

DEVELOPING A METHODOLOGY FOR DRAWING UP GUIDELINES ON BEST MEDICAL PRACTICES

Recommendation Rec(2001)13
adopted by the Committee of Ministers
of the Council of Europe
on 10 October 2001
and explanatory memorandum

French edition :

Le développement d'une méthodologie dans l'élaboration de lignes directrices pour de meilleures pratiques médicales (Recommandation(2001)13 et exposé des motifs)

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2. This publication contains the text of Recommendation Rec(2000)13 and its explanatory memorandum.

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Preface

In 1999, the European Health Committee (CDSP) set up a Committee of Experts on Developing a Methodology for drawing up Guidelines on Best Medical Practices. The committee was asked to develop a framework for drawing up clinical practice guidelines in member states, with a view to determining their objectives, the responsibilities for drawing them up, the role of various parties concerned (professional bodies, governmental organs, insurance companies, patients), the manner in which they are drawn up (methodology), the methods for their implementation and evaluation of their effectiveness. The committee attempted to harmonise the national and international methodology of translating the best available evidence into the best medical practice.

Quality of medical practice and good professional conduct is in the interest of the individual patient, who is today an active and well-informed participant in the health care process. It also increases efficiency and this contributes to cost containment in health care.

All member states are presently involved in assessment and accountability in health care, including quality evaluation of medical practices and interventions. Such quality evaluation is possible if guidelines on best practice are available.

Clinical practice guidelines are tools for making decisions in health care more rational, for improvement in quality of health care delivery and for strengthening the position of the patient. The success and failure of clinical practice guidelines depend on their medical value, on social, legal and ethical aspects involved as well as on their implementation in daily practice. Important points for attention when developing a policy on such guidelines from a managerial perspective include the possibilities of "systematic bias" in drawing up guidelines, the conditions for their implementation (for instance non-coercive rather than coercive incentives

for their adherence), their application from the perspective of the patient, respect of clinical judgement and clinical autonomy.

The ensuing recommendation proposes a coherent and comprehensive national policy framework for the production, appraisal, updating and active dissemination of evidence-based clinical practice guidelines. The main aim is to support and promote good clinical practice in the best interest of the patient and to improve the quality and effectiveness of health care.

* * *

The committee of experts met four times, on 11 and 12 March 1999, 16 and 17 September 1999 and 2 and 3 March 2000 in Strasbourg, and 24 and 25 August 2000 in Zurich. At their final meeting the committee invited representatives from ECRI (an American research organisation), EORTC, (European Organisation for Research and Treatment of Cancer), the American Agency for Healthcare Research and Quality (AHRQ) and the American National Guideline Clearinghouse to participate in the meeting and present their respective organisation's experience related to guideline programmes. It was composed as follows:

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Recommendation Rec(2001)13

of the Committee of Ministers to member states on developing a methodology for drawing up guidelines on best medical practices

*(Adopted by the Committee of Ministers on 10 October 2001
at the 768th meeting of the Ministers' Deputies)*

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common action in the public health field;

Bearing in mind the provisions of the Convention for the Protection of Human Rights and Fundamental Freedoms and of the European Social Charter;

Recalling that Article 3 of the Convention on Human Rights and Biomedicine requires that contracting parties provide equitable access to health care of appropriate quality, Article 4 requests that any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards and Article 10 emphasises the right of everyone to know any information about his or her health;

Recalling the recommendations of the Committee of Ministers to member states, No. R (97) 5 on the protection of medical data, No. R (97) 17 on the development and implementation of quality improvement systems in health care, No. R (99) 21 on the criteria for the management of waiting lists and waiting times in health care, as well as No. R (2000) 5

on the development of structures for citizen and patient participation in the decision-making process affecting health care ;

Recognising that health policies and health care systems should be based on best available evidence ;

Recognising that medical evidence incorporated in guidelines may support national decisions on prioritisation of health needs based on ethical, social, and financial issues, structural differences of health care systems and variations in epidemiology and health data, but should not be used for purely cost containment or rationing purposes ;

Recognising the right of patients and citizens to be provided with and to have easy access to relevant information about their health and health care in a format and language they can understand ;

Considering that the same principles of best medical practices apply equally to primary, secondary and tertiary care and to all health professions as well as to health promotion, prevention, diagnosis, treatment, rehabilitation, and other aspects of health care ;

Recognising that, in different nations, guidelines on best medical practices are developed in variable ways in a complex environment of health care systems and of ethical, economic, social, legal and other factors ;

Considering that the methodology for the development and implementation of guidelines crosses national boundaries and that the evaluative interpretation of evidence requires substantial resources and expertise and should be shared ;

Recognising the necessity of promoting harmonisation of national and international regulations related to quality research and applied clinical research ;

Recognising that guidelines are but one of the tools to improve the quality and appropriateness of health services and therefore should not serve as a substitute for sound clinical judgement nor replace professional responsibility of providers nor patients' preferences ;

Considering that the main aim of the guidelines is to support and promote good clinical practice in the best interest of patients and therefore should be used as a policy instrument, whose legal interpretation and status depends on circumstances pertaining to each country,

Recommends that the governments of member states:

i. develop a coherent and comprehensive national policy framework that:

- ensures that the national methods for the production and appraisal of guidelines on best medical practices comply with internationally accepted, current state of the art practices;

- ensures that policy makers, health care professionals, citizens and patients appreciate the advantages of using the best available evidence to provide information to support medical decisions;

- supports the production, use and timely updating of nationally and locally relevant, evidence-based guidelines for clinical practice and medical treatment policies, targeting important issues in health care;

- ensures that guidelines are produced and implemented in consideration of the legal aspects inherent to the guidelines;

- ensures that guidelines are implemented in an appropriate manner, and that their effects on the clinical process and its results, as well as on the legal consequences with regard to the patient and those who provide medical care, are monitored;

- facilitates the availability and use of guidelines, as well as the availability of information on their aim, legal status, legal implications, health care literature and databases to citizens, patients and professionals in language they can understand and formats they can use easily;

ii. promote international networking between organisations, research institutions, clearing houses and other agencies that are producing evidence-based medical information;

iii. support an active, targeted dissemination of these recommendations and the explanatory memorandum, paying special attention to individuals and organisations involved in decisions within health care.

Appendix to Recommendation Rec(2001)13

I. Guidelines in support of health care

The main aim of clinical practice guidelines is to support and promote good clinical practice.

Guidelines are produced and used in the complex environment of a health care system with its ethical, economic, legal and other aspects; these aspects need to be taken into consideration in each country.

II. Topic selection

Guideline topics should be selected for development to support and assist decision-making on important issues in health care.

Prioritisation of guideline topics may be based on the epidemiology of health problems, health inequalities, variations in the provision and quality of care, emergence of new technologies, or other factors that create a need for high quality, updated information.

The existence of presently available evidence-based guidelines should be considered in the prioritisation of topics for development.

III. Guidelines development

Guidelines should be produced by multiprofessional groups in a systematic, independent and transparent fashion, using appropriate quality criteria.

End user involvement through a wide review and/or testing of the pilot version is necessary before adopting a guideline for implementation.

If guidelines are adapted from other countries or areas, they must be re-edited and reviewed or tested for applicability in the new environment.

IV. Dissemination of guidelines

The funding for guideline dissemination, implementation, evaluation, and updating must be carefully considered at the same time as the decision is made to develop the guideline. Funding support may vary. The source of support must be transparent.

Guidelines should target multiple audiences (professionals, patients, and policy makers) and be available in suitable formats for these different groups.

Guideline dissemination should be planned, active, sustainable, and ensure high accessibility.

Guideline clearing houses or guideline production programmes facilitate the accessibility of multiple guidelines on similar problems and may increase guideline quality.

V. Guideline implementation

For the most effective implementation of guidelines, a systematic approach to managing the quality of health care and determining those responsible is essential.

Various guideline dissemination and implementation strategies should be used in combinations to ensure maximum effect.

Professional, organisational, financial, and regulatory incentives and disincentives need to be considered together with other barriers and facilitators of guideline use at both national and local levels (tailored implementation).

In implementing guidelines, the best interest of the patient should be served and professional responsibility and patients' rights should be respected.

Guidelines must become an essential element in the undergraduate and clinical training of health care professionals as well as in the continuing professional development of health care teams.

VI. Evaluation of guidelines and of their impact

Tools for evaluating the quality of existing guidelines should be used to decide which guidelines should be implemented.

Well-planned monitoring of guideline effects is essential, and especially the impact of guidelines on health outcomes needs further development and evaluation.

Guidelines can include a list of essential indicators that can be used for evaluating the results of guideline implementation.

An internationally co-ordinated research network should study the methodology of guidelines evaluation and impact monitoring, including the impact of guidelines on learning process and medical knowledge of professionals.

VII. Updating

The guideline production process must include clear policies and responsibilities on guideline updating.

Explanatory memorandum

Introductory statement

The Committee of Experts on Developing a Methodology for drawing up Guidelines on Best Medical Practices (SP-MPR) agreed with the terms of reference that the high quality of medical practice and good professional conduct are in the interest of the individual patient, who is today a more demanding and active participant in the health care process. The committee noted that all member states of the Council of Europe are presently involved in assessment and accountability in health care, including quality evaluation of medical practices and interventions. Such quality evaluation is made easier when clinical guidelines on best practices are available.

Clinical practice guidelines are tools for making decisions in health care more rational, for the improvement in quality of health care delivery and for strengthening the position of the patient. At best, they may also help to increase efficiency, and this contributes to cost containment in health care. The success and failure of clinical practice guidelines depend on their quality, medical value, on social, legal and ethical aspects involved as well as their implementation in daily practice.

Important points for attention from a managerial perspective on guidelines include the possibility of errors and misjudgement in drawing up guidelines, the conditions for their implementation (for instance coerciveness and incentives), their application from the perspective of the patient, and continuing respect for clinical judgement and clinical autonomy.

The committee agreed that it is therefore important to develop a framework as guidance to member states for drawing up clinical practice guidelines. There is a particular need to determine the objectives of

guidelines, the responsibilities for drawing them up, the role of various parties concerned (professional bodies, governmental organs, insurance companies and other funding bodies, patients and citizens), the manner in which the guidelines are drawn up (methodology), the methods for their implementation, and evaluation of their effectiveness.

In the terms of reference given by the CDSP, the committee of experts was invited to :

1. Make a state of the art survey of current policy practices in member states in drawing up good clinical practice and medical treatment policy guidelines ;
2. Make an inventory of their function, the advantages and limitations of guidelines when viewed upon as part of the professional standard, including their role in court proceedings ;
3. Make proposals on the methodology to be used in developing these guidelines, particularly on :
 - i. scientific and other conditions ;
 - ii. the practical modalities for developing guidelines (the body responsible for developing guidelines, the involvement of professional groups, patient participation and the like) ;
4. Make proposals for dissemination of good clinical practice and medical treatment policy guidelines and the promotion of their implementation in daily medical practice ;
5. Identify the practical, social, ethical and legal conditions for implementation of such guidelines in daily practices ;
6. Identify the essential requirements with which norms and standards for best medical practices have to comply, and the assessment of their effectiveness.

The following chapters deal with each of the terms of reference in turn. Chapter 1 describes the current guideline policies in Europe. Chapters 2, 3 and 4 set out the various functions of guidelines and make proposals

for the methodology to be used in drawing up clinical practice guidelines as well as in distributing and implementing them in health care. Chapter 5 discusses additional practical, social, ethical and legal issues of using guidelines. The role of norms and standards is covered in Chapter 6, which also includes definitions of the terminology used in this explanatory memorandum.

The list of references includes core publications in the field of guidelines, but not all references used by the committee of experts have been listed. Information about organisations and other agencies active in guideline production, dissemination, or implementation can be found at their websites, which are listed in Appendix 1. In the list of references for this memorandum, some core publications about these organisations are also listed. Examples of defining the levels of evidence in guidelines are given in Appendix 2.

Chapter I – Current policy practices

Terms of reference 1

Make a state of the art survey of current policy practices in member states in drawing up good clinical practice and medical treatment policy guidelines

A survey of the current state of development, dissemination and implementation of good clinical practice guidelines (CPGs) in European countries was reported in 1999. Forty-six replies were received from sixteen European countries (Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Poland, Spain, Sweden, Switzerland, and United Kingdom). Since many countries did not reply to this ProGuide survey, members of the committee of experts extended a shorter version of the survey by a targeted questionnaire to countries that were not included in the original survey. Responses were received from Bulgaria, Moldova, Poland, Romania, Slovak Republic, and Slovenia.

The weaknesses inherent in conducting both surveys and in interpreting their findings are quite clear. The collection of the data was confounded for several reasons. There are many different definitions as to the type of

publication that qualifies as a clinical practice guideline. National or speciality contact points that would be well informed of all questions of guideline development and use are difficult to identify. Within many countries, even persons closely involved with guidelines had problems in identifying all activities and players. These problems may partly explain the low response rate to the surveys and further complicate interpretation of the data. Nevertheless, a broad qualitative overview can be presented. Members of the committee of experts participate in an extensive network of guideline developers, and, against this background, it can safely be stated that major substantive guideline programmes are not in existence yet in the countries not included in the surveys.

The surveys show that there are widespread initiatives around the development of guidelines for clinical practice and for medical treatment policies in numerous European countries. In addition, measures to assure guideline quality and to support their implementation are widely used. However, only a few countries have built practical and well co-ordinated approaches.

In several countries, guideline-related activities seem to be scattered, or have just begun to be co-ordinated. Local adaptation of guidelines is still rare, and subsequently guidelines can seldom be implemented with a feeling of true ownership. The principal explanation for this is that a wide range of organisations may be involved, including governmental and non-governmental policy makers, governmental agencies involved in health care, scientific organisations, health care delivery organisations – particularly hospitals, and medical specialist societies. Health care financing organisations have a role in some countries.

In some countries the quality of guideline development is assured, amongst other means, by developing and publishing standards for guideline development and appraising existing guidelines. Examples include the methodology for guideline development published by the Scottish Intercollegiate Guideline Network (SIGN) and the methodological recommendations and quality criteria published by the German Association of Scientific Medical Societies (AWMF). Other examples include the consensus development programme established by the National Organisation for Quality Assurance in Hospitals in the Netherlands, the guideline production programme of the Swiss Medical Association, of l'Agence nationale d'accréditation et d'évaluation en

santé (ANAES) in France, and the setting up of a guidelines clearing house by the Agency for Quality in Medicine (AZQ) in Germany.

Through its Biomed programme the European Union has funded a collaboration creating an instrument for appraising guidelines. This Agree (Appraisal of Guidelines for Research and Evaluation in Europe) instrument has been piloted across more than a hundred guidelines in a dozen countries and a revised version is now being validated. The Agree instrument has been well received and may become the tool to assess the methodology used by different guideline developers in different nations. It is described in more detail in Chapter III.

Chapter II – Functions of guidelines

Terms of reference 2

Make an inventory of their function, the advantages and limitations when viewed upon as part of the professional standard, including their role in court proceedings

1. *The main aim of clinical practice guidelines is to support and promote good clinical practice*

The main aim of clinical practice guidelines (CPGs) is to promote and support good clinical practice and inform the public about it, while taking account of available resources. It must be stressed that guidelines are only one of the many optional tools for improving the quality of care, and a multifaceted approach is required.

Clinical practice guidelines are systematically developed statements to assist important professional and patient decisions about appropriate health care for specific circumstances. There has always been a body of opinion providing guidance to individual professionals. The novel aspect of evidence-based guidelines is the systematic way in which they are developed, and their explicit nature.

CPGs must be developed using state of the art methodology and be critically appraised before implementation is considered because many CPGs are developed using methodology that is not robust or is of uncertain quality or origin.

2. *Guidelines are produced and used in the complex environment of a health care system with its ethical, economic, legal and other aspects; these aspects need to be taken into consideration in each country*

Guidelines, which have been produced using validated guideline development methods, can be used in many ways by citizens, patients, professionals, health care organisations and those responsible for drafting and implementing health policies. When evidence has been systematically collected and there is sound data on effectiveness, it forms a good basis for further interpretation. Adaptations of guidelines can include local applications for different types of available skills and technology, economic evaluations or versions edited specifically for citizens, patients or policy makers.

Such clinical practice guidelines have several primary and secondary functions. They can be used to support health care decisions, be referred to in legal proceedings, to provide information about cost effectiveness and they can help to link research, education and practice. All these functions are dependent on each country's societal values and situation; the basic approaches are discussed in more detail below.

Support of health care decisions

Guidelines can be used to plan health care for individuals or populations. They help to make decisions in health care more rational and transparent. Whatever the use, they are to be interpreted in a sensible and practical manner and applied with discretion. They presuppose an average patient rather than the particular individual who is being treated. Therefore, guidelines are not a substitute for sound clinical judgement. A guideline must be flexible in the sense that it identifies exceptions and indicates how patient preferences can be incorporated.

When aiming at quality care for individuals and for specific groups of patients the use of CPGs can improve the consistency of care (reduction of inexplicable variations) and help to achieve better health outcomes.

CPGs can also support patients in making informed choices. A properly developed patient version of a clinical practice guideline, tailored to the educational and socio-economic status of the lay population in language that they can understand and use, enables patients to make appropriate

choices concerning their health problems. Citizens should be aware of the existence of these lay versions of CPGs, told how to get hold of them, and be provided with them when they are patients.

Neither the existence of a patient or carer version of a CPG nor the assumption that individual patients are familiar with it replaces the doctors' obligation to apply the principles of informed consent.

Use in the courts

The medico-legal status of clinical practice guidelines is a frequently raised question. Since guidelines are not issued by legislative bodies, they are not legal rules. However, they may have or acquire legal significance, for instance when they are incorporated into binding rules or when they are applied by a court as auxiliary standards to decide a case of professional misconduct or malpractice.

Courts may use guidelines as auxiliary standards to decide a case of medical malpractice. It should be noted, however, that guidelines are not likely to be used as the sole basis for evaluating negligence, and in many jurisdictions, they may not even be seen as having a special status in law. Usually the perceived value of guidelines in a court will be conditional on several factors, in particular the extent to which they are based on scientific evidence, reflect a consensus among peers, and are issued by a group or institution with authority.

Basically, guidelines will not provide definite answers even when they do not allow for much flexibility in application. A particular course of action must be judged in the light of the specific health problem and the specific circumstances of a given patient. Sometimes, there can be competing guidelines, for instance developed in different hospitals or regions; in other cases, expert testimony may be used in a court to challenge the authority of a guideline. For all these reasons, the courts will not automatically equate compliance with guidelines with good medical practice.

Mere deviation from a guideline is unlikely to be considered as negligent, unless the practice concerned is so well established that no responsible doctor would fail to adhere to it. This is not to say that a guideline – if not decisive in establishing negligence – cannot have other implications in court proceedings, for instance in that it may shift the burden of proof: if

a doctor has not complied with a guideline, he may be required to prove that the harm to the patient was not caused by non-compliance.

The above considerations of the medico-legal status of guidelines are generic. Since variations in practice, legislation and interpretation do occur between nations, it should be for each country to establish the interpretation and status of guidelines in courts.

The legal aspects of CPGs are further developed in each of the following chapters.

Promotion of cost-effective care

Cost containment is one of the functions of CPGs, but it is not the primary goal. Guidelines can be used to identify and discontinue ineffective, obsolete and costly practices. However, the active implementation of CPGs may lead to an increase in the provision and uptake of specific interventions and treatments, based on highly dependable evidence. This will require the allocation of additional and sustained human and financial resources.

This potential effect of guideline implementation emphasises that it is important to set health priorities and choose topics for guideline development in a broad, national socio-economic context. Good care costs. But bad care costs much more in the long term, for example as the complications of inappropriately managed problems, such as blindness, renal failure and stroke develop in inappropriately managed diabetic patients. The challenge of the future is to produce guidelines that incorporate information on cost as well as effectiveness.

Opportunities to use financial resources more appropriately arise by making evidence-based decisions for disease management based on CPGs, always taking into account the imperative of clinical judgement and respecting the appropriate degree of flexibility depending on the individual patient. Guidelines cannot alone offer sufficient basis for financing decisions; but such decisions cannot be made effectively without the kind of information that guidelines developed using state of the art methodology provide.

Linking medical science, practice and education

Systematic reviews of literature diffuse the results of good research and provide an important feedback for health care providers and consumers

and in turn to academic medicine. The transfer of knowledge and information, and the number of individuals expert in critical appraisal have increased constantly as CPG development programmes have been successfully established in several countries and adapted locally. Numerous new research questions have been identified for health service research that are relevant to the delivery of health care and the promotion of health.

The practical adaptation of CPGs, which have been developed appropriately by national organisations, gives an opportunity for local or regional ownership. This process ensures that the particular local issues and priorities are taken into account in choosing which guidelines to implement and in designing the delivery of local or regional services. The availability of graded evidence and recommendations, which are free of advocacy, facilitates local decision-making. Guidelines are more likely to have an effect if they are adjusted to suit local epidemiology, structures of care and resources.

CPGs have an important place in the curricula of undergraduate, post-graduate, and continuing education of health professionals. The education needs to incorporate a healthy critical attitude toward guidelines and an ability to appraise their quality. In postgraduate education, the methodology of guideline development in general and the practice of critical appraisal of medical literature in particular should be presented.

Chapter III – Methodology of guideline development

Terms of reference 3

Make proposals on the methodology to be used in developing these guidelines, particularly on:

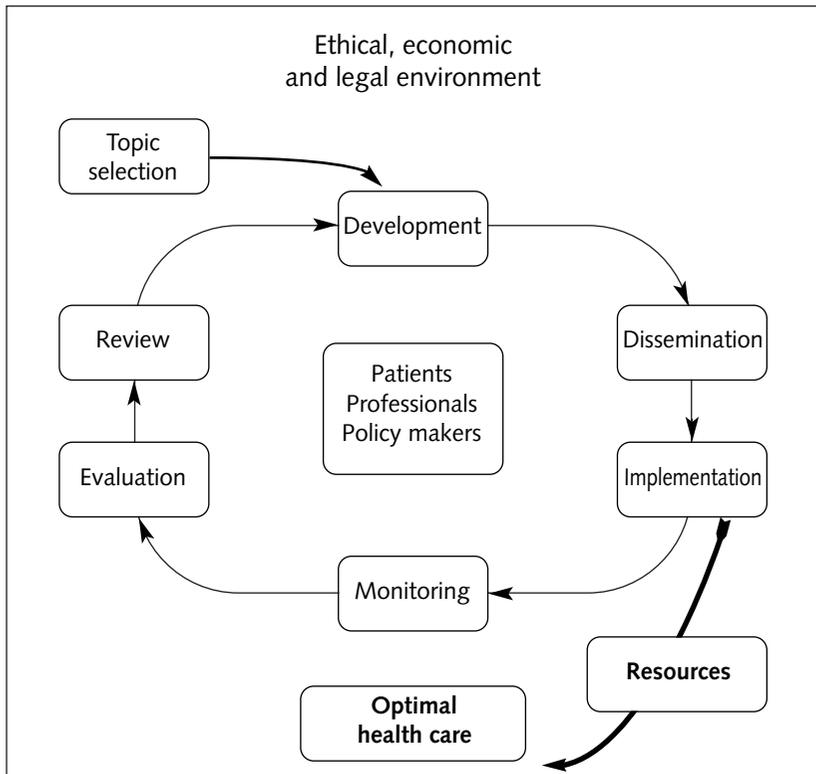
- i. *the scientific and other conditions*
- ii. *the practical modalities for developing guidelines (the body responsible for developing guidelines, the involvement of professional groups, patient participation and the like)*

The process of developing guidelines must be systematic, independent and transparent. The primary target group are the health professionals and the main responsibility for the development of guidelines should rest with them and their organisations. Other interested parties –

patients, funders, and policy makers – should be involved whenever appropriate. Guidelines should be available and understandable to these important target groups.

Given this objective, guidelines should be based firmly on scientific evidence and clinical outcomes data, interpreted through professional experience and complemented with expert opinion when necessary. The following chapters deal with the successive stages of the elaboration and application of guidelines. The overall process of guideline production and implementation is presented in Figure 1.

Figure 1 – Overview of the process of guideline production and use
Guidelines production and use



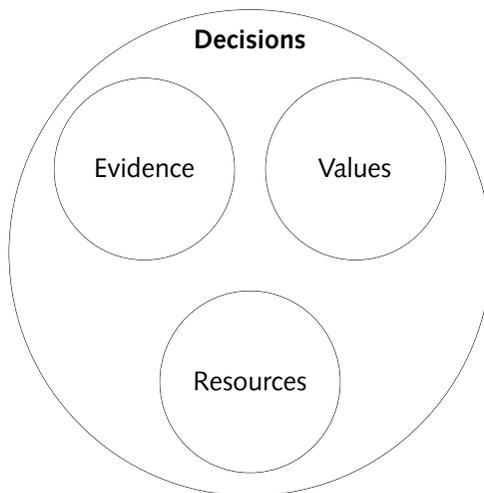
Topic selection

1. *Guideline topics should be selected for development to support and assist decision-making on important issues in health care*

Guideline development and implementation require time and expertise. It is not possible to provide guidelines quickly for all or even most of the problems that patients, professionals or health care politicians face daily. Prioritisation of topics is therefore necessary. Optimally, it is done jointly by health care professionals, epidemiologists, policy makers and citizens, as each of these groups participates in decisions about health care. Each of these groups also attaches different values to the importance of various topics.

Guidelines can be used to assist health policy decisions at all levels in society: national, regional, community, and individual patient level. Of course such decisions cannot be made using guidelines as the only source of information but high quality guidelines can offer reliable data on the effectiveness of interventions which can then be combined with societal values in the context of available resources (see Figure 2). Guidelines are most useful when they make the effectiveness data (or the lack of it) available to health care professionals and lay persons in a comprehensive and understandable manner.

Figure 2 – Elements of health care decisions (based on Muir Gray, 1997)



When guidelines are not available, groups of professionals (for example, specialities or “schools” that have different approaches toward the prevention, diagnosis, treatment or rehabilitation of persons with certain health problems) may disagree on the relative merits of various types of interventions. To prove their point of view, it is usually easy to present a number of scientific publications that support it, and to overlook others that contradict it. A similar situation may arise when guidelines are produced non-systematically by various interest groups. Only by systematically searching and combining studies is it possible to extract a balanced point of view.

An important issue in health care is often a complex question, and the possible approaches can also carry rewards or disincentives to concerned parties. For example, decisions on the diagnosis and treatment of osteoporosis involve many stakeholders and include questions of new diagnostic procedures and new therapeutic agents, which have various benefits and side effects (see Box 1). Such major policy decisions create both political and commercial interests, and often are subject to public discussion. When a guideline provides a common basic source of information, it is easier to separate clinical facts from value and resource questions.

- 2. Prioritisation of guideline topics may be based on epidemiology of health problems, health inequalities, variations in the provision and quality of care, emergence of new technologies, or other factors that create a need for high quality, updated information.*

Epidemiology of health problems

The number of different diagnoses a general practitioner makes yearly has been estimated to be between three and four hundred; of these, the most common thirty-three diagnoses cover approximately two-thirds of the work. The most common health problems vary slightly from country to country, depending on how health care has been organised and what tradition there is in self-care. They usually include upper respiratory tract infections, other acute infections (urinary, skin and gastrointestinal), simple anxiety/tension states and superficial injuries. Preventive care, maternity care and well-baby clinics as well as contraceptive advice are also among the major causes for consultation.

Box 1 – Example of technical questions and roles of interest groups in health policy decisions : Screening for osteoporosis

Questions

How common is this health problem ?

How well do different risk factors (age, diet, other diseases, bone density) predict fractures ?

What are the effects of the preventive options (calcium, exercise, hormones etc.) in the short term (on bone density, balance, etc.) and do they actually decrease the number of fractures ?

How good are the various diagnostic methods (radiography, bone densitometry, etc.) in separating high-risk persons from low-risk persons, and at what cost ?

Interested groups and their issues

Persons at risk: anxiety, cost of screening and prevention, side effects, satisfaction

Diagnostic personnel: workload, training, expertise, income

Other health professionals (primary care, health educators): workload, patient information

Service providers: resource transfers from other health problems

Policy makers: equality of access and quality of services, effectiveness

Medical industry: sales of diagnostic equipment, preventive drugs

More serious common acute problems include anaemia, dyspepsia, fractures, and depression. Of the more chronic health problems, the most commonly encountered in primary care include obesity, hypertension, diabetes, asthma and chronic bronchitis, congestive heart failure, stroke, alcoholism and chronic musculoskeletal problems.

The range of health problems encountered by hospital practitioners also varies depending on local epidemiology and the organisation of care. The most common ones include accidents, obstetric deliveries, cardiovascular problems (myocardial infarction, stroke), problems with vision (cataracts, glaucoma), serious infections (pneumonia, upper urinary tract) and cancers.

For some of the common health problems, the content and organisation of care have been widely agreed on. A typical example is maternity care, due to long tradition and the presence of a professional interest group (midwives). Diseases, such as diabetes or asthma, have in many countries received support from strong patient organisations as well as large and active bodies of researchers.

Health inequalities

Persons suffering from similar health problems do not always receive similar care. Increasingly detailed health service statistics often show quite a notable variation in the provision of services. Behind such regional variation, there may also be age- or gender-related differences in access to care. Illnesses may, of course, be more common or severe in certain groups. For example, cardiovascular diseases are much more common in males than females before the age of 50 years. Often there are no such valid reasons for service variation – instead, they simply reflect inequalities in care.

Variation in the quality of care

Statistics may also provide information about other aspects of service quality. Drug reimbursement data may show major variations in the prescription of inhaled corticosteroids (primary drug for asthma), although disease prevalences are similar. Some regions may prefer medical treatment of benign prostatic hypertrophy, while others promote surgery. Variations in treatment of various diseases, such as back pain, (surgical or conservative), cataract (frequency and waiting times for operation) or acute respiratory infections (selection of antibacterials) have been shown in numerous countries. A more severe sign of low quality is the clustering of patient complaints to one or a few units.

When wide variation in the provision of care is observed, the process of producing a clinical guideline may already start changes. A good guideline requires several months of work – its gestation period is usually between the human nine months and the elephants' two years. Discussions sparked by the development process as well as open consultations about the content of the guideline prepare the ground for change. Sometimes merely pointing out the variation may be sufficient for the poorest units to start improving their care processes. Variation also brings up the question of equality and thus is important in prompting the need to change.

Emergence of new technologies

New drugs, diagnostic methods, and other procedures are often introduced in the medical culture very rapidly. The efficacy studies (done in optimal environments) may show a notable improvement; often, however, the benefit in typical health care organisations (effectiveness) is much less dramatic. New technologies have sometimes been observed to spread very rapidly. Importantly, diagnostic and operative technologies are often widely used even before any effectiveness studies are available.

New technologies may be promoted very actively; often this happens by comparing them favourably to old, established ones that are used for the same purpose. In marketing, a typical approach is to show (large) relative risk reductions instead of (small) absolute ones, giving an impression of remarkable improvement, when actually the change is marginal (see Box 2). Especially when marketing is aggressive, it may well be useful to produce a guideline based on properly done health technology assessments (HTAs) with sensible comparisons to established policies. Sometimes a well-done and actively marketed HTA will suffice as a tool for change.

Box 2 – Different ways of presenting effectiveness data.

A new drug for hypertension, Lancelot, was clinically tested against the best older drug, Arthur, on 20 000 patients. Lancelot was shown to prevent 50% of deaths due to cardiovascular diseases over a year of use. Lancelot costs 10 more euro per month than Arthur. The actual numbers of deaths observed were 6/10 000 Arthur patients and 3/10 000 Lancelot patients. This does account for a Relative Risk Reduction (RRR) of 50% : $[(6 \text{ patients} - 3 \text{ patients})/6 \text{ patients}] = 50\%$, but the Absolute Risk Reduction (ARR) is only $(0.06\% - 0.03\%) = 0.03\%$. This means that three patients in ten thousand (or 1 in 3 333) avoid death in one year.

To prevent one death, it is then necessary to treat 3 333 patients for one year with Lancelot instead of Arthur. This costs 400 000 euro. As the patients' life expectancy increases by five years on average, the cost per life year saved is then 80 000 euros. The cost per life year saved is slightly higher than the cost of saving one year in patients undergoing renal dialysis.

Other needs for updated information

National or local issues may bring up the need for a clinical guideline. Policy decisions on starting or discontinuing screening or changes in reimbursement for chronic diseases, for example, typically provoke a public discussion and sometimes loud demands from interest groups. An existing guideline may help in such cases, but in these instances it is usually too slow a solution to produce a new CPG. Rapid technology assessments may also be used here to provide a common basis for policy discussions.

3. *The existence of presently available evidence-based guidelines should be considered in the prioritisation of topics for development*

Several countries have their own, more or less extensive guidelines programmes, and often list the topics or even provide full versions of the guidelines on their web pages. When considering a topic, it is useful to check whether there are recent, validly developed or favourably appraised guidelines or systematic reviews on the subject being considered. A systematic approach to this is useful, and several clearing houses now collect and assess existing guidelines in different languages. The Internet addresses for major guideline organisations and clearing houses are available in the appendix.

When a guideline has been produced using a thorough and clearly described search of literature and its conclusions and recommendations are transparently based on these data, it is possible to adapt the content to a new surrounding instead of repeating the time-consuming scientific work. For example, the Swedish HTA agency has made and updated extensive literature reviews on the treatment of back pain and substance abuse; these reviews are utilised by the Finnish guidelines groups and translated (for both language and context) into a new, slightly different health care setting.

Guidelines development

The Institute of Medicine has listed desirable attributes in guidelines in 1990 (Box 3). A set of quality criteria for CPGs has been developed recently by the Agree group, including twenty-three items covering guideline scope and purpose, involvement of interested parties, identification

and use of evidence, rigour of development, clarity, applicability, and editorial independence. Several guidelines programmes have also published their own development procedures.

The comments below are mostly based on the methodologies used by the Scottish Intercollegiate Guidelines Network (SIGN) and the Finnish Current Care guideline programme.

**Box 3 – Desirable attributes of clinical practice guidelines
(IOM 1990)**

- Validity
- Strength of evidence
- Estimated outcomes
- Reliability/reproducibility
- Clinical applicability
- Clinical flexibility
- Clarity
- Multidisciplinary process
- Scheduled review
- Documentation

Guidelines can be developed using a variety of approaches. The traditional way of making medical recommendations was non-systematic, and thus at risk of being biased. In these traditional reviews recommendations were decided upon first, usually by a group of experts based on consensus, and the evidence supporting the recommendations was searched for after the decision. The problem lies in the ease of finding studies to back up almost any recommendation. When evidence is thoroughly and systematically searched for, even experienced clinicians are often surprised to realise that many common treatment practices have no scientific basis.

At present, the preferred guideline development method is to search explicitly and systematically for pertinent evidence to answer each central question being addressed in the guideline. Recommendations are then formulated on the basis of available best evidence. Ideally, a guideline anchors not only to available evidence, but also to explicit estimates of the outcomes of alternative practices. Recommendations are also dependent on the ethical, legal, social and economic environment to

various degrees. Examples of descriptions used for levels of evidence and for grades of recommendations are given in Appendix 2.

In addition to being evidence-based, guidelines may be outcomes-based. Here the magnitudes of expected effects are openly estimated and the benefits and harms weighed against each other by the experts in the guideline group. This can shift the basis of guideline recommendations from qualitative to quantitative reasoning. This method requires special skills (statistics, mathematics, economics), time, and resources. With continuous improvement of registers of procedures and outcome data banks, such an outcomes-based approach to the construction of guidelines can become an effective instrument for shaping best medical practices.

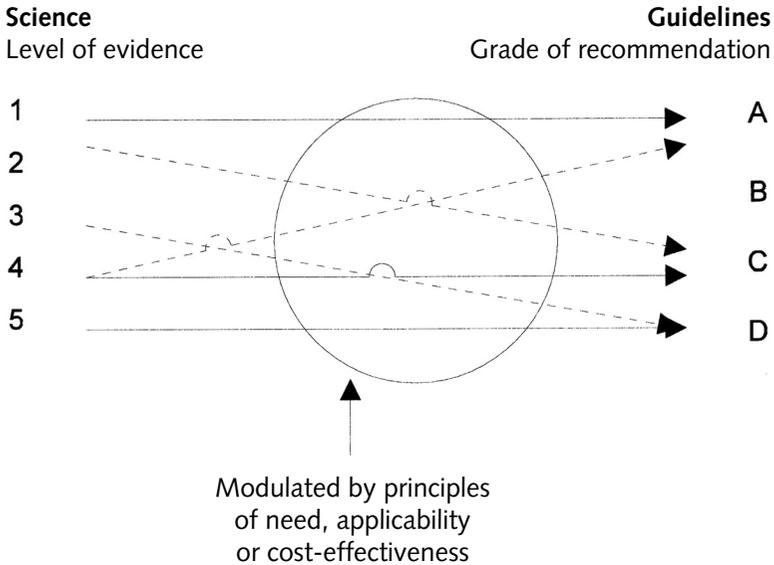
In the absence of sound evidence, the group may produce statements about essential care decisions using a consensus approach. There remains however the question if the practices recommended by the guideline have actually been shown to be effective in improving health outcomes. Neither is there always a direct link between the level of evidence and the strength of the recommendations (see Figure 3). When studies have been done on highly selected patients, for example, the evidence for applying results in the general population may be considered weaker than otherwise.

Sometimes there is very little data to support an important decision in health care, and in these cases, experts in the guideline group may decide the grade of recommendation to be higher than the evidence in usual cases would allow. Major differences in cost consequences between interventions (for example, when treatment A costs a hundred times more than treatment B) can also prompt the experts to change the grade of recommendation.

Changes in interpreting the evidence may also take place at the implementation stage. While guidelines should predominantly remain based on scientific and professional considerations, there may be a need to modulate and weigh the evidence locally according to value judgments, priorities and local conditions. Translating guidelines into regional treatment programmes or local practice policies may thus mean changes in the content of recommendations.

Figure 3 – The relationship between level of evidence and strength of guideline recommendations

(Descriptions of levels of evidence and grades of recommendation are shown in Appendix 2).



1. *Guidelines should be produced by multiprofessional groups in a systematic, independent and transparent fashion, using appropriate quality criteria*

When the United States Institute of Medicine planned its guidelines programme, they strongly recommended participation from essential interested parties in the guidelines production process. This means including both primary care and secondary care representatives, both senior academics and practising juniors, all specialities and personnel groups involved in caring for the target group. Patient representatives should also be included in the development process. Unless this is done successfully, a guideline risks being criticised for many different reasons not least for overlooking speciality views, being inappropriate for daily practice or for not including the views of patients.

A systematic manner of reviewing the literature and formulating the recommendations based on evidence helps in evaluating the quality of the guideline. A clear description of the techniques used should be easily available to all users. The development process also needs to be documented sufficiently well to track the sources of eventual problems later. The ways of suggesting corrections to the guideline and the updating processes also need to be described for the guideline to retain its validity. An important step in guideline production is the formulation of essential recommendations in guidelines, so that they can be translated into simple, easily measurable clinical actions.

Ideally, in addition to data on effectiveness, guidelines should also include information about the costs of various interventions. The recommendations may in many cases be influenced by cost data, especially at the local and health policy level. Health professional members of the guideline groups are usually not familiar with health economic methodology. It is useful to include trained health economists in the group to assist in the development of the guideline and to widen the views.

Guidelines can be evaluated using various generally or internationally accepted quality criteria. These can be utilised by end users, patients, or policy makers. Ideally, guideline production processes are originally planned using such quality criteria to ensure their validity, applicability and acceptability. A set of guideline quality criteria has been developed and tested in nine European countries by an international collaborative group (see Box 4).

From the legal point of view, as described in Chapter 2 in this memorandum, guidelines are a part of the professional standard. Therefore, guideline development must first and foremost involve the profession, and occur according to certain internal standards; otherwise, it may guide practice in the wrong direction. To some extent, a guideline can be compared to a medical device or drug, for which the liability of the manufacturer includes defects in the product. In addition, insufficient or inadequate information on the scope and limits of the product may cause liabilities. Until now, however, this appears to be a theoretical rather than a practical issue for guidelines. It is wise to consider these aspects in advance in the light of national law, especially in the production of multiple guidelines.

Box 4 – An instrument of guidelines appraisal criteria developed by the group Agree (Appraisal of Guidelines for Research and Evaluation in Europe)

Scope and purpose

1. The overall objective(s) of the guideline is (are) specifically described.
2. The clinical question(s) covered by the guideline is (are) specifically described.
3. The patients to whom the guideline is meant to apply are specifically described.

Stakeholder involvement

4. The guideline development group includes individuals from all the relevant professional groups.
5. The patients' views and preferences have been sought.

Rigour of development

6. Systematic methods were used to search for evidence.
7. The criteria for selecting the evidence are clearly described.
8. The methods used for formulating the recommendations are clearly described.
9. The health benefits, side effects and risks have been considered in formulating the recommendations.
10. There is an explicit link between the recommendations and the supporting evidence.
11. The guideline has been externally reviewed by experts prior to its publication.
12. A procedure for updating the guideline is provided.

Clarity and presentation

13. The recommendations are specific and unambiguous.
14. The different options for management of the condition are clearly presented.
15. Key recommendations are easily identifiable.

Applicability

16. The target users of the guideline are clearly defined.
17. The potential organisational barriers in applying the recommendations have been discussed.
18. The potential cost implications of applying the recommendations have been considered.
19. The guideline is supported with tools for application.
20. The guideline presents key review criteria for monitoring and/or audit purposes.
21. The guideline has been piloted among end users.

Editorial independence

22. The guideline is editorially independent from the funding body.
23. Conflicts of interest of guideline development members have been recorded.

- 2. End user involvement through a wide review and/or testing of the pilot version is necessary before adopting a guideline for implementation*

It is usually not practical to involve all interested groups in the demanding and often tedious process of reviewing literature and producing recommendations. If this is possible, as may be the case for guidelines that have a fairly narrow scope, it can assist the successful formulation of the content and individual recommendations in the guideline. Often it is more practical to arrange for opinions to be included at a later stage. Whichever manner is used, it is an essential step for both guideline development and in preparing for successful implementation.

When an acceptable draft of the guideline is ready, comments to it can be invited. Scotland has a long experience of arranging open national meetings, where the draft is presented by the experts involved and comments from the ensuing discussion are fed back to the CPG development group. SIGN also posts this draft guideline on its web site for a limited time period, and incorporates the comments in the editing process. After this work, an edited version of the guideline is circulated to various organisations and individuals for peer review. The CPG development group then compiles the comments in the guideline during the last phase of editing.

User feedback on the Finnish Current Care guidelines is also invited by an extensive consultation round, involving both primary and secondary care, private and public service providers, various schools of practice, patient groups, and any other individuals or organisations the CPG development group wants to consult. The consultation round often changes the guideline for important practical issues (see Box 5).

- 3. If guidelines are adapted from other countries or areas, they must be re-edited and reviewed or tested for applicability in the new environment*

To develop an evidence-based guideline from scratch (that is, starting from the very beginning with literature search, evaluation, etc.) consumes much time and human resources. The basic data needed to create a clinical guideline is mostly transferable to other countries and conditions. When nationally developed guidelines are translated into

Box 5 – Changing a guideline by consultation

An evidence-based guideline on the treatment of extrauterine pregnancy was prepared in Finland, recommending that the progress of the pregnancy should be followed by measuring the levels of chorion-gonadotropin (hCG). The level of this hormone falls dramatically when the embryonic tissue stops growing so you can see whether the pregnancy has been terminated successfully. During the comment round, one medium-sized hospital said they only could use a qualitative hCG test which did not provide all the information required for the decisions, and asked how they could best monitor these patients outside office hours. The guideline group still recommended exact testing as optimal, but added a paragraph on decisions based on qualitative tests.

There is a happy ending to the story: a year after the guideline was published, the commenting hospital started using the exact hCG test, after calculating that it would actually decrease their treatment costs in this condition.

various languages and made available on the Internet, they can help other countries in the development as well as implementation of high quality guidelines.

Transferring guidelines from one setting to another can be done quickly, but it raises many possible problems. The process of re-editing involves multiple translations: into other languages but also into different epidemiology, resources and practice patterns which need to be observed. It is also essential for the acceptability of CPGs that the national experts in the subject matter approve of and support the use of the guideline. In situations where the practice changes notably, it is useful to anticipate the reactions of the target population – both professionals, politicians, and the public. Many countries are experimenting with different ways of translating or producing their own guidelines (see Box 6).

Countries also differ in their traditions. For example, the guidelines for sore throats in Finland, the Netherlands, Norway and Scotland are all based on practically the same evidence, but they vary in their recommendations on testing for streptococcal infection. This variability is partly caused by the different laboratory facilities in primary care in these

Box 6 – Strategies for developing guidelines in Romania

Guidelines developed in Romania previously tended to be large (130-400 pages) academic documents rather than immediately useful guides to clinicians in their daily practice. The new approach is to use several strategies for developing guidelines:

- i. Developing guidelines from first principles (that is, starting with a literature review to identify relevant studies and research);
- ii. Starting with the results of meta-analyses of the literature, and updating where necessary;
- iii. Starting from a foreign guideline and modifying it in the light of subsequent research findings and according to Romanian conditions.

The most often used approach is the third one. Considerable savings in time and cost were achieved by starting from the foreign meta-analyses and even more by starting with the already developed guidelines.

countries: they may send patients to an outside laboratory for the test or have local laboratory nurses to perform and read the test at the practice premises. Countries also have different antibiotic policies: they may liberally use narrow-spectrum antibiotics or have a nationwide programme on cutting down unnecessary use of antibacterials.

Even when guidelines are based on the same evidence and draw similar conclusions, they will be used in variable circumstances. Issues of resources and practice patterns may create a need to change the recommendations. If a guideline is partly based on economic evaluations, the question is even more complex. The relative costs of health care personnel, drugs, etc. vary from country to country, and estimates of the economic consequences of different treatments must be recalculated for each country.

One of the most controversial questions is whether the medical considerations in a guideline may be modified by non-medical factors, particularly financial or budgetary constraints. However, taking costs into account does not necessarily compromise the professional or legal status of the guidelines. CPGs should advise against unnecessary or harmful interventions. If an expensive treatment has only marginal

added value to a cheaper old one, it is obvious that a guideline can recommend the less costly alternative. New technologies that have not been evaluated properly can be recommended only for research use.

What guidelines need to offer is not the maximum possible treatment but rather what is appropriate or reasonable. What is essential is that they do not go below the level of what responsible medical opinion would consider necessary.

Chapter IV – Dissemination and implementation

Terms of reference 4

Make proposals for dissemination of good practice and medical treatment policy guidelines and the promotion of their implementation in daily medical practice

Clinical practice guidelines should assist health professionals in decisions about best medical practices. The implementation of guidelines means getting the information and knowledge across from written text to practical action in the health care system. It is not enough that guidelines are developed systematically and according to needs; they must also be implemented to have an effect on practice in the health care system.

It has been clearly shown that mere production and publication of a guideline does not change practice. Therefore, when deciding about producing a guideline, the entire process described in Figure 1 should be considered in order to facilitate the actual penetration of the recommendations. Similarly, practical problems and gaps in a guideline are often identified in the implementation phase and must be fed back to the development and updating process.

Dissemination of guidelines

1. *The funding for guideline dissemination, implementation, evaluation, and updating must be carefully considered at the same time as the decision is made to develop the guideline. Funding support may vary. The source of support must be transparent*

Careful consideration of the planning and resources needed for the entire chain of events described in Figure 1 is required, before a multi-disciplinary guideline development group is recruited. A major cost of

CPG development lies in the expert time and effort that is needed, and securing sufficient support for this work is a core question in guideline development. To facilitate expert work, sufficient support structures for literature searching, critical appraisal methodologies, statistical expertise, editing and distribution need to be ascertained and provided both for the primary development and the regular updates of each guideline. But also, guideline dissemination, implementation and evaluation require many types of resources: printed information, facilitators, training programmes, etc. Merely developing a guideline, no matter how well it is done, is a waste of resources unless the other stages are also planned and secured.

- 2. Guidelines should target multiple audiences (professionals, patients, and policy makers) and be available in suitable formats for these different groups*

Guideline users are very different in their need for information and ability to understand scientific terminology, data and argument. Generally, it would be useful to produce simultaneously at least three different versions of a guideline. In addition to the extensive professional version, a short patient version and an executive summary for health policy purposes need to be edited separately. The “official” extensive version with its background documentation should, however, be available to other user groups as well. A summary card, containing the main recommendations from a CPG, may also be useful for clinicians. All these versions can be available both in paper and in electronic formats.

In many guideline programmes, patient versions are produced alongside the professional version and are based on it. An experienced medical journalist writes these in lay language, picking up the points that are essential for most patients. Patient versions can be distributed by patient organisations, health journals, and other marketing channels. Electronic patient versions available through the Internet can be supported by help functions for easier comprehension.

Executive summaries of guidelines for health policy makers are also produced systematically by some guideline programmes. The background documents to these summaries discuss the main recommendations and usually also their economic effects. The distribution of such documents needs to be planned separately. Ideally, their effects should be evaluated.

Before finalising the text, it is useful to invite persons from outside the guideline development group to read the entire text and comment on it for content clarity. When several people are responsible for writing parts of the CPG draft, it is recommended that a single author edit the entire draft text at a fairly early stage. This both ensures linguistic style and is a good check for comprehensiveness and internal consistency.

3. *Guideline dissemination should be planned, active, sustainable, and ensure high accessibility*

Guideline production, dissemination and implementation go hand in hand. As discussed earlier, it is vital that the dissemination of a guideline (including necessary resources) is planned as part of the production. The various phases of guideline development provide a very useful marketing possibility for the CPG and especially those recommendations that differ from existing practice. Wide distribution and easy availability of draft versions facilitate discussions about the content. The risk is, however, that earlier versions of the guideline are implemented and changes in the final one are not observed. An expiry date on guideline drafts – as well as on published guidelines, for updated versions – is useful to prevent this. Success in the dissemination of guidelines also needs to be evaluated.

Guidelines can be disseminated both in print and in electronic form (for computers). Each form reaches slightly different audiences. The enormous benefit of electronic publishing is easy updatability; it also carries less cost than paper publishing. The two should optimally be used together. Electronic guidelines can be produced using hypertext links in a fashion that permits a very quick consultation of the guideline during practice sessions. When the same guidelines are presented in electronic or paper versions, the doctors use them in similar fashion. The publishing mode does not have an effect on guideline adherence. Practising doctors prefer short, comprehensive and flexible guidelines. Collections of guidelines available at one location are much more useful than separate guidelines that need to be searched for in various books, journals, databases, or on Internet sites.

Support from universities for CPG implementation is useful. One of the methods is getting guidelines into the clinical curricula. In CME (continuing medical education) programmes, guidelines can be a useful tool for

quality management exercises and skills improvement. In general, the dissemination should take place through as many channels as possible, as the various formats of providing the CPGs reinforce each other and the importance of the message.

Using opinion leaders (such as esteemed colleagues or clinical effectiveness co-ordinators) is a possible top-down method. As a local mode of implementation, it is often practical to train the entire health care team to understand and use CPGs and their recommendations. Quality improvement systems can be applied as part of a dissemination strategy (see also Recommendation No. R(97)17 of the Committee of Ministers on quality improvement systems). Health professionals can often benefit from reading both the scientific and the patient versions of the same guideline.

Among the grass roots modes of implementation, the effect of patients providing information to doctors has been studied very little. Increasingly, however, educated patients do bring guidelines and other materials accessible through libraries or the Internet to their physicians. An important role for professionals is to interpret guideline recommendations to individuals and to adapt them skilfully into specific patient situations.

4. Guideline clearing houses or guideline production programmes facilitate the accessibility of multiple guidelines on similar problems and may increase guideline quality

In countries without national guideline programmes, the amount of available guidelines with often low methodological quality and sometimes with conflicting messages may grow uncontrollably. To guarantee easy access and transparency, as well as to provide some guidance on guideline quality, clearing houses have been established in some countries. Clearing houses may function as directories of available guidelines, or they may provide evaluative services, looking at the methodological quality of guidelines as well as the adequacy of their recommendations before inclusion in their databases.

Guideline clearing houses may offer either abstracts or full-text versions of guidelines; the latter are often provided as links to the provider net pages. They can also offer a discussion forum, bibliographies of

methodology, and tools for critical appraisal of guidelines. A clearing house usually neither can nor should recommend what to use. Similarly, guideline programmes cannot require that their products be implemented. The decision to choose and use any guideline rests with health policy makers and service providers. It must be mentioned that even outside guideline programmes and clearing houses many collections of guidelines are available; these are, however, usually not selected or evaluated for quality and may give quite unfounded information.

Guideline production programmes are usually national (see Appendix 1 for their websites). Typically, a programme has produced twenty to sixty guidelines using a systematic structure, offering methodological and practical help for professionals, and taking care of the distribution and/or implementation of the guidelines as well. The programmes usually take one to three years to get into full action, as training the professionals, building up the structures and securing funding will require a sizeable effort in the beginning.

For professionals, it is very helpful to be able to find guidelines for different health problems from the same source. This probably also facilitates actual use in daily practice. When guidelines are systematically produced or evaluated, the professionals also can read about the relevant methodology once only and then assume all other products from the same source are similar in quality, instead of going to the trouble of appraising each guideline separately.

Guideline programmes and guideline clearing houses are a natural part of many countries' health care development strategies. They are usually linked to many other developments supporting evidence-based health care management. Such links may include collaboration with health technology assessment agencies, the Cochrane Collaboration, continuing medical education programmes, etc. Networking between guideline programmes, producers, evaluators and users provides practical support and decreases unnecessary repetition of work. Such networking should be encouraged both within and between countries.

Guideline implementation

Guideline recommendations do not translate into practice by magic. They need to overcome all kinds of resistance in both professionals,

patients and organisational arrangements. Planned and active implementation policies are an essential part of any guideline production process that wants to reach its goal of improving health care.

1. *For the most effective implementation of guidelines, a systematic approach to managing the quality of health care and determining those responsible is essential*

Guidelines should be seen as an integrated part of whatever quality improvement system the actual health care facility has, and as such be linked to the internal controls and processes of the organisation. The systematic approach of development, dissemination, implementation and evaluation coincides with the essential elements of quality work: plan, do, check, and act.

Professional ownership of the guideline is crucial to effective implementation. This can be taken care of through professional participation in the processes of planning, development and decision-making. Hearings or comment rounds can be effective tools in both the dissemination and the implementation process. When guidelines are developed or adjusted locally, implementation is enhanced.

Guidelines can be implemented by using them as a basis for creating practice policies. The basic problem addressed by practice policies is that most health decisions are too complicated to be made on a one-by-one, day-to-day basis. Practice policies have been used for centuries to help solve this problem. They enable practitioners and researchers to analyse decisions before the fact, cast the conclusions as policies, and apply the policies to simplify future decisions. In this process, the guideline is also tailored to suit the practical circumstances of the organisation applying it.

Practice policies can have immense leverage. One well-designed policy – such as washing hands between deliveries of babies – can improve the quality of care for hundreds of thousands of patients. For years these policies were similar to ill-defined standards and “accepted practice”, based on global subjective judgment. The policy makers performed their tasks without sorting out the underlying questions (“global”), in their heads (“subjective”) according to their individual opinions (“judgments”). These procedures did not systematically consider the evidence pertaining to important outcomes or patients’ preferences.

2. *Various guideline dissemination and implementation strategies should be used in combinations to ensure maximum effect*

In most guideline implementation projects, different strategies need to be combined for optimal effectiveness. Various types of strategies are listed in Box 7. No single intervention seems to be sufficient for changing practice patterns quickly, let alone permanently. The most effective strategies vary according to the health problem, professionals, and practice setting. The various elements of the implementation need to be planned in detail, and adjustments must often be made to accommodate the specific needs of guideline users.

Box 7 – Strategies for implementing guidelines. Modified from Thorsen T & Mäkelä M: *Changing Professional Practice*, 1999

Educational

Distributing materials	Patient-mediated interventions
Conferences	Audit and feedback
Local consensus processes	Reminders
Outreach visits	Peer review
Local opinion leaders	Tailored interventions

Financial interventions (toward providers or patients)

Payment modes	Incentives
Salary	Grants
Capitation	Penalties
Fee-for-service	

Organisational interventions

Changes in facilities	Multidisciplinary teams
Telemedicine	Case management
Patient participation	Revision of professional roles
Record and information systems	

Regulatory interventions

Changes in liability	Accreditation
Management of complaints	Licencing

Some of the most effective implementation strategies include electronic reminders in computer-based systems, academic detailing (outreach visits by a medical adviser giving advice directly to the professional

in the practice setting) and the use of multifaceted implementation strategies. The most effective implementation methods are all closely linked to real life situations. To develop a guideline without spending resources on the implementation process is to waste resources.

Among the most important aspects of dissemination and implementation are the ready availability of guidelines in daily practice, easy readability, and practical applicability. Physicians need – or at least they report they could use – new information in their work for several patients each day, for common health problems as well as for more rare diseases. If the guidelines are readily available, physicians report that they change their decisions to adjust to the guideline in more than half of the cases where they consult guidelines.

Health professionals use different information sources during their daily work. Some prefer printed text, others search the Internet, and many want to enhance the effects of their decisions by providing printed information for their patients. Sometimes a physician may want to go deeper into the background of a recommendation before she/he can make up her/his mind for treating an individual patient. Guidelines that appear in multiple formats facilitate this personal approach. Electronic guidelines can exploit the hypertext functions to provide quick or detailed advice in the same package.

A guideline should be available at every health worker's desk at the time when it is needed. Integrating guidelines in computerised decision support systems is an effective implementation strategy, especially with patient-specific interactive reminders. Short versions, pocket editions and charts – electronically or on paper – may be useful in the multiple working locations of health professionals.

3. *Professional, organisational, financial, and regulatory incentives and disincentives need to be considered together with other barriers and facilitators of guideline use at both national and local levels (tailored implementation)*

Health authorities may use guidelines as a tool to guide practice in accordance with the requirements of law and professional standards (see Boxes 8 and 9). In supervision by system audit or inspection, guidelines may be used to help decide about acceptable levels of performance.

Similarly, professional competence may be tested using guidelines as a tool, keeping in mind the necessary individual flexibility.

Economic or other incentives can be used to facilitate implementation. Economic incentives may be directed towards the health worker, the employer, the fundholder or the responsible health care organisation. Other incentives such as professional acknowledgement or social status can be considered when appropriate. In some countries, professionals can earn continuous professional development points for participation in CPG work; this is an added incentive for participation.

While incentives to enhance implementation may be useful, one should be careful about putting direct sanctions on non-compliance. Although guidelines are not binding rules, they may acquire a binding character, in particular when they are incorporated in a contract or statutory law,

Box 8 – Legal aspects of guidelines : Example from Norway

The contents of the professional guidelines of the Norwegian Board of Health are not directly legally binding for the recipients. Guidelines can contain references to regulations and decisions that are compulsory. The contents are to be regarded as recommendations and advice. For areas in which the Norwegian Board of Health, according to acts and regulations, has authority to give binding orders to health services, these orders are given in the form of individual decisions or regulations.

This does not mean that the regulations and advice given in professional guidelines have no legal importance. In the professional guidelines, the Norwegian Board of Health often describes a practice or a procedure that must be regarded as reflecting generally accepted professional standards. In this way, the Norwegian Board of Health indicates what is a justifiable standard according to health legislation. Those who choose solutions that differ to a substantial degree from the recommendations in the guidelines must be prepared to document and substantiate their choices. There are several examples which show that the Norwegian courts, in their evaluation of whether an action has been taken with due care, or whether an action is justifiable, have taken into account the norms for acceptable practice that have been formulated in guidelines.

Box 9 – Guideline implementation : Romania as an example

The dissemination and implementation of guidelines in Romania are closely related activities. The most common form of dissemination, and that usually undertaken by the developer of the guideline, is through publicity to clinicians, health authorities and consumers, to inform them of the availability and content of the new CPG. This may be supplemented by seminars and presentations to learned societies, etc. Initial dissemination of CPGs is often of the primary guideline, which is generally not immediately useful to most clinicians or administrators because of its size and comprehensiveness.

The implementation phase of the guideline process is carried out by individuals, professional groups, institutions and health service managers who implement the guidelines by ensuring that systems are put in place to support the practices recommended by the guidelines. These implementation processes cover a wide range of activities:

- individual clinicians can adopt the practices recommended in the guidelines;
- development or adaptation of the guidelines for use by consumers;
- professional groups can incorporate the recommendations into education and training courses, and into peer review activities;
- together with professional groups, hospitals and health services can adapt the primary guideline to provide flow charts and diagrams to provide ready access to the relevant sections of the CPG to clinicians; they can review drug formularies and diagnostic practices and equipment to ensure that available resources support guidelines implementation; care pathways based on the guidelines can be developed and necessary organisational changes made;
- on the basis of the recommendations in the CPGs, health service managers and funders can review the organisation of services and the funding arrangements to ensure that they encourage and do not impede the implementation of the guidelines;
- information systems at the clinical and health service level need to be reviewed to ensure that sufficient information on the quality of care and health outcomes resulting from guideline use will be to contribute to the review and modification of the CPG at the end of its scheduled review period. Information systems that support the review process would also assist in identifying variations in care quality.

An important part of any credible guidelines implementation strategy will have to be explicit consideration of the information systems issues – without it, the monitoring and evaluation will be significantly impeded.

either directly or indirectly (through reference). Even in such cases, non-compliance should not automatically lead to sanctions.

Guidelines are no substitute for sound professional judgement. However, when a physician does not act according to a guideline, she/he must be able to offer good reasons for it. If the patient is harmed, she/he may need to justify her/his decision in court. On the other hand, compliance with a guideline does not protect the professional from liability, especially if she/he should have realised that actions promoted in the guideline would not have had the desired effect in particular circumstances.

Guidelines are translated into practice through the interplay of scientific and political decisions. While it is essential that guidelines be developed using a strict scientific procedure, it is equally imperative that society can incorporate its value judgements and preferences at various stages in the process. The choice of guideline topics, for example, needs both scientific and health policy input. Health care organisations and their funders typically want to participate in choosing which guidelines should be actively implemented first. And finally, the implementation of any guideline requires work at the frontline, in wards and departments. The care processes that might most benefit from changes toward best medical practice may not be those that the health workers see as most needing changes. In Box 10, the responsible actors and their domains of guideline implementation work are shown as an example of how the scientific and policy work can be divided.

Decisions about guideline implementation are taken at many levels. Nationally, decisions about which guidelines will be produced depend on the public health significance of the topics, national health priorities, etc. When guidelines are produced, scientific quality and professional involvement are mandatory bases for choices. At regional and local levels, decisions to implement guidelines also include structural factors, such as manpower, available skills, equipment, distances, and other realities of resource use. And finally, the patient may have an opinion.

The roles of the various actors can be illustrated with an example of a patient group, men suffering from advanced benign prostatic hyper trophy. In Finland, a guideline for this disease includes an economic evaluation. According to the Finnish study, the two available forms of

treatment are both highly effective, while the cost of an operation for this disease is comparable to the cost of treating it for fourteen to twenty-four months with medication. Moreover, the operation cost is carried mainly by the local community, while medication costs are paid by the state health insurance scheme. The choice of whether to offer an operation as a first-line treatment for these patients will not only depend on which treatment is most effective. The availability of operation theatres and skilled surgeons and the need to use these resources for treating other health problems may be decisive regionally.



Regional treatment programmes – based on the guideline – can then be built to agree about a new division of labour between general practitioners and surgeons, giving primary care more responsibility for diagnostic procedures and early treatment to free resources at the central hospital for operations. A practical decision-supporting device can be used to present the patients clear, comprehensive information about the benefits, risks and side effects involved in each treatment. After all, it is the patient who has to live with the results: does he prefer to get up several times at night, to wear a diaper for urine leaks, or to suffer from drug- or operation-induced impotence?

4. In implementing guidelines, the best interest of the patient should be served and professional responsibility and patients' rights should be respected.

Health care decisions must always serve the best interest of individual patients, within the limits of scientific knowledge and the ubiquitous resource constraint. Guidelines can be a strong asset in this by providing the necessary information for the discussions between the patient and the professional.

In many cases, the standard approach recommended in a guideline may not appeal to the patient, who together with her/his doctor may choose a different solution to her/his health problem. Such informed dissent can mean choices to have more or fewer diagnostic or treatment procedures than suggested in a guideline. A 75-year-old nurse diagnosed with invasive breast cancer, for example, refused an operation and treatment with cytostats. Her choice was to select a life that perhaps would be a few months shorter, but would leave her mobile and independent, over a period of aggressive weekly treatments and unpleasant side effects.

Decisions to deviate from guideline recommendations, and the reasons behind them, should always be registered clearly in the patient record. It is always the responsibility of the health professional to inform the patient about the available options for diagnosis and treatment, and to respect the patient's values while striving toward a joint decision.

5. *Guidelines must become an essential element in the undergraduate and clinical training of health care professionals as well as in the continuing professional development of health care teams*

To promote implementation of guidelines, they should be actively used in training health professionals. Participation in CPG development and implementation can be part of the requirements of, for example, continuing medical education, and specialist qualifications can include questions and practical checkpoints to ensure knowledge and coherence with the recommendations of guidelines.

The use of small-group methodology and problem-based learning approaches may be useful to adjust national guidelines to local conditions and to inform local health personnel about the recommendations. In the implementation process, local opinion leaders should be actively used to persuade their allies into practices that correspond to the advice in the guideline.

Evaluation of guidelines and of their impact

1. *Tools for evaluating the quality of existing guidelines should be used to decide which guidelines should be implemented*

Not all guidelines are valid or even useful. Using bad guidelines may do more harm than good. When health policy makers, professionals or other service providers start choosing guidelines for implementation, they need to ask several questions about the quality of the guideline. Many of these have been covered in previous chapters. The Agree checklist for determining the quality of the guideline development methods was referred to earlier (Chapter 3, Box 4).

In health care organisations, it is seldom possible to introduce more than a few guidelines at a time for implementation. Applying a new guideline into daily practice takes time and effort. Especially when guidelines are being used for the first time, a guideline should be selected that features both an evidence-based content and a previously successful use in practice.

2. *Well-planned monitoring of guideline effects is essential, and especially the impact of guidelines on health outcomes needs further development and evaluation*

Guideline implementation has been demonstrated to have positive effects in several studies, but the size of the effect varies and is often quite

modest. When applying guidelines in new situations and environments, there may be unforeseen factors that enhance or prevent the application of the guideline. A process evaluation for all new guideline implementation projects is therefore recommended. In addition, for health policy reasons, it is useful to gather data on the effects of the guideline.

It is much easier to evaluate the success of the implementation of a guideline on process factors and other surrogate markers than it is to show actual benefits on clinical outcomes. Even intermediate health outcomes (for example, measurement of blood glucose levels in diabetes) may be difficult to collect in a systematic, comparable fashion. True health outcomes often take a long time to become obvious. To measure the effect of the implementation of a diabetes guideline by showing a decrease in diabetes-related deaths would require following thousands of patients over several years, including a control group in which the guidelines are not being used. The evaluation of such an intervention would be complicated, as the control group is likely to benefit from the information in the guideline over time. It is also otherwise difficult to conduct such studies properly. Even ethical issues are difficult to avoid, as control patients would be denied treatments for which there is a strong evidence base.

3. Guidelines can include a list of essential indicators that can be used for evaluating the results of guideline implementation

To monitor guideline effectiveness, high-quality criteria are needed. As discussed above, such criteria are difficult to measure. It seems even more difficult to develop and validate good criteria that would be :

- easy to measure ;
- available from regular records ;
- comparable between units ; and
- indicative of true health outcomes.

When developing evidence-based guidelines, however, the content experts often formulate and select essential points of action : which basic questions about diagnosis, treatment, and follow-up should be answered in order to write a good guideline? Logically, these answers should include data for developing a criterion for acceptable levels of care.

Some guideline development groups are required by the development methodology to include useful indicators or groups of indicators (minimum

data sets) that could be used to evaluate the effects of the guideline (see Box 10). The methods of developing and validating such tools require extensive information about the results reached in everyday practice and multiprofessional expertise. They should not be formulated lightly or without empirical data. Indicators facilitate both self-assessment and comparisons with other care providers but require the most careful interpretation because of confounding factors such as case mix.

4. *An internationally co-ordinated research network should study the methodology of guidelines evaluation and impact monitoring, including the impact of guidelines on the learning process and medical knowledge of professionals*

Box 11 – Indicators in national guidelines

The national guidelines in Sweden include a number of indicators that can be used for evaluating the intermediate and true health outcomes of the interventions. Obviously, these indicators do not only measure the actual impact of interventions recommended in the guideline. Other factors such as lifestyle, compliance, and general conditions in society also have effects that are difficult to separate from health care effects.

In order to be able to follow some of these indicators, the Swedish Medical Board funds a number of National Quality Registers. These provide a knowledge base for some of the national guidelines and serve as a tool for benchmarking and for evaluating health care quality in general.

Suggested quality indicators for the structure and process of care of patients with coronary heart disease complicated by arrhythmias are:

- Resuscitation: plan for training, diffusion
- Contact with quality registers (CVD (electrocardiology), pacemaker and defibrillator registers)
- General electrocardiology: availability of cardiologist specialist
- Specialised electrocardiology: patient volumes and specialty levels

The quality indicators for health outcomes are available from the registers and include mortality as well as several diagnostic and therapeutic interventions.

Updating

1. *The guideline production process must include clear policies and responsibilities on guideline updating*

Guidelines must be regularly updated, as technological advances, new drugs and studies providing new data on effectiveness abound. For example, the introduction of magnetic resonance imaging has dramatically changed the diagnostic process in many health problems, and guidelines written before the widespread use of this diagnostic technology are outdated.

The optimal interval for updating may vary according to the topic and other factors. An interval of five years may be sufficient. However, such a long interval requires that there is a possibility of quick partial updating of the guideline in case a dramatic new innovation changes part of the guideline. The minimum requirement for any guideline is that it should state a best-before date, that is, it should give a time limit after which it can no longer be considered valid for application.

Updating is easiest when the original production process has been systematic. Literature searches and the strategies used to find answers to specific questions can be saved and then used again: for updates, the searches then only need to cover the period after the previous guideline issue. Even when updating methodologies are well structured, it is essential that the guidelines group monitors what is happening in their field and recognises any significant new breakthroughs.

If a guideline has been controversial, and especially in cases where the data for some of the issues has been of low quality or otherwise insufficient, it may also be necessary to provide a discussion channel for guideline users and critics. Optimally, this process has been part of the guideline production process and continues in an open and scientific fashion throughout the guideline's life cycle. If the discussion brings up strong controversial opinions, an update may be best produced using some type of consensus procedure involving all schools of thought and central critics.

Guideline review processes should be as clear and well-planned as the original production process. The same elements are needed: systematic search, critical appraisal, statement formulation, field test or comment

round and new implementation. There is as yet very little data on how guideline updates are received and implemented, and research in this area is necessary.

A guideline revision may be a completely new guideline or an appendix to an old one. It is essential that users are aware of the possibility of different versions of guidelines circulating. A best-before date helps in preventing confusion. Electronic publishing and distribution through the Internet offers one practical solution.

Chapter V – Further practical, social, ethical and legal issues

Terms of reference 5

Identify the practical, social, ethical and legal conditions for implementation of such guidelines in daily practice

Many of the practical and legal issues have already been discussed in earlier chapters. For example, those aspects relating to the use of guidelines in court cases are covered in Chapter 2, their significance in guideline development in Chapter 3, and in implementation in Chapter 4. Here the remaining questions are gathered and discussed.

According to well-established definition, practice guidelines are developed to also assist patient decisions about appropriate health care. When clinical practice guidelines are available to patients and the general public this will increase their opportunities to participate in decision-making and feel a true involvement in health matters. This provides a useful tool in the allocation of community health resources. Ideally, guideline production processes should involve patients, their family members, patients' organisations and the public at large. Issues of access and patient empowerment are pivotal and fundamental. However, conflicts may arise on what the evidence actually is and how it is interpreted and applied in specific, individual cases.

In medical decision-making medical knowledge is linked to practical circumstances and values. Especially when knowledge is incomplete or includes many uncertainties, the significance of value judgements increases. Values may include quantifiable health values such as death or permanent disability, monetary values, or less easily measurable values such as autonomy, satisfaction, or equal opportunities. The values

considered can either be explicitly expressed or remain implicit and are usually a mix of those held by professionals, patients, other interested parties, or society at large.

Clinical judgement is a complex process. Depending on their education, experience, cultural roots and personal characteristics, health professionals as decision makers can use several approaches to solve the problems of their patients. This approach can be chosen partially rationally and partially intuitively and can be explicit or implicit. Explicit and quantitative decision-making means that the underlying problem is reduced into its components; answers to each component are searched, and then recombined to a decision. The data required to make such informed decisions, the uncertainties, and the timing of the choices should be identified and quantified where possible.

Decision analysis should also identify the alternative actions and consider all valued outcomes. There are frequently unavoidable trade-offs between attainable levels of health status and required resources. Guidelines can help health personnel to deliver services according to the best available knowledge. Guidelines can hinder undocumented practice and prevent disagreement between different professions and levels in the health care system. Ideally, they can help society to deliver services according to health care needs, within available resources.

Guidelines limit clinical freedom to a certain extent. Publicly paid systems should not allow a medical practice which is undocumented, unsafe or more expensive than necessary. Patients' rights and wishes to undergo investigations or treatments must be respected. It is important that any ethical decisions are made explicitly and are open to public debate while guidelines are developed.

If guidelines are to be helpful not only to doctors but also to patients, they should not limit the possibilities to provide the treatment which is most suitable in the individual case, and should not simply be imposed on professionals by hospital management or third party payers. That would result in a standardisation of care that leaves insufficient room to do justice to the needs of each individual patient. Neither are guidelines a simple tool for allocating scarce resources at the population level. It is fundamental that evidence is kept separate from practical and political decisions. It follows that social priorities should neither influence the

evidence-based content of guidelines, nor should insurers use them as a back door for introducing rationing and cost-containment only. The notion of “good practice” should not be abused by serving other purposes than the best interest of patients.

Guidelines can have a positive bearing on the communication between doctor and patient. The quality and effectiveness of the information process may be improved since a guideline will structure the different steps, rank the relevant alternatives and indicate one or more of them as the appropriate course of action. At the same time, guidelines should not deprive patients of their right to be informed about reasonable and realistic medical alternatives, as well as of the option of doing nothing. If such alternatives exist or if they are not included in the guideline, the patient should be informed, and the doctor should take into account preferences expressed by the patient unless this would be in conflict with the professional standard.

Particularly in a situation of uncertainty, patient's wishes and preferences should be seriously considered. When best possible care for an individual patient does not clearly manifest itself in the professional standard as elaborated in the guideline, the voice of the patient carries more weight. A guideline may also be inapplicable to certain sub-groups of the population, as their health problems may manifest themselves to a more or less severe extent or require a different type of treatment than usual.

Expected benefits from guidelines are counterbalanced by a number of perceived problems. These include the high number of guidelines of variable quality, formats that are far from being user-friendly, inaccessibility, difficulties of integration into daily care processes, concerns about the applicability of CPGs to different environments, and the resource implications both of developing and implementing CPGs.

Both health professionals and patients need to be aware of the legal implications of adhering to or not following guidelines. As the role of guidelines in legal proceedings differs from country to country, it is essential that at least guideline programmes and clearing houses clarify the legal conditions of implementing guidelines in general to their potential users.

Similarly, many issues in guideline development and implementation are closely linked to the social, political, and health care systems in each country. For example, questions of regional equality or shortage of professionals may create a need to modify guideline implementation. It is impossible to design an optimal model of guideline production and use that could be transferred as such to all circumstances. Many of the basic principles of guideline development are, however, so well established by both scientific evidence and practical experience, that they should be utilised as the cornerstones of guideline construction and use.

Chapter VI – Guidelines and standards

Terms of reference 6

The essential requirements with which norms and standards for best medical practices have to comply and the assessment of their effectiveness

The vocabulary used in clinical practice guidelines and best medical practices includes many concepts that are vaguely defined and difficult to agree on. There is the further complication that many European languages use very specific terminologies. A word carrying one clear meaning in one language may signify something quite different in the neighbouring country. Words can have different nuances, for example in relation to exactness, burden of responsibility and legal significance. It is therefore necessary for all those who want to develop and implement guidelines to examine the use of different terms in their own social and language context.

Guidelines and other health care policies can be thought of as generic decisions – recommendations intended for populations or groups of patients rather than for a single patient. This generates an effect of uncertainty. Individual variability adds to the complexity of setting the policies. Both factors together introduce a third factor into the health policy process – the need for flexibility.

When the outcomes of an intervention are uncertain or variable, or when patient preferences are not exactly known or vary considerably, health professionals must be given flexibility to tailor their approaches, albeit based on a common policy, to suit individual cases. This need is addressed by having three types of policies according to their intended

flexibility: guidelines, options and standards. In this explanatory memorandum, the committee of experts has used these and other central terms in a very specific meaning as follows.

Clinical practice guidelines (CPGs), as defined by the Institute of Medicine (1992), are systematically developed statements to assist important practitioner and patient decisions about appropriate health care for specific circumstances. CPGs are intended to be flexible. As discussed in earlier chapters, and depending on the patient's health problem and other characteristics, guideline recommendations can and should be tailored to fit individual needs. Deviation from a guideline does not by itself imply malpractice. A guideline may, for example, recommend penicillin as the drug of choice for certain infections, but give an option of using other antibiotics for patients who are allergic to penicillin.

Evidence-based guidelines are produced using the available best evidence, with a systematic literature search and review, and are updated regularly or have a designated last day of use.

Available best evidence may consist of results of randomised trials, systematic reviews, qualitative studies, or other types of information, depending on the clinical question. If evidence is conflicting or absent, statements about essential care can be agreed on by expert consensus, obtained by one of the formal methods such as Delphi.

Options are neutral with respect to recommending the use of an intervention. They merely note that different interventions are available, and different people make different choices. In the treatment of benign prostatic hypertrophy, for example, the choice between an operation or the use of a hypertrophy-decreasing drug may be strongly influenced by what types of side-effect risks the patient can accept.

Standards in many countries imply that they are intended to be applied rigidly and must be followed in virtually all cases in a defined medical situation. Other terms for standards are "rules", "strict" indications or contraindications, "strict criteria", "protocols" and "appropriate or inappropriate practices". The rule to always cross-match the suitability of blood for the patient before transfusion is an example of a standard.

However, the term “standard” may be applied in different ways in medicine. It is occasionally used in the sense of a “norm”. Alternately the term is also applied to the definition (quantification) of objectives (average quality, model, standard of living). In this sense, standards define the exact quantity, the degree of fulfilment of a criterion for an adequate, acceptable and optimal level of quality. The standard indicates which objective one regards as being achievable and also wishes to achieve, or the objective which should be set.

Norm is a document that has been reached by consensus and accepted by a recognised institution. It defines characteristics of activities or their results that are aimed for. Norms should always be based on the dependable results of science, technology and experience, and should promote optimum advantage to society.

Indicator is a quantifiable measure of the health care process or outcome that describes the level of some criterion of care.

Integrated care pathways are agreements that describe the division of work in taking care of a defined group of patients within a geographical area (regional) or institution (local). These may or may not be based on CPGs.

Good clinical practice consists of a set of interventions that are based on best available evidence and have scientific proof of effectiveness (best medical practices); in addition, these interventions are acceptable to the patient, ethically sound, and feasible with available resources.

Appendix 1

Guideline programmes and clearing houses

Website addresses for agencies producing guidelines or keeping stock of guidelines produced by others. Updated in July 2000.

Austria

Bundesministerium für soziale sicherheit und generationen

www.bmsg.gv.at/

Health Technology Assessment Unit at the Institute of Technology Assessment

www.oeaw.ac.at/ita/hta/

Belgium

Public Health Medibel-net

<http://health.fgov.be/>

Sites of the Belgian ministry of Social Affairs, Public Health and the Environment

www.minsoc.fgov.be/en/index.htm

Denmark

Statens Institut for Medicinsk Teknologivurdering

www.dihta.dk

Finland

FinOHTA

www.stakes.fi/finohta/e

Medical Society Duodecim (National clinical guidelines)

www.duodecim.fi/kh/

France

Agence nationale d'accréditation et d'évaluation en santé (ANAES)

www.anaes.fr/ANAES/anaesparametrage.nsf/

CHU de Rouen, Répertoire des lignes directrices de pratique médicale & tables rondes consensus francophones

www.chu-rouen.fr/ssf/recomfr.html

Institut national de la santé et de la recherche médicale (Inserm)
www.inserm.fr/servcom/servcom.nsf

Ministère de l'Emploi et de la Solidarité (recommandations)
www.sante.gouv.fr/htm/recherch/index.htm

Unions régionales des médecins libéraux. Les conférences de consensus
et recommandations de l'Andem
www.upml.fr/andem/andem.htm

Germany

Association of the Scientific Medical Societies (AWMF)
www.awmf-leitlinien.de

German Guidelines Clearinghouse/Agency for Quality in Medicine, Cologne
www.leitlinien.de

Ireland

Department of Health and Children
www.doh.ie/cgi-bin/search/searchdohc

Italy

Agenzia per i servizi sanitari regionali Programma Nazionale per le Linee-guida
www.assr.it/lguida/index.html

Gimbe, Gruppo Italiano per la Medicina Basata sulle Evidenze
www.gimbe.org/Link/Linee-guida.htm

Istituto Superiore di Sanità
www.iss.it/scientifica/pubblica/lineguida/comnaz.htm

Netherlands

De federatie Koninklijke Nederlandsche Maatschappij tot bevordering der
Geneeskunst (KNMG) Artsennet
www.knmg.nl

Dutch Institute for Healthcare Improvement Overzicht Medische Richtlijnen van
het Kwaliteitsinstituut CBO
www.cbo.nl/richtl/overzicht2.htm

Dutch College of General Practitioners
www.artsen.net

Norway

Senter for medisinsk metodevurdering
www.oslo.sintef.no/smm/index.htm

Statens helsetilsyn
www.helsetilsynet.no/

Poland

Centrum Monitorowania Jakosci w Ochronie Zdrowia (CMJ)
Centre for Quality Monitoring in Health Care
<http://quality.cmj.org.pl/standardy/standardy.htm>

Spain

Agencia d'Avaluacio de Tecnologia i Recerca Mediquea
<http://www.aatm.es/>

Ministerio de sanidad y consumo, Guias de practica clinica
www.msc.es/

Sweden

Socialstyrelsen, Medicinsk faktadatabas
www.sos.se/mars/rktflik.htm

Statens beredning för medicinsk utvärdering
www.sbu.se/

Switzerland

Swiss Medical Association

United Kingdom

Centre for Evidence-Based Medicine NHS
<http://cebmr2.ox.ac.uk/>

The Health Evidence Bulletins – Wales
<http://hebw.uwcm.ac.uk/>

NHS Centre for Reviews and Dissemination
www.york.ac.uk/inst/crd/welcome.htm

NHS R&D Health Technology Assessment
www.hta.nhsweb.nhs.uk/

UK-Medical Portal, Collection of British Guidelines
www.medic8.com/ClinicalGuidelines.htm

The Royal College of Physicians
www.rcplondon.ac.uk/pubs/index.html

The Scottish Intercollegiate Guidelines Network (SIGN)
www.sign.ac.uk

United States

AHRQ National Guidelines Clearinghouse
www.guidelines.gov

Appendix 2

Examples of levels of evidence in guidelines

(From AHCPR and SIGN (See references for sources))

Statements of evidence, AHCPR

- 1a Evidence obtained from meta-analysis of randomised controlled trials (RCTs).
- 1b Evidence obtained from at least one RCT.
- IIa Evidence obtained from at least one well-designed controlled study without randomisation.
- IIb Evidence obtained from at least one other type of well-designed quasi-experimental study.
- III Evidence obtained from well-designed non-experiential descriptive studies, such as comparative studies, correlation studies and case studies.
- IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

Grades of recommendations, AHCPR

- A Requires at least one RCT as part of a body of literature of overall good quality and consistency addressing the specific recommendation.
(*Evidence levels 1a, 1b*)
- B Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation.
(*Evidence levels IIa, IIb, III*)
- C Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality.
(*Evidence level IV*)

Scottish Intercollegiate

Guideline Network (SIGN) levels of evidence and grades of recommendations

Levels of evidence	
1 ⁺⁺	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1 ⁺	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 ⁻	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2 ⁺⁺	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2 ⁺	Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2 ⁻	Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, eg. case reports, case series
4	Expert opinion
Grades of recommendations	
A	At least one meta-analysis, systematic review, or RCT rated as 1 ⁺⁺ , and directly applicable to the target population; <i>or</i> A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1 ⁺ , directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2 ⁺⁺ , directly applicable to the target population, and demonstrating overall consistency of results; <i>or</i> Extrapolated evidence from studies rated as 1 ⁺⁺ or 1 ⁺

- | | |
|---|---|
| C | A body of evidence including studies rated as 2 ⁺ , directly applicable to the target population and demonstrating overall consistency of results;
<i>or</i>
Extrapolated evidence from studies rated as 2 ⁺⁺ |
| D | Evidence level 3 or 4; <i>or</i>
Extrapolated evidence from studies rated as 2 ⁺ |

References and further reading

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