



National Programme for Disease Management Guidelines

Responsible agencies:

German Medical Association

National Association of Statutory Health Insurance Physicians

Association of the Scientific Medical Societies

Organisation:

German Agency for Quality in Medicine (AQuMed/AEZQ)

Method Report

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R 1. Objectives and basic principles of the National Disease Management Programme [NDMG Programme]

1.1 Rationale

Medical guidelines are an important instrument to promote quality and transparency in health care. The specific function of guidelines is

- to present scientific evidence and practical experience relating to specific disease management problems;
- to carry out methodological and clinical evaluation;
- to clarify opposing views;
- to define the current approach of choice balancing the benefits and harms;
- to promote good clinical practice taking account of the available resources and to provide the general public with relevant information.

The objective is to place decision making in medical care on a more rational basis and to strengthen the position of the patient as a partner in the decision-making process. Guidelines have already become an essential part of the daily clinical routine and in the future will increasingly influence diagnostic and/or therapeutic actions.

This is the background against which the members of the Association of the Scientific Medical Societies (AWMF) and the self-governing bodies of the medical profession (GMA and NASHIP) have been developing guidelines over many years. These guidelines generally focus on specific disease situations and defined subareas of healthcare provision and only rarely specify an organisational framework for patient care. In order to promote the interlinking of medical services into integrated cross-sectoral care structures (e.g. integrated care (IC) contracts, Disease Management Programmes (DMP)), guidelines are required to complement these aspects and offer solutions for interfaces between various sectors, including interdisciplinary solutions involving all the relevant healthcare professions ("disease management guidelines").

For this reason, at the initiative of the German Medical Association, the GMA, NASHIP and AWMF contractually agreed in 2003 on joint sponsorship of the National Disease Management Programme (NDMG Programme). The Programme is coordinated by the German Agency for Quality in Medicine (AQuMed) [1-3].

1.2 Objectives

The NDMG Programme focuses on the development and implementation of *multidisciplinary care guidelines* for selected diseases with a high prevalence and takes account of the principles of evidence-based medicine. In particular, the content of the National Disease Management Guidelines serves as the basis for the development of concepts of structured and integrated care [4].

The primary objectives of the **NDMG** Programme are:

- distribution of evidence-based and formally consented recommendations on interdisciplinary approaches for specific diseases;
- preparation of proposed solutions for interfaces both between different disciplines and between different healthcare sectors (primary prevention – secondary prevention – treatment – rehabilitation);
- distribution of NDMG based quality indicators (QI);
- distribution of high quality patient information through patient guidelines;
- widest possible implementation of the NDMG recommendations and quality indicators;
- consideration of NDMG recommendations through integrated care contracts or contracts for structured disease management programmes;
- consideration of NDMG recommendations in medical training, continuing medical training and specialist medical training, as well as in quality management systems.

In this way the quality of care should be improved and the position of the patient strengthened. It is also anticipated that consideration of the recommendations will result in increased efficiency in the healthcare system (Council of Europe 2002) [5].

1.3 Definitions

- National Disease Management Guidelines (NDMG) are “systematically developed statements to assist decision making about appropriate healthcare strategies for specific clinical problems within the framework of structured medical care”. They are intended to provide guidance in the sense of “treatment and decision pathways” from which deviation is permitted or, in justified cases, even recommended.
- The decision on whether to follow a particular recommendation must be taken by the clinician, taking into account individual patient circumstances and available resources [5].
- National Disease Management Guidelines only become effective when their recommendations are implemented appropriately into daily clinical practice serving individual patients. Prior to their application in individual cases, they must be checked for applicability at regional or local level and adapted if necessary.
- As is the case with any clinical guideline, a set of National Disease Management Guidelines is explicitly not a directive which is approved, set down in writing and published by a legally authorised institution, regulating what must or must not be done within the jurisdiction of this institution, with non-compliance resulting in specified sanctions [6].

1.4 Target groups and scope of application

The recommendations of NDMG are aimed at

- all clinicians working in the healthcare sectors addressed by particular National Disease Management Guidelines;
- cooperation partners of the medical profession (e.g. other medical professionals in the healthcare system, third party payers, health administration);
- patients and their families (e.g. parents, partners), in particular by using the specific patient guidelines;
- the general public for information on good medical practice.

The **NDMG** are, in addition, explicitly aimed at

- those responsible for “structured disease management programmes” and “integrated care contracts” as well as
- the scientific medical societies and other publishers of guidelines, whose guidelines in turn form the basis for the **NDMG**.

R 2. Responsible agencies/ financing

The NDMG Programme is a joint project between the GMA, NASHIP and AWMF who cooperate jointly and uniformly for the purposes of the publication and continued development of the NDMG Programme based on the NDMG Method Report [7]. Conceptual and financial issues are agreed within the “Planning Group of the Agency for Quality in Medicine” (AQuMed) [1]. Coordination, editing and maintenance of the NDMG is the responsibility of AQuMed in collaboration with the AWMF’s Guidelines Commission. The NDMG Programme is jointly financed by the GMA, NASHIP and AWMF.

R 3. Publishers

The **publishers** of the NDMG Programme and accordingly of the individual **NDMG** are the programme partners, the GMA, NASHIP and AWMF. In addition, all professional associations and organisations involved in the development of a set of National Disease Management Guidelines (see section R4) are named in the imprint as cooperation partners of the publishers.

R 4. Composition of the guideline groups

The objective is that the groups should be multidisciplinary and representative of the target addressees of the NDMG. Organisation of the nomination process is the responsibility of AQuMed.

Member associations of the AWMF who are actively involved in the relevant NDMG subject areas and, in relation to pharmacotherapeutic issues, the Drug Commission of the German Medical Association (Arzneimittelkommission der deutschen Ärzteschaft (AkdÄ)), are primarily approached and invited to appoint a representative and a deputy representative for the guideline groups within the NDMG Programme. If the expertise of a professional association is required within the Programme in relation only to specific issues, the relevant professional association can be invited specifically for discussion of these specific issues and consensus on the recommendations or for peer review of the relevant chapter/section of the NDMG (see also section 7.3.2). Nomination of the relevant experts is the responsibility of the organisation concerned.

Patient representatives should be involved in the whole process of producing the guidelines. Their appointment takes place via the GMA’s National Patients’ Forum (for the procedure see section R5).

Depending on the subject area of the relevant NDMG it may be necessary and desirable to involve other professional groups and experts who do not belong to the aforementioned organisations in the preparation of the guidelines. The representatives of other professional groups (e.g. occupational therapists, physiotherapists, nursing staff) are entitled to vote in the formal consensus process on recommendations which fall within their field of responsibility and competence (see also section 7.3.2). Like other experts who may be involved in a consultative capacity but not as the appointed representative of a professional group, they are normally not entitled to vote beyond this. Justified exceptions are, however, possible in agreement with the participating partners in the NDMG Programme through the Planning Group of the AQuMed (see section R2).

At the first, constituent meeting in each case the composition of the group for developing the relevant **NDMG** is checked by the experts to ensure that it is representative. If necessary, a subsequent appointment process can be initiated. The procedure for any subsequent appointment follows the procedure outlined above.

If necessary, the substantive work within a NDMG Group can be coordinated by a steering group. The members of the steering group are chosen from within the membership of the NDMG Group and should represent the most important target groups for the relevant guidelines.

The participating partners in the NDMG Programme are informed about all meetings of the guidelines groups by being sent invitations, discussion documents and minutes and they may appoint a monitor.

In addition, all **NDMG** are publicly announced through publication on the NDMG Programme’s website and through notification by the AWMF and the Guidelines International Network (G-I-N) (<http://www.versorgungsleitlinien.de>, <http://www.awmf-leitlinien.de>, <http://www.g-i-n.net>).

R 5. Patient participation

Alongside the currently best available scientific data, evidence-based guidelines and clinical expertise, the experiences of and solutions proposed by patients/patient organisations [8] in relation to the disease management situation for a particular disease represent a valuable information source for formulating recommendations for the disease management process. In view of this, the GMA, NASHIP and AWMF have agreed on the consistent involvement of patients in the NDMG Programme and jointly with the National Patients' Forum [9] have formed an interest group made up of representatives of umbrella organisations for self-help groups as well as the GMA and NASHIP. The involvement of patients extends to the preparation of the NDMG, the NDMG appraisal in the course of the public consultation phase and preparation of patient guidelines relating to the relevant NDMG. Taking account of the fact that there is currently no uniform methodology for efficient patient involvement in the Guidelines Programme [9], the National Patients' Forum has prepared a participation proposal [10] (see flowchart in Annex 1).

R 6. Topic selection/ prioritisation

The participating partners in the NDMG Programme agree on suitable topics on the basis of an open topic proposal process and by using generally accepted formal prioritisation and consensus processes. Decisions are made by the AQuMed Planning Group (see section R2). The prioritisation process relates both to the choice of suitable topics for the development of National Disease Management Guidelines and to the prioritisation of the key aspects to be worked on within the topic areas. A preliminary flowchart for the prioritisation process has been developed by the "NDMG Methodology" working group (see flowchart Annex 2):

- The priority is:
 - "potential for improvement through National Disease Management Guidelines".
- Also to be taken into account are:
 - "cross-sectoral treatment need";
 - "incidence of the disease" and
 - "burden of disease".

R 7. Development and consensus process

Coordination of NDMG development is the responsibility of AQuMed. An activity plan and time schedule is drawn up for the development process relating to each set of guidelines. Following submission of these plans/time schedules, each NDMG shall be notified to the AWMF and G-I-N for announcement in the relevant databases.

The primary function of the first meeting of the guideline group is to verify the completeness and conformity of the guideline group; to introduce the methodology used in preparing NDMG and to foster a spirit of understanding and constructive cooperation.

The first meeting also serves as an introductory workshop for the guideline group which will focus in particular on the principles and methodology of preparing National Disease Management Guidelines on the basis of high quality guidelines and best available evidence as well as on the methodology of developing quality indicators derived from strong guideline recommendations. Since, in the preparation of National Disease Management Guidelines, both guidelines and aggregated evidence such as systematic reviews, meta-analyses and HTA (Health Technology Assessment) reports as well as, if applicable, primary literature are consulted as an evidence base (see section 7.1), the various approaches are laid out in brief. In addition, the particular requirements which the development of quality indicators from guideline recommendations imposes on the generation and formulation of recommendations are highlighted.

Following the definition of key issues (core areas) at the start of the guidelines process the key topics are specified according to defined criteria (e.g. priority disease management problem, relevant variability in healthcare provision), which may be developed through a supplementary systematic analysis of the relevant literature.

In developing the National Disease Management Guidelines major consideration is given to the concepts of the Guidelines International Network (GIN) [11], the guideline recommendations of the Council of Europe [5], the evaluation criteria for guidelines issued by the GMA and NASHIP [6], the “Guidelines Manual” issued by the AWMF and AQuMed [12], the recommendations of the German Guideline Clearinghouse [13] and the German Instrument for Methodological Guideline Appraisal (DELBI) [14]. Development is based on the flowchart shown in Annex 3.

7.1 Sources

In accordance with the objectives and particular characteristics of the NDMG Programme and international efforts for cooperation and division of labour in the field of guideline development [11], guidelines that are already available serve as the primary source for development of the NDMG.

The pre-selection of possible source guidelines is made on the basis of the outcome of a systematic guideline search. The criteria to be taken into account in this process are laid out in Annex 4.

The selection of the guidelines is made in accordance with the criteria of the German Instrument for Methodological Guideline Appraisal (the abbreviation **DELBI** stands for the **Deutsches Leitlinien-Bewertungs-Instrument**). Particular regard must be paid to the quality criteria on Methodological Rigour of Development laid down in domain 3 [15]. In relation to the selection of guidelines, in order to be able to serve as sources of “aggregated evidence”, it is of particular importance that the recommendations made have been systematically developed and are based on transparent evidence.

The so-called **source guidelines** identified in this way form the basis for the development of the NDMG. Where appropriate, in relation to individual issues such as pharmacotherapy, other guidelines known as **reference guidelines** are consulted. Here too, the emphasis is on the quality of the methodological approach. In selecting the source and reference guidelines, the guidelines of the professional associations involved in the development of the NDMG are to be taken into account.

Where the primary use of **guidelines** is the basis for formulating NDMG recommendations, a synopsis of the guidelines is performed focusing on the substantive content and aspects which should be addressed in the NDMG. The objective of this synopsis is a comparative analysis of the recommendations in the individual guidelines related to the underlying literature and its evaluation (grading the strength of the evidence). The grading schemes used for this purpose must be explained. If several different schemes are used, a reconciliation table is developed for uniform presentation in the NDMG. Additional systematic searches for other **sources of aggregated evidence** (e.g. systematic reviews, meta-analyses and HTA reports) and **primary studies** are carried out in respect of issues which are *not adequately answered* in the source guidelines, in relation to which *contradictory recommendations* are given in the source guidelines or in relation to which a *need for updating* exists. The decision regarding extended searches for evidence is made in the same way as the decision specified in section R 7. of the group of experts on the setting of priorities in dealing with issues, namely by consensus of the guideline group (see section 7.3).

In the Guidelines Report drawn up to accompany the relevant NDMG, the methodological approach with regard to the search for, selection and evaluation of sources must be set out in detail; the principles of the present Method Report have general application in this regard. If fundamental divergences are necessary in an individual NDMG, the reasons must be set out separately in the relevant Guidelines Report.

7.2 Formulation and grading of the recommendations

7.2.1 Formulation of the recommendations on the basis of guidelines

In developing National Disease Management Guidelines, the focus is on the use of guidelines as sources of pre-processed evidence (see section 7.1). An essential pre-requisite for adaptation of recommendations from source guidelines is that the evidence on which they are based and the corresponding strength of the evidence is demonstrated and transparent. In this case both the recommendation and the grading given to the evidence are taken over unchanged and steps 1-3 of the evidence evaluation can be omitted (see section 7.2.2). In cases of doubt, a supplementary search and evaluation of the primary literature according to the criteria of evidence-based medicine is necessary for therapeutic, diagnostic or prognostic questions arising in the course of the **NDMG** development process, so that all steps must be gone through (see section 7.2.2).

7.2.2 Formulation of recommendations on the basis of reviews and primary literature

In this approach reviews (systematic reviews, meta-analyses and HTA reports) or primary literature serve as the evidence source for the formulation of recommendations. Depending on the question, the evaluation of the evidence is carried out on the basis of the approach used by SIGN [16] or by the Centre for Evidence-Based Medicine in Oxford [17].

The systematic consideration of evidence for formulating and grading recommendations is based on the approach developed by the international GRADE group (**G**radings of **R**ecommendations, **A**ssessment, **D**evelopment and **E**valuation Working Group) [18]. This involves the following steps:

1. *Evaluation* of the evidence as regards the *methodological quality* – grading of the *strength of the evidence*.
2. Presentation of the evidence relating to a point at issue preferably in the form of an *evidence table*; as far as possible this should contain a differentiated presentation *according to all relevant outcomes*.
3. *Derivation of the content of the recommendation* from the selected, presented and evaluated evidence.
4. Grading of the recommendation as regards the *clinical relevance and applicability* of the methodologically produced evidence (clinical evaluation, “considered judgment”).
5. *Separate* presentation of the *methodological quality* of the relevant literature (strength of the evidence) and *grading of the recommendation* (strength of the recommendation).

The evaluation of the literature is presented in an evidence table (for sample see Annex 5). Depending on the issue, the Oxford or SIGN classification of the evidence is used and if applicable additional evaluation criteria are shown in the evidence table. Appropriate checklists to evaluate the methodological quality of the studies involved are generally used as the basis for classification of the evidence. For selected issues GRADE-Profilier is used in agreement with the group of experts. Since this involves considerable additional expense, however, a comprehensive assessment of the body of evidence in line with GRADE methodology is not performed in relation to each issue.

In accordance with the GRADE approach however, for all topics, patient-relevant outcomes for benefits and disadvantages are defined, rated and weighed against each other in formulating and grading the recommendations (see section 7.2.3.).

7.2.3 Grading of the recommendations

The NDMG methodology provides for the award of recommendation grades by the members of the guideline group as part of a formal consensus process (see section 7.3). In relation to this, explicit criteria are predefined for the clinical assessment of the applicability and transferability of the evidence (see also section 7.2.2).

These are:

- patient preferences;
- effect sizes and consistency of the results of the studies;
- clinical relevance (suitability of the measures of the effectiveness of the study for disease management, relevance of the control groups and the doses tested);
- the relationship between desirable and undesirable clinical outcomes;
- pathophysiological and clinical credibility;
- the applicability of the NDMG to the target patient group;
- the practicability of the NDMG in everyday medical practice (achievement potential, resource requirements and consumption etc.) and
- the interfaces between the service providers.

The grading of recommendations in the NDMG process corresponds to the symbols shown in **Table 1**.

Table 1: NDMG Grades of Recommendation

Grade of recommendation	Description	Symbol
A	Strong recommendation	↑↑
B	Recommendation	↑
0	Option	↔

As a rule, the evidence grade should determine the recommendation grade. An average evidence grade should therefore result in an average recommendation grade. The above-mentioned consensus aspects may, however, lead to a justified upgrading or downgrading of the recommendation grade compared to the evidence grade. The reasons must be set out in detail. This must be particularly borne in mind as strong recommendations (A recommendations) serve as the basis for the derivation of potential quality indicators (see also section 10.2, [19; 20]).

Care must be taken when formulating the recommendations to ensure that they are as clear and unambiguous, action-oriented and easy to understand as possible and that their recommendation grades are already indicated by the choice of auxiliary verb (e.g. “shall” for a strongly positive recommendation / “shall not” for a strongly negative recommendation in relation to an unnecessary or outdated measure).

Recommendations for disease management and decision-making processes are to be shown along with various options for action as clinical algorithms based on a uniform syntax [21; 22] and developed using suitable programmed [23] (for an overview of the symbols used, see Annex 6 [12; 23]).

7.3 Consensus process

7.3.1 Informal consensus process

The formulation of relevant issues, if applicable to supplement the core content defined in the prioritisation process, and identification of the need for systematic searches for evidence are agreed by informal consensus of the guideline group (moderated discussion). The adoption and grading of recommendations takes place within the scope of a formal consensus process.

7.3.2 Formal consensus process

The nominal group technique is the process used for the final formulation and grading of the recommendations [21; 24; 25]. Formalised written voting procedures can be used in addition, i.e. the Delphi technique or a modified Delphi process [24].

The nominated representatives of all the organisations involved in producing the Guidelines take part in this process (see section R4). Each organisation has one vote in the voting process; non-voting Group members act in an advisory capacity.

The voting process among the members of the guideline group is moderated by neutral, experienced experts who have been trained in the relevant consensus technique. The cornerstones of the process are an explicit statement of the evidence base which was taken into account in the formulation of the recommendations and the criteria for reaching consensus (see section 7.2.3), as well as a systematic approach in relation to the collection, presentation and consolidation of the participants' individual contributions. The conduct of the process, the voting outcomes, deviations from levels of evidence and recommendation, as well as areas in which no consensus was reached and there may be minority opinions, must be set out with the relevant reasons, if applicable in the Guidelines Report accompanying the NDMG.

The full process cycle with all content contributions are recorded in minutes which shall be provided to the AQuMed Guidelines editorial office on request.

7.4 Aspects of membership of specific groups of population (gender/diversity)

Biological gender, the socio-cultural definition of the gender role and membership of different ethnic groups influence both health and also differences in the incidence and progression of diseases, as well as access to the healthcare system and interaction with service providers [26-29]. Any scientific knowledge relating to relevant differences with regard to these aspects must be taken into account in the literature search and in relation to handling the relevant issues. The difficulty in this regard is the lack of studies and the fact that their methodological quality is frequently inadequate.

7.5 External review

Prior to publication of the final version of the NDMG, the draft version is posted on a publicly accessible discussion platform for three months for comment.

The start of this external review process is announced by the participating partners and professional associations through their respective publication channels.

Contributions from interested members of the professional public, representatives of various interest groups and other individual contributions are collected by the NDMG editorial office, processed and passed on to the expert panel for comment. If any changes to the draft guidelines are required, these are discussed during a subsequent telephone conference or meeting. All comments are discussed and the corresponding decisions reached is recorded along with the relevant reasons. The minutes are annexed to the formal consensus process and may be requested in accordance with the process outlined under section 7.3.2.

A further option for external review is the opinion of foreign experts. Opinions may either be obtained by targeted submission of the NDMG to known experts or through the website of the Guidelines International Network (G-I-N)).

7.6 Aspects of health economics

The NDMG Programme recognises the importance of the cost effectiveness of service provision but still places the focus on optimising the quality of care. In response to the increasing number of enquiries from users of the NDMG about the costs of guideline-based treatments, a cost estimate for various treatment

options (e.g. NDMG for Asthma, 2nd edition) is set out for defined issues within the relevant NDMG in cooperation with the relevant guideline authors and experts from the Drug Commission of the German Medical Association (AkdÄ).

These estimates are, of course, very uncertain and only provide an empirical survey as at the time of publication of the NDMG. Unfortunately, reliable data in respect of health economical issues is very rarely available.

R 8. Period of validity/updating

8.1 Period of validity and monitoring

The **NDMG** are given a validity date. The date of adoption by the joint Planning Group is deemed to be the date of publication. As far as possible, guidelines will be revised and re-issued every four years calculated from the date of adoption.

8.2 Maintenance

During the period of validity of a set of NDMG, latest research findings necessitating an interim update of the recommendations in the NDMG are sought in different ways. One procedure has been developed by the HTA Centre at the University of Bremen [30], the other by AQuMed. At present both procedures are being tested as regards safety and feasibility.

Literature searches are complemented by regular surveys of the author panel responsible for the relevant NDMG and patient guidelines to assess the need for updating. Structured questionnaires adapted to the requirements of the addressees are used for this purpose (for questionnaires, see Annexes 7 and 8).

In the case of relevant new findings, an interim update and information for the public is provided through the website of the NDMG editorial team within AQuMed with responsibility for ensuring NDMG are up-to-date (<http://www.versorgungsleitlinie.de>). Necessary corrections, changes or editorial revisions to the agreed text published on the internet are recorded. In order to ensure the transparency and traceability of any changes, all versions of the NDMG are available on the website arranged chronologically by date and version number: (<http://www.versorgungsleitlinien.de/methodik/archiv>).

8.3 Updating process (revision)

Around six months prior to the expiry of the validity period the NDMG is reviewed by the author panel and editorial team to decide the extent to which it is necessary to update and possibly revise the NDMG. The scope of the review (full or modular) varies depending on whether the guidelines have already been revised as part of the maintenance process (see section 8.2.), on the results of an updated guideline search and on the outcome of a survey of the NDMG experts into relevant current research, as well as on the need for revision in the view of the editorial team responsible for the patient guidelines (see Annexes 7 and 8).

The methodological process for amending the NDMG as part of an updating process conforms with the methodology set out in sections 7.2 and 7.3. In each case only the most recent version of NDMG is valid.

R 9. Presentation, distribution and implementation

9.1 Presentation

The constituent parts of a set of NDMG are indicated in accordance with the relevant topic in the Guidelines Report. This invariably consists of a long version with references, a short version, implementation guidance (white coat pocket guides and practice guides), patient guidelines to the NDMG and the Guidelines Report.

9.2 Distribution and implementation

The distribution and acceptance of NDMG necessary for their implementation is supported by targeted measures. This includes electronic publication on the internet as well as publication in print form.

In the case of online presentation, access to the HTML version of the NDMG is organised on three levels (see Annex 9):

- Level 1: corresponds to the short version with the recommendations (Part A of the full document).
- Level 2: also contains background information on the discussions and reasons for the recommendations (Part H of the full document).
- Level 3: this level also includes links to the sources on which the recommendations are based (references, evidence tables, PubMed links, Part L of the full document).

The following elements form part of the distribution and implementation process:

- publication as a “Guidelines Set” (short version + white coat pocket guide+ practice guides/medical staff + patient versions + Guidelines Report);
- publication of the key elements in the *Deutsches Ärzteblatt*;
- distribution via publication media and conference events organised by the cooperating professional associations and organisations;
- press conferences;
- information to joint self-governance bodies and to professional organisations;
- integration of the NDMG content into existing quality management systems (e.g. QEP or KTQ);
- establishment of internet-based modules for accredited continuing medical education.

The electronic version of the guideline is available on the joint web presence of AWMF and GMA/NASHIP within AQuMed (<http://www.versorgungsleitlinie.de>) and via the AWMF's Guidelines Database (<http://awmf-leitlinien.de>). All parts of the NDMG can be accessed there free of charge. A short version summarising essential key recommendations will be distributed in print form through the scientific medical societies. In addition, the distribution of the patient guidelines will be supported by the combined patient representatives forming the Patients' Forum.

R 10. Evaluation and quality indicators

10.1 Evaluation

Evaluation of the NDMG should be carried out in relation to the objectives specified in section R1:

- distribution of evidence-based and formally consented recommendations on interdisciplinary approaches for specific diseases;
- distribution of NDMG based quality indicators and patient guidelines;
- widest possible implementation of the NDMG recommendations;
- consideration of NDMG recommendations through contracts for structured disease management programmes and integrated care contracts;
- consideration of NDMG recommendations in medical training, continuing medical training and specialist medical training, as well as in quality management systems.

10.2 Quality indicators (QI)

The most important components of the evaluation process are guideline-based quality indicators [24]. The aim is to specify suitable quality indicators already in the NDMG. Existing programmes and organisational structures should be taken into account in this regard.

10.2.1 Methodology for developing quality indicators within the NDMG

The “Quality Indicators for NDMG” expert panel has developed a methodology for the development of NDMG quality indicators based on the QUALIFY tool that facilitates the formulation of provisional quality indicators (QI) (for which no underlying data is yet available). A detailed explanation of this methodology can be found in the Quality Indicators Manual [19; 20].

Using this methodology, proposals for QI are drawn up from the objectives and strong recommendations (recommendation grade A) of the relevant NDMG. They are developed as ratio-based QI, meaning that they consist of numerators and denominators. The potential QI are **evaluated** by the NDMG authors in a multi-stage process according to the following **five criteria**:

1. importance for the healthcare system
2. risk of malfunction
3. clarity of definitions
4. strength of the indicator recommendation (evidence grade of the underlying literature + expert consensus)
5. influenceability of the indicator specification

In addition a **description of three further criteria** takes place:

6. risk adjustment
7. barriers to implementation
8. data availability

10.2.2 Process of developing quality indicators from NDMG

To facilitate the development of QI, the formulation of guideline objectives and guideline recommendations must be as specific as possible. This should already be taken into account in the corresponding formulation of the NDMG during the development process.

Conversion into possible quality indicators and comparison with existing indicators is carried out by AQuMed. Already existing national or international quality indicators are explicitly taken into account in relation to proposals for quality indicators for NDMG. For this purpose, following a search in specific databases, a synopsis of existing national and international quality indicators (in conformity with the process outlined in section 7.1) is drawn up for the NDMG authors. Following an exploratory assessment of measurability by AQuMed, a methodological appraisal of the quality indicators is carried out by the NDMG authors on the

basis of the above five criteria. The final selection is made during a formal consensus process (see section 7.3.2).

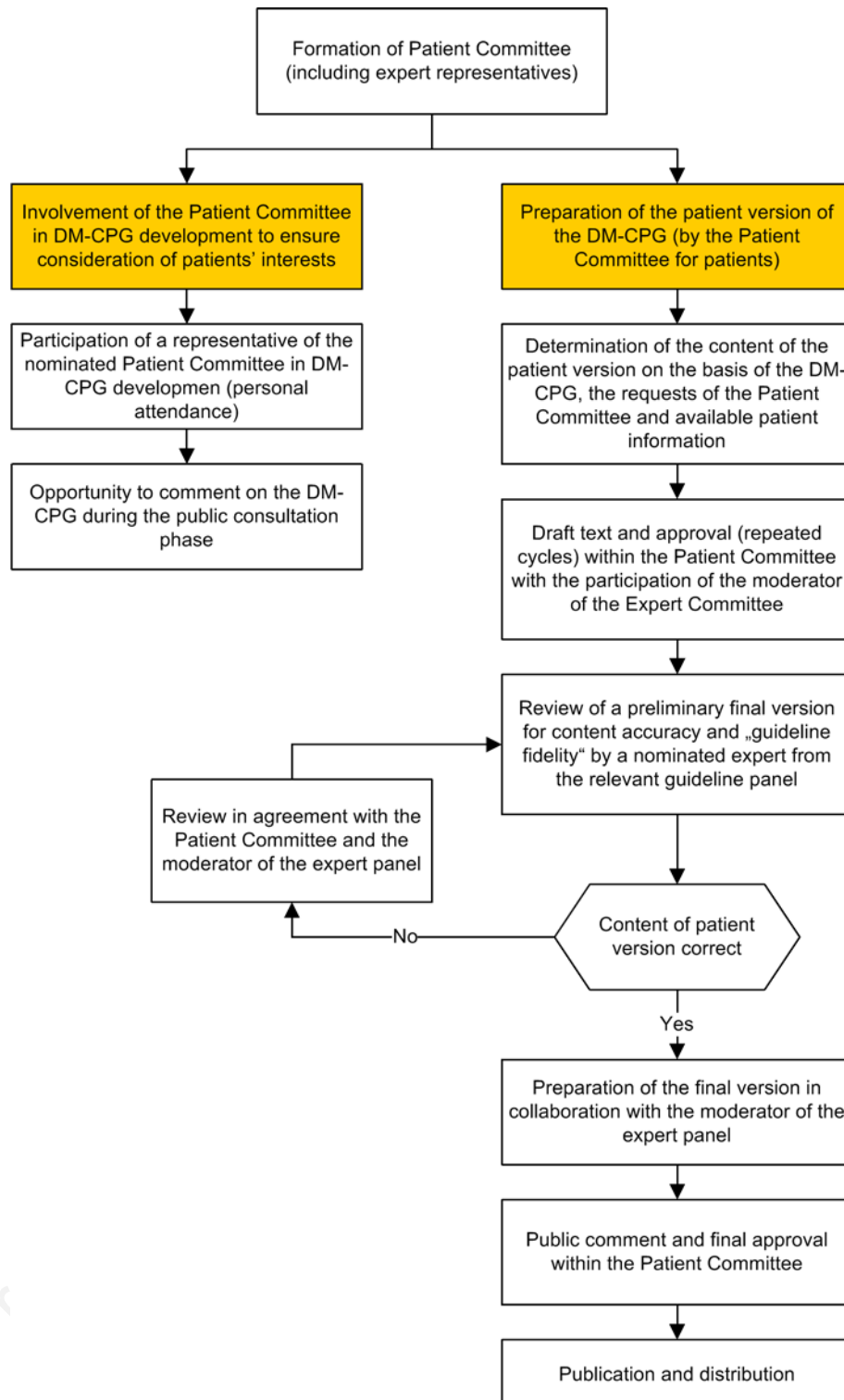
R 11. Editorial independence; statement of conflicts of interest

Development of the NDMG content is editorially independent from the funding bodies of the National Programme for Disease Management Guidelines, the GMA, AWMF and NASHIP. They merely fund coordination and methodological support for developing the guidelines and their distribution.

All members of the guidelines development group are obliged to disclose any conflicts of interest in connection with the development of NDMG in writing to the publishers (for the form, see Annex 10); the procedure recommended by the AWMF is to be used to handle conflicts of interests [31]. Irregularities in the sense of exertion of influence on the group due to defined conflicts of interest may have consequences ranging from restriction of the expert's voting right to expulsion from the NDMG author panel.

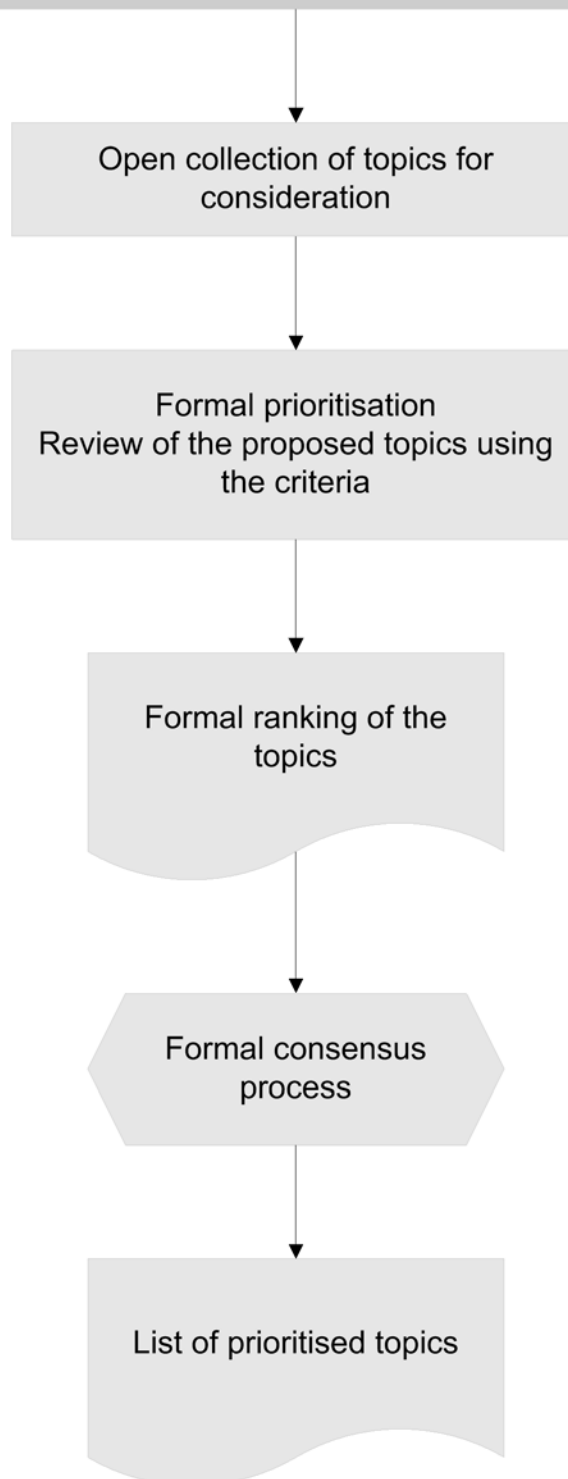
Annexes

Annex 1: Patient participation in the NDMG process

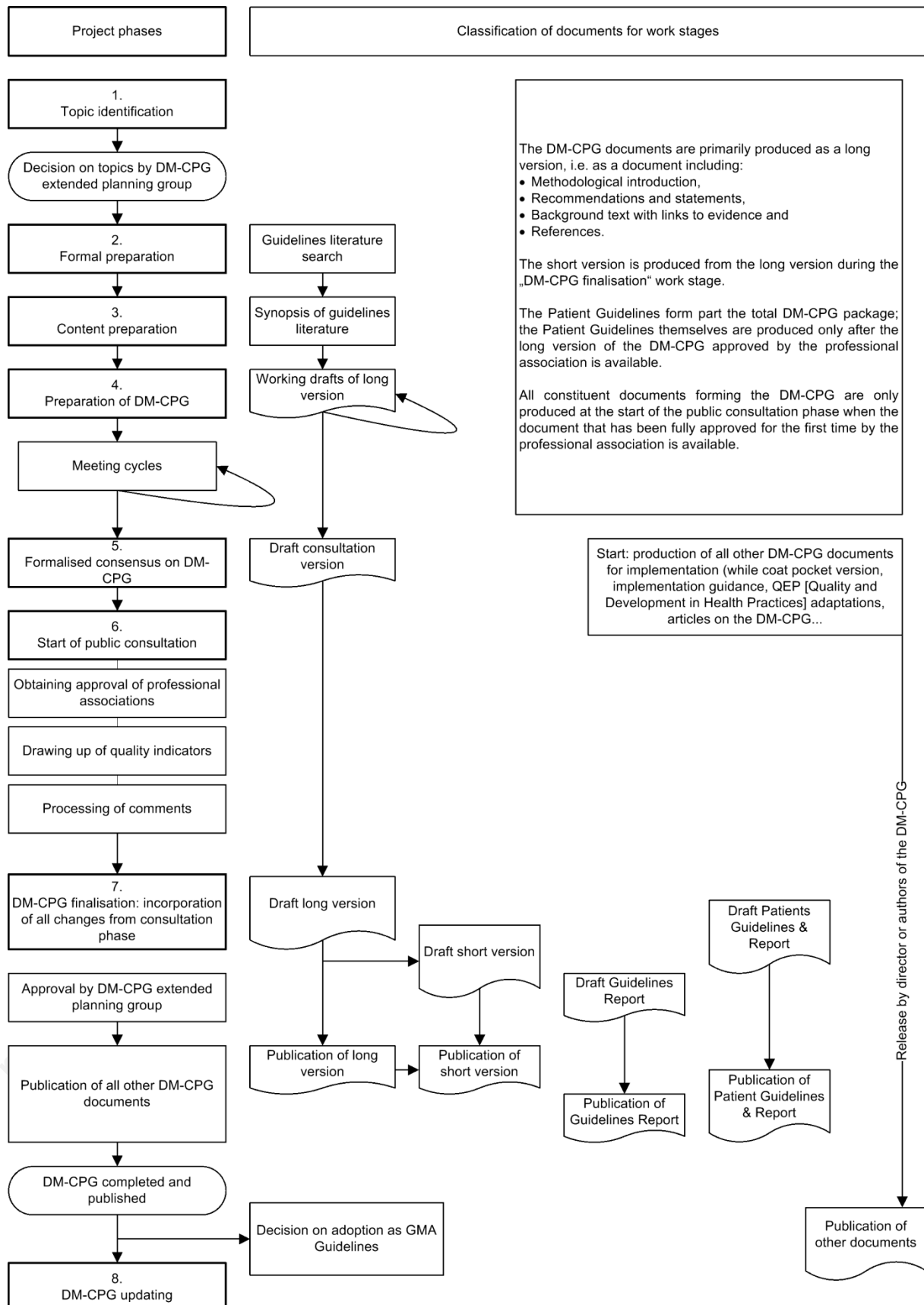


Annex 2: Prioritisation in the NDMG process

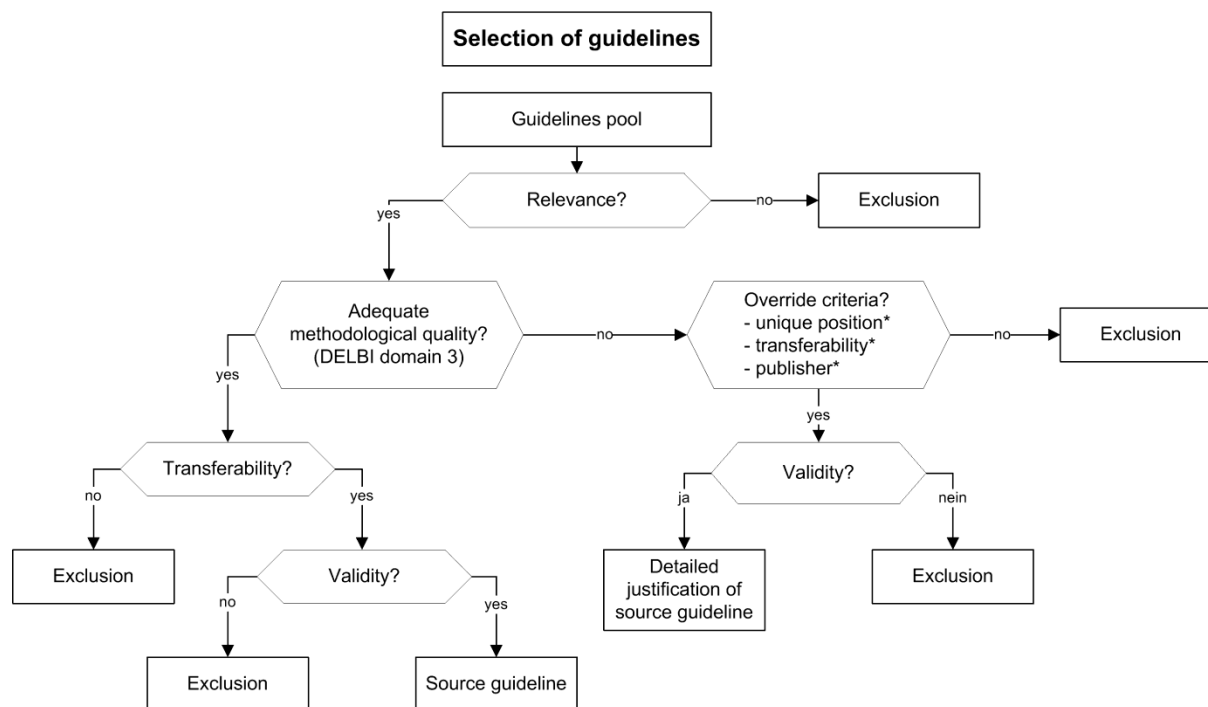
Flowchart for a criteria-based prioritisation process



Annex 3: Flowchart for NDMG preparation



Annex 4: Criteria for selection of guidelines



* In the case of inadequate methodology, guidelines may be used in full or in part if

- different methodological production of the guidelines is probably not possible
- the guidelines are not interest-led
- the guidelines were issued in Germany by recognised institutions and they are of importance in the public discussion
- no international guidelines are available.

Annex 5: Evidence Table Template

Chapter no./title

A) Aggregated evidence

A1) Guidelines

Source	Text	Evidence/ recommendation grade	Literature sources	Methodological evaluation
	Recommendations in main text; background text only if absolutely necessary for understanding	Level of Evidence Grade If not found: n.A.	All literature sources relating to the recommendation citing author and year	Information on the methodological quality of the evidence base, resp. formal consensus process

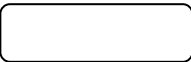
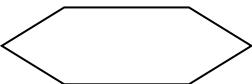


A2) Systematic review, meta-analysis, HTA

Study type	Authors / year	Studies/material investigated	Which interventions were reviewed	Characteristics of studies included/results (findings relating to therapeutic effects, diagnostic quality etc.)	Literature sources	SIGN/Oxford evidence level	Remarks
Systematic review, Meta- analysis, HTA reports		Database search strategies Period Study designs included	Intervention/ comparative intervention; Endpoints Important patient characteristics	1. Short statement regarding the study quality 2. Statement of the results (benefits/disadvantages) (always indicating absolute numbers and stating the confidence intervals)	Author/year for all studies included		e.g. Methodological explanations

B) Primary studies

Article (author, year)/ study type	Number of patients/patient characteristics	Intervention/if applicable monitoring	Comparative intervention	Outcomes	Results	Evidence level	Remarks
						SIGN/ Oxford	
RCT Cohort study Case control study Case series; case report(s) Cross-sectional study	n= Important characteristics of the study population: average age, gender (if applicable), average duration of disease (indicate mean values with range) Important disease-specific characteristics (e.g. average HbA1c value for diabetes, tumour stages for cancer) Important additional information e.g. comorbidities	Intervention: Monitoring: Indicate mean or median value with range		1. Primary endpoints first 2. ... 3. ... 4. Secondary endpoints	0. Study quality, e.g. originally planned number of participants not achieved; dropout rate 1. Primary endpoints - always state absolute numbers; - with risk reduction or increase not only relative but also absolute indications. - always also state confidence intervals 2. ... 3. ... 4. Secondary endpoints		Methodological features; explanation for award of SIGN-“-”, “+” or “++” If applicable, special conclusions by the authors

Annex 6: Standardised terminology for clinical algorithms

Clinical state	
Decision node	
Field of action (activity)	
Logical sequence	
Numbering	1

Annex 7: Questionnaire for medical experts on the need for revision

Dear medical experts for the NDMG for XXX

Using this questionnaire, we kindly ask you to give us information on the **need for revision of the NDMG**. It would be useful if you could differentiate between topics for which, in your view, there is an immediate need for revision, and topics that you consider could be dealt with as part of the regular process of updating the guidelines.

1. Topics for **immediate** revision (please state a maximum of 5 topics and place them in order of relevance)

- a.
- b.
- c.
- d.
- e.

Please note that because of limited resources, there must be very strong reasons for the urgent handling of changes:

- new discoveries (e.g. a completely new therapeutic approach)
- uncertainty caused by inconsistent data (e.g. conflicting standards in use)
- lack of standards (e.g. multiple therapies)

Please justify your proposals and state the relevant literature.

2. Topics for **later** revision (please state a maximum of 5 topics and place them in order of relevance)

- a.
- b.
- c.
- d.
- e.

All proposals will be summarised and circulated to the whole group of experts in order to identify the issues in a joint discussion and to reach consensus on the best method of handling the revision.

Thank you for your support.

Annex 8: Questionnaire for patient experts on the need for revision

Updating of the National Disease Management Guidelines for XXX

Explanation of the clinical picture	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Incidence of the disease	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Particular features of the disease (e.g. periodic occurrence etc.)	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>

Information on particularly affected (at risk) persons	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Differentiation from similar diseases	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Impact of the disease on the patient's life	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Treatment options	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>

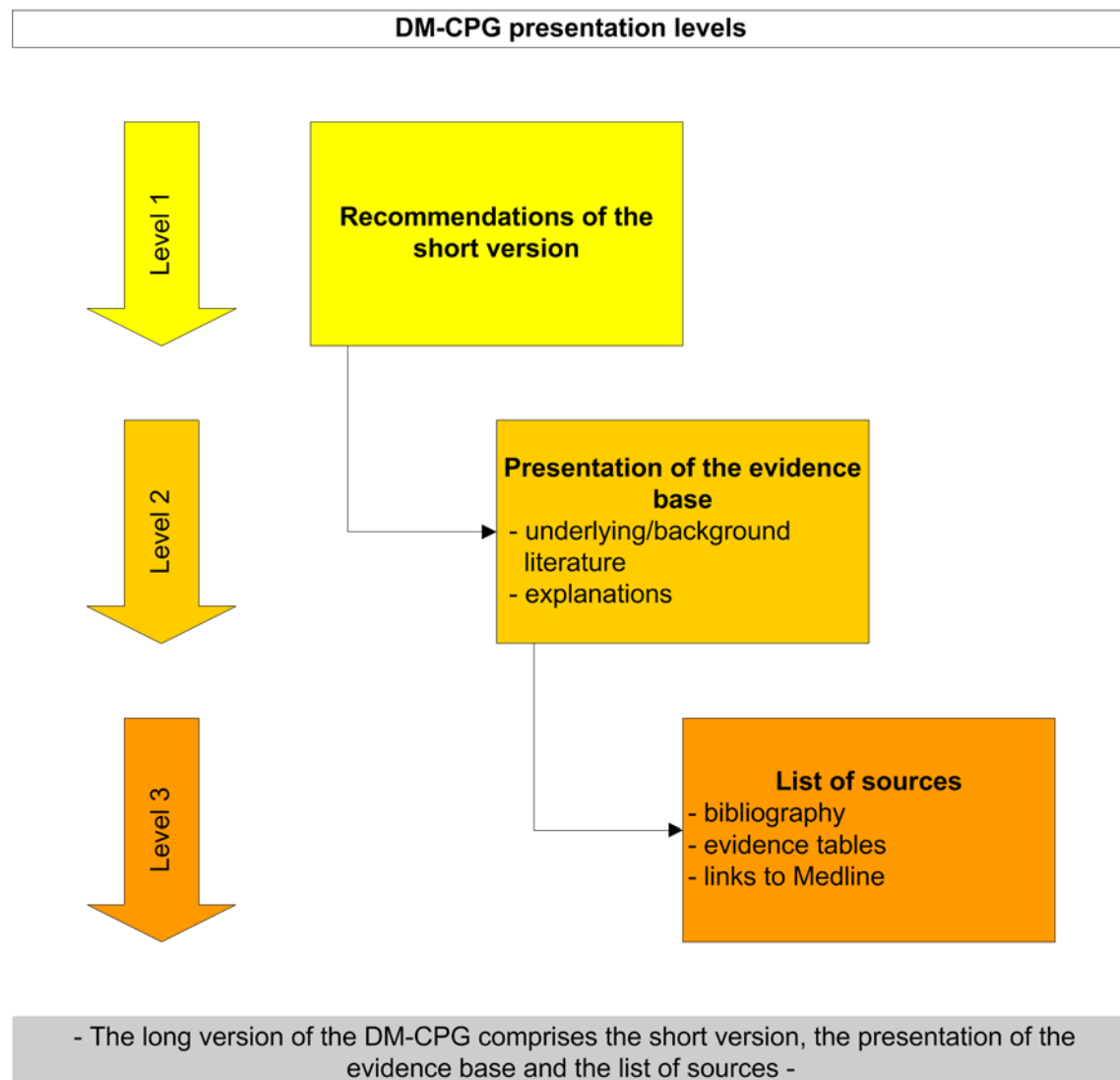
Age-specific factors affecting treatment	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Gender-specific factors affecting treatment	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Dependency of treatment on the degree of severity of the disease	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Statements on “alternative medicine” treatment methods	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>

Benefits of the presented treatment(s)	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Side-effects of the presented treatments	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Quality of life with treatment	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Quality of life without treatment	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>

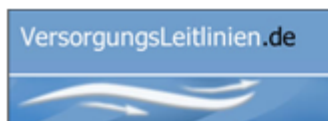
Persons and health professionals involved in the treatment	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Statements on transitions in healthcare structures	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Statements on self-management of the disease	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Statements on the need for long-term medical care	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>

Statements on the need for long-term psychological care	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Statements on the need for long-term social care	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>
Additional aspects (prevention, genetic counselling, meaningful follow-up diagnosis, other)	
<p><i>We consider an addendum to be</i></p> <p><input type="checkbox"/> necessary</p> <p><input type="checkbox"/> unnecessary</p>	<p>Which:</p>

Annex 9: Three levels of online presentation of NDMG



Annex 10: Declaration of conflicts of interest



Declaration of conflicts of interest

National Disease Management Guidelines

(Title, AWMF registration number)

for the attention of

Director, AQuMed

Preamble

In addition to professional expertise, the development of guidelines for medical care demands the avoidance of commercial dependencies or other conflicts of interest that influence the content of the guidelines. The degree of influence and significance of the various tangible (e.g. financial or commercial) and intangible (e.g. political, academic or personal) relationships that can exist may vary. Accordingly, conflicts of interest are in many cases unavoidable but not necessarily problematic as regards the influencing of the content of the guidelines.

Disclosure of relationships and the conflicts of interest arising out of them by the authors of the guidelines and the participants in the consensus process is crucial for the assessment of the quality of the guidelines, and also for their general legitimacy and credibility as perceived by the general public and policy-makers.

The declarations are provided to the guidelines coordinator at the start of the guidelines project. In the case of longer term projects, provision of an additional statement in the course of the project may be necessary. Whether the interests disclosed call into question the neutrality that serving as an expert in guidelines development requires or in what areas the professional judgment of an expert could be inappropriately influenced by third party interests must be discussed and assessed within the guidelines group.

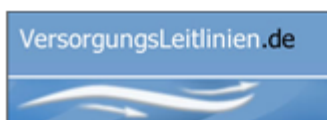
The content of the declarations and the results of the discussion on handling conflicts of interest should be presented openly in the Guidelines Report. Reference should be made in the long version of the Guidelines to the process of collection and assessment of the declarations.

We kindly ask you to complete and sign the declaration below.

Additional literature:

AWMF (2010) Recommendations of the AWMF on the handling conflicts of interest by professional associations. GMS Mitt AWMF 2010;7:Doc8.

Internet: <http://www.eqms.de/static/en/journals/awmf/2010-7/awmf000206.shtml> (access: 30.6.2010)



Declaration

The declaration affects financial and commercial (tangible) as well as psychological and social (intangible) aspects and interests of the members themselves and/or of their personal or professional partners **within the last three years.**

Please provide specific information on the following points:

1. Work as an advisor or consultant or paid work as a member of a scientific advisory council of a healthcare company (e.g. pharmaceutical industry, medical products industry), or a for-profit contract research organisation or an insurance company.

☐ no
☐ yes

If yes, please provide specific information:

2. Fees received for presenting lectures or providing training or paid authorship or coauthorship commissioned by a healthcare company, a for-profit contract research organisation or an insurance company.

☐ no
☐ yes

If yes, please provide specific information:

3. Financial allowances (external funding) for research projects or direct funding of employees of the relevant organisation received from a healthcare company, a for-profit contract research organisation or an insurance company exceeding appropriate reimbursement of costs for the planning, performance and documentation of clinical or experimental studies.

☐ no
☐ yes

If yes, please provide specific information:

4. Proprietary interests in drugs/medical products (e.g. patents, copyrights, sales licences)

☐ no
☐ yes

If yes, please provide specific information:

5. Ownership of shares, share capital or funds with equity interests in companies in the healthcare industry

☐ no
☐ yes

If yes, please provide specific information:

6. Paid authorship or co-authorship of articles commissioned by pharmaceutical, biotechnology or medical technology companies in the last five years

☐ no
☐ yes

If yes, please provide specific information:



7. Personal relationship with an authorised representative of a healthcare company
☐ no
☐ yes
 If yes, please provide specific information:
8. Member of relevant professional associations or societies in connection with the guidelines development; appointed representative for developing the guidelines
☐ no
☐ yes
 If yes, please provide specific information:
9. Political, academic (e.g. affiliation to particular „schools“), scientific or personal interests that could cause possible conflicts
☐ no
☐ yes
 If yes, please provide specific information:
10. Present employer; relevant previous employers during the last three years:
☐ no
☐ yes
 If yes, please provide specific information:
11. In your opinion, do any significant conflicts of interest arise for you or for the entire Guidelines Group out of the points listed above?
☐ no
☐ yes
 If yes, please state a proposal for discussion in the Guidelines Group (e.g. abstention in relation to particular issues):
12. Relevant changes should be notified promptly in writing to the Director of AQuMed. Membership of another expert panel within the National Disease Management Guidelines Programme requires a declaration to be made again.
13. In the case of potential conflicts of interest, the Guidelines Group decides, after consultation, on the necessary measures to be taken, such as exclusion from discussion and voting in relation to certain product-related issues or topic areas and, if necessary, termination of membership.

If a member does not agree with the measure specified in item 13, he/she can ask the President of the German Medical Association, the President of the AWMF or the Chief Executive Officer of NASHIP for a final decision which must be taken by the aforementioned persons and the Director of AQuMed unanimously.

I confirm that I have taken note of these regulations and affirm that the information I have provided is true and accurate.

Membership of the expert panel for the National Disease Management Guidelines for

Name/address (stamp)

Place, date

Signature

Literature

replaced by 5th edition, version 1 in December 2017

L. Literature

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