EUROPEAN PARLIAMENT 2014 - 2019

Committee on the Environment, Public Health and Food Safety

2014/2207(INI)

4.2.2015

DRAFT REPORT

on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance
(2014/2207(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Piernicola Pedicini

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CONTENTS

Page

MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance
(2014/2207(INI))

The European Parliament,

– having regard to its legislative resolution of 23 April 2009 on the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare-associated infections[1],

– having regard to the Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections (2009/C 151/01),

– having regard to the reports of 13 November 2012 and 19 June 2014 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 its resolution of 4 October 2013 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[2],

– having regard to its resolution of 11 December 2012 on 'the Microbial Challenge - Rising threats from Antimicrobial Resistance'[3],

– having regard to the Commission communication of 15 November 2011 on the Action plan against the rising threats from 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 the Council conclusions of l December 2014 on patient safety and quality of care, including the prevention and control of healthcare associated infections and microbial resistance,

– having regard to Decision 1082/2013/EU of the European Parliament and the Council of 22 October 2013 on serious cross border threats to health,

– having regard to the 'Conceptual framework for the international classification for patient safety' drawn up by the World Health Organisation (WHO),

[1] OJ C 184E, 8.7.2010, p. 395.
[2] Texts adopted, P7_TA(2013)0435.
[3] Texts adopted, P7_TA(2012)0483.

– having regard to the first ECDC/EFSA/EMA joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals - Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA),

– having regard to Rule 52 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A8-0000/2015),

A. whereas patient safety is key to overall healthcare quality;

B. whereas the volume of data available on the prevalence and incidence of adverse events in EU Member State healthcare systems is at present limited, but is steadily growing, and whereas the latest available data date back to 2008;

C. whereas it is estimated that between 8 % and 12 % of patients admitted to hospitals in the EU suffer from adverse events while receiving healthcare, and whereas nearly half of these events could be avoided;

D. whereas a multidisciplinary approach guarantees appropriate medical treatments;

E. whereas the current economic crisis is having a direct impact on patient safety, as many Member States have reduced budgets and staffing levels in their healthcare systems;

F. whereas electronic health (eHealth) and home-care medical treatments have a high potential for improving the quality and efficiency of medical treatments while contributing to a patient-centred approach and better healthcare performance;

G. whereas continuous training of doctors is crucial to avoid adverse events, including adverse drug events (ADEs), which are estimated to cost the EU healthcare systems some EUR 2.7 billion per year in care expenses and account for 1.1 % of all hospitalisations in the EU;

H. whereas health systems and healthcare facilities should be managed independently from political choices, and whereas managers should be appointed on the basis of merit and not of political affiliation;

I. whereas the most common healthcare-related adverse events are healthcare-associated infections (HAIs), medication-related events and complications arising during or after surgical operations;

J. whereas HAIs are a major public health problem in the Member States (some 4.1 million patients suffer from an HAI in the EU annually, although 20-30 % of these infections are considered to be preventable by intensive hygiene and control programmes), and this places a heavy burden on limited health service budgets;

K. whereas HAIs caused by multidrug resistant bacteria are increasing;

L. whereas one of the main causes of antimicrobial resistance is the misuse of

antimicrobials, including antibiotics, and in particular their excessive use;

M. whereas the use of antibiotics in animals can affect antibiotic resistance in humans;

N. whereas antimicrobial resistance has increased worldwide for bacterial pathogens, leading to increasing prevalence of HAIs and treatment failures in human and animal infectious diseases at national, European and international levels;

O. whereas resistance to antibiotics for certain bacteria is at least 25 % or more in several Member States; whereas antibiotic resistance is spreading much faster than the introduction of new antibiotics into clinical practice;

P. whereas it is estimated that every year in the EU at least 25 000 people die of infections caused by resistant bacteria;

Q. whereas it is of paramount importance to encourage pharmaceutical companies to invest in developing new antibiotic compounds, in particular with activity against prevalent multidrug-resistant Gram-negative bacteria such as *K. pneumoniae* and *Acinetobacter*;

R. whereas it is vital to ensure patients' rights and public confidence in health services, by providing fair financial compensation in case of adverse events arising from faulty medical provision;

S. whereas Article 168 of the Treaty on the Functioning of the European Union stipulates that Union action must complement national policies;

IMPLEMENTATION OF THE COUNCIL'S RECOMMENDATIONS ON PATIENT SAFETY

Feedback on the Commission's second implementation report

1. Welcomes the latest measures put in place by Member States to improve general patient safety and reduce the incidence of HAIs, and more particularly the progress made by Member States in developing patient safety strategies and reporting and learning systems;

2. Notes, however, that the second implementation report still shows uneven progress among Member States on patient safety, and regrets the fact that some Member States have obviously slowed down implementation of the Council recommendations because of financial constraints resulting from the economic crisis;

3. Calls on Member States to make sure that the healthcare system is not affected by austerity measures and to ensure a sufficient number of healthcare professionals specialised in infection prevention and control, as well as hospital hygiene for a more patient-centred approach;

4. Recommends that the Commission continue monitoring the implementation of the provisions on patient safety in the Member States;

Leads for improvements

5. Welcomes the work of the EU working group on patient safety and quality of care on comparable indicators to assess patient safety, and calls on the Member States to implement such indicators;

6. Urges the Member States to implement or develop the following measures:

   a) continue their efforts to improve patient safety by taking, if they have not already done so, new measures in order to fully implement the Council's recommendations;

   b) collect updated data on the prevalence and incidence of adverse events in their own territory and enhance early warning alert systems;

   c) ensure appropriate training of doctors and other healthcare professionals and set up monitoring systems to verify that their competences are up-to-date with hospital hygiene practices and the technology in place;

   d) ensure the adoption of a multidisciplinary approach in medical treatments;

   e) ensure that medical professionals inform patients when a medicine is used off-label and provide patients with information on the potential risks in order to enable them to give informed consent;

7. Highlights the potential benefits of eHealth in reducing adverse events by tracking information flows and improving the understanding of medical processes, as well as through digital prescriptions and alerts on drug interaction; calls on the Commission and the Member States to further explore the possibilities offered by eHealth in the area of patient safety;

8. Notes that patient safety is not widely embedded in the undergraduate education of healthcare workers, nor in on-the-job-training or the continuing training of health professionals;

9. Calls on the European Medicines Agency (EMA) to develop guidelines on the off-label/unlicensed use of medicines based on medical need, as well as to compile a list of off-label medicines in use despite licensed alternatives;

Reporting and accountability/liability issues

10. Invites the Member States to improve their reporting systems for adverse events and medical errors by developing measures that encourage accurate, blame-free and anonymous reporting by health professionals and patients;

11. Encourages the Member States to set up independent bodies to liaise with professionals when reporting on healthcare facility failures having an impact on patient safety;

12. Invites the Member States to be more rigorous in verifying and enforcing the ban on non-medical external staff performing medical treatment; points out that this is happening with employees of companies that provide sophisticated medical machinery

to hospitals; therefore, calls on Member States to introduce a mandatory registration of the presence of product specialists during therapeutic treatments;

13. Calls on the Member States to provide for collective redress mechanisms in their national law so as to allow the introduction of fair compensation systems for patients who have suffered an HAI or a medical error;

14. Invites the Commission to report on national practices of collective redress in HAI-related cases and to launch a consultation aimed at debating the possibility of harmonising collective redress in HAI cases at European level;

FIGHTING ANTIMICROBIAL RESISTANCE

State of play and promising solutions

15. Welcomes the Commission's work on antimicrobial resistance and on the prevention and control of HAIs, as well as the coordination and surveillance efforts of the European Centre for Disease Prevention and Control (ECDC);

16. Welcomes the joint work on antimicrobial resistance of the ECDC, the EMA and the European Food Safety Authority (EFSA);

17. Notes with concern that between 2010 and 2013 the percentages of *K. pneumoniae* resistant to fluoroquinolones, third-generation cephalosporins and aminoglycosides, as well as combined resistance to all three antibiotic groups, significantly increased in many Member States and at EU level; further notes that during the same period resistance to third-generation cephalosporins also significantly increased in many Member States and at EU level for *E. coli*;

18. Regrets that the past 25 years have witnessed both a lack of awareness of the importance of rational use of antimicrobial agents, and antibiotics in particular, and a stagnation in drug development in the field of antimicrobial medicines;

19. Welcomes and encourages further research for new antimicrobial drugs, in particular antibiotics with activity against prevalent multidrug-resistant Gram-negative bacteria such as *K. pneumoniae* and *Acinetobacter*, as well as for alternative methods aimed at fighting HAIs without using antibiotics;

20. Considers it of paramount importance that the Commission should ensure the continuation of the EU Action Plan on Antimicrobial Resistance post-2017, with an emphasis on the prevention and control of healthcare-associated infections;

Recommendations regarding antibiotic use in human medicine

21. Calls on the Member States to promote the responsible and sensible use in human medicine of all antimicrobial agents and in particular antibiotics;

22. Urges the Member States to implement or develop the following measures:

a) regulate the prescription of antibiotics for treatment or prophylaxis so that an appropriate use of medicines is ensured, specifying the therapeutic objective and selecting the appropriate drug therapy;

b) regulate the sale of antibiotics so that patients can buy only the specific quantity of antibiotics as prescribed by their doctors;

c) ensure patients' adherence to and compliance with antibiotic treatments as prescribed by medical professionals;

d) ensure that antibiotics are used in hospitals only for the correct indications, at the correct dose and for the shortest duration possible as recommended by evidence-based guidelines;

e) intensify infection control, in particular from a cross-border perspective, by properly screening patients transferred from a country/region/hospital known for its high prevalence of multidrug-resistant bacteria;

f) launch awareness campaigns on the rational use of antibiotics and the risks entailed by increasing antibiotic resistance; these campaigns should address parents and carers responsible for young children as well as elderly people, and should always be followed by an assessment of their outcomes;

Recommendations regarding antibiotic use in veterinary medicine in general and in husbandry in particular

23. Calls on the Member States to introduce or develop the following measures:

a) Promote the responsible and sensible use in veterinary medicine of all antimicrobial agents and in particular antibiotics that are critically important in human medicine, such as fluoroquinolones and third- and -fourth generation cephalosporin;

b) Introduce legal tools to restrict the use of antibiotics in animals if a significant risk to public health is identified;

24. Urges the Member States to regulate any conflicts of interest involving veterinarians who both sell and prescribe antibiotics;

25. Calls on the co-legislator, when negotiating the proposal for a regulation **on veterinary medicinal products** 2014/0257 (COD), to make recommendations in line with the One Health principle, and more particularly:

– to adopt provisions aimed at banning or limiting the off-label use in animals of certain antimicrobials authorised only in human medicine, following a risk assessment of such use;

– to introduce the mandatory registration of all off-label antimicrobials by prescribers of veterinary medicines as well as by the competent national authorities;

COLLABORATIVE APPROACHES WITHIN THE EUROPEAN UNION

26. Calls on the Commission and the Member States to further engage in a dialogue with all stakeholders and develop a coordinated, comprehensive and sustainable EU strategy for patient safety, as well as to put forward concrete solutions to be implemented at EU, national, regional, local and/or primary care levels;

27. Encourages pharmaceutical company partners to contribute with their best assets (compounds and ideas) to pre-competitive joint projects; believes that the Innovative Medicine Initiative (IMI) should be given the flexibility to explore any new findings emerging from those projects;

28. Welcomes the Joint Programme Initiative on Antimicrobial Resistance, which allows Member States to agree on research needs so to avoid duplication;

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

EXPLANATORY STATEMENT

Introduction

Patient safety[1] and fighting drug resistance, and antimicrobial resistance in particular, are topics that are undoubtedly familiar to health service managers and, moreover, those who have in recent years been following the proceedings of Parliament's Committee on the Environment, Public Health and Food Safety.

These matters have been dealt with extensively both in the World Health Organisation (WHO) and by European institutions (Commission and Council) and specialised agencies (ECDC, EMA, EFSA).

The substantial fund of information available to draw on has made it easier to pinpoint the main problems, but it also entails a need for thorough study in order to produce new suggestions that could constitute the added value of this report compared with Parliament's most recent acts.

Parliament, in late 2013 (Rossi report), the Commission, in 2014 (second report on the implementation of the 2009 Council recommendation), and the Council itself, in December 2014 (conclusions of the Employment, Social Policy, Health and Consumer Affairs Council), have all made their contributions, specifically emphasising the constitutional obligation under Article 168 TFEU whereby the EU, without encroaching on their responsibilities, is called upon to encourage cooperation among Member States and to complement national health policies with a view ultimately to ensuring a high level of human health protection.
As well as the European institutions, specialised agencies have been doing valuable work, first and foremost the ECDC, which carries out surveillance and coordination tasks and which, aided by the EMA and the EFSA, has just produced (January 2015) a major report, the first of its kind, on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance to bacteria from humans and food-producing animals.

Patient safety

The draft report proceeds from the premiss that patient safety, in other words a patient's right not to be harmed, or put at risk of harm, by medical treatment, has to be viewed as central to the quality of health services.

The figures available suggest that as many as 8% to 12% of hospital patients in the EU, that is to say, more than 3 million people, according to data which admittedly are not entirely up to date, are suffer harm or even adverse events[2], including healthcare-associated infections, nosocomial or otherwise (HAIs)[3], many of which (20%-30%) are considered to be

[1] Defined by the WHO as the prevention of avoidable errors and adverse effects to patients associated with health care.

[2] An adverse event is one causing harm to a patient.

[3] For the purposes of this report, HAI means any infection which occurs during or following medical treatment (for diagnostic, therapeutic, or preventive purposes) and which was not present or incubating when the treatment

preventable.

What are the main factors adding to the risk to patients?

The Commission noted back in 2012 that patient safety was being undermined by austerity measures entailing across-the-board cuts in health services and directly affecting the quality of care: such a situation is truly intolerable.

This draft report has attempted to single out various contributory causes that are jeopardising patient safety, some perhaps more than others, although they are all linked to the extent that they are together creating a vicious circle which appears, especially in some Member States, to be translating into an alarming increase in the spread of certain deadly pathogens.

The causes involved include the following:

a) the fact that there are not enough proper patient safety policies and programmes at national level;
b) the difficulty of reporting adverse events and gathering standardised data;
c) neglect of the need to provide proper training for health professionals and monitor their performance;
d) the lack of early warning and active surveillance systems;
e) improper use, often for cultural reasons, of drugs that create resistance;
f) the practice, unfortunately still widespread in some Member States, of using technical personnel instead of medical staff to carry out therapeutic treatment, which should be a matter for doctors only;
g) the ways in which medicines are sold and, in particular, the forms of packaging used for antibiotics, which in some countries make it impossible to buy only as much as needs to be taken for a given course of treatment;
h) in some countries, off-label use of drugs, that is to say, not in accordance with the specifically authorised indications and forms of administration, is viewed as a valid therapeutic alternative, even though its efficacy might not be proven. It could, however, constitute a risk and should therefore be carefully regulated;
i) overuse or misuse of antibiotics, misguided prescriptions, and even iatrogenic effects (ADEs – adverse drug events), which according to recent figures involve a total annual cost of EUR 2.7 billion;
j) overuse of antibiotics in feed for food-producing animals, which also increases antibiotic resistance in humans;
k) the slow-down, not to say stagnation, in research in to alternative new drugs.

Rapporteur's recommendations

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began. The infectious micro-organisms (bacteria, fungi, parasites, and other transmissible agents) involved in HAIs can come either from the patient's own body (intestines, skin, etc.), in which case they are called endogenous infections, or from the outside 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 (contracted in healthcare establishments, whether by in-patients or by outpatients) and infections contracted 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.

Your rapporteur believes that treatment should centre on patients; health services should not be subjected to unwarranted cuts ostensibly dictated by austerity. There has to be investment in continuing training, monitoring of medical and healthcare provision, alert systems, and preventive preparatory action if adverse events are largely to be averted, including those caused by the use of drugs.

Over the years the need for a risk assessment method based on the principle of 'reporting without punishment' has made itself felt more strongly in all Western countries. Such an approach could help to establish the causes of adverse events or potential risks, but it must definitely not create a situation in which patients are – firstly – exposed to risk or even harmed as a result of undergoing medical treatment and – secondly – deprived of means of redress affording the possibility of compensation without delay.

That is why I suggest that independent bodies be made responsible for reporting adverse events and potential causes of adverse events; in addition, they should be called upon to determine forms of compensation for categories of patients harmed in the same way as a result of events of a similar kind that occurred while they were being treated.

One area in which regulation should, to my mind, be considered is the presence of product specialists in treatment settings.

I have also called for healthcare facilities to be managed by persons selected on the strength of their ability, on merit, and not as a result of political affiliation or favouritism.

Antibiotic resistance

Antimicrobial resistance is the ability of a micro-organism (for example a bacterium, a virus, or a parasite) to resist the action of an antimicrobial agent. It is a way in which the micro-organism adapts to its environment. Antimicrobial resistance reduces or destroys the efficacy of the antimicrobial in curing or preventing the infection caused by the micro-organism. As regards antimicrobial resistance in the EU, the biggest problem is that bacteria can develop resistance to the action of an antibiotic.

Antibiotics help to reduce the mortality and morbidity of bacterial diseases. They are also an essential tool for modern medicine: standard procedures such as transplants, chemotherapy for cancer, and orthopaedic surgery might even be impossible to carry out without potent antibiotics.

Unfortunately, antibiotics are too often put to improper use. They are, for example, needlessly prescribed for viral infections, on which they have no effect. Similarly, when diagnosis is not accurate, broad-spectrum antibiotics (that is to say, antibiotics which kill many different bacteria and not just the ones causing the disease), as opposed to specific treatments, are prescribed by default.

Antibiotics were also used in the EU as livestock growth promoters until the practice was banned in 2006.

Inappropriate use of antibiotics has led over time and all over the world to the emergence and selection of resistant bacteria.

The latest figures available, supplied by the ECDC, the EMA, and the EFSA, show that overall, and despite some recent advances, antimicrobial resistance is a growing public health problem in hospitals and in the EU.

Between 2010 and 2013, for example, the percentage of *K. pneumoniae* resistant to fluoroquinolones, third-generation cephalosporins, and aminoglycosides, and combined resistance to all three antibiotic groups increased significantly in the EU/EEA as a whole. *E. coli*. resistance to third-generation cephalosporins also rose sharply at EU/EEA level in that period.

In countries with high levels of multidrug resistance, including resistance to carbapenems, only a few treatment options are available, polymyxins being one. In those countries, polymyxin resistance is serving as a powerful warning that the options for treating infected patients are becoming even more limited.

The rapporteur firmly believes that responsible, well-targeted use of antibiotics in both human and veterinary medicine and global infection control strategies aimed at all health sectors (hospitals, long-stay facilities, and outpatient clinics) should form the foundations for effective action to prevent the selection and transmission of antibiotic-resistant bacteria. More specifically, he considers that the following areas of action should be tackled as a matter of priority:

- careful use of the antibiotics available (in human and veterinary medicine), that is to say, only when
  an appropriate prescription (specifying the dosage, dosage intervals, and duration of the treatment) states that they are necessary;
- national and cross-border measures to limit the movement of patients infected with resistant bacteria;
- hygiene precautions to control the transmission of resistant strains between infected persons, including hand hygiene, screening for the transport of strains, and isolation of patients suffering from infections caused by resistant bacteria;
- research and development focusing on antibiotics, with new ways of proceeding and new approaches to alternative treatments.

The rapporteur congratulates the ECDC and hopes that it will continue its coordination and surveillance efforts, in particular in the European Antimicrobial Resistance Surveillance Network (EARS-Net) and the European Surveillance of Antimicrobial Consumption Network (ESAC-Net). He also applauds the work of the European Medicines Agency and the European Food Safety Authority. He welcomes the ECDC/EFSA/EMA first joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals and is calling for synergy to be taken further where the three agencies are concerned and extended to encompass the appropriate national authorities.

There is one final point which the rapporteur wishes to stress: it must be ensured that health policies are not scaled down on account of the economic crisis and austerity policies and that

the aim of achieving the highest possible standard of patient safety, as laid down by the EU, is not placed in jeopardy.

He feels that the Commission should continue to keep a close watch on the Member States' progress regarding Parliament and Council recommendations and inform the public about all the latest advances in patient safety and in the development of new drugs to help reduce the upward trend in adverse events being seen in the EU.