

Directive On Patients' Rights In Cross-Border Healthcare

EPF Position Statement

April 2016



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1. Introduction

All EU policies are obliged to ensure a high level of human health protection, whilst the organisation, management, financing and delivery of healthcare remain the responsibility of the EU Member States. (Art. 168 TFEU) Several judgments of the European Court of Justice over the years confirmed that patients have in certain cases the right to access healthcare products and services in other Member States than their own, with the cost being borne by their own health system. To clarify the situation, the European Commission in 2008 published a proposal for a directive on the application of patients' rights in cross-border healthcare. Following a lengthy legislative process, Directive 2011/24/EU was published in the EU official Journal on 9 March 2011. Member states had until 25 October 2013 to implement the Directive in their own laws

EPF engaged intensely with the draft legislation during its development. We believe the final directive, although it fell short of our ambitions, still has the potential to improve access and quality of healthcare if implemented in a patient-centred way by the Member States. Certain aspects of the Directive can be built upon for long-term improvements, such as stronger European cooperation on safety and quality, health technology assessment, eHealth, and European Reference Networks.

EPF has undertaken extensive awareness-raising among patient communities across the EU. We published a toolkit with guidance to patient organisations and recommendations for implementation of the directive in 2012.¹ In 2013-15 we implemented a series of regional and national meetings covering all EU Member States, with the aim to support patient organisations' involvement at national level.²

In September 2015 the European Commission published its first report to the European Parliament and the Council on the implementation of the directive. It also published an evaluative study³ in March 2015 and a special Eurobarometer⁴ in May 2015. The Eurobarometer survey indicated that fewer than 2 out of 10 respondents felt well-informed about their rights in cross-border healthcare. Only one European in 10 was aware of the existence of National Contact Points.

This is consistent with EPF's findings. During our seminars, patient representatives from many Member States said they had not received information about the directive or even knew about the existence of their National Contact Point.

¹ Available at www.eu-patient.eu/whatwedo/Policy/Patients-Mobility/

² A summary report from these events is available at www.eu-patient.eu/globalassets/policy/cross-borderhealthcare/cbhc-summary-report-final_external.pdf

³ http://ec.europa.eu/health/cross_border_care/docs/2015_evaluative_study_frep_en.pdf

⁴ http://ec.europa.eu/public_opinion/archives/eb_special_439_420_en.htm#425

Most Member States were late in transposing and implementing the directive into their national laws, and many have not publicised the directive widely. This is a likely reason for the generally low awareness among EU citizens of their rights.

In addition, several Member States appear not to have applied the directive correctly in key areas such as prior authorisation, administrative procedures, and information to patients: “...there are a considerable number of Member States where the obstacles placed in the way of patients by health systems are significant, and which, in some cases at least, appears to be the result of intentional political choices: some of the current systems of prior authorisation are more extensive than the current numbers of requests would appear to justify; in many cases it is not clear exactly which treatments require prior authorisation; lower reimbursement tariff standards used in the home Member State are a clear disincentive; there are a number of burdensome administrative requirements which may well deter patients.” (Commission’s report, p. 13)

In terms of the numbers of patients travelling abroad for treatment, not all Member States were able to supply data to the Commission and the data collection is not comparable from one country to another. (e.g., some countries report all reimbursements without specifying whether they were given under the Directive or the Regulation.) However, the overall conclusion is that the numbers are still very small. Possible exceptions are France, Luxembourg, Denmark and Finland. (See Commission’s report, p.7)

2. Key areas of the directive identified by patients

The present paper draws on the feedback gathered so far from patient organisations as well as EPF’s previous position papers on cross-border healthcare⁵, which have identified the most important issues from the patient perspective. We have also integrated responses received to our online survey of patient representatives (data collected mostly in Q1-Q2 2015). Although the information is not scientifically validated and there are differences between Member States, we believe overall the feedback received indicates that more needs to be done to ensure that patients everywhere in the EU are well informed about their rights and how to exercise them; and that patient organisations are meaningfully involved at the national level in monitoring the implementation of the directive.

2.1. Patients’ rights

The original purpose of the directive was to clarify patients’ legal rights. However, as based on implementation to date, from the patient perspective this objective has not been achieved.

⁵ available at www.eu-patient.eu/whatwedo/Policy/Patients-Mobility/

EPF believes that patients' rights, equity of access, quality of care and empowerment are inextricably linked— in order for any right to be meaningful, patients need to know they have a right, and it has to be possible to exercise that right in practice.

We recommend that there should be a European-wide framework for monitoring and implementing patients' rights. In particular, there should be a mechanism to address complaints in cases where patients feel their rights have been violated. A patients' Ombudsman could be set up at EU level with a network of ombudsmen in all Member States – some of which already have established patient ombudsman offices.

The EU Executive Agency (CHAFEA) has recently commissioned a study mapping patients' rights across the EU.⁶ Preliminary results indicate that patients' rights systems vary across Member States, and whilst certain rights are well established, there are significant weaknesses in enforcement. In addition, the study did not look at factors that affect people's capacity to make use of their rights in practice (such as information, health literacy and bureaucracy). Once the study is published EPF will engage with the results.

EPF Recommendation:

- The Commission should undertake a regular mapping of patients' rights across the EU, building further on the results of the study commissioned by CHAFEA, when available. The mapping should focus not only on what rights exist in law, but the concrete implementation and enforcement of these rights.
- The possibility to establish a patients' Ombudsman at EU level should be considered, linked to the network of ombudsmen in Member States. The system of patient ombudsmen and their effectiveness at national level should be further studied.
- The Commission should establish a robust data collection framework that collects key data in order to facilitate comparison between Member States (e.g., use of Directive vs Regulation). This should not be too burdensome for National Contact Points to collect.

2.2. Information to patients

Information is both a right in itself and a fundamental prerequisite to exercising one's rights. Information needs are complex, and the current level and quality of what is provided is too often patchy and not geared to patients' needs. A particular challenge is finding the right balance between providing comprehensive information and information that is simple enough to be understood.

"Are patients in your country getting all the necessary information regarding cross-border healthcare (rights and entitlements, reimbursement, difference between directive and regulation, prior authorisation, et cetera)?" (EPF Survey)

YES 27%

NO 72%

⁶ Tender no. CHAFEA/2014/Health/03 concerning mapping patients' rights in all Member States in the European Union.

As a result, patients face a “labyrinth” of confusing, sometimes insufficient and sometimes too detailed information.

The EPF report from our regional conferences provides an overview of what questions patients would have and what information they would need at different stages of their decision-making and the “patient journey”.⁷

Information can also be a politically sensitive subject. Whilst some member states have taken on board the importance of providing comprehensive information to patients, some others appear to have taken the approach of providing minimal information and not communicating the existence of the National Contact Point effectively to their citizens. The quantity and quality of information that NCPs are providing at the moment is variable, as shown by the EC evaluative study.

Being able to compare different options is vital. Information about the financial aspects of cross-border healthcare is particularly important for patients to be able to make a meaningful choice.⁸

The EU evaluative study showed that many NCPs were not able to provide detailed information on what costs and how much would be reimbursed. Furthermore, in some cases the NCP and health insurers provide different answers to patients’ queries regarding the documents needed for reimbursement.

Patients should be able to understand all their entitlements, including where it may be possible to have certain extra costs reimbursed (e.g. those relating to disabilities or travel) or the possibility to benefit from a specific procedure in order to reduce the patients’ burden of having to pay upfront. Patients also say there is a lack of clarity on the prices of medicines and costs of treatment, and on reimbursement rates in the home country.

HEALTH INEQUALITIES

These issues are of course neither new nor exclusively related to cross-border healthcare. Feedback from patients indicates that they find even their own health/social care system difficult to navigate. Many patients and families experience having to “fight the system” just to get information about their rights and access to the services they are entitled to. This is even more of a problem for patients with low levels of health literacy or those in a marginalised or vulnerable situation.

Our findings are in line with the special Eurobarometer of May 2015 which indicated that only about half of the respondents felt they are well-informed about the right to be reimbursed

⁷ “Summary report: main conclusions and recommendations arising from EPF’s series of regional conferences 2013-14”, available at http://www.eu-patient.eu/globalassets/policy/cross-borderhealthcare/cbhc-summary-report-final_external.pdf

⁸ EPF summary report, as above.

for healthcare *in their own country*.⁹ It is vitally important to improve the accessibility and navigability of the home health/social care system for everyone, not only in the cross-border healthcare context, to address the existing health inequalities between and within countries.

The transparency provisions of the directive offer huge potential, not only to individual patients but also to patients' organisations, empowering them as advocates for improvements in the national healthcare provision. However, they need to be properly implemented and health literacy principles should be applied throughout. Implementation needs to consider health and social inequalities in order to ensure that all people can benefit from better information about their rights and entitlements.

THE ROLE OF THE NATIONAL CONTACT POINTS

National Contact Points (NCPs) play a critical role in providing information and support for patients to make meaningful decisions, beginning with the decision on whether to seek treatment at home or abroad.

Some Member States have established several NCPs; for example, the UK has separate regional contact points¹⁰ and Sweden has different contact points for "incoming" and "outgoing" patients. Therefore, there are a total of 32 NCPs across the EU. All of them have a website and email or online contact form, and most have a telephone number and an office address.

A very strong message from the EPF events is that the NCP should be a gateway rather than a gatekeeper in healthcare, "working with the patient, for the patient" and that it should be assessed independently for its performance even if it is integrated in the organisational structure of the national Ministry or a health insurance provider. In 2015 EPF developed a checklist for the "ideal NCP" based on feedback from our regional events. The checklist is available in the summary report and includes recommendations for information provision, accessibility, operational quality and fundamental principles.¹¹

Building up a regular partnership with patient organisations will be the key to ensuring that the services provided by NCPs the real-life needs of patients and that information is disseminated effectively to patient communities at local level. (See also section on "the role of patient organisations", below.)

⁹ Special Eurobarometer 425, page 15.

¹⁰ England, Scotland, Wales, Northern Ireland and Gibraltar. This means that, in total there are 32 National Contact Points covering all EU Member States. Non-EU Member States Norway and Iceland also have National Contact Points for healthcare. The full list is available at http://europa.eu/youreurope/citizens/health/planned-healthcare/get-more-info/index_en.htm

¹¹ Checklist for National Contact Points" contained in the EPF summary report from the regional events, available at www.eu-patient.eu/globalassets/policy/cross-borderhealthcare/cbhc-summary-report-final_external.pdf

We are also aware from the feedback received by NCPs at EPF events that whilst some of them are very well resourced, many of them lack funds and staff. Clearly all NCPs cannot provide an optimal level of service if they do not have the resources to do so. More work is therefore needed to define the needs of NCPs to ensure more consistency in the quality of their work across the EU. This should be combined with the development of objective performance criteria for NCPs, developed together with patient organisations.

EPF recommendations:

- The Commission should co-ordinate a process to develop European-level guidelines on what is the *core information* that must be provided to patients by NCPs and *recommendations on best practice*, e.g. *applying health literacy principles*. This will ensure information meets patients' needs, is understandable, accessible and of high quality. The guidelines should be developed in consultation with patient organisations and they should be applied in all Member States. Patient queries received by the NCPs could be a useful guide to identifying information needs and frequently asked questions.
- *Standardised templates* should be developed across the EU for all application forms used by NCPs, with patient organisations to ensure they are user-focused.
- NCPs should clearly communicate to patients the total implications of different options in a way that enables patients to compare and arrive at a meaningful decision – including which rights and entitlements they have under the Directive or under the Regulations, the quality of care and total cost. Member States must ensure the consistency of information from different sources, such as the NCP and insurance providers.
- NCPs should be independently assessed using a set of objective performance criteria. The EPF “checklist” can provide a basis for development of a set of performance criteria for NCPs at European level.
- NCPs should engage with patient organisations on a regular basis to review the situation and plan joint work to resolve practical issues arising from the implementation of the Directive. NCPs should specifically involve patients in developing and reviewing the information they provide.
- Information pooling and sharing should be ensured regarding existing information, for example national and EU portals on medicines, devices and clinical trials. The user-friendliness and accessibility of these portals should be reviewed on an ongoing basis together with patients.
- Dedicated funding should be made available to ensure the effective functioning of NCPs from EU as well as Member State funds, particularly in resource-poor Member States.

2.3. Equity of Access

All patients in Europe should have the right to obtain safe, high-quality healthcare, whether in their own country or abroad. Their access to such care should be based on need rather than means, in accordance with the fundamental values of solidarity, equity and universality.

Timely diagnosis and prompt treatment are crucial to avoid complications of diseases and consequently increased healthcare costs, both for patients and the health system. Costs of care, both direct and indirect, contribute to the financial burden borne by patients and their families.¹²

The Directive has potential to improve access, but it contains several gaps and uncertainties. Unless those areas are addressed, it may even have the unintended effect of exacerbating the existing health and socio-economic inequalities across the EU. Notably, patients from poorer countries may not be able to afford treatment across the border where the cost is higher; whilst differences in costs may encourage “health tourism” from wealthier countries, with private healthcare providers marketing themselves to patients from abroad. This aspect should in our view be closely monitored.

“Are the reimbursement provisions sufficient to ensure access to treatment based on need?” (EPF Survey)

YES 38% **NO 62%**

Increasing transparency, including about what healthcare is covered in the “benefits basket” in different Member States, will lead to a greater awareness in the patient communities of gaps and inequalities. This could be an opportunity to advocate for improved access and quality of care.

Below, we examine three specific areas in the directive: prior authorisation, upfront payment and reimbursement.

PRIOR AUTHORISATION

Member States are entitled to require prior authorisation for certain types of care.¹³ Currently they are mainly using Article 8(2)(a), which refers to healthcare that is subject to planning in order to maintain domestic access or to control costs/avoid waste, and which either involves overnight hospital stay or the use of highly specialised infrastructure or equipment.

Member States are obliged to communicate clearly which treatments are subject to prior authorisation. However, they are currently not doing so. According to the EC report:

¹² EPF position statement on health inequalities, 2010, available at www.eu-patient.eu/globalassets/policy/healthinequalities/epf-position-dec2010.pdf

¹³ See EPF guidance on the cross-border healthcare directive (2013), available at http://www.eu-patient.eu/globalassets/policy/cross-borderhealthcare/2013-11-18_cbhc_guidance-final.pdf

- 7 Member States¹⁴ are not applying any prior authorisation.
- 6 Member States apply prior authorisation for a detailed list of treatments
- 14 Member States apply prior authorisation for overnight stay and highly specialised care. However, only 5 specify which treatments are covered by the criterion of “highly specialised”.
- 1 Member State even requires prior authorisation “for everything, with exception of one specialist consultation per year per patient.”

The evaluative study also points out that interpreting information on prior authorisation “usually requires some degree of medical expertise” and in fact patients usually contact their health insurance providers for that information.

Lack of clear information is a deterrent to many patients to seeking healthcare. The situation undermines the Directive’s original objective, which was to *create clarity on patients’ rights and entitlements* and enable patients to make informed choices. It may also have inadvertently increased the admin burden on some national authorities, because patients requested prior authorisation even when it was not necessary. In any case, the EC report questions whether extensive systems of prior authorisation are justified and proportional, given the very small numbers of people applying for authorisation. The time to process prior authorisation requests also varies greatly: whilst 9 Member States reported taking fewer than 20 days on average¹⁵, three reported 30 days or more.¹⁶

UPFRONT PAYMENT

One major barrier to access is the requirement that patients pay up-front for cross-border care and are reimbursed afterwards. This is not acceptable from an equity perspective; it places the burden on the patients and their families, who are already in a vulnerable position. Many patients will not be able to benefit in practice from their new right under the Directive.

Access to healthcare should be based on “needs, not means”. Most patients with chronic conditions do not wish to access healthcare abroad; they would much rather be cared for close to home and would only consider going abroad when there is no other acceptable option. It is therefore essential that patients who need to access cross-border healthcare can do so on an equitable basis, regardless of their social or economic position.

The directive does in fact allow Member States to facilitate access if they decide to: either by making use of *prior notification* by which patients could obtain a prior authorisation (even if not strictly required) and in exchange receive written confirmation of the level of

¹⁴ Austria, the Czech Republic, Estonia, Finland, Lithuania, the Netherlands and Sweden. The non-compliant Member States are not named in the report.

¹⁵ Bulgaria, Croatia, Denmark, Ireland, France, Luxembourg, Slovakia, Spain and the UK

¹⁶ Hungary, Cyprus and Slovenia

reimbursement they are entitled to. This would help them to have more clarity on their entitlement and calculate the costs more accurately.

The second option would go further towards alleviating the burden on patients and would involve Member States putting in place *mechanisms for direct transfer of costs* between institutions across borders. Such a mechanism already exists under the arrangements for the coordination of social security systems (EU Regulation No. 883/2004). However so far Member States have not been willing to use these mechanisms for cross-border healthcare under the directive.

REIMBURSEMENT

This section addresses reimbursement, including the relevant administrative procedures and timelines.¹⁷ Member States can limit the rules on reimbursement only for so-called “overriding reasons of general interest” (Article 7(9) of the directive), as long as the limitations are necessary and proportionate and do not form an unjustified barrier to free movement. The EC report notes that Member States have not notified to the Commission any decisions to limit reimbursement, but nevertheless some of them are doing so:

- “At least three” Member States link the reimbursement tariff to the costs of private or non-contracted healthcare providers which means that the reimbursement rate to patients is lower than it should be.
- Three Member States require patients to demonstrate why it is medically necessary to go abroad for treatment.
- Five Member States ask for a referral from a professional in the home country. (Member States can ask for a referral if that is the normal practice of the national healthcare system, but according to EU rules they should recognise the qualifications of equivalent professionals in other Member States.)
- “At least four” Member States require patients to provide a sworn translation of invoices.
- One Member State requires patient to get all documents certified by their consul in the country of treatment.

The definition of a reasonable time for the processing of reimbursements is also a grey area. The directive requires that reimbursements are processed within a “reasonable time” (which is not defined). The evaluative study shows that this time varies considerably, from less than 20 days to more than 80 days.

Furthermore, the directive applies to all healthcare services, including eHealth services. However, its application to eHealth is unclear because some Member States reimburse eHealth consultations and others do not.¹⁸

¹⁷ For an overview of the provisions on reimbursement, please see the EPF Guidance document, pp. 8-9.

¹⁸ See EC report, p.6

RECOGNITION OF CROSS-BORDER PRESCRIPTIONS

Member States must as a rule recognise prescriptions issued abroad. Implementing legislation was adopted in December 2012 for the recognition of prescriptions and measures to enable health professionals to verify the authenticity of prescriptions issued in other Member States, including a list of contents to be included in cross-border prescriptions.¹⁹ To avoid confusion, prescriptions should be made using the common name²⁰ rather than the brand name of the medicine (with the exception of biological medicines, for which both names must be included).

It is important to be aware that the Directive does not affect national pricing and reimbursement rules. Thus, if the medicine prescribed abroad is not reimbursed in the home country, the home country is not required to reimburse it under the directive. Other factors, such as shortages, also affect the availability of medicines across the EU. Thus, patients and prescribers should clarify whether the prescribed medicine is reimbursed and will be available to the patient in the home country.

EPF recommendations:

- Member States should ensure that accurate and easily understandable information on exactly which treatments are subject to prior authorisation and which are not is available on the NCP website, including information on the criteria applied and the application procedure for prior authorisation.
- Member States should stop applying requirements for reimbursement that are not justified under the directive.
- Member States should consider the possibility to cover extra costs beyond the strict reimbursed amount, in particular costs related to disability or travel in certain cases to ensure equity of access. Transparent information on this should be available. Patient organisations could be consulted when considering exceptional cases.
- Prior authorisation coupled with a prior notification of reimbursement should be available for any patients who wish to use it.
- Member States should implement mechanisms for direct payments across borders using existing systems where needed. In the longer term, a mechanism should be created for providing adequate cover for patients/families who are forced to access treatment abroad due to unmet need; the provisions of the EU Regulation should be used where appropriate.

¹⁹ Commission Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.

²⁰ INN or International Non-proprietary Name, i.e. the name of the active ingredient

- As part of the formal EU impact assessment, evidence should be collected on the positive or negative impact of the Directive on access and health inequalities, with specific considerations for patients with chronic conditions and people with disabilities.
- Data should be collected on treatments that are authorised by the European Medicines Agency but not reimbursed or otherwise not available in some Member States, with the aim to effect policy changes for equity of access.

2.4. Patients with rare diseases

Patients with (suspected) rare diseases and their families are in a particularly vulnerable position. A global lack of expertise is the major reason for patients with rare diseases having to seek cross-border healthcare. Time is a particular concern, as patients often undergo a number of consultations before being diagnosed correctly.

The CBHC Directive can be attractive for patients with rare diseases when the healthcare they seek is included in the national basket of benefits and does not require prior authorisation – the protocol of care for a specific rare disease may include care that are commonly found in the basket of benefits in many countries. However, patient organisations report that prior authorisation seems to be by far the normal practice for rare disease patients, perhaps because in most cases the care required falls under the prior authorisation requirements.

For this reason, the directive states that member states should better exploit the possibilities offered by the existing Social Security Regulations for the referral of patients abroad in cases where diagnosis and treatment is not available in the home country. It is also vitally important that patients are made clearly aware of the differences between the two sets of legislation, and their rights under each.

For patients affected by rare diseases, the actual process of prior authorisation may be an obstacle. Such authorisation usually involves a clinical evaluation by doctor(s) designated by national authorities, who often lack the necessary expertise on the specific diseases. Expertise on rare diseases is scarce by definition and concentrated in a few centres.

If a patient is suspected to be affected by a rare disease and applies for prior authorisation, a clinical evaluation should be carried out and scientific advice can be requested if no expert can be found in the home country. This provision is rather vague, so it is important that patient organisations draw the attention of the national authorities to the specific problems faced by patients with rare diseases. The authorities should do everything they can to facilitate those patients' access to expert diagnosis and treatment.

Although patients' need for treatment should be assessed on an individual basis, there is a need for more clarity on what constitutes "undue delay". At the moment, there is no common understanding on this and member states have various approaches.

Generally speaking, for patients with rare diseases the main problem is still lies the lack of knowledge of people affected by rare diseases about the very existence of NCPs, the rights and opportunities offered by the new legislation, the interaction with the pre-existing Regulation and understanding whether the Regulation or the Directive provides the best support. When seeking medical diagnosis or care abroad, patients with rare diseases still undertake their path in isolation, although at times helped by their clinicians.

The right to a second opinion can be impaired by the reluctance of clinicians to entrust a patient to another expert team abroad, or a reluctance to meet the patient's request for prior authorisation for a preferred treatment abroad, when a treatment is available in their home country, but it is not the one of choice of patients (for example due to more advanced treatment protocol applied abroad, or to the availability of better equipment)

Notwithstanding this, clinical experts on the disease still remain best placed to provide the clinical evaluation necessary for prior authorisation.

EPF recommendations:

- In cases of (suspected) rare diseases, where the treatment in question is not within the basket of benefits, Member States should always apply the EU Regulation 883/2004 to ensure access to appropriate expert diagnosis and treatment. Patients and the public should be clearly advised of this option in advance. NCP should be made aware of the possibility of applying EU Reg. 883/2004 as an alternative to the CBHC Directive and should be able to address individual patients to the most appropriate legal instrument and related pathway.
- Centres of expertise (where they exist) designated under national rules, should be entrusted with the clinical evaluation that national authorities require prior to granting prior authorisation.
- There should be a better understanding across the EU on what constitutes “undue delay” for patients. This should be done with the involvement of patient organisations.

2.5. Safety and quality of care

Good quality of care is a fundamental patient's right, and closely linked to equity of access. Patients should be able to have confidence that the treatment they are having is safe. Access to treatment is not meaningful unless the treatment provided is of good quality.

The directive includes important obligations to the Member States to be transparent to citizens on the safety and quality of healthcare in the country. It also includes an obligation to Member States to collaborate with each other on safety and quality, on the development of guidelines and standards but also in other fields that have a bearing on quality such as eHealth, health technology assessment and European Reference Networks.

According to the investigations of the European Commission, quality of care is not a key driver in patients' choices regarding cross-border healthcare. This would be in line with the findings of the EPF events, where patient representatives attended to say that they expect quality to be good and the treatment to be safe, but this would not be the main reason for seeking care abroad (though there may be some exceptions, particularly in rare diseases). What patients do want is easy access to comprehensive and understandable information on safety and quality of care.

Continuity of care is a patient safety issue, particularly in cross-border context. Even though the EC report and study did not identify this as an issue now, possibly due to the very small numbers of patients accessing cross-border healthcare, there is more room for collaboration on, for example, application of clinical guidelines in different countries and communicating safety information to patients on discharge, for example how they should manage side effects and what they should do in case of complications.

INFORMATION ON SAFETY AND QUALITY

Information on quality and safety is often difficult to understand for a lay patient. The criteria and indicators used vary widely. There is often too much information or information on aspects that are not relevant for patients.

NCPs tend to provide generic information, sometimes only links to national laws or regulatory documents, but. "only a few websites published practical and easily understandable information ... to help patients make an informed choice." (study, p. 49) This is not an adequate application of the directive, as it does not help patients make sense of complex legal and medical information. The lack of comparable safety standards is also an issue for insurance providers across countries. (study, p. 54) Patients apparently tend to rely mostly on feedback from other patients, or on the advice of a trusted healthcare professional.

Patients would like to have information that is simple, relevant, concise and comparable, both across institutions or providers within the country but also across EU Member States. In short: information needed to make a meaningful decision. It should be provided in a format that is accessible for persons with disabilities and easily understandable to lay persons.

The EU study notes that "no universal definition of 'quality standards' currently exists across Member States that would support cross-border healthcare provision.

Information about healthcare providers and health professionals is only available on request from the NCP. Some Member States make extensive use of the "internal market information system" to make enquiries to other Member States about healthcare providers – others do not. From a patient perspective, it would be preferable to have an "at a glance" resource to check the qualifications and fitness to practice of providers and professionals. These could eventually be combined into a "one-stop" EU level portal which could link to all the national resources.

IN CASE SOMETHING GOES WRONG

If a patient is harmed in a healthcare context, it is vital that the mechanisms for complaints, compensation and redress are transparent, prompt, supportive to the patient/family, and effective. Mechanisms for complaints and redress should be transparent, simple, effective, swift and easy to understand, based on good governance principles and with clear information for patients on the procedures, their rights and various alternatives.

This is currently not the case. Not all NCP websites provide even general information on whom to contact in the event of harm.²¹ The EC study found that only two of the NCPs contacted with specific questions regarding procedures in the event of harm were able to give answers. Although this was only a sample of NCPs, nevertheless it is worrying from a patients' rights perspective.

EPF recommendations:

- Relevant, understandable information about safety and quality of care should be provided to patients that *enables them to make comparisons and meaningful judgements*.
- Guidance should be made available for patients on how to interpret safety and quality information, including lay-friendly explanation of key concepts. This could be an opportunity for collaboration between patient organisations and safety and quality experts.
- Easy to understand, step-by-step procedures for complaints and redress to be established right away and to be made available on the NCP websites.
- Member States should collaborate at European level to encourage upward convergence of national safety and quality standards, for example through benchmarking and key indicators.
- In the longer term, easily understandable information on the right to practice / qualifications of health providers should be made available to patients and the public through a widely accessible medium, e.g. a web-based platform.

2.6. European collaboration

Other areas where the directive has significant future potential is in encouraging closer European cooperation through European Reference Networks, on eHealth, and on health technology assessment.

EUROPEAN REFERENCE NETWORKS

Informal networks already existed in some rare diseases for many years, but the Directive gave them a legal basis and clear objectives. ERNs bring together specialised centres and

²¹ EC evaluative study: 19 out of 32, not named.

other healthcare providers across Member States to work together in areas of highly specialised healthcare, rare and complex diseases requiring a concentration of expertise. The aim is to pool knowledge, cases and resources to 'facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare'.²²

The establishment of the networks has begun with the establishment of a Board of Member States, which will approve proposals. The first call for networks was launched on 16 March 2016.²³ The Commission's report states it is working with healthcare providers and authorities to raise awareness of the possibilities offered by ERNs and to gather support for potential networks.

Some patient organisations are collaborating with specialist healthcare providers to create the clinical network which could join a ERN, such as in the field of Spina Bifida and Hydrocephalus (in a Rare Malformations ERN).²⁴ EURORDIS is very actively involved and makes available a wealth of material on its website, including its 2012 position paper on ERNs.²⁵

EPF recommendations:

- The Commission should work closely with patient groups to raise awareness of European Reference Networks and specialised centres, and to ensure that they function in a patient centred way.
- Patient representatives are integral to the decision and opinion-making process in European Reference Networks and should be a mandatory member of ERN Boards and clinical committees.
- The scope of thematic European Reference Networks should be inclusive of complex diseases, as well as rare diseases, expanding to cover rare sub-populations of chronic diseases and clinical areas aligned to personalised medicine as well as rare and highly specialised mental health conditions.
- The Commission should support the establishment of clinical services provided in a virtual environment by ERNs, through provided standard interoperable IT Platform for all ERNs.
- A sustainable funding mechanism should be set up for ERNs at European level.

THE EHEALTH NETWORK

EPF argued strongly for the importance of including eHealth and telemedicine in the Directive. If implemented effectively, eHealth has the potential to increase access to healthcare across and within Member States, as well as improve patient safety in particular through more effective communication and continuity of care.

²² For more information, see the directive, Article 12 and EPF guidance, pp. 15-16.

²³ Details of this call are available at http://ec.europa.eu/health/ern/implementation/call/index_en.htm

²⁴ Source: International Federation for Spina Bifida and Hydrocephalus (IF)

²⁵ See www.eurordis.org/european-reference-networks

eHealth and telemedicine is a fast-growing sector, and likely to become more mainstream in future. The directive has highlighted that there is no common framework of regulation on eHealth including its reimbursement. Effective patient information, shared electronically, is a crucial patient safety support in a domestic context as well as in cross-border care. Other aspects of eHealth are dealt with EPF's specific position paper on the topic (forthcoming) and our eHealth project reports.

Access to one's health record is key to patient empowerment and effective self-management. EPF believes that patients should be co-owners of their health data, together with health professionals. Patients should not only have free access to their own health records, but the record – including mental and physical health should be designed so that it is at least partly controlled and 'owned' by the patient. This is already a reality in some parts of EU Member States; in others, patients cannot even access their own records easily, or they are charged fees.

EPF recommendations:

- Promotion of e-health interoperability should be a priority to improve global patient records and continuity of care.
- Prompt, free-of-charge access by patients to their own medical records should be implemented across the EU, not only in cross-border context. If the record is electronic it should be made accessible to people with different disabilities and impairments.
- National bodies involved in the eHealth and HTA networks should engage actively with patient organisations.

HEALTH TECHNOLOGY ASSESSMENT

The Directive established a voluntary network for cooperation between the bodies and authorities in Member States responsible for health technology assessment (HTA). The HTA network was established through a Commission implementing decision²⁰ in June 2013.²⁶ The objectives of the network are to support cooperation between national bodies responsible for HTA, to avoid duplication and increase efficiency.

EPF advocates to promote patients and patient organisations' involvement in HTA processes, via fora such as HTAi, ISPOR and EU projects (EUNetHTA stakeholder Forum) and the HTA network. We believe that an EU strategy for HTA collaboration post-2020 should entail not only legal and financial dimensions, but also a structural dimension that allows the effective involvement of patients, in line with the Values and Quality Standards for patient involvement in HTA set by HTAi and the definition of "meaningful patient involvement" developed by the Value+ project.²⁷

²⁶ For more information, see EPF guidance, pp. 16-17

²⁷ Meaningful involvement implies that patients take an active role in activities or decisions that will have an impact on the patient community; their involvement is both necessary and valued because of the *specific*

Patient representatives need capacity-building to support their meaningful involvement. The European Patients' Academy on Therapeutic Innovation (EUPATI) has included HTA in its educational toolkit, and established national Platforms for patient education. There is undoubtedly scope for expanding such training.²⁸

EPF recommendations:

- Frameworks and methodologies should be developed to systematically incorporate and encourage patient input to HTAs, including rapid HTA/relative effectiveness assessment.
- Patient representatives should receive appropriate, timely, and effective training so that they can best contribute to HTA, e.g. through use of existing tools such as the EUPATI Toolbox and through engaging national EUPATI platforms.

3. The role of patient organisations

Patient organisations can play a powerful role. They have a wealth of expertise and can channel the direct patient experience during the “healthcare journey” to pinpoint areas of weakness or system failure— an important source of information for better health policy and service design.

By providing information to their members and fellow stakeholders patient organisations are already providing a valuable service both to patient communities and the NCPs. They can highlight challenges to national authorities and the Commission but also participate in developing solutions. They can provide feedback to National Contact Points on the services and performance and collect patient stories of their experiences, which can help other patients but are also an important source of evidence for decision-makers.

Under the directive NCPs are obliged to consult stakeholders, including patient organisations. We believe that particularly in situations where the NCP is under-resourced, the involvement of patients' representatives should be considered as essential for providing information to patients and that this would be beneficial for patients as well as the NCPs

Currently, however, NCPs are not engaging enough with patient organisations. Although some NCPs are keen to work with patients, and many NCPs expressed great interest when attending EPF regional and national workshops, in the Commission's report “the attention given by the interviewed NCPs to patient organisations [was] almost non-existent.”

It should be borne in mind that patient organisations are constrained by a chronic lack of resources in times of funding and staff. Some organisations function almost entirely on a

knowledge they develop through the *lived experience* of being patients. Such involvement must be appropriately *planned, resourced and evaluated* according to the values and purposes of all participants. More information and tools available at <http://www.eu-patient.eu/whatwedo/Projects/ValuePlus/>

²⁸ <https://www.eupati.eu/category/health-technology-assessment/>

voluntary basis. Only larger and well-funded patient organisations have sufficient resources to “plug the information gaps” and to collect useful data on demand and uptake. Furthermore, in some countries there is no umbrella organisation of patients at national level.

EPF recommendations:

- Patients’ organisations should monitor the Directive as far as is feasible within their resources, and provide information to EPF on good and bad practices, for example through the EPF “Network of patient representatives on cross-border healthcare”.
- In order to increase understanding and trust between patient communities and national bodies on issues relating to the application of the directive and on access to care more widely, we would recommend dedicated meetings between the relevant government/statutory bodies and patients’ representative organisations.
- There should be a reflection process with the aim to ensure the long-term sustainability and functioning of patient organisations, including those at European-level and national/local level. This should include making EU funding more accessible to patient organisations and public funding for core functions such as maintaining a secretariat.
- Especially in rare diseases and disabilities, the existence of helplines across Europe to inform patients about rare diseases²⁹ could be used to provide more information on patients’ rights regarding cross-border care, both under the Directive and under the Regulation.

4. Conclusions and next steps

The European Commission is required to report on the operation of the directive every three years, with the next report due in the autumn of 2018. EPF is in close contact with the European Commission and regularly providing feedback. We are also engaging with interested Members of the European Parliament.

Through our regional events we established an **informal network of patient representatives** across the EU member states, who wished to collaborate with us and with each other on cross-border healthcare.

In 2016 we will invite this network to engage with the implementation in their countries and involve them in planning for a **conference during 2017** as a follow-up activity. Our aim will be to review progress achieved, to bring together patient representatives, National contact points, policy-makers, health professionals and other relevant stakeholders.

²⁹ European Network of Rare Disease Help Lines (ENRDHLs) for more information see Hoyez et al. (2014) at www.ncbi.nlm.nih.gov/pubmed/24797216; also see EURORDIS at www.eurordis.org/content/help-line-services

5. Selected references and links to more information

European Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (4 September 2015) available at http://ec.europa.eu/health/cross_border_care/key_documents/index_en.htm

European Commission website with links to National Contact Points: http://europa.eu/youreurope/citizens/health/planned-healthcare/get-more-info/index_en.htm

European Patients' Forum conference report, "Cross-Border Healthcare: is it Working for Patients Across the EU?" (13 July 2015) available at www.eu-patient.eu/whatwedo/Policy/Patients-Mobility/

European Patients' Forum report "Main Conclusions and Recommendations arising from the EPF series of Regional Conferences 2013-14" (18 March 2015) available in English at www.eu-patient.eu/globalassets/policy/cross-borderhealthcare/cbhc-summary-report-final_external.pdf

Evaluative study on the cross-border healthcare Directive, final report (21 March 2015) available in English at http://ec.europa.eu/health/cross_border_care/docs/2015_evaluative_study_frep_en.pdf

Special Eurobarometer no. 425 "Patients' Rights in Cross-Border Healthcare in the European Union", report available in English at http://ec.europa.eu/public_opinion/archives/ebs/ebs_425_en.pdf

Special Eurobarometer no. 425, country fact sheets for all EU Member States available in English and the national languages at http://ec.europa.eu/public_opinion/archives/eb_special_439_420_en.htm#425