



European Commission  
DG Health and Consumer Protection



Présidence luxembourgeoise  
du Conseil de l'Union européenne

## Patient Safety – Making it Happen!

### Luxembourg Declaration on Patient Safety

Access to high quality healthcare is a key human right recognised and valued by the European Union, its Institutions and the citizens of Europe. Accordingly, patients have a right to expect that every effort is made to ensure their safety as users of all health services.

#### Background:

The health sector is a high-risk area because adverse events, arising from treatment rather than disease, can lead to death, serious damage, complications and patient suffering. Although many hospitals and healthcare settings have procedures in place to ensure patient safety, the health care sector still lags behind other industries and services that have introduced systematic safety processes.

A number of investigations from all over the world have underlined the need for and the possibility of reducing the number of adverse events in the health sector. Current data show that almost half of all preventable adverse events are a consequence of medication errors.

Accordingly, tools must be introduced aimed at reducing the number and consequences of adverse events. The health sector should be designed in a way that errors and adverse events are prevented, detected or contained so that serious errors are avoided and compliance with safety procedures is enhanced.

As a result of the work done in this field by many players and institutions and the evidence gathered, it is now clear that the first step that needs to be taken should be to establish a culture of patient safety throughout the entire health system. Risk management must be introduced as a routine instrument within the running of the entire health sector. A precondition for risk management is an open and trusting working environment with a culture that focuses on learning from near misses and adverse events as opposed to concentrating on “blame and shame” and subsequent punishment.

Health sector induced harm to patients imposes a heavy burden on society. Investment in patient safety therefore has the potential to generate savings in expenditure coupled with an obvious benefit to patients.

Focus on patient safety leads to savings in treating patients exposed to adverse events and the consequential improved use of financial resources. In addition, savings are achieved in administration costs associated with complaints and applications for compensation. Most importantly, patient safety contributes to an increase in quality of life. In order to achieve this, the culture of safety can be improved significantly in various ways.

In light of the above, the conference recommends that “Patient Safety” has a significant place high on the political agenda of the EU, nationally in the EU Member States and locally in the health care sector.

#### The conference recommends the EU Institutions:

- ❖ To establish an EU forum with participation by relevant stakeholders to discuss European and national activities regarding patient safety.
- ❖ To work in alliance with WHO Alliance towards a common understanding on patient safety issues, and to establish an “EU solution bank” with “best practice” examples and standards.

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- ❖ To create the possibility of support mechanisms for national initiatives regarding patient safety projects, acknowledging that patient safety is in the programme of DG Health and Consumer Protection
- ❖ To ensure that EU regulations with regard to medical goods and related services are designed with patient safety in mind.
- ❖ To encourage the development of international standards for the safety and performance of medical technology.
- ❖ To ensure that the European regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.

### The conference recommends to the National Authorities:

- ❖ To provide patients with full and free access to their personal health information whilst ensuring data accuracy and that patients fully understand their treatment. It is acknowledged that “informed patients” are well positioned to safeguard their own health.
- ❖ To consider the benefits of a national voluntary confidential reporting systems of adverse events and near misses.
- ❖ To work towards the introduction of risk management routines, for example, by developing guidelines and indicators as a part of a quality assessment system in the health care sector.
- ❖ To optimise the use of new technologies, for example, by introducing electronic patient records. Such records would include the personal medical profile and decision-making support programs for health professionals with a view to reducing medication errors and increasing compliance rates.
- ❖ To establish national fora, with participation by relevant stakeholders, to discuss patient safety and national activities.
- ❖ To safeguard working conditions for all health care professions and to ensure that policies on recruitment and retention are linked to patient safety.
- ❖ To recognize and support the user training provided by medical devices, tools and appliances manufacturers thereby ensuring the safe use of new medical technology and surgical techniques.
- ❖ To include patient safety in the standard training of health professionals combined with integrated methods and procedures that are embedded in a culture of continuous learning and improvement.
- ❖ To ensure that national regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.
- ❖ To create a culture that focuses on learning from near misses and adverse events as opposed to concentrating on “blame and shame” and subsequent punishment.

### The conference recommends to health care providers:

- ❖ To facilitate a collaborative care approach between health professionals and health care providers, aimed at enhancing patient safety.
- ❖ To implement work place projects focusing on patient safety and to establish an open culture to deal with errors and omissions more effectively.
- ❖ To initiate a co-operation between patients/relatives and health care professionals in order that patients/relatives are aware of near misses and adverse events.

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LUXEMBOURG DECLARATION