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National Disease Management Guidelines

Quality Indicators

– A Manual for Authors

– Short Version –

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EDITOR:**Agency for Quality in Medicine (German abbreviation: ÄZQ)**

Joint Institution of the German Medical Association
and the National Association of Statutory Health Insurance Physicians

AUTHORS:**EXPERT PANEL QUALITY INDICATORS FOR NATIONAL DISEASE MANAGEMENT
GUIDELINES**

Dr. rer. soc. Lutz Altenhofen, Zentralinstitut für die kassenärztliche Versorgung, Köln
Dr. med. Gunnar Blumenstock, M.A., MPH, Institut für medizinische Biometrie, Tübingen
Dr. med. Franziska Diel, MPH, Kassenärztliche Bundesvereinigung, Berlin
Dr. med. Klaus Döbler, Bundesgeschäftsstelle Qualitätssicherung, Düsseldorf
Prof. Dr. med. M. san. Max Geraedts, Institut für Gesundheitssystemforschung, Universität Witten/Herdecke
Prof. Dr. med. Wilfried H. Jäckel, Abteilung Qualitätsmanagement und Sozialmedizin
Universität Freiburg
Dr. med. Regina Klakow-Franck, M. A., Bundesärztekammer, Berlin
Dr. med. Susanne Kleudgen, M.sc., Kassenärztliche Bundesvereinigung, Berlin
PD Dr. med. Ina Kopp, Arbeitsgemeinschaft wissenschaftliche Fachgesellschaften, Marburg
Dr. med. Monika Nothacker, MPH, Ärztliches Zentrum für Qualität in der Medizin, Berlin
Prof. Dr. rer. nat. Dr. med. Günter Ollenschläger, Ärztliches Zentrum für Qualität in der Medizin, Berlin
Dr. med. Anne Reiter, Bundesgeschäftsstelle Qualitätssicherung, Düsseldorf
Dr. med. Susanne Weinbrenner, MPH, Ärztliches Zentrum für Qualität in der Medizin, Berlin
Dr. rer. nat. Ulrich Zorn, MPH, Bundesärztekammer, Berlin

EDITORIAL WORK AND MAINTENANCE

Agency for Quality in Medicine
[Joint Institution of the German Medical Association (BÄK)
and the National Association of Statutory Health Insurance Physicians (KBV)
commissioned by BÄK, KBV and AWMF]

CONTACT

ÄZQ – Redaktion Nationale VersorgungsLeitlinien
Wegelystr. 3/Herbert-Lewin-Platz, D-10623 Berlin
Phone: +49-30-4005-2504 - Fax: +49-30-4005-2555
E-mail: versorgungsleitlinien@azq.de
Internet: <http://www.versorgungsleitlinien.de>

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

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1. Background and Objective

National Disease Management Guidelines (NDMGs) provide transsectoral recommendations on the diagnosis, the treatment and the interface management of diseases. In 2005 the agencies responsible for the NDMG program (namely BÄK, KBV, AWMF) agreed to have quality indicators determined for every NDMG.

The following methods for the identification, selection and assessment of quality indicators were developed by the NDMG Quality Indicators expert panel. The aim is to establish indicators for each NDMG that can be used to review and evaluate guideline-compliant delivery of disease-specific care. Quality indicators for NDMGs shall not only be established for individual steps of care; primarily, such quality indicators should be determined that are able to map the chain of care or to reveal deficits at the interfaces of care. The collection of quality indicators is meant to contribute to guideline implementation and the improvement of the quality of medical care and to help support the further development of the NDMGs themselves [1].

The specific NDMG methodology for the determination of quality indicators will be outlined in following Chapter (Chapter 6 of the Long Version).

This Manual is meant to inform NDMG authors that are actively involved in the process of quality indicator determination.

References

- [1] Kopp I, Geraedts M, Jäckel WH, Altenhofen L, Thomeczek C, Ollenschläger G, Nationale VersorgungsLeitlinien – Evaluation durch Qualitätsindikatoren. Med. Klinik 2007; 102: 67B-82 (Nr.8)

2. Quality Indicators for National Disease Management Guidelines (NDMG)

(M. Nothacker, A. Reiter)

The following chapter describes the specific methodology used to determine NDMG quality indicators. NDMG quality indicators need to be determined for important areas of diagnosis or therapy or the required interface management. The aim is to establish indicators that can be used to review and evaluate guideline-compliance of the respective medical care. Quality indicators for NDMGs shall not be established for individual steps of care alone. In the first place, quality indicators should be determined that are able to map the chain of care or to reveal deficits at the interfaces of care.

The indicators selected during the NDMG development process are preliminary methodically assessed indicators. Their application in practice, though, requires additional specifications (e.g., specific data fields) and their full methodological assessment. Therefore each quality indicator will have to be pilot-tested.

The criteria for the preliminary methodological assessment have been derived from QUALIFY, an instrument for assessing quality indicators which was developed by experts of the former Federal Agency for Quality Assurance (German abbreviation: BQS) in 2006 [2]. QUALIFY comprises 20 criteria subsumed under three major categories. Altogether, five criteria have been selected to assess quality indicators from National Disease Management Guidelines. Information should also be provided for three other criteria which need not be assessed though (see Sect. 3).

Identifying Quality Indicators during the NDMG Development process

Basic Information

When they start their guideline work NDMG authors are provided with basic information on quality objectives and quality indicators. Both guideline objectives as well as guideline recommendations are quality objectives. The objectives of guidelines will rather be outcome driven while recommendations of a guideline will generally be given for structures and processes. Particular care must be taken that the formulation of guideline objectives as well as the corresponding recommendations is as specific as possible. Only specific formulations can ensure a measurable change of health care problems. Hence, a strong recommendation should only be given if its action target can be operationalized.

In addition, NDMG authors will learn about the criteria to be used for the assessment of quality indicators for the guideline to be developed (see below).

Accompanying Literature Search for Quality Indicators

At an early stage guideline authors will be provided with already implemented national and international quality indicators after a special search has been conducted. A comprehensive systematic search for quality indicators cannot be performed as an only database-related process yet. Therefore the search for national indicators will mainly be run in the following sources: disease management programs, external inpatient quality assurance (by BQS – federal committee of quality assurance - until 2009) or transsectoral quality assurance (from 2010 both by the AQUA Institute) and the set of ambulatory indicators of the “AQUIK”-project of the Federal Association of SHI Physicians as well as ambulant indicators of the “QUISA”-project of the AQUA Institute. If required, other national sources will be considered as well. An additional an international topic-related search for existing indicators is conducted in various databases (e.g., National Quality Measures Clearing House, Pubmed). Also, quality indicators mentioned in source guidelines are extracted. The national and international quality indicators identified on a certain topic are made available to the guideline authors in the form of a synopsis.

Prioritization of Quality Objectives

The NDMG methodologists involved will prioritize the most important core objectives if necessary. The required core processes or structures for these objectives will be determined by the corresponding recommendations. In analogy to the selection of topics during the NDMG development process (R6), this prioritization will take into account the following criteria:

- potential for improvement achieved through the NDMG;
- *[diseases with]* transsectoral treatment demand;
- frequency of the special disease aspect;
- burden of disease [3].

Synopsis of Potential Indicators from the NDMG and Existing Indicators

In the next step the core objectives and recommendations of the guideline are converted into potential quality indicators. A synopsis is prepared including the indicators identified through the national and international searches and subdivided according to the various guideline sections. Potential indicators will generally be displayed as rate-based indicators, that is, a denominator and a numerator will be defined. A special case of a rate-based indicator is rare events (so called “sentinel events”) requiring, by all accounts, a quality check. Both forms of quality indicators are possible for guideline indicators.

Assessment of Potential NDMG Quality Indicators

Assessment Criteria

The assessment of NDMG quality indicators by the guideline authors is performed in a structured manner using the criteria from the QUALIFY instrument, which was developed by the BQS [2] (All QUALIFY criteria see Appendix 1)

The assessment is - as mentioned before - a preliminary one. The development of indicators has to be completed before a final overall assessment can be conducted. For example, the question of the availability of data cannot be definitely answered until through pilot-testing it is clearly defined which data is needed.

The list of possible indicators will be assessed using the following criteria:

- Importance of the quality characteristic captured with the quality indicator for patients and the health care system;
- clarity of the definitions;
- Indicator expression can be influenced by providers;
- Consideration of potential risks / side effects;
- Evidence- and consensus-basis of the indicator

The assessment of the evidence- and consensus-basis of the indicator is different from the approach used in the QUALIFY system. The analogous criterion in QUALIFY "indicator evidence" was adapted for application in guidelines. There is no new appraisal of the evidence for the assessment of NDMG quality indicators; instead, the "A" ratings of recommendations will be adopted as positive assessment of this criterion. Due to the processing of the evidence and the formal voting procedure for recommendations with a strong grade of recommendation the evidence- and consensus-basedness of the indicator is taken for granted, even if it is pure expert consensus. Apart from grade "A" recommendations the objectives that have been formulated and established for the guideline by interdisciplinary consensus will also be considered potential quality indicators.

The assessment of indicators will be conducted using the following response categories:

Response categories:

1 = Disagree

2 = Rather disagree

3 = Rather agree

4 = Agree

The only criterion where “yes” or “no” answers are indicated is “Consideration of potential risks / side effects”.

NDMG authors will provide information about three more QUALIFY criteria, namely:

- risk adjustment;
- data availability;
- implementation barriers.

These three criteria are not incorporated in the assessment since they are not regarded as primarily conducive to the prioritization of indicators for guidelines. Information on these criteria will be recorded, though, so they can be taken into account for the further development– for example, in a pilot test.

The criteria mentioned above will be explained subsequently.

1. Importance of the quality characteristic captured with the quality indicator for patients and the health care system

The following (core) statement will be assessed: “The indicator captures essential aspects of quality of life, morbidity or mortality or indicates essential care processes or care structures relevant to them.”

There is consensus in the literature that this quality criterion is a fundamental prerequisite to a reasonable use of quality indicators (e.g., AWMF and ÄZQ 2001; McGlynn 2003; JCAHO 2006).

For lack of a sufficient knowledge base individual arguments (large number of cases, high burden of disease, etc.) for the importance of an indicator will not be weighed. Rather, all arguments shall be included in the assessment while taking due account of the NDMG authors’ personal expertise. A favorable assessment requires the presence of at least one argument.

The importance of the indicator may be due to, for example:

- the frequency and/or severity of an adverse event (high risk)
- a large number of cases in the area of care under investigation
- high costs
- high variation in care (established or presumed)
- a low level of care overall
- the capturing of essential steps of the treatment process, in particular of processes across interfaces;
- current changes in the delivery of health care or of guidelines;

- current changes in the general conditions (e.g., remuneration, Medical Service Centers, Disease Management Programs) with potential disincentives for the delivery of health care;
- compatibility with national/regional objectives for quality in the health care system;
- great public interest, especially among patients.

Information on which to base assessments

In cooperation with the methodologists the NDMG authors are expected to demonstrate the relevance of every possible indicator, if feasible.

They should collect as much relevant information as possible to assess the core statement. Information sources may include, for example, quality assurance data (e.g., external quality assurance by the BQS), data from registries, epidemiological data from health reports, administrative routine data, statistics (e.g., causes of death statistics) or national and international publications. The assessors' information gained in their respective fields of experience (e.g., quality circles, self-help organizations) is relevant as well.

2. *Clarity of the Definitions*

The following statement will have to be assessed: "The indicator is clearly and unambiguously defined."

This quality criterion evaluates whether the indicator is based on clear and unambiguous definitions throughout the process - from its collection to its interpretation through its users. It is an important prerequisite to ensure high reliability, sensitivity and specificity. Hence, this is a key quality criterion that must always be assessed. If there is a lack of clarity and unambiguousness, the outcomes of the quality indicator will rather be random and thus not powerful enough.

The indicator must be defined clearly and unambiguously. In particular, it must be possible to define the following aspects of a quality indicator:

- calculation of the indicator (denominator and numerator);
- data and data collection method;
- data sources, measuring method;
- reporting method;
- recipients/intended purpose.

In the preliminary assessment of NDMG indicators only the first aspect need to be considered.

Information on which to base assessments

In order to assess the core statement assessors will have to check the following information for the preliminary assessment: possibility of deriving an unambiguous calculation rule (numerator, denominator). The possibility of applying a measuring method (e.g., wound infections are classified according to CDC), possibility of a reference range (or, the possibility of 100%) is not yet possible to assess without data. Also specific data fields can only be determined after risk adjustments (e.g., as contributing factors) have been conducted and calculation rules defined, and must then undergo assessment.

3. Indicator expression can be influenced by providers

The following statement will have to be assessed: "The quality indicator refers to an aspect of care that can be influenced by the quality assessed providers."

The criterion is used to evaluate whether the quality assessed health care provider can actually influence the outcome of care within the existing care structures by means of process control.

This criterion is an essential prerequisite to improving quality by using quality indicators, and has also been considered a major criterion in the literature. Quality indicators must refer to aspects of care where the indicator value can actually be influenced by the quality assessed players. If the assessed aspect of care cannot be influenced in real-life health care situations, it is unable to provide any benefits in terms of quality improvement.

Examples of positive and negative influence:

A quality indicator like "number of prenatal examinations" is difficult to be influenced by the obstetrician since these examinations are the responsibility of other physicians.

On the other hand, an indicator like "details about the safety margin in breast cancer surgery provided by histologists" can definitely be influenced by the surgeon since details about the safe surgical margin is information that is indispensable in assessing the correct performance of the surgical procedure.

Information on which to base assessments

The assessment of the core statement is based on the empirical experience of the experts conducting the assessment. In individual cases, it might be necessary to run an additional search (e.g., on the actual availability of certain treatment methods in a particular setting).

4. Evidence and consensus basis of the indicator

The following statements will have to be assessed:

With structure indicators: "The presence of the measured structure leads to an improved outcome."

With indicators for treatment indications: "Meeting the measured indication criteria leads to a positive benefit/risk ratio."

With process indicators: "The presence of the measured process leads to an improved outcome."

With outcome indicators: "The measured outcome can be influenced by the health service provider."

The evidence- and consensus-basis of the quality indicator indicates whether there is evidence or expert consensus that optimal indicator values reflect improved medical care. In systematic consensus procedures the scientific evidence from the literature and underlying source guidelines will be considered along with practical clinical experience. The definition depends on the kind of indicator (structure, process or outcome indicator).

The following definitions are used:

- For structure indicators:
There is scientific evidence (and/or expert consensus) that an improved outcome occurs if the measured structure is present (relationship between structure and outcome)
- For process indicators:
There is scientific evidence (and/or expert consensus) that an improved outcome occurs if the measured process is present (relationship between process and outcome)
- Indicators for medical indication (as a special case of process indicators):
Meeting the measured indication criteria leads to a favorable risk/benefit ratio (relationship between indication and outcome).
- For outcome indicators:
There is scientific evidence (and/or expert consensus) that the measured outcome can be influenced by the health care provider (relationship between outcome and process/structure). Definition of a point in time suitable for measuring the outcome:
There is scientific evidence that important statements can be derived at the time of treatment outcome measurement.

Information on which to base assessments

The information on which to base the assessment of the evidence- and consensus-basedness of the indicator includes the scientific studies and source guidelines underlying NDMG recommendations or objectives and the clinical expertise of NDMG authors. The grade of recommendation of the National Disease Management Guideline will be adopted.

The level of evidence deriving from the underlying studies or the level of evidence provided by the source guidelines as well as the strength of the recommendation established on the basis of clinical expertise will be displayed in a transparent manner. If available, the level of consensus will be indicated in addition to the grade of recommendation. The indicator will hence be broken down into three separate sub-aspects:

- the level of evidence,
- the grade of recommendation, and
- the level of consensus (if available).

The grade of recommendation is most important to the assessment of the indicator.

5. Consideration of Potential Risks/Side Effects: "Are there potential risks of false incentives?"

The following statement will have to be assessed: "There are no risks known or the known or suspected risks are considered, if necessary, through the use of the indicator."

This criterion does not assess whether, in principle, the use of unsuitable (e.g., inadequately risk-adjusted) indicators can create disincentives (e.g., for risk selection) in a reporting context.

The assessment of this quality criterion consists of two steps:

1. Will the indicator provide potential disincentives? And if so:
2. Will these disincentives be counterbalanced by suitable measures such as, for example, the use of parallel indicators (antagonists)?

Examples of quality indicators generating disincentives will help to promote wider understanding of this criterion. So – for example – a quality indicator "Avoiding perforation in cases of acute appendicitis" The use of this quality indicator could create an incentive to make the indication for an appendectomy too broad to avoid perforations at all costs.

The risk of such a false incentive can be controlled by using a parallel indicator "confirmation of the suspected diagnosis, acute appendicitis, by histological findings". If a parallel indicator is necessary, both indicators should be used together or not at all.

Potential disincentives might be controlled by pointing out these risks when describing the indicator (rationale) or by providing a guide to interpretation or by defining upper and lower reference ranges for the quality indicator in question.

This criterion does not evaluate whether in principle the use of inappropriate (e.g. not sufficiently risk-adjusted) indicators in the context of public reporting can give false incentives (e.g. for risk selection).

Potential false incentives can possibly also be controlled by referring to the risks in the description of the indicator (rationale) or in an interpretation aid or by using upper and lower reference ranges for the quality indicator of concern.

Information on which to base assessments

For the assessment of the core statement, as much relevant information as possible should be compiled. Sources of information can for example be data from the quality assurance activities (e.g. performance measurement by BQS), in particular from the *Structured Dialogue* and feedbacks from the hospitals. Also, an essential source of information is the clinical judgment, which undesired consequences can occur with the pursuit of the quality goal. Furthermore, the evaluators can contribute also from their areas of expertise (e.g. quality circles, self-help organizations, scientific societies, pay-for-performance).

Assessment: Yes / No

If the answer to the 5th criterion is “Yes”, a list of potential risks will be prepared.

Additional Criteria

The following criteria will be considered, but they will not be assessed.

6. Data Availability

The following statement is considered: “The data will be routinely recorded by the health care provider, or an acceptable level of effort is needed to collect additional data.”

The Data Availability Criterion will be reviewed along with the criterion of data collection effort of the QUALIFY instrument since the development of a joint base of information to be applied to both aspects is reasonable. The extent to which the data collection burden is acceptable is directly related to the relevance of the quality indicator. With a low overall level of care, a large number of cases and a high expectation of benefit, a higher data collection burden can be warranted.

All data that can be used to calculate the quality indicator will be reviewed in order to assess this core statement. It makes sense to distinguish between administrative routine data that are available without further efforts, clinical routine data that are available without requiring further efforts only if software assisted clinical documentation systems are accessible, and data that are specifically collected for quality assurance purposes and must be recorded and always call for additional efforts (for a description see Table 1).

Table 1: Availability, collection and recording burden categorized according to the type of data

Information Base

Type of data	Data availability, data collection/recording burden
Administrative routine data	Data have been recorded electronically and are already available in databases

Clinical routine data	Data are available on paper but need to be recorded electronically unless they are already available in databases
Data to be additionally recorded	Additional data must be collected and recorded electronically

7. Risk Adjustment

The following statement will be considered as part of the preliminary assessment:

“All known relevant factors that have an influence on the outcome of the quality indicator can be considered.”

This quality criterion is relevant insofar as the results should actually reflect the quality of care and not the case mix of the health service provider under assessment. Most frequently, the factors influencing an indicator are patient characteristics such as severity of disease and comorbidities. Patient preferences may also be considered in this context. In addition, factors may be influential that are related to the patients' social class or place of residence. The evaluation of this quality criterion requires high methodological and professional medical competencies on the assessors' part. Factors that have an essential influence on the indicator value shall be identified, collected and considered for adjustment when they are later applied in practice.

Information Base

All known contributing factors shall be listed.

8. Barriers to Implementation

The following statement will have to be assessed: “There are no known barriers to implementation, or they can be taken account of through adequate measures.”

This quality criterion refers to potential barriers that might compromise the appropriate use of an indicator. Examples for such barriers are, for example, additional costs for the health care system incurred from the delivery of indicator-compliant medical care or conflicting recommendations of competing guidelines.

Consideration needs to be given to the fact that poor understandability of the indicator or an inappropriately high data collection demand may represent barriers to implementation. For the full methodological assessment these factors will be assessed as independent quality criteria.

However, existing implementation barriers do not automatically constitute a methodological flaw of the quality indicator. On the contrary, extra costs resulting from indicator-compliant health care delivery can, for example, be taken as an explicit reason for the relevance of an

indicator (see the importance of the quality characteristic covered by the quality indicator to patients und health care system). In this context it is certainly relevant whether the assessment of the quality of care through quality indicators is conducted on a voluntary basis or whether participation therein is mandatory.

There is no experience in addressing this criterion. In the development of guidelines where barriers to successful implementation need to be overcome this criterion is included in methodological guideline assessment though. It is not mentioned in relevant information sources about quality indicators. Future experience will show whether this quality criterion will stand the test or whether it may possibly be put to a more effective use at the level of evaluation of indicator sets.

Information on which to base the assessment

In order to evaluate the core statement, indicator-specific barriers that might hinder the successful implementation of a quality indicator need to be identified on the basis of specific expertise in the respective health care area. In individual cases supplementary searches by using, for example, the DRG grouper might be helpful.

4. Assessment-based Selection of Quality Indicators

Acceptance thresholds have been defined for the first five criteria:

1. Importance of the quality characteristic captured with the quality indicator for patients and the health care system
2. Clarity of the definitions
3. Indicator expression can be influenced by the providers
4. Evidence- and consensus-base of the indicator
5. Consideration of potential risks / side effects

The acceptance threshold for a quality indicator was determined as a positive assessment of at least 75% in the written assessment process (75% "rather agree" or "agree" ratings). At least 75% of the NDMG authors involved need to participate in this written assessment.

Following the written assessment a consensus conference of NDMG authors takes place where both accepted (in written form) and unaccepted indicators are discussed. The respective indicators will finally be accepted into the set of preliminarily assessed indicators if at least a 75% consensus is achieved.

The three criteria of data availability, risk adjustment and implementation barriers are used in a descriptive sense.

5. Presentation of Quality Indicators in NDMGs

The – preliminarily- assessed quality indicators are presented in the Section “Quality Management and Quality Indicators” of the respective NDMG.

Information on risk adjustment, data availability and implementation barriers compiled by the authors is provided together with specifications of the indicators proposed; the latter can be found in the guideline. If required, the necessity of further specification will be indicated. The quality indicators will be marked as being preliminarily assessed.

Appendix 1:

Table 2: QUALIFY - criteria

Category	Criterion
Relevance	Importance of the quality characteristic captured with the quality indicator for patients and the health care system
	Benefit
	Consideration of potential risks / side effects
Scientific soundness	Indicator evidence
	Clarity of the definitions (of the indicator and its application)
	Reliability
	Ability of statistical differentiation
	Risk adjustment
	Sensitivity
	Specificity
Feasibility	Validity
	Understandability and interpretability for patients and the interested public
	Understandability for physicians and nurses
	Indicator expression can be influenced by providers
	Data availability
	Data collection effort
	Barriers for implementation considered
	Correctness of data can be verified
	Completeness of data can be verified
	Complete count of data sets can be verified

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