Basic information

2013/2022(INI) INI - Own-initiative procedure	Procedure completed
Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated infections **Subject** 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	ROSSI Oreste (EFD)	31/01/2013
	Shadow rapporteur SOMMER Renate (PPE) SCHALDEMOSE Christel (S&D) TAYLOR Rebecca (ALDE) RIVASI Michèle (Verts/ALE) YANNAKOUDAKIS Marina (ECR) MAŠTÁLKA Jiří (GUE/NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	

European Commission

Commission DG	Commissioner
Health and Food Safety	BORG Tonio

Key events

Date	Event	Reference	Summary

13/11/2012	Non-legislative basic document published	COM(2012)0658	Summary
11/03/2013	Committee referral announced in Parliament		
25/09/2013	Vote in committee		
04/10/2013	Committee report tabled for plenary	A7-0320/2013	Summary
22/10/2013	Decision by Parliament	T7-0435/2013	Summary
22/10/2013	Results of vote in Parliament		
22/10/2013	End of procedure in Parliament		

Technical information

Procedure reference	2013/2022(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 55
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/11372

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE510.691	27/05/2013	
Amendments tabled in committee		PE514.775	18/07/2013	
Committee report tabled for plenary, single reading		A7-0320/2013	04/10/2013	Summary
Text adopted by Parliament, single reading		T7-0435/2013	22/10/2013	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2012)0658	13/11/2012	Summary
Commission response to text adopted in plenary	SP(2014)62	07/03/2014	

Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151 /01) on patient safety, including the prevention and control of healthcare associated infections

2013/2022(INI) - 13/11/2012 - Non-legislative basic document

PURPOSE: to present a report on the implementation of Council Recommendation on patient safety.

BACKGROUND: in June 2009, the Council adopted a Recommendation on patient safety, including the prevention and control of healthcare-associated infections. The Recommendation consists of two chapters.

1) The first chapter concerns general patient safety, where Member States are asked to put in place a series of measures with a view to minimising harm to patients receiving healthcare. These measures include:

- developing national policies on patient safety ;
- empowering and informing patients;
- establishing reporting and learning systems on adverse events;
- promoting the education and training of healthcare workers;
- developing research on the issue.

The Recommendation invites Member States to share knowledge, experience and best practice and to classify and codify patient safety at EU level by working with each other and with the Commission.

2) The second chapter concerns the prevention and control of healthcare-associated infections (HAIs), where 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 strategy should comprise:

- infection prevention and control measures at national/regional level and at the level of healthcare institutions, and
- providing surveillance systems, the education and training of healthcare workers, information to patients, and research.

The report summarises the main actions taken at Member State and EU level with regard to the Council Recommendation.

CONTENT : in accordance with the above-mentioned Recommendation, the Commission presents, on the basis of Member States' reports, a summary of the main actions taken as regards the implementation of the Recommendation by June 2011 (July 2012 for the general patient safety part). The report **highlights those areas of the Recommendation needing further attention.** It is accompanied by a Commission Staff Working Document providing a more detailed technical analysis of the replies received by EU Member States and Norway.

Actions taken at Member State level: most Member States have taken a certain number of the measures recommended:

- **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;
- **on encouraging training on patient safety**, most countries have taken measures in healthcare settings, though only a few have formally embedded patient safety in education and training programmes for health professionals;
- **regarding systems on adverse events** (systems providing information about the causes of adverse events and recording their numbers by type), the existing reporting and learning systems have been considerably improved in two main aspects: their blame-free character and offering patients the possibility of reporting events. However, there is still room for improvement in this crucial area;
- **on empowering patients**, efforts focus on hospital healthcare through the involvement of patient organisations on patient safety, with only a few examples of actions addressing primary care;
- on research, the report notes the establishment of national research programme on patient safety in 10 Member States. Existing research covers patient safety culture, reducing the risk of medication errors, improving patients' competence in medication safety, healthcare-associated infections, and prevention of falls in the elderly population;
- on the prevention and control of HAIs, 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. Thirteen 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. Most of the strategies for the prevention and control of HAI are linked to strategies for the prudent use of antimicrobial agents in human medicine and/or patient safety strategies.

Actions taken at EU level: Directive on cross-border healthcare: the Recommendation complements other EU initiatives. Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights seeks to clarify the rights of patients when accessing care in another EU Member State. It also seeks to ensure that such care is safe and of good quality. It therefore includes several provisions relating to the safety and quality of healthcare. The implementation of the actions envisaged by the Recommendation will be considered as a reference for assessing safety standards under the Directive.

Apart from the Directive, the report discusses the funding of several actions, particularly in terms of the EU Health Programme or the 7th Framework Research Programme (for a total amount of EUR 16 million.)

With regard to HAIs, the Commission has adopted an 'Action plan against the rising threats from antimicrobial resistance' which contains 12 actions to be implemented with EU Member States.

Focus of future work: the report notes that there are still various areas of the Recommendation with considerable room for improvement. Based on the findings of the report, 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**;
- 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;
- 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;
- 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;
- repeat national point prevalence surveys of HAI;
- 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;
- improve the information on HAI for patients;
- develop an evaluation system with a set of indicators in Member States to assess the implementation of the strategy/action plan.

-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.

The Recommendation invites the Commission to consider the extent to which the proposed measures are working effectively. 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.

Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151 /01) on patient safety, including the prevention and control of healthcare associated infections

2013/2022(INI) - 04/10/2013 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted an own-initiative report by Oreste ROSSI (EPP, IT) as a follow-up to the report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151 /01) on patient safety, including the prevention and control of healthcare associated.

According to estimates, **health-care associated infections (HAIs) are contracted by an estimated 5% of patients in hospitals**. HAIs, which have a high impact in terms of morbidity, mortality (with 37 000 people dying directly of such infections in the EU) and cost (estimated at over EUR 5.5 billion per annum Union-wide), constitute a major public health problem in the Member States.

Against this background, the report recommended that issue of patient safety, and in particular the prevention and control of HAIs, be given a **place near the top of the political agenda in the EU**, both at national level in the Member States and at regional and local level.

Members welcome the measures put in place by Member States with the principal aim of improving general patient safety and preventing the incidence of HAIs. They also welcome the fact that some of the actions recommended by the Council have thus far been implemented by only a **limited number of Member States**, and that there is **room for improvement** – in both hospital and non-hospital care.

Improving patient safety in Europe, including by preventing and controlling HAIs: **Member States are urged to** continue their efforts to improve patient safety by taking, if they have not already done so, additional measures, including setting up action plans for combating HAIs. Measures should aim to:

empower citizens in respect of patient safety and the prevention and control of HAIs;

- promote **thorough and continuous training**, based on well-defined standards, of healthcare workers in the area of patient and healthcare worker safety;
- encourage **research into patient safety** using an evidence-based approach with a focus on implementation and focusing in particular on forms of therapy that offer an alternative to treatment with antibiotics;
- introduce, or strengthen if they already exist, arrangements for **reporting** adverse events – in particular those involving medicines and medical devices.
- improve the **information** provided to patients by healthcare establishments;
- support **research into the prevention and control of HAI**s, particularly those caused by methicillin-resistant Staphylococcus aureus (MRSA), Clostridium difficile and other emerging difficult-to-treat infections.

Prevention: Member States are called upon to: draw up national guidelines for **hand hygiene** and general cleaning of hospitals and care homes; (ii) promote targeted action to prevent errors in hospitals; (iii) encourage efforts to study hospital outbreaks; (iv) conduct specific information and training **campaigns** to raise awareness among patients and healthcare professionals of the issue of antimicrobial resistance.

The state of health of patients (particularly older persons and persons with reduced mobility) returning home after a period of hospitalisation must be assessed thoroughly when they leave hospital.

Communication, education and training: the report recommended Member States to:

- conduct **specific awareness-raising and training measures** concerning HAIs which are aimed not only at healthcare professionals but also, for example, formal and informal carers and hospital volunteers who have contact with patients;
- introduce **national guidelines** for health professionals on how to train patients in the use of antibiotics.

Patients' rights: Member States are invited to: (i) ensure that patients trust their health systems and, in particular, to involve patients closely in patient safety; (ii) involve patient organisations in the development of new laws and health programmes; (iii) designate at local level an authority or a contact person responsible for providing patients with information and data concerning patient safety; (iv) encourage practising doctors to inform patients of their rights and the possibilities open to them in terms of lodging complaints and reporting errors and adverse events.

Control, diagnosis and follow-up: the Commission, the relevant EU agencies and the Member States are called upon to consider action to **ensure the provision of feedback on patient safety**, not only from medical staff but also from patients. Members called on the European Centre for Disease Prevention and Control (ECDC) to draw up, in cooperation with the EMA, a **list of pathogens** that can cause serious or potentially fatal antibiotic-resistant infections and pose a serious health risk.

European and international cooperation: Members called on the Member States and the Commission, in conjunction with the WHO and the OECD, to improve cooperation with a view to **developing standardised definitions**, terminology and indicators in the area of patient safety, in particular so as to ensure that high-risk patients can be isolated should a pandemic or cross-border threat emerge.

The report emphasised the importance of establishing an effective **European network of national surveillance systems** which would work, on the basis of standardised criteria to be adopted by the Commission and the Member States.

Member States are called upon to collaborate in the creation of **platforms** which allow the sharing of information concerning adverse events in healthcare.

Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151 /01) on patient safety, including the prevention and control of healthcare associated infections

2013/2022(INI) - 22/10/2013 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution on the report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated.

In its resolution, Parliament recommended that issue of patient safety, and in particular the prevention and control of HAIs, should be given a **place near the top of the political agenda in the EU**, both at national level in the Member States and at regional and local level.

According to estimates, **health-care associated infections (HAIs) are contracted by an estimated 5% of patients in hospitals**. HAIs, which have a high impact in terms of morbidity, mortality (with 37 000 people dying directly of such infections in the EU) and cost (estimated at over EUR 5.5 billion per annum Union-wide), constitute a major public health problem in the Member States.

Members welcomed the measures put in place by Member States with the principal aim of improving general patient safety and preventing the incidence of HAIs. They also welcomed the fact that some of the actions recommended by the Council have thus far been implemented by only a **limited number of Member States**, and that there is **room for improvement** – in both hospital and non-hospital care.

Improving patient safety in Europe, including by preventing and controlling HAIs: Member States are urged to continue their efforts to improve patient safety by taking, if they have not already done so, additional measures, including setting up action plans for combating HAIs. Measures should aim to:

- **empower citizens** in respect of patient safety and the prevention and control of HAIs;
- promote **thorough and continuous training**, based on well-defined standards, of healthcare workers in the area of patient and healthcare worker safety;
- encourage **research into patient safety** using an evidence-based approach with a focus on implementation and focusing in particular on forms of therapy that offer an alternative to treatment with antibiotics;
- include measures to prevent the occurrence of and combat the spread of **antimicrobial resistance**, including the development of new antimicrobials;
- improve the **information** provided to patients by healthcare establishments;
- support **research into the prevention and control of HAI**s, particularly those caused by methicillin-resistant Staphylococcus aureus (MRSA), Clostridium difficile and other emerging difficult-to-treat infections.

The resolution urged the Commission and the relevant EU agencies to introduce, or strengthen if they already exist, **arrangements for reporting adverse events** – in particular those involving medicines and medical devices – which make it possible to identify those responsible in the event of a breakdown in the chain of care. Member States are urged to **re-evaluate their adverse event reporting structures.**

Prevention: while acknowledging that the EU may not interfere with the Member States' competences in the field of health, Parliament has encouraged the Member States and their delegated partners to:

- **make sufficient human, financial and technological resources available** to ensure that care provided in the home or in hospital is of the highest possible quality, calling on them, in particular, to allocate adequate budgets to patient safety and to ensure that care provided in the home or in hospital is of the highest possible quality;
- also prioritise effective workforce planning as a means of **ensuring that staffing levels are adequate** to deal with increasing patient throughput and the attendant negative impact on infection control practices.

Member States are called upon to: draw up national guidelines for **hand hygiene** and general cleaning of hospitals and care homes; (ii) promote targeted action to prevent errors in hospitals; (iii) encourage efforts to study hospital outbreaks; (iv) conduct specific information and training **campaigns** to raise awareness among patients and healthcare professionals of the issue of antimicrobial resistance.

Communication, education and training: Parliament recommended Member States to:

- conduct **specific awareness-raising and training measures** concerning HAIs which are aimed not only at healthcare professionals but also, for example, formal and informal carers and hospital volunteers who have contact with patients;
- introduce **national guidelines** for health professionals on how to train patients in the use of antibiotics.

Patients' rights: Member States are invited to: (i) ensure that patients trust their health systems and, in particular, to involve patients closely in patient safety; (ii) involve patient organisations in the development of new laws and health programmes; (iii) designate at local level an authority or a contact person responsible for providing patients with information and data concerning patient safety; (iv) encourage practising doctors to inform patients of their rights and the possibilities open to them in terms of lodging complaints and reporting errors and adverse events.

Control, diagnosis and follow-up: Parliament called on:

- the Commission, the relevant EU agencies and the Member States are called upon to consider action to **ensure the provision of feedback on patient safety**, not only from medical staff but also from patients;
- all Member States to introduce **specific national HAI prevalence surveys**;
- the European Medicines Agency to develop guidelines on the off-label use of medicines;
- the European Centre for Disease Prevention and Control (ECDC) to draw up, in cooperation with the EMA, a **list of pathogens** that can cause serious or potentially fatal antibiotic-resistant infections and pose a serious health risk.

European and international cooperation: Parliament called on the Member States and the Commission, in conjunction with the WHO and the OECD, to improve cooperation with a view to **developing standardised definitions**, terminology and indicators in the area of patient safety, in particular so as to ensure that high-risk patients can be isolated should a pandemic or cross-border threat emerge.

The resolution emphasised the importance of establishing an effective **European network of national surveillance systems** which would work, on the basis of standardised criteria to be adopted by the Commission and the Member States.

Member States are called upon to collaborate in the creation of **platforms** which allow the sharing of information concerning adverse events in healthcare.