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REPORT FROM THE COMMISSION TO THE COUNCIL

The Commission's Second Report to the Council on the implementation of Council Recommendation 2009/C 151/01 on patient safety, including the prevention and control of healthcare associated infections

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1. Introduction

Council Recommendation 2009/C 151/01[1] put forward a range of measures on general patient safety and healthcare-associated infections (HAI) and invited the Commission to report on whether the measures are working effectively and to consider the need for further action.

The Commission's first report, which was published in 2012,[2] demonstrated satisfactory progress in the development of national policies and programmes on patient safety. It also identified areas requiring further effort: the education and training of healthcare workers in patient safety, empowering patients and developing a culture of learning from errors.

The report showed uneven progress across the EU. Some Member States reported that implementation had been slowed by financial constraints resulting from the economic crisis. The Commission therefore proposed that its monitoring of the implementation of the *general patient safety* provisions be extended for another two years.

The part of this report on general patient safety is based on Member States' responses to a questionnaire from the Commission, replies to the public consultation[3] and the results of the Eurobarometer survey on citizens' experience and perception of the safety and quality of healthcare.[4] It also presents EU-level activities supporting the implementation of the Recommendation in the area of general patient safety.

Recent findings by the European Centre for Disease Prevention and Control (ECDC) show that HAI continue to be a problem in Europe. The chapter on HAI presents EU-level activities in support of Member States' implementation of the Recommendation.

2. Implementation at Member-State level

This chapter summarises the main action taken at Member-State level and, where possible, its impact and progress as compared with the situation in 2012. It is based on replies received from all EU Member States;[5] and from Norway and the South Denmark region[6] who replied on a voluntary basis. References to 'countries' should be taken to mean the EU Member States and Norway. The headings reflect the structure of the Recommendation.

1 Council Recommendation (2009 C 151/01) of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections (OJ C 151, 3.7.2009, p. 6).

2 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 (COM(2012) 658 final).

3 Report of the public consultation on patient safety and quality of care, June 2014; http://ec.europa.eu/health/patient_safety/policy/index_en.htm

4 Eurobarometer B80.2 Patient safety and quality of care published in June 2014; http://ec.europa.eu/health/patient_safety/policy/index_en.htm

5 DE sent an off-line partial reply, included in the analysis.

6 When Danish replies from regional and national level are the same, they are reported as those of Denmark.

Development of policies and programmes on patient safety

The Member States have made progress on developing policies on patient safety since the Recommendation was adopted. 26 countries developed or are finalising patient safety strategies or programmes, either free-standing or under other national policies. More countries provided supporting documents than in 2012 (21 in 2014 against eight in 2012). Most gave examples of indicators to evaluate the strategies. 23 countries identified a competent authority responsible for patient safety (19 Member States in 2012), but only 16 provided documents to support this. All but one authority cooperate with authorities in other countries, both within and outside the EU.

All countries reported on patient safety measures in place. Patient safety standards are mandatory in 20 countries (11 in 2012) and recommended in four others. 19 countries use patient safety guidelines, in most cases developed at national level, by the health ministry or a dedicated agency. However, the replies show that the understanding of standards and guidelines varies across countries. Some countries report on specific standards for a type of adverse event, others on quality management systems and others take reporting and learning systems as examples. This makes it difficult to assess and compare progress across the EU.

The Recommendation encourages Member States to use information and communication systems to support the development of national policies and programmes on patient safety. The replies show that this provision is mainly understood as calling for websites with information about policies. Only a few countries reported on the use of reporting and learning systems, e-learning methods or electronic patient registries.

Patient empowerment

The 2012 report concluded that insufficient action had been taken to empower patients, both in terms of involving patient organisations in policy making and informing patients on patient safety measures.

24 countries said they involved patient organisations in the development of patient safety policies (20 in 2012), including 12 countries which provided examples of specific administrative and legal acts requiring such involvement. In the majority of countries, organisations can provide feedback, most often at meetings organised by competent authorities or via public consultations.

With respect to individual patients, Member States are recommended to disseminate information on patient safety standards, safety measures to reduce or prevent errors, the rights to informed consent to treatment, complaint procedures and available redress. Here, considerable progress was reported: 18 countries provide patients with information on all the above (only five in 2012) — with the right to informed consent and complaint procedures being the most widely communicated. Among all countries, only 18 gather feedback from patients about the availability and accuracy of information provided, mostly via surveys.

The Recommendation called on countries to develop core competencies for patients on patient safety. No progress has been made in this field since 2012 as in many countries the term remains unclear. It would therefore be appropriate to clarify this concept further so as to foster common understanding and uptake by the Member States.

Reporting and learning systems on adverse events

Further progress was reported on establishing reporting and learning systems. These exist in 27 countries (15 in 2012), mostly at national (21) and healthcare-provider level (13). However, where multiple systems are in place, they are rarely 'interoperable' (only seven out of 26). Also, only six Member States' systems fully respond to the Recommendation's requirements that they should:

- provide extensive information about adverse events;
- be differentiated from disciplinary procedures for healthcare workers;
- allow patients to report; and
- complement other safety reporting systems, e.g. those on pharmacovigilance or radiation safety.

Information from reporting systems is mostly disseminated in newsletters, health ministry reports and at conferences. Several countries use it to detect alerts, monitor trends and/or produce guidelines or recommendations. Half the Member States with such reporting systems share information so as to be able to learn from each other. However, only a few countries reported that errors are analysed at healthcare-provider level and lessons are drawn to improve quality and safety.

In 25 countries, reporting by healthcare workers has increased over the past four years, but only 15 countries report the same with regard to patients. Both figures are higher than in 2012.

Education and training of healthcare workers

This area remains under-implemented. Most countries reported that they encouraged multidisciplinary training on patient safety in healthcare settings, but three quarters do not provide information about the actual delivery of such training in hospitals.

Patient safety is not widely embedded in the undergraduate and postgraduate education of healthcare workers, on-the-job-training and the continuing professional education of health professionals, except in six Member States.[7] In eight Member States, it is not formally required at any level or for any health professionals. In countries with formal requirements to include patient safety in education and training, patient safety is mostly part of on-the-job-training for doctors, nurses and pharmacists.

State of implementation by countries

Chart 1 shows implementation progress by country, based on countries' self-assessment as to whether the following are in place:

- patient safety strategies;
- competent authority;
- specific measures to prevent medication errors, HAI and complications during or after surgical intervention;
- ICT tools to support patient safety;

[7] No information from DE.

- measures to involve patient organisations in policy making;
- measures to ensure dissemination of information about patient safety to patients;
- core competencies for patients;
- reporting and learning systems in place;
- reporting and learning systems fulfilling criteria as defined by the Recommendation;
- mechanisms to encourage reporting by health professionals;
- multidisciplinary training on patient safety in hospitals;
- patient safety embedded in the education and training of health professionals; and
- measures to inform health professionals about patient safety standards, guidelines or best practices.

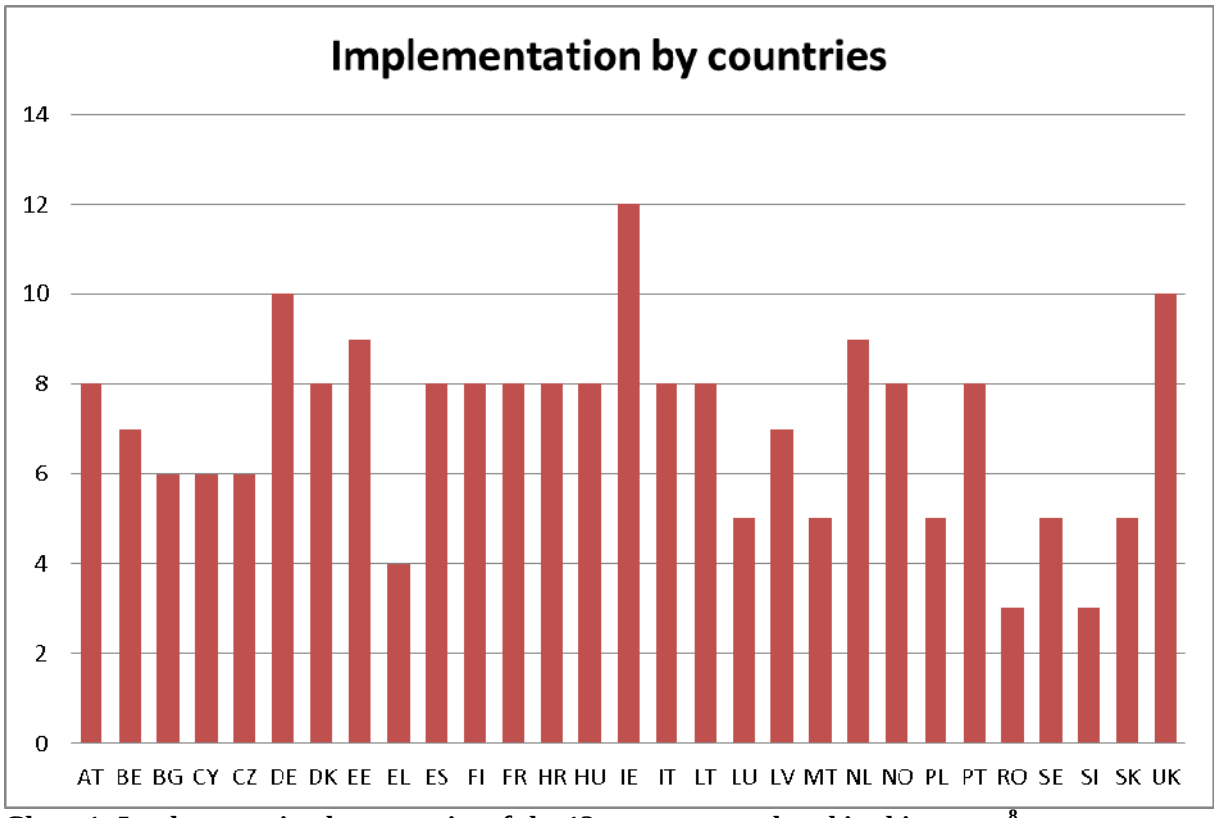

Chart 1: Implementation by countries of the 13 measures analysed in this report[8]

As the chart shows, most countries have in place at least half the measures analysed in this report, a few countries are close to full implementation of the 13 measures while 11 have implemented less than half the recommendations.

3. Coordination of work at EU level

In addition to action by Member States, the Recommendation calls for action at EU level to develop common definitions, terminology and comparable indicators, and share best practice. The Commission has been coordinating the following activities in support of such action:

[8] Only full replies to the questions, i.e. including supporting documents or providing examples, were acknowledged.

Exchange of knowledge, experience and good practice

The exchange of knowledge in patient safety and quality of care is facilitated at EU level in two main fora. One is the Commission's working group on patient safety and quality of care,[9] which brings together representatives of EU Member States and EFTA countries, international organisations (WHO and OECD) and EU stakeholders: patients, health professionals, healthcare managers and experts in quality of care. The working group is consulted on current and planned activities in patient safety and quality of care at EU level. It can also produce reports or recommendations at the Commission's invitation or on its own initiative. In addition, it provides a platform for members to share knowledge about initiatives at national level, stakeholders' activities and the outcomes of research projects.

A second forum for the exchange of good practice is an EU co-financed three-year joint action among Member States and stakeholders on patient safety and quality of care (PaSQ).[10] Its main tasks are to identify existing safe clinical practices and good organisational practices in the EU, to arrange for the exchange of knowledge about them and to test the transferability of patient safety practices to healthcare settings in other countries.

The active participation of all EU Member States, Norway and other stakeholders in this joint action and the success of exchange mechanism events which took place in this framework confirm a clear demand among stakeholders for this kind of cooperation at EU level. However, as a time-limited financing mechanism, the joint action will come to an end in March 2015. The Member States and other partners have suggested setting up a permanent network which would continue and expand on the current activities. Possible new activities which could be developed by such a network include a peer-review system for healthcare quality improvement organisations and a mechanism for the rapid exchange of patient safety incidents and solutions.

Tools to support implementation

To support implementation of the Recommendation, the working group has produced practical guides on:

- the education and training of health professionals in patient safety[11] – this provides a catalogue of existing modules and programmes with their content, target audience, faculty capacities, learning outcomes and evaluation. It also includes a list of success factors in setting up patient safety modules and training for different groups of health professionals at different levels; and

- the effective setting-up and functioning of reporting and learning systems[12] – this refers to existing knowledge and experience of how Member States have organised established reporting systems. It includes practical recommendations, encourages a reporting and learning culture and outlines the technical infrastructure required for setting up and maintaining the systems.

[9] See http://ec.europa.eu/health/patient_safety/events/index_en.htm

[10] See http://www.pasq.eu/

[11] Key findings and recommendations on education and training in patient safety across Europe. Report of the Commission's working group on patient safety and quality of care. April 2014 http://ec.europa.eu/health/patient_safety/policy/index_en.htm

[12] Key findings and recommendations on reporting and learning systems for patient safety incidents across Europe. Report of the Commission's working group on patient safety and quality of care. April 2014 http://ec.europa.eu/health/patient_safety/policy/index_en.htm

To complement this work, the Commission asked the WHO to adapt the *Conceptual Framework (CF) for the International Classification for Patient Safety*[13] for reporting on patient safety incidents in the EU. This consists of developing a 'minimal information model' for reporting patient safety incidents, to be used as a template by healthcare institutions to collect, review, compare and analyse incident reports. The information model will be accompanied by common terminology to designate and define the main types of patient safety incidents.

The Commission has also co-financed the OECD-led Health Care Quality Indicators Project,[14] which has developed a set of quality indicators, including patient safety, at health-system level, whereby the impact of particular factors on the quality of health services can be assessed. 24 EU Member States and Norway currently participate in the project.

In 2010, although not in response to the Recommendation, EU pharmaceutical legislation[15] was revised with respect to pharmacovigilance activities. Since July 2012, Member States have been required to ensure that, where suspected adverse reactions arise from an error associated with the use of a medicinal product, reports to their pharmacovigilance reporting systems are also made available to the authorities responsible for patient safety.

Finally, the Commission Green Paper on mHealth[16] highlights benefits of using telemedicine and mHealth solutions for ensuring patient safety.

4. Research and Health Programme

The Commission has addressed patient safety and HAI by funding several European-wide projects under the First and Second Health Programmes and the Sixth and Seventh Framework Programmes for Research and Technological Development. The Third Health Programme (2014-20)[17] and the new research programme Horizon 2020 (2014-2020)[18] provide for funding for further projects on patient safety and quality of healthcare, including HAI.

At Member-State level, research programmes on patient safety have been developed in half of the Member States. A lack of financial resources is reported as the main barrier to developing research at national level.

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13 http://www.who.int/patientsafety/implementation/taxonomy/conceptual_framework/en/

14 http://www.oecd.org/health/health-systems/healthcarequalityindicators.htm

15 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 on Community procedures for authorisation and supervision of medicinal products and establishing a European Medicines Agency, as amended by Regulation (EU) No 1235/2010 of 15 December 2010;
Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code on medicinal products for human use, as amended by Directive 2010/84/EU of 15 December 2010.

16 Green Paper on mobile Health ("mHealth") COM(2014) 219 final.

17 Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014, p. 1).

18 Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC.

5. Impact of the Recommendation

This chapter is based on information received from countries and complemented by results from the public consultation and the Eurobarometer survey.

Countries' replies show that the Recommendation raised awareness about patient safety at political level (21 replies). In 16 countries, it triggered concrete national/regional action, such as the development of patient safety strategies and programmes, the inclusion of patient safety in health legislation or the creation of reporting and learning systems. In some countries, it strengthened and supported existing patient safety programmes and confirmed their consistency with EU policies.

According to countries' self-assessments, the Recommendation raised awareness about patient safety at healthcare setting level (20 replies). Only half of countries judged that it had had an impact on empowering patient organisations and individual patients.

For 65 % of the respondents to the public consultation, the Recommendation contributed to improving patient safety. The replies confirm that it raised awareness at political level but point to low levels of awareness in healthcare settings, in particular as regards patient empowerment.

The Eurobarometer showed that the Recommendation did not change EU citizens' perception of the safety of care. As in 2009, over 50 % of respondents thought that patients could be harmed by hospital and non-hospital care.

Also, 25 % of respondents said that they or their family experienced an adverse event. Patients now report considerably more adverse events than in 2009 (46 % vs. 28 %). Most respondents felt, however, that such reporting does not lead to specific action being taken.

Finally, EU citizens say that they usually assess the quality of a particular hospital on the basis of its general reputation or other patients' opinions. This seems to indicate that objective information about the quality of care in hospitals is not easily accessible by patients.

6. Areas of interest identified by Member States and stakeholders

In their contributions to this Report, Member States identified the following areas for further cooperation at EU level:

- patient safety policies and programmes (21 replies);
- the development of blame-free reporting and learning systems and encouraging reporting by both health professionals and patients (21 replies); and
- the development and review of patient safety standards (20 replies).

The Commission received 181 replies to the public consultation, the main contributors being health professional organisations, patient and consumer organisations and hospitals. The respondents identified a need for improvement in the following areas:

- patient safety in non-hospital care;

- ensuring education and training not only for health professionals, but also for patients, families and informal carers;
- encouraging the use of new technologies for the benefit of patient safety;
- supporting the harmonised EU-wide surveillance of HAI and comprehensive assessment guidelines on patient safety standards complemented by checklists and indicators to be used across countries; and
- ensuring equal possibilities of redress for errors in treatment for all EU citizens.

72 % of respondents think there would be added value in enlarging the scope of EU action from patient safety to the wider quality of care. Patient safety is seen as a result of good quality healthcare. Specific proposed action at EU level included:

- establishing a common definition of 'quality of care';
- developing an EU strategy on health-related information for patients;
- considering gathering patients' experience as an element of quality improvement systems;
- setting up a permanent European forum to promote and share best practice in patient safety and quality of care, building on the joint action, e.g. work on a system of quality standards in healthcare organisations, issuing guidelines, setting targets and benchmarking; and
- taking account of the impact of workforce shortages and working conditions on the quality of care and encouraging better coordination of care.

Many respondents said the proposed action would also contribute to implementation of Directive 2011/24/EU.[19]

7. EU action relating to healthcare-associated infections

The Recommendation sets out action to be taken on HAI by Member States and at EU level. The sections below present steps taken at EU level to support Member States' action.

Legislative action

The Recommendation provides that Member States should use case definitions agreed at EU level to allow consistent reporting of HAI. Commission Decision 2012/506/EU of 8 August 2012 includes in its annex general and specific systemic case definitions of HAI, including reporting instructions for each of the conditions.[20] These case definitions of HAI will help not only to considerably improve surveillance across the EU, but will allow assessing the impact at EU level of the preventive measures undertaken.

HAI are covered by the new Decision No 1082/2013/EU on serious cross-border health threats.[21] The Decision strengthens the Health Security framework in the EU as regards preparedness planning, risk

[19] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patient rights in cross-border care (OJ L 88, 4.4.2011, p. 45).

[20] Commission Implementing Decision 2012/506/EU amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 262, 27.9.2012, p. 40).

[21] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

assessment, risk management and coordinating measures, including risk communication aspects.[22] Its provisions will apply to HAI.[23]

Activities in the area of surveillance

The ECDC network for the surveillance of healthcare-associated infections (HAI-Net) coordinates different modules to support Member States in establishing or strengthening the active surveillance systems referred to in Article II.8.c of the Recommendation.

Since the Recommendation was published, one EU-wide point prevalence survey was organised in acute care hospitals in 2011-12 (ECDC PPS)[24] and two in long-term care facilities (LTCFs).[25] Targeted surveillance of HAI was implemented continuously through the surveillance of surgical site infections (SSIs) and the surveillance of HAI in intensive care units (ICUs).

Overall, the level of participation in the European HAI surveillance modules was considered high in nine countries or regions (AT, DE, ES, FR, IT, LT, MT, PT and UK-Scotland), medium in 13 (BE, CZ, EE, FI, HU, LU, NL, NO, RO, SK, UK-England, UK-Northern Ireland and UK-Wales) and low in 11 countries (BG, CY, DK, EL, HR, Iceland, IE, LV, PL, SE and SI).

Guidance documents and reports

The ECDC produced several guidance documents and reports to support Member States:

In the area of appropriate use of antibiotics a systematic review and evidence-based guidance to improve the compliance of healthcare professionals with appropriate administration, timing, dosage and duration of perioperative antibiotic prophylaxis for the prevention of surgical site infections was published.[26]

In the area hospital infection control programmes**,** a systematic review on hospital organisation, management, and structures in place relating to healthcare-associated infection prevention identified a manageable set of 10 key components of hospital infection control programmes.[27]

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[22] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1)

[23] HAI was covered by Decision No 2119/98/EC.

[24] Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals, 2011-2012. Stockholm: ECDC; 2013

[25] Point prevalence survey of healthcare-associated infections and antimicrobial use in European long-term care facilities. April–May 2013. Stockholm: ECDC, 2014; Point prevalence survey of healthcare-associated infections and antimicrobial use in European long-term care facilities. May–September 2010. Stockholm: ECDC; 2014 (both in press)

[26] Systematic review and evidence-based guidance on perioperative antibiotic prophylaxis. Stockholm: ECDC; 2013

[27] These key components include: 1) organisation of infection control on a hospital level; 2) bed occupancy, staffing, workload, and pool/agency nurses; 3) ergonomic aspects; 4) appropriate use of guidelines; 5) education and training; 6) auditing; 7) surveillance and feedback; 8) multimodal and multidisciplinary prevention programmes taking into account principles of behavioural change; 9) engaging champions in prevention programmes; and 10) the role of a positive organisational culture. Zingg W, Holmes A, Dettenkofer M, et al. *Hospital organisation, management, and structure in the context of healthcare-associated infection prevention: a systematic review*. Lancet Infect Dis 2014: in press.

For nursing homes and other long-term care facilities, national performance indicators for infection prevention and control and antimicrobial stewardship were developed and assessed, which will be used as a basis for monitoring improvements of Member States in this area.

Finally, core competencies for infection control and hospital hygiene professionals have been developed and are already being used by Member States.[28]

8. Conclusions

Healthcare-associated infections

By leading to the adoption of a general and specific case definition for HAI and providing a standardised methodology and framework for the national surveillance of HAI, EU-level action contributed to strengthening HAI surveillance systems in the EU.

In particular, the ECDC's Europe-wide point prevalence survey of HAI and antimicrobial use in 2011-12 contributed to the improved collection of data on HAI, even in Member States that had not previously started with this activity.

The point prevalence report[29] and the Commission's first implementation report[30] indicate that Member States should focus their efforts on ensuring the targeted surveillance of HAI in surgical site infections, intensive care units and nursing homes and other long-term care facilities.

Further measures by Member States are needed to improve the routine case ascertainment of HAI, through the development of national diagnostic guidelines, continued training of healthcare workers in applying case definitions of HAI and the reinforcement of laboratory and other diagnostic capacity in healthcare institutions.

More specifically, the Europe-wide point prevalence survey – highlighted the need to ensure

- adequate numbers of specialised infection control staff in hospitals and other healthcare institutions
- sufficient isolation capacity for patients infected with clinically relevant microorganisms in acute care hospitals
- standardised surveillance of alcohol hand rub consumption.

To further support Member States preventing and control healthcare-associated infections and in supporting the implementation of the Recommendation, both the Commission and ECDC have prioritised addressing HAI.[31]

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[28] European Centre for Disease Prevention and Control; *Core competencies for infection control and hospital hygiene professionals in the European Union*. Stockholm: ECDC; 2013.

[29] European Centre for Disease Prevention and Control (ECDC); *Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals: 2011-12*. Stockholm: ECDC: 2013.

[30] 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 (COM(2012) 658 final).

General patient safety

The Recommendation has successfully raised awareness about patient safety at political level and triggered changes such as the development of national patient safety strategies and programmes and the development of reporting and learning systems in many EU Member States. It has created a climate that is conducive to improving patient safety in the EU.

However, it has had less of an impact in increasing patient safety culture at healthcare setting level, i.e. encouraging health professionals to learn from errors in a blame-free environment. The impact on empowering patients is only partial. The education and training of health professionals remains an area in which Member States and stakeholders have pointed to a need for further effort. Also, implementation of the Recommendation has not strengthened EU citizens' confidence in the safety and quality of healthcare in their country.

Meanwhile, patient safety remains an issue in the EU, as confirmed by over 90% of responses to the public consultation and by EU citizens' perceptions. This is supported by research[32] highlighting significant gaps between knowledge and practice in patient safety strategies and arguing that a substantial proportion of European citizens are at risk of receiving suboptimal care as a consequence.

In this context, the Commission considers there is a need for continued effort at EU level to support Member States in improving patient safety and quality of care. The following measures could be of particular relevance for further EU work, in close collaboration with Member States and stakeholders:

1. A common definition of quality of care and further support for the development of common terminology, common indicators and research on patient safety;
2. EU collaboration on patient safety and quality of care to exchange good practices and effective solutions. This could build on the current joint action and be extended to other topics identified by Member States and stakeholders;
3. Developing guidelines on how to provide information to patients on quality of care;
4. Development with Member States of an EU template on patient safety and quality of care standards to achieve common understanding of this concept in the EU;
5. Reflection with Member States on the issue of redress as provided for in Directive 2011/24/EU);
6. Encouraging the development of training for patients, families and informal carers using also ICT tools; regular updating and dissemination of the guide on patient safety education and training for health professionals; and

[31] For example, ECDC will develop a repository of existing guidance and other documents, to foster the exchange of best practices and the development of such documents in settings where they do not yet exist. Furthermore, ECDC will develop a monitoring and evaluation system with a set of indicators to assess the implementation of national strategies/action plan and their success in improving prevention and control of HAI.

[32] Sunol, R. et al. 2014, *Evidence-based organisation and patient safety strategies in European hospitals.* International Journal for Quality in Health Care 2014; pp. 1–9.

7. Encouraging reporting as a tool to spread a patient safety culture; regular updating and dissemination of the guide on the setting-up and functioning of reporting and learning systems.

These measures could also support an optimal implementation of Directive 2011/24/EU.