

Development of guideline-based quality indicators

Methodology for the German
Guideline Program in Oncology

Version 2.0, July 2017

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1. Information about this publication

1.1. Editor

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1.4. Changes compared to version 1.0

The previous document has been editorially revised. Sections 4.7 and 7 have been supplemented. In particular, in version 2.0, the process of updating the existing quality indicator (QI) dataset has been described in more detail.

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 2.0. 2017, available from: <http://www.leitlinienprogramm-onkologie.de/methodik/informationen-zur-methodik/>

2. Aim of this information

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 and quality initiatives in oncology.

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, by which the quality of cancer care and adherence to guideline recommendations can be measured. These QIs serve as internal quality management for medical institutions as well as for benchmarking with other institutions. This process was developed according to the aims of the German National Cancer Plan [1-3]. 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 [4] and implemented for each guideline topic [5, 6]

In addition to the guideline developers and methodologists, 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 single steps of the process 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].

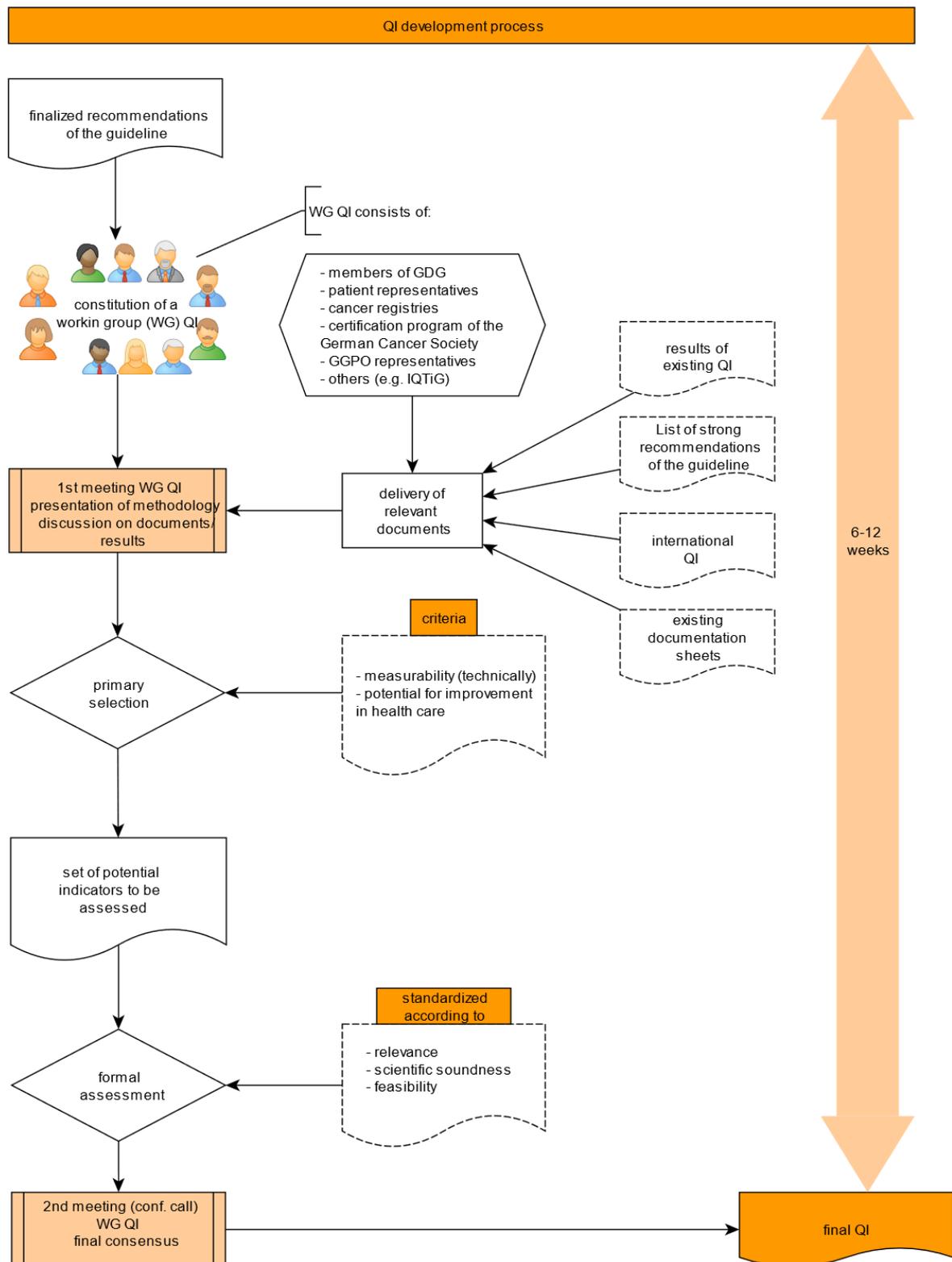


Figure 1: Summary of the quality indicator (QI) development process within the German Guideline Program in Oncology.

4.1. Composition of a representative group of quality indicator developers

Generally, the development of QI 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 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 certified centres, clinical cancer registries and other relevant quality management initiatives. The process is supervised and methodologically supported by a representative of the GGPO office and a representative of the AWMF.

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	Commission for certification (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 performed.

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 list of quality indicators based on guideline recommendations

In general, 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, considered “should be done”, are taken into account, since it is assumed that the addressed actions of these recommendations are supposed to 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. Furthermore, specific aims of the guideline can be considered for QI development if explicitly stated. Nominator and denominator basing on recommendations and / or defined specific aims are defined as far as possible.

4.2.2. Search for international quality indicators

An exploratory search for QIs based on the guideline topic should be performed using bibliographic databases (Medline via PubMed), the US QI Database (NQMC) and webpages of institutions providing oncological guidelines and/or quality indicators (e.g. AHRQ, NHS Scotland, KCE, oncoline, and others). Each of the searches need to be adapted to the specific guideline topic because there is no comprehensive QI database.

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.

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 prepared for the first QI WG meeting (e.g., updated QIs of the guidelines 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). Based on this primary QI list, a primary selection is obtained by QI WG consensus according to the following exclusion criteria:

- A1: the recommendation can not 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 [8]:

- 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 recommendations (AWMF Regelwerk, 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 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.

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).

Table 2. Standardised sheet for the formal assessment of quality indicators.

QI number	Potential quality indicator	Recommendation or statement	Information for the guideline concerning a) Quality aim b) Evidence	
1.	N			
	D			
Information on data availability (Date: xx/yy/2017): [needs to be filled out by cancer registry or certification system] Registration is ensured by the cancer registry using the standardised oncology-based dataset and its modules yes / no Registration is part of the GCS certification system yes / no If required, which supplement is necessary?				
			No	Yes
1.	Criterion: The quality indicator includes the potential for improving relevant patient outcomes.			
2.	Criterion: The indicator is clearly and unambiguously defined.			
3.	Criterion: The quality indicator is related to a supply aspect that can be influenced by the service provider.			
4.	Criterion: Are there any risks of incorrect control by the indicator that cannot be corrected?			
5.	Criterion: The data is routinely documented by the service provider or an additional survey requiring a reasonable level of effort.			
			Comment	
Risk adjustment Can patient-specific factors (e.g., age, comorbidities, stage of disease) influence the quality indicator?				
Barriers for implementation Are there any barriers to implementation which need to be taken into account?				

4.5. Second meeting of the quality indicator working group (conference call)

A moderated conference call 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 changes of the written assessment during the phone 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.

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 entire 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 at the OL Office.

5. Pilot testing

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

6. Validation

The final set of QIs is transferred to the Cancer registries and the certification commissions with the objective of implementation [9-12]. It is the responsibility of these institutions to decide to implement a set of QI completely or partially. However, QI should 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 needs to be reported to the QI WG by the representative of the certification commission. (see examples: [9-12]).

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. 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. The corresponding process is shown in Figure 2.

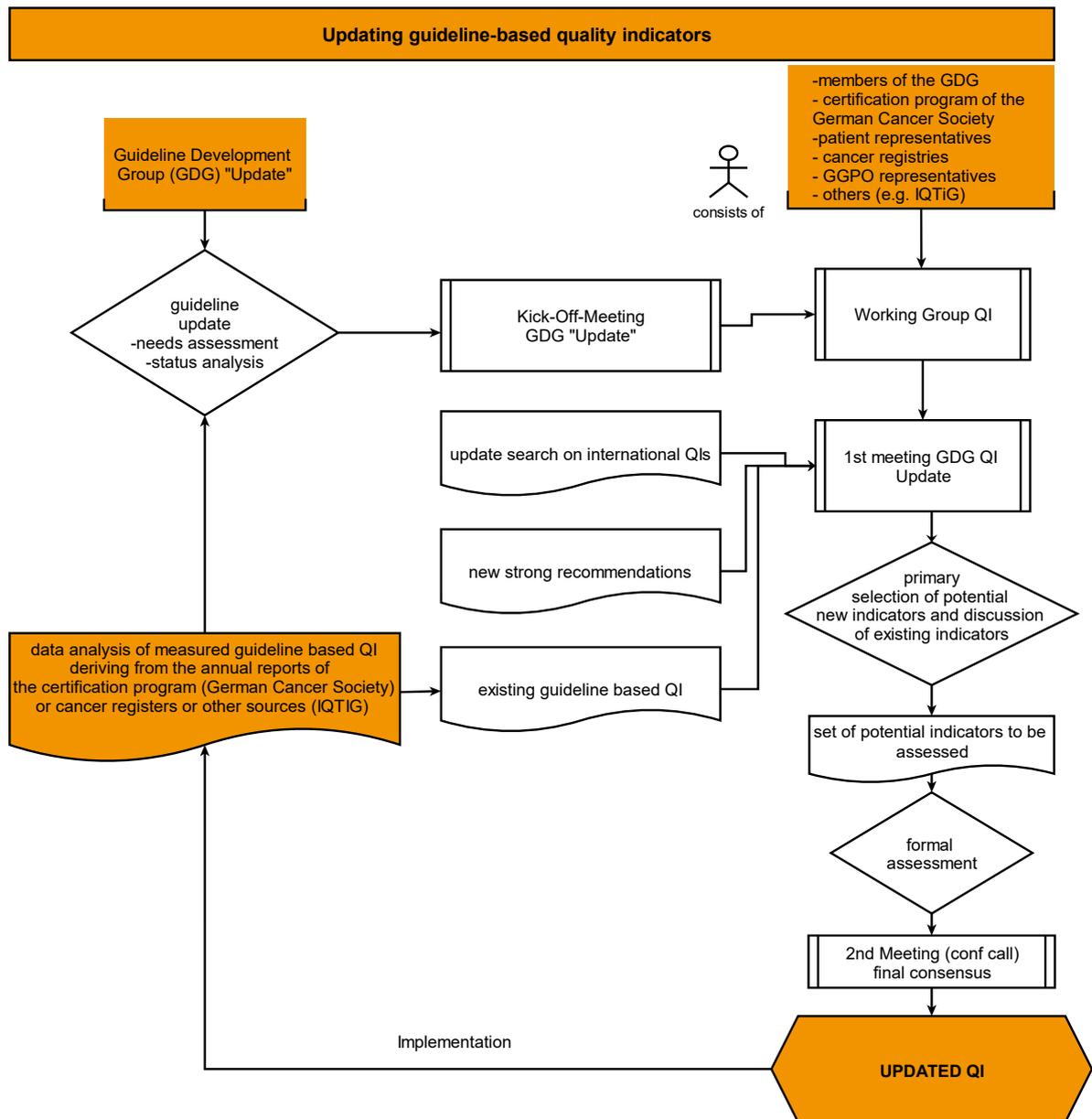


Figure 2: Summary of the process to update quality indicators within the German Guideline Program in Oncology.

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 information of implemented guideline based quality indicators is brought back to the GDG at the begin of the guideline update process. Thereby it is possible to react formulating the updated recommendations. Independent of this, again a quality indicator working group (QIWG) has to be constituted in the defined composition. Beside creating new QI deriving from new, strong guidelines recommendations the current QIWG has to assess the results of documented guideline based QI. This may lead to continuing, modifying or retiring the former guideline based QI.

8. Literature

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