European Commission

Patient Safety in the EU: 2014

What is the issue?

### ✶ Types of adverse events

Healthcare-associated infections (HAI):

are directly responsible for **37 000** deaths / year

contribute to a further **110 000** deaths / year

cost hospitals over **€5.4 billion** / year

Medication-related errors	Surgical errors
Medical device failures	Errors in diagnosis

Failure to act on the results of tests

✶ Patients think they can be harmed

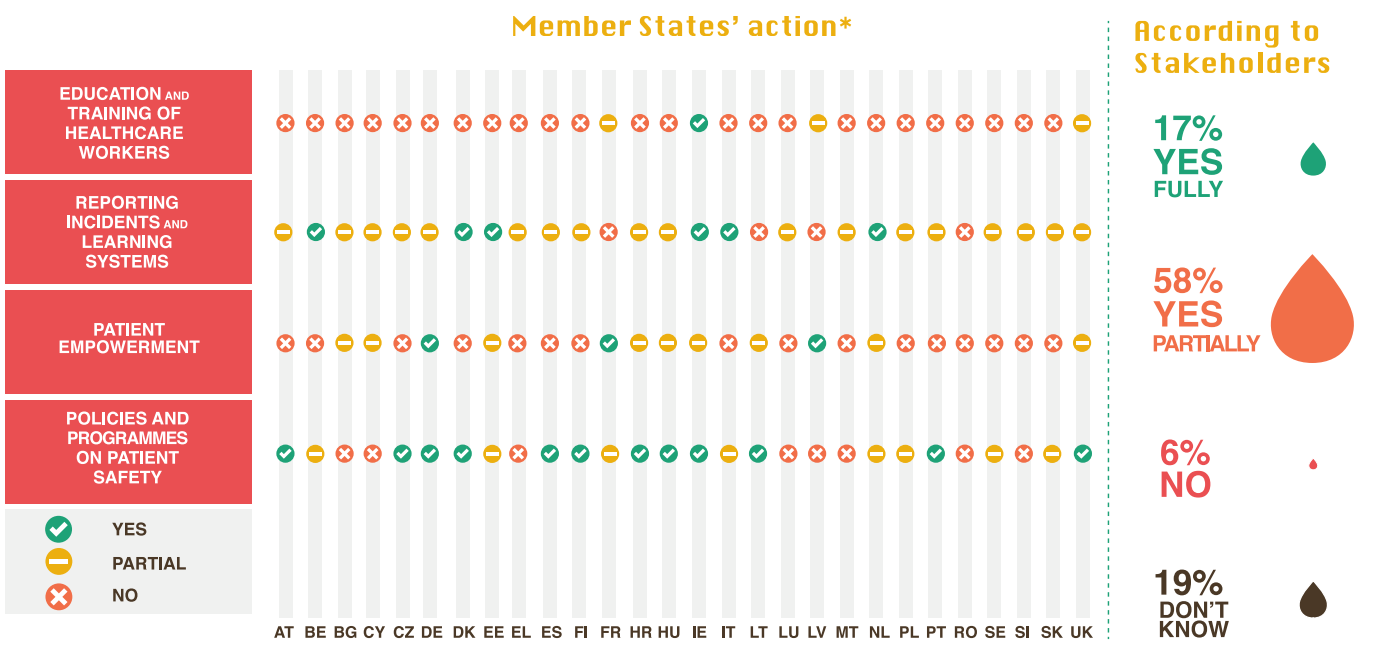EU citizens who think that **patients could be harmed by hospital care**

53%

- 🟥 57%-100%
- 🟧 50%-56%
- 🟩 0%-49%
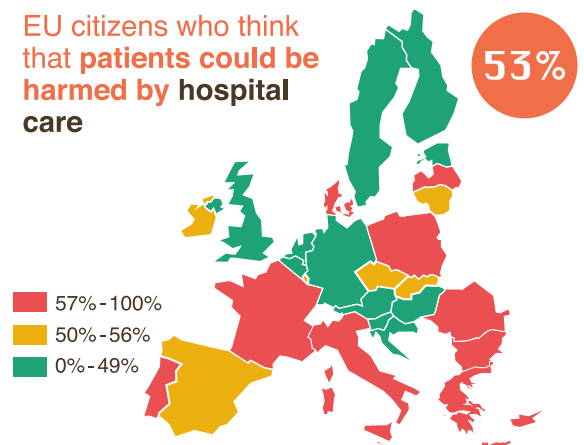
✶ **91%** of STAKEHOLDERS think patient safety is an issue

What is the EU response?

### ✶ 2009 EU Council Recommendation on patient safety

2014 state of implementation

Member States' action*

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK
EDUCATION AND TRAINING OF HEALTHCARE WORKERS																												
REPORTING INCIDENTS AND LEARNING SYSTEMS																												
PATIENT EMPOWERMENT																												
POLICIES AND PROGRAMMES ON PATIENT SAFETY																												

- ✔ YES
- ➖ PARTIAL
- ✖ NO

According to Stakeholders

- **17%** YES FULLY
- **58%** YES PARTIALLY
- **6%** NO
- **19%** DON'T KNOW

✶ Impact of the Recommendation

According to Member States it has:

Increased awareness at

Political level **21**/27*

Healthcare setting level **20**/27*
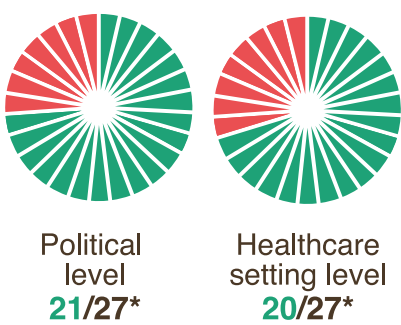
Triggered concrete action

16/27*
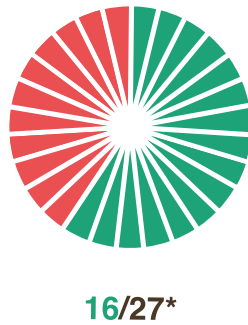
According to Stakeholders it has

Improved patient safety

- **65%** AGREED
- **35%** say: TO CERTAIN EXTENT
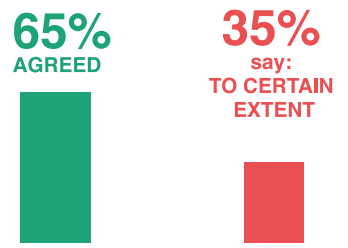
Areas to improve

Education and training of healthcare workers

Patients...**

...experiencing an adverse event...

27%

- 🟥 30%-100%
- 🟧 25%-29%
- 🟩 0%-24%

...reporting it...

46%

- 🟩 50%-100%
- 🟧 43%-49%
- 🟥 0%-42%

Reporting incidents and learning systems

...to what result

37%	Nothing happened
20%	The doctor/nurse apologized
17%	An explanation for the error was provided by the healthcare facility
12%	Measures have been taken to prevent similar errors in the future by the healthcare facility
11%	The healthcare facility did not accept liability for the adverse event
6%	The person responsible was disciplined
6%	Financial compensation was given
6%	Legal proceedings are still underway
5%	Action was taken against the healthcare facility responsible
4%	Other (spontaneous)
3%	Don't know

Patient empowerment

Patients...**

...receiving information on risks of HAI

- 🟩 43%-100%
- 🟧 36%-42%
- 🟥 0%-35%

EU average

- **11%** DON'T KNOW
- **39%** YES
- **50%** NO
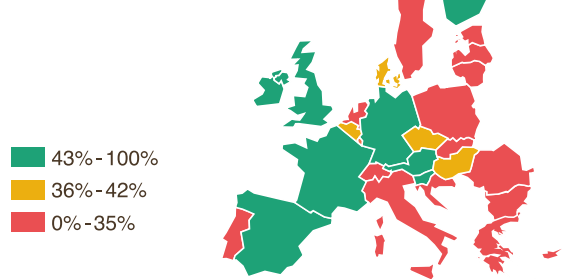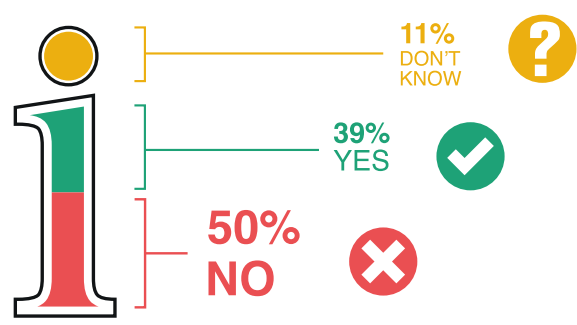
✶ Assesment based on reporting by MS
✶✶ Source: Eurobarometer 80.2

Health

![European Commission] **EUROBAROMETER**

Patient Safety and Quality of Care

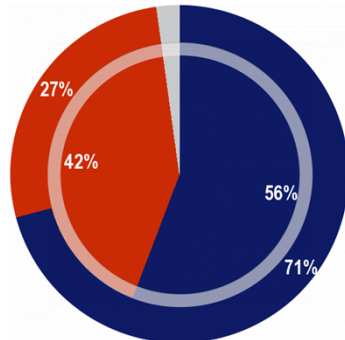|		Number of interviews:	Fieldwork:
EU28		27.919	23/11-02/12/2013
IT		Number of interviews: 1.019	Fieldwork: 23/11-28/11/2013

Methodology: face-to-face

1. OVERALL QUALITY OF HEALTHCARE

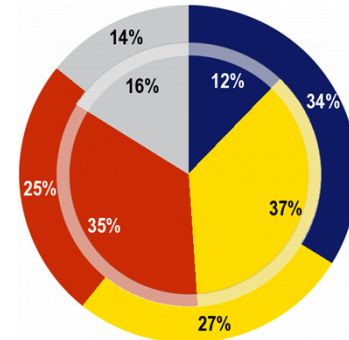QC2. How would you evaluate the overall quality of healthcare in (OUR COUNTRY)?

EU28 ● Outer pie   IT ◐ Inner pie

	EU28		IT	
	EB80.2 2013	2013-2009	EB80.2 2013	2013-2009
● Total 'Good'	71%	+ 1	56%	+ 2
● Total 'Bad'	27%	- 1	42%	- 2
● Don't know	2%	=	2%	=

QC3. Based on what you know, do you think that the quality of healthcare in (OUR COUNTRY) compared to other EU Member States is …?
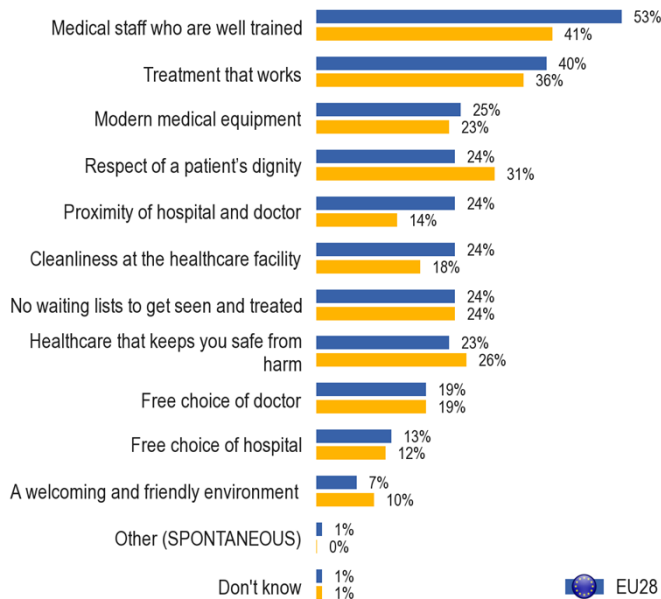
EU28 ● Outer pie   IT ◐ Inner pie

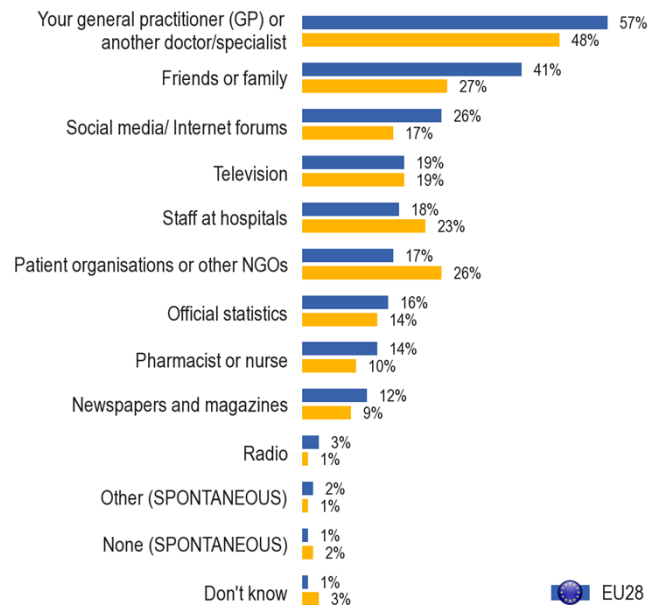|	EU28		IT	
	EB80.2 2013	2013-2009	EB80.2 2013	2013-2009
● Better	34%	+ 1	12%	- 3
● The same	27%	- 3	37%	- 2
● Worse	25%	- 1	35%	- 2
● Don't know	14%	+ 3	16%	+ 7

2. INFORMATION ON QUALITY OF HEALTHCARE

QC1. Of the following criteria, which are the three most important criteria when you think of high quality healthcare in (OUR COUNTRY)?

	EU28	IT
Medical staff who are well trained	53%	41%
Treatment that works	40%	36%
Modern medical equipment	25%	23%
Respect of a patient's dignity	24%	31%
Proximity of hospital and doctor	24%	14%
Cleanliness at the healthcare facility	24%	18%
No waiting lists to get seen and treated	24%	24%
Healthcare that keeps you safe from harm	23%	26%
Free choice of doctor	19%	19%
Free choice of hospital	13%	12%
A welcoming and friendly environment	7%	10%
Other (SPONTANEOUS)	1%	0%
Don't know	1%	1%

(MAX. 3 ANSWERS)

QC4. What are the three main sources you would use to seek information on quality of healthcare?

	EU28	IT
Your general practitioner (GP) or another doctor/specialist	57%	48%
Friends or family	41%	27%
Social media/ Internet forums	26%	17%
Television	19%	19%
Staff at hospitals	18%	23%
Patient organisations or other NGOs	17%	26%
Official statistics	16%	14%
Pharmacist or nurse	14%	10%
Newspapers and magazines	12%	9%
Radio	3%	1%
Other (SPONTANEOUS)	2%	1%
None (SPONTANEOUS)	1%	2%
Don't know	1%	3%

(MAX. 3 ANSWERS)

EUROBAROMETER 80.2 RESULTS FOR ITALY

EUROBAROMETER

Patient Safety and Quality of Care

EU28	Number of interviews: 27.919	Fieldwork: 23/11-02/12/2013
IT	Number of interviews: 1.019	Fieldwork: 23/11-28/11/2013

Methodology: face-to-face

## 3. PERCEIVED LIKELIHOOD OF BEING HARMED BY HEALTHCARE SERVICES

QC6a. How likely do you think it is that patients could be harmed by hospital care in (OUR COUNTRY)? By hospital care we mean being treated in a hospital as an outpatient or inpatient.
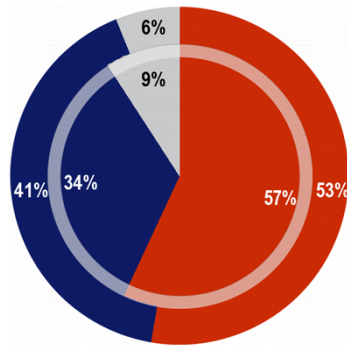
EU28 ◉ Outer pie   IT ◉ Inner pie

	EU28		IT	
	EB80.2 2013	2013-2009	EB80.2 2013	2013-2009
● Total 'Likely'	53%	+ 3	57%	+ 2
● Total 'Not likely'	41%	- 5	34%	- 7
● Don't know	6%	+ 2	9%	+ 5

QC6b. And how likely do you think it is that patients could be harmed by non-hospital healthcare in (OUR COUNTRY)? By non-hospital health care we mean receiving diagnosis, treatment or medicine in a clinic or surgery of your general practitioner or in a pharmacy.
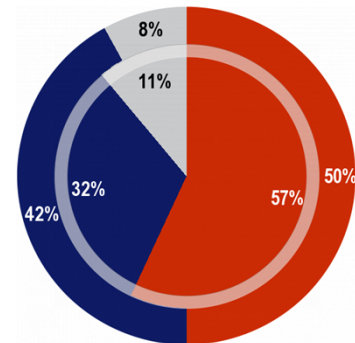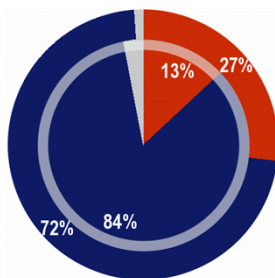

EU28 ◉ Outer pie   IT ◉ Inner pie

	EU28		IT	
	EB80.2 2013	2013-2009	EB80.2 2013	2013-2009
● Total 'Likely'	50%	+ 4	57%	+ 6
● Total 'Not likely'	42%	- 7	32%	- 12
● Don't know	8%	+ 3	11%	+ 6

4. EXPERIENCE OF ADVERSE EVENTS

QC7. Have you or a member of your family ever experienced an adverse event when receiving healthcare?
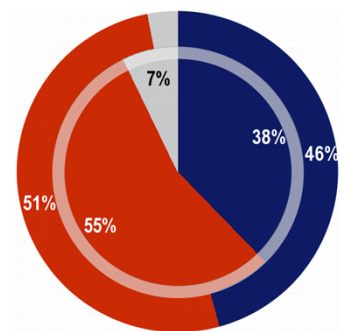

EU28 ◉ Outer pie   IT ◉ Inner pie

	EU28		IT	
	EB80.2 2013	2013-2009	EB80.2 2013	2013-2009
● Yes	27%	+ 1	13%	- 2
● No	72%	=	84%	+ 5
● Don't know	1%	- 1	3%	- 3

Respondents were explained that being harmed when receiving healthcare is also referred to as "adverse events". "Adverse events" include hospital infections; incorrect, missed or delayed diagnoses; surgical errors; medication related errors (wrong prescription, wrong dose, dispensing error in pharmacy, wrong administration route); medical device or equipment related errors.

QC9. And did you or the member of your family involved report it?

EU28 ◉ Outer pie   IT ◉ Inner pie

	EU28		IT	
	EB80.2 2013	2013-2009	EB80.2 2013	2013-2009
● Yes	46%	+ 18	38%	+ 15
● No	51%	- 19	55%	- 15
● Don't know	3%	+ 1	7%	=

Base: respondents who have experienced an adverse event

Please note that the basis is too low for this question for this country (n=129) and therefore results are only indicative.

EUROBAROMETER 80.2 RESULTS FOR ITALY

Patient Safety and Quality of Care

EU28 — Number of interviews: 27.919 — Fieldwork: 23/11-02/12/2013

IT — Number of interviews: 1.019 — Fieldwork: 23/11-28/11/2013

Methodology: face-to-face

5. INFORMATION ON PATIENT SAFETY

QC14a. Have you or a member of your family been hospitalised or admitted to a long-term care facility (such as nursing home or home for the elderly) in the last 12 months?

Yes, hospitalised — 17% / 15%

Yes, admitted to a long-term care facility — 4% / 8%

No — 79% / 78%

Don't know — 1% / 0%

EU28 / IT

(MULTIPLE ANSWERS POSSIBLE)
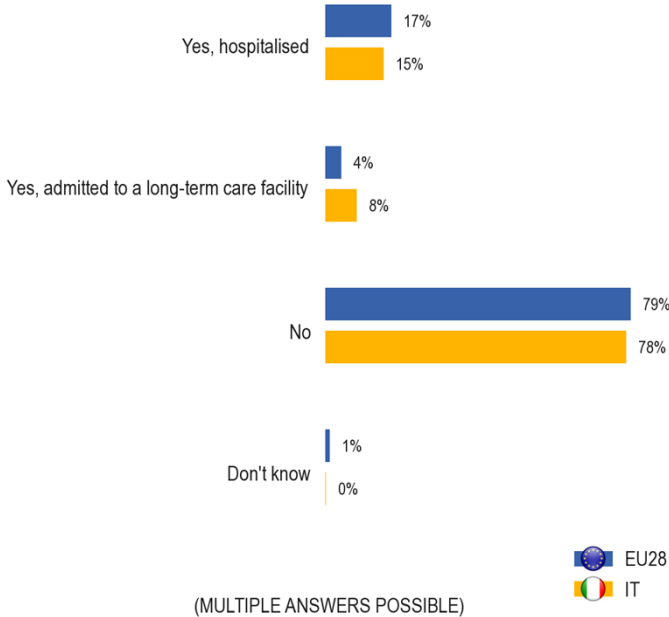
QC14b. Did you or a member of your family receive any information on the risk of healthcare-associated infection?

11% — 20% — 39% — 12% — 68% — 50%

● Yes ● No ● Don't know

EU ● Outer pie   IT ● Inner pie
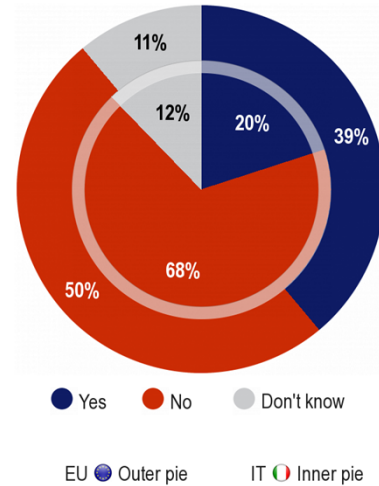
Base: respondents who have been hospitalised or admitted to a long-term care facility

6. WRITTEN CONSENT FOR SURGICAL PROCEDURES

QC13a. Did you or a member of your family undergo any surgical procedure within the last three years? This can be any type of surgical procedure, ranging from minor surgery, perhaps as a day patient in a hospital, to a major surgical procedure.

23% — 38% — 61% — 75%

EU28 ● Outer pie   IT ● Inner pie
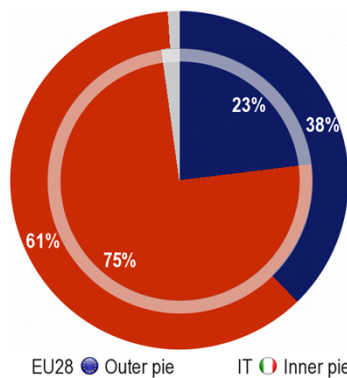
	EU28		IT	
	EB80.2 2013	2013-2009	EB80.2 2013	2013-2009
● Yes	38%	+ 1	23%	- 2
● No	61%	- 1	75%	+ 2
● Don't know	1%	=	2%	=

QC13b. Were you or your family member asked for written consent beforehand?

11% — 10% — 15% — 9% — 12% — 6% — 69% — 68%

EU28 ● Outer pie   IT ● Inner pie
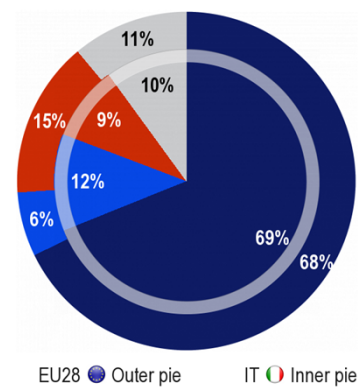
	EU28		IT	
	EB80.2 2013	2013-2009	EB80.2 2013	2013-2009
● Always	68%	+ 1	69%	- 8
● Sometimes	6%	- 1	12%	+ 3
● Never	15%	- 2	9%	+ 2
● Don't know	11%	+ 2	10%	+ 3

Base: respondents who underwent any surgical procedure within the last three years

EUROBAROMETER 80.2 RESULTS FOR ITALY

3

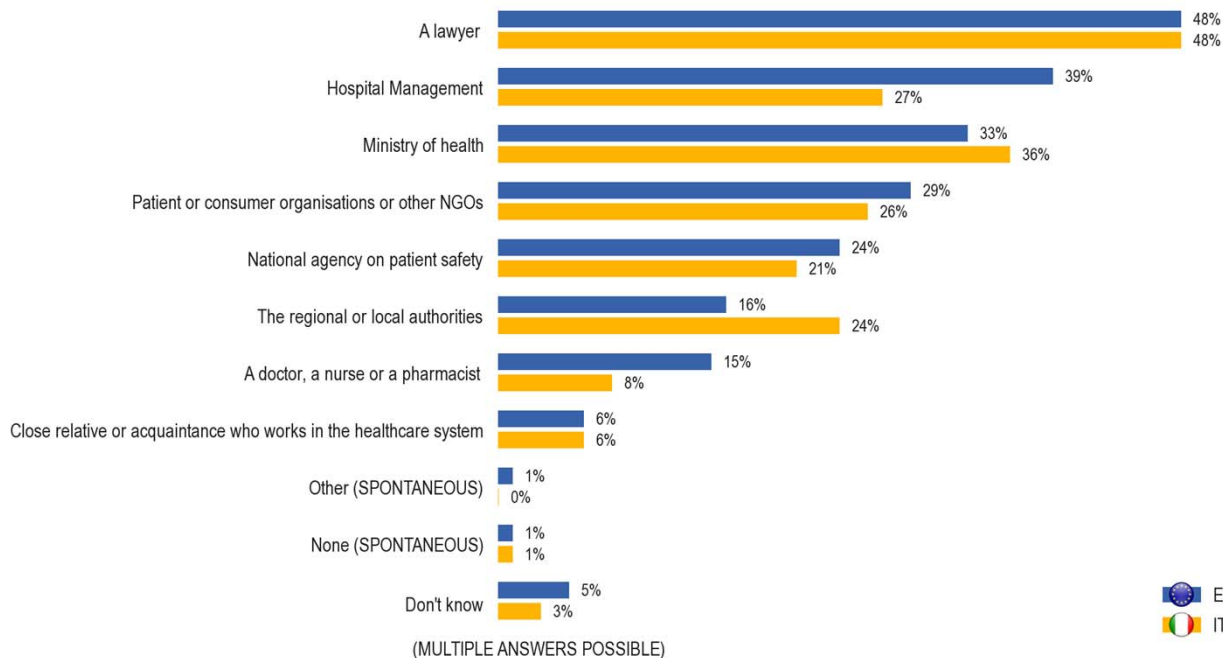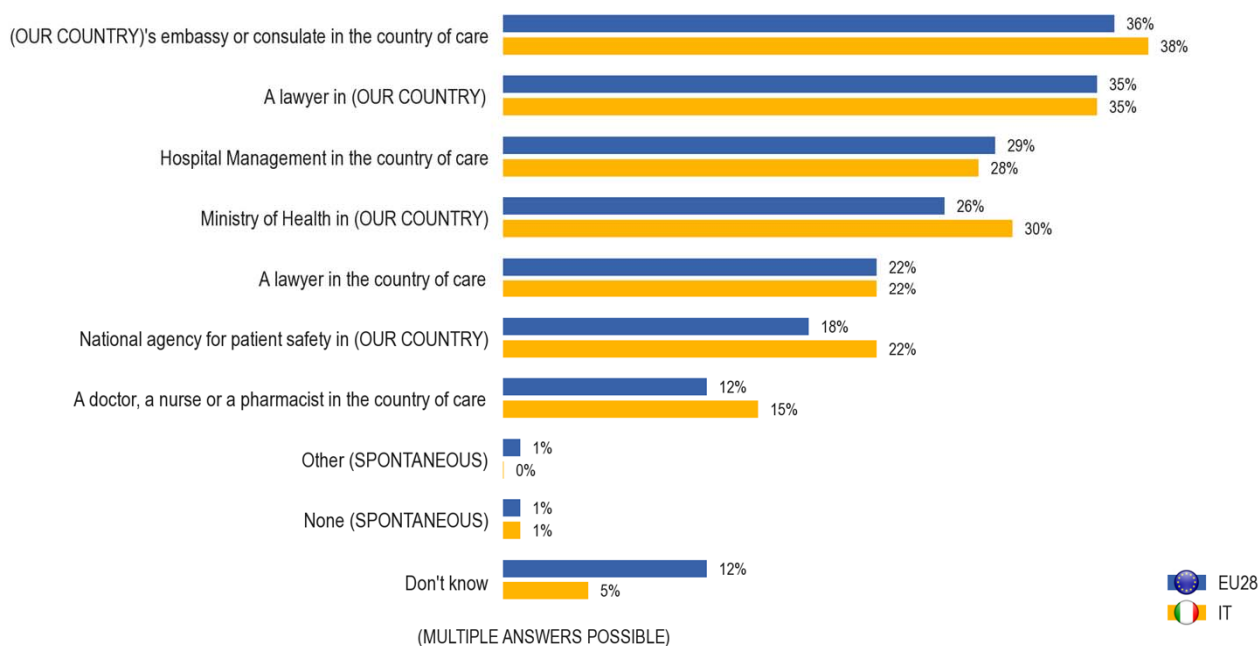| **Patient Safety and Quality of Care** | EU28 | | Number of interviews: 27.919 | Fieldwork: 23/11-02/12/2013 |
| | IT | | Number of interviews: 1.019 | Fieldwork: 23/11-28/11/2013 |

Methodology: face-to-face

7. SEEKING HELP IF HARMED WHEN RECEIVING HEALTHCARE

QC18. From which of the following can you seek help in relation to redress if you or a member of your family is harmed whilst receiving healthcare in (OUR COUNTRY)?

	EU28	IT
A lawyer	48%	48%
Hospital Management	39%	27%
Ministry of health	33%	36%
Patient or consumer organisations or other NGOs	29%	26%
National agency on patient safety	24%	21%
The regional or local authorities	16%	24%
A doctor, a nurse or a pharmacist	15%	8%
Close relative or acquaintance who works in the healthcare system	6%	6%
Other (SPONTANEOUS)	1%	0%
None (SPONTANEOUS)	1%	1%
Don't know	5%	3%

(MULTIPLE ANSWERS POSSIBLE)

■ EU28
■ IT

QC19. And where can you seek help in relation to redress if you or a member of your family is harmed whilst receiving healthcare in another EU Member State?

	EU28	IT
(OUR COUNTRY)'s embassy or consulate in the country of care	36%	38%
A lawyer in (OUR COUNTRY)	35%	35%
Hospital Management in the country of care	29%	28%
Ministry of Health in (OUR COUNTRY)	26%	30%
A lawyer in the country of care	22%	22%
National agency for patient safety in (OUR COUNTRY)	18%	22%
A doctor, a nurse or a pharmacist in the country of care	12%	15%
Other (SPONTANEOUS)	1%	0%
None (SPONTANEOUS)	1%	1%
Don't know	12%	5%

(MULTIPLE ANSWERS POSSIBLE)

■ EU28
■ IT

**EUROBAROMETER 80.2
RESULTS FOR ITALY**

PATIENT SAFETY

AND HEALTHCARE-ASSOCIATED INFECTIONS

Health

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.

Table of contents

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.

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[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

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[7] No information from DE.

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;
- 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.

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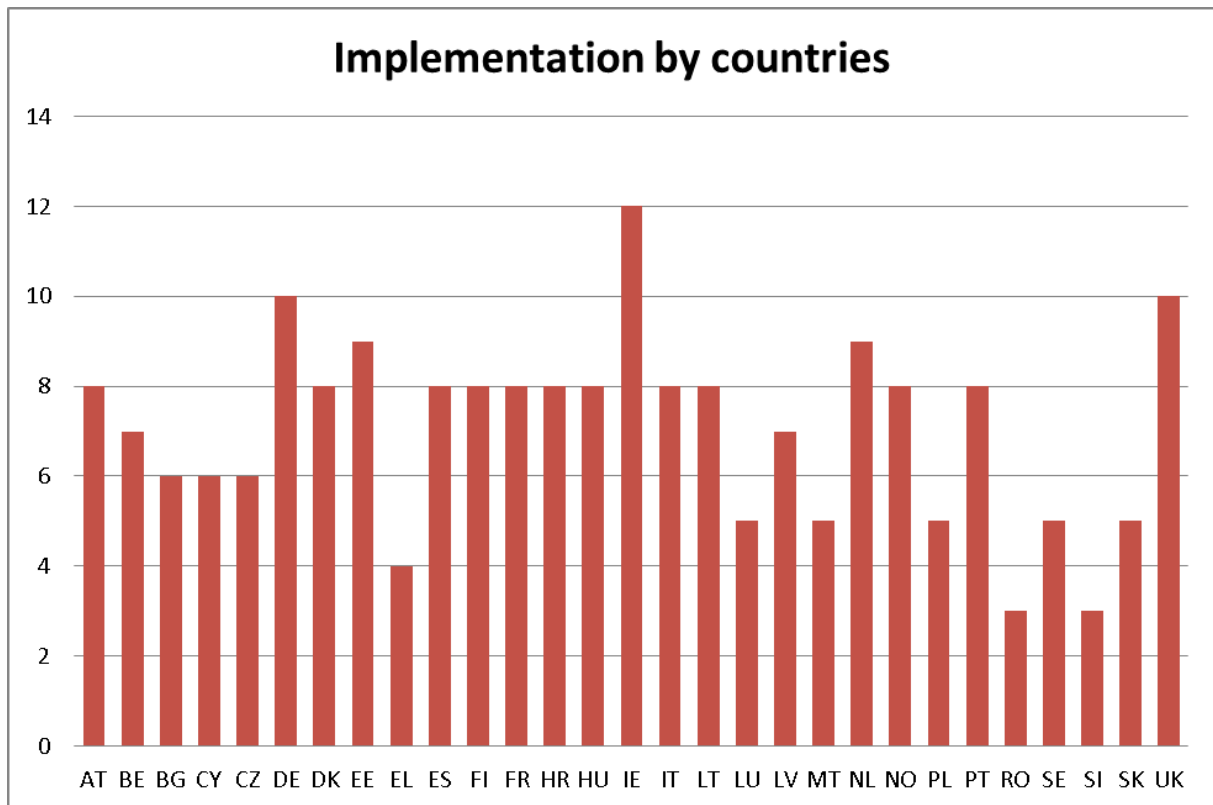
Chart 1: Implementation by countries of the 13 measures analysed in this report[8]

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:

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

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

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

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.

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[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.

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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.

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.

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.

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[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).

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 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).

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[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).

[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)

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]

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.

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[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.

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

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]

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,

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[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).

[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.

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

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.

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[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.

http://ec.europa.eu/health/patient_safety/policy/index_en.htm

Report on
The Public Consultation on Patient Safety and Quality of Care

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EXECUTIVE SUMMARY

The public consultation on patient safety and quality of care clearly demonstrated that the civil society (over 90%) still see patient safety as an issue in the EU. One major concern of respondents was that nearly five years after the Recommendation has been adopted, in several countries it is only partially implemented (58% of respondents is convinced of it) and many barriers are still in place preventing its full implementation.

The most relevant barriers identified were:

- severe budget and resources cuts due to the economic crisis, which is particularly concerning when combined with the lack of political will and of healthcare professionals' engagement in patient safety. In fact, with the austerity imposed by the economic crisis, patient safety could not be prioritized enough in the political agendas;

- at the healthcare setting level, a top-down attitude by clinicians particularly regarding patient involvement;

- failure to achieve high levels of awareness in hospitals of the importance of patient safety;

- predominating "blame-cultures" which prevents focusing on causes of errors and ways to eliminate them;

- reporting, which is still not understood as a learning facilitator and with insufficient IT infrastructures to support data analysis.

The public consultation showed an overwhelming support for all areas of potential action to improve patient safety identified by the European Commission. Besides, the most effective tools that could help better implementation of the Recommendation, according to most respondents, are the involvement of health professionals, national binding legislation, and the involvement of patient organisations, followed by EU-cooperation on patient safety.

However, respondents identified different issues not or not sufficiently covered by the Recommendation and that should have a crucial role in the future EU action, such as:

- comparable public reporting and data, control and redress mechanisms (e.g. with guidelines on patient safety standards complemented by checklists and indicators);

- more financial resources should be given to education and training for healthcare workers and informal carers, cooperation, best practices exchange, mutual learning and investments in IT technologies;

- encouraging the set-up of appropriate information and communication (e.g. through networks, fora, improvement projects) targeting both general public and healthcare staff.

- patient empowerment, as well as fields such as primary care, mental health care and informal care, inequalities in access to care and to redress and compensation for errors in medicine.

Moreover, the majority of the contributors (72%) thought that there would be an added value in enlarging the scope of EU action from patient safety to wider quality of care.

In fact, patient safety is seen as a core dimension of quality of care which needs to be safe, effective and respectful of patients' needs and dignity.

Furthermore, problems concerning the healthcare workforce should be taken more into consideration in the future. This concerns for example the doctor/patients and nurse/patient ratio affected by the impact of cuts in health expenditure on patient safety or working conditions of health professionals.

1. INTRODUCTION

In 2009 patient safety has been addressed at EU level in a comprehensive manner, through adoption of an overarching strategy on patient safety, in the form of a Council Recommendation[1]. The Recommendation included actions to be implemented by EU Member States that covered: embedding patient safety as priority issue in public health policies, empowering patients and promoting patient safety culture among health professionals, appropriate training and possibility of learning from errors.

The Recommendation envisaged for the Commission to assess three years after the adoption to what extent the proposed measures work effectively. To this end, the Commission published an implementation report in November 2012 where it appeared clear that the financial crisis slowed down the implementation and that more time was needed to make it work properly. This is why the Commission proposed to extend the implementation period for another two years.

Patient safety is a core aspect of quality care and it represents the first step to reach quality both in the context of health services and in performance of healthcare systems.

2014 represents an important year for reflection about the future of EU action on patient safety and quality of care. A second implementation report on patient safety – based on information from Member States competent authorities will certainly contribute to this reflection as it will assess progress with implementation of the Recommendation, state whether the proposed measures work effectively and consider the need for further action.

To supplement information from Member States, the European Commission decided to seek the opinion of civil society about general patient safety issues throughout the EU. For this purpose the Commission ran a public on-line consultation on patent safety in the EU between 4 December 2013 and 28 February 2014. The public consultation requested opinions on: whether patient safety measures included in the Recommendation 2009 are implemented and contribute to improve patient safety in the EU; which areas of patient safety are not covered by the Recommendation and should be; what should be done at EU level on patient safety beyond the Recommendation; whether quality of healthcare should be given more importance in the future EU activities.

The public consultation represented an opportunity for all interested stakeholders to give their views and suggestions on possible areas of action on patient safety at the EU and MS level.

This summary document aims to provide an overview of the main opinions expressed by the respondents to the consultation.

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1 Council Recommendation on patient safety, including the prevention and control of healthcare associated infections (2009/C151/01).
http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf

2. THE QUESTIONNAIRE

The questionnaire was divided into 3 parts. The first set of questions asked for respondent information, while the second and the third ones consisted of a total of 11 specific questions about patient safety and quality of care.

The second section, the main one, concerned the implementation of the Council Recommendation 2009/C 151/01 and consisted of 5 questions and 5 sub-questions asking whether the Recommendation was or not implemented in Member States, contributing or not to improve patient safety and, if yes, through which tools. Respondents were also asked to identify the barriers to the implementation, the provisions of the Recommendation of particular relevance in their countries and the areas not included in the Recommendation that would benefit from action at EU level.
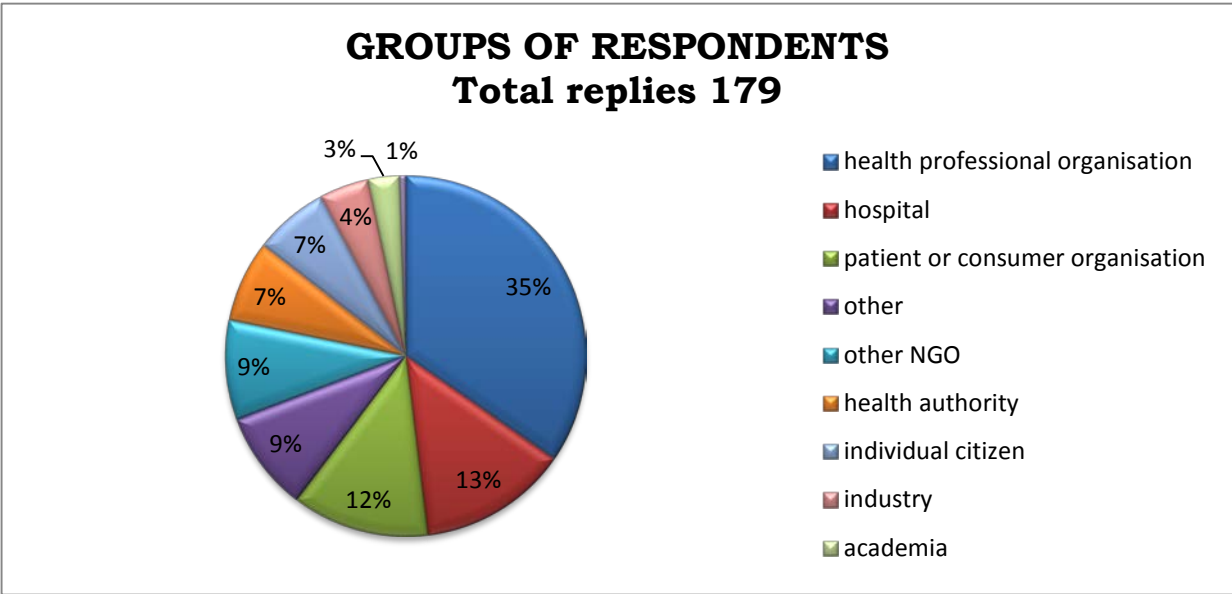
The third and final section of the questionnaire addressed future EU action on patient safety and quality of healthcare, focusing on what should be done beyond the Recommendation and asking whether quality of healthcare should be given more importance in the future EU activities.

3. THE RESPONSES

3.1 Overview of all responses

In the first part of the questionnaire we asked respondents to provide personal information in order to exactly know who they were, which group they belonged to, what country they were from and also how many citizens they represented[2]. We received 179 contributions including 10 outside of the on-line system. All replies are included in this report. Chart 1 shows a distribution of replies by different groups of respondents that according to the questionnaire were divided into the following groups:

Chart 1: Overview of the responses received.

GROUPS OF RESPONDENTS
Total replies 179

- health professional organisation — 35%
- hospital — 13%
- patient or consumer organisation — 12%
- other — 9%
- other NGO — 9%
- health authority — 7%
- individual citizen — 7%
- industry — 4%
- academia — 3%, 1%

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2 The Analysis in this Report reflects the groups that respondents indicated they belonged to.

As shown in the table above, health professional organisations represented the biggest group with 36% of the total number of respondents, followed by hospitals with 13%, patient or consumer organization with 12%, other NGO with 9%, other with 9%, individual citizens with 7%, health authorities with 7%, industry with 4%, academia with 2% and a National Parliament with 1%.

Chart 2: Overview of the respondent countries.

RESPONDENTS BY COUNTRY

	BE	Other	UK	DE	ES	NL	FR	SE	IT	IE	PL	DK	FI	HU	SI	AT	BG	PT	HR	CY	EL
No of replies	43	25	20	19	15	8	7	7	6	5	4	3	3	3	3	2	2	2	1	1	1
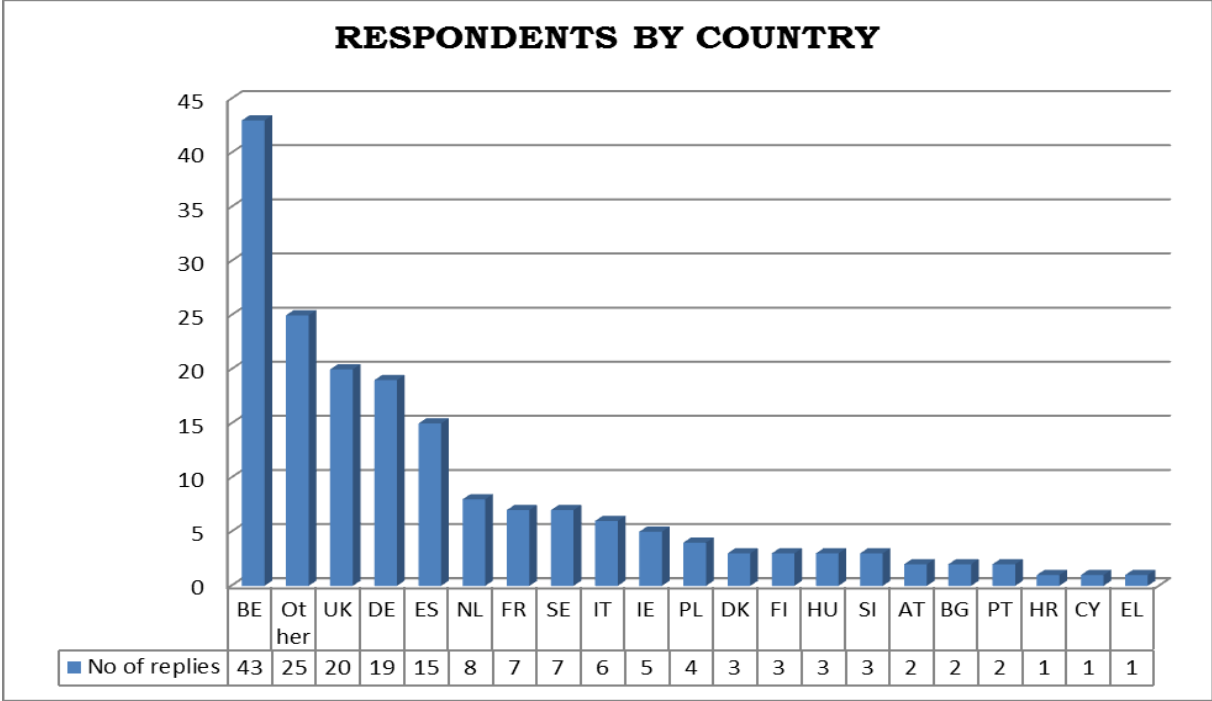
With regard to countries who replied to the questionnaire, as we can see in the column chart, Belgium provided most contributions, followed by Germany, United Kingdom and Spain. It could also be noticed that there is a high percentage of replies coming from the group classified as "other" that include either European or international organizations.

It is also important to underline that no correspondents indicated they did not wish to have the replies posted online. Accordingly, all contributions have been posted, together with this report, on the health section of the European Commission's *Europa* website:

http://ec.europa.eu/health/patient_safety/consultations/patient_safety_quality_care_cons2013_en.htm

Moreover, 10 off-line replies are also available on the website mentioned above.

3.2 Analysis of the replies to the different sections of the questionnaire

Implementation of the Council Recommendation 2009/C 151/01

3.2.1 PATIENT SAFETY AS AN ISSUE IN EU COUNTRIES

As it can be noticed in the chart below, when asked whether patient safety is an issue in their countries, the large majority of respondents (91%) indicated that yes it was, while only few respondents answered no (4%) or did not know (5%).

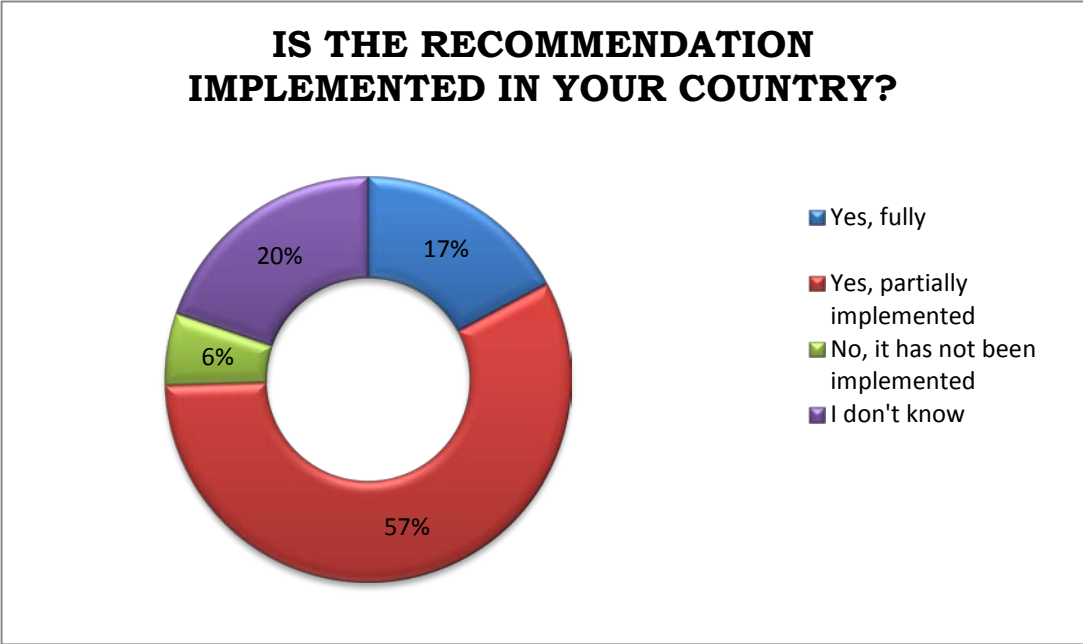Chart 3: Patient safety as an issue.
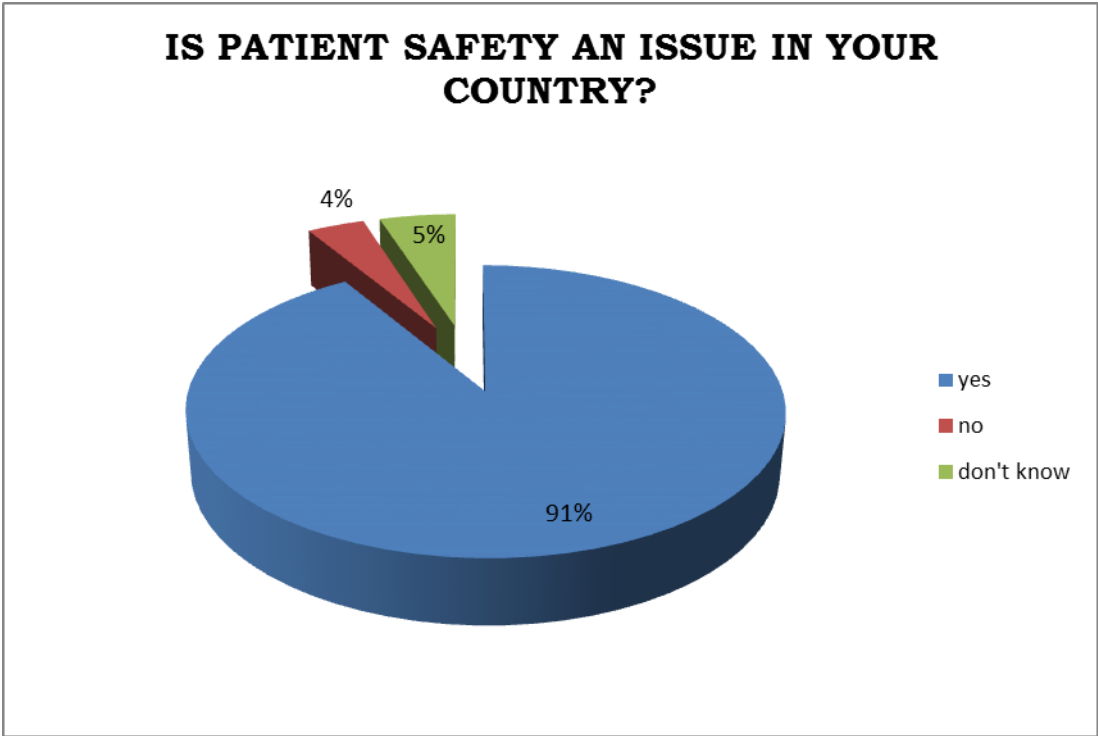
It is interesting to notice that, among those respondents who did not consider patient safety as an issue, the majority were individual citizens.

3.2.2 RECOMMENDATION IMPLEMENTATION LEVEL

When asked whether the Recommendation was implemented in their countries, the vast majority of contributors (74%) gave a positive answer, but it is important to underline that only 17% referred to a full implementation, while the remaining part (57%) only referred to a partial implementation (Chart 4). In this context, the largest group who thought that the recommendation was implemented, either fully or partially was the one of health professional organizations, followed by hospitals.

Chart 4: Recommendation implementation level.

IS THE RECOMMENDATION IMPLEMENTED IN YOUR COUNTRY?

- Yes, fully
- Yes, partially implemented
- No, it has not been implemented
- I don't know

17%
57%
6%
20%

3.2.3 CONTRIBUTION TO PATIENT SAFETY IMPROVEMENT

If respondents stated that the Recommendation was fully or partially implemented, they were asked to state if in their opinion it contributed to improve patient safety in their country. On one hand the result was quite encouraging because more than a half of respondents (65%) said yes, but on the other hand only the 26% of them answered "yes definitely", while the 39% said "yes, but to certain extent".

Chart 5: Did the Recommendation implementation contribute to improve PS in your country?

DID THE RECOMMENDATION IMPLEMENTATION CONTRIBUTE TO IMPROVE PATIENT SAFETY?

- Yes, definitely
- Yes, to certain extent
- No
- No opinion

26%
39%
3%
32%
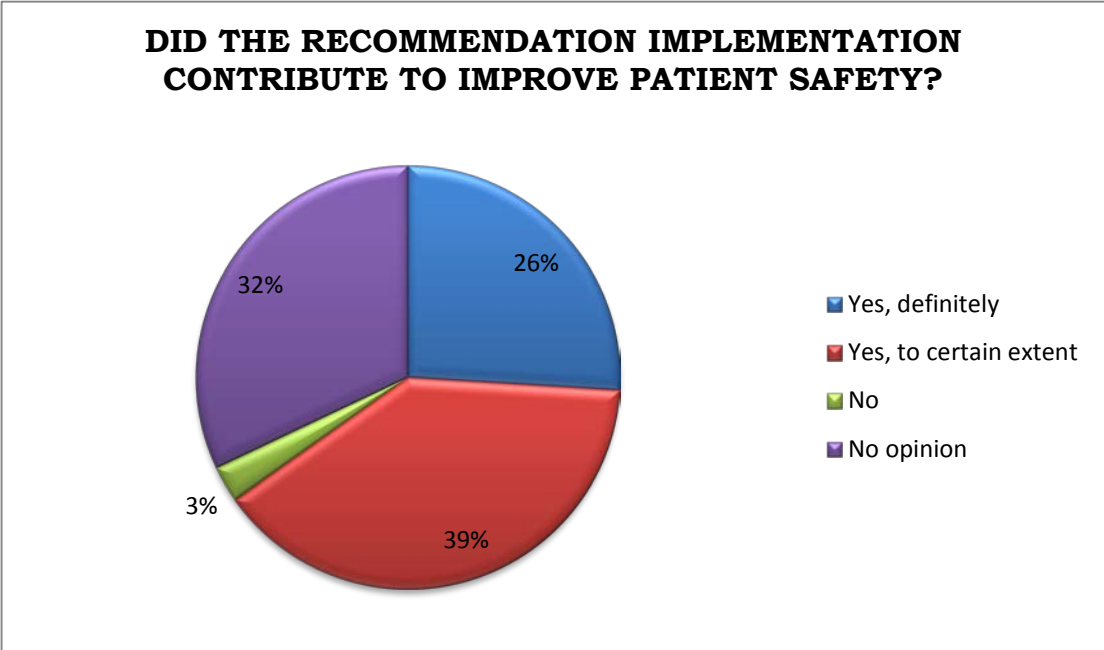
It can also be noticed that mostly health professional organizations and hospitals replied "yes, definitely" or "yes, to certain extent".

Moreover, the participants who thought that the Recommendation did not contribute to improve patient safety were asked to explain the reasons for that. The main ones seem to be:

❖ **Lack of** clear and comprehensible **communication** from the European Commission to citizens on vision and mission *«with a very complicated and publically not-visual organisational structure of projects»*;

❖ A **missing linkage with other regulations** (e.g. hygiene and infection prevention law) and **regulations** *«which are dispersed and fully known only by few experts»*;

❖ **Lack of a governmental organisation** being identified as epicentre for coordinated patient safety actions;

❖ The fact that **MS** already **have their own safety programmes** which cover the content of the Recommendation or that can be even more complete *«national programmes have put safety issues on the agenda in the Netherlands before the Recommendation»*;

❖ Lack of an **efficient monitoring and evaluation system**;

❖ The concept of patient safety cannot be limited to a set of procedures or guidelines addressing only certain aspects of healthcare obstacles. There is an evident **need for a multi-disciplinary approach** that tackles problems during every step of the patient healthcare pathway.

To sum up, the chart below reviews the main reasons why, according to respondents, the Recommendation did not help to improve patient safety:

Chart 6: Why the Recommendation did not contribute to improve Patient Safety.
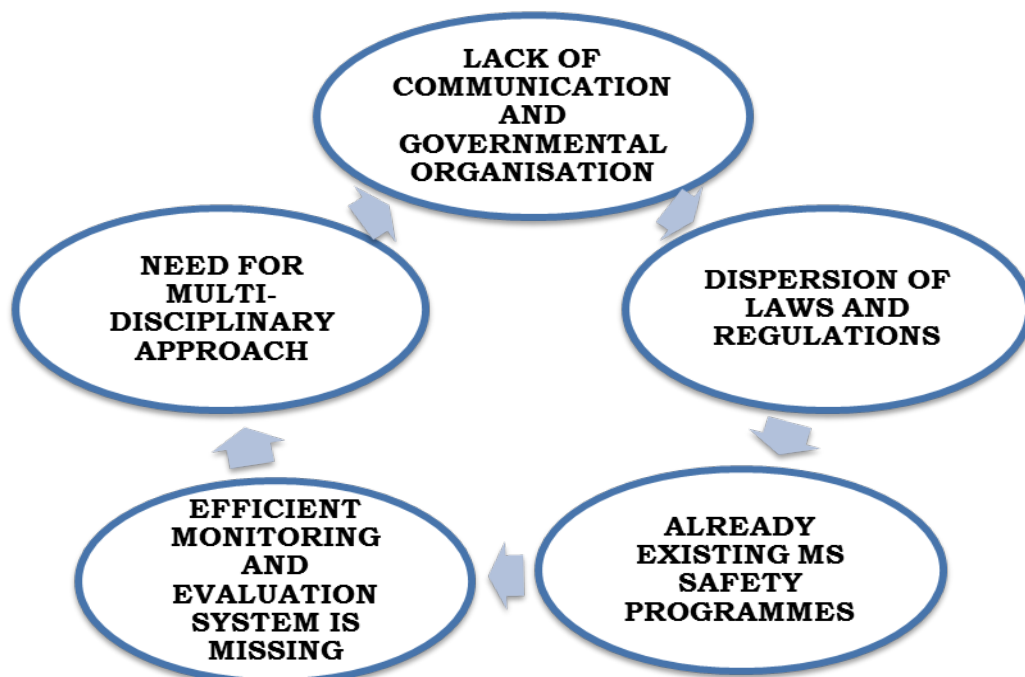
3.2.3 NECESSARY CHANGES HELPING THE IMPLEMENTATION

Where the respondents thought the Recommendation was fully or partially implemented, then an open question asked them about the necessary changes to be introduced in order to implement the Recommendation.

Respondents from different countries mentioned similar ways of introducing the necessary changes even if the Recommendation implementation is not homogeneous in all MS.

Firstly, concerning the legislative context, contributors mentioned the **adoption of laws, decrees, action plans and programmes** to enforce quality in healthcare, improve outcomes and enhance patient safety. Some examples include *patient safety strategies*, *programmes for optimizing the use of antimicrobials, «national multiannual programmes* on quality and patient safety by means of annual contracts with financial aid for participating hospitals».

Secondly, national **guidelines and indicators** for the prevention of healthcare-associated infections (e.g. Emergency Care Summaries) were indicated as crucial elements for change. An added value was also found in **voluntary reporting systems on adverse events** and in the reinforcement of the **services of preventive medicine and public health.**

Some respondents also talked about "mandatory" measures on one hand, and "softer" approaches on the other one. The first range would include meeting **quality indicators** and **reporting adverse events** and have **security committees** in inpatient healthcare centres, while the second one concerns **awareness raising, campaigning, and spreading good practice** (e.g. flu vaccination, hand hygiene, encouraging staff and patient feedback).

Lots of respondents also underlined the crucial role of the **programmes in collaboration with local communities and regional authorities** *«respecting and complementing the actions that each one of them develops in the exercise of their powers».* Some examples include information campaigns, meetings, scientific societies, clinical guidelines and the incorporation of ICTs protocols.

In addition, it is relevant to notice that respondents put the focus also on the impact that *public relations*, *media coverage* and *networking* have *«helped by Ministry of Health and health institutes webpages, together with the participation of NGOs, public health organizations, professional organizations, regulatory bodies, users of services, healthcare organizations/providers, patients' organizations and healthcare authorities».*

Chart 7: Changes helping the Recommendation implementation

3.2.4 HELPFUL TOOLS FOR A BETTER IMPLEMENTATION

With regard to the tools that could help in case of partial or absent implementation of the Recommendation, respondents were given five different options and a multiple choice between them was also possible. The proposed tools were:

- National binding legislation
- EU co-operation on patient safety
- Involvement of patient organisations
- Involvement of health professionals
- Others
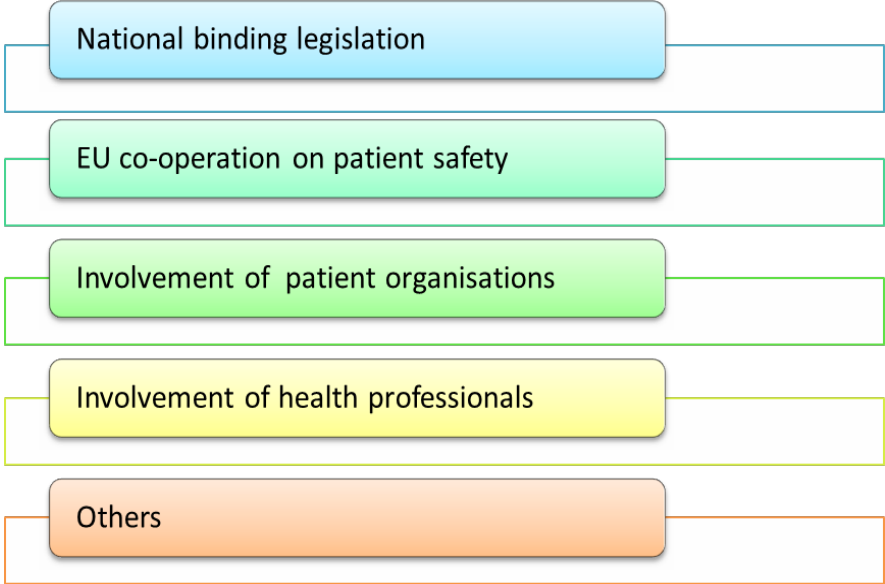
The chart below clearly illustrates the importance that each one was given by respondents.

Chart 8: Tools for a better Recommendation implementation.
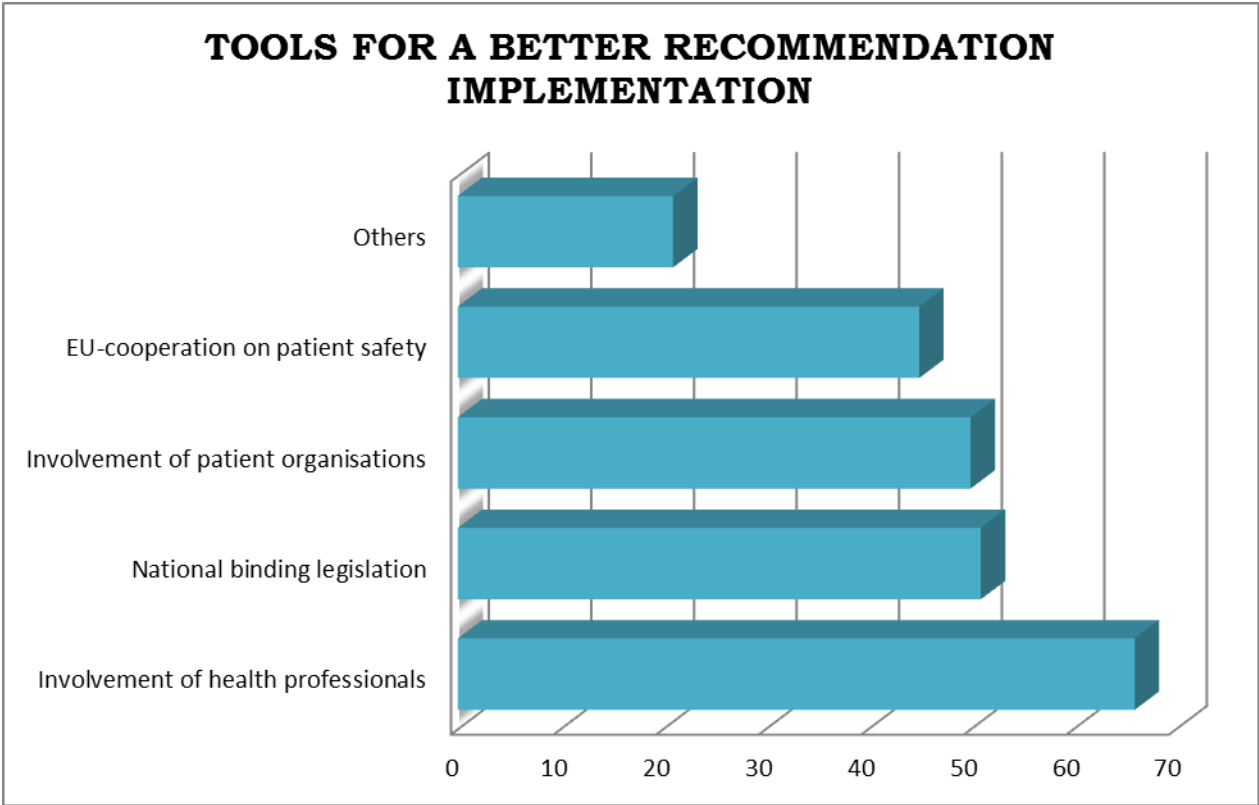
As already stated, a multiple choice was possible and the vast majority of contributors chose a combination of the five tools proposed by the Commission. What should be underlined is that the combination that received more preferences is national binding legislation, EU co-operation on patient safety, involvement of patient organisations and involvement of health professionals (18%). This was followed by the one that put together both involvement of patient organisations, health professionals and national binding legislation (11%). It is interesting to see how nobody pointed to EU co-operation only and just 2 respondents chose only national binding legislation only. Therefore, we can highlight one more time the strong need of real cooperation between EU and national legislations perceived by the civil society.

Focusing on the groups of respondents some remarks can be made. Firstly, it can be noticed that on one hand 22 out of 66 respondents belonging to health professional organisation group thought the EU-cooperation on patient safety is a tool for a better implementation of the Recommendation. On the other hand, none of the individual citizens thought the same. Concerning the second tool proposed by the questionnaire "Involvement of patient organisation", this was of course chosen by the majority of the patient or consumer organisations, but also by 17 out of 66 health professional organisations and 7 out of 23 hospitals. Moreover, National binding legislation was pointed out by 17 out of 66 health professional organisations, 5 out of 12 individual citizens and 4 out of 13 health authorities. Finally, the last tool proposed which was "Involvement of health professionals" was mostly chosen by health professional organisations (28 out of 56), individual citizens (5 out of 12) and hospitals (7 out of 23).

An open question also asked respondents who chose "others" to be more specific and indicate what they meant by "other tools". Many ideas were given and all of them agreed that the starting point is recognizing patient safety as a priority for both EU and MS and that a real "patient safety culture" is needed.

In order to reach these results there are, according to respondents, different tools that if effectively implemented can lead to better results. Some examples are:

- ❖ **Multifaceted and multi-disciplinary change in management strategies**, establishing national multidisciplinary PS societies that gather different profiles of healthcare professionals, patients and other stakeholder representatives. «*In order to improve patient safety, particularly in wound care, multidisciplinary teams are essential*».

- ❖ **To liaise with all services providers** (independent and community midwives);

- ❖ **Initiatives of various professional groups to identify incidents and improve practice** «*Employees of healthcare settings can be exposed to pathogens and become patients themselves. Family members of patients and homecare workers must understand risks infections and be aware of how to appropriately use medical technology to avoid contamination*»;

- ❖ **An epidemiological by monitoring automated systems** «*using computer systems integrating clinical, microbiological and epidemiological information*»;

- ❖ **Uniform national guidelines** (e.g. on the use of antibiotics or for clinical practice);

- ❖ **Standardization of healthcare services** for the promotion of best practices, efficiency and quality in relation to goods and services. One of the biggest benefits

is their identical implementation across Europe and the obligation of National Standardization Bodies to withdraw any existing conflicting national standards;

❖ **Insurance industry inclusion** in the discussion forum;

❖ **More engagement of politicians** and **CEOs of healthcare organisations**, **media** at European, national and local level, **universities** and **training institutions**;

❖ **An EU Directive which would legally impose minimum standards on patient safety** (e.g. on infection prevention) **to improve patient safety in every MS and to facilitate cross-border health care.** «*It should include common terminology, mechanisms to encourage innovation, the provision of appropriate patient safety standards and a focus on the occupational safety of healthcare workers*»;

❖ **Involvement of patients, consumer organisations, education provision stakeholder community, software, packaging and pharmaceutical industries** in the discussion and decision making process concerning patient safety. «Having the subject of the Recommendation constantly on the political agenda is most likely to trigger activities in this respect».

❖ **Patient empowerment** building patients trust and confidence by giving them sufficient information to allow them to take responsibilities;

❖ **Training of healthcare professionals on the appropriate use and disinfection of medical technology** to avoid the spread of infections;

❖ **Service accreditation and clinical audit** to improve quality of healthcare;

❖ **Mandatory reporting with harmonized reporting systems across the EU and harmonized metrics and indicators**;

❖ **National early warning score** «*a national system for recognising very sick patients whose condition is deteriorating and who need more intensive medical or nursing care*»;

❖ **Development of homecare services.**

In addition, a coordinated approach by all stakeholders is necessary because patient safety cannot be a priority if only addressed by health institutions/professionals, patients or other specific stakeholders.

Last but not least, more research and reports on the cost-effectiveness of health technologies used to improve patient safety is needed in order to make everybody more conscious and convinced that patient safety is not only an obligation but also an opportunity.

3.2.5 BARRIERS TO THE RECOMMENDATION IMPLEMENTATION

The barriers to implement patient safety Recommendation across EU countries are varied and multi-factored. However, respondents provided many inspiring contributions.

It was firstly found that the **economic crisis**, the consequent **reduction of resources** and the **cost-saving approaches** represent important barriers. They are blamed to «*have slowed down the integration of patient safety into education and training of health professionals and the strengthening of information campaigns addressed to health*». In fact, with the policy austerity the patient safety issue has not been prioritized enough, due to the financial matters predominating in the political agendas.

Most often there is also a **conflict of priorities** between financial and patient-orientated goals (on all levels from micro to macro level of the health care system). In this context several respondents thought that there is a **lack of political will** «*which often reflects lack of good leadership*» and also healthcare professionals' engagement. We could also talk about an organizational culture that is reluctant to change and that leads to **attitudinal barriers**.

Additionally, the **cultural handling** with regard to mistakes represents a barrier: «*usually we ask "who did that?" instead of asking what happened, why did it happen and what could we have done to prevent this to happen*». According to most respondents a **"blame free" culture** should be more advocated. Last but not least a barrier that concerns "culture" has to do with **reporting**, as it is still not understood as a learning facilitator and health promoter.

In addition, a barrier is represented in many cases by the **top-down attitudes** by clinicians particularly regarding patient involvement and awareness. Patients' will and proposals are still not having the support and consideration that they deserve. It was also underlined how hospital managers and decision makers often struggle to appropriately prioritize the roll out of patient safety measures, despite their long term positive economic impact.

On the other hand, it was found that policymakers have **not** achieved **high levels of awareness** in hospitals **of the importance of patient safety**. «*There is also a lack of design, measurement and monitoring in education and training which make really difficult to improve and sustain patient safety*». This leads to another barrier related to coordination which is the **fragmentation of provisions and organization** that makes really hard to bring patient safety improvements into practice.

Finally, **technologies** can also be barriers when IT infrastructures to support data analysis are not or not sufficiently provided. This also makes more difficult to achieve **transparency** and **accountability of national health care services**.

To sum up, the diagram below reviews the main groups of barriers to the Recommendation implementation identified by respondents:

Chart 9: Barriers to the Recommendation implementation.
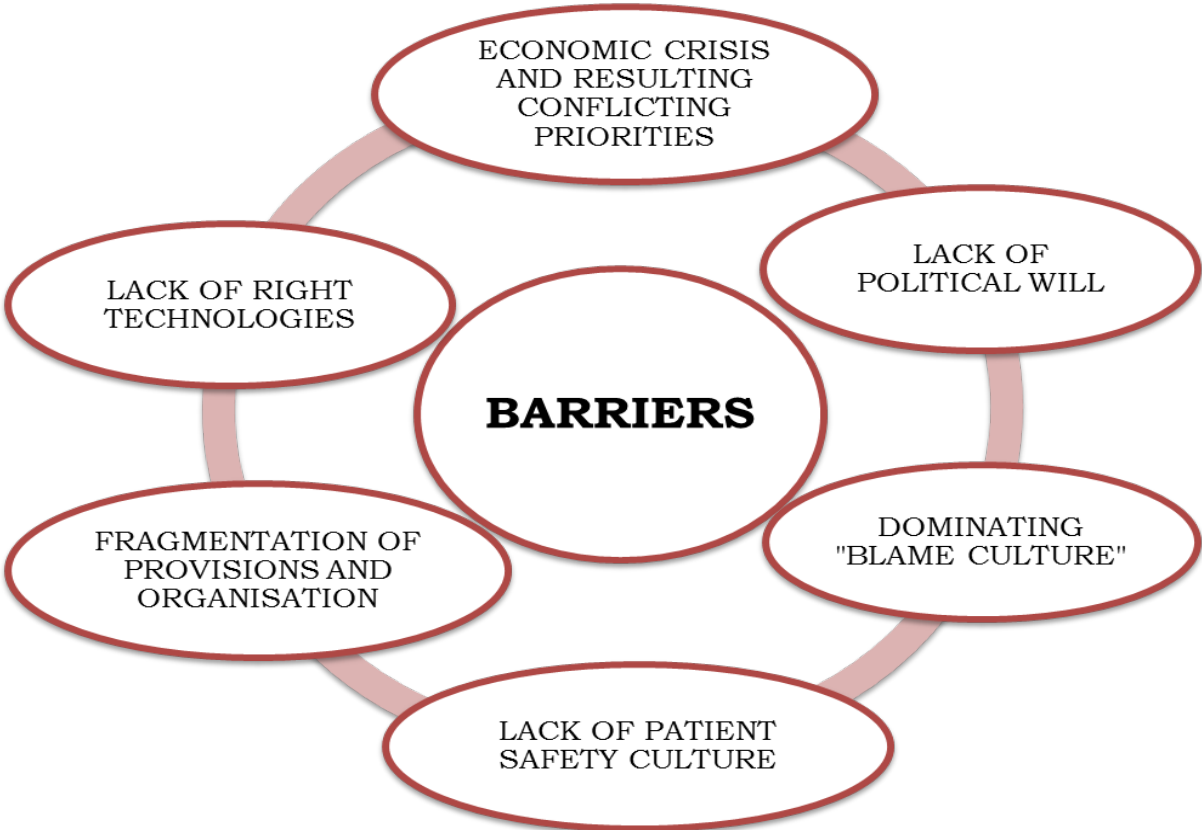
## 3.2.6 PARTICULARLY RELEVANT PROVISIONS OF THE RECOMMENDATION

Respondents were asked to give a judgement choosing between "very relevant"/"relevant/"not particularly relevant"/"not relevant at all" to the five provisions of the Recommendation showed in the table below (for full text please refer to the Recommendation on patient safety

http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf).

Chart 10[3]: Relevant provisions of the Recommendation.
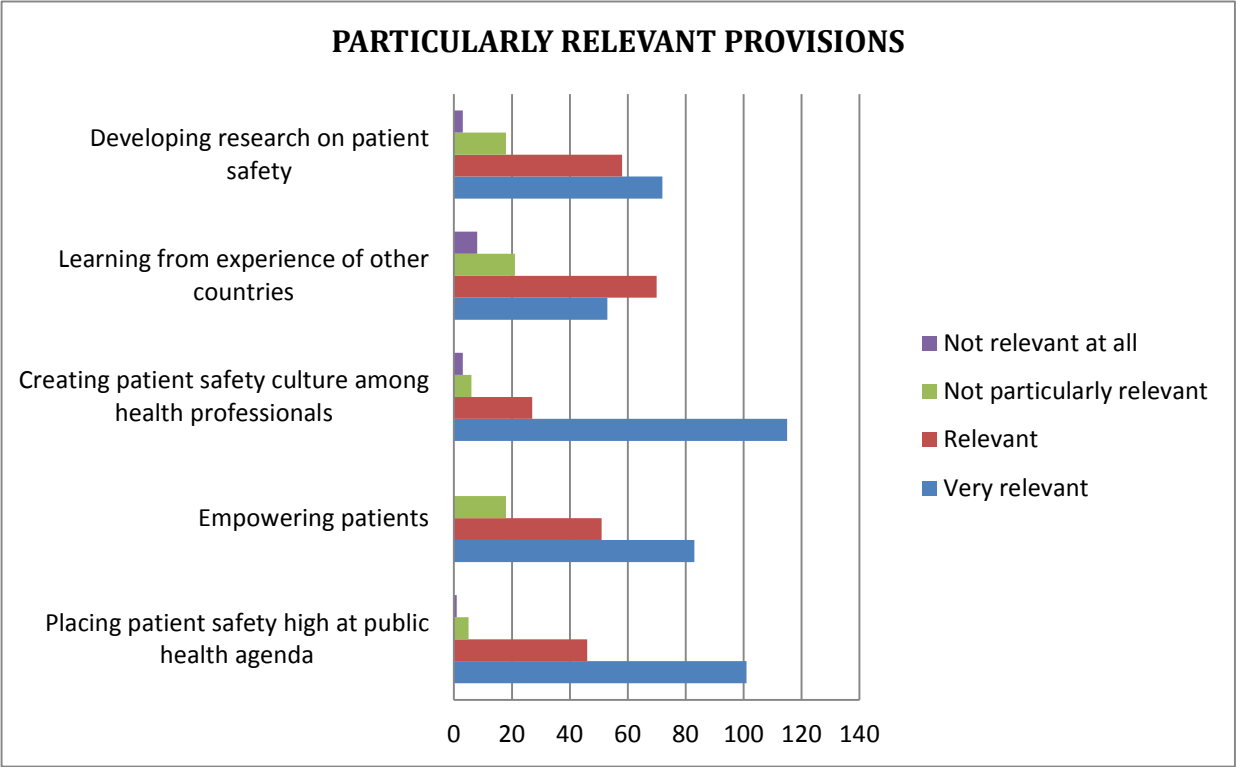
The chart shows that all provisions were considered very relevant by the majority of respondents, above all "creating patient safety culture among health professionals" and "placing patient safety high at public health agenda". It is interesting to notice how most contributors thought that learning from experience of other countries is more a "relevant" than "very relevant" provision. Last but not least, it is an encouraging and positive result that only few respondents answered that the provisions were "not relevant at all" or "not particularly relevant".

Looking at the opinions of the group of respondents about the provisions proposed by the questionnaire, we can make some more interesting comments:

- **"Developing research on patient safety"** was indicated as very relevant mostly by academia, hospitals, health professional organisations, industries, NGO's and patient or consumer organisations;

- **"Learning from experience of other countries"** was found to be very relevant by the majority of academia, health Authorities, health professional organisations, individual citizens and patient or consumer organisations and relevant mostly by hospitals and NGO's. However, we should also notice that 12% of health professional organisations, 16% of individual citizens and 21% of health authorities found this provision not particularly relevant.

- **"Creating patient safety culture among health professional"** was pointed out as very relevant by health professional organisations, health Authorities, hospitals, academia, industries, NGO's and patient or consumer organisations. However, it is

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[3] The calculation is based on 153 received replies.

interesting to underline the fact that 17% of hospitals thought that this was a not particularly relevant provision;

- **"Empowering patients"** was indicated as very relevant by hospitals, patient or consumer organisations and NGO's, while academia, health professional organisations, individual citizens and Industries mostly thought it was relevant. On the other hand it is to be noticed that 18% of health professional organisations, 17% of hospitals and 16% of individual citizens thought that this provision was not particularly relevant;

- **"Placing patient safety high at the public health agenda"** was mostly found very relevant by health professional organisations, health authorities, academia, industries, NGO's and individual citizens.

3.2.7 IMPORTANT AREAS OF PATIENT SAFETY NOT COVERED BY THE RECOMMENDATION

The Council Recommendation covers already key pillars of patient safety, but according to respondents, there is still a need to address more issues in different crucial areas to improve patient safety.

Firstly, many contributors thought that the Recommendation largely evades **transparent** and **comparable public reporting and data** (e.g. about negative results in clinical trials, accountability of health care services and explicit reference and inclusion of anti-microbial resistance). In this context there is a need of **specific attention on control** (e.g. traceability of medical devices or data protection) and **redress mechanisms** (e.g. about compensation for victims of adverse events) as they play a fundamental role as deterrents against bad practises in patient safety. *«There should be gratification for good compliance and sanctions for low compliance».*

Secondly, it was found that **IT technological innovation** should be *«a major driver of better outcomes in itself».* Many contributors also thought that **eHealth and mHealth** are still not sufficiently used for patient safety. Besides, further action should be taken in order to protect data used in the framework of eHealth. *«Electronic means facilitate the transmission of data relating to the health of a patient among healthcare professionals in order to achieve a high quality healthcare».* Unambiguous data protection rules should be applied to protect data used in the framework of eHealth.

Certainly, there is also an imperative **need of financial programs** enhancing safety in low incomes EU Member states for an equal access to modern care. **More financial resources** should also be used **on prevention** of healthcare associated infections, drug related adverse events, pressure ulcers, nutritional status and missed diagnosis.

Moreover, quality needs to be considered as crucial and respondents highlighted the lack of certified quality management systems, of requirements for healthcare organisations to obtain **international accreditation of** their **quality mechanisms**. Contributors believe these mechanisms would be useful to create a "learning and continuously improving service" to increase safety and reduce avoidable harm.

Also a real health literacy and universal application of collaborative care principles would contribute to a better quality of patient safety. In addition, another area which requires **more involvement is education and training for healthcare workers, students and**

carers that should include many more measures, for example to address the issue of health profession role development and to implement a supporting **psychological supervision** system for concerned healthcare-professionals. Health systems cannot deliver high quality care without a well-trained health workforce. *«The provision of good quality healthcare relies on a skilled and highly motivated workforce».*

If on one hand respondents were concerned about healthcare professionals, on the other hand they underlined the need for **medication review, reconciliation, reduction of poly-pharmacy** and **empowerment of patients** *«by methods such as patient counselling upon receipt of their dispensed prescriptions».*

It is also essential to take more into consideration patient safety in **mental health care**. Last but not least, attention should be also put on improving patient safety in **primary care**, **wound care, nutrition and hydration** and growing practices such as **euthanasia**.

To sum up, respondents found many areas and specific topics that the Recommendation fails to address or only partially does in order to create valid and reliable methods to assess and improve the **patient safety culture**.

Chart 11: Areas of patient safety not covered by the Recommendation.

18
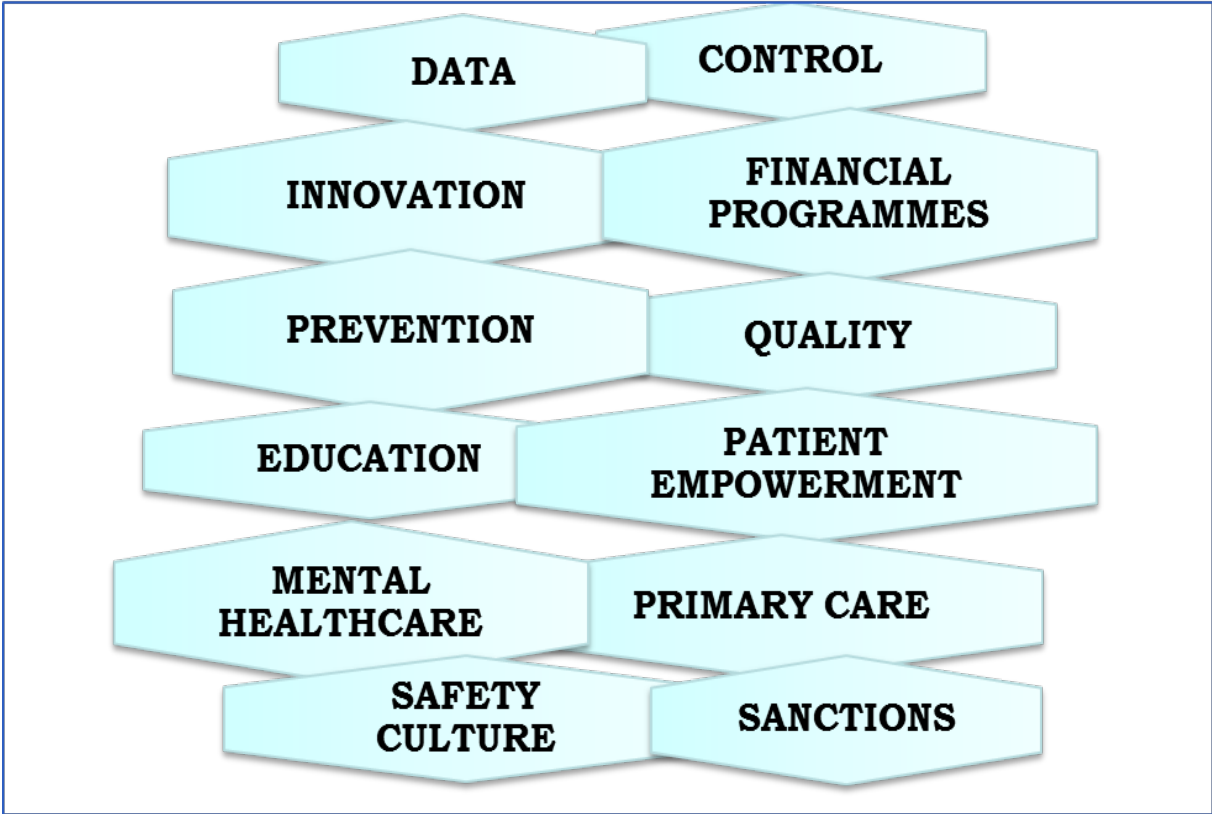
Future EU action on patient safety and quality of healthcare

3.2.8 NEXT EU ACTIONS/INITIATIVES ON PATIENT SAFETY BEYOND THE EXISTING RECOMMENDATION

The European Commission has supported since 2005 co-operation of EU Member States and stakeholders on patient safety and quality of care, by organising and co-funding different forms of information exchange and practical mutual learning. Most of the recent activities (e.g. Working Group of Patient Safety and Quality of Care, EU Network on Patient Safety and Quality of Care, research projects) supported the implementation of the Council Recommendation 2009. To help a reflection on what next should the EU do on patient safety beyond the provisions of the existing Recommendation, respondents were asked to identify areas where EU action could bring added value.

In this context, respondents identified the following areas to be further strengthened:

- supporting **cooperation** (e.g. between professionals, patients and authorities), **best practices exchange** and **mutual learning** as crucial elements to be used more and more efficiently;

- improving patient safety in **non-hospital care**. EU future initiatives should recognise informal care as a form of care at an equal level with institutionalized ones: they should be complementary;

- addressing issues concerning **healthcare workforce** (e.g. **doctor** and **nurse/patient ratio**) and ensuring **education and training** not only for them, but also for patients, families and **informal carers**, taking into account **younger carers needs**. A greater number of doctors trained and deployed to deliver internal medicine, specialist medical teams working across the hospital and the community and focus on early consultant review are also key factors to be considered.

- encouraging use of **new IT technologies** for the benefit of patient safety (e.g. computerised prescription order entry, bedside scanning of medicines at the point of administration and electronic health records). *«Technology is also related to data protection»*. Some respondents underlined how, in the respect of Art. 168 TFUE, an EU standard of information technology for both patients' and healthcare workers' information taking data protection into account is required.

- supporting the development of harmonized EU wide and more **prevention** of healthcare associated infections, comprehensive assessment **guidelines** on patient safety standards complemented by **checklists and indicators** to be used across the countries. *«Working on safety assessment guidelines should also support the exchange of knowledge and focus on bringing about real organisational change at local level»*.

- addressing and overcoming **inequalities in terms of discrimination and stigmas in access** (especially amongst particularly vulnerable groups) to good quality health services. Also, ensuring equal possibilities of redress and compensation for errors in medicine for all EU citizens;

- not limiting patient safety to the safety of medical treatments. A focus on **cases of need** *«which broadens the understanding of safety with accessibility to services and the general organisation of healthcare (waiting list, payment of services or drug)»*, on

all phases of patient care pathways (preventive care, treatment and rehabilitation) is required.

3.2.9 ADDED VALUE IN ENLARGING EU WORK FROM PATIENT SAFETY ONLY TO WIDER QUALITY OF CARE

When asked whether there is or not an added value in enlarging EU work from patient safety only to wider quality of care, the vast majority of them (72%) said yes, the 11% thought that no, while it is interesting to notice how the 17% had no opinion about the topic. It is interesting to highlight that the majority of all groups of respondents answered "yes". More specifically, all academia and industries gave an affirmative answer, while 27% of patient or consumer organisations, 25% of NGO's, 21% of health authorities said "no" and 17% of hospitals and 16% of individual citizens had no opinion about the topic.

Chart 12: Added value in enlarging EU work from patient safety only to wider quality of care.
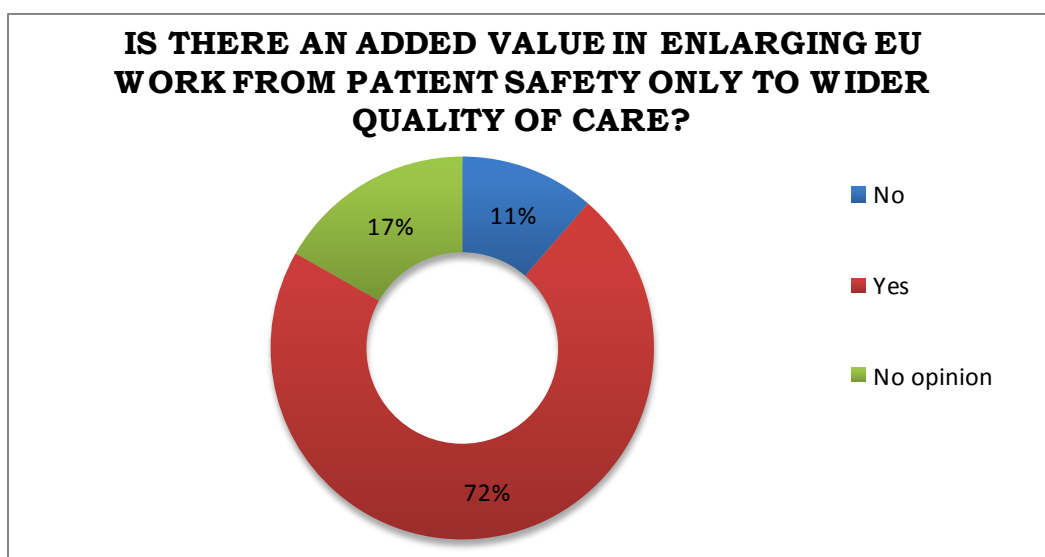
Respondents saw patient safety as a core aspect and a result of quality of care. When talking about quality they referred to a health that needs to be safe, effective, respecting patients' needs and dignity.

The concrete proposed actions at EU level include:

- developing a **common definition of quality of care**, always taking into account the differences between the healthcare systems in the MS. However, «*care must be taken not to decrease the importance of patient safety by including it in a bigger and broader project*»;

- developing an **EU strategy on health-related information to patients**, considering capturing patient experience and social care as elements of quality improvement systems. In this context, «*when it comes to long term care, informal carers, such as family, are a strong component that should not be ignored*»;

- focusing on a **"multidisciplinary approach" between physical and mental health** (key for high quality wound care for example);

- setting up a **permanent European forum** to promote and share best-practises in patient safety and quality of care based on the PaSQ joint action but with enlarged mandate, e.g. work on a system of quality standards in healthcare organisations, issuing guidelines, setting targets and benchmarking;

- taking into consideration the **impact of shortage of workforce and working conditions** on quality of care and encouraging better coordination of care;

- considering **patient safety and quality of care** in the context of financial-economic recovery and «*good health care as an investment instead of a financial burden*». This is also considering the fact that the developments in improved patient safety will serve the agenda to drive up quality care well.

Many respondents said the proposed solutions would also benefit implementation of Directive 2011/24/EU[4].

Some respondents also mentioned other dimensions, such as timeliness, efficiency and equity in access to healthcare and cost-effectiveness. However, these relate to quality of health systems.

Regarding respondents whose answer to the question was "no", some of them justified it with the concern that «*enlarging EU's action towards quality of care would establish quantitative and qualitative comparisons between national healthcare systems eluding their inner differences and the issue they face in the overall context of financial constraints through a "blame and shame" system*» which could considerably hamper the overall efficiency of the EU's action. Another argument against the enlargement was that «*EU should not expand its effort but concentrate its resources on the issue of patient safety in order to make an effective contribution*», avoiding the risk of losing focus and priorities. Finally, some respondents considered that the difficulties in the implementation of the Recommendation are different in MS. An extension could mean an increase of the difficulties of the Recommendation implementation and the fulfilment of the established measures.

At last, respondents who had no opinion about the question asked explained it by either saying that they had no sufficient information or knowledge about it or blaming the lack of clarity and comprehension of the question.

3.2.10 ADDITIONAL CONTRIBUTIONS

The last question of the questionnaire was an open one allowing respondents to make the last remarks, comments and evaluations to give some more contributions and added value to the public consultation.

The majority of contributors remarked one more time how the **lack of adequate financial resources** and the **economic and social impact of the crisis** we are going through are the major drawbacks for patient safety. Moreover, inequalities in access to care should be taken into account when talking about quality, especially the most vulnerable groups are concerned. So, **involvement and empowerment of patients**, especially vulnerable ones, are vital elements of high quality healthcare. However, some respondents also underlined that even if healthcare costs must be within some limits, the discussion around this aspect and «*the*

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[4] 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.

solutions must remain in respect to life» trying to **fight discriminations, stigmas and inequalities** in access to healthcare and treatment. *«The safety of patients is at acute risk from a variety of repressive policies and painful inequalities in access to services».*

In addition, the vast majority of contributors advocated for a more constant support to **joint research, cooperation, exchange of knowledge and good practice as** *«they will stimulate and sustain improvements, driving the development of patient safety and quality of care continuously forward».* However, all this is found to remain too superficial. More concrete action should be seen in practice. To give a concrete example, it is crucial, according to most respondents, that all graduates have the competences to treat patients safely. In order to do this **the competences must be agreed, disseminated, implemented, assessed and monitored**. *«Each MS should ensure it has an educated and qualified workforce to deliver the highest standard of quality of care and safety for the patients».* In this context, it is important to have a mutual recognition of professional qualifications that should be based on content and range of competencies that medical education develops and not on length of training.

Another remarkable point made by several respondents concerns the **need of a real "culture of safety in healthcare systems"** as a fundamental tool to insure high-quality patient care. The emphasis should not be on blame culture but it should be amended to a learning culture. Unfortunately, it was underlined by respondents that *«a blame culture persists where the healthcare workforce is afraid to speak up and incidents go unreported».*

A **permanent exchange network for patient safety and quality of care among MS** resulted to have a pivotal role to improve performance and sustainability of care quality. This care quality should also be thought *«as highly correlated with work satisfaction, working conditions and well-being of health care workforce».*

Moreover, lots of contributions were concerned about **control, surveillance, monitoring and prevention of healthcare associated infections**. These four key factors should be more homogeneous across Europe. *«Published evidence-based guidelines (e.g. on practical Infection Prevention and Control measures) should have mandatory character and patients should be better informed and involved in public campaigns».* These elements together with the use of **innovative technologies** are crucial to **reduce avoidable adverse events**.

Respondents also would like to see **medication safety, drug use** and **patient safety methods for dental care** assume a central place in the development of EU Health Policy.

Finally, some contributors found that as long as there are very significantly differences in health systems in the MS it is not possible for the EU to finance projects with direct impact on patients. Current projects co-financed by EU on patient safety mainly target the policy level, while their impact at on healthcare setting level is not always effective.

Last but not least, lots contributors thought that most of the EU patient safety work does not reach beyond the expert level people involved in the activities. Wider dissemination of the work is therefore encouraged as valuable knowledge and contributors never reach the environments that work to enhance patient safety.

I

(Risoluzioni, raccomandazioni e pareri)

RACCOMANDAZIONI

CONSIGLIO

RACCOMANDAZIONE DEL CONSIGLIO

del 9 giugno 2009

sulla sicurezza dei pazienti, comprese la prevenzione e il controllo delle infezioni associate all'assistenza sanitaria

(2009/C 151/01)

IL CONSIGLIO DELL'UNIONE EUROPEA,

visto il trattato che istituisce la Comunità europea, in particolare l'articolo 152, paragrafo 4, secondo comma,

vista la proposta della Commissione,

visto il parere del Parlamento europeo (¹),

visto il parere del Comitato economico e sociale europeo (²),

visto il parere del Comitato delle regioni (³),

considerando quanto segue:

(1) L'articolo 152 del trattato prevede che l'azione della Comunità, che completa le politiche nazionali, si indirizza al miglioramento della sanità pubblica, alla prevenzione delle malattie e affezioni e all'eliminazione delle fonti di pericolo per la salute umana.

(2) Si stima che negli Stati membri una quota compresa tra l'8 % e il 12 % dei pazienti ricoverati presso ospedali soffrono di eventi sfavorevoli mentre ricevono assistenza sanitaria (⁴).

(3) Il Centro europeo per la prevenzione e il controllo delle malattie (ECDC) ha stimato che le infezioni associate all'assistenza sanitaria colpiscono in media un paziente ricoverato su venti, ossia 4,1 milioni di pazienti all'anno nell'UE, e che 37 000 decessi sono provocati ogni anno da siffatte infezioni.

(4) La scarsa sicurezza dei pazienti rappresenta un grave problema per la sanità pubblica ed un elevato onere economico per le scarse risorse sanitarie disponibili. Gli eventi sfavorevoli, sia nel settore ospedaliero che in quello delle cure primarie, sono in larga misura prevenibili e la maggior parte di essi sono riconducibili a fattori sistemici.

(5) La presente raccomandazione si basa, integrandolo, sul lavoro in materia di sicurezza dei pazienti svolto dall'Organizzazione mondiale della sanità (OMS) attraverso la sua Alleanza mondiale per la sicurezza dei pazienti, dal Consiglio d'Europa e dall'Organizzazione per la cooperazione e lo sviluppo economico (OCSE).

(6) La Comunità, tramite il settimo programma quadro di ricerca e sviluppo (⁵), sostiene la ricerca nei sistemi sanitari, segnatamente in relazione alla qualità dell'assistenza sanitaria nell'ambito del tema «Salute», ponendo in particolare l'accento sulla sicurezza dei pazienti. Quest'ultima riceve particolare attenzione anche nell'ambito del tema «Tecnologie dell'informazione e della comunicazione».

(7) La Commissione, nel suo libro bianco «Un impegno comune per la salute: approccio strategico dell'UE per il periodo 2008-2013» del 23 ottobre 2007, inserisce la sicurezza dei pazienti tra i settori d'azione.

(¹) Parere del 23 aprile 2009 (non ancora pubblicato nella Gazzetta ufficiale).
(²) Parere del 25 marzo 2009 (non ancora pubblicato nella Gazzetta ufficiale).
(³) Parere del 22 aprile 2009 (non ancora pubblicato nella Gazzetta ufficiale).
(⁴) Relazione tecnica «Improving Patient Safety in the EU» (Migliorare la sicurezza dei pazienti nell'UE), elaborata per la Commissione europea, pubblicata nel 2008 dalla RAND Corporation.

(⁵) Decisione n. 1982/2006/CE del Parlamento europeo e del Consiglio, del 18 dicembre 2006, concernente il settimo programma quadro della Comunità europea per le attività di ricerca, sviluppo tecnologico e dimostrazione (2007-2013) (GU L 412 del 30.12.2006, pag. 1).

(8) Secondo i dati disponibili emerge che gli Stati membri si collocano su livelli diversi per quanto riguarda lo sviluppo e l'attuazione di strategie efficaci e globali in materia di sicurezza dei pazienti (¹). La presente raccomandazione mira quindi a creare un quadro volto a stimolare l'elaborazione di politiche e azioni future, sia negli Stati membri che tra Stati membri, al fine di affrontare le questioni chiave che attendono l'UE nel settore della sicurezza dei pazienti.

(9) È opportuno informare e responsabilizzare i pazienti, coinvolgendoli nel processo volto a garantire la loro sicurezza. Essi dovrebbero essere informati sulle norme di sicurezza dei pazienti, sulle migliori pratiche e/o sulle misure di sicurezza poste in atto nonché sul modo di reperire informazioni accessibili e comprensibili sui sistemi di reclamo e ricorso.

(10) È opportuno che gli Stati membri creino, mantengano o perfezionino sistemi globali di segnalazione e di apprendimento volti a registrare l'estensione e le cause degli eventi sfavorevoli, con l'obiettivo di sviluppare soluzioni ed interventi efficaci. La sicurezza dei pazienti dovrebbe fare parte integrante dei programmi di istruzione e formazione del personale sanitario, ovvero di coloro che forniscono le cure in prima persona.

(11) Occorre raccogliere dati comparabili e aggregati a livello comunitario per elaborare programmi, strutture e politiche di sicurezza dei pazienti efficaci e trasparenti, e divulgare le migliori pratiche tra gli Stati membri. Al fine di agevolare l'apprendimento reciproco, è necessario elaborare, in cooperazione tra gli Stati membri e la Commissione europea, una terminologia comune nel settore della sicurezza dei pazienti e indicatori comuni, tenendo conto del lavoro svolto dalle pertinenti organizzazioni internazionali.

(12) Gli strumenti delle tecnologie dell'informazione e della comunicazione, come le cartelle sanitarie elettroniche o le prescrizioni elettroniche, possono contribuire a migliorare la sicurezza dei pazienti, ad esempio analizzando in maniera sistematica le possibili interazioni o allergie a medicinali. Gli strumenti delle tecnologie dell'informazione e della comunicazione dovrebbero essere altresì volti a migliorare la comprensione degli utilizzatori dei medicinali.

(13) È opportuno elaborare una strategia nazionale complementare alle strategie mirate a un uso prudente degli agenti antimicrobici (²), che includa la prevenzione e il controllo delle infezioni associate all'assistenza sanitaria tra gli obiettivi nazionali in materia di pubblica sanità e

miri a ridurre il rischio di infezioni associate all'assistenza sanitaria nelle istituzioni sanitarie. È fondamentale che le risorse necessarie per attuare le diverse componenti della strategia nazionale vengano stanziate nel quadro del finanziamento di base destinato alla prestazione dell'assistenza sanitaria.

(14) La prevenzione e il controllo delle infezioni associate all'assistenza sanitaria dovrebbero fare parte delle priorità strategiche a lungo termine delle istituzioni sanitarie. Tutti i livelli gerarchici e tutte le funzioni dovrebbero cooperare per modificare i comportamenti e l'organizzazione in base a un approccio improntato sui risultati, definendo responsabilità a tutti i livelli, organizzando strutture di sostegno e risorse tecniche locali e creando procedure di valutazione.

(15) I dati disponibili sulle infezioni associate all'assistenza sanitaria non sempre sono sufficienti per consentire alle reti di sorveglianza di procedere a raffronti significativi tra le istituzioni, per sorvegliare l'epidemiologia degli agenti patogeni associati all'assistenza sanitaria e per valutare e guidare le politiche in materia di prevenzione e controllo delle infezioni associate all'assistenza sanitaria. Di conseguenza è opportuno creare o rafforzare sistemi di sorveglianza a livello delle istituzioni sanitarie nonché a livello regionale e nazionale.

(16) Gli Stati membri dovrebbero mirare a ridurre il numero di persone affette da infezioni associate all'assistenza sanitaria. Al fine di conseguire una riduzione delle infezioni associate all'assistenza sanitaria, dovrebbe essere incoraggiata l'assunzione di personale sanitario specializzato nel controllo delle infezioni. Inoltre, gli Stati membri e le loro istituzioni sanitarie dovrebbero prendere in considerazione il ricorso a personale di collegamento incaricato di sostenere il personale specializzato nel controllo delle infezioni a livello clinico.

(17) È opportuno che gli Stati membri operino in stretta collaborazione con l'industria della tecnologia sanitaria per incoraggiare una migliore progettazione a favore della sicurezza dei pazienti, al fine di ridurre l'insorgenza di eventi sfavorevoli nell'ambito dell'assistenza sanitaria.

(18) Al fine di raggiungere i summenzionati obiettivi in materia di sicurezza dei pazienti, comprese la prevenzione e il controllo delle infezioni associate all'assistenza sanitaria, gli Stati membri dovrebbero assicurare un approccio autenticamente globale, tenendo conto degli elementi più adeguati che hanno un'incidenza reale sulla prevalenza e sugli oneri degli eventi sfavorevoli.

(19) È opportuno che l'azione comunitaria nel settore della pubblica sanità rispetti pienamente le responsabilità degli Stati membri per l'organizzazione e la prestazione dei servizi sanitari e delle cure mediche.

(¹) Safety improvement for Patients in Europe (Miglioramento della sicurezza dei pazienti in Europa) (SIMPATIE), progetto finanziato nel quadro del programma comunitario relativo alla sanità pubblica 2003-2008, (http://www.simpatie.org).

(²) Si vedano ad esempio le conclusioni del Consiglio sulla resistenza agli antimicrobici, adottate il 10 giugno 2008.

RACCOMANDA,

ai fini della presente raccomandazione intendendosi per:

«evento sfavorevole», un incidente con conseguenze negative per un paziente;

«conseguenze negative», conseguenze implicanti una disabilità fisica strutturale o funzionale e/o qualsiasi effetto nocivo che ne deriva;

«infezioni associate all'assistenza sanitaria», affezioni o patologie correlate alla presenza di un agente infettivo o dei suoi prodotti in connessione con l'esposizione a strutture o procedure sanitarie o a trattamenti sanitari;

«sicurezza dei pazienti», il fatto che un paziente non subisca conseguenze negative non necessarie o non sia esposto a potenziali conseguenze negative associate all'assistenza sanitaria;

«indicatore di processo», un indicatore riferito alla conformità con attività convenute quali l'igiene delle mani, la sorveglianza, le procedure operative standard;

«indicatore strutturale», un indicatore riferito a risorse quali il personale, un'infrastruttura o un comitato;

AGLI STATI MEMBRI:

I. RACCOMANDAZIONI SU TEMI GENERALI ATTINENTI ALLA SICUREZZA DEI PAZIENTI

1. di sostenere la creazione e l'elaborazione di politiche e programmi nazionali in materia di sicurezza dei pazienti tramite:

   a) la nomina dell'autorità o delle autorità competenti o di ogni altro organo responsabile per la sicurezza dei pazienti sul proprio territorio;

   b) l'inserimento della sicurezza dei pazienti tra i temi prioritari nelle politiche e nei programmi sanitari a livello nazionale, regionale e locale;

   c) il sostegno allo sviluppo di sistemi, procedure e strumenti più sicuri e di facile impiego, compreso l'uso delle tecnologie dell'informazione e della comunicazione;

   d) la revisione e l'aggiornamento regolari delle norme di sicurezza e/o delle migliori pratiche applicabili all'assistenza sanitaria fornita nel loro territorio;

   e) l'incentivazione delle organizzazioni professionali del settore sanitario a svolgere un ruolo attivo nel quadro della sicurezza dei pazienti;

   f) l'inclusione di un approccio specifico volto a promuovere pratiche di sicurezza per la prevenzione degli eventi sfavorevoli più frequenti, quali gli eventi correlati alle medicazioni, le infezioni associate all'assistenza sanitaria e le complicazioni che si verificano durante o dopo un intervento chirurgico;

2. di responsabilizzare e informare i cittadini e i pazienti tramite:

   a) il coinvolgimento a tutti i livelli appropriati delle organizzazioni e dei rappresentanti dei pazienti nell'elaborazione di politiche e programmi in materia di sicurezza dei pazienti;

   b) la fornitura ai pazienti di informazioni concernenti:

      i) le norme in vigore in materia di sicurezza dei pazienti;

      ii) i rischi, le misure di sicurezza esistenti per ridurre o prevenire gli errori e le conseguenze negative, comprese le migliori pratiche, e il diritto al consenso informato alla terapia, al fine di facilitare la scelta e la decisione del paziente;

      iii) le procedure di reclamo e i mezzi di ricorso disponibili nonché le condizioni applicabili;

   c) la valutazione delle possibilità di dotare i pazienti di competenze di base in materia di sicurezza dei pazienti, segnatamente di conoscenze, attitudini e capacità di base essenziali per l'ottenimento di un'assistenza sanitaria più sicura;

3. di sostenere l'istituzione o il rafforzamento di sistemi di segnalazione e di apprendimento relativi agli eventi sfavorevoli, privi di carattere punitivo:

   a) che forniscano informazioni sulla portata, i tipi e le cause degli errori, degli eventi sfavorevoli e dei quasi-incidenti;

   b) che incoraggino il personale sanitario a segnalare attivamente gli eventi sfavorevoli, mediante un ambiente aperto, equo e non punitivo. Tale sistema di segnalazione dovrebbe essere differenziato dai sistemi disciplinari degli Stati membri e dalle procedure relative al personale sanitario e, se del caso, le implicazioni giuridiche relative alla responsabilità del personale sanitario andrebbero chiarite;

c) che forniscano, se del caso, ai pazienti, ai loro parenti e ad altri prestatori di assistenza informale l'opportunità di riferire le proprie esperienze;

d) che integrino gli altri sistemi di segnalazione in materia di sicurezza, come quelli relativi alla farmacovigilanza e agli strumenti medici, evitando, nella misura del possibile, segnalazioni multiple;

4. di promuovere, al livello adeguato, l'istruzione e la formazione del personale sanitario riguardo alla sicurezza dei pazienti:

a) incoraggiando l'istruzione e la formazione multidisciplinare in materia di sicurezza dei pazienti di tutto il personale sanitario, degli altri lavoratori del settore e del competente personale direttivo e amministrativo delle strutture sanitarie;

b) integrando il tema della sicurezza dei pazienti nei programmi di studio universitari e post-universitari, nella formazione impartita sul posto di lavoro e nello sviluppo professionale continuo del personale sanitario;

c) valutando lo sviluppo di competenze di base in materia di sicurezza dei pazienti, segnatamente di conoscenze, attitudini e capacità di base essenziali per l'ottenimento di un'assistenza sanitaria più sicura, da diffondere tra tutto il personale sanitario nonché tra il personale direttivo e amministrativo competente;

d) fornendo e diffondendo informazioni a tutto il personale sanitario sui parametri per la sicurezza dei pazienti, le misure esistenti in materia di rischio e sicurezza per ridurre o prevenire gli errori e le conseguenze, comprese le migliori pratiche, e per promuovere il loro coinvolgimento;

e) collaborando con le organizzazioni attive nell'istruzione professionale in campo sanitario per assicurare che nei piani di studio della scuola secondaria e nell'istruzione e formazione impartita agli operatori sanitari si tenga in debito conto la sicurezza dei pazienti, compreso lo sviluppo delle capacità necessarie per gestire e realizzare le modifiche di comportamento necessarie per migliorare la sicurezza dei pazienti attraverso una modifica del sistema;

5. di classificare e di misurare la sicurezza dei pazienti a livello comunitario mediante la cooperazione tra di loro e con la Commissione, al fine di:

a) sviluppare definizioni e una terminologia comuni, tenendo conto delle attività internazionali di normalizzazione quali la Classificazione internazionale per la sicurezza dei pazienti attualmente in fase di sviluppo da parte dell'OMS, nonché dei lavori del Consiglio d'Europa in questo settore;

b) elaborare un insieme di indicatori affidabili e comparabili per individuare i problemi legati alla sicurezza, valutare l'efficacia degli interventi volti a migliorare la sicurezza e agevolare l'apprendimento reciproco tra Stati membri. In tale contesto occorre tener conto dei lavori svolti a livello nazionale e delle attività internazionali quali il progetto dell'OCSE sugli indicatori di qualità dell'assistenza sanitaria e il progetto della Comunità sugli indicatori sanitari;

c) raccogliere e condividere dati e informazioni comparabili sul tipo e numero di risultati ottenuti in materia di sicurezza dei pazienti, al fine di agevolare l'apprendimento reciproco e orientare la fissazione di priorità, nella prospettiva di aiutare gli Stati membri a rendere pubblici, in futuro, i pertinenti indicatori;

6. di condividere le conoscenze, le esperienze e le migliori pratiche lavorando insieme e con la Commissione nonché con i pertinenti organismi europei ed internazionali riguardo:

a) all'elaborazione di programmi, strutture e politiche efficaci e trasparenti in materia di sicurezza dei pazienti, compresi sistemi di segnalazione e di apprendimento, allo scopo di affrontare gli eventi sfavorevoli nel settore dell'assistenza sanitaria;

b) all'efficacia degli interventi e delle soluzioni in materia di sicurezza dei pazienti attuate a livello di strutture sanitarie e alla valutazione della loro applicabilità in altri contesti;

c) ai principali allarmi in materia di sicurezza dei pazienti secondo modalità tempestive;

7. di sviluppare e di promuovere la ricerca sulla sicurezza dei pazienti;

II. RACCOMANDAZIONI SUPPLEMENTARI ATTINENTI ALLA PREVENZIONE E AL CONTROLLO DELLE INFEZIONI ASSOCIATE ALL'ASSISTENZA SANITARIA

8. di adottare e di attuare al livello appropriato una strategia per la prevenzione e il controllo delle infezioni associate all'assistenza sanitaria che persegua i seguenti obiettivi:

a) attuare misure di prevenzione e controllo a livello nazionale o regionale per sostenere il contenimento delle infezioni associate all'assistenza sanitaria, in particolare:

i) per applicare, se del caso, misure standard e basate sui rischi in materia di prevenzione e controllo delle infezioni in tutte le strutture sanitarie;

ii) per promuovere la coerenza e la comunicazione delle misure di prevenzione e di controllo delle infezioni tra gli operatori sanitari che hanno in cura o assistono un determinato paziente;

iii) per mettere a disposizione orientamenti e raccomandazioni a livello nazionale;

iv) per incoraggiare il rispetto delle misure di prevenzione e di controllo tramite il ricorso a indicatori strutturali e di processo nonché ai risultati dei processi di accreditamento o certificazione in vigore;

b) rafforzare la prevenzione e il controllo delle infezioni a livello delle istituzioni sanitarie, in particolare incoraggiando queste ultime ad istituire:

i) un programma di prevenzione e controllo delle infezioni che affronti aspetti quali le modalità organizzative e strutturali, le procedure diagnostiche e terapeutiche (ad esempio una politica per l'impiego corretto degli antibiotici), le risorse necessarie, gli obiettivi di sorveglianza, la formazione e l'informazione dei pazienti;

ii) adeguate misure organizzative per l'elaborazione e il monitoraggio del programma di prevenzione e controllo delle infezioni;

iii) adeguate misure organizzative e personale qualificato per l'attuazione del programma di prevenzione e controllo delle infezioni;

c) istituire o rafforzare sistemi di sorveglianza attiva:

i) a livello nazionale o regionale:

— organizzando ad intervalli regolari, se del caso, indagini sulla diffusione delle infezioni;

— tenendo conto dell'importanza di sorvegliare l'incidenza di determinati tipi d'infezione al fine di raccogliere dati di riferimento nazionali accompagnati da indicatori di processo e strutturali per valutare la strategia;

— organizzando la tempestiva individuazione e segnalazione alla pertinente autorità degli organismi a rischio associati all'assistenza sanitaria o dei raggruppamenti di infezioni associati all'assistenza sanitaria, secondo le modalità stabilite a livello di Stato membro;

— notificando i raggruppamenti e i tipi di infezione pertinenti per la Comunità o a livello internazionale, conformemente alla legislazione comunitaria (¹) o alle normative internazionali in vigore;

ii) a livello delle istituzioni sanitarie:

— incoraggiando una documentazione microbiologica e fascicoli relativi ai pazienti di elevata qualità;

— sorvegliando l'incidenza dei tipi d'infezione specifici, avvalendosi di indicatori di processo e strutturali per valutare l'attuazione delle misure di controllo delle infezioni;

— prendendo in considerazione la possibilità di ricorso alla sorveglianza di particolari tipi di infezioni e/o di ceppi particolari di agenti patogeni associati all'assistenza sanitaria per l'individuazione tempestiva degli organismi a rischio associati all'assistenza sanitaria o dei raggruppamenti di infezioni associate all'assistenza sanitaria.

iii) utilizzando, se del caso, i sistemi di sorveglianza e gli indicatori raccomandati dall'ECDC e le definizioni di caso concordate a livello comunitario conformemente alle disposizioni della decisione n. 2119/98/CE;

d) favorire l'istruzione e la formazione del personale sanitario,

i) a livello degli Stati membri o a livello regionale definendo ed attuando programmi specializzati di formazione e/o d'istruzione al controllo delle infezioni per il personale addetto al controllo delle infezioni e rafforzando la formazione sulla prevenzione e il controllo delle infezioni associate all'assistenza sanitaria per il rimanente personale sanitario.

ii) a livello delle istituzioni sanitarie:

— assicurando regolarmente la formazione di tutto il personale, compresi i quadri, riguardo ai principi base dell'igiene, della prevenzione e del controllo delle infezioni;

(¹) Ad esempio decisione n. 2119/98/CE del Parlamento europeo e del Consiglio, del 24 settembre 1998, che istituisce una rete di sorveglianza epidemiologica e di controllo delle malattie trasmissibili nella Comunità e i regolamenti sanitari internazionali (GU L 268 del 3.10.1998, pag. 1) e regolamento (CE) n. 726/2004 del Parlamento europeo e del Consiglio, del 31 marzo 2004, che istituisce procedure comunitarie per l'autorizzazione e la sorveglianza dei medicinali per uso umano e veterinario, e che istituisce l'agenzia europea per i medicinali (GU L 136 del 30.4.2004, pag. 1).

— assicurando regolarmente la formazione specializzata del personale incaricato di compiti particolari riguardanti la prevenzione e il controllo delle infezioni associate all'assistenza sanitaria.

e) migliorare l'informazione fornita ai pazienti da parte delle istituzioni sanitarie:

  i) rendendo disponibili informazioni obiettive e comprensibili sul rischio di infezioni associate all'assistenza sanitaria, sulle misure di prevenzione da esse adottate nonché sul modo in cui i pazienti possono contribuire alla prevenzione di tali infezioni;

  ii) fornendo informazioni specifiche, ad esempio sulle misure di prevenzione e controllo, ai pazienti colonizzati o infettati da agenti patogeni associate all'assistenza sanitaria;

f) sostenere la ricerca in settori quali l'epidemiologia, le applicazioni delle nanotecnologie e dei nanomateriali, le nuove tecnologie e i nuovi interventi preventivi e terapeutici, nonché il rapporto costi/efficacia della prevenzione e del controllo delle infezioni;

9. di prendere in considerazione, per l'attuazione coordinata della strategia di cui al punto 8), nonché ai fini dello scambio d'informazioni e del coordinamento con la Commissione, l'ECDC, l'Agenzia europea per i medicinali e gli altri Stati membri, la creazione, se possibile entro 9 giugno 2011, di un meccanismo intersettoriale o di sistemi equivalenti corrispondenti all'infrastruttura in ciascuno Stato membro, che collaborino con il meccanismo intersettoriale

esistente istituito conformemente alla raccomandazione n. 2002/77/CE del Consiglio, del 15 novembre 2001 sull'uso prudente degli agenti antimicrobici nella medicina umana, o che siano integrati in tale meccanismi (1);

III. **RACCOMANDAZIONI FINALI**

10. di diffondere il contenuto della presente raccomandazione tra le organizzazioni sanitarie, gli organi professionali e d'istruzione e incoraggiarle a seguire gli approcci suggeriti affinché gli elementi chiave possano entrare a fare parte della pratica quotidiana;

11. di riferire alla Commissione riguardo all'attuazione della presente raccomandazione entro 9 giugno 2011 e successivamente su richiesta della Commissione, onde contribuire al seguito della presente raccomandazione a livello comunitario;

INVITA LA COMMISSIONE

ad elaborare, entro 9 giugno 2012, una relazione di attuazione al Consiglio che valuti l'impatto della presente raccomandazione sulla base delle informazioni fornite dagli Stati membri, al fine di analizzare il grado di efficacia delle misure proposte e di valutare la necessità di azioni ulteriori.

Fatto a Lussemburgo, il 8 giugno 2009.

Per il Consiglio
Il presidente
Petr ŠIMERKA

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(1) GU L 34 del 5.2.2002, pag. 13.