Leitlinienprogramm Onkologie

Development of guideline based quality indicators

Methods paper for the German Guideline Program in Oncology

Version 1.0

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DKG Krebsgesellschaft · Deutsche Krebshilfe Helfen. Forschen. Informieren. · AWMF

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1. Information about this methods paper

1.1. Editor

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of the German Cancer Society, German Cancer Aid and the Association of the scientific medical societies in Germany

Working Group Methodology

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2. Aim of this information

This document provides an overview about the methodology of developing guideline based quality indicators (QI) in the frame of the German Guideline Program in Oncology. This paper is addressed to guideline developers, health care providers and quality initiatives in oncology (s. national cancer plan, aim 5 and 8(1)).

3. Background

The German Cancer Society, German Cancer Aid and the Association of the Scientific Medical Societies in Germanyjointly launched the German Guideline program in Oncology in 2008. The program aims to foster the development, implementation and evaluation of evidence based clinical practice guidelines in oncology. From these guidelines Indicators for measuring quality of structure, processes and outcomes can be developed, by which quality of cancer care and adherence to guideline recommendations can be measured. These quality indicators (QI) are serving internal quality management of medical institutions as well as benchmarking with other institutions. Generally, QI are developed particularly for areas in which potential for improvement is seen by guideline developers and other actors in the health care system.

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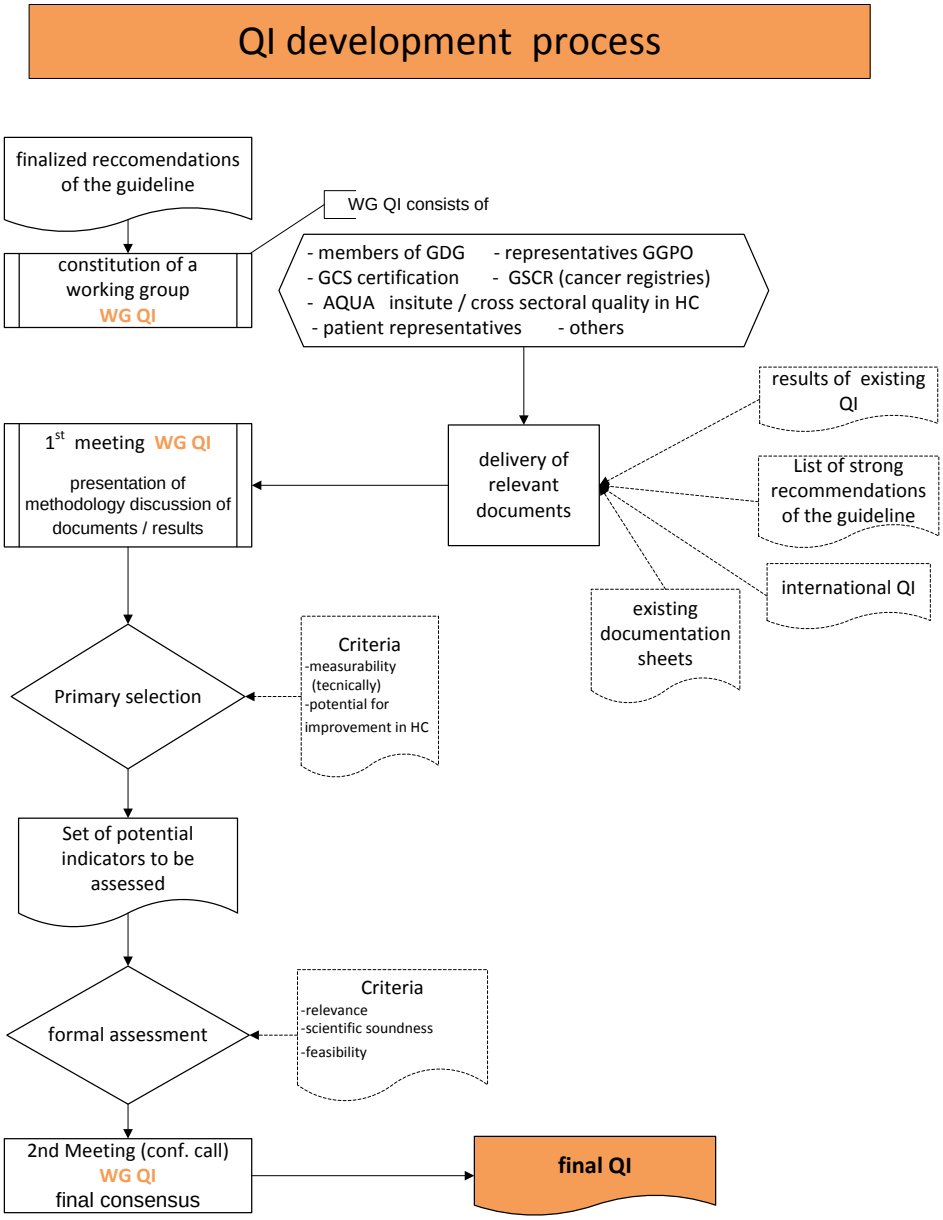
4. The Quality Indicator Development Process

With starting guideline projects in 2008 a concept for a standardized QI development basing on current guidelines was developed according to the methodology of the German Disease Management Guidelines and the assessment tool QUALIFY (2)(3) .

Beside guideline developers and methodologists patients or patient representatives as well as stuff being involved in documentation and assessment of relevant quality initiatives are regularly involved in the development of QI within the GGPO. (s. chapter. 4.1). Further potential indicators are prioritized in a first step regarding measurability and the potential for health care improvement. (see chapter 4.3).

Figure1: Summary of the Quality Indicator Development Process (QIEP) within the GGPO



4.1. Constitution of a representative group of QI developers

Generally, the topic of developing QI is addressed during a Kick off Meeting of a GDG. It is explained that the members of this QI development group should be elected at the latest during the last consensus conference. This QI group should be interdisciplinary and resourced with persons covering the relevant guideline topics. Regularly, representatives of the users and operators of the QI are involved: commissions of certified centers, 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 QI working group

No of representatives	Institution	voting right
3-7	Experts from the Guideline Development Group (GDG)	+
1-2	Patients / Patients Representatives from the GDG	+
1	Cancer Registries	+
1	Commission for certification (DKG)	+
1	AQUA Institute)*	+
2	GGPO Office and AWMF (1 representative, respectively)	-

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

4.2. Preparing documents

In order to prepare the 1st meeting of the QI working group the following steps should be taken. (See 4.2.1-4.2.4).

Results of the below described searches are summarized in a synopsis and distributed to the Working group members prior to the first meeting.

These works should be done by persons methodologically experienced in the field of quality indicators and documentation.

4.2.1. Creating a primary list of QI basing on guideline recommendations

Generally, the QI development process is addressed during the kick off meeting of the GDG. It is emphasized that only strong recommendations can be transformed to potential QI and that recommendations should be formulated as specific as possible. Recommendations with a Grade of recommendation A or formulated as a “should be done” are taken into account, regardless whether this is evidence or consensus based. Further, specific aims of the guideline can be considered for QI development if explicitly stated.

4.2.2. Search for international QI

An exploratory search for QI for the guideline topic has to be performed using international databases (e.g. Pubmed, AHRQ / NQMC, NHS Scotland, oncoline and others). The search has to be performed adapted to the specific guideline topic since there is no comprehensive QI database.

4.2.3. Search for existing national datasets

In a next step a screening and synopsis of existing national requirements for documentation (ADT-Basis dataset with organ specific modules, catalogue of requirements of the certified centers, obligations for documentation by law, and others). Members of the GDG are asked about other existing topic specific systems for documentation. Taking existing or planned documentation systems into account is an important precondition for the realization of a data economizing documentation.

4.2.4. Search for results of nationally measured QI

In case of measured and analyzed (if applicable guideline based) QI in Germany these results are prepared for the first QI WG meeting. (e.g. updating QI of the guideline diagnostic, therapy and after-care of breast cancer (4)).

4.3. 1st Meeting of the WG QI

The aim of this meeting is to preselect potential QI out of the data collection (created like mentioned above: 4.2.1-4.2.4.) Based on this primary QI list a primary selection is created by the QI WG consenting according to the following exclusion criteria:

A1: no potential for improvement in health care
A2: lack of (technical) Measurability
A3: others (e.g. doublets of QIs deriving from two different recommendations)

These criteria for exclusion are derived from 2 basic requirements which are represented in the German Assessment instrument QUALIFY as “relevance” (improvement for health care) and clarity of definition (specific, unambiguous potential measurable wording.

Accepting a QI is following the rules for consenting recommendations (AWMF Regelwerk http://www.awmf.org/leitlinien/awmf-regelwerk.html). That means a majority of 75% is required.

4.4. Written assessment of potential QI

The preselected set of potential QI has to be assessed regarding the categories relevance, scientific quality and practicability according to the QUALIFY instrument by all members of the QI working group. Here for a standardized sheet is used (see table 1, special thanks to the German National Disease Management Guidelines). Out of 20 criteria of QUALIFY 4 can be assessed explicitly and 3 can be commented on. The criterion "evidence or consensus based" is implicitly answered by documenting the body of evidence underpinning the recommendations of the guideline and is not assessed again. Assessment is done using a 4 point likert scale (no, rather no, rather yes, yes). After the written assessment results are dichotomized. A QI is accepted if agreement is ≥ 75% for every criterion.

Table 1:

Sheet for the formal assessment

	1 no	2 rather no	3 rather yes	4 yes
1. Criterion: Impact of the QI referring tot he Health Care System (Importance) The following hast o be assessed: "The indicator includes relevant aspects of quality of life, morbidity or mortality."				
2. Criterion: Clarity of definition The following hast o be assessed "The indicator is defined clearly and unambiguously"				
3. Criterion: Influenceability of the QI value The following hast o be assessed: „The QI is related to an aspect of health care which can be influenced by the mentioned stakeholders."				
	no		**yes**	
4. Criterion: Consideration of potential risks / side effects. The following hast o be assessed (as an aspect): „Are there uncorrectable risks of malfunction by the indicator?"				
	comment			
Risk adjustment The following hast o be assessed „All known relevant influencing factors can be taken into account" Are there persons or groups for who the QI can be used, like age, Stadium, Co morbidity and others?				
Barriers for implementation The following hast o be assessed „There are no barriers for implementation or they can be eliminated through suitable actions" Are there barriers for implementation to be taken into account?				
Data availability The following hast o be assessed: "Data are documented routinely by the care provider or the additional documentation requires a reasonable effort.				

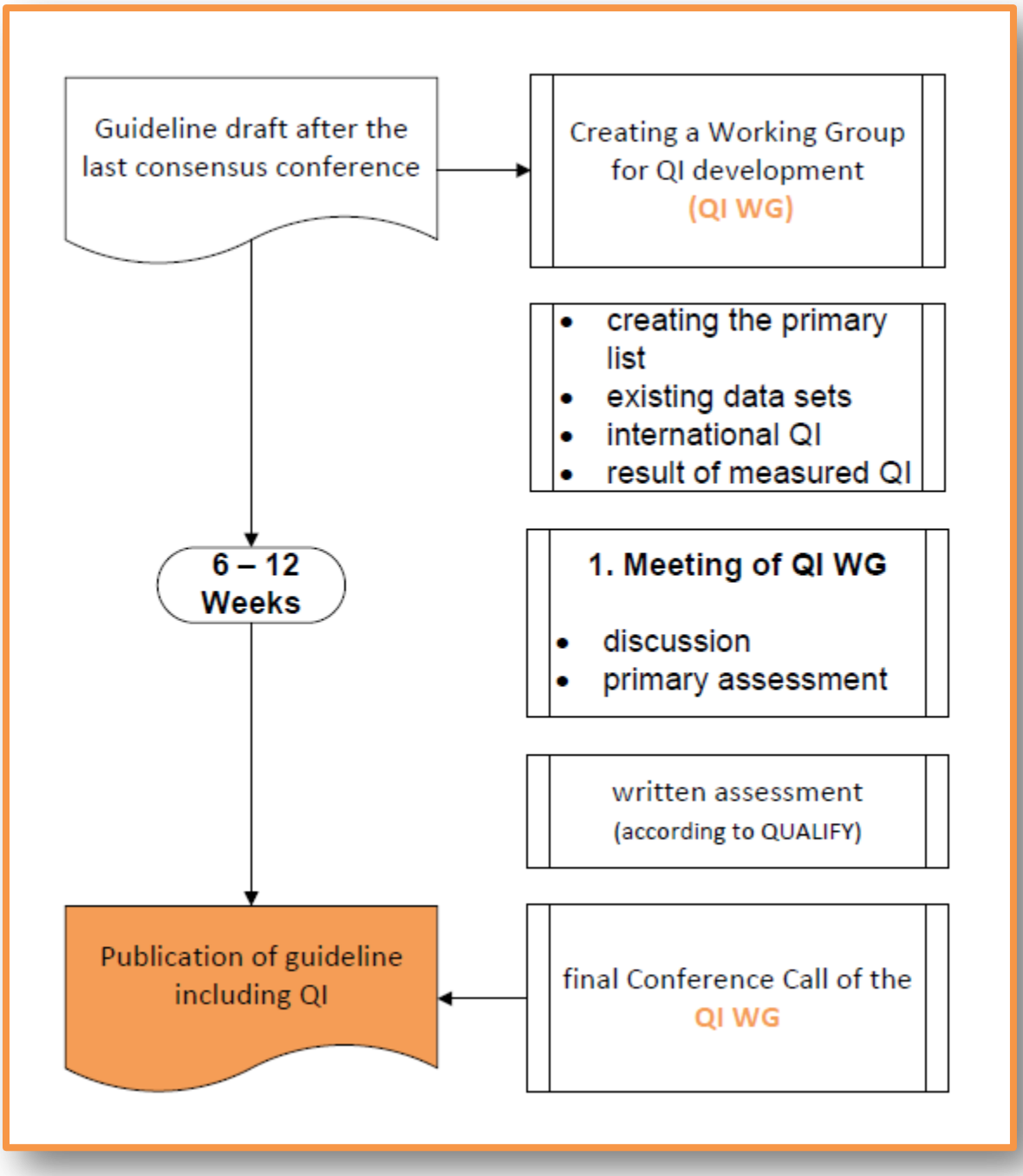
4.5. 2. Meeting of the WG QI (conference call)

A moderated conference call takes place after having analyzed the written assessments. Herein the results of the assessment are discussed and the final set of QI is defined. For this voting an agreement of ≥ 75% per indicator is needed.

4.6. Time Frame

Basically, the work of the QI group can be started directly after the final consenting of recommendations. According to experience the whole process can be finalized within 6 weeks. Jointly finding an appointment and resources for checking international QI have to be considered.

Figure 2: Time periods of QI development according to the guideline development



5. Piloting

Piloting of single QI in a defined setting is not planned.

6. Validation

The final set of QI is transferred to the catalogue of requirements of the certified centers. The results of the QI have to be displayed for the annual audit. Feedback of documenting hospitals or cancer registries and providers of tumor documentation are used for investigating practicability, plausibility, and content validity. These datasets are used for assessing the direct methodological properties (e.g. discrimination ability) of the QI, where possible. The determined improvement potential has to be reported to the QI WG by the representative of the certification commission.

7. Updating

QI always rely on the current guideline. Therefore, updating a guideline is accompanied by reactivating the QI WG in order to analyze the results of measured QI and to clarify the need for updating the formerly developed QI.

8. Literature

1. Bundesgesundheitsministerium. Nationaler Krebsplan. Handlungsfelder, Ziele und Umsetzungsempfehlungen [Internet]. 2013. Verfügbar unter: http://www.bmg.bund.de/fileadmin/dateien/Publikationen/Praevention/Broschueren/Broschuere_Nationaler_Krebsplan_-_Handlungsfelder__Ziele_und_Umsetzungsempfehlungen.pdf

2. NVL-Methodik — Versorgungsleitlinien.de [Internet]. Versorgungsleitlinien.de Programm für National VersorgungsLeitlinien. 2013 [zitiert 30. Oktober 2013]. Verfügbar unter: http://www.versorgungsleitlinien.de/methodik/index_html

3. Reiter A, Fischer B, Kötting J, Geraedts M, Jäckel WH, Barlag H, u. a. QUALIFY-Instrument. Ein Instrument zur Bewertung von Qualitätsindikatoren [Internet]. 2013 [zitiert 30. Oktober 2013]. Verfügbar unter: http://www.bqs-institut.de/innovationen/qualify-instrument.html

4. Follmann M, Kopp IB, Klinkhammer-Schalke M, Pottkämper K, Wesselmann S, Wöckel A, u. a. gms | G-I-N Conference 2012 | Updating Guideline based Quality Indicators. The Methodology of the German Breast Cancer Guideline Development Group [Internet]. 2013 [zitiert 14. August 2013]. Verfügbar unter: http://www.egms.de/static/en/meetings/gin2012/12gin048.shtml