Position of HFE in cooperation with Eurofedop on patient safety, including the prevention and control of healthcare associated infections

Brussels (Belgium), 29.05.2013

Bert Van Caelenberg, Vice-President of HFE

MEP Oreste Rossi’s (EFD, Italy) report on the implementation of the Council Recommendations 2009 has been recently published and I want to provide you with a quick overview pertaining to HFE’s recommendations launched last year. The full report is attached.

In general, the report is reflective of many of the recommendations put forward by Health First Europe. Areas such as information to patients, training for healthcare professionals and stronger reporting systems, have all been included in the current draft. These were the points that we as Eurofedop have put on the agenda and have been included in the report. For example, the report:

- calls for the collection of comparable indicators;
- calls for education and training measures for healthcare workers in the area of patient safety (We as Eurofedop have been insisting on including this in the report.);
- calls on Member States to carry out specific awareness-raising and training measures on HCAIs aimed at healthcare professionals and carers (Once more, here we have been lobbying as Eurofedop to include this in the report.);
- urges Member States to introduce or strengthen reporting systems
- urges Member States to implement measures to reduce HAIs both inside and outside of hospitals, improve information to patients on HAIs and support research into HAIs;
- calls on Member States to use the most advanced technological means to guarantee optimal safety.
However, although HFE’s top 3 recommendations have been touched upon, the report hasn’t gone as far as we would like. For example:

1) HFE recommendation: Setting minimum standards for patient safety at the EU level, including harmonised/comparable reporting systems and sharing of best practice for implementation through Member States
   - no minimum standards suggested/nor are there targets; rather calls on Member States to continue efforts to collect comparable, up-to-date information on patient safety and HAIs

2) HFE recommendation: Setting measurable improvement targets for patient safety determined by each Member State, monitored by the EU
   - No targets set

3) HFE recommendation: Developing a European strategy to prevent HCAIs and encouragement for adoption for all Member States
   - calls on Member States and the European Commission to increase cooperation with ECDC and WHO to standardise measures, share best practices, and monitor HAIs, but stops short of an EU strategy

The updated timeline for the report has just been released and the next steps include:

- Workshop: 30 May 2013 (3:15-6:00)
- Consideration of draft report in ENVI: 20 June 2013
- Deadline for amendments: 27 June 2013
- Vote in ENVI: 18 September 2013
- Vote in Plenary (indicative): October 2013

We will be closely following the debates and we will be in touch with further information following this week’s patient safety workshop in the European Parliament.

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Encl. : 2013/2022(INI)
DRAFT 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 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,

– 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 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 Rule 48 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0000/2013),

General remarks

A. whereas patient safety\(^1\) is key to overall healthcare quality;

B. whereas the volume of data available on the prevalence and incidence of adverse events\(^2\) in EU Member State healthcare systems is, at present, limited, but is steadily growing;

\(^1\) defined by the WHO as freedom for a patient from unnecessary harm or potential harm associated with healthcare.

\(^2\) An adverse event is an incident which results in harm to a patient.
C. whereas the most common healthcare-related adverse events are healthcare associated infections (HAIs), medication-related events and complications arising during or after surgical operations;

D. 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 the failure of medical equipment, errors in diagnosis and failure to act on the results of tests;

E. whereas some adverse events are the result of risks inherent in necessary operations or courses of medication, while others are the result of avoidable medical errors and shortcomings and failings in the healthcare supply chain;

F. whereas, furthermore, elderly patients and patients with immunodeficiencies or chronic diseases, in particular degenerative diseases, are especially vulnerable to healthcare-related adverse events;

G. 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;

H. 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;

I. whereas HAIs can occur as a result of time spent in healthcare establishments or during the provision of any healthcare services, including home-based services (in particular as a result of contamination of medical instruments or equipment);

J. whereas pathogens, in particular antimicrobial-resistant pathogens, can also be spread as a result of failure to follow basic rules of hygiene not only in environments such as healthcare establishments but also in the home;

K. whereas, furthermore, people’s increasing mobility within and between national healthcare systems inside the EU and their freedom to seek medical treatment outside their countries of residence are making it easier for resistant micro-organisms to spread rapidly from one Member State to another;

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1 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 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 elderly dependent people) or in the home.
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 reducing the incidence of HAIs;

2. Welcomes the steps taken by the Commission to improve general patient safety by promoting mutual learning between Member States and putting forward common definitions and terminology for patient safety;

3. Criticises the fact that, to date, no classification for patient safety has been proposed 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;

4. Criticises the fact that, to date, too few Member States
   – have taken steps to improve the provision of HAI-related information to patients by healthcare establishments;
   – have provided support for research into HAIs;

5. Welcomes the Commission’s work on HAI prevention and control, as well as the coordination and surveillance efforts of the European Centre for Disease Prevention and Control (ECDC) in this connection;

6. Calls for the collection of comparable indicators on patient safety by Member States to be continued and for all the Member States to become involved in this work;

7. 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

8. Recommends that the issue of patient safety and, in particular, that of the prevention and control of HAIs be given a place near the top of the political agenda in the European Union, both at national level in the Member States and at regional and local level;

a) Measures to improve general patient safety

9. Urges the Member States to continue their efforts to improve patient safety by taking, if they have not already done so, new measures in order to fall fully into line with the Council’s recommendations;

10. 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;
– education and training measures for healthcare workers in the area of patient safety;
– cross-border activities in the area of patient safety;
– measures to encourage research into patient safety;

11. Urges the Member States to introduce, or strengthen if they already exist, arrangements for reporting adverse events 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;

12. Urges the Commission to consider the headline initiatives and, in particular, to determine whether increased involvement on the part of regional and local authorities could be a suitable way of ensuring that the measures and decisions taken are effective;

13. 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;

14. Urges the Member States to use all relevant statistical instruments to describe and analyse adverse events;

15. Calls on the Member States to prioritise a data-based approach and, in particular, to draw up, on the basis of case studies and feedback, common guidelines applicable throughout the Union;

b) Measures designed to reduce the number of HAIs

16. Urges the Member States to continue their efforts to implement, if they have not already done so, additional measures to 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;
– improve the information provided to patients by and outside healthcare establishments;
– support research into the prevention and control of HAIs;

17. Urges the Commission to consider the scope for the conclusion of partnership agreements between it 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;

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

a) Prevention

18. Calls on the Member States 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, and urges them, in particular, not to cut the budgets allocated
to patient safety, a key issue for European healthcare systems at a time of global spending reviews;

19. 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 of instruments, etc.) both in and outside hospital (in particular vis-à-vis patients and their families);

20. 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);

21. Calls on the Member States to use the most advanced technological means available to guarantee optimum patient safety, and, in particular, to introduce across the board electronic health passports containing all relevant information about the patient, including his or her antecedents;

22. Emphasises, as regards home care, that:
   - the state of health of patients (particularly elderly 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 hygiene matters, the need to comply with procedures and prescriptions;
   - the use of throwaway medical equipment must be encouraged as far as possible;

b) Communication, education and training

23. Calls on the Member States to carry out specific awareness-raising and training measures concerning HAIs which are aimed not only at healthcare professionals (doctors, nurses, paramedics, etc.), but also, for example, at carers;

24. 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;

25. Calls on the Member States to provide patients with information about 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, and urges them to inform patients about complaints procedures and the legal remedies available to them should adverse events in healthcare occur;

26. 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;

27. Calls for the introduction of compensation systems (in particular if adverse events in healthcare occur) which are harmonised at EU level;
d) **Diagnosis and follow-up**

28. Calls on the Member States to encourage the submission of reports and the provision of feedback concerning patient safety not only from medical staff, but also from patients and their relatives;

29. Urges the Member States to adopt standardised criteria to identify places where contamination with HAIs occurs (including facilities outside hospitals) and to continue their efforts to collect comparable, up-to-date information on general patient safety and HAIs;

30. Calls in particular on those Member States which conduct specific national HAI prevalence surveys using a harmonised methodology developed by the ECDC to do so on a regular basis, and urges those Member States which do not do so to introduce such surveys;

31. Recommends that regional or local working parties be set up to consider specific issues relating to patient safety; by way of an example, working parties could focus on accident prevention among elderly people, reducing operation-related risks or reducing the risk of medication-related errors;

e) **European and international cooperation**

32. Calls on the Member States and the Commission to step up cooperation, including with the WHO and the OECD, with a view to standardising measures, definitions, terminology and indicators in the area of patient safety;

33. Calls on the Member States to share, where they exist, good practice benchmarks in the area of general patient safety, and, in particular, to share, where they exist, good practice benchmarks in the area of the prevention and control of HAIs and the transmission of multi-resistant bacteria;

34. Encourages the ECDC in its efforts to support and standardise the monitoring of HAIs, and, in particular, calls on it to continue developing structure and process indicators;

35. Calls on the Member States to establish a joint database to be used to compile information concerning adverse events in healthcare and to encourage the use of all relevant data collection mechanisms (including those based on confidential declarations);

f) **Monitoring and reporting**

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

37. 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 long-term funding it needs to fulfil its coordination and monitoring remit;

38. 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 4.1 million people, each year and are directly responsible for 37 000 deaths. It is estimated that 20% of HAIs could be avoided. Elderly 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 in June 2014.