COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

**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 clearinghouses 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.