DGGG Guidelines Programme: Status Quo – Quo Vadis!

DGGG-Leitlinienprogramm: Status quo – quo vadis!

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Abstract

The Guidelines programme of the German Society of Gynaecology and Obstetrics (DGGG) is an executive part of the DGGG Guidelines Commission. It includes in-house planning and organisation of all guidelines as well as representation outside of the DGGG. This article does not concern the development of the guidelines as much as it concerns the planning, organisation, registration, editing and publication of the guidelines in context of the DGGG Guidelines programme. It targets interested parties, especially authors and coordinators of guidelines.

Introduction

Matthias W. Beckmann (Erlangen) has confirmed his succession of Rolf Kreienberg (formerly Ulm) in December 2012 as DGGG Guidelines Commissioner and was confirmed by the DGGG Board of Directors. Previously, Rolf Kreienberg became a member of the Executive Committee of the AWMF and Director of the permanent “Guidelines” commission of the AWMF in May of 2013. The DGGG Guidelines programme is supported by the DGGG Guidelines Commission, which consists of members of the individual focus groups (FG) of the DGGG (Fig. 1). The structure and the resulting responsibilities and tasks of the newly established guidelines programme are subject to the changing times. The professional handling of guidelines within other societies has led DGGG to pursuing this central restructuring. In particular, this concerns comprehensive and transparent organisation (registration, communication processes, etc.), commissioning the creation of guidelines, as well as clearly regulated procedures via the DGGG Guidelines Commission and the DGGG Board of Directors in cooperation with the Association of the Scientific Medical So-

Zusammenfassung

Das Leitlinienprogramm der Deutschen Gesellschaft für Gynäkologie und Geburtshilfe (DGGG) ist ein exekutiver Teil der DGGG-Leitlinienkommission. Es umfasst die Planung und Organisation aller Leitlinien innerhalb wie auch die Repräsentation außerhalb der DGGG. Dieser Beitrag soll weniger die Leitlinienentwicklung, sondern mehr die Planung, Organisation, Anmeldung, Redaktion und Publikation der Leitlinien im Rahmen des DGGG-Leitlinienprogramms darstellen. Zielgruppe sind Interessierte, insbesondere Autoren/innen bzw. Koordinatoren/innen von Leitlinien.

cieties in Germany (AWMF). The process of guideline creation is the foremost issue [1–3].

In the run-up to working on structured guidelines, detailed knowledge of AWMF regulation [4] in the current version 1.0 and familiarity with the specific nomenclature is beneficial. For example, the AWMF differentiates between

1. “current guidelines” [5],
2. “pending guidelines” [6] and
3. “expired guidelines”.

The first point of the classification defines valid guidelines with a definitive period of validity (designation from beginning to end). For current guidelines, this is between 3–5 years. The second point of the classification is defined by a concrete registration procedure for new guidelines or guideline revisions.

Policy (Levels of Classification)

It is mandatory to define the classification stage of guidelines at the beginning of planning. This is the yardstick for later monetary, organisational and time expenditures. There are three levels: the

lowest stage (S1), the middle stage (S2) and the highest stage (S3) [2, 4].

The lowest class is defined by a compilation of recommendations for actions by a non-representative group of experts. The methodical generation of a consensus here is of little importance compared to the other guideline stages.

In 2004, Stage S2 was split into two sub-stages, one based on evidence research (S2e) and the other based on structural consensus (S2k). From practical experience, doing only evidence research of current literature is preferred by many past guideline authors as opposed to the documented and structural finding of a consensus by a representative panel. The highest Stage S3 combines the two procedures into a complete work of highest methodological relevance.

Nomenclature

AWMF register number/Guideline title

The next step is registering with the AWMF with a registration number. This unique AWMF register number will be part of a guideline throughout its life. The syntax (XYZ/XYZ) has two parts. The first three digits define the responsible AWMF society (only one entry is possible with multiple jurisdictions). The last three digits are for creating a continuous identification number

for the guidelines. The combination of the two parts provides a unique register number and formally differentiates between a guideline and an advisory opinion on stage S1. Binding guidelines and, for example, horizontal guidelines of the German Medical Association are not included. In some cases, the guidelines title can be changed when revisions include new topics. Approval of the DGGG Guideline Secretariat is required. This shall not unduly complicate later matching of past guidelines.

Leading/participating society(s)

Also, the representatives or delegates of the participating AWMF society or non-AWMF society/organisation/lobby are expressly mentioned in the registration process and later in the published version. Not every society can register guidelines with the AWMF. To date, the AWMF has registered 168 select societies (as of January 2014) via a transparent registration procedure. During the admission procedure, the society must meet 10 admission criteria in order for their application to be approved by a three-quarter majority of the Delegates Conference that takes place twice a year. Nevertheless, non-AWMF societies can participate in the creation of guidelines but cannot register them themselves. Their participation is actually expressly desired. The defined interest group or target group of specified guidelines principally requires their representation for the creation of those guidelines.

Fig. 2 DGGG template of DIA version.

Author of guidelines/elected representative

In order to make the development process effective on the part of the authors, it makes sense to appoint a lead author or coordinator in/for the control group. This appointee is responsible for communication with the DGGG Guidelines Secretariat and coordinates the registration and creation process. The team of authors consists of elected representatives of the focus groups (FG) of the DGGG and the expert and/or non-expert societies/organisations. Specifically, the elected representative of the DGGG FGs are not appointed by the lead author of the guidelines in this new guidelines programme procedure, but instead are recommended by the respective FG following an enquiry about such by the lead guidelines author. The elected representative to-be is either confirmed or rejected by the DGGG Guidelines Commission or the representing DGGG Guidelines appointee. The same scenario applies to the lead author him/herself. This newly established procedure provides for maximum transparency when it comes to the selection of elected representatives.

Versions of guidelines documents

The AWMF policy allows guideline authors to publish their guidelines in differently edited versions. There must be no subject unconformities in the synopsis of all versions. Besides the long version, common versions are short versions/practice versions published in journals, a patient version, an international long or short version in English, and now also a DIA version. So far, 7 DIA versions are published on the AWMF homepage (► **Table 1**) and additional DIA versions are being worked on. This version serves to preserve the thematic link to the long version by summarising all statements. This means, all DIA versions or single slides can be distributed or used in training events (seminars, conferences, etc.) without any problems. The template for the DIA version is provided by the DGGG Guidelines Secretariat (► **Fig. 2**). The first illustrative example was and is the guidelines coordinated by Prof. Dr. Uwe Ulrich from Berlin for the "015-045 Diagnosis and treatment of endometriosis" [7].

Table 1 Already published DIA versions (as of 19 February 2014).

AWMF number	Guideline title
015-005	Stress incontinence in women [14]
015-023	Vaginal operative deliveries [15]
015-028	Bacterial vaginosis in Obstetrics and Gynaecology [16]
015-045	Diagnosis and treatment of endometriosis* [7]
015-052	Female genital malformations [17]
015-071	Treatment of inflammatory breast diseases during lactation [18]
032-035	Diagnosis and treatment of malignant ovarian tumours [19]

Guideline Status

The processing of all guidelines that have been published to date has been enormously taxing on the DGGG Guidelines Secretariat. This concerned cataloguing and chronological cataloguing of all digital guidelines found. Only since 2004 have they been available in digital format. Of these 400 versions, almost 260 guidelines (long versions) are currently invalid and therefore have no direct clinical relevance. The legal relevance, especially in the context of expert processes, forced the long-term availability of all of these documents in the guidelines secretariat and they are therefore also available to DGGG members and interested parties. A system was created for cataloguing these guidelines. Besides the unique date and numerical assignment of the guidelines version, a new "Present status" was implemented. It is divided into the following values:

1. **Valid:** As a valid guidelines it corresponds to the "current guidelines" of the AWMF [5].
2. **New:** Corresponds to a planned new publication of a set of guidelines. This status can be temporarily found as "registered guidelines" of the AWMF [6] only if the registration procedure has been completed.

Table 2 Archived guidelines which were transferred to other guidelines or planned guidelines (as of January 2014).

AWMF number	Guideline title	AWMF number	Guideline title (transferred to)
015-021	Antenatal care and labour induction with status post C-section	–	Possibly new C-section guideline
015-022	Presence of fathers in C-sections	–	New C-section guidelines
015-046	Placenta disorders in status after C-section	–	New C-section guidelines
015-054	Absolute and relative indications for C-section	–	New C-section guidelines
015-056	Postoperative monitoring of C-section patients	–	New C-section guidelines
015-064	Laparoscopic supracervical hysterectomy (LASH)	–	New hysterectomy guidelines
015-012	Postpartum disorders of bladder and pelvic floor function	015-005	Stress incontinence [10, 14]
		015-006	Descent in women [20]
015-013	Bladder emptying disorders	015-005	Stress incontinence [10, 14]
		015-006	Descent in women [20]
015-037	Contraception in women with type 1 and type 2 diabetes mellitus	015-015	Contraception
015-014	Urogenital atrophy	015-062	Hormone therapy in peri- and postmenopause [21]
015-033	Recommendation for sonographic diagnosis in asymptomatic postmenopausal patients	015-062	Hormone therapy in peri- and postmenopause [21]
015-038	Consensus recommendations for hormone therapy (HT) in menopause and postmenopause	015-062	Hormone therapy in peri- and postmenopause [21]
015-042	Antifungal therapy of vaginal yeast colonisation	015-072	Vulvovaginal candidiasis
015-003	Laparoscopic surgery of ovarian tumours	032-035	Diagnosis and treatment of malignant ovarian tumours [11, 19]
015-009	Urinary tract infection of women	043-044	Urinary tract infections [22]
015-010	Urinary tract infection in pregnancy	043-044	Urinary tract infections [22]
015-041	Recommendations for Chlamydia trachomatis infection in pregnancy	059-005	Infections with Chlamydia trachomatis

3. **Revision:** Corresponds to guidelines that are currently being revised. This status can be temporarily found as “registered guidelines” of the AWMF [6] only if the registration procedure has been completed. After a set of guidelines has been created, this status changes to *valid* if it was successful or *expired* if it has failed.

4. **Expired:** Corresponds to guidelines that are no longer valid. This status is temporary for one year. If the content is being revised, that status of the guidelines changes to *Revision*, or if there is no revision it changes to *Archived*. Since the beginning of January 2014, these guidelines are available for download from the DGGG homepage and accessible to all interested parties [8].

5. **Archived:** Corresponds to a set of guidelines after the expiration of one-year with an *Expired* status. Since the beginning of January 2014, *archived* guidelines are available for download on the DGGG homepage and are accessible to all interested parties [8]. These *archived* guidelines often have duplicate entries (AWMF number with guidelines title), depending on the number of revisions. For this status, a sub-status was established at a later point in time. It is called *transferred* and corresponds to a set of guidelines, which, after consultation with the author of the guidelines, is transferred to guidelines of a different name or has been transferred already (● Table 2). It will not be published in the future.

DGGG Guidelines Programme Homepage

In light of the new direction of the DGGG Guidelines programme, there was no way around completely redesigning the DGGG homepage (<http://www.dggg.de/leitlinienstellungnahmen/>). This process was split into three phases:

Phase I was concluded in October 2013 and includes the following changes:

1. Link to the AWMF homepage for all currently registered guidelines authored by DGGG or guidelines that DGGG participated in. The different layouts of DGGG and AWMF were matched. The primary reason for this decision was the lack of transparency as to which version is or was valid at what point in time. A direct download to the guidelines without a link was available for an extended period of time, even though the guidelines may not have been valid any more. The document was not marked as *expired* or *archived*. This increased confusion and the risk of erroneously assuming a document was valid. These direct links to the AWMF will be maintained by the DGGG office in Berlin from now on.

2. All new statements of the DGGG were issued a consecutive number. Similar to the guidelines, this will make it easier to match the statements in the future. Past statements were not issued a number.

Phase II will be concluded in the spring of 2014 and includes the following changes:

1. Making available all *archived* guidelines (2004–2012). This step was already concluded at the beginning of January 2014.

2. Making available all archived statements. The goal is to have this step completed by the end of February 2014.

3. Expansion of offering of the following documents/links (only accessible to DGGG members) [9] in context of the structural reform of the guidelines.

a) Structure paper as the basis of guidelines creation and guidelines structure,

b) Standard Operating Procedure (SOP Version 10.10.2013) marks the detailed flow and communication channels of guidelines development/revision of guidelines (● Fig. 3),

c) AWMF registration form as specially adjusted and partially pre-filled DGGG version (● Fig. 4),

d) AWMF registration form (fill-in help) as specially adjusted DGGG version (● Fig. 5),

e) Travel expense form for guidelines authors

- f) Funding application for guidelines authors
- g) Link to AWMF policy
- h) Link to Conflict of Interest declarations (Col) for guidelines authors

Phase III should be concluded at the end of 2014 and includes the following changes:

1. Making available all *archived* guidelines (before 2004). These versions of the guidelines are available in non-digital formats only. This chronological categorisation will pose the biggest challenge.
2. Further content and interface adjustments.

Publication

Full publication is one of the critical processes of guidelines work. The work, which often takes several years, must be publicised in an appropriate manner. A distinction is made between the publication of all guidelines documents (also full version) on the AWMF homepage and the versions for international distribution (short or long versions) in English. Previous guidelines were often published in the “Frauenarzt” (Gynaecologist) magazine. With the increased development of S2/S3 guidelines of high methodological quality from Germany, it was necessary to find a new publication outlet. The DGGG Guidelines programme has decided in favour of the “Geburtshilfe und Frauenheilkunde (GebFra)” (Obstetrics and Gynaecology), published by the Thieme Publishing [10–13]. Listing in the database of the National Library of Medicine (NLM), known as MEDLINE, is expected in 2014. This means that all guidelines versions published there can be found via pubmed.org or other search interfaces, at the very least as an abstract. This process will increase exposure in English-speaking territories enormously.

Workshops

To get to know better all processes of guidelines planning/organisation as well as guidelines creation (not covered here), the first workshop of the DGGG Guidelines programme was held on 18.1.2014 in Erlangen. Based on this success, an additional workshop will be offered this year for select guidelines authors.

Overview of Tasks of the DGGG Guidelines Secretariat

The tasks currently assigned to the DGGG Guidelines Secretariat in the context of DGGG Guidelines organisation are manifold and in part only briefly described here.

1. Planning, coordination and financing of the DGGG Guidelines programme
 - a) Registration of new or revised guidelines: new registration or update (guidelines class stays the same)/upgrade (guidelines class is raised, rarely downgraded) of existing guidelines.
 - b) Communication with the participants
 - c) Communication with AWMF
 - d) Selection and concentration of topics
 - e) Ensuring the archiving of all guidelines/correspondence: in digital format for the first time thanks to a special document management program.
2. Participation in the DGGG Guidelines Commission meeting (2×/year)
3. Participation in the AWMF Delegates Conference (2×/year)
4. Maintaining the DGGG homepage with the numerous improvements thus far
5. Conducting workshops
6. Processing external requests (IQWIG, AQUA, DIMDI, medical associations, colleagues, etc.)
7. Regular news updates via newsletter to all DGGG members

Objectives of the DGGG Guidelines Programme

If the basis of the daily work is structured and economised, then the conditions for the planning of new goals are met. The prioritisation and rationalisation of issues across the entire catalogue of guidelines should be a new focal point. The focus should be on overriding issues and with the assignment of such to the responsible working groups of the DGGG. In doing so, the tight financial and time resources should be used in a more structured way, especially in terms of creating guidelines. With regard to the creation of guidelines with ever inter-disciplinary and inter-professional cooperation, this step seems to be inevitable. Another focus point is the improvement of international distribution of German guidelines. Thanks to the excellent cooperation of our Austrian and Swiss colleagues in committee work as well for the creation of new guidelines, the overall effort, which is often volunteered, can be reduced in this regard without risking a loss in quality. Of course not all topics and opinions can be combined due to country-specific differences.

Conflict of Interest

None.

Standard operating procedure (SOP) for the creation/revision of guidelines
at the German Society of Gynaecology and Obstetrics (DGGG, registered association)
in cooperation with the Association of the Scientific Medical Societies in Germany
(AWMF, registered association)

Fig. 3 Standard Operating Procedure (SOP) for guidelines organisation [9].

SOP Anmeldung/Überarbeitung Leitlinie V10.10.2013

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Registration form for Guidelines Projects (DGGG version)

Version as of 15 October 2010, modified on 11 June 2013

Title of the guidelines:	
Type of registration:	☐ New guidelines ☐ Upgrade or ☐ Update of AWMF register no. 015/
Planned class:	☐ S1 ☐ S2e ☐ S2k ☐ S3
Date of registration:	
Scheduled date of completion (day/month/year):	
Reasons for topic:	
Objective of the guidelines:	
Connection to existing guidelines:	Indicate AWMF register no.:
Registrar (person):	DGGG Guidelines Officer: Prof. Dr. med. M. W. Beckmann
Registering AWMF society(s):	DGGG (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe)
Participation of other AWMF societies:	
DGGG focus group of the guidelines coordinator/society/organ:	Other:
Contact person (Guidelines Secretariat):	DGGG-Leitliniensekretariat, Frauenklinik, Universitätsklinikum Erlangen, Universitätsstraße 21–23, 91054 Erlangen, E-Mail: fk-dggg-leitlinien@uk-erlangen.de , Tel.: 091 31/85-44063 or -44060
Guidelines coordination (name):	
Coverage area:	
Targeted patient group:	
Addressees of the guideline (target group):	
Planned methodology (type of evidence basing, type of consensus finding):	
Additional project information (available yes/no, if yes: where?):	

Please fill out this form, save as PDF file and attach as a **separate file** (E-Mail attachment, **do not add to the text area of the E-Mail!**) and E-Mail to: fk-dggg-leitlinien@uk-erlangen.de

Fig. 4 Registration form (DGGG version) [9].

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Fill-in Aid for Registration form for Guidelines Projects (DGGG version)

Version as of 15 October 2010, modified on 5 June 2013

Title of the guidelines:	Please select a meaningful short-as-possible title proposition for your guidelines.
Type of registration:	☐ New guidelines ☐ Upgrade or ☐ Update of AWMF register no.
Planned class:	Please specifically indicate, S1, S2e, S2k, S3. A decision aid for the selection of the class can be found under http://www.awmf-leitlinien.de Column Guidelines Policy → Guidelines Register , Classification of the Development Stages
Date of registration:	Day/month/year
Scheduled date of completion (day/month/year):	Please indicate the scheduled date of completion. Please note: Past this date, the DGGG Guidelines Secretariat will inquire about the status of the project.
Reasons for topic:	Please indicate why you have chosen this guidelines topic. The explanation should contain information about maintenance frequency and potential for improvements.
Objective of the guidelines:	Please specify the objectives of the guidelines and what is to be achieved with the publication and implementation.
Connection to existing guidelines:	Please indicate if these guidelines' content overlaps with existing guidelines or registered guideline projects, e.g., which guidelines already concern individual topics of your guidelines or has (partially) already made corresponding recommendations. You can use the search function on the AWMF Guidelines homepage for this. Please indicate the AWMF register number.
Registrar (person):	DGGG Guidelines Officer: Prof. Dr. med. M. W. Beckmann
Registering AWMF society(s):	DGGG (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe)
Participation of other AWMF societies:	Please indicate which AWMF societies were already asked to participate in your guidelines. Please note: Representatives of all addressees of the guidelines named below should participate in the development, if interested.
DGGG focus group of the guidelines coordinator/society/organ:	Please indicate which DGGG focus groups , societies and organisations were already asked to participate in your guidelines (e.g. patients' organisations, professional associations; please also indicate societies outside the AWMF). Please note: All representatives listed under Addressees of the guidelines should be involved in the development of the guidelines if interested.
Contact person (Guidelines Secretariat):	DGGG-Leitliniensekretariat, Frauenklinik, Universitätsklinikum Erlangen, Universitätsstraße 21–23, 91054 Erlangen, E-Mail: fk-dggg-leitlinien@uk-erlangen.de , Tel.: 091 31/85-44063 or -44060

Fig. 5 Help for filling in the registration form (DGGG version), page 1 only [9].

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