

AN OPEN CONSULTATION ON PATIENT SAFETY IN THE EUROPEAN UNION

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What is the purpose of this consultation?

The European Commission launched on 25 March 2008 an eight week public consultation on patient safety. The results of this will help in the development of the Commission's proposal for on general patient safety issues planned for the end of 2008. That proposal will address the important issue of patient safety throughout the European Union (EU) and will include a detailed first pillar, addressing healthcare-associated infections (HCAI), on which separate public consultations have already been held.

The two primary objectives of the Commission's general patient safety proposal will be:

- to support Member States in their efforts to minimise harm to patients from adverse events in their health systems, through appropriate policies and actions to improve safety and, therefore, quality of care.
- to improve EU citizens' confidence that they will receive sufficient and comprehensible information available on levels of safety and available redress in EU health systems, including healthcare providers in their own country and in other Member States.

Patient safety issues can affect all EU citizens. The Commission would like to have the views of all those involved in this field from the patient and consumer to national competent authorities, from the health professional to the healthcare manager and anyone else who wishes to participate.

Why the need for action on patient safety?

Despite the aim across Europe to provide safe, high quality care in EU health systems, there is an increasing awareness that patients receiving care can incur injuries and adverse outcomes as a consequence of medical and clinical management. Research has indicated that significant levels of error occur within the provision of healthcare which can often result in injury to patients.

Patient safety-related terminology varies greatly but as a guide to some of the key terms used in this document, the following may be of help.

Patient safety is defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare. A **patient safety incident** is an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. A patient safety incident has a more constrained meaning than the term incident which, when used in a general context, has a wider meaning as an event or circumstance which could have resulted, or did result, in harm to any person and/or a complaint, loss or damage. An **adverse event** is an incident which results in harm to a patient. **Harm** implies impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death and may thus be physical, social or psychological .

Adverse events (which include unsafe care, medical errors, clinical errors and healthcare-related harm) take place in all settings where healthcare is delivered, including in primary care, secondary care, community care, social care and private care, in acute and chronic care.

Patient safety is wide in its scope and seeks to prevent harm and minimise a range of

potential adverse events in healthcare systems. Possible adverse events include medication-related errors such as patients receiving the wrong dose, wrong medicine, or through the wrong administration route, healthcare-associated infections, surgical errors (including wrong-site surgery, where for example the wrong limb is amputated), medical device and equipment-related failures. Other frequently occurring adverse events include those due to errors in diagnosis or the failure to act on the results of tests.

There is growing evidence concerning the incidence, prevalence and causes of adverse events in health systems in EU Member States and internationally, for example from the USA. Many studies suggest that approximately one patient in ten is harmed by the process of healthcare. However, it is dangerous to extrapolate research findings and assume that this is representative of the situation in all EU Member States.

It should be recognised that only a few EU Member States have collected information on the prevalence of adverse events, so data on safety levels and the associated economic costs of unsafe care is either partial or does not exist at all in many Member States. Nevertheless, the studies and research that have been carried out up until now suggest huge health costs and economic costs arising from adverse events. It is also true that many studies have suggested that targeted programmes, policies and initiatives can improve patient safety levels.

Although patient safety is narrower in its definition than healthcare quality more generally, it is the foundation of any high quality health system. As such it is recognised as a major concern for governments and competent authorities, as well as health professionals and civil society across Europe. Traditionally, efforts to address the challenges of patient safety were focussed on specific factors such as the safety of medicines or medical devices, or in specific areas like antimicrobial resistance. However, adverse events happen in the context of dynamic healthcare systems, staffed by busy individuals. A number of actors are involved in those systems, as well as numerous processes, procedures, communications and equipment. The type of healthcare setting itself will also be an influencing factor on safety levels. Therefore, the focus should be a broad one.

EU added value

The organisation and delivery of health services is primarily the competence of Member States. However, adhering to the principles of subsidiarity (particularly article 152(5) of the EU Treaty) and proportionality, the EU has a responsibility where necessary to act so as to support Member States to cooperate and coordinate their activities.

There is already legislation and/or policies on a number of specific patient safety-related issues at the EU level:

- The Community contributes to reducing risks by adopting legislation on the quality and safety of blood, tissues, cells and organs and by funding projects in this area to regulate the safety of these substances.
http://ec.europa.eu/health/ph_threats/human_substance/blood_tissues_organs_en.htm.
- A number of initiatives on injury prevention and safety promotion (including in healthcare settings), are ongoing at the EU level.
http://ec.europa.eu/health/ph_determinants/environment/IPP/ipp_en.htm.
- Plans to revise the legislation at the EU level in the area of pharmacovigilance are currently being developed.
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance_acs/index.htm.
- EU medical devices legislation has recently been revised to emphasis the safety aspects of how devices are used in practice.
http://ec.europa.eu/enterprise/medical_devices/index_en.htm.

- The European Medicines Agency has recently revised the Guideline on the acceptability of names for human medicinal products processed through the Centralised procedure (CPMP/328/98 revision 5).
<http://www.emea.europa.eu/pdfs/human/regaffair/032898en.pdf>. It is also pursuing further developments in the area in an attempt to reduce medication errors due to look-alike and sound-alike medicines on the basis of comments received during its recent consultation.
<http://www.emea.europa.eu/pdfs/human/regaffair/2529608en.pdf>.
- Work is ongoing on the use of eHealth tools to improve patient safety.
http://ec.europa.eu/information_society/activities/health/policy/index_en.htm and
<http://europa.eu/scadplus/leg/en/lvb/l24226f.htm>.
- Patient safety research has been included in the European Commission's 7th Framework Programme (<http://cordis.europa.eu/fp7/health/>), which should help to substantially improve the quantity and quality of European patient safety research.

The Commission's plans for a proposal on patient safety will attempt to complement the current legislation, work and policies in place at the EU level, by addressing wider systemic issues such as culture, leadership, education, information, reporting and redress .

Supporting European Community action would further develop past and current Community-funded patient safety-related projects and complement efforts at national level as well as other important European or global work in this area. In addition to this, EU action in this area could support Member States in their efforts to ensure that patient safety is a core element of the quality of healthcare services and that preventable harm to patients throughout the EU will be reduced. The key operational objectives of this action are for Member States to pool resources, exchange and share information, experiences and expertise at the EU level, and to develop close cooperation among Member States, so as to provide more clarity on best practice in patient safety.

How can I contribute?

Contributions should be completed on-line by 20 May 2008. Contributions will be made publicly available on the website of the European Commission once the consultation period is over, unless a specific request for confidentiality is made, in which case only an indication of the contributor will be disclosed.

Please complete your response in one of the official languages of the European Union. The questionnaire should take no more than twenty minutes to complete on-line. Do not worry if you do not feel in a position to answer **all** the questions. Obviously it would help us if you could answer as many of them as you are comfortable with, but please just complete the questions/sections you feel you can rather than choose not to complete at all if there are some issues on which you feel you are unable to voice an opinion.

What will happen next?

All contributions will be carefully analysed. A summary of the outcome of the consultation will be published on the **website**.

Following the public consultation, the European Commission intends to address a Communication to the Council of the European Union together with proposals on patient safety and healthcare-associated infection for Commission adoption by the end of 2008

Any questions?

Please contact:

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