

Patients' Rights in the European Union Mapping eXercise

Final Report
Executive Summary

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EXECUTIVE SUMMARY

This report aims to provide an overview of patients' rights in all EU Member States, Norway and Iceland by mapping national patients' rights legislation, soft-law, structures and enforcement procedures ensuring the rights of patients. The mapping exercise was performed from January to September 2015 providing a cross-sectional view of the patients' rights situation in the 30 countries under study.

The mapping exercise included a literature review, a review of activities funded by the EU Health programme, the Research and Innovation Framework Programme and by the European Partnership on Active and Healthy Ageing (EIP-AHA). Furthermore, qualitative assessment of the patients' rights situation was undertaken by national patients' rights experts by means of a survey. Preliminary results were presented and discussed with a wide range of relevant stakeholders at a workshop on September 10th and 11th 2015 in Brussels.

A conceptual model for this comparative mapping of patients' rights was developed as a starting point for the assessment. The three domains of patients' rights assessed cover **(1) basic individual rights, (2) consumer- based rights and (3) procedural rights**. Basic individual rights cover the right to informed consent; to privacy and dignity; to access to the medical file; and to information on one's health. Consumer based rights entail the right to choose one's provider, to a second opinion, to safe and timely treatment (patient safety and quality of care) and to information concerning care options. Procedural rights include the right to complain, to compensation, and to participate in decision-making. However, these different patients' rights subjects cannot be totally separated from each other.

The survey tool assessed the following patients' rights subjects: (I) the formal recognition of the right and/or the way it is embedded in broader national laws; (II) the implementation of the right in practice; (III) the application of the right in the cross-border context; (IV) the use of the right in practice; and (V) available remedies and procedures when the right is not respected. Furthermore, broader positioning of patients' rights within the health system and the impact of the Council of Europe's work on the situation of patients' rights was assessed.

In the area of **basic individual rights** all Member States, as well as Norway and Iceland, are developing a legal approach to defining and implementing patients' rights to self-determination and confidentiality (rights to consent and information; privacy; accessing records). This is not a surprise because these rights are embedded in several individual human rights frameworks. While most Member States are developing a legal and more unified approach for basic patients' rights, their actual enforcement remains an issue. Low sensitivity and poor knowledge among citizens, professionals and policy makers are reported as main stumbling blocks for the development of patients' rights, together with the paternalistic model of the doctor-patient relationship that still subsists in several countries.

The right to self-determination, as expressed in the rights to informed consent, the closely related right to information, and the right to privacy and confidentiality, is strongly protected in the vast majority of countries. In many countries, privacy is actually more protected than the right to self-determination due to strong data protection legislation. The right to access one's medical file is also provided for in most Member States, although many respondents reported that some hospitals try to limit access in practice. Many countries charge a small fee for a copy of the medical record.

With regard to the more **consumer-oriented rights**, the results of the mapping exercise are more diverse. These rights represent a more recent trend inspired by an increased emphasis on ensuring quality and safety in the health sector, but also more generally on responsiveness and efficiency in public service provision. At least in some cases, the development of a body of more consumer-oriented patients' rights seems to be directly inspired by the transposition process of Directive 2011/24/EU on the application of patients' rights in cross-border health care. These rights are not yet well-established in many countries. Although the right to freely choose one's healthcare provider is increasingly acknowledged as a patient right, it is still often restricted by regulation and reality. Geographical restrictions in provider choice are increasingly lifted, and in some cases openings are even created to private or non-contracted care if access cannot be guaranteed with public or contracted providers (e.g. Denmark). Nonetheless, provider choice can be an important source of inequity, especially for people living in rural and remote areas as well as for people who cannot afford private healthcare provision.

Furthermore, the information required to enable provider choice is often not sufficiently available. Various countries have invested substantially in centralized information points (e.g. call centers, web sites) providing information to citizens about healthcare providers. Initiative "[1177](#)" (a 24/7 phone line and web site), which is a collaborative project between all county councils and regions in Sweden, is a good example. Many countries have also instituted an obligation for providers to inform citizens about various aspects that can be instrumental to making a choice. However, reliable information on performance, which is the most sought out type of information, is generally the least available. In some (7) countries legal requirements exist for providing clear and objective information about provider performance (outcomes, quality indicators, safety standards, rights/fitness to practice). However, the required level varies between countries. No specific legal requirements in this regard exist in the other countries.

The right to a second opinion is closely linked to the right to freely choose one's provider. A small majority of countries formally recognize the right to a second opinion. In other countries it is subsumed in the right to freely choose a provider. In several countries the right to a second opinion (and the assumption of related costs) is subject to strict rules and conditions. Sometimes the right will be limited to certain (mostly life-threatening) conditions. Sometimes the second opinion must come from a provider in the same hospital or region. Sometimes only one referral is allowed per treatment or care process. However, most disturbing is the high level of discretion given to the treating physician to "allow" the patient to exercise the right to a second opinion.

In contrast to the concept of a right to safe and quality treatment, many respondents refer to the obligation of the provider, sometimes framed as a patients' right to receive a certain standard of care. This obligation/right remains very broad and is not further specified. In addition, from a process perspective, a majority of countries operate professional standards and clinical guidelines whereas the use of protocols is practiced to a lesser extent. Outcomes are reported publicly in Scandinavian countries (Denmark, Finland, Iceland, Norway) but this practice is not common in many other countries.

Mechanisms for the **enforcement of patient rights** are very varied country-by-country. Within countries, most jurisdictions have a wide range of mechanisms for investigating and responding to complaints. These range from very traditional, court-based inquiries in Civil, Criminal and Administrative Law, and particularly in the Law of medical liability or

personal injury, through established alternative dispute resolution fora, particularly Ombudsmen, to mediation.

There is a degree of required cultural orientation in negotiating the range of mechanisms. Even where similar mechanisms are used, different jurisdictions have different rules and expectations about the different roles of various stakeholders in the enforcement processes. This is seen at many levels: for example, timescales for making complaints differ widely, as do methods of making complaints; Ombudsmen may be available, but the extent of their power and where they are situated in the system differ.

Establishing fault remains the main criteria for compensation. In the majority of jurisdictions, compensation is only available where fault (negligence) can be established. In some jurisdictions no fault compensation has been established, and in a very small number, a hybrid exists where fault is the required route for compensation at Law, but schemes have been developed to address where patients with damages will not be compensated.

Alternative Dispute Mechanisms do not tend to produce compensation or rectification for a patient. Where Ombudsmen or other non-court complaint schemes are provided, the range of resolution tools available to these mechanisms is limited, often to issuing an opinion about the case or to administrative Law remedies (specific performance). Apology and explanation are not often mentioned as goals or outcomes in dispute resolution. Country experts do not point to many parts of systems that are designed to explain to patients what actually happened and to give apologies to patients. This could be implied where an internal procedure is undertaken by the health care provider or institution and a report has to be given to the patient. However, the idea of apologizing to the patient does not appear. This could relate to the use of fault-based compensation schemes that are in place, and that are separate from the internal reviews.

In some jurisdictions, patients who wish to complain are given assistance. The processes are very complex, and in some jurisdictions there are duties on different stakeholders to assist the patient in making a complaint (and in some this extends to assisting in negotiating settlements). Insiders (Member States' own citizens) will have knowledge of how to negotiate the processes - or at least where to go to seek help in that negotiation. Outsiders will need strong guidance and help in accessing the underpinning 'unconscious knowledge' of citizens - the background knowledge of the legal and normative culture of one's own community - and it is not clear that National Contact Points have been created with a duty to provide at least signposts to this information.

From the Country Expert Survey it is clear that **Council of Europe** activities are not reported to have a great influence on individual States. Decisions of the European Court of Human Rights are followed in the countries, but there are few decisions that directly bite on patient rights without leaving scope for a margin of appreciation.

The impact of Directive 2011/24/EU on the application of patients' rights **in cross-border health care** on the development of patients' rights varies between individual Member States. While for some countries it may have been mainly indirect, in several Member States (such as Austria, Belgium, Luxembourg, Finland, Hungary, Latvia, Malta, Norway, Poland, Spain) the Directive has been indeed a driver for the development of patients' rights, especially those that are more consumer-oriented. The basic mode of operation is that the Directive pushes Member States to be more transparent about rights patients have. While no specific provisions exist for cross-border patients in many

Member States, existing laws regarding informed consent, privacy and access to the medical record equally apply to all health care provided in their territory. However, language and technical support (e.g. translation services, e-copy of medical record, common single consent model, common patient and discharge summaries) may help cross-border patients to enforce basic patients' rights.

However, there is a need to clarify the very notion of patients' rights in the context of the Directive by providing accurate information to the Member States. The rights contained in this Directive are not the basic patients' rights in the sense of a sick individual but rights of a patient in his capacity as a recipient - and even more a potential recipient - of health services. The answers of the respondents make it clear that policy makers in many countries regard patients' rights in the traditional way. As this could hamper the implementation of the Directive in daily life, a broader concept of patients' rights, including the various dimensions as covered in this mapping exercise, could be promoted. Examples of good practice in this regard are Norway, where the Patients' Rights Act was revised in 2011 and now also includes "users" of care services; and the Netherlands, where the Act of 9 December 2014 on long-term care contains rules on the participation and co-decision making of the client.

The obligations that Article 4 of the Directive imposed on Member States clearly inspired some countries to push forward some of the more consumer-oriented patients' rights. As a principle, Directive 2011/24/EU extends patients' choice to healthcare providers in another Member State irrespective of whether or not they are contracted by the statutory health system in that Member State. This raises two particular and related issues: Firstly, several Member States signalled that in the context of the transposition of the Directive private non-contracted providers were claiming "equal treatment" with foreign providers whose services would be reimbursed under the Directive even without being contracted by the cross-border patients' health insurer. Second, in countries (e.g. in Austria, Netherlands) with differential reimbursement rates for contracted and non-contracted providers, the application of lower reimbursement levels to non-contracted cross-border providers could be regarded as a disincentive for patient mobility.

Finally, it must be acknowledged that the aim of this study was to provide a **mapping** of national patients' rights. Rights related to social coverage for health care or linked ethical questions were not considered. Moreover, the review of literature has only included English language sources. The assessment of each national situation is based on a single country expert review (backed up with other available source). In this regard the mapping aimed at providing a comparative overview of patients' rights currently in place in EU Member States, Norway and Iceland.

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