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Overview

The Declaration for Patient Safety aims to call upon health authorities, policymakers, healthcare professionals, providers and patients to join hands to prevent unnecessary harms in healthcare by promoting safer health systems and high quality standards on patient safety across Europe. This initiative, launched by Health First Europe, is open to all organisations and individuals as it is intended to create a framework to stimulate policy development and actions in and between Member States to guarantee patient safety.

Definitions of concepts

The following working document intends to give some background information about the 10 calls listed in the Declaration for Patient Safety, reporting EU-wide references and data.

By using the term 'patient safety', the Declaration and its working document refer to "*the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum; an 'acceptable minimum' refers to the collective notions of current knowledge, resources available and the context in which care was delivered and weighed against the risk of non-treatment or alternative treatment.*"¹

The word 'harm' is defined as an "*impairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological.*"²

A 'patient' is a person receiving healthcare, such as medical intervention, procedure or diagnostic test. The term could also include patient's relatives or other surrogates who are involved or affected by patient's care.³

Last, 'adverse event' refers to an incident during care that results in patient harm, including:

- Medication errors;
- Healthcare-associated infections (sometimes also referred to as hospital-acquired or nosocomial infections);
- Patient falls;
- Pressure ulcers (pressure injury);
- Venous thromboembolism (VTE) - comprising deep vein thrombosis (DVT) or pulmonary embolism (PE);
- Diagnostic error (incorrect or delayed diagnosis);
- Death during interventions with typically low mortality rates.⁴

¹ WHO, Technical report on Conceptual Framework for the International Classification for Patient Safety, January 2009, pp. 15-16. http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf

² Ibid.

³ Ibid.

⁴ WHO, op. cit. p. 106.

The burden of patient harm

The World Health Organisation (WHO) estimates that patient harm is the 14th leading cause of the global disease burden, alike illnesses such as tuberculosis and malaria. In some European countries, the burden of patient harm is comparable to that of chronic diseases (e.g. multiple sclerosis and some types of cancer).¹

Unsafe care has not only a dramatic impact on patient's life, but also a high financial cost for the whole society. The Organisation for Economic Co-operation and Development (OECD) estimates that around 15% of hospital spending in OECD countries can be attributed to treating safety failures.²

Detailed data on the economic burden for the public healthcare sector in all EU Member States are currently not available; however, calculations based on two European references estimate a direct cost of about EUR 21 billion or 1.5% of health expenditure for EU Member States in 2014.³

Additionally, it is worth considering the overall impact of the economic crisis on healthcare systems. Austerity measures have put great pressure on healthcare budgets. As it has been flagged by a recent report of the European Parliament, since the crisis started, many EU countries instead of properly addressing cost-efficiency issues, have radically reduced budgets and resources for staffing, often leading to poor patient safety.⁴

Indeed, the first European Commission Report on the implementation of Council Recommendation of Patient Safety (2012) warned that national financial constraints resulting from the economic crisis have slowed the implementation of the Council Recommendation.⁵

Looking at the costs due to patient harm and the pressure on healthcare budgets, developing strong and high quality patient safety policies is not just a human imperative, but also a matter of cost-efficiency. Evidence shows that the prevention of adverse events contributes effectively to the reduction of the economic burden incurred by national health systems.⁶

¹ OECD, The Economics of Patient Safety: Strengthening a value-based approach to reducing patient harm at national level, March 2017, p. 47. http://www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety_5a9858cd-en;jsessionid=6gui8p7gjfrmp.x-oecd-live-02

² OECD, op. cit. p.18.

³ European Commission, Costs of unsafe care and cost effectiveness of patient safety programmes, written by Gesundheit Österreich Forschungs- und Planungs GmbH and SOGETI, February 2016 https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/2016_costs_psp_en.pdf

⁴ European Parliament, Report on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance, 2014/2207(INI), adopted in May 2015.

⁵ European Commission, Report on the implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare associated infections, COM (2012) 658, November 2012, p. 12. https://ec.europa.eu/health/sites/health/files/patient_safety/docs/council_2009_report_en.pdf

⁶ European Commission, February 2016, loc. cit.

EU and Member States' commitment

Legally binding on EU institutions and national governments since 1st December 2009, the Charter of Fundamental Rights of the EU entrenches Member States' commitment to guarantee that:

"Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities."

In addition to the abovementioned Article 35, the Charter includes other provisions that can refer either directly or indirectly to patients' rights, such as human dignity, the right to life, the right to the integrity of the person, the right to security, the right to the protection of personal data, the rights of the elderly, the right to social security and social assistance.

When it comes to health, EU countries often face common challenges and problems, as they need to adapt to constant developments in medical science. The EU action is defined by Article 6 of TFUE as follows:

"The Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States. The areas of such action shall, at European level, be: (a) protection and improvement of human health."

In line with the principles of proportionality and subsidiarity, EU policies in public health aim only to support EU Member States' efforts to protect the health of their citizens and to modernise healthcare systems, contributing to the Commission's 2014-2019 priorities on growth and jobs. Consequently, patient safety is primarily responsibility of EU Member States and the EU can only encourage cooperation and support national actions.

In this framework, the EU is a crucial arena to bring together representatives from all 28 EU Member States, to monitor the development of EU patient safety and quality agenda, exchange best practices and lessons learned, and ultimately shape common standards and guidelines.

The Council Recommendation on Patient Safety is the milestone of EU patient safety actions. Through its adoption in 2009, the Member States committed to put in place a series of measures with a view to minimising harm to patients receiving healthcare. These measures include: developing national policies on patient safety, empowering and informing patients, establishing reporting and learning systems on adverse events, promoting training of healthcare staffing, share knowledge, experience and best practices.¹

The Recommendation is accompanied by other EU initiatives. In this regard, it is worth mentioning the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, which includes several provisions on patient safety and quality of healthcare (e.g. collaboration of Member States on standards and guidelines, patients' rights to be informed on healthcare providers and on the safety standards applied).

¹Council of the European, Council Recommendation on patient safety, including the prevention and control of healthcare associated infections, 2009/C 151/01, June 2009.

EU citizens' perception and trust

A Eurobarometer survey on patient safety and quality of care ran in 2013 in all 28 Member States; the findings have shown that EU citizens are losing trust on healthcare systems. The objective of this survey was to review changes that had occurred since the adoption of the Council Recommendation on patient safety and healthcare associated infections in 2009. According to its final report, the Council Recommendation did not improve EU citizens' perception of the safety of care.¹

Over 50% of respondents believe that patients could be harmed by hospital care, while 25% of respondents said that they or their relatives experienced an adverse event. It is worth noting that opinions have worsened since the earlier survey ran in 2009 with a 3% point increase respectively in the proportion of respondents who think harm from hospital is likely.²

The findings of a 2014 Public Consultation on patient safety are still rather negative: over 90% of the civil society still see patient safety as an issue in the EU. The major concerns of the respondents are (1) the severe budget and resource cuts resulting from financial constraints and lack of political will; (2) insufficient action taken to empower patients; (3) low levels of awareness of the importance of patient safety; (4) predominating "blame-cultures" which prevents focusing on causes of errors and ways to prevent adverse events; and (5) deficiencies in reporting mechanisms.³

Calls for action

Call N. 1 – Foster citizen awareness and patient empowerment – through:

- Educational campaigns to raise awareness on safety in healthcare setting;
- Including patients' perspective into patient safety strategies;
- Systematic involvement of patients and their representatives in policy development.

According to the findings of the 2014 Public Consultation on patient safety, the Council Recommendation has succeeded in raising some awareness on patient safety at political level. One of the most visible results is the development of national patient safety strategies in many EU Member States. Nevertheless, the evidence still shows a very low impact in increasing citizens' awareness, especially within the healthcare setting (equally among professionals and patients).⁴

Citizens' awareness about the risks and importance of prevention is a *conditio sine qua non* for involving patients into the political debate and putting forward their point of view. Ultimately, an active involvement of patients is critical for shaping an effective patient safety strategy and for the functioning of the whole healthcare system. Clinical governance frameworks and patient-engagement initiatives are considered important assets to build a positive safety culture and integrated patient safety programmes.

¹ Eurobarometer, Report of the Special Eurobarometer survey on patient safety and quality of care, n. 411, June 2014 https://ec.europa.eu/health/patient_safety/eurobarometers/ebs_411_en

² Eurobarometer, op. cit., p. 15

³ European Commission, Report on the Public Consultation on patient safety and quality care, 2014

⁴ Ibid.

For this purpose, the Council called on involving patient organisations and representatives in the development of policies and programmes on patient safety.¹ This issue addresses the call to ensure the patient perspective is well reflected by empowering patients, involving their representative organisations in patient safety programmes, including those on the prevention and control of healthcare associated infections.

It is crucial to develop strategies and tools to make patients more involved in treatment discussions and give them active voice in their therapeutic decisions. Therefore, Patient Associations need to be involved in training programmes and awareness raising campaigns about adverse event reporting.

Patient engagement in policy development has been proved in only twelve EU countries, which provided examples of specific administrative and legal acts requiring such involvement. In the majority of Member States, so far, public consultations are the most used tools to provide feedback.²

Call N. 2 – Promote a blame free safety culture – through:

- Prioritising patient safety in the political agenda on health;
- Annual report on the status of patient safety before national Parliaments;
- Effective actions to promote safety culture in all health settings;
- Consistent and blame-free reporting systems across the EU for healthcare harms and risk monitoring.

The available evidence suggests that the mortality burden resulting from unnecessary patient harm is a crucial public health issue. Different studies on adverse event rate in various European countries estimate dramatic figures: in Spain 4.4% of patients experiencing adverse events died, in Denmark 6.1%, in the UK 8.0%, in Sweden 3.0%, in the Netherlands 7.8%.³

In addition, it is worth stressing that the economic crisis and the resulting cost-saving approaches have slowed down the integration of patient safety into education and training of health professionals. In the last years, financial issues and constrains have regrettably dominated the European political agendas at the expense of matters like patient safety.

Therefore, it is in the interest of the whole society to embed patient safety as a high priority in the health political agenda. National Ministries of Health should monitor and report the state of play before national Parliaments, as well as provide detailed statistics and ways ahead on patient safety. As called by the Council, patient safety is a priority issue in health policies both at national and local level, while encouraging health professional organisations to have an active role.⁴

To promote a safety culture, key stakeholders should be engaged and invited to discuss about the same topics to give different perspectives.

¹ Council of the European Union, 2009, op. cit. Article 2(a).

² European Commission, Report on the implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare associated infections, COM (2012) 658, June 2014, p. 3. https://ec.europa.eu/health/sites/health/files/patient_safety/docs/ec_2ndreport_ps_implementation_en.pdf

³ OECD, op. cit. p.21

⁴ Council of the European Union, 2009, op. cit. Article 1(e).

Throughout the creation of Patient Safety Forums with participation of representatives from Patient Associations, Governmental Bodies, Healthcare Institutions, Industries, Ministry of Health and other policy makers, it would be possible to create preventive guidelines on the management of adverse events to be leveraged and adapted in different countries, and to identify and disseminate effective solutions for patient safety.

An effective system for reporting healthcare harm is considered essential to make patients' voice heard and assess patient safety status. However, only six Member States fully have implemented EU requirements on blame-free reporting and learning systems (e.g. provide extensive information about adverse events, allow patients to report, complement other safety reporting systems, etc.). The development of reporting and learning systems is considered an area for further cooperation at EU level. In EU countries, the multiple and inconsistent systems currently in place are rarely interoperable. The reporting systems could seem rather fragmented: across the EU, adverse events are reported to doctors, nurses or pharmacists (52%) hospital management (45%), regional or local authorities (6%), national patient safety agencies (4%) or health ministries (3%).

Call N. 3 – Risk prevention to minimise adverse events – through:

- Effective prevention and planning strategies to prevent adverse events;
- Tackling faulty systems, processes and conditions that lead people to commit mistakes or shortage of prevention.

Up to the 17% of all hospitalizations are affected by one or more adverse events, within 30% - 70% are potentially preventable.¹ Medication errors are the single most common preventable cause of adverse events in medication practice and a major public-health burden with an estimated annual cost between 4.5 billion and 21.8 billion Euros. They can occur at any stage of the medication delivery process, from prescription to administration and those occurring at the administration stage are the hardest to be intercepted.² Evidence on medical errors shows that 50% to 70.2% of such harm can be prevented through comprehensive systematic approaches to patient safety.

On any given day, about 80.000 patients have at least one healthcare-associated infection (HAI), i.e. one in 18 patients in a European hospital. Recent work by the World Health Organization (WHO) shows that surgical site infection (SSI) is the second most frequent type of HAI in Europe.

Statistics show that strategies to reduce the rate of adverse events in the European Union alone would lead to the prevention of more than 750.000 harm-inflicting medical errors per year, leading in turn to over 3.2 million fewer days of hospitalization, 260.000 fewer incidents of permanent disability, and 95.000 fewer deaths per year.³ Biosecurity measure, such as clear indications regarding the classification of disinfectants to be used for skin antisepsis before surgery and injection, recommendations dedicated to prevention of administration medication errors, innovative technologies to avoid cross contamination, infection control programme, training, eHealth solutions, active

¹ OECD, op. cit. p.23

² European Medicines Agency, Press Release: Tackling medication errors: European Medicines Agency workshop calls for coordinated EU approach, 1st March 2013.

³ The World Health Organisation, Data and statistics <http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/data-and-statistics>

surveillance systems for key resistant to screen patient and healthcare workers for resistant bacteria can reduce the incidence of adverse events and ultimately save lives.

Call N. 4 – Surveillance systems and data availability – through:

- A European scheme to consolidate and share science-based data regarding adverse events in order to make data more comparable;
- Developing tailor-made patient safety indicators across the EU;
- Regular knowledge exchanges among Member States and EU institutions for shaping effective policies and practices.

Regular surveys, consistent surveillance networks, interoperable at local and national level, and other monitoring mechanisms will allow meaningful comparisons between institutions and will represent key guidance for policymakers in shaping strategies on the prevention and control of healthcare associated infections.¹

Having a regular and consistent monitoring mechanism will also help decision-makers to assess the considerable financial impact of safety failure and eventually make effective choices. About 15% of total hospital activities and costs are direct results of adverse events, ranged between 0.2% - 6% share of public hospital spending.²

Once effective surveillance mechanisms and report systems are in place and the lack of data is addressed, it is essential to develop a common scheme to consolidate and share the resulting findings and comparable data across the EU.

The majority of civil society acknowledged the promotion of transparent and comparable data (e.g. about negative results in clinical trials, accountability of health care services and explicit reference and inclusion of anti-microbial resistance) as a key action on patient safety.³

The current lack of consolidate and available data on prevalence and cost of adverse events in each EU country is considered one of the many challenges for assessing patient safety in Europe. Most of the literatures and statistics are available on non-EU states (e.g. US, Canada) while Europe experiences a small number and high-varied published figures on adverse events. National figures on adverse events are usually taken from few hospitals, while numbers and costs of adverse events are known to vary substantially across a single State.

Ultimately, patients and healthcare professionals will both benefit from an increased exchange of information, EU-wide collection of data and sharing of best practice. Comparable and aggregate data to be shared at EU level on patient safety programmes, quality level, structures and policies, and best practices are likely to facilitate the development of mutual learning, common terminology and indicators and, most importantly, the overall quality of healthcare.⁴

¹ Council of the European Union, 2009, op. cit. Recital 15

² OECD, op. cit. p. 9

³ European Commission, Report on the Public Consultation on patient safety and quality care, 2014

⁴ European Commission, Communication on patient safety, including the prevention and control of healthcare-associated infections, COM(2008) 836.

The Council has already called *“to gather and share comparable data and information on patient safety outcomes in terms of type and number to facilitate mutual learning and inform priority setting, with a view to helping Member States to share relevant indicators with the public”*¹

The creation of different partnerships with research and innovative institutions, healthcare institutions and universities in different Member States to develop a standardized and integrated system to collect data based on similar indicators would help to provide more statistical data affecting patient safety. This data would also be helpful to identify areas of action based on defined priorities.

This recommendation should be also applied to researches and publications on patient safety (at a national and EU level). European studies asset that healthcare setting and decision-makers will benefits from a common database where national health institutions, research centres and services showcase their research findings, surveys and studies on best practices.²

It is worth mentioning that the lack of existent data also relates to poor training and education of health care professionals (HCPs) on reporting of adverse events and its impact on patient outcomes and public health. It is relevant to provide to HCPs educational tools that could help not only to train them with standards of reporting on safety information, but also on how that can impact better treatment decisions, reduce preventable adverse events, reduce percentage of hospitalizations and costs for the national health systems, and contribute to better inform patients and increase their quality of life.

Call N. 5 – Guarantee the rights to personalised treatment – through:

- Increased use of approved treatments and innovative technologies according to the medical need of patients and empirical advice of practitioners;
- Uptake of innovative technologies and treatments that work best for individual patients in order to prevent or minimise adverse events and wrongly administered treatment;
- More mutual learning initiatives aiming at identifying related clinical best practices.

EU citizens consider treatment that works as the second most important criteria on high quality healthcare.³ The EU regulatory system is based on the comprehensive assessment and approval of medical products, accompanied by detailed descriptions of how medicines and technologies should be used.

Personalised healthcare is considered more effective and it helps to reduce error and the length of hospitalisations. It provides targeted treatment to patients, allowing the right therapy to reach the right patient at the right time. Physicians should be able to prescribe the best therapy for a patient guided by therapeutic assessments and free of economic burdens and decisions driven by other parts of the healthcare system, such as hospital administrators.

¹ Council of the European Union, op. cit. Article 5(c)

² European Commission, February 2016, loc. cit.

³ Eurobarometer, loc. cit.

The current limitations of personalised treatment require investments to uptake innovative technologies and further strengthen research in this field. In Europe, not all patients have access to innovative methods of better-targeted diagnosis and treatments: according to the Council, this lack is a significant challenge that Member States need to address.¹

Most Europeans believe that innovative technologies are crucial to reduce avoidable adverse events. The Council has already called upon Member States to work closely with the health technology industry to encourage better design for patient safety in order to reduce adverse events.²

Learning initiatives and continuous training of healthcare professionals on new medicines and ground-breaking technologies are thus essential to help the healthcare staff to provide effective and personalised treatment to patients.

Last, but not least, the right to quality health services, enshrined in the Charter, requires healthcare settings and professionals to provide satisfactory levels of performance, comfort and human relations; needless to say, that the quality of these provisions are directly linked to the specific need of a patient.³

Call N. 6 – Respect the right to information – through:

- Clear guidelines at national level on patient informed consent for all treatments to allow patients to make informed decisions based on professional advice;
- Measures to facilitate patients' access to their medical dossiers and clarify their legal rights in case of adverse events.

The EU law guarantees to every patient the right to receive information on safety and quality standards and to get a copy of medical records, in order to secure continuity of care across borders. Member States and health settings shall allow patients to make informed decisions by providing them with information on their rights to healthcare as well as on the quality and safety of care.

As it was also recalled by the Council, national authorities shall guarantee dissemination of information on patient safety standards in place, potential risks and best practices.⁴ Notwithstanding some improvements, the situation in Member States is still fragmented, and the European Commission has identified this issue as a critical area for further EU work, recommending the development of common guidelines on how to provide information to patients on quality of care.⁵

Finally, according to several EU-wide studies, there is still need for more transparency on how facilities ensure patient safety in their organisations and quality outcome measures in a public accessible website or database, in order to inform citizens and patients and eventually allow them to make informed decisions.⁶

¹ Council of the European Union, Council Conclusion on personalised medicine for patients, 15054/15, 7 December 2015

² Council of the European Union, 2009, op. cit. Article 17

³ Active Citizens Network, European Chart of Patient Safety: basis document, November 2002. http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf

⁴ Council of the European Union, 2009, op. cit. Article 4(d)

⁵ European Commission, June 2014, loc. cit.

⁶ European Commission, February 2016, loc. cit.

Call N. 7 – Uptake evidence-based medicines and technologies – through:

- The use of evidence-based medicines and medical technologies to decrease any potential harm.

If used correctly, medicines and medical technologies provide opportunities to prevent patient harm and enhance patient safety in hospitals. Their use shall be in line with official guidance on which products are appropriate for which treatments. In order to provide effective and targeted treatments, healthcare professionals and healthcare management shall follow evidence-based procedures on use of such products to decrease any potential harm associated with the delivery of care.

Evidence-based methodology in the field of public health has been defined as ‘...*the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients*’.¹ Specifically, according to the European Centre for Disease Prevention and Control (ECDC), evidence-based medicine includes five stages: 1) defining the health problem; 2) searching for evidence; 3) assessing the quality of the evidence; 4) implementing the evidence; and 5) monitoring and evaluation.²

Evidence-based practices rely on continuous research and on the uptake of innovative solutions: the implementation of innovative and reliable technologies should represent the pillar of evidence-based methodology in healthcare.³

Call N. 8 – Provide smarter and safer healthcare systems – through:

- Reliable eHealth solutions to receive more personalised ‘citizen-centric’ healthcare;
- The use of new technologies, for example electronic patient records, electronic prescriptions and health cards, to reduce wrongly administered treatments and adverse events.

As it was pointed out by the Council Recommendation on Patient Safety, “information and communication technology tools, such as electronic health records or e-prescriptions, can contribute to improving patient safety, for instance by systematically screening for potential medicinal product interactions or allergies”. eHealth instruments have a great potential in improving healthcare performance as well as in term of understanding the medical products.⁴

In addition, the European Parliament has highlighted the high potential of IT technologies for “improving the quality and efficiency of medical treatments while contributing to better healthcare performance”: there is some evidence that eHealth can reduce the risk of adverse events by tracking information flows and improving the understanding of procedures. Therefore, the European Parliament called Member States to further explore the varied possibilities offered by eHealth in patient safety (e.g. electronic patient records, health cards, mobile health, computerised prescription, etc.).⁵

¹ Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996 Jan 13;312(7023):71-2.

² European Centre for Disease Prevention and Control, Evidence-based methodologies for public health – How to assess the best available evidence when time is limited and there is lack of sound evidence, 2011.

³ Ibid.

⁴ Council of the European Union, 2009, op. cit. Recital 12.

⁵ European Parliament, loc. cit.

The position of the Parliament has been additionally endorsed by EU citizens as reported by the findings of the Public Consultation on patient safety that recognised eHealth as one of the major drivers of better healthcare quality, despite eHealth tools are still not sufficiently used for patient safety.¹

Call N. 9 – Protect personal data – through:

- The protection of privacy of patient records in order to build trust in eHealth solutions and facilitate the exchanges of information and lessons learned on adverse events.

Effective data protection is vital for building trust in eHealth: without it, cross-border deployment, exchange of health data and cooperation between healthcare settings are not feasible.

As it has been recalled several times by the European Data Protection Supervisor (EDPS), the data protection legal framework should be considered not only in respect of the transfer and exchange of personal data but also in respect of the collection of data. As a cornerstone of patient empowerment and protection, it is vital to provide patients with clear information about the processing and collection of their data in eHealth applications.

Technology is linked to data protection and should not be seen as a barrier to the deployment of eHealth but as a main enabler of trust.²

Since the adoption of Directive 95/46/EC, EU countries must apply common rules on the protection of individuals with regard to the processing of personal data and on the free movement of such data.³ However, technology moves fast, so the challenges that legislators need to cope with (e.g. cloud computing, wellbeing data processing, big data collection, etc.). Member States shall assess their laws on electronic health records and, if and where needed, review data protection rules with a view to modernising and strengthening their harmonisation at national and EU level.

Call N. 10 – Increase resources for healthcare staffing – through:

- Proper working conditions for all healthcare professionals, which are essential for reducing risks for patients and promoting a culture of continuous learning on patient safety;
- Patient safety fully included in the standard training of health professionals;
- Effective support and training to ensure the safest use of new medical technologies.

Healthcare staffing is the cornerstone of any strategy aiming at reducing risks to patients: an adequate number of qualified professionals in each healthcare setting is essential to ensure patient safety. There is good evidence that the increases in adverse events have been directly correlated to low levels of staffing.⁴

¹ European Commission, Report on the Public Consultation, 2014, loc. cit.

² European Data Protection Supervisor, Opinion of the on the Communication from the Commission on eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century https://edps.europa.eu/sites/edp/files/publication/13-03-27_ehealth_action_en.pdf

³ European Parliament and of the Council, Directive 95/46/EC of the on the protection of individuals with regard to the processing of personal data and on the free movement of such data, 24 October 1995.

⁴ Canadian Health Services Research Foundation. Staffing for Safety: A synthesis of the evidence on nurse staffing and patient safety, September 2006. http://www.ccpnr.ca/PDFs/Nurse_Staffing_and_Patient_Safety_2006.pdf

Across the EU, everyone has the right to be treated by qualified healthcare professionals, be they doctors, dentists, nurses, midwives or pharmacists. The Council has already called the Member States to enhance multidisciplinary patient safety education and training of all health professionals and relevant management and administrative staff in healthcare settings.¹

Civil society gives great value on the education of healthcare staffing: according to the latest Eurobarometer survey on patient safety, well-trained staff is recognised as the main criterion (53%) for high quality healthcare.

Despite the Council Recommendation and the EU citizens' emphasis on education, the European Commission assessed that training of health professionals still remains an area under-implemented that urges further effort. Most EU countries reported that they encouraged multidisciplinary education programmes on patient safety within hospitals, but three quarters do not provide any additional information about the actual delivery of such training.²

Not all academic curricula at university for healthcare professionals (HCPs) include subjects dedicated to patient safety, reporting and management of adverse events. Patient safety should be embedded in healthcare professionals' curricula from the university path to the clinical practice.

The lack of human resources in hospitals makes difficult the allocation of time for the implementation of process optimisation and continuous training on how to manage adverse events. The identification of existing safe clinical practices and good organisational practices in different EU countries could promote the exchange of knowledge related to patient safety practices and safe use of medicines between hospitals and countries. As a result, this would reduce investment of time and human resources in hospitals and enhance culture of best practice, quick learning and multidisciplinary work.

HCPs should also develop the necessary skills and competencies with respect to patient safety in their clinical practice. HCPs safety competences toolkit should be prepared and adapted by healthcare Institutions in EU countries. The toolkit would include, but limited to: development skills and attitudes with respect to safety in daily practice; multidisciplinary cooperation to optimise patient safety and quality of care; risk awareness by anticipating and taking control of potential hazardous situations for patients; clear and open communication with colleagues, patients and caregivers.

¹ Council of the European Union, 2009, op. cit. Article 4(a)

² European Commission, June 2014, loc. cit.

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- Active Citizenship Network
- Aktion Meditech
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- European Federation of Associations of Patients with Haemochromatosis (EFAPH)
- European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA)
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Health First Europe is a non-profit, non-commercial alliance of patients, healthcare workers, academics and healthcare experts and the medical technology industry. We aim to ensure that equitable access to modern, innovative and reliable medical technology and healthcare is regarded as a vital investment in the future of Europe. We call for truly patient-centred healthcare and believe that every European citizen should benefit from the best medical treatments available.

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