



National Programme for Disease Management Guidelines **NVL**

under the auspices of

**German Medical Association (GMA)
Association of the Scientific Medical Societies (AWMF)
National Association of Statutory Health Insurance Physicians
(NASHIP)**

National Disease Management Guideline

Asthma

Guideline Report

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EDITORS

German Medical Association (GMA)

Association of the Scientific Medical Societies (AWMF)

National Association of Statutory Health Insurance Physicians (NASHIP)

AUTHORS – Guideline Report NVL “Asthma”

M. Lelgemann, L. Heymans, G. Ollenschlaeger – Agency for Quality in Medicine (AQuMed)

I. Kopp - Association of the Scientific Medical Societies (AWMF)

S. Kleudgen - National Association of Statutory Health Insurance Physicians (NASHIP)

U. Zorn - German Medical Association (GMA)

Editorial Work and Maintenance

Agency for Quality in Medicine (AQuMed/AEZQ)

(Joint Institution of GMA and NASHIP)

Commissioned by GMA, AWMF, NASHIP



CONTACT

AQuMed/AEZQ – Editorial office for "Disease Management Guidelines"

Wegelystr. 3 / Herbert-Lewin-Platz

D-10623 Berlin

Phone: +49-30-4005-2500

Fax: +49-30-4005-2555

Email: versorgungsleitlinie@azq.de

Internet: <http://www.versorgungsleitlinie.de>

– Comments and proposals for change to the above address only –



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R 1. Justification and Objectives of the National Programme for Disease Management Guidelines

In 2003, the German Medical Association (GMA), the Association of the Scientific Medical Societies (AWMF) and the National Association of Statutory Health Insurance Physicians (NASHIP) have contractually agreed to co-operate to establish and fund a Joint Committee for a „National Programme for Disease Management Guidelines“ (NVL Programme) [1].

The aim of the NVL Programme is:

- to co-ordinate, present and implement key recommendations for certain prioritised problems of healthcare;
- outline clinical treatment processes for special diseases across different health care sectors, to describe the decision making arising within them and to define the respective approach of choice;
- in particular, to give recommendations about the arrangement and co-ordination of care amongst all the medical disciplines concerned and other healthcare professions;
- to define the interfaces between both the different medical disciplines and the different areas of care (primary prevention – secondary prevention – curative treatment – rehabilitation) and determine their contents;
- to identify peculiarities of the German healthcare system and formulate process recommendations rooted in them, taking into consideration international literature;
- to update recommendations according to the most current state of medical knowledge in consideration of the criteria of evidence-based medicine;
- to identify barriers to the implementation of guideline recommendations and point out solutions;
- to enable effective strategies for dissemination and implementation of these recommendations by including all disciplines, organisations and patients involved and the formal consensus built upon such an approach;
- to work towards the systematic integration of recommendations developed within the scope of this programme with both (continuing) medical education and training and quality management systems.

The development of the NVL “Asthma” between August 2002 and June 2005 was organised by the Agency for Quality in Medicine on behalf of the German Medical Association (GMA), the Association of the Scientific Medical Societies (AWMF) and the National Association of Statutory Health Insurance Physicians (NASHIP). The methods and processes of guideline development within the scope of the NVL Programme are generally described in the NVL Method Report [2] and for the NVL “Asthma” specifically outlined in the present NVL Report Asthma (available online at <http://www.versorgungsleitlinien.de>).

Essentially, National Disease Management Guidelines are developed in consideration of the concepts of the Guidelines International Network G-I-N [5], the guideline recommendations of the Council of Europe [4], the evaluation criteria for guidelines issued by GMA and NASHIP [3], the Guideline Manual by AWMF and AQuMed [6], the recommendations of the German Guideline Clearinghouse [7] and the German DELBI Instrument for the Methodological Appraisal of Guidelines [8].

A NVL - like any other clinical guideline - is expressly not intended to constitute a directive, which is a regulation controlling action or failure to act, which has been approved, laid down in writing and published by a legally authorised institution, which is binding upon this institution’s legal sphere of action and whose disregard would entail specific sanctions [3; 4].

A NVL will come into effect only if its recommendations are taken into account in the care of individual patients. Prior to its application in the individual treatment of patients NVLs must be reviewed for their applicability to the regional or local level and adapted if necessary.



R 2. Target Groups of National Disease Management Guidelines

A National Disease Management Guideline (**NVL**) is a “systematically developed statement to assist decisions about the appropriate medical measures for special clinical circumstances within the scope of structured healthcare”. It is meant to facilitate orientation in the sense of “treatment and decision pathways”, from which deviation is not only allowed but even recommended in certain duly justified cases.

The decision whether to follow a specific recommendation or not must be made by the physician taking into account both the individual patient’s case and the resources available [3; 4].

The recommendations of National Disease Management Guidelines are directed

- predominantly towards physicians in all areas of healthcare;
- towards the co-operation partners of the medical profession (e.g. health care professionals, healthcare purchasers);
- towards affected patients and their personal environment (e.g. parents, partners), namely by making use of special patient information);
- towards the general public to provide information about good medical practice.

In addition, **NVLs** explicitly both address

- the editors of “Structured Treatment Programmes“, as they serve as a basis for the development of future “Structured Disease Management Programmes“ and
- the Scientific Medical Societies and other guideline editors, whose guidelines will in turn form the basis of **NVLs**.

R 3. Aims

In the face of the high asthma prevalence and incidence in Germany and the broad variation in the quality of healthcare delivery increased efforts are needed in order to optimise the clinical management of asthma. This includes reliable and generally accepted definitions of what is necessary and appropriate in prevention, diagnosis and therapy.

Within the scope of the Programme for National Disease Management Guidelines, the Scientific Medical Societies concerned with the prevention, diagnosis, treatment and rehabilitation of asthma in children, adolescents and adults have reached a consensus on the core contents of a National Disease Management Guideline for Asthma in 2005.

The **NVL “Asthma”** aims to disseminate evidence-based recommendations that can be used to establish a more rational basis for decisions in the medical care of people at risk for or people with asthma. This is how the quality of care can be improved and the position of the patient be strengthened. And what is more, consideration of guideline recommendations can contribute to increased efficiency in healthcare (Council of Europe 2002 [4]).

R 4. Composition of the Guideline Group

GMA, AWMF and NASHIP are those responsible for the **NVL “Asthma”**. Primary contact for the appointment of guideline authors are the AWMF member societies and the German Drug Commission (AkdÄ). The scientific medical societies relevantly concerned with the medical management of asthma patients of all ages have been addressed by the responsible bodies and asked to send representatives to the **NVL** expert group. Their nomination is in the responsibility of the scientific medical societies thus addressed.

In accordance with the procedure described above, the guideline group has a multidisciplinary composition.

At its constituent meeting the representativeness of the **NVL** development group was reviewed by the experts. Late nominations via the editors (responsible bodies and scientific medical societies/organisations involved) were not considered necessary.



In the course of the **NVL** development it was recommended to ensure internal co-ordination of the guideline contents between the scientific medical societies concerned and the respective professional associations.

BÄK and KBV have intermittently sent consultants from the responsible departments to take part in the meetings of the expert panel as observers and accompany the development processes of the **NVL "Asthma"**.

Altogether 14 meetings (incl. four telephone conferences) of the **NVL "Asthma"** guideline group were held from August 2002 till Mai 2005.

Table 1: Representatives of the medical societies / organisations involved in the development of the NVL "Asthma"

Appointed Representative	Medical Society / Organisation	Function within the NVL group	Institution / Place
Prof. Dr. med. Dietrich Berdel*	Society of Pediatric Pneumology (GPP)	GL author	Marien-Hospital, Wesel
Prof. Dr. med. Roland Buhl*	German Society of Pneumology (DGP)	GL author	Medical Clinic III of the Johann Gutenberg University, Mainz
Prof. Dr. med. Rainer Dierkesmann*	German Society for Internal Medicine (DGIM)	GL author	Clinic "Schillerhoehe", Dept. Allergology, Medicine, Environmental Medicine, Gerlingen
Heymans Lothar	Agency for Quality in Medicine (AQuMed)	Secretary	AQuMed, Berlin
PD Dr. med. Ina Kopp	Association of the Scientific Medical Societies (AWMF)	Moderator	AWMF, Marburg
Prof. Dr. med. Wilhelm Niebling*	German Society of General Practice and Family Medicine (DEGAM)	GL author	General Practice, Titisee-Neustadt
Prof. Dr. Dr. med. Guenter Ollenschlaeger	Agency for Quality in Medicine (AQuMed)	Moderator, Director of the German National Disease Management Programme	AQuMed, Berlin
Dr. med. Konrad Schultz*	Section 'Prevention and Rehabilitation' of the scientific sections of the DGP	GL author	Special Clinic Allgaeu Centre of Behavioural Medicine in Pneumology, Allergology, Dermatology, Psychosomatics, Pfronten
Prof. Dr. med. Dieter Ukena*	German Drug Commission (of the German Medical Profession) (AkdÄ)	GL author	Clinic for Pneumology, Clinical Centre Bremen-Ost, Bremen
Prof. Dr. med. Peter von Wichert	Association of the Scientific Medical Societies (AWMF)	Observer of the AWMF Board	AWMF, Duesseldorf
Prof. Dr. med. Heinrich Worth*	German Airway League (DAL)	GL author	Medical Clinic I, Clinical Centre Fuerth

* Voting representatives of the medical societies in the Nominal Group Process



R 5. Patient Involvement

The aim of the patients' active involvement in the **NVL** Programme is, on the one hand, to include their views in **NVLs** and, on the other hand, develop patient versions of **NVLs**. The participation of patients in the development and assessment of **NVLs** will be arranged with the Patient Forum at the German Medical Association.

The foundation of the Patient Forum in 2002 was initiated by the German Medical Association [9] and represents a co-operative association of the following organisations and institutions:

- BAG SELBSTHILFE e.V. - Bundesarbeitsgemeinschaft SELBSTHILFE von Menschen mit Behinderung und chronischer Erkrankung und ihren Angehörigen (Federation of Self-Help Associations for the disabled and chronically ill and their relatives);
- Deutsche Arbeitsgemeinschaft Selbsthilfegruppen e.V. (German Association of Self-Help Groups);
- Forum chronisch Kranker und behinderter Menschen im PARITÄTISCHEN (a forum of the chronically ill and disabled, member organisation of the DEUTSCHER PARITÄTISCHER WOHLFAHRTSVERBAND, a German Welfare Association);
- German Medical Association (joint association of the regional medical associations in Germany);
- National Association of Statutory Health Insurance Physicians (KBV).

This platform aims to foster the exchange of common experiences, information and concerns among the medical profession and patient self-help groups.

At the express wish of the Patient Forum patient involvement in the development of the **NVL "Asthma"** was achieved by

- accompanying the development process in the form of a review and feedback procedureⁱ and by
- developing a patient guideline based on the **NVL "Asthma"**.

To this end, the Patient Forum appointed a topic-specific expert group consisting of 6 patient representatives:

- 3 representatives to be appointed by the umbrella organisations;
- 3 persons suffering from the disease in question, also to be appointed by the umbrella organisations;
- 1 moderator from the AQuMed.

The umbrella organisations are represented by:

- Dr. Jutta Hundertmark-Mayser, Deutsche Arbeitsgemeinschaft Selbsthilfegruppen e. V. (DAG SHG; the German Association of Self-Help Groups);
- Mr. Christoph Nachtigaller, BAG SELBSTHILFE e.V. - Bundesarbeitsgemeinschaft SELBSTHILFE von Menschen mit Behinderung und chronischer Erkrankung und ihren Angehörigen (Federation of Self-Help Associations for the disabled and chronically ill and their relatives);
- Mr. Armin Schafberger, Deutsche Aidshilfe e.V. (German AIDS Relief, member organisation of the DEUTSCHER PARITÄTISCHER WOHLFAHRTSVERBAND).

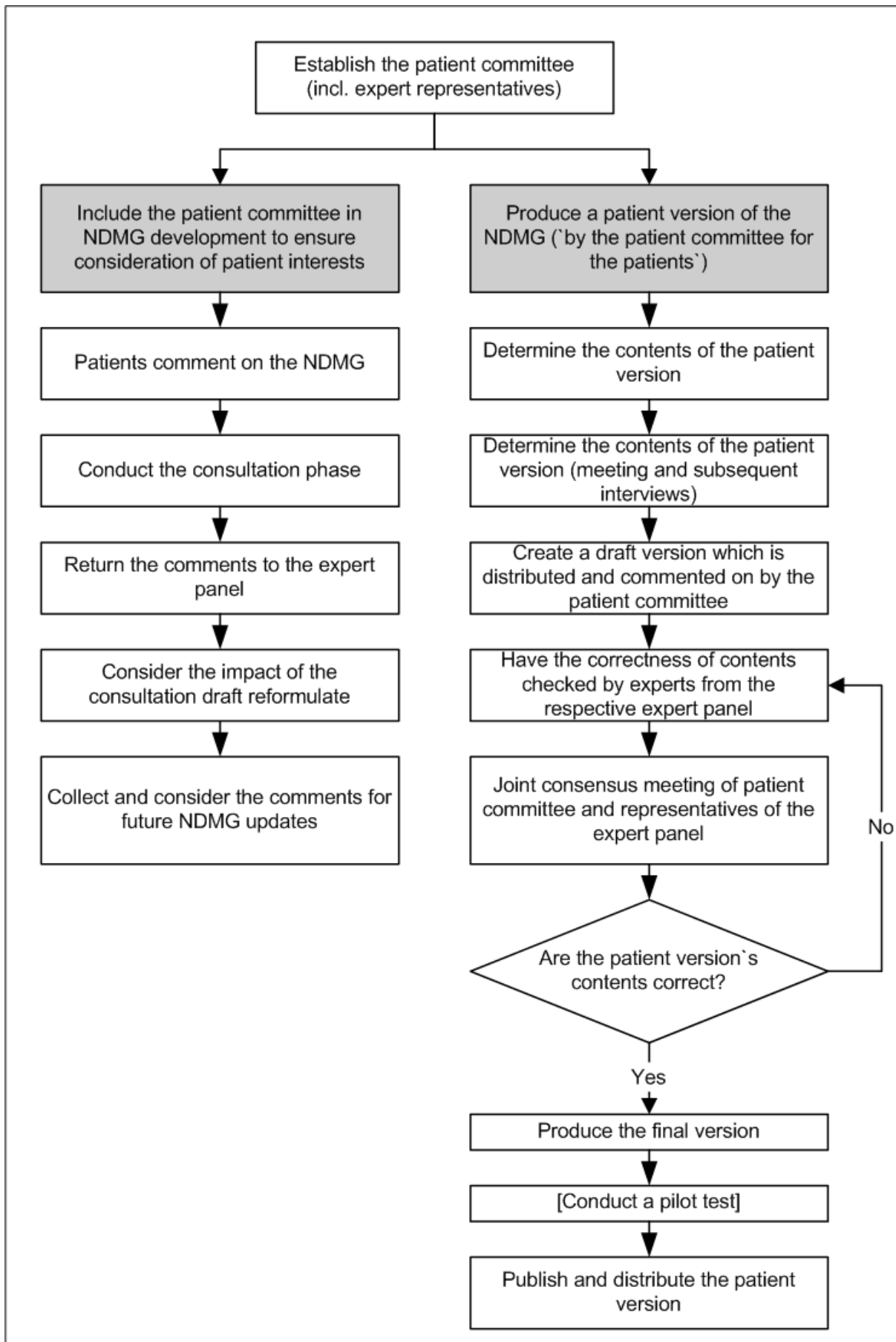
The interests of affected patients are being represented by:

- Mrs. Ingrid Voigtmann, Vice-Secretary of the Deutscher Allergie- und Asthmabund (DAAB; the German Allergy and Asthma Association),
- Mrs. Andrea Wallrafen, Executive Secretary of the DAAB,
- Mrs. Malise Koester, President of the DAAB.

The draft for consultation version of the **NVL "Asthma"** was consented to by the expert panel and submitted for comments to each member of the patient committee. The comments to this consultation draft received from the patient committee will be of relevance for the development of the patient version and the next revision of the **NVL "Asthma"**.

ⁱ Due to the late stage of development of the NDMG Asthma and the very recent implementation of this procedure patients have only been involved since the beginning of the public consultation phase of the guideline process.

Figure 1: Patient Involvement in Flow Chart Form



R 6. Structure and Issues

The main topics and the level of in-depth-analysis in the NVL “Asthma” followed the comments and suggestions of the Guideline Clearinghouse Report on asthma [10].

On this basis, the structure illustrated in **Table 2** was agreed upon. According to the objectives of the Programme for National Disease Management Guidelines special focus was placed on the various aspects of healthcare co-ordination.

Table 2: Structure and Issues of the NVL “Asthma”

1.	Definition, epidemiology, forms of asthma
2.	Diagnosis <ul style="list-style-type: none"> • Medical history • Objective measurements to confirm the diagnosis (adults) • Objective measurements to confirm the diagnosis (children and adolescents) • Algorithm for the allergologic work-up • Differential diagnosis
3.	Therapy <ul style="list-style-type: none"> • Targets of asthma management • Exercised-induced asthma • Pharmacological therapy in adults (stepwise approach) • Pharmacological therapy in children and adolescents (stepwise approach)
4.	Drugs <ul style="list-style-type: none"> • Long-term and on-demand therapy as well as important adverse drug effects
5.	Inhalation systems – prescription, technique, training
6.	Non-medical interventions <ul style="list-style-type: none"> • Patient education • Physical training • Respiratory and physiotherapy • Smoking cessation • Psychosocial disease and management concepts • Weight control
7.	Asthma episodes in adults
8.	Asthma episodes in children and adolescents <ul style="list-style-type: none"> • Management of asthma episodes in children <i>over</i> age 2 • Management of asthma episodes in children <i>under</i> age 2
9.	Asthma during pregnancy <ul style="list-style-type: none"> • Pharmacotherapy during pregnancy • Asthma episodes during pregnancy • Pharmacotherapy during lactation
10.	Measures of asthma prevention <ul style="list-style-type: none"> • Primary prevention • Secondary prevention • Tertiary prevention
11.	Rehabilitation
12.	Measures with insufficient or lacking proof of effectiveness
13.	Co-ordination of care <ul style="list-style-type: none"> • Primary medical care • Referral: attending physician → qualified specialist or qualified facility • Hospital admission • Induction of rehabilitative measures • Occupational asthma
14.	Quality promotion and quality management

R 7. Sources

In accordance with international efforts for co-operation and division of labour in the field of guideline development [5] the German guideline group decided to **adapt a current evidence-based foreign guideline** that addressed consented central topics and issues, namely the “**British Guideline on the Management of Asthma of 2003/2004 (BTS Guideline)** [11]” (hereafter called **source guideline**).

In addition, recommendations of and comments on the following guidelines and documents of German scientific medical societies and professional associations were taken into account:

- **Treatment recommendation for Bronchial Asthma of the Drug Commission (of the German Medical Profession) of 2001** [12];
- **Guideline for the Diagnosis and Treatment of Asthma of the German Airway League and the German Society of Pneumology** [13];
- **Disease Management Programme for Bronchial Asthma in Children and Adolescents** issued by the professional Association of Paediatricians in co-operation with numerous medical societies [14].

Selection of Guidelines:

The selection of the guidelines was based on a systematic guideline search. The search conducted for the Guideline Clearinghouse Report Asthma was updated according to the procedure adopted by the Clearinghouse [10].

The **NVL** group accepted the Clearinghouse quality criteria as quality features that a guideline should fulfil in order to qualify as a source guideline. Great importance was attached to the recommendations' being systematically developed and based on reproducible evidence.

Adaptation of the Source Guideline:

First, the English-language source guideline was translated into German. Then the translated text was commented on by the members of the working group and central topics (see above, **Table 2**) assigned to individual experts or members of the guideline group.

After the experts had principally decided to take the BTS guideline as their basis, a second commenting round followed in a structured form.

The methods of adaptation followed the procedures adopted by, for example, the New Zealand Guidelines Group of 2001 for the adaptation of national guidelines [15] as well as other projects of guideline adaptation [16-18].

The members of the **NVL** group agreed on the principles of guideline modification outlined below:

The text of the original guideline may only be changed or modified if

- an updating is necessary since new information (new publications) have to be considered;
- the statements or recommendations of the original guideline are insufficient or inadequately supported by scientific evidence;
- there is a relevant difference in the healthcare situation of the UK and Germany.

Reviewing the original guideline for the first time revealed that the following aspects needed to be complemented:

- epidemiological aspects of asthma problems in Germany,
- specific features of asthma diagnosis in Germany,
- aspects of medical drug supply in Germany,
- education and training programmes in Germany,
- aspects of the German rehabilitation system,
- co-ordination of care within the German healthcare system,
- quality promotion and quality management in the German healthcare system.



R 8. Selection and Evaluation of Recommendations

Following the structure of the NVL “Asthma” (see Chapter R 6) 60 recommendations were extracted from the source guideline.

All the recommendations in the original guideline were reviewed for appropriateness of content of the underlying evidence (original evidence tables at <http://www.sign.ac.uk/guidelines/fulltext/63/index.html>). Complementary literature searches were conducted on all issues that according to the experts needed to be complemented and/or updated.

In particular, these were structural issues and problems of healthcare delivery related to the German healthcare system. The complementary search has thus been focussed on guidelines and healthcare delivery recommendations of German author groups.

Levels of Evidence and Grades of Recommendations

The judgement of the evidence underlying the key recommendations of the present disease management guideline -- just like the source guideline -- is based on the following evidence grading system of the Scottish Guideline Network SIGN [19] (<http://www.sign.ac.uk>).

Table 3: Grading the evidence of the NVL “Asthma”

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

The evidence grading of the literature adopted from the source guideline was left unchanged.

Table 4: Classification of Guideline Recommendations in terms of Grades of Recommendation

Grade of recommendation	Description	Symbol
A	strongly recommended	↑↑
B	recommended	↑
C	recommendation unclear	↔

As outlined in the current method report on the Programme for National Disease Management Guidelines [2], the grades of recommendation used in the NVL “Asthma” follow the classification of GRADE Working Group [20].

In addition to the underlying evidence the grades of recommendation take into account ethical obligations, the clinical relevance of the studies’ effectiveness measures, the applicability of the study results to the targeted patient group and their applicability in everyday clinical practice⁶.

The NVL methodology thus includes the assignment of grades of recommendation through the guideline authors within the scope of a formal consensus process.

Therefore a Nominal Group Process [21-23] was conducted on July 22, 2004 and moderated by Assistant Professor Dr. Kopp (AWMF) and attended by the named representatives of all the scientific medical societies involved in the development of the guideline.

This process proceeded in 6 steps:

- silent reading of the guideline manuscripts and
- opportunity to take down notes on the key recommendations and the evidence grading suggested;
- registration of statements and alternative suggestions for all recommendations in an individual circulation procedure conducted by the moderator; speaker contributions for explanatory purposes only;
- pre-voting on all grades of recommendations and alternatives suggested;
- discussion of those items where no "strong consensus" could be achieved in the first round;
- final voting.

All 60 extracted recommendations were passed based on a "strong consensus" (approval rate of more than 90%). The outcome protocol of these meetings can be requested from NVL.Asthma@azq.de.

R 9. External Reviewing

Prior to the publication of the final version of the NVL “Asthma” the draft version was posted on a publicly accessible discussion platform for three months (January to March 2005).

The beginning of this external reviewing procedure was announced by both the responsible bodies and the scientific medical societies involved in their respective publication platforms (e.g. by announcement in *Deutsches Ärzteblatt*).

Contributions by interested members of the public, representatives of different interest groups or other individual contributions were collected by the NVL editorial office and passed on to the expert panel for comments. The experts’ decision to accept/reject the contents of each contribution and the reply to the commentator was adopted by consensus.

Both the number of suggested changes and comments and the changes actually required were recorded and the recordings of changes can be requested from NVL.Asthma@azq.de.



R 10. Validity and Updating

Validity Period and Updates

This guideline was published in June 2005. It remains valid until the next updated version will be published or – at the latest – till May 31, 2007.

The guideline is intended to be updated and re-edited every two years – starting from the date of its print publication.

Responsibility for Updating

If new and relevant findings require a revision of the **NVL “Asthma”**, the body responsible for the **NVL** updating process (i.e. the editorial office of AQUMED) will provide a short-term update and inform the public through its website (<http://www.versorgungsleitlinie.de>).

Adaption Protocol

The necessary corrections, changes or editorial revisions of the consented text published on the Internet will be recorded. In order to ensure the transparency and traceability of these changes, the type and date of change, its reasons and responsibilities will be recorded in tabular form. The responsibility for the protocols lies with the AQUMED editorial office.

Presentation of References

The list of references included in the **NVL “Asthma”** and the current **NVL Report “Asthma”** was prepared using the literature database software Reference Manager (Professional Edition, version 11).

A Note about Internet-based Information

Documents and information freely accessible on the Internet have been specially marked in the list of references and provided with a reference date [cited: date notation in the order *year, month, day*].

The respective Internet address (URL) has been fully provided as „Available from:“.

Example:

Bundesärztekammer (BÄK), Kassenärztliche Bundesvereinigung (KBV), Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF). Vertrag über eine Kooperation zum Zwecke der Entwicklung und Beschlussfassung im Rahmen des Nationalen Programms für Versorgungs-Leitlinien. Köln, Düsseldorf: 2003 [cited: 2005 Jul 28]. Available from: <http://www.aezq.de/aezq/0index/vertraege/pdf/awmfvertragfinal.pdf>

R 11. Presentation

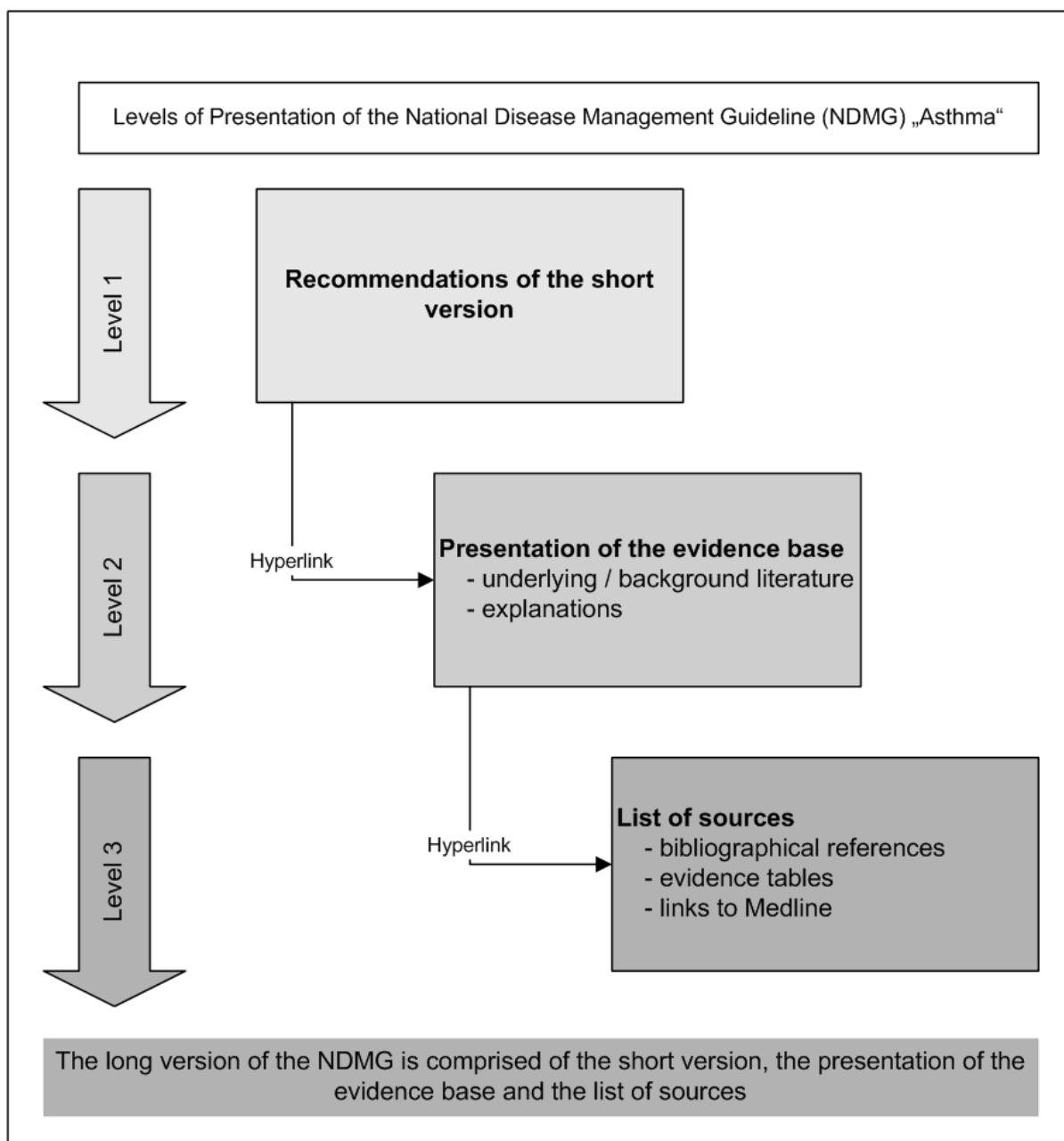
The formal structure of the NVL “Asthma” follows the principles outlined below:

Level 1: Recommendations and statements. This level corresponds to the currently effective short version of the NVL (website presentation, linked with Level 2).

Level 2: Background and evidence. In addition to Level 1, this level provides a discussion and explanation of recommendations (website presentation, linked with Level 3).

Level 3: Sources. In addition to Level 2, this level includes links to the original references underlying the individual recommendations (website presentation, with links to Medline or full text article, if available).

Figure 2: Levels of Presentation of the NVL “Asthma”





At Level 1 the key recommendations are supplied with grades of recommendation and presented in different colours, depending on whether they apply to adults or to children/adolescents or to all target patients.

Particular care was taken over the wording to ensure that the recommendations were action-oriented and easily understandable, if possible, and that their grades of recommendation was already indicated by the choice of auxiliary verb (e.g. "should" for a strong positive recommendation / "should not" for a strong negative recommendation in the case of a superfluous or outdated intervention).

Different decisional options are illustrated by means of, for example, algorithms which are based on a uniform syntax [23; 24] and have been developed using the ALGO programme (Version 1.2) [25] (for a survey of the symbols used see Appendix 2: Standardised Terminology for Clinical Algorithms [6]).

R 12. Application, Dissemination

The dissemination of the **NVL "Asthma"** is the editors' responsibility. The electronic version of the guideline is made accessible via the common Internet presentation of AWMF and GMA/NASHIP at <http://www.versorgungsleitlinie.de> of the Agency for Quality in Medicine (AQuMed), which provides free access to all three levels of the **NVL "Asthma"**. A short version summarising essential key recommendations will be distributed in print form through the scientific medical societies. In addition to the short version, a (short and long) patient version will be developed in co-operation with the patient representatives and made available in both electronic and print form. Its dissemination is supported by the patient representatives that are united in the Patient Forum.

Implementation and Public Relations

Proper implementation requires the dissemination and acceptance of a guideline, which is thus accompanied by specific measures. These include, among other things, the electronic presentation on the Internet just as its publication in print:

- publication as a "Guideline Set" (long version + pocket version + quick reference guide for practice/hospital staff + patient version);
- publication of the short version in the medical journal *Deutsches Ärzteblatt*;
- distribution through the publication platforms and conference meetings of the co-operating scientific medical societies;
- press conference;
- supply of information to the relevant institutions such as the Gemeinsame Bundesausschuss (Federal Joint Committee) (for future Disease Management Programmes) and to the Federal Office for Quality assurance BQS (quality indicators);
- setting up Internet-based modules for accredited continuing medical education.

In a joint project with the University of Witten/Herdecke interactive modules for accredited continuing medical education are being created on the basis of the recommendations of the **NVL "Asthma"** (<http://www.leitlinien-wissen.de>).

R 13. Evaluation

The aim is to evaluate the **NVL "Asthma"** as to its influence on structures, processes and outcomes of healthcare delivery, achievement of health targets, resource consumption and cost-effectiveness as well as their impact on "Structured Disease Management Programmes" (DMPs). Vital components of this evaluation are guideline-related quality indicators. If possible already existing quality indicators should be used, especially if they are used for measurements within DMPs.

As regards the further development of the **NVL "Asthma"** the intention is to establish contacts to the BQS to optimise quality indicators on an appropriate basis by also taking into consideration their broad applicability.ⁱⁱ

ⁱⁱ Bundesgeschäftsstelle Qualitätssicherung (Federal Office for Quality Assurance). Programmes and quality reports at <http://www.bqs-online.de> (available from March 23, 2005)



R 14. Editorial Independence

The development of the **NVL “Asthma”** was editorially independent from the funding bodies. Co-ordination and methodological support of guideline development is funded within the scope of the "Programme for National Disease Management Guidelines". The responsible bodies include the German Medical Association (BÄK), the National Association of Statutory Health Insurance Physicians (KBV) and the Association of the Scientific Medical Societies (AWMF).

Travel expenses incurred for the meetings of the guideline development group are covered by the medical societies involved; the experts work on an honorary basis and free of charge.

All members of the guideline development group have disclosed potential conflicts of interest pertaining to the development of the **NVL “Asthma”** to the editors in written form (Acknowledgement Form see Appendix 1). In the voting procedure (Nominal Group Process) related to the **NVL** development process only the guideline authors listed in Table 1 were entitled to vote.



R 15. Appendices

Appendix 1: Conflict of Interest Acknowledgement Form for NVL authors

Statement about potential conflicts of interest to be submitted by members of the expert panels participating in the joint Programme for Disease Management Guidelines of BÄK, AWMF and KBV

Preamble

Members of expert panels participating in the joint Programme for Disease Management Guidelines of BÄK, AWMF and KBV are required to disclose potential conflicts of interest with this activity.

The experts are personally responsible for the disclosure of potential conflicts of interest. The statement is deposited with the Director of the AQUMED.

There is a vast variety of financial, political, academic or private / personal relationships of varying intensity and relevance which might represent potential conflicts of interest. The question whether these interests will jeopardize the neutrality and impartiality that serving as an expert requires, shall not be settled on the basis of detailed regulations, but rather in terms of a self-statement of the experts.

Statement

The experts' declaration of their independence relates to both financial and commercial facts and interests of the members themselves and is to be submitted to the Director of the AQUMED, who guarantees confidentiality of the information received.

Please disclose information about the following items:

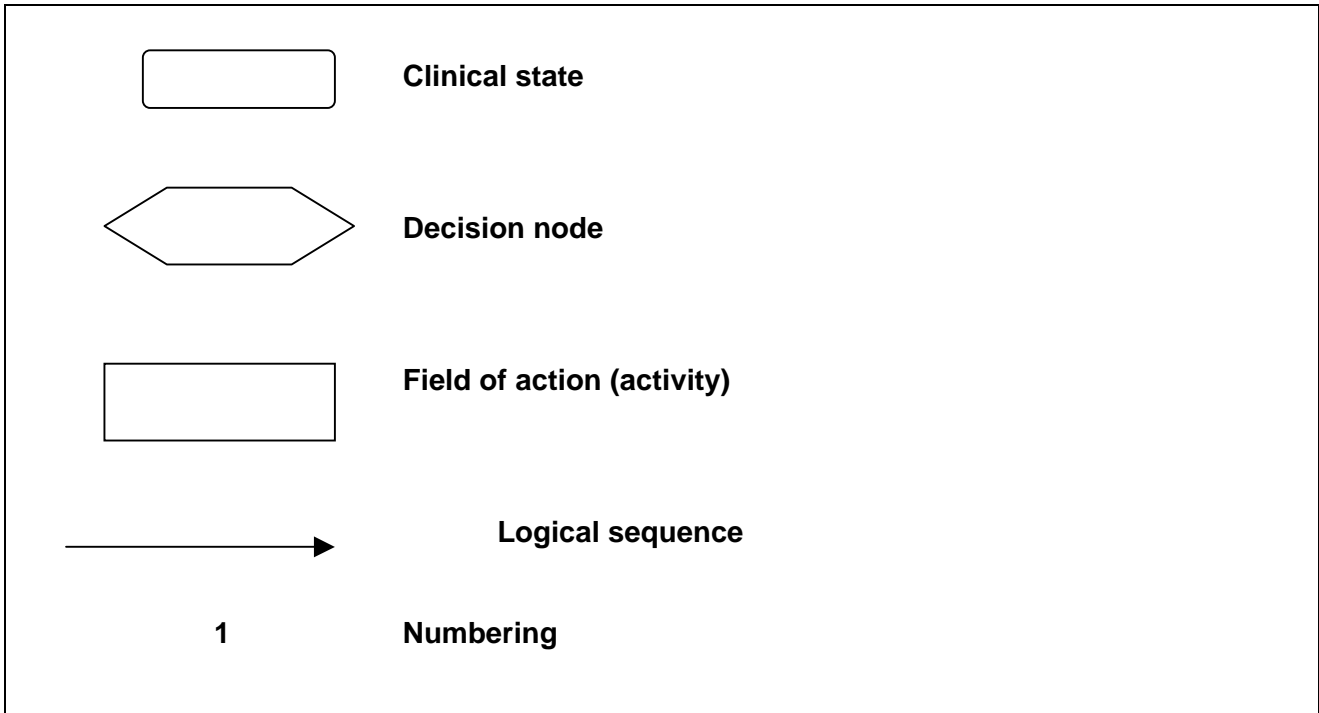
- consulting or reviewing activities for industrial companies, paid participation in the scientific advisory board of a pharmaceutical, biotechnological or medico-technical company
o no o yes, which?
- financial allowances received from the pharmaceutical, biotechnological or medico-technical industry or commercial contract research organizations that exceed the appropriate compensation for the design, conduct and documentation of clinical or experimental studies
o no o yes, which?
- proprietary interests in medical drugs/medical products (e.g. patents, copyrights and royalties from such rights)
o no o yes, which?
- possession of stocks, share capital or equity funds of the pharmaceutical or biotechnological industry (information only required if the amount of 50,000 € is exceeded per security type)
o no o yes, which?
- paid authorship or co-authorship in publications commissioned by pharmaceutical, biotechnological or medico-technical companies during the past 5 years
o no o yes, which?
- The Director of the AQUMED should receive timely notification of relevant changes in writing. Participation in another expert panel for the National Programme for Disease Management Guidelines requires renewal of this declaration.
- Further relations between members of the expert panels of the joint Programme for Disease Management Guidelines and the industry (e.g. allowances paid on the occasion of industry-funded meetings, receipt of monetary and non-monetary donations, financial support for attending conferences or the organisation of specialist conferences) are subject to a regulation published by the various associations in October 2000 under the title "Joint View on the Criminal Assessment of Co-operations between the Industry, Medical Institutions and their Staff" (encl.).
- In the case of potential conflict of interest the Director of the AQUMED, after consultation, decides on the necessary steps to be taken, such as his/her exclusion from discussion and voting of certain product-related issues or topics and if necessary termination of membership.
- If a member does not agree to the measure described in item 8 effected by the Director of the AQUMED, he/she can ask the President of the German Medical Association, the President of the AWMF or the 1st Chairman of the KBV for a final decision, which the above mentioned persons and the Director of the AQUMED must reach unanimously.

Being aware of these regulations I affirm that the above statements are true and correct.

Name/address (stamp)

Date, signature

Appendix 2: Standardised Terminology for Clinical Algorithms [6]





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