Quality of Health Care / Hospital Activities

1. EXECUTIVE SUMMARY:
report of the working party on quality care in hospitals

This is the report of the Working Party on Quality Care in Hospitals of HOPE's Sub-Committee on Co-ordination.
It aims to provide information on the general principles of quality, quality management and quality challenges in health care. The challenge of quality is founded on the basic principle of reducing the number of errors, which is still a great challenge for health care. Latest research demonstrates that almost every tenth patient suffers from preventable harm and adverse effects related to their care and that variation among health care providers is large and cannot be explained by patient characteristics.

The Working Party started its work a few years ago. A survey was carried out which demonstrated that the concepts and principles relating to quality management in health care differ from one country and culture to another. The same was true for quality system audits and the principles for their credibility and authorisation (accreditation and certification). Since then many projects in health care have demonstrated that the general management and quality assurance principles apply well for health care. Projects like the 'Expert' demonstrated that health care should learn from all the different quality management programs.

Considering the number or errors and the variation existing in health care, the basic principles of process management are still a challenge. The management of processes requires making them transparent and measurable. It seems that there are different mechanisms preventing this to be effectively done in health care. Health care experts often feel threatened if transparency leads to less autonomy. The complex processes and the differences between individual patients also create a challenge for the methods used to evaluate and manage the processes. There is a need for a constructive way to commit both hospital managers and clinicians. One good example of this is Clinical Governance used in United Kingdom.

The general principles and frameworks for management apply well for health care. Health care has some specific features when compared to other enterprises. Examples of this are the very complex organisations with a very wide range of knowledge, intensive expertise and often the very complex processes relating to individual patients. This creates an even bigger challenge for management and leadership. All the means that enable a more systematic and effective use of resources for the good of the patient should be used. Many of the management systems and quality techniques are applicable to health care. Health care can also learn from other enterprises on how to use these techniques. To promote learning from other enterprises we need to use the same concepts as often as possible.

This report relates quite often to the ISO 8402 standard, which is a world wide used vocabulary for quality management and quality assurance.

To demonstrate quality a third party can audit the health care provider. There are international principles to demonstrate the credibility of these audits that should also be used in health care. In the European Union co-ordination of principles for conformity assessment have been delegated to the European Co-operation for Accreditation (EA). The EU governments have agreed EA to be the body to evaluate and confirm the credibility of third party audits. EA and the health care quality auditors should clarify the field of certification and accreditation. This is important also from the internal market point of view, which suggests that in future patients will have more possibilities in getting their health care from different EU countries.

2. INTRODUCTION:
HOPE IN THE EUROPEAN UNION

HOPE is the Standing Committee of the Hospitals of the European Union. The members are the national hospital associations or responsible authorities of the EU countries. Its office is located in Leuven, Belgium. The head of the office is Secretary-General Professor Kris Schutyser from Belgium. The key executives at the present time are the President, Jorma Back from Finland, and Vice-president, Gerard Vincent from France. The main activities of HOPE are the executive committee, the plenary assembly (the annual meeting), the exchange programme for young health managers and the work in two sub-committees. The sub-committee on economics and planning is chaired by WJ de Gooijer from the Netherlands and the sub-committee on co-ordination by K Essinger from Sweden.

Through the sub-committees and plenary assembly HOPE acts as a discussion forum for the hospital associations for different topics. It publishes the annual yearbook: 'Hospital Healthcare Europe', other reports and organises seminars. The topics discussed and views formulated are distributed to member countries as well as European Union. On important issues HOPE aims to act as an active non-governmental organisation recognised by the EU.

The quality of hospital care and quality management has been a long-term interest of HOPE. There have been publications and seminars organised about this topic. For many years there has been a working party on quality as one of the activities of the sub-committee on co-ordination. It has been recognised that quality management and related issues have been dealt with in a variety of ways in different countries The quality working party aims to support co-operation of actors and transfer of information in the field of quality management, quality systems and, in addition, their recognition. M. Liukko from Finland chairs the working group. In the year 2000 the members are/were:

- Harant P., France;
- Hastert M., Luxembourg;
- Holmgren E., Sweden;
- Pisco L., Portugal;
- Schutyser K., HOPE - Belgium;
- Skalkidis Y., Greece;
- Quintana Tr"as, O., Spain.

3. QUALITY MANAGEMENT IN HEALTH CARE

3.1. General background

Quality and quality management covers a wide range of topics. The qualities of health care services offered to the public are guaranteed in many ways. The National Laws oblige purchasers and providers to arrange and offer medical care and health care as well as other health services. Many European countries have defined the rights of the patients through legislation. These laws include norms about the patients' right to receive (accessibility) good (quality) health care and medical care.

Some countries have laws about patient injuries. These acts protect the patients' status in the event of medical treatment malpractice. There are also laws and regulations about health care professionals dealing with competency and other criteria to ensure the level of quality of care. Many European countries have other legislation to ensure the high quality standard of health care services, for example medicine acts, acts on protection against radiation, and safety at work acts. The Ministries of Social Affairs and Health have specified the obligations of the various Acts by issuing decrees. The Acts determine, at a general level, the organisational structure of services, the obligations of purchasers and providers of health care and the rights of patients. However, the Acts do not specify the quality requirements and/or the quality level of the services provided.

Many factors affect the quality of clinical care. The objective of specialisation and the further training of doctors, nurses and other professional groups is to maintain the high quality level of health care personnel and their skills. National norms and recommendations concerning care methods and practices complement the skills obtained from health care training material. The clinical skills of each employee are usually evaluated by their immediate superiors. Clinical audits are being increasingly carried out to assess and develop level and content of quality in more detail by systematically collecting and evaluating information.

The European Union has legislation on certain issues of health care. EU directives regulate the quality of medical devices and blood products. The European Union has a mandate in the area of health protection and is increasingly discussing the issue of health services stimulated by the fact that citizens move as employees from one country to another and need health care where they live.

3.2. Patients' rights

During the last few years France and the Netherlands have been innovative in their civil law and 'bioethical legislation'. In countries like Finland, Sweden, Denmark, and recently in Belgium, legal initiatives were taken to define specific patients' rights, in the UK the publication of a Patients' Charter was undertaken. However, in too many countries and in too many domains of health and

healthcare the (national) legal situation is intolerably obscure for the patient. The citizen is in the first place barely protected by the law in his body and person in comparison with the mass of legislation on assets, property transactions, and on the obligations once again concerning primarily assets. This legal insecurity on the most basic questions concerning the patient-carer relationship (person or institution) should be removed. It concerns questions on explicit consent given beforehand or not, on who should consent if the patient is incapable of doing so. This concerns the rights of spouses and the rights of parents over their children, on the right to truth, on the right to protection of one's private life and on health and death. This is even more so for certain categories of patients - the elderly, the mentally ill, those with chronic problems who are, moreover, often absent from the debates. Ethics have a very important role here but they cannot replace law, which should also intervene in the health field, not only in case of catastrophes (trials of responsibility), but also, and above all, in prevention through clear general rules.

The socio-legal, system-organisational and policy making aspects, have been underestimated and under analysed. Often energy seems to concentrate on biomedical and scientific progress or to other exceptional and even catastrophic events (liability) instead of creating at the basis the many missing clear general legal rules for the more and more complicated relations within basic healthcare in the broad sense. Such legalistically well formulated basic rules applying human rights in healthcare could even have the interesting effect of preventing the risk of iatrogenic damage to the patient and should anyway be decided through real democratic health policy options. In this respect the Council of Europe's convention on human rights and biomedicine is an initiative in the right direction.

3.3. Strategic issues

Hospitals are very complex institutions (enterprises), where the quality of care depends on a lot of possible tensions created through the degree of autonomy of the many professionals, doctors, nurses' etc. and the necessary organisation of the institutions. The associations (also the European and international ones) both of professionals and institutions have an important role to play in finding the right balance in present and future relations within hospitals. The status of doctors in some countries creates a challenge from this respect because of a quasi-absolute independent status of doctors in hospitals (the Netherlands, Belgium, Luxembourg, Germany, Switzerland, U.S.A., Canada, and partially France). In some countries doctors are an integral part of the hospital and employed by it. Even in those hospitals medical doctors often take an independent consultants role. In this role they work with the patient and demand all the technical resources possible for the care despite the local circumstances and the resources of the hospital. This creates a risk for a legally split not-integrated hospital.

In several European health care systems the lawmakers and health care managers feel the tension created by well-organised professional and institutional

associations. On the extreme these expectations of the professionals continue to make imprecise pictures of the archetypal split (dualistic) hospital, which offered a roof to the - separated - doctor-patient relationship, when regulating health care organisation, hospital, health insurance, professional practice and discipline, professional training and specialisation etc. This leads to a number of consequences and it handicaps those initiatives that are aimed at developing really integrated institutions and networks of health in line with the developments in health care and society. It can make the legal position of the patient and his/her personal safety as well - rather dubious.

In an extreme case this creates an obligation for the hospital to inform the patient, before his hospitalisation, about the legal relationship between a hospital and its medical specialists. When amending the Dutch Civil Code by introducing the medical treatment contracts of 1 April 1995, even the Dutch legislator could not figure out anything better than to impose shared liability to hospitals for their physicians (hence a kind of negative integration) for dealing with catastrophic malpractice, instead of clarifying the legal position of the hospital patient. In practice these new rules of civil law aren't even adequate to regulate the care offered in an integrated way especially in chronic situations (of old age patients) by growing networks in primary health and social care, linked to hospitals or not.

The hospitals should define (also legally) and organise their relations with the healthcare professionals in such a way that they can truly guarantee and assume their own institutional responsibility for the promotion of health of their patients in the most literal and realistic way. In practice before health education and promotion will be able to contain a clear subsection empowering patients through correct information on patients' rights a lot of very basic legalistic work will have to be done nationally and/or internationally.

3.4. Patients and other customers of health care

The concept of quality management and customer are important in health care in relation to other enterprises. To enable comparison of health care to other enterprises this report often uses the general vocabulary of quality management produced by ISO - The International Standards Organisation. The ISO 8402 standard is general vocabulary of quality management, which as such is not specific to any quality technique or management system.

Quality management focuses on the customer. The patient is expecting to receive good quality care. The definition of quality (ISO 8402) is: *'Totality of characteristics of an entity (product or service) that have an influence on its ability to satisfy stated or implicit needs'.*

The concept of the customer is very interesting from the health care point of view. The ISO 8402 defines customer as: *'Recipient of a product provided by the supplier'*.

Another approach to the patient-customer concept is used in the European pre Standard (concepts to support continuity of care) where the patient is the Subject of Care and defined as: *'Person or defined group of persons having received, receiving, or to receive health care'.*

In many European countries the concept of customer is not used within the health care context instead of patient. The customer is seen to be too much market oriented and that it should not be used to equal or replace the concept of the patient. Quality as a science and the general frameworks of quality management use the concept of customer. There is a need to relate the concepts to each other at least at a general level. It is important to recognise the different types of customers that health care has. This will help us to understand the health care specific mechanisms for customer orientation and satisfaction. The customers can be grouped into external and internal customers. One important customer group or a supplier are the subcontractors.

A. External customers

High-quality operations are based on satisfying customer needs. In the health care sector, there are many customer groups. The most important customer is the patient, but purchasers are also customers. Other customers include the patient's family and insurance companies. The prerequisites for high-quality services are to identify and fulfil the needs of the various customers. Patient needs are varied. Customer satisfaction (functional quality) covers only part of customer needs in the health care sector. In addition, patients expect to receive high-quality clinical treatment which will improve their health (technical quality), even though they are not able to specify the aspects of the clinical quality of their treatment.

Two-thirds of all resources allocated to social services and health care are spent on the provision of services. Eighty per cent of the annual needs of people for services are simple and non-recurrent, and account for some twenty per cent of the available resources. Twenty per cent of people need services that require expertise in several fields. These needs consume eighty per cent of all the available resources. Individual citizens perceive the service system as a network of experts from many fields. It is important to identify the service networks which use resources and which require co-operation between various organisations and service providers.

B. Internal customers

Within social service and health care organisations it is important to identify the various internal customers and related services, such as diagnostic and support services that are required for the realisation of the care process. Large organisations often consist of many independent units which provide services for

one another. These centres purchase services from each other after negotiating and agreeing upon the price and quality of the services.

C. Subcontractors

The health care purchasers and different authorities are increasingly purchasing services from private service providers. Many support services have been transferred to other service providers, but care services are also increasingly purchased from private providers. The providers of purchased services are required to offer high-quality services and ensure quality management with regard to the provision of these services. The providers are increasingly asked to prove the quality of their operations by means of external quality assurance.

4. THE CONCEPTS OF QUALITY MANAGEMENT IN HEALTH CARE

There are a variety of concepts and methods used in relation to quality management, quality systems and their recognition. This was clearly demonstrated in the survey done by HOPE's SCC sub-committee. To support comparability there is needs to recognise the differences in the concepts used and agree on at least some of the basic concepts used internationally. The quality working group aims to produce the information and tools to discuss the issue within HOPE. Through the discussion it will be possible to define the need and content for a HOPE policy on the issue.

ISO 8402 contains the general vocabulary relating to quality management and quality assurance which is used, for example, by the European Society for Quality. The key concepts in this field, such as total quality management and quality management, are defined in the vocabulary.

Quality management: All activities of the overall management function that determine the quality policy, objectives and the responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system.

Total quality management: Management approach of an organisation centred on quality, based on the participation of all members of an organisation and aiming at long-term success through customer satisfaction and benefits to all members of the organisation and to society.

Quality system: Organisational structure, procedures, processes and resources needed to implement quality management.

Other related concepts include quality assurance, quality policy, quality system, quality manual, and quality auditing. The use of uniform concepts makes it possible to use a common language and to achieve a common understanding about quality in and between organisations both nationally and internationally. The most common concepts relevant to health care are included in the annex 1.

Another organisation producing standards and concepts relating to health care is the **European Committee for Standardisation - CEN**. The European Commission and the European Free Trade Association have given a mandate for CEN to produce European Standards.

This report uses some of the concepts defined in the draft European pre Standard for the Çsystem concepts to support continuity of careÈ which has been prepared, under the supervision and responsibility of Working Group II, by the Project Team 030 of CEN Technical Committee 251 ÇHealth InformaticsÈ according to mandate M/255 by the EC and EFTA.

The health care related activities include the development of standards for medical and other laboratories, which are used for accreditation, recognised at the European Union level. **In medical and other laboratories** there are European (CEN) standards used to ensure the competency of the laboratories to produce reliable results. The quality management principles of the EN 45001 standard, which is used in the accreditation of laboratories, and of the ISO guide 25 are convergent with the ISO 9000 standard. However, they do not require as much detailed documentation or the full detail on quality management and development procedures.

Other health care relevant standards deal for instance with medical technology and the environment. Many of the CEN standards have been accepted as worldwide standards by the ISO. Every European country has a national agency for standardisation that is responsible for translations of the standards and their implementation at the national level. CEN and the national agencies also have the responsibility to ensure co-operation of the expertise in the field of each standard.

5. THE GENERAL IDEOLOGY OF QUALITY MANAGEMENT

There are a few basic principles to be considered in relation to quality and management of activities. The total quality management ideology and quality sciences focus on some general topics that are relevant for all activities in health care. Health services are processes despite the content (cure - care - prevention - health promotion). Some of the key topics are discussed below.

5.1. Write what you do

The documentation of your activities is necessary for different reasons. You need to document your activities (products) to inform your clients (patients as well as purchasers). Your staff needs a description of the activities being planned and instructions to ensure that their work is carried out as required. The documentation should use an evidence based approach and this has actually been the aim in the clinical guidelines and protocols produced by different health care experts.

5.2. Do as you write

The idea behind a documented quality system is that work is carried out according to the quality manual and protocols that have been developed. In health care this raises an interesting challenge. We have a long tradition of producing guidelines and protocols to define good practice for care as well as prevention. There is very little research and evidence to demonstrate how well these guidelines have been implemented in every day practice. Many of the guidelines have been criticised as being too scientific and impossible to implement in real life. The requirement of following the quality manual might help the production of more practical guidelines and also lead to more discipline in carrying out what has been promised.

5.3. Measure your performance

The evidence based care approach is based on research and use of appropriate statistical methods. There are regular clinical trials and research being carried out and most health care organisations participate or have participated in them. Many of the health care experts have included in their basic education, knowledge and understanding of statistical methods. Considering this background it is interesting to note that it is the exception if a health care organisation uses statistical methods to evaluate and manage their everyday performance. The evaluation of performance is a basic requirement in ISO quality systems and EFQM models.

5.4. Improve your performance

You cannot improve your performance if you don't measure it. The Demings quality PDCA circle (Plan-Do-Check-Act) is quite well known in health care today.

There have been numerous quality projects where the principles of continuous quality improvement have been successfully implemented in health care. The challenge for health care is to ensure that everyday activities are included as part of the quality system and quality improvement projects.

6. TOTAL QUALITY MANAGEMENT - TQM

Total quality management is a concept used to describe the totality of management techniques and strategies.

Total quality management (TQM) is a management method which emphasises quality and is based on the participation of all the members of the organisation. Its long-term objectives include success brought about by customer satisfaction, which will also result in benefit to members of the organisation and to society in general (ISO 8402, EFQM).

Health care has some special characteristics that have to be taken into account when applying the principles of total quality management and the methods of quality management. These characteristics include:

1. a political management system in relation to the active management of the organisation;
2. the expectations and values of the citizens in relation to the health care services available;
3. the management of an individual organisation as part of a network or a local entity;
4. the integration of the organisation's wide range of expertise in the care process and in the organisation's internal division of labour.

The political management system directs the use of resources allocated by society for health care and the realisation of political values in health care. Different health care experts have different views on the content and quality indicators of the care process, which is based on their own expertise. Individual citizens also have their own values and expectations of health services. The managers who are responsible for health care in practice have to reconcile all these values and views.

These special characteristics must be taken into account, and management has to be made more transparent, by specifying the responsibilities and powers of the political and organisational management and the specialists who participate in the care process. The aim is to achieve process management based on patient needs and to establish a management system based on the process management.

6.1. Why does the health care organisation exist? - THE MISSION

All organisations have a mission which states the reasons for the existence of the organisation. The health care organisations key mission is to promote the health of the patient (customer). The European Pre-standard (WG - II 030): System of concepts to support continuity of care uses the concept health issue: *An issue*

related to a subject of care health, in the specific perspective of a health care party.
A health issue can correspond to a health problem, a disease, an illness, a requested procedure (therapeutic or preventive) etc.

The most common activities of the health care organisation are services where the patient (client) meets a health care expert or a team to which she/he presents a health issue to be resolved. The common patient expectations and goals of this service are usually described as gain of information, health and functional status.

The health care system has a wider mission in relation to the population. Health care is a key actor in prevention and other population and society targeted activities. International studies have shown however, that the impact of health care on society and wellbeing of the population is limited. There are estimates to suggest that the influence of health care is one fifth when compared to the impact of the society (education, environment, employment etc). Health care is also often quite powerless in tackling the problems of society. Prevention and management of for instance, the drug problem, is probably more successful if the key actors of the local society (mayor, local board and the citizens) can agree a strategy and actions to be taken. Health care professionals can give supportive expertise to this community activity.

6.2. WHAT does the health care organisation perform? - TASKS AND DUTIES

The mission of the health care organisation is the basis for the tasks to be performed. Tasks are described as bigger entities which include more detailed activities. These tasks can be defined for instance as hospital care, ambulatory medical care, home care, rehabilitation etc. The health care organisation often has tasks of health promotion and prevention. These society or population targeted tasks are carried out according to national or local strategies and often require co-ordination of the health system with other public and private organisations.

6.3. THE MANAGEMENT SYSTEM

6.3.1 The ISO and EFQM models

The use of ISO quality systems and EFQM (European Foundation for Quality Management) model is spreading within health care. They are general management models that aim to ensure fact based management at all levels in the organisation. These are general schemes and the organisation must itself define what are the detailed activities to be managed. In other words what is the management system to be used for. Both approaches focus strongly on processes and their management and outcomes.

It has been interesting to see that many hospitals and health care organisations have build management systems that do not cover the clinical processes (care and prevention). This is interesting considering that good patient care (cure and prevention) contains the key added value of the hospital function. There are many reasons why grasping the clinical process is difficult. The care processes are often very complex and their description in detail is difficult. The tradition of the autonomy of experts, like physicians, doesn't promote transparency of the activities or activities seen as part of a system. On the other hand a management system that doesn't grasp the core activity of the expert - the clinical process - doesn't interest the clinicians. The clinicians will never feel committed to this kind of management system.

ISO 9000 standards and Quality Award criteria are applicable for the quality management of health care organisations. The identification of the process outcome and assessment of the realisation of the processes is the starting point for the management of variation. One of the basic ideas of ISO 9000 quality system standards was originally to ensure management of processes in a standard way to diminish errors and variation. This is the first phase in development according to the modern quality approach. The aim is to reduce or at least manage the variation in the way the organisation has set its target. The variation should be considered for all measurements which assess the efficiency of processes, such as customer feedback, the effectiveness of processes, and their benefit to the patient's health. Examples of comprehensive quality management systems are the ISO 9004-2 standard and the Quality Award criteria, both of which are based on the management and development of processes. The organisation's key objectives and the objectives for processes, derived from the key objectives, are set out in the quality policy. Process management requires systematic monitoring of the results and the implementation of the process.

ISO 9000 standards are the basis for a documented quality system. The Quality Award criteria place a strong emphasis on the use of quality techniques in the development of processes, competitiveness and focus on customers. In the last twenty years, the ISO standards and the Quality Award criteria have developed into dynamic quality management methods, which make continuous quality improvement possible at all levels of an organisation. They emphasise the significance of self-assessment, which is carried out at the different levels of the organisation, as a tool for development. The ISO standards and the Quality Award criteria are general quality management criteria which are applicable to all fields of activity. However, their successful use requires that the quality criteria and other means of defining the content and outcome of the activities. The criteria of Çgood practiceÈ are defined and dependent on the expertise available. After the criteria have been defined, it is possible to integrate quality management into various fields and units, for example, within the organisation or in the different phases of the care chain.

In 1995 Malcolm Balridge published the pilot Quality Award Criteria for Health Care Services. These criteria have been reviewed in 1998 and 2000. A similar development has occurred in Sweden.

Sweden: Q.D.L Quality, Development and Leadership

Q.D.L is a model developed by the Federation of County Councils. The model is based on the Swedish Award U.S.K. which is similar to the Malcolm Balridge Award. Q.D.L is also closely related to the E.F.Q.M.-model and the fact is that a hospital, which has used Q.D.L., has started to take an interest on E.F.Q.M. as a kind of next step. The purpose of Q.D.L is to promote development of healthcare based on total patient/other customer satisfaction, employee involvement and process orientation. With Q.D.L. the management receives an assessment which identifies the kind of changes that can be done which will result in improvement. The purpose of Q.D.L. is to improve the probability of making the right decisions. Q.D.L can be used as an instrument of self evaluation or evaluation with external examiners.

The instrument is built on three cornerstones:

- The way of asking questions which leads to understanding the function of the systems
- A generic model of the organisation makes a frame in which area the questions are focused. It puts the patient/other customer, employees and processes in focus. This is the principal criterion in Q.D.L.
- The Core Values are the essence of Q.D.L. and the purpose of the Core Values is to support the methods of work in the organisation, which leads to excellent results on patient satisfaction, clinical/processes results and efficiency connected with the development of human resources.

By answering the questions a description of the system and the methods used in the organisation are made. The review team makes an evaluation of the way the Core Values have been introduced into the organisation. The evaluation results in a report where powerful forces as well as the improvement possibilities are highlighted. This in turn can identify priority areas where improvements are needed and what impact the improvement work has on total quality.

Q.D.L has been used since 1996 and the experience so far is:

- It gives the management and employees an overall picture of the systems in the organisation
- It creates engagement
- It creates a common approach and language
- It makes clear the meaning of patient/customer focused development and continuous improvement
- It leads to improved results and higher efficiency.

To work with and implement Q.D.L. effectively demands patience! The experience is that Q.D.L. takes a long time to implement, as it requires major organisational changes in culture and employee mindset. Still it is widely felt that the change in culture is necessary if health care is to match the demands and needs of the future. Q.D.L/E.F.Q.M. is consequently a model which can help health care accomplish this change in culture because it concentrates on how continuous improvement has an effect on patient need and satisfaction. This approach is also supported in the approach to quality made by the National Board on Health and Welfare.

The European Quality Award Criteria are published by the European Foundation for Quality management (EFQM). http://www.efqm.org EFQM was founded in 1988 by the Presidents of 14 major European companies, with the endorsement of the European Commission. The present membership is in excess of 600 organisations ranging from major multinationals and important national companies to research institutes in prominent European Universities. The model was launched to the public and voluntary sector and reported in 1999. There has been a pilot group for education and health care testing the model. It has lead to the formation of a health care network that has actively shared their experiences of the implementation of the EFQM model and none recently has been looking at a new project concerning indicators for health care quality. The EFQM model places emphasis on nine performance areas, namely:

- Leadership
- People
- Policy and Strategy
- Partnership and Resources
- Processes
- People results
- Customer results
- Society results
- Key performance results

The European Commission supports the use of the EFQM model. The Commission has published the European Quality Policy that can be found from the homepages http://europa.eu.int/comm/dg03 The Quality policy is meant to lead to an increase in competitiveness accompanied by an improvement in society's conditions. The Commission has other initiatives open to member states:

- In co-operation with EPQM, DG II, DGIX, and EIPA the Commission has discussed how the European Quality award for public administration could be launched
- The European Company Benchmarking Network has prepared with support from the Department of Trade and Industry in the United Kingdom and the Commission a methodology to facilitate the assessment and comparison of processes. This initiative also covers the use of benchmarking techniques in

public services in order to examine and improve efficiency, effectiveness and the quality of services
- A pilot project with EOQ was launched in 1993-1997 in order to train public officers on quality management.

6.3.2. The Health Care Accreditation and related methods

The term accreditation (applied to organisations rather than to speciality clinical training) reflects the origins of systematic assessment of hospitals against explicit standards. It developed in the USA in 1917 as a mechanism for the recognition of training posts in surgery. That model was the beginning of the Joint Commission on the Accreditation of Health Care Organisations (JCAHO) (http://www.jcaho.org/), exported via Canada to Australia in the 1970s and arriving in Europe in the 1980s. It is most evident in the UK where the King's Fund Institute (http://kingsfund.org.uk/) launched its criteria and started their program. Since then the Kings Fund criteria and program or a similar program has been started in many European countries. These models conform to varying decrees with the original Kings Fund model. Many of the models used in Europe have also used the JCAHO, EFQM and ISO 9000 standards in combination to produce the more useful model for each country. The use of the model varies depending on the source that is running it in the various countries. In some countries the organisations are non-profit making (UK), in some government initiated (France) and in other countries for profit consultancy organisations. The support and commitment to the programs varies. JCAHO has also founded the Joint Commission International Accreditation in 1998. They use criteria published in 1999 that were developed by an international task force. Joint Commission has accredited a hospital in Barcelona, Paris (American Hospital) and is presently involved with the Copenhagen hospitals corporation.

France - ANAES

A typical example of health care accreditation is the program of ANAES (http://www.anaes.fr) in France. The accreditation procedure was introduced into the French Health care system under law no. 96-346 of April 24, 1996. The Agence Nationale d'AccrŽditation et d'Evaluation en SantŽ was commissioned to develop the criteria and program to be used. Accreditation is a compulsory procedure for public and private hospitals of all types.

The accreditation procedure was inspired by models from English-speaking countries, which have been developed over many years following the initiative of health professionals aiming to improve the quality of services delivered to patients. At the same time, care has been taken that these models were adapted to suit the specific culture and the characteristics of the French health care system. The independent nature of the procedure conducted by ANAES is similar to the approach taken by the bodies responsible for accreditation in other countries.

The objectives of the accreditation are:

- To assess quality and safety of care
- To assess a health care organisations ability to ensure continuous improvement in quality of overall patient care
- To formulate explicit recommendations
- To involve professionals at all stages of the quality initiative
- To provide external recognition of the quality of care in health care organisations
- To improve public confidence.

The focus is on the patient: accreditation is first and foremost concerned with the patients progress through the health care organisation and care network, and with the co-ordination of patient care. It focuses on patient safety, continuous quality improvement, and involvement of professionals working in the health care organisation and long term commitment on quality improvement.

The accreditation procedure was launched in 1999. The gradual development of the accreditation initiative has been planned to take about 5 years. The aim has been to have 300 organisations in the program in 1999 and 500-800 organisations a year later. Each hospital has to initiate the process by April 2001. The organisation is expected to enrol for the program and provide with the application form detailed information including an organisation chart, a document describing the health care organisation and its activities, the development plan, a social audit for the last three years, patient information booklets and building plans.

The health care organisation will carry out a self-assessment against the standard and send the results to ANAES. Later the program will involve an accreditation survey. A multidisciplinary team of at least three members including a doctor, a paramedical professional and an administrator carries out the survey. A dialogue between the team of visitors and the health care organisation is encouraged by ensuring that the team has at least one professional who works in the same type of health care organisation as the one being surveyed.

In order to ensure consistency in the way the accreditation procedure is applied across all health care organisations and to ensure that its fundamental principles are complied with, an Çaccreditation surveyors charterÈ has been produced. The surveyors are required to conduct a minimum of six surveys over a two-year period, although they may not spend more than a third of their working time on accreditation.

6.4. THE MEASUREMENT SYSTEM

ISO quality system and EFQM model aim to be "fact based" management systems. This means that all the improvement and management activities should

be based on data and information gathered from the activities of the organisation. This is comparable to the concept of evidence based medicine. The quality systems idea is to reach the evidence based thinking at the level of every day practice of health care. There are numerous studies about care methods, but very little attention or means are there to ensure that these research based care methods are carried out in the practice of health care.

6.4.1. The objectives

The attainment of objectives is evaluated in different ways, for example, by obtaining feedback from customers and by measuring the clinical quality and efficiency of care. The development of activities requires many kinds of measurement. The utilisation of information, which is continuously gathered from routine statistics, patient documents and other sources, in the assessment and development of activities is a major challenge in the health care sector. Routine statistics provide quantitative information on the use of resources. However, to assess how efficiently the resources are used, their benefit to patient health must be evaluated. Health care specialists evaluate patients' health as part of the normal patient care process. These assessments can be used in quality management, for example, if they are classified numerically. Different indicators and classifications have also been developed to measure the benefit to the patient's health; these make it possible to systematically monitor and assess the usefulness of care.

There are many international projects developing indicator systems for health care. One of the most developed systems is the ORYX initiative by the Joint Commission on Health Care Accreditation in USA. (http:// www.jcaho.org) Within the ORYX initiative a set of indicators and measures have been evaluated. The validity, reliability and other characteristics of different measures have been evaluated as well as the way they can be used by the health care organisation. The focus is on the outcome measures. The Joint Commission is requiring the health care organisations to select a set of measures to be used and these measures are used as part of the external audits. Similar systems are also developed in many European countries.

The diagnostic and support services are an integral part of care and generate a large amount of information. Services are usually provided for the unit which is responsible for total care and which assesses the quality of these services and their necessity as part of the whole. Quality management of diagnostic and support services is based on their own expertise, which is used, for example, when the right working methods ('good practice guidelines' and the indicators of quality required for monitoring are specified.

6.4.2. The accuracy of the measurements

The accuracy of measurement is dependent on the measurement methods and equipment used. Health should be measured by using validated (international) methods, the precision of which has already been verified. There are numerous internationally recognised measures for functional capability, quality of life, severity of disease etc. These should be used as part of evaluating the every day performance and outcome of the health care organisation.

There is a lot of high technology used in diagnosis and treatment. The accuracy of the technology should be verified to ensure patient safety and the accuracy of the measures used. The accuracy and calibration of the equipment used in health care must be based on the clinical need. The clinicians must specify the accuracy of equipment required for the assessment of the patients' condition. For example, the accuracy of the equipment used in clinical and physiological laboratories must, whenever possible, be based on calibration methods and procedures that are traceable. Calibration is carried out by comparing the equipment's performance with standard equipment, the accuracy of which has been verified. Usually the accuracy is verified in a traceable way by using national or international measurement standards.

Kuopio University hospital was certified according to ISO 9002 standard in 1999. One of the most interesting findings was the fact that the accuracy of medical technology is poorly managed. The hospital identified 4072 pieces of technological equipment in the hospital and identified the clinical based need for 3259 (80 % of the total) pieces to be calibrated. Only 436 pieces were under continuous maintenance and calibration. For 783 devices there had to be new procedures created for maintenance and calibration. For the rest the calibration and maintenance procedures existed, but were not performed in a systematic way.

The unit also has to specify what level of accuracy must be used in practice. To specify the reliability of measurements, the unit carries out a series of measurements. On the basis of these measurements, it is able to assess the inaccuracy of measurement caused by the patient, employees, and local circumstances. This information is needed for clinical decision-making. In Lappeenranta health centre a study was conducted where the blood pressure manometers used every day were calibrated and the measurement uncertainty evaluated. The calibration was done against a manometer calibrated by a notified body (VTT-automation). 32 devices where studied, out of which six had so serious malfunctions that they could not be calibrated. For the rest calibration was done at the level of 250, 200, 150, 100 and 50 mmHg.The health centre manometers pointed at the average 153 mmHg at the level of 150 mmHg for the test device (minimum 148 and maximum 158) and of the average error of the manometers and 106 mmHg at the level of 101 (minimum 96 and maximum 104). The measurement uncertainty was evaluated so that the manometer and the patient stayed in on room and eight health centre experts (doctors and nurses) came into the room to measure the blood pressure. In these stable conditions the measurement uncertainty was still larger than +/- 15 mmHg, even for a series of

three to four measures. This demonstrated how important it is to manage the maintenance of health care technology and that the basic principles of measurement systems and their accuracy are not understood in health care well enough.

6.4.3. The measurement reports

The unit and the organisation use information that is systematically collected to evaluate the quality of their own activities and to identify potential areas of improvement. The monitoring and assessment of practical activities are not the same as the scientific study of efficiency; they mean systematic evaluation and development of the respective activities of the unit. The unit must decide what information to collect and use. Possible information includes changes in the patient's health (for example, measured using an appropriate health indicator or based on a medical examination), the realisation/non-realisation of treatments according to the agreed practice, the evaluation of the smooth progress of care, the patient's assessment of the clinical quality of care, and the assessments by the unit's own specialists of the unit's clinical quality of care.

The analysis of the results requires the application of statistical methods. Some results can be evaluated using cross-tabulation or by comparing mean values. The starting point for the systematic development of quality is the identification of variation in the results, for example, with the help of a control charts. A control chart is a practical application of a method based on statistics. It is used to identify the range of variation in the measurement results which is characteristic of the given process, and the variation which differs from this characteristic and which requires some sort of action. More demanding statistical methods are used in scientific health care studies to make multivariate analyses possible. These are also necessary for the analysis of health care processes as part of normal activity. In practice before their introduction, it is worthwhile using simpler statistical methods in the first instance to identify the variation for which more complicated statistical methods will be necessary.

6.4.4. The responsibilities for measuring

The standards of the ISO quality system and the quality award (EFQM) criteria require systematic assessment procedures and their documentation at all levels in the organisation. The organisation itself has to specify the objects to be assessed and measured, and the indicators that are applied. The principles of systematic quality management demands that the attainment of the objectives specified in the organisation's quality policy be verified by assessing the efficiency of the processes.

Table.1.Examples of statistics and measurements used for the monitoring of process efficiency

- Number of encounters, treatments and other care procedures during a certain period of time
- Statistics used for the assessment of effectiveness (health outcome, care need and functional capability measures and indicators)
- Undesirable effects in the process (infections, mortality, pain, etc.)
- Use of time in the process (the number of calls and treatments, the duration of action of medicines and treatments)
- Costs of the process (total costs and detailed costs)

6.4.5. The development of the processes is the basis of identification and management of process variations

All processes have a characteristic progression. Treatments and rehabilitation bring about changes in the patients' health, which vary from one patient to another. The care process includes phases, the number and content of which can be measured with an appropriate indicator. Units should identify the variation and average change in the outcome of patient care and in the phases of the process. For the monitoring to make sense, the patients must be grouped, as monitoring based on individual diagnoses is too slow a method to generate feedback applicable to the development of the process. The nomenclatures and classifications used in health care can be applied when patients are grouped.

During the implementation of processes, similar variations take place in the realisation of individual treatments and in the content of treatments as a whole. Systematic monitoring is well able to assess processes with a standard content. These include technical operations, which are carried out in the same way for all patients. However, the content of some aspects of patient care cannot be specified in detail. An example of a process with a varied content is the interaction between the patient and a member of the nursing staff. The quality assurance of these processes requires a different approach. The content of the care relationship can be influenced, for example, by specifying the qualification of the nursing staff to make sure that they possess the desired communication skills. The content of the care relationship and the quality of care can be assessed, for example, by using the peer review/clinical audit methods, in which the assessment is based on expertise. An important point is that the unit establishes comprehensive and systematic procedures with which it can assess the quality of processes and which are continuously used to monitor activity.

Unforeseeable changes can often take place during a health care process. Patient care does not progress as planned, or the problem changes, for example, due to an additional disease or a complication. The identification of these changes and their number as well as their inclusion into statistics is a prerequisite for their decrease and for the identification of preventive measures.

6.5. THE QUALITY LEVEL

The level of quality in health care is being ensured through various mechanisms. The government and other authorities have a long history of dealing with the competency of clinicians through licensing or similar activities. These methods are essential for the basis of the modern health care system. These methods do not look at the performance of the individual clinicians. The health services research has shown that there are 2-4 fold differences between the clinicians in the clinical outcome and the way clinicians follow, for instance the clinical guidelines developed through the health care sciences.

There have been various quality management schemes developed within the health care system. There are a number of quality and organisational criteria developed to ensure good quality care. Many of these have been developed under the umbrella of ISQUA (The International Society of Quality in Health Care) (http://www.isqua.org.au) and health care experts, international and national organisations (medical specialists, nurses etc). These criteria vary a lot from each other and between countries. Many of the criteria focus mainly on structures and other means to ensure the prerequisites for the good quality care and not so much on the actual clinical processes and their management.

6.5.1. The quality requirements of health care services

Purchasers, providers and health care experts have developed quality criteria for the assessment of purchased services. Quality management that corresponds to a quality system and certain criteria defining the content of the activities have often been required from service providers. The assessment of the quality requires defined procedures to be used by the assessors.

The Governments and Ministries of Social Affairs and Health are responsible for the quality of activities in its administrative field. The quality standard of activities can be affected by means of legislation, for example, by defining the specialists' qualification. Health care legislation determines the minimum criteria for quality. The National Board for Medico-legal Affairs and similar authorities monitor the activities in the health care sector and, within the limits of their power, tackle any defects that have been detected. The totality of the society's resources must be taken into account when drawing up national criteria.

Health care specialists are needed to specify and verify the standard of quality of the activities. Universities, international and national research and development centres carry out research, generate information and develop quality criteria for health care. Many European countries have founded a unit or an institute for assessment of health care technology and methods and their effectiveness. The medical and other health scientific societies, the medical associations, medical specialists' associations, the nurses unions and other specialists participate in the development of quality criteria and care practices. There is a need for national and European stakeholders to share information about these activities to prevent

overlap. The criteria that specify the clinical quality standards in health care must be based on scientific evidence and expertise.

6.5.2. The clinical audits

The quality of the clinical care is often difficult to measure. Many of the activities carried out by health care experts cannot be defined as standard procedures. The good care is based on the assessment of the situation of the patient and consideration of the health care expert. The consideration is based on the basic and specialist training and the experience. In the best case the patient feels that her/his needs are taken into account and the care carried out is the best for the total situation. The clinical expertise and its quality need a different approach for assessment. The peer reviews done by other experts of the same area can work as an assessment of the complex and many-sided content of the care received by the patient. Many countries are actively developing their clinical audit systems.

An example of these clinical audit schemes is the Visitatie in the Netherlands. It has originally been developed for the selection and monitoring of speciality medical training. It has since been developed into a quality assessment tool. It focuses on clinical practice, professional development and service quality. Visiting teams are mostly clinical and often uni-disciplinary. Standards tend to be derived implicitly from practice guidelines and personal experience. Reports are not available to the public.

6.5.3. The clinical governance

Clinical governance relates to activities carried out in UK with the support of the NHS Executive. The consultation document on quality in the new NHS ÇA first Class ServiceÈ suggests clinical governance can be defined by a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. In the North Thames region this definition was felt to be too broad and they defined clinical governance to be the means by which organisations ensure the provision of quality clinical care by making individuals accountable for setting, maintaining and monitoring performance standards.

Clinical governance has a broader approach compared to clinical audit. The expert is asked to audit his performance, but also demonstrate how to improve the performance and maintain it. It also emphasised the responsibilities of both clinicians and managers in the delivery of care. The responsibilities can be described:

- A clinician is responsible for providing individual patient care of high quality and being able to demonstrate this by setting standards and monitoring acceptable standards

- A health institution is responsible for providing services of high quality and being able to demonstrate this by setting standards of the systems set up to provide the services and ensuring that clinicians deployed by the institution are fulfilling their individual responsibilities.

6.6. THE QUALITY IMPROVEMENT

The improvement of performance should be based on data. The medical and health care sciences have produced a lot of information in relation to evidence based care methods. Overall, according to experts, evidence based health care covers only about one fifth of all the activities carried out by health care professionals at the moment. Many of the care procedures have not been evaluated for different reasons. In some cases the benefit for the patient is self-evident. The speed of the development of health care technology and care methods has been so rapid, that systematic evaluations are just being carried out. Health care has functions that cannot be evaluated through a strict statistical approach. The need for support, information and caring for the person have always been essential parts of health care in practice. However, all of the activities of care can be evaluated. Most of the activities carried out by a health care expert or an organisation can be evaluated using statistical methods or other quality techniques.

6.6.1. Statistical methods

Systems theory and SPC - Statistical Process Control

The scientific quality approach is mainly based on a systems theory. The starting point is that all work is a process and part of a system. A system is a group of parts that interact to accomplish something. According to the systems theory, when the aim is to optimise activity it is essential to understand how the parts of the system interact. Systems aim at stability (minimisation of variation). The development of quality is based on the management of stability and, after that, on conscious deviation from stability.

Techniques have been developed based on systems theory to manage and analyse the variation of processes (the system). One commonly used technique is the SPC (statistical process control), in which the aim is to identify variations in the process variables and the specific and random factors which cause such variations. A control chart is often used to identify variations, which makes it possible to identify the normal variations of the variable which is being examined (random factors) and the measurement results outside the normal variations (specific factors). For the purposes of the development of quality, attention should be focused on the measurement results that are detected outside the normal variations. There is plenty of literature and training available concerning systems theory and SPC.

6.6.2. Other statistical techniques

More developed tools are also available for health care organisations as well as other enterprises. These methods like Taguchi, Six Sigma or The Quality Function Deployment (QFD) enable the health care organisation to analyse its performance, the properties of its products etc. in a much more systematic way than we have been accustomed to so far. In general, these methods have been used very little by health care organisations so far. Lack of resources has forced health care organisations to improve their performance. The existing variation is also a challenge to be met. The experiences from other enterprises suggest that the use of these methods could also save resources thus helping health care personnel to manage the growing workload. The health care expert needs to be trained for these methods if they are to use them in their everyday practice.

6.6.3. The quality techniques

The properties of the product are routinely analysed by competitive companies. In health care there has also been customer satisfaction surveys carried out by many of the quality focused organisations. The customer expectations can never be fully met by the health care organisations, because of the limitation to the resources. All of the industrialised countries have ways of regulating the health care market in an attempt to use the available resources in the best way possible. This attempt is increasingly challenged by the citizens (patients) who increasingly act like consumers of health care products and consume products that do not have the evidence of modern science behind them. The properties of these products can and should be analysed both from the consumer and the provider perspective. There are numerous quality techniques available for these analyses that would help to make the products of health care more transparent and through that the subject of debate by patients and health care experts.

The Quality Function Deployment (QFD) is a systematic method for analysing customer needs and for planning processes and products based on this analysis. The method makes it possible to compare and measure the characteristics of the products and the phases of the process simultaneously and in detail. Using this technique, the organisation's activities can be analysed and developed at different levels, everything from process management to long-term planning of the organisation. Products that are difficult to specify, such as expert services, can be assessed and measured systematically.

Process development techniques are often based on problem solving. When the problem is being specified, the aim should be to generate factual information with the help of appropriate indicators and measurements. Problems can be analysed with different techniques, such as the scatter diagram, the Pareto chart, the histogram, the herringbone technique and the check sheet. Useful ways of trying out different alternative solutions to problems include piloting, simulation, and looking for good practices. The results must be assessed to make sure that

the solution works. The new way of action can then be introduced as part of a continuous quality management system.

7. PROCESS MANAGEMENT

7.1. The challenge for better process management

Donald Berwick and Lucian L Leape published an overview of recent studies of medical errors and harm in the British Medical Journal, July 1999. With the rising complexity and reach for modern medicine have come startling levels of risk and harm to patients. A recent study in two of the most highly regarded hospitals in the world discovered serious or potentially serious medication errors in care of 6.7 out of every 100 patient's. The Harvard Medical Practice Study (a), which reviewed over 30 000 hospital records in New York State, found injuries from care itself (adverse effects) to occur in 3.7 % of hospital admissions, over half of which were preventable and 13.6 % of which led do death (b). If these figures are extrapolated to American health care in general then over 100,000 Americans die each year as a result of preventable errors in their hospital care. The costs of medical errors are high in financial terms as well, estimated to be almost $4700 per preventable adverse drug event in one American hospital (c). There are studies on the subject going on in Europe suggesting that the same problem occurs in Europe (d, e).

Berwick's article in July 1999 was an invitation to scientists and professionals involved in quality to write about the issue. In March 2000 the BMJ published a special issue devoted to medical harm and its prevention. The annual toll exceeds the combined number of deaths and injuries from motor and air crashes, suicides, falls, poisonings and drowning. There are examples of how the number of errors can be limited and the level of quality improved. Lower error rates in reading radiographs can be sustained by redesigning the system. Information technology offers us tools for better management. Portable computerised prescribing may reduce errors. Interesting findings from a study by Sexton et al demonstrate that health care experts are more likely to deny their fatigue, stress and errors compared to aviation personnel. Reason would suggest that health care needs to be seen as a system instead of focusing on individuals and their errors. All the studies demonstrate well the need to change the way of thinking among health care experts and managers.

The issue of Medical Harm also interests the experts dealing with medical law. V.A Sharpe and A.I Faden published a book on the issue in 1998 and it was thoroughly reviewed in the European Journal of Health Law 6/1999. The historical evolution of the concept of medical harm has concentrated on the last two centuries although the issue itself was noted in the Code of Hammurabi (1700 BC). The Code of Ethics of the American Medical Association (AMA) of 1847 expressed the ideal of patient welfare, although in the background was seen the consideration over the harm to the reputation of the physician. The idea of Çend result systemÈ (to prevent failures in the future and unnecessary surgery) based on a complete medical record was introduced by E.A. Godman (around 1916) but was rejected by the hospital administrators because of financially negative

effects. It was however the starting point of the Joint Commission on Accreditation of Healthcare Organisations (JCAHO). The authors also introduce the term ÇcomiogenicÈ, broadening harm done by doctors (iatrogenic) to all providers of care (ÇkomeinÈ=care). The harm to patients should be looked at from an even broader perspective including the pharmaceutical and other industries. Health care should be perceived more from a system point of view to give a more comprehensive picture of the interactions of the different elements of the care. Over the past decades there has been growing concern in relation to resources and the expectation that physicians will act as the gatekeepers to obtaining care. Comiogenic harm can be caused by denying patients the care available using various mechanisms like standards (requirement for evidence based care), setting priorities etc. The authors challenge a wider (including others than doctors) value based discussion of the values behind the scientific evidence of the care.

The prevention and management of the medical and other health care errors is called risk management. Over past decades there have been systematic efforts to improve the health care performance in relation to adverse events. There is also lack of evidence as to what degree of risk can be avoided. The above studies suggest that there is an enormous challenge. There are studies from USA suggesting that staff after enthusiastic training report only half the adverse events, and not necessarily the worst ones.

7.2. The description of the processes

For the patient/customer, any given process is a chain of treatments and other measures taken consecutively. A description drawn up in this way is usually enough to outline the entity. The general description of the care process is the frame; those responsible for the process can continue to describe the clinical content of the various phases of the process in detail, if they consider it appropriate. It may be reasonable to describe part of the clinical process by further supplementing the phases that are perceived by the patient. To keep the process description as clear as possible and to make sure that it doesn't become too large, it may be justified to describe most work phases in more detail in the instructions that help implement the process. As a result, a documented entity is formed, in which the division of labour and co-operation between the various phases of care is clearly specified.

The general frame of the process can be seen as the phases seen through the patients eyes. The patient sees the process as entities like a nurse interview, a doctor encounter, a laboratory test, a surgical procedure etc. She/he cannot often evaluate the content of these phases that can include numerous details that require high expertise. For the patient the process is a journey where different experts and organisations form a network producing the care process based on her/his individual needs.

The patient (customer, subject of care) presents a health issue (health problem, disease, illness, requested procedure) which is often given a label, possibly a diagnosis. The care is a period of service (for instance a hospital stay) during which one health care provider delivers healthcare services to a subject of care, with regard to one or more health issues. All the contacts to health care providers that related to the same health issue form an episode of care. The episode of care can consist of activities of one health care provider or many.

A care plan refers to the service package offered to a patient/customer in a given operational organisation. The care plans can address one or more health issues. From the point of view of the health organisation these plans can be used as the basis of the quality system, aggregating individual processes into manageable entities. The clinical guidelines and other Çgood practiceÈ descriptions can be attached to the care plans, thus increasing the requirement for discipline of clinical practice. According to the quality systems idea, service providers and the organisations must follow the description of processes and the instructions. The quality system of individual service providers includes the processes of the organisation. The provider alone produces some of the processes, while some processes form part of a care chain from various providers. For the care plan to function effectively, an important point is to identify the nodes between these partial processes and the instructions that these nodes require. When the quality system is being documented, it is important to make sure that the responsibilities and obligations of the various processes, the instructions of operations and other characteristics of the quality system are not in contradiction with each other.

Many factors affect people's well being and health. The analysis of the need for social and health care services locally requires that the well being and any shortcomings in the well being, of inhabitants in individual municipalities and regions be reviewed. A strategy for promoting well being and health locally can then be drawn up.

The service network available to people is described in a local service/health care plan. These plans define for example the division of labour between the various organisations and care plans which require co-operative procedures. The plan can also include the principles by which purchased services are arranged, their quality criteria and the patients' freedom of choice within the local service system.

The local service plan can be seen as the basis for local care programmes, which define the treatment and prevention of specific diseases and health problems. In these programmes the nodes in the care chain are defined (transfers of patients, for example, from one hospital to another) and the instructions which ensure efficient operation of these nodes. The local experts define the recommendations concerning treatment and treatment practices to be used.

The local care programme should be based on a care recommendation. A clinical guideline, which according to PT-II-030:

'is a set of systematically developed statements to assist health care providers and subjects of care decisions about health care services to be provided with regard to a health issue in specified clinical circumstances. Clinical guidelines are generic. They concern no actual subject of care in particular. They reflect a broad statement of good practice, with little operational detail. Clinical guidelines should be structured and contain standards, criteria and indicators for measurement'.

Clinical guidelines are expected to be based on scientific research and its critical assessment. Many care processes include a care chain, in which the different phases of care are implemented by public and private providers of social and health care services (the service package offered to a patient/customer). The efficiency of the patient care plan requires that the activities of health care experts in relation to clinical guidelines are defined organisational or local work instructions. This will promote the use of the best clinical knowledge in everyday clinical practice.

Quality systems are usually drawn up for each individual service organisation. In practice, a large hospital or large social services department and health care organisation can include more than one quality system. Large operational entities can have completely separate service systems, the interfaces between which are based on the customer groups using these entities. They can also form part of a single comprehensive quality system. In this case, the documentation for the entire system describes only general principles, while the quality management of operations is realised as part of the process management of the units.

7.3. The assessment of the implementation and results of the processes

The most important aspects of the health care process are patient care and other measures taken to promote health. The customer in these processes is usually one patient (subject of care). The population-targeted activities as a whole are processes, in which the customer is the entire population. The population can be defined geographically or based on epidemiological data etc.

The key processes in health care are the diagnostic procedures, patient care, rehabilitation, prevention and the promotion of health.

The description of processes is important so that the processes can be managed, assessed, and developed. It is worthwhile describing the processes from the point of view of the patient/customer and the employer/work group. Processes often include medical treatment and prevention measures and procedures. The objectives should mainly be based on patient/customer needs.

A useful basic description is the flowchart technique, which can be complemented with a written description. The specialists who are responsible for the process and those who participate in it should join forces to develop the most appropriate

description method. Flowcharts, organisation charts and other procedures integrate the care process with the activities of the unit and the organisation.

How detailed the description should be and what form it should take depends on the process and on the objective of the description (whether the description, for example, promotes the flexible implementation of the process or co-operation during the process). The aim of the description is not to document self-evident facts related to clinical work but to make sure that the processes are implemented as required. Those responsible for the process and those who participate in the process decide upon the details of process implementation, and draw up the instructions which ensure the correct implementation of the process. Using protocols for procedures and actions and work instructions, which provide the most important instructions for clinical activities, ensures the correct implementation of the processes. In the instructions, reference is made to manuals, recommendations concerning care, and other corresponding documents that include descriptions of patient care and activities that the organisation has decided to implement, or the implementation of which is required. The aim of directions for procedures and actions is usually to specify and direct large entities which, for example, require co-operation between different specialists. The directions for procedures and actions can be specified in more detail in work directions; these are used to guide and specify individual tasks or parts of processes that have been defined in more detail. Only part of the knowledge based on health care expertise is included in the description of the process content and in the instructions.

Table 2. Examples of the content and use of protocols/instructions for activities and work

The protocols/instructions:
* Make sure that the process is implemented as required
* Specify the division of tasks and type of co-operation
* Specify the care methods used, the written descriptions of which can be found in manuals and other source material
* Specify how measurements should be carried out (equipment, tests, checks) in regard to the accuracy required based on clinical needs
* Specify the responsibilities, duties and competence required in the different process phases

Examining and taking care of patients often requires co-operation between several health care units. Quality management in the various units is based on the expertise in each individual field. The instructions needed and the indicators suitable for the assessment of quality are therefore based on this expertise. For example, laboratories often form separate quality systems that have their own quality manuals. It is particularly important for the entire organisation to recognise the nodes between the different processes in the patient care system when transferring the patients from one unit to another. In these nodes, it is

necessary to specify the instructions, the internal customers and other factors that will ensure smooth operation in this interface. As well as functions that are directly related to care, there are different support functions in the organisation, which are parts of the entire organisation's quality system.

8. THE EXTERNAL QUALITY ASSURANCE PROCEDURES

8.1. The concepts and types of external audits

Internationally accepted methods that have been proved to be effective are mainly used for external quality assurance. Information about the efficiency of the quality system is obtained by means of assessments, or audits. Audits are classified into first-party, second-party and third party audits. First-party audits are called internal audits in the ISO quality system, but, in a broader sense, all systematic self-assessments carried out by the organisation are first-party audits. The Quality award schemes (EFQM, Malcolm Balridge and national) emphasise the use of the criteria for self-assessment. Many of the health care accreditation schemes include a self-assessment and improvement based on the assessment, a requirement before the external audit. Self-assessment is a good means of identifying improvement potential and of creating a basis for a systematic improvement of quality.

Second-party assessments refer to audits performed by the customer for the producer of the service or product. The customer in health care can be seen from different aspects (see page 6-7). In health care the purchasers who often audit the health care organisations they purchase from usually do the second party audits

Audits performed by a third party, i.e. an independent party, include assessments carried out by certification bodies. Quality Award contests are external quality assessment methods which have been recognised internationally. Among the competitions in which companies in EU countries have participated are the Malcolm Balridge, the European Quality Award, and the national Quality Award competitions. The accuracy and repeatability of the Quality Award criteria and of the points awarded is not verified by a third party; neither are these quality assessment methods accredited. Therefore, they are not suitable for comparisons between organisations. They focus on the excellence of the organisation and can be used to identify top performance organisations as benchmarks for others. Client/producer models place emphasis on the status of the municipality as the purchaser of services and as the party that organises competitive bidding among providers. Competitive bidding for services is not very common in municipal health care services yet. Quality assurance is an important point in competitive bidding. Methods whose reliability has been verified should be used for quality assessment.

8.2. The European Union perpective

During the development of quality systems there have been different marks and certificates developed. Some health care marks and certificates have been developed within health care expertise. There hasn't been much collaboration with the existing international schemes for standardisation and

accreditation/certification. The EU countries have agreed standardisation for different enterprises to be carried out through CEN (the European Standardisation Organisation) (http://www.cenorm.be) and ISO (The International Standards Organisation) (http://www.iso.ch). There is also the European Co-operation for Accreditation (EA), which EU and national governments have given the authority to evaluate and ensure the credibility of marks and certificates given out through third party audits.

In 1989 the European Community put forward the so-called "Global Approach to testing and certification", a comprehensive policy on conformity assessment activities for the Single Market. It was primarily developed to support the Single Market for goods and Community industrial policy. The creation of the Single Market is based on a legal system. This legal system needs to be underpinned by a technical environment that fosters the necessary level of confidence among public authorities, economic operators and consumers alike. Key elements in addressing this technical environment are:
- The quality/safety of products
- The competence and responsibilities of suppliers
- The competence and responsibilities of third parties
- The convergence of markets
- Confidence.

The framework/system that was necessary to reflect these considerations was built on two pillars: the regulatory policy (conformity with essential requirements) and industrial policy (responsibilities of the operators). The guiding principles of the Global Approach are the following:
- Ensure the consistent approach to conformity assessment in both regulated and non regulated spheres
- Ensure a consistent approach to conformity assessment in community legislation.

The "Global Approach" (refers here to EU terminology) can bring benefits since it emphasis the respective responsibilities of national public authorities and the private sector, it is a framework for building confidence and promotes the use of quality tools. It is also an instrument that can be used to bring greater coherence between regulatory concerns and trade and competitiveness objectives, thus making it an effective tool for community integration.

8.3. The European Co-operation for Accreditation http://www.european-accreditation.org

The recognition of competence of the third party audits:

- Accreditation means recognition of competence. Test laboratories and certification bodies are examples of organisations that can be accredited to assess health care organisations.

The major role of the European Co-operation for Accreditation EA is to develop, evaluate and ensure the maintenance of the equivalence of competence of such bodies across Europe, through mutual recognition of agreements. To encourage this network of equivalence to develop worldwide and to provide the technical basis for realising the concept "tested or certified once - accepted everywhere".

The member bodies of EA are accreditation bodies, which have governmental recognition in a country being a member state of European Economic area, a member state of EFTA or a country that has formally been identified by EU or EFTA a candidate country for membership in EU or EFTA. EA has signed a Memorandum of Understanding with the European Commission concerning co-operation in the field of conformity assessment. In some countries the status of national accreditation bodies has been prescribed by law or government regulations.

At international meetings, the accreditation bodies harmonise their procedures and interpretations to ensure that accreditation is performed according to uniform principles in different countries. EA promotes the development of regional groupings of accreditation bodies outside Europe by signing bilateral agreements with such groups or with individual accreditation bodies. EA also functions within the wider framework on the International Accreditation Forum (IAF) and the International Laboratory Accreditation Co-operation (ILAC).

In international mutual assessments, the accreditation bodies evaluate each other's functional competence by using the following standards as criteria:

- EN 45003 (General Criteria for Laboratory Accreditation Bodies), and

- EN 45010 (General Requirements for Assessment and Accreditation of Certification/Registration Bodies).

Accreditation can be used to prove the credibility and quality of certificates issued by certifying bodies and the correctness of laboratory tests to external interest groups. The certification body, which is being accredited, must satisfy the requirements of the EN 45012 standard (Certification Bodies. General Requirements for the Certification of Quality Systems). The ISO 10011 standard 'Guidelines for Auditing Quality Systems: Part 1: Auditing. Part 2: Qualification Criteria for Auditors. Part 3: Managing Audit Programmes' is applied to the quality assurance of audits carried out by certification bodies.

The laboratory which is being accredited must fulfil the requirements of the EN 45001 standard (Operation of Test Laboratories: General Requirements) and the ISO Guide 25 (General Requirements for the Competence of Calibration and Testing Laboratories). The guidelines of EAL/G25, (Guideline on the Accreditation of Clinical Laboratories) help interpret the requirements.

Other standards and conformity assessment systems relevant to health care include:
- ISO 9000 - quality management systems
- EN 14001/EMAS environmental management systems
- BS 7799 information security
- EU requirements in different sectors, e.g. medical devices
- GLP, GMP etc.

Certification means assessment of conformity with specified requirements. This is validated with a mark or certificate. Among the objects that can be certified are quality systems, end products, and persons. In Finnish health care, quality system certificates according to the ISO 9001 or 9002 standard have been awarded to some rehabilitation institutes and occupational health units. ISO 9001, 9002 and 9003 are internationally accepted standards used for the verification of conformity with the requirements for quality systems.

EA has established Committees for Health Care where health care experts have been invited as members. The committee is a forum for discussions with interested parties about accreditation and certification in Health Care Sector. The aim is to harmonise the accreditation and certification activities for health care in Europe. The other purpose of the Committee is to ensure that the health care experts have influence at a European level on how accreditation and certification in implemented.

The EA held a seminar on Quality Assurance and Accreditation in the Health Care Sector in October 1999. The role of EA in relation to different fields of laboratory medicine has become clear. Also the implementation of the European standards and the support for the implementation needed is improving. The experience of the introduction of ISO quality systems in various EU countries was discussed. There is a growing body of published knowledge on how to use ISO quality system in health care as a whole. There is a need to produce guides for the different fields of health care and the need for a possible international ISO 9000 interpretation for health care is being discussed. EA has decided to set up a task force to clarify the use of the standard EN 45012 in Health Care. This standard defines the requirements for the certification bodies when they are accredited.

8.4. ISQUA and the Alpha Agenda

The accreditation/certification and their credibility have also been tackled by ISQUA (The International Society for Quality in Health Care) http://isqua.org.au. ISQUA was founded in 1985 by a group of health care quality professionals. Avedis Donabedian had deeply influenced many of the original groups. Now incorporated in Australia, ISQUA has members in over sixty countries. The society is a non-profit organisation, managed by an Executive Board which is elected every two years. ISQUA organises annual quality conferences and publishes the International Journal for Quality in Health Care.

One of the activities of ISQUA is the Alpha programme, which aims to harmonise the principles of the health care accreditation schemes. The Alpha Agenda and The Health Care Accreditation issues are discussed annually in a seminar usually held in conjunction with the annual ISQUA meeting. ISQUA has funded the International Accreditation Federation to manage the accreditation issues. It has two programmes in progress to aligning the health care accreditation activities namely the International Principles Programme and the Accreditor Support and Assessment Program.

The aims of the Alpha Agenda are:
- Demonstrate internationally that accreditation is a credible evaluation process
- Demonstrate that external and objective evaluation of a national accrediting organisation is possible and desirable and there is a means to do this
- Respond to an ongoing need for a forum and organisation structure through which knowledge and experience about accreditation could be shared.

8.5. Other health care related activities

There are also other health care specific audits and marks developed mainly by the representatives of the expert groups. Some of these audits have been formalised as clinical audit programmes that are used as quality measurement schemes. These activities add useful and important information on the broader overall quality management perspectives.

9. OTHER EUROPEAN HEALTH CARE QUALITY MANAGEMENT ACTORS

9.1. The European Organisation for Quality (EOQ)

The European Organisation for quality is an organisation that works together with other European organisations like EA to promote good quality management in Europe. It respects assessment principles of EA. It has a scheme for the registration of quality personnel:
- EOQ quality professional: responsible for devising and applying quality techniques
- EOQ quality systems manager: responsible for the creation and implementation of a quality system within a company and/or organisation
- EOQ quality auditor: competent to conduct external (third party) audits
- EOQ environmental auditor: qualified to conduct external (third party) environmental audits
- EOQ TQM assessor: responsible for assessing a company or organisation (third party).

9.2. The European Society for Quality in Health Care (ESQH)

The European Society for Quality in Health care is a network of national societies dedicated to quality in health care at national and international levels. It was founded by a group of presidents and former presidents of national societies for quality in health care in Europe under the auspices of ISQUA. It is committed to the achievement of its aims through collaborative action within the network and in association with other health and quality related organisations in Europe.

9.3. Building the bridges

There have been several initiatives to combine the different approaches to quality management and external quality assurance procedures.

One of the projects has been the 'Expert' (External Peer Review Techniques), which was a Biomed 2 funded research project. It was lead by Charles Shaw with invited partners from Europe and international collaborators from USA, South-Africa, Australia It looked at four common external audits schemes: Visitatie (clinical audit), EFQM, ISO and Health Care Accreditation. It produced information on the different techniques and established a network. During the project the techniques and their validity, among other things, were analysed. The reports of Expert offer information of the different external peer review techniques and encourage further collaboration between the different models.

There are many guides in relation to of the ISO 9000 quality system standard as it applies to the health care sector. Examples of these are:
- The National Standards Authority of Ireland: "Health Services Application of ISO

9002 in a hospital environment
- Swiss National Alliance for Quality in Health Care in association with the Swiss Accreditation Body (SAS): "H-9001/2"
- SGS Yarsley International (SGS) in UK: " BS EN ISO 9000: Guidance notes for its application to hospitals
- Health Quality Service in association with the Kings Fund Institute: The Kings Fund Criteria conversion structure to ISO 9002, without identification of cross-reference to the specific of ISO clauses. The method has been accredited by UKAS
- The American society for quality: "The 20 quality - System Requirements of ISO 9001/9002 Hospitals, Outpatient Clinics and Surgical Centres"
- The Joint Commission on Health Care Accreditation:" ISO - 9000 and JCAHO Comprehensive Accreditation Manual for Hospitals Crosswalk"
- Council of Standards Australia/Council of Standards New Zealand: "Guide to AS/NZS ISO 9001, 9002 and 9003 for health services"
- Standards Institute of Israel (Sii): "Check List for Assessments of Medical Service Providers"
- There is general guides with reference to ISO standards in several countries like Finland (FALRA) , Netherlands (TNO-Pace standards) , Sweden (Socialstyrelsen) and USA (The Joint Commission International Standards for Hospitals).

There are also other initiatives and means to bridge the different quality management techniques and external quality assurance procedures. In the Netherlands the harmonisation council (HKZ) has been set up to recognise and integrate different models with national policy and legislation. The Dutch accreditation body is part of the council to support the development of EA conformity assessment principles. The research and development centre NIVEL has produced health care area specific ISO 9000 standards (for ex. Pharmacy, Home Care) that have been approved for certification.

In the United Kingdom a Health Quality Service was founded by The King's Fund Institute to form an impartial body to undertake accreditation. UKAS has accredited HQS for ISO certification and health care accreditation with their ISO 9002 combination to the Kings Fund Criteria. The Clinical Pathology Accreditation (UK) Ltd. refers to ISO 9001 and ISO 43 (Proficiency testing by inter-laboratory comparison) as basis of their standard.

In Finland the Finnish Association of Local and Regional Authorities was one of the first health care administrative bodies to formulate a clear policy about quality management in health care and the role of different techniques. The policy was published in 1998 and is also available in Swedish and Spanish (Matti.Liukko@Kuntaliitto.fi). The Finnish policy was formulated with eleven recommendations, which are presented in annex 2.

10 THE HOPE PERSPECTIVE

This document aims to be informative and constructive in relation to quality management and health care. The HOPE perspective is to enhance collaboration between different players within the quality management field. The collaboration is needed to clarify certain concepts and principles used within the context of the European Union internal market of health care services and service providers. HOPE recognises the mandate of the European Union to be limited in relation to health care, but it also recognises that this mandate is gradually widening, because of free movement of European Union citizens and their need of health care in the European Union area (Kohll and Decker and other cases) The responsibility for financing and organising health care will remain with each European Union State, according to the European treaties, but these independent states will gain from collaboration to produce good quality health care.

The European Union is already harmonising the qualifications of health care personnel and other basic structural requirements. There are clear health care related activities that already guarantee basic quality elements for some health care activities like blood products and medical devices. Increasingly there are directives and other norms for the health care technology being discussed within EU. The European Commission is actively interested in the patients (citizen's rights) and these activities will lead to a need to harmonise the basic principles and concepts in relation to health care services and their quality. HOPE encourages national governments to actively take actions together with other member countries in clarifying certain basic concepts, rules and principles.

The basic concepts and principles of total quality management are applicable to health care. The challenge is to find a practical interpretation of these concepts and principles. The interpretations should focus on maximising the patient's benefits in relation to the quality of care and how it is described to her/him. Because of this health care should use the same concepts that are used within other enterprises. Within the European Union these concepts and principles are well documented in the CEN (The European Committee for Standardisation) and ISO (International Standards Organisation). It seems that EU is outsourcing this very important activities and competencies to CEN for standardisation and EA for conformity assessment. The ISO 8402 standard for the vocabulary of quality management defines the basic concepts in relation to quality. The European Co-operation for Accreditation has produced the basic concepts to be used in relation to third party audits. Concepts like accreditation and certification are used in relation to different activities in health care. HOPE encourages The European Union and the European Co-operation for Accreditation to analyse and clarify the use of these concepts in European health care.

There are different management schemes like EFQM, ISO and Health Care Accreditation. They all seem to focus to certain basic issues like the mission, organisational structure, document control, risk management, human resource

management, outcome measurement etc. While ISO 9000 and EFQM focus strongly on the processes, many of the health care accreditation programmes focus on organisational structure and capabilities. It seems that the focus has been excessively on the techniques and too little on how they should be used. There is strong evidence that processes are not managed well enough considering the preventable harm done and patient independent high variation among health care providers. HOPE encourages health care organisations to focus on patient care processes and building the quality system to support that

There are more or less explicit demands for quality management in different EU countries. The EFQM model is widely respected and used in EU health care as well as other enterprises. The ISO 9000 quality system standards have also been adapted. There are various documents to help the interpretation of these general management schemes for health care use. There are various health care management schemes developed under the umbrella of ISQUA. Many of these schemes include the principles of ISO 9000 quality system and EFQM model element Various health care specialities have also produced their own quality system standards and quality criteria of the services. HOPE encourages collaboration between these models to ensure the best elements of each:
- Limiting the number of errors and management of process variation (ISO 9000)
- Introducing the client perspective and continuous quality improvement philosophy (EFQM)
- Appropriate health care structure and competency as the building block to ensure the capability to carry out good health care practice according to guidelines based on scientific evidence. (Health Care Accreditation)

The biggest challenge however is the focus. The quality management schemes can produce good quality only if they are used to manage the key function of health care: the patient care process. The number of errors and variations between patient groups demonstrate clearly that health care has a great challenge in front of it. This challenge requires new attitudes and ways of work from health care managers and clinicians.

To ensure comparability and credibility of health care marks, certificates, criteria and themes, we need international co-operation. The national governments and the commission in EU have recognised the EA. There is a committee for health care in EA to ensure that the health care specific issues will be dealt with accordingly to ensure both the credibility of the third party audits and their relations to the health care expertise. This also ensures credibility with the rest of society. In many European Union countries there has been a solution found in this respect (for example UK, Netherlands and Finland). HOPE encourages the member states and the European Union to ensure the credibility of third party audits by the principles of EA. This requires clear policies from the ministries dealing with the health care issues in respective countries and collaboration of the organisation giving out marks and certificates with EA. The aim should be that each European Union member state could describe the principles and

requirements in relation to third party audits used in their health care. Each country should be encouraged by EU to produce these descriptions in relation to the common European standards and principles formulated through EA.

Hope continues the work within the health quality issue. The quality working party is the key group for HOPE on this issue. HOPE will be actively involved and will explore the activities of European Co-operation for Accreditation, the European Commission, the European Committee for Standardisation, the European Society for Quality, the European Foundation for Quality Management, the European Society for Quality in Health Care and the International Society for Quality In Health Care. The Quality working party will continue to explore the developments in the area of concepts and principles relating to quality management and their recognition.

ANNEX 1. Key concepts for quality management in health care:

Audit / Assessment

- Quality audit: Systematic, independent examination carried out to determine whether quality activities and their results conform to specific plans, whether the plans are implemented efficiently, and whether the plans are appropriate with regard to the objectives (ISO 8402).
- Certification and accreditation are based on an assessment of the company's/organisation's documents and practical operations. The assessment is performed by an independent third party.
- Internal audits are regularly performed by the company's/organisation's own personnel.
- Supplier audits are performed by the company to assess, for example, the suppliers of materials and services.
- In peer reviews, representatives of equal organisations assess each other's expertise.

Accreditation means recognition of competence. By means of accreditation, certification organisations and testing and calibration laboratories can prove that they fulfil certain requirements based on international agreements. Accreditation can be used to prove to external interest groups the reliability of laboratory tests and certificates issued by certification bodies.

Certification means assessment of conformity to specified requirements. A certification body assures (i.e. by issuing certification) that the company's/organisation's quality system fulfils the requirements of the appropriate ISO 9000 standard. Certification can be used to prove the efficiency of the quality system to external interest groups.

Quality: Totality of characteristics of an entity (product or service) that have an influence on its ability to satisfy stated or implicit needs (ISO 8402).

Quality manual: Document stating the quality policy and describing the quality system of an organisation (ISO 8402).

Quality policy: Overall intentions and directions of an organisation with regard to quality as formally expressed by the top management (ISO 8402).

Process: A set of inter-related resources and activities which transform inputs to outputs.(ISO 8402).

Product: The result of activities or processes (ISO 8402).

ANNEX 2. Quality management of the health services provided and purchased by the municipalities

Concepts

Recommendation 1. International quality management and quality assurance vocabulary (ISO 8402) is applicable to health care services

Customers

Recommendation 2. The quality of health care services is based on customer (patient) needs which are satisfied by the services

Process management

Recommendation 3. The processes are recognised as part of the regional service plan and care programmes based on the regional health and welfare strategy together with public and private service providers in the social and health care sector

Recommendation 4. The development of the quality of health services is based on the description of the processes and the assessment of their implementation and results

Recommendation 5. The key processes in health care are the diagnostic procedures, patient care, rehabilitation, prevention measures and the promotion of health

Recommendation 6. The development of processes is based on a systematic, continuous assessment of the outcome and effectiveness of these processes

Recommendation 7. The starting point for the quality management and development of processes is the identification of process variations

Quality management

Recommendation 8. ISO 9000 standards and EFQM criteria are applied to the management and quality management of health care organisations

Recommendation 9. Systematic quality development methods are used to develop the activities

External quality assurance procedures

Recommendation 10. The accreditation bodies for health care are the national accreditation bodies representing their country in the European Co-operation for Accreditation

Recommendation 11. Certification bodies and other third party audit systems should be accredited

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