

Implementation of a Quality Management System for Clinical Practice Guidelines with the Scientific Medical Societies in Germany: The AWMF Guideline Register

Cathleen Muche-Borowski, Monika Nothacker, Ina Kopp

Association of the Scientific Medical Association's Institute for Medical Knowledge
Management at the University of Marburg



- Guidelines are -nationally and internationally- an important decision making tool
- Minimum criteria for developing high-quality guidelines were published in 2012 (G-I-N standards)
- High-quality guidelines require financial and human resources with a wide range of skills and expertise across the different professions
- in Germany, guidelines are developed by the scientific medical societies („bottom-up“ vs. „top-down“ approach)

AWMF (Association of Scientific Medical Societies) pursues the following tasks and goals:

- to further develop the methodology
- to improve guideline competence within member societies
- to support the medical societies developing guidelines
- to promote interdisciplinarity and patient involvement
- to recognize the need for guidelines (prioritization)
- to make guidelines available free of charge on the Internet

Development of quality management following the Plan-Do-Check-Act (PDCA)-cycle

- 1) Establishing structures and processes
- 2) Implementing a quality management system for guidelines
- 3) Further continuing expansion of quality management to date

1) Establishing structures and processes **(1995-1999):**

Important structural and process elements were:

- Convening a standing commission for guidelines at AWMF
- Appointing guideline delegates within the societies
- Formulating the first guidance for guidelines and introduction of a guideline classification (S1 to S3), indicating the degree of systematic development
- Initiation of quality improvement
- Sharing methodological knowledge

Development of quality management following the plan-do-check act (PDCA)-cycle

- 1) Establishing structures and processes
- 2) Implementing a quality management system for guidelines
- 3) Further continuing expansion of quality management to date

2) Implementing a quality management system for guidelines (2000-2010) includes:

- The development of methodological standards to develop evidence-based guidelines
- Setting up a manual to support the ongoing methodological development
- Adapting the AGREE evaluation instrument (harmonizing methodological procedures internationally)
- Establishing a structured dialogue
- Introducing initial rules focused on fostering consensus-building/interdisciplinarity
- The registration process for guidelines under planning and development (registration form as project outline) (2004)
- Deleting outdated guidelines (maximum validity 5 years) (2008)

Development of quality management following the plan-do-check-act (PDCA)-cycle

- 1) Establishing structures and processes
- 2) Implementing a quality management system for guidelines
- 3) Further continuing expansion of quality management to date

3) Further continuing expansion of quality management to date:

The key elements of this cycle were and are:

- Implementing a total of seven rules
 - The registration process for guideline planning and development (status as per 2013)
 - Explanation of and procedure for dealing with conflicts of interest (form) (status as per 2010 with updated beta version for testing)
 - Classification of the S1, S2k/S2e, S3 development stage (status as per: 2010)
 - Submission for publication (status as per 2010)
 - Deletion of outdated guidelines from the AWMF Guideline Register (maximum validity 5 years) (status as per 2008)

3) Further continuing expansion of quality management to date:

The key elements of this cycle were and are:

- Structured external appraisal of each submitted guideline by two reviewers
- Evaluation documentation and structured dialogues
- Regular seminars for guideline developers
- Development of a curriculum for guideline advisers
- Training and exchange of expertise at annual guideline conferences

1) Establishing structures and processes:

	Helou 1998			
Documentation of guideline development	Criteria met			
Clear naming of the responsible institution	100%			
Representative composition of the guideline committee	-			
Transparency of the literature search documentation	-			
Description of methods used to evaluate the strength of evidence	-			
Naming the methods used to make recommendations	75%			
Description of the methods used for phrasing recommendations	60% incomplete			

2) Implementing a quality management system for guidelines

	Helou 1998	Kopp 2002		
Documentation of guideline development	Criteria met	Criteria met		
Clear naming of the responsible institution	100%	100%		
Representative composition of the guideline committee	-	25%		
Transparency of the literature search documentation	-	23%		
Description of methods used to evaluate the strength of evidence	-	28%		
Naming the methods used to make recommendations	75%	76%		
Description of the methods used for phrasing recommendations	60% incomplete	17%		

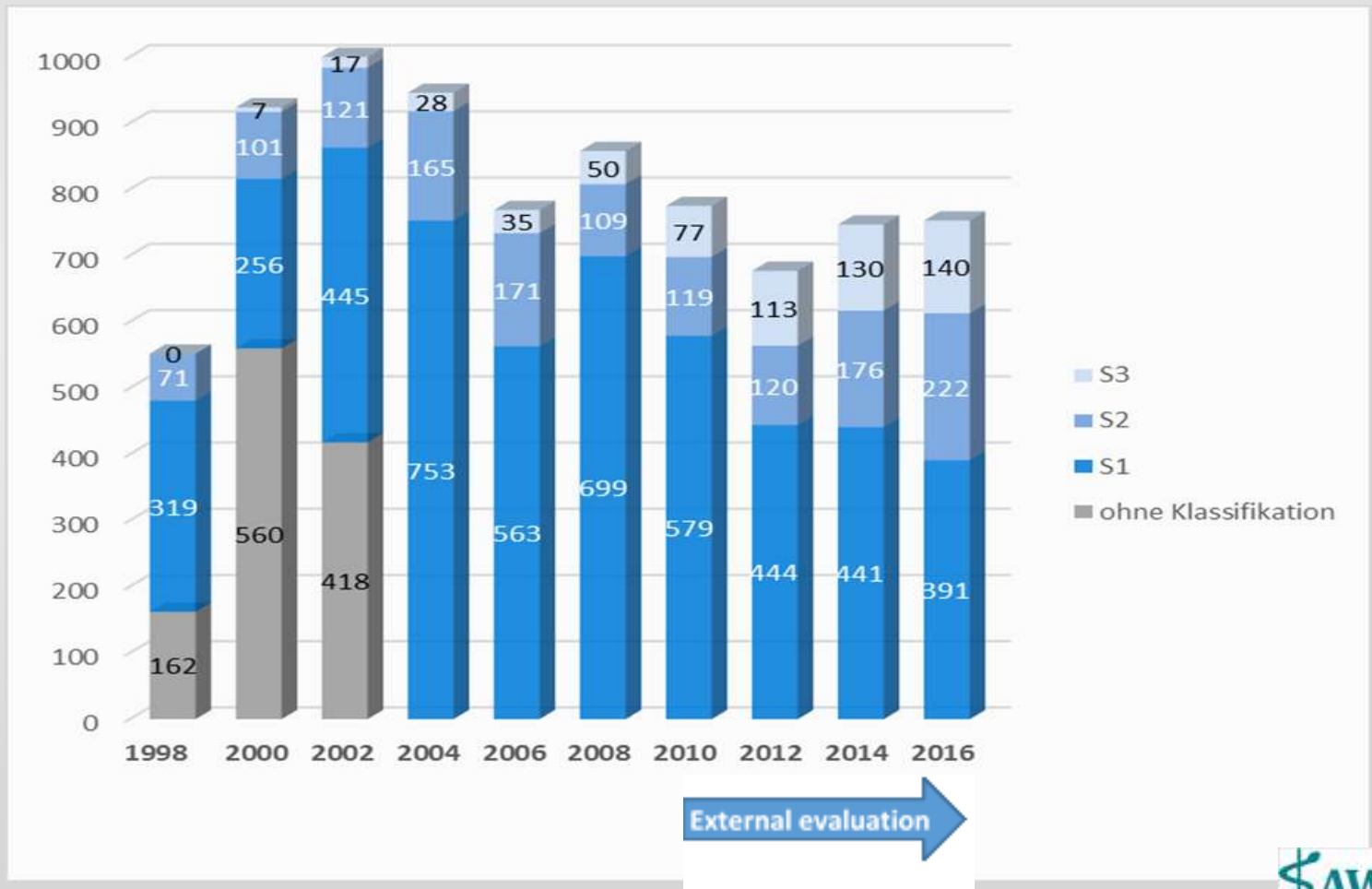
2) Implementing a quality management system for guidelines

	Helou 1998	Kopp 2002		Graham 2001
Documentation of guideline development	Criteria met	Criteria met		Criteria met
Clear naming of the responsible institution	100%	100%		100%
Representative composition of the guideline committee	-	25%		55%
Transparency of the literature search documentation	-	23%		18%
Description of methods used to evaluate the strength of evidence	-	28%		21%
Naming the methods used to make recommendations	75%	76%		Not included
Description of the methods used for phrasing recommendations	60% incomplete	17%		26%

3) Further continuing expansion of quality management to date:

- Continuous development: reduction of S1 guidelines and increase of S2 / S3 guidelines
- AWMF Guidance (manual and rules) was published in 2011/2012
- Col are transparent in ALL Guidelines published via AWMF
- S3-guidelines in the AWMF register fully meet the international methodological requirements for high-quality guidelines

Development of the Guideline Register 1998-2016



1. There has been a cultural change from individual expert opinions to evidence-based, interdisciplinary and multi-professional consensus-built guidelines.
2. The scientific medical societies are constantly motivated to create high-quality guidelines under their own responsibility with the support of the AWMF.
3. The AWMF has been accepted by the scientific medical societies and established as their umbrella organization and network.

4. By analyzing the formal methodology, the guideline groups have accepted the 3-stage classification; the methodological quality of their guidelines is comparable with international guidelines.
5. The guideline groups have accepted structured external evaluations of the guidelines they submitted; thereby contributing to building a highly valuable Guideline Register with its established seven rules.
6. “quality assurance is only achieved by working with and not against doctors“

Thank you for your attention!

Dr. Cathleen Muche-Borowski, MPH

Association of the Scientific Medical Societies –
Institute for Medical Knowledge Management (AWMF-IMWI)

e-mail: muche-borowski@awmf.org

imwi@awmf.org