



EUROPEAN PARLIAMENT

2009 - 2014

Plenary sitting

A7-0320/2013

4.10.2013

REPORT

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 infections
(2013/2022(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Oreste Rossi

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MOTION FOR A EUROPEAN PARLIAMENT 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 infections (2013/2022(INI))

The European Parliament,

- having regard to the Luxembourg declaration on patient safety of 5 April 2005,
- having regard to the report of the second meeting of the Informal Network on Infection Prevention and Control in Health Care (June 2008),
- having regard to the communication of 15 December 2008 from the Commission to the European Parliament and the Council on patient safety, including the prevention and control of healthcare-associated infections (COM(2008)0837),
- having regard to the Commission's Impact Assessment of December 2008,
- having regard to its resolution of 23 April 2009 on the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare-associated infections¹,
- having regard to the Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections,
- having regard to the special Eurobarometer survey (No 327) on 'Patient Safety and Quality of Healthcare', published in April 2010,
- having regard to the report of the World Health Organisation (WHO) entitled 'Core components for infection prevention and control programmes',
- having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare,
- having regard to the report of 13 November 2012 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,
- having regard to the annual epidemiological reports for 2008 and 2012 of by the European Centre for Disease Prevention and Control (ECDC),
- having regard to the ECDC's technical document entitled 'Core competencies for infection control and hospital hygiene professionals in the European Union', published on 26 March 2013,

¹ OJ C 184E, 8.7.2010, p. 395.

- having regard to the Commission’s staff working paper of 18 November 2009 on antimicrobial resistance (SANCO/6876/2009r6),
- having regard to the joint technical report of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), published on 17 September 2009, entitled ‘The bacterial challenge: time to react – A call to narrow the gap between multidrug-resistant bacteria in the EU and the development of new antibacterial agents’,
- having regard to the special Eurobarometer survey (No 338) on antimicrobial resistance, published in April 2010,
- having regard to its resolution of 12 May 2011 on antibiotic resistance¹,
- having regard to the Commission recommendation of 27 October 2011 on the research Joint Programming Initiative ‘The Microbial Challenge – An Emerging Threat to Human Health’ (C(2011)7660),
- having regard to its resolution of 27 October 2011 on the public health threat of antimicrobial resistance²,
- having regard to the Commission communication of 15 November 2011 on an action plan against antimicrobial resistance (COM(2011)0748),
- having regard to the Council conclusions of 22 June 2012 on 'The impact of antimicrobial resistance in the human health sector and in the veterinary sector – a "One Health" perspective',
- having regard to its resolution of 11 December 2012 on ‘The Microbial Challenge – Rising threats from Antimicrobial Resistance’ (2012/2041)³,
- having regard to Rule 48 of its Rules of Procedure,
- having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0320/2013),

General remarks

- A. whereas patient safety⁴ and wellbeing are key to overall healthcare quality, and efforts to increase the safety of patients are dependent on the implementation of effective and long-term policies and programmes across Europe;
- B. whereas high-quality healthcare is the cornerstone of any high-quality health system and whereas access to high-quality healthcare is recognised as a fundamental right by the EU,

¹ OJ C 377E , 7.12.2012, p. 131.

² OJ C 131, 8.5.2013, p. 116.

³ Texts adopted, P7_TA(2012)0483.

⁴ Patient safety is defined by the WHO as freedom for a patient from unnecessary harm or potential harm associated with healthcare.

the European institutions and European citizens;

- C. whereas Article 168 of the Treaty on the Functioning of the European Union stipulates that Union action must complement national policies and must be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health;
- D. whereas, therefore, the EU's action in the field of patient safety consists in helping Member States to coordinate their efforts in this area and supporting their actions in fields where its intervention can provide added value;
- E. whereas it is essential to maintain citizens' confidence in the health systems of the European Union;
- F. whereas the volume of data available on the prevalence and incidence of adverse events¹ in EU Member State healthcare systems is, at present, limited, but is steadily growing;
- G. whereas the issue of patient safety is becoming a growing concern in health systems throughout the world, including in Europe;
- H. whereas the results of the Eurobarometer survey on 'Patient Safety and Quality of Healthcare' indicate both that European public opinion is highly aware of this issue and also that there is a marked lack of information on patient safety;
- I. whereas healthcare-related adverse events for the patient or his or her unborn or future descendants are: healthcare-associated infections (HAIs)², medication- or medical device-related events, including those resulting from off-label use, diagnostic errors, and complications arising during or after surgical operations;
- J. whereas some adverse events are the result of risks inherent in operations or courses of medication deemed necessary by healthcare personnel, while others are the result of avoidable medical errors, shortcomings and failings in the healthcare supply chain;
- K. whereas it is estimated that between 8 % and 12 % of patients admitted to hospitals in the EU suffer from adverse events while receiving healthcare, including HAIs, errors during treatment or surgery, problems arising from failure or inadequate decontamination of medical equipment, errors in diagnosis, and failure to act on the results of tests;
- L. whereas demographic changes are leading to an increase in the proportion of older patients,

¹ An adverse event is an incident which results in harm to a patient.

² For the purposes of this report, HAI means any infection which occurs during or following the provision of medical services (for diagnostic, therapeutic or preventive purposes) and which was not present or incubating prior to such provision. The infectious micro-organisms (bacteria, fungi, parasites and other transmissible agents) involved in HAI cases may come either from the patient's own organism (intestines, skin, etc), in which case they are called endogenous infections, or from the patient's environment, in which case they are known as exogenous infections or cross-infections. The term 'healthcare associated infection' covers all infections associated with healthcare systems in general and with individual treatment pathways. These include nosocomial infections (acquired in healthcare establishments, either as an inpatient or an outpatient) and infections acquired during treatment provided outside healthcare establishments, in collective facilities (such as medium- and long-stay facilities, in particular care homes for older people) or in the home.

who are frequently prescribed a large number of different medicines but are often unable to cope with taking them correctly;

- M. whereas, furthermore, older patients and patients with immunodeficiencies or chronic diseases, in particular degenerative diseases, are especially vulnerable to healthcare-related adverse events, such as: diagnostic errors; lack of follow-up to medical examinations; the prescription, dispensing or administration of an inappropriate (e.g. off-label) medicine, of an incorrect dose or of two medicines which should not be combined; failure or poor decontamination of medical equipment; and infection of surgical scars;
- N. whereas international studies estimate that between 13 % and 16 % of hospital costs (or one euro in seven) are incurred as a result of healthcare related incidents;
- O. whereas, however, it is estimated that between 30 % and 40 % of adverse events in both hospital and out-of-hospital (ambulatory) care appear to be caused by systemic factors and are therefore avoidable;
- P. whereas a lack of financial, technical and human resources is particularly associated with an increased risk of healthcare-related adverse events;
- Q. whereas the economic crisis has slowed down the implementation of measures adopted by the Member States in 2009, as a result of changed priorities in public health;
- R. whereas any natural or legal person has the right to make public or distribute, in good faith and in safety, information on a fact, an item of data or an action, as soon as a lack of knowledge of this fact, this item of data or this action appears to present a danger to public health;
- S. Whereas patient safety enjoys a high priority on the political agenda; whereas the Member States established a mechanism for debate related to patient safety issues and other work in this area in 2005; whereas a working group was established, through which the Commission intends to promote the work and activities of the Member States, its active members being the WHO (especially through the World Alliance for Patient Safety), the Council of Europe, the OECD, and European associations of patients, physicians, nurses, pharmacists, dentists and hospitals;
- T. whereas HAIs are among the most common and the most dangerous causes of involuntary harm to patients;
- U. whereas HAIs, which, on average, are acquired by 5 % of patients admitted to hospital, are a major public health problem in the Member States and place a heavy burden on limited health service budgets;
- V. whereas for the period 2011-2012 the annual number of patients acquiring at least one HAI during a stay in an acute care hospital in the EU as a whole was estimated to be 3.2 million¹.

¹ According to the Commission's answer to written question E-004648/2013, given on 14 June 2013.

- W. whereas 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;
- X. whereas HAIs can occur as a result of time spent in all settings in which healthcare is provided, including primary, community, social, private, acute and chronic care, during the provision of any healthcare services, or at home (in particular as a result of errors in dosage, errors in packaging the medicine, contamination through medical instruments or equipment, or contact with patients and healthcare professionals);
- Y. whereas a HAI contracted during a hospital stay may not display symptoms until after the patient has been discharged;
- Z. whereas the average length of a hospital stay in the Member States is falling;
- AA. whereas the ECDC has the task, with the involvement of international experts, of developing scientific recommendations for evidence-based measures for the effective prevention of HAIs;
- AB. whereas patients with chronic or degenerative diseases often receive home care instead of being admitted to hospital;
- AC. whereas the condition of some people with chronic or degenerative diseases often requires permanent and continuous medical assistance, very frequently necessitating, in particular, the use of medical devices (cardiac stimulators, respiratory devices, catheters, urinary catheters, etc.);
- AD. whereas the use of such medical devices carries a risk of infection;
- AE. whereas pathogens, in particular antimicrobial-resistant pathogens, can also be spread as a result of failure to follow basic hygiene precautions in environments such as healthcare establishments and in the home;
- AF. whereas simple and cost-effective action to prevent HAIs, such as sanitation education (in particular, the promotion of hospital hygiene), already exists or is currently being tested on an experimental basis, with promising results, and whereas potential alternative, cost-effective ways of combating HAIs could usefully be explored;
- AG. whereas, since the micro-organisms responsible for HAIs are capable of colonising the human body for long periods, patients can spread them not only during their hospital stay but also afterwards, and whereas HAIs can thus affect all care premises, medium- and long-term care establishments, and even the patient's home;
- AH. whereas only 13 Member States have implemented national surveillance of *Clostridium difficile* infections¹ and in only three of these surveillance systems are general

¹ According to reply from the Commission E-004649/2013 these 13 countries are: Austria, Belgium, Bulgaria, Denmark, Germany, Finland, France, Hungary, Ireland, the Netherlands, Spain, Sweden and the UK: <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2013-004649&language=EN>

practitioners also involved in the data collection - a situation that should be improved;

- AI. whereas, furthermore, people's increasing mobility within and between national healthcare systems inside the EU, the increasingly cross-border nature of healthcare in Europe and freedom to seek medical treatment outside one's country of residence are making it easier for resistant micro-organisms to spread rapidly from one Member State to another;
- AK. whereas the issue of antimicrobial resistance is a serious, and in some countries growing, threat to patient safety that can complicate recovery from and treatment of infections and increases national health costs;
- AL. whereas HAIs are often difficult to treat, as the micro-organisms responsible for them are frequently resistant to antimicrobial agents;
- AM. whereas in the EU, Iceland and Norway alone antimicrobial resistant bacteria cause some 400 000 infections and 25 000 deaths annually, with at least EUR 1.5 billion spent on extra healthcare costs and productivity losses;
- AN. whereas antibiotic resistance in Europe is continuing to increase, and for certain bacteria may be 25 %, or even more, in several Member States;
- AP. whereas the latest available data indicate that antibiotic resistance markers for the bacteria involved in HAIs highlight an increasing global trend towards multi-resistance, and, in particular, increases in the percentages of *Enterobacteriaceae* resistant to third-generation cephalosporins and of methicillin-resistant *S. aureus*;
- AO. whereas there is a decline in the development of new antimicrobials;
- AQ. whereas development of resistance to antimicrobial agents is a natural and unavoidable consequence of their use, but whereas it can be limited if they are used prudently and rationally;
- AR. whereas the development of resistance to antimicrobial agents can be accelerated, in particular, by the inordinate and indiscriminate use of these products in human medicine, which, combined with insufficient hygiene and infection control, can compromise the effective use of an already limited number of existing antimicrobial agents;
- AS. whereas, in view of the lack of development of new antibiotics/antimicrobial agents, it is vital for current antimicrobial agents to be used effectively for as long as possible;
- AT. whereas, in view of the lack of development of new antibacterial medicines, the Commission and the Member States should work together to support the development and availability of such products, making use of the ECDC and the expertise of the European Medicines Agency (EMA);
- AU. whereas farming policies promote the occurrence of antibiotic resistance, both through the food chain and through animal waste entering the water cycle;
- AV. whereas consumption of antibiotics is higher among people who are objectively the least

well-informed, and whereas better objective knowledge of antibiotics is associated with more responsible behaviour in terms of their use;

AW. whereas certain Member States do not have a solid regulatory and legal framework to support and make compulsory the rational use of medicines, and whereas there are considerable disparities in Europe in terms of consumption of antibiotics, in the context of both community and hospital care;

AX. whereas there is a need to educate and raise awareness among those involved in antimicrobial use, including policymakers, health professionals and the general public, in order to encourage the necessary changes in the behaviour of prescribers, dispensers and citizens;

AY. whereas, since the adoption in 2009 of Council Recommendation 2009/C 151/01, substantial effort has been invested in improving patient safety in the Member States, particularly by embedding it as a priority in public health policies in all Member States, by designating a competent authority responsible for patient safety (in 19 Member States), and encouraging training in patient safety in healthcare establishments (in 23 Member States);

AZ. whereas, since the adoption in 2009 of Council Recommendation 2009/C 151/01, substantial effort has been invested in adopting and implementing strategies (national and regional) for the prevention and control of HAIs in the Member States, particularly through the adoption of guidelines on their prevention and control and by setting up active HAI surveillance systems (or strengthening those that already exist);

BA. whereas, on the other hand, some of the actions recommended by the Council in its Recommendation 2009/C 151/01 on how to improve patient safety in the Member States have thus far been implemented by only a limited number of Member States, and whereas there is room for improvement – in both hospital and non-hospital care – particularly in respect of patient empowerment and the overall training of health professionals and carers, as well as in the implementation of European classifications on patient safety and the development of European guidelines on patient safety standards;

BB. whereas some of the specific measures the Council recommended for preventing and combating HAIs in the Member States have been implemented in only a limited number of Member States, and whereas progress is still possible, particularly in respect of provision of information to patients by healthcare establishments and support for research into the prevention and control of HAIs;

Implementation of the Council's recommendations: major improvements made, but further progress required

1. Welcomes the measures put in place by Member States with the principal aim of improving general patient safety and preventing the incidence of HAIs, in particular by;
– all Member States drawing up patient safety policies and the fact that many Member States

- have made these policies a priority of their healthcare policy;
- the designation of a competent authority responsible for patient safety (in most Member States);
 - the gradual establishment of mechanisms for reporting adverse events and learning lessons from such failings;
 - the widespread introduction of patient safety training campaigns in healthcare establishments;
 - the implementation, in France, Slovakia and the Netherlands, of cross-border patient safety strategies (in addition to the national strategy);
 - collaboration between countries and between regions with a view to carrying out the actions recommended by the Council and implemented by 21 Member States (plus Norway), in many cases in the context of projects cofinanced by the EU,

but asks as a matter of urgency that these efforts be increased;

2. Welcomes the steps taken by the Commission to improve general patient safety by promoting exchange of best practice between Member States and devising definitions and terminology for patient safety, and in particular:
 - the Commission’s fostering of exchange of information on initiatives concerned with patient safety and quality of care, in the context of the Working Group on Patient Safety and Quality of Care;
 - the Commission’s cofinancing of the OECD-led project on healthcare quality indicators, which has made it possible to collect comparable indicators of patient safety in 11 countries;
 - the EU’s cofinancing, under the Seventh Framework Programme for Research, of six research projects on general patient safety;
 - the adoption of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients’ rights in cross-border healthcare, which seeks not only to clarify the rights of patients when accessing care in another Member State, but also to ensure that such care is safe and of good quality;
3. Welcomes the work conducted by the Commission and the ECDC, in conjunction with health authorities in the Member States, on HAI prevention and control;
4. Welcomes the Commission’s action in the area of preventing and combating HAIs, which is closely linked to its action in the area of resistance to antimicrobial agents; welcomes, in particular, the financing provided by the Commission for research projects on HAIs and antimicrobial resistance, especially those having a European dimension, such as IPSE (Improving Patient Safety in Europe), IMPLEMENT (Implementing Strategic Bundles for Infection Prevention and Management), and PROHIBIT (Prevention of Hospital Infections by Intervention and Training), which seeks to analyse existing practical guidelines on prevention of HAIs in European hospitals and test a strategy for preventing

bloodstream infections linked to central venous catheters (infections which are particularly worrying in that they are associated with significant morbidity and a high level of directly related mortality);

5. Welcomes the coordination and monitoring work of the ECDC, and in particular:

- its activities in coordinating the European network for surveillance of HAIs, particularly surgical site infections, HAIs acquired in intensive care units and antimicrobial use in long-term care facilities (HALT-2), as well as its support for the European project to support capacity building for surveillance of *Clostridium difficile* infections (ECDIS-Net);
- its coordination of a European study on HAI prevalence and antimicrobial use in acute care hospitals;
- its development of guidance for the prevention and control of *Clostridium difficile* infections;
- its publication of recommendations to prevent the spread of carbapenemase-producing *Enterobacteriaceae*;
- its support for the development of guidelines and indicators (on structure and method) for preventing HAIs.

6. Recognises that no classification or reporting system for patient safety exists at EU level for the purpose of identifying, understanding and analysing the factors involved in patient safety, with a view to learning and improving the relevant systems;

7. Acknowledges that, to date, too few Member States:

- have integrated patient safety into the education and training of health professionals;
- have action plans in place for combating HAIs;
- have taken steps to improve the provision of HAI-related information to patients by healthcare establishments;
- have provided support for research into HAIs;

8. Calls for the collection of comparable indicators on patient safety by Member States to be continued, and for all the Member States, with support from the Commission, to become involved in this work;

9. Calls on the Member States to continue and step up bilateral and multilateral cooperation on patient safety, as well as national and/or regional action in this area;

**Improving patient safety in Europe, including by preventing and controlling HAIs:
general recommendations**

10. Recommends that the 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;

a) Measures to improve general patient safety

11. Urges the Member States 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, in order to fall fully into line with the Council's recommendations;
12. Urges the Member States, in particular, to take, or step up if they are already being implemented:
 - measures to make the public more aware of initiatives in the area of patient safety and empower patients in this area;
 - measures for the thorough and continuous training, based on well-defined standards, of healthcare workers in the area of patient and healthcare worker safety, and in particular the introduction of patient safety training modules (covering various areas including medical devices and rational and diligent use of medicines) in one or more study or training variants for healthcare professionals and carers, as well as measures for education and awareness-raising aimed at patients and their carers in the area of patient safety;
 - cross-border activities in the area of patient safety;
 - measures to 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 and a response to resistance to antibiotics, including bacteriophage therapy;
 - measures to support multidisciplinary wound care as part of patient safety programmes at Member State level;
 - measures to prevent the occurrence of and combat the spread of antimicrobial resistance, including the development of new antimicrobials;
13. Calls on the European Medicines Agency (EMA) to draw up a list of off-label medicines which are used in spite of there being an approved alternative; calls on the Member States to ensure that medical professionals and patients are informed when a medicine is used off-label;
14. Urges 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 and learn lessons from such breakdowns, to make those arrangements known to the public and easy to use, and to ensure that all procedures are transparent;
15. Urges the Member States to re-evaluate their adverse event reporting structures, to assess whether such reporting is taking place in a 'no-blame' culture, and to ensure that healthcare professionals can come forward with information candidly, without negative consequences for themselves personally;
16. Calls on the Member States to adopt measures which raise the quality – and not just the

quantity – of reporting on adverse events, so that reporting contains information which can really improve safety, and which makes it easy to call up data from the system for a comprehensive and systematic evaluation;

17. Calls on the Member States to do far more to incorporate patients' information into electronic systems dealing with patient safety and adverse events, and to systematically evaluate that information, precisely in order to prevent errors;
18. Urges the Member States, the Commission and the relevant EU agencies to use all relevant technological and statistical tools to describe and analyse adverse events;
19. Urges the Commission and the Member States to make the public more aware of initiatives in the area of patient safety, and to empower patients in this area;
20. Urges the Commission to consider once again the calls for the introduction of a database listing good practices with a view to fostering exchanges of such practices among the Member States; believes that an adverse events database could prevent such events occurring in future and could serve as an example of good practice for providers;
21. Encourages the Member States to share best practices through a data-based approach and, in particular, to draw up, on the basis of case studies and feedback, common guidelines to be applicable throughout the Union;
22. Calls on the Member States to apply, wherever possible, hospital patient safety strategies and programmes in non-hospital care environments (in long- and medium-stay facilities, but also in the home);

b) Measures designed to guard against and reduce the number of HAIs

23. Urges the Member States to set clear national targets for the reduction of HAIs, and to implement, if they have not already done so, additional measures to guard against and reduce the number of HAIs, with a view to falling fully into line with the Council's recommendations, and in particular measures to:
 - prevent HAIs both inside and outside hospitals by the systematic implementation of the One Health approach, whereby both medical and veterinary professionals undertake to prevent resistant infections and reduce the use of antibiotics;
 - improve the information provided to patients by healthcare establishments, including information on the prevalence of HAIs in those establishments;
 - support research into the prevention and control of HAIs, particularly those caused by methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile* and other emerging difficult-to-treat infections and focusing in particular on forms of therapy that offer an alternative to treatment with antibiotics and a response to antibiotic resistance, including bacteriophage therapy;
24. Urges the Commission to consider the scope for the conclusion of partnership agreements between itself and individual Member States or directly between Member States with a view to preventing and resolving HAI problems in hospitals and in the context of home

care; calls on the Commission to support further work on the prevention and control of HAIs through the forthcoming EU Health Programme;

Improving patient safety in Europe, including by preventing and controlling HAIs: specific approaches and recommendations

a) Prevention

25. While acknowledging that the EU may not interfere with the Member States' competences in the field of health, and acknowledging the differences existing in terms of healthcare policies and systems among Member States, encourages 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;
26. Calls on the Member States and the Commission to foster, including by means of awareness-raising campaigns, good practices in all areas, in particular all those linked to hygiene (hand hygiene; sterilisation and optimum decontamination of medical instruments and devices), both inside and outside hospital (in particular vis-à-vis patients and their families);
27. Calls on the Member States to draw up national guidelines for hand hygiene and general cleaning of hospitals and care homes;
28. Calls on the Member States to promote targeted action to prevent errors in hospitals, including the implementation of the WHO Surgical Safety Checklist;
29. Calls for more and better coordinated research to avoid the spread of HAIs;
30. Calls on the Member States to encourage efforts to study hospital outbreaks and find a way of preventing the spread of healthcare associated infections;
31. Encourages Member States to develop their national practices on the appropriate use of antibiotics, in order to limit the spread of antimicrobial resistance and ensure that antibiotic treatment remains effective;
32. Calls on the Commission and the Member States to develop platforms and protocols allowing health data portability, while ensuring that such activities respect the relevant European data protection legislation;
33. Calls on the Member States to draw up specific safety protocols for chronic degenerative and disabling diseases which necessitate round-the-clock assistance outside hospital (in long- and medium-stay facilities, but also in the home);

34. Emphasises, as regards home care, that:

- 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, with a view, in particular, to evaluating and countering the risk of falls;
- patients and their carers must be properly informed, in particular about hand hygiene and the need to decontaminate reusable medical instruments and devices, as well as the need to comply with procedures and prescriptions;
- equipment used should be disposable or subject to thorough decontamination procedures if reused;
- the taking of basic precautions should be encouraged, in particular as regards the storage and use of medicines, and patients should, in particular, be made aware of the risks involved in using medicines that have no marketing authorisation;

35. Urges the Member States to provide the Commission with information on vaccination programmes for healthcare professionals, including the levels of coverage achieved within healthcare institutions;

36. Urges the Member States to encourage information input by health professionals on how patients can avoid being harmed as a result of contact with the health system;

37. Calls on the Member States to take measures to increase patients' families' involvement in preventing errors in medication and self-treatment;

b) Communication, education and training

38. Recommends that Member States conduct specific awareness-raising and training measures concerning HAIs which are aimed not only at healthcare professionals (doctors, nurses, paramedics, etc), but also, for example, formal and informal carers and hospital volunteers who have contact with patients;

39. Calls on the Member States to introduce national guidelines for health professionals on how to train patients in the use of antibiotics;

40. Calls on the Member States to conduct specific information and training campaigns to raise awareness among patients and healthcare professionals of the issue of antimicrobial resistance;

41. Calls on the Member States to draw on, and accord proper importance to, the expertise built up as a result of patients' own experience when compiling best practices;

c) Patients' rights

42. Calls on the Member States to do what they can to ensure that patients trust their health systems and, in particular, to involve patients closely in patient safety;

43. Calls on the Member States to involve patient organisations in the development of new laws and health programmes;

44. Calls on the Member States to designate at local level an authority or a contact person responsible for providing patients with information and data concerning patient safety, in order to strengthen public confidence in the safety of health systems through the increased provision of adequate and understandable information;
45. Encourages the Member States to provide patients with information on risks, safety levels and the measures taken to prevent adverse events in healthcare, in order to ensure that patients can give informed consent to the treatment they are being offered and, more generally, to enable patients to learn more about the issue of patient safety; requests that the Member States inform patients, through the appropriate organisational structures, about complaints procedures and the legal options available to them should adverse events in healthcare occur (e.g. through a patients' rights representative);
46. Encourages the Member States and regional and local authorities to prioritise, as far as possible, approaches based on mediation when adverse events in healthcare occur;
47. Calls on the Member States to 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;
48. Acknowledges that the EU may not interfere with the Member States' competencies in the field of health; encourages the Commission, nonetheless, to establish collective redress mechanisms in cross-border cases where multiple patients are affected by healthcare-related adverse events resulting from the same cause;

d) Control, diagnosis and follow-up

49. Calls on the Commission, the relevant EU agencies and the Member States to consider action to ensure the provision of feedback on patient safety, not only from medical staff but also from patients; stresses that their reporting should be transparent at all levels;
50. Calls on those Member States which conduct specific national HAI prevalence surveys using a harmonised ECDC methodology to do so on a regular basis, and encourages all Member States to introduce such surveys; urges the Commission to look more closely at the Global Microbial Identifier system¹, which is supported by a large number of researchers throughout the world, and which can monitor and detect alert healthcare-associated organisms and boost capacity to respond to the spread (including the cross-border spread) of infections;
51. Recommends that regional or local working parties be set up to consider specific issues relating to patient safety; suggests by way of example that such working parties could focus on accident prevention among older people, reducing operation-related risks, or reducing the risk of medication-related errors;
52. Calls on the Member States to encourage hospitals and care homes to focus on basic care tasks such as observation of patients and assessment of pressure sores, which are a major but often hidden problem for hospitalised patients and inmates;

¹ <http://www.globalmicrobialidentifier.org/>

53. Calls on the European Medicines Agency to develop guidelines on the off-label use of medicines, on the basis of medical need and taking account of patient protection;
54. Calls on the 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; calls for that list to be updated on a regular basis with information supplied by the ECDC's European Surveillance of Antimicrobial Consumption Network (ESAC-Net) and European Antimicrobial Resistance Surveillance Network (EARS-Net);
55. Recommends that a list of HAIs which should be screened for in all hospitals and healthcare establishments in the EU be drawn up in cooperation with the EMA and the ECDC;

e) European and international cooperation

56. Calls 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;
57. Emphasises 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, to identify and monitor places where contamination with HAIs occurs (including facilities outside hospitals), as well as the way in which HAIs spread; urges the Member States to continue their efforts to collect comparable, up-to-date reference data on general patient safety and HAIs; calls on the Member States to publish the data concerned on an annual basis;
58. Calls on the Member States to share, where they exist, good practice benchmarks in the area of general patient safety, and, in particular in the area of the prevention and control of HAIs and the transmission of multi-resistant bacteria (e.g. measures to prevent the spread of legionella bacteria in hospital hot-water systems);
59. Acknowledges the importance of the ECDC's Antimicrobial Resistance and Healthcare-associated Infections Programme (ARHAI), particularly in its efforts to support and standardise the monitoring of HAIs, offer scientific advice, and provide training and communication;
60. Calls on the Member States collaborate in the creation of platforms which allow the sharing of information concerning adverse events in healthcare, encouraging the use of all relevant data collection mechanisms whilst ensuring that such activities respect the applicable European data protection legislation; stresses that patients must be dealt with in accordance with ethical principles and their personal data must be protected;
61. Calls on the Commission and the Member States to cooperate in introducing incentives for the development of new antibacterial medicines; considers that such incentives should be introduced as part of an appropriate EU legislative framework, with a view to fostering cooperation between the public and private sectors in order to revitalise antimicrobials-related research and development;

62. Believes that, under the Eighth Framework Programme for Research, which is to commence in 2014, the EU should cofinance research into general patient safety, HAIs and resistance to antimicrobial agents;

f) Monitoring and reporting

63. Urges the Member States and the Commission to extend by at least two years the monitoring of the actions taken to implement the recommendation on patient safety, including the prevention and control of HAIs;

64. Urges the Member States to step up their cooperation with the ECDC in the area of the prevention and control of HAIs; encourages national authorities in particular to ask the ECDC to carry out regular in situ audits and to publish the reports submitted to them by the ECDC, and emphasises, in that connection, the need to ensure, under future multiannual financial frameworks, that the ECDC receives the *adequate* funding that it needs to fulfil its coordination and monitoring remit;

65. Instructs its President to forward this resolution to the Council, the Commission, the Committee of the Regions and the Member States.

EXPLANATORY STATEMENT

Patient safety: an overriding issue in EU public health policy

Access to safe healthcare is the cornerstone of a high-quality health system and is recognised as a fundamental right for European citizens by the EU and the European institutions. Patients are therefore entitled to expect that every effort should be made to ensure their safety.

There are substantial risks in the healthcare sector owing to the possibility that an incident in the course of the patient's treatment unrelated to the condition being treated could cause serious harm, suffering, complications or even death. Some such incidents are associated with the risks inherent in vital operations or drugs, but others are caused by avoidable medical errors or by shortcomings or deficiencies in treatment systems.

An estimated 30-40% of adverse events related to medical treatment, in both the hospital sector and community care, are preventable. These include healthcare-associated infections (HAIs), which are contracted by an estimated 5% of patients in hospitals, or 3.2 million people, each year and are directly responsible for 37 000 deaths. It is estimated that 20% of HAIs could be avoided. Older patients and patients with immunodeficiencies are at particular risk of contracting HAIs, and efforts to combat them are often complicated by resistance to antibiotics.

Ensuring patient safety is above all a matter of improving quality of life, but harm caused to patients by adverse events during treatment also places a significant burden on society, which is aggravated in times of economic crisis. For example, in certain Member States growing numbers of patients are contracting *Clostridium difficile* infections, which account for about 5% of all HAIs in Europe and are estimated to be the cause of 2% of hospital readmissions. The financial burden of such infections on Europe's healthcare systems is estimated to be EUR 3.7 million in 2013. Quite apart from the obvious benefits for patients, investment in patient safety could therefore be a source of potential cost savings: emphasis on patient safety reduces the costs incurred in treating patients experiencing adverse events associated with healthcare, and therefore means better use is made of financial and human resources. With a view to achieving these goals, the culture of patient safety can be significantly enhanced in a number of ways.

Summary of the Council's recommendations on patient safety and preventing and combating HAIs

The Council Recommendation of 9 June 2009 (2009/C 151/01) called for the implementation of a series of measures to improve patient safety in the EU.

- a) In its first chapter, on general patient safety, Member States were asked to put in place a series of measures with a view to minimising harm to patients receiving healthcare. These measures included:
 - support for the establishment and development of national policies and programmes on patient safety;
 - empowering patients;

- establishing blame-free mechanisms for reporting adverse events and learning lessons from such failings;
- promoting education and training measures for healthcare workers in the area of patient safety;
- furthering relevant research activities.

The Recommendation also invited the Member States to share knowledge, experience and best practice and to classify and measure patient safety at EU level by working together and with the Commission and other relevant international organisations.

- b) The second chapter was given over to the prevention and combating of HAIs: the Recommendation asked Member States to adopt and implement a strategy at the appropriate level for the prevention and control of HAIs, comprising dedicated measures at national or regional level and in individual healthcare institutions (notably introducing active surveillance systems, publishing guidelines, training and educating healthcare workers, informing patients and supporting research into HAIs).

Preliminary assessment of follow-up to the Council's recommendations on patient safety and preventing and combating HAIs

In November 2012 the Commission published, on the basis of the information provided by Member States, an assessment of action taken to comply with the Council recommendation. Most Member States claimed to have taken a variety of actions as envisaged by the recommendation:

- most Member States have made patient safety a priority in public health policies and designated a competent authority responsible for patient safety;
- most countries have encouraged training on patient safety in healthcare establishments;
- the reporting systems introduced have provided information on existing shortcomings and have been considerably improved, but remain far from perfect;
- considerable efforts have been made, chiefly in hospitals, to empower patients;
- all Member States have launched national research programmes on patient safety;
- most Member States have implemented a combination of measures to prevent and control HAIs, linked in most cases to strategies for the prudent use of antimicrobial agents in human medicine and/or patient safety strategies.

At the same time, measures have been taken at European level with the financing of a number of initiatives, particularly as part of the Programme of Community Action in the Field of Health and the 7th Framework Programme for Research (which has provided a total of EUR 16 million).

The Member States' reports, which the Commission has now summarised, show that, despite the progress made since 2009, there is still scope for considerable improvement.

Position of the rapporteur and summary of his main recommendations

The rapporteur notes that some of the Council's recommendations on how to improve patient safety in the Member States have thus far been implemented by only a few Member States,

and that there is room for improvement in hospital and non-hospital care, particularly in respect of patient empowerment and the overall training of health professionals and carers. Further efforts must also be made to implement European classifications on patient safety and to draw up European guidelines on patient safety standards. The rapporteur would also like to add that some of the specific measures the Council recommended to prevent and combat HAIs have been implemented in only a limited number of Member States, and that progress should still be made, particularly in respect of informing patients and supporting research into the prevention and control of HAIs.

The rapporteur calls on the Member States to take or strengthen measures to empower citizens in respect of patient safety and the prevention and control of HAIs, and to inform and train healthcare professionals, patients and their carers, to cooperate with other Member States and to strive to promote research on patient safety and into HAIs. Member States should also continue their efforts to harmonise healthcare classifications and collect comparable indicators. The rapporteur encourages the Member States and regional and local authorities to prioritise, as far as possible, approaches based on mediation when adverse events associated with healthcare occur, and calls for the introduction of compensation systems that are harmonised at EU level.

Against a backdrop of an aging European population and the alarming rise of resistance to antimicrobial medicines, the rapporteur stresses that patient safety and, in particular, the prevention and control of HAIs should be placed near the top of the political agenda in the European Union, at national, regional and local level. The rapporteur wishes to place particular emphasis on the fact that the Member States must allocate sufficient resources, including from their budgets, on patient safety. The rapporteur stresses the added value of the ECDC, and its coordination and monitoring work, in preventing and controlling HAIs, and emphasises the need to ensure, under future multiannual financial frameworks, that the ECDC receives the long-term funding it needs to fulfil its coordination and monitoring remit.

The Council Recommendation asked the Commission to consider the extent to which the proposed measures were working effectively. As some measures were initiated only recently or are still in the pipeline, the rapporteur supports the proposal to draw up a second progress report in June 2014.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	25.9.2013
Result of final vote	+: 58 -: 0 0: 0
Members present for the final vote	Elena Oana Antonescu, Sophie Auconie, Pilar Ayuso, Paolo Bartolozzi, Sergio Berlato, Lajos Bokros, Franco Bonanini, Biljana Borzan, Milan Cabrnach, Spyros Danellis, Chris Davies, Jill Evans, Elisabetta Gardini, Matthias Groote, Satu Hassi, Jolanta Emilia Hibner, Karin Kadenbach, Christa Kläß, Eija-Riitta Korhola, Jo Leinen, Corinne Lepage, Peter Liese, Kartika Tamara Liotard, Zofija Mazej Kukovič, Linda McAvan, Vladko Todorov Panayotov, Gilles Pargneaux, Antonia Parvanova, Andrés Perelló Rodríguez, Mario Pirillo, Pavel Poc, Frédérique Ries, Oreste Rossi, Dagmar Roth-Behrendt, Kārlis Šadurskis, Horst Schnellhardt, Richard Seeber, Claudiu Ciprian Tănăsescu, Salvatore Tatarella, Thomas Ulmer, Sabine Wils, Marina Yannakoudakis
Substitute(s) present for the final vote	Margrete Auken, Erik Bánki, Mark Demesmaeker, Jutta Haug, Marusya Lyubcheva, Miroslav Mikolášik, Vittorio Prodi, Renate Sommer, Rebecca Taylor, Vladimir Urutchev, Anna Záborská, Andrea Zanoni
Substitute(s) under Rule 187(2) present for the final vote	Ioan Enciu, Sabine Lösing, Kerstin Westphal, Dubravka Šuica