Basic information

2009/0003(CNS) CNS - Consultation procedure Recommendation	Procedure completed
Patient safety, prevention and control of healthcare associated infections **Subject** 4.20 Public health 4.20.01 Medicine, diseases 4.20.06 Health services, medical institutions 4.20.07 Medical and para-medical professions 4.60.08 Safety of products and services, product liability	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	SARTORI Amalia (PPE-DE)	15/01/2009

Committee for opinion	Rapporteur for opinion	Appointed
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Employment, Social Policy, Health and Consumer Affairs	2947	2009-06-08

Key events

Date	Event	Reference	Summary
15/12/2008	Legislative proposal published	COM(2008)0837	Summary
03/02/2009	Committee referral announced in Parliament		
31/03/2009	Vote in committee		Summary
03/04/2009	Committee report tabled for plenary, 1st reading/single reading	A6-0239/2009	
23/04/2009	Decision by Parliament	T6-0287/2009	Summary
23/04/2009	Results of vote in Parliament		

23/04/2009	Debate in Parliament		
08/06/2009	Act adopted by Council after consultation of Parliament		
08/06/2009	End of procedure in Parliament		
03/07/2009	Final act published in Official Journal		

Technical information

Procedure reference	2009/0003(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Recommendation
Legal basis	EC Treaty (after Amsterdam) EC 152-p4
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/72156

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE419.906	30/01/2009	
Amendments tabled in committee		PE421.189	02/03/2009	
Committee report tabled for plenary, 1st reading/single reading		A6-0239/2009	03/04/2009	
Text adopted by Parliament, 1st reading/single reading		T6-0287/2009	23/04/2009	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2008)0837	15/12/2008	Summary
Document attached to the procedure	SEC(2008)3004	15/12/2008	
Document attached to the procedure	SEC(2008)3005	15/12/2008	
Commission response to text adopted in plenary	SP(2009)3507	25/06/2009	
Non-legislative basic document	COM(2012)0658	13/11/2012	Summary
Follow-up document	SWD(2012)0366	13/11/2012	
Non-legislative basic document	COM(2014)0371	19/06/2014	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0632/2009	24/03/2009	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

EP/Council Recommendation 2009/0703(01)
OJ C 151 03.07.2009, p. 0001 Summary

Patient safety, prevention and control of healthcare associated infections

2009/0003(CNS) - 13/11/2012

On the basis of information provided by the Member States, the current Commission report follows up the Council Recommendation of June 2009, on patient safety, including the prevention and control of healthcare-associated infections. The Recommendation consists of two chapters:

- in the first chapter on **general patient safety**, Member States are asked to put in place a series of measures with a view to minimising harm to patients receiving healthcare;
- in the second chapter on the **prevention and control of healthcare-associated infections (HAIs)**, Member States are asked to adopt and implement a strategy at the appropriate level for the prevention and control of HAIs and to consider setting up an inter-sectoral mechanism or equivalent system for the coordinated implementation of such a strategy.

This Report summarises the **main actions taken at Member State and EU level by June 2011** (July 2012 for the general patient safety part) and highlights those areas of the Recommendation needing further attention.

1) Main actions taken at Member State level: most Member States have taken a variety of actions as envisaged by the Recommendation.

On general patient safety, most Member States:

- have embedded patient safety as a **priority** in public health policies and designated a competent authority responsible for patient safety;
- have encouraged **training** on patient safety in healthcare settings, though only a few have formally embedded patient safety in education and training programmes for health professionals.

The existing **reporting and learning systems** have been considerably improved in two main aspects: their blame-free character and offering patients the possibility to report. However, there is still room for improvement in this crucial area. The same applies to provisions for **patient empowerment**. Also, efforts focus on hospital healthcare, with only a few examples of actions addressing primary care.

On the prevention and control of HAI:

- 26 out of 28 responding countries have implemented a combination of actions to prevent and control HAI, in most cases (77 %) as part of a national/regional strategy and/or action plan;
- 13 Member States report that the Recommendation has triggered initiatives on HAI, in particular the implementation of an inter-sectoral mechanism or equivalent system, preparation/revision of strategies, and information campaigns addressing healthcare workers.

2) Main actions taken at EU level:

On general patient safety, the European Commission has:

- pursued the following activities to promote mutual learning among Member States and propose common definitions and terminology for patient safety;
- fostered the exchange of information on initiatives concerned with patient safety and quality of care;
- allocated EUR 3 600 000 for a three-year collaboration on patient safety, in the form of a joint action for the years 2012-2015, the EU has co-financed six research projects on general patient safety, to a total amount of EUR 16 million.

On the prevention and control of HAI:

- to have an "Action plan against the rising threats from antimicrobial resistance"; The Commission's 'Action plan against the rising threats from antimicrobial resistance';
- to fund numerous research projects in the area of HAI and antimicrobial resistance within the Sixth and Seventh Framework Programmes for Research and Technological Development (2002-2006 and 2007-2013).

The European Centre for Disease Prevention and Control (ECDC) coordinates the European surveillance of surgical-site infections, HAI in intensive care units and antimicrobial resistance.

3) Improvements to make: The report notes there are still various areas of the Recommendation with **considerable room for improvement**. The priority areas on which future work should focus include:

General patient safety:

- At Member State level:

- actively involve patients in patient safety, in particular provide information to patients on safety measures, complaint procedures and patients' rights to redress, work on a common understanding and development of core competencies for patients, and encourage patients and their families to report adverse events;
- collect information on adverse events through further developing reporting and learning systems;
- ensure a non-punitive context for reporting on adverse events and evaluate reporting progress;
- extend patient safety strategies and programmes from hospital care to non-hospital care as well.

*- **At EU level***:

- collaborate with a view to proposing guidelines on how to construct and introduce patient safety standards beyond the Recommendation;
- make progress on common terminology on patient safety;
- pursue exchange of best practice, e.g. systematic integration of patient safety in the education and training of health professionals at all levels;
- develop research in the area of patient safety, including studies on the cost-effectiveness of patient safety strategies.

Prevention and control of healthcare associated infections:

*- **At Member State level**:*

- ensure adequate numbers of specialised infection control staff with time set aside for this task in hospitals and other healthcare institutions;
- improve the training of specialised infection control staff and better align qualifications between Member States;
- reinforce tailored basic infection prevention and control structures and practices in nursing homes and other long-term care facilities;
- repeat national point prevalence surveys of HAI as a means to monitor the burden of HAI in all types of healthcare institutions, to identify priorities and targets for intervention, to evaluate the impact of interventions and to raise awareness;
- ensure that surveillance of infections in intensive care units and surgical site infections is in place;
- implement surveillance systems for the timely detection and reporting of alert healthcare associated organisms and strengthen the ability to respond to the spread (including across borders) of such organisms and prevent their introduction into healthcare settings;
- improve the information on HAI for patients and strengthen their involvement in the compliance with infection prevention and control measures;
- develop an evaluation system with a set of indicators in Member States to assess the implementation of the strategy/action plan and its success in improving the prevention and control of HAI.

*- **At EU level***:

- continue the development of guidance on the prevention and control of HCA, including tailored guidance for nursing homes and other long-term care facilities;
- develop research in the area of the prevention and control of HCA, including studies on cost-effectiveness of prevention and control measures.

As in many Member States and at EU level the actions have been implemented only recently or in some cases are still under implementation, it might be advisable to carry out such an **assessment again in two years' time**, taking the current report as a comparative reference. This is why the

Commission proposes extending the monitoring of the implementation of the general patient safety provisions of the Recommendation for another two years.

In June 2014, the Commission will prepare a second progress report taking into account the mid-term results of the joint action on patient safety and quality of care.

Patient safety, prevention and control of healthcare associated infections

2009/0003(CNS) - 19/06/2014

Council Recommendation 2009/C 151/01put forward a range of measures on general patient safety and healthcare-associated infections (HAI) and invited the Commission to report on whether the measures are working effectively and to consider the need for further action.

The Commission's first report (see summary of 13/11/2012) showed uneven progress across the EU. Some Member States reported that implementation had been slowed by financial constraints resulting from the economic crisis. The Commission therefore proposed that its monitoring of the implementation of the general patient safety provisions be extended for another two years.

Patient safety

General assessment: Member States have made progress on developing policies on patient safety since the Recommendation was adopted. 26 countries developed or are finalising patient safety strategies or programmes. More countries provided supporting documents than in 2012 (21 in 2014 against eight in 2012). Most gave examples of indicators to evaluate the strategies.

However, the report notes that the Recommendation has had **less of an impact in increasing patient safety culture at healthcare setting level,** i.e. encouraging health professionals to learn from errors in a blame-free environment. The impact on empowering patients is only partial. According to countries' self-assessments, the Recommendation raised awareness about patient safety at healthcare setting level (20 replies). Only half of countries judged that it had had an impact on empowering patient organisations and individual patients.

The report discusses the actions taken at EU level and notes the Commission Green Paper on mHealth highlights benefits of using telemedicine and mHealth solutions for ensuring patient safety.

Education and training of health professionals: this remains an area in which Member States and stakeholders have pointed to a need for further effort. Most countries reported that they encouraged multidisciplinary training on patient safety in healthcare settings, but three quarters do not provide information about the actual delivery of such training in hospitals.

Patient safety is not widely embedded in the undergraduate and postgraduate education of healthcare workers, on-the-job-training and the continuing professional education of health professionals, except in six Member States. In eight Member States, it is not formally required at any level or for any health professionals.

Public perception: Eurobarometer B80.2 survey on patient safety and quality of care published in June 2014 showed that the Recommendation did not change EU citizens' perception of the safety of care. As in 2009, over 50 % of respondents thought that patients could be harmed by hospital and non-hospital care. 25 % of respondents said that they or their family experienced an adverse event. Patients now report considerably more adverse events than in 2009 (46 % vs. 28 %). Most respondents felt, however, that such reporting does not lead to specific action being taken.

Further action: the Commission considers there is a need for continued effort at EU level to support Member States in improving patient safety. The following measures could be of particular relevance for further EU work:

- a common definition of quality of care and further support for the development of common terminology, and common indicators and research on patient safety;
- EU collaboration on patient safety and quality of care to exchange good practices and effective solutions- this could build on the current joint action and be extended to other topics identified by Member States and stakeholders;
- developing guidelines on how to provide information to patients on quality of care;
- development with Member States of an EU template on patient safety and quality of care standards to achieve common understanding of this concept in the EU;
- reflection with Member States on the issue of redress as provided for in Directive 2011/24/EU);
- encouraging reporting as a tool to spread a patient safety culture;
- regular updating and dissemination of the guide on the settingup and functioning of reporting and learning systems.

Healthcareassociated infections (HAI)

By leading to the adoption of a general and specific case definition for HAI and providing a standardised methodology and framework for the national surveillance of HAI, EUlevel action contributed to strengthening HAI surveillance systems in the EU.

In particular, the European Centre for Disease Prevention and Control (ECDC) Europe-wide point prevalence survey of HAI and antimicrobial use in 2011-12 contributed to the improved collection of data on HAI, even in Member States that had not previously started with this activity. Since the

Recommendation was published, one EU-wide point prevalence survey was organised in acute care hospitals in 2011-12 and two in long-term care facilities.

Overall, **the level of participation in the European HAI surveillance modules was considered high in nine countries** or regions (AT, DE, ES, FR, IT, LT, MT, PT and UKScotland), medium in 13 (BE, CZ, EE, FI, HU, LU, NL, NO, RO, SK, UK-England, UK-Northern Ireland and UK-Wales) and low in 11 countries (BG, CY, DK, EL, HR, Iceland, IE, LV, PL, SE and SI).

The point prevalence report and the Commission's first implementation report indicate that Member States should focus their efforts on **ensuring the targeted surveillance of HAI in surgical site infections, intensive care units and nursing homes** and other long-term care facilities.

Further measures by Member States are needed to improve the routine case ascertainment of HAI, through the development of national diagnostic guidelines, continued training of healthcare workers in applying case definitions of HAI and the reinforcement of laboratory and other diagnostic capacity in healthcare institutions.

More specifically, the Europe-wide point prevalence survey highlighted the need to ensure **adequate numbers of specialised infection control staff in hospitals** and other healthcare institutions sufficient isolation capacity for patients infected with clinically relevant microorganisms in acute care hospitals standardised surveillance of alcohol hand rub consumption.

To further support Member States preventing and control healthcare-associated infections and in supporting the implementation of the Recommendation, both the Commission and ECDC have prioritised addressing HAI.

Patient safety, prevention and control of healthcare associated infections

2009/0003(CNS) - 15/12/2008 - Legislative proposal

PURPOSE: proposal on general patient safety issues as well as on the prevention and control of healthcare associated infections.

PROPOSED ACT: Council Recommendation.

BACKGROUND: it is estimated that between 8% and 12% of patients admitted to hospitals in the EU suffer from adverse events whilst receiving healthcare. The Commission, through the 7th Framework Programme for Research and Development, supports research in health systems. The White Paper "Together for Health: A Strategic Approach for the EU 2008-2013"identifies patient safety as an area for action.

CONTENT: this proposal sets out recommendations for specific actions that Member States can take, either individually, collectively or with the Commission, to improve the safety of patients.

With regard to **general patient safety issues**, Member States should:

- support the development of national policies and programmes by : designating the competent authority responsible for patient safety; embedding patient safety as a priority issue in health policies; and supporting the development of safer systems, processes and tools;
- empower and inform citizens and patients by involving patient organisations in the development of policies on patient safety, and disseminating information to patients on risk, levels of safety and measures in place to reduce or prevent errors, and ensure informed consent to treatment;
- strengthen reporting and learning systems on adverse events that provide adequate information on the extent, types and causes of errors, adverse events and near misses, and encourage healthcare workers actively to report;
- promote education and training of healthcare workers on patient safety by encouraging multi-disciplinary patient safety education and training of all health professionals and ensuring that patient safety receives proper attention in the higher education curricula;
- adequately classify, codify and measure patient safety, by working with the European Commission to develop common definitions and terminology, and to share comparable data on patient safety outcomes;
- share knowledge, experience and best practice at European level.

With regard to the **prevention and control of healthcare associated infections**, Member States should implement a national strategy for the prevention and control of healthcare associated infections, pursuing certain specified objectives. These include: implementing prevention and control measures to support the containment of healthcare associated infections; enhancing infection prevention and control at the level of the healthcare institutions; and supporting research.

Lastly, the Recommendation states that Member States should consider the establishment 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.

Patient safety, prevention and control of healthcare associated infections

2009/0003(CNS) - 23/04/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 521 votes to 6, with 5 abstentions, a legislative resolution amending, under the consultation procedure, the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare associated infections.

The main amendments are as follows:

Scale: Members point out that the numbers affected range from 6.7 million to 15 million hospital in-patients, along with more than 37 million primary care patients. It is estimated that, on average, healthcare-associated infections (HCAIs) occur in one patient in twenty, that is to say, 4.1 million patients a year in the EU, and that about 37 000 deaths are caused every year by the after-effects of such infections.

Reduction targets: Member States should provide the means necessary to bring about a 20% reduction in the number of persons in the European Union affected annually by adverse events resulting from healthcare, the target thus being to reduce such events by 900 000 cases a year by 2015. They should also set local and national targets for recruitment of health professionals specialising in infection control, taking into account the recommended target ratio of one nurse for every 250 hospital beds by 2015.

Informing patients: patients should be informed about treatment risks and Member States should introduce legal mechanisms to facilitate the lodging of claims for damage to health, including against pharmaceutical companies. There should also be confidential sharing of information between health authorities in different Member States on health professionals who have been found guilty of negligence or malpractice.

Education and training of healthcare workers: Member States should provide adequate education and training for all healthcare workers so that they use medical technology appropriately in accordance with the function and specifications outlined in the instruction manuals in order to prevent health risks and adverse effects, including those arising from unintended reuse of devices.

Cooperation with the Commission: the scale and cost of the data collection, and use of the data collected, should not be disproportionate to the expected benefits. The data should only be collected in order to achieve the objective of reducing HCAIs through common learning.

Best practice: Members States should promote opportunities for cooperation and exchange of experience and best practice between hospital managers, clinical teams and patient groups across the European Union on patient safety initiatives at the local level.

Prevention: the Parliament stressed the need to provide: (a) effective risk assessment mechanisms, including pre-admission diagnostic screening of patients; (b) adequate protection for healthcare staff, through vaccination, post-exposure prophylaxis, routine diagnostic screening, provision of personal protective equipment and the use of medical technology that reduces exposure to blood-borne infections; (c) effective infection prevention and control in long-term nursing and rehabilitation facilities.

It is also necessary to enhance infection prevention and control at the level of the healthcare institutions and ensure the highest standards of cleanliness, hygiene, and, where necessary, asepsis as regards medical equipment and patient care facilities.

In order to reduce nosocomial infections, it is also important to: (i) promote hand hygiene among health professionals; (ii) implement necessary staff vaccination campaigns; (iii) foster education and training of healthcare and paramedical, focusing in particular on nosocomial infections and viral antibiotic resistance; (iv) support research, for instance into potential medical applications of nanotechnologies and nanomaterials.

Member States should also: (i) report every healthcare-associated infection outbreak affecting a significant number of patients to the European Centre for Disease Prevention and Control; (ii) conduct awareness campaigns for the public and for healthcare workers with the aim of reducing practices which lead to antimicrobial resistance.

Actions by the Commission: the Commission should consider where existing Community legislation could be strengthened to improve patient safety, for example by ensuring that, when healthcare professionals cross borders within Europe, the professional regulators share information about any disciplinary procedures concluded or pending against individuals, and not just their initial qualifications.

Using the practical guide drawn up by the World Health Organisation in 2002, entitled ‘Prevention of hospital-acquired infections’, the Commission is invited to produce a document aimed at patients on the prevention of nosocomial infections. It is also called upon to bring forward proposals to prevent the circulation of counterfeit drugs and harm to patients and health workers from needlestick injuries.

Patient safety, prevention and control of healthcare associated infections

2009/0003(CNS) - 09/06/2009 - Final act

PURPOSE: to encourage Member States to take measures to improve patient safety, including the prevention and control of healthcare-associated infections.

ACT: Council Recommendation on patient safety, including the prevention and control of healthcare associated infections.

CONTENT: it is estimated that in Member States between 8 % and 12 % of patients admitted to hospital suffer from adverse events whilst receiving healthcare. The European Centre for Disease Prevention and Control (ECDC) has estimated that, on average, healthcare associated infections occur in one hospitalised patient in 20, 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.

The Community, through the seventh framework programme for research and development, supports research in the quality of healthcare provision. The Commission, in its White Paper ‘Together for Health: A Strategic Approach for the EU 2008-2013’, identifies patient safety as an area for action.

This Recommendation lists the measures that Member States can take - alone, collectively or together with the Commission - in order to improve patient safety.

In terms of **patient safety**, Member States are called upon to:

- **support the establishment and development of national policies and programmes by**: (i) designating the competent authority or authorities responsible for patient safety on their territory; (ii) embedding patient safety as a priority issue in health policies and programmes; (iii) supporting the development of safer systems, including the use of information and communication technology; (iv) regularly updating safety standards and/or best practices; (v) encouraging health professional organisations to have an active role; (vi) including a specific approach to promote safe practices;
- **empower and inform citizens and patients by**: (i) involving patient organisations and representatives in the development of policies and programmes on patient safety; (ii) disseminating information to patients on: risk, safety measures which are in place to reduce or prevent errors and harm, and to facilitate patient choice and decision-making; complaints procedures and available remedies and redress and the terms and conditions applicable; (iii) considering the possibilities of development of core competencies in patient safety;
- **support the establishment or strengthen blame-free reporting and learning systems** on adverse events;
- **promote education and training of healthcare workers** on patient safety by: (i) encouraging multidisciplinary patient safety education and training of all health professionals; (ii) embedding patient safety in higher education, on-the-job training and the continuing professional development of health professionals; (iii) considering the development of the core knowledge, attitudes and skills required to achieve safer care; (iv) disseminating information to all healthcare workers on patient safety standards, risk and safety measures in place, including best practices; (v) collaborating with organisations involved in professional education in healthcare;
- **classify and measure patient safety by working with each other and with the Commission** (to develop common definitions and terminology, develop a set of reliable and comparable indicators, and share comparable data and information at EU level);
- **share knowledge**, experience and best practice by working with each other and with the Commission and relevant European and international bodies;
- **develop and promote research** on patient safety.

In terms of the **prevention and control of healthcare associated infections**, Member States should:

- **adopt and implement a national strategy**, pursuing the following objectives: (i) implement prevention and control measures at national or regional level to support the containment of healthcare associated infections; (ii) enhance infection prevention and control at the level of the healthcare institutions; (iii) establish or strengthen active surveillance systems; (iv) foster education and training of healthcare workers; (v) improve the information to the patients by healthcare institutions; (vi) 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;
- **consider the establishment, if possible by 9 June 2011, 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 on the prudent use of antimicrobial agents in human medicine.

The Commission is called upon to produce, by 9 June 2012, an implementation report to the Council assessing the impact of this Recommendation, on the basis of the information that Member States must provide by 9 June 2011.