



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.1.2009  
COM(2008) 837 final/2

2009/003 (CNS)

Corrigendum

Annule et remplace le COM(2008)837 du 15.12.2008  
Concerne toutes les versions linguistiques (pp. 1 et 2).

Proposal for a

**COUNCIL RECOMMENDATION**

**on patient safety, including the prevention and control of healthcare associated  
infections**

**{COM(2008) 836 final}  
{SEC(2008) 3004}  
{SEC(2008) 3005}**

(presented by the Commission)

Proposal for a

## **COUNCIL RECOMMENDATION**

### **on patient safety, including the prevention and control of healthcare associated infections**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular the second subparagraph of Article 152(4) thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the European Parliament<sup>2</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>3</sup>,

Having regard to the opinion of the Committee of the Regions<sup>4</sup>,

Whereas:

- (1) Article 152 of the Treaty provides that Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health.
- (2) It is estimated that in EU Member States between 8% and 12% of patients admitted to hospitals suffer from adverse events whilst receiving healthcare<sup>5</sup>.
- (3) Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources. A large proportion of adverse events are preventable, both in the hospital sector and in primary care, with systemic factors appearing to account for a majority of them.
- (4) The Commission's proposal builds upon, and complements, work on patient safety carried out by the World Health Organisation (WHO) through its World Alliance for Patient Safety, the Council of Europe and the Organisation for Economic Cooperation and Development.

---

<sup>1</sup> OJ C , , p. .

<sup>2</sup> OJ C , , p. .

<sup>3</sup> OJ C , , p. .

<sup>4</sup> OJ C , , p. .

<sup>5</sup> Technical report 'Improving Patient Safety in the EU' prepared for the European Commission, published 2008 by the RAND Cooperation.

- (5) The Commission, through the 7th Framework Programme for Research and Development, supports research in health systems, in particular in the quality of healthcare provision under the Health Theme, including a focus on patient safety. The latter is also given particular attention under the Information and Communication Technology Theme.
- (6) The White Paper "Together for Health: A Strategic Approach for the EU 2008-2013" of 23 October 2007<sup>6</sup> identifies patient safety as an area for action.
- (7) Evidence suggests that EU Member States are at different levels in the development and implementation of effective and comprehensive patient safety strategies<sup>7</sup>. Therefore, this initiative intends to create a framework to stimulate policy development and future action in and between Member States to address the key patient safety issues confronting the EU.
- (8) Patients should be informed and empowered by involving them in the patient safety process; they should be informed of levels of safety and on how they can find accessible and comprehensible information on complaints and redress systems.
- (9) Member States should set up or improve comprehensive reporting and learning systems so that the extent and causes of adverse events can be captured in order to develop efficient solutions and interventions. Patient safety should be embedded in the education and training of healthcare workers, as the providers of care.
- (10) Comparable and aggregate data should be collected at Community level to establish efficient and transparent patient safety programmes, structures and policies, and best practices should be disseminated among the Member States. To facilitate mutual learning, a common terminology for patient safety and common indicators need to be developed through cooperation between Member States and the European Commission, taking into account the work of relevant international organisations.
- (11) Information and communication technology tools, such as electronic health records or e-prescriptions, can contribute to improve patient safety, for instance by systematically screening for potential medicinal product interactions or allergies.
- (12) The European Centre for Disease Prevention and Control (ECDC) has estimated that healthcare associated infections affect about one in twenty hospital patients.
- (13) A national strategy, complementary to strategies targeted towards the prudent use of antimicrobial agents, should be developed incorporating prevention and control of healthcare associated infections into national public health objectives and aiming to reduce the risk of healthcare associated infections within healthcare institutions. It is essential that the necessary resources for implementing the components of the national strategy are allocated as part of the core funding for healthcare delivery.
- (14) The prevention and control of healthcare associated infections should be a long-term strategic priority for healthcare institutions. All hierarchical levels and functions

---

<sup>6</sup> COM(2007) 630 final.

<sup>7</sup> Safety improvement for Patients in Europe (SIMPATIE) project funded under the Community's Public Health Programme 2003 – 2008, [www.simpatie.org](http://www.simpatie.org)

should cooperate to achieve result-oriented behaviour and organisational change, by defining responsibilities at all levels, organising support facilities and local technical resources and setting up evaluation procedures.

- (15) Insufficient data on healthcare associated infections are available to allow meaningful comparisons between institutions by surveillance networks, to monitor the epidemiology of healthcare associated pathogens and to evaluate and guide policies on the prevention and control of healthcare associated infections. Therefore, surveillance systems should be established or strengthened at the level of healthcare institutions and at regional and national level.
- (16) To achieve the patient safety objectives mentioned above, including the prevention and control of healthcare associated infections, Member States should ensure a fully comprehensive approach while considering the most appropriate elements having a real impact on the prevalence and burden of adverse events.

HAS ADOPTED THE FOLLOWING RECOMMENDATION:

PART I: ACTIONS BY MEMBER STATES

## **I. Definitions**

For the purpose of this Recommendation, the definitions set out in Annex 1 apply.

## **II. General patient safety issues**

- (1) Member States should support the establishment and development of national policies and programmes by:**
  - (a) Designating the competent authority or authorities responsible for patient safety on their territory;
  - (b) Embedding patient safety as a priority issue in health policies and programmes at national as well as at regional and local levels;
  - (c) Supporting the development of safer systems, processes and tools, including the use of information and communication technology.
- (2) Member States should empower and inform citizens and patients by:**
  - (a) Involving patient organisations and representatives in the development of policies and programmes on patient safety at all levels;
  - (b) Disseminating information to patients on risk, levels of safety and measures in place to reduce or prevent errors, and ensure informed consent to treatment, to facilitate patient choice and decision-making;
- (3) Member States should establish or strengthen reporting and learning systems on adverse events that:**

- (a) Provide adequate information on the extent, types and causes of errors, adverse events and near misses;
  - (b) Encourage healthcare workers to actively report through the establishment of a reporting environment which is open and fair. This reporting should be differentiated from Member States' disciplinary systems and procedures for healthcare workers, and the legal issues surrounding the healthcare workers' liability should be clarified.
- (4) Member States should promote education and training of healthcare workers on patient safety by:**
- (a) Encouraging multi-disciplinary patient safety education and training of all health professionals, other healthcare workers and relevant management and administrative staff in healthcare settings;
  - (b) Collaborating with organisations involved in professional education in healthcare to ensure that patient safety receives proper attention in the higher education curricula and in the ongoing education and training of health professionals.
- (5) Member States should adequately classify, codify and measure patient safety, by working with the European Commission:**
- (a) To develop common definitions and terminology, taking into account international standardisation activities;
  - (b) To develop a set of common core reliable and comparable indicators at EU level to identify safety problems, to evaluate the effectiveness of interventions aimed at improving safety, and to facilitate mutual learning between Member States;
  - (c) To gather and share comparable data and information on patient safety outcomes in terms of type and number at EU level to facilitate mutual learning and inform priority setting.
- (6) Member States should share knowledge, experience and best practice at European level by:**
- (a) Sharing best practice and experience of their efforts to establish efficient and transparent patient safety programmes, structures and policies, including reporting and learning systems, to address adverse events in healthcare;
  - (b) Sharing experiences on the effectiveness of patient safety interventions and solutions at the healthcare setting level and evaluate the transferability of these.

### **III. Prevention and control of healthcare associated infections**

- (1) Member States should adopt and implement a national strategy for the prevention and control of healthcare associated infections, pursuing the following objectives:**

- (a) Implement prevention and control measures at Member State level to support the containment of healthcare associated infections;
  - (b) Enhance infection prevention and control at the level of the healthcare institutions;
  - (c) Establish or strengthen active surveillance systems at the Member State level and at the level of the healthcare institutions;
  - (d) Foster education and training of healthcare workers at Member State level and at the level of healthcare institutions;
  - (e) Improve the information given to patients;
  - (f) Support research.
- (2) **Member States should consider the establishment, if possible within one year after the adoption of this Recommendation, of an inter-sectoral mechanism for the coordinated implementation of the national strategy as well as for the purposes of information exchange and coordination with the Commission, the ECDC and the other Member States<sup>8</sup>.**

#### **IV. Additional recommendations**

- (1) Member States should disseminate the content of this Recommendation to healthcare organisations, professional bodies and educational institutions and encourage them to follow the approaches suggested so that the key elements can be put into everyday practice.
- (2) Member States should complement the key elements set out in parts II and III of this Recommendation by the supporting actions set out in Annex 2.
- (3) Member States should report to the Commission on the implementation of this Recommendation within two years of its adoption and subsequently on request by the Commission with a view to contributing to the follow-up of this Recommendation at Community level.

#### **PART II: REPORT BY THE COMMISSION**

- (1) The Commission is invited to produce, not later than three years after the adoption of this Recommendation, an Implementation Report to the Council assessing its impact, on the basis of the information provided by Member States, to consider the extent to which the proposed measures are working effectively, and to consider the need for further action.

---

<sup>8</sup> The work of this inter-sectoral mechanism should complement the work of, or be integrated into, the inter-sectoral mechanism referred to in Council Recommendation n° 2002/77/EC on the prudent use of antimicrobial agents in human medicine.

Done at Brussels,

*For the Council  
The President*

## ANNEX 1

### DEFINITIONS

Adverse event	Incident which results in harm to a patient. Harm implies impairment of structure or function of the body and/or any deleterious effect which arises from that.
Antimicrobial agents	Substances produced either synthetically or naturally by bacteria, fungi or plants, used to kill or inhibit the growth of micro-organisms including bacteria, viruses and fungi, and of parasites, in particular protozoa.
Healthcare associated infection	Healthcare associated infections (in hospitals also referred to as nosocomial or hospital-acquired infections) are diseases or pathologies (illness, inflammation) related to the presence of an infectious agent or its products as a result of exposure to healthcare facilities or healthcare procedures.
Healthcare institution	An institution where healthcare workers provide secondary or tertiary care.
Health professional	A professional whose job involves providing healthcare services and who is registered with the appropriate Member State competent authority.
Healthcare worker	All staff involved in the direct delivery of healthcare.
Infection control link staff	Health professionals working in clinical wards/departments who act as a liaison between their wards/departments and the Infection Prevention and Control Team. Infection control link staff helps promote infection prevention and control in their wards/departments and give feedback to the Infection Prevention and Control Team.
Patient care plan	A document written to provide direction for the delivery of nursing or multidisciplinary care.
Patient safety	Freedom for a patient from unnecessary harm or potential harm associated with healthcare.
Primary care	Healthcare provided by community based health professionals who act as a first point of consultation for patients.
Process indicator	An indicator referring to the compliance with agreed activities such as hand hygiene, surveillance, standard operating procedures.
Programme	A broad framework of goals to be achieved, serving as a basis to define and plan specific projects.
Secondary care	Specialised healthcare provided by specialist health professionals who generally do not have first contact with patients.
Structure indicator	An indicator referring to any resource, such as staff, infrastructure,



	committee.
Tertiary care	Specialised healthcare - usually on referral from primary or secondary medical health professionals - by specialist health professionals working in a healthcare institution that has personnel and facilities for special investigation and treatment.

## ANNEX 2

### SUPPORTING ACTIONS

#### **1. General patient safety issues**

- (1) Member States should support the establishment and development of national policies and programmes by:**
  - (a) Ensuring that clear safety standards which are applicable to healthcare provided on their territory are regularly reviewed and updated;
  - (b) Ensuring that health professional organisations have an active role in patient safety.
  
- (2) Member States should empower and inform citizens and patients by:**
  - (a) Disseminating information to patients on complaints procedures and available remedies and redress, if they are harmed by healthcare, and on the terms and conditions applicable;
  - (b) Considering the development of core competencies in patient safety (i.e. the core knowledge, attitudes and skills required to achieve safer care) for patients.
  
- (3) Member States should establish or strengthen reporting and learning systems on adverse events that:**
  - (a) Provide opportunities for patients, their relatives and other informal caregivers to report their experiences;
  - (b) Complement other safety reporting systems, such as those on pharmacovigilance and medical devices, whilst avoiding multiple reporting where possible.
  
- (4) Member States should promote education and training of healthcare workers on patient safety by:**
  - (a) Embedding patient safety in undergraduate and postgraduate education, and the continuing professional development of health professionals;
  - (b) Considering the development of core competencies in patient safety (i.e. the core knowledge, attitudes and skills required to achieve safer care) for dissemination to all healthcare workers and relevant management and administrative staff;
  - (c) Providing and disseminating information to all healthcare workers on risk, levels of safety and measures in place to reduce or prevent errors and promote their involvement.
  
- (5) Member States should adequately classify, codify and measure patient safety by:**

- (a) Paying attention to definitions, terminology and international activities such as the International Classification for Patient Safety being developed by WHO and the Council of Europe's work in this area;
  - (b) Making available indicators for safety problems both for national level and for the level of the healthcare settings.
- (6) Member States should share knowledge, experience and best practice at European level by:**
- (a) Sharing major patient safety alerts with each other in a timely manner;
  - (b) Collaborating together, and with ECDC, the European Commission and relevant international organisations.
- (7) Member States should develop and promote research on patient safety:**
- (a) Including research on issues and interventions in all sectors of the healthcare system and the economic costs of adverse events and interventions.

## **2. Prevention and control of healthcare associated infections**

- (1) Member States should develop national strategies for the prevention and control of healthcare associated infections by:**
- (a) Implementing prevention and control measures at Member State level and in particular:
    - Implementing standard and risk-based infection prevention and control measures in all healthcare settings;
    - Integrating infection prevention and control measures into patient care plans;
    - Ensuring that guidelines and recommendations are available at Member State level;
    - Encouraging the adherence to prevention and control measures by using structure and process indicators, as well as the results of accreditation or certification processes in place.
  - (b) Enhancing infection prevention and control at the level of the healthcare institutions.

The following structures are recommended to be put in place:

- A Healthcare Associated Infection Prevention and Control Programme addressing aspects such as organisational and structural arrangements, diagnostic and therapeutic procedures (e.g. antimicrobial stewardship), resource requirements, surveillance objectives, training and information to patients;

- An interdisciplinary Infection Prevention and Control Committee for the elaboration and the monitoring of the Healthcare Associated Infection Prevention and Control Programme;
  - An Infection Prevention and Control Team, with the task of implementing the Healthcare Associated Infection Prevention and Control Programme.
- (c) Establishing or strengthening active surveillance systems by:
- At Member State level:
    - Organising prevalence surveys at regular intervals;
    - Establishing and strengthening coordinated networks for the surveillance of the incidence of targeted infection types to establish national reference data, accompanied by process and structure indicators to evaluate the national strategy;
    - Ensuring real time surveillance and prompt reporting to the relevant body of clusters of healthcare associated infections;
    - Reporting of clusters and infection types of relevance for the EU or international level in accordance with the legislation in place.
  - At the level of healthcare institutions:
    - Ensuring the quality of microbiological documentation and patient records;
    - Surveillance of the incidence of targeted infection types, accompanied by process and structure indicators to evaluate the implementation of infection control measures;
    - Real time surveillance of clusters of particular infection types and/or particular strains of healthcare associated pathogens.
  - Using, wherever possible, surveillance methods and indicators as recommended by ECDC and case definitions as agreed upon at EU level.
- (d) Fostering education and training of healthcare workers by:
- At Member State level:
    - Defining and implementing specialised infection control training and/or education programmes for infection control staff and strengthening education on the prevention and control of healthcare associated infections for other healthcare workers.
  - At the level of healthcare institutions:

- Providing regular training for all healthcare staff, including managers, on basic principles of hygiene and infection prevention and control;
  - Providing regular advanced training for personnel having particular tasks related to the prevention and control of healthcare associated infections.
- (e) Improving the information given to patients by healthcare institutions:
- accurate and understandable information about the risk of healthcare associated infections, about the measures implemented by the healthcare institution to prevent them and on how patients can help to prevent them;
  - specific information (e.g. on prevention and control measures) to patients colonised or infected with healthcare associated pathogens.
- (f) Supporting research:
- epidemiology, new preventive and therapeutic technologies and interventions and on cost-effectiveness of prevention and control.