

The development and implementation
of quality improvement systems (QIS)
in health care

Recommendation No. R (97) 17
and explanatory memorandum

Health and Society

**The development and implementation
of quality improvement systems (QIS)
in health care**

**Recommendation No. R (97) 17
adopted by the Committee of Ministers
of the Council of Europe
on 30 September 1997
and explanatory memorandum**

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Recommendation No. R (97) 17

of the Committee of Ministers to member states on the development and implementation of quality improvement systems (QIS) in health care

*(Adopted by the Committee of Ministers on 30 September 1997
at the 602nd 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;

Considering that receiving health care is a fundamental right of every individual and each community;

Bearing in mind Article 11 of the European Social Charter on the right to the protection of health;

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",

Noting that continuous improvement of this quality of care is a key priority for all member states, particularly in a situation of economic restraints and reduced budgets in health care;

Considering that good quality care covers:

- structural and organisational aspects of care provision, such as accessibility;
- process aspects such as professional excellence and efficient use of resources; and
- good outcome to the care;

Considering that the outcomes in terms of patients' health, well-being, and satisfaction are particularly important;

Considering that users should necessarily participate in their own health care and recognizing that health professionals should provide them with complete and clear information;

Considering that it is necessary for each member state to promote the general education of the public about problems of health, health promotion, and disease prevention and disease management methodology;

Considering that ensuring quality health care is an obligation of all member states and demands planned, systematic and continuous attention and action, as well as the mobilisation of all the actors, including researchers;

Considering that a multitude of research results demonstrate the importance of iatrogenic risks, both medication and non-medication related, which arise in the practice of medicine;

Considering that quality improvement in health care is a relatively new field and so far not fully developed,

Recommends that the governments of the member states create, where appropriate, policies and structures that support the development and implementation of "quality improvement systems" (QIS), that is, systems for continuously assuring and improving the quality of health care at all levels, according to the guidelines in the Appendix set out hereafter.

I. Dimensions of quality improvement systems

A. *Procedures and processes for quality improvement*

1. The following essential features of quality improvement systems should be implemented:

- identification of quality problems and successes;
- systematic collection of data on care provision;
- standards and evidence-based guidelines for high-quality, cost-effective care;
- implementing necessary changes by effective mechanisms and strategies;
- measuring the impact of changes;
- exploiting best practices.

B. *Organisation of quality improvement*

2. Such systems should be set up at all levels of care provision: individual care providers, health practices, hospitals and other health institutions in agreement with each other. The same requirements for health-care quality assurance should be established in all public and private health institutions.

C. *Responsibilities: the actors in quality improvement*

3. All the different parties involved in health care (providers, patients, funders, managers, and authorities) need to participate in setting up and maintaining these quality improvement systems in close and continuous co-operation.

4. Health-care providers should themselves develop, set up, and maintain quality improvement systems adapted to their health-care settings and make these systems transparent to others.
5. Funders should contribute to quality improvement by requiring the establishment of quality improvement systems in their contracts with practitioners, hospitals, and health-care organisations.
6. Health policy makers should create the necessary framework for policies, laws, and regulations concerning quality, accompanied by appropriate evaluation and updating procedures.
7. Managers in health care should assume leadership in setting up such systems in their organisations.

II. Key issues in QIS: general principles

A. *Practice guidelines*

8. Guidelines should be developed systematically, disseminated effectively to professionals as well as the public, and their effects monitored.

B. *Technology assessment and quality improvement*

9. Health care should be improved by applying methods of evidence-based medicine and utilising the results of technology assessment in decision making, directing appropriate attention to laboratory quality assurance.

C. *Quality indicators and information systems*

10. Health-care information systems should be set up using relevant care and process quality indicators and allow for timely production, feedback and reliable comparisons of health-care data. In all cases, individual patient data must be kept confidential.

D. *The patient's perspective*

11. Information on the needs, priorities, and experiences of patients at all levels of care provision should be gathered through appropriate methods ensuring the active participation of patients.

E. *Managing change*

12. Quality improvement systems should include effective mechanisms and strategies:
 - for achieving necessary changes in a planned and managed way;
 - for involving all the actors in care processes and decision making, in particular, patients.

III. Conditions for implementation of QIS

13. The necessary conditions should be created, in accordance with each member state's legal and political systems, for setting up and implementing quality improvement systems, namely:
 - support structures such as agencies, boards, committees, and networks;
 - making full use of available resources and, where necessary,

providing resources and specific financing mechanisms for quality assessment, assurance, improvement and development;

- pre- and postgraduate education for health-care providers to gain knowledge of, and acquire skills in, quality assessment and improvement systems;
- appropriate incentives for participation in quality improvement.

IV. Evaluation of QIS

A. Public accountability

14. Public accountability of quality improvement systems should be examined through objective external assessment by independent bodies and appropriate communication of the results.

B. Feedback

15. The results of external assessment should be used to support continuous internal evaluation and improvement.

V. Research and development

A. National efforts

16. All necessary measures should be taken to promote research into, and development of, quality improvement.

B. European co-operation

17. Exchange and co-operation in quality improvement at the national as well as at the European level should be encouraged. Quality issues should be included into European co-operative initiatives (for example data exchange and handling).

Explanatory memorandum

General considerations

Quality is an essential and indispensable component of health care and is a normal attribute of each health care activity, along with volume and cost. Good quality patient care is a right of every patient and community and has become a priority for all member states, especially in a situation of limited resources and budgetary restrictions.

One of the priority aims of national health policies and of the World Health Organisation (WHO) is the promotion of quality of care in terms of equal access to care, quality of life and user satisfaction, and cost-effective use of resources. It is legitimate for societies to expect a systematic and rigorous evaluation of care in order to know whether health resources are used appropriately and to achieve provision of the best possible quality of care.

There are many reasons that militate in favour of a policy of quality development. At the ethical and social levels, there is an increasing demand for empowerment of patients, thereby securing their rights as citizens and as patients to influence their care and to receive information. Similarly, the public and the health-care authorities expect greater accountability of health-care service organisations and of the health-care professions. At a professional level, health-care providers have always endeavoured to deliver the best care possible and have a great interest in improving their performance through evaluation. They are aware of the uncertainties that persist in the field of health-care, of the variations in practice, of the rapid development of medical knowledge and of an increasing demand for evidence-based medicine. At an economic level, with a growing share of the gross national product devoted to health, European countries have limited opportunities to ensure high quality and to afford constant improvements in medical technology. They must use resources appropriately. Managers of hospitals and primary care settings are also concerned with maximising

the opportunities for the provision of a high standard of care in a cost-effective manner.

Quality improvement systems: general principles

Health-care practices and institutions have the responsibility to assure and improve good quality of patient care systematically through what is referred to as "quality improvement systems" (QIS). These can be seen as a collection of procedures, measures and actions aimed at assuring that patient care meets specific criteria now and in the future. These procedures and actions are concerned with the complete care provision process, from identifying a health-care need in a patient to the outcomes of actual care. Such systems have two functions, one internal and one external. For the care providers, the practices or health-care institutions, they are a tool for continuous learning about and improvement of care. Self-assessment and internal evaluation are crucial for this goal. For society, the public, patients, funders and policy makers, the systems demonstrate how a care provider, a practice, a team or a hospital manages quality improvement. This demands external evaluation of the system. The structural and systematic character of the quality improvement activities is crucial in such a quality improvement system. It is equally crucial that the system is feasible, acceptable for the users and accessible to others involved.

1. *Definitions*¹

We may define a quality improvement system as a “set of related and planned activities and measures, at various levels in the health-care organisation, aimed at continuously assuring and improving the quality of patient care”.

To explain the various elements of this definition :

¹ See the definitions of terms in the "Glossary"

- a. Activities and measures : the system is dealing on the one hand with all the steps in a quality improvement cycle (identifying problems in the quality of care, data collection and assessment of care, setting guidelines and criteria, improving care) and on the other hand with managing the quality improvement well (by creating the necessary structures, policies and conditions for it).
- b. Related and planned: the various activities are linked to each other; they are well prepared and well based, they have clear aims and use effective tools and strategies.
- c. At various levels in health care : the activities should be performed and managed well at various levels, at a central level (leadership) as well as at decentralised levels (hospital, local committees, practices, teams, units, individual care providers) and both in primary and secondary care.
- d. Continuously : quality improvement is undertaken as a continuous process. On the one hand, this implies that important aspects of care are continuously checked for quality and improved when needed. On the other hand, it means that new aspects are continually selected for quality improvement. It is built in and integrated into normal care processes.
- e. Assuring and improving : this means various things: continually checking whether patient care meets quality criteria, maintaining good quality where it exists, identifying good practices (benchmarking), changing practice when required, implementing clinical research and medical technology assessment results in practice, introducing (new) valuable procedures, techniques and guidelines, etc.
- f. Quality of patient care : aspects of the structure (organisation, staff, etc.), process (performance) and the outcomes of care (health status, quality of life, satisfaction, costs) should all be assessed and improved when needed. Opinions from various parties (care providers, patients, funders, authorities) on good quality of care should be included in quality assessment and improvement activities.

The governments of the various member states should create the necessary policies and structures to support the development and implementation of such quality improvement systems and take care to ensure that the different parties in health care all take their responsibility in achieving this.

2. Features of quality improvement systems (QIS)

The concrete quality improvement systems may vary between countries, because of their current organisation of health care and their history in quality improvement. Systems for quality improvement may also differ between hospitals, health-care institutions, primary care, health centres and single-handed ambulatory care practices. However, some general features are common to the different quality improvement systems.

Systematic quality improvement is based on the following principles:

- a.* Recognition of the great diversity between member States with regard to their level of development of quality policies.
- b.* A preventive approach to quality, taking into consideration proactive measures at the early stages of developing policies, in planning of the organisation and delivery of health care.
- c.* Patients' needs, opinions, and experience of all aspects of their care (the structure, process and outcome) add invaluable information to systematic quality improvement and should be regularly used as feedback.
- d.* Systematic quality improvement must form a permanent, integral part of the daily work of all categories of staff.
- e.* Systematic quality improvement is a professional responsibility of the health care providers. This refers to the responsibility to determine a good level of care, considering the views of patients and the public. It also reflects the need to gain more insight into the current quality of their

work and how it is progressing. This insight provides an incentive for further quality improvement. Therefore, particular attention should be devoted to making available to them all the necessary tools for evaluation of their activities.

f. Systematic quality improvement must not be used in a punitive manner. The central focus is on the processes of care and service rather than on the performance of individuals. Experience shows that the quality of care is better promoted by strengthening health providers' opportunities for self-assessment and self-regulation rather than by imposing means of control and punitive measures.

g. Care processes often form long sequences of events involving various health professionals. Thus, the approach on quality improvement activities must be multiprofessional. The activities imply collaboration between the various health-care professions, and between the health and social sectors.

h. Systematic quality improvement is based on committed leadership. Managers at all levels are responsible for the establishment of organisational structures to ensure the incorporation of quality improvement into daily routines and to foster the staff's commitment to and involvement in the process.

i. The whole activity is based on a formulation of goals of the quality strived for. Quality goals should be set through a dialogue between health care providers, patients, and political and administrative decision-makers.

j. Rational choice of these goals should be in concert with the established health priorities of the national health policy, aimed at balancing marginal costs and benefits of all competing actions. It is particularly important in situations, where some goals of good quality are in mutual conflict, such as accessibility and efficiency in countries with small population density. In such a case decentralisation favours

more equal access, whereas economies of scale call for greater centralisation of services.

k. Systematic quality improvement is a positive approach. The aim is to identify the best results and to use them to improve practice as a whole, rather than to identify and eliminate poor outcomes. Nevertheless, when poor outcomes are identified, action should be taken to shift them towards the average or to eliminate them; for example, all cases of iatrogenic effects (medication and non-drug related) should be analysed with a view to acting accordingly.

l. Activities should be based on the collection of data and information and not on suppositions. Quality improvement activities must be based on scientific principles and methods as in traditional medical science.

Appendix to the recommendation

I. Dimensions of quality improvement systems

A. Procedures and processes for quality improvement

Every good quality improvement system consists of various interrelated activities, performed with effective and feasible tools. The activities performed are part of a continuous cyclic process integrated in daily work. Such a process is basically concerned with four related activities:

- identification and selection of areas needing improvement, and problem definition (through needs assessment and problem analysis using a variety of sources);
- setting or selecting guidelines, criteria or targets for good quality care (by consensus development, evidence-based setting of guidelines, local arrangements on care provision, identifying good practices, benchmarking, etc.);
- data collection on, and assessment of, actual quality of care (measuring actual care, determining variation, evaluating whether quality criteria have been met, etc): this may be done "internally" (by the care providers involved or institutions themselves) or "externally" (by others, such as patients, funders or specific organisations);
- performing change (by quality improvement strategies or programmes or by solving problems, evaluation of progress).

Quality improvement activities, the methods used and the steps taken in this cyclic process may differ according to the type of health care and the care provision setting (hospital care/primary care). A clinical chemical laboratory will, for instance, guarantee the quality of its procedures and test results by continuously or periodically evaluating the test values, studying whether these are within acceptable ranges, and intervening when this is not the case. A hospital unit team may first brainstorm on problems related to the organisation of specific care processes and then collect some data on the extent of the problem,

define good practice or set targets for improvement. It will subsequently try to solve the problem and, finally, measure whether the targets have been achieved. A health care organisation may develop a new clinical guideline for the management of a specific selected health condition, which presents problems in practice. A strategy for implementing the guideline, including a set of effective interventions, will be next developed and carried out, followed by an assessment on whether or not the implementation was successful.

These four basic activities may therefore be used in different orders and with different emphases, dependent on the specific goal and setting. Different methods may be used as part of each of these four basic activities.

B. Organisation of quality improvement

This is concerned with the good organisation of the various quality improvement activities and processes, involving the different parties in health care and creating supportive conditions for quality improvement at the different organisational levels in health care. Quality improvement should be well organised at the central level (country, district), the local level (hospital, local or regional organisation for home care, collaboration practices, etc), the unit level (practice team, hospital unit) and the individual level (individual health care provider).

Methods for organising quality improvement will differ at the various levels: for instance, continuous professional development at an individual level; practice visits or quality circles at a team level; total quality management (TQM) approaches at a hospital level; and evidence-based guideline development or professional recertification systems at a central level. Organising quality improvement also implies that activities at the level of hospitals and larger institutions for health care will differ from those at the level of small primary care practices and health centres. The resources, structures and policies relevant to the various levels differ. Individual professionals can be motivated to

participate in quality improvement by training them and providing them with (extra) time and money. Expert support to start improvement activities is crucial particularly at a team or practice level. At a hospital level one requires leadership and ability to set up committees and working parties; at a central level, it is important to have regulations and formal structures for maintaining the system and the motivation and involvement of all parties.

C. Responsibilities : the actors in quality improvement

A second feature of a QIS is the adequate involvement of the various interested parties in health care. A global distinction can be made here between health care providers/professionals, patients, funders and health policy makers and managers as the actors in quality improvement. Each party has a valuable contribution to make, based on its specific features and strength.

The role of the various parties in QIS should be defined as concretely as possible:

Health care professionals and institutions should set up "internal quality improvement systems" in which identifying quality problems, setting guidelines, assessing care and implementing change is primarily an activity of the profession or the institution itself. They should, however, make their internal system public and visible to other parties, not only the plans but also the results of the quality assurance and improvement activities and measures. This can be done in a regular "quality improvement report".

Patients, their well-being and protection of their health are the central focus of health care. Their perspective should be taken into account in the care delivery process and in the QIS. They should play a part in internal QIS, but may also - through their organisations - perform "external" evaluations of the professional, institutional QIS. Patient information (health-care needs, priorities, expectations, opinions, health status, quality of life, experience, complaints, satisfaction, assessments,

etc.) at all stages of care provision is very useful for the identification of quality problems, the setting of guidelines and the assessment and improvement of actual care. Such information should be collected regularly and systematically (through group interviews, surveys, observations, complaint procedures, etc.). Patient organisations will also be involved in external evaluations of professional and institutional QIS.

Funders should contribute to the internal QIS by providing data on specific aspects of care provision (for example, cost-effective performance, identification of dangerous or unnecessary services and procedures). Their main role will be involving the professional or institutional QIS in their contracts with care providers, hospitals, practices and health care provider organisations. They should also provide the necessary resources and budget for setting up such QIS in an effective manner.

Health policy makers and managers will be involved at a national and regional level as well as at the level of institutions and practices. Policy makers should create the necessary framework of laws and regulations for the underpinning of professional and institutional QIS as well as the support structure for it (committees, boards, facilitators, etc). Management teams in hospitals and health care provision organisations need to have an important leadership commitment to the setting up of QIS in their organisation. This will include setting up support structures, collecting the necessary data, providing education on quality improvement, providing specific staff for quality improvement and providing resources for quality improvement activities.

Conditions for quality improvement

A third important dimension of quality improvement systems is concerned with creating the necessary conditions for setting up, implementing and maintaining quality improvement. Actually, this is the management side of quality improvement. Such conditions are:

- *policies*: laws and regulations by health authorities; mission statements and policies by professional organisations; management teams of institutions creating a framework for quality improvement; etc.

- *structures*: forming committees and boards with a special responsibility for stimulating quality improvement activities etc; when necessary, committees responsible for determining the compatibility of the quality improvement systems and their instruments with ethical principles.

- *resources*: providing staff for specific quality improvement tasks; providing (extra) time and money for professionals and practices/teams; providing education on quality improvement and expert support for the implementation of quality improvement systems; providing tools for quality improvement (computers, databases, protocols and other materials); etc.

II. Key issues in quality improvement systems: general principles

A. Practice guidelines

Practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. The efficacy of guidelines in changing clinical practice and affecting patient outcomes depends on the methods that are used in their development, dissemination and implementation.

a. *State of the art*

The use and promotion of practice guidelines has increased rapidly in health care since the early 1980s. Many countries have launched programmes for the systematic development of guidelines. The Swedish Council for the Evaluation of Medical Technology (SBU) has a continuing process of producing guidelines based on the systematic reviews of relevant literature. Guidelines by the American Health Care and Policy Research Institute (AHCPR) are also evidence-based and a patient version is published together with the professional guidelines. The British National Health Service has a unit (Centre for Reviews and Dissemination, CRD) for producing and distributing systematic literature reviews.

The Dutch College of General Practitioners (Nederland Huisartsen Genootschap, NHG) uses a systematic process of producing and disseminating guidelines for primary care. The Finnish Medical Society Duodecim has developed for primary care the Physicians' Desk Reference and Database (PDRD) which can be used either in a computerised version or as a book. In addition to these systematic approaches, several countries have used consensus procedures to develop guidelines, especially in controversial areas.

Guidelines should first be developed in the most important areas, determined by the prevalence and the gravity of health problems and in accordance with the national health policy priorities.

b. *Effectiveness of guidelines*

Guidelines have been shown to improve the care process, but their effect on patient outcome is not very strongly established. Guidelines are more likely to have an effect if they are adjusted to suit local circumstances: national guidelines are better observed than international ones, and a regional or local adaptation of a guideline has an added effect conveyed by key persons who have participated in the adaptation process. Guidelines are also implemented more intensively when disseminated

with active educational methods (educational visits, opinion leaders), and when implemented in a way that brings the guidelines directly to the consultation (computerised patient-specific reminders). There is evidence that multiple interventions and computer-based decision support are also likely to affect practice.

Nationally set standards and consensus statements seem to have a limited impact on practice. Even if health care practitioners are well aware of guidelines and believe they are complying with the recommendations, the change in practice often remains minimal.

c. Quality of practice guidelines

The quality of guidelines depends on various factors. The process of developing guidelines must be systematic, transparent and include all stakeholders. The recommendations must be clear, written for well-defined clinical circumstances and populations, and based on the best available evidence.

Guidelines are more readily acceptable when the process of development includes input from both experts and future users of the guideline. A systematic literature review is a prerequisite for producing valid guidelines. The highest level of evidence provided by randomised controlled trials is impossible to find for every recommendation in a practice guideline.

Evidence obtained through other controlled studies, observational studies, or expert opinion must then be used. The users of the guideline appreciate that the scientific validity of the recommendations is stated in a clear and systematic manner. Exceptions to the recommendations should be identified in the guidelines.

The importance of the health problem targeted by the guidelines and the available health-care resources should be observed. In addition to considering the relative effectiveness of health-care interventions, guidelines should take into account the cost-effectiveness of the proposed interventions. Whenever new evidence of the issues covered

by a guideline appears, or when new health care technologies are introduced, the guidelines need to be reviewed. For this purpose, a systematic method of updating guidelines is needed. A further development of mathematical modelling and computer optimisation of the most cost-effective guidelines would depend on the availability of national and regional data bases.

To function as practical tools in health care decisions, guidelines should use a clear language and a user-friendly format. Optimally, the users of health-care services should have access to an easily understandable patient guideline as well as a more detailed professional version. For care providers, it is essential that guidelines can be easily found and quickly referred to during consultations.

d. *Implementation and monitoring*

The target groups of the guidelines should be carefully considered, and the methods used for the distribution of guidelines should support their adaptation. Patients and the media can be efficient promoters of guidelines. In optimal circumstances, guidelines become a natural part of quality improvement systems.

The effects of guidelines on the improvement of health care processes and especially on health outcomes should be monitored systematically. The knowledge gained from this monitoring is best used in the continuous process of updating and implementation of the practice guidelines.

Physicians have been concerned about the possibility of using guidelines in litigation processes. The question has been discussed in several countries. The common conclusion is that guidelines are unlikely to be used as a sole basis for evaluating negligence, unless they are so well established that no responsible doctor would fail to comply with the guideline. This is evaluated also against customary practice and the specific patient case. An open discussion of the status of guidelines in the medico-legal field is a necessary step in introducing guidelines in all

countries.

Some countries have experimented using guidelines in health care contracts. For this purpose, the guidelines need to include indicators of structures, processes, or outcomes of care; most guidelines do not

Quality aspects of guidelines development

1. The process of developing guidelines must be systematic, transparent, and include all stakeholders.
2. The level of evidence for the recommendations must be stated clearly, and a systematic effort to find the best possible evidence should be made.
3. The populations and the clinical circumstances where the guidelines are to be used should be defined.
4. Exceptions to the recommendations should be pointed out in the guidelines.
5. Guidelines should be useful, accessible, feasible, and understandable for both the professionals and the public.
6. Guidelines should take into account the cost-effectiveness of the proposed interventions.
7. Guidelines must be updated regularly and especially when new evidence or new technology have emerged.
8. Guidelines should be disseminated in a planned manner, through several media, and to both the professionals and the public.
9. The effects of guidelines should be monitored and results considered in the development and dissemination of guidelines.

contain indicators and the processes used for developing guidelines differ from those used for indicator development. Using guidelines in contracting should be done with the understanding that a separate agreement about quality indicators is usually necessary.

B. *Technology assessment and quality improvement*

Technology assessment (TA) is used for the evaluation of the effectiveness of health care methods. Both new and established methods for prevention, diagnosis, and treatment can and should be evaluated. The effects of many common interventions in health care have never been properly evaluated against a placebo or do-nothing option. When

the technology used during pregnancy and childbirth was evaluated by the Oxford Perinatal Research Unit, only a third of widely used interventions were clearly shown to provide a health benefit to either the mother or the baby. Most interventions lacked such evidence, and over 20% of the interventions were shown to be actually harmful to mother, child, or both.

Technology can be evaluated at three different stages: in the pre-market stage in selected patient populations usually in highly controlled environments (technical feasibility), in the early introductory stage, where it is used in selected settings for a wider population by skilled practitioners (efficacy), and in unselected populations and varying settings by practitioners whose amount of experience with the technology differ (effectiveness). A technology that functions well in optimal situations may turn out to be ineffective in real health-care situations. And finally, a question of economics (cost-effectiveness) can be asked: an effective technology may be so costly when compared to other options that it is unsuitable for wider use.

When the results of evaluations are used for quality improvement, it is often best to use the results from real-life settings (effectiveness). Instead of basing judgment on data from individual studies, systematic reviews are useful to accumulate the available information. Increasingly, TA includes economic analyses comparing the cost-effectiveness of different treatment options. Technology assessment can provide us with information about which methods should be used in what ways, but decisions can seldom be based on TA data alone. The data needs to be applied to the situations where it will be used, and value judgments are often needed. The results of TA can be incorporated into clinical guidelines.

Many industrial countries have established their own units for health care technology assessment. These units collaborate in producing and spreading information about the efficacy, effectiveness, and efficiency of health-care interventions. The international Cochrane collaboration produces and disseminates systematic reviews of the effects of health-care interventions and maintains their currency when knowledge increases. These efforts should be strongly supported, as they provide valuable information that can be used to maintain and increase the quality of health care.

C. *Quality indicators and information systems*

Quality indicators

The development, choice, and use of indicators for the quality of care interests the providers, users, and funders of the health-care services and is optimally done jointly by them. Good indicators are scientifically based, relevant to health outcomes, understandable, and ethically acceptable. They must be measurable in the routine practice and feasible to use for monitoring and improving health-care services. The set of indicators that will be used to portray the quality of care in a given health problem, clinical circumstance, or institution should be comprehensive for the planned purposes.

The development and choice of indicators for the quality of care must be based on information about both the effectiveness of medical care interventions and the present level of achievement in the health-care system for which indicators are being set. The traditional way of setting targets for health care has concentrated exclusively on maximum achievement. For example, in diabetes care the target has been to achieve tight control of blood sugar levels, as estimated by a normal HbA_{1c} level. In practice, this indicator is not necessarily measured yearly from all diabetic patients, and only a small proportion of the patients have HbA_{1c} levels below 7%.

WHO/Europe has been active in developing common indicators in several areas of health care. The software to support quality work has been developed for diabetes care and hospital infections.

An example of benchmarking : Diabcare

Specific needs : Ten million Europeans suffer from diabetes. Studies have shown great variability of outcomes in industrial countries, with more than half the patients being inadequately treated.

Preferably existing data : During each diabetes consultation, several measurements are usually taken to evaluate the effect of treatment. Some of these are commonly used in all circumstances (for example, fasting blood sugar levels) and are more useful in forming a basis for comparisons than data that only are collected of a subgroup of diabetics (eg. users of insulin pumps) or in special settings (for example, university clinics).

A comprehensive set of indicators chosen from existing data: A monitoring group with representatives from several European countries, WHO, and the International Diabetes Foundation reached an agreement on the basic data to be gathered about diabetics. They selected indicators for the quality of process (for example inspection of feet during consultation), intermediate outcomes (e.g. HbA_{1c} levels), and true health outcomes (for example, late complications such as amputations) from a variety of measures that already were in use.

Used by the providers, consumers, and funders: The indicators were jointly selected by representatives of patients and professionals. Although patients do not use the data directly, they give their informed consent to the data being collected systematically, participate in filling in the form, and take it from the hospital to their general practitioner.

Timely feedback and easy comparison: The data set has been used for benchmarking, for example in France, where 90 hospitals have supplied their yearly figures to a common data bank. Some organisations have drawn their data from computer-based systems, others from paper records. These figures are available nationally without provider identification.

Using these tools, individual hospitals can compare their own results with the best results achieved (benchmarking), and try to find out how equally good results could be achieved in their own care. An example of such benchmarking is the Diabcare programme, where the criteria of sound information system development have been observed.

In Great Britain, the Medical Audit Advisory Groups (MAAGs) have assisted health-care units to develop their own quality procedures, including the local development of quality indicators. The process of developing indicators has been fairly tedious and slow, and the indicators have been so variable that comparisons between units have not been possible. Similar experience from Finland has shown that several primary care units had developed their own questionnaires to measure patient satisfaction. These questionnaires varied from very short (two questions) to extensive (more than 40 questions). The development of a common, fairly detailed questionnaire for hospital patients has been well received, especially as the health-care units have the opportunity to compare their results with others. For comparison purposes, the identity of the units is concealed.

SPRI in Sweden and STAKES in Finland have developed several quality indicators for primary care in collaboration with the health centres. They address mostly common problems, such as diabetes, hypertension, asthma, queues in health centres, maternity care, etc. Norwegian general practitioners are also currently working with the development of possible indicators for several common health problems. In Great Britain, ECCHO (European Co-ordinating Centre for Health Outcomes) is collecting data on the types of indicators used in evaluating outcome. A similar group has been active in Germany. The Danish Audit Project Odense has for years used a system for collecting data during busy practice sessions, for a wide variety of topics. This has been adopted to some extent also in Norway and Sweden, and used in experiments in Estonia.

Information systems

Health care needs and produces large quantities of information. The systems for collecting, saving, and retrieving this information vary depending on the resources and historical developments. High quality can be achieved using very simple methods of data collection and analysis. To utilise the existing information systems effectively, a

number of basic requirements must be observed regardless of which methods are available.

Health status indicators measure the quality of the health-care system as a whole, therefore they should guide the comprehensive planning of the services. In routine work, however, greater use should be made of intermediate indicators, linked with the intermediate goals of the health policy.

For quality purposes, routinely collected data should be used as indicators whenever possible. Additional data collection should be simple, cheap, and provide quick answers to clearly set questions. Information systems should be user-friendly and the health-care providers should be able to extract the necessary information on their own.

In health-care units, indicators are measured using the available patient record systems. Not all units are computerised, and those that are do not necessarily include all patient information in a computerised format. Many software producers now include in their programmes the possibility for the end user to analyse its own data. However, it will, for a fairly long time also be necessary to develop and use methods for collecting data from paper records or during consultations.

When data are produced for statistical purposes for the whole country, the producers of primary data should be able to use their own data in their quality improvement processes. When summary statistics have been compiled, the processed data should be returned quickly and in a readable format to the units providing the original figures, preferably with facilities for comparing results with other units. For mandatory data collection, the producers can be identified, but for voluntarily collected data, the results should be publicised without producer identification. A critical self-evaluation against the indicators and a development of networks for voluntary data exchange between health-care units should be encouraged. In all quality work, it is essential to secure the confidentiality of individual patient data.

Easy access to current medical information is an essential element of quality. Traditional libraries provide only a part of the necessary knowledge. Modern methods of information retrieval through electronic searches, CD-ROMs and the Internet are becoming increasingly

available especially in larger health-care units. The professionals should have easy access to medical information at their own premises; ideally, they should be able to consult the information sources during clinical work. Health-care workers should receive sufficient training in using the modern systems for information retrieval. Sound health-care information must also be accessible to patients in lay terminology.

Quality aspects of information systems and indicators

1. Information systems should be user-friendly.
2. The existing information systems should be utilised effectively.
3. The producers of primary data should be able to use their own data themselves in their quality improvement processes.
4. Centrally collected data should be processed and sent back quickly and in a user-friendly format.
5. For mandatory data collection, the producers can be identified.
6. For voluntary data, the results should be publicised without producer identification.
7. In all cases, individual patient data must be kept confidential.
8. Variation should be clearly described in a manner that helps quality improvement in the units.
9. Indicators should be extracted from routine data whenever possible.
10. The quality of the indicators used should be acceptable, and the set of indicators chosen for use comprehensive.
11. Critical self-evaluation against the indicators and a development of networks for voluntary data exchange between health care units should be encouraged.

D. Patient's perspective

The issues

The patient's point of view is an invaluable guide in assessing whether or not the right health service is being provided. The emphasis must therefore be on empowering and informing patients and helping them to participate in decisions about the way in which services are provided.

Social, economic, cultural, ethical and political developments have given rise to a movement in Europe towards a fuller elaboration and fulfilment of the rights of patients. New and more positive concepts of patients' rights have been advocated, e.g. in "The Rights of Patients in Europe". Much work has already been done to increase patients' involvement in decisions about, and individual choice of, their health care.

To further strengthen these developments, the WHO regional office for Europe has published a declaration on the promotion of patients' rights in Europe. In its scope and focus, the declaration reflects peoples' aspirations not only for improvements in their health care but also for fuller recognition of their rights as patients. This embraces both the perspective of health-care providers and that of patients.

The Parliamentary Assembly of the Council of Europe has also addressed the need to assure the quality of health care and has made recommendations on a quality pledge in health care and clinical and biological examinations. Its aim was to provide a mechanism to guarantee and improve the quality of medical care, in particular, and to ensure that care is dispensed in a humane way with due respect for the right of each individual to social and health protection. It recognises that all citizens can play an active part in this process.

To give an example of patients' rights and guarantees concerning the provision of health care, the United Kingdom published the Patient's Charter in 1992. This sets out national standards for major health services and sources of information to monitor the performance of those who provide the service such as hospitals and primary care services. The Department of Health and Social Security provides annual statistics

(league tables) of individual establishments to show performance and achievements. The mechanism also includes procedures for patients to complain and to express their views.

Clearly there are considerable problems in ensuring that patients are involved in every step and level of the health service machinery and in particular that they participate in the process of quality assurance. A lack of consensus on the definition of consumer involvement is demonstrated by the variety of methods employed in different countries and within individual states. Increasingly, consumers themselves will be making more demands to be involved in the monitoring and evaluation of health care and to request information on which to base discriminating choices.

Methods of involving patients

The question of what constitutes good practice in consumer involvement in the provision, planning and monitoring of health services has not been fully addressed. Kelson, in *Consumer Involvement Initiatives in Clinical Outcomes*, reviews the issues in the identification of good practice and highlights the importance of involving patients in quality assurance. A major reason for including this perspective in the evaluation of clinical audit lies in the observation that health professionals and patients differ in their perceptions of quality of care and may be striving for different outcomes.

Involvement can cover a whole range of activities from minimal consultation to full and active participation. Documentation on methods of involvement is vast. For example, a series of books by McIver discusses alternative ways of obtaining the views of different user groups: in-patients and users of casualty departments, out-patients, mental health services, primary and community care services.

Many of the techniques described have, however, received little evaluation, and the methods described are neither exhaustive nor mutually exclusive.

Quantitative surveys

Quantitative surveys represent the most popular method of obtaining information from consumers. These are : population surveys; patient satisfaction surveys.

Population surveys are used to establish national and local community values and priorities for health, and provide a health audit of the population. The ascertainment of health needs serves two purposes: first, it is often presented as a way of responding to the consumer; second, measures of health status are required as outcome measures. There are some drawbacks if the information is used in isolation to plan alternative health-care provision (Oregon experiment 1991).

Patient satisfaction surveys are important measures in establishing what consumers think of the service. Satisfaction is an important influence on whether a person seeks medical advice, on compliance, on therapeutic outcome and on health status, and is a useful tool for assessing consultations and clinician-patient communication. Survey methods can take various forms, such as structured self-completion questionnaires, administered interviews and postal questionnaires. In 1990, WHO published a questionnaire for health interview surveys Measuring Consumer Satisfaction with Health Care to facilitate and encourage member states to measure consumer satisfaction. One of the purposes of the standardised questionnaire was to make available comparison between different population groups or countries (WHO 1990).

There are some limitations on surveys, as results often show high levels of satisfaction and do not provide an opportunity to expand on patients' views. Surveys may fail to reveal why people behave in a certain way and how they would like services to improve.

Qualitative surveys

Qualitative surveys are more likely to uncover areas of dissatisfaction. It is suggested that health care evaluation and efforts to maintain and improve quality may benefit from using qualitative methods which are more appropriate for "opening up" a new field of research and data collection (in-depth interviews, focus groups, nominal group techniques, observational studies and case studies). Qualitative surveys enable purchasers and providers to find out the user's point of view and may

make the participant feel more actively involved. Most importantly, qualitative surveys enable the users to set the agenda for the topics to be considered, thereby allowing the issues they feel to be important to be addressed.

The following are all ways in which qualitative surveys can be conducted :

- consumer audit;
- critical incidence technique (CIT);
- focus groups;
- health forums and community meetings;
- consensus conferences;
- patient participation groups.

The way forward

Future attempts to identify and therefore promote good practice in consumer involvement initiatives will depend on progress in three areas: the development of a consensus regarding what constitutes good practice; the development of organisational infrastructures that permit the evaluation of existing practices and development of new initiatives; the dissemination of such evaluations to contribute to integrated strategies for developing and refining models of good practice. These developments need to be underpinned by training initiatives which serve to inform participants (health professionals, managers and consumers) about the best ways of achieving effective and mutually acceptable consumer involvement.

E. Managing change

Recognition of complexity

Managing change within an environment as dynamic as health care, and maintaining an organisation which is receptive to change, is an extremely complex process. It involves a wide range of interdependent relationships, as well as building the skills to develop such an

environment (Pettigrew). Change is often perceived as bringing risks which create driving and restraining forces and pressures within the organisation. Generally there is a natural resistance to change unless the value of change is recognised and threats are removed at an early stage.

Clear objectives

It is important to define clear objectives concerning the achievement of goals, milestones, what needs to be done and how achievements will be measured. Most important, those affected by change need to know why changes have to be made and the likely benefits achieved through the change.

Planning for change involves a cyclical process of fundamental elements such as planning, implementation and evaluation of the effect of change, and mechanisms need to be put in place for effective communication in order to ensure ownership at all levels.

Building a Strategy

In order to achieve set goals, a strategy needs to define the planning, implementation and evaluation stages and plan for effective communication. It should include principles governing change and put into place mechanisms which ensure that goals are achieved. This would need to address key issues such as:

- addressing prerequisites to change;
- approaches to change
- identifying driving and restraining forces
- identifying key players and stakeholders;
- building an action plan;
- establishing a communication network.

Prerequisites to change

A number of key factors need to be considered which will influence the degree of success.

Professional culture, some professional groups are more resistant to change than others and require different approaches in order for them to accept ownership of new ways of practice.

Social behaviour and values also play a big part in the way in which change is achieved. Public opinion and political pressures are powerful influences, and over the past decade major reforms and changes in the organisation and delivery of health care have taken place across most European countries (Saltman 1994).

Organisational conditions are the foundations on which to build. Change can only happen if the organisational conditions allow the process to take place. It is of little use to set goals which are impossible to achieve because supporting mechanisms are not in place, not planned for or impossible to create.

Resources need to be identified. Most of the OECD member countries face persistent difficulties with financing, delivering and performance of their health care systems. Resources required to make changes in the delivery of health care therefore need to be offset by potential gains and benefits and agreed at the outset.

Body of knowledge and expertise. There needs to exist a critical mass of knowledge before an informed choice can be made about the likely success of achieving certain goals. People with the expertise are also needed to ensure that set goals are achieved.

Approaches to change

Planning for change necessitates the recognition that there is a potential opportunity to systematically improve the quality of the service. The idea will need to be shared and explored, enabling those involved in the process of change to agree on goals and share responsibility. The Nominal Process has proven successful in many instances. Having agreed goals, it is essential to identify factors which will either help or

hinder the process of achieving set goals and influence progress. One systematic process of identifying these forces is a well established method known as Force Field Analysis. The process includes ways of identifying and prioritising strong positive and negative forces. This will set the scene for identifying key players and stakeholders and help formulate the action plan in order to strengthen positive forces and weaken negative influences (publications on both the Nominal Process and Force Field Analysis are widely available).

Involving key players and stakeholders at an early stage will help to ensure that these processes are successfully implemented, and new practices accepted by those affected by change. An understanding of the forces for and against change will enable project leaders of change to deal more effectively with anxieties and uncertainty which change is likely to produce. Conversely it will also help to identify stakeholders who will support the process of change and become "product" champions. It is important that this process involves health-care providers and consumers.

Building an action plan

The action plan is an essential blueprint for implementing change and should include:

- a set of specific activities,
- milestones and expected output,
- a time frame for interrelated and interdependent activities,
- key people responsible for delivering the output,
- mechanisms for monitoring progress,
- contingency plans for managing deviation from planned progress,
- evaluation indicators to measure success.

Communication strategy

Effective communication is the key to successful implementation of change and therefore it is vital to identify at an early stage who needs to know what at what stage. This is a skilful operation and can help to avoid unnecessary "blocks" through raised anxieties and "passive" co-operation. Establishing a good communication network can not only help to ensure better co-operation but enhance the end product through enthusiasm, drive and ownership.

III. Conditions for implementation of QIS

To achieve the implementation of QIS the necessary conditions in the form of policies, structures and resources must be created. Other important conditions are education and motivation. At all levels, individuals and organisations need to address these important questions.

Policies

A policy on quality represents the overall quality intentions and direction of an organisation as regards quality, as formally expressed by senior management. (ISO 8402).

The purpose of quality policy is to motivate providers, authorities and organisations in the health-care area to develop quality, set strategic targets and promote achievement of these targets. Quality policy expresses the basic values and quality philosophy that direct the central quality targets and activities. Quality policy cannot remain empty phraseology; instead it should guide people in their everyday work by clearly defining responsibilities and activities.

To ensure commitment to the implementation of quality policy it should be prepared in collaboration with authorities and funders, client, patient and professional organisations and service providers. Citizen and patient organisations should play an important role in discussing quality matters and formulating quality policies at all levels.

At the international and national level health-care authorities and organisations should be concerned with policy setting, regulation, information gathering on an aggregate scale, and evaluation of activities. The objective of a national policy for quality improvement is joint

action to make it an obligation and a permanent part of activities throughout the health-care system. A national policy should be based on the specific health-care system and the special circumstances and needs of that country.

In addition, national authorities should consider the need for supportive legislation. Naturally the extension of legislation depends on the formal structure of health services in each country. Because legislation in itself cannot ensure quality improvement in health care, it should build a framework to ensure the implementation of QIS.

At the regional level, health-care authorities should set quality improvement in focus by formulating and incorporating the quality policy in the health-care plans for each region. As part of each plan the authorities should require each health-care institution in the region to establish local quality policies.

At the local level, the management teams of hospitals and primary health care settings are ultimately responsible for establishing the quality policy, and decisions concerning initiation, development, implementation and maintenance of the quality improvement system. Each health-care organisation should develop and present quality improvement policies and programmes for their organisation. Each programme needs to reflect the working of the organisation.

Health professional associations and societies can support quality improvement by discussing quality matters and committing themselves to quality policies. This applies especially to the national as well as the international level.

Structures

At all levels, authorities and organisations need to consider in what ways organisations can be structured to enable useful quality improvement to occur. The need to form committees and boards with special responsibility in stimulating quality improvement should be considered. As a golden rule, quality improvement committees and boards, etc. should be multiprofessional to ensure joint action on quality improvement.

National authorities should consider using existing national, regional or local institutions, and/or establishing special bodies or committees to complete these tasks. At the regional level, the authorities can establish regional committees or steering groups to handle this work in each priority health area (for instance, regional audit committees).

Managers of hospitals and primary health care settings, and units within them, are responsible for planning and ensuring the implementation of the QIS process in the daily routines of all health providers. This includes facilitating interdisciplinary and intersectoral co-operation. Special attention should therefore be paid to internal organisation of local activities. This could be the task of steering groups and teams established for this purpose, such as so-called quality circles, audit teams etc. The appointment of task forces may also be considered.

Professional associations and societies can also create organisations with a special interest in quality improvement and which aim at pointing out priority health areas for assessment, organising education, supporting multiprofessional collaboration, establishing databases etc.

Resources

Quality improvement requires resources in terms of staff, time and money.

Systematic quality improvement should become an integral part of daily work. However, it may be necessary to provide extra time and money for professionals in hospitals and practices as well as staff and expert support for specific quality improvement tasks.

There is also a need for resources to provide education on quality improvement and for the tools necessary for quality improvement, such as the establishment of databases, protocols, clinical guidelines, etc.

Quality improvement should be funded as part of the health-care budget and proper resources should be allocated. Ways to accomplish this must be considered at all levels. The activities should be carried out efficiently, and their feasibility and likely impact should determine their priority. Health-service staff and managers should agree in advance on what to do with any savings that result from quality improvement. Such

agreements can provide incentives to implementation.

Quality improvement activities should be seen as a long-term investment. The results have a cost-cutting effect by helping the health care system to avoid unnecessary and inappropriate procedures, errors and complications. Thus, on the whole, improving the quality does not necessarily entail extra costs.

Education

Education is vital if staff are to understand the process of systematic quality improvement. It is an investment activity : learning how to improve should be an integral activity of health care teams and organisation.

Professional development should be a lifelong process of learning. Pre- and post-qualifying education and continuing professional development for health-care professionals should include the development of skills and knowledge about systematic quality improvement.

The curriculum and programme content should reflect the need to develop the knowledge and skills of practitioners to systematically improve the quality of health services. A great deal of knowledge is acquired as a result of day-to-day experience : the climate of the organisation can help in promoting the culture of lifelong learning amongst staff. The traditions and rules that prevail in an organisation determine its norms and values : they should motivate a concern for QIS.

Adult learners bring with them a wealth of experience and personal knowledge. Yet whilst adult learners are highly motivated, they require an environment receptive to their needs in order to realise their potential. Clinical teams in particular represent a vast collection of experience and have the potential to work together, to learn from each other and to improve practice.

Motivation

Systematic quality improvement requires a motivated staff. If health care staff take pride in their work, they will be motivated to improve their performance. This commitment, however, requires education and involvement which enable the staff to take responsibility for the quality of their service.

The organisation should therefore channel the energy of its staff towards improving their service and creating the necessary conditions to enable staff to discover better ways of working. For this purpose, it must make known its longer-term view on systematic quality development. The efforts of the health staff should then be recognised and valued.

The improvement of the quality of the service should be a common objective : involving all staff and status within the hierarchy should not be an obstacle to the development of new ideas.

IV. Evaluation of quality improvement systems

A. Public accountability

Internal evaluation, improvement, and maintenance of good quality is complemented by the possibility of external evaluation. This is in the best interest of patients, funders, and health care providers. Most countries have long traditions of assuring professional competence, while the evaluation of health care organisations is still rare.

External evaluation of individuals and organisations should support continuous internal evaluation and improvement. The criteria for such evaluation should be formulated by qualified experts, including the peers of those to be evaluated. Both the criteria and the systems of applying them must be transparent, and the methods by which they are applied should be reliable and valid.

Most countries evaluate professional competence only at the time when it is first achieved; in some countries, recertification procedures for some professions have been introduced. Recertification may include testing to evaluate knowledge and skills or it can be granted on the basis of proven participation in continuing medical education or other professional activities. Recertification can include mechanisms for improving the professional competence of those who do not fulfil the criteria in the first place.

In an organisation, a thorough internal evaluation is necessary before an external evaluation can be performed; the results of the external evaluation, conversely, can be effectively used by the organisation in its own quality work. External evaluation should usually be done by an independent and recognised organisation, but mutual peer evaluations can be used. A sufficient number of employees of the organisation should participate in the external evaluation process. External evaluation of an organisation should cover all aspects of care. The quality of care given and patient satisfaction should be measured as part of the evaluation.

The Quality Improvement Report is a document that contains all essential information from internal or external evaluation. The form of this document may differ, reflecting the methods and principles used. Usually such reports contain information about :

- number and educational level of professionals,
- structures and methods for data collection,
- quality improvement activities either in process or completed,
- evaluation of patient satisfaction,
- evaluation of the institutional structures,
- evaluation of management strategies,
- evaluation of systems for identifying areas needing improvement,
- evaluation of the methods for implementing change,

- evaluation of the conformity of practice to pre-set guidelines or quality manuals
- when possible, evaluation of the achieved results in health and well-being.

A regular and clear documentation of key quality aspects allows a health-care organisation to determine how well it has deployed its resources to improve the quality of care and service provided to patients. Where the evaluation reveals unmet goals, recommendations can be made for appropriate changes which then are incorporated in the subsequent QI plan. The level of detail and the ways of communicating the results to personnel, patients, and other stakeholders is decided by the organisation itself.

Laboratory quality reports

In many countries, medical laboratories have joined in evaluating the quality of their work. A typical method is to send samples of similar control sera to all participating laboratories, who then analyse these samples as part of their daily routine analyses.

In Greece, for example, the medical laboratories perform an analysis of 18 common clinical chemistry values, such as serum glucose, creatinine, sodium, potassium and cholesterol. The target value is determined by first calculating the mean of the results from all participating laboratories. Values that differ by more than ± 3.5 standard deviations from this mean are considered outliers and excluded from the actual mean value, which is then used as the target.

The results are then plotted on a special form that includes both general information of the results and the specific results of the laboratory that receives the form. The means and the variation are reported. The cumulative results of each individual laboratory over time are indicated.

In communicating the results of external evaluation, accountability and confidentiality must be balanced. When an organisation agrees to voluntary evaluation, it is clear that the results of the evaluation are owned by the organisation and at liberty to publicise, subject, of course, to proper safeguards for patient confidentiality. Prior agreement about the extent and ways of sharing the results outside the evaluated organisation is essential. Results should preferably be published in an aggregate format and as anonymous data.

Governments should make sure that suitable mechanisms for external evaluation exist in each country, both for evaluating the competence of health-care professionals and for voluntary external evaluation of health-care organisations. External evaluation can be done in different ways, including certification and accreditation.

B. *Feedback*

The results of external assessment should be used to support continuous internal evaluation and improvement.

V. Research and development

A. *National efforts*

Systematic quality improvement is a relatively new but very important field in health care requiring its own theories, methods, tools, experiences, educational programmes and implementation strategies. Even in countries where the implementation of systematic Quality Improvement has already been started, research and development activities are necessary for the continuous refinement of systematic quality improvement techniques.

Multidisciplinary research and development activities should focus on making systematic quality improvement evidence-based, generalised, and transferable to various health-care settings in Europe. Among others they should cover :

- development, evaluation, dissemination, and monitoring of clinical practice guidelines,

- evaluation of quality indicators including patients and 'employees' perspectives and long-term outcomes,
- development of patient information systems and procedures for participation of patients in quality improvement,
- development and evaluation of countrywide strategies for the implementation of systematic quality improvement,
- comparative analysis of countrywide quality improvement policies and implementation strategies in Europe,
- development of systems of incentives for good quality,
- development of curricula for continuous and continuing education in quality improvement for all professions in health care,
- evaluation of techniques for consensus finding in small groups and continuous and problem oriented quality circles.

It is important to give systematic quality improvement a sound scientific basis. Ineffective measures of quality improvement are not only inefficient but may also decrease the quality of health care. National institutes for quality improvement research in health care or equivalent research networks are necessary to promote research and development in quality improvement. A close co-operation with the health care providers is required.

B. *European co-operation*

The ongoing process of implementing quality improvement including the impact of these recommendations should be monitored in all member states and the exchange of experiences and collaboration in quality improvement research should be stimulated by specific exchange programmes at European level. Comparisons of the different European approaches to quality improvement will lead to more effective and efficient systematic quality improvement in all European countries.

Glossary

This glossary contains a selection of terms frequently used in the field of evaluation and most have been used in this paper. Some terms have been borrowed from known fields such as epidemiology and health while others are specific to evaluation. The definition of the more recent terms often varies from one writer to another. When giving several definitions of a single term, we have chosen those that are based on in-depth conceptual analysis or on the experience of bodies or institutions, even those outside the health system.

Accessibility

The possibility available to a patient or population of receiving necessary, adequate care at a reasonable cost, at a given time and in a given place.

Accreditation

Accreditation is a voluntary procedure external to an establishment, for the purpose of obtaining public and peer recognition of the quality of that establishment. It also serves to incite establishments to attain given standards.

Assessment of care

A process which makes it possible to guarantee each patient the range of diagnostic and therapeutic acts whereby he can achieve the best results in terms of health, in accordance with the current state of medical science, at the most cost-effective price for an equivalent result, with the least iatrogenic risk and with a view to his greatest satisfaction in terms of procedures, outcome and human contacts within the health system. (World Health Organisation)

Audit

- An audit is a set of techniques for analysing and evaluating the methods of an enterprise.

- An audit is an evaluation method which serves to compare, using given criteria, a practice or activity (conducted in a medical or nursing context or by an organisation) with a pre-determined system of reference. It will produce proposals or recommendations with the aim of improving quality.

In the English-speaking world, the term medical audit covers all kinds of evaluation conducted by the profession, be it peer-review, data collection and analysis, or any other forms of audit.

In France, *audit clinique* usually refers to self-assessment done on a clinical subject (medical or nursing care).

Coding

Conversion of a message generally using a numeric or alphanumeric system.

Consensus conference

A consensus conference aims to identify within the community concerned the points of agreement and disagreement relating to a health intervention, be it a diagnostic procedure, treatment strategy or aspects of health-system organisation. It helps to generate and disseminate information capable of changing inappropriate practices with the aim of improving the quality of health care. It can maintain the state of the art and assist in decision-making. A panel meets to analyse and discuss the scientific information presented publicly by experts on a chosen issue.

Consumer

An individual member of a population who is a current or potential user of health services.

Cost-benefit

Cost-benefit analysis consists of calculating on the same scale the cost ratio of a medical strategy in relation to its benefit. In such a study, the real costs and outcomes are expressed in monetary units. Analysis of this kind serves to determine whether a medical strategy produces a net

benefit for the community.

Cost-effectiveness

Cost-effectiveness analysis serves to compare strategies which differ in their costs and effects. It is expressed in monetary units per indicator of medical effectiveness (for example. Francs per year of life saved).

Cost-utility

Cost-utility analysis links the costs of a medical action to its consequences expressed on a single indicator of effectiveness weighted by a subjective appreciation of quality of life. (see QALY in the Glossary).

Criterion

- A characteristic whose value, observed in a group or individual, serves to place that group or individual in a previously-defined category.

The use of criteria is necessary in the following situations:

- inclusion - or non-inclusion - of subjects in a survey (definition of the population under study);
 - screening (to decide on further examinations, or preventative or curative action);
 - diagnosis (to calculate prevalence, incidence, relative risk, etc)
 - judgement (to evaluate an intervention).
- A previously determined factor relating to health care, which can be used to measure and compare the quality and suitability of a specific aspect of care.

Effectiveness

The observed effectiveness of a procedure in practice. It depends on five factors: efficacy, accuracy of the diagnosis, the competence of health professionals, observance of patients and social coverage.

Efficacy

For the individuals in a defined population, the probable benefit of a given medical technique, for a specific medical problem, in ideal conditions of use.

- the terms effectiveness and efficacy are sometimes interchanged. "Utility" is sometimes used as a synonym for "efficacy".

Efficiency

Evaluation of the results of a medical procedure in relation to the means used (money, resources and time). The ratio between the cost and the results achieved. The ratio between the cost and the advantages for the population concerned (lower morbidity and mortality rates, reduction in individual "suffering", fewer inequalities in dealing with sickness).

Empirical criterion

Criterion derived from data reflecting the real performance of a group of professionals.

Guidelines, clinical guidelines and practice parameters

These are proposals developed methodically to help practitioners and patients in their decisions as to whether a treatment is appropriate in given clinical circumstances.

Health indicator, index

Qualitative or quantitative variable used to evaluate the state of health. The word indicator is generally used to qualify parameters expressing one of the components of health, whereas indices present a more global picture. Indices and indicators may be defined for a population or an individual.

Indicator conditions

Specific, well-defined health problems which can be used to assess and measure the quality of health care. They occur frequently and respond to the appropriate treatment on which a consensus exists.

Indirect costs

Loss of productivity as a result of illness, hours of work lost as a result of sickness. These costs can be estimated on the basis of income.

Intangible costs

Estimate of costs relating to the suffering and inconvenience caused to the patient by the treatment. No financial flow is involved.

Medical technology

The term medical technology includes the techniques, medicines, equipment and procedures used by health professionals in dispensing health care to individuals, and the systems within which such care is dispensed. This very broad definition covers all medical activity.

Norm

This term has two different meanings:

- "that which is usual"; a value is considered normal if it is in a range covering a high percentage (albeit arbitrarily defined) of observations. A norm of 95% is frequently chosen.
- "that which is desirable", in relation to the occurrence of a health situation. The norm can then be defined in relation to the probability of that situation arising; for example, the normal cholesterol level defined in relation to the risk of heart attack.

In both cases, there is an arbitrary component. Norms vary depending on the state of knowledge, the frequency of pathologies and the possibilities of intervention.

Normative or prescriptive criterion

Criterion determined by professionals defining required conduct in given circumstances.

Opportunity cost

A fundamental economic concept which identifies the value or benefit that the resources used or consumed would have produced from the best alternative use.

Outcome (assessment of)

Refers to the effects of the treatment dispensed in terms of health gain and patient satisfaction.

Peer review

Assessment of a health professional's performance by one or more individuals in the same field with the same qualifications.

This method has been developed in particular within "peer review organisations" (PRO), bodies run by doctors and responsible for assessing care and treatment of patients within the "Medicare" programme.

Profile

A set of data concerning a chosen variable correlated with another variable, serving to document an aspect of health care. For example, the profile of a consultant for a patient population over a period of time. Profile analysis can identify inappropriate health care, follow changes in attitude and conduct over time, and document the effectiveness of evaluation systems and quality development.

QALY (Quality-Adjusted-Life-Year)

The QALY is a indicator of effectiveness weighted by a subjective appreciation of quality of life.

It determines the cost per year of life gained, and takes account of

quality of life as a result of pathological states. This indicator is supposed to facilitate comparison of various diagnostic and therapeutic interventions.

Quality

The properties and characteristics of a product or service that render it capable of satisfying expressed or implicit needs.

Quality of care

Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge.

The potential components of the quality of health care include the following:

- accessibility, efficacy
- effectiveness, efficiency
- patient satisfaction, security of the environment in which care is dispensed and the appropriateness of care.
- assessment of the degree to which health care has been implemented and achieved and results have been attained.

Quality assurance

- The combined actions, both pre-determined and systematic, necessary to inspire appropriate confidence in the fact that a product or service will satisfy requirements relating to quality.
- Quality assurance will not be complete if the requirements do not fully reflect user needs.
- In the interests of effectiveness, quality assurance generally implies ongoing evaluation of the factors influencing the appropriateness of the design or specifications for the applications

envisaged; it also implies verifications and audits of production, installation and control operations. Inspiring confidence can imply providing proof.

- In business enterprises, quality management is used as a management tool. In contract situations, quality assurance is also used to inspire confidence in the supplier.

- Measure of the level of care provided and, whenever necessary, of the machinery to improve it.

Quality control

Operational techniques and activities used to satisfy requirements relating to quality.

Quality management

- Aspect of general management which determines quality policy and implements it.

Notes 1. Attainment of the desired level of quality requires the commitment and involvement of all members of the enterprise whereas responsibility for quality management lies with the management.

2. Quality management comprises strategic planning, allocation of resources and other systematic activities such as planning, operational activities and evaluation in relation to quality.

- Quality management includes efforts to measure quality of care and develop programmes to improve quality of care until it reaches suitable standards. This term often replaces the term "quality assurance".

"Références médicales opposables"

Medical references are scientifically recognized criteria for defining useless or ineffective medical prescriptions or treatment. They are also indicators of the frequency with which patients use certain treatments and prescriptions. The signatory parties to the French medical convention, following the opinion of the French joint medical

committee, draw up a list of medical references which may be used to challenge a practitioner's usual practice having regard to the necessary efficiency of treatment and, where appropriate, to the specific nature of the practitioner's exercise (1993 national convention).

Quality standards

These are standards defining the minimum level, optimum level or acceptable level of a procedure or outcome.

A standard may be used to define an ideal condition, a usual condition or a condition of reference.

A measure of the quality or quantity established by an authority, a profession or consumers, which serves as an assessment criterion.

Research protocol

Description of all the phases of a study, comprising : the definition of aims, the choice of population, sampling procedures if any, data collection methods, validation procedures and analysis plan.

Structures

The attributes of the environment in which treatment is dispensed including material, human and organisational resources.

System of reference

The combined references on which a medical audit or evaluation activity is based.

Technology assessment

A process aiming to examine the short- and long-term consequences of the use of a technology on individuals and on society as a whole. It takes account of safety, efficacy, effectiveness, cost and cost-benefit, as well as social, economic, and ethical implications; it also updates areas needing further research.

Total quality management (TQM)

Management method focusing on quality and based on the participation of all the group's members, with a view to long-term success through customer satisfaction and benefits for the group members and for society.

Summary

One of the priority aims of national health policies and of the World Health Organisation is the promotion of quality of care in terms of equal access to care, quality of life and user satisfaction and cost-effective use of resources. Recommendation (97) 17 stresses the importance of creating policies and structures that support the development and implementation of "quality improvement systems" and sets out guidelines thereto. The explanatory memorandum describes in detail the procedures and processes necessary for the implementation of quality improvement systems.