

International Conference on Clinical Practice Guidelines

September 4, 1998, Frankfurt/Main

Prof. Dr. W. Lorenz, Marburg:

Strategies in the Development of Clinical Practice Guidelines: The Three Level Concept System of the Association of the Scientific Societies (AWMF)

Clinical practice guidelines are not simple facts in medicine how to diagnose, treat and follow-up patients in the frame of a given social system. They are complex constructs including given clinical scenarios, a sequence of heuristically and analytically derived rules and finally a culturally defined outcome - items which need a generalist's approach - like that of Alexander von Humboldt - and not a specialist's narrow-minded and biased decision.

Slide 1

Quality of care

... degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge ...

K. Lohr, WHO meeting in Velen (Germany), 1997

This was defined quite elegantly by K. Lohr in the WHO meeting in Velen which combined all the players in the political and social system which are interested in guidelines: the money providers for health care, the health care providers, the political supervisors of the system in the role of the Ministry of Health, but not the most important target of all this efforts: the patients. This is typical, still typical, for the present debate about clinical practice guidelines in many societies.

The definition of quality of care avoids the term „patient“. It addresses individuals and populations. But the definition addresses desired health outcomes and current professional knowledge, and this is a very sophisticated terminology. I agree with that terminology.

Slide 2

Clinical practice guide-lines

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

K. Lohr, WHO meeting in Velen (Germany), 1997

Clinical practice guidelines were defined in relation to the quality of care:

They contain very sophisticated parts which need a further careful interpretation:

- "systematically" means unbiased methodology
- "assist" means that they are not laws, but boundaries for the individual doctor
- "patient" means that quality of life issues are always included
- "appropriate" is open to a whole battery of methods in medical decision making including utilities, QALies and other measures and
- finally "specific clinical circumstances" may also vary considerably between different countries.

It is this part of the American definition with which I have the greatest difficulties. "Specific clinical circumstances" means hardly the social system or the cultural system for which the guidelines are coined.

Slide 3

Cultural influences on quality of care

... this emphasis reflects a growing awareness among social psychologists that culture affects virtually everything we do ... the potential for cultural clashes is enormous. At the end of the 20th century, understanding culture's impact is a very practical necessity ...

Phillipchalk: Invitation to Social Psychology (1997)

The new basic science in medicine, social psychology, has emphasized the importance of cultural influences on the quality of care.

Phillipchalk expressed that in his book: Invitation to social psychology, and included a warning. The potential for cultural clashes is enormous. At the end of the 20th century, understanding culture's impact is a very practical necessity. Why is that relevant for clinical practice guidelines?

Slide 4

A simple view into the domains of social psychology illustrates this relation: the value of experience and intuition is fundamental for

Domains of social psychology related to quality of care

Major domains	Subdomains	Outcome specifics
<ul style="list-style-type: none"> Understanding ourselves and others 	<ul style="list-style-type: none"> Social cognition: mental heuristics Social perceptions of ourselves and others Attitudes: self-reports 	<ul style="list-style-type: none"> Daily decision making by doctors (experience, intuition) Expectation from treatments Quality-of-life assessment
<ul style="list-style-type: none"> Understanding social influence 	<ul style="list-style-type: none"> Group influence 	<ul style="list-style-type: none"> Consensus procedures
<ul style="list-style-type: none"> Understanding social relations 	<ul style="list-style-type: none"> Prejudice and discrimination 	<ul style="list-style-type: none"> Experienced social stigma Mechanical versus hermeneutic approach to outcome

Modified from Lorenz, Troidl, Solomkin et al: World J. Surg. (1998)

guidelines and evidence-based medicine. Quality of life as part of the outcome construct influences the formulation of guidelines in oncology, in minimal-invasive surgery, in rheumatology and in many other disciplines. The formulation of guidelines depends on consensus procedures. Finally, desired health outcomes are negatively influenced by social stigma, positively by social desirability and by the whole concept of disease: only mechanical by correcting abnormalities from the species design or by respecting and curing subjective, individual suffering.

We have used the particular technique of Delphi rounds in social psychology to analyse cultural influences on defined health outcomes as they are part of the definition „Quality of health care“

Slide 5

Cultural influences on desired health outcomes

Continents countries	Longevity > OH > SQL	Good Health objective	Q. of Life subjective
India	+	+	+
Israel	+	+	+
Tunesia	+	+	+
France	0	0	0
Australia	+	+	+
Germany	0	+	+
North-America	+	0	+
China (HK)	+	+	+
Denmark	0*		

* a balance between all of them

Lorenz, Troidl, Wulff et al: Surg Res Around the World (1998)

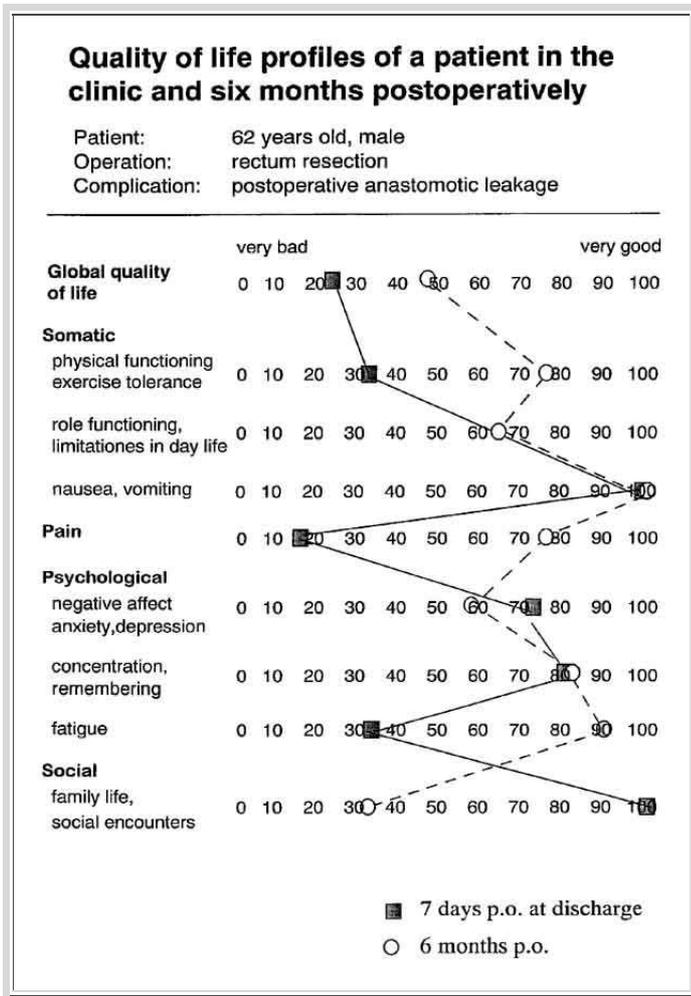
Three outcomes were distinguished: survival - good objective health measured in terms of functionality and good quality of life measured with psychometric instruments. Cultural heterogeneity is expressed in these results: Six of nine countries or continents favoured a value scale of longevity -> objective health -> subjective quality of life, but according to P.L. Fagniez in France, myself and H. Troidl in Germany and H. Wulff in Scandinavian countries this was not so in our societies. Scandinavia, in our days, favours a balance between all of them and is especially fond of „well-dying“, Germany favours almost exclusively objective health and France is very similar to the Sandinavian countries: it does not differentiate the 3 outcomes.

Slide 6

What that means in reality is shown in the quality-of-life profiles of a patient with total mesorectal excision for rectal cancer.

In a cultural system which is mostly orientated to objective disease the patient is sent home within a very short time of only 8 days. Doctors consider wound healing and objective health as good that he can go home, but his quality of life is very bad. He does not function physically very well, especially he has considerable pain, also probably because he has still to suffer from a clinically not very important anastomotic leakage, he is psychologically depressed and anxious and especially fatigue. However, his social relations are optimum, everybody from family and friends takes care of him. 6 months after operation, he has much improved his quality of life, pain and fatigue have gone, but social life is down since nobody understands his anxiety for recurrence of cancer (social stigma). Guidelines for tumor follow-up will be totally different if only objective disease or if quality of life is considered,

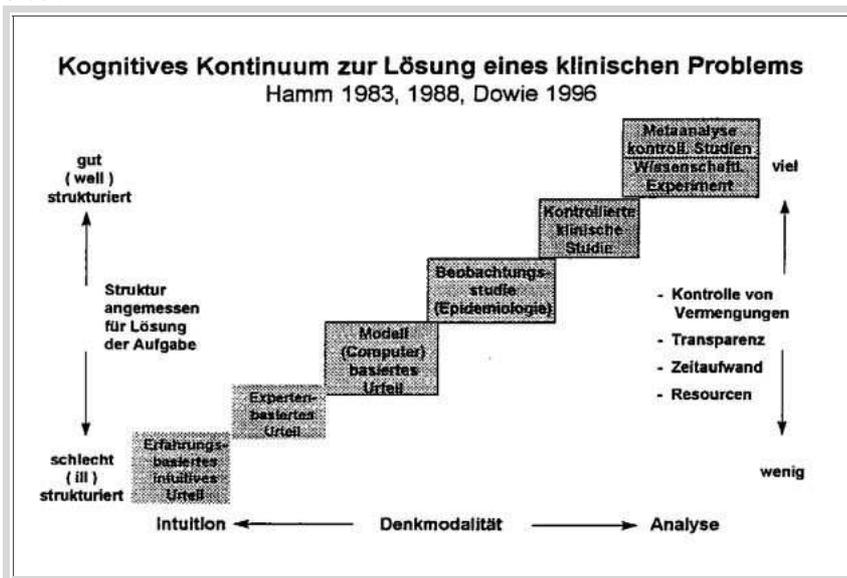
too.



Hence other desired health outcomes produce not only other guidelines, but also other ways to achieve the guidelines. This is the **second part of my presentation**.

The cognition theory behind the American guideline programme are the modes of enquiry to solve a clinical problem.

Slide 7



Six modes are distinguished which psychologically are placed in a particular direction. The lowest value is added to experience and intuition of an ordinary physician, the highest value to a combination of randomised trials in a formal metaanalysis or in a scientific experiment which may well be a study in animals. How in the time of failed sepsis trials this can be hold true has to be carefully explained - it seems no longer to be self-evident. Please recognize that also the expert judgement is not rated very high, and that the introduction of a formal assessment by a computer improves the value of the judgement to a medium quality. You know that terms and words act highly psychologically: experience-based intuition is considered as ill-structured, Dowie entitled his lecture as the pathology of clinical judgement by a clinician.

Slide 8

Experience-based intuitive judgement

... we found considerable cross-cultural difference of opinion about intuition. In the German tradition, intuition was judged much more reliable („the experienced clinician is usually right“)

Once again, however, we found considerable cross-cultural difference of opinion about intuition. In our consensus conference we recognized that in the German tradition intuition was judged much more reliable than in the Western community. Where does such a difference come from?

than in the Western community („intuition is distorted by misjudgement of probabilities“) ...

Lorenz, Troidl, Wulff et al: Surg Res Around the World (1998)

Slide 9

Heuristics and some of their biases in intuitive reasoning		
Heuristic	Evaluation of probabilities	Bias (examples)
<ul style="list-style-type: none"> • Representativeness • Availability • Adjustment, anchoring 	<p>by the degree to which A (symptome) resembles by more or less frequent occurrence of A or B in one's surrounding</p> <p>by keeping a previously obtained value for A and B also for the future</p>	<ul style="list-style-type: none"> • insensitivity to prior probabilities • Illusory correlation • imaginability • retrievability of instances • insuffic. adjustment • subjective probability distributions (calibration)

From: Gross, Lorenz: Theor Surg 5: 54 (1990)

The work is related to two giants in the psychological process of medical decision making: Kahnemann and Tversky. They and others - mostly their juniors - analyses intuitive or heuristic reasoning and proposed three major instruments: representativeness, availability and adjustment and anchoring. Representativeness is used in every diagnosis: a diagnosis is very probable if as many as possible symptoms including the cues resemble the disease. False diagnosis, however, occurs if in the particular area, city, country the disease is rare. Or a false diagnosis occurs if the clinician believes in a good outcome of operation after several bad outcomes - it is the rouge-noir problem of roulette, gambler's fallacy.

Also for availability and anchoring such biases have been demonstrated and extensively studied leading to a very bad judgement about heuristic or intuitive reasoning despite the fact that doctors use it since thousands of years.

Slide 10

Dreyfus-Skala von Experten	
Stadium	Kennzeichen
Neuling	Er verwendet Regeln, um Grundelemente einer Aufgabe herauszupicken und einfache Entscheidungen zu fällen
Fortgeschrittener Anfänger	Er beginnt, Cluster (Häufchen) von Situationselementen als ein Ganzes wahrzunehmen
Kompetent	Er hat die meisten dieser Funktionen verinnerlicht, aber für eine Diagnose und Therapieplanung auf hohem Niveau muß er sich noch immer auf Kochbuchdenken verlassen
Profizient	Er handhabt Aufgaben ohne Zögern und offensichtlichen Aufwand. Er hat ein Gespür für wichtige Punkte einer Aufgabe entwickelt. Er erledigt viel ohne spezifische Regeln, aber große Entscheidungen muß er oft noch sorgfältig analysieren
Experte	Der wirkliche Experte hat alle Aspekte des Entscheidungsprozesses verinnerlicht. Er sieht die Probleme, er sieht die Lösung, und er handelt entsprechend

J. Hilden, Theor Surg 6: 89 (1991)

However, there is a crucial condition which has to been overlooked in the experimental studies of intuitive judgement: the qualification of the expert.

Indeed, a novice and an advanced beginner needs cook book thinking and therefore a lot of systematic analysis, but the expert has another attitude and is successful in solving a clinical problem in another way: He sees the problem, he sees the solution and he acts accordingly.

This has led to conflicts when formalised clinical algorithms were proposed to advanced clinicians.

Slide 11

Clinicians became aggressive, because they found their solutions quicker by intuition than following guidelines, and our friends here in

Computerized Algorithms and pediatrician's Management of Common Problems in a Community Clinic

... clinical algorithms cannot be successfully sustained with physicians for common problems. They were too tedious for the physicians to follow during routine care ...

Margolis, Pliskin et al., Acad Med. 67: 282 (1992)

the audience concluded: read the slide!

Slide 12

Consensus statements, practice guidelines, clinical trials: are they meant to treat individual patients?

... The basis for this increased role (of practice guidelines) is the assumption that statistical analysis is the be-all, end-all of medical knowledge rather than an integral part, including intuition, judgement ... Intuition is as valuable and important as analytical thinking in surgery

Abernathy, Hamm (1995) Surgical Intuition, Hanley-Belfus, p. 15

Four years after our study Hamm changed his position and very kindly cited our paper 40 times in his book with the surgeon Abernathy from Denver, Colorado.

The basis for this increased role of guidelines: Read the slide: Intuition is as valuable and important as analytical thinking in surgery. Are there experimental studies in social psychology to support such a statement? Yes!

Slide 13

Global judgements versus decision-model-facilitated judgement: are experts internally consistent?

Scenario: Appropriateness of carotid endarterectomy, 17 different scenarios, expert versus decision model with expected utilities

- Result:**
- Correlation between panel's median global utility (clinician) versus median expected utility (decision model) excellent (Spearman rank CC 0.88)
 - Panelists appeared to be internally consistent: individual probabilities and utilities correlated with their global judgements

Oddone et al., Med. Dec. Mak. 14: 19 (1994)

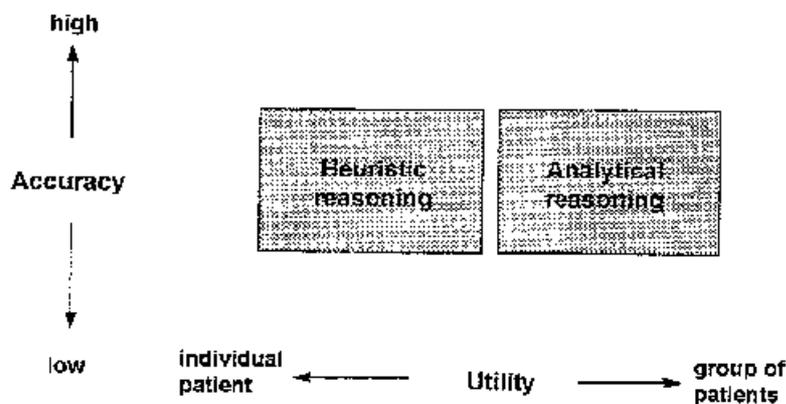
The scenarios were clinical cases in which the indication for carotid endarterectomy was evaluated by experts versus a computerised system which was created by decision makers and clinicians and used the classical model of decision trees with so-called **expected utilities**.

The term appropriateness is well-known to you. In German it means „Angemessenheit“ and is part of K. Lohr's definition of quality of health care as well as the vocabulary in our Ministry of Health.

But what was the result of the study? The experts were **internally consistent**, they were not contradictory in themselves and their judgement correlated highly with the evidence-based model using computers.

Slide 14

The two modes of enquiry to solve a clinical problem



Hence we remodel the modes of enquiry to solve a clinical problem.

We have basically two modes: Heuristic reasoning or intuition and evidence-based analytic reasoning. We have different scales. On y-axis we have in the first example of Hamm the structure of task whereas here we introduce quite practically the criterion of accuracy. On the x-axis we place utility: heuristic reasoning is better for the individual patient, analytical reasoning or evidence-based medicine better for the whole group.

Slide 15

Individuals and groups responsible for clinical practice guidelines: degree of formalisation in the consensus process

Responsible authority	Consensus methodology
Single personality	not formal
Single personality-	formal: „group-think“ advisory group
Expert group	not formal
Scientific society	not formal, but formal elements
Consensus-development	formal: experts, panel conference
Delphi group process	formal: anonymous experts repeated consensus rounds
Nominal group process	formal: Delbecq technique
Discussion forum	formal: experts, individual judgement published

Lorenz, Troidl, Fingerhut, Rothmund: Europ. J. Surg. 162 Suppl. 576, p. 5

Our model has great consequences for the development of clinical practice guidelines:

Read the slide!

Expert groups can be made informal or formal, e.g. in a Nominal group process. But they are no longer automatically insufficient, as proposed in the American model for guideline development.

The first part of this presentation with its emphasis on cultural heterogeneity, on outcomes and on the role of different modes of enquiry to solve a clinical problem including intuition and experts had to be so detailed because otherwise the German strategy for the development of guidelines is not understandable. It is not in contrast to the American position, it is not in contrast to evidence-based medicine mainly in the UK, but it uses expert opinion, consensus processes and evidence-based medicine in a **defined combination**.

Slide 16

Factors considered for development of clinical practice guidelines in Germany

- Health care system
- Culture with special attitudes to authority, uncertainty, outcome values, intuition
- Medical education system
- Social system in total

Selbmann, Lorenz et al.: Lancet 348: 1631 (1997)

This combination is orientated on our German health care system (Selbmann, 1996), on our culture which strongly has a different attitude to authority, to uncertainty, to outcome values and to intuitive judgement, on our existing medical education system and on very practical demands to produce not only guidelines for a few clinical scenarios with high costs, but to produce guidelines in most medical disciplines in a reasonably short time to satisfy the various players in our present social system.

Slide 17

Strategy in the Development of Clinical Practice Guidelines: three-level-concept of AWMF

- Check-lists by expert panels of scientific societies
- Statements following consensus processes guided by social psychology
- Statements following consensus process with systematic reviews (EBM, BES)

Lorenz, Sitter, Hartel: Proc. 3rd Conference on quality assurance in medical profession, BÄK and AWMF, p. 53 (1996)

When therefore the Association of the Scientific Medical Societies in Germany (AWMF) was committed by the Ministry of Health to design and to conduct a clinical guideline programme in 1993, under the chairmanship of Karl-Heinz Vosteen, the Honorary President of AWMF, a strategy was accepted which is shown on the next slide.

The three-level concept includes check-lists of expert panels of all scientific societies and is considered as the step which will be achieved in the shortest possible time. The second level, consensus conferences, Delphi rounds or Nominal group processes, needs more time and money and was restricted to particular problems, more or less examples. The third level included the big American guidelines with consensus processes and Evidence-based medicine or Best-evidence synthesis.

Slide 18

General procedures for development of clinical practice guidelines in AWMF (1)

a) Development: Start 1993

- Guide-lines as topics of all AWMF meetings (2 x year): chairpersons of all individual societies
- election of guide-line representatives for each society
- Guide-line formulation by expert panels of societies: approval by the board of societies and AWMF
- Guide-line formulation by intersociety expert panels
- Quality circle for guide-line development: Conferences of

During the last about 4 years we have achieved the following reality.

We started by the end of 1993. The AWMF assembly of members includes usually 2 individuals from each society, about 200 from 100 medical societies of which usually 120 - 130 participate. This large body of communicators was confronted with the guideline development twice a year. In this body of leading members of the societies one or two guideline representatives were elected for each society. These representatives created a quality circle for guideline development which meets twice a year.

The guideline representatives and the board of the societies were responsible for meetings of expert panels for guideline formulation. They invited methodologists named and selected by the AWMF to support guideline development by consensus procedures, usually

- all guide-line representatives (2 x year)
- Methodological support of societies by AWMF

Nominal group processes. The result had to be approved by the societies whose president and general secretary had to sign the guidelines. Finally the guideline coordinators of the AWMF had to approve the products before they were published in the Internet and in more detail in the journals of the societies. In addition, a series of guidelines were already formulated by interactive groups of several societies, if necessary. The most important examples were those on oncology, surgical heparin prophylaxis and duration of antibiotic treatment after abdominal infections.

Slide 19

Clinical practice guidelines for management of exocrine pancreatic carcinoma -1-

Procedure for consensus: Expert groups (n=10), 1996

- Surgical Society
- Society for Haematology and Oncology
- Society for Internal Medicine
- Society for Pathology
- Society for Radiology
- Society for Gastroenterology
- Röntgen Society

One example of pancreatic cancer is shown in the next slides, derived from the publication of our Surgical Society.

Procedure for consensus: several meetings of the expert group. They included several societies.

Slide 20

Clinical practice guidelines for management of exocrine pancreatic carcinoma -2-

Management of exocrine pancreatic cancer

1. Preoperative diagnostics (standards of GCS, Jan 1995)
2. Preoperative therapy
3. Operative therapy with curative approach
4. Adjuvant therapy
5. Radiation therapy
6. Palliative treatment
7. Follow-up (diagnostics and care)
8. Rehabilitation

Rules for the management of exocrine pancreatic cancer in these intersections, about 5 - 6 pages, similar to a consensus statement including areas where further research was needed.

Slide 21

**Clinical practice guidelines published by AWMF
(<http://www.uni-duesseldorf.de/AWMF/II/II-list.htm>)
and the individual scientific societies**

Discipline	No. of CPG
- Operative medicine	225
- Internal Medicine	40
- Gynaecology & Obstetrics	1
- Paediatrics	89
- Radiology	45
- Neurology	27
- Psycho-social disciplines	8
- Pathology	1
- Others	108
Total	544

Such guidelines were published by AWMF and the individual scientific societies in more than 500 cases.

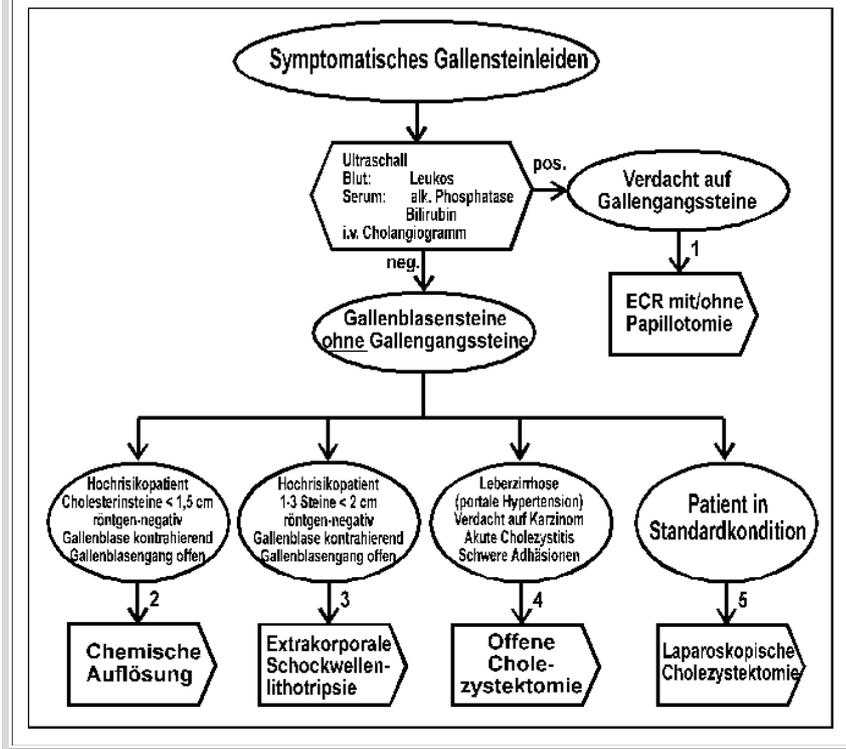
Hence the goal for the first step was reached including a considerable amount of work. The necessity to search consensus was new and was a considerable challenge for the German society. The result as a good performance was considered as the first step in evaluation.

Please recognize that operative medicine was leading, but that also conservative medicine achieved more and more the goals. The whole movement of guideline development had first to be started in this country. It did not fit to an authoritative system and was therefore in the best sense „revolutionary“.

Slide 22

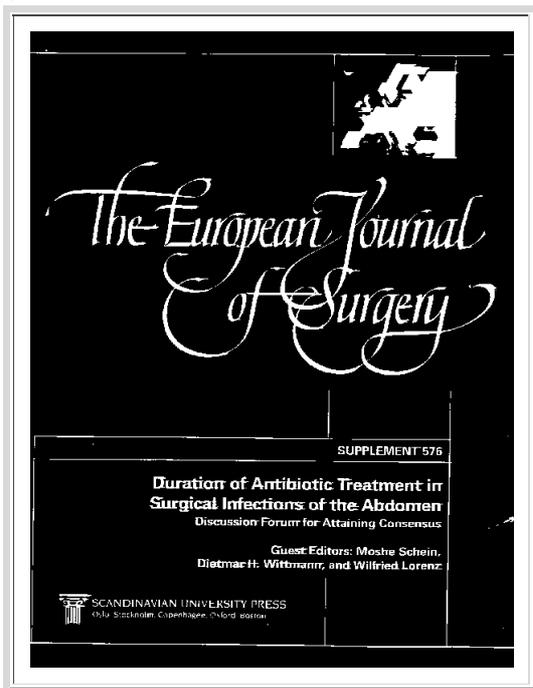
Treatment of cholelithiasis - the first consensus conference of the German Surgical Society on defining surgical standards

The second level of guideline development were formal consensus conferences, following the NIH procedure and its European modification by Vang in Technology Assessment. The result was a clinical algorithm. Symptomatic gallstone disease. The third level of guideline development, the big American guideline with full publication of a



booklet with evidence-based medicine and with a defined consensus procedure was achieved again in the Surgical Society and was designed as an international guideline for principal reasons.

Slide 23



This was the published issue in Eur. J. Surgery (1996). The steering committee selected the international body of experts for a discussion forum: written statements for each of the scenarios or clinical conditions.

Slide 24

- Discussion Forum - Duration of Antibiotic Treatment in Surgical Infections of the Abdomen	
Steering committee	- Schein (New York), Wittmann (Milwaukee), Lorenz (Marburg)
	- Lorenz, Troidl, Rothmund, Heemken, Hau, Künneke et al., Lechleuthner et al. (FRG)
	- Pollok (UK)
Participants:	- Berstein, Wittmann, Condon, Dellinger, Solomkin (USA)
	- Saadia, Lipman (South Africa)
	- Nyström (Sweden)

These were the experts on a world-wide scale. The proposal of the steering committee relied on expert opinion and thereafter on a test in hospitals national-wide in Israel.

Consensus statement:

- Reemst et al. (Netherlands)
- Bohnen, Hirshberg, Mattox (Canada)
- Frileux, Parc, Fingerhut et al. (France)
- Schein, Wittmann, Lorenz (USA, FRG)

Slide 25

Table II. Maximum recommended days of postoperative antibiotic treatment (guidelines and current literature) and percentage of "correct" answers among Israeli surgeons

From Schein *et al.* (144).

Clinical Condition	Maximum recommended (days)	Median answer (days)	Range answer (days)	Correct (%)
Acute appendicitis				
- non perforated	2	1	(0-7)	70
- perforated	5	5	(1-7)	60
Perforated ulcer				
- Diagnosis < 12 h	2	2	(0-7)	42
- Diagnosis > 12 h	5	5	(0-7)	66
Colonic injury				
- Diagnosis < 12 h	2	5	(0-7)	8
- Diagnosis > 12 h	5	7	(1-7)	39
Acute diverticulitis				
- Local peritonitis	5	7	(1-7)	47
- Diffuse peritonitis	7	7	(1-7)	100
Intestinal Ischemia	2	5	(0-7)	14

This is shown on this slide.

The consensus after all contributions of the forum is shown in the next slide.

Slide 26

Table IV. Recommended duration of antibiotic administration: assessing consensus

Consensus calculated from the responses of the contributors to the Forum. In cases where the recommendation included a range of days the intermediate figure was used (5-7 days-6 was used).

**0 days implies single-dose prophylaxis.

Clinical condition	Median (days)	Range (days)
Acute appendicitis		
- non perforated	**0	0-1
- perforated	3	1-5
Perforated ulcer		
- Diagnosis > 12 h	0	0-2
- Diagnosis > 12 h	4	3-6
Colonic injury		
- Diagnosis > 12 h	0	0-1
- Diagnosis > 12 h	3.5	2-6
Acute diverticulitis		
- Local peritonitis	4.5	1-6
- Diffuse peritonitis	5	5-7
Intestinal Ischemia	1	0-6

You see changes.

The result of the discussion forum was approved by the German Society of Surgery and was published both in its communications and in the Internet.

We have problems with the further handling of the guidelines in our society and show you therefore our procedures.

Slide 27

General procedures for development of clinical practice guidelines in AWMF (2)

b) Publication

Publication, implementation (political) and evaluation.

Performance is good, but change of strategies and improvement of outcome according to Cochrane or Lusted is a difficult task. We look still for **clinically relevant** criteria.

- Preparation of guide-lines for Internet (Office of AWMF)
- Publication of full version of guide-lines in proceedings of the societies
- Publication as scientific papers

c) Implementation

- Joint meetings of AWMF with GMA (BÄK) on guidelines for implementation
- Publication procedures of societies

d) Evaluation

- Performance
- Search for criteria
- Experiments with clinical algorithms

Slide 28

A taxonomy for clinical guidelines

Probability of being effective	Development strategy	Dissemination strategy	Implementation strategy
High	Internal	Specific educational intervention	Patient-specific reminder at time of consultant
Above average	Intermediate	Continuing medical education	Patient-specific feedback
Below average	External-local	Mailing targeted groups	General feedback
Low	External - national	Publication in professional journals	General reminder

Russell, Grimshaw in: Roland, Hospital referrals, Oxford Univ. Press, pp. 179-211 (1992)

In this situation, the taxonomy for clinical guidelines published by Russell and Grimshaw seems particularly useful.

Read the slide.

Slide 29

Strategies for development, dissemination and implementation of guide-lines

... in simple terms, guidelines are more likely to be effective if they are developed by those who are to use them, if they are disseminated through education programmes designed for this purpose, or if they are implemented in conjunction with patient-specific reminders at the time of consultation ...

Russell, Grimshaw in: Roland, Hospital referrals, Oxford Univ. Press, pp. 179-211 (1992)

The conclusion from this table are several criteria for evaluation:

- development by those who use them - we think the members of the societies and the medical associations (Berufsverbände)
- education programmes which are provided by the societies and associations
- patient-specific reminders at the time of consultation - we do have that!!!, except in clinical trials.

Slide 30

Summary

- **AWMF has a strategy for guide-line development: adapted to Germany**
- **Three levels of development: check lists, consensus statements, big guide-lines with EBM**
- **Implementation major task of GMA (BÄK) (joint ventures with AWMF)**
- **Evaluation by a quality circle of GL representatives**
- **Evaluation: a critical problem. Search for criteria.**

Summary

Read the slide!

Experiments with Clinical algorithms

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