

## **Methodology for the Preparation and Revision of Guidelines from the German Diabetes Association (DDG)**

The scientific and political legitimation of evidence-based consensus guidelines is high [Ollenschläger et al., 2000]. This probably explains the high acceptance of this type of guideline in comparison with others [Cabana et al., 1999; Klazinga et al., 1994]. The EBM strategy for the development of the existing guidelines followed the procedure defined by AHCPR and SIGN (see Table 1).

The methodological approach for the guideline development process attempts to meet the requirements of evidence-based medicine. It is based upon nationally and internationally accepted quality criteria that were defined by the Agency for Health Care Policy and Research [AHCPR, 1992], the Evidence-Based Medicine Working Group [Hayward et al., 1995], the Scottish Intercollegiate Guidelines Network [SIGN, 1999], the German Association of the Scientific Medical Societies [AWMF, 2004] and the German Agency for Quality in Medicine [ÄZQ, 1999]. A detailed description has been published separately ([www.leitlinien.de](http://www.leitlinien.de), [www.aezq.de](http://www.aezq.de)).

### **Selection of the Experts**

For each guideline, the managing committee and the guidelines commission of the DDG have established panels of experts composed of recognised authorities in the relevant fields.

### **Literature Search**

Dr. B. Richter is responsible for the coordination between the expert panel and the work group in the selection of the literature search terms.

For each project group, a complete search strategy of medium sensitivity is developed for the Ovid-operated MEDLINE database, for example, and later adapted to the Cochrane Library and Embase. If necessary, a supplementary search in other databases is conducted.

The list of references obtained from the various databases are checked for duplicates by using a bibliographic programme, sorted according to publication year, and converted into PDF files. The titles and abstracts are sent to the experts per e-mail.

Definition of the original papers to be procured for the experts.

To guarantee transparency and reproducibility of the literature search, the search strategies and terms are published in the appendix of every guideline.

### **Appraisal and Evaluation**

Experienced physicians and biometrists classify the studies and analyses of study designs on the basis of their scientific conclusiveness into levels of evidence I-IV as proposed by AHCPR and SIGN (see Table 1). When opinions diverged, the case is discussed and classified by consensus. Evidence is evaluated according to internationally accepted quality criteria (see above). Clinical studies are divided into different levels corresponding to their scientific validity and significance and, additionally, weighted according to their clinical relevance. For example, meta-analyses of randomised controlled clinical studies and randomised controlled studies receive the highest ranking.

The weighting of the final intervention recommendations (screening, prevention, diagnosis, treatment and rehabilitation) with strengths of recommendation A to C is undertaken by clinically experienced experts based on the supporting evidence and clinical relevance.

In areas in which the clinical evidence must be weighted differently from the scientific evidence, the strength of recommendation is determined by interdisciplinary consensus (see Table 2).

Recommendations for which there is insufficient or no external evidence available, but are known to be indispensable from clinical experience, could receive the highest strength of recommendation A.

In contrast, interventions for which levels of evidence Ia or Ib exist, could receive the lowest strength of recommendation if their clinical significance is only marginal. The necessary transparency is achieved through the linking of both the supporting external evidence and the strength of recommendation to the respective recommendations (see Table 1).

### **Preparation Process**

After the conclusion of the systematic literature search by the Cochrane Metabolic and Endocrine Disorders Group and peer review by the experts, a draft version of the guidelines is formulated based on the core statement of the documented and evaluated publications.

Additionally, internal evidence (unpublished results of studies, experience of experts) from rounds of discussions with competent experts and experts from related disciplines, are integrated into the draft version.

The discussion draft, after checking for practicability and plausibility and revision, is published in the web site of the DDG. Thus, the draft is presented to a wider forum for critical evaluation with a call for active participation in the compilation of the guidelines through the contribution of comments, supplementary information and suggestions for modifications.

All suggestions received before printing are discussed by the expert group and are taken into consideration commensurate with their relevance.

The diabetes guidelines are examined again by the guideline commission and adopted by the managing committee of the DDG.

Each evidence-based diabetes guideline is first published in the journal "Diabetes and Metabolism;" each actualisation is published in the web site of the DDG ([www.deutsche-diabetes-gesellschaft.de](http://www.deutsche-diabetes-gesellschaft.de)).

**Table 1)**

Published papers are classified into levels of evidence based on their scientific validity [modified according to AHCPR, 1992; SIGN, 1996]

<b>Levels of Evidence (level)</b>	
<b>Ia</b>	Evidence based on meta-analyses of randomised controlled studies
<b>Ib</b>	Evidence based on at least one randomised controlled study
<b>IIa</b>	Evidence based on at least one well-planned, nonrandomised controlled study
<b>IIb</b>	Evidence based on at least one well-planned, nonrandomised and not controlled clinical study, e.g., cohort study
<b>III</b>	Evidence based on well-planned, nonexperimental, descriptive studies, such as e.g., comparative, correlation, or case-control studies
<b>IV</b>	Evidence based on reports from expert committees or expert opinions and/or clinical experience of recognised authorities

**Table 2)**

Weighting and recommendation with strengths of recommendation [modified according to AHCPR, 1992; SIGN, 1996]

<b>Strength of Recommendation</b>	<b>Supporting Evidence</b>
A	Level of evidence Ia, Ib or from the clinical point of view first class
B	Level of evidence IIa, IIb, III or from the clinical point of view second class
C	Level of evidence IV or from the clinical point of view third class

### **Further Development of Guidelines**

The existing guidelines are scientifically valid guidelines on the selected priority diseases. Important information: The diabetes guidelines do not include diagrammatic procedural instructions and algorithms. This function is fulfilled by the clinical practise guidelines, which are based on the scientific guidelines and contain all guideline-relevant aspects for practical implementation including algorithms (clinical practise guidelines of the German Diabetes Association, 2001). Furthermore, a patient version has been drawn up, in which these recommendations are explained in language easily understood by patients and which is available in the internet ([www.diabetes-deutschland.de](http://www.diabetes-deutschland.de)).

### **Internationalization of Guidelines**

The internationalization of the German guidelines constitutes an important development. This includes consideration of European guidelines within the German guidelines as well as translation of the German versions and their implementation in other European countries and beyond.

In the context of internationalization two German guidelines already have been translated into English, among them "Psychosocial Aspects of Diabetes" and "Diagnosis, Therapy and Long-term Management of Neuropathy Type 1 and Type 2 Diabetes mellitus". A proper and scientifically correct translation was assured by hiring a scientist whose native language is English, by proof reading through experts

from the guidelines expert committee and by authorizing the translation through the speaker of the expert committee. Furthermore the guideline "Nutrition and Diabetes mellitus", which has been developed in coordination with the German Diabetes Society (DDG) is already available as an English language European version, has now been translated into German.

The evidence-based guidelines are valid until May 2007.  
The diabetes guidelines will be updated in a timely manner should new and relevant scientific findings become available.

### **Financing of the Guidelines**

These guidelines were prepared by the scientific medical association (German Diabetes Association) independent of interest groups.

They are financed with funds from the German Diabetes Society and the National Diabetes Action Forum (Nationales Aktionsforum Diabetes, NAFDM), which is coordinated by the German Diabetes Union (Deutsche Diabetes-Union). A portion of the funds was raised from membership dues and donations and from the fees paid by companies for their exhibits at the annual DDG congress. Additional funds were raised as uncommitted donations to the DDG from the German Industry Forum for Diabetes (IFD).

All experts worked voluntarily and received no remuneration. Travel and offices expenses were reimbursed according to the directives of the DDG, which are based on prevailing university guidelines.

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