

**National Programme for
Disease Management Guidelines**
under the auspices of the
German Medical Association



**National Disease Management
Guidelines**

Method Report

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Masthead

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Table of Contents

Masthead	2
Table of Contents	2
1. Definitions	3
2. Programme Justification	3
3. Objectives of Disease Management Guidelines	3
4. Target Groups	4
5. Authors/Editors	4
6. Responsible Body/Financing	4
7. Topic Selection	4
8. Guideline Development and Consensus Process	4
9. Identification and Interpretation of Evidence	5
10. Evaluation of Methods and Content	6
11. Pharmaco-Economic Aspects	6
12. Versions	6
13. Updating	7
14. Dissemination and Implementation	7
15. Evaluation	7
16. References	7



1. Definitions

- A disease management guideline is a "systematically developed statement to assist with decisions about appropriate health care for specific circumstances". It is meant to facilitate orientation in the sense of "treatment and decision pathways", from which deviation is allowed or, in reasonable cases, even recommended.
- A disease management guideline should neither be regarded as an instruction for a misunderstood „standardised health care“ (the so-called "cookbook medicine") nor does it reflect the attitudes of individual specialists or experts. Rather, a guideline represents a consensus reached by a multidisciplinary panel of experts according to well-defined and transparent procedures for specific clinical approaches. The consensus is based upon a systematic search and analysis of the existing literature.
- **It is possible that the recommendations of a disease management guideline cannot be employed usefully in all circumstances. Whether to follow a certain recommendation or not must be decided by the individual health care provider, taking into account both the individual patient situation and the resources available.**
- A disease management guideline will take effect only if its recommendations are being considered in the care of the individual patient. As a national guideline, it will have to be reviewed for its applicability on a regional or local level and adapted, if necessary.
- **A disease management guideline is expressly not intended to constitute a directive, i.e. a regulation controlling action or failure to act, which has been approved, laid down in writing and published by a legally authorised institution and is binding upon this institution's legal sphere of action. Non-compliance would entail specific sanctions.**
- The development of guidelines within the scope of the National Programme for Disease Management Guidelines under the auspices of the German Medical Association will be based essentially on consideration of the "Evaluation Criteria for Clinical Practice Guidelines – as approved by the Boards of the German Medical Association and the National Association of Statutory Health Insurance Physicians, June 1997" (1), the „Guideline Manual“ of AWMF and AQuMed (2) and the recommendations of the Guideline-Clearing-Project of AQuMed (3).

2. Programme Justification

Prompted by consultations with the Co-ordinating Committee according to Sect. 137 f of the Fifth Book of Social Code on the definition of requirements for disease management programmes, the German Medical Association will be patron of the „National Programme for Disease Management Guidelines under the auspices of the German Medical Association (DMG)“.

Disease management programmes should be based on uniform treatment recommendations. So far, German evidence-based consensus guidelines required for that purpose have not been available in all respects. The National Programme for Disease Management Guidelines provides the conceptual basis for disease management programmes and ensures that regular updates reflect the currently best available state of medical knowledge according to the criteria of evidence-based medicine.

3. Objectives of Disease Management Guidelines

The National Programme for Disease Management Guidelines focuses on both the development and implementation of certain consented key recommendations of German guidelines and evidence-based treatment recommendations for specific prioritised problems of health care issued by various organisations. In particular, it is meant to promote the application of evidence-based treatment recommendations in patient care that have been developed by the Scientific Medical Societies, the German Drug Commission of the German Medical Profession as well as other authors. And special



emphasis is placed on the demands made by those institutions that are responsible for using evidence-based guidelines in the development of criteria of care and / or programmes for structured health care delivery (Disease Management Programmes) according to the Fifth Book of Social Code.

4. Target Groups

Primarily, disease management guidelines are directed at all practising clinicians in Germany. They also serve to inform the general public.

In addition, disease management guidelines are explicitly targeted to guideline editors, as they provide a common basis for the development of both future and further guidelines as well as related products (e.g. practice versions, patient information, CME measures).

5. Authors/Editors

Editors and authors of guidelines and evidence-based treatment recommendations contributing to the development of national guidelines for a specific health care topic will be invited by the President of the German Medical Association to attend a first co-ordinating meeting. In general, contact will be both the Association of Scientific Medical Societies (AWMF) or the relevant medical society and the Drug Commission of the German Medical Profession. In advance, though, an internal agreement between the scientific medical society and the respective professional association must be reached on the issue of responsibility. The primary aim of this agreement is to clarify whether the various authors / editors are able to obtain a consensus about the development of a common National Disease Management Guideline with the German Medical Association as moderator.

6. Responsible Body/Financing

It will be the task of the Agency for Quality in Medicine to co-ordinate, edit and maintain the disease management guidelines developed within the scope of the National Programme for Disease Management Guidelines under the auspices of the German Medical Association. Basic financing for AQuMed is provided equally by the German Medical Association and the National Association of Statutory Health Insurance Physicians.

Specific costs of the National Programme for Disease Management Guidelines (such as co-ordination, editorial work and maintenance) will be paid by the German Medical Association. The guideline editors will both cover the experts' travel expenses and the costs of disseminating the disease management guidelines.

7. Topic Selection

Selection of topics for the development of a National Disease Management Guideline will mainly be instigated by recommendations passed by the Co-ordinating Committee in accordance with Sections 137 e and f of the Fifth Book of Social Code.

8. Guideline Development and Consensus Process

According to a decision of the Board of the German Medical Association the following criteria for the development of a disease management guideline will have to be met:



- Consideration of the guideline methodology adopted by AWMF and AQuMed [Association of Scientific Medical Societies in Germany (AWMF), Agency for Quality in Medicine (AQuMed). The German Guideline Manual (German, English abstracts) *Z aerztl Fortb Qual sich* 2001; **95 Suppl. I**: 1-84]
- Consideration of the criteria of evidence-based medicine [Sackett DL, Richardson WS et al. Evidence based Medicine – German Edition. Germering 1999, Kunz R, Ollenschläger G et al. Lehrbuch Evidenzbasierte Medizin in Klinik und Praxis. Cologne 2000]
- Consideration of the recommendations of the German Guideline-Clearing-Project of AQuMed
- Presentation of the evidence underlying the key recommendations of the disease management guideline
- Compliance with the formal instructions of the German Medical Association for the publication of disease management guidelines
- An advance internal agreement between the scientific medical societies and the respective professional associations concerning the issue of responsibility is mandatory.
- Common authorship of the German Medical Association and the editors of guidelines and / or evidence-based treatment recommendations underlying the disease management guideline.

The consensus process developing between authors, editors, external experts and / or potential users of a disease management guideline will be moderated by neutral experts.

In general, decisions must be unanimous. If consensus cannot be obtained, differing votes will have to be disclosed by providing authorship details and underlying evidence. The course of the consensus-building process with respect to time frames and content as well as vote results must be laid down in a protocol.

The German Medical Association will delegate the organisational realisation of the National Programme for Disease Management Guidelines to the Agency for Quality in Medicine (AQuMed). It must be ensured that no competing interests exist between the National Programme for Disease Management Guidelines and the German Guideline Clearinghouse established at AQuMed.

9. Identification and Interpretation of Evidence

Reflections on the retrieval of evidence for a disease management guideline must start with the clinical question for which relevant statements the presentation of evidence levels from the literature appears desirable and / or necessary. Subsequently, a search of international databases for literature and guidelines such as Medline, the Cochrane Library, DrugdexR, www.leitlinien.de is to be performed. The search results will then be selected according to inclusion and exclusion criteria which derive from the specific clinical question. The assessment of trials must take into account generally valid biometric requirements such as suitability of main outcome measures as far as statement, adequate sample sizes, representativeness of the study population, clinically relevant dosages and the significance of outcomes are concerned. In general, systematic errors might be encountered at the level of information selection and assessment. Evidence is classified according to four levels. The search strategy and evaluation of the evidence will be explained in the long version of a disease management guideline.

Classification for key recommendations according to levels of evidence) [Association of Scientific Medical Societies in Germany (AWMF), Agency for Quality in Medicine (AQuMed). The German Guideline Manual



(German, English abstracts) *Z aerztl Fortb Qual sich* 2001; **95 Suppl. I**: 1-84 , p 41]

Grade

Statements of Evidence

I a

Evidence obtained from meta-analysis of randomised controlled trials

I b

Evidence obtained from at least one randomised controlled trial

II a

Evidence obtained from at least one well-designed controlled study without randomisation

II b

Evidence obtained from at least one other type of well-designed quasi-experimental study

III

Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies

IV

Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

10. Evaluation of Methods and Content

Disease management guidelines must undergo appraisal within the scope of the German Guideline Clearinghouse that has been established by the health care self-governing bodies at AQuMed. In addition, these guidelines will be published in peer-reviewed journals.

11. Pharmaco-Economic Aspects

The National Programme for Disease Management Guidelines recognises the importance of cost aspects as defined by appropriate provision of health care within the framework of statutory health insurance. While quality assurance will always be the absolute priority, the National Programme for Disease Management Guidelines does not close its mind to questions of efficiency, as far as the latter, for the benefit of patients, is compatible with the principles of rational diagnosis and therapy. National disease management guidelines have implicit saving potentials, for in the long term a rational drug therapy will usually turn out to be also an efficient therapy. As far as the implementation of benefit-cost analyses is concerned it needs to be emphasised, though, that due to a lack of sufficient data for the majority of treatment interventions a reliable assessment of economic implications seems to be hardly feasible.

12. Versions

National disease management guidelines consist of a

1. **short version** that is meant to explain key topics of care and care recommendations, on which the editors of underlying guidelines have obtained a consensus, to identify the underlying



guidelines and specify the date of updating.

2. **long version**, which in addition to the content of the short version includes a reference collection and the guideline methodology. The „reference collection“ comprises a compilation of full texts and the evidence of underlying guidelines including a specification of the search strategies, a consistent classification of the evidence and the methods used to develop the guidelines.

13. Updating

Disease management guidelines should be reviewed, updated and edited every two years. If novel and relevant findings require an updating of recommendations the organisation responsible for the maintenance of guidelines will immediately make an announcement on its website (Agency for Quality in Medicine - www.azq.de). Maintenance and updating of disease management guidelines are the responsibility of AQuMed.

14. Dissemination and Implementation

The dissemination and implementation of disease management guidelines is the editors' responsibility.

15. Evaluation

The aim is to evaluate disease management guidelines with respect to their influence on drug prescription, their costs and impact on various treatment targets within the scope of the Disease Management Programme in accordance with Sections 137 f and g of the Fifth Book of Social Code.

16. References

1. German Medical Ass., Nat. Ass Statutory Health Insurance Physicians (BAEK / KBV) German Guideline for Clinical Practice Guidelines (Beurteilungskriterien für Leitlinien in der medizinischen Versorgung). *Dtsch Arztebl* 1997; **94**: A2154-2155, www.leitlinien.de (in English)
2. Association of Scientific Medical Societies in Germany (AWMF), Agency for Quality in Medicine (AQuMed). The German Guideline Manual (German, English abstracts) *Z aerztl Fortb Qual sich* 2001; **95 Suppl. I**: 1-84, www.leitlinien.de
3. Agency for Quality in Medicine (AQuMed) commissioned by BAEK, KBV, DKG, GKV, PKV, RV. Guideline Clearing Reports. www.leitlinien.de (German, English: Hypertension, Abstracts of all reports). Schriftenreihe der ÄZQ (German)