COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Recommendation Rec(2006)7
of the Committee of Ministers to member states
on management of patient safety and prevention of adverse events in health care

(Adopted by the Committee of Ministers on 24 May 2006
at the 965th meeting of the Ministers' Deputies)

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

Considering that the aim of the Council of Europe is to achieve a greater unity between its members and that this aim may be pursued in particular by the adoption of common rules in the health field;

Considering that access to safe health care is the basic right of every citizen in all member states;

Recognising that although error is inherent in all fields of human activity, it is however possible to learn from mistakes and to prevent their reoccurrence and that health-care providers and organisations that have achieved a high level of safety have the capacity to acknowledge errors and learn from them;

Considering that patients should participate in decisions about their health care, and recognising that those working in health-care systems should provide them with adequate and clear information about potential risks and their consequences, in order to obtain their informed consent to treatment;

Recalling that Article 2 of the Council of Europe's Convention on Human Rights and Biomedicine (ETS No. 164) establishes the primacy of the human being over the sole interest of society or science, and recalling its Article 3 on the equitable access to health care of appropriate quality;

Considering that the methodology for the development and implementation of patient-safety policies crosses national boundaries and that their evaluation requires substantial resources and expertise and should be shared;

Recalling its Recommendations Nos. R (97) 5 on the protection of medical data, R (97) 17 on the development and implementation of quality improvement systems (QIS) in health care, and R (2000) 5 on the development of structures for citizen and patient participation in the decision-making process affecting health care, and its Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security, which explicitly suggests working in partnership with other health professionals;

Noting the relevance of the World Health Organisation (WHO) "Health for All" targets for the European Region (target 2) and of its policy documents on improving health and quality of life and having regard to its Health Assembly Resolution 55.18 (2002) on "Quality of care: patient safety", which recognises the need to promote patient safety as a fundamental principle of all health systems;

Considering that patient safety is the underpinning philosophy of quality improvement and that all possible measures should therefore be taken to organise and promote patient-safety education and quality of health-care education;

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

Recognising the need to promote open co-ordination of national and international regulations concerning research on patient safety,

Recommends that governments of member states, according to their competencies:

i. ensure that patient safety is the cornerstone of all relevant health policies, in particular policies to improve quality;

ii. develop a coherent and comprehensive patient-safety policy framework which:

a. promotes a culture of safety at all levels of health care;
b. takes a proactive and preventive approach in designing health systems for patient safety;
c. makes patient safety a leadership and management priority;
d. emphasises the importance of learning from patient-safety incidents;

iii. promote the development of a reporting system for patient-safety incidents in order to enhance patient safety by learning from such incidents; this system should:

a. be non-punitive and fair in purpose;
b. be independent of other regulatory processes;
c. be designed in such a way as to encourage health-care providers and health-care personnel to report safety incidents (for instance, wherever possible, reporting should be voluntary, anonymous and confidential);
d. set out a system for collecting and analysing reports of adverse events locally and, when the need arises, aggregated at a regional or national level, with the aim of improving patient safety; for this purpose, resources must be specifically allocated;
e. involve both private and public sectors;
f. facilitate the involvement of patients, their relatives and all other informal caregivers in all aspects of activities relating to patient safety, including reporting of patient-safety incidents;

iv. review the role of other existing data sources, such as patient complaints and compensation systems, clinical databases and monitoring systems as a complementary source of information on patient safety;

v. promote the development of educational programmes for all relevant health-care personnel, including managers, to improve the understanding of clinical decision making, safety, risk management and appropriate approaches in the case of a patient-safety incident;

vi. develop reliable and valid indicators of patient safety for various health-care settings that can be used to identify safety problems, evaluate the effectiveness of interventions aimed at improving safety, and facilitate international comparisons;

vii. co-operate internationally to build a platform for the mutual exchange of experience and knowledge of all aspects of health-care safety, including:

a. the proactive design of safe health-care systems;
b. the reporting of patient-safety incidents, and learning from the incidents and from the reporting;
c. methods to standardise health-care processes;
d. methods of risk identification and management;
e. the development of standardised patient-safety indicators;
f. the development of a standard nomenclature/taxonomy for patient safety and safety of care processes;
g. methods of involving patients and caregivers in order to improve safety;
h. the content of training programmes and methods to implement a safety culture to influence people's attitudes (both patients and personnel);

viii. promote research on patient safety;

ix. produce regular reports on actions taken nationally to improve patient safety;

x.   to this end, whenever feasible, carry out the measures presented in the appendix to this recommendation;

xi.   translate this document and develop adequate local implementation strategies; health-care organisations, professional bodies and educational institutions should be made aware of the existence of this recommendation and be encouraged to follow the methods suggested so that the key elements can be put into everyday practice.

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Appendix to Recommendation Rec(2006)7

A. Prerequisites

1.   In developing patient-safety strategies, governments should take a proactive, preventive and systematic attitude: to admit that errors happen, to identify and manage risk points in processes, to learn from errors and minimise their effects, to prevent further occurrences of patient-safety incidents and to encourage both patients and health-care personnel to report those patient-safety incidents they are confronted with. This could be achieved by proactive management and systematic design of safe structures and processes.

2.   Patient safety should be recognised as the necessary foundation of quality health care, and should be based on a preventive attitude and systematic analysis and feedback from different reporting systems: patients' reports, complaints and claims as well as systematic reporting of incidents, including complications, by health-care personnel. The patient-safety strategy should become an integral component of the overall continuing quality-improvement programme (Recommendation No. R (97) 17 on the development and implementation of quality improvement systems (QIS) in health care). Investment in patient safety, as in quality improvement, should be considered as economically sound and good value for money.

3.   A system-based approach presupposes the systematic design of safe structures, procedures and processes, together with corrective reactions in response to safety incidents. It is accepted that errors are a consequence of normal human fallibility and/or deficiencies of the system; these could be prevented by improving the conditions in which humans work. The aim is a system designed with built-in defences.

4.   Patient-safety programmes should use the same language, consistent terminology and be focused around similar concepts. "Patient-safety incident" is understood as any unintended and/or unexpected incident that could have led, or did lead, to harm for one or more patients receiving healthcare. In this document it is covered by various expressions, including "adverse event", "medical/clinical error" and "near miss".

5.   Patient safety is dependent on many factors, including: an adequate level of resources; sufficient financing; an appropriate number of well-trained staff; appropriate buildings; use of high-quality material, technical equipment and medicines; the establishment of standard diagnostic and therapeutic procedures (clinical practice guidelines); a clear division of tasks and responsibilities; appropriate and smooth connections between processes; proper information systems; accurate documentation and good communication between health-care professionals and teams, patients and informal caregivers. The creation of suitable working conditions and atmosphere through: correct work organisation, the reduction of stress and tension; the provision of good, safe, social and health conditions for health-service workers; and increased motivation reduces the role of the "human-factor" issues in patient-safety incidents. It includes prevention of causes contributing to (near) incidents and errors, such as: time-pressure on health-care providers (leading to insufficient time to communicate properly among professionals and with patients and other informal caregivers); frequent "handing over" of patients from one health-care professional to another (which leads to poor communication and errors related to poor transfer of information); shortage of staff; pressure on health-care professionals to quickly discharge a patient from hospital; intrusion of commercial elements in health care and side-effects of competing commercial insurance companies.

B. Cultures of safety/environment

1.	Credibility at the highest level of a health-care system is the key factor for developing a safety culture. Government and other decision makers' policy and action should support measures to allow health-care organisations to be open and fair in all they do:

a.	the first stage in developing a safety culture is to define the existing culture of a system and organisation. A safety culture is essentially a culture where everyone has a constant and active awareness of her/his role and contribution to the organisation, and of the potential for things to go wrong. It is an open and fair culture, where people are able to learn about what is going wrong and then put things right;

b.	developing a safety culture in an organisation needs strong leadership and careful planning and monitoring. It also requires changes and commitment to safety at all levels of the system, from government to clinical teams and supporting staff;

c.	a clear and strong focus on patient safety should be established through the health-care system and organisations: safety should be valued as the primary priority of healthcare, even at the expense of productivity or "efficiency";

d.	the commitment to quality and safety should be articulated at the highest level of the health-care system and translated into policies and political support of public-health and patient-safety issues;

e.	necessary financial and logistical resources, incentives and rewards should be provided by the health-care system to make this commitment possible:

–	risk management in health-care organisations should be obligatory and controlled;
–	individual incentives and rewards should be completed by team incentives and rewards;
–	individuals should be rewarded for taking safety-oriented initiatives, even if they turn out to be wrong;

f.	quality and risk-management concepts and activities should be included in the under- and postgraduate educational programmes of all health-care professions;

g.	recognised national focal points for patient safety, with relevant health-care professionals, should be created and supported;

h.	the government should ensure that no legal action is taken in case of self-reported incidents.

2.	A system-based approach is the proven way to improve patient safety. Risk management is based on, and integrated in, quality management and also takes into account human-factor engineering in structures and human-factor principles in processes.

a.	Effective risk management requires understanding of human behaviour, the varieties of human error, and the conditions likely to cause such error.

b.	It must be accepted that people will make mistakes and that processes and equipment will sometimes fail. It must be accepted that under specific circumstances and for various reasons individuals can make errors.

c.	The systems-based approach takes into account many components recognised as contributing to an incident or to the events leading up to it (see figure 1, Explanatory Memorandum). This moves the investigator away from focusing blame on individuals and looks at what was wrong with the system in which the individuals were working.

d. Systems should therefore be designed and maintained to reduce as far as possible the likelihood of patient harm caused by mistakes. By accepting this approach, organisations can focus on change and develop defences and contingency plans to cope with these failures, and can learn lessons and potentially stop the same incident reoccurring or harming patients and providers of care.

3. At the level of health-care organisations, the chief executive, the board and administrative and clinical directors need to establish an environment in which the whole organisation learns from safety incidents and where staff are encouraged to both proactively assess and immediately report risks.

These should be consistent with already established quality-management systems, of which it should be an integral part (Committee of Ministers' Recommendation No. R (97) 17 on the development and implementation of quality improvement systems (QIS) in health care).

a. Quality and risk management should be led by the highest level of the organisation and translated into shared values, norms and behaviour at all levels.

b. Health-care organisations should introduce systems allowing them to regularly conduct safety-culture assessments and learn from them. Safety should be expressed by quality indicators and followed up.

c. At all levels, from top management to frontline, staff should be educated in human-behaviour (human-factor) and risk-management principles. Potential accidents should be proactively identified and assessed (for example by Failure Modes Effects and Criticality Analysis (FMECA)). Systems and processes should be developed to manage the risks.

d. Health-care professionals should interact and communicate openly with and listen to patients. Communication with the public should be transparent.

e. Communication between individuals and teams and across organisational levels should be frequent, cordial, constructive and problem-oriented. Organisational management is kept informed about and involved in the improvement of patient safety.

f. At all levels, actual patient-safety incidents, problems and errors should be properly reported when they occur. Local policies describe clearly how organisations will manage staff involved in incidents, complaints and claims. Staff should be comprehensively trained in clinical and administrative procedures for responding to a serious error. Reporting of incidents should be promoted, locally and nationally.

g. At all levels, problems and errors should be treated openly and fairly in a non-punitive atmosphere. The response to a problem must not exclude individual responsibility, but should focus on improving organisational performance rather than on individual blame.

h. Incidents should be reviewed and investigated thoroughly, transparently and fairly, free from hindsight bias. Problem analysis should focus on organisational performance. All staff should be trained in teamwork-based problem solving and encouraged to use root-cause analysis to learn how and why incidents happen.

i. Solutions to prevent incidents should be implemented through changes in structure and processes. Safety lessons should be communicated to frontline staff and other relevant professional health-care groups and integrated into training curricula. Ongoing interdisciplinary educational programmes allow for discussions about causes and prevention of errors and adverse events. Incidents should be shared with other organisations to broaden learning as much as possible.

j. Best-practice examples and "success stories" should be collected and disseminated.

C. Assessment of patient safety – The role of indicators

1.   There is a major need to assess patient safety on an ongoing basis, implement a learning organisation, demonstrate ongoing safety improvement and determine when lapses in patient safety occur.

2.   Systematic collection and analysis of patient-safety indicators should help prevent future "unsafe" methods of care and, in the long term, their adverse effect on treatment.

3.   Patient safety is an outcome of many factors, especially safe practices within the framework of a safe system. While patient safety is the ultimate goal, belonging to "good outcomes", what ultimately determines safety is a safer care environment during the patients' whole "journey of care".

4.   Prior to embarking on actual patient-safety assessment activities, a systematic strategy should be established at an institutional or regional level to measure, report, and use information about the most common services associated with a high probability of error.

5.   The assessment of process safety should be carried out through both qualitative and quantitative methods.

6.   The qualitative methods map the various activities that exist in the routine delivery of services, for example using methods used in pathways analysis without, however, recommending one pathway as more appropriate than another. The purpose of the descriptive phase is to "map the genome of safety" in the delivery of care and services.

7.   The quantitative approach uses indicators and epidemiological methods of analysis to systematically quantify distinct aspects of processes and their immediate outputs in relation to:

–   adverse events;
–   adverse events causing harm to patients;
–   adverse events causing harm to providers; and
–   for the risk of adverse events.

8.   In 2004, the Organisation for Economic Co-operation and Development (OECD) produced a report on patient-safety indicators that would best allow the assessment of patient safety in an ongoing way, given current available knowledge. A total of 21 patient-safety indicators were selected (OECD health technical paper DELSA/ELSA/WD/HTP(2004)18, www.oecd.org/els/health/technicalpapers), which address hospital patient-safety incidents and include only measures that focus on specific clinical outcomes. Another approach is to use indicators that apply at an organisational level, for example whether a hospital or practice uses electronic prescribing, or has implemented practices that have been shown to reduce the rate of ventilator-associated pneumonia.

9.   Quality and safety indicators should be determined and reasonably applied to the entire treatment process (both outpatient and hospital treatment).

D. Data sources – Reporting systems

D.1. Patient-safety incident reporting

1.   The primary objective of an incident reporting system is the enhancement of patient safety, by learning from adverse events and mistakes made. Reporting and collection of incident data is meaningful only if the data is analysed and evaluated and if feedback is given to the professionals involved in the incident, and to all others who could learn from the incident.

2.   Incident reporting systems are not intended to identify and punish the individual staff members involved in patient-safety incidents.

3.   Incidents may be reported by health professionals, patients and relatives, or by other informal caregivers and suppliers.

4.   An incident reporting system should:

a.   preferably be voluntary in nature; in most instances the professional in question is the only one who knows about a near miss or an adverse event (alternatively: the system may be mandatory on the part of the institution, giving the controlling bodies an opportunity to measure the institution against a standard or an obligation). A mandatory system for individual health-care personnel could completely demotivate those directly involved in the provision of health care and who are invited to participate in such reporting systems);

b.   be at least confidential; however, if the event is to be analysed in order to learn from it, the names of the personnel involved may need to be known locally (that is, inside the actual institution);

c.   be anonymous, at least at regional and national levels;

d.   be non-punitive with respect to those who report, but provide no immunity if supervisory bodies or legal authorities need to be informed of the event in some way, because of its consequences for the patient;

e.   be objective with findings and recommendations;

f.   encourage unrestricted reporting by all working in the health-care system;

g.   provide incentives (for example, express recognition) for reporting;

h.   receive reports of serious and fatal events caused by incidents, near misses, and hazardous situations that could have led to safety incidents;

i.   be independent of regulatory or accrediting processes;

j.   use a single format for the reporting of all incidents, preferably including discrete categories for onward reporting to public authorities or for separate analysis. Where a variety of reporting formats already exists, the definition of a standard set of minimal data should be agreed upon, to be used in every subsequent reporting system.

5.   The greatest effect on safety and quality improvement is generated locally when the institution uses patient-safety incident reporting as part of a continuous system of safety and quality improvement:

a.   local safety and quality initiatives should be promoted in all health-care units and organisations;

b.   ongoing assessment of the patient-safety policy should start at the lowest level possible within the service.

6.   A national framework for incident management should be defined and implemented, to capture from local systems those patient-safety incidents where national learning and action can prevent future reoccurrence. Where appropriate this information could then be shared with patient-safety organisations or government departments in the other European countries.

7.   As a final goal to be reached after gaining experience at local level, a national incident reporting system should be considered: comprehensive, which should be covering all levels and areas of health-care provision, including the private sector.

8.   Aggregation of data regionally, nationally or internationally will be particularly useful for uncovering systematic failures and the accumulation of certain incidents or failures in new equipment that cannot be readily identified at the local level, in other words, those which can only be revealed by a larger dataset. Rigorous methods should be used in order to guarantee representativity of the data and to minimise any possible bias. Institutions have to be equipped with appropriate resources to achieve this purpose.

9.   The development of Internet-based reporting systems should make the establishment of national and European-wide safety-incident databases easier to maintain and less costly to operate.

10.   Experience from different countries varies as to whether there is a need to make reporting and analysis of patient-safety incidents a legal obligation.

11.   When designing patient-safety incident reporting systems it may be an advantage to have in place a complaints system, a patient compensation system and a supervisory body for health professionals. These should complement the patient-safety incident reporting system, and together these systems would form an overall integrated system for managing risks, both "clinical" and "non-clinical".

D.2. Use of data

1.   Reporting and collection of patient-safety data is meaningful only if the data is intelligently analysed and information is, where appropriate, fed back to health-care professionals, managers and patients.

2.   The Root Cause Analysis process is a systematic and comprehensive means of collecting and analysing data following a patient-safety incident. It does not end at the investigative process. It also includes the design, implementation, evaluation and follow-up of improved safety systems.

3.   There needs to be a clear understanding and agreement with health-care institutions and professionals on how the data collected will be put to use.

4.   The collection and use of data will also need to comply with domestic and European data-protection legislation.

5.   Effective data collection depends on the willingness of frontline clinical staff. The following barriers to reporting exist, which should be removed through appropriate policies:

a.   fear of blame, resulting from a lack of open and fair culture;

b   fear of the reports being used out of context by the media and others;

c.   lack of feedback as to what has changed as a result of the report;

d.   lack of time to report;

e.   lack of support from the management of the organisation;

f.   lack of legal protection against using the information for purposes other than learning;

g.   breaches of confidentiality or anonymity leading to ineffective separation of incident reporting systems from disciplinary and regulatory bodies.

D.3. Other sources of information on patient safety

1.   Patient-safety incident reporting systems can be established as "stand-alone" systems or can be integrated with systems for recording complaints and compensation claims or applications for benefits (the different sources of information will depend on the situation in each country). Each organisation should develop systems to analyse this information and to learn from it.

2.	A patient-complaints system should be regarded as an instrument ensuring patient rights, but representing a minor part of reported data on patient safety:

a.	complaints, criticism or suggestions, whether oral or written, made by patients or their representatives, should be taken seriously, and handled appropriately and sensitively;

b.	patients should feel able to approach the staff who provided the service, and professionals should make every attempt to resolve complaints locally at an early stage;

c.	the primary objective of any system is to provide the fullest possible opportunity for investigation and resolution of the complaint, as quickly as circumstances allow.

3.	Clear procedures for recording and analysing patient complaints should be defined, which should be simple and integrated by all stakeholders:

a.	the process should be fair, transparent, flexible and conciliatory and should be easy to access for all service users;

b.	rigid, bureaucratic and legalistic approaches must be avoided.

4.	In addition to patient-safety incident reporting, all other reporting systems and channels should be used to collect data. There should be a register of such sources, such as those for medical device failures, complaints, legal claims, applications for disability benefits, death inquests, and reports of adverse drug reactions: mechanisms should be introduced at regional or national level to collect this information and share the lessons learned from these systems with those able to take action.

E. Medication safety – A specific strategy to promote patient safety

1.	The use of medicines represents the most frequent health-care intervention in developed countries. Medication errors are the most common single preventable cause of adverse events and European health authorities should consider them as an important public health issue.

2.	Medication safety comprises both adverse drug reactions and medication errors. A clear distinction has to be made between them. In a recent World Health Organisation (WHO) report adverse drug reactions (pharmacovigilance) were linked to product safety, whereas medication errors were linked to the safety of health-care services.[1]

3.	A medication error is defined as follows: "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."[2]

4.	The following key dimensions in the provision of care should be taken into account in order to prevent medication errors:

a.	the organisation and structures used within health care that govern the prescription, dispensing, administration, and monitoring of medication use;

[1] WHO Quality of care: patient safety Report EB113/37 by the Secretariat to the Executive Board, 4 December 2003, 6p.
http://policy.who.int/cgi-bin/om_isapi.dll?hitsperheading=on&infobase=ebdoc-en&record={809}&softpage=Document42
[2] National Co-ordinating Council for Medication Errors Reporting and Prevention NCC MERP Taxonomy of Medication Errors. 1998
http://www.nccmerp.org/pdf/taxo2001-07-31.pdf

b.   the patient-safety culture in health care that promotes the understanding of activities that may have a high risk of undesirable outcomes with the use of medication, in the overall care process;

c.   the use of indicators that can establish a baseline for the actual incidence of undesirable events;

d.   the level of understanding among staff of the necessary and ongoing observations that need to be made to prevent or minimise the likelihood of errors in medication use.

5.   A recognised national focal point for safe medication practices should be designated in each country in a collaborative and complementary way with pharmacovigilance systems for reporting medication errors, analysing causes and disseminating information on risk reduction and prevention.

6.   European health authorities should recognise medication safety as a priority, promoting Europe-wide standards for safe medication practices and share and disseminate data and strategies for prevention and risk reduction between countries.

7.   The nature, causes, frequency and clinical consequences of medication errors in hospitals and home-care settings in Europe should be assessed.

8.   The improvement of the system of medication use requires the prevention of medication errors at every stage, including:

a.   improvement of packaging and labelling of medicines as well as proprietary and non-proprietary nomenclature, in co-operation with European regulators and the industry;

b.   safer selection and procurement of medicines, including a medication-error-risk assessment of drugs and medical devices during formulary and purchasing decisions;

c.   safer storage of medicines in clinical areas in hospitals, where unit-based floor stock should be restricted, and home-care settings;

d.   safer prescribing of medicines, helped by the availability of complete patient records, electronic prescribing, decision support and clinical pharmacy services;

e.   safer medicine preparation, by minimising the preparation in clinical areas and supplying ready-to-use medicines;

f.   safer dispensing of medicines, enhancing the ability to intercept medication errors, and reducing dispensing errors by the use of automated dispensing systems;

g.   safer administration of medicines, through clear and legible labelling of medicines up to the point of care, bar-coding, minimising the storage of high-risk medicines and the use of standardised procedures;

h.   safer monitoring of medicines based on regular medication reviews and the proactive detection of adverse drug events;

i.   independent, updated and accessible information on medicines must be available to health-care providers and patients, and considered with patient information when prescribing, dispensing, and administering medication;

j.   patients' and citizens' education for safer medicine use, considering patients as active partners in their care;

k.   safer communication about medicines for individual patients between health-care providers.

9.   In this context, reference is made to an ongoing project of the Committee of experts on pharmaceutical questions (P-SP-PH) on safe medication practices.

F. Human factors

1.	In order to reduce and prevent patient-safety incidents, health professionals must understand their own behaviour patterns, their decision-making process and their ability to cope with challenging situations in daily activities.

2.	Health professionals should be given the opportunity to learn how to handle guilt and be supported to avoid becoming "the second victim" of the safety incident.

3.	Support from the organisation to the health professionals is crucial to make disclosure of the incident possible and to enable continuation of work in health care, where risks will always exist and adverse events happen.

4.	Decision-making supports such as reference works and reminders cannot replace sound human and clinical reasoning.

5.	Sharing decision making with patients should be learned and applied in practice when appropriate.

6.	All measures that increase patients' compliance with their treatment should be implemented in order to avoid both poor outcomes and safety incidents.

7.	Education and training curricula for all health professions should include basic knowledge on: the principles of clinical decision making, risk awareness, risk communication, risk prevention, individual and collective attitudes and behaviour in the case of adverse events (medical, legal, financial and ethical aspects).

8.	Continuous education should contribute towards building a safety culture in health care by changing attitudes, from an illusion of infallibility to acceptance of human error and to the ability to learn from mistakes.

9.	Interdisciplinary co-operation, a non-hierarchical structure and open communication in health-care organisations are necessary for building a safety culture. In some specialities systematic training in team work is indispensable.

G. Patients' empowerment and citizens' participation

1.	Policy makers, planners and organisations delivering health care must place patients and the public at the centre of delivering safe health care:

2.	Citizens should be able to rely on the safety of their health services. Information should be available to the public about the safety of their health services, together with safety improvement measures.

3.	Patients using health services must have adequate information available, allowing them to include safety considerations when making decisions:

a.	this information should allow patients to balance the risks and benefits of different treatment options;

b.	when asking for the patient's informed consent, a clinician must explain the risks and benefits of the treatment in terms that the patient can understand;

c.	patients, along with health-care staff, should be involved at an early stage in the design and testing of medical procedures, devices and equipment;

d.	patients should receive information about who is responsible for their treatment, especially when this involves interdisciplinary co-operation, and learn how to establish a positive relationship with health professionals;

e. patients and relatives should be made aware of their own "risky" behaviour and encouraged to adopted more appropriate habits.

4. People who have been harmed because of their treatment must be taken care of openly, honestly and with compassion – a transparent communication policy should be followed:

a. patients must feel able to speak up when they feel that something could go, or has gone, wrong during the course of their treatment;

b. organisations should have mechanisms to allow patients to report safety incidents to health-care organisations, so that these organisations can learn from what has gone wrong;

c. these reporting systems should be in addition to the organisations' complaints procedures;

d. patients who have been harmed because of their treatment should have the possibility of receiving financial compensation without lengthy legal action.

H. Patient-safety education

1. Education for patient safety should be introduced at all levels within health-care systems, including individual public and private health-care organisations. The main focus should be on educating health-care professionals, including managers and senior figures involved in health-care governance, in patient-safety issues relevant to their function. In order to promote a change in attitudes towards greater patient safety, informing and educating to this end should begin for future doctors, nurses and other health professionals, and for administrators, as part of their training.

2. Education for patient safety should also be introduced for patients and their families, the general public, the media, consumer organisations, health purchasers and insurers, corporate organisations, government bodies and other relevant organisations. The main focus should be on raising awareness of patient-safety issues.

3. Patient Safety Education Programmes (PSEPs) should be developed and implemented by all educational institutions providing health-related curricula; professional accrediting bodies; certifying and licensing boards; and diploma appraisal and revalidation bodies.

4. Issues or topics for consideration in developing PSEPs should include, as a minimum:

a. the essence of a good patient-safety culture;

b. risk assessment, decision making and proactive management of safe health-care processes;

c. moral, legal and technical considerations;

d. human-factor considerations;

e. patients' perspective of safety and their values together with the point of view of health professionals;

f. essential communication and interaction considerations for health-care professionals and teams;

g. informed consent – scope and content;

h. reporting and analysing patient-safety incidents;

i. root-cause analysis and learning from patient-safety incidents;

j. open disclosure of patient-safety incidents;

k.   shared decision making.

I. Research agenda

The development and implementation of an effective patient-safety policy requires sound evidence (as opposed to mere opinion). Therefore, applied research on patient safety is a vital component of a comprehensive strategy to address this problem. Areas that should be considered for inclusion in research programmes include:

a.   descriptive, qualitative studies of patient-safety incidents in all health-care settings, including out-patient care, home care, acute hospital care and rehabilitation;

b.   analytical, quantitative epidemiological, preferably prospective, studies to identify risk factors for patient-safety incidents and iatrogenic complications;

c.   experimental research on human factors and human error, and on modifiable factors that decrease the likelihood of error. The studies on human-technology interaction should be included;

d   evaluation of the most effective ways of involving patients in the prevention and management of incidents;

e.   development and validation of patient-safety indicators;

f.   simulation studies and small-scale pre-tests to identify potentially effective interventions to improve patient safety;

g.   evaluations of the real-life effectiveness of interventions to improve patient safety, and of unintended side-effects of such interventions;

h.   studying the processes of care and safer practices;

i   development and introduction of instruments promoting the prevention of adverse events. The Failure Mode and Effects Analysis (FMEA) is one example of tools to prevent a failure before any harm is done. Less known in health-care organisations, they should be adapted, tested and, where appropriate, implemented;

j.   appropriate procedures to ensure safety of experimental diagnostic and therapeutic procedures;

k.   methods (including e-learning and other innovative approaches) to educate health professionals in a safety culture and in safe practice.

J. Legal framework

1.   Legislation constitutes one of the most important regulatory mechanisms in health care, but the diversity of existing legal traditions and practices in Europe calls for a country-specific approach.

2.   Member states shall consider the following elements:

a.   Legal approaches regarding a patient safety reporting system should:

    i   put in place national and local policies and mechanisms enabling a timely and explicit assessment of the nature of the incident:

        – what must be reported and to whom*;*
        – what can be reported;
        – what kind of incidents should be reported in the context of the reporting system;

ii. oblige all providers of health-care services – both public and private – to receive, record and analyse reports on patient-safety incidents for use in the improvement of patient safety and treatment;

iii. ensure that reports on patient-safety incidents, which may be attributed to specific individuals, can be exchanged within the group of people who locally handle tasks pursuant to paragraph ii. above;

iv. ensure that reports on patient-safety incidents can be passed on to clinical databases and other registers where health information is recorded with a view to increasing documentation and improving quality in the area of patient safety;

v. comply, as regards approaches under paragraphs iii. and iv., with professional-secrecy and data-protection rules, for example by providing the information in a register in an anonymous form;

vi. ensure the confidentiality of the reporting procedure, that is, ensure the identity of the reporting health-care professional or patient shall not be disclosed to patients or to the public; if the event is to be analysed and learned from, the names of the personnel involved may need to be known locally (that is, inside the actual institution);

vii. ensure the legal protection of the reporting health-care professional, that is, ensure that a health-care professional reporting to the system shall not, as a sole result of such reporting, be subjected to disciplinary investigation or measures by the employing authority, or reprisals such as supervision or criminal sanctions by the courts;

viii. not, as regards the questions of when, by whom and how the reporting is to be done, be a matter of free choice or open to random decision making but must follow an established, well-justified policy.

3. Legal approaches regarding patients' rights should:

a. ensure that complaints, criticism or suggestions made by patients or their representatives are taken seriously and handled appropriately;

b. ensure that patients are immediately informed of an adverse event and of any events entered into the patient's medical file;

c. ensure that patients who have been harmed by a patient-safety incident are entitled to receive financial compensation;

d. ensure the presence of an efficient and sufficient supervisory system to identify and manage cases of malpractice;

e. take into consideration the fact that any incident can have multiple legal consequences, depending on the nature and severity of the incident and on the causal relationship between the process of care and an adverse event.

4. It may appear difficult to establish a patient-safety reporting system without compromising patients' rights. However, if the public is ready to accept the presence of a confidential, anonymous, non-punitive reporting system the public must be assured that its legal and financial rights will be protected. The existence of a fair and open complaints system, a just and adequate compensation system and an efficient and reliable supervisory system will certainly make the process easier and politically more acceptable. Promoting a "no blame" culture is not intended to diminish the effective legal protection of patients.

K. Implementation of the patient-safety policy

A successful implementation of the patient-safety policy requires concerted activities of all stakeholders, and in particular:

a.   health-care staff involvement from the very beginning, starting with the development of a patient-safety strategy;

b.   prompt feedback to all health-care professionals and patients involved in a patient-safety incident at the local level;

c.   putting emphasis on the development of a simple, non-bureaucratic safety enhancement system;

d   in corporate health-care organisations, patient safety starts at the top; therefore management should offer leadership and support and implement a learning organisation, to assess the contribution of professionals;

e.   raising citizens' awareness through information for, and involvement of, citizens in patient-safety issues;

f.   informing the public of results achieved by patient-safety actions (transparency);

g.   obligation for health-care units to report on the implementation of patient-safety measures;

h.   adjusting, if necessary, existing systems of care by medical, economic, legal and political measures to improve patient safety;

i.   continuous quantitative assessment of the patient-safety policy at national and, where available, international level. It should be reported back in due time to enable the future updating of the policies inspired by the recommendation as well as the text of the recommendation itself;

j.   the implementation of patient-safety policies should not be conditioned or inhibited by financial considerations. The safety of medication and interventions is the essential feature of health-care provision and its cost should be included in the general budget, instead of being covered by special tariffs and reimbursement schemes. Health-care providers should receive an adequate payment through normal channels, for their quality services;

k.   member states can decide upon financing of research projects according to their perceived needs and established priorities.