Health Reform Support

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Method for developing quality standards in accordance with the Health Quality Act

Methodology manual
Version 3.1

Adopted by the Standing Coordination Committee in March 2026

Imprint

Members of the quality standards working group (in alphabetical order):
Margarita Amon (Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection, Vienna, BMSAGPK)
Eva Kaser (Upper Austrian Health Fund)
Ingrid Kern-Homolka (Austrian Health Insurance Fund)
Birgit Kraft (Austrian Health Insurance Fund)
Nicola Maier (Lower Austrian Health and Social Fund)
Verena Radner (Austrian Health Insurance Fund)
Annemarie Rotter (Tyrolean Health Fund)
Georg Stummvoll (Social Security Institution for the Self-employed)
Patrizia Theurer (BMASGPK)
Eva Wolfbauer (Styrian Health Fund)

Specialist support (Austrian National Public Health Institute, Gesundheit Österreich GmbH):
Sonja Neubauer
Alexander Eisenmann

Project assistant:
Katharina Kroisz

External reviewers (Version 3.0)
Isolde Sommer, Department for Evidence-based Medicine and Evaluation, University for Continuing Education Krems
Thomas Semlitsch, Institute of General Practice and Evidence-based Health Services Research, Medical University of Graz

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Summary

Background

Section 4 of the Austrian Health Quality Act (Gesundheitsqualitätsgesetz, GQG) stipulates that the Federal Minister of Health may "support the development of quality standards for the provision of certain health services with the involvement of the parties concerned [...]" and "may recommend [these] as Federal Quality Guidelines or issue them as Federal Quality Directives by means of a regulation [...]". In 2008, the Austrian National Public Health Institute was commissioned to develop a method for establishing quality standards (QSs) for the first time. The aim of this updated and revised version (v3.1) is to take recent national and international developments into account as well as previous experience gained in drafting 'quality standards'.

Methodology

In 2008, the Federal Ministry of Health commissioned the Austrian National Public Health Institute (Gesundheit Österreich GmbH, GÖG) and the associated Austrian National Institute for Quality in Health Care (Bundesinstitut für Qualität im Gesundheitswesen, BIQG) to develop a method for drawing up standards for patient care in the Austrian healthcare system based on the Health Quality Act. An updated version of the resulting Methodology Manual was published in 2019 (v2.0).

In the summer of 2023, the need to update the Methodology Manual was assessed once again at the request of the expert group on healthcare processes (Fachgruppe Versorgungsprozesse, FG VP). Proposals for an updated version of the Methodology Manual were collected and a draft was compiled. Subsequently, this draft was revised and agreed upon by the quality standards working group in the course of several meetings. Two external experts reviewed the draft version. The final version of the Methodology Manual was approved by the Standing Coordination Committee in June 2024. At the beginning of 2026, Subsection 3.9.3.1 was adapted as agreed and version 3.1 of the Methodology Manual was approved and published.

Results

Quality standards should become an integral part of comprehensive quality assurance in the Austrian healthcare system. Quality standards are primarily intended to define nationwide minimum requirements for patient care. In addition, quality standards can set objectives for optimized care. This applies particularly to areas of action with significant potential for intervention and development. Recommended measures should be evidence based and realistically achievable in relation to their benefits and harms. The specific implementation of the recommendations is based on regional conditions.

This updated Methodology Manual (v3.1) aims to provide a comprehensive outline of the process of creating quality standards, including principles for preparing all future quality standards in accordance with the Health Quality Act.

The creation of quality standards follows a step-by-step procedure, with the selection of topics preceding the process of creating them.

In the first drafting phase, an introductory overview of the initial situation is drawn up as part of the preparatory work. This provides the basis for defining the core elements of the quality standard, including any underlying documents (in particular (clinical) guidelines).

The second phase involves the creation of the quality standard itself, which entails the formulation of up to 15 recommendations. The document must be structured in a standardized manner and the chapters on individual recommendations must follow a defined outline. The (care-related) recommendations of a quality standard are formulated based on a search for potentially suitable interventions for a corresponding improvement in quality. The evidence base and grade of recommendation must be made explicit. Regarding the measurability and verifiability of the implementation of the individual recommendations, corresponding quality indicators should be defined in the quality standard that are causally related to an outcome relevant to healthcare and/or patients. These outcomes form the basis for monitoring.

Quality assurance is also carried out as part of standardized processes (peer review and public consultation).

Once the content-related work and processes have been finalized, the quality standard is submitted to the client for approval and release for publication. Comprehensive publication strategies are pursued to disseminate the quality standard.

Conclusion

The updated method applies to the establishment of new quality standards starting with the publication of this Methodology Manual (v3.1). It also involves decision-making processes that determine, on a case-by-case basis, whether an update should be carried out based on the updated method. The Methodology Manual remains valid for a maximum of five years; if necessary, it may be revised earlier.

Keywords

Quality standard(s), method(s), recommendation(s), quality indicator(s)

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Abbreviations

AGREE	Appraisal of Guidelines for Research and Evaluation
AG QS	quality standards working group (Arbeitsgruppe Qualitätsstandards)
A-IQI	Austrian Inpatient Quality Indicators
A-OQI	Austrian Outpatient Quality Indicators
AWMF	Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.)
BIQG	Austrian National Institute for Quality in Health Care (Bundesinstitut für Qualität im Gesundheitswesen)
BMASGPK	Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection (Bundesministerium für Arbeit, Soziales, Gesundheit, Pflege und Konsumentenschutz)
BQLL	Federal Quality Guideline (Bundesqualitätsleitlinie)
BQRL	Federal Quality Directive (Bundesqualitätsrichtlinien)
B-ZK	Federal Target-Based Governance Commission (Bundeszielsteuerungskommission)
FG VP	expert group on healthcare processes (Fachgruppe Versorgungsprozesse)
GÖG	Austrian National Public Health Institute (Gesundheit Österreich GmbH)
GQG	Health Quality Act (Gesundheitsqualitätsgesetz)
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
IC	integrated care (Integrierte Versorgung)
LKF	procedure-oriented hospital financing (Leistungsorientierte Krankenanstaltenfinanzierung)
NICE	National Institute for Health and Care Excellence
ÖSG	Austrian Structural Plan for Health (Österreichischer Strukturplan Gesundheit)
QS(s)	quality standard(s)
QBE	Austrian National Quality Reporting System (Qualitätsberichterstattung)
RSG	Regional Structural Plan for Health (Regionaler Strukturplan Gesundheit)
SOP(s)	standard operating procedure(s)
StKA	Standing Coordination Committee (Ständiger Koordinierungsauschuss)
ZS-G	target-based health governance (Zielsteuerung Gesundheit)

1 Introduction and objectives

1.1 Legal basis

Section 4 of the Austrian Health Quality Act (Gesundheitsqualitätsgesetz, GQG) stipulates that the Federal Minister of Health may "support the development of quality standards for the provision of certain health services with the involvement of the parties concerned, in particular the relevant health professions and patients". In accordance with the Health Quality Act, quality standards contain "specifications for one or more of the dimensions of quality work specified in Section 5 (structural, process or outcome quality)". The Health Quality Act further stipulates that the federal government may link quality indicators to quality standards, the contents of which also constitutes elements of Austrian quality reporting. When developing quality indicators, attention must be paid to their international comparability.

1.2 Background

In 2008, based on the GQG, the Federal Ministry of Health commissioned the Austrian National Public Health Institute/Federal Institute for Quality in Healthcare (Austrian Health Quality Act, GÖG/Bundesinstitut für Qualität im Gesundheitswesen, BIQG) to develop a method for establishing standards for the care of patients in the Austrian healthcare system.

The aim of this updated and revised version of the Methodology Manual (v3.1) is to consider recent national and international developments as well as experience gained to date from the practical development of quality standards. For instance, the focus of quality standards has shifted in recent years toward integrated care (IC), the structures of the committees within target-based health governance (Zielsteuerung Gesundheit, ZS-G) have changed and concrete experiences from the development process of earlier quality standards have highlighted a need for optimization in some process steps. Moreover, a routine revision of the Methodology Manual five years after its last update (in 2019) is in line with standard international practice. Based on the agreement reached in version 3.0 to conduct a pilot trial of a two-stage review in place of external peer review during the development of the Quality Standard for the Integrated Care of Chronic Wounds. The Methodology Manual was formally updated in early 2026 and Section 2.1 and Subsection 3.9.3.1 were rewritten.

This updated Methodology Manual (v3.1) is intended to enhance transparency in the development of quality standards by clearly describing the individual steps involved in the process. This includes both the procedures related to the thematic preselection and content development of the quality standards as well as the related framework conditions. To ensure high-quality standards, the Methodology Manual serves as the foundation for developing all future quality standards in accordance with the GQG.

1.3 Foundations for the development of quality standards

1.3.1 Definition

In the GQG, quality standards are defined as "describable regularities or specifications regarding equipment, procedures or behaviour" in the provision of healthcare services. Accordingly, in the context of healthcare delivery, quality standards can be regarded as an umbrella term for all standards and recommendations for patient care as the GQG does not provide a more detailed, specific definition. To ensure clarity regarding what constitutes a quality standard in the narrower sense, also during the development process, the following specification has been established for the current and future development of quality standards:

Quality standards are primarily intended to establish nationwide minimum requirements for patient care. In addition, quality standards may also formulate goals aimed at optimal care, particularly for fields of action with significant potential for intervention and development. Recommended measures should be evidence based in relation to their benefits and harms and realistically implementable. The concrete implementation of the recommendations is carried out in each case based on regional conditions.

Quality standards should become an integral part of comprehensive quality assurance in the Austrian healthcare system. In this sense, the implementation of and adherence to quality standards should be linked to other instruments of management, measurement and quality assurance. These include, in particular, the Austrian Structural Plan for Health (ÖSG), the Regional Structural Plans for Health (RSG), quality reporting (inpatient and outpatient), procedure-oriented hospital financing (LKF), the Austrian Inpatient Quality Indicators (A-IQI), the Austrian Outpatient Quality Indicators (A-OQI) and the Austrian National Quality Reporting System (QBE).

1.3.2 Objectives and non-objectives

The overarching objective of quality standards is to support high-quality, cross-sectoral healthcare and, thereby, to create benefits and the conditions for informed decisions by patients.

The existence of a currently valid, appropriate and methodologically sound clinical guideline (primarily from German-speaking countries or, if available, from regions with a comparable healthcare context) is a prerequisite for the development of a quality standard on medical topics.

The development of quality standards does not involve clinical (medical, therapeutic or similar) recommendations. Such recommendations are the subject of relevant clinical guidelines issued by professional societies and associations.

Instead, quality standards contain recommendations regarding necessary or beneficial framework conditions that make high-quality healthcare possible in the first place. These recommendations primarily relate to processes in patient care (so-called care-related recommendations, such as procedural guidelines for the emergency response chain in the event of a stroke, etc.). In line with the concept of IC, these processes include improving transitions between the individual phases of care, levels of care and areas of care.

Issues or regulations regarding financing and/or remuneration as well as human resources are not part of quality standards and are, therefore, explicitly defined as non-objectives. These points must be clarified during implementation.

In addition to clarifying any direct or indirect implications (e.g. financial, legal or personnel implications), the political and organizational implementation of quality standards requires concrete implementation steps that must generally be carried out at state level while taking regional conditions and requirements into account. Therefore, implementation is also a non-objective of the process of developing quality standards.

1.3.3 Target audience

Quality standards are generally intended for all individuals responsible for the organization and quality of care for the patient group to which the quality standard concerned applies. In addition, quality standards are intended for healthcare providers involved in the direct care of the affected patient group as well as for the interested public.

1.3.4 Validity and publication

Unless a need for earlier updating is identified, the validity period of a quality standard is five years from publication. Quality standards developed on behalf of the Federal Ministry of Health or within the framework of target-based health governance are published on the website of the Federal Ministry of Health along with key documents from the development process (background documents, introductory overview, core elements, consolidated table of comments). In addition, quality standards may also be published on other websites (in particular those of the institution that developed them, such as GÖG, the commissioning body, such as the BMASGPK, the federal states or social insurance institutions) for the purpose of broad dissemination. The commissioning body is responsible for disseminating the quality standard.

2 Development of a quality standard

The evaluation results for the initial methodology guideline (GÖG/BIQG 2011) published in 2012 already showed that dividing up the development process for quality standards into separate stages as outlined below can be considered appropriate:

- Topic selection and prioritization (upstream processes),
- Preparatory work on the quality standard (in particular the creation of an introductory overview and core elements),
- Creation of the quality standard,
- Downstream processes (including political and organizational implementation, monitoring and evaluation).

The workflow depicted in Figure1 takes this step-by-step development process into account, defines details for the various process stages and supplements these with upstream processes and information on potential responsibilities. Each individual phase concludes with a result that can be published independently.

Figure1: Process stages in the development of a quality standard

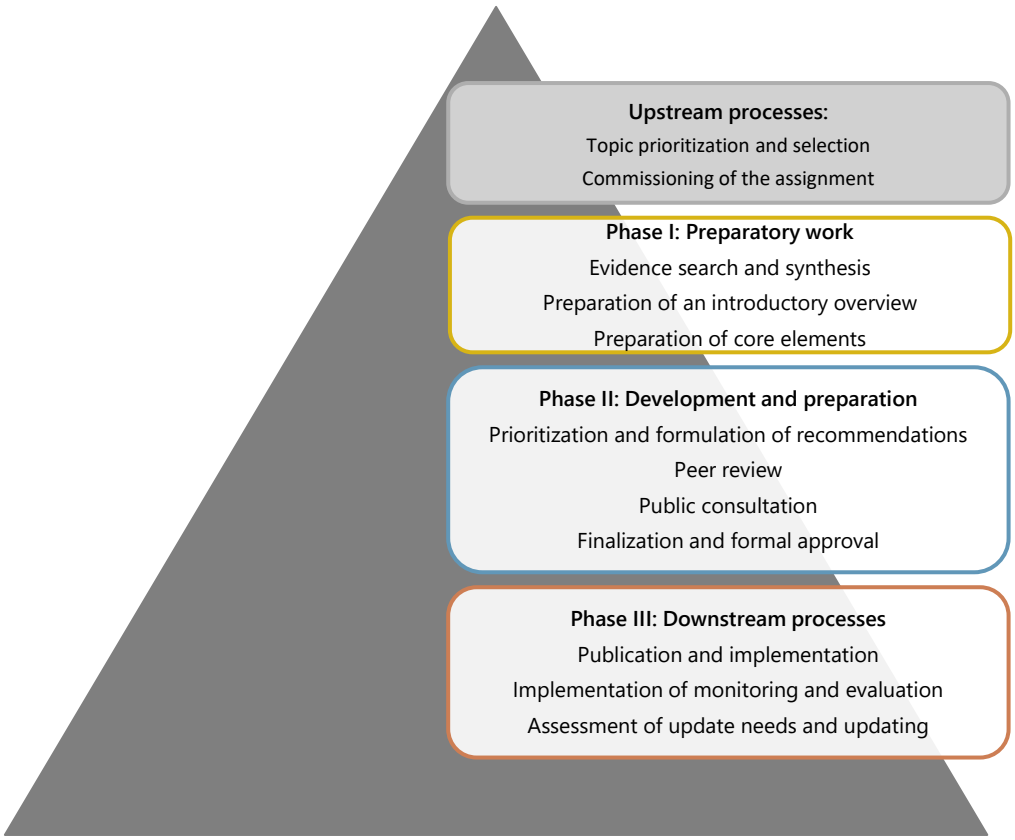


Illustration: GÖG/BIQG

2.1 Upstream processes: Topic prioritization and selection process

The prioritization and selection of topics precede the process of developing a quality standard. In November 2025, the Standing Coordination Committee (StKA) adopted the concept "Prioritization of topics for quality standards in accordance with the GQG" (BMASGPK 2025). The identification, prioritization and selection of topics for quality standards in accordance with the GQG should then be carried out based on the process and criteria outlined in the concept.

In accordance with the concept, key healthcare providers should be involved in the identification of topics. The prioritization and selection of topics then follow the criteria and procedures outlined in the concept.

The prioritization process and its results must be documented to ensure transparency. The individuals or groups who submitted topics should, in any case, be informed of the prioritization results.

At the end of the prioritization process, the target management partners within target-based health governance – represented by the Standing Coordination Committee or the Federal Minister of Health – typically commission the issuing institution (usually the Austrian National Public Health Institute) to elaborate a quality standard. The overarching decision-making bodies are the Federal Target-Based Governance Commission and the Standing Coordination Committee. These bodies define the work items through their annual work programme and commission a subordinate body with its development, usually an expert group, hereinafter referred to as the "commissioning body". This body may make use of further subordinate structures (usually project or working groups), which are hereinafter referred to as the "appointed body". These are required to report to the commissioning body. The commissioning body formally approves of the work carried out and subsequently reports to the higher-level decision-making bodies.

The selection and number of topics to be addressed must be made considering the total resources available for the development, monitoring, evaluation and updating of the quality standard(s). In this context, it seems appropriate to conduct a topic identification, prioritization and selection process at least once per target-based health governance period.

2.2 Phase I: Preparatory work

The goal of the first phase of developing quality standards is to define the core elements of the standard (scoping). These core elements include, above all, the topic (e.g. the disease, care issue), the patient group affected, the prioritized care area(s) and the (clinical) guideline(s) to be used. This requires commissioning the preparation of an introductory overview of the initial situation and engaging a suitable appointed body**,** which defines the core elements of the quality standard based on their introductory overview of the initial situation and the foundational documents. (The results from this phase accompany the further development process of the quality standard in Phase II.)

2.2.1 Introductory overview as the basis for preparing a quality standard

As a basis for developing a quality standard and for defining the core elements of a specific quality standard, a summary overview of essential information for the subject area concerned is drafted at the beginning of the development process (ideally by the institution commissioned to develop the quality standard, see below) based on a review of available evidence (see Subsection 2.3.4).

This introductory overview provides information on the following aspects taking findings from the upstream topic prioritization and selection process into account:

- Research question (including information on the burden of disease),
- Patient group affected (population, target group),
- Current care practices (treatment/care) including, where applicable, available patient experiences (results of patient surveys) or information on potential differences regarding access to or utilization of services or regarding groups with special care needs,
- Method and results of a systematic literature search for valid Austrian and international guidelines and quality standards that are potentially suitable as foundational documents for the quality standards:
  - The search for guidelines and standards should be conducted in the AWMF database (https://www.awmf.org/leitlinien.html), the TRIP medical database (https://www.tripdatabase.com/) and the international guideline library (GIN database: https://www.g-i-n.net/library/international-guidelines-library).[1]
  - The databases used, the search terms and selection criteria (inclusion and exclusion criteria) as well as the search and selection results and the search period must be documented.
  - For the guidelines and standards included based on the selection criteria, a quality assessment is performed in accordance with AGREE II[2] and the results are presented in the introductory overview.
  - If no suitable guidelines or standards have been identified, an additional evidence search is conducted for systematic reviews, expert consensus statements, standard operating procedures and evaluation reports, etc. as potential foundational documents for the quality standard. The search for systematic reviews should be conducted, at a minimum, in the Cochrane Library (https://www.cochranelibrary.com) and in PubMed (https://pubmed.ncbi.nlm.nih.gov).[1]
  - The methodology and results of this evidence search must be documented.
  - The selection of foundational documents is carried out by the appointed body based on an assessment of their methodological quality and considering their content relevance and applicability in the Austrian context. Source documents are defined as those from which the recommendations for the so-called recommendation pool for the quality standard are extracted.
- Data sources available in Austria (where applicable, for indicator development and monitoring/evaluation),
- Laws that could affect the quality standard or that the quality standard could influence,

[1] Sources last accessed on 09.02.2026

[2] AGREE II: https://www.agreetrust.org/wp-content/uploads/2014/03/AGREE_II_German-Version.pdf [Accessed on 09.02.2026]

- Stakeholders affected beyond target-based health governance.

In addition, the scoping phase should identify fields of action. For this purpose, in addition to the information mentioned above, data from the literature (and, where applicable, from other written sources such as parliamentary inquiries or public media) as well as input from experts may be used. The latter may be surveyed in writing either selectively (identified individuals, peer review members) or, if necessary, comprehensively and systematically (all participating actors and stakeholders).

2.2.2 Defining the core elements of the quality standard

The commissioning body is informed that the introductory overview of the initial situation has been completed (and it is subsequently published in accordance with the provisions defined in Section 2.4). The contents are discussed by the appointed body and on this basis, the core elements of the quality standard are defined as listed below:

- Disease/care topic (for non-disease-related standards),
- Target group: affected individuals or patient group,
- Fields of action: prioritized care areas with a particular need for intervention,
- Foundational documents (see Subsection 2.2.1),
- Databases/data sources for developing, monitoring and/or evaluating indicators (e.g. registry data, data from diagnosis and procedure documentation,
- Institutions for peer review where already designated (see Subsection 2.3.9)
- Specific target audiences as well as specific objectives and non-objectives of the quality standard where required

In addition, the anticipated potential benefits of the quality standard as a whole (including for patients and healthcare providers) should be outlined.

When developing a quality standard, it is necessary to assess the extent to which aspects of gender medicine can be meaningfully taken into account (both in the recommendations and in the indicators). The results of this assessment must be documented in writing, for example in minutes or reports.

A timeline with milestones must be established for the development process.

The definition of the core elements of the quality standard marks the conclusion of Phase I. They are published upon completion.

2.3 Phase II: Development of the quality standard

The objective of the second phase is to develop a quality standard in accordance with the methods, processes and reporting components outlined below. Any deviations from these must be described and justified in the methodology chapter of the quality standard.

2.3.1 Scope

The central part of a quality standard is the recommendations chapter, which may include up to 15 recommendations. In the case of highly complex topics, it is necessary to subdivide the standard into one or more related quality standards.

To ensure readability, the quality standard should preferably include references to relevant documents created during the preparatory work and/or published elsewhere (e.g. the Methodology Manual, the introductory overview of the initial situation); additional information should only be provided if it is necessary for understanding. To facilitate the applicability and implementability of the quality standard, the number of recommendations should, where possible and appropriate, be limited so that only relevant recommendations with the most favourable benefit-risk ratio are included (see Subsection 2.3.5).

2.3.2 General structure

A quality standard should be structured as follows:

- Title page
- Imprint and publication date
- Table of contents plus lists of figures, tables and abbreviations
- Glossary
- Abstract (summary of recommendations, including an English summary)
- Introduction/Background: Initial situation (reference to or summary of the introductory overview of the initial situation) and mandate (defined core elements)
- Methodology: Reference to the Methodology Manual, including any deviations or specific details
- Recommendations
- Validity period
- Monitoring and evaluation
- Determination of the need for updates and updating
- Bibliography
- Appendix (if applicable)

2.3.3 Structure of the recommendations chapter

Each recommendation in the recommendations chapter should be structured as follows, if possible:

- Recommendation (see Subsection 2.3.5),
- Reasons why the recommendation is useful/necessary (background),
- Definitions of terms used in the recommendation, if applicable,
- Target-group-specific explanations of what the recommendation means for the stakeholders involved and for patients,
- Evidence base, strength of evidence and grade of recommendation (see Subsections 2.3.6 and 2.3.7),
- Quality indicator(s), if applicable (see Subsection 2.3.8),
- Additional comments, if applicable.

2.3.4 Creation of the recommendation pool

"Core elements" (see Subsection 2.2.2) relate to prioritized care areas with a particular need for intervention (fields of action) and foundational documents as well as specific objectives and non-objectives for the quality standard. Foundational documents are then used to extract potentially suitable recommendations for the quality standard ("recommendation pool") by the issuing institution.

The procedure for systematic literature research to identify suitable foundational documents (such as guidelines and standards) is described in Subsection 2.2.1.

If foundational documents and any additional sources already identified as part of the introductory overview do not include recommendations for all objectives and fields of action defined in the core elements, a further in-depth search may be conducted for suitable sources for the recommendation pool. The search method and the selection of these additional sources must also be documented.

For each recommendation in the recommendation pool, the evidence base and strength of evidence are specified (see Subsections 2.3.6 and 2.3.7).

2.3.5 Prioritization and formulation of recommendations

Recommendations should be formulated clearly and concisely, preferably as a statement centred on the patient (or, alternatively, the organizational unit responsible), for example:

- Patients with [disease] should/ought to/may be offered [intervention].
- Patients with [disease] should/ought to/may receive [intervention].
- [A specific service/organization] should/ought to/may offer [...].

Furthermore, the recommendations should be as succinct, measurable and specific as possible and, ideally, formulated in a single sentence that addresses only one requirement for high-quality care. If there are legal requirements for (parts of) the recommendations, these should be cited explicitly. The normative effect of the legal requirements remains unaffected by the recommendations.

Recommendations from the recommendation pool are discussed and agreed upon by the commissioning body or the appointed body, resulting in a maximum of 15 recommendations to be prioritized and included in the draft version of the quality standard. In the process, various aspects are taken into account such as the level of evidence and the (estimated) relevance or feasibility.

The final wording of the recommendations is developed by consensus by the commissioning body or the appointed body. Minutes of the proceedings are written up after each meeting. If a disagreement arises that cannot be resolved during the discussion, it is recorded in writing. The commissioning body subsequently decides on points of disagreement.

The final version of the recommendations must be submitted to the commissioning body for approval and release for public consultation. The entire process described in this subsection must be documented.

2.3.6 Evidence base

The scientific and empirical basis (evidence base) and the level of evidence are explicitly stated for each recommendation. This information is provided based on a recognized framework[3,4] that must be specified in the quality standard. The evidence base represents the strength of evidence reported in the supporting documents. If information on the evidence base is missing from the source documents, a selective search for systematic reviews is conducted, at a minimum, in the Cochrane Library (https://www.cochranelibrary.com/) and PubMed (https://pubmed.ncbi.nlm.nih.gov/) databases. The databases used, the inclusion and exclusion criteria and the search period must be documented.

If no evidence base is identified, the appointed body may, nevertheless, issue a consensus statement. The strength of evidence must be indicated accordingly (e.g. expert consensus).

2.3.7 Grade of recommendation

Following the same procedure as for the prioritization and formulation of recommendations (see Subsection 2.3.5), the appointed body determines the grade of recommendation (based on the AWMF's rules for guideline development, see Table1). This reflects how much confidence can be placed in the presumed effect and considers, amongst other things,

- the strength of the evidence,
- the benefit-risk ratio,
- ethical, legal and economic considerations,
- patient relevance and patient preferences,
- applicability to the target patient group and the Austrian healthcare system,
- feasibility in everyday practice/in various areas of care.

Table1: Levels of recommendation and wording for recommendations

Level of recommendation	Description	Wording	Symbol
A	Strong recommendation	should (not)	↑↑ **(↓↓)**
B	Recommendation	ought (not) to	↑ **(↓)**
0	open	may be considered	↔

Source: Association of the Scientific Medical Societies in Germany 2023

2.3.8 Quality indicators

With regard to the measurability and verifiability of the implementation of individual recommendations, corresponding quality indicators should be defined in the quality standard that have a causal relationship with a care- and/or patient-relevant endpoint. These also form the basis for monitoring (see Subsection 2.4.2). To keep the documentation and data collection

[3] The strength of the evidence is usually indicated using Roman or Arabic numerals that denote the type of evidence base (ranging from expert opinion to meta-analyses of randomized controlled trials).

[4] The strength of evidence can, for example, be assessed using the GRADE framework (see GRADE handbook; gradepro.org).

effort as low as possible, data from existing documentation systems or surveys should be used for this purpose.

2.3.9 Quality assurance

As steps toward quality assurance, external evaluation and public consultation are conducted based on a standardized, transparent process outlined in a guide for conducting peer review and public consultation.

2.3.9.1 Peer review

The draft quality standard is generally subjected to review by a maximum of 15 independent external experts. Relevant institutions are invited to nominate experts with an appropriate methodological and technical background for the peer review. The institutions to be invited are selected by the appointed body and brought to the attention of the commissioning body. In any case, one external reviewer must be invited from a patient advocacy group.

Peer review serves to provide a professional and methodological assessment of the quality standard by verifying its content and accuracy from a professional perspective. An assessment of its form, language and structure, including design/layout, is not the subject of the peer review. A written declaration regarding potential conflicts of interest is obtained from the external experts in advance.

Changes proposed by the external reviewers must be substantiated with evidence and justified. A standardized form provided in advance (individual "consolidated table of comments") must be used for this purpose. The feedback from the external experts is reviewed by the appointed body and entered in a consolidated table of comments.

The comments are subsequently discussed and responded at a moderated meeting with the external reviewers and representatives of the appointed body. The consolidated table of comments having been made available to all participants in preparation for the meeting. The revised consolidated table of comments serves as a basis for decision making by the commissioning body/the appointed body, which ultimately decides on whether the feedback is to be included or not and finalizes the draft version of the quality standard. The reviewers receive corresponding structured feedback.

The consolidated table of comments, including justifications, must be published no later than the publication date of the quality standard.

2.3.9.2 Public consultation

Revised following peer review, the quality standard is then subjected to a public consultation, which also serves as an expert assessment of the quality standard, i.e. they review its content for correctness, coherence, transparency and comprehensibility. To this end, the quality standard is made available online, free of charge and with full accessibility, for a period of approximately one month. Both individuals and institutions (e.g. professional associations, professional bodies and interest groups, etc.) may participate in the public consultation. Institutions are proactively

informed about the consultation by the issuing institution, and the start of the consultation is communicated on a website. Proposed changes must be supported by evidence and justified.

Similar to the process for peer review, feedback from the public consultation is first compiled by the issuing institution and processed and then submitted for discussion to the appointed/commissioning body. The changes are then discussed and finalized by this body. This marks the completion of the drafting process for the quality standard in terms of content. The consolidated table of comments is published simultaneously with the quality standard.

2.4 Phase III: Downstream processes

Once the substantive work and processes have been completed, the quality standard is submitted to the commissioning body/bodies for approval and publication clearance.

In the event of delays relating to the schedule published as part of the core elements or a complete cessation of work, corresponding information must be made public.

To disseminate the contents of the quality standard, arrangements should be made for its (wide) publication (including qualitaet-gesundheit.gv.at). The dissemination measures to be implemented by the individual target management partners and the issuing institution must be specified for each quality standard.

The commissioning body is responsible for the dissemination of the quality standard.

2.4.1 Implementation of monitoring and evaluation

Monitoring and evaluation are essential tools for analysing the impact of the quality standard.

Monitoring is a continuous process that serves to measure the degree of implementation of the individual recommendations in the quality standard using previously defined quality indicators (see Subsection 2.3.9) in order to be able to intervene if necessary. Key aspects of monitoring should, if possible, already be defined in the quality standard (including underlying data sources, its frequency/schedule and commissioning/implementing institution). Monitoring should take place primarily within the validity period of a quality standard.

In addition, a decision must be made in a timely manner before the quality standard's validity period expires as to whether a more comprehensive evaluation should be conducted based on the available monitoring results. Such an evaluation, in the sense of an empirical analysis of surveys of relevant stakeholders, for example, can provide more detailed information on aspects of implementation (e.g. awareness, reasons for implementation or non-implementation) and identify the need for changes to the quality standard. The evaluation concept should be developed by consensus amongst the target management partners.

The results of assessments conducted and related conclusions are to be summarized and published in a monitoring and/or evaluation report and incorporated into the process for determining the need for updates.

2.4.2 Assessment of update needs and updating

The need for updates must be reviewed in a timely manner before the quality standard's validity period expires. This entails reviewing the validity of the content and any changes to the content of the foundational documents (e.g. the guidelines) and their potential impact on the content of the quality standard. In addition, the results of the monitoring and any evaluation conducted are to be taken into account (see checklist in the appendix).

Consequently, the validity may be extended ("renewed"), an update of the quality standard may be initiated, or the quality standard may be declared invalid. A renewal is generally granted for one to two years, with a second renewal permitted provided that the total duration of the renewal period does not exceed three years.

If necessary (e.g. due to significant changes in the foundational documents or the state of the scientific debate), a quality standard may be updated before its expiration date.

3 Entry into force of the updated methodology and validity period of the Methodology Manual

The updated methodology applies to the development of new quality standards once the Methodology Manual has been published. When updating quality standards, a decision should be made on a case-by-case basis as to whether this can and should be carried out based on the updated methodology.

The validity period of the Methodology Manual is a maximum of five years; it may be revised earlier if necessary.

4 Update of the Methodology Manual

The work and quality assurance steps outlined below were carried out as part of the update of the Methodology Manual in its current version (v3.1).

Commissioning GÖG to determine the need for an update

In May 2023, the expert group on healthcare processes commissioned GÖG, on the recommendation of the appointed body (working group), to begin assessing the need for an update to version 2.0 of the Methodology Manual and to submit a corresponding draft by autumn 2023, including a clear list of any changes.

Compilation of experiences from previous work

Based on this mandate, the need for updates to the Methodology Manual (v2.0) was assessed during two internal workshops at GÖG in the summer of 2023 and concrete proposals for the update were developed and documented.

Literature update and literature search for methodology manuals on the development of quality standards

In addition, the literature cited in the Methodology Manual was updated and a selective web search was conducted for methodology manuals on the development of quality standards. Relevant results and findings were incorporated directly into the aforementioned workshops and the revision of the Methodology Manual.

Revision of the Methodology Manual

Based on the workshop and research results, GÖG developed a draft of the Methodology Manual (v3.0), which it presented to the responsible working group in October 2023. The draft was updated based on written feedback from the target management partners, discussed again at the meeting on 13 December 2023 and finalized at the meeting on 1 February 2024. Subsequently, it was decided to subject the draft to an external review for quality assurance purposes. A subsequent public consultation was deemed neither beneficial nor necessary given the extent of the changes made.

Review by external experts

Version 3.0 of the Methodology Manual underwent an external review in March 2024 by two reviewers from the fields of evidence-based medicine and evaluation as well as general practice and evidence-based health services research. One reviewer delegated the review to a colleague and personally reviewed only Subsections 2.3.4 to 2.3.6 of the Methodology Manual. At the working group meeting on 2 April 2024, a decision was made to incorporate the comments from the external reviewers and the draft was approved for submission to the expert group on

healthcare processes. Due to the minor nature of the changes, a further external review of the updated version 3.1 was not conducted.

Finalization of the revised version of the Methodology Manual (v3.0) and its approval by the expert group on healthcare processes

Based on the external review, the revised version of the Methodology Manual was approved by the expert group on healthcare processes in April 2024 and by the Standing Coordination Committee in June 2024.

Further revision of the subsections on prioritization (2.3.5) and quality assurance (2.3.9) of the Methodology Manual (v3.1)

Based on the agreement reached in version 3.0 to conduct a pilot study on an expanded review process in lieu of external peer review during the development of the Quality Standard for the Integrated Care of Chronic Wounds, the Methodology Manual was formally updated in early 2026 and the subsection on external peer review was rewritten based on a review of the experiences gained during the pilot study. In addition, Section 2.1 was adapted in accordance with the prioritization concept approved by the Standing Coordination Committee in November 2025.

References

AWMF (2023): AWMF-Regelwerk „Leitlinien" (Version 2.1 2023) [online]. Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF) – Ständige Kommission Leitlinien. https://www.awmf.org/regelwerk/ [Accessed on 25. 02. 2026]

BMASGK (2019): Methode zur Erstellung von Qualitätsstandards. Version 2.0. Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz, Vienna

BMASGPK (2025): Priorisierung von Themen für Qualitätsstandards gemäß GQG. Konzept. Bundesministerium für Arbeit, Soziales, Gesundheit, Pflege und Konsumentenschutz, unpublished

Gesundheitsqualitätsgesetz: Bundesgesetz zur Qualität von Gesundheitsleistungen (Gesundheitsqualitätsgesetz – GQG), BGBl. I Nr. 81/2013, in der geltenden Fassung

GÖG/BIQG (2011): Metaleitlinie Version 1.2 Methode zur Entwicklung und Evaluierung von Bundesqualitätsleitlinien gemäß Gesundheitsqualitätsgesetz. Gesundheit Österreich GmbH / Geschäftsbereich BIQG, Vienna

GÖG/BIQG (2013): Methode zur Erstellung von Qualitätsstandards gemäß Gesundheitsqualitätsgesetz (ersetzt Metaleitlinie 1.2), Gesundheit Österreich GmbH / Geschäftsbereich BIQG, Vienna

NICE (2021): NICE Quality Standards. Process Guide [online]. National Institute for Health and Care Excellence (NICE). https://www.nice.org.uk/process/pmg43/chapter/using-nice-quality-standards [Accessed on 25.02.2026]

NICE (2023): Selecting and prioritising quality standard topics [online]. National Institute for Health and Care Excellence. https://www.nice.org.uk/what-nice-does/standards-and-indicators/quality-standards/selecting-and-prioritising-quality-standard-topics [Accessed on 25.02.2026]

Appendix

Checklist for determining the need for an update and, consequently, for updating, implementing an update or declaring the quality standard invalid

<table>
<tr><td colspan="2">Check whether data from the monitoring process or an evaluation report are available
(see the chapter on monitoring and evaluation in the quality standard concerned)
Key questions: Are data available from the monitoring process?
Has an evaluation been conducted and is an evaluation report available?
Can a need for updating be derived from these conclusions?</td></tr>
<tr><td colspan="2">and/or</td></tr>
<tr><td colspan="2">Check underlying guidelines or reference documents
Key question: Are there any new or updated guidelines or source documents?</td></tr>
<tr><td colspan="2">and/or</td></tr>
<tr><td colspan="2">Inquire with any relevant professional societies (typically those involved in the creation of the previous version) regarding (topic-specific) updates
(if there are professional societies with thematic expertise)
Key question: Do the relevant professional societies see a need for updates (especially regarding topic-related developments)?</td></tr>
<tr><td colspan="2">Results and next steps (2 options)</td></tr>
<tr><td>If the need for an update is “NO” then

• Recommendation to the client to extend the quality standard concerned for a maximum of 3 years (or shorter, if applicable)</td><td>If there is a need for an update (“YES”)
due to
monitoring/evaluation results
and/or
new/updated terms of reference/basic documents
and/or
professional societies expressing a need for updates
then

• Revision of the quality standard based on new evidence by the issuing institution (“Assessment”),
• Re-examination by the commissioning/appointed body,
  • Goal: Evaluation and formulation of the revised recommendations (“Appraisal“),
• Communication of results to the commissioning party, adaptation if necessary, and final approval (“Decision”)</td></tr>
</table>