European Commission

Report on

The Public Consultation on Patient Safety and Quality of Care

Health

Disclaimer:

This paper should be regarded solely as a summary of the contributions made by stakeholders to DG Health and Consumers' public consultation on patient safety and quality of care. It cannot in any circumstances be regarded as the official position of the Commission and its services.

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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.

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.

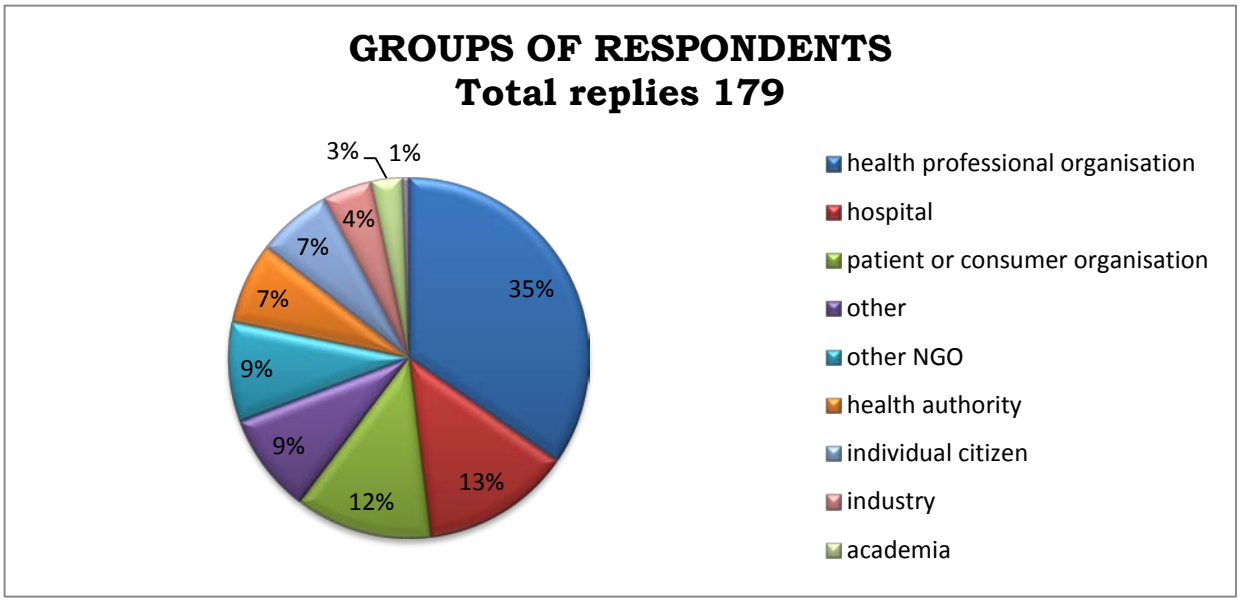
The third and final section of the questionnaire addressed future EU action on patient safety and quality of healthcare, focusing on what should be done beyond the Recommendation and asking whether quality of healthcare should be given more importance in the future EU activities.

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:

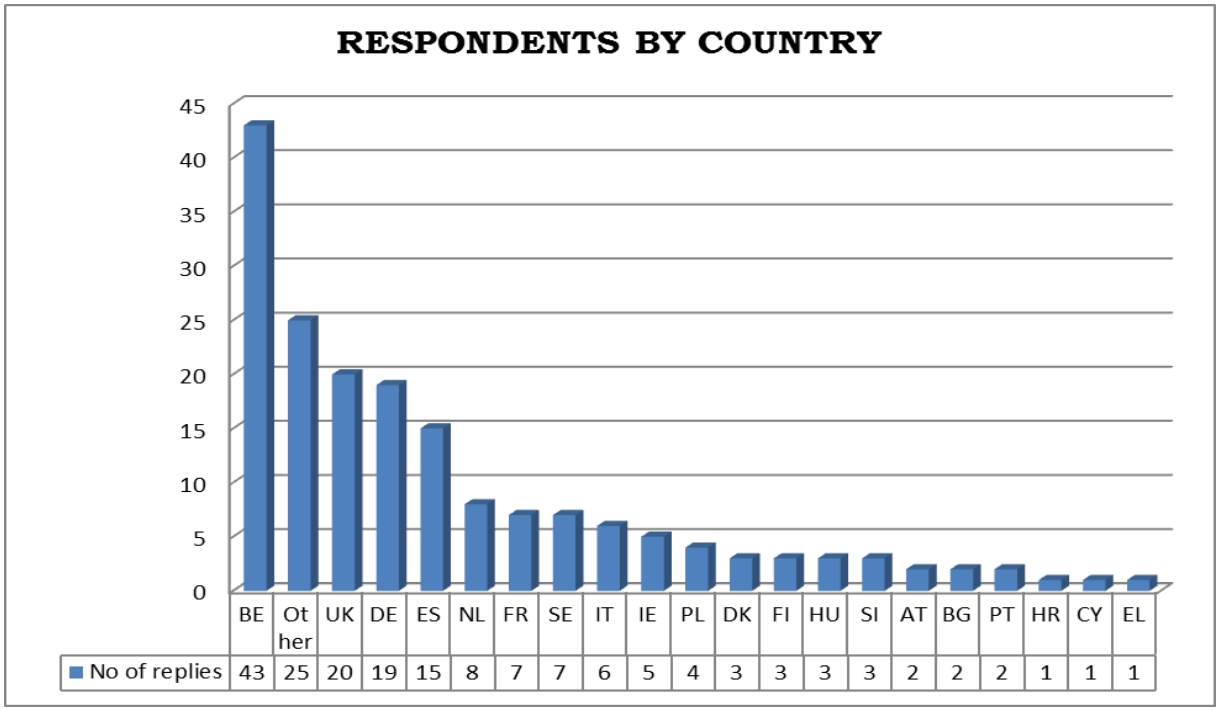
Chart 1: Overview of the responses received.



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.



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.

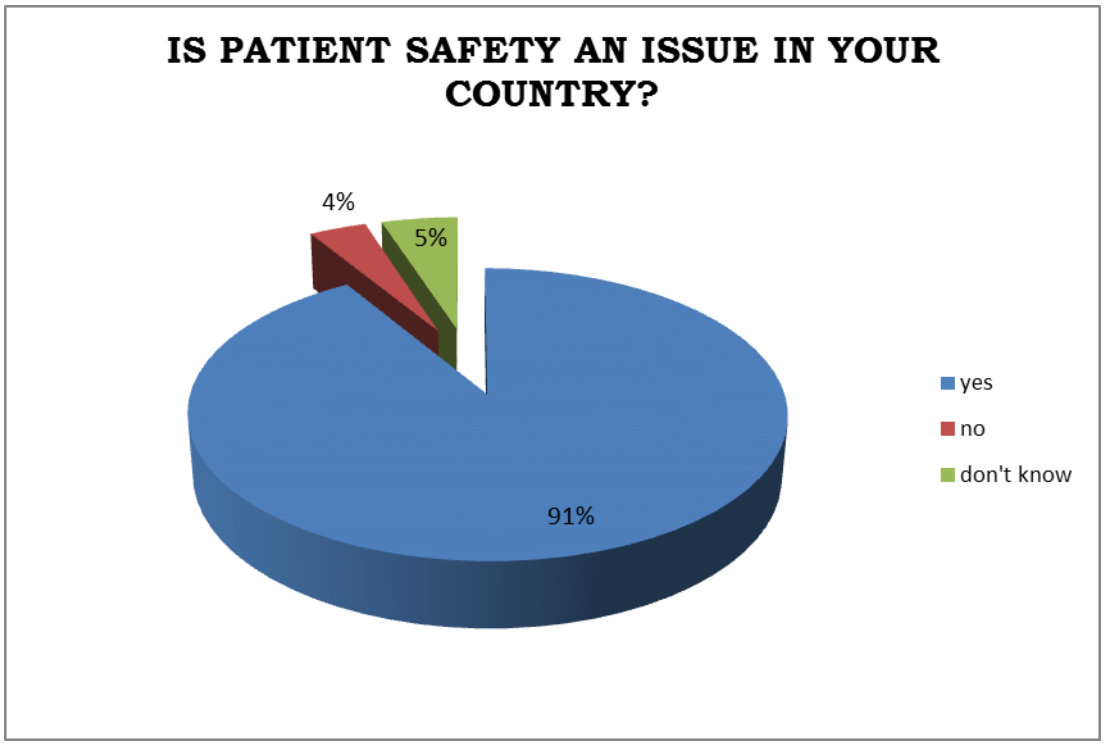
3.2 Analysis of the replies to the different sections of the questionnaire

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.

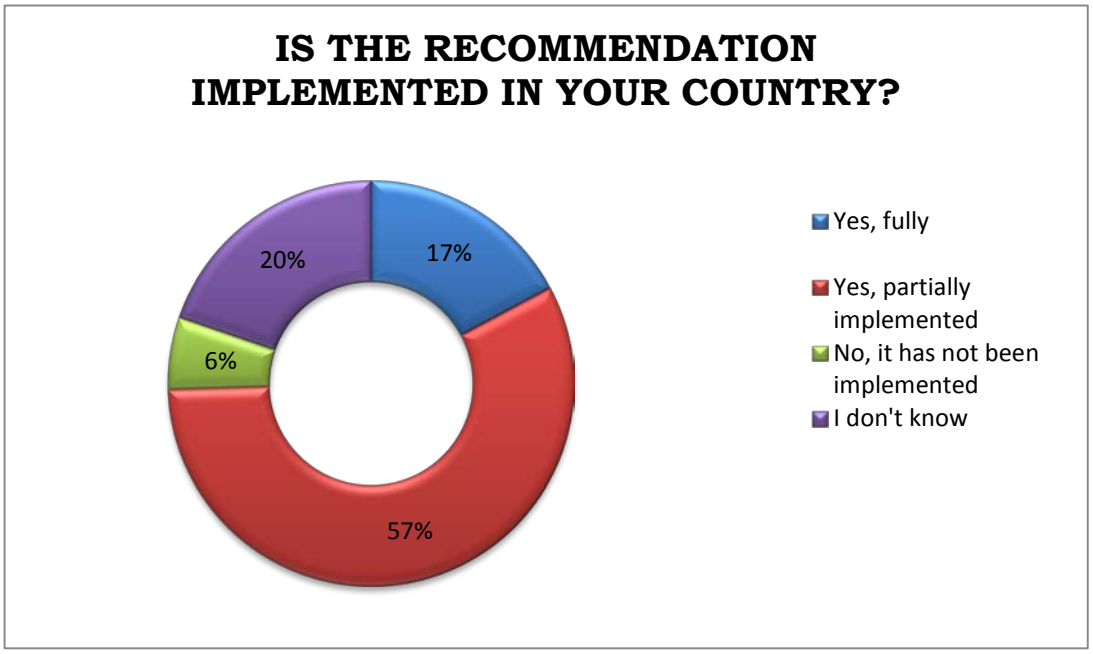


It is interesting to notice that, among those respondents who did not consider patient safety as an issue, the majority were individual citizens.

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.

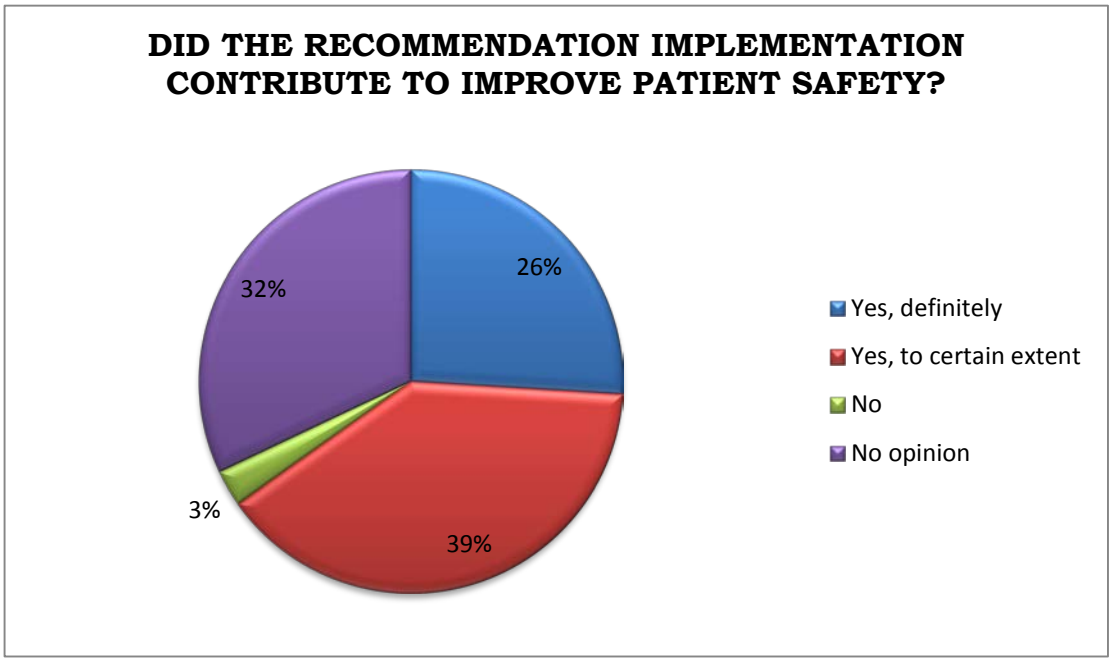
Chart 4: Recommendation implementation level.



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?



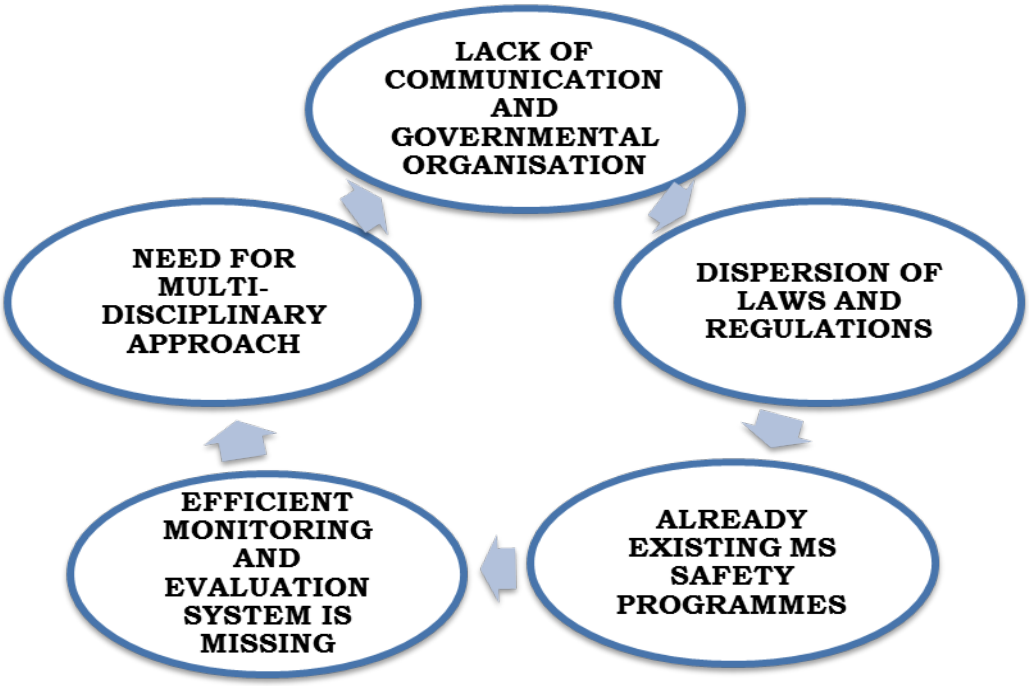
It can also be noticed that mostly health professional organizations and hospitals replied "yes, definitely" or "yes, to certain extent".

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).

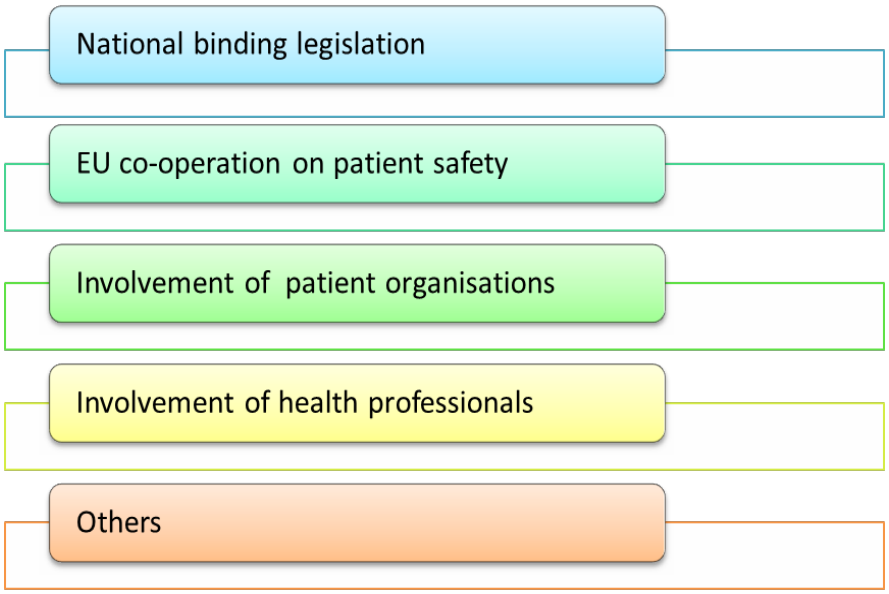
Lots of respondents also underlined the crucial role of the **programmes in collaboration with local communities and regional authorities** *«respecting and complementing the actions that each one of them develops in the exercise of their powers»*. Some examples include information campaigns, meetings,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

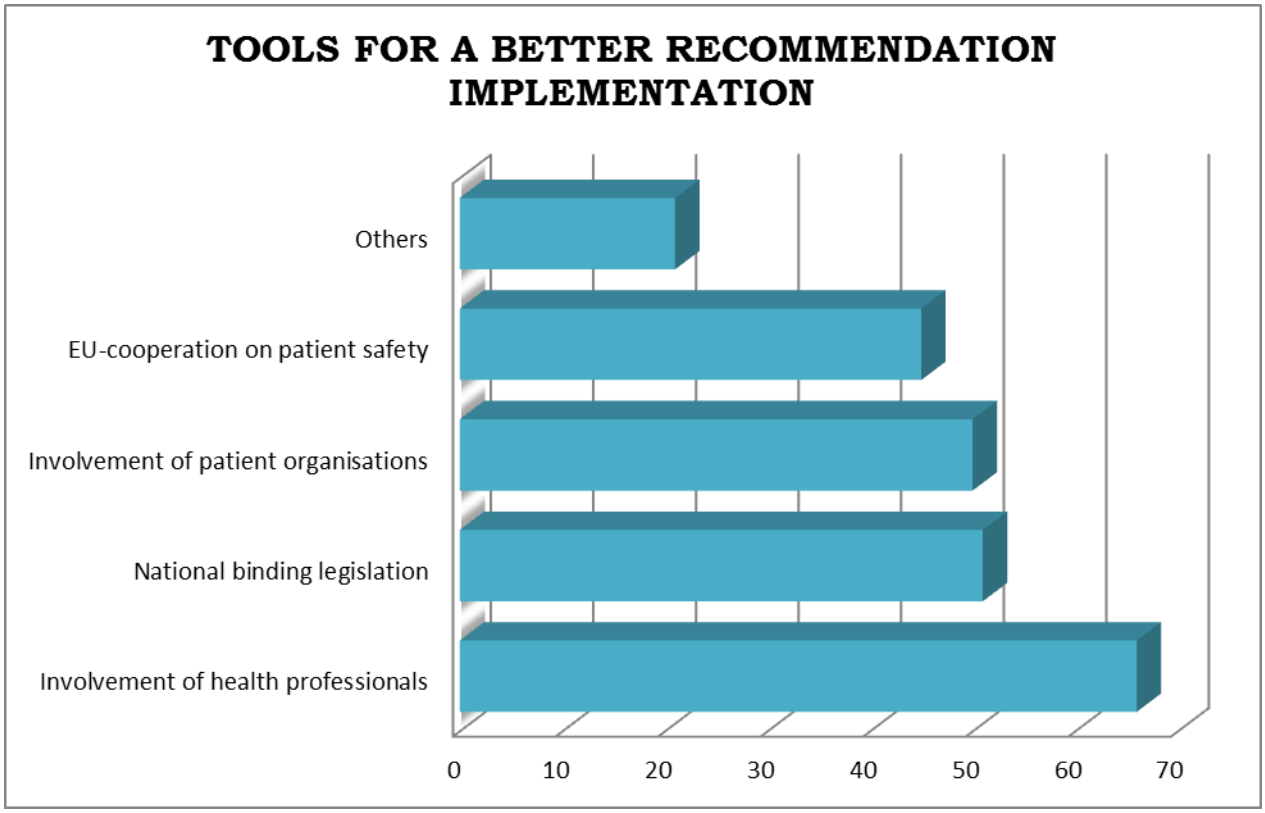
3.2.4 HELPFUL TOOLS FOR A BETTER IMPLEMENTATION

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:



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.

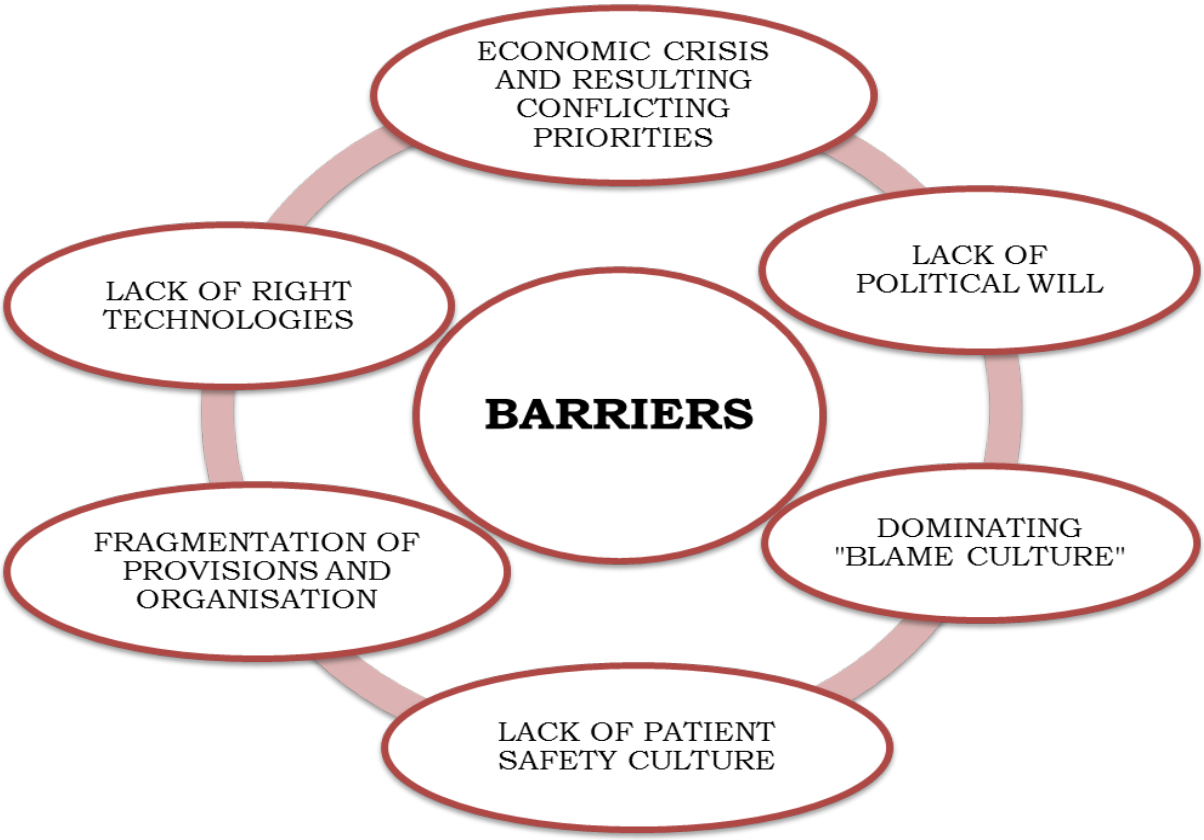
In addition, a barrier is represented in many cases by the **top-down attitudes** by clinicians particularly regarding patient involvement and awareness. Patients' will and proposals are still not having the support and consideration that they deserve. It was also underlined how hospital managers and 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.

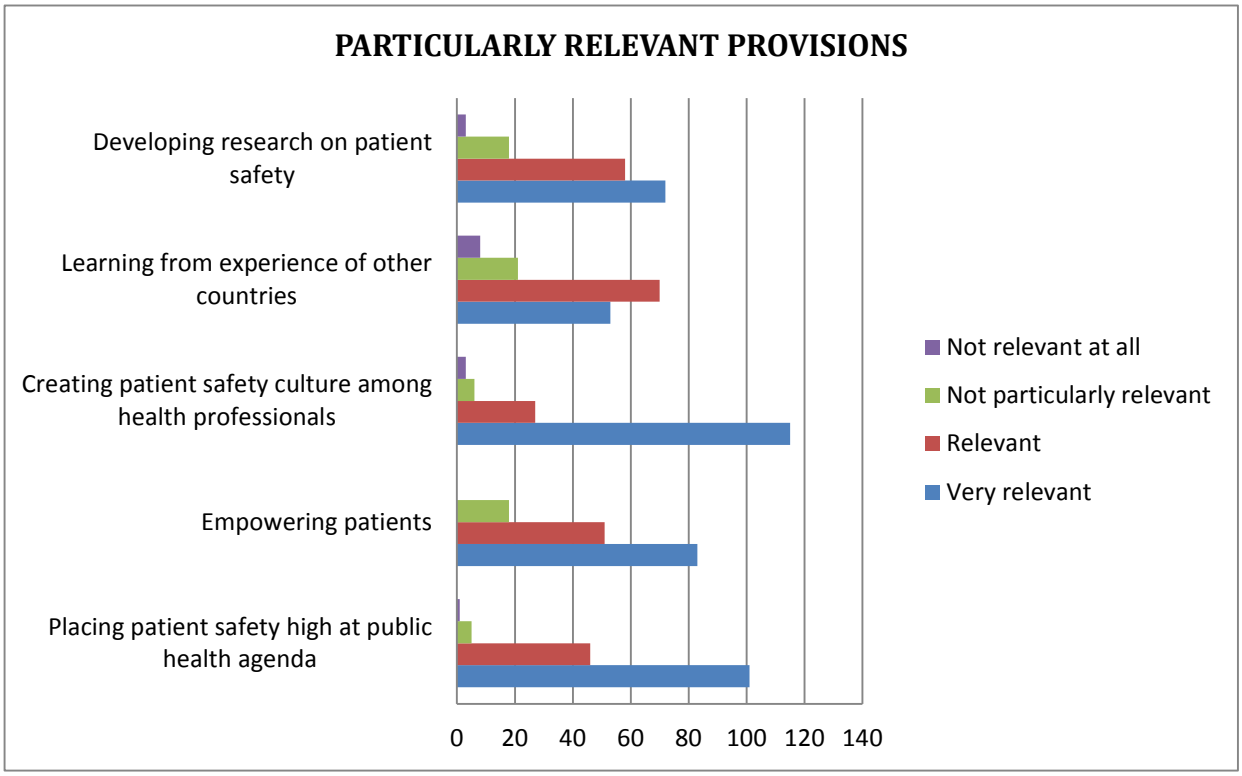


3.2.6 PARTICULARLY RELEVANT PROVISIONS OF THE RECOMMENDATION

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

[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**

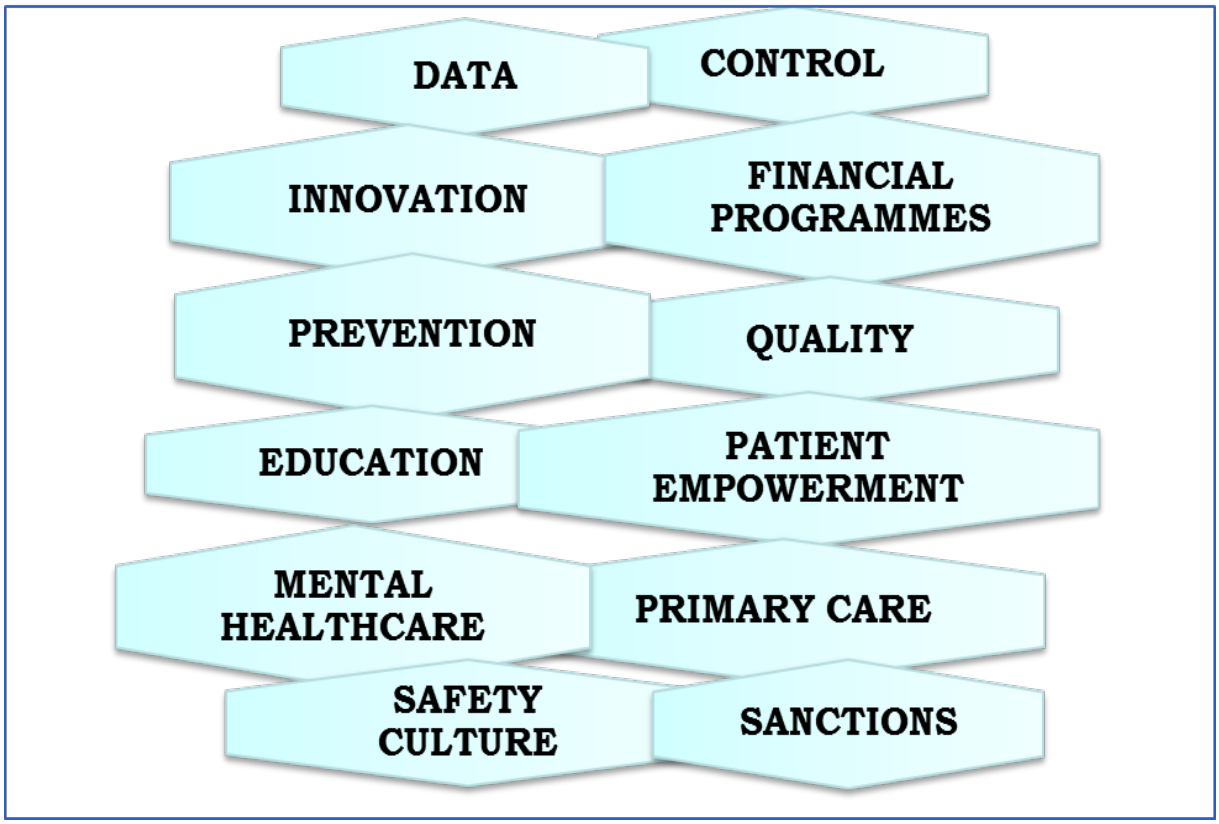
carers that should include many more measures, for example to address the issue of health profession role development and to implement a supporting **psychological supervision** system for concerned healthcare-professionals. Health systems cannot deliver high quality care without a well-trained health 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.



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:

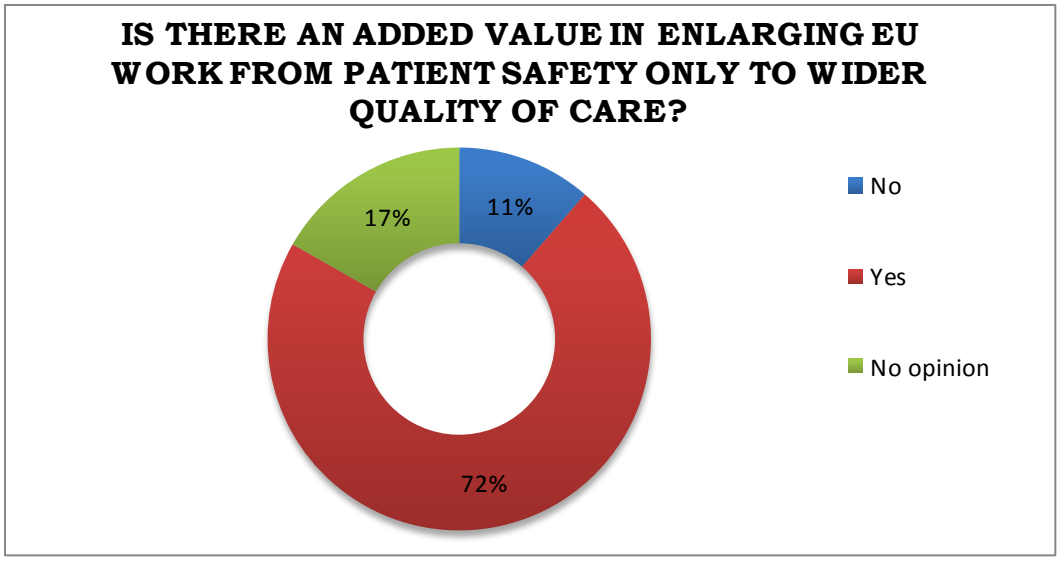
- supporting **cooperation** (e.g. between professionals, patients and authorities), **best practices exchange** and **mutual learning** as crucial elements to be used more and more efficiently;
- improving patient safety in **non-hospital care**. EU future initiatives should recognise informal care 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*

[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.