefore they should precisely define both the operating target (absolute/relative efficacy, efficiency, practicability of healthcare interventions) and the specific problem area / setting (prevalence of the aspect of care addressed, optimisation potential of the quality of care and the health benefit expected from the guideline) for which they were developed.

The description of objectives and problem areas should assist evaluation of the guideline's impact on healthcare and its use as a tool for quality management (see also item 21, derivation of review criteria for monitoring and / or audit purposes).

**The statement must be responded to by “Strongly Disagree” “1”** if either the objective is unclear or not mentioned.

**Responding by “2”** requires the description of general aims (e.g., optimisation of care on the level of structural, process and outcome quality, support of physicians with the management of particular conditions, training aids for professional newcomers).

**Responding by “3”** requires the description of specific aims (e.g., prevention of [long-term] complications of diabetes; reduction of the risk of subsequent complications in patients following myocardial infarction; reasonable and cost-effective prescription of antidepressive drugs; improvement of the quality of life in patients with bronchial asthma).

**Responding by “Strongly Agree” “4”** requires the precise description of the specific aims and the health benefits expected from the implementation of the guideline (e.g., quantification of risk reduction).

**2. The clinical questions / problems addressed by the guideline are specifically described.**

Strongly Disagree

1	2	3	4
---	---	---	---

Strongly Agree

A detailed description of the clinical questions / problems covered by the guideline should be provided, particularly for the questions underlying key recommendations. This description is part of the work of the authors' group because issue-specific evidence must be sought and the recommendations should be adjusted to the needs of the physicians and patients addressed by the guideline.

The clinical decision problems within medical history taking / risk assessment, diagnosis and treatment are specifically described in the guideline.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain information about the issues / problems underlying key recommendations.

**Responding by “2” requires** that the guideline only provides information on some clinical questions underlying the key recommendations.

**Responding by “3”** requires that information is provided on the majority of clinical questions underlying the key recommendations.

**Responding by “Strongly Agree” “4”** requires that the guideline provides information on all clinical questions underlying the key recommendations.

**3. The patients to whom the guideline is meant to apply are specifically described.**

Strongly Disagree

1	2	3	4
---	---	---	---

Strongly Agree

The application of a guideline can be limited to certain patient groups or stages of disease, or it may refer to all patients affected.

The patient group(s) to which the guideline is meant to apply should be clearly described, namely in terms of age, sex, information about the disease, disease severity and comorbidity.

**The statement must be responded to by “Strongly Disagree” “1”** if the patient target group is not mentioned or can only be indirectly inferred from the guideline text.

**Responding by “2”** presupposes that the patient target group is mentioned.

**Responding by “3”** requires the additional provision of characteristics determining the inclusion or exclusion of patients such as age, sex, certain levels of severity, comorbidities (e.g., if a guideline for the treatment of depression only refers to patients with major depression according to the DSM-IV Criteria and does not apply to patients suffering from psychotic symptoms or to children).

**Responding by “Strongly Agree” “4”** requires that a precise description of the patient group and, in addition, of the health care setting is provided to which the guideline is meant to apply (e.g., if a guideline for the treatment of diabetes mellitus only refers to Type-2 diabetics without cardiovascular disease and describes primary care only).



## Domain 2: Stakeholder Involvement

### 4. The guideline development group includes members from all relevant professional groups.

Strongly Disagree

1	2	3	4
---	---	---	---

Strongly Agree

The willingness to adhere to guidelines increases to the extent to which the development process is transparent and the development group representative for the user group. Thus we recommend that not only all professional groups affected by the subject but other interest groups as well be involved in the guideline development process. Participation can be achieved directly through authorship or participation in the consensus or review process, or through public discussion before guideline release.

Usually the professional groups affected are those being addressed by the guideline, but also groups needed at intersectional points of care (e.g., paramedics / emergency physicians in myocardial infarction management, nursing staff).

**The statement must be responded to by “Strongly Disagree” “1”** if no information is provided about the composition of the development group, or if authors are only mentioned by name and it is not possible to assign them to a certain professional group or functional area.

**Responding by “2”** requires that in addition to the authors’ names a clear description of the professional or interest groups represented by the respective authors is provided.

**Responding by “3”** requires that it can be clearly seen from the information that all the professional groups addressed by the guideline have been involved in the guideline development process.

**Responding by “Strongly Agree” “4”** requires additional information about the kind of involvement of those professional or interest groups not directly addressed by the guideline (e.g., the involvement of nursing professionals in a pure ‘physician’ guideline). This information may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline.

## 5. The patients' views and preferences have been sought.

Strongly Disagree

1	2	3	4
---	---	---	---

Strongly Agree

The application of a guideline may be impeded if the patients' preferences or needs have not or not adequately been considered. Patients / relatives should thus be involved in the guideline development process. Their involvement may be of a direct nature through active participation in the authors' group or of indirect nature through participation in a review process or public discussion prior to the release of the guideline. Ideally, each guideline is always accompanied by an appropriately worded patient version.

**The statement must be responded to by "Strongly Disagree" "1"** if patients have not been involved or if - on the basis of the information (not) provided - the kind and extent of their involvement can only be conjectured.

**Responding by "2"** requires that patient representatives have been indirectly involved (e.g., through a review process or public discussion of the guideline including the modification of content prior to release).

**Responding by "3"** requires the direct involvement of patients in the guideline development process.

**Responding by "Strongly Agree" "4"** requires that additional information is presented about the decisional implications of patient involvement. This information may be provided by the guideline itself or in a guideline report. The guideline report must clearly be indicated in the guideline.

## 6. The target users of the guideline are clearly defined.

Strongly Disagree

1	2	3	4
---	---	---	---

Strongly Agree

A guideline directly applies to particular groups, but its recommendations or procedures may be of relevance to other health professionals even though they have not been specifically addressed by the guideline; also, it may be used for informational purposes.

Potential users should be clearly defined so they can immediately determine if the guideline is relevant to them. Particularly, it should be stated which professional medical groups from the ambulatory and inpatient setting are addressed and whether non-medical staff (and other providers), patients and health policy makers are included in these target users (e.g., for utilising quality specifications determined by the guideline).

The user groups described above must be distinguished from those groups that are indirectly concerned. These groups are not involved in the individual decision processes and proceedings based on the guideline recommendations but are nevertheless affected by the outcome of these processes. For example, changes in the prescription behavior of physicians may have an impact on the pharmaceutical industry or funding institutions / purchasers of healthcare.

Note that the applicability of a guideline may very well be limited by guideline-independent specifications determined by these indirectly affected groups (see also item 19).

**The statement must be responded to by “Strongly Disagree” “1” if the users have not been defined.**

**Responding by “2”** requires that relevant user groups are referred to in the context of the guideline or that clear inferences can be drawn.

**Responding by “3”** requires that the users are clearly referred to.

**Responding by “Strongly Agree” “4”** additionally requires that further (indirect) users (interfaces) are pointed out (e.g., users from sickness funds).

## 7. The guideline has been piloted among target group members.

Strongly Disagree

1	2	3	4
---	---	---	---

Strongly Agree

Prior to its comprehensive implementation the guideline should be piloted among the user group or at least a representative sample of it in order to increase its acceptance. Such a pilot test enables the group of authors to reveal potential problem or white spot areas by the feedback of the user group, e.g., on usefulness, practicability and acceptance of the guideline and, if necessary, to incorporate updates.

**The statement must be responded to by “Strongly Disagree” “1”** if no pilot test has been conducted or if no such information is provided.

**Responding by “2”** requires a piloting procedure mentioned in the guideline.

**Responding by “3”** requires that the guideline contains information about the piloting method (e.g., interviews to determine the applicability of the guideline; application tests in practice).

**Responding by “Strongly Agree” “4”** additionally requires that both the procedure and the results of the pilot test are specified. This information may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline.

## Domain 3: Methodological Rigour of Development

### 8. Systematic methods were used to search for evidence.

Strongly Disagree

1	2	3	4
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Strongly Agree

Due to the vast number of publications on different clinical issues it is critical for the way in which the search for information is being conducted that as many resources as possible be identified for a specific issue in order to be able to generate recommendations during the following assessment procedure.

The strategy used to search for evidence should be described in detail, including both a list of the search terms used and the sources consulted as well as the time period covered. Sources may include electronic databases (such as MEDLINE, EMBASE, CINAHL), databases of systematic reviews (e.g., The Cochrane Library, DARE), handsearching of journals, conference proceedings and other guidelines (e.g., by the US National Guideline Clearinghouse or the German Guideline Clearinghouse). All key questions should be addressed by the literature search (see also item 2).

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain any information on the search for evidence.

**Responding by “2”** requires that the guideline provides information about the methods used to search for the literature to make obvious at least that the search was conducted systematically and methodically.

**Responding by “3”** requires that the search methods are specified in the guideline, including a list of the search terms used and the databases consulted.

**Responding by “Strongly Agree” “4”** requires that the guideline contains a complete specification of the search methods including the search terms used, databases consulted and if applicable further sources as well as information about the search results (at least the number of hits) and the time period covered. Any search limitations must be explicitly stated. This information may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

**9. The criteria for selecting the evidence are clearly described.**

Strongly Disagree

1	2	3	4
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Strongly Agree

The criteria for selecting the scientific evidence constitute the basis of guideline recommendations. In practice, not all the available sources of information are considered when formulating the recommendations of a guideline; instead, only certain sources are included. Depending on the guideline's scope of application (e.g., supraregional / regional; hospital / practice or cross-sectoral) and other factors (quality or type of data sources / studies, language, availability or approval state of the methods used), different criteria may be applied which should be explicitly stated. In particular, the reasons for excluding evidence must be clearly defined and stated.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not mention any criteria for including / excluding evidence.

**Responding by “2”** requires that basic information must be provided about how the evidence was selected.

**Responding by “3”** requires that the guideline contains information about the selection of the evidence supporting key recommendations. Reasons are given for including/excluding evidence.

**Responding by “Strongly Agree” “4”** requires that the guideline contains detailed information about the criteria used for selecting the evidence for all recommendations. Information about the reasons for both including and excluding evidence should be provided. A general remark (such as “considered / not considered because of primary care requirements”) cannot be regarded as adequate. This information may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

**10. The methods used for formulating the recommendations are clearly described.**

Strongly Disagree

1	2	3	4
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Strongly Agree

There should be a description of the methods used for formulating the recommendations and how final decisions were arrived at. These methods include informal voting systems and formal consensus techniques (such as consensus conferences, Nominal Group Technique or Delphi processes).

As far as the reproducibility of the recommendations and thus the acceptance of a guideline is concerned, the presentation of the (if possible, formal) methods used to formulate recommendations is of central relevance.

**The statement must be responded to by “Strongly Disagree” “1”** if no information is provided about the methods used to formulate the recommendations.

**Responding by “2”** requires information showing clearly that a consensus-finding process has taken place.

**Responding by “3”** requires information showing clearly that formal consensus-finding methods have been used. At least, this applies to key recommendations.

**Responding by “Strongly Agree” “4”** requires information showing that formal consensus techniques have been applied which also provide a strategy for solving problems in case of disagreement. Areas where no consensus could be reached are explicitly stated, just as the methods for resolving the conflict are specified.

**11. Health benefits, side effects and risks have been considered in formulating the recommendations.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Many clinical procedures differ with respect to their effects on different levels; guidelines are supposed to provide relevant decision aids to different users. A guideline should consider both the health benefits to be expected as well as potential side effects and risks of the recommendations so that trade-off comparisons of recommended and alternative procedures can be conducted. These may be information about objective (such as morbidity, mortality) or subjective outcome parameters (e.g., quality of life). In this context the different effects on the expected health outcome should be described. For example, a guideline for the treatment of breast cancer can discuss the implications which its recommendations may have on survival rates, quality of life, extent of adverse treatment effects or symptoms, and compare these to the effects of alternative procedures. This kind of information may be provided in the text or by tabular comparison (balance sheets).

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain information about whether potential benefits, side effects or risks of the recommendations have been considered. A simple note in the guideline (e.g., a reference to the product information on a drug) is not sufficient to warrant more than a grade “1” answer.

**Responding by “2”** requires that the guideline contains information about benefits, side effects and risks of the key recommendations.

**Responding by “3”** additionally requires that the information about benefits, side effects and risks are supported, if possible, by the results of trials identified through the search for literature about these issues (e.g., risk studies, outcome studies, cost-benefit analyses or other sources) and / or linked to statistical measures (such as Number Needed to Treat [NNT], Number Needed to Harm [NNH]). Where no such measures may be generated for recommendations this should at least be mentioned in the guideline report (see item 29).

**Responding by “Strongly Agree” “4”** additionally requires that the information given allows the user to conduct a trade-off comparison to alternative procedures or the natural history of the disease, at least for the key recommendations. This information is not limited to a single dimension (e.g., to mortality data only).



**12. There is an explicit link between the recommendations and the supporting evidence.**

Strongly Disagree

1	2	3	4
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Strongly Agree

An indispensable part of a guideline is the reproducible presentation of the sources underlying the recommendations. These include both references and other sources supporting individual recommendations, and the evaluation of these sources in terms of “levels of evidence” and “grades of recommendation.”

**The statement must be responded to by “Strongly Disagree” “1”** if no link is provided between the recommendations and the supporting literature.

**Responding by “2”** requires that literature links to the recommendations are at least partially provided.

**Responding by “3”** requires that at least the key recommendations are linked to the supporting literature throughout and at least contain information about the respective “grades of recommendations” or “levels of evidence.”

**Responding by “Strongly Agree” “4”** requires that the guideline contains additional information about the levels of evidence for the respective recommendation. Furthermore, the guideline should explicitly indicate those parts where no evidence (i.e., evidence from studies etc.) could be identified and where recommendations are thus based on expert consensus, or where the authors have deliberately deviated from recommendations derived from studies.

**13. The guideline has been externally reviewed by experts prior to its publication.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Reviewing a guideline before it is published ensures that, for example, potential uncertainties or missing parts can be identified, which in the end may enhance guideline applicability. The review group should include experts from the medical field, methodologists and, if applicable, patient representatives. The methods used for reviewing and the results of the review process should be presented. Reviewers should not have been involved in the guideline development process.

**The statement must be answered by “Strongly Disagree” “1”** if there is no indication that the guideline has been reviewed by external experts or if a review process has been announced after publication of the guideline.

**Responding by “2”** requires that the guideline contains a reference indicating that an external review process has been completed or that the guideline has been published in a peer-reviewed journal.

**Responding by “3”** additionally requires that the reviewers’ names and their affiliation with scientific professional associations and / or organisations have been mentioned.

**Responding by “Strongly Agree” “4”** additionally requires that both the methods used and the results of such a review process are presented. This information may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

**14. A procedure for updating the guideline is provided.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Guidelines summarise state-of-the-art knowledge from which recommendations are generated. Hence, it is necessary to continuously review the guideline in terms of the need for an update process. The guideline should clearly state by whom these reviews are performed and how the resulting changes are pointed out in the guideline.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain information about the procedure for updating the guideline or if it just mentions that the guideline “is to be updated”.

**Responding by “2”** requires that the period of validity of the guideline must be mentioned at least once.

**Responding by “3”** additionally requires that a contact person responsible for the updating of the guideline is mentioned by name.

**Responding by “Strongly Agree” “4”** requires that a procedure for updating the guideline is provided, including a presentation of the methods or measures used, a timescale and the persons responsible. If possible, updated sections should be easily recognisable in the revised version of the guideline.

## Domain 4: Clarity and Presentation

### 15. The recommendations of the guideline are specific and unambiguous.

Strongly Disagree

1	2	3	4
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Strongly Agree

Based on the methodological procedures used for the literature search and the selection of recommendations, the formulation of these recommendations and their incorporation into the context of the entire guideline is of central relevance to its acceptance and applicability. The recommendations should be provided in unambiguous and intelligible language. Further, they should clearly refer to the respective treatment situation (patient, method), i.e., be specific. A recommendation should provide specific and precise information about which approach is appropriate in which situation and for which particular group of patients, as permitted by the body of evidence. If recommendations cannot be specifically and unambiguously defined, this should be stated clearly in the guideline.

**The statement must be responded to by “Strongly Disagree” “1”** if, on the whole, presentation and / or wording of the guideline recommendations lack specificity and unambiguouslyness.

**Responding by “2”** requires that the presentation and / or wording of the guideline recommendations are at least partly specific and unambiguous.

**Responding by “3”** requires that for the greater part the presentation and / or wording of the guideline recommendations are specific and unambiguous (e.g., that children from age 2 and older suffering from acute otitis media must receive antibiotics if the symptoms persevere for more than 3 days or aggravate despite appropriate treatment with analgesics; in such cases children should be treated with amoxicillin for 7 days. This recommendation should be complemented by specifying an appropriate dosing regimen).

**Responding by “Strongly Agree” “4”** requires that the presentation and / or wording of the guideline recommendations are specific and unambiguous throughout. In addition, areas where the recommendations cannot be clear or specific are explicitly indicated.

**16. The different options for the management of the condition are clearly presented.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Management options for the condition covered in the guideline can derive from the areas of screening, prevention, diagnosis, therapy and rehabilitation. If necessary, the different options provided for the different recommendations should be clearly presented in the guideline (see also item 11).

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not present any treatment options for the addressed problems.

**Responding by “2”** requires that the guideline presents different management options for at least some areas.

**Responding by “3”** requires that the guideline presents different management options for most areas, together with a list of decision criteria for the respective options.

**Responding by “Strongly Agree” “4”** requires that the guideline clearly presents the options together with a list of well-founded decision criteria for all the options presented. If possible, reference should be made to target criteria such as patient preferences, efficiency, effectiveness or others.

**17. Key recommendations of the guideline are easily identifiable.**

Strongly Disagree

1	2	3	4
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Strongly Agree

A guideline contains a number of recommendations, some of which are key recommendations. These key recommendations that provide answers to essential clinical problems should be easily and clearly identifiable to the guideline user.

Within the guideline this may be achieved by creating a logical structure, highlighting key recommendations in a clear way and supplementing the guideline with a summary of the key recommendations in terms of a short version. Complex recommendations (e.g., recommendations with several subordinate decision options) can, for example, be presented in flow chart format.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain any key recommendations.

**Responding by “2”** requires that the guideline contains some key recommendations, even if these are not easily identifiable.

**Responding by “3”** requires that some key recommendations are easily identifiable (e.g., in highlighted text modules or tables).

**Responding by “Strongly Agree” “4”** requires that easily and clearly identifiable key recommendations are provided throughout the guideline.

**18. The guideline is supported with tools and/or materials for application.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Due to its methodological prerequisites, its developmental requirements and the associated supporting information the size of a guideline usually becomes so large that this may impede its simple application in daily practice.

Therefore it is reasonable to prepare the contents and recommendations of a guideline in different formats and sizes. These include, for example, short versions, quick reference guides, computer supports, and additional information material or patient versions.

All material pertaining to a guideline or material designed to improve its applicability should be easily accessible and, if possible, made available free of charge or available at the lowest possible price.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain any tools or material supporting its application. This also applies if the guideline does not contain any clear reference to this material and/or information about how to access them. Responding by “1” is also required if the material mentioned in the guideline is not available.

**Responding by “2”** requires that the guideline does not contain a clear reference to existing material.

**Responding by “3”** requires that the guideline contains a summary of the recommendations including levels of recommendation and / or a short version and, if applicable, more references to additional material.

**Responding by “Strongly Agree” “4”** requires that the guideline contains several tools supporting the application of the guideline. At least, these include a summary of the recommendations linked to respective levels of recommendation, a short version and a patient version. Further material must be clearly denoted and available.

## Domain 5: General Applicability

### 19. The potential organisational barriers in applying the recommendations have been discussed.

Strongly Disagree

1	2	3	4
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Strongly Agree

Guideline recommendations may require changes in the current organisation of care within health institutions (practices, hospitals, departments etc.) or on a structural level (even in the total network of all healthcare organisations) or behavioral changes of healthcare providers. These potential changes may impede or even prevent the implementation of guideline recommendations. Changes that are necessary in order to truly implement these recommendations should be systematically analysed and discussed.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not discuss barriers to its implementation or if these can only be conjectured.

**Responding by “2”** requires that potential barriers are pointed out in the guideline.

**Responding by “3”** requires that the guideline points out potential barriers and offers the most relevant contributions towards a potential solution of any associated problems.

**Responding by “Strongly Agree” “4”** requires that the guideline systematically discusses and clearly presents factors that may impede or promote its implementation (force-field analysis).



**20. The potential cost implications of applying the recommendations of the guideline have been considered.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Usually guidelines are expected to make more efficient use of resources though, in fact, additional resources may be needed for applying the recommendations of a guideline. For example, these may include additional and more specialised staff, new equipment or (more) expensive drugs, and all these factors may have budget impact.

The potential implications that guideline application has on resources should be discussed in the guideline. Generally, health economic analyses will only be available or feasible for selected topics. However, all guidelines may offer a fundamental statement (e.g., by means of example calculations) about their potential impact on the use of resources.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain any information about potential cost implications arising from the application of guideline recommendations.

**Responding by “2”** requires that the guideline mentions potential cost implications arising from the application of the guideline recommendations, at least for selected areas, and discusses possible consequences or control strategies.

**Responding by “3”** requires that the guideline mentions potential cost implications from the implementation of the guideline recommendations for most areas and discusses possible consequences or control strategies. Areas for which the guideline cannot provide sufficiently specific statements (e.g., due to missing data) are specially marked.

**Responding by “Strongly Agree” “4”** requires that the guideline provides a detailed discussion of potential cost implications that is supported by decision analysis data (such as cost-benefit analyses), if possible. Example calculations should be provided for areas where there are not enough data so that at least dimensions may be estimated or necessary measures be planned for quantification purposes. Generally, those parts of the guideline where such a statement still cannot be provided should be explicitly marked throughout the guideline. This information may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in the guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

**21. The guideline presents key review criteria for monitoring and / or audit purposes.**

Strongly Disagree

1	2	3	4
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Strongly Agree

The implementation of guidelines may be enhanced by measuring the utilisation of the guideline and the implications deriving from its application. This requires review criteria that allow three different aspects to be assessed:

- a. the conformity of healthcare delivery to guideline recommendations, i.e., monitoring the application of a guideline in daily practice,
- b. the individual treatment success, i.e., the individual outcome quality,
- c. the impact that the guideline has on all patients affected, i.e., the population-related outcome of the application of the guideline.

Such review criteria may help to determine systematic potentials for improvement. In addition, review criteria may provide data necessary for users, data transmission and the coordination of services at different healthcare interfaces (e.g., outpatient / inpatient care). These review criteria should be derived from the (key) recommendations and outlined in the guideline. To enhance the methodological quality of clinical review criteria the requirements to be met have been set down in an executive summary [24].

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain any review criteria or only refers to review criteria presenting individual laboratory or measuring parameters without general aspects of the clinical review criteria being fulfilled.

**Responding by “2”** requires that the guideline contains review criteria that can be used to review healthcare outcomes (at least for orientation purposes).

**Responding by “3”** requires that the guideline contains review criteria that have been defined with respect to the key recommendations. If possible, reference values / reference ranges pertaining to these sets of criteria have been defined so that risk patients / groups / conditions can be identified reliably.

**Responding by “Strongly Agree” “4”** requires that the guideline contains methodologically well-founded (sets of) review criteria that refer to (key) recommendations and which may be used for evaluating both the application of the guideline and the quality of the outcomes achieved. The (sets of) review criteria should be formulated in such a way as to also project the data that will have to be obtained or needed at different interfaces. The review criteria should be integrated into an overall plan for the evaluation of the guideline.

## Domain 6: Editorial Independence

### 22. The guideline is editorially independent of the funding organisation(s).

Strongly Disagree

1	2	3	4
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Strongly Agree

Funding or other support of the work of guideline groups may come from external sources (such as state authorities, organisations from the medical field or the pharmaceutical industry). Support may comprise complete funding of this work, or funding part of the content-related working phases (e.g., certain work meetings or hotel accommodation) or certain guideline production costs (such as printing costs, Internet versions, etc.). Each form of (financial) support should be explicitly stated, and it should be pointed out that neither the work of the guideline authors nor their recommendations have been unduly influenced.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain any information / explanation pertaining to financial support.

**Responding by “2”** requires that the guideline provides information about both the responsible organisation (editors) and any additional financial or other support of the guideline.

**Responding by “3”** requires that the guideline provides information about the funding or supporting organisation and details about how the guideline work has been funded.

**Responding by “Strongly Agree” “4”** requires that apart from naming the funding and / or supporting bodies the guideline must contain information about the nature and volume of the funding. This should take the form of an explicit statement pointing out that no influence on the contents of the guideline has been exercised by the funding and/or supporting bodies. The information may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

**23. Conflicts of interest of the members of the guideline development group have been recorded.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Each member of a guideline development group has different professional and private interests and affiliations so that conflicts of interest may occur (e.g., if recommendations in the guideline deviate from the guideline developer's own scientific results). This also applies if the author's own research is supported by a pharmaceutical company and conducted in a field referred to by the guideline.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not address any potential conflicts of interest.

**Responding by “2”** requires that the guideline contains a global statement confirming that the financial support does not exert any influence on the guideline work.

**Responding by “3”** requires that the guideline contains a statement about a potential conflict of interest providing details about the aspects asked for (e.g., by means of a standardised form).

**Responding by “Strongly Agree” “4”** requires that the procedure for identifying potential conflicts of interest is explicitly stated in the guideline, including its results. This information may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

## Domain 7: Applicability to the German Healthcare System

### 24. There are recommendations for preventive, diagnostic, therapeutic, and rehabilitative measures for different areas of care.

Strongly Disagree

1	2	3	4
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Strongly Agree

Depending on its area of application and its objectives, a guideline may contain recommendations for various health care settings or treatment contexts. These may be addressed directly, which means that the area addressed is fully covered by the objectives and definitions of the guideline and its content is in full compliance with the guideline topic; or they may be indirectly addressed as interfaces, which are essentially the following areas of care: diagnosis, prevention and health promotion, primary or secondary ambulatory care, hospital services, ambulatory or inpatient rehabilitation.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain recommendations for decisions that are specific to different areas of care.

**Responding by “2”** requires that the guideline contains fundamental recommendations for decision-making that clearly distinguish between the “possibility of outpatient treatment” or the “need for inpatient treatment”.

**Responding by “3”** requires that the guideline contains clear information about key recommendations for the decision about the “possibility of outpatient treatment” or the “need for inpatient treatment”. These also comprise (if indicated) the area of rehabilitation.

**Responding by “Strongly Agree” “4”** requires that the guideline generally contains recommendations for decision-making with respect to different areas of care. These cover all relevant areas and, if possible, are supported by trial results. They may also address indirect interfaces. The information should clearly define the area of care to which a patient under certain conditions (stage of disease or problem constellation) will have to be primarily assigned (e.g., management of patients after cardiac transplantation by an outpatient clinic or an office-based cardiologist, management of patients with mild asthma by a GP, cases with severe asthma or special forms of asthma by a pneumologist; indications for ambulatory or inpatient rehabilitative measures).

**25. There is information as to which measures seem to be unsuitable, redundant or outdated.**

Strongly Disagree

1	2	3	4
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Strongly Agree

The recommendations of evidence-based guidelines, which are supported by current data about diagnosis, treatment, etc., refer to necessary and reasonable measures. Concerning the objectives of the guideline, the appraisal of studies and other sources provides a sound basis for also addressing unsuitable, redundant or outdated measures. If possible, a guideline should not only describe the recommendations to be newly implemented but also point out those recommendations that should no longer be regarded as valid. As these may add excessive volume to the guideline, only the most relevant ones (such as clearly outdated measures) should be mentioned in the guideline itself; others can be included in a guideline report.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain references to unsuitable, redundant or outdated measures.

**Responding by “2”** requires that the guideline contains references to unsuitable, redundant or outdated measures.

**Responding by “3”** requires that the guideline contains references to unsuitable, redundant or outdated measures including information about the respective grades of recommendation.

**Responding by “Strongly Agree” “4”** additionally requires that information is provided about the systematic search and appraisal of the relevant literature that has been carried out. These details may be provided by the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline.

**26. The clinical information of the guideline is organised in such a way as to ensure that the process of clinical decision-making is systematically presented and easily understandable.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Guidelines should reflect the process of clinical decision processes in health care. A precisely defined problem should be presented in such a way that the guideline provides an answer to a clear question about a specific clinical situation. Decision situations and action recommendations leading to a definitive solution (the desired outcome) should be presented using conditional logic in terms of IF-THEN statements (so-called “clinical algorithms”).

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not present the information in such a way that the clinical decision process is logically structured and easily understood.

**Responding by “2”** requires that the guideline presents the clinical information in such a way that the decision process can easily be understood.

**Responding by “3”** additionally requires that reproducibility of the decision process is facilitated by tabular or graphic presentation (flow charts).

**Responding by “Strongly Agree” “4”** additionally requires the presentation of relevant decision situations necessitating deviation from the regular course (branching points, e.g., occurrence of emergency situations) and alternative care processes (e.g., in emergencies or different areas of care).

**27. A strategy / concept for the easy accessibility and dissemination of the guideline is presented.**

Strongly Disagree

1	2	3	4
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Strongly Agree

As the publication of a guideline in, for example, medical journals only will not reach all the target users, its dissemination through different channels is reasonable in order to achieve broad accessibility. Guideline accessibility may be enhanced by making them freely available on the Internet (e.g., by posting them onto relevant guideline databases) or disseminating them as special inserts through the official platforms of user groups. The publication of a guideline should be broadly announced. Also, the guideline should contain ordering notes for all versions available to directly alert the user to additional material.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not include a concept of easy accessibility / dissemination.

**Responding by “2”** requires that the guideline itself is easily accessible, i.e., published accessibly (e.g., in print media).

**Responding by “3”** requires that except for the print version the guideline plus supplementary material is accessible in at least one ubiquitously and rapidly available version. For example, this may be a PDF file of the print version available free of charge, if possible.

**Responding by “Strongly Agree” “4”** requires that the guideline plus supplementary material has been published on an open, global platform. It contains references to all versions and informational sources available.



**28. A concept for implementing the guideline is described.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Implementation means putting recommendations into practice (i.e., individual action and / or behaviour of physicians and other healthcare providers, of patients and other affected persons) [25]. A successful transfer usually requires the combination of different complementary strategies in the sense of a complex concept.

These include considerations about how recommendations can be transferred to established institutions and groups, such as quality circles and consumer groups, and how they can be incorporated into daily practice or clinical information systems in order to ensure their immediate availability during patient encounters. Another element of the implementation concept is the integration of guidelines into medical training and continuous medical education programmes for physicians and other health care professionals.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not suggest/present an implementation concept.

**Responding by “2”** requires that the guideline presents a general implementation plan.

**Responding by “3”** requires that by providing a detailed implementation plan the guideline ensures the involvement of relevant users, for example, other groups of physicians who regularly treat or are involved in the treatment of the addressed patients.

**Responding by “Strongly Agree” “4”** additionally requires an explanation of how the guideline is to be integrated into both medical training and continuing medical education programmes. In addition, the implementation plan includes a feedback mechanism in order to monitor the implementation process and to identify potentials for improvement.

**29. The guideline is supplemented by a description of the methods used (guideline report).**

Strongly Disagree

1	2	3	4
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Strongly Agree

The methodological and content-related work of guideline authors / developers is very demanding and must possibly be run in different groups through repetitive consultation and decision processes.

All decisions made during the development process concerning recommendations must be explained to the future user so as to ensure the reproducibility of the decisions and thus the applicability of the guideline. This is of particular importance in the case of decisions leading to the acceptance or refusal of recommendations.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not provide information about the methods used for the development of the guideline.

**Responding by “2”** requires that the methodological steps taken during the development of the guideline are summarised in such a way as to ensure the reproducibility of the individual working and decision processes.

**Responding by “3”** requires that the methodological steps taken are presented in such a way as to ensure the reproducibility of all the essential working and decision processes.

**Responding by “Strongly Agree” “4”** requires that a detailed guideline report is available providing comprehensive information about the decision basis, all decision processes and also on the exclusion of recommendations. It also includes information on contents, the names of all attending persons, polling outcomes and voting results of the guideline meetings.

## Domain 8: Methodological Rigour of Development when Using Existing Guidelines

### Instructions for Use:

Guidelines may – to various degrees – include recommendations that have been developed on the basis of existing guideline recommendations as well as recommendations that have been developed on the basis of systematically searched primary studies, systematic reviews and meta-analyses.

The development of guideline recommendations on the basis of existing guidelines will have to meet specific quality criteria. The items of Domain 8 are to be assessed if:

- the guideline authors have indicated that they have systematically considered existing guidelines (incl. searches for existing guidelines) for the development of their own guideline recommendations, or if
- it is obvious to the guideline appraisers that other guidelines were used as a source of evidence in the development of the new guideline.

### 30. Systematic methods were used to search for existing guidelines.

Strongly Disagree

1	2	3	4
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Strongly Agree

When searching for existing guidelines the most essential quality criterion is that the search be conducted in a systematic and transparent manner and properly specified. The search strategy used to identify existing guidelines should be described in detail; this description comprises a list of the search terms used and the sources consulted as well as information on the time period covered. The sources may include electronic bibliographical databases such as MEDLINE, EMBASE, CINAHL and / or guideline databases (e.g., [www.awmf-leitlinien.de](http://www.awmf-leitlinien.de), [www.leitlinien.de](http://www.leitlinien.de), [www.g-i-n.net](http://www.g-i-n.net), [www.guideline.gov](http://www.guideline.gov)).

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not contain any information about the search for existing guidelines.

**Responding by “2”** requires that a description of the methods used to search for existing guidelines must at least indicate that a systematic approach has been applied.

**Responding by “3”** requires that a systematic search of databases has been mentioned. The names of the databases consulted must be specified.

**Responding by “Strongly Agree” “4”** requires that, in addition to information on the systematically searched databases, details are included about the search terms used, the search history, the time period covered and, if applicable, the use of further sources. This information may be provided in the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

**31. The criteria for selecting guidelines as a source of evidence (so-called source guidelines) are transparently and explicitly described.**

Strongly Disagree

1	2	3	4
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Strongly Agree

In common daily practice, not all available guidelines will be used as a source of evidence; instead, only particular guidelines (so-called source guidelines) will be included.

Depending on the scope of application for which a guideline is valid (e.g., supra-regional / regional; hospital / practice or cross-sectoral), different criteria (relevance, methodological quality, generalisability, editorship, uniqueness, validity, experience with implementation) may be applied in selecting the source guidelines. These criteria should be explicitly stated. In particular, the reasons for excluding (a) guideline(s) must be clearly defined.

**The statement must be responded to by “Strongly Disagree” “1”** if no criteria have been provided for the particular choice of source guidelines.

**Responding by “2”** requires that the reasons for including and / or excluding guidelines are explicitly outlined.

**Responding by “3”** requires that the reasons for including or excluding a guideline must be explicitly stated separately for each guideline.

**Responding by “Strongly Agree” “4”** requires that the reason(s) for the inclusion or exclusion of the individual guidelines must be explicitly described. As far as the included and excluded guidelines are concerned, this decision must be supported by a formal appraisal which should be conducted using an approved instrument (e.g. AGREE, DELBI). As far as possible, the results of this appraisal should be presented on a comparative basis, either in the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

### 32. The quality of the source guidelines was reviewed.

Strongly Disagree

1	2	3	4
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Strongly Agree

If a recommendation has been derived from existing guidelines (so-called source guidelines) the quality of the underlying recommendations needs to be reviewed. This includes the systematic, tabular comparison of the recommendations in the source guidelines (specifying, if possible, the levels of evidence and grades of recommendation) and the literature underlying these source guidelines. The guideline authors should also have verified whether the recommendations in the source guidelines are fully covered by the literature cited in the respective source guideline.

**The statement must be responded to by “Strongly Disagree” “1”** if the authors failed to both systematically present the recommendations of the source guidelines and to review the literature underlying these recommendations.

**Responding by “2”** requires that the recommendations of the source guidelines have been presented and, if possible, specify the levels of evidence and grades of recommendation. If several source guidelines have been used this information must be displayed in a tabular comparative format.

**Responding by “3”** requires that the recommendations of the source guidelines are presented together with the respective levels of evidence and grades of recommendation and the underlying literature of the source guideline. If several source guidelines were used this information must be displayed in a tabular comparative format.

**Responding by “Strongly Agree” “4”** additionally requires that the guideline authors have specified that the underlying literature cited in the source guideline was verified. This information can either be included in the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

**33. The evidence base of the source guidelines was complemented by systematic update searches of primary evidence.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Update searches need to be performed if there is any indication that the evidence in the guidelines used as a source of evidence (so-called source guidelines) no longer reflects the current evidence base.

The search strategy used to identify the evidence should be described in detail; this description comprises a list of the search terms used and the sources consulted as well as information on the time period covered. These sources may include electronic bibliographical databases such as MEDLINE, EMBASE, CINAHL, databases of systematic reviews (e.g., The Cochrane Library, DARE), manually searched journals as well as conference proceedings.

**The statement must be responded to by “Strongly Disagree” “1”** if the guideline does not include any information about update searches.

**Responding by “2”** requires that the description of the methods used to perform update searches must at least indicate that a systematic procedure has been applied.

**Responding by “3”** requires that the guideline must specify the methods used to perform update searches, including details of the search terms used and the databases consulted.

**Responding by “Strongly Agree” “4”** requires that the guideline contains a complete specification of the search methods, including the search terms used and the databases consulted and, if applicable, further sources as well as details of the search results (at least the number of hits) and the time period covered. Any search limitations must be explicitly defined. Assigning a “4” rating is also acceptable when a plausible explanation - based on the appraisal of the source guidelines - has been provided that there was no need to conduct update searches. Details of the update searches can either be included in the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.

**34. All modifications to the recommendations of the source guidelines are clearly specified and accounted for.**

Strongly Disagree

1	2	3	4
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Strongly Agree

Using existing guideline recommendations to generate an evidence-based recommendation requires a clear identification of the extent to which the newly developed recommendations correspond to those of the source guidelines. Any modification to or (unchanged) adoption of recommendations from source guidelines should be accounted for. A recommendation will be regarded as “modified” if the wording of the recommendation is different from the wording in the source guideline.

**The statement must be responded to by “Strongly Disagree” “1”** if no information is provided about any modification to or adoption of existing recommendations.

**Responding by “2”** requires that any modification to or adoption of existing recommendations must be denoted, or it must be explicitly indicated that no modifications have been made.

**Responding by “3”** requires that any modification to and / or adoption of existing recommendations must be denoted and partly accounted for.

**Responding by “Strongly Agree” “4”** requires that any modification to and / or adoption of existing recommendations must be denoted and fully accounted for. This information can either be included in the guideline itself or in a guideline report (see item 29). The guideline report must clearly be indicated in the guideline. According to these requirements the description in a guideline report must individually refer to the respective guideline; it is not sufficient to provide basic information only.



**DELBI - Short Version**

<b>German Instrument for Methodological Guideline Appraisal (DELBI)</b>					
<b>Version: June 2005 + Domain 8 (2008) – Short Version</b>					
<b>Domain 1: Scope and Purpose</b>		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
1	The overall objective of the guideline is specifically described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	The clinical questions / problems addressed by the guideline are specifically described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	The patients to whom the guideline is meant to apply are specifically described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Domain 2: Stakeholder Involvement</b>		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
4	The guideline development group includes members from all relevant professional groups.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	The patients' views and preferences have been sought.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	The target users of the guideline are clearly described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	The guideline has been piloted among target group members.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Domain 3: Methodological Rigour of Development</b>		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
8	Systematic methods were used to search for evidence.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	The criteria for selecting the evidence are clearly described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	The methods used for formulating the recommendations are clearly described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Health benefits, side effects and risks have been considered in formulating the recommendations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	There is an explicit link between the recommendations and the supporting evidence.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	The guideline has been externally reviewed by experts prior to its publication.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	A procedure for updating the guideline is provided.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Domain 4: Clarity and Presentation</b>		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
15	The recommendations of the guideline are specific and unambiguous.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	The different options for the management of the	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>German Instrument for Methodological Guideline Appraisal (DELBI)</b>				
<b>Version: June 2005 + Domain 8 (2008) – Short Version</b>				
	condition are clearly presented.			
17	Key recommendations of the guideline are easily identifiable.			
18	The guideline is supported with tools and / or materials for application.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Domain 5: General Applicability</b>		<b>1</b>	<b>2</b>	<b>3</b>
19	The potential organisational barriers in applying the recommendations have been discussed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	The potential cost implications of applying the recommendations of the guideline have been considered.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21	The guideline presents key review criteria for monitoring and / or audit purposes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Domain 6: Editorial Independence</b>		<b>1</b>	<b>2</b>	<b>3</b>
22	The guideline is editorially independent of the funding organisation(s).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	Conflicts of interest of the members of the guideline development group have been recorded.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Domain 7: Applicability to the German Healthcare System</b>		<b>1</b>	<b>2</b>	<b>3</b>
24	There are recommendations for preventive, diagnostic, therapeutic and rehabilitative measures in different areas of care.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25	There is information as to which measures seem to be unsuitable, redundant or outdated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	The clinical information of the guideline is organised in such a way as to ensure that the process of clinical decision-making is systematically presented and easily understandable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	A strategy / concept for the easy accessibility and dissemination of the guideline is presented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	A concept for implementing the guideline is described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29	The guideline is supplemented by a description of the methods used (guideline report).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Domain 8: Methodological Rigour of Development when Using</b>		<b>1</b>	<b>2</b>	<b>3</b>

<b>Existing Guidelines</b>					
30	Systematic methods were used to search for existing guidelines.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31	The criteria for selecting guidelines as a source of evidence (so-called source guidelines) are transparently and explicitly described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32	The quality of the source guidelines was reviewed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33	The evidence base of the source guidelines was complemented by systematic update searches of primary evidence.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34	All modifications to the recommendations of the source guidelines are clearly specified and accounted for.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Rating 1: Strongly Disagree</b> <b>Rating 4: Strongly Agree</b>					

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