

Development of guideline- based quality indicators

Methodology for the German
Guideline Program in Oncology

Version 3.0, April 2021

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1. Information about this publication

1.1. Editors

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1.4. Changes compared to the prior version (2.1)

Sections [4.2.2](#) and [4.3](#) were supplemented. In particular, the process of including guideline groups concerning the approval of indicators was broadened.

1.5. Citation

German Guideline Program in Oncology (German Cancer Society, German Cancer Aid, Association of the Scientific Medical Societies). Development of guideline-based quality indicators: methodology for the German Guideline Program in Oncology, version 3.0. 2021, available from: <http://www.leitlinienprogramm-onkologie.de/methodik/informationen-zur-methodik/> (accessed mm/dd/yyyy).

2. Aim and intended audience

This document provides an overview of the methodology for developing guideline-based quality indicators (QIs) established by the German Guideline Program in Oncology (GGPO). This publication is intended for guideline developers, health care providers in oncology, and quality initiatives in oncology (see National Cancer Plan, goals 5, 6, and 8 [1, 2] and international methodologists in the field of Quality Measurement and Guideline development .

3. Background

The German Cancer Society (DKG), German Cancer Aid (DKH) and the Association of the Scientific Medical Societies (AWMF) in Germany jointly launched the German Guideline Program in Oncology (GGPO) in 2008. This program aims to foster the development, implementation, and evaluation of evidence-based clinical practice guidelines in oncology. From these guidelines, indicators for measuring the quality of structure, processes and outcomes can be developed based on recommendations, by which the quality of cancer care and adherence to guideline recommendations can be assessed. These QIs serve internal quality management for medical institutions as well as for benchmarking with other institutions. Quality indicators are generally developed for areas in which the guideline developers and others in the health care system have identified potential for improvement.

4. The quality indicator development process

With the first guideline project starting in 2008, the concept of establishing standardised QIs based on current guidelines was developed according to the methodology of the German Disease Management Guidelines and the QUALIFY assessment tool [3, 4] and implemented for each guideline topic [5, 6]

In addition to the guideline developers and methodologists from the GGPO and the certification program of the German Cancer Society, patients or patient representatives and staff involved with collection of documentation and assessment of relevant quality initiatives are regularly involved in the development of QIs within the GGPO (section [4.1](#)). The individual steps of the development of guideline-based quality indicators are described in the following chapters and summarized in [Figure 1](#). The described methodological processes correspond to the reporting standards of the Guidelines International Network (G-I-N) [7].

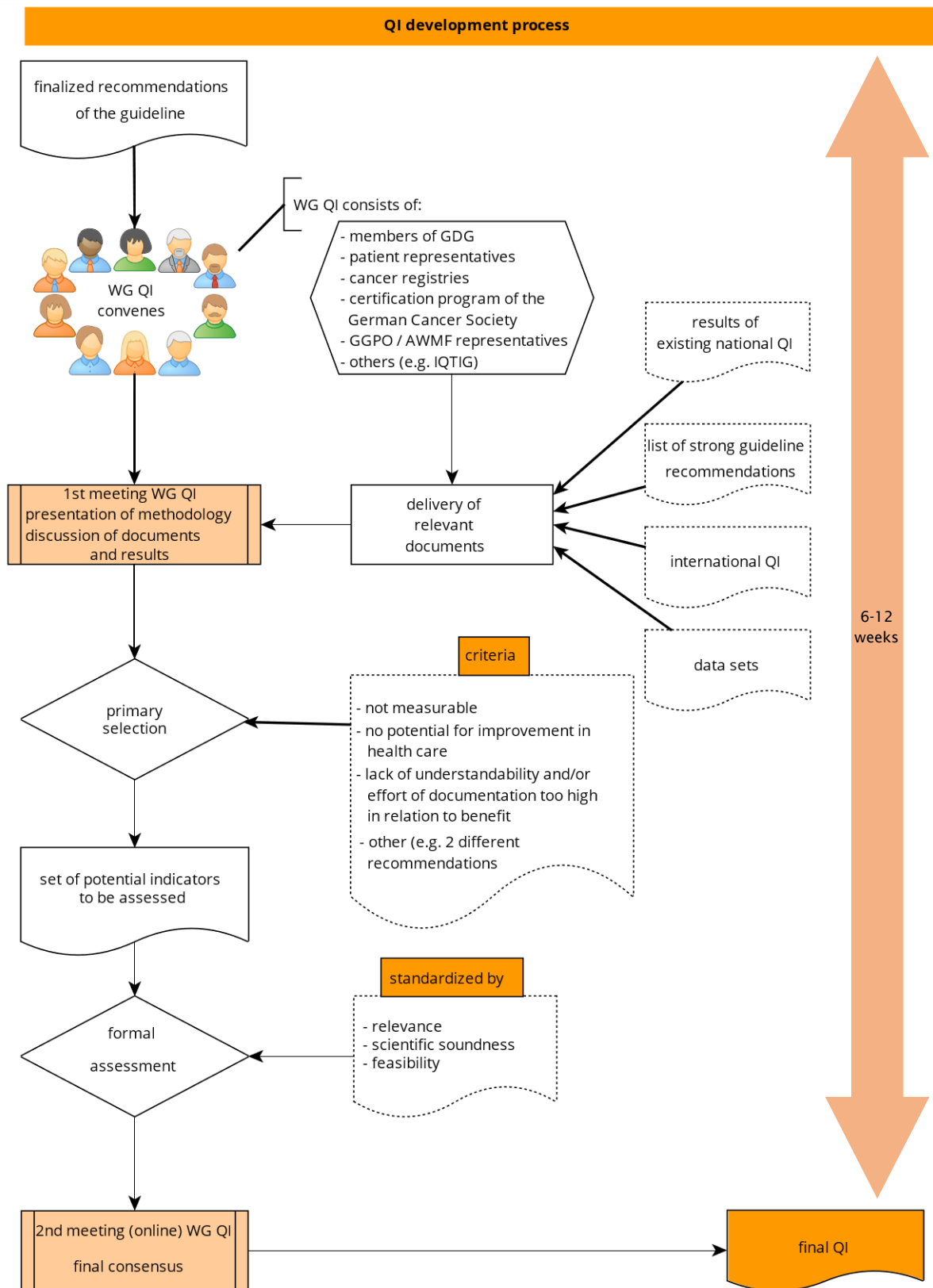


Figure 1: Summary of the quality indicator (QI) development process within the German Guideline Program in Oncology.

4.1. Composition of a representative group of quality indicator developers

Generally, the development of QI from guideline-based recommendations is addressed during the kick-off meeting of the GDG. In this meeting, it is explained that the members of this QI development group should be elected during the last consensus conference at the latest. This QI working group should be interdisciplinary and composed of persons covering the relevant guideline topics. The representatives of the users and operators of the QIs that are usually involved include commissions of centres certified by the certification commissions of the German Cancer Society, clinical cancer registries via the Association of German Tumour Centres (ADT) and other relevant quality management initiatives (see [Table 1](#)). The process is supervised and supported methodologically by a representative of the GGPO office and a representative of the AWMF and the certification program of the German Cancer Society.

Table 1. Composition of the quality indicator (QI) working group.

Number of representatives	Institution	Voting right
3-7	Experts from the Guideline Development Group (GDG)	+
1-2	Patients and patient representatives from the GDG	+
1	Cancer registries	
1	Certification system of the DKG	
1	IQTIG Institute*	
2	GGPO office and AWMF (one representative from each)	-

*For indications with an existing assignment from the Federal Joint Committee for sectoral or cross-sectoral quality management.

4.2. Preparation of documents

In preparation for the first meeting of the quality indicator working group (QI WG), the steps outlined in sections [4.2.1](#) through [4.2.4](#) are completed.

The results of the research described below are summarised in a synopsis and distributed to all members of the working group prior to the first meeting. This should be done by individuals who are methodologically experienced in QIs and documentation.

4.2.1. Creating a primary set of quality indicators based on guideline recommendations

The QI development process is addressed during the kick-off meeting of the GDG. It is emphasised that only strong recommendations can be translated into potential QIs, and that these recommendations should be as specific as possible. Recommendations with a grade of recommendation A (“should be done”), are considered, since it is assumed that the interventions addressed in these recommendations (or their forbearance in case of negative recommendations) have a clear benefit for most of the patients and therefore are eligible for QI development. This is regardless of whether the recommendations are evidence or consensus based, as study-based evidence is usually not available for every aspect of a guideline. Despite this, the GDG may see a significant potential for improvement concerning a recommendation formulated via expert consensus. Furthermore, specific aims of the guideline can be considered for QI development if explicitly stated (quality of results). If possible, the nominator and denominator are defined from these recommendations and / or defined specific aims at this point.

4.2.2. Search for international quality indicators

A systematic search for QIs based on the guideline topic should be performed using bibliographic databases (PubMed, Cochrane), as well as websites of known national and international institutions developing or publishing QI in oncology. Since no comprehensive QI database is available, each search must be adapted to the specific guideline topic.

4.2.3. Search for existing national datasets

In the next step, existing national requirements for documentation (ADT-basic data set with organ-specific modules, catalogue of requirements of the certified centres, obligations for documentation by law, etc.) are screened and compiled. Members of the GDG are asked about other existing topic-specific systems for documentation. Taking existing or planned documentation systems into account is important to limit documentation effort.

4.2.4. Search for results of nationally measured quality indicators

In case of measured and analysed (guideline-based if applicable) QIs in Germany, these results are collected for the first QI WG meeting (e.g., updated QIs relevant for planning of the guideline for diagnostics, therapy and follow-up care of breast cancer [5]).

4.3. First meeting of the quality indicator working group

The aim of the first meeting of the QI WG is to pre-select potential QIs identified in the data collection stage (as described in sections [4.2.1](#) through [4.2.4](#)). It should be planned as a personal meeting; an online conference is possible. Based on this primary QI list, a primary selection is obtained by QI WG consensus according to the following exclusion criteria:

A1: the recommendation cannot be operationalized (generally not measurable)

A2: no potential for improvement in health care,

A3: lack of understandability and/or effort for documentation too high in relation to the benefit

A4: other (e.g., duplicates QIs from two different recommendations).

These exclusion criteria are derived from four criteria for QI basic requirements, which are defined in the German Assessment Instrument QUALIFY [4]:

- Importance of the quality characteristic captured with the quality indicator (category “relevance”)
- Clarity of the definition of the indicator and its application (category “scientific soundness”)
- Understandability and interpretability (category “practicability”)
- Data collection effort (category “practicability”)

Acceptance of a QI occurs by a vote, following the rules for consensus finding for recommendations (AWMF rule book, available from <http://www.awmf.org/leitlinien/awmf-regelwerk.html>), meaning that a majority of 75% of the votes is required.

4.4. **Written assessment of potential quality indicators**

The preselected set of potential QIs need to be assessed using a standardized sheet (see [Table 2](#)). The questionnaire is based on the criteria mentioned above from the category “relevance” (additionally: taking into account “potential risks / side effects”), scientific soundness and practicability of the QUALIFY instrument agreed upon by all voting members of the QI WG. Two additional criteria (“risk adjustment” and “barriers to implementation”) can be commented on. The criterion “evidence or consensus based” is answered by documenting the body of evidence underpinning the recommendations of the guideline and is not assessed again.

To support the assessment of the criterion “documentation effort” the cancer registries and the certification system (and others if available) are providing information about the data availability for implementation of the quality indicator, taking into account the oncological basic data set including its organ-specific modules and the requirements imposed by the certification process.

Assessment is conducted using categories “no” and “yes”. Basing on the results of the written assessment a QI is accepted if the agreement is greater than or equal to 75% for each criterion. (Attention: Different from the criteria 1, 2, 3 and 5 the answer “no” for criterion 4 is taken as approval).

4.5. **Second meeting of the quality indicator working group**

A moderated online conference is conducted after all members of the working group have evaluated the written assessments. The results of the assessment are discussed and the final set of QIs are defined. In case of any changes of the written assessment during the online conference, results are documented, and votes recalculated. For the final acceptance of a QI, agreement of greater than or equal to 75% is needed for each assessment domain. The GDG is provided with the results for consenting acknowledgment. Feedback is possible and will be handled by the QI WG.

4.6. **Time frame**

The work of the QI WG can begin immediately after final consensus of the recommendations has been reached. Based on experience, the whole process can be finalised within 6–12 weeks (see [Figure 1](#)). Consideration should be given to the common determination of dates and the time required to search for international QIs.

4.7. **Documentation**

The procedure of generating and updating the QIs should be comprehensively documented according to the procedure described in section 4. All documents compiled during the process should be accessible in the guideline report or can be provided by the GGPO office on request.

5. **Pilot testing**

Pilot testing of QIs in a defined setting is not regularly planned. Projects can be supported on request.

6. **Validation**

The final set of QIs is transferred to the Cancer registries, the certification commissions of the German Cancer Society and potential other institutions with the objective of implementation [8-15]. It is the responsibility of these institutions to decide to implement the set of QI completely or partially. However, implemented QI must not be changed. The annual results of the QI documented by hospitals or cancer registries, or provider of documentation systems are used to investigate practicability, plausibility, content validity and - if possible - for the assessment of the direct methodological characteristics such as the ability to discriminate. The observed potential for improvement must be reported to the QI WG by the representative of the certification commission (see section 7).

7. **Re-evaluation and updates**

The QIs always refer to the current guideline. Therefore, when updating the guideline, the QI WG needs to be reactivated to evaluate the results of the measured QIs and to determine whether the previous QIs need to be updated. For guidelines updated as a living guideline, the QI WG convenes once every three years. During the guideline update process the information of already implemented and analysed guideline-based QI needs to be reported to the complete guideline development group. In addition to the aggregate annual results of the certified centres presented by the certification program of the German Cancer Society, the representatives of the Association of German

Tumour Centres are requested to present the QI results of the cancer registries, if possible. The corresponding process is shown in [Figure 2](#).

Changes and additions compared to the first quality indicator development process are displayed above. The aim is to close the quality circle, which means that the results of existing and implemented guideline-based quality indicators are presented to the GDG at the beginning of the guideline update process. Thereby, it is possible to early during the status analysis of updated recommendations. Independent of this, a quality indicator working group must be reconstituted using the established composition. Beside creating new QI deriving from new, strong guidelines recommendations the current QI WG must assess the results of established, guideline-based QI. This may lead to adoption, modification, or retirement the former guideline-based QI.

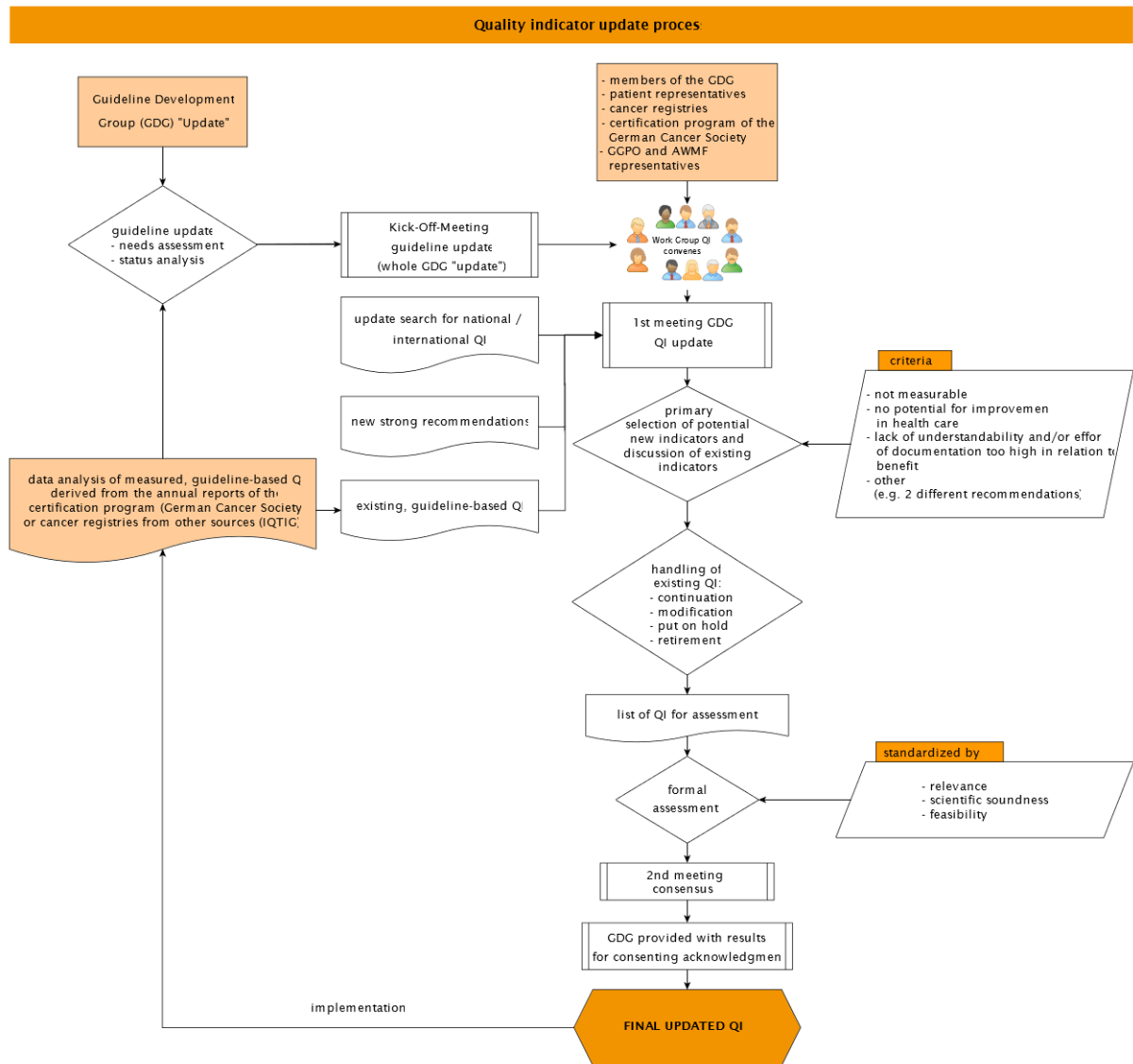


Figure 2: Summary of the process to update quality indicators within the German Guideline Program in Oncology.

8. Literature

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