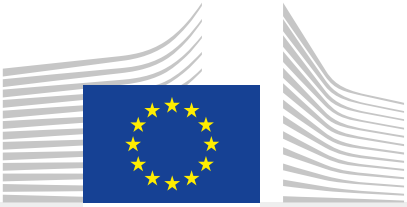

INFORMATIVE TEXT

Quality and safety standards

Health and Food Safety

Informative text

Quality and safety standards

This informative text aims to provide National Contact Points for Cross-border Healthcare (NCPs) with information on quality and safety standards within the EU. As set out below, Directive 2011/24/EU places obligations on NCPs in providing information on quality and safety standards towards patients.

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① Introduction

Directive 2011/24/EU on patients' rights identifies **quality of care** as a possible motivation for patients in accessing health services abroad, as it aims to establish rules for facilitating access to safe and high-quality cross-border healthcare.[1] This is in line with the findings of the special Eurobarometer 425 on patients' rights in cross-border healthcare, where receiving better quality treatment was identified as the second main reason for seeking treatment abroad, after receiving treatment that was not available in the home country.[2]

Patient safety and quality of care can be considered as a serious concern. For example, it is estimated that 8-12% of admitted in EU hospitals suffer from adverse events. Daily, one out of 18 patients in European hospitals have at least one healthcare-associated infection. Yearly, at least 37,000 patients die at the result of such infection.[3]

As FRISCHHUT says, when it comes to quality and safety of healthcare, not only patients' rights and quality of care are highly interdependent, but also **information** on quality is crucial.[4] A lack of information can give raise to multiple challenges for patients. Besides, unsafe care can result in an economic burden for public health systems. More specifically, in 2014 adverse events resulted in an economic burden for the public healthcare sector with a direct cost of EUR 21 billion or 1.5 percent of healthcare expenditure within the EU.[5] As a result, in cross-border healthcare, quality of care can both be considered as a motivation to go abroad, as well as a barrier.[6]

The delivery of healthcare is a responsibility of individual EU countries. However, Member States are expected to guarantee a certain level of quality of care. More specifically, the European Court of Justice has confirmed that one can assume that health services provided according to national regulations in any EU country will be of adequate and equivalent quality.[7]

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[1] Recital 10 and 39, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (hereafter Directive 2011/24/EU).

[2] European Commission, Special Eurobarometer 425 Patients' rights in cross-border healthcare in the European Union, May 2015.

[3] European Commission, Special Eurobarometer 411, Patient Safety and quality of care, 2014, 3.

[4] A. HENDRIKS, "High-quality of care throughout Europe – But Do We Speak the Same Language?", Eur J of Health Law 2016, 14; M. FRISCHHUT, "Standards on quality and safety in cross-border healthcare", in A. DEN EXTER (ed.), *cross-border health care and European Union Law*, 2017, 59.

[5] European Commission, *Costs of unsafe care and cost-effectiveness of patient safety programmes: Final report*, February 2016,

[6] M. FRISCHHUT, "Standards on quality and safety in cross-border healthcare", in A. DEN EXTER (ed.), *cross-border health care and European Union Law*, 2017, 59.

[7] See for example Judgement of 28 April 1998, *Kohll*, C-158/96, EU:C:1998:171, para 47-49; ; Judgement of 28 April 1998, *Decker*, C-120/95, EU:C:1998:167, para 42-43; H. LEGIDO-QUIGLEY, M. MCKEE, K. WALSHE et al., "How can quality of healthcare be safeguarded accross the European Union.", *BMJ* 2008, 920-923.

Directive 2011/24/EU obliges the Member State of treatment to ensure that cross-border healthcare is provided,- taking into account the principles of universality, access to good quality care, equity and solidarity -, in accordance with standards and guidelines on quality and safety laid down by the Member State of treatment.[8] Besides, the member state of treatment has to ensure that patients receive (upon request) from the NCP information on these standards and guidelines, including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards and guidelines and information on the accessibility of hospitals for persons with disabilities.[9]

The Directive 2011/24/EU also prescribes that Member States shall render mutual assistance as is necessary for the implementation of the Directive, including cooperation on standards and guidelines on quality and safety and the exchange of information.[10]

② Definition of quality of care

Several authors have described quality of care as a set of different dimensions: "*the most frequently used dimensions include (in descending order of frequency):* ***effectiveness, efficiency, access, safety, equity, appropriateness, timeliness, acceptability, patient responsiveness or patient-centeredness, satisfaction, health improvement and continuity of care****. These dimensions are, however, neither comprehensive nor mutually exclusive"*.[11] For example the World Health Organisation (WHO) describes quality of care as: "*the extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care must be safe, effective, timely, efficient, equitable and people-centred*"

Besides, patient safety is defined by the Council of Ministers as "*freedom, for a patient, from unnecessary harm or potential harm associated with healthcare*".[12]

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[8] Article 4(1)(b) Directive 2011/24/EU.

[9] Article 4(2)(a) Directive 2011/24/EU.

[10] Article 10(1) Directive 2011/24/EU.

[11] Helena Legido-Quigley et al., *Assuring the Quality of Health Care in the European Union: A case for action*, WHO 2008, 2-5; M. FRISCHHUT, "Standards on quality and safety in cross-border healthcare", in A. DEN EXTER (ed.), *cross-border health care and European Union Law*, 2017, 63.

[12] Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, *0J* C151/1, 2009; M. FRISCHHUT, "Standards on quality and safety in cross-border healthcare", in A. DEN EXTER (ed.), *cross-border health care and European Union Law*, 2017, 63.

③ Impact of EU law on national law[13]

The delivery of healthcare is a responsibility of individual EU countries. However, already for a long time the European Union takes into account the importance of the protection of human health across all policy area.[14] This falls within the competence of the EU for example based on article 114, para 3 TFEU, that states: "*The Commission, in its proposals* [...] *concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective*".

In 2006 the Council has stated the common values and principles, that underpin the health systems of the different Member States, making a difference between the overarching values of universality, access to good quality care, equity and solidarity, and the operating principles of quality, safety, care that is based on evidence and ethics, patient involvement, redress, privacy and confidentiality.[15] As a result, quality is both an overarching value as an operating principle.[16]

The Council conclusion of 2006 states that : "*All EU health systems strive to provide good quality care. This is achieved in particular through the obligation to continuous training of healthcare staff based on clearly defined national standards and ensuring that staff have access to advice about best practice in quality, stimulating innovation and spreading good practice, developing systems to ensure good clinical governance, and through monitoring quality in the health system. An important part of this agenda also relates to the principle of safety*". Besides, the Council conclusion stipulates about patient safety that: "*Patients can expect each EU health system to secure a systematic approach to ensuring patient safety, including the monitoring of risk factors and adequate, training for health professionals, and protection against misleading advertising of health products and treatments*".[17]

Also case law of the European Court of justice has set forth some principles with regard to quality of care. For example, in the Smits and Peerbooms case[18], a Dutch health insurer refused to refund cross-border healthcare as the treatment concerned was experimental and thus "*not regarded as normal within the professional circles concerned*". The Court held, however, that to justify a restriction (on reimbursable cross-border care) it has to been taken into account "what is considered normal according to the state of

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[13] For a broader explanation, see M. FRISCHHUT, "Standards on quality and safety in cross-border healthcare", in A. DEN EXTER (ed.), *cross-border health care and European Union Law*, 2017, p. 59-86; available online at https://www.eaptc.net/Legal-Papers/HC_EU_Law.pdf.

[14] https://ec.europa.eu/health/funding/programme_en.

[15] Council Conclusions on common values and principles in European Health systems, *OJ* C146/1, 2006.

[16] M. FRISCHHUT, "Standards on quality and safety in cross-border healthcare", in A. DEN EXTER (ed.), *cross-border health care and European Union Law*, 2017, 67.

[17] Council Conclusions on common values and principles in European Health systems, *OJ* C146/1, 2006.

[18] Case C-157/99, *Smits and Peerbooms*.

international medical science and medical standards generally accepted at international level". Hereby, the court emphasizes that "*only an interpretation on the basis of what is sufficiently tried and tested by international medical science can be regarded as satisfying* [...]".

All the above-mentioned aspects (TFEU, common values and principles, case law,...) were integrated in the Directive 2011/24/EU on cross-border healthcare, the aim of which is to establish rules for facilitating access to safe and high-quality cross-border healthcare.[19]

④ Practice of quality and safety standards within the European Union

In 2009 the Council published its recommendation on patient safety, including the prevention and control of healthcare associated infections. [20] The Council recommendation prescribes amongst others that member states must support

- the establishment and development of national policies and programmes on patient safety;
- empowerment and informing of citizens and patients (e.g. by disseminating information on which patient safety standards are in place, the right to informed consent, complaints procedures,..);
- the establishment of blame-free reporting and learning systems on adverse events;
- education and training of healthcare workers;
- cooperation on patient safety amongst member states;
- develop and promote research on patient safety.[21]

The report from the Commission to the Council of 2012 showed that a few years after publishing the Council recommendation of 2009, most Member States have taken a variety of actions. All countries have developed specific policies on patient safety. In most member states a competent authority responsible for patient safety at national or regional level has been established by a legal act. Also most countries have reported that they have promoted the education and training of healthcare professionals. Besides, most member states have established a reporting or learning system. The existing reporting systems have been improved in two ways: blame-free reporting and reporting by the patient. However, the report concluded that there is still room for improvement in this area, as well as with regard to patient empowerment and patient safety strategies

[19] Recital 10, Directive 2011/24/EU.

[20] Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, *OJ* C 151/01.

[21] Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, *OJ* C 151/01.

in non-hospital care.[22] In the second report of 2014 it was concluded that the Council recommendation had successfully raised awareness about patient safety at political level. However, it had less impact at healthcare setting level. For example, the education and training of health professionals remains an area needing further effort. Besides, the Commission considered that continued effort is needed with regard to:

- The establishment of a common definition;
- EU collaboration;
- Development of guidelines on how to provide information;
- EU template on patient and safety standards;
- Efforts with regard to redress;
- Encouraging the training for patients, families and informal carers, using also ICT tools;
- Encouraging reporting as a tool to spread a patient safety culture.[23]

In some sectors the European Union has set out a framework for minimum harmonisation on quality and safety standards. More specifically, this is the case in the Directives on blood[24], tissues and cells[25] and organs[26].

FRISCHHUT states that all three directives have a similar approach with regard to rules on quality and safety. The three Directives:

- Require a competent authority, that is responsible for the implementation of the requirements set out in the Directive;
- Set up requirements with regard to qualification and training of the persons concerned who are involved in the described tasks;
- Require inspections and control measures;
- Set out rules for quality management (e.g. on documentation, record keeping, reporting systems,…)
- Establish rules on traceability.[27]

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[22] Report from the commission to the council on the basis of Member States' reports on the implementation of the Council recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated infections, 2012.

[23] Report from the commission to the council: The Commission's Second Report to the Council on the implementation of Council Recommendation 2009/C 151/01 on patient safety, including the prevention and control of healthcare associated infections, 2014.

[24] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, *OJ* L33/30, as amended in 2009, *OJ* L188/14.

[25] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, *OJ* L102/48, as amended in 2009, *OJ* L188/14.

[26] Directive 2010/53/EU of the European Parliament and of the Council of 7 Juli 2010 on standards of quality and safety of human organs intended for transplantation, *OJ* L207/14.

[27] M. FRISCHHUT, "Standards on quality and safety in cross-border healthcare", in A. DEN EXTER (ed.), *cross-border health care and European Union Law*, 2017, 83.

⑤ Guidelines and minimum requirements for information provision on quality and safety by NCPs

Article 4(1)(b) of Directive 2011/24/EU states that:

"*1. Taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare shall be provided in accordance with:*

(a) the legislation of the Member State of treatment;

(b) standards and guidelines on quality and safety laid down by the Member State of treatment; and

(c) Union legislation on safety standards."

Besides, article 4(2)(a) stipulates that:

"*2. The Member State of treatment shall ensure that:*

(a) patients receive from the national contact point referred to in Article 6, upon request, relevant information on the standards and guidelines referred to in paragraph 1(b) of this Article, including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards and guidelines and information on the accessibility of hospitals for persons with disabilities;"

As a result, regardless of the fact that there is still no common definition of quality of care within the EU and guidelines or examples on how to inform patients on quality of care are still very limited, it is within the task of NCPs to comply with their obligations under Directive 2011/24/EU. It is thus important that NCPs try to collaborate and to exchange good practices in this matter. In any case, when information on quality of care or patient safety is requested, NCPs will have to make a continued effort in providing such information. The importance of quality of care and patient safety and the current developments in this field must be kept in mind.

Based on all the above-mentioned, it can be recommended that NCPs provide, upon request, information on:

- ✓ **Information on the applicable quality and safety standards**
  - Which standards apply? (e.g. with regard to evidence-based practices for routine care, discharge, complications, medication use, accessibility of hospitals for patients with disabilities,..)
- ✓ **Information on who sets such standards**
  - Information on the competent authority
  - Is there governmental supervision?
  - ….
- ✓ **Information on which healthcare providers are subject to these standards**
  - Including information on training and qualification
- ✓ **Information on inspections and control measures**
- ✓ **Information on who monitors compliance with these standards**
- ✓ **Information (when available) on the general reputation of hospitals**
- ✓ **Information on the rules on quality management**
  - Information on the rules on documentation, reporting systems, traceability,…
- ✓ **Information on European reference networks and health technology assessment**
- ✓ **….**