

Moving a step forward to promote patient safety and quality of care in Europe

MARIA IGLESIA⁽¹⁾, GEORGIOS MARGETIDIS⁽²⁾, SABRINA MONTANTE⁽³⁾, ELENA AZZOLINI⁽⁴⁾, WALTER RICCIARDI⁽⁴⁾

(1) European Commission, DG Health and Consumers Commission European Commission, Brussels, Belgium;

(2) European Commission Consumers, Health and Food Executive Agency, Luxembourg;

(3) Brussels Office, Università Cattolica del Sacro Cuore, Brussels, Belgium; (4) Section of Hygiene, Institute of Public Health, Faculty of Medicine, Università Cattolica del Sacro Cuore, Rome, Italy.

CORRESPONDING AUTHOR: Sabrina Montante, Brussels Office, Università Cattolica del Sacro Cuore Place du Champ de Mars 2, 1050 Brussels, Belgium. Tel: 0032-02-5187642; email: sabrina.montante@rm.unicatt.it

DOI: 10.2427/11034

CONFLICT OF INTEREST: None declared

Improving safety and quality of care has always been at the heart of national, European and international policies. The premises of such concern have their roots in the times of the Greek physician Hippocrates of Cos, about the 4th century BC, with the directive *primum non nocere* (“first do no harm”).

When being treated, patients hope and trust that their health-related problems will be appropriately handled and well looked after [1]. They would expect the people and organizations caring for them to make their safety the first priority, to be treated in an appropriate environment, with a minimal risk of infection. Equipment should be used in good working order and in the proper way, medicines should be given on time and in the correct doses, treatments should be appropriate for their conditions, with procedures performed correctly and in a timely and effective way. Unfortunately 53% of European Union (EU) citizens think that patients could be harmed by hospital care [2].

Every year between 8 and 12% of people admitted to hospitals in the EU suffer from an adverse event while receiving healthcare [3]. Furthermore, an estimated 37,000 patients die in the EU as a result of healthcare-related infections, many of which are preventable [4]. In addition to the human cost, there is a heavy price to pay in financial terms - the costs related to hospital infections alone amount to some € 7bn every year [5]. We do not yet, however, have a complete picture of the cost of unsafe care.

Patient safety and quality of care have therefore been a top EU priority, reflected in Council Recommendation 2009/C 151/01 [4], which proposed an overarching EU-level strategy to promote patient safety and address healthcare-associated infections. A review on the implementation of the Council Recommendation, published on 19 June 2014, the Patient Safety Package [2], suggests that the Recommendation has had significant impact, raising awareness of patient safety at political level and triggering concrete actions, including development of patient safety strategies and programmes. Patients are now more

aware of the possibilities of reporting adverse events, and patient organisations are more involved in developing policies. On the other hand, the review highlights deficiencies in the education of health professionals on patient safety and the persistence of a 'blame culture' in many countries.

A further important push to action has been given through the 2011 Directive (2011/24/EU) on patients' rights in cross border healthcare [6], the first major piece of EU legislation on health services. This not only clarifies patients' rights to choose treatment in another EU country and be reimbursed; it also facilitates access to safe and high quality healthcare everywhere in Europe. In particular it demands much greater transparency - including on quality and safety systems and standards - from health systems and providers across the EU.

In order to strengthen the effectiveness of EU health systems, the need is to continue and to step up the work on patient safety and quality of care. In this context, the European Commission together with the Faculty of Medicine of the Italian University "Università Cattolica del Sacro Cuore" and the Italian Ministry of Health organised a Conference in Rome, Italy, on December 2-3, 2014 under the umbrella of the Italian Presidency, involving health professionals, patients representatives, policy-makers and journalists from both mainstream as well as specialized media. The Conference was organised by the EU Consumers, Health and Food Executive Agency to raise awareness of EU policy on patient safety and quality of care, and to showcase successful projects addressing priority issues. During the Italian Presidency significant progress in the area of safety and quality has been made leading to the approval of Council Conclusions on patient safety and quality of care, including the prevention and control of healthcare-associated infections and antimicrobial resistance. In the midst of a period of political transition in Europe, Italy has chosen to raise the political profile of the discussion on this subject, taking an important step forward in improving the cooperation between Member States. This has been done in line with the current national priority of decreasing healthcare costs while at the same time maintaining efficiency and quality standards. The current challenges are urging Italy and all European countries to change perspective and to conceive health systems innovation not just as a result of further investments but also deriving from optimization and improvement of investments and assets already in place, putting quality and safety at the center, avoiding possible waste, overcoming fragmentation of care, promoting integration between different sectors, education and training and a strong monitoring & evaluation system.

The event took place at the Faculty of Medicine of Università Cattolica del Sacro Cuore demonstrating the role that research has played and will continue to play in producing evidence for the formulation of strategies and targeted policies. The utilization of health research in decision-making should contribute to policies that can eventually lead to desired outcomes [7]. Evidence should be especially used in clinical decision making. Even when research is available, it is often not used in practice and adapting the research to practice can be challenging because of numerous barriers and deficit of facilitators to change. More knowledge and a better use of the knowledge available is essential for understanding the extent and causes of patient harm and for developing innovative solutions that can be adapted to different contexts.

Policy consequences of these findings can be relevant for patient movement in Europe.

During the discussion, great emphasis was put on the central role of patients, the importance of healthcare professional training and the positive impact of 'blame-free' reporting systems.

It was clear from the Conference that patient safety and quality of care are now on the top of the political agenda across Europe, and that the 2009 Recommendation, together with other high-level EU Initiatives, had been a significant catalyst and enabler activities in Member States. This was evidenced by the Council Conclusions on Patient Safety and Quality of Care [8], adopted on December 1st, 2014, where EU Member States committed to implement the 2009 Council Recommendation more strictly, especially around education and training - "*an area where we should do better and more than we have done so far*".

Key issues mentioned under the Council Conclusions include: clear and unbiased

information- “patients that are well informed about healthcare make better decisions”; exchange of good practices to drive up standards at EU level; accountability and the importance of identifying authorities in charge of patient safety; the need for approaches that allow transparency; blame-free reporting by health professionals or patients, critical to provide an environment in which errors could be identified and learned from, rather than hidden away.

The same elements were also highlighted during the Conference. In addition, monitoring was identified as a critical issue, although it is important that it doesn't become an end in itself but a mechanism to trigger action. Monitoring and benchmarking were distinguished as being key tools for assessing performance, and self-assessment tools may be important ways for organisations to track and improve their own performance. However, it was also noticed that defining the most appropriate performance indicators is a challenge. In this respect, and in trying to clarify some of these intractable nodes, an opinion was published on October 2014 from the European Commission Expert Panel on Effective Ways of Investing in Health [9], on the development of a Europe-wide health system performance framework. Indeed, sound and timely scientific advice is an essential requirement for the European Commission in supporting of EU member states efforts for building or maintaining modern, responsive and sustainable health systems. To this end, the European Commission has set up a multidisciplinary and independent Expert Panel, made up of 12 members, which provides advice on effective ways of investing in health (Commission Decision 2012/C 198/06). The core element of the Expert Panel's mission is to provide the European Commission with independent advice in the form of opinions in response to questions (mandates) submitted by the Commission on matters related to health care modernization, responsiveness, and sustainability. The opinion “Future EU Agenda on quality of health care with a special emphasis on patient safety” recently published by the Expert Panel highlighted the need to develop a health system performance assessment framework at EU level. This could help to identify the necessary dimensions of quality measurement and advance the discussion on these issues in Europe.

According to the Expert Panel the difference can only be made at the front line or nano-level, whether this is a ward, an outpatient clinic, a GP ward or a community care service. Nevertheless, successful and evidence based, specific interventions also need to be supported by larger organizational changes. In this regards, cooperation and exchange of practices among different organizations and Member States are crucial. The lessons learned from a wide set of systems and healthcare providers can help decision makers to manage the complexity of healthcare organizational challenges.

The Conference also presented the European projects advancing in such exchange of practices and addressing key patient safety and quality of care issues, such as healthcare-associated infections and antimicrobial resistance. The need, as it was also recognised by the Panel, is to move beyond the hospital setting, and to consider risks and quality of care throughout the patient journeys within health systems.

In conclusion, there was broad agreement on the need to continue driving this work forward, both at the level of organisations actually delivering care to patients, as well as at higher strategic levels. Healthcare professionals have a critical role to play, and need to be more fully engaged, for example through additional training or continuing professional development. Above all, patients need to be empowered and provided with access to information to ensure that the patient voice receives the attention it deserves.

References

- [1] Patient safety and quality of healthcare. Special Eurobarometer 327. European Opinion Research Group EEIG. April 2010. Available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_327_sum_en.pdf
- [2] Patient Safety Package. European Commission. June 2014. Available at: http://ec.europa.eu/health/patient_safety/policy/package_en.htm
- [3] Conklin A, Vilamovska A-M, de Vries H, Hatziaandreu

- E. Improving patient safety in the EU. Assessing the expected effects of three policy areas for future action. Cambridge: RAND, 2008.
- [4] Council Recommendation 2009/C 151/01 on Patient safety, including the prevention and control of health-care associated infections. Official Journal of the European Union. 5 June 2009. Available at: http://ec.europa.eu/health/ph_systems/docs/patient_rec2009_en.pdf
- [5] WHO. Fact sheet on Health care-associated infections (HCAI) endemic burden worldwide. 2011. Available at: http://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf
- [6] Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. Official Journal of the European Union. 9 March 2011. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>
- [7] WHO Evidence-Informed Policy Network (EVIPNet) Global Steering Group Meeting 3-4 September 2014 Geneva Switzerland. Available at: <http://www.who.int/evidence/EVIPNetGSGGenevareport.pdf>
- [8] Council of the European Union. Council conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance. 1 December 2014. Available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/145976.pdf
- [9] Expert Panel on effective ways of investing in Health (EXPH). 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

