

International Conference on Clinical Practice Guidelines

September 4, 1998, Frankfurt/Main

Prof. Dr. H. Reinauer, President of the AWMF:

AWMF and Clinical Guideline Program in Germany

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Association of the Scientific Medical Societies AWMF	
Members:	121 constituent medical societies
Founded:	1962
Organisation:	scientific and non-profit
Organs:	General Assembly of Delegates Board Commissions

The Association of the Scientific Medical Societies of Germany (AWMF) is an umbrella organisation and has been founded about 30 years ago. AWMF consists actually of 121 members societies (fig. 1).

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Aims of AWMF	
Interdisciplinary statements and resolutions	
	<ol style="list-style-type: none"> 1. General conditions of medical research 2. Funding of medical research 3. Basic education in medicine 4. Postgraduate training 5. Definition of developing medical fields 6. Development of clinical practice guidelines
Co-operation with:	
	<ol style="list-style-type: none"> 1. Association of the Medical Faculties (MFT) 2. Federal Commission on Health Research (GFR) 3. Scientific Advisory Board of the Federal Medical Council (BÄK) 4. Commission on Postgraduate Training
Public relations:	
	<ol style="list-style-type: none"> 1. Press conferences 2. Information centre for publication media
International co-operations	
	<ul style="list-style-type: none"> • CIOMS • Royal Society of Medicine (UK) • Federatie v. Medisch Wetenschap. Verenigingen FMWV (NL) • Ass. de Soc. Scient. Méd. Belges ASSMB (B)

The foundation group intended to improve the public relation and to inform interested people about real facts and recent developments in health care and by this way to avoid the predominance of alternative medicine in daily journals and broadcasting (television). Therefore we had established an information centre for publication media which has been used by reporters, broadcasters, and PR staff more or less effectively. During the last 30 years the main activities of AWMF changed and became broader (fig. 2). The main field is the general conditions for medical research, the basic education in medicine, the postgraduate training, the classification systems in health care, developing medical fields and in 1993 we came to the development of clinical practice guidelines.

At national level AWMF has co-operations with the Association of the Medical Faculties of Germany, with the Federal Commission for Health Research, with a Scientific Advisory Board of the Federal Medical Council, and with some commissions at the Federal Medical Council.

One of our main problems is the international co-operation with similar umbrella organizations in Europe which does not develop in that way we would like to realise. Unfortunately, we have no comparable organisations in United Kingdom, France and other European Countries nor in Overseas. We are member of CIOMS (Council for International Organisations of Medical Sciences at WHO), we have also a cooperation agreement with the Royal Society of Medicine and Scientific Federations in the Netherlands and Belgium contacts. But let me state at this point we would have much more impact within the European Union and world wide if we could establish a European Association of the Scientific Medical Societies.

The AWMF acts on direct order of the member societies or their delegates. The delegates of AWMF meet twice a year in this hotel in Frankfurt and then we are analysing the general conditions of the medical research, clinical research, research funding, the different implications of legal

acts on education and research and we finish with several recommendations or resolutions which we then pass to the governments, political parties or other institutions. I have to mention that a permanent commission „doctors and lawyers“ is working since many years with very good effect concerning the mutual informations and we try to have more influence on the way of thinking of lawyers.

I would not like to analyse critically our activities in detail but let me state that the AWMF is one of the largest organisations of scientific medical societies with about 150,000 scientists and physicians and has increasing influence in health care and research policy in Germany.

Years ago the AWMF published a brochure about „Prevention, standards and future developments in the medical specialities“. This brochure was one of the reasons why the Expert Committee of the Health Care System suggested us to develop clinical practice guidelines (CPG) in the different fields of medicine.

The mission was: Which diagnostic and therapeutic procedures are necessary for the single patient? Which procedures are unnecessary or even obsolete? Which diagnostic and therapeutic procedures should be performed in practices or policlinics and which medical procedures must be performed only in the hospitals?

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Clinical Practice Guidelines

are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

(IOM, 1990)

The definition of CPG (fig. 3), given by the IOM (Institute of Medicine), and the recommendation of KLAZINGA had been well considered and accepted (fig. 4).

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Guideline development is a combination of scientific analyses and social dynamics. The methodology of a guideline development programme should relate to the ultimate goal as well as to the foreseen implementation of the guideline.

(KLAZINGA, 1994)

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Methodology

> Input

- scientific evidence (literature reviews, meta-analyses, literature synthesis)
- professional opinions (experts)
- practice experience
- cost concerns

> Process

- experts from medical societies
- consensus conferences
- different ways of official commitment
- evidence and adding value judgements

> Output

- written document
- distribution, publication
- implementation strategy

The methodology and the criteria of acceptable guidelines are shown in the next two fig. 5 and 6. These figures are self-explaining and clearly document the scientific basis of guidelines.

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Criteria for acceptable guidelines

- Reliability and reproducibility
- Scientific validity
- Clinical applicability
- Clinical flexibility
- Clarity
- Multidisciplinary approach
- Scheduled review
- Documentation of procedures, evidence etc.

(K. N. LOHR, 1997)

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The main problem which we have to solve is the relevant terminology in this field. I would strongly argue against the term "standard"

Terminology

> Standard (Metrology)

Primary standard has the highest metrological qualities in a specified field.

ISO, 1984

General: A level of quality, skill, ability or achievement by which someone is judged.

> **Recommendation** = official advice given to someone, especially about what to do

> **Advice** = an opinion given to someone about what he should do

Dictionary of Contemporary English, 1995

because this term is indeed occupied by the metrology field and defined as the highest metrological quality in a special field (ISO definition from 1984), though the term "standard" in a more generally sense may be considered a high level of quality, skill, ability or achievement by which someone is judged (fig. 7).

In Germany we have two categories of guidelines:

1. Guidelines which are mandatory or obligatory and which have to be followed. Guidelines of this kind are the "Guidelines for Quality Assurance in Medical Laboratories" based on the Calibration Act.
2. Guidelines (Leitlinien) which are optional and may be adapted to the problems of the single patient. They are recommendations for patient management. They should offer advice to physicians about the different steps of clinical management. Therefore the German term "Leitlinien" (white line on the highway) is more appropriate. We should carefully distinct between these two kinds of guidelines.

In Germany we started rather late with the development of clinical practice guidelines. As you know clinical practice guidelines had been already developed long before in United States, in the United Kingdom and many other countries and these countries had already gathered practice and experience in that field.

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Central hypothesis

> Scientific evidence and clinical judgement can be systematically combined to produce clinically valid, operational recommendations for appropriate care that can and will be used to persuade clinicians, patients and others to change their practices in ways that lead to better outcomes in health care.

(FIELD and LOHR, 1992)

The central hypothesis for CPG has been defined by Field and Lohr in 1992 (fig. 8) and they stated that "scientific evidence and clinical judgement should be combined to produce clinically valid operational and recommendations for appropriate care that can and will be used to persuade clinicians, patients and others to change their practices in ways that lead to better outcome in health care". I think this central hypothesis indeed is very helpful to explain the significance of clinical practice guidelines and shows the role of clinical judgement in this process.

The scientific evidence can be generated by literature reviews, meta analyses, literature synthesis. Here is Evidence Based Medicine one of the main arguments. I shall come back to this point later but let me state just now, that beside EBM we need professional opinions, practice experiences and later cost concerns.

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Criteria for acceptable guidelines

1. Reliability and reproducibility
2. Scientific validity
3. Clinical applicability
4. Clinical flexibility
5. Clarity
6. Multidisciplinary approach
7. Scheduled review
8. Documentation of procedures, evidence etc.

(K. N. LOHR, 1997)

The criteria for acceptable guidelines have been defined by several authors. I would like to show you those of Catherine Lohr from 1997 (fig. 9). She presented these criteria and I think they are valid and generally well accepted. Our position is that experts from medical societies should develop the guidelines in their special field and should vote on these in appropriate consensus conferences. The final version of the guideline should be a written document. Distribution and publication of the CPGs have been done by the Internet which is well accepted by an increasing number of physicians.

How did we proceed with the guideline development strategy?

The Board of the AWMF organised several conferences with the member societies to help them developing and evaluating their guidelines. The last conference was in January, 1998. During these conferences we had intensive considerations and discussions on the format of the guidelines, on the consensus process, and on the evaluation of guidelines. Some medical societies wrote manuals instead of guidelines in diagnosis and therapy. Others had long and short versions of the guidelines and some of the societies developed only check lists or decision trees (algorithms). The short versions and check lists of the scientific medical societies have been [published by AWMF in the "Internet"](#). If you are looking into the Internet then each guideline should carry three different labels:

- Date of production
- Kind of consensus process
- Date of the next update.

In Germany the interest in clinical practice guidelines development is very high, mainly at the Federal Medical Chamber (Federal Medical Council) but also at the health insurance companies and also at the politicians. The reasons for this interest are different.

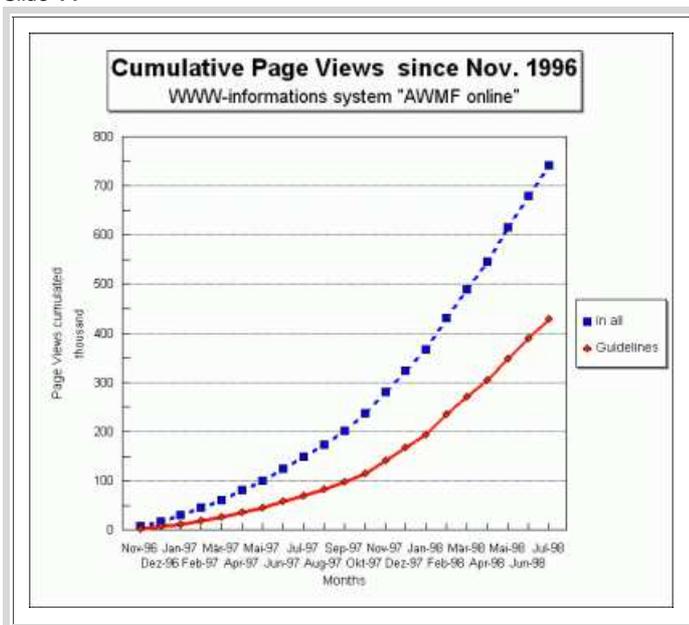
During a rather long period there was an open discussion who should develop clinical practice guidelines but meanwhile by the enormous activities of our member societies we have done the job and others have neither the capacity nor the experts and nor the acceptance to develop clinical practice guidelines. At the Federal Medical Council there is a active group and they took over the criteria for acceptability from the AWMF and from the guidelines in Scotland and founded a "Clearing Commission". Therefore I would like to state very clearly that the development, the clearing of the structure, the subjects, and the recommendations must be done at AWMF. The implementation of the guidelines should be performed in co-operation with the competent scientific medical societies.

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Clinical Practice Guidelines of the Association of the Scientific Medical Societies in germany (AWMF)		
	WWW-published	in preparation
Anaesthesiology and Intensive care	17	---
Dermatology	12	---
Hospital Hygiene	20	---
Internal Medicine	42	?
Neurology	27	48
Neurosurgery	21	---
Oncology	13	---
Ophthalmology	8	---
Orthopaedics	12	30
Otorhinolaryngology	66	---
Pediatrics	89	> 100
Pharmacology	1	---
Phlebology	11	---
Psychiaty and Psychotherapy	8	55
Radiology and Nuclear Medicine	53	---
Surgery	136	---
Urology	14	8
Others	6	---
Total	556	241

Now let me summarise what we did in the last four years: We have published the short versions of 556 clinical practice guidelines in the Internet and we have 241 guidelines in preparation (fig. 10).

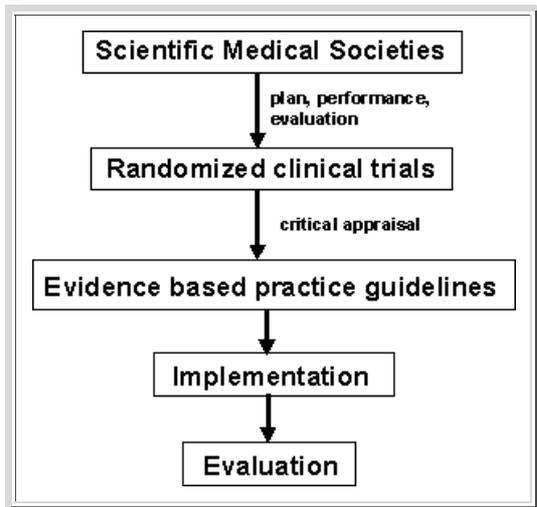
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The publication in the Internet is well accepted. In fig. 11 you see the "page views", that means, we registrate how many people are looking per day or per month at our guidelines in the Internet and you see that we had from November 1996 until July 1998 more than 400.000 views at our guidelines.

There are several problems which must be solved in the next time concerning the quality of our published guidelines.

1. The consensus process must be harmonised. You will hear some details about this consensus process from Prof. Lorenz.
2. There are interdisciplinary parts within these guidelines which must be harmonised between the concerned medical societies. Some societies like pharmacology, pathology, clinical pathology, microbiology etc. have to bring in their knowledge and experience in diagnosis and therapy into the existing guidelines. This process is on the way but not finished.



3. The main problem is now how to implement these guidelines into the health care system. In fig. 12 I show you the well accepted procedure from the plan to develop clinical practice guidelines going over to implementation and evaluation. The implementation of clinical practice guidelines should be performed in co-operation with the Federal Medical Council (in German „Bundesärztekammer“), with the Association of the Licence Doctors in Medicine (Kassenärztliche Bundesvereinigung) and with the Association of the Health Insurance Companies. We have also suggested to monitor the effect of clinical practice guidelines in hospitals and practices by appropriate quality assurance schemes which should be evaluated and give feedback for the amendment of clinical practice guidelines.

The implementation of the guidelines is the main problem and the reason of this problem is the actual reimbursement for health care services, which is actually based on the principle „fee for service“. Therefore we have to amend our reimbursement system in health care and generate a system „fee for complex services“ that means for procedures covered by the clinical practice guidelines. I am hopeful that in one of the next presentations we shall get some informations how the implementation of clinical guidelines into the health care may be realised. The minimal approach to go on with this strategy in Germany is to implement some guidelines as model in the health care system and get some experience in this field.

- Critics**
1. Economic aspects of guidelines are not or poorly considered
 2. There is yet a research-practice gap
 3. Guidelines concerning relevant problems in the health care system should have priority
 4. Patients and health insurance companies should be enclosed in the expert groups for the development of clinical practice guidelines
 5. Evidence based medicine is not the main element of guidelines
 6. Lack of strategy for implementation and monitoring of the acceptability and effectivity of guidelines
 7. Special guidelines should be tested as models before being implemented

The fig. 13 summarises the critics which we have gathered in Germany during our guideline development. First of all the reproach that the economic aspects of guidelines have not been considered. We had indeed avoided this point during the first period but have now to consider the economic aspects of guidelines.

There is a great discussion how to focus on those guidelines which are highly relevant in health care system (Guidelines for the general practitioner). In item 4 you see that patients and health insurance companies should be enclosed in the expert groups, we don't favour this view. Some incompetent people argued that Evidence Based Medicine is not the main element of our guidelines. Let me clearly state: If a scientific medical society is not familiar with the evidence based medicine in its field then their members are not competent nor is this organisation a scientific medical societies. The evidence based results are produced by the scientific medical societies.

Legal implications of the guidelines cannot be avoided and - indeed - we have already some more or less qualified reactions and considerations from the politicians, from the health insurance companies and from lawyers and courts.

Unfortunately, the terminology and the way of thinking of lawyers is different from medical people and therefore we are confronted with long discussions. One of the problem is the term: „standard“ which they use preferentially and do not realise that this term is too narrow and has a special significance. We argue: Guidelines need a broad corridor and must be adaptable to the health problems of the single patient.

- Legal implications of CPG's in Germany**
1. Social law (Sozialrecht)
 2. Liability law (Haftungsrecht)
 3. Medical Profession Law (Ärztliches Berufsrecht)

But coming back to the legal implications we would like to discuss with you which effects are created by the CPGs on the legal aspects of the medical profession (fig. 14).

Social law (Sozialrecht): This law regulates the financing of medical procedures by the health insurances (Medicare; Medicaid). The CPGs seem to become important instruments to create remuneration complexes for the medical doctors and also define which of the procedures are redundant or even obsolete. I think the acceptability of CPGs will be highly dependent on the forthcoming health care regulations.

Liability law (Haftungsrecht)
 This point brings us in a very critical position, since lawyers could use the CPGs in assessing professional blunders of physicians and use the CPGs as the gold standard within health care. Therefore we must clearly state that CPGs are recommendations.

The third legal implication may be the **Medical Profession Law (Ärztliches Berufsrecht)**. We do not promote to enclose our guidelines into the Medical Profession Law, since then they become mandatory and do not allow the individual treatment of a patient. We need the

width of a "broad corridor" for the CPGs.

Summary:

The AWMF has produced more than 500 clinical practice guidelines as a real bottom-up development and have published them in the Internet. They had done and do all this work without any financial support or funding. By this way they clearly state their independent position and view when developing clinical practice guidelines. We have generated facts but we must continue to improve and to harmonise the different guidelines, to clear them if necessary and we should be ready for co-operation with all those institutions who are competent for the implementation and monitoring of the clinical practice guidelines. We think by this way we have done an important contribution for the improvement of patient care in Germany. On the other hand we need the international co-operation in this field and therefore I am looking forward to have interesting discussion with you all during this international conference.

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