



WHO

REGIONAL OFFICE FOR EUROPE

SCHERFIGSVEJ 8
DK-2100 COPENHAGEN Ø
DENMARK

TEL.: (45) 39 17 17 17
TELEFAX: (45) 39 17 18 18
TELEX: 15348 AND 12000

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GUIDELINES IN HEALTH CARE PRACTICE

Report on a WHO Meeting

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MANAGING HEALTH FOR ALL DEVELOPMENT

By the year 2000, management structures and processes should exist in all Member States to inspire, guide and coordinate health development, in line with health for all principles.

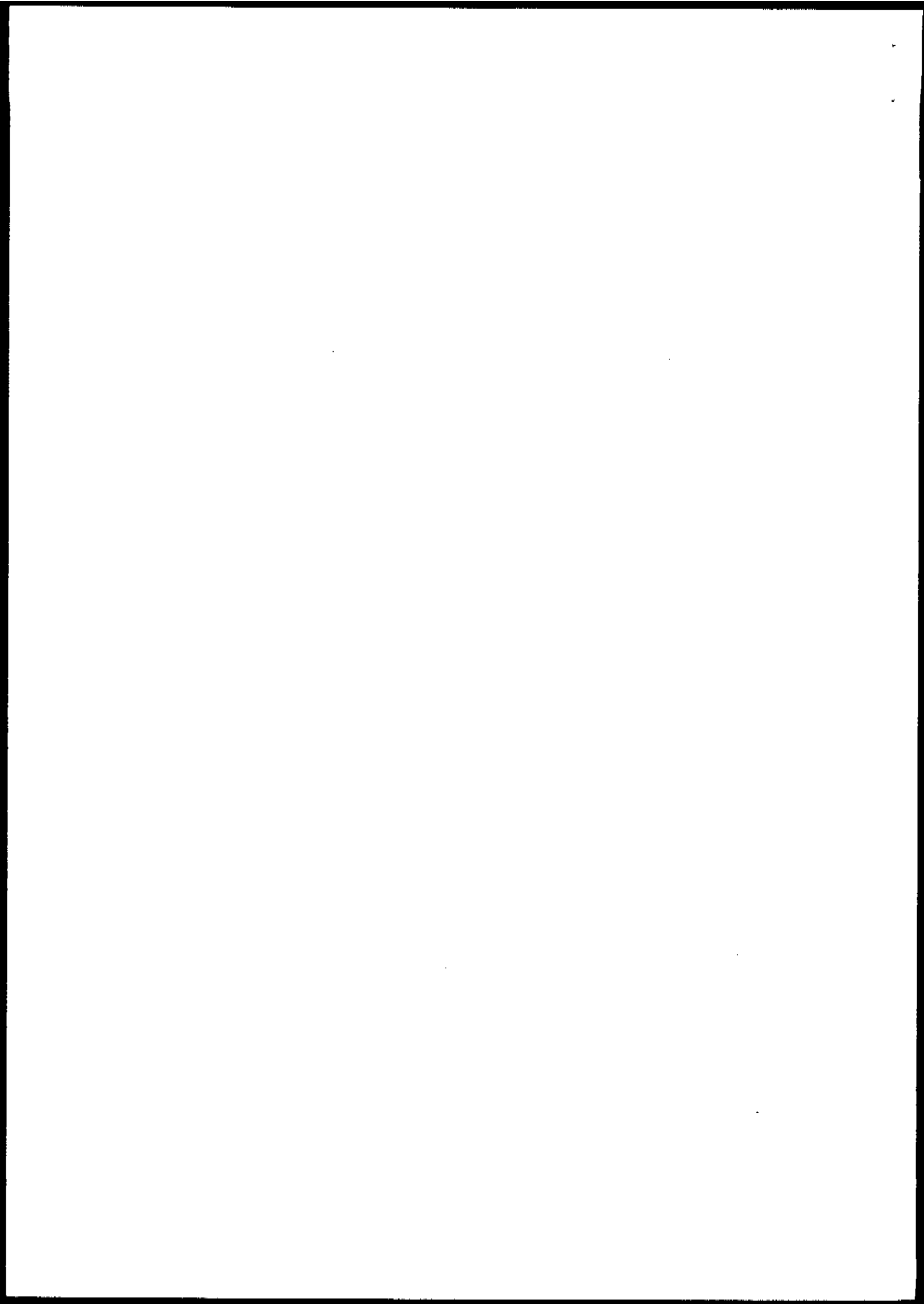
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1. BACKGROUND

Health care reform initiatives are currently underway in most countries, driven in particular by recent unsustainable increases in health care costs. Considerable attention is now being focused on ways of improving health outcomes through initiatives aimed at improving the quality and cost-effectiveness of health care. There is widespread support, particularly from health care purchasers and increasingly from providers, that health care practice guidelines will have a major role to play in reducing inappropriate practice and improving the quality (effectiveness) and efficiency of care.

An epidemic of guidelines is now inundating the health services in many countries. However, only a minority of these guidelines are explicit, evidence-based, and with planned dissemination, implementation and evaluation strategies. Numerous groups and organizations are now involved in guidelines research and development and it is timely for this expertise to be shared and for agreement to be reached on appropriate and effective approaches to guideline development and implementation.

2. PURPOSE OF THE MEETING

The meeting was organized to enable groups and organizations to exchange experience and discuss strategies for the development, implementation and evaluation of health care guidelines. A specific objective of the meeting was to produce an outline of a guideline for guidelines. (See list of participants in Annex 1.)

Professor Hans Konrad Selbmann and Dr Kathleen Lohr were appointed Co-chairpersons of the Meeting. Professor Rodney Jackson agreed to be the Rapporteur while Dr Dorothea Bronner took responsibility for the German version of the report. Dr Herbert Zöllner acted as Secretary.

3. MAIN CONCLUSIONS OF THE MEETING

3.1. Guideline definition

Guidelines are generally defined as "systematically developed statements to assist practitioners and patients make decisions about appropriate health care for specific circumstances."

Guidelines are "tools" to help decision-makers make better decisions and therefore it is essential that both development and implementation strategies are clearly focused on the "end user" decision-makers. This report does not distinguish between the terms protocol, guideline and recommendation; all are essentially tools to inform decision-making.

3.2. Key recent developments

Although the development of health care guidelines is not a new process, there have been a number of recent developments which are having or will have a major impact on the process.

- i. The emphasis on a systematic approach, explicitness, validity (based where possible on external evidence of effectiveness) and clear implementation and evaluation strategies. There remain many areas of health care practice where external evidence of effectiveness is lacking; however, a guideline development process which emphasizes validity can help identify these gaps and be a stimulus for research.

- ii. The increasing acceptance that the production of individual guidelines should be considered as part of national programmes in which agreed guidelines for guidelines are followed. A related issue is the acknowledgement that health care guidelines have major economic consequences and therefore organizations involved in funding health care must be involved in the process.
- iii. The realisation that there are parallel initiatives, expertise and experiences from groups and organizations involved in quality management and assurance, decision analysis, health economics, technology assessments and evidence-based medicine. It is clear that a multi-disciplinary effort coordinated ideally through national programmes would enhance the development of health care guidelines.

3.3. Guidelines for guidelines

The following are the components the participants considered essential to the development and implementation of health care guidelines.

A. *Guideline development*

- There need to be credible organizations which take on overall leadership and responsibility for guideline development.
- Clear goals need to be defined early with explicit discussion about the important values, ethical and legal issues and costs which will influence the development process.
- Topic selection should be considered formally to ensure that priority is given to topics which are most relevant to the target organization's needs. This may involve a formal or informal needs assessment.
- The key stakeholders, including the purchasers, the patients and, in particular, the decision-makers who will use the guidelines, need to be involved in the development process. The main role of these stakeholders is to identify the key decisions that need to be made in a specific health care circumstance, the important outcomes that need to be considered, and the social, ethical, legal and cost constraints within which the guideline must operate.
- A formal guideline development process should be agreed at the outset in which the different components required for the final guideline (e.g. a decision algorithm, evidence table, balance sheet, etc.) and the development team's approach to group decision-making (e.g. nominal group technique) should be determined.
- An explicit, systematic and critical review of the evidence relating to the possible alternative decisions and their respective important outcomes and costs is required. Gaps in the evidence should be identified and explicit acknowledgement made when guidelines must be based on inadequate evidence.
- Guidelines should be pilot tested, reviewed, revised and edited by the end users (i.e. the decision-makers).

B. *Guideline dissemination and implementation*

- The key strategy is to produce multiple appropriate guideline "products" which are clearly targeted at the end users. For example, a particular set of guidelines may produce a detailed manual for the specialist, a booklet for the general practitioner and a pamphlet for the patient.

- Barriers to implementation should be identified.
- Multiple strategies for implementation which take the potential barriers into account should be developed, including: the involvement of opinion leaders; integration with educational activities and quality management and assurance programmes; and the development of financial/professional incentives.
- Continuing monitoring of guideline use and adherence, satisfaction of decision-makers and patients and, where possible, the impact on health-related outcomes, should be planned for prospectively.
- Continuing appraisal and updating of guidelines should be planned for at the onset of implementation.

4. OVERVIEW OF MAJOR TOPICS DISCUSSED IN THE MEETING

Over the two days of the Meeting (programme in Annex 2) the major part of the programme involved a series of presentations on key issues related to the development and implementation of guidelines. In addition, there were a number of brief presentations on recent experiences in different countries, and two working group exercises were held. The first working group exercise illustrated different approaches guidelines have taken to informing decisions, using two guidelines on the management of raised blood pressure as a case study, and in the second workshop groups used a modified nominal group process to develop the "guidelines for guidelines" described in 3.3 above. In the section below the key topics discussed during the meeting are briefly summarized. The content of this section is based on the written papers prepared for the meeting; the original papers are available on request. There is only limited comment on presentations not accompanied by written papers and many of the country-specific details are not reported; however, the major issues from these presentations are mentioned.

4.1. The pathology of decision-making in health care and decision analysis in guideline development and clinical practice

Health care guidelines have been considered to be increasingly necessary and desirable because of the general perception that many health care professionals and systems are not performing as well as they could. Several sources of concern about the quality of professional health care practice have converged over the last 30 years. Major economic, technological, social and demographic developments, accompanied by changing attitudes and expectations of the public, have forced the medical profession to become more openly and explicitly accountable for their decisions; physicians' performance had previously generally gone unquestioned, except for clear cases of negligence. There are two key approaches to the evaluation of health care practice; first, a "criterion-referenced" approach in which the question asked is: are health care professionals doing what they should be doing according to a pre-set standard? Second, there is a "norm-referenced approach" in which the question asked is: are health care professionals doing what other health care professionals are doing? Each approach can be differentiated by whether the evaluation focuses on the decision process or on the knowledge and judgement which goes into it.

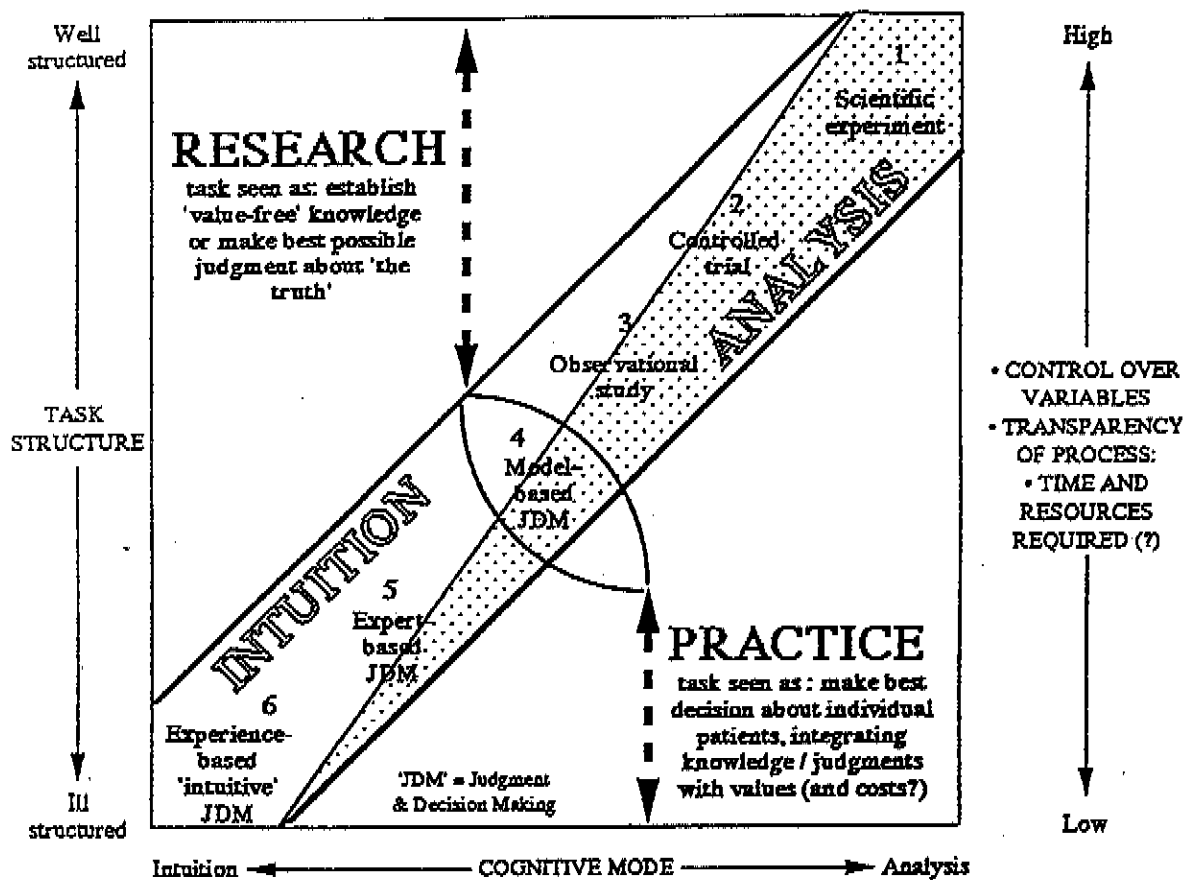
Most of the evaluation of health care practice has focused on variations in practice (i.e. are health care professionals doing what other health care professionals are doing?) and there is general agreement that there are major variations in health care practice that cannot be explained by case mix or the specific context. It has also been established that health care professionals vary greatly in the cues they use to arrive at judgements, in the weights they assign to those cues and in the

principles by which they combine them. The major empirical finding is that they tend to believe they are engaging in a very complicated process and they appear to underrate the inherent uncertainty present in the task they face.

It has been argued that health care practitioners behave differently from each other largely because they do not have access to the best evidence or they are unable to make an effective critique of the evidence. However, an alternative view suggests that the research-practice gap arises because of a failure to address a fundamental conflict in approach between the practitioners and researchers arising from their different modes of thinking. Whereas the researcher takes an analytical approach to thinking, clinicians are more likely to take an intuitive approach; these two approaches are seen as the extremes of a cognitive continuum (Fig. 1) (1, 2).

Figure 1

The Cognitive Continuum, modes of evaluation and the 'research-practice gap' *



NOTE: The analysis and/or intuition contained in any implementation of a given mode may be of varying quality. This quality dimension is not represented in the diagram.

Most practitioners are absorbed in the value-saturated task of making a decision about an individual patient with multiple characteristics. In contrast, the researcher is attempting to exclude all value considerations in order to arrive at objective knowledge. It is suggested that this mismatch of tasks is the key reason for the research-practice gap and that unless clinical guidelines address these issues, the research-practice gap will be replaced by the guidelines-practice gap.

Traditionally health care professionals have lived at the intuitive extreme of the cognitive continuum (mode 6 of Fig. 1) and have drawn on the pure experimental research at the analytical extreme (mode 1 in Fig. 1), albeit unsystematically. Evidence-based medicine practitioners acknowledge the weakness of an approach based on intuition and make use of the range of evidence, but the decision analyst would argue that they still emphasize expertise and judgement (mode 5 in Fig. 1) as the starting point. In contrast, the decision-analysis-based decision-making approach draws explicitly from all modes in the cognitive continuum using a modelling approach; this explicit approach puts more emphasis on modelling than on expertise.

At the centre of both guideline development and clinical decision-making in general, the basic activity going on is the evaluation of alternative courses of action. Following a decision analysis approach, it is argued that the clinician does not need a textual summary of what the guideline developers decide is the appropriate course of action, but instead a clinically relevant adaptation of the model the guideline developers used to come to their recommendations. This clinically relevant model could be run using the characteristics of each individual patient; the model is known as the clinical guidance tree. With the increasing sophistication and complexity of medical practice and comparative evidence of effectiveness and cost-effectiveness, the task of deciding who should be treated, taking into account the probability of effectiveness, costs, and patient preferences, is often beyond the scope of the individual brain. Following the decision analysis approach, a clinical guidance tree, which would ideally be computerized, could be not only the guideline development tool, but also the guideline itself, as well as the implementation and evaluation tool.

4.2. Quality of health care practice guidelines and the quality of health care

Quality in health care has been defined by the Institute of Medicine of the US Academy of Science as: "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This model of quality of care offers four constructs important to the development, implementation and evaluation of practice guidelines. First, by referring to health services as a whole, the implication is that a guideline programme should be intended to improve the quality of care that will cover an equally broad set of health interventions, practitioners, institutions and types of patients. Second, by specifying populations as well as individuals, the definition draws attention to the different perspectives of individuals, various population subgroups and society at large. In setting priorities for guideline development, these broader population issues should be taken into account. Third, the phrase "desired health outcomes" highlights the link between the process and the intended end result (i.e. the link between practice guideline and quality of care). Finally current professional knowledge highlights the role of guidelines in systematically summarizing the evidence relevant to daily practice.

The Institute of Medicine has also proposed comprehensive criteria for judging specific guidelines (3) and guideline programmes (4, 5). These criteria have been widely acknowledged as gold standards in the field and were discussed during the meeting. As they have been described in depth elsewhere, they are not specifically covered in this report.

4.3. The importance of evidence in guideline development

As previously discussed, the purpose of practice guidelines is to help decision-makers make informed decisions. At least three types of information and judgement are needed for practice guidelines to lead to a rational conclusion. First, clinical judgement is needed to identify and diagnose health problems, to learn what health outcomes are important to the patient and to identify what diagnostic, preventive, treatment or rehabilitation options should be considered.

Second, to estimate the effects of different options on health outcomes, judgements must be made about their effectiveness and adverse effects. Information on effectiveness and adverse effects should come from comparative studies, particularly systematic reviews of reliable and valid evidence. Taken together, these first two types of judgement and information provide estimates of the expected outcomes associated with the options considered. It is then necessary to make judgements about trade-offs between benefits, harms and costs.

The core element of systematically developed evidence-based practice guidelines is an explicit and systematic review of the available comparative evidence. There is more likely to be agreement if good evidence is available. Moreover, if the process is explicit there is less likely to be unexplained variation between recommendations in different guidelines on the same topic. Those developing guidelines should consider prospectively what study designs are likely to provide valid, reliable data with which to answer their questions. First, it is important to be cautious about including non-randomized studies in a review of the effects of health care given the potential for bias, which generally leads to an overestimate of the effects. Non-randomized studies are, however, the studies of choice for establishing prognosis (cohort studies) and the accuracy of diagnostic tests (cross-sectional studies). Second, given the difficulties involved in locating all relevant studies and the risk of publication bias, extensive efforts are required to produce complete systematic evidence reviews. Given these problems, guideline developers should consider using existing reviews such as those produced by the Cochrane Collaboration or the US Agency for Health Care Policy and Research (AHCPR). Because medical knowledge and practice environments evolve continuously, guidelines have a shelf life after which they should be reassessed.

4.4. Strategies for dissemination and implementation of clinical guidelines

There is a wide range of strategies available for dissemination and implementation of guidelines, from simply publishing recommendations through educational, marketing, behavioural, social interactional and organizational approaches. However, research is largely lacking on their effectiveness, and strategies which have been demonstrated to be effective in one setting have been shown to be ineffective in others. Some lessons can nevertheless be drawn from reviews of the available evidence (6-8).

First, no strategy is probably superior; different strategies contribute effectively when they fit a particular guideline as well as the features of the target group.

Second, different guidelines may demand different implementation strategies, e.g. feedback and reminders appear to be effective in changing test-ordering behaviour or implementing preventive procedures; outreach visits are effective in changing prescribing behaviour.

Third, more complex and intensive strategies are usually more effective, particularly a combination of interventions linked to specific obstacles to change.

Fourth, different groups of clinicians will experience different obstacles, therefore segmentation of the target group will often be necessary.

In summary, implementing guidelines is not a single action, but a stepwise process in which development of the guidelines, dissemination among the target group, adoption by this group, implementation in actual practice and maintaining the routine all deserve serious attention. A stepwise, cyclical approach is required which involves developing a concrete guideline,

identifying obstacles to implementation, linking interventions to obstacles, carefully planning and implementing the change process, and evaluating progress.

4.5. Evaluation of health care practice guidelines

Despite the proliferation of clinical guidelines, until recently there was uncertainty about their capacity to change clinical behaviour. Grimshaw & Russell have systematically and exhaustively searched for studies of guideline evaluations and published two reviews; an initial review including 59 studies (7) followed by an update with 91 (9). Of the studies, 34 addressed preventive care, 35 clinical care, and 22 prescribing or use of investigations. Two thirds were based in primary or ambulatory care. The review showed that most guidelines had expected positive effects on the process (81/87) and outcome (12/17) of health care. Most of the interventions were shown to have some effect at least some of the time, although the effect sizes varied enabling the reviewers to identify which aspects of guideline programmes were associated with greater effects on clinician performance. A summary of the factors influencing the successful implementation of guidelines is given in Table 1.

Table 1. Factors influencing the successful introduction of guidelines

Relative probability of being effective	Development strategy	Dissemination strategy	Implementation strategy
High	Internal	Specific educational intervention	Patient-specific reminder at time of consultation
Above average	Intermediate	Continuing medical education	Patient-specific feedback
Below average	External local	Posting targeted groups	General feedback
Low	External national	Publication in professional journal	General reminder of guidelines

Although the Grimshaw & Russell review provides evidence of guideline effectiveness and an indication of the more effective strategies, there remain a number of limitations in the current evidence. First, most studies were of short duration and it is unclear whether the effects can be sustained. Second, the impact of guidelines on nurses has not been addressed in many studies. Third, the issues involved in dissemination and implementation of multiple guidelines, as required in non-specialist practice, has not been studied. Fourth, the cost-effectiveness of guideline programmes has received little attention to date. Finally, our relatively poor understanding of the clinical decision-making process, which is the key target of guidelines, hampers further elaboration of guideline implementation.

4.6. Cost-effectiveness of health care guidelines

There is now general agreement that health care practice guidelines should focus on cost-effectiveness rather than effectiveness alone, yet few guidelines explicitly consider cost. In a Medline search of the literature from 1992–1996 using guidelines, costs, cost-analysis, or cost-benefit analysis as key words, only 24 relevant articles were identified. Recently recommendations have been made for the conduct of cost-effectiveness analysis (10–12). It is recommended that analyses should be measured from a societal perspective reflecting the public interest. Second, these costs should reflect the marginal or incremental costs, rather than total costs; in other words

the difference in resource use between usual care and that recommended by guidelines. Third, effects should generally be measured using quality-adjusted life years as a common metric for recording the effects of different metrics.

In addition the costs of developing and implementing guidelines, which are seldom considered, should be taken into account. These costs are particularly relevant when guidelines relate to rare conditions. Similarly the development and implementation costs of local guidelines may be relatively large in comparison with the costs of care of the number of patients involved.

4.7. Ethical and legal aspects of health care guidelines

There are ethical and legal implications of many aspects of health care guidelines, including the distribution of health care resources, negligence, malpractice without negligence, and physician and patient autonomy. Probably the most important aspect relates to the distribution of health care resources, which has been one of the major motivations for guideline development. Explicitly or implicitly guidelines have both health care improvement and economic goals. Guidelines will always have foreseeable economic consequences, therefore the economic goals should be explicitly defined. There are at least four major potential economic goals of guidelines: first, to reduce unnecessary and harmful care; second, to encourage optimal care for acceptable costs; third, to encourage acceptable care for optimal costs, and fourth to encourage care in "the corridor" between the second and third goals above.

The appropriate economic goal should be determined before decisions are made as to whether guidelines should have policy or reimbursement implications, on the definitions of appropriate care, or on who should be expected to use the guidelines. When economic goals are inconsistent, unrealistic, or unstated, the credibility and likelihood of implementation of guidelines is jeopardized.

There are two major theoretical ethical approaches to choosing between economic goals: first, the social contract theory approach, which tends to favour the goal of optimal care for acceptable costs; and second, utilitarianism, which favours the goal of acceptable care at optimal costs. There are no straightforward solutions regarding the choice of economic goals but there are a number of pragmatic solutions including: transparency of economic criteria; internal consistency (i.e. within a guideline or guideline programme); external consistency (e.g. the political and economic framework); validity (e.g. cost-utility analysis in usual practice situations); flexibility (e.g. taking patient values into account); and standardization of cost-utility and cost-effective analyses. Finally public debate about the ethical and legal aspects of guidelines and public participation in the guideline process must be encouraged.

4.8. Guidelines and quality management

Quality management comprises "all activities that determine the quality policy, objectives and responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement" (ISO norm). The problem-oriented quality improvement cycle, or PDCA cycle (plan, do, check, act) has been developed to improve clients' satisfaction with the effectiveness and efficiency of health care. The PDCA cycle involves a series of steps including: problem recognition; analysing the underlying process; searching for and implementing solutions; evaluation; and (where successful) integrating preventive quality assuring measures in the process. Guidelines are specifically required in the problem recognition, problem-solving and quality assurance steps of the cycle; indeed it can be argued that quality management cannot exist without practice guidelines of the care process. A promising approach,

which has been used nationally and across countries, is to embed guideline development in a process of quality development, including: (i) a protocol of key indicators that reflect best knowledge and evidence about the critical factors for success (from literature and consensus meetings); (ii) a participatory, voluntary and confidential system of hands-on experience with daily data collection, analysis and feedback that takes account of local conditions; (iii) a system of analysis of outcome and feedback to clinicians asking the best achievers to come forward and share their methods and knowledge; and (iv) constant reinterpretation of best available evidence against benchmarks, leading to continuous learning and quality development (13).

4.9. Guideline developments in Europe

A number of countries in Europe have launched programmes for the systematic development and implementation of guidelines, although few are nationally coordinated. Finland, France, the Netherlands, Scotland and Sweden, for example, have some form of nationally coordinated programme. Many other countries have a range of local or national guideline activities run by professional medical, local and regional authorities or health research organizations. There are two main approaches to guideline development being followed in the nationally coordinated programmes; the top-down and bottom-up approaches.

In France, for example, the centrally coordinated National Agency for the Development of Medical Evaluation (ANDEM) has produced an extensive series of national guidelines using a range of methods such as expert consensus conferences, systematic evidence-based development processes based on the US Agency for Health Care Policy and Research (AHCPR) methodology (taking up to two years per guideline), and less intensive medical references (taking up to six months per guideline). Regional dissemination along with local and national audits supported by legal and professional regulation have resulted in widespread awareness of the guidelines.

The Swedish Council for the Evaluation of Medical Technology (SBU) uses expert groups to produce reviews based on systematic literature reviews. Since 1988 they have produced over 20 systematic reviews on the use and effectiveness of medical technology. Many of the reports are extensive, but some have been distributed as guidelines and the evaluation of one guideline on preoperative routines indicates it has had a major impact on practice.

In the Netherlands, a nationally coordinated programme for setting clinical guidelines in general practice has followed a more bottom-up approach. A series of over 60 guidelines have been developed over seven years by general practitioners, rather than specialists, through the Dutch College of General Practice. The systematic evidence-based process followed is similarly rigorous to the French and Swedish programmes, with each guideline taking up to one and a half years and US \$75 000 to develop. Core groups of five to eight experienced general practitioners develop the guidelines following set criteria; these are then reviewed by specialists and a randomly selected group of general practitioners. Dissemination has been mainly through a professional general practice journal. Extensive evaluation has been carried out on a number of the earlier guidelines which have in general been well received. The guidelines have been presented as a support for daily work and not a tool for controlling doctors. They are not seen by Dutch doctors as suitable for licensing or budgeting purposes, although evaluation suggests they have nevertheless been cost-effective.

Guideline development in many other European countries involves a mix of activities without systematic and explicit nationally agreed criteria such as those used in the French and Dutch initiatives.

There is a considerable level of guideline activity in countries such as the United Kingdom. Many initiatives in the United Kingdom have been supported through funding from the National Health Service (NHS) Research and Development (R&D) Programme which now receives almost 1.5% of the total NHS budget. There are a number Royal College guideline programmes and a pilot English guidelines appraisal programme using explicit quality development criteria, while the NHS has a Centre for Reviews and Dissemination which undertakes two to four systematic reviews per year and distributes the results as research reports and compact guideline pamphlets aimed at decision-makers.

The United Kingdom component of the Cochrane Collaboration and a number of evidence-based practice units have also been funded through the NHS R&D programme and are either directly or indirectly (through, for example, the production of evidence reviews and critical appraisal training programmes) involved in guideline development.

There is also considerable guideline activity in Germany, with clear distinctions being made between mandatory guidelines and recommendations. There is no nationally coordinated approach although there have been national developments. The Association of Scientific Medical Societies (AWMF) have, for example, coordinated a library of over 170 Internet-based guidelines. A bottom-up initiative from the national Surgical Society has been based on developing clinical algorithms from experiences with individual patients. Quality assurance schemes in Germany have also been instrumental in the development of guidelines, which are clearly necessary for evaluation programmes.

In Spain, guideline developments have focused more on preventive and public health activities. For example, the Spanish Society of Family and Community Medicine has drawn up, disseminated and supported the adoption of evidence-based recommendations for prevention.

In eastern Europe, recent major political and economic changes have made guideline development difficult. Historically many central directives came through guidelines. While in some countries (such as the Russian Federation) it may be possible to build new guideline programmes based on previous structures, in other countries (such as the Czech Republic) guidelines are associated with the old political regimes and are now considered unacceptable. However, the development of health insurance programmes, decentralization of services, increased physician autonomy, increased international contact and availability of new technology, have led to major increases in cost and greater variation in care. As a result, there has been renewed interest in quality and cost control mechanisms such as guidelines.

4.10. Guideline developments outside Europe

The discussion included two presentations from the United States and one from New Zealand, and was not intended to provide a comprehensive review of international developments.

4.10.1 Major US initiatives

Many of the major recent initiatives in guideline development have come out of the United States. One of the main factors responsible for the level of activity has been the extraordinary growth in US health care costs. As a result of unsustainable growth in costs, the health care system, in which patients traditionally chose doctors freely and in which payments were based on services rendered, has changed dramatically in recent years. It is now a predominantly managed care model in which patient choice is limited to a specific panel of doctors, services are closely scrutinised, and payments tightly controlled. The growth of managed care as a means of

controlling costs has lead to strong incentives for assessing and controlling clinical practice to help keep costs down while attempting to maintain high quality. Practice guidelines are now playing an increasing role in this process.

Federal legislation in 1989 created the Agency for Health Care Policy and Research (AHCPR), which has been the major Federal agency explicitly created to sponsor guidelines. Based on recommendations from the Institute of Medicine on the desirable attributes of clinical practice guidelines, that stressed credibility and accountability, the AHCPR initiated a guideline development programme that was explicitly evidence-based, where possible, and used professional judgement in the absence of evidence. Between 1989 and 1996, 19 guidelines were produced by the AHCPR. The programme also had detailed and extensive strategies for encouraging guideline implementation, monitoring and evaluation.

Numerous other agencies and organizations within the US have guideline programmes, including federal agencies such as the National Institute of Health (Consensus Development Programme), professional organizations such as the American College of Physicians, and many of the health care insurers. Given the development of thousands of new guidelines, increasing acceptance of evidence-based methods and limited resources, the AHCPR has initiated a new programme which will replace the current guideline development programme.

The new evidence-based practice programme will be based on three initiatives. First, the development of up to eight evidence-based practice centres, which will be responsible for producing systematic evidence reports on important topics. The evidence reports will include evidence summaries and tables, costs and research issues, extensive bibliographies, and (when needed) meta-analyses, decision analyses and cost-effectiveness analyses.

The second initiative will involve the establishment of a national guideline clearing house, which will be supported by a public-private partnership, be an inclusive, truly national, on-line clearing house, and will be available to clinicians, societies, plans and States. Users will be able to access information quickly, which will include guideline summaries, full text when available, and have annotated comparisons of processes and recommendations on different guidelines covering the same issue.

The third initiative will involve product research and evaluation relating to development methods, implementation strategies and quality improvement measures and programmes. The advantages of the new programme will include opportunities to improve the science base of guidelines nationally, to expand national capacity, decrease duplication, increase uniformity and enhance public-private partnerships.

The other major national guideline-related initiative in the US has been the NIH Consensus Development Program (CDP). Although not initially intended to produce guidelines for medical practice, the consensus statements emerging from these conferences have often been thought of as guidelines. The aim of this 20-year-old programme was to be a vehicle for synthesizing and assessing new medical data on topics of public health significance, from research applicable to practice, but where controversy and uncertainty still remain. Since 1976 there have been 102 consensus conferences and 15 technology assessments using a similar process. The process is based on the scientific court approach which holds that it is still necessary for reasoned and unbiased health scientists and professionals to arrive at some conclusions and recommendations in the interest of public health, even when medical science certainty does not exist.

The statements produced are immediately available to conference attendees and the press. The final documents are put on the NIH Office of Medical Applications of Research (OMAR) home page on the World Wide Web; within six months of the conference they are published in pamphlet form and 50 000–10 0000 are distributed. The statements are usually also published in the Journal of the American Medical Association. OMAR has had a programme in place to monitor the impact of NIH Consensus conferences for many years, using surveys of various data bases and of physicians' knowledge and behaviour before and after several conferences.

OMAR also has a programme in place to review statements that are five or more years old. Statements are reviewed by the major NIH sponsoring institution and they either remain current in the original form, remain current with modification in the form of supplementary material, are discontinued and a new consensus conference planned, or are discontinued without a new conference being planned. Of 60 conferences held between 1977–1987, 8 statements have been continued, 11 supplemented, 41 discontinued and 7 conferences repeated. There were 43 conferences held between 1988–1997; 34 statements have been continued, 4 supplemented, 5 discontinued and 1 conference repeated.

The programme remains an important NIH activity with six conferences planned for 1997.

4.10.2 Recent New Zealand initiatives

In 1992, the New Zealand Ministry of Health convened the National Advisory Committee on Core Health and Disability Support Services (later renamed the National Health Committee – NHC) to advise the government on the core health services which should be publicly funded. The NHC quickly concluded that it was inappropriate to attempt to define a simple list of services that should be funded (as in the Oregon experiment). They argued that defining access criteria for publicly funded services required a more sophisticated approach involving a description of the circumstances in which effective services will offer the greatest benefit to an individual while being mindful of competing claims on resources.

The NHC therefore advocated the use of practice guidelines as a means of describing the circumstances in which services should be publicly funded. In 1992 the first phase of the guideline programme was initiated with the funding of ten pilot guideline development projects, ranging from the management of raised blood pressure through to well baby care. Over 25 projects funded through this initiative are either completed or under way.

In 1996, a second overlapping phase of the guideline programme was introduced both to speed up the development process and improve their acceptance. Rather than continuing to take the lead in developing each project, the NHC has decided also to build up a critical mass of expertise in guideline development among the health care professionals. By moving the responsibility for the development process towards the end users, the Committee believes guidelines are more likely to be considered relevant to the targeted decision-makers and are more likely to be received favourably. Also as the number of practitioners involved in the development process increases, more guidelines can be produced.

In phase one of the guideline programme the key method of development was through consensus conferences. No explicit uniform process was recommended, although a number of general principles were followed, including an emphasis on usual rather than exceptional practice, the need for transparency, and a consumer focus. As a result the final guidelines produced varied greatly in quality and form.

The emphasis in the second phase of the programme has been on the need for guidelines to be explicitly evidence-based and mindful of resources, and for the development process to be more structured. To this end the NHC has established a three-year government-funded programme to run intensive training courses in guideline development for health care professionals. In 1996 the first course was run and involved approximately 20 medical practitioners from a range of specialities. A one-week introductory course was held in New Zealand, followed a month later by a two-week practical development course in Seattle, USA. The attendees were tutored by the Guideline Development team at Group Health, a health maintenance organization that has been using evidence-based practice guidelines for over five years. On returning to New Zealand the attendees are expected to bring together guideline development teams to work on projects initiated in Seattle. Two further cohorts of health care practitioners (including non medical health care professionals) will attend similar courses in 1997 and 1998.

The recent New Zealand experience with developing a critical mass of formal guideline development expertise among health care professionals represents a primarily bottom-up approach by training end users of guidelines to develop their own explicit evidence-based guidelines which meet nationally determined criteria.

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PARTICIPANTS

Dr Enno Aufderheide
Projektträger der DLR
Südstr. 125
53175 Bonn
Germany

Tel: 0049 228 3821 140
Fax: 0049 228 3821 257
E mail: Enno.Aufderheide@dlr.de

Dr Christian Behles
Deutsches Institut für Medizinische
Dokumentation und Information - DIMDI
P.O. Box 42 05 80
50939 Cologne
Germany

Tel: 0049 221 4724 304
Fax: 0049 221 411 429
E mail: behles@dimdi.de

Ms Iris Blomberg
National Board of Health and Welfare
Public Health
Socialstyrelsen
10630 Stockholm
Sweden

Tel: 0046 8 783 3166
Fax: 0046 8 783 3346
E mail: iris.blomberg@sos.se

Dr Dorothea Bronner
Projektträger der DLR
Südstr. 125
53175 Bonn
Germany

Tel: 0049 228 3821 149
Fax: 0049 228 3821 257
E mail: Dorothea.Bronner@dlr.de

Professor Anton Frans Casparie
Institute for Health, Policy and Management
Erasmus University of Rotterdam
Post Box 1738
3000 DR Rotterdam
The Netherlands

Tel: 0031 10 408 8256
Fax: 0031 10 452 6086
E mail: knoester@facb.bm6.eur.nl

Professor Jack Dowie
Faculty of Social Science
The Open University
Walton Hall
Milton Keynes MK7 6AA
United Kingdom

Tel: 0044 1908 274 066
Fax: 044 171 254 7576
E mail: j.a.dowie@open.ac.uk

Professor Gene Feder
Department of General Practice and Primary Care
St. Bartholomew's and the Royal London School
of Medicine & Dentistry
New Science Block
Charterhouse Square
London EC1M 6BQ
United Kingdom

Tel: 0044171 982 6032/6012
Fax: 0044 171 982 6103
E mail: g.s.feder@mds.qmw.ac.uk

Dr John H. Ferguson
Office of Diseases Prevention, OMAR
National Institute of Health
Federal Building, Room 618
7550 Wisconsin Avenue, MSC 9120
Bethesda, Maryland 20892-9120
United States of America

Tel: 001 301 496 5641
Fax: 001 301 402 0420
E mail: jferg@helix.nih.gov

Dr Béatrice Fervers
Fédération Nationale Des Centres de Lutte Contre
le Cancer (FNCLCC)
Centre Léon Bérard
28, rue Laennec
69003 Lyons
France

Tel: 0033 4 78 78 2801
Fax: 0033 4 78 78 2804/2712
E mail: fervers@lyon.fnclcc.fr

Professor Wolfgang Gaebel
Psychiatrische Klinik der Heinrich-Heine
Universität
Bergische Landstr. 2
40629 Düsseldorf
Germany

Tel: 0049 211 922 2000
Fax: 0049 211 922 2020
E mail:

Dr Max Geraedts
Institut für Medizinische
Informationsverarbeitung
Universität Tübingen
Westbahnhofstr. 55
72070 Tübingen
Germany

Tel: 0049 7071 298 5901
Fax: 0049 7071 49527
E mail: geraedts@uni-tuebingen.de

Dr Marcella Giesen
Projektträger der DLR
Südstr. 125
53175 Bonn
Germany

Tel: 0049 228 3821 227
Fax: 0049 228 3821 257
E mail:

Professor Richard Grol
Centre for Quality of Care Research (WOK)
Post Box 9101
6500 HB Nijmegen
Netherlands

Tel: 0031 243 615302
Fax: 0031 243 540166
E mail: rgrol@hsv.kun.nl

Dr Heidemarie Haeske-Seeberg
Deutsches Krankenhausinstitut e.v.
Projektgeschäftsstelle für Fallpauschalen und
Sonderentgelte
Teerstegenstr. 3
40474 Düsseldorf
Germany

Tel: 0049 211 47051 26
Fax: 0049 211 47051 30
E mail:

Professor Rodney Jackson (*Rapporteur*)
Department of Community Health
School of Medicine
University of Auckland, Auckland
New Zealand

Tel: 0064 9 373 7599
Fax: 0064 9 373 7503
E mail: rt.jackson@auckland.ac.nz

Dr Kamil Kalina
Ministry of Health of Czech Republic
Palackého náměstí 4
12000 Prague 2
Czech Republic

Tel: 042 2 2497 2520/ 809 790
Fax: 0042 2 290091/ 801 222
E mail:

Dr Douglas B. Kamerow
U.S. Department of Health and Human Services
Agency for Health Care Policy and Research
Office of the Forum for Quality and Effectiveness
in Health Care
Willco Bldg., Suite 310
6000 Executive Blvd.
Rockville, MD 20852
United States of America

Tel: 001 301 594 4015
Fax: 001 301 594 4027
E mail: dkamerow@po6.ahcpr.gov

Professor F.W. Kolkman
Landesärztekammer
Baden-Württemberg
Jahnstrasse 40
70597 Stuttgart
Germany

Tel: 0049 711 769 890
Fax: 0049 711 769 8950
E mail:

Dr Anna V. Korotkova
Research Public Health Institute
"MedSocEconoInform"
Ministry of Health
ul. Dobrolubov, 11
127254 Moscow
Russian Federation

Tel: 007 095 979 92 73
Fax: 007 095 219 3840
E mail: 104633.1501@compuserve.
com

Professor Karl W. Lauterbach
Universität Köln
Institut f. Gesundheitsökonomie, Medizin u.
Gesellschaft
Gleueler Straße 176
50931 Köln
Germany

Tel: 0049 221 4302304
Fax: 0049 221 4302304
E mail:

Dr W. Lemmnitz
Universität Bremen
FB6 Rechtswissenschaft
Bremen
Germany

Tel:
Fax:
E mail:

Dr Kathleen N. Lohr (*Co-Chairperson*)
Health and Social Policy Division
Research Triangle Institute
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park,
North Carolina 27709 2194
United States of America

Tel: 001 919 541 6512
Fax: 001 919 541 5945
E mail: klohr@rti.org

Mr William Lohr
Cecil G. Sheps Center for Health Services
Research
University of North Carolina
725 Airport Road,
Chapel Hill, North Carolina, 27599-7590
United States of America

Tel: 001 919 966 6956
Fax: 001 919 966 5764
E mail: bill_lohr@unc.edu

Professor Wilfried Lorenz
Klinikum der Phillips-Universität
Zentrum f. Operative Medizin I
Theoretische Chirurgie
Baldingerstraße
35033 Marburg
Germany

Tel: 0049 6421 28 2220
Fax: 0049 6421 28 8926
E mail:

Dr Paul Lubecki
AOK Bundesverband
Kortrijker Strasse 1
53177 Bonn
Germany

Tel: 0049 228 843 378
Fax: 0049 228 331 315
E mail:

Mr Eberhard Luithlen
Bundesministerium für Gesundheit
Referat 217
Am Propsthof 78 a
53121 Bonn
Germany

Tel: 0049 228 941 2170
Fax: 0049 228 941 4925
E mail:

Professor Marjukka Mäkela
National Research and Development
Centre for Welfare and Health
Services and Quality Unit
P.O. Box 220
00531 Helsinki
Finland

Tel: 00358 9 3967 2290
Fax: 00358 9 3967 2227
E mail: marjukka@stakes.fi

Dr Hervé Maisonneuve
Agence Nationale pour le Développement de
l'Évaluation Médicale
159 rue Nationale
75640 Paris Cedex 13
France

Tel: 0033 1 42 167325
Fax: 0033 1 45 84 06 51
E mail:

Mr Cord Meyer
Bundesministerium für Gesundheit
Referat 217
Am Propsthof 78 a
53121 Bonn
Germany

Tel: 0049 228 941 2171
Fax: 0049 228 941 4925
E mail:

Professor Günter Ollenschlaeger
Ärztliche Zentralstelle für Qualitätssicherung
Aachenerstr. 233-237
50931 Köln
Germany

Tel: 0049 221 4004 0
Fax: 0049 221 4004 590
E mail:

Professor Myriam Ovalle
General Council of Nursing
School of Health Sciences
University Complutense
Fuente Del Rey, No. 2
28023 Aravaca - Madrid
Spain

Tel: 0034 1 334 5520
Fax: 0034 1 334 5503
E mail:

Ms H. Claudia Pagliari
University of Aberdeen
Health Services Research Unit
Department of Public Health
Drew Kay Wing Polwarth Building
Foresterhill
Aberdeen AB25 2ZD
Scotland

Tel: 0044 1224 681 818
Fax: 0044 1224 663 087
E mail: h.c.pagliari@abdn.ac.uk

Dr Matthias Perleth
Hannover Medical School
Department of Epidemiology and Social Medicine
OE 5410
30623 Hannover
Germany

Tel: 0049 511 532 4451
Fax: 0049 511 532 5347
E mail: perleth@epi.mh-hannover.de

Professor Hans J. Reinauer
Arbeitsgemeinschaft der Wissenschaftlichen
Medizinischen Fachgesellschaften (AWMF)
Diabetes Forschungsinstitut
Aufm Hennekamp 65
40225 Düsseldorf
Germany

Tel: 0049 211 3382240
Fax: 0049 211 334006
E mail: awmf@uni-duesseldorf.de

Dr Sabine Richard
Bundesverband der Betriebskrankenkassen
Kronprinzenstr. 6
45128 Essen
Germany

Tel: 0049 201 179 1217
Fax: 0049 201 179 1016
E mail:

Dr Christoph Röger
Kassenärztliche Bundesvereinigung
Herbert Lewin Str. 3
50931 Köln
Germany

Tel: 049 221 4005 290
Fax: 0049 221 4005 151
E mail:

Professor Doris Schiemann
Fachhochschule Osnabrück
Fachbereich Wirtschaft
Albrechtstr. 30
49076 Osnabrück
Germany

Tel: 0049 541 969 2013/3000
Fax: 0049 541 969 2989
E mail:

Dr Rotraud Scholz
Deutsche Krankenhausgesellschaft
Teerstegenstr. 9
40474 Düsseldorf
Germany

Tel: 0049 211 45473 0
Fax: 0049 211 45461
E mail:

Professor H. Konrad Selbmann (*Co-Chairperson*)
Institut für Medizinische
Informationsverarbeitung (IMI)
Universität Tübingen
Westbahnhofstr. 55
72070 Tübingen
Germany

Tel: 0049 7071 29 85217
Fax: 0049 7071 49527
E mail:

Ms Barbara von Stackelberg
Deutsches Grünes Kreuz
Im Kilian
Schuhmarkt 4
35037 Marburg
Germany

Tel: 0049 6421 293 128
Fax: 0049 6421 2 29 10
E mail:

Dr Franz F. Stobrawa
Bundesärztekammer
Herbert Lewin Str. 1
50931 Köln
Germany

Tel: 0049 221 4004 0256
Fax: 0049 221 4004 378
E mail:

Dr Christoph Straub
Verband der Angestellten-Krankenkassen e.v.
Frankfurter Str. 84
53721 Siegburg
Germany

Tel: 0049 2241 108 322
Fax: 0049 2241 108 248
E mail:

World Health Organization
Regional Office for Europe

Ms Connie Petersen
World Health Organization
Regional Office for Europe
Scherfigsvej 8
2100 Copenhagen
Denmark

Tel: 0045 3917 1539
Fax: 0045 3917 1870
E mail: cop@who.dk

Dr Herbert Zöllner (*Secretary*)
World Health Organization
Regional Office for Europe
Scherfigsvej 8
2100 Copenhagen
Denmark

Tel: 0045 3917 1347
Fax: 0045 3917 1870
E mail: hzt@who.dk

PROVISIONAL PROGRAMME

SUNDAY, 26 JANUARY 1997

- 18:00 - 20:00 Registration of participants
20:00 - 21:30 Welcome (with reception hosted by DLR German Research Institute for Air and Space Travel)

MONDAY, 27 JANUARY 1997

1. RELEVANCE OF GUIDELINES IN HEALTH CARE

- 09:00 - 09:15 Opening statements (Ministry of Health of Germany; WHO secretariat)
- 09:15 - 09:30 Introduction and terms of reference (Herbert Zöllner, WHO)
Adoption of meeting agenda and programme (Chairperson)
- 09:30 - 10:00 Pathology of decision-making in health care practice (introduced by Jack Dowie)
- 10:00 - 11:00 Guidelines as tools for decision-making in health care (working groups)
- 11:30 - 12:00 Continued (group reports and discussion)
- 12:00 - 12:30 Quality of health care practice guidelines and quality of health care (introduced by Kathleen Lohr)

2. LIFE CYCLE OF GUIDELINES

- 13:30 - 14:00 The importance of evidence in guidelines development (introduced by Marjukka Mäkela)
- 14:00 - 14:30 Strategies for the implementation and dissemination of guidelines (introduced by Richard Grol)
- 14:30 - 15:00 Monitoring and updating of health care guidelines in routine practice (introduced by Hervé Maisonneuve)
- 15:00 - 15:30 Evaluation of health care practice guidelines (introduced by Gene Feder)

3. GUIDELINES IN INTERNATIONAL COMPARISON

- 16:00 - 16:30 Strategies of health care guidelines development in Europe (introduced by Marjukka Mäkela)
- 16:30 - 17:30 Guideline practice in European countries (brief presentations from The Czech Republic, Germany, Finland, France, Spain, The Netherlands, Norway, The Russian Federation and United Kingdom (introduced by Kalim Kalina, Hans Reinauer, Marjukka Mäkela, Hervé Maisonneuve, Myriam Ovalle, Richard Grol, Andy Oxman, Anna Korotkova and Gene Feder))

TUESDAY, 28 JANUARY 1996

4. ROLE OF GUIDELINES IN HEALTH CARE SYSTEMS

- 08:30 - 09:00 Cost effectiveness of health care guidelines (introduced by Anton Casparie)
- 09:00 - 09:30 Ethical and legal aspects of health care guidelines (introduced by Karl Lauterbach)
- 09:30 - 10:00 Decision analysis as basis for clinical guidelines and practice (introduced by Jack Dowie)
- 10:30 - 11:00 Guidelines outside Europe (introductions on tools and experiences in Canada, the United States of America and New Zealand (John Ferguson, Douglas Kamerov and Rodney Jackson)

5. GUIDING THE DEVELOPMENT AND USE OF GUIDELINES

- 11:30 - 12:30 Development of a guideline for guidelines development (working groups)
- 13:30 - 13:45 Continued (group reports)
- 13:45 - 14:15 Development of a strategy for updating guidelines and health care practice (introduced by Kathleen Lohr)
- 14:15 - 14:45 Guidelines and quality management (introduced by Hans Konrad Selbmann)
- 14:45 - 15:00 Steps to finalize and communicate the products of the meeting (Rapporteur and Chairperson)