



CPME/AD/Brd/290303/10/EN/fr

At its Board meeting, Brussels, March 29th, 2003, the CPME adopted the following policy : **Recommendation on patient safety** (CPME 2003/034 Final EN/fr)

A number of international investigations have now documented the need to reduce the number of adverse events in the health sector.

This has been demonstrated in the USA and Australia. Smaller studies indicate this to be the case in Europe as well, but there is a need for a deeper quantitative understanding of the situation in the various EU member states.
(Please see bibliography in document CPME 2002/087 final)

It is necessary to acknowledge that only the top of the iceberg is visible and being dealt with; the number of patients' complaints and compensations are extremely small compared with the number of adverse events that occur in the course of medical care and cause serious harm to patients.

On that background barriers must be introduced with the aim of eliminating, minimizing or blocking the consequences of adverse events. The health care system must be designed in a way that errors are caught and contained and that serious consequences of errors are avoided. This is called risk management and can never be based on individual responsibility.

In September 2002 the CPME adopted a policy regarding patient safety (CPME 2002/087 final)

The paper contains a number of recommendations for the further work on patient safety both for the CPME and for the national medical associations.

CPME should

- work to establish a voluntary, confidential reporting system;
- work towards a common internationally recognized terminology;
- work towards an integration of standards for patient safety in the national accreditation systems.



The CPME members should

- work towards an open and learning culture;
- ensure that patient safety is part of the training;
- place patient safety on the political agenda;
- support a national study of patient records;
- arrange a conference on the subject;
- conduct discussions with the patient organizations
- facilitate publication of scientific articles in the national medical journals.

Patient safety is already indirectly on the agenda in the European Union in relation to specific areas, for example medical devices and pharmaceuticals. But it is not yet recognized that the health care system is a high risk area and that it lacks the security systems, security organization, and regulated risk analysis which has long been a well-integrated part of both the atomic energy and airline industries.

Patient safety must have a much more prominent place in public health not only to reduce unnecessary patient suffering and complications, but also to realize savings in the health care sector that can be channeled elsewhere in the system.

Therefore, patient safety must be incorporated in the public health program as an important preventive element, and greater awareness about the subject must be ensured.

It is important to view patient safety as an integrated part of the health care area. This will facilitate the selection of a strategy for the health care area which will not impede further development of patient safety and a common strategy for all the areas of the health care system.

One of the preconditions for successful risk management is a change of the medical culture from "the name and shame" practice to a more "learning culture." An openness that will encourage the exchange of experience and learning is needed. For many years this kind of learning has been an essential part of the work routines of, for example, airplane pilots.

Another precondition is a change of the legislation ensuring that reporting of adverse events and near miss episodes cannot afterwards be used in any legal action against the person in question.



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Therefore, an important tool to increase patient safety is an unconditionally confidential reporting system for adverse events and near misses that can bring these out in the open to further facilitate knowledge about the epidemiology of adverse events and near misses.

Thus, what is needed is to establish a learning culture, to introduce necessary change of legislation and to establish a reporting system which can function both nationally and at a European level.

Furthermore, patient safety should be a significant element in a common accreditation system.

Standards for risk management and patient safety must be incorporated in the national accreditation systems. This will contribute to ensuring that adverse events are actually being reported and that analysis of and suggestions on dealing with them are being managed in accordance with the principles and procedures laid down for risk management. Thus, the hospitals' management of adverse events will become an important part of the total quality assessment of the hospitals. Serious and effective risk management will be a precondition to accreditation. Effective risk management and better patient safety will be rewarded.

Patient safety should also be included in the medical training.

The CPME Subcommittee on Organization of health care is working with a draft paper on "CPME action program for increasing competence of health care personnel and the capability of health care providers to adequately deal with patient safety issues." This paper is an implementation of the CPME policy paper on patient safety with regard to the recommendation to ensure that patient safety is included in medical training. The paper includes a draft questionnaire on the status of national work regarding patient safety.

The division of work between the national and European level is still important – a two-tier strategy. The ongoing implementation of the CPME-recommendations from 2002 must be closely monitored so that all initiatives aim in the right direction.



At present there is a need for:

- a survey of the national initiatives on the patient safety area
- establishment of contact and cooperation at European level between the health professionals' European organizations.
- facilitation of the necessary paradigm shift by putting patient safety on the political agenda, for example by establishing a new forum on European level with participation of the relevant stakeholders
- introduction of an internationally recognized terminology which can facilitate comparative analysis
- the description and recommendation of principles for establishing voluntary, confidential reporting systems for adverse events and near misses and
- the description and recommendation of risk management routines as part of the quality assessment systems in the health sectors.