

THE GERMAN GUIDELINES CLEARING HOUSE (GGC) – RATIONALE, AIMS AND RESULTS

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INTRODUCTION

The role of clinical practice guidelines (CPGs) as a tool for quality management in health care is now widely accepted in Germany – not only by health professionals, but also in politics. As a consequence, the federal parliament passed a new social code in 1999, stating that 'every year, quality indicators for ten priority health problems – developed from evidence-based guidelines – have to be implemented on a national level'.¹

However, the number and quality of the available CPGs has become an issue of concern since the German scientific medical societies started their CPG programme in 1995. This is because the majority of the more than 900 CPGs accessible through the world wide web (www.awmf-leitlinien.de) relied on expert opinion more than on scientific evidence. Until 2000, they often lacked a thorough and transparent development process,^{2,3} a situation which is comparable to that in other countries.⁴ Against this background, the concept for a guideline clearing house was developed by experts from the German self-governing bodies in health care in 1997⁵ in order to assure and to improve the quality of CPGs. In 1999, the German Guidelines Clearing house (GGC) was established at the Agency for Quality in Medicine – a joint institution of the German Medical Association (GMA) and the National Association of Statutory Health Insurance Physicians (NASHIP) – in partnership with the German Hospital Federation and the Federal Association of the Statutory Sickness Funds. In spring 2000, the GGC finished its first project – the *National Hypertension Guidelines Clearing Report*. This is the first time that the goals, procedures, methods and results of the GGC are presented in an English language publication.

BACKGROUND: THE GERMAN GUIDELINES CLEARING HOUSE'S RATIONALE

In Germany CPGs were introduced into the political discussion as early as 1924.⁶ Since then, guidelines have been published by a variety of interested groups in the health care system under different names, i.e. 'recommendation' (Empfehlung), 'guideline' (Leitlinie) and 'directive' (Richtlinie). Mandatory national guidelines (i.e. directives) for preventive services in primary care have been implemented within the regulations of the social sickness funds (covering nearly 90% of the German population) since the late sixties.⁷ Guidelines are also part of disease management contracts between statutory sickness funds and state associations of statutory health insurance physicians. Contracted physicians are only paid if they are willing to offer and to record the health care specified in guidelines (e.g. for diabetes mellitus⁸). By the use of evaluated implementation tools,^{9,10} diabetologists practising in ambulatory care across nearly all of Germany have succeeded in obtaining special contracts for performance of ambulatory diabetology based on CPGs.

However, the Association of the Scientific Medical Societies (AWMF), representing 130 individual medical societies, ignored these activities and started a new, comprehensive CPG programme in 1995 – leading to about 1,000 national CPGs after five years. And more CPGs are published by additional players, such as the regional chamber of physicians, professional associations, hospital groups and networks of private surgeries (for an overview – look at GGC's website: www.leitlinien.de), in the German health care system. All these well-meant and competitive activities between 1995 and 1999 have resulted in an uncontrolled growth of German CPGs with often low methodological quality and sometimes even conflicting recommendations (see Table 1).

TABLE 1 Major problems of German clinical practice guidelines.*
<ul style="list-style-type: none"> • Negligible information on the evidence of the recommendations. • Lack of disclosure of development strategy/process/sponsorship/accountability/implementation tool. • Conflicting guidelines on relevant topics. • Focus on specialist care, given the academic background of the authors. • Little to no relevance for primary care.
* until 1999

CHARACTERISTICS OF THE GERMAN GUIDELINES CLEARING HOUSE

Clearing houses may function either simply as directories of available guidelines, or they may provide evaluative services, assessing the methodological quality of guidelines as well as the appropriateness of their recommendations before inclusion in their databases.

Given the specific background (see Table 1), the GGC was built up as a national centre of excellence which:

- appraises the methodological quality and the appropriateness of CPGs;
- networks between guideline programmes, producers, evaluators and users (see Figure 1);
- collaborates with other health care quality programmes (e.g. Health Technology Assessment (HTA) agencies, the Cochrane Collaboration, CME programmes);
- guarantees easy access and transparency; and
- provides practical support for everybody interested in CPGs (see Table 2).

INSTRUMENTS AND METHODS OF GUIDELINE CLEARING

Taking into account published experiences and recommendations in the field of CPG methodology, the instruments, methods and procedures of the GGC were developed by a national committee of experts established

FIGURE 1
The German network for development and implementation of evidence-based guidelines.

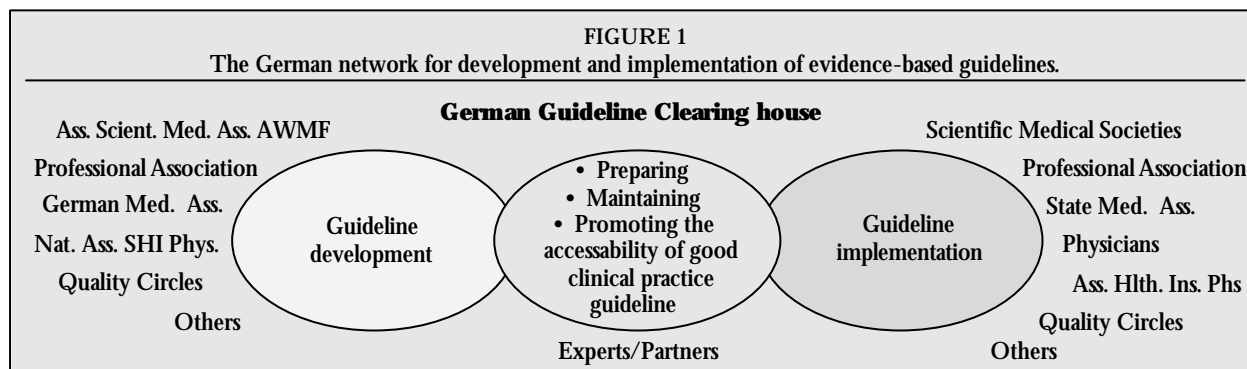


TABLE 2
Characteristics and aims of the German Guidelines Clearing house.

GGC – a national centre of excellence with the following tasks:

- development of CPG methodology;
- critical appraisal of CPGs;
- prioritisation of CPG topics;
- information on CPGs' existence/quality;
- implementation of CPGs on national/regional/local level; and
- coordination of CPG evaluation.

by the GMA and the NASHIP in 1997 (Table 3). This committee represented a broad spectrum of medical specialties, health care services and related fields (anesthesiology; clinical epidemiology; Cochrane Collaboration; emergency medicine; evidence-based medicine; health economics; internal medicine; laboratory medicine; legal counselling; medical education; medical informatics; medical librarians; pathology; pediatrics; primary care; quality management; sickness funds; and surgery). Key documents which served as blueprints or background papers during the instrumental development are *Guideline for Guidelines*;^{11, 12} checklist for critical appraisal;^{13, 14} prioritisation;¹⁵ appraisal of appropriateness;¹⁶ CME tools for implementation.¹⁷

PROCEDURES AND RESULTS OF GGC: THE GUIDELINE CLEARING PROJECT – HYPERTENSION 2000

Background and objectives

In 1999, the Guideline Clearing Project – Hypertension 2000 was initiated by the GGC's sponsors in order:

- to identify and review published guidelines on hypertension in German and English language;
- to establish criteria for future guideline development and implementation;
- to familiarise stakeholders in Germany with state-of-the-art management of hypertension;
- to identify key topics for a future national evidence-based guideline; and on the whole
- to develop the quality of hypertension management in Germany.

Methods

Search procedures.

By means of a comprehensive literature search – using Medline, Healthstar, Embase, National Guideline Clearing

TABLE 3
Instruments of the German Guideline Clearing house.

Aims	Instruments
Development of CPG methodology	<ul style="list-style-type: none"> • Committee of experts for developing a CPG clearing method
Critical appraisal of CPGs	<ul style="list-style-type: none"> • German <i>Guideline for Guidelines</i>⁸ • German checklist for critical appraisal of CPGs^{19, 28} • Procedure for appropriateness of appraisal of CPGs' recommendations^{18, 19} • Standard guideline clearing procedure²⁰
Prioritisation of CPG topics	<ul style="list-style-type: none"> • Procedure for prioritisation of CPG topics²¹
Information on CPGs existence/quality	<ul style="list-style-type: none"> • German Guidelines Information Service (GERGIS) (www.leitlinien.de/eng/)
Implementation of CPGs on national/regional/local level	<ul style="list-style-type: none"> • CME tools for CPG implementation^{22, 23}

house (www.guideline.gov) and the guideline databases available through the German Guideline Information Service (www.leitlinien.de) – 132 guidelines on hypertension were identified for the period from 1990 until 1999.

Formal appraisal.

Of those, 34 fulfilled the pre-established inclusion criteria (i.e. German and English language, national guideline, cited references published after 1994) to serve as blueprints for a German evidence-based guideline on hypertension. These CPGs were assessed with the help of the German checklist for critical appraisal of CPGs, and 11 of 34 passed the checklist's minimal quality criteria as a basis for the clearing process.

TABLE 4

Results of the guideline clearing project hypertension 2000 – appraisal of the recommendations on appropriateness and of methodological quality.

Key topics of a German hypertension CPG (*1)	Appraised CPGs (*2)											
	CDN 1	CDN 2	USA 1	USA 2	D 1	UK	SA	USA 3	WHO	NZ	D 2	
General management of hypertension												
• = Benchmark Texts (*3)												
Definition of hypertension						•						
BP-measuring	•					•						•
Medical history, evaluation			•			•						
Case-finding , screening												
Specialist referral						•						
Risk estimation						•				•		
Laboratory tests	•											•
Choice of drug treatment						•						
Non drug treatment		•										
Follow-up/motivation				•		•			•			•
Comorbidity	•					•						
Prevention		•										
Quality assurance, audit				•		•						
Tools for dissemination, implementation	•	•	•	•	•	•		•	•	•		•
Future research		•							•			
Pharmacotherapy												
Indication/risk estimation	•											
Choice of drugs	•								•			
Preferred/avoided therapy	•			•					•			
Drug combination					•	•			•			
Mono vs combination therapy									•			
Specific drugs					•			•				
Obsolete drugs												•
Compliance with drug therapy			•						•			•
Side effects/interactions					•			•				
Drug monitoring								•				
Therapy step-down												•
Economic considerations			•									
Other drug treatment									•			
Emergencies			•		•							
Drugs used in pregnancy			•									

TABLE 4 *continued*

Indicators of methodological quality (*4)	Results of formal appraisal (*5)										
	CDN 1	CDN 2	USA 1	USA 2	D 1	UK	SA	USA 3	WHO	NZ	D 2
1. CPG development	15	14	14	11	11	8	7	8	6	6	5
2. CPG content	16	17	15	16	15	14	16	14	13	14	7
3. CPG practicability	4	3	5	6	4	0	0	6	2	0	4

Explanations: *1: Key topics of a national hypertension guideline – as identified by the focus group; *2: Best available evidence-based guidelines – as identified by the focus group; *3: Links of key topics (*1) and benchmark texts (*2); *4: Indicators of methodological quality according to the appraisal checklist;¹⁹ *5: Sums of ‘yes-answers’ concerning the quality indicators (highest ranking: left column; lowest ranking: right columns).

Links of key topics of a German hypertension guideline, as recommended by the clearing project, to examples from the 11 appraised evidence-based guidelines that covered each of these topics best²⁴

Appraisal of clinical appropriateness of the recommendations.

The appraisal of the appropriateness of the recommendations was performed by a multi-disciplinary focus group of experts from different backgrounds (primary and secondary care, clinical pharmacology and clinical epidemiology), all of whom were familiar with evidence-based medicine. All experts confirmed no conflict of interest; of them, one had been involved in a CPG production programme before or during the clearing process.

Disclosure of appraisal results.

The results of both the methodological appraisal as well as the appraisal of clinical appropriateness were documented on a structured abstract form. The focus group consented on a guidelines clearing report containing structured abstracts, comments on CPG methods and recommendations and methodological features which should be employed for the development of a national guideline on hypertension for Germany (like systematic retrieval and a selection of evidence or explicit links between recommendations and the supporting evidence). This was followed by a detailed description of 16 key topics (including screening, risk stratification, clinical assessment, pharmacological and non-pharmacological therapy, patient education, as well as dissemination and implementation strategies for health care providers and health care users and the requirement of a re-evaluation of the guideline) on content issues. All suggestions and recommendations were accompanied by explicit examples from the 11 existing evidence-based guidelines that covered each of these topics best (see Table 4). The whole report is available for the public on the internet (www.leitlinien.de).

Results (see Table 4)

Methodological appraisal.

Eleven out of 132 guidelines were in accordance with the formal minimal standard with a wide range within the following domains: ‘description of the development process’; ‘authors’ declaration on conflict of interest’; ‘explicit link between recommendations and the supporting evidence’; ‘management options’; ‘tools for implementation’.

For future national hypertension guidelines the focus group suggested the following procedures:

1. the recommendations should be developed using professional association standardised and transparent consensus methods based on evidence retrieved and selected in a systematic way;
2. links should be established between recommendations and supporting evidence;
3. specific guideline versions should be formulated for defined groups of health care professionals as well as for consumers/patients;
4. guideline-based educational tools should be developed; and
5. periodical updates of the hypertension guideline need to be ensured.

Appraisal of guidelines’ content.

None of the guidelines comprised information on the key elements of a national hypertension guideline for Germany (as identified by the focus group), such as:

1. definition of hypertension: epidemiology, health care problems, intended guideline users/goals;
2. blood pressure measurement;
3. medical history and physical examination;
4. case-finding/screening;
5. indications for referral;
6. risk-stratification;
7. diagnostic procedures;
8. therapeutic goals/indications for therapy;
9. non-pharmacological interventions;
10. pharmacotherapy;
11. follow-up/patient education/motivation/compliance;
12. comorbidity, hypertension in childhood/elderly/pregnancy;
13. primary prevention;
14. quality assurance/quality management;
15. dissemination/implementation; and
16. open questions/challenges for the future.²⁵

HAVE THE AIMS AND GOALS OF THE CLEARING PROJECT BEEN ATTAINED?

Appraisal of guidelines’ methodological quality and appropriateness

The above mentioned procedures and results demonstrate that it was possible to establish a systematic approach for critical appraisal of clinical practice guidelines in Germany within an acceptable period of time (three years).

Using internationally accepted quality criteria we were able to identify and to rank the best available guidelines on hypertension in German and English language according to their validity, applicability and clinical appropriateness. Therefore, it was an important step to draw up a methodology for appraising the appropriateness which enhanced the quality development of our national guideline programme.

Following the clearing report, the editors of the two German hypertension guidelines were asked to coordinate their activities in the future. The focus group responsible for the clearing project will supervise the expected collaboration and its results.

Thus the clearing programme will – hopefully – end in an evidence-based national guideline programme for Germany, without producing the guidelines by itself, rather leaving this task to the medical community. The ongoing clearing projects on other topics (tumor pain, back pain, Type 2 diabetes mellitus, asthma) will show whether these activities will have long-term effects.

Network between guideline programmes, producers, evaluators and users

These activities would not have become reality without networking between all parties interested in clinical practice guidelines. The institutionalisation of the GGC in 1999, and the application of its instruments during the project Hypertension 2000 can be regarded as the starting period/point of a national programme for more quality in practice guidelines. Before 1999, the AWMF – the umbrella association of the scientific medical societies – opposed intensively the activities of the self governmental bodies in the CPG field. Since then, a close collaboration between AWMF and the GGC has been taken up with regular joint meetings, joint prioritisation and joint instruments aiming at good clinical practice guidelines.²²

Collaboration with other health care quality programmes

The development of a new concept for evidence-based postgraduate education in Germany is an additional consequence of the clearing project. The National Academy for Continuing Medical Education has been asked to build up a CME programme on management of hypertension on the grounds of the results, comments, discussions and examples of the hypertension report. Numerous audit groups and networks of physicians – predominantly in ambulatory care – have started to use the clearing report as a tool for continuing medical

education on the management of hypertension.

Furthermore, health policy makers are planning to integrate GGC's projects and their results into the framework of activities for continuous quality improvement according to the new Social Law for Germany (see Table 5).

As outlined in Figure 1, the priorities and projects of the GGC programme are planned and performed in close collaboration with several German health care quality programmes, e.g. the German Cochrane Centre (www.cochrane.de), the German Network for Evidence-Based Medicine and its members (www.ebm-netzwerk.de), the German Association for Quality Assurance in Medicine and its members (www.aqs.de) and the German HTA Agency (www.dimdi.de). International partners of the GGC are the Scottish Intercollegiate Guidelines Network (www.sign.ac.uk), the US National Guideline Clearing House (www.guideline.gov) and the AGREE collaboration (agreecollaboration.org).²⁶

Easy access of guidelines and practical support

The first and the most relevant of all GGC's projects was to guarantee easy access to guidelines as well as practical support for everybody interested in that field – long before GGC's official establishment in 1999. The homepage of the GGC (www.leitlinien.de) (i.e. the German Guideline Information Service 'GERGIS') has been the first German internet site on guideline programmes. Focusing on the quality of CPGs and linking to all known guideline websites in German, English, French and Dutch language, we were able to implement the ideas of 'good and evidence-based clinical practice guidelines' into German health care, and health care policy, within a relatively short period of time: GERGIS was launched in spring 1997. Only two years later, the state ministers of health and the federal parliament referred to the GGC's activities when advising all parties in health care to use and to implement good and evidence-based CPGs.²⁷

THE FUTURE OF GGC

What are the perspectives of all these activities? Is the existence of a CPG clearing house a short running event? Or is such an institution necessary – given the specific situation of the German health care system?

- In winter 2000, 44 months after the first ideas on the GGC,⁵ there are more and more German stakeholders interested in collaboration or partnership with GGC.

TABLE 5
Implementation of guidelines in the German health care system.

Federal/state parliaments define	⇒	Legal framework for quality in health care
Self-governing bodies define	⇒	Priority health care topics
GGC identifies	⇒	Evidence-based and practicable guidelines
Self-governing bodies define	⇒	GL based quality assured regulations and budget
Regulating self-governing bodies implement	⇒	GL based education and TQM programmes
Health professional guarantee	⇒	High quality health care

- The GGC has started to establish a clearing house for patient information (www.patienten-information.de).
 - The GGC is preparing electronic technologies to enable country wide implementation of appraised CPGs.
- There seem to be major and challenging tasks ahead for the GGC.

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