

# Briefing Paper on Patient Safety

## with a focus on the role of patients and families

European Patients' Forum

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## Introduction

Patient safety has been a priority for EPF since the founding of our organisation. EPF believes that patient safety is everyone's business. Patient safety goes to the heart of the work for equitable patient-centred healthcare across EU. The [EPF Strategic Plan 2014-2020](#) focuses on safety within a broader approach of patient-centred healthcare under one of the six strategic goals.

### *GOAL 2: Healthcare Access and Quality*

To contribute to improvements in health systems that enable equitable access to sustainable and high-quality healthcare designed and delivered to meet patients' and informal carers' needs at all levels of care, embracing innovation in all its forms.

Among the key actions to reach this goal, EPF is working to identify solutions to make healthcare systems more sustainable while preserving and strengthening health services' quality, safety and equitable access for all patients.

This paper provides a background for EPF's members and other interested parties on patient safety as an important dimension of quality of care, how this has been addressed in EU policy, and EPF's involvement at EU level. It stresses the importance of patients' empowerment and involvement in improving safety, and some of the challenges involved in realising that.

Please note that this paper deals with the *general concept of patient safety* in the healthcare environment. There are specific issues around the safety of medicines and devices, safety of injections and surgeries, hand hygiene, blood safety, antibiotic resistance, etc. However, these topics require lengthy discussion that goes beyond the scope of this briefing paper.<sup>1</sup> This paper also does not address *negligence or malpractice* (see "Annex: key terms", p. 18).

## What is patient safety and why does it matter?

Patient safety is the foremost attribute of quality of care as defined by the World Health Organization (WHO).<sup>2</sup> It is both a *goal* (a state of being that is free from unnecessary harm) and a *practice* (processes and structures that aim to make healthcare safer).

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<sup>1</sup> On medication errors, see the European Medicines Agency [on this topic](#) and on [pharmacovigilance](#). On other selected patient safety issues, please see [http://www.who.int/topics/patient\\_safety/en/](http://www.who.int/topics/patient_safety/en/). See also EPF's work on pharmacovigilance, falsified medicines, and other medicines and medical devices-related topics, on [www.eu-patient.eu](http://www.eu-patient.eu).

<sup>2</sup> Care that is effective, efficient, accessible, acceptable/patient-centred, equitable and safe. See *Quality of care: a process for making strategic choices in health systems*. WHO, 2006. pp. 9-10. [www.who.int/management/quality/assurance/QualityCare\\_B.Def.pdf](http://www.who.int/management/quality/assurance/QualityCare_B.Def.pdf)

These definitions of patient safety capture both aspects:

**Patient safety:** “the absence of preventable harm to a patient during the process of health care”

**[The process or discipline of] patient safety:** “the coordinated efforts to prevent harm, caused by the process of health care itself, from occurring to patients”.<sup>3</sup>

Safety covers every event that may occur in hospital settings but also in any other healthcare settings, including primary care, nursing homes, or patients’ homes. Some examples include harm caused as a result of a wrong diagnosis, wrong clinical decision or intervention, wrong dose of medicine, side-effects of medicines or other treatments, hazards posed by sub-standard products, human and system failures.

Data on medical errors and adverse events in healthcare show that despite an intense focus on this topic for more than a decade, the levels of incidents have not reduced as much as we would wish.<sup>4,5</sup> The WHO estimates that as many as one in 10 patients is harmed while receiving hospital care in developed countries. The number is higher in less developed countries. At any time, 1.4 million people worldwide suffer from infections acquired in hospitals.<sup>6</sup>

23% of Europeans were directly affected by medical error

18% experienced a serious medical error in hospital

11% were prescribed the wrong medication

(Eurobarometer, January 2006)

Medical errors and healthcare-related adverse events occurred in 8–12% of hospitalisations in Europe.

(RAND Europe, 2009)

Such figures have an impact on patients’ trust in the healthcare system, with around 50% of EU citizens believing there is a risk of being harmed by hospital care. Of them 9% feel this is very likely, and 41% fairly likely. Almost the same numbers felt it was very or fairly likely that they could be harmed in nonhospital care.<sup>7</sup>

Unsafe care has not only consequences for patients’ health and well-being, but also an important economic impact, as revealed in the literature review by the PaSQ Joint Action.<sup>8</sup> It

<sup>3</sup> World Health Organisation, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems*, 2005.

<sup>4</sup> Medical Errors. Special Eurobarometer, January 2006. European Commission, [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_241\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_241_en.pdf)

<sup>5</sup> Conklin, A. Room for improvement; Strong patient safety systems could limit health, social and economic harms from medical error. RAND Europe, 2009 [http://www.rand.org/content/dam/rand/pubs/research\\_briefs/2009/RAND\\_RB9472.pdf](http://www.rand.org/content/dam/rand/pubs/research_briefs/2009/RAND_RB9472.pdf)

<sup>6</sup> “Ten facts about patient safety” at [www.who.int](http://www.who.int)

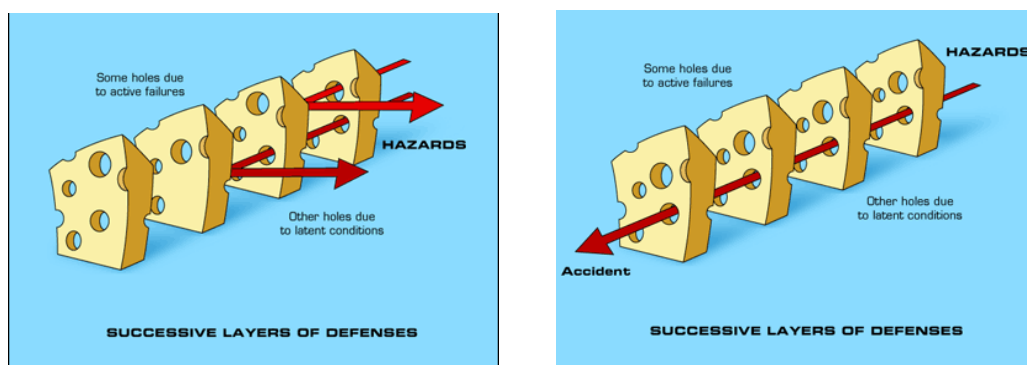
<sup>7</sup> Special Eurobarometer 327, Patient safety and quality of healthcare, April 2010. European Commission, [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_327\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_327_en.pdf)

<sup>8</sup> Taofikat Agbabiaka, José Joaquín Mira, Martina Lietz, Valentina Hafner and Bruce Warner. A literature based analysis of the cost of adverse events to Europe, PaSQ project, 2013.

is estimated that out of the complications due to adverse events identified in 9% of hospital admissions, 44% may be preventable. An estimated 43 million hospitalisation-related adverse events worldwide each year result in 23 million DALYs (disability-adjusted life years, i.e. the years of life lost to disability). The study on whose basis the estimation was done confirmed that preventable adverse events are leading causes of illness and death worldwide, and extra stays in hospital caused by adverse events in the EU and Norway account for some 3.5 million DALYs. Translated into money, the estimated additional cost from preventable adverse events would be €13.7 billion (in 2013).

## Patient safety as a systems issue

Safety incidents in healthcare are often not attributable to only one error, but happen as a result of a “sum of vulnerabilities”.<sup>9</sup> An illustration of this kind of *system failure* in the literature is the so-called “Swiss Cheese Model”<sup>10</sup> which shows how adverse events are caused by a combination of system failures and human errors. In the model, the system is represented by slices of cheese, which normally will be aligned in such a way that the holes do not overlap. Therefore, a safety risk might happen at one layer, but it will be stopped by the next one.



The Swiss Cheese Model

(Source: [http://patientsafetyed.duhs.duke.edu/module\\_e/swiss\\_cheese.html](http://patientsafetyed.duhs.duke.edu/module_e/swiss_cheese.html))

In real life, each “layer” has its vulnerabilities which may result in a safety risk for patients. Examples of such vulnerabilities might be a lack of medical materials, poor communication within the care team, or between the care team and management, lack of updated knowledge or skills of the professionals involved, poor procedures, lack of personnel, overworked staff, lack of supervision, and so on.

<sup>9</sup> World Health Organisation, “WHO Draft Guidelines for Adverse Event Reporting and Learning Systems”, 2005.

<sup>10</sup> Source for the illustration: “Swiss Cheese” Model – James Reason, 1991. The book reference is: Reason, J. (1990) Human Error. Cambridge: University Press, Cambridge. An example of sequential errors as described in the Swiss Cheese Model is available here: [http://patientsafetyed.duhs.duke.edu/popup/module\\_e/swiss\\_cheese.html](http://patientsafetyed.duhs.duke.edu/popup/module_e/swiss_cheese.html)

Over the years it has become evident that “adverse events occur not because bad people intentionally hurt patients but rather that the system of health care today is so complex that the successful treatment and outcome for each patient depends on a range of factors, not just the competence of an individual health-care provider.”<sup>11</sup>

In light of this, addressing safety from a patient perspective is to ensure that the healthcare organisation/system takes all possible measures to prevent vulnerabilities in the care process, communicates openly about errors and “near-miss” situations, analyses them and uses those experiences as continuing learning tools to improve safety. Patients and patient organisations should be involved in these processes and in all aspects of the care continuum, to the extent that they wish to be.

## Patient safety culture

The traditional approach to patient safety incidents stressed putting blame on the individual health professionals and their errors. This is referred to as “blame culture”. It is human nature to wish to identify someone who is to blame; and people tend to believe that punishment works to prevent future incidents. It may also be the only possibility for patients or their families to obtain compensation if there is no “blame-free” system of compensation in place. However, “[s]ystemic improvements cannot be made as long as we focus on blaming individuals. This willingness to assign blame is thought to be one of the main constraints on the health system’s ability to manage risk and improve care.”<sup>12</sup>

As far back as 1999, the ground-breaking report *To Err is Human* recognised that most medical errors are the result of unavoidable human error, and that punishment would not reduce future errors but might achieve the opposite by providing a perverse incentive for professionals to stay silent. “The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. This does not mean that individuals can be careless. People must still be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.”<sup>13</sup>

The key to addressing errors in a healthcare system (which could be an organisation, a unit or a team) is therefore to promote a *patient safety culture*.

<sup>11</sup> [http://www.who.int/patientsafety/education/curriculum/who\\_mc\\_topic-1.pdf](http://www.who.int/patientsafety/education/curriculum/who_mc_topic-1.pdf)

<sup>12</sup> WHO educational information sheet, “What is patient safety?”

[http://www.who.int/patientsafety/education/curriculum/course1\\_handout.pdf](http://www.who.int/patientsafety/education/curriculum/course1_handout.pdf)

<sup>13</sup> *To Err Is Human. Building a Safer Health System*. Executive summary. Kohn LT, Corrigan JM and Donaldson MS, editors. Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, DC, 1999. Available to read online at <http://www.nap.edu/read/9728/chapter/1>

One definition of patient safety culture was developed in the EUNETPAS project, in which EPF was a partner:

“An integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the processes of care delivery.”<sup>14</sup>

Another useful definition is:

“A safety culture is where staff within an organisation have a constant and active awareness of the potential for things to go wrong. Both the staff and the organisation are able to acknowledge mistakes, learn from them, and take action to put things right.

To reduce the likelihood of incidents occurring, patient safety needs to be addressed at an institutional level, ‘from trust board to ward’, as well as by designing out errors in processes and equipment.”<sup>15</sup>

Building a patient safety culture might require changing the attitudes of professionals, developing teamwork, translating research evidence into practice, considering patients as partners in the healthcare process (to the extent they can and wish to participate) and ensuring that expectations for outcomes are realistic and in the best interest of patients. Safety culture starts with recognising the possibility of error and ensuring continuous learning and improvement processes are in place. Senior leadership accountability is very important to build a culture of safety in any organisation.<sup>16</sup>

## Addressing patient safety at the European Union level

In recent years, the European Commission has placed a special focus on quality of care and patient safety, considering the latter as a specific issue independent from quality of care. However, since 2010 there has been a shift towards addressing quality in a broader sense at European level, with special emphasis on the idea that patient safety is an aspect of quality. This has been increasingly accepted by Member States and its priority was confirmed by the public consultation performed as part of the release of the European Commission’s “Patient safety package” in 2014.

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<sup>14</sup> European Society for Quality in Health Care(2006) in EUNETPAS Report on Patient Safety Culture, p. 7 available at [http://ns208606.ovh.net/~extranet/images/EUNetPaS\\_Publications/wp1\\_patient\\_safety\\_culture\\_report\\_focusing\\_on\\_indicators\\_version2.pdf](http://ns208606.ovh.net/~extranet/images/EUNetPaS_Publications/wp1_patient_safety_culture_report_focusing_on_indicators_version2.pdf)

<sup>15</sup> Source: [www.nrls.npsa.nhs.uk/resources/patient-safety-topics/human-factors-patient-safety-culture](http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/human-factors-patient-safety-culture)

<sup>16</sup> Sammer CE1, Lykens K, Singh KP, Mains DA, Lackan NA. What is patient safety culture? A review of the literature. J Nurs Scholarsh. 2010

## The legal framework

EU collaboration on patient is based on two important reference points, the first being the *Council Recommendation on Patient Safety* including the prevention and control of health care associated infections of 2009.<sup>17</sup>

The Council recommendation was developed on the basis of a *2008 Commission Communication* on patient safety (COM(2008) 836 final), which aimed at supporting Member States “to put in place adequate strategies to prevent and control adverse events in healthcare, including healthcare associated infections, and to improve EU citizens' confidence that they have sufficient, comprehensive and comprehensible information on safety and available redress in EU health systems”.

The CR includes a series of specific measures that Member States are expected to implement to improve patient safety. The first part of the Recommendation covers general patient safety issues and the second part refers specifically to the prevention and control of healthcare-associated infections.

EPF has for many years participated actively in the *European Commission's Expert Group on Patient Safety and Quality of Care* and contributed a patients' perspective to the Commission Communication and the subsequent Council Recommendation. The latter contains a special section requiring Member States to inform and empower patients and citizens, and for Member States to involve patient organisations in the development of policies and programmes at national level.

However, in terms of implementation, the Commission identified patient involvement and empowerment as one of the less implemented areas of the CR in its progress reports of 2012 and still in 2014. Other poorly implemented areas

The **legal framework on patient safety** derives from the Treaty on the Functioning of the European Union (TFEU), whose Article 168 stipulates that a high-level of health protection must be ensured in all EU policies and activities.

Different types of legislation derive from the EU competencies as set out in the Treaties: in areas where the EU has no clear powers to pass binding legislation, it relies on so-called “soft law” (Recommendations and Communications) and mutual collaboration/exchange of best practices. Patient safety is such an area, as the responsibility for organisation of health systems and delivery of healthcare remains with the Member States. The CR is therefore not legally binding, but nevertheless has quite a lot of political weight especially since its application has been monitored by the Commission.

The EU can pass directives or regulations to harmonise Member States' laws only in specific areas defined in Article 168(4) TFEU, which include the safety and quality of pharmaceuticals, medical devices, blood, tissues and cells of human origin. The cross-border healthcare is a directive because it has a dual legal basis, deriving both from Art. 168 and from internal market legislation (Art. 114).

<sup>17</sup> [http://ec.europa.eu/health/patient\\_safety/docs/council\\_2009\\_en.pdf](http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf)



are reporting and learning systems, and embedding patient safety in the education and training of professionals.

The second, more recent, reference point for patient safety is the *EU Directive on the application of patients' rights in cross-border healthcare* (Directive 2011/24/EU).<sup>18</sup> The Directive contains important provisions regarding quality and safety of healthcare. For example, it requires Member States to provide cross-border healthcare in accordance with applicable safety and quality standards and guidelines, to provide information to patients on those standards and guidelines, and to collaborate with each other on the development of these. For more information please refer to EPF's extensive policy work on cross-border healthcare, available on our website.<sup>19</sup>

### EU collaboration and exchange of good practices

The collaborative approach in patient safety and quality of care, focusing on exchange of information and sharing of good practices, has been driven mainly by projects co-funded under the EU Health Programme involving Member States and EU stakeholder organisations.

The *European Union Network on Patient Safety and Quality of Care* (PaSQ) was a Joint Action in which EPF was an associate partner. The Joint Action ran from April 2012 until March 2016. The project's objectives were to support Member States in the implementation of the Council Recommendation; initiate co-operation on quality of healthcare; and facilitate the sharing of good practices in patient involvement. PaSQ served to further strengthen co-operation between EU Member States, international organisations and EU stakeholders on issues ...”

#### Excerpt from the 2009 Council Recommendation

[Recommends that Member States]

- “2. Empower and inform citizens and patients by:
- (a) involving patient organisations and representatives in the development of policies and programmes on patient safety at all appropriate levels;
  - (b) disseminating information to patients on:
    - (i) patient safety standards which are in place;
    - (ii) risk, safety measures which are in place to reduce or prevent errors and harm, including best practices, and the right to informed consent to treatment, to facilitate patient choice and decision-making;
    - (iii) complaints procedures and available remedies and redress and the terms and conditions applicable;

<sup>18</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>

<sup>19</sup> For example, the EPF guidance document for patient organisations (2012), position paper (2015) and reports from our series of regional conferences, available at <http://www.eu-patient.eu/whatwedo/Policy/Patients-Mobility/>

transferability, and also supported the implementation of a selection of proven good practices in some Member States.<sup>20</sup>

The PaSQ Joint Action built on the experience of a previous project under the health programme, EUNetPaS (2008-2010) which had led to the establishment of patient safety platforms in several Member States. In that project, EPF was also involved and contributed to the development of *A Guide for Education and Training in Patient Safety*.<sup>21</sup>

## EPF's focus on patient safety

As mentioned in the introduction, patient safety is a core priority for EPF and we are highly active in this field. In addition to the contributions mentioned above, through the European Commission's Expert Group, EUNetPaS and PaSQ, we have worked closely with international organisations and stakeholders on patient safety-related topics.

EPF has long advocated for more action at EU level on quality of care and for the vital importance of the patients' perspective in defining quality. In 2010, EPF contributed to the draft Commission reflection paper "*Quality of healthcare: policy actions at EU level*", which emphasised the importance of patient-centred healthcare and recognised patient involvement as a cross-cutting theme with relevance to most elements of healthcare quality.<sup>22</sup> In February 2014 EPF responded to the *public consultation* launched by DG Sante (then SANCO) to explore the priority areas on patient safety and quality of care at EU level, including whether quality of healthcare should be given more importance in the future.

EPF has also collaborated with the *WHO Regional Office for Europe*, in our role as the EU-level umbrella patient organisation, in the area of patient safety. In 2007, we reviewed the document "National health system quality and safety strategies: guidance for WHO Europe member states", stressing the importance of the need to provide adequate resources for patient organisations in order to enable them to participate in a meaningful way in safety and quality interventions.

In November 2010, we participated in a new initiative on "Patient safety and patients' rights", which explored linkages between patient safety and patients' rights, and particularly the possibilities to improve patient safety by enhancing patient empowerment and health literacy. EPF contributed in a workshop and reviewed the report resulting from this project, which was published by WHO in 2013.<sup>23</sup>

We have consulted our membership on several occasions on their priorities and perceptions

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<sup>20</sup> See the Joint Action website: [www.pasq.eu](http://www.pasq.eu)

<sup>21</sup> For more information see [www.eu-patient.eu/whatwedo/Projects/EUNetPaS/](http://www.eu-patient.eu/whatwedo/Projects/EUNetPaS/)

<sup>22</sup> Commission draft reflection paper no. 9366/10, page 7 (March 2010)

<sup>23</sup> Exploring patient participation in reducing health-care-related safety risks. Available at [www.euro.who.int/\\_data/assets/pdf\\_file/0010/185779/e96814.pdf](http://www.euro.who.int/_data/assets/pdf_file/0010/185779/e96814.pdf)

regarding patient safety. Our *membership survey in 2012-13* focused on checking awareness of the existence of EU recommendations in this field; patient organisations' involvement; and priorities identified by patient organisations at national level. The findings showed that

- Slightly more than half of the respondents (58%) knew about the CR
- Nevertheless many had some role in developing patient safety information or participating in consultations in their country
- Patient involvement was seen as a poorly implemented area of safety
- EPF was by far the most common source of information on EU recommendations (80%), followed by patient organisations at national level (13%)
- Patient organisations did not receive much information from their national bodies
- Patient organisations were seen as important source of capacity-building for patients in patient safety.

## The patients' role in patient safety

The Commission's second implementation report on patient safety (2014) recognised that the experiential knowledge of patients and families is a valuable resource for health professionals and that this experience should be gathered as an element of quality improvement systems. Patients' involvement is also vital for instilling a patient safety culture in the healthcare system.<sup>24</sup>

EPF would like to see patient organisations take a more active stance on patient safety at policy level. Nevertheless, we acknowledge the challenges related to individual patients' involvement in this area and the need for empowerment.

Patients play a vital role in the management of chronic conditions. They live with their condition every day and become experts through lived experience, on the condition itself and its impact on their life, the impact of treatments, and the positive aspects as well as failures of the healthcare system which they rely on a regular basis.

Supporting and promoting the ***meaningful involvement of patients***, both individually and collectively in improving patient safety, is one of the priorities for EPF. "Meaningful patient

### Seven Steps to Patient Safety

1. Safety culture
2. Lead & support staff
3. Integrated risk management
4. Promote incident reporting
5. *Involve patients and the public*
6. Learn and share lessons
7. Implement solutions

Source: NHS (UK) National patient safety agency – guidance [document](#) (2004)

<sup>24</sup> Reports of sub-groups of the PSQC WG on education in patient safety and reporting-learning systems, April 2014. Available at [http://ec.europa.eu/health/patient\\_safety/policy/package\\_en.htm](http://ec.europa.eu/health/patient_safety/policy/package_en.htm)

involvement” as defined by EPF<sup>25</sup> is based on the premise that patients have a *specific expertise* derived from lived experience – simply from being patients, which is a valuable source of *experiential knowledge*. The patient’s perspective is not the same as the lay/consumer perspective. The patient’s knowledge is derived from living with a condition day-to-day and from being in frequent contact with the healthcare system.

For the PASQ Joint Action, the following definition of patient involvement was developed on the basis of Value+:

**Patient involvement** refers to “the extent to which patients and their families or caregivers, whenever appropriate, participate in decisions related to their condition (e.g. through shared decision-making, self-management) and contribute to organisational learning through their specific experience as patients (e.g. patient reporting of adverse events or participation in root cause analysis related to their care).

**Collective patient/public involvement** is the extent to which patients and citizens, through their representative organisations, contribute to shaping the health care system through involvement in health care policy-making, organisation and delivery.”<sup>26</sup>

Let us deal with *collective involvement* first. At collective level, patient organisations play a role in informing and educating the patient community as well as conveying patient feedback to health professionals. They are effective at advocacy, with direct and regular contacts with their grass-roots community. Through channelling their members’ direct experiences, patient organisations are able to represent their views and concerns at health policy level, ensuring that health services are developed with the patient at the centre and that they meet the patients’ real needs and preferences.

Through advocacy and participation in health policy making, patients and patient organisations can be involved in shaping healthcare systems to be more patient friendly and empowering to patients. Levels of meaningful involvement are often illustrated by the “ladder” model first developed by Arnstein in 1969<sup>27</sup> (see illustration, below). This model has been variously adapted, including for patient involvement in research by the PatientPartner project.<sup>28</sup>

At *individual level*, patients can contribute by getting actively involved in their care. Their experience of their healthcare journey is a rich resource of information and learnings about gaps and failures in the system and can function as a “last safety barrier”. Patients observe

<sup>25</sup> “Patients take an active role in activities or decisions that will have consequences for the patient community, because of their *specific knowledge and relevant experience as patients*. The involvement must be planned, appropriately resourced, carried out, and evaluated as to its outcomes, impact and the process itself, according to the values and purposes of all participants.” (EPF project “VALUE+”, 2009).

<sup>26</sup> European Patients Forum for PaSQ project, adapted from the Value+ project

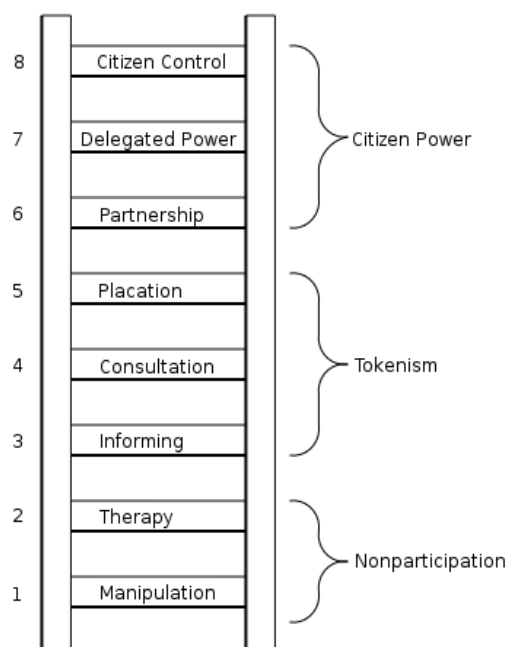
<sup>27</sup> Arnstein, Sherry R. "A Ladder of Citizen Participation," *JAIP*, Vol. 35, No. 4, July 1969, pp. 216-224. Accessed at <http://lithgow-schmidt.dk/sherry-arnstein/ladder-of-citizen-participation.html>

<sup>28</sup> PatientPartner (2010) project funded under EU FP7. [www.patientpartner-europe.eu](http://www.patientpartner-europe.eu)

much during their journey; health professionals should take this seriously, give patients opportunities to speak, listen to what they have to say, and take action.

An important caveat regarding individual patients' involvement is that each person's individual circumstances and preferences should always be respected. Some patients do not wish to get involved. Patients are already burdened with having a disease and having to cope with treatment, being in hospital, etc. The risk of emphasising individual patient involvement is that the burden of responsibility may be inappropriately shifted from the professionals to the patient, even if this is not the intention.

In our view, the responsibility for safety should never be shifted inappropriately onto the shoulders of the patient. While patient involvement is in principle something positive and should be promoted, and whilst many patients would be happy to take a more active role in managing their condition and controlling their life, they should always have the right to "opt out" as it were.



**Arnstein's ladder of participation**  
(see reference no. 26)

Literature indicates that patients' willingness to get involved varies, for example people in an acute situation or facing a very severe illness are less willing and able to be involved in decision-making, whereas patients who are managing chronic conditions routinely are more willing and able to do so even in a hospital environment, which can often be profoundly disempowering for patients. Other factors include characteristics of patients, such as demographic characteristics, and the attitude of health professionals.<sup>29,30</sup> Communication is an opportunity and a risk factor for patient safety: patients facing communication difficulties and language barriers are more exposed to safety issues.<sup>31</sup>

Equipping patients with the capacity to take active part in their care and creating an enabling environment for this to happen – **patient empowerment** – requires committed efforts and a change in attitudes from health professionals regarding the "proper role" of patients. Health

<sup>29</sup> Lawton, Rebecca and Armitage, Gerry, The role of the patient in clinical safety. The Health Foundation, May 2012.

<sup>30</sup> Davis, R. E., Jacklin, R., Sevdalis, N. and Vincent, C. A., Patient involvement in patient safety: what factors influence patient participation and engagement?. Health Expectations. 2007

<sup>31</sup> Kingston-Riechers J, Ospina M, Jonsson E, Childs P, McLeod L, Maxted J. Patient Safety in Primary Care. Edmonton, Alberta: Canadian Patient Safety Institute & BC Patient Safety and Quality Council; 2009.

professionals should be trained to become more aware of the needs of their patients, including those of communication and information, the capacity to provide feedback, and level of knowledge and skills. These measures are part of building a patient safety culture.

It is also crucial to empower patients in all aspects of health and care through high-quality information and by building **health literacy**. Health literacy is a key dimension of patient empowerment, and highly relevant to patient safety.<sup>32</sup> Low health literacy is associated with reduced use of preventive services and management of chronic conditions, and higher mortality.<sup>33</sup> It can also lead to problems such as medication errors, misdiagnosis due to poor communication between providers and patients, low rates of treatment adherence, hospital readmissions, and other related complications or conditions.<sup>34</sup>

Health literacy entails people's knowledge, motivation and competencies to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course.<sup>35</sup>

Health literacy also supports patients in becoming aware of their experience and role, further channelling their input into the daily experience, such as participating in *shared decision-making* concerning treatment.<sup>36</sup> It is not only about patients as recipients of information, but also about patients finding the confidence and the language which allows them to participate in the care process to the extent that they wish to do so.

On 21 November 2013, EPF organised an *internal workshop with our members*, with the aim of planning future activities on patient involvement in patient safety. Participants gave the following recommendations:

- Patient involvement in patient safety should start from the provision of understandable, accessible and reliable information
- Patients should have opportunities during their interactions with healthcare – the patient journey – to speak up about any aspect of their condition or treatment, without being labelled as “difficult patients”.

<sup>32</sup> See EPF paper on patient empowerment (2014) available at [www.eu-patient.eu/whatwedo/EPFCampaign2014Elections/Background-papers/](http://www.eu-patient.eu/whatwedo/EPFCampaign2014Elections/Background-papers/)

<sup>33</sup> Berkman ND et al., Literacy and Health Outcomes; AHRQ; Rockville, MD, 2004

<sup>34</sup> Nielsen-Bohlman L, Panzer AM, Kindig DA (2004), A Prescription to End Confusion. Project brief; Vernon JA, Trujillo A, Rosenbaum S, DeBuono B (2007). Low health literacy: Implications for national policy. [http://publichealth.gwu.edu/departments/healthpolicy/CHPR/downloads/LowHealthLiteracyReport10\\_4\\_07.pdf](http://publichealth.gwu.edu/departments/healthpolicy/CHPR/downloads/LowHealthLiteracyReport10_4_07.pdf)

<sup>35</sup> Sorensen K et al., Health literacy and public health: A systematic review and integration of definitions and models BMC Public Health. 2012

<sup>36</sup> “a collaborative process that allows patients and their providers to make healthcare decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.” Informed Medical Decisions Foundation, <http://www.informedmedicaldecisions.org/what-is-shared-decision-making/>

- An important area to be addressed is the patient-professional relationship, particularly some doctors' attitudes towards the patient.
- Education on patient safety should be also directed towards parents and carers. Their awareness of preventable errors would benefit patients as well as healthcare organisations.
- There might be opportunities for healthcare organisations to gain input from patients through introducing Patient Advisory Boards, “virtual offices” or patient social networks.

## Conclusions and next steps

Patient safety as a concept is under discussion for many years being considered an important dimension of the quality of care. Patient safety as a discipline and practice has gained momentum in recent years, being stimulated by research but also by EU recommendations issued on the topic and related legislation. However, although the 2009 Council Recommendation includes very specific actions in relation to patient safety, progress to implement them in the Members States is variable.

Patient involvement in patient safety, a necessity for the health systems, needs to become a reality and part of a shift towards a patient/person-centred healthcare approach. Patients are often referred to as “the most underused resource” for improving the quality and efficiency of healthcare. They can play an active role in care, becoming partners or “co-producers” of well-being and safety. Patients, families and carers to their representative organisations also play an important role in awareness raising and capacity building around safety and quality of care.

More broadly, EPF views safety as one fundamental aspect of *quality of care*. Patients' participation in evaluating and co-designing healthcare services can ensure improved quality and patient-centredness. The Third EU Health Programme in fact states that “Healthcare practices should be informed by feedback from, and communication with, patients.” (Regulation (EU) No 282/2014, recital 12).

EPF believes that the patient-prioritised outcomes as well as the patient experience of care should be included as indicators for assessing the quality of healthcare and health systems' performance. This does not mean using “patient satisfaction surveys” as a tick-box exercises, the incorporation of meaningful measures – including, where necessary, qualitative – for outcomes and care processes.

### EPF survey on patient perceptions of quality in healthcare

Based on our many years of involvement in EU policy around safety and quality of care, EPF developed in 2015 a study on “Patients' perceptions of quality of in healthcare”. The survey

aims to explore the key dimensions of quality identified in literature from a patient perspective, with the aim of developing policy recommendations on quality of care.

The report from the survey will be published at the end of 2016. With this work we aim to contribute to the European debates around quality, including a possible common definition of quality of care, and prepare the ground for discussions on appropriate indicators for measuring patient-centredness of healthcare and patient empowerment. The survey is also closely linked to EPF's activities supporting the implementation of the Cross-Border Healthcare Directive.

### **Special focus on patient safety: EPF work plan for 2016-2017**

Patient safety is one of EPF's priority areas under the "Access to high-quality healthcare" theme. In 2016, EPF will organise a capacity building workshop for our members interested in working with us on patient safety. In late 2016 we will hold a conference at EU level on "The patients' role in patient safety".

Following the conference and building on its outcomes, we will launch a task force with patient representatives and other stakeholders to develop a set of "core competencies" for patients and families to empower them in the area of safety, as foreseen in the Council recommendations of 2009.

We will also continue as active member of the European Commission's Expert Group, reformulated in 2015, which advises the Council working party on public health issues at senior level in developing the EU patient safety and quality agenda. Our work with the European Medicines Agency will continue to address medicines-related safety issues. We also participate in tender projects on self-care, both in minor conditions (PISCE) and in chronic conditions (PRO-STEP).

Patient representatives who are interested in the topic of patient safety can email us at: [policy@eu-patient.eu](mailto:policy@eu-patient.eu)



## Further information

### General information about patient safety

WHO Patient Safety Curriculum Guide - Handouts: Patient safety topics

[http://www.who.int/patientsafety/education/curriculum/Curriculum\\_Tools/en/index1.html](http://www.who.int/patientsafety/education/curriculum/Curriculum_Tools/en/index1.html)

WHO safe surgery campaign page

<http://www.who.int/patientsafety/safesurgery/en/>

WHO infection control and hand hygiene page

<http://www.who.int/gpsc/en/>

### Patient engagement in patient safety

WHO toolbox

[http://www.who.int/patientsafety/patients\\_for\\_patient/resources/en/](http://www.who.int/patientsafety/patients_for_patient/resources/en/)

WHO patients for patient safety videos

[http://www.who.int/patientsafety/patients\\_for\\_patient/videos/en/](http://www.who.int/patientsafety/patients_for_patient/videos/en/)

Leaflet for patients “What you need to know before and after surgery”, WHO patient information for surgical safety

[http://www.who.int/surgery/publications/patients\\_communication\\_tool.pdf?ua=1](http://www.who.int/surgery/publications/patients_communication_tool.pdf?ua=1)

Hand hygiene campaign: the patients’ voice (WHO)

[http://www.who.int/gpsc/5may/5may2013\\_patient-participation/en/](http://www.who.int/gpsc/5may/5may2013_patient-participation/en/)

“Ask Me 3: Good Questions for Your Good Health”, an educational programme that encourages patients and families to ask three specific questions of healthcare providers. National Patient Safety Foundation, United States: <http://www.npsf.org/?page=askme3>

### Patient involvement and empowerment

EPF background briefing on patient empowerment

[http://www.eu-patient.eu/globalassets/campaign-patient-empowerment/briefing\\_paperpatient-empowerment\\_final\\_external.pdf](http://www.eu-patient.eu/globalassets/campaign-patient-empowerment/briefing_paperpatient-empowerment_final_external.pdf)

Value + materials on meaningful patient involvement

<http://www.eu-patient.eu/whatwedo/Projects/ValuePlus/>

## Annex: Key terms

Below we give some definitions of commonly used terms in patient safety, which were not addressed in the paper itself. (Please note these are not the only possible definitions, but we find useful for the purposes of this paper)

### **Adverse event**

“An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.” The term is sometimes used interchangeable with *incident* or *adverse incident*.<sup>37</sup>

### **Patient safety incident**

Any healthcare-related event that was unintended, unexpected and undesired and which could have or did cause harm to patients. This is different from adverse event because it includes also *near misses*. Near-misses or “close calls” are defined serious errors or mishaps that had the potential to cause an adverse event but failed either by chance or because it was noticed before harm occurred.<sup>38</sup>

### **Harm**

Harm refers to a patient’s health or quality of life which is negatively affected by any aspect of their interaction with healthcare. Some incidents of harm are preventable, while others are recognised as complications of care, e.g.: an allergic reaction to medication. The severity and impact of (unintentional) harm can range from a brief inconvenience and self-limiting symptoms, to hospitalisation, disabling injury, or even death.<sup>39</sup>

### **Error**

The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning). Errors may be *errors of commission* (doing something) or *omission* (not doing something), and usually reflect deficiencies in the systems of care. Errors are unintentional.<sup>40</sup> *Latent errors* are defects in the design, organisation or maintenance in the system that lead to operating errors, typically with some time delay.<sup>41</sup>

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<sup>37</sup> World Health Organisation, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems*, 2005.

<sup>38</sup> Ibid.

<sup>39</sup> <http://www.evidenceintopractice.scot.nhs.uk/patient-safety/what-is-patient-safety.aspx>

<sup>40</sup> National Health Services Scotland: <http://www.evidenceintopractice.scot.nhs.uk/patient-safety/what-is-patient-safety.aspx>

<sup>41</sup> World Health Organisation, “WHO Draft Guidelines for Adverse Event Reporting and Learning Systems”, 2005.

### ***Negligence***

Negligence is a type of *violation*; a conscious deviation from accepted standards of practice (whether by action or omission), for example deliberately inadequate record-keeping because the person in charge is “too busy”.<sup>42</sup> (Please note that legal definitions of negligence in a healthcare context will be different depending on national legislation)

### ***Medical malpractice***

Malpractice is defined by Wikipedia as “legal cause of action that occurs when a medical professional deviates from standards in his or her profession, thereby causing injury to a patient.” It is therefore a legal term and will be defined differently according to national legislation.

### ***Sentinel event***

This term is sometimes seen in patient safety literature and it refers to “any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness. Sentinel events specifically include loss of a limb or gross motor function, and any event for which a recurrence would carry a risk of a serious adverse outcome. Sentinel events are identified under [The Joint Commission] accreditation policies to help aid in root cause analysis and to assist in development of preventative measures.”<sup>43</sup>

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<sup>42</sup> NHS Scotland, <http://www.evidenceintopractice.scot.nhs.uk/patient-safety/what-is-patient-safety.aspx>

<sup>43</sup> Wikipedia, source: Joint Commission. The Joint Commission is a US-based non-profit organisation that accredits more than 21,000 healthcare organizations and programmes in the United States.