

EPF proposed amendments

2014/2207(INI)

DRAFT REPORT

on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance

Committee on the Environment, Public Health and Food Safety

Rapporteur: Piernicola Pedicini

Amendment 1

Motion for a resolution

Recital T (new)

	T. whereas patients, families and patient organisations play a key role in advocating for safer care, and their role should be promoted through patient empowerment and participation in the healthcare process and policy at all levels;
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Justification:

Patients and citizens play a vital role in fighting for safer healthcare. This is clearly recognised in the 2009 Council Recommendation (whose recommendations on patient and citizen empowerment remain regrettably under-implemented, despite progress in some areas).¹ The 2014 Council Conclusions also ask Member States to “encourage the participation and empowerment of patients, families and their informal caregivers, as well as patient organisations ... and promote patients’ participation in decision-making in the healthcare process in order to contribute to the prevention of adverse events” (point 28.g). Furthermore the patients’ role is recognised in the Reflection process on chronic diseases² and the paper on “Future EU Agenda on quality of health care with a special emphasis on patient safety” by the European Commission’s Expert Panel (EXPH).³ However, despite all this, concrete action is still lacking at policy level.

The European mapping study on patient empowerment, EMPATHIE, launched in follow-up to the reflection process on chronic diseases, makes a number of recommendations for EU collaboration in this area, including: the development of a European Strategy and Action Plan on patient empowerment; provision of information and education to patients; developing new professional skills, knowledge and attitudes for patient-centred practice; self-management supported by technology; and increasing transparency to citizens and patients on quality of healthcare.⁴ These recommendations should now be taken forward jointly by the EU Institutions.

1 Second implementation report of the European Commission on patient safety and healthcare-related infections, June 2014 available at http://ec.europa.eu/health/patient_safety/docs/ec_2ndreport_ps_implementation_en.pdf

2 Reflection Process on Chronic Diseases, Final Report of 8 October 2013 available at

http://ec.europa.eu/health/major_chronic_diseases/docs/reflection_process_cd_final_report_en.pdf

3 Final report on Future EU Agenda on quality of health care with a special emphasis on patient safety, 9 October 2014.

Available at http://ec.europa.eu/health/expert_panel/opinions/docs/006_safety_quality_of_care_en.pdf

4 Presentation of the European Commission: http://ec.europa.eu/health/workforce/docs/ev_20141124_co04_en.pdf.

The final report of EMPATHIE is awaiting publication By the European Commission (DG Sante) at the time of writing.

Amendment 2

Paragraph 9.a (new)

	9a. Calls on the European Commission and Member States to develop EU Guidance on the provision of information to patients on patient safety in collaboration with stakeholders, particularly patient organisations
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Justification:

Well-informed, health-literate patients have been shown to be more discerning about their health, in a position to make more informed choices and decisions, and more likely to seek earlier diagnosis and recover faster. The converse is also true.⁵ There is a clear need for patient-friendly information about safety generally, and about medicines specifically, including their potential benefits and potential risks. However, medical professionals tend to overestimate the information they provide, and patients' understanding of it, while patients tend to want more information.⁶ Low quality information is a source of medication errors, adverse events and poorer outcomes.⁷

High-quality, understandable and comparable information is a key factor in empowering patients to make informed decisions and increasing health equity. Transparent and accessible information to patients and citizens must therefore be at the core of the future EU agenda on patient safety and quality of care.

Paragraph 30(d) of the Council Conclusions of 2014 asks Member States and Commission to “explore the feasibility to present a proposal for Council Recommendation on the provision of information to patients on patient safety following the Council Recommendation 2009/C 151/01, and following further preparatory work with the Member States on the dimensions of quality of healthcare”. This action will also support the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, which requires Member States to provide patients with transparent information on their safety and quality standards and guidelines.

⁵ “Health Literacy – part 2: evidence and case studies”, World Health Communication Associates, 2010, pp. 20-22. Available online at www.whcaonline.org/uploads/publications/WHCAhealthLiteracy-28.3.2010.pdf

⁶ Coulter, A (2007) “Evidence on the effectiveness of strategies to improve patients' experience of cancer care”, Cancer Reform Strategy Patient Experience Working Group. Available at www.pickereurope.org/Filestore/PIE_reports/project_reports/Cancer_reform_strategy_Macmillan.pdf

⁷ *Health Literacy: the Solid Facts*. WHO 2013, p. 54.

Amendment 3

Paragraph 9b. (new)

	9b. Calls on the European Commission and Member States to develop EU guidance for patients' involvement in patient safety strategies and actions in collaboration with stakeholders, particularly patient organisations
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Justification:

Patients' involvement, both individually (e.g. by taking an active role, self-management) and collectively (e.g. through advocacy, participation in quality and safety improvement initiatives, and dissemination of information) is a key aspect of developing a patient safety culture. Patients' experience during the healthcare "journey" is a rich resource of information about gaps and failures in the system, as well as a valuable educational tool for healthcare professionals⁸.

Patient involvement and empowerment have been identified as key action areas by the Member States and stakeholders participating in the Joint Action on Patient Safety and Quality of Care (PASQ).⁹ Whilst some individual Member States – such as Denmark¹⁰ – are taking steps to involving patients and citizens^{11, 12}, and interesting work has been done outside the EU¹³, there is currently no EU-wide overview or coherent strategy on patient involvement and empowerment in safety and quality.

The European Commission and Member States should therefore implement Paragraph 29(e) of the 2014 Council Conclusions which asks for "EU guidance for patient/citizens' involvement in strategies on patient safety taking into account the work of the World Health Organisation". This should be done with the active involvement of those concerned, i.e. patients and their representative organisations.

⁸ Can patients be teachers? The health Foundation, October 2011. Available at: <http://www.health.org.uk/public/cms/75/76/313/2809/Can%20patients%20be%20teachers.pdf?realName=br0eQj.pdf>

⁹ <http://pasq.eu/Portals/PaSQ/Dokumenti/Permanent%20PaSQ%20Network%207%204%20%202014%20Version%201%204%20Final.pdf>

¹⁰ For the campaign "Hello healthcare!" and other initiatives, see Danish Society for Patient Safety at www.patientsikkerhed.dk/in-english/projects.aspx

¹¹ Good Practices collected in the PaSQ project, available at: <http://pasq.eu/Wiki/PatientSafetyandQualityofCareGoodPractices.aspx>

¹² Reporting and learning systems for patient safety incidents across Europe, http://ec.europa.eu/health/patient_safety/docs/guidelines_psqcwg_reporting_learningystems_en.pdf.

¹³ E.g. "Safety is Personal. Partnering with Patients and Families for the Safest Care" The National Patient Safety Foundation's Lucian Leape Institute (2014) Report of the Roundtable on Consumer Engagement in Patient Safety. Available at http://c.ymcdn.com/sites/www.npsf.org/resource/resmgr/LLI/Safety_Is_Personal.pdf

Amendment 4

Paragraph 9c. (new)

	9c. (new) Urges the Member States to involve patients' organisations and representatives formally in the development of policies and programmes on patient safety at all appropriate levels, and to provide them with appropriate support to carry out patient safety activities;
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Justification:

Paragraph 2 of the Council Recommendation is still poorly implemented by Member States, and is identified as a priority action at member state level in the Commission's report.¹⁴ In the preliminary results of EPF's membership survey, respondents regarded patient organisations as an important source of information and capacity-building for patients (64%) and 65% recommend involving patients and citizens more in promoting patient safety in their country.¹⁵

The collective involvement of patients (through their representative organisations) is important for several reasons: first, to provide a users' perspective to the (re)design and delivery of healthcare services in order to ensure the healthcare environment is patient-centred and empowering for the individual users of healthcare. Therefore it is important to involve patients in developing policy and initiatives in this area. Secondly, patient organisations can ensure that patient safety messages are effectively communicated to patient and consumer communities. Patient organisations have close links with their "grassroots" communities and can effectively support policies at local, regional and national levels. Their own efforts in developing patient safety resources should also be further recognised and supported.¹⁶

¹⁴ Commission report, p. 13

¹⁵ EPF membership survey, preliminary results presented to the European Commission's Working Group on Patient Safety & Quality of Care, 8 March 2013. Not yet published.

¹⁶ Examples of patient safety initiatives and resources developed by patient organisations:

- *The Patient University in Barcelona, run by the University of Barcelona in cooperation with the Spanish Patients' Forum (EPF member) and the Joseph Laporte Library. This online patient University includes courses and information toolkits for patients about specific chronic diseases and disease self-management.*
<http://www.universidadpacientes.org/index.php>
- *The "Handbook for Patients for Hospital stay" and "10 Tips for Patients" in Denmark, developed by the Danish Society for Patients' Safety. The guide offers tips for patients admitted to hospitals, such as: what issues to be aware during the hospital stay, what questions to ask, etc.; it can also be used as a notebook to track treatment on a daily basis. A Finnish guide to hospital stay was developed on the basis of this.*
http://patientsikkerhed.dk/fileadmin/user_upload/documents/About/Patient_Handbook.pdf ;
http://patientsikkerhed.dk/fileadmin/user_upload/documents/About/Ten_tips_for_patients.pdf
- *EPF's sister organisation the International Alliance of Patients' Organizations (IAPO) has developed an Patient Safety Advocacy Toolkit, a modular resource to help patient organisations engage and contribute to safety of healthcare. The toolkit includes a book and a CD and focuses on a number of specific safety issues such as: taking medicines correctly, hospital acquired infections, medical errors, maternal and child health and safety issues, etc.*
<http://www.patientsorganizations.org/showarticle.pl?id=803>

Amendment 5

Paragraph 9d. (new)

	9d. (new) Calls on the Member States to cooperate on defining minimum patient safety standards and indicators for safety and quality of healthcare EU wide, in consultation with all relevant stakeholders including patient organisations.
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Justification:

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare requires each member state to have in place standards for patient safety and quality of care; it also requires for member states to cooperate with each other on standards and guidelines on safety and quality.

EPF believes that common minimum patient safety standards should be developed at EU level, to ensure improvement of patient safety across the European Union. We also call for explicit, measurable and well-defined indicators for this to really happen in practice. We urge for a partnership between all institutions involved in patient safety, in a "no shame no blame" culture, based on trust and transparency. The process should be undertaken in consultation with all stakeholders including meaningful involvement of patients' representatives.

We suggest that the European Commission or an independent multi-stakeholder body could be responsible for setting and monitoring performance against safety standards, with a well-defined set of quality criteria and an ongoing monitoring approach.

Amendment 6

Paragraph 22, indent c

c) ensure patients' adherence to and compliance with antibiotic treatments as prescribed by medical professionals;	c) ensure develop strategies to support patients' adherence to and compliance with antibiotic and other appropriate treatments as prescribed by medical professionals;
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Justification:

Correct adherence to all prescribed treatments, not only antibiotics, is a vital patient safety issue. Non-adherence is however very complex: the reasons behind it involve factors related to individual patients, but also professional support and the wider care process.¹⁷ Research indicates there is no “one size fits all” solution to address it. Instead, strategies must focus on supporting patients to adhere, taking a multi-stakeholder, patient-centred approach.¹⁸ This includes patient empowerment; self-management support; targeted health literacy and information resources for patients; and ensuring professionals have the skills and attitudes to engage in shared decision-making with patients. A professional training resource already exists in “Managing and Supporting Medication Adherence. A framework for the education and training of health professionals in Europe”, developed by the FP7-funded project ABC (Ascertaining Barriers to Compliance).¹⁹ These recommendations should be translated into professional training and clinical practice.

Note: The European Patients' Forum will make recommendations on adherence as an EU policy priority in a forthcoming position paper “Adherence and Concordance” (to be published in March 2015).

¹⁷ See for example Horne, R et al. (2005) *Concordance, adherence and compliance in medicine taking*. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D, December 2005. http://www.nets.nihr.ac.uk/_data/assets/pdf_file/0007/81394/ES-08-1412-076.pdf

¹⁸ CPME, EFPIA, EPF, PGEU (2011) “Improving the sustainability of healthcare systems through better adherence to therapies: a multi-stakeholder approach” Joint briefing paper <http://www.pgeu.eu/en/events/details/5-improving-the-sustainability-of-healthcare-systems.html>

¹⁹ <http://abcproject.eu/index.php?page=publications>