



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 5 June 2009
(OR. en)**

10120/09

**Interinstitutional File:
2009/0003 (CNS)**

LIMITE

SAN 140

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: **COUNCIL RECOMMENDATION on patient safety, including the
prevention and control of healthcare associated infections**

COUNCIL RECOMMENDATION

of

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,

Having regard to the opinion of the European Parliament¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

¹ Opinion of 23 April 2009 (not yet published in the OJ).

² Opinion of 25 March 2009 (not yet published in the OJ).

³ Opinion of 22 April 2009 (not yet published in the OJ).

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 eliminating sources of danger to human health.
- (2) It is estimated that in Member States between 8 % and 12 % of patients admitted to hospital suffer from adverse events whilst receiving healthcare¹.
- (3) The European Centre for Disease Prevention and Control (ECDC) has estimated that, on average, healthcare associated infections occur in one hospitalised patient in twenty, that is to say 4,1 million patients a year in the EU, and that 37 000 deaths are caused every year as a result of such infections.
- (4) 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, both in the hospital sector and in primary care, are preventable with systemic factors appearing to account for a majority of them.
- (5) This Recommendation 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 (OECD).

¹ Technical report "Improving Patient Safety in the EU" prepared for the European Commission, published 2008 by the RAND Cooperation.

- (6) The Community, through the Seventh Framework Programme for Research and Development¹, 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.
- (7) The Commission, in its White Paper "Together for Health: A Strategic Approach for the EU 2008-2013" of 23 October 2007, identifies patient safety as an area for action.
- (8) Evidence suggests that Member States are at different levels in the development and implementation of effective and comprehensive patient safety strategies². Therefore, this Recommendation 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.
- (9) Patients should be informed and empowered by involving them in the patient safety process. They should be informed of patient safety standards, best practices and/or safety measures in place and on how they can find accessible and comprehensible information on complaints and redress systems.

¹ Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).

² Safety improvement for Patients in Europe (SIMPATIE) project funded under the Community's Public Health Programme 2003-2008, www.simpatie.org.

- (10) Member States should set up, maintain 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.
- (11) 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.
- (12) Information and communication technology tools, such as electronic health records or e-prescriptions, can contribute to improving patient safety, for instance by systematically screening for potential medicinal product interactions or allergies. Information and communication technology tools should also aim to improve the understanding of users of the medical products.

- (13) A national strategy, complementary to strategies targeted towards the prudent use of antimicrobial agents¹, 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 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) Sufficient data on healthcare associated infections are not always 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 levels.

¹ For example Council conclusions on Antimicrobial Resistance adopted on 10 June 2008.

- (16) Member States should aim to reduce the number of people affected by healthcare associated infections. In order to achieve a reduction in healthcare associated infections, recruitment of health professionals specialising in infection control should be encouraged. Furthermore, Member States and their healthcare institutions should consider the use of link staff to support specialist infection control staff at the clinical level.
- (17) Member States should work closely with the health technology industry to encourage better design for patient safety in order to reduce the occurrence of adverse events in healthcare.
- (18) 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.
- (19) Community action in the field of public health should fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care,

HEREBY RECOMMENDS,

applying the following definitions for the purpose of this Recommendation:

"Adverse event" means an incident which results in harm to a patient;

"Harm" implies impairment of the structure or function of the body and/or any deleterious effect arising therefrom;

"Healthcare associated infections" means diseases or pathologies related to the presence of an infectious agent or its products in association with exposure to healthcare facilities or healthcare procedures or treatments;

"Patient safety" means freedom, for a patient, from unnecessary harm or potential harm associated with healthcare;

"Process indicator" means an indicator referring to the compliance with agreed activities such as hand hygiene, surveillance, standard operating procedures;

"Structure indicator" means an indicator referring to any resource, such as staff, an infrastructure or a committee;

THAT MEMBER STATES:

I. Recommendations on general patient safety issues

- (1) Support the establishment and development of national policies and programmes on patient safety by:
 - (a) Designating the competent authority or authorities or any other competent body or bodies 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 and user-friendly systems, processes and tools, including the use of information and communication technology;
 - (d) Regularly reviewing and updating safety standards and/or best practices applicable to healthcare provided on their territory;
 - (e) Encouraging health professional organisations to have an active role in patient safety;
 - (f) Including a specific approach to promote safe practices to prevent the most commonly occurring adverse events such as medication-related events, healthcare associated infections and complications during or after surgical intervention.

- (2) 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 appropriate levels;
 - (b) Disseminating information to patients on:
 - (i) patient safety standards which are in place;
 - (ii) risk, safety measures which are in place to reduce or prevent errors and harm, including best practices, and the right to informed consent to treatment, to facilitate patient choice and decision-making;
 - (iii) complaints procedures and available remedies and redress and the terms and conditions applicable;
 - (c) Considering the possibilities of development of core competencies in patient safety namely, the core knowledge, attitudes and skills required to achieve safer care, for patients.
- (3) Support the establishment or strengthen blame-free reporting and learning systems on adverse events that:
- (a) Provide 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, fair and non punitive. This reporting should be differentiated from Member States' disciplinary systems and procedures for healthcare workers; and, where necessary, the legal issues surrounding the healthcare workers' liability should be clarified;
 - (c) Provide, as appropriate, opportunities for patients, their relatives and other informal caregivers to report their experiences;
 - (d) Complement other safety reporting systems, such as those on pharmacovigilance and medical devices, whilst avoiding multiple reporting where possible.
- (4) Promote, at the appropriate level, 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) Embedding patient safety in undergraduate and postgraduate education, on-the-job training and the continuing professional development of health professionals;
 - (c) Considering the development of core competencies in patient safety namely, the core knowledge, attitudes and skills required to achieve safer care, for dissemination to all healthcare workers and relevant management and administrative staff;

- (d) Providing and disseminating information to all healthcare workers on patient safety standards, risk and safety measures in place to reduce or prevent errors and harm, including best practices, and promoting their involvement;
 - (e) 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, including the development of the skills needed to manage and deliver the behavioural changes necessary to improve patient safety through system change.
- (5) Classify and measure patient safety at Community level, by working with each other and with the Commission:
- (a) To develop common definitions and terminology, taking into account international standardisation activities such as the International Classification for Patient Safety being developed by WHO and the Council of Europe's work in this area;
 - (b) To develop a set of reliable and comparable indicators, to identify safety problems, to evaluate the effectiveness of interventions aimed at improving safety and to facilitate mutual learning between Member States. Account should be taken of the work done at national level and of international activities such as the OECD healthcare quality indicators project and the Community Health Indicators project;

- (c) To gather and share comparable data and information on patient safety outcomes in terms of type and number to facilitate mutual learning and inform priority setting, with a view to helping Member States to share relevant indicators with the public in the future.
- (6) Share knowledge, experience and best practice by working with each other and with the Commission and relevant European and international bodies on:
- (a) The establishment of efficient and transparent patient safety programmes, structures and policies, including reporting and learning systems, with a view to addressing adverse events in healthcare;
 - (b) The effectiveness of patient safety interventions and solutions at the healthcare setting level and the evaluation of the transferability of these;
 - (c) Major patient safety alerts in a timely manner.
- (7) Develop and promote research on patient safety.

II. Additional recommendations on prevention and control of healthcare associated infections

- (8) Adopt and implement a strategy at the appropriate level for the prevention and control of healthcare associated infections, pursuing the following objectives:
 - (a) Implement prevention and control measures at national or regional level to support the containment of healthcare associated infections and in particular:
 - (i) to implement standard and risk-based infection prevention and control measures in all healthcare settings as appropriate;
 - (ii) to promote consistency in, and communication of, infection prevention and control measures between healthcare providers treating or caring for a particular patient;
 - (iii) to make guidelines and recommendations available at national level;
 - (iv) to encourage 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) Enhance infection prevention and control at the level of the healthcare institutions in particular by encouraging healthcare institutions to have in place:
 - (i) an infection prevention and control programme addressing aspects such as organisational and structural arrangements, diagnostic and therapeutic procedures (for example antimicrobial stewardship), resource requirements, surveillance objectives, training and information to patients;
 - (ii) appropriate organisational governance arrangements for the elaboration and the monitoring of the infection prevention and control programme;
 - (iii) appropriate organisational arrangements and qualified personnel with the task of implementing the infection prevention and control programme;
- (c) Establish or strengthen active surveillance systems by:
 - (i) at national or regional level:
 - organising prevalence surveys at regular intervals, as appropriate;
 - taking into account the importance of surveillance of targeted infection types to establish national reference data, accompanied by process and structure indicators to evaluate the strategy;

- organising the timely detection and reporting of alert healthcare associated organisms or clusters of healthcare associated infections to the relevant body as per requirements at Member State level;
 - reporting of clusters and infection types of relevance for the Community or international level in accordance with the Community legislation¹ or international regulations in place;
- (ii) at the level of healthcare institutions:
- encouraging high quality microbiological documentation and patient records;
 - performing the surveillance of the incidence of targeted infection types, accompanied by process and structure indicators to evaluate the implementation of infection control measures;
 - considering the use of surveillance of particular infection types and/or particular strains of healthcare associated pathogens for the timely detection of alert healthcare associated organisms or clusters of healthcare associated infections;
- (iii) using, where appropriate, surveillance methods and indicators as recommended by ECDC and case definitions as agreed upon at Community level in accordance with the provisions of Decision No 2119/98/EC;

¹ For example Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community and the International Health Regulations (OJ L 268, 3.10.1998, p. 1) and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

- (d) Foster education and training of healthcare workers by:
 - (i) at national or regional 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;
 - (ii) at the level of healthcare institutions:
 - providing regular training for all healthcare personnel, 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) Improve the information to the patients by healthcare institutions:
 - (i) making available objective and understandable information about the risk of healthcare associated infections, the measures implemented by the healthcare institution to prevent them and on how patients can help to prevent those infections;
 - (ii) providing specific information, for example on prevention and control measures, to patients colonised or infected with healthcare associated pathogens;

- (f) Support research in fields such as epidemiology, the applications of nanotechnologies and nanomaterials, new preventive and therapeutic technologies and interventions and on the cost-effectiveness of infection prevention and control.
- (9) Consider, for the coordinated implementation of the strategy referred to in (8) as well as for the purposes of information exchange and coordination with the Commission, the ECDC, the European Medicines Agency and the other Member States, the establishment, if possible by ...^{*}, of an inter-sectoral mechanism or equivalent systems corresponding to the infrastructure in each Member State, collaborating with, or integrated into, the existing inter-sectoral mechanism as set up in accordance with Council Recommendation No 2002/77/EC of 15 November 2001 on the prudent use of antimicrobial agents in human medicine¹.

III. Final recommendations

- (10) Disseminate the content of this Recommendation to healthcare organisations, professional bodies and educational institutions and encourage them to follow the approaches suggested therein so that its key elements can be put into everyday practice.
- (11) Report to the Commission on the progress of the implementation of this Recommendation by ...^{*} and subsequently on request by the Commission with a view to contributing to the follow-up of this Recommendation at Community level.

^{*} OJ: please insert date two years after the adoption of this Recommendation.

¹ OJ L 34, 5.2.2002, p. 13.

HEREBY INVITES THE COMMISSION TO:

Produce, by ...*, an implementation report to the Council assessing impact of this Recommendation, 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.

Done at,

For the Council
The President

* OJ: please insert date three years after the adoption of this Recommendation.