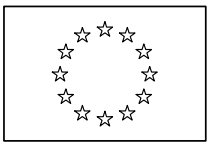

COMMISSION OF THE EUROPEAN COMMUNITIES

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# COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

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

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## 1. INTRODUCTION

Despite the obvious benefits of modern medicine there is growing awareness that healthcare interventions may sometimes result in preventable harm to the patient. Patient safety[1] is an issue of increasing concern in healthcare systems all over the world. Infections in hospitals and other healthcare settings are a particular problem for patients and health services in all countries and receive considerable media and political attention.

Among the most commonly occurring adverse events[2] are healthcare associated infections (HCAIs)[3], medication-related events and complications during or after surgical interventions. Some adverse events are linked to the intrinsic risks of necessary interventions or medications. Other adverse events, however, are caused by potentially avoidable medical errors, for example, errors in diagnosis, failure to act on the results of tests, prescribing, dispensing or administering the wrong medicine, or in the wrong dose or in combination with an inappropriate medicine, or by the failure of medical equipment. The Commission has already taken specific steps in many areas to address the issue of patient safety. However these have focused mostly on specific sources of risk such as the safety of medicines, medical devices and resistance to antimicrobials. Building on those achievements, this Communication on patient safety aims to outline an integrated approach, placing patient safety at the core of high quality healthcare systems by bringing together all factors that have an impact on the safety of patients.

Although patient safety is narrower in its definition than healthcare quality more generally, it is a key foundation of any high quality health system. Implementing effective quality and patient safety improvements is of concern to many European countries, regardless of the characteristics of their health systems, and is of interest to many international organisations such as the WHO, which recently published an overview of quality strategies in the 27 European Union Member States, or the OECD, which is currently working on healthcare quality indicators. Building on this experience and in collaboration with Member States, the Commission is developing a reflection process to consider how far the EU can play a role in assisting Member States on quality of healthcare issues.

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1 Patient safety is defined by the WHO as freedom for a patient from unnecessary harm or potential harm associated with healthcare.

2 An adverse event is an incident which results in harm to a patient.

3 For the purpose of this Communication, HCAI are defined as any disease or pathology (illness, inflammation) related to the presence of an infectious micro-organism (bacteria, fungi, viruses, parasites and other transmissible agents) or its products as a result of exposure to healthcare facilities or healthcare procedures.

## 2. CALL FOR ACTION

(1) In October 2004, the World Health Organization (WHO) launched the World Alliance for Patient Safety[4] in response to World Health Assembly Resolution 55.18[5] urging WHO and Member States to pay the closest possible attention to the problem of patient safety.

(2) In April 2005 the Luxembourg declaration on Patient Safety[6], recognised that access to high quality healthcare is a key human right to be valued by the EU, its Institutions and the citizens of Europe.

(3) The High Level Group on Health Services and Medical Care[7], which was established in 2004 to provide a mechanism for practical cooperation on making health systems work together better, set up a working group on patient safety. In 2007, the High Level Group endorsed a recommendation prepared by this working group, identifying areas where European collaboration and coordination on patient safety could bring added value.

(4) In 2006, in its Conclusions on Common Values and Principles in European Union Health Systems[8], the Council acknowledged that patients can expect each health system in the EU to secure a systematic approach to ensuring patient safety, including the monitoring of risk factors, and adequate training for healthcare workers, and protection against misleading advertising.

(5) In 2006, the Council of Europe adopted a Recommendation of the Committee of Ministers to its member states on management of patient safety and prevention of adverse events in healthcare[9].

(6) Patient safety is identified as an area for action in the Commission's Health Strategy White Paper of October 2007[10]. One of the actions set out in the second programme of the Community action in the field of health (2008-2013)[11] with the objective of improving citizens' health security is to promote measures to improve patient safety through high quality and safe healthcare, including in relation to antibiotic resistance and nosocomial infections.

(7) Building on all of these developments, patient safety, including the prevention and control of healthcare associated infections, was made a strategic item under the Commission's legislative and work programme 2008. Accordingly, the Commission is

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4 http://www.who.int/patientsafety/en

5 World Health Assembly Resolution WHA55.18. Quality of care: patient safety (18 May 2002).

6 http://europa.eu.int/comm/health/ph_overview/Documents/ev_20050405_rd01_en.pdf

7 Commission Decision of 20 April 2004 setting up a High Level Group on Health Services and Medical Care - C(2004) 1501.

8 Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

9 Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care.

10 White Paper "Together for Health: A Strategic Approach for the EU 2008-2013" - COM(2007) 630.

11 Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-2013) (OJ L 301, 20.11.2007, p. 3).

putting forward this Communication and a proposal for a Council Recommendation on patient safety, including the prevention and control of healthcare associated infections.

## 3. THE ISSUE

### 3.1. Prevalence and Burden of Adverse Events

There is a limited but growing body of evidence concerning the extent of adverse events in health systems in EU Member States. National studies from the UK, Spain and France provide the bulk of current evidence in Europe on in-patient adverse event prevalence and its implications.

In the UK, a report by England's Chief Medical Officer in 2000, *An Organisation with a Memory*, revealed that patient safety was a major problem: data showed that at least 400 patients died or were seriously injured in adverse events involving medical devices in 1999 and that nearly 10,000 people had experienced serious adverse reactions to medicinal products. According to the 2006 Spanish National Study on Hospitalisation-Related Adverse Events (ENEAS), 9.3% of hospital patients in Spain in 2005 suffered adverse events and 42.8% of these were deemed preventable. A recent French national survey of in-patient adverse events (Michel, 2007), found that in the course of seven days' observation per unit at least one adverse event occurred in 55% of surgical units and 40% of medical units. 35.4% of the adverse events were considered to have been preventable.

From the national studies mentioned above, and from interviews with key stakeholders conducted for the impact assessment informing this initiative, it is estimated that, in the EU, between 8% and 12% of patients admitted to hospitals suffer from adverse effects while receiving healthcare.

HCAIs, a key focus of the current initiative, are among the most frequent and potentially harmful causes of unintended harm, affecting an estimated one in twenty hospital patients on average, corresponding to 4.1 million patients every year in the EU[12]. HCAIs are often difficult to treat due to antimicrobial resistance of the micro-organisms causing these infections.

Many factors contribute to the worrying magnitude of HCAI rates. Organisational and behavioural factors include high bed occupancy, increased movements of patients within and between healthcare systems**,** sub-optimal staff to patient ratios, insufficient compliance with hand hygiene and other infection prevention and control practices, incorrect use of indwelling devices by healthcare staff. Other factors, such as the inappropriate use of antimicrobial agents, are relevant beyond healthcare institutions.

Owing to the ability of HCAI and other infectious micro-organisms to colonise humans for prolonged periods, patients may disseminate them during and after their hospital stay. In this way HCAIs can affect all healthcare settings, care homes and even the patient's home.

[12] Refer to the impact assessment.

### 3.2. The public perception of patient safety

Responses to the public consultation on patient safety that the Commission conducted from 25 March to 20 May 2008[13] indicated that about 20% of the 185 respondents had suffered from an adverse event. An overwhelming majority of participants gave strong support for both national and Community action on patient safety. There is also evidence of widespread public concern throughout the EU about patient safety and adverse events as a significant issue that needs to be addressed[14].

### 3.3. The State of Play

Some aspects of patient safety are already addressed at Community level. For instance, the safety of medicines is addressed in the legislation on pharmaceuticals, including on pharmacovigilance,[15] which is currently being reviewed with a view to significantly improve patient safety; the safety and performance of medical devices in the medical devices Directives[16]; and medication errors arising from look-alike and sound-alike medicines are being examined by the European Medicines Agency, which is developing new requirements for medicinal products naming. There is legislation addressing the safety of human tissues and cells[17] as well as blood and blood components[18]. The 'open method of coordination' (OMC) addresses quality of healthcare, including safety and patient centeredness. The European Centre for Disease Prevention and Control (ECDC)[19] operates surveillance networks and assists the European Commission in operating early warning systems for emergency situations. The Recommendation on cross-border interoperability of electronic health record systems[20] aims at improving care and reducing adverse events by making key clinical data, contained in electronic health records (including data on medications), accessible when the patient is treated in another country. There are also a number of European Community projects on patient safety, including HCAIs, financed under the Research Framework Programmes or the Programmes of Community action in the field of health[21].

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13 http://ec.europa.eu/health/ph_consultations/consultations_en.htm.

14 For example, the Eurobarometer of 2005 on medical errors, http://ec.europa.eu/health/ph_publication/eurobarometers_en.htm.

15 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. 1-33; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67-128.

16 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17); Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1); Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

17 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

18 Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

19 Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

20 Commission Recommendation C(2008) 3282 of 2 July 2008 on cross-border interoperability of electronic health record systems.

21 OJ L 271, 9.10.2002, p. 1; OJ L 301, 20.11.2007, p. 3.

These actions, however, do not fully meet the needs of patients or governments to improve the safety of patients in EU healthcare systems. They tend to focus on specific causes or factors, and do not address the overall cultural, leadership, systemic, communication and process barriers to improved safety.

## 4. RATIONALE FOR A EUROPEAN ACTION

Among the challenges that make action on patient safety particularly pressing are rising public expectations, an ageing society and advances in medical treatment. Health systems across Europe face common challenges as they adapt to constant developments in medical science. Although the problem of patient safety is primarily the responsibility of Member States, the European Union can encourage cooperation between Member States and support their actions in areas where EU intervention can have an added value.

This initiative intends to foster political commitment by Member States to make patient safety a priority in national public health objectives. Evidence suggests that EU Member States are at different levels of political awareness and priority-setting and, therefore, at different stages in the development and implementation of effective, comprehensive patient safety programmes, strategies and processes[22].

The EU can also play a role in collecting comparable and aggregate data at Community level and in disseminating best practices among the Member States to establish efficient and transparent patient safety programmes, structures and policies. To facilitate mutual learning among Member States, a common 'language' or 'taxonomy' for patient safety and common indicators need to be developed.

These actions will help patients to make informed choices about their care in terms of safety. This is particularly relevant for patients that access healthcare in a Member State other than their own. Patients should know how safe those health systems are, and what support they or their family can expect when harmed by an adverse event.

Finally, the limited time-span of EU projects means that there is no guaranteed longer-term action on patient safety in the Community. The EU can play a role in considering how best to achieve and sustain effective collaboration on patient safety between Member States in the longer term.

In summary, EU activity in the area of patient safety can provide added value in the following ways: the EU can provide political weight and visibility to patient safety; economies of scale can be achieved through Community-wide collection of data and sharing of best practice; patients can benefit from an increased dissemination of information on levels of safety and available remedies and redress; and sustainability of EU action on patient safety can be ensured.

[22] Safety improvement for Patients in Europe (SIMPATIE) project funded under the Community's Public Health Programme 2003 – 2008, www.simpatie.org, and Technical report 'Improving patient safety in the EU' prepared for the European Commission, published 2008 by the RAND Corporation.

## 5. OBJECTIVES AND AIM OF THIS INITIATIVE

The objective of this initiative is to protect EU citizens from preventable harm in healthcare by supporting Member States to put in place adequate strategies to prevent and control adverse events in healthcare, including healthcare associated infections, and to improve EU citizens' confidence that they have sufficient, comprehensive and comprehensible information on safety and available redress in EU health systems. This initiative on patient safety is intended to create a framework to stimulate policy development and future action in, and between, Member States to address the key patient safety issues and problems confronting the EU.

## 6. OPERATIONAL ACTIONS AT MEMBER STATE LEVEL

Member States have the prime responsibility for protecting and improving the health of their citizens. As part of that responsibility, it is for them to decide on the organisation and delivery of health services and medical care, reflecting Article 152 of the Treaty. However, as shown above, effective cooperation and coordination between countries can lead to increased patient safety.

Accordingly, a number of actions to be implemented either at national or European level (or a combination of the two) are put forward by this Communication and the accompanying proposal for a Council Recommendation on patient safety, including the prevention and control of healthcare associated infections.

Member States are recommended to:

(1) Support the establishment and development of national policies and programmes on patient safety in general terms.

(2) Inform and empower patients by involving them in the patient safety policy process, by informing them of levels of safety and, if things go wrong, how they can find accessible and comprehensible information on complaints and redress systems.

(3) Set up or improve comprehensive blame-free reporting and learning systems so that the extent and type and causes of adverse events are captured to enable resources to be efficiently channelled into developing solutions and interventions which can then be shared at the EU level. Such reporting on adverse events should be done in a constructive, rather than a punitive or repressive, manner so that healthcare providers feel confident that they can report without fear of negative consequences.

(4) Ensure that patient safety is embedded into the education and training of healthcare workers, as the providers of care.

In addition, the proposal for a Council Recommendation puts forward a number of specific recommendations on the key patient safety issue of healthcare associated infections. Member States are recommended to: implement prevention and control measures to support the containment of HCAIs; enhance infection prevention and control at the level of healthcare institutions; establish or strengthen active surveillance systems; foster education and training of healthcare workers on infection prevention and control; improve the information given to patients; and support research.

## 7. OPERATIONAL ACTIONS AT EU LEVEL

At the EU level, the Commission should, in close collaboration with Member States:

(1) Take the necessary initiatives to develop common definitions, terminology and indicators on patient safety. This action should build on the work undertaken by international bodies such as the WHO, the OECD and the Council of Europe and exploit, where appropriate, the results of relevant research projects at the EU level. Agreed indicators should also be developed for public reporting of safety levels.

(2) Facilitate sharing information and best practice on patient safety, including on the prevention and control of HCAIs. Sharing major patient safety alerts should also be possible at the EU level.

(3) Continue promoting European research programmes on patient safety particularly focusing on filling the current research gaps and on complementing existing research on national level.

(4) Consider how best to achieve and sustain effective collaboration on patient safety between Member States in the longer term.

## 8. IMPLEMENTATION

In order to facilitate the coherent implementation of the recommended actions the Commission will, where necessary, develop guidelines in close cooperation with Member States, including on the prevention and exposure of healthcare workers to healthcare-associated pathogens.

The Commission can in particular foster with ECDC the development of guidance on best practice on the prevention and control of healthcare associated infections, promote the availability of training opportunities and assist Member States to develop infection control training and curricula for infection control staff and healthcare workers. In addition to the current coordination of European surveillance of healthcare associated infections and information exchange about outbreaks, the Commission can foster with ECDC the development and implementation of surveillance of infection control structure and process indicators in order to evaluate the implementation of the recommended actions in the Member States and assist Member States to establish or strengthen surveillance on healthcare associated infections.

Not later than three years after the adoption of this Communication and the Recommendation, the Commission will produce an Implementation Report assessing the impact of this initiative, on the basis of the information provided by Member States, to consider the extent to which the proposed measures are working effectively and consider the need for further action.

## 9. CONCLUSION

Adverse events in healthcare can potentially affect every patient and family and represent a serious health burden for the EU. Moreover, the need to bring together expertise and make efficient use of the limited available resources means that patient safety is an area where European cooperation can add particular value to the actions of the Member States. The

Commission has already taken individual initiatives in the past, such as addressing certain aspects of patient safety in Community legislation, or fostering research and collaboration on patient safety by Community co-funded projects. But more action is needed to ensure that these individual strands of work are sustained and brought together into a coherent overall strategy for patient safety, both at Community level and within Member States.

With this Communication and the accompanying proposal for a Council Recommendation, the Commission aims to put in place an integrated approach to patient safety. This offers the potential to maximise the scope for cooperation and mutual support in this difficult area across the EU as a whole. It will support Member States in putting in place their own national and regional strategies for patient safety. And by doing so, it will provide patients and their families with a tangible benefit from European integration in their daily lives.