Patients' Rights in the European Union Mapping eXercise

Final Report

Written by PRE-MAX Consortium
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EUROPEAN COMMISSION

Directorate-General for Health and Food Safety (SANTE)
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Unit B.3 Cross Border Healthcare and eHealth Unit (B3)

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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.

RÉSUMÉ EXÉCUTIF

Ce rapport a comme but de fournir un aperçu sur les droits du patients dans les États Membres de l'Union Européenne, y compris la Norvège et l'Islande en réalisant une modélisation des législations nationales des droits des patients, des stratégies, des structures ainsi que les procédures de mise en vigueur des droits des patients. Cet exercice de modélisation a été réalisé de janvier à septembre 2015 en apportant une vision transversale sur la situation des droits des patients dans les 30 pays étudiés.

Cet exercice de modélisation inclut une analyse bibliographique, une révision des activités financées par le Programme Santé de l'UE, Programme-cadre pour la recherche et le développement technologique et par le Partenariat européen d'innovation pour un vieillissement actif et en bonne santé (EIP-AHA). De plus, une évaluation qualitative de la situation des droits des patients a été menée via une enquête réalisée auprès d'experts des droits des patients au niveau national. Les résultats préliminaires ont été présentés et débattus avec un large spectre d'importants acteurs pendant un atelier ayant eu lieu le 10 et 11 Septembre 2015 à Bruxelles.

Un modèle conceptuel pour cette modélisation comparative des droits des patients a été développé comme point de départ pour l'évaluation. Trois domaines des droits des patients ont été évalués **(1) droits individuel de base (2) droits des consommateurs (3) droits procéduraux.** Les droits individuels de base couvrent le droit au consentement éclairé; droit au respect de la vie privée et à la dignité ; droit d'accès au dossier médical ; droit à l'information sur son état de santé. Les droits des consommateurs comportent le droit au libre choix du prestataire, droit d'obtenir un deuxième avis, droit au traitement sécurisé et en temps opportun (sécurité des patients et qualité des soins) et droit aux informations concernant les différentes options de traitements. Les droits procéduraux incluent le droit de porter plainte, de recevoir une compensation et de participer à la prise de décision. Toutefois, ces différents sujets/thèmes des droits des patients ne sont pas totalement indissociables.

L'outil d'enquête a permis d'évaluer chacun de ces sujets des droits des patients : (I) la reconnaissance formelle du droit et / ou la manière dont il est intégré dans les lois nationales au sens large, (II) la mise en œuvre pratique de ce droit, (III) l'application du droit dans le contexte transfrontalier, (IV) l'utilisation pratique du droit, (V) les voies de recours et les procédures disponibles dans le cas du non-respect de droit. En outre, la position au sens large des droits des patients dans le système de santé et l'impact de l'action du Conseil de l'Europe sur la situation des droits des patients ont été évalués.

Dans le domaine des **droits individuels de base**, tous les Etats Membres ainsi que la Norvège et l'Islande, développent une approche juridique pour définir et mettre en œuvre des droits des patients à l'autodétermination et à la confidentialité (droits de consentement éclairé; vie privée ; accès au dossier médicale). C'est sans surprise car ces droits sont repris dans plusieurs cadres de droits de l'Homme. Alors que la plupart des Etats Membres développent une approche juridique plus unifiée des droits de patients de base, leur mise en application reste problématique. Une sensibilité limitée et de pauvres connaissances parmi les citoyens, les professionnels et les décideurs politiques sont signalées comme étant un frein majeur pour le développement des

droits des patients, conjointement avec le modèle paternaliste de la relation médecin-patient qui subsiste encore dans plusieurs pays.

Le droit à l'autodétermination, tel qu'il est exprimé dans le droit au consentement éclairé, étroitement lié au droit à l'information, et du droit à la vie privée et à la confidentialité, est fortement protégé dans la grande majorité des pays. Dans de nombreux pays, le droit à la vie privée est en fait mieux protégé que le droit à l'autodétermination en raison des solides législations en matière de protection des données. Le droit d'accès au dossier médical est également assuré dans la plupart des Etats Membres, bien que de nombreux correspondants ont signalé qu'en pratique certains hôpitaux tentent de limiter l'accès. De nombreux pays réclament une petite redevance pour obtenir une copie du dossier médical.

En ce qui concerne les droits axés sur les consommateurs, les résultats de l'exercice de modélisation sont plus variés. Ces droits représentent aussi une tendance plus récente qui porte l'attention sur la l'assurance de qualité et de sécurité dans le secteur de la santé, mais aussi plus généralement sur la réactivité et sur l'efficacité dans la prestation des services publics. Au moins, dans certains cas, le développement d'un ensemble de droits de patients plus orientés sur le consommateur semble être directement inspiré par le processus de transposition de la Directive 2011/24/UE sur l'application des droits des patients en matière de soins de santé transfrontaliers. Ces droits restent encore à être mis en place dans beaucoup de pays. Bien que le droit de choisir librement son prestataire de soins est de plus en plus reconnu comme un droit du patient, il est souvent encore limité par la réglementation ou la réalité. Des restrictions géographiques sont de moins en moins fréquentes lors du choix du prestataire de soins. Dans certains cas l'ouverture aux prestataires privés ou non-conventionnés est même crée au cas où l'accès ne peut être garanti par des prestataires publics ou conventionnés (par exemple : Danemark). Néanmoins, le choix du fournisseur peut être une important source d'inégalité, particulièrement pour les habitants de zones rurales et désertes, de même que pour les personnes ne pouvant pas se permettre la fourniture de soins privés.

Par ailleurs, souvent l'information requise pour opérationnaliser le libre choix du prestataire n'est pas suffisamment disponible. Divers pays ont investi considérablement dans des points d'informations centralisés (ex : centres d'appel, site web), qui fournissent d'information aux citoyens sur les prestataires de soins. Un bon exemple est l'initiative « 1177 » (une ligne de téléphone disponible 24h/24h et 7j/7 et un site web) qui est un projet collaboratif entre toutes les autorités de santé et les régions en Suède. Plusieurs pays ont aussi institué une obligation pour les prestataires de soins d'informer les citoyens concernant les divers aspects pouvant être essentiels pour faire un choix. Cependant, le type d'information le plus recherché mais le moins disponible concerne la performance. Dans certains (7) pays, des dispositions juridiques ont été mise en place pour fournir d'information claire et objective à propos de la performance des prestataires (résultats, indicateurs de qualité, standards de sécurité, agrément/aptitude à pratiquer). Toutefois, le niveau requis diffère selon le pays. Il n'y a pas de dispositions juridiques à ce sujet dans les autres pays.

Le droit d'obtenir un deuxième avis est étroitement lié au droit de libre choix du prestataire de soins. Une faible majorité des pays a formellement reconnu ce droit au deuxième avis. Dans certains pays, il est dérivé implicitement du droit au libre choix du prestataire. Dans plusieurs pays, le droit au deuxième avis (et la couverture des

frais liés) est sujet à des règles et des conditions strictes. Parfois, ce droit sera limité à certaines conditions (principalement mortelles). Parfois, un deuxième avis devra venir d'un autre prestataire du même hôpital ou de la même région. Parfois, une seule référence sera autorisée pour chaque traitement ou processus de soins. Toutefois, le plus inquiétant est le niveau très élevé de discrétion du médecin traitant à « autoriser » le patient d'exercer ce droit à un deuxième avis.

Contrairement au concept de droit à un traitement sécurisé et de bonne qualité, la plupart des correspondants à l'enquête se réfèrent à l'obligation du prestataire, parfois formulé comme un droit du patient à recevoir un certain standard de soins. Cette obligation/ce droit reste très large et n'est pas plus spécifié. De plus, à partir d'une perspective de processus, une majorité de pays opère avec les standards professionnels et les lignes directrices cliniques alors que l'utilisation des protocoles est pratiquée dans une moindre mesure. Les résultats sont rapportés publiquement dans les pays Scandinaves (Danemark, Finlande, Islande, Norvège) mais cette pratique n'est pas coutume dans bon nombre de pays.

Les mécanismes de mise en application des droits de patients sont assez variés pays par pays. Au sein de certains pays, la plupart des juridictions ont un grand éventail de mécanismes pour examiner et répondre aux plaintes. Ceux-ci comprennent aussi bien des enquêtes judiciaires traditionnelles relevant des tribunaux en matière de droit civil, pénal et administratif, et particulièrement du droit de responsabilité médicale ou de dommages et intérêts, que des plateformes de résolution de dispute ou de médiation extrajudiciaire, comme le Ombudsman.

Un degré d'orientation culturel est requis dans la négociation de l'ensemble des mécanismes. Même là où des mécanismes similaires sont utilisés, les différentes juridictions ont des règles et des attentes différentes en ce qui concerne les différents rôles des multiples acteurs dans les processus de mise en application. Cela se voit à plusieurs niveaux : par exemple, les délais de dépôt de plaintes diffèrent considérablement, tout comme les procédés de formulation des plaintes; les médiateurs (Ombudsmen) peuvent être disponibles, mais l'étendue de leur pouvoir et leur position dans le système différent.

Le principal critère pour l'indemnisation reste la détermination d'une faute commise. Dans la majorité des juridictions, une compensation est uniquement disponible lorsque la faute (négligence) peut être établie. Dans certaines juridictions, aucun système de compensation n'a été établi, et dans un très petit nombre, un système hybride existe lorsque la faute est la voie nécessaire pour une compensation au niveau légal, mais des systèmes ont été développés pour traiter les cas où des patients avec des dommages et intérêts ne seront pas compensés.

En général, des mécanismes extrajudiciaires de règlement de disputes ne produisent pas d'indemnisation ou de rectification pour le patient. Là où des médiateurs ou d'autres systèmes de plainte extrajudiciaires sont prévus, l'éventail d'outils de résolution mise à disposition de ces mécanismes est limité, souvent des avis consultatifs sur l'affaire ou le recours aux remèdes de droit administratif (performances spécifiques). Des excuses et des explications sont rarement mentionnées comme objectifs ou résultats dans la résolution de disputes. Les correspondants nationaux ne mentionnent pas souvent des parties du système conçues pour expliquer aux patients ce qui est arrivé et de présenter des excuses aux patients. Cela pourrait être implicite lorsque une procédure interne est entreprise par

le prestataire ou un établissement de soins de santé et où un rapport doit être remis au patient. Cependant, l'idée de présenter des excuses aux patients n'y apparaît pas. Cela pourrait être lié aux régimes de compensation en place, et qui sont séparés des examens internes.

Dans certaines juridictions, les patients qui souhaitent se plaindre reçoivent de l'assistance. Les processus sont très complexes, et dans certaines juridictions, les différents acteurs ont l'obligation d'aider le patient à déposer plainte (voire à aider à la négociation d'un compromis). Les citoyens des Etats Membres auront souvent une certaine connaissance comment naviguer ces processus – ou en tous cas savoir où obtenir de l'aide dans cette négociation - tandis que les étrangers auront davantage besoin d'assistance plus solide et de l'aide pour accéder aux « savoir inconscient » sous-jacent des citoyens – les connaissances de base de la culture juridique et normative de sa propre communauté. Il n'est pas clair si les Points de contact nationaux ont été crées avec l'obligation de fournir au moins des indications à cette information.

D'après l'enquête d'experts nationaux il apparaît que les activités du Conseil de l'Europe n'ont pas de grande influence sur les Etats individuels. Les décisions de la Court Européenne des Droits de l'Homme sont respectées dans les pays, mais il y a peu de décisions qui sont directement liés aux droits de patients sans laisser de marge d'appréciation.

L'impact de la **Directive** 2011/24/UE sur l'application des droits des patients en matière de **soins de santé transfrontaliers** sur le développement des droits des patients varie entre les Etats membres. Alors que pour certains pays cet impact a été jusqu'ici principalement indirect, pour d'autres États Membres (comme l'Autriche, la Belgique, le Luxembourg, la Finlande, la Hongrie, la Lettonie, Malte, la Norvège, la Pologne, l'Espagne) la Directive a été effectivement un moteur pour le développement des droits de patients, surtout ceux qui sont plus axés vers le consommateur. Le principe de base est que la Directive force les États Membres à être plus transparents en matière de droits des patients. Alors qu'aucune disposition spécifique n'existe pour les patients transfrontaliers dans de nombreux Etats Membres, les lois existantes concernant le consentement éclairé, la confidentialité et l'accès au dossier médical s'appliquent également à tous les soins de santé dispensés sur le territoire. Cependant, la connaissance de la langue et un soutien technique (ex: service de traduction, copie électronique du dossier médical, un modèle unique et commun de consentement, un registre d'entrée et sortie de patients commun) peuvent aider les patients transfrontaliers à faire respecter leurs droits fondamentaux des patients.

Néanmoins, il est nécessaire de clarifier la notion même des droits des patients dans le cadre de la Directive en fournissant des informations précises aux Etats Membres. Les droits énoncés dans la Directive ne sont pas les droits des patients de base au sens d'une personne malade, mais les droits d'un patient en sa qualité de bénéficiaire – voir même un bénéficiaire potentiel – de services de soins de santé. Les réponses des correspondants indiquent clairement que dans de nombreux pays les décisionnaires considèrent les droits des patients de manière traditionnelle. Comme cela pourrait entraver la mise en œuvre de la Directive au quotidien, un concept plus large des droits des patients, y compris les différentes dimensions couvertes dans cet exercice de modélisation, pourrait être favorisé. Des exemples de bonnes pratiques à cet égard sont la Norvège, où l'Acte sur les Droits des Patients a été révisé en 2011 et

inclus désormais également les « utilisateurs » de services de soins; et les Pays-Bas, où la Loi du 9 Décembre 2014 sur les soins de longue durée contient des règles concernant la participation et la codécision du client.

Les obligations de l'article 4 de la Directive imposée aux États Membres a clairement inspiré certains pays à faire avancer certains droits des patients à caractère plus consommateur. En principe, la Directive 2011/24/UE étend le choix des patients concernant les prestataires de soins dans un autre Etat Membre, indépendamment de savoir si oui ou non ils sont contractés par le système de santé de cet Etat Membre. Des questions spécifiques et liées se soulèvent. Premièrement, plusieurs États Membres ont signalé que dans le contexte de la transposition de la Directive des prestataires privés et non conventionnés, est réclamé un traitement égal par rapport aux prestataires étrangers, dont les prestations seraient remboursées dans le cadre de la Directive sans même être conventionnées par l'organisme d'assurance du patient transfrontalier. Deuxièmement, certains pays (ex: Autriche, Pays-Bas) appliquant traditionnellement un remboursement différentiel pour différents types de prestataires contractés ou non, l'application des niveaux de remboursement plus bas pour les prestataires de soins transfrontaliers non contractés pourrait être perçue comme un frein pour la mobilité des patients.

Enfin, il faut reconnaître que le but de cette étude était de fournir une modélisation des droits des patients nationaux. Les droits liés à la couverture sociale pour les soins de santé ou liées à des questions d'éthiques n'ont pas été considérés. En outre, la revue bibliographique a seulement inclus les sources en Anglais. L'évaluation de chaque situation nationale est basée sur un examen d'expert unique (sauvegardé avec une autre source disponible). À cet égard, la modélisation vise à fournir un aperçu comparatif des droits des patients en place dans les Etats Membres de l'UE, la Norvège et l'Islande.

ZUSAMMENFASSUNG

Dieser Bericht zielt darauf ab, eine Übersicht der Patientenrechte in allen EU Mitgliedsstaaten, Norwegen und Island zu geben. Hierzu wurden nationale Patientenrechtsgesetzgebungen, rechtlich nicht bindende Regelungen (Soft-Law), Strukturen und Durchsetzungsverfahren, die die Rechte von Patienten sicherstellen, zusammengetragen. Die Bestandsaufnahme erfolgte zwischen Januar und September 2015 und gibt eine Querschnittssicht auf die Situation von Patientenrechten in den 30 berücksichtigten Ländern.

Die Bestandsaufnahme schließt eine Literaturrecherche, eine Bewertung von Aktivitäten, die durch das EU Gesundheitsprogramm, durch das Forschungs- und Innovationsrahmenprogramm und durch die Europäische Innovationspartnerschaft „Aktives und gesundes Altern" gefördert sind, ein. Darüber hinaus wurde eine qualitative Bewertung der Patientenrechtesituation von nationalen Experten auf dem Gebiet der Patientenrechte mittels eines Surveys durchgeführt. Erste Ergebnisse wurden auf einem Workshop am 10. und 11. September 2015 in Brüssel präsentiert und mit einer großen Auswahl von relevanten Vertretern besprochen.

Ein Konzeptmodel für die vergleichende Analyse von Patientenrechten wurde bei Beginn entwickelt. Die drei Bereiche von Patientenrechten umfassen **(1) die Grundrechte des Einzelnen, (2) Rechte gestützt auf den Verbraucherschutz und (3) Verfahrensrechte.** Grundrechte des Einzelnen beinhalten das Recht auf Einwilligung nach erfolgter Aufklärung, auf Schutz der Privatsphäre und Würde, auf Einsicht in die Patientenakte und auf Informationen zur eignen Diagnose. Rechte gestützt auf den Verbraucherschutz umfassen das Recht auf freie Arztwahl, auf eine Zweitmeinung und auf eine sichere und zeitnahe Behandlung (Patientensicherheit und Versorgungsqualität) und auf Informationen zu Behandlungsoptionen. Verfahrensrechte schließen das Recht auf Beschwerde, auf Schadenersatz und auf Teilnahme am Entscheidungsfindungsprozess ein. Letztlich können diese verschiedenen Aspekte von Patientenrechten nicht gänzlich voneinander getrennt werden

Das Befragungsinstrument hat alle Aspekte von Patientenrechten hin untersucht auf: (I) die formale Anerkennung des Rechts und/ oder die Art und Weise wie es in übergeordnetes nationales Recht eingebunden ist, (II) die Durchsetzung des Rechts in der Praxis, (III) die Anwendung des Rechts im grenzüberschreitenden Kontext, (IV) den Gebrauch des Rechts in der Praxis und (V) die Rechtsmittel und Verfahren falls das Recht nicht geachtet wird. Darüber hinaus wurden die allgemeine Stellung von Patientenrechten im jeweiligen Gesundheitssystem und der Einfluss von Aktivitäten des Europarats auf die Situation von Patientenrechten untersucht.

Im Bereich der **Grundrechte des Einzelnen** haben alle Mitgliedstaaten sowie Norwegen und Island eine rechtliche Herangehensweise entwickelt, um das Recht auf Selbstbestimmtheit und Vertraulichkeit (Rechte auf Zustimmung und Information, Schutz der Privatsphäre, Akteneinsicht) zu definieren und durchzusetzen. Dies ist nicht überraschend, da diese Rechte Bestandteil von verschiedenen Konventionen zu Menschenrechten sind. Während die meisten Mitgliedsstaaten rechtliche Herangehensweisen entwickeln und vereinheitlichen, bleibt ihre tatsächliche Geltendmachung weiterhin eine Aufgabe. Eine niedrige Sensibilisierung und Kenntnisstand unter Bürgern, medizinischem Personal und politischen Entscheidern

werden als einer der wichtigsten Hemmschuhe für die Weiterentwicklung von Patientenrechten angeführt, zusammen mit der paternalistischen Haltung im Arzt–Patienten Verhältnis, welches in einigen Ländern noch fortbesteht.

Das Recht auf Selbstbestimmung, ausgedrückt durch das Recht auf Einwilligung nach erfolgter Aufklärung, das verwandte Recht auf Information und das Recht auf Schutz der Privatsphäre und auf Vertraulichkeit, ist stark geschützt in einer großen Mehrheit der Länder. In vielen Ländern ist das Recht zum Schutz der Privatsphäre stärker geschützt als das Recht auf Selbstbestimmung aufgrund einer rigiden Datenschutzgesetzgebung.

Im Hinblick auf die **Rechte gestützt auf den Verbraucherschutz** gehen die Ergebnisse unserer Bestandsaufnahme weiter auseinander. Diese Rechte stehen für einen jüngeren Trend, angestoßen durch eine gesteigerte Betonung von Qualität und Sicherheit im Gesundheitswesen, zielen aber auch auf allgemeine Reaktionsverbesserung und Effizienz bei der Erbringung öffentlicher Dienstleistungen. Zumindest in ein paar Fällen ist die Entwicklung eines Grundgerüstes von auf Verbraucherschutz gestützten Patientenrechten augenscheinlich direkt angeregt durch den Umsetzungsprozess der Richtlinie 2011/24/EU über die Ausübung der Patientenrechte in der grenzüberschreitenden Gesundheitsversorgung. Diese Rechte sind in vielen Ländern noch nicht voll etabliert. Obwohl das Recht auf freie Arztwahl in zunehmendem Maße als Patientenrecht anerkannt wird, ist es oft beschränkt durch Vorschriften und der Realität. Geographische Restriktionen bei der Auswahl der Behandlung werden mehr und mehr weggenommen und in manchen Fällen wird eine Öffnung hin zu privaten und nicht-vertraglich gebundenen Behandlungen ermöglicht, wenn eine Versorgung durch öffentliche und Vertragsanbieter (z.B. Dänemark) nicht gewährleistet werden kann. Gleichwohl, die freie Arztwahl kann eine wichtige Quelle für Ungleichheiten sein, insbesondere für Menschen in ländlichen und abgelegenen Gegenden und für Menschen, die sich eine private Behandlung nicht leisten können.

Des Weiteren sind Informationen, die eine freie Arztwahl ermöglichen, oft nicht hinreichend vorhanden. Verschiedene Länder haben deutlich in zentrale Informationsstellen (z.B. Callcenter, Internetseiten) investiert, die Informationen über Gesundheitsdienstleister für Bürger bereitstellen. Ein gutes Beispiel ist die Initiative "1177" (eine Rund-um-die Uhr Telefonleitung und Internetseite), ein gemeinschaftliches Projekt zwischen Kreisverwaltungen und Regionen in Schweden. Viele Länder haben eine Verpflichtung für Dienstleister institutionalisiert, um ihre Bürger über verschiedene Aspekte, die für eine Entscheidung über die Auswahl dienlich sind, zu informieren. Aber verlässliche Informationen über die Leistungsfähigkeit sind im Allgemeinen kaum vorhanden, wenngleich diese die am meisten nachgefragte Art der Information ist. In einigen (7) Ländern bestehen rechtliche Verpflichtungen, um klare und objektive Informationen über die Anbieterleistungen (Behandlungsresultate, Qualitätsindikatoren, Sicherheitsstandards, Recht/ Tauglichkeit zur Berufsausübung) zu veröffentlichen. Aber das Anforderungsniveau unterscheidet sich zwischen den Ländern. In anderen Ländern gibt es keine spezifischen rechtlichen Verpflichtungen in dieser Hinsicht.

Das Recht auf eine Zweitmeinung ist eng verbunden mit dem Recht auf freie Arztwahl. In einer kleinen Mehrheit der Länder gibt es eine formelle Anerkennung des Rechts auf eine Zweitmeinung. In anderen Ländern wird dieses Recht mit dem Recht auf freie Arztwahl zusammengefasst. In mehreren Ländern ist das Recht auf eine Zweitmeinung

(und die Übernahme verbundener Kosten) vorbehaltlich strenger Regeln und Voraussetzungen. Manchmal ist dieses Recht auf bestimmte (meistens lebensbedrohliche) Erkrankungen beschränkt. Zuweilen ist nur eine Überweisung pro Behandlung oder Versorgungsepisode erlaubt. Aber sehr beunruhigend ist das hohe Maß an Ermessen, das dem behandelnden Arzt zugestanden wird, um dem Patienten das Recht auf eine Zweitmeinung zu "erlauben".

Im Gegensatz zum Konzept eines Rechts auf eine sichere und qualitativ hochwertige Behandlung, verweisen viele befragte Experten hier auf die Verpflichtung der Behandelnden, zuweilen formuliert als Patientenrecht auf einen bestimmten Standard der Behandlung. Diese Verpflichtung/ dieses Recht bleibt oft sehr allgemein und wird nicht weiter definiert. Ferner, aus Verfahrenssicht, handhaben eine Mehrheit der Länder Ausbildungsstandards und klinische Behandlungsleitlinien wohingegen Ablaufprotokolle in einem geringeren Umfang genutzt werden. Behandlungsresultate werden in skandinavischen Ländern (Dänemark, Finnland, Island, Norwegen) öffentlich gemacht, aber diese Praxis ist in vielen anderen Ländern nicht verbreitet.

Mechanismen zur ***Durchsetzung von Patientenrechten*** unterscheiden sich von Land zu Land. In den Ländern haben die meisten Rechtssysteme eine Fülle von Mechanismen, um Beschwerden zu untersuchen und darauf einzugehen. Diese gehen von sehr traditionellen bei den Gerichten angesiedelten Beweisaufnahmeverfahren im Zivil-, Straf- und Verwaltungsrecht, und insbesondere gestützt auf das Arzthaftungsrecht oder Personenschaden, über alternative Streitschlichtungsstellen, insbesondere Ombudsmännern, bis hin zur Mediation.

Es gibt einen Grad an kultureller Verbundenheit, die benötigt wird, um die verschiedenen Mechanismen einzuschätzen. Auch wo ähnliche Mechanismen benutzt werden, haben verschiedene Rechtssysteme verschiedene Regelungen und Erwartungen an die unterschiedlichen Rollen von Akteuren im Durchsetzungsprozess. Das kann man an vielen Stellen beobachten: zum Beispiel unterscheiden sich Fristen und die Art und Weise, wie Beschwerden einzureichen sind, deutlich. Ombudsmänner können vorhanden sein, aber der Grad ihrer Einflussnahme und wo sie im System verortet sind, unterscheiden sich.

Die Feststellung der Schuld bleibt das wichtigste Kriterium für eine Entschädigung. In der Mehrzahl der Rechtssysteme kann ein Schadenersatz nur erfolgen, wenn eine Schuld (Fahrlässigkeit) festgestellt wird. In einigen Rechtssystemen gibt es keine Schadenersatzregelung, und in einer sehr geringen Anzahl existieren Mischformen, wo für ein Recht auf Entschädigung die Schuld gerichtlich festgestellt werden muss, aber daneben wurden Institutionen aufgebaut, um Patienten ohne gerichtlich-festgestelltes Recht auf Entschädigung finanziell zu helfen.

Alternative Streitschlichtungs-Mechanismen neigen dazu, keine Entschädigung oder Mangelbeseitigung für den Patienten herbeizuführen. Wo Ombudsmänner oder andere außer-gerichtliche Beschwerdesystem etabliert sind, ist die Wahl der Konfliktlösungs-Instrumente für diese Mechanismen begrenzt, oft um eine Stellungnahme zu dem Fall oder den Rechtsmitteln abgegeben. Eine Entschuldigung oder Erklärung wird als Ziel oder Ergebnis der Streitschlichtung nicht oft genannt. Die Länderexperten weisen nicht auf viele Teile des Rechtssystems hin, die so konstruiert sind, dass Patienten erklärt bekommen, was eigentlich passiert ist oder durch die Patienten eine Entschuldigung erhalten. Dies könnte einbezogen werden bei einer internen Überprüfung durch den behandelnden Arzt oder die Einrichtung und wenn ein Bericht an den Patienten

gegeben werden würde. Aber die Vorstellung, sich bei Patienten zu entschuldigen, taucht hier nicht auf. Dies könnte mit den Schadenersatz-Systemen, die auf eine Feststellung der Schuld basieren, zusammenhängen, welche zurzeit etabliert sind und welche getrennt sind von internen Überprüfungen.

In einigen Rechtssystemen, in denen Patienten sich beschweren wollen, wird ihnen Hilfestellung gegeben. Die Abläufe sind komplex. In einigen Rechtssystemen besteht die Verpflichtung für verschiedene Akteure dem Patient zu helfen, eine Beschwerde einzureichen (und in einigen geht dies soweit, dass bei der Aushandlung eines Vergleichs unterstützt wird). Eingeweihte (die eigenen Bürgers eines Mitgliedsstaats) werden das Wissen haben, um diese Abläufe zu bewältigen – oder zumindest wo sie Hilfe erhalten können. Nicht-Eingeweihte werden eine ausgedehnte Beratung benötigen, um sich das grundlegende unbewusste Wissen von Bürgern anzueignen – das Wissen um die rechtliche und normative Kultur der eigenen Gesellschaft – dabei ist nicht klar, ob die nationalen Kontaktstellen geschaffen wurden mit der Verpflichtung, um wenigstens den Weg zu diesem Wissen zu weisen.

Es wird deutlich durch die Expertenbefragung, dass die Aktivitäten des ***Europarats*** keinen großen Einfluss auf individuelle Staaten haben. Entscheidungen des Europäischen Gerichthofes für Menschenrechte werden in Ländern befolgt bzw. nachvollzogen, aber nur wenige Entscheidungen sind so griffig in Bezug auf Patientenrechte ohne dabei die Möglichkeit für einen Ermessensspielraum zu lassen.

Der Einfluss der Richtlinie 2011/24/EU über die Ausübung der Patientenrechte ***in der grenzüberschreitenden Gesundheitsversorgung*** auf die Entwicklung von Patientenrechten variiert in den individuellen Mitgliedsstaaten. Während der Einfluss in einigen Ländern indirekter Natur gewesen sein dürfte, war die Richtlinie in verschiedenen Mitgliedsländern (z.B. in Österreich, Belgien, Luxemburg, Finnland, Ungarn, Lettland, Malta, Norwegen, Polen, Spanien) in der Tat eine Triebkraft für die Entwicklung von Patientenrechten. Die grundlegende Wirkungsweise der Richtlinie ist dabei, Mitgliedsländer zu einer größeren Transparenz bezüglich der Rechte, die Patienten haben, zu drängen. Während es keine besonderen Vorschriften für grenzüberschreitende Patienten in vielen Ländern gibt, so sind die bestehenden Gesetze in Bezug auf Einwilligung nach erfolgter Aufklärung, auf Schutz der Privatsphäre und auf Einsicht in die Patientenakte gleichermaßen anwendbar auf alle erbrachten Gesundheitsleistungen im jeweiligen Staatsgebiet. Jedoch würden Sprach- und technische Unterstützungen (z.B. Übersetzungsdienst, elektronische Auszüge aus der Patientenakte, ein vereinheitlichtes Einwilligungsmodel, einheitliche Patienten-Kurzakten und Entlassbriefe) vermutlich grenzüberschreitenden Patienten helfen, ihre grundlegenden Patientenrechte durchzusetzen.

Jedoch besteht Bedarf, das Verständnis von Patientenrechten im Kontext der Richtlinie zu klären, indem genauere Informationen an die Mitgliedsstaaten gegeben werden. Die Rechte, die die Richtlinie beinhaltet, sind nicht die grundlegenden Patientenrechte im Sinne eines kranken Einzelnen sondern die Rechte eines Patienten in seiner Eigenschaft als Empfänger – und viel mehr als potenzieller Empfänger - von Gesundheitsdienstleistungen. Die Antworten der Befragten machen deutlich, dass politische Entscheider in vielen Ländern Patientenrechte in traditioneller Weise auffassen. Da dies aber die Umsetzung der Richtlinie in der täglichen Praxis behindern könnte, könnte demgegenüber ein breiteres Verständnis von Patientenrechten gefördert werden, eingeschlossen der verschiedenen Dimensionen, die diese

Bestandsaufnahme abgedeckt hat. Beispiele guter Praxis sind in dieser Hinsicht Norwegen, wo das Patientenrechte- Gesetz überarbeitet in 2011 wurde und nun die „Benutzer" von Gesundheitsdienstleistungen beinhalten und die Niederlande, in denen das Gesetz zur Langzeitpflege (9.Dez. 2014) Regelungen zur Teilnahme und Mitentscheidung des Klienten beinhaltet.

Die Verpflichtungen, die Artikel 4 der Richtlinie Mitgliedsstaaten auferlegt, sind deutlich inspiriert durch ein Bemühen hin zu einigen der am Verbraucherschutz orientierten Patientenrechten. Zum Beispiel erweitert die Richtlinie 2011/24/EU die Wahlmöglichkeiten von Patienten auf Gesundheitsanbieter in anderen Mitgliedsländern unabhängig davon, ob mit diesen Verträge mit dem Gesetzlichen Gesundheitssystem im Mitgliedsstaat bestehen oder nicht. Das wirft zwei besondere und verwandte Punkte auf: Erstens, verschiedene Mitgliedsstaaten gaben an, dass im Zusammenhang mit der Umsetzung der Richtlinie private nicht-vertragsgebundene Anbieter eine „Gleichbehandlung" forderten im Hinblick auf ausländische Anbieter, deren Leistungen über die Richtlinie erstattet würden, ohne vertragliche Grundlage mit dem Krankenversicherer des grenzüberschreitenden Patienten. Zweitens: in Ländern (z.B. Österreich, die Niederlande) mit unterschiedlichen Erstattungssätzen für Vertrags- und nicht-vertraglich gebunden Anbieter kann die Anwendung von niedrigeren Erstattungssätzen auf nicht-vertragliche, grenzüberschreitende Anbieter als Hinderungsfaktor für Patientenmobilität gesehen werden.

Letztlich sollte nicht unerwähnt bleiben, dass es das Ziel dieser Studie war, eine Bestandsaufnahme von nationalen Patientenrechten zu geben. Rechte bezüglich der sozialen Absicherung oder verbundene ethische Fragestellungen wurden hier nicht berücksichtigt. Auch hat die Literaturrecherche lediglich englischsprachige Quellen berücksichtigt. Die Beurteilung der jeweiligen nationalen Situation basiert auf einer einzelnen Expertenbewertung (gestützt auf andere vorhandene Quellen). In dieser Hinsicht verfolgte die Bestandsaufnahme das Ziel, einen vergleichenden Überblick zugeben, welche Patientenrechte in EU Mitgliedsstaaten, Norwegen und Island vorhanden sind.

1. INTRODUCTION

Patients' rights play an important role in health system development. Initially based on fundamental human rights of integrity and self-determination, they are especially critical in the intimate context of medical care and are particularly relevant safeguards given the information asymmetry between patients and medical professionals. From the individual rights *as a patient,* the concept has gradually expanded to also incorporate the rights *to become a patient* (i.e. social patients' rights) addressing issues of coverage, access and entitlements. More recently, we observe a further expansion towards "consumer" patients' rights, which are more focused on issues of information, quality and choice. All in all, these various patients' rights reflect and support a broader trend of patient empowerment, which aims to emancipate citizens who are receiving, or are about to receive, medical care, and to give them a more active role in decisions regarding their own care and care process[1]. It can even extend to trends of involving patients – or their patient organizations – more closely in policy making.

Patient empowerment in its various forms is essentially determined at national level and to some extent reflects different local cultural contexts, especially when it relates to ethical questions, for example, related to the beginning- and end-of-life. However, an international dimension cannot be denied, especially because of the imperative of human rights, enshrined in international agreements and expectations, such as the Universal Declaration of Human Rights (1948) and the European Convention of Human Rights (1950). Through the adoption in 2000 of the Charter of Fundamental Rights of the European Union these fundamental patients' rights have not only been officially reaffirmed and recognized as part of the universal values shared by all EU Member States but they must be observed in the development and application of EU law[2].

The relevance of patients' rights for the EU, and the call for a more explicit endorsement of patients' rights at that level, followed indirectly from the application of EU integration principles to the health sector. As early as 1984, the European Parliament adopted a Resolution inviting the European Commission to submit a proposal for a "European Charter on the Rights of Patients", taking into account the freedom of establishment for doctors and practitioners of paramedical professions. In 2002, Active Citizenship Network promoted the idea of a European Charter of patients' rights in the context of increasing citizen and patient mobility and the enlargement of the EU. Also the further developments in EU consumer policy, and the increased attention to patient safety and medical liability, have stirred the debate on patients' rights. With the EU's increased focus on innovation in the fields of medicine (e.g. personalised medicine) and of ICT (e.g. e-health), new implications and challenges for patients' rights will certainly arise, especially with regard to privacy issues. Developments in these areas are already seen in the recent legislative revision of the EU Clinical Trials regime and the on-going attempts to revise the Data Protection regime. However, Member States have used different routes to protect patients' rights: *some have chosen to express it in terms of the rights of patients; others in*

[1] See also A. Coulter, S. Parsons and J. Askham, Where are the patients in decision-making about their own care?, HEN-OBS Policy Brief, 2008

[2] The accession of the EU as individual party to the European Convention of Human Rights was adopted in 2013 but still needs to undergo a long process of scrutiny and ratification.

terms of the obligations of health care providers. Enforcement is also carried out differently: in some Member States it is through the courts, in others through boards, ombudsmen, etc.

With the adoption of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare it may seem that patients' rights are now fully incorporated in EU law. However, the Directive essentially focuses on the social and consumer patients' rights in the context of cross-border health care. With the exception of the right to reimbursement of cross-border care, it doesn't specify particular rights for patients but rather ensures that procedures and structures are in place in Member States to guarantee common operating principles that *all EU citizens would expect to find (…) in a health system anywhere in the EU*. For ensuring quality and safety this only relates to information on existing standards and guidelines[3].

On the other hand, the national contact points are expected to increase information flows and awareness on patients' rights in all their facets. To increase transparency around patients' rights, not only reimbursement rights but also the more classical patients' rights is key. In the preparatory phase prior to the Directive, the public consultation clearly showed that it was not only legal uncertainty about the statutory coverage that prevented patients from seeking health care in another Member State than their own. Also the uncertainty about the non-financial conditions within which healthcare is provided, was considered a significant obstacle. This is why the European Commission in 2007 decided to take an integrated approach, also addressing the wider "flanking" measures and conditions necessary for citizens to have confidence regarding the care they would receive throughout the EU, including information, quality and safety, continuity of care, as well as mechanisms to ensure appropriate remedies and compensation in the case of harm[4].

Beyond the scope of cross-border care, Member States are facing a number of common challenges, which require them to pay increasing attention to the issue of patients' rights: for example, the growing complexity of healthcare interventions and the rise in ethical questions, demographic changes with an ageing population and a rising burden of chronic conditions (including mental health problems), the prioritization of quality and safety of health care, the empowerment of citizens and the increased attention of cultural preferences. These elements require Member States to develop a coherent strategy around citizens' and patients' rights with respect to health care.

Within this context the mapping exercise of existing patients' rights in 30 countries (including the 28 EU Member States, Norway and Iceland) provides an overview of the various legal frameworks as well as other policy tools and mechanisms in place (or in the making) to define, implement and enforce patients' rights. More particularly, the study has

[3] W. Palm and R. Baeten, The quality and safety paradox in the patients' rights Directive, European Journal of Public Health, 2011, 272-274

[4] Palm W, Wismar M, Van Ginneken E, Busse R, Ernst K, Figueras J. Towards a renewed community framework for safe, high quality and efficient cross-border healthcare within the European Union. In: Wismar M, Palm W, Figueras J,Ernst K, Van Ginneken E (eds). Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity. World Health Organization on behalf of the European Observatory on Health Systems and Policies. Copenhagen, 2011: 32.

- Identified, analyzed and mapped national laws and other policy instruments (strategies, charters, etc.) that guarantee patients' rights in all 30 countries;
- Described and assessed structures, procedures and mechanisms that have been set up to enforce the patients' rights that have been defined by the above-mentioned legislation (including soft-law);
- Mapped patients' rights that are drawn from relevant Council of Europe instruments and documents as well as from its institutions' activities (incl. the European Court of Human Rights);
- Drawn conclusions from a workshop discussion with experts and Commission officials to develop a minimum set of patients' rights that could be defined and implemented at EU level.

2. METHODOLOGY

2.1 General approach

Before all, international comparisons and mapping exercises require a sound and solid conceptual framework to map and categorise various approaches and national strategies. This has been a first priority in this project. An exercise to map national approaches according to their enforceable character and type of legislation was already undertaken by Nys and Goffin (2011)[5]. This has been the basis to develop a more specific conceptual framework for this project, laying out the various dimensions in defining, enshrining and implementing patients' rights. We discerned various patients' rights aspects according to three domains:

- Basic individual rights, such as the right to informed consent; to privacy and dignity; to access to the medical file
- Social rights, such as access to health care; reimbursement; equal treatment
- Consumer-based rights, such as to choose one's provider, to second opinion, to safe and timely treatment (patient safety and quality of care)

In addition, two sets of cross-cutting rights can be distinguished:

- Procedural patients' rights, such as the right to complain, to compensation, and to participate in decision-making are integrated in each of the domains because they help to enforce various patient's rights
- Informational patients' rights, such as the right to information about one's health, about treatment options, about rights and entitlements, including the basket of care and information about providers.
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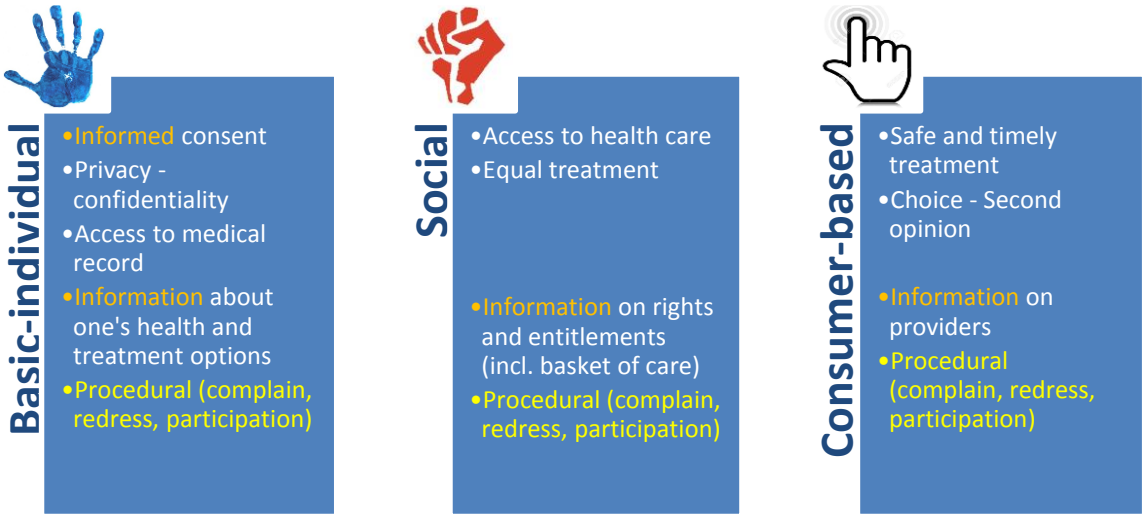

[5] H. Nys and T. Goffin, Mapping national practices and strategies relating to patients' rights, in Wismar M, Palm W, Figueras J,Ernst K, Van Ginneken E (eds). Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity. World Health Organization on behalf of the European Observatory on Health Systems and Policies. Copenhagen, 2011: 159-216

Clearly, these different patients' rights could not be totally separated from each other. Some could even be considered as 'derived' rights that help to implement and enforce other rights. For example, the right to informed consent has obvious links with the right to information. This right to information includes different kinds of information: about one's health, about one's rights and entitlements, about treatment options. The right to information in its turn is related to the procedural right of access to the medical file as it is an important lever to 'enforce' the right to informed consent. Also the other procedural rights to complain and compensation to some extent depend on the access to the medical file to prove any harm or errors. Also the right to second opinion can be considered as a 'derived' or 'connected' right of the right to choose one's provider.

For the sake of this mapping exercise we have focused on the patients' rights domains of basic individual rights and, consumer-based rights (indicated with *), including the linked procedural rights that help to enforce them. The social patients' rights related to coverage for health care have been left out due to the scope of this mapping exercise. Also patients' rights in relation to ethical questions are not addressed in this study.

The patients' rights subjects under study have been clustered in the following way:

- Self-determination
  - a) The right to informed consent
    - i) The right to information about one's health
    - ii) The right to participate in (clinical) decision-making /to choice of treatment options (*)
- Confidentiality
  - b) The right to privacy
  - c) The right to access one's medical record
- Choice
  - d) The right to choice of healthcare provider (incl. ...) (*)
    - i) The right to second opinion (*)
    - ii) The right to information about the healthcare provider (*)
- Quality and safety
  - e) The right to safe and high-quality treatment received in a timely manner (*)
- Procedural rights
  - f) The right to complain
  - g) The right to compensation
  - h) The right to information about rights and entitlements (*)

Please find the final version of the survey template in the Annex 1.

2.2 Literature review and review of funded actions

The mapping exercise included a literature review. The aim was to locate published information (studies, reports etc.) on areas that would benefit from greater formal cross-border co-operation and collaboration in healthcare provision, or information that would assist in developing a methodology to investigate this.

The term cross border was included in searches in relation to quality of care; these only produced 8 relevant hits. For this work a search was carried out using PubMed and the terms health care and cross-border. Health care is used as a MESH term in PubMed, and includes delivery of health care, as well as the three words individually. Cross-border also includes "cross border" as two separate words. This search produced 498 hits, all of which were reviewed. In addition, searching was also carried out using Google Scholar and Google. These searches began with the four words cross, border, health and care. The types of documents included in the search results are peer-reviewed articles, journal entries and book chapters. The results are provided as tables of bibliographic information for the identified references, combining the results from the PubMed and Google searches. The results have been grouped into the following categories.

Cross-border and inter-regional projects and studies	32 results
Health care "tourism" – reproduction	32 results
Health care "tourism" – other, non-specific	16 results
Patients' rights and legal issues	42 results
Telemedicine, E-health, information exchange	19 results
Trade in health services	5 results
Other	20 results

The term health "tourism" was used as it appears in a number of the results, but it intended to cover any travel for treatment.

In addition, more detailed information on the state of patients' rights in Member States was also made available through the Observatory's HiT health system reviews, which include a special section on patient empowerment.

The 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) intended to identify funded projects and other mechanisms relevant to patient rights (patient rights laws, enforcement procedures and Council of Europe activities). Eligible activities needed to be funded in the last ten years (cut-off year 2005). The used search terms include "patient rights", "quality of care", "patient

safety", "choice", "provider", "privacy", "consent", "health record", "consumer right", "indicators" and "guidelines". The respective databases of the above mentioned funding mechanisms were used:

- The Projects and Results service of FP7. FP6, FP5 linked to CORDIS
- http://cordis.europa.eu/guidance/about-projects_en.html
- The Project database of the Health programmes administered by CHAFEA
- http://ec.europa.eu/chafea/projects/database.html
- The Search form of the EIP- Active and Healthy Ageing tapping into Resources and Projects specifically
- https://webgate.ec.europa.eu/eipaha/index/search

2.3 Survey among national experts

The qualitative assessment of the patients' rights domestic situation was undertaken by national patients' rights experts by means of a survey. The survey combined the data collection for (1) the review of legislation, (2) enforcement procedures and (3) the ratification status for the relevant treaties of the Council of Europe. The combination of the review in one survey tool has been useful, since the definition, promulgation and enforcement[6] of patients' rights are closely interrelated.

The project drew on previous experience and research in this field, including the work done as part of the EU-funded EuroGentest project on Harmonizing Genetic Testing across Europe (see http://europatientrights.eu/). The network of country experts that was established under this project, consisting of legal experts mainly in the field of health law, has been reactivated successfully to respond to the new survey. Based on that past experience an effective exchange with the country correspondents and follow up has been organised. Since this type of information and the level of detail on all countries have not been readily available in international literature, it has been important for this project to rely on such a network to get the latest developments in the country.

The collected data has been analysed, systematised and included in a country-by-country matrix, together with information drawn from other sources including available information and knowledge drawn from previous projects and existing international literature.

2.4 Review of Council of Europe activities

This review was undertaken in two ways. The Council of Europe publishes its treaties and conventions, extensive literature about the formal acceptance of its activities by its Member States, and other reports and working documents. The Activities of the European Court of Human Rights have similar official reports and statistics. A review of these official sources was the first part of this review. The second part was of the

[6] Some procedures of enforcement have been the object of research e.g. Mackenney and Fallberg, Protecting Patient's Rights, A comparative study of the ombudsman in healthcare, 2004.

perceived impact of Council of Europe activities in the Member States, and this was surveyed by including questions in the survey among national experts about the impact of Council Europe and European Court of Human Rights activities in their countries.

2.5 Workshop

Preliminary results have been presented and discussed with a wide range of relevant stakeholders during a workshop on September 10th and 11th 2015 in Brussels. The workshop has been the occasion to test and discuss the evidence produced in the Tender's work with a group of national and European stakeholders. The generated insights supported the definition of a minimum set of patients' rights and their implementation at both national and European level. Furthermore, a number of new questions in connection to the mapping exercise have been raised. In order to prepare the discussion at the workshop a discussion paper has been prepared which participants have received in advance. This paper and the programme of the workshop are included in Annex 5 and 6.

2.6 Limitations of the study

The mapping exercise of national patients' rights relied on a key-expert's review of the national situation with one expert providing the assessment of patients' rights for her / his country. This has been refined and validated with the help of literature, if available, and added by a discussion of overall findings during the workshop. Nevertheless, the subjectivity of single answers -their attitude towards the situation of patients' rights in her/ his country – cannot be disregarded and should be considered in the findings of the study.

Furthermore, the rights related to social coverage for health care or linked ethical questions were not considered. Moreover, the review of literature included only English language sources. In this regard the mapping aimed at providing a first comparative overview what patients' rights are in place in EU Member States, Norway and Iceland.

3. RESULTS

3.1 Patients' rights law and enforcement –an overview

In the following sections the findings of the mapping exercise on patients' right in all Member States of the EU, Norway and Iceland are presented first – in this section per patient rights domain – basic individual, consumer based and procedural rights. In the following subsection combined findings per country are displayed.

3.1.1 General context

Gradually all Member States are developing a legal approach to defining and implementing patients' rights. Only a few Members States are lacking a special law on patients' rights (Austria, Bulgaria, Ireland, Italy, and Malta). However, the legal framework on patients' rights usually extends beyond the scope of a single patients' rights law. Other specific legal acts or governmental decisions addressing specific issues or aspects, the application of general principles derived from civil, criminal or administrative law, or even direct reference to the Constitution will complete the picture. Even if in most cases the adoption of a patients' rights law meant an important shift towards a more patient-oriented approach, still in many cases laws defining the obligations of health professionals or deontological codes continue to be an important source for patients' rights.

Clearly, countries like Finland, the Netherlands and Hungary belong to the patients' rights pioneers. They also represent a different approach in terms of legally defining and implementing patients' rights: the nominate contract model (Netherlands), a special patients' rights law with legally enforceable rights (Hungary) and the vertical or public model (Finland). These pioneers were followed by a next group of countries in the late 1990s and early 2000s, which often were inspired by the adoption and ratification process of the Council of Europe's Biomedicine Convention. Among the most recent group of countries introducing special patients' rights legislation, some actually consolidated or coordinated their existing framework (e.g. Germany, Denmark) while others were pushed by increased public interest (e.g. Portugal) or inspired by patients' rights law in neighbouring countries (Luxembourg).

The driving force often was the fundamental rights movements that generated from the societal awakening in the 1970s. This was sometimes also supported by the development of health law as a separate legal discipline. In some Central European countries the political transition in the early 1990s created a boost for patients' rights. Civil society, especially patients' organisations, played an important role in many countries to put patients' rights on the political agenda (e.g. France, Romania). More recently, media coverage of patients' rights violations have helped to increase awareness around this issue. Low sensitivity and poor knowledge among citizens, professionals and policy makers are reported to be one of the 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.

Whereas fundamental patients' rights seem to have become well-established in most Member States, this seems to be less the case for the more consumer-oriented rights.

They also represent a more recent trend that is inspired by an increased attention for ensuring quality and safety in the health sector, but also more generally for responsiveness and efficiency in public service provision. At least in some cases the development of body of more consumer-oriented patients' rights seems to be directly inspired by the transposition process of the Directive 2011/24/EU on the application of patients' rights in cross-border health care.

For all types of patients' rights alike the main problem remains the actual enforcement of patients' rights. At least for six countries weak enforcement was explicitly mentioned as one of the main challenges (Croatia, Cyprus, Greece, Poland, Romania, and Slovenia). On the other hand, it seems that courts are increasingly engaging in this field. Also a lot of alternative enforcement mechanisms are emerging, ranging from monitoring bodies (Bulgaria), patients' rights advocates (Hungary) and ombudspersons (Poland) to legal representation of individuals by patient associations (France).

Impact of Directive 2011/24/EU on the situation of patients' rights in EU Member States, Norway and Iceland

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. In Latvia, for instance, due to responsibilities provided by the transposition on the Directive, the operation of the Treatment Risk Foundation was started in October 2013. The basic mode of operation is that the Directive pushes Member States to be more transparent about rights patients have. Some of the specific issues reported by respondents related to the application of patients' rights in the context of cross-border patients are highlighted here. These cover for example informed consent and access to medical record possibly impeded by language problems, choice of provider and information for cross-border patients, procedural rights and continuity of care.

While in many member states no specific provisions exist for cross-border patients, the existing laws regarding ***informed consent, privacy or access to the medical record*** equally apply to all health care provided on their territory. However, for some country respondents it is clear that the cross-border situation may require some special attention. Some highlight the possibility to receive an e-copy of the medical file for cross-border patients (Estonia, Luxembourg, Romania, Slovenia). In France and Norway, mandatory translating services are covered by law with regard to domestic and cross-border patients not able to communicate in the official language of the country. In the UK, NHS trusts offer on the of basis the NHS Constitution, section 3a on the patients' right to information [7] either translated patient information (leaflets) or translation services upon request to non-native speakers. The latter often

[7] NHS Constitution for England (2013), available at http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf

implemented as a telephone translation service.[8] Finally, the EXPAND cross-border project (among others in Luxembourg) aims to make cross-border patient data sharing more efficient.

Many countries foresee as a general condition to grant prior authorization for cross-border care that the service is part of the statutory benefit basket but cannot be provided within medically necessary time limits. Although in principle prior authorization cannot be granted on the basis of ***quality and patient safety*** reasons, this seems to be a strong motivation for cross-border care. Although the Directive 2011/24/EU provides for the possibility of member states to require and refuse prior authorization for treatment by providers who would raise quality and safety concerns, none of the countries except Romania seems to have actually implemented specific regulations in that respect. In that later respect, Romain Government Degree No 304/2014 requests Romain citizens to obtain a document on the quality of the health care professional from the national contact point of the intended country of treatment as pre-condition to grant prior authorization.

As a principle Directive 2011/24/EU extends patients' ***choice options*** 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 questions:

First, to what extent does this put pressure on member states to extend choice options and also allow reimbursement for non-contracted providers domestically? Indeed, several Member States signalled that in the context of the transposition of the cross-border care 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. In Estonia an amendment to the legislation was pushed in 2013 by private providers that would allow patients to obtain specialist day care and inpatient care without waiting time from any provider while receiving full reimbursement from the statutory health insurance fund at a later date. Even if from a legal perspective this could not be sustained, the political argument was that in this way no public health insurance money would be exported, as otherwise patients would get the treatment in Latvia or Finland.

Secondly, to what extent are member states allowed to limit reimbursement for cross-border care to rates that are applicable to non-contracted providers? Indeed, some countries traditionally apply differential reimbursement for different types of providers. For instance, in Austria a patient who seeks treatment with a non-contracted provider, will obtain a lower reimbursement of 80% of the fee that would have been paid directly to a contracted physician performing the same service. Also in the Netherlands patients with an in-kind policy, which guarantees them free-of-charge health services from providers who have been contracted by their health insurer, can only obtain reimbursement at a lower level if they seek treatment from a non-contracted provider (Article 13 of the Dutch Health Insurance Act). Based on the so-called "hindrance criterium" this level should be "substantial" so that it treatment from a non-contracted

[8] Gan, S (2012) LOST IN TRANSLATION:HOW MUCH IS TRANSLATION COSTING THE NHS, AND HOW CAN WE BOTH CUT COSTS AND IMPROVE SERVICE PROVISION? Health2020.org, available at http://www.2020health.org/2020health/Publications/publications-2012/Translation-Services.html

provider remains a financially feasible option for the patient. In a written to a question from Dutch MEP Ria Oomen-Ruyten in September 2013 (E-010662/13) Health Commissioner Borg made clear that this lower reimbursement could not automatically apply to cross-border health services: *"the application of reimbursement tariffs or amounts lower than those used for care received from contracted providers in the Netherlands would amount to a disincentive for patients to use their rights to cross-border healthcare. It would therefore constitute an obstacle to the exercise of free movement, and would need to be justified with reference to overriding reasons of general interest. It would also need to be demonstrated that this obstacle was both proportionate and necessary with regard to the desired objective."* The Dutch government proposed to abolish the insurers' obligation to reimburse non-contracted care, at least for secondary care, which would reduce free choice of provider in the Netherlands. In an advice to the First Chamber the highest administrative court has found this proposal consistent with European law, i.e. the Directive 2011/24. However, the amendment was not adopted in Parliament.

Another issue is whether the absence of choice options domestically because the specific care or expertise is not available in the country (e.g. rare diseases) could justify to getting care and/or second opinion in another member state. Also the applicability of conditions that actually limit choice need to be questioned as to their conformity with EU rules, such as referrals by a domestic provider or the requirement that first all domestic treatment options have to be exhausted.

The Country Expert reports show that in the area of ***enforcement*** the Directive has produced little specific impact. Countries all had complaint and compensation schemes in place, and individuals coming from outside the country are not given special routes to complaint or compensation. In line with the Directive, individuals seeking to use their cross-border rights are simply treated as 'insiders' for the purposes of enforcement.

National Contact Points are charged with providing information to those who enquire about the processes of enforcement. It is clear from the country experts' reports that the processes of enforcement are extremely complex in each Member State. In some jurisdictions, National Contact Points will be able to point to particular institutions within the system who have duties to assist any individual (including those from outside the jurisdiction) who are making complaints. This is not uniform across the system. It remains to be seen how far National Contact Points themselves will see their role in providing information as providing information not only about the specific enforcement rights and processes, but about the more general legal landscape that it is essential to know and understand to make effective complaints. For example, where compensation is within the general civil Law, it is necessary to understand the way in which the general tort of negligence operates. It remains to be seen how far individual National Contact Points go in providing this broad information about the national legal processes.

3.1.2 Basic individual rights

Self-determination and confidentiality

All Member States are developing a legal approach to defining and implementing the basic fundamental or classic patient rights to self-determination and confidentiality (including the rights to consent; privacy; and accessing medical records). These rights are embedded in several individual human rights frameworks (for example the Biomedicine Convention). In a way this mapping exercise concludes that we will arrive at a minimum set of patient rights in all 30 States.

Despite a common base for basic individual rights, the rights to consent, privacy and accessing medical records are protected by ***multiple mechanisms in each Member State***. The right to privacy is perhaps the most heavily protected, with strong penalties in many states for breaches of confidentiality and data protection. Most countries also have strong protections for the right to consent, with some notable exceptions such as Latvia. The right to access one's medical record is also provided for strongly in most member states, although many respondents reported that some hospitals do try to limit access in practice.

Despite most countries have a strong legislative basis for patients' right to **self-determination**, in some countries remain some processes which could impede the right to informed consent. For example, in one of the countries under study, several hospitals require patients to sign a "general consent form" before they can be seen by a doctor. Such "basic consents" actually take the form of a contractual obligation, meaning that a patient cannot even be admitted to a hospital without consenting in advance to whatever a doctor may recommend. These procedures appear to be incompatible with informed consent as it is normally understood. In the same country, patients do not have a right to different treatment options, but rather to "the professional choice of the physician". Given that consent is a prerequisite to seeing a doctor, it is perhaps unsurprising that limits are also placed on choosing different options, but these facts suggest that greater emphasis on self-determination is required in a few member states.

The right to **privacy** is even more strongly protected than the right to self-determination in most European countries, with various civil, criminal and constitutional protections in place and clear complaint and redress mechanisms, often via Data Protection Directorates/Inspectorates. However, there are a few exceptions; in some cases, an "old-fashioned" attitude to privacy still dominates despite new legal safeguards. In one country, there appear to be few procedures for safe data processing, and patients are sometimes examined in front of other patients, violating their right to privacy. This situation may be largely due to the fact that healthcare professionals remain relatively unaware of the importance of privacy and confidentiality. In another country, details of celebrity's medical records are occasionally leaked to news media, but this represents an illegal transgression rather than widespread practice due to weak regulation or ignorance of the importance of confidentiality.

3.1.3 Consumer based rights

Choice

Choice in health care is a complex issue. It can relate to various aspects (e.g. provider, insurer, insurance plans). It can be modified in various ways (e.g. gatekeeping, financial incentives, etc.). In some countries choice is an intrinsic value of the health systems, in others it is more regarded as a tool to increase efficiency and improve quality. Countries have put in place different mechanisms to enable choice. The right to participate in clinical decision-making/to choice of treatment options is only formally recognised in Finland, the Netherlands and Norway. For the other Member States many respondents answer yes, but on closer look they are referring to the right to give or refuse informed consent.

The right to second opinion is closely linked to the right to choose one's provider. A small majority of Member States has formally recognized this right to a second opinion. In other Member States it is subsumed under the right to freely choose a physician.

Information is key to making an informed choice about what healthcare provider to consult. Specific legal requirements for providing clear and objective information about providers regarding their performance (outcomes, quality indicators, safety standards, rights/fitness to practice are established in Belgium, Denmark, Ireland, Luxembourg, Netherlands, Norway and Slovenia but the level is varying between them. No specific legal requirements in the other Member States.

Enabling choice through reporting on outcomes of quality of care and patient safety

In order to operate provider choice patients are increasingly looking for information on the quality of healthcare providers. Reliable and systematic sources of information are still lacking in many countries. However, a number of Member States are starting to organise public reporting on the status of quality of care and patient safety to support transparency in domestic health systems. The quality indicators and outcomes used differ as well as the institutions that publish these reports. Providing transparent and reliable information on quality outcomes of providers is in the first place seen as a responsibility of the state. In the first place many countries have instituted a duty on the individual providers to inform their patients on their performance or aspects of it (e.g. patient safety, waiting lists). For instance, since 2007 all German hospitals are required to publish results on 27 selected indicators collected by Bonus Quality System (BQS).

But governments also invest in producing centralised and comparative information. In England quality outcome information is published on the NHS Choices website (http://www.nhs.uk/pages/home.aspx). Also the Care Quality Commission, the independent regulator of all health and adult social care services provided by the National Health Service, local authorities, and the independent sector in England, rates performance for every provider on the basis of 5 questions (http://www.cqc.org.uk/search/services/hospitals).

Continued on next page

In the Netherlands the governmental National Health Care Institute guides patients in their choices by providing information on quality indicators on delivery care, rehabilitation and hospital services (http://www.kiesbeter.nl/). Also the Norwegian Health Directorate takes a leading role in publishing quality indicators (https://helsenorge.no/kvalitetsindikatorer) and providing up-to-date relevant information (patient's rights, waiting times and quality information) to patients about the different hospitals through the information service Free Hospital Choice Norway. In Sweden the National Board of Health and Welfare and the association of local health authorities and regions (SALAR) collaborate to develop an annual comparison and ranking across county councils (Öppna jämförelser), including a comparison of hospitals based on a composite of some 50 indicators. In Romania the Ministry of Health started to develop a performance ranking of hospitals in 2011, which can be consulted on its web site. In Estonia the health insurance fund publishes reports on selected indicators for the main 19 acute hospitals as part of the Hospital Network Development Plan (HNDP) and provides information on family physicians' performance. In France the National Health Authority (Haute Autorité de Santé – HAS) publishes a mix of yearly collected performance indicators based on the accreditation process (www.scopesante.fr). In Italy based on the set of indicators collected since 2009 by the National Health Outcomes Programme a public reporting system was developed late 2013 (www.doveecomemicuro.it). In Germany the new Institute for Quality Assurance and Transparency in Health Care (IQTiG) is also required to publish results of the quality assurance measures in an appropriate manner and in a form understandable to the general public. The German association of health insurance funds developed a rating system for long-term care providers (www.pflegenoten.de).

Despite of the progress made many of the quality reports are not updated on a regular basis. Furthermore, the information is not systematically available for all providers. This is also why the state effort is in many countries complemented by private initiatives. These can be in the first place patient associations or consumer organizations. Examples are the Belgian consumer organisation Test-Achats, which publishes comparative information on hospital quality (Belgium http://www.test-aankoop.be/gezondheid/hospitalisatie) or the Dutch Patients' and Consumers' Federation which developed a patient reporting system to rate individual healthcare providers (www.zorgkaartnederland.nl). In Germany the private non-profit Bertelsmann Foundation together with the main patients and consumer organisation developed a healthcare provider search engine based on patient reporting (https://www.weisse-liste.de). Also media like newspapers and magazines increasingly publish comparative information on hospitals The French magazine Le Point (http://www.lepoint.fr/) publishes an annual ranking of hospitals and private clinics covers 64 medical specialties including activities such as psychiatry, depression or schizophrenia. Le Point's ranking is jointly based on the PMSI, the Health Information System in French hospitals and a questionnaire. In Sweden even the Confederation of Swedish Enterprises initiated comparative information about providers (www.omvard.se), which is partly based on information collected through National Patient Surveys that are conducted every two years.

Second opinion

Although patients are always free to consult another doctor to receive a second opinion the question whether this right should be formally recognized and covered under the statutory health system is less universally accepted. While in certain countries the right to second opinion is implicitly included in the right to choose one's provider, in countries which apply some kind of gatekeeping mechanisms it requires a more explicit form of recognition and regulation. In several countries the right to second opinion (and the assumption of related costs) is subject to strict rules and conditions. In general it will be subject to referral, hence the explicit approval of the treating physician. Sometimes it will be limited to only one referral per treatment or care process (Estonia, Norway, Slovenia, Spain). Certain countries limit second opinion to certain providers, most often public or contracted providers but sometimes even more restricted to providers in the same hospital (Slovenia), or specific ones listed per pathology (as in some Italian regions) or chosen by the treating physician (Poland). In some cases the second opinion can be also provided by a non-contracted provider or even a foreign provider (Estonia, Italy). Some countries limit the right to second opinion to certain conditions (Denmark, Italy, Spain, Sweden). In Denmark where second opinion is not formally recognized a special second opinion panel is set up by the Health and Medicines Authority for severely sick patients who have been given up by their provider. This panel will assess whether the patient may benefit from experimental treatment at a private hospital in Denmark or a hospital abroad. The decision to refer the patient to this panel is in the hands of the treating physician. In Italy for patients suffering from a rare disease (or for whom a suspected diagnosis of rare disease was made) a clinical evaluation by experts of the National Network for Rare Diseases is possible. If no experts can be found within the national territory - or if the expert's opinion is inconclusive - scientific advice can be asked to foreign expert centres.

What is the most disturbing is the high level of discretion of the treating physician in "allowing" the patient to exercise the right to second opinion. In Poland the right to second opinion was framed as a right to appeal to a medical opinion or a medical decision. This medical appeal is to be filed to a Medical Commission operated by the Patient Rights Ombudsman office. The Commission takes a decision on the basis of the medical records and any necessary examination. In 2013, 28 objections were filed but only 2 met the formal requirements and were proceeded to the Commission.

Quality and patient safety

In contrast to the concept of a right to safe and quality treatment many respondents refer here to the obligation of the physician, sometimes framed as a patient right, to adhere to a standard of care. In many countries 'the standard of care patients/clients are entitled to expect' is very broadly described in various legal acts as "meeting certain patients' expectation and or "adhering to the current scientific medical knowledge". The right is embedded in the contractual relationship between provider and patient (e.g. Austria), in dedicated patient rights acts (e.g. Finland, Iceland) or can be recognized in a set of different laws (e.g. Italy) However, this remains often very broad and not further specified.

The obligation of professionals to adhere to a certain standard of care is structurally ensured by the formal recognition via licensing and accreditation of healthcare professionals in almost all countries and to a lesser degree - but increasingly - of healthcare institutions (e.g. hospitals) providing care. Poland is an exception here only providing voluntary system of accreditation. To ensure a defined standard of care, continuous professional development (CPD) is mandatory in approximately half of EU countries for a number of healthcare professions. For physicians, mandatory CPD schemes have been implemented in 12 countries (UK, IRL, DE, GR, HU, IT, NL, NO, PL, SK, SL) and voluntary schemes in four countries (AU, BE, ES, SW).[9] For the nursing profession found CPD is compulsory in 14 EU countries (UK, BE, CY, CZ, EST, FR, IT, LV, LIT, RO, SK).[10] For medical specialties CPD is compulsory in 18 EU member states and voluntary in 13 countries. For dentists, 14 countries reported a compulsory CPD scheme[11]. None of the EU countries reported mandatory CPD schemes for midwives. However, the number of countries that have link the compliance with compulsory CPD schemes directly with the revalidation of licenses or accreditation is considerably lower. In many instances, the impact or sanctions following non-compliance remain unclear. Moreover, countries differ regarding the requirements on CPD (number of study days/ credits in a certain period) and the specificity of established guidelines for CPD.[12]

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. Reporting publicly about outcomes is practiced in Scandinavian countries (Denmark, Finland, Iceland, Norway,) but not common in many other countries. Countries which have not stipulated patient safety and quality formally include Ireland and Malta.

Implementation of patient safety and quality policies is a task often spread over various institutions in the healthcare sector including typically the Ministry of Health, professional chambers and a dedicated institute for quality. The recognition of the right to treatment in a timely manner, hence provisions on waiting times and list are to a lesser degree – compared to quality and safety - formally recognized in the 30 countries. Among the countries addressing waiting time, some have set maximum waiting times whereas others only have established criteria how waiting lists need to be established without specifying limits.

[9] Murgatroyd, G. (2011) 'Continuing professional development: the international perspective' General Medical Council Research paper.

[10] European Federation of Nurses (EFN) (2012) 'EFN country report on continuing professional development in nursing', available at http://www.efnweb.be/wp-content/uploads/2012/11/EFN-Report-on-CPD-June-2006-Final-rev-22-10-2012.pdf

[11] Bullock, A., Bailey, S., Cowpe, J., Barnes, E., Thomas, H., Thomas, R., Phillips, S., Kavadella, A., Kossioni, A., Tsiklakis, K., Karaharju-Suvanto, T.,Suomalainen, K., Kersten, H., Povel, E., Giles, M., Walmsley, A., Soboleva, U., Liepa, A. and Akota, I. (2013) 'Continuing professional development systems and requirements for graduate dentists in the EU: survey results from the DentCPD project' *European Journal of Dental Education* 17(sup 1) pp. 18-22.

[12] European Commission (2013). EAHC/2013/Health/07 Study concerning the review and mapping of continuous professional development and lifelong learning for health professionals in the EU – Final Report, available at http://ec.europa.eu/health/workforce/docs/cpd_mapping_annex3a_en.pdf

Blame free reporting system - Denmark

The implementation of an incident reporting system in Denmark started in 2004, since then health personnel in hospitals can report incidents. The successful implementation required a change in culture among healthcare professionals seeing the reporting as learning opportunity rather than for victim blaming. Moreover, the success of the system was dependent on ensuring a blame-free environment in which incidents could be reported. The incident reporting system has been opened up to all providers in the healthcare system in 2010. From 2011 onwards even patients, their relatives and municipalities are now eligible to report incidents as well. 182 000 incidents reports from the healthcare system were entered into the database in 2013, of which approximately 1.5% was reported by patients and their families. However, because of the successful implementation of the reporting systems the reported number of incidents reported has increased. It is now a challenge to follow-up and act upon all incidents received. Furthermore, it has caused currently political pressure because of the perceived increased safety problems in Danish health care institutions putting politicians in a difficult position. Therefore, politicians are questioning the success of the system as numbers are not going down.

European Commission (2014). Key findings and recommendations on Reporting and learning systems for patient safety incidents across Europe. European Commission, Patient Safety and Quality of Care working group.

Torben Mogensen (2014), Reporting and learning systems, Contribution to panel discussion at Cluster Meeting Rome, 3rd December 2014

3.1.4 Enforcement and Redress

Enforcement and redress in relation to patient rights pose a number of interesting questions, which emerge from the country expert reports.

The information can be considered around three issues:

- The legal basis for the claim. Here there is a range within the Member States. The range that is clear is: disciplinary action from professional regulatory bodies or practice licensing authorities; administrative breaches (separating breaches of constitutional or Human Rights Law from explicitly 'patient rights Law' breaches); civil Law issues (separating breaches of contract issues from tortious liability); and overtly European Union-generated rights and duties (separating general Law, e.g. data protection, from the specificities of Cross-border Patient Rights as defined in the Directive.
- The forum in which the enforcement or redress issues are addressed. The range here is from formal courts (including appeals to courts from more informal fora); Ombudsmen (both general ombudsmen and healthcare specific ombudsmen); Mediation councils and practices; out-of-court settlements where a lawyer or lawyers operate to manage settlements; Complaint procedures within the healthcare provider's administrative system; Professional bodies' complaints procedures; Complaint to a non-medical tribunal or authority; other mechanism.

- Outcome range. Here we are concerned with the actions taken to redress breaches. The range here is: criminal (imprisonment and fines); professional disciplinary action (removal or suspension of license to practice); financial compensation (either based on a fault system or a no-fault system); 'specific performance' (e.g. rectification of records, corrective therapy); apology (with or without admission of liability); explanation; and, effectiveness measures or reports.

Legal basis for the claim

The biggest difference between Member States is in the basis of civil liability in tort Law. In the majority, the traditional basis for medical injury compensation is negligence, which requires the breach of a duty of care based on fault (i.e. an unacceptable act by the health carer or provider, an act that, for example, no reasonable practitioner would have done) and the establishing of a causal link between the action and the damages. In many jurisdictions this remains the basis of an action - indeed, even when alternative dispute resolution is available, in most jurisdictions "fault-based" negligence remains as a back-stop for determining compensation when other elements of the claim have been addressed. However, in some jurisdictions, there has been a move to compensation through "no-fault" systems. Here, the requirement to prove that the cause of the harm was unconscionable, or beyond normal or reasonable practice, is removed. The schemes are underwritten by insurance schemes and the only matter to be proved is the evidential question, 'what happened?' In terms of cross-border patient rights, this difference could be significant (especially patients coming from an expectation of no-fault systems to a fault-based approach).

There are a number of jurisdictions where the 'breach of statutory duty' is used in relation to the more consumer-based patient rights (e.g. rights in relation to choice) where the outcome is not a matter of negligence, but rather a more 'procedural' breach. These breaches are also, in some jurisdictions, addressed through breaches of contract Law, either between the patient and the health provider, or the patient and the insurer, or through Administrative Law.

Experts did not, in the vast majority, refer to criminal sanctions (but they did not indicate that criminal sanctions were not available, for example, in the case of gross misconduct or of assault (unjustified treatment without consent). Where there is a general set of duties imposed by European Law without the possibility of exemption for breach (for example, where the MS is subject to a European Directive as is the case in data protection), then these can be presumed. We have rather taken the view in this study that criminal sanctions, unless the experts indicate to the contrary, are, like fitness to practice and other professional standards mechanisms, rather unrelated to the enforcement of patient rights for the individual patient in question. His or her dispute seems, in those situations, to be more the vehicle for a different journey; sanctions are not, except in a few cases, about helping the patient, except in the abstract. This leads to something that is missing in the Country reports: apology and explanation. It might be implied in the nature of the internal inquiries, but where there is fault-based compensation, it is unlikely that an apology will be quick in coming in the process.

Fora

Again, here the back-stop position of the formal courts is not always articulated, but in the vast majority of the reports Civil and Administrative Courts are large players in the process of enforcement and compensation - particularly in relation to compensation. That said, it is striking how many jurisdictions use Ombudsmen for dispute resolution in breaches of patient rights. Ombudsmen are designed to redress something of the imbalance of power in a formal court setting, by ensuring that the weaker party (and here we assume that is the patient) is not disadvantaged by the formality of approaching Law and making a complaint. Whilst an Ombudsman operates within strict processes of administrative justice, their interaction with the patient (in this case) is more informal. Many jurisdictions rather limit the contribution that Ombudsmen make to the process, perhaps limiting them to administrative Law issues with administrative Law, process-based remedies. Mediation is available in some jurisdictions, but it does not seem to be widely employed.

Many jurisdictions start the complaint process with an informal complaint between the patient and the health carer (the person or institution that has caused the alleged breach of duty). Then there are duties to disclose information on the carer, and there are duties to inform the patient, in some jurisdictions, about alternative measures. What is clear is that the range of fora for addressing patient rights is broad, with some jurisdictions opting for more patient-accessible mechanisms than others (judging from the comments of the experts on the effectiveness of the system). The procedures operated by professional bodies in their complaints fora are an issue in this aspect.

In a large number of jurisdictions, some participant in the process is charged with a statutory duty to assist the complainant in his or her negotiation of the process. This can range from assistance with funds to pay for legal advice, to a duty on the health care provider to give clear information about the complaints procedures. In many jurisdictions, some participant has a strong duty to assist. However, it is not clear how this is perceived by the patient; if the assistance-giver is sufficiently independent of other parties in the process to allow the patient to trust the assistance. This requires further study, especially as the National Contact Points will be seen, it could be imagined, as places where at least clear explanations of the way that the system works can be found. A final point is that the Country Reports show that there are many gaps in the narratives; understandably, there are whole areas where individuals have simple background, cultural knowledge of the way that systems work - the expectations that one can have about the system, where information really can be found, etc. This can be described as the local dialect of the Law and patient rights, and it is not immediately apparent to outsiders; insiders will know the normative language and its context, outsiders will be lost to a very large extent.

National Agency for Patients' Rights and Complaints - Denmark

It is apparent from the study that there is an enormous range of mechanisms for patients to negotiate in seeking to enforce one's rights or seek redress for breach of those rights (particularly mistake or negligence). Assistance in negotiating this wide range of procedures must be valuable for patients. In Denmark, the National Agency for Patients' Rights and Complaints provides this level of service.

It has four principle responsibilities:

- to provide "a single point of access for patients who wish to complain about the professional treatment in the Danish health service";
- to deal "with complaints about the disregard of patient rights and complaints about the Patient Insurance Association's decisions over compensation";
- to provide "for the administration of the system for reporting inadvertent incidents within the health service, and helps to make sure that the knowledge gained from these incidents and patient and liability suits is used preventatively"; and,
- to offer "guidance on rights to healthcare in other countries in accordance with Danish legislation, EU regulations and other international agreements". (from homepage of website)

http://www.patientombuddet.dk/?sc_lang=en

Compensation and redress

We have some details in the expert reports on financial compensation. However, this is an area where more detail is needed. For example, very few experts refer to imprisonment or fines, but we know (for example, in data protection Law) that both are required for some breaches. What is striking is that none of the experts referred to apology or explanation in their reports, but at the same time, this is often reported to be what patients who have suffered breaches of their rights seek from the process of complaint.

Under the Convention on Human Rights and Biomedicine there are three components: judicial protection (including injunctive relief) (Article 23); compensation for 'undue damage' from a procedure (Article 24); and, sanctions for breaches of the Convention rights (Article 25). From the survey, it is clear that enforcement of rights produces a very broad spectrum of processes, not all of which are available in each Member State.

Within this part we are concerned with Procedural Rights – the ways by which patient rights are protected and enforced in the Member States. We have considered this in two dimensions: we asked the Country Experts about the specific enforcement of the traditional and modern rights, and about general issues of the right to complain, to receive compensation, and to receive information about rights and entitlements; we

have then considered these issues within an analytical framework of the legal basis of the mechanism, the fora within which they operate, and the range of redress that is available.

A new model for redress: separating redress and professional liability - Austria

Since 2001 an additional redress model for patients has been in introduced in Austria. On the background that the legal practice shows that the enforcement of indemnity claims may take years of court proceedings and is often difficult for patients because the burden of proof lies with the patient.

In cases where redress linked to the liability of professionals and providers is not possible, because evidence for the harm caused by a provider is hard to establish, a fund for redress of harm has been established. The fund is financed by patient fee per day of hospital stay and is administered by the regional patient advocacy and an independent commission decides on redress for individual cases. There is an overall limit of approx. 22000€ for redress from the fund in individual cases.

The new model is *an addition* to the existing system and patients are supposed to investigate if the existing civil law measures for redress are deemed to be successful. Only, in cases where this seems not promising, a petition to the fund may be successful. However, a redress from the fund does not bar patients from a civil law process. There is no legal claim to redress from the fund.

NÖ Patienten-und Pflegeanwaltschaft (2001). Rechtliche Informationen 2001-06-29 - Entschaedigung nach Behandlungsschaden. St Poelten, Austria: NÖ Patienten-und Pflegeanwaltschaft

General Context

This mapping exercise considers the enforcement mechanisms in the abstract – i.e. not how they are applied in practice (how discretions are used or the standards of evidence that are required for a successful complaint or action, or whether the system is adequately funded to make it available to patients) but the range of possibilities that are available in the Law. In this General Context section, it must be stressed that not all the mechanisms described occur in each jurisdiction.

Legal bases range from sanctions in the Civil or tortious liability for compensation is seen through either a no-fault approach, or a fault- or negligence-based system. Administrative or constitutional Law (including human rights Law) is also used as the basis for an action, with redress being available either through the formal court structure or through more informal 'ombudsmen' or other tribunals. It is interesting that the Directive on Cross-border Patient Rights does not of itself create legal bases for redress, although in a number of jurisdictions the National Contact Point is indicated as a procedural route. The fora that are available to address breaches of patient rights are from the formal to the informal. Criminal, civil, administrative and constitutional courts are possible forums for complaint, as are professional 'courts', ombudsmen and tribunals. In the first instance, however, a complaint will be made to the health care provider, be that the professional directly dealing with the treatment

or the institution within which the care is provided. Here, a range of dispute resolution mechanisms is used, again with varying degrees of formality. At this general level, however, it is very interesting to see that two of the key elements that patients making a complaint might want to see are not present in the patient rights legal landscape: explanation and apology.

Sources of the Law differ between jurisdictions. A large number of Member States have specific patient rights legislation containing the right to complain. Equally, many use general Laws relating to compensation, or the general tort Law system to find a solution to the complaint. This relates most obviously to quality of care issues, and the long-established area of medical negligence – areas that have a physical or psychological damage. What is not as well established is redress for a breach of a right *per se*. This diversity in approaches to procedural rights within each jurisdiction that ensure the patient's ability to complain and 'manage' any adverse effects of their treatment, and that could make complaint difficult and unpredictable, is amplified in the cross-border situation. Take for example, the enforcement of the right to informed consent.

From the Country Correspondent reports, there are many Member States where the full range of legal remedies and mechanisms is available to a patient, i.e. the patient can pursue his or her complaint through the criminal Law, the civil Law of Tort (medical liability), through a parliamentary or health Ombudsman, and/or through a professional hearing (or that their complaint could initiate a professional action as well), and that this process might be started through an informal complain made to the health carer or the institution, or to other bodies (Austria, Hungary, Italy, Netherlands, Portugal and the UK). In other jurisdictions, the expert reports that there are no specific procedures for informed consent, but that the general Law applies, which could mean that all the above actions are available (Iceland, Latvia, Lithuania, Luxembourg, and Slovenia). In Germany, only the criminal liability was mentioned, whereas in other jurisdictions, the criminal Law was not mentioned, only the general civil Law (Belgium, Croatia, France, Norway, and Poland). It should be noted that there are variations within this civil liability. For example, the experts from Belgium and Sweden pointed to the difficulty in making a medical negligence claim for breach of informed consent regulations, and Estonia indicated that the burden of proof was on the patient. Some experts indicated the role of a National Agency for Patients' Rights And Complaints (Denmark), an Office of Patient Rights (Greece), Malpractice Commission (Romania), or Health Care Surveillance Authority (Slovakia). What was particularly interesting in the context of the survey being about Directive and cross-border patient rights, no expert mentioned the role of the National Contact Points in this context. Further, no expert discussed how rules of which Law and which forum would apply in the international context.

What is clear is that a patient coming from outside a Member State will have a complicated and culturally different (often almost opaque) system to consider. It is unclear how far this will act as a barrier to deciding to use rights to cross-border treatment under the Directive, but it certainly raises the question of how far harmonization of processes, or at least a strengthening of the role of the National Contact Point.

Dissemination and Communication of Patient Rights: The NHS Constitution and Handbook – the UK

The National Health Service has been an iconic feature of UK life since its inception in 1948. However, its universal, free at the point of use, approach perhaps did not articulate the underpinning rights of patients. This was to a very large extent remedied with the publication of the "NHS Constitution" with the accompanying "Handbook to the NHS Constitution". First published in 2012 and revised in 2015, the Constitution is designed with the following in mind: "The aim of the Constitution is to safeguard the enduring principles and values of the NHS… It is intended to empower the public, patients and staff by setting out existing legal rights and pledges in one place and in clear and simple language" (Handbook, p. 3) It outlines "rights", "pledges" and "responsibilities"; the "legal obligations" that patients (and staff) have, the "ambition" of the NHS beyond the legal obligations, and the "expectations of how patients, the public and staff can help the NHS work effectively and ensure that finite resources are used fairly" (Handbook, p. 4).

This is can be seen as an important change in the NHS. The Constitution is written in plain English, and covers in 16 pages only, all aspects of NHS Patient Rights. It starts with the guiding principles of the NHS, particularly the expectations of professionalism and patient-centricity; the values that underpin the conduct of the NHS, including partnership with the patients, respect and dignity, equality, empathy and the commitment to "improving lives". Thereafter, it outlines access, privacy, choice, patients' responsibilities, and the rights and pledges (and expectations) relating to NHS staff. It includes aspects of enforcement. It concerns both the traditional rights and the modern rights.

Alongside the NHS Constitution is the Handbook. This articulates in much greater detail the legal bases of the rights, pledges and responsibilities - in some 156 pages. It gives the principles that are clear in the Law, and discusses where they are more aspirational or not fully clear. It articulates policy, and it seeks to flesh out the areas that are issues of practice, discretion or debate.

http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx

Lay summaries of patients' rights law – the Netherlands

Dutch patients' organisations such as the Patient federation NPCF (https://www.npcf.nl/) and Zorgbelang Nederland (www.zorgbelang-nederland.nl) publish on their websites lay summaries on patients' rights in the Dutch context. The summaries include easy understandable information using short and practical relevant information – sometimes with the help of examples - on a number of patients' rights domains such as:

- rights of information
- informed consent
- right to free choice of provider
- right to confidentiality
- right to privacy
- right to access the medical file
- right to complain
- right to second opinion
- duties of patients

In addition to the short information provided on the websites the NPCF produces downloadable brochures with more extensive information. More information (in Dutch) can be found at the organisations websites.

3.2 Patients' rights law – a country-by-country review

AUSTRIA

General context

A comprehensive patients' rights law is lacking in Austria. The general approach taken is rather a political one. Non-binding Patients' Rights Charters are established through agreements between the Federation and individual Federal States. Nine Federal States have so far concluded such agreements: Burgenland, Carinthia, Lower Austria, Upper Austria, Salzburg, Styria, Tyrol, Vorarlberg and Vienna. Enforceable patients' rights arise from several other legal provisions: constitutional, civil, criminal or administrative laws, including laws regulating different professions in the healthcare sector. Also court decisions play an important role, especially national supreme court decisions relating to rights and duties arising from the treatment contract (specifically relating to informed consent). Together with the international movement on patients' rights, they have been a major driver for their development. On the more-consumer oriented patients' rights, the high degree of fragmentation (including the division of powers between the Federal and State level) as well as the lack of transparency has hampered its development and enforcement. It also doesn't fit with the more traditional approach to health care.

Self-determination & confidentiality

The right to consent is recognized in the Austrian constitution and specific provisions in civil and criminal law, and is also regulated by administrative laws. The duty to inform has been further specified in several Supreme Court decisions. Written consent is not required except in specific cases (such as IVF treatment). Consent to a treatment contract and consent to treatment are treated separately.

Patients have a right to information on different treatment options and can choose not to be informed about certain information. There are no specific duties to cross-border patients. In terms of enforcement, criminal, civil and administrative court proceedings can be initiated.

The right to privacy recognized in the constitution and Data Protection Act, and specific provisions in civil and criminal law; it is also regulated by administrative laws. Exceptions to this right apply in certain cases (such as public interest). The Health Telematic Act imposes strict provisions on exchange of electronic data, which also apply to cross-border patients. Criminal, civil and administrative court proceedings can be initiated if right is not respected.

The right to access records is well-established and recognized in constitutional, administrative and civil law. Rights in this area were strengthened via the Electronic Health Record Act (2012). Enforcement of this right is via a breach of contract claim.

Quality & safety

The right to safe and quality treatment in a timely manner is part of the treatment contract and as such implemented in civil law. Healthcare professionals have the obligation to provide treatment in compliance with the current international state of

science. Limitations on treatment to be provided are implemented in social security law. Treatment of patients has to be adequate and appropriate, but shall not exceed what is necessary. This right is content of the treatment contract and as such can be legally pursued in case of any breach quality assurance responsibilities in the healthcare sector.

Besides, there are public funding and private activities aiming at increasing patient safety in practice. E.g.: the Austrian Platform for Patient Safety

There is no regulation regarding acceptable waiting times. However, federal states have to implement transparent waiting list regimes for elective operations and invasive diagnostics in case of waiting times of more than four weeks. Patients have the possibility to address Patient Ombudsmen or in case of damages patients can initiate court proceedings.

Prior authorization for cross-border healthcare in order to receive the (full) amount of domestic treatment costs (not only 80 %) has to be granted, if the person is entitled to domestic social security coverage and if treatment in Austria cannot be provided in due time. Prior Authorization can then still be rejected, if this treatment abroad would mean a significant risk to the patient or to public health or if there are severe concerns for patient safety due to a low standard and quality of treatment.

Choice

Free choice of providers and unrestricted access to all care levels (general practitioners, specialist physicians and hospitals) are characteristic features of the Austrian health care system. This right is part of the general rules regulating the treatment contract. Every patient has the right to choose his or her treating physician or hospital, provided there is free capacity. According to § 145 (1) Social Security Act patients' preferences have to be respected to the extent this is in line with the patient's specific condition and as long as this choice does not cause any additional social security costs. If the patient chooses a non-contracted provider reimbursement will be lower (80% of the fee that would have been paid for a contracted physician performing the same service). Within public hospitals only first-class patients or patients with additional private insurance can choose their treating physician, although the Constitutional Court started this would be against the constitutional principle of equality (Art. 7 B-VG - Austrian Constitution).

To choose a healthcare provider patients can rely on various sources, such as a hospital directory developed by Gesundheit Österreich GmbH (GÖG) (www.spitalskompass.at), the Arbitration Boards of the Medical Chambers of the Federal States (http://www.aerztekammer.at/) or patients' ombudsmen or representatives ("Patientenvertretungen"), organized by Federal States. There are no systematically produced quality reports available to assist patients in their choice of a physician. A specific legal requirement for providing transparent information about quality of care or performance of individual healthcare providers is lacking. The Health Ministry's Health Portal or the Hospitals Directory only report on minimum numbers of interventions in particular specialties or publish quality reports by individual hospital operators. Hospitals also don't systematically publish their waiting lists. Since 2011 the Federal Hospital Act obliges federal states to implement transparent waiting list regimes for elective operations and invasive diagnostics in case of waiting times of more than four weeks. In some federal states only patients on waiting lists are entitled

to receive this information. As to prices, hospitals have to provide transparent information only if there is uncertainty about social security coverage. The Federal Hospital Act and Physicians Act were amended as a result of the implementation of the Patients' Rights Directive.

There is no formal legal right to second opinion but all contracted physicians (GPs and specialists) can be accessed by patients free of charge without needing a referral. Referral is only required to receive radiological examination or laboratory diagnosis.

BELGIUM

General context

With the law of 22 August 2002 on the rights of the patients a legal approach has been taken in Belgium, based on a contractual relation between the patient and provider. It is mainly focused on traditional patients' rights as it generated from the discussion on the ratification of the Biomedicine Convention in the 1990s. Only in 2014 a right to receive limited information about the healthcare provider (insurance and registration status) was included, also under impulse of the patients' rights directive. For its enforcement, patients are referred to the classical liability procedures (civil; criminal, disciplinary).

Self-determination & confidentiality

The right to consent is stipulated in Article 8 of the Patient Rights Law. Written consent not usually required, and presumed consent is permitted in emergency situations. The Patient Rights Law makes a distinction between info concerning patient's health status and information given in order to gain consent, but in practice this distinction is not often made. Information on alternative treatment options must be provided and a right not to know exists, with some exceptions. There is no formal entitlement to shared decision-making, and there are no provisions for cross-border patients. The main current issues are a move from 'normal and foreseeable' risks to 'relevant risk' theory. In terms of enforcement, the PRL provides no sanctions when the right to consent is not respected, meaning that medical liability is the only avenue.

The right to privacy is also protected in Patient Rights Law, as is a right to protection of intimacy. There is a very important legal obligation to protect privacy, which is enshrined in Criminal Code (with exceptions). There are no specific duties to cross-border patients, and no particular evidence of use of this right in practice.

Patients have a right to access medical record within 15 days, which is also provided for via the Patient Rights Law. This right is not intended to satisfy information needs, but only to facilitate access in order to protect privacy. No provisions for cross-border patients.

Quality & safety

The patient has the right to receive high-quality health care that meets his or her needs, with respect for his or her human dignity and his or her self-determination, and without any discrimination on any grounds whatsoever. The precise implication of the

expression 'high-quality health care' is further explained in the explanatory memorandum, requiring a physician to act according to 'the applicable standards and the current state of scientific knowledge'. The applicable standards refer, among others, to guidelines and protocols set up by the medical profession.

Article 20 of the Hospital Law requires that the quality of the medical activity in a hospital be evaluated. The medical department heads are required to cooperate with the medical director in carrying out quality assurance activities. Each health care institution in Flanders (general hospital, psychiatric hospital, rest and nursing home, and centre for mental health care) must implement a quality policy by establishing a quality manual and quality plan. The quality manual describes the vision and objective of the internal quality policy. This manual is translated into a quality plan that includes a description of the existing situation and operational objectives concerning specific areas imposed by the government.

The law regulating the practice of the main health care professions (the so called Royal Decree n°78) only allows the practice of these professions to persons who have obtained a given university degree together with a registration of this degree (visum) by the ministry of health. In 2007 the federal ministry of health launched a first multi-year plan on quality and safety. The current multi-year plan came into effect in 2013 and will run until 2017. This plan encourages hospitals to introduce improvement measures in four areas: 'high risk' medication; safe surgery; identity vigilance and transmural care.

Neither legal rules nor guidelines in Belgium exit on timely treatment.

The prior authorization has to be refused by the advisory physician of the competent sickness fund when after a clinical evaluation it appears with reasonable certitude that the patient would be exposed to a patient-safety (including healthcare provider) risk that can be considered as unacceptable, given the possible benefits of the cross-border treatment.

Choice

Article 6 of the Patients' Rights Law (PRL) states that a patient has the right to freely choose and change his or her healthcare professional, except for some restrictions in cases determined under the law (e.g. prisoners, mentally ill patients admitted against their will etc.). It applies to all types of providers. No referral is needed to see a specialist. However, since 1999, financial incentives have been introduced to strengthen the position of the GP as the preferred entrance point. For consultations with the GP who holds the global medical file, the patient's co-insurance is reduced by 30%. Also an increased reimbursement applies for the first visit to a specialist if referred by a GP (up to the preferential reimbursement rate). In hospitals, the choice may be limited in practice (in some specialties). Also the choice for certain doctors may entail higher user fees. The right to second opinion follows naturally from the freedom of choice.

Information to patients about providers mainly comes from sickness funds and patients' associations. Based on the right to informed consent contained in Article 8 PRL patients have to be informed about the financial consequences of any decision. Following the implementation of the Patients' Rights Directive providers also have to inform patients about personal or collective protection with regard to professional

liability (Art. 8/1) as well as on their authorization or registration status (Art. 8/2). Too little information about the quality of care is available to the patients to help them in their choice. Based on the Flemish Indicators project hospitals can on voluntary basis post information on five relevant quality criteria on their website. No specific obligation exists about information on waiting times.

BULGARIA

General context

Patients' rights in Bulgaria are still rather in the stage of awareness raising. There is no special law on patients` rights. However, in 2009 the Public Council on the Rights of the Patient was established, an advisory and monitoring body that is to monitor and analyse all activities related to patient rights and support the development of patients' rights legislation.

Self-determination & confidentiality

The right to consent is protected by Article 88 of the 2004 Health Act. Consent is normally verbal, and patients have right not to know, with some exceptions. Patients have a right to information on planned treatment and alternatives. No cross-border patient provisions. In terms of enforcement, the Medical Audit Agency imposes fines and guilds have competencies.

The Health Act recognizes a right to privacy, which is also enshrined in Art 145 of the Criminal Code. Information can only be shared where treatment is continuing at another hospital, where there is a threat to the health of another person, of for various forensic, statistical or public health reasons. No specific cross-border patient provisions exist. Enforcement works via obligations and contracts act.

Patients can access records via medical personnel; there are no electronic records, though lab results can be obtained over the internet. There are no cross-border patient provisions, and enforcement is via the Administrative Law.

Quality & safety

The Bulgarian Constitution guarantees availability of medical help by right of health insurance and free medical aid, regulated governmental control over health-care activities, the production of pharmaceuticals, bio materials and medical devices. The implementation of the constitutionally stated governmental control are regulated by special laws introducing licensing and registration regimes for carrying out medical activities, retail and wholesale of drugs

There is a licensing regime on medical institutions under Medical Institutions Act 1999. The act defines the types of hospitals in the country and their commercial and administrative law status.

An example how the right to safe and quality treatment received in a timely manner is exercised in practice is challenged provides a judicial decision of the Court of EU. Case C-173/09, Georgi Elchinov v. National Health Insurance Fund.

Choice

Bulgarian citizens have are free to choose their general practitioner, specialist, diagnostic laboratory and hospital without territorial restrictions. However, in order to benefit from social coverage, the provider needs to be contracted. Also referral from their GP or a specialist contracted by the National Health +Insurance Fund (NHIF) is required to access specialized outpatient or inpatient care. Only mothers are free to choose a paediatrician for their children and a gynaecologist for themselves without GP referral. In hospital patients can only choose their treating physician if they are willing to pay extra. Similarly, the right to second opinion only exists for patient who can afford to pay out of pocket.

Information about health providers' accreditation assessment is available on the Ministry of Health web page. The NHIF is obliged by law to provide information to the insured about contracted health care providers and pharmacies. Citizens can receive up-to-date information through their regional offices as well as municipal offices. However, the information policies of both the Health Ministry and the NHIF have been assessed as insufficient, especially on the scope and quality of health services.

CROATIA

General context

Croatia has long tradition of medical and law science favouring a human approach of physicians towards patients (cf. Andrija Štampar). It developed a comprehensive legal framework for the protection of patients' rights. Next to a special patients' rights Protection Act (2004), various other acts guarantee patients' rights, including regulations regarding the medical profession, e.g. the Medical Practice Act and Act of nursery, the Code of medical ethics and deontology. Apart from the criminal act that contains provisions about malpractice, enforcement is a weak point. The Patients' Rights Protection Act is foreseeing the establishment of a commission for the protection of patients` rights. Within civil society the Croatian Association for the Promotion of patients' rights is pushing for the further improvement of patients' rights.

Self-determination & confidentiality

Rights to consent, to information and to participation in decision-making are all enshrined in the Patients` Rights Protection Act. Law stipulates that written consent should be given, but in practice it can be given verbally and lack of written consent is does not prove that consent was not given. Information should cover the following: "health condition, including medical evaluation of income of certain diagnostic or therapeutic procedure, recommended medical examination and procedure and date when they can be done, possible advantages or risks of performing or avoiding certain medical examination or procedure, right to decide on certain medical examination or procedure, possible alternatives on recommended medical procedures, course of health care proceeding, further health care proceeding, the recommended way of life, [and] rights and procedure for exercising their rights from health insurance." No specific duties for cross-border patients exist but Croatia has implemented Directive 2011/14 EU, meaning that discrimination against foreigners is forbidden. Enforcement

or rights is via the Civil Obligations Act and the Patients` Rights Protection Act. Physicians can also be brought before the Croatian Medical Chamber.

The right to privacy is stipulated in Articles 4, 25 and 28 of the Patients` Rights Protection Act, Article 1 of the Law on Protection of Personal Data No specific duties for cross-border patients, Article 21 of the Medical Practice Act, and Article 2 of the Code of Medical Ethics and Deontology.

Right to access record protected by Article 23 of Patients` Rights Protection Act as well as in Article 23 of Medical Practice Act and Article 29 of Dental Practice Act. Access via help of staff. No specific cross-border provisions exist for patients.

Quality & safety

Every patient has an equal right to quality and continuous health care appropriate to his state of health in accordance with generally accepted professional standards and ethical principles (Article 2 of Patients` Rights Protection Act). The Inspectorate of the Ministry of Health is the main body responsible for implementation of patients` safety and quality policies. Waiting lists and waiting times are defined by Ministry of Health; maximum waiting times vary. Also there is a system of prioritization for specific treatments.

Choice

The patients' right to choose freely their healthcare provider (medical doctor and dentist) is formally recognized by Article 22 of the Health Protection Act. There are no restrictions in terms of geographical area or financial status. However, patients need a referral from a GP to access specialized care either in- or outpatient, except for gynaecologists and paediatrician. Also the right to second opinion is recognized and stipulated in Article 10 of Patients` Rights Protection Act.

Various actors provide information about available providers and treatments, including the Croatian Institute on Public Health, the Health Insurance Fund, the Ministry of Health as well as patients' associations. Each health care provider is responsible for providing information about performance, waiting lists and prices. The introduction of a new performance-based payment system and the development of an e-health information system (including e-waiting lists) since 2012 is expected to improve the situation and even provide comparative information on providers.

CYPRUS

General context

The legal framework on patients' rights in Cyprus consists of a law on the safeguarding and the protection of the rights of patients (2005). It includes 17 patients' rights and a mechanism for monitoring and resolving patients' complaints about patients' rights violations. In addition, other guarantees are found in other legal provisions contained in the Constitution, the personal data protection law, etc. Although patients' rights are considered an essential element for ensuring the quality of health care, there are no special provisions on more consumer-oriented patients'

rights, but Contract Law provision could be used for that purpose. Respect and enforcement of patients' rights still remains an important challenge. This is also related to the subsisting patriarchal doctor-patient relationship in Cyprus that translates into relatively low awareness and sensitiveness levels among citizens. However, the 2001 "Charter on the Rights of Patients" that was produced by a Patients' Rights Movement NGO (KIDDA) and the ratification of the Biomedicine Convention in 2002 contributed to the development of patients' rights legislation.

Self-determination & confidentiality

The right to consent is recognized in Article 11 (1) of the Patient Rights Act. The Processing of Personal Data (Protection of the Individual) Law of 2001 (138(I)/2001)[13]and The Law about the Removal and Transplantation of Organs of Human Origin 2012 are also relevant. Consent can only be given orally if thereafter provided in writing as soon as possible, and can be presumed in cases of incapacity. Patients must also be given information in written form, also concerning specific risk information on different treatment options. Patients have a right not to know. No specific right to participation, but the role of the patient has been enhanced under the Patients' Rights Act. No specific cross-border patient provisions, but the Patient Rights Act provisions can be seen as covering these. The Cross-Border Health Care Law also protects the right to information.

The right to privacy recognized in Article 16 of the Patients' Rights Act, which states that "no intrusion is permitted on the private and family life of the patient without the patient's consent unless, this is necessary for diagnosis, treatment or care." (This is a rather wide exception.) The right to privacy and family life is embedded as a broader right under Article 15 of the Constitution of the Republic of Cyprus. The right to medical secrecy also protected by the Patient Rights Act, with some exceptions. Data is protected by the Processing of Personal Data Act. The Cross-Border Health Care Law protects the privacy of cross-border patients. The Patients' Right Act (Articles 17 and 18) protects the right to access records "within a reasonable time", with no specific cross-border patient provisions.

Quality & safety

Every patient in Cyprus shall have the right to health care, appropriate to the needs of his health to be provided within a reasonable time according to those needs: Provided that, in the case of a medical emergency the patient shall have the right to receive urgent health care unconditionally. Also Article 4(2) stipulates that the patient shall have the right to receive good quality health care, characterized by high technical standards as well as human relations between the patient and the health care services provider.

With regard to health care providers each group/type has their own regulations regarding the process of application, qualifications and renewal of their license. The Ministry of Health has launched a plan on quality assurance and within that framework of quality assurance programme each hospital introduces its own procedures and policies. The plan on quality assurance aims to identify areas for improvement, formulate guidelines for best practice and evaluate the delivery of care. The Ministry of

[13] http://www.cylaw.org/nomoi/enop/non-ind/2001_1_138/index.html

Health has established a quality assurance committee, the National Committee for Quality Assurance and Risk Management, which includes representatives from all branches of the Ministry of Health. It envisages a process whereby all hospitals in Cyprus would be accredited with an international body, and has developed an action plan to strengthen quality assurance in all health facilities. In the private sector almost all Private Hospitals/clinics have acquired ISO 9001:2008 which concerns the Quality and Safety of Services for patients.

Choice

According to Article 4.5.a Patients' Rights Act The patient shall have an inalienable right to choose and to change the medical institution or health care services provider, provided that this is compatible with the functioning of the health care system. Choice under the public system is limited to providers employed under the public sector[14]. There is no strict gate-keeping or referral system but in practice, long waiting lists implicitly limit public sector access, even though the law stipulates that health care is to be provided within reasonable time (Article 4.1). Private patients can access any doctor at any time but their private health insurance may impose specific conditions.

The right to choice is supported by both the right to information (Article 10) and the right to second opinion (Article 10.7). Providers are obliged to respect this right and provide any reasonable assistance, such as providing a copy of the patient's medical record. Upon admission patients have to be informed about the identity and professional position of every person providing health care to him, as well as the regulations regarding the conditions and procedures of stay and provision of health care in the institution (Article 8.a). Also the Pancyprian Medical Association (http://www.cyma.org.cy/) provides information about the specializations of each doctor and whether they have renewed their professional license, including information about CME status. Information about performance is not kept systematically and not officially available. Also information on waiting times is lacking. Prices applicable in the private sector are at the discretion of each doctor (Art. 16-18 Regulations of Medical Profession Deontology).

CZECH REPUBLIC

General context

The main source for patients' rights in the Czech Republic is the Special Act no. 372/2011 Coll. on Health Care Services. Other specific patients´ rights are included in special laws like the Act no. 373/2011 Coll. on Specific Health Care Services. The legal approach is the result of a process that started after transition in the early 1990s. Judicial decisions as well as the adoption of the Oviedo Convention have contributed to strengthening patients' rights.

[14] According to plans for the future introduction of the universal General Health System (GHS) patients eligible for low cost health services will be allowed to choose their own doctor no matter if the doctor is employed by the public or private sector.

Self-determination & confidentiality

The right to consent is enshrined in Oviedo Convention and also in the Act no. 372/2011 Coll. on Health Care Services. Verbal and implied consent are sufficient legally, but written consent is normally sought by providers. Civil Code states that in situations where written consent is not prescribed, "it is presumed that consent was given." Information should be provided regarding diagnosis, prognosis, risks and benefits of proposed treatment, information of alternative treatments. There is right not to know, with exceptions. No provisions for cross-border patients. Enforcement operates via claims for moral damages.

Right to privacy also protected by the Act on Health Care services, as well as the Oviedo Convention and also in the Ethical Code and Disciplinary Code of the Czech Medical Chamber. Enforcement is ensured via civil, administrative, criminal and disciplinary laws. No specific CBP provisions.

Right to records also protected by Convention and the Act on Health Care services. Access is free and should take place in presence of staff. No cross-border patient provisions. Enforcement ensured by the Office for Personal Data Protection.

Quality & safety

Right to safe and quality treatment received in a timely manner is formally recognized partly in the Oviedo Convention. There is a mix of approaches to ensure patient safety in the Czech Republic. Some of them are formal and obligatory: the process of authorization to provide health care services by Regional Offices and MoH; the control of providing health care services provided by Regional Offices and MoH or the special administrative control in specific areas e.g. by State Institute for Drug Control. Some of approaches are not obligatory but can be formal, i.e. certification (e.g. ISO) and accreditation by accreditation agencies. And some of approaches are informal like publishing of guidelines adopted by professional associations.

Accessibility of medical care in time and in region is regulated by Governmental Order no. 307/2012 Coll., on Regional and Time Accessibility of Medical Care. The government can, in the form of Governmental Order, define paid cross-border services which need previous authorization. Patients can take civil action, can complain to administrative bodies, when there is serious breach of duties, also penal proceeding can be applied.

Choice

The rights to free choice and to second opinion are both formally recognised in §28 Act n° 372/2011 Coll. on Health Care Services. In principle, Patients can freely contact any health care provider, GP, specialist, hospital etc., although some limitations exist for seeing a provider not contracted by the patient's health insurance fund. Patients register with a primary care physician of their choice, but can switch to a new one every three months without restriction. Patients are free to obtain care directly from a specialist of their choice without referral, even though it is not recommended that they do so. In contrast, a patient is admitted to inpatient care only and exclusively upon referral from a physician (except in cases of medical emergency).

There is no central point for patients to obtain information in order to choose a provider. Information comes mainly from the Ministry of Health and Regional Offices. Providers have a duty to publicly inform about identification of health care facility, working time, prices, etc. A unified system to assess the performance of various providers and quality of health services is still lacking. There is, however, some advancement in this area. For example, a registry managed by the Czech Institute of Health Information and Statistics gathers information on adverse events. So far 40% of inpatient providers (measured in bed capacity) participate in this project which aims at supporting best practices by information sharing. Several other projects are spearheaded by the state or regional governments, whereas others are run by professional or civic organizations, such as the National Reference Centre (Národní Referenční Centrum, NRC) or the Czech Oncological Society (ČLS JEP).

DENMARK

General context

Denmark has a comprehensive and legal framework protecting patients' rights that encompasses both fundamental and more consumer oriented rights. The Health Act (Consolidating Act no.1202 of 14 November 2014) is complemented by a series of more specific laws (e.g. Consolidating Act no. 1113 of 7 November 2011 on Complaints and Compensation within the Health Care Services; Consolidating Act no. 877 of 4 August 2011 on Authorization of Health Care Professionals and on Health Care Services) and the application of general legal provisions (e.g. administrative and criminal law). This is the result of a steady development process in Danish health law over the last 30 years that started in 1988 with the the establishment of a special Patients Complaints Board. Next to the ratification process of the Biomedicine Convention, changes in the general Danish data protection regulation also contributed in strengthening rights of patients by ensuring their right to access their medical file. More consumer-oriented rights, such as access to treatment, waiting time and free choice of provider, become more prominent partly through general policies promoting more efficiency in the public sector.

Self-determination & confidentiality

The right to consent is recognized in the Health Act (and the Act on Artificial Reproduction). Consent to research is regulated by the Act on Research Ethics Review on Health Research Projects. Verbal consent is normally required, though written consent is sometimes necessary for comprehensive interventions. Presumed consent is only possible for "ordinary treatment". Patients must be told of all possible options. No cross-border patient provisions, but there is an obligation to provide interpretation (article 50 of the Health Act). A comprehensive body of case law exists. Enforcement is via complaints to The National Agency for Patients' Rights and Complaints.

The right to privacy is recognized in the Health Act and the Act on Processing of Personal Data, with the former affording more protections to patients. There are also provisions in the Penal Code: "general rules on confidentiality are laid down in the penal code for public employees (article 152), licensed health care professionals (article 152 b) and the assistants of licensed health care professionals (article 152 c)." No special rules for cross-border patients. A comprehensive body of case law also

exists for privacy. Enforcement via the National Agency for Patients' Rights and Complaints.

The right to access records is provided in the Health Act. For information gathered outside the clinical context, administrative law applies. Records are available online via sundhed.dk within 7 days of request for no fee. Parents normally allowed to access children's (under 18) records. Data cannot be added and cannot be erased within ten years of last data registration. No specific cross-border patient rules. Again, a there is a comprehensive body of case law. Enforcement is also via the National Agency for Patients' Rights and Complaints.

Quality & safety

The general aim of the Health Act is to ensure that patients' needs may be fulfilled in regards to easy and equal access to the health care services, treatment of high quality, comprehensive treatment, free choice, easy access to information, transparent health care services and short waiting time for treatment.

Quality assurance aspects with regard to health care professionals' performance are primarily monitored through the licensing, inspection and control system which is monitored by the Danish Health and Medicines Authority. A number of health care professionals need to have a license to use specific titles and to perform specific procedures/services. Regions and the Municipalities are responsible to ensure quality development of the services. In addition, the Act also lay down obligations to report information to national databases to ensure collection of reliable data for quality assessment and development. As a special initiative the Danish Health Care Quality Program (DDKM) has been developed and the Danish Institute for Quality and Accreditation in Health (IKAS) has been established. According to the Health Act – a legal obligation exists for health care professionals to report adverse events to the Regions or the municipalities. Patients may also report adverse events. The Danish Health and Medicines Authority continuously develops and revises clinical guidelines, which are available at the Authorities website.

Article 88 of the Health Act Regions allows the patient to have extended free choice of hospitals, if the Regions cannot meet the maximum waiting times. In general, the maximum waiting time is two month for hospital treatment. However, if the patient is suffering from a very serious condition, the maximum waiting time is instead one month.

Prior authorization for XBC may be refused if the patient would be exposed to an unacceptable patient-safety risk (including healthcare provider if treated at a hospital in another Member State. The patient can issue a complaint to The National Agency for Patients' Rights and Complaints.

Choice

The right to free choice of provider is recognized in the Health Act, both for hospital care (Art. 86 and 87) and GPs (article 59.5; and Executive Order no. 966 of 29 August 2014 on Choice and Change of General Practitioner and Treatment by Practicing Doctors). For primary care, Danish citizens can either choose for a permanent or family-doctor model (Group 1) or a complete freedom of choice (Group 2). Group 1 patients are required to register with a particular GP, subject to some geographical

restrictions, who will have to provide a referral whenever specialist care is needed. Health care provided is free of charge and patients can change their GP at all times. Group 2-patients are free to consult any GP and any specialist without referral. They will receive reimbursement for the same amount as for Group 1 patients but providers can charge higher fees. The large majority of Danish citizens belong to group 1. Even with referral patients can freely choose the specialist. Patient can also seek treatment in any public hospital in all five Danish Regions as well as in a few listed specialized, private hospitals. However, hospitals may limit access to treatment for patients from outside the Region if treatment capacity is limited. When treatment cannot be provided in the Region within stipulated maximum waiting times (1 or 2 months depending on the severity of the condition), patients can choose a private hospital or even a hospital abroad, provided this hospital has an agreement with the Regions for this (extended right of free choice).

The patient is entitled to receive information about both the general and the extended right of free choice to hospital treatment (see article 90 of the Health Act). Regions and hospitals have a legal obligation to inform patient within 8 weekdays about possible date for treatment and waiting times at other hospitals (in the Region as well as in other Regions). Information about waiting times for hospital and specialist treatment may also be available at the official national health website (www.sundhed.dk). The website of the Danish Medicines and Health Authority provides information about providers' fitness to practice (article 13 of Consolidating Act no. 877 of 4 August 2011 on Authorisation of Health Care Professionals and on Health Care Services). The National Agency for Patients' Complaints and Compensation sometimes published decisions of the Disciplinary Board with the name of the providers (in case of severe or continuous criticism) for a period of two years (see article 17 in Act on Complaints and Compensation within the Health Care Services (Consolidating Act no. 1113 of 7 November 2011). There is no legal obligation for providers to provide information about fees and price for group 2 patients.

There is no general right to second opinion. However, severely sick patients who have been given up by their provider may request an assessment by a special second opinion panel, which is set up by the Danish Health and Medicines Authority. This panel will assess whether the patient may benefit from experimental treatment at a private hospital in Denmark or a hospital abroad. The patient needs to be referred to the panel by the doctor treating him/her. Detailed rules are laid down in article 30 in Executive Order no. 958 of 29 August 2014 on Right to Hospital Treatment.

ESTONIA

General context

The main instrument regulating patients' rights in Estonia is the Law of Obligations Act, which includes a special chapter on the Contract for Provision of Health Care Services. However, many other relevant legal provisions are scattered over a number of other laws and regulations. Estonia is still in the early phase of developing a comprehensive framework on patients' rights. The main driver for its development is Estonia's membership of international institutions such as the EU, Council of Europe, WHO etc.

Self-determination & confidentiality

Provisions concerning right to consent in various specific Acts governing different areas of healthcare, the main one being the Law of Obligations Act. Others include: the Human Genes Research Act, the Medical Devices Act § 212, the Communicable Diseases Prevention and Control Act, the Artificial Insemination and Embryo Protection Act, the Termination of Pregnancy and Sterilisation Act, and the Procurement, Handling and Transplantation of Cells, Tissues and Organ Act. The Mental Health Act § 2 defines "informed consent". Consent is assumed and rarely written, although it is required by law for surgery. Requirements for providing information vary between providers. There are guidelines concerning rights of cross-border patients. In enforcement, the burden of proof lies with the patient.

The Law of Obligation act guarantees the right to privacy; the Health Services Organization Act covers data protection and enforcement via Estonian Data Protection Inspectorate. Patients have the right to restrict access to their records to particular healthcare providers.

The right to access records is covered by the Law of Obligation Act and also stipulated in the Personal Data Protection Act and Public Information Act. Access to records is facilitated with assistance of practitioner, and the first 20 pages of copied data are free. The Health Services Organization Act (section 505) guarantees the same rights to cross-border patients: "Patients who wish to receive or who receive cross-border health services shall have remote access to their treatment documents or have the possibility to receive copies thereof."

Quality & safety

Health care services shall at the very least conform to the general level of medical science at the time the services are provided and the services shall be provided with the care which can normally be expected of providers of health care services. The regulation of minister of social affairs on availability and timeline of health services is the sub-regulation relating to the issue. The health care providers have their own structural norms, process protocols, outcome indicators. However the big health care providers (hospitals, etc.) are working in the close cooperation and contest with providers of other regions to have good quality management. The institution in charge of health care providers is the Health Board who is working with close interactions of the Estonian Health Insurance Fund and coordinated by Ministry of Social Affairs. To the date there is no revoked license of physician. The problem is related to the physician describing the addiction medicines (i.e. narcotic medicines) to the patients (mostly from not indicated to the medication). After the criminal investigation the legal body is ended up but the physician will establish the new one.

The waiting times are defined by health care provider and depend upon funding of the Health Insurance Fund. The practice on how the right to safe and quality treatment received in a timely manner (incl. the specific procedures or remedies) is incipient.

Choice

Since 2006 citizens in Estonia can freely choose their doctor or hospital, provided they are contracted with the Estonian Health Insurance Fund (EHIF). At the primary care level they have to register in the practice list of a family physician (Health Care Services Organization Act § 8. (3)). They have the right to change their family physician on the basis of a written application and the transfer will become effective as of the first day of the following calendar month. Patients need a family doctor's referral to see most specialists and to be admitted as a non-emergency inpatient. Since 2012, only patients with severe conditions needing special monitoring may continue visiting the specialist without a new referral.

Information about available providers and treatments can be retrieved from health practitioners as well as from specific non-profit unions or associations. Healthcare providers are legally obliged to provide information on availability, accessibility and prices (Health Services Organization Act § 505). This is done mostly through web sites. The EHIF provides information through its web site, local service desks, call center and other channels, including a list of contracted providers, information on entitlements and prices etc. The Health Board, which is coordinated by the Ministry of Social Affairs and works in close interaction with the EHIF, also produces information, but this is mainly health care statistics and reports on economic activities in the field of health care. Public information on performance and quality is still limited. Since 2012 the EHIF has started to publish reports on selected indicators for the main 19 acute hospitals (part of the Hospital Network Development Plan – HNDP) and also provides information on family physicians' performance. Waiting times are closely monitored by the EHIF and maximum waiting time targets were introduced in 2001.

The right to second opinion is recognized by the Health Insurance Act (Division 3, § 40) but it is subject to strict rules and conditions. The EHIF will only assume the related costs of the second opinion once per treatment event to the extent specified in the list of the health services. If the second opinion is sought with a non-contracted provider in Estonia a written contract needs to be concluded between the insured person and the health insurance fund. Also providers abroad can be consulted. The treating physician must provide the insured person with a referral letter and transmit all documents regarding health services rendered or copies thereof to the provider of the second opinion.

FINLAND

General context

The development of patient rights in Finland stems from the general societal awakening to strengthening respect for fundamental rights and self-determination since the 1970s. Finland was one of the pioneers in terms of legally defining and implementing patients' rights through the Patient Rights Act 785/1992 (1992) and Patient Injury Act (1986). The legal framework is completed by a series of other relevant legislation, including a set of legal obligations imposed on healthcare professionals to respect the patient's rights to self-determination and confidentiality. Patients' rights are seen essential to protecting the confidential relationship between patient and healthcare provider.

Self-determination & confidentiality

The Patient Rights Act guarantees the right to consent and dictates the types of information to which patients are entitled: "A patient shall be given information about his/her state of health, the significance of the treatment, various alternative forms of treatment and their effects and about other factors related to his/her treatment that are significant when decisions are made on the treatment given to him/her." Written consent is not normally used and there is a right not to know. The Act guarantees that decisions are made with the "mutual understanding" of the patient. There is no direct support for cross-border patients, and only official languages are used, though citizens from other Nordic countries receive translation services free of charge. There are no specific enforcement pathways. Right seems to work in practice, but "self-determination is a particular challenge in longitudinal care of older people, disabled and mentally ill patients" – work continues on a measure to "enhance self-determination of social care customers and patients, and to set conditions for personally restrictive measures in social and health care."

The right to privacy is a fundamental right protected by the Constitution and the Patient Rights Act. The Act on National Electronic Health and Social Care Archives, the Data Protection Act and the Act on Healthcare also impose obligations. Public health care professionals are also subject to legislation governing civil servants (specific criminal liability). There are no specific cross-border patient provisions. There is a large body of reports, surveys and case law. Privacy enforcement is via Patient Rights Act 14 § (offence) and Data Protection Act, and also potentially via the Penal Code.

The right to access records is protected by Patient Rights Act 5 § para 3; Data Protection Act 26 §; Act on Openness of governmental activities (621/1999) 10 – 12 §, Act on Electronic, Social and Health Care Records. No specific cross-border patient provisions. An online service is currently being developed.

Quality & safety

The Finish Patient Rights law defines the right to good health and medical care and related treatments and Access to treatment. Timeframes for access are determined in Health Care Act Health care actors must have plans on quality and patient safety. There is a magnitude of provisions concerning accreditation, reporting requirements, best practice-guidelines etc. Health professionals must be licensed and registered in a publicly available register. Harmonised Principles of Care find their basis now in Health Care Act 7 §, but they were initiated already in 2005. They concern criteria on non-urgent care. MoH has also issued a decree on criteria of urgent care and conditions for specialised emergency rooms. The aim of the decree is to make sure that equality, safety and quality of patient care is met throughout the country. Current Care Guidelines are independent, national, evidence-based clinical practice guidelines. They are intended as a basis for treatment decisions. The National Institute for Health and Welfare has published a Patient safety manual in 2011. National and regional authorities monitor the performance of health care services. Health care act 50-53 §§ dictate the times for urgent and non-urgent care. The assessment of needs for treatment shall be based on harmonized principles (prioritization).

Reimbursement of cross-border services require that the treatment belongs to the national service selection refer ref to in Health Care Act 7 a §. This service selection is based on quality and safety of treatments.

National Institute for Health and Welfare (THL) monitor the performance and reports to the National Supervisory Authority for Health and Social Affairs (Valvira). The National Supervisory Authority for Health and Social Affairs has posed threat or fines on health care providers because they have not been able to deliver on time.

The general Patient rights Act provisions regarding objection and complaint, etc. are applicable. Also, the National Authorities may pose sanctions for non-compliance of time-lines. To appeal of decisions made by the Social Security Institution can be appealed to administrative court or to the appeal board of social security, depending on the decision to which of these.

Choice

With the Health Care Act N° 1326/2010, which has entered into force in 2014, the right to free choice of health care provider has been formerly recognized (47 § and 48 §). However, choice is limited and regulated. People can choose to register with one of the different primary health centre units operating in their municipality. They can exceptionally be treated in another health centre in case of emergency or during temporary stay in another region. They can also choose to register outside their municipality of residence (extended choice). Transfer to another health centre is only possible once a year upon written notification. Within the health centre the patient can choose his or her attending professional, subject to restrictions arising from the expediency of the service provision. Access to specialized care requires a referral from a licensed physician. Any secondary health care provider in the country can be chosen. Next to the public healthcare system citizens can also opt to seek treatment with a private provider (partial coverage by the National Health Insurance) or in occupational health care (provider chosen by the employer).

Basic information about access and legal rights is found on web sites of healthcare providers, municipalities as well as the single access point to public services in Finland (http://www.suomi.fi). There are no legal requirements to publish indicators on quality and safety. However, the National Institute for Health and Welfare (THL) has a specific programme to improve and monitor quality and safety in health care and provide information to patients. Decree 341/2011 requires that patients are informed about the safety plan of individual healthcare providers. Local authorities and joint municipal authorities for hospital districts must publish waiting times at 4 months intervals (Health care act 55 §).

There are no specific provisions on the right to second opinion.

FRANCE

General context

France has a law on patient rights (2002-303) since 2002. Before that the deontology code since 1995 defined physicians' duties towards patients. Patients' associations have played an important role in the development of patients' rights, especially in the aftermath of the scandal of blood contaminated by HIV. As a result a compensation scheme was introduced for all infections contracted through medical activities. Patients associations also participate in hospital administrative committees and in research ethics committees. They can represent individual patients in court and seize the Commission for indemnification.

Self-determination & confidentiality

The 1994 law on respect for the human body makes informed consent necessary. The Code of Medical Ethics provides further stipulations, stating that "The physician must provide a fairly clear and appropriate information to the person that he examines cares or advises about his health condition, the investigations and treatment offered; throughout the disease, the physician respects the personality of the patient in his explanations and make sure of their understanding." Generally consent is oral, except in certain circumstances. Information should be provided in written form, and there is a right not to know. The law on patient rights regards the patient as a partner in decision-making. Cross-border patients have the same rights as those living in the country, and provision of translators is mandatory. Enforcement is via general procedures and disciplinary sanctions.

Privacy is protected by both the civil and the criminal codes and the public health code. A breach can be punished by a penalty of one year in prison and a fine of up to 15,000 euros. Data protection law regulates e-records and the commission for freedom and electronic data controls and protects data.

Patients can directly access their file; each hospital has a special service to this end. There is a right to correct data in the record. Cross-border patients have the same rights.

Quality & safety

The Public Health code states: Everyone has, given his condition and the urgency of the interventions that he or she requires, the right to receive the most appropriate care and benefit from the therapeutic efficacy of which is acknowledged and that guarantee the best security health, in light of medical knowledge proved. All the professionals must have a license to practice. Conditions are defined par the public health code for professionals coming from other EU member states. The public health code defines the criteria. Safety and quality of health care by: 1) binding measures of activity authorizations or implantation of equipment, organization of public and private health facilities, technical operating conditions in high-risk areas, monitoring the use of health of products) 2) vigilance systems which allow the detection of adverse events 3) health facilities certification system Good practice recommendations for professionals are developed at national level by the High Health Authority. Health facilities have an obligation present to the public their indicators of quality and safety of care. Recommendations and guidelines are provided to professionals by the HAS

and by scientific societies of professionals. They describe the state of the art for the specialists. The social security verifies the quality of care or medical products delivered.

Better conditions for oocyte donation when access is quicker in another state because the waiting list in France is too long so the patients are allowed to go abroad and the social security reimburses a large part of the expenses.

The French law (social security recommendations) respects the provisions of the Directive 2011/24/EU, e.g. refusal when there could be an unacceptable risk, or when the quality of care is not guaranteed.

Choice

The patients' right of free choice of provider (practitioner and health facility) is one of the fundamental principles of the French health system that is recognized by law (Article L. 1110-8.1 Public Health Code, Article 6 Deontology Code). This also supposes a right to second opinion (Articles R 4127-60-62 of the Public Health Code). The statutory health insurance reimburses health services provided by all licensed providers without geographical restrictions. However, some physicians (so-called sector 2 providers) are not applying the national agreement tariffs and have the right to practise extra-billing. No referral is needed to access specialist doctors or hospital care. However, with the 2004 health care reform a soft form of gatekeeping was introduced. Under the voluntary 'preferred doctor scheme' (médecin referent), patients are asked to register with a preferred doctor of their choice, whom they should visit before accessing another doctor. They can opt out of this pathway and have direct access to specialists or other GPs for an additional out-of-pocket payment that is 40% of the SHI tariff. The preferred doctor is most often a GP, but people can also choose a specialist of any kind working in the private or public sector. Also linked to the generalised application of user charges and the extra-billing, some concern has been expressed about the actual ability of patients living in remote areas or with limited financial capacity to choose their provider (HCAAM 2006).

Information on healthcare providers is not systematically organised. Providers are not allowed to advertise their services. They only provide general information. However, increasingly information on quality and performance is publicly made available. Based on the accreditation process by the National Health Authority (Haute Autorité de Santé – HAS) a mix of yearly collected performance indicators are published (www.scopesante.fr). Physicians who underwent a practice appraisal can disseminate this information. Also patients' associations are very active in generating information for patients (www.leciss.org). Newspapers and magazines publish a yearly star ranking of public and private hospital services (e.g. http://hopitaux.lepoint.fr).

GERMANY

General context

Germany has a well-developed and historically reasoned strong implementation of fundamental patients' rights as well as more consumer-oriented patients' rights. Based on jurisprudence they were dispersed over various sources, mainly the general civil code (BGB) and the social code (SGB V). To increase their transparency and consistency they were re-edited in the special Patients' rights Act (2013). Choice (of doctor and of therapies) and proper information are seen as elemental elements to ensure the right of physical integrity, which requires the patient's consent to every action of the doctor. A very strong national reform strategy involving a whole range of institutions (e.g. German Medical Association, ethics commissions, sickness funds, medical faculties) and the media are considered important drivers for the further development of patients' rights.

Self-determination & confidentiality

In Germany the general civil code and criminal law ensure protection of the right to consent. Verbal consent is sufficient, but written consent is often used for evidentiary purposes. There is a broad duty to inform patients orally or in writing, including information about different treatment options. The duty to inform entails the duty to help cross-border patients to understand via translation. The right not to know is not defined directly in law but is widely seen as part of the "allgemeines Persönlichkeitsrecht" (Art. 2 I i.V.m. 1 I GG) and the "Recht auf informationelle Selbstbestimmung". In 2003 the Oberlandesgericht Celle defined it as the "reversed manifestation of the right to informational self-determination (NJW 2004, 449-451).

The right to privacy is regulated "in § 203 I 1 StGB and also in § 9 Musterberufsordnung der Ärztekammern." The German criminal code stipulates the consequences of a violation of the obligation to secrecy in §203 StGB with a maximum sentence of one year in jail.

The right to access records is recognized in § 630g BGB, which provides a right to immediate and comprehensive access to and electronic duplicates of records (on a paid basis) "to the extent that there are no considerable therapeutic grounds or third-party rights at stake to warrant objections to inspection." The right to access records passes to heirs after death, and there is no right to alter/erase records. No specific cross-border patient provisions. In practice it is easy to access data but almost impossible to check whether it is being kept confidential.

Quality & safety

There is a right to be accepted by a statutory insurance company which grants access to adequate medical health care, while its quality standard is guaranteed by legal regulations as the requirement of approbation to be a practicing physician as well as regularly enforced quality management for hospitals and the pharmacy. This, in association with the IQWIG, ensures the safety and quality of treatment. A specific law guaranteeing treatment in a timely manner is not given. The IQWiG is an independent scientific institute that evaluates the quality and efficiency of health care. The institute investigates what therapeutic and diagnostic services are feasible and valuable and

communicates its findings to the health care professions, patient and the general public.

There is no right to timely treatment. It's a well-known problem in Germany that there are not enough specialized physicians in rural areas. Also, some professions generally have very long waiting times (e.g. psychotherapeutics).

Choice

Patients in Germany enjoy the right to free choice of provider (SGB V § 76). In the statutory health insurance (SHI) this is limited to SHI-accredited physicians and hospitals contracted by the sickness funds. However this covers the majority of them, respectively 98% of ambulatory physicians and 99% of hospital beds. Patients select their own family physician but can only change once every quarter. However, they don't act as gatekeepers and patients frequently choose office-based specialists directly. Since 2004 measures were introduced to strengthen the coordinating role of family physicians, including a quarterly co-payment for physician visits (Praxisgebühr) to enhance gate-keeping that was abolished again in 2013. Sickness funds were required to offer the option to enrol in a "family physician care model", potentially with a bonus for complying with the gate-keeping rules. For patients participating in disease management programmes (DMP) or integrated care contracts choice is confined to participating providers and access to specialist care is subject to referral by the patient's coordinating family physician. Private patients are in principle not restricted in their choice.

There is no central administrative authority to provide information about providers and availability of services but various actors are actively engage in this, including sickness funds, professional chambers and provider federations, patient organizations. Web sites such as the German hospital directory (www.german-hospital-directory.com) or health navigator sites set up by individual sickness funds help patients to find the appropriate provider. The Citizens Advice Bureaus, which are operational in all sixteen States, evaluate the quality and cost of medical services. Hospitals included in the state-level hospital requirement plans are obliged by law (SGB V § 137) to publish quality reports every two years. Since 2007, all hospitals have been required to publish results on 27 selected indicators collected by Bonus Quality System (BQS). The new Institute for Quality Assurance and Transparency in Health Care (IQTiG) that was established in 2014 is also required to publish results of the quality assurance measures in an appropriate manner and in a form understandable to the general public. Based on these risk-adjusted comparative overviews or benchmarks of quality in key areas of hospital services are created and published on the internet. Finally, Germany also has developed a rating system for long-term care providers (www.pflegenoten.de).

The right to second opinion is derived from the formal right to free choice of provider. It is also explicitly mentioned in the Patient Charter that was published in 2002. Sickness funds also actively provide support for their members looking for second opinion.

GREECE

General context

Although already the first reference to "rights of hospitalized patients" was found in 1992, the legal approach to patients' rights in Greece is still in its early stages of development. A long tradition of medical paternalism and a lack of public awareness (among medical professionals and patients) could only be turned by the open-minded approach of a small group of legal experts and policy-makers, working mostly in the field of fundamental rights. Next to references in the Constitution and specific laws (e.g. on transplantation, assisted reproduction) the most important source for patients' rights is the law on Medical Ethics (l. 3418/2005), which develops the patients' rights in more detail. Even if non-binding, the opinions and recommendations of the Hellenic National Bioethics Commission are also considered influential to fill any gaps in the legislation. The status of enforcement still remains weak but very recently case-law before the courts started to emerge. Also control mechanisms and institutions were created to support patients' rights implementation, e.g. the Ombudsman's office, the Office of Patient Rights in the Ministry of Health.

Self-determination & confidentiality

The right to consent is recognized in the law ratifying the Oviedo Convention and the Law on Medical Ethics, as well as several more specific laws: article 1 of Law 3089/2002 (on assisted reproduction, 1456 CC), article 5 of law 3305/2005 (also on assisted reproduction); article 7 of Law 3984/2011 (on transplantation); article 47 of the Law 2071/1992 (on the National Health Service); and articles 205 of Ministerial Decision ΔΥΓ 3/89292/2003 (on clinical trials – Dir. 2001/20). In the vast majority of cases consent is presumed, but younger doctors ask for verbal consent. Written consent is used by some hospitals for surgery, and is essential for clinical trials. Information provided to patients must be comprehensive and there is a right not to know. There are specific provisions for cross-border patients. There have been only a few court cases. Enforcement is via the Ministry's Office for Patient Rights, at the hospital level, or at the Ombudsman's office.

The right to privacy is formally recognized in various instruments: "Constitution: article 9 para 1 sec. b, article 9 A (on data protection); Law decree 54/1974 (ratification of the ECHR): article 8; Law 2619/1998 (ratification of the Oviedo Convention): article 10 para 1; Law 2472/1997 (on data protection – Dir. 46/95); Law decree 1565/1939 (on medical profession): article 23 a; Law 3418/2005 (on Medical Ethics): articles 8 para 2, 3, 5 (confidential relationships as a physician's duty), 13 (medical secrecy), 14 (data protection in medical registries); Civil Code (as amended by Law 3089/2002 on assisted reproduction): article 1460 (donor anonymity); Law 3305/2005 (on assisted reproduction): article 8 para 6 (confidentiality of donors' data); Law 3984/2011 (on transplantations): article 10 (anonymity of deceased donor and organ recipient); and Ministerial Decision ΔΥΓ 3/89292/2003 (on clinical trials – Dir. 2001/20): article 5 (confidentiality of participants' data). Processing of data requires written consent. The law on cross-border patients mentions the rights to privacy and data protection. The national data protection authority is highly active in enforcement.

The right to access records is recognized explicitly, with copies on request via application to hospital authorities. After death, heirs exercise rights of access. Cross-

border patients have the same rights. Data Protection Authority can impose administrative sanctions following reports of violations. The ombmudsman's office has issued several decisions on refusal of access. Consent implied, verbally or written.

Quality & safety

The Greek Law 3418/2005 makes an explicit reference to "quality, safety and efficiency" in its Article 4, stating in particular a physician's duty a) to cooperate with colleagues and health practitioners, in order to avoid medical malpractice, to ensure patients' safety, to minimize the unnecessary costs, and to maximize efficient health care; b) to provide prescriptions, as necessary for ensuring the quality, safety and efficiency of health care or treatment; and c) to contribute to the creation and implementation of mechanisms and methods aimed to improve the intending to the quality of health care. The same law provides, also, for a number of clear criteria for ensuring a standard level of quality services, repeatedly making reference to the need for each physician to act only: a) in accordance with evidence-based medicine. However, no reference to time considerations exists.

The NOH has a responsibility to ensure that the services provided by its affiliated private healthcare providers meet certain quality and safety standards. According to a recent ministerial decision medical protocols and guidelines should be issued under the responsibility of the Central Health Council and the medical scientific societies, with the aim to cover all medical acts related to the e-prescribing system but there is no evidence about their implementation in practice. The Ministry and the NOH control the outcomes on a permanent basis, by receiving relevant data from hospitals and other healthcare services and by performing inspections. The central organ for inspections of the Ministry is the Health Inspectors' Body, which has general competence of coercive control, backed with administrative sanctions

In general, public healthcare services follow priority schedules, for receiving patients. This is decided by the service administration, on the doctors' proposals.

Case-law in administrative courts regarding collaborations of the NHS with private laboratories and clinics, or administrative inspections (regarding, for example, licensing, or quality standards), exists. The Ombudsman's office also has addressed cases of patient complaints.

At present the preparation of protocols to be implemented generally, and the issue of the ministerial decision on cross-border care are expected.

A person may report a relevant case to the Ombudsman's office (applicable to public health services only). A patient can also refer to the courts, in the context of medical liability, or in the context of administrative law, asking for compensation – if, for example, doctors or administrative organs have violated formally existing prioritization rules.

Choice

The right to free choice of provider is not formally recognized in Greece but it is presupposed in the organic law creating the national health service (ESY Law 2071/1992) and the Law regarding the rights and duties of the physician (l. 3418/2005). In practice, choice options differ according to the health funds citizens

are affiliated to and their financial capacity to afford private health care. Several funds, such as those of bank employees, self-employed, civil servants offer freedom of choice between a private and a public doctor. In addition many funds operate own or contract with health centres, mainly in urban areas. Patients can choose any primary healthcare center that is either public or contracted by their specific health fund. Since there is no formal gatekeeping and referral system, they can also go directly to any public hospital (also for outpatient consultations) and can opt for a second opinion in another one. Within the hospital patients usually cannot choose their treating specialist doctor and have to accept substitute care from assistants working under his supervision. Since 2002 doctors working in public hospitals can attend patients privately in afternoon outpatient visits. The increasing waiting lists and regional variations in availability of health care are adding to the inequalities in accessibility.

The Greek Ministry of Health has a general responsibility regarding providing information to citizens. A central telephone line of the ESY informs about the availability, waiting times and prices at public hospitals. Also the various social insurance funds, medical associations or medical scientific societies as well as patients' organizations and specialized state organizations provide information about providers in different specialty fields (e.g. transplants, diabetes). However, information on costs and quality of services is generally lacking.

Patients have an explicit right to ask for a second opinion in an ongoing treatment (so-called medical consultancy). In that case the patient can freely choose one or more "advisory physicians" (Article 22 para 1 of l. 3418/2005). The caring physician can also suggest one. He remains responsible for the treatment but can disclaim any responsibility or decide to withdraw.

HUNGARY

General context

Hungary was among the first countries in Europe where patients' rights were codified in statutory law. Spurred by the Szószóló Foundation, an NGO established in 1994 to represent patients' interests, the Health Care Act was adopted in 1997 that introduced a patient-oriented approach, which is applicable in all health care institutions, both state and private. Upon acceptance into the institution and before treatment, the health care provider has to inform the patient about his patients' rights, the possibilities for their enforcement and the internal rules of the institution. Violations of patients' rights are sanctioned by various legal norms, including the Criminal and Civil Code. The law also provides for non-litigious resolution of disputes between patients and healthcare providers through a Mediation Council. The Commissioner for Fundamental Rights, the National Center for Patients' Rights, Children's Rights and Documentation (OBDK - established by government decree in 2012) and the network of patients' rights advocates play a key role in the enforcement of patients' rights.

Self-determination & confidentiality

The Health Care Act of 1972 recognized the duty to inform patients. The Health Care Act of 1997 protects the right to informed consent, and the Civil Code ensures that individual has final word regarding body and health. Patients are entitled to receive

comprehensive and individualized information. Article 15(3) of the Health Care Act entitles patients to participate in clinical decision-making regarding their own health, but "the lack of health literacy often limits the enforcement of his right". There are no specific provisions for cross-border patients, but the Health Care Act requires provision of interpreters if necessary. Article 14 provides for a right not to know. With regard to enforcement, criminal sanctions can be imposed, or damages claimed.

In terms of a right to privacy, there is a stronger emphasis on the patients' personality rights and the rights to confidentiality and medical secrecy than on privacy. Confidentiality must be respected, with some exceptions, and there are no provisions for cross-border patients. Article 25(1) of the Health Care Act states that "a patient shall have the right to have persons involved in his health care disclose his health care and personal data which they might learn in the course of delivering such care to those entitled thereto and to have them handle such data confidentially."

Data protection is strongly emphasized in Hungarian law. Medical documentation is at the disposal of the health care provider, but data contained therein is at the disposal of the patient, meaning that "the patient has the right to gain knowledge of the data contained in the medical documentation concerning the patient." Copies are available on a paid basis. Incorrect medical data cannot be deleted after a complaint; "the originally included data remains visible." No provisions for cross-border patients.

Quality & safety

In Hungary, healthcare services shall only be provided in the possession of an operator's license. The healthcare administration (the Office of the Chief Medical Officer, OTH) shall only issue the license if the petitioner fulfils the statutory requirements relevant to the specific service ("de minimis requirements") including having liability insurance. The Health Care Act defines quality health care services and provide the general outlines of the quality management system. Specifically, the Health Care Act prescribes for healthcare providers to operate internal quality control systems.

Besides the often applied general quality control frameworks (ISO 9001), to date, some healthcare-specific frameworks also appeared (DIN EN 15224:2012) in the practice of healthcare providers. These include the definition of general quality requirements, and their benchmarking of performance, control, assessment, improvement and documentation; however, these do not include in a mandatory fashion any system of basic conditions relevant to the practice of professional activities. This is why the ISO framework is often complemented by a system of standards defining professional quality requirements as well.

The professional foundations of Hungarian healthcare are guaranteed by the application of professional guidelines and adjacent local protocols (rules of procedure) based on evidence-based medicine and on the consensus of the different professions.

Choice

Section 8.1 of the Health Care Act recognizes the patient's "right to choose his attending physician with the agreement of the healthcare provider of the level justified by his condition and, unless a legal rule sets forth an exception, the physician so chosen, provided it is not precluded by the professional contents of the health service

justified by his condition, by the urgency of care or the legal relationship serving as the basis for the use of the service." Also this right may be exercised in accordance with the rules of operation of the healthcare provider (Section 8.2). Patients usually – but not necessarily - register with a GP in their geographic area of residence. The GP are meant to act as a gatekeeper. Except for certain disciplines, patients need to get a referral from their family doctor to access secondary care. If they bypass the referral system they will have to pay user charges. Patients are generally referred to the nearest outpatient care institution or to another specialized health care institution if the nearest hospital does not perform the particular treatment. Patients can also ask to be referred to another healthcare provider, who can charge an extra fee for this. He may refuse if there is no financial free capacity or if it would endanger care for patients in his catchment area.

Patients in Hungary have a right to second opinion "in connection with any diagnosis made or therapy recommended by his attending physician, or regarding his planned discharge from an in-patient institution or referral to another healthcare provider." (Section 8.3)

ICELAND

General context

The WHO patient rights framework was transferred into law in Iceland in 1997 with the Act on the rights of patients no. 74/1997. The objective of the Patients' Rights Act is to ensure specific rights for patients in accordance with general human rights and human dignity, and thus to strengthen patients' legal status vis-à-vis the health service and to support the confidential relationship between patients and health-care practitioners. It also accords patients the right to the best health service available for their condition. Moreover, patients have the right to continuity of service and cooperation between all health-care practitioners and institutions involved in their treatment.

More specific acts, e.g. on medical records and patient insurance as well on the obligations of healthcare providers (including ethical codes), together with general provisions in the Constitution and administrative and criminal law complete the framework. These developments follow from a generally increased awareness of human rights; advances in knowledge and technology as well as the EEA-Agreement (particularly for consumer-oriented rights). The Ministry of Welfare is responsible for ensuring that information on patients' rights, patients' associations and health insurance is accessible to patients. It is made available at health-care facilities and at the premises of self-employed health-care practitioners.

Self-determination & confidentiality

The right to consent is recognized in the Act on the Rights of Patients (Articles 5-11), in the Act on Biobanks and Health Databanks (Articles 3 and 7), and the Act on Medical Research (Articles 18-24). The appropriate form of consent depends on the context. Patients are entitled to comprehensive information (Information about condition, prognosis, treatment (including risks and benefits, alternative treatment options, consequences of refraining from treatment) with no form specified. There is a

right not to know. The Act on the Rights of Patients stipulates a right to interpretation for cross-border patients.

The right to privacy is enshrined in the Act on the Rights of Patients (Articles 12-13), the Act on Healthcare Practitioners (Articles 17-18), and the Act on Medical Records (Articles 7, 13, 19 and 21. There is a legal obligation to respect confidentiality, with some exceptions. There are no specific provisions for cross-border patients.

The right to access records is protected by the Act on Medical Records. A request for access is directed to a specially nominated supervisor of health records within each institution. Copies are available, and there is a right to alter records.

Quality & safety

The Act on the rights of patients in Iceland states: "The patient has the right to the best health service available at each time. The patient has the right to service appropriate to his/her condition and prognosis at each time and the best knowledge available. The healthcare practitioner shall endeavour to establish a sound relationship with the patient. The patient has the right to continuity of service and cooperation between all healthcare practitioners and institutions involved in the treatment." Binding licensing of healthcare practitioners, including various thresholds, see Articles 3-12 of the Act on healthcare practitioners and numerous administrative regulations for different types of practitioners. Binding licensing of healthcare facilities, including thresholds for staffing, housing, equipment etc. applies.

The Medical Director of Health issues clinical guidelines and quality indicators (cf. administrative regulation no. 1148/2008). The Directorate is responsible for quality development and the monitoring of health services and healthcare practitioners. There is a system of mandatory reporting of unforeseen incidents The Medical Director of Health makes a plan for quality development within the health service, which shall be submitted to the Minister for confirmation. The quality development plan shall aim to enhance the quality and security of health services, and be conducive to its development. Healthcare facilities and healthcare practitioners shall in the making of quality plans take account of the Medical Director's confirmed quality development plan. The Medical Director of Health assesses quality and performance within the health service with respect to yardsticks laid down by the Minister in Regulations. Comparable findings of quality and performance assessment shall be published in health reports

Acceptable waiting times are provided in the Act on the rights of patients, Article 18: "If a patient has to wait for treatment, the physician concerned shall explain the reasons for the delay and provide him/her with information on the estimated waiting time. If it is possible to receive the necessary treatment sooner elsewhere, the patient must be made aware of the fact." No list of acceptable waiting times has been published on the website of the Medical Director of Health. Prioritization Act on the rights of patients, Article 19: "If it proves necessary to place patients waiting for treatment in order of priority, the order should be based primarily on medical grounds, and other professional criteria, as the case may be.

Directive 2011/24/EU has not been implemented in Iceland, but Parliament is considering a bill intended to implement it. Currently, the framework for cross-border care is in the following terms: "If a health insured person urgently requires

internationally recognised medical treatment abroad, cf. Article 44, when it is not possible to provide the necessary assistance in Iceland, health insurance will pay the cost of the treatment. The same applies to the cost of the stay, pharmaceuticals and medical assistance needed abroad in connection with the treatment. Also, health insurance will pay a travel grant to the health insured person and an escort in special circumstances.

Choice

The patients' rights to choose their medical provider and to obtain a second opinion are recognized in Article 20 Patients' Rights Act N° 74/1997. "Notwithstanding the division of the country into different health regions, a patient has the right to consult the physician most convenient to him. A patient also has the right to seek the opinion of another physician regarding diagnosis, treatment, condition and prognosis. The same applies to other healthcare practitioners." In the absence of a gatekeeping system patients have unrestricted access to medical specialists outside hospitals. In practice, provider choice is restricted by the limited number of providers outside the Capital Region.

The government operated website www.island.is provides user oriented information on where to seek different types of healthcare services. The Directorate of Health (DH) maintains a list of all licensed healthcare facilities under Article 26 of the Health Service Act, which can be consulted on its web site. Also healthcare facilities in health regions and those of Primary Health Care of the Capital Area have an obligation to keep users of services informed of the activities of their facilities (Article 12 Health Service Act). Based on the Directorate's role in monitoring health services and healthcare practitioners and fostering quality development data on waiting times and other performance-related information is gathered (Article 4 Act on the Medical Director of Health and Public Health) and made available to the public. While the DH keeps a register of medical misconduct and medical errors, these data are not systematically published. However, incidences of medical error or medical misconduct often enter the media either via coverage of a particular court case or as a result of freedom of information applications (Act No. 50/1996).

IRELAND

General context

The approach to patients' rights in Ireland is a mix of legal and quasi-legal approaches. The framework consists of a mix of legislative instruments, disciplinary codes for health practitioners, health policy documents, and guidelines from the Irish national health service provider (HSE). Some of the fundamental patients' rights such as the right to self-determination, right to privacy and procedural rights largely arise from the jurisprudence of the Irish Supreme Court in interpreting the Irish Constitution 1937. As consumer rights (e.g. information and choice) are newer rights, they tend to be based on legislation, which also provides for legal mechanisms of enforcement. The development of patients' rights in Ireland is mainly driven by national reform strategies, reports and controversies in the media, and constitutional jurisprudence of the courts.

Self-determination & confidentiality

The right to consent is recognized through case law (e.g. Walsh v Family Planning Services & ors [1992] IR 496; Geoghegan v Harris [2000] IR 536; Fitzpatrick v White [2007] IESC 51), policy documents (e.g. Health Service Executive National Consent Policy, 2013), and disciplinary codes (e.g. Medical Council's Guide to Professional Conduct and Ethics, 2009). There is no requirement for consent to be written, though some practitioners prefer this form. Information should be clear and comprehensible and tailored to patients, including alternative treatment options. There is a right not to know. In terms of participation, there is a National Strategy for Service User Involvement. There are no specific cross-border patient provisions, but translation is available where necessary; "a professional interpreter should be sought rather than relying on the patient's family or carers." Reforms are in progress with regard to capacity. Enforcement is via general complaints mechanisms.

The right to privacy is a constitutional right, but it also provided for in Data Protection and Freedom of Information Acts. No specific cross-border patient provisions. The main issues reported relate to use of data in specific contexts such as clinical audit, teaching activities and research. Enforcement is via the Data Protection Commissioner.

The right to access one's medical records is provided in the Freedom of Information Acts 1997-2014 and in the Data Protection Acts 1998-2003. Access to records is straightforward: they are available via written request for a 6 euro fee within 40 days. There are limited exceptions to release of data. Enforcement is via the Data Protection Commissioner or the Freedom of Information Commissioner.

Quality & safety

In Ireland, quality and safety is not described as a legal right as such but rather a standard of care that patients/service users are entitled to expect. The HSE has published a National Charter which sets out what patients can expect from their health service: At present there is no licensing system for healthcare facilities such as hospitals but this is expected in 2016. The standards with which healthcare facilities will have to comply are set by the Health Information and Quality Authority and these set out clearly the expectation of patients and the public in relation to safe and quality treatment HIQA carries out announced and unannounced site inspections in relation to matters such as hand hygiene and publishes its reports online. The Department of Health publishes clinical guidelines on a range of topics including MRSA, early warning, clinical handover etc. The HSE has a dedicated division for patient safety which publishes guidelines on matters such as risk management, audit, and clinical governance: There is also a national patient safety initiative through which healthcare organisations declare their ongoing commitment to patient safety.

Waiting periods are a big source of controversy in Ireland due to the budgetary cuts sustained by the health service during the economic recession. The National Treatment Purchase Fund is responsible for the collection, collation and publication of in-patient and day case waiting lists. All public hospitals have the responsibility to ensure they meet the maximum waiting time guarantees for their patients. These admission targets are 8 months for adults, 20 weeks for paediatrics, 13 weeks for endoscopy and 12 months for first outpatient appointment. There is no specific avenue for patients to challenge waiting lists but they could complain to the Ombudsman

The HSE states that any service which is provided by the public health services in Ireland can be availed of under the Cross Border Directive.

Choice

Where private patients can freely choose their healthcare provider, patients treating in the public sector are more limited in their choice. They may choose a GP from a panel of GPs in their area who have contracts with the Health Service Executive (HSE) to provide general medical services. For patients holding a medical card or a GP Visit Card, which entitles them to care free of charge, choice may be restricted to those providers operating within the Primary Care Reimbursement Scheme (PCRS). Patients usually may only be referred to specialists by their GP and may discuss any choices available in that regard with the GP depending on which specialists provide services within the public system.

The HSE provides a map of health services available in each geographical area which may accessed by patients (www.hse.ie/eng/services/maps). Under supervision of professional regulatory bodies such as the Medical Council and the Competition and Consumer Protection Commission, individual providers may publish information relating to their service as long as it is factually accurate and not misleading. Patients may access information relating to fitness to practice or any disciplinary sanctions imposed on practitioners through the professional regulatory bodies. Data on waiting times are collated by the National Treatment Purchase Fund (NTPF) as part of the government's health reform strategy. The NTPF is designed to ensure that public patients who have been waiting excessively long for treatment have the choice to obtain, at public expense, treatment in the private sector either in Ireland or abroad.

The right to a second opinion is provided in the Medical Council's Guide to Professional Conduct and Ethics (para.60). In practice, the patient has to ask the doctor to refer him to another provider and to make copies of medical records available for that purpose. A second opinion may be sought in private settings, but in public setting choice may be limited depending on which specialists are available. It may include doctors in other member states.

ITALY

General context

Italy doesn't have a specific law on patients' rights. They are mostly derived from the fundamental right to health contained in Article 32 of the Constitution and the general principles of dignity, solidarity, autonomy and professionalism that underpinned the institution of the National Health Service in 1978. Several rights are explicitly encompassed in the law establishing the National Health Service (833/1978) and the Code of Ethics of Physicians (last update in 2014). Fundamental patients' rights have been steadily implemented by statutes, public interventions and judicial enforcement expanding both their scope and effectiveness. More consumer-oriented rights have undergone an increasing revision/curtailment due to increasing financial constraints. Several initiatives at national and local level aim at raising patients' rights awareness.

Self-determination & confidentiality

The right to informed consent is expressly stated in the act that ratified the Oviedo Convention 1997 (Italian Act n. 145/2001). However, a legal framework including Constitutional principles, statutory laws, case-law and soft law had already be defined it. Fundamental rights are expressed in the constitution. Consent is usually given verbally. Information must be comprehensive, including risks of different treatments and of non-treatment. Explicit right not to know. Final decision on treatment lies with patient. No specific SBP provisions, but services designed to break down language and culture barriers. Challenges regarding Jehovah's Witness refusal of blood, and the issue of whether even competent patients are making rational decisions. Supreme court ruling means that failure to respect right to consent can result in criminal sanctions.

Right to privacy. Code of Data Protection states that everyone has the right to personal data protection. Same code guarantees this to CBPs as well. Data Protection Authority strictly protects data, criminal sanctions available.

Data Protection Code also enshrines right to access records, obtain a copy and alter records. Access regulated by medical institutions. Record storage fragmented between providers. DP Authority has guidelines on e-records.

Quality & safety

The right to quality of care emerges from several statutes dealing with specific services and in the CME. Law no. 502/1992 explicitly deals with quality of assistance and treatments apportioning the tasks of ensuring and monitoring them between the State and the Regions. Quality assurance and risk prevention in healthcare delivery are mutually related which requires healthcare facilities to analyse clinical risks, envisaging and putting in place solutions necessary for their management, bearing in mind dispute prevention and reduction of insurance costs. The contours of the quality of care are defined by the CME in several norms, in terms of continuity of care, professional quality, and patient safety and clinical risk management. It is compulsory for every healthcare professional to improve their knowledge through Continuous Education in Medicine (CEM). Against this background, in Italy, accreditation is an activity that promotes and verifies the level of excellence in consideration not only of the minimum requirements stipulated in national laws but also in consideration of the services provided. Accreditation is conditional to regular assessment of the quality of the organizational, managerial and technological infrastructure of healthcare providers and of the skills and practices of health professionals.

The National Plan on Waiting Lists 2010-2012 published some guidelines to monitor waiting times. In particular, performances and services are divided in class of priority: Urgent <72h, <10 days, <30 days, <60days, to be planned. The referral operator is entitled to identify the class. At least in theory when a public entity is involved their decisions can be challenged before an administrative court or if there is a risk an injunctory relief can be requested to an ordinary court. Such a procedure has been historically used in cases of doubts on the appropriateness of a treatment (see for instance the so called Stamina litigation).

Cross border health care is subject to prior authorization only when: a) it is subject to planning requirements relating the goal of ensuring, in the national territory, sufficient

and permanent access to a balanced range of high quality care or to the intention to ensure the supervision of costs and avoid, as far as possible any wastage of involves treatments presenting a particular risk for the patient or the population; or c) it is provided by a healthcare provider that could raise serious and specific concerns relating to the quality or safety of the services provided.

Article 10 of the Act 38/2014 states that against a refusal of authorization, a patient could make a complaint before the General Director of the ASL within 15 days. The Director should answer then in the next 15 days or the patients can file a case before both an administrative and ordinary courts.

Choice

The organic law establishing the national health service SSN (Act 833/1978) as well as the Code of Medical Ethics (Article 27) recognise a patient's right to both freely choose a physician and to freely choose among the proposed treatments. However, this right must be exercised within the limits provided for by law, especially those pertaining to the organization of the delivery of healthcare. This means that choice is restricted to those facilities and accredited professionals with whom the SSN has established specific relationships. Also the organizational rights of each local health authority (ASL) and the availability constraints have to be taken into account. Patients can either receive treatment within the ASL of their place of residence or in another ASL (in the same Region or in another Region) (Article 8ter and following D.L. no. 502/1992), in which case the ASL of residence will pay for the services. Every citizen can choose his or her GP or paediatrician at any time, provided that the number of registered patients on his list has not reached the allowed maximum (1,500 for GPs and 800 for paediatricians). This choice is effectively valid for one year and is tacitly renewed, but patients can change at any time. Doctors must accept all patients and can only refuse a patient or remove them from their list due to exceptional and proven reasons of incompatibility (see also Article 28 Code of Medical Ethics). The primary care physician acts as a gatekeeper to higher levels of care. Only some types of specialist care, like dental care, obstetric and gynaecological services are accessible without referral. Direct access is also guaranteed for private (intra-moenia) specialist services without public coverage. Given the level of decentralisation, the degree of choice may vary between Regions, with some Regions (e.g. Lombardy) having opened provision of health care to private actors. Within the hospital patients do not have the right to choose their treating hospital specialists.

To facilitate the provider choice the Italian Ministry of Health has a statutory duty to publish and regularly update the list of all public and private institutions that provide high-performance medical specialities, indicating the availability of high-tech equipment as well as the prices for the most relevant services (Article 14. 6, of D.L. 30 December 1992, no. 502). The National Plan on Waiting Lists 2010-2012 published guidelines to monitor waiting times (Article 50 Act 326/2003).Information regarding waiting times can be retrieved from a central booking service (Centro Unico di Prenotazione – CUP). CUP operators can suggest both public and private accredited hospitals where a specific intervention would be available sooner. As to performance and quality of health services, the National Health Outcomes Programme since 2009 develops an articulate system of indicators. While these data are not publicly accessible a research-driven initiative was started late 2013 to publicly report health outcomes data (www.doveecomemicuro.it).

The right to second opinion is not explicitly recognised within the public health service and each local health authority and public hospital has developed their own protocols. In some cases the right to second opinion is limited to specific conditions with a list of specialists per pathology. For patients suffering from a rare disease (or for whom a suspected diagnosis of rare disease was made) a clinical evaluation by experts of the National Network for Rare Diseases is possible (Art. 9 para 4 of law 38/2014). If no experts can be found within the national territory - or if the expert's opinion is inconclusive - scientific advice can be asked to foreign expert centers.

LATVIA

General context

Patients' rights development in Latvia only started in 2000, when a group of lawyers and healthcare professionals established the „Patients' Rights Office", a small NGO supported by international private and public donors. While some issues, like the right to health care and the treatment of patients with mental illnesses, were already regulated by the 1997 Medical Treatment Law, the first real Patients' Rights Law came into force in March 2010. However, the traditional paternalistic model of doctor-patient relationship still prevails in many respects and there is still a considerable gap between the legal situation and real practice. Patients' rights are sometimes considered in opposition to "doctors' rights". Despite of a poor knowledge about patients' rights they attract a lot of media coverage and public interest. They are more based as fundamental patients' rights rather than consumer oriented rights.

Self-determination & confidentiality

The right to consent is recognized in the Patient Rights Law, but the patient does not have a right to choose treatment: "if several types of medical treatment are permissible, a patient has the right to the professional choice of the physician" The right to self-determination and right to choose are limited by the obligation to comply with doctors' instructions. In many cases requirements of the Patient Rights Law are not fulfilled. Some hospitals require patients to sign a general consent in order to be treated in hospital. There is a right to relatively basic information: "A patient has the right to receive information regarding his or her state of health from the attending physician, including regarding the diagnosis, the plan for medical treatment, examination and rehabilitation of the disease, the prognosis and consequences, the functional restrictions caused by the disease and the opportunities for prophylaxis, as well as the right to receive information after examinations and surgical or other type of invasive intervention performed within the framework of medical treatment regarding the results of the medical treatment, regarding the previously unforeseen outcomes and the reasons thereof." (Article 4.3) There is no entitlement to be informed of different treatment options, and no right to participation in decision-making other than the right to consent to a specific treatment. There is a right not to know but no specific provisions for cross-border patients. The National Health Services states that the "key obligation of the patient is to care for their health and get actively involved in the treatment process, and to provide the doctor with all information necessary for the treatment." No reforms are currently proposed and there are no specific enforcement remedies if rights are not respected.

There is no specific right to privacy; in the Patient Rights Law any such rights are covered by the right to data protection. There is, however, a right to receive treatment in privacy. There is also no legal obligation to respect confidentiality, though there is an administrative penalty of up to EUR 350 for breaches and misuse of data can be in breach of the Criminal Code. ("Previously such obligation was stated by the Medical Care Act, Art. 50.1., but since the PRL was enacted, the relevant article was removed.") There are no specific provisions regarding cross-border patients. Right to privacy is a particularly challenging issue in Latvia, where breach of privacy is a "daily practice". There is some case law relating to privacy. Enforcement is via the Health Inspectorate or State Data Inspectorate.

The Patient Rights Law provides a right to access and alter records and obtain copies. Written request is required. In practice there may be difficulties in obtaining records, as some hospitals try to restrict access. Copies should be free but some institutions charge. There are no provisions for cross-border patients and all medical records are written in Latvian. No research publications are known to exist on the topic of access to records, but there is some case law. Enforcement is via the State Data Inspectorate.

Quality & safety

The right to safe and quality treatment received in a timely manner is formally recognized. The PRL, Section 5.2 provides: "A patient has the right to a respectful attitude and qualitative and qualified medical treatment regardless of the nature and severity of his or her disease." The PRL, Section 5.4 provides: "A patient has the right to timely medical treatment. A medical treatment institution, to which the patient has turned, shall provide information regarding the opportunities and terms for the receipt of medical treatment, as well as regarding other medical treatment institutions where appropriate medical treatment may be received." The Medical Treatment Law, states: "Medical treatment shall be performed in conformity with clinical guidelines or by methods used in medical treatment and an evaluation of the safety of use of medicinal products and the effectiveness of the medical treatment, which is performed taking into account medical principles based upon evidence. To assure control over the quality of the provided healthcare services, the healthcare institution shall develop, approve, and implement a quality management system that ensures continuous control. The following shall be entitled to provide healthcare services in the respective profession independently: 1) Registered healthcare professionals. 2) Persons listed in the Registry of Health Care Professionals and Medical Support Staff. The Health Inspectorate of Latvia is a state administrative institution supervised by the Ministry of Health of the Republic of Latvia. One of its functions is to supervise the implementation of the laws and regulations governing healthcare institutions, and to check the quality and capacity of professional healthcare services.

Since January 2015 there are waiting times for medical care in few cases stated by the Regulations of Cabinet No. 1529. It is stated that a visit to a General Practitioner should be provided within 5 working days. Furthermore it is provided that the first consultation of an oncologist or haematologist should be provided within 10 working days, however waiting time for required diagnostic procedures or following consultation is not stated. It is stated that a person with predicted disability should receive required ambulatory or rehabilitation care services required in the Individual Rehabilitation Plan within 15 working days and planned operations within 5 month.

There is no system established for a patient to challenge decisions about waiting times besides a general right to dispute.

According to the Cabinet Regulations No. 1529, prior authorization should not been granted where the NHS has been informed about potential dangers for the person while receiving healthcare services abroad, as well as when there are serious concerns regarding the quality of service and safety in a particular healthcare institution.

Currently, there is no comprehensive quality management system that encompasses reliable quality indicators and mechanisms for monitoring and continuous quality improvement. Analysis of health service outcomes and quality of care is hampered by lack of data on key indicators, such as patient safety, both at national and organizational level.

Choice

The right of free choice of provider has existed since 1991 and is guaranteed under Latvian law (Article 8 Law on the Rights of Patients 2010). In principle choice applies to all providers but in the context of state-covered healthcare choice is limited to the list of contracted providers. Patients can freely choose their family doctor, provided the maximum number of patients to be treated according to his contract has not been reached yet. The GP acts as the main point of entry into the health care system and as the gatekeeper to secondary ambulatory and hospital care, except some specialist services (e.g. paediatrician) for which no referral is needed. In practice choice in the statutory system is often limited, in particular in rural areas, because of waiting lists and unavailability of alternative providers to choose from.

Information for patients from reliable sources, especially on quality of care, is still limited. However, Article 4.1 of the Patients' Rights Act states that "a patient has the right to information regarding the opportunities for the receipt of health care services and the procedures for the payment for health care services. This information shall be available to the public." General information about health care services, prices and co-payments ceilings is provided by the National Health Service, mainly through its website or call center. Also medical facilities provide general information to patients, such as registration status, the identity of practitioners, available services. Outpatient institutions are also obliged to publish a price list. The NHS is collecting data on waiting times every month but information is difficult to obtain. The Patients' Rights Act guarantees a patient's right to information about the quality of care but information is limited. The Centre for Disease Prevention and Control only publishes outcome data as general health/disease statistics. Some institutions give information that they have been implementing a quality management system and/or provide healthcare services of high quality.

The right to second opinion only exists for private patients. There is no legal provision to enforce it within the statutory health system.

LITHUANIA

General context

Patients' rights in Lithuania are well-established and patient-oriented. The Law on the Rights of Patients and Compensation for the Damage to Their Health No I-1562 was adopted in 1996. It contains a mix of fundamental and more consumer-oriented patients' rights. Certain elements (e.g. access to medical records) are further specified through governmental executive acts. Also relevant provisions are found in the Civil Code. Patients are familiar with the means of redress in case damage is caused to their health and they do know the means of enforcement of their rights, like the complaints procedure with the State Health Care Accreditation Agency. Also competent state authorities provide information to patients on patients' rights, health care providers, pricing etc. Patients' rights are constantly debated in the media and in Parliament.

Self-determination & confidentiality

The right to consent is protected by Chapter III of the Law on the Rights of Patients and Compensation for Damage to their Health, and by Section Two of Chapter XXXV of the Civil Code of Lithuania. Written consent is required for surgery. The right to information is broad and must include alternatives. There is a right not to know. There are no special provisions for cross-border patients but translations should be made available. There has been some case law and several academic articles. No specific remedies or enforcement avenues exist.

The right to privacy is enshrined in Article 22 of Constitution of Lithuania and Article 2.23 of Civil Code of Lithuania. It is also protected by Articles 8 and 9 of the aforementioned Law on the Rights of Patients. Written consent is required for disclosure. There are no special provisions for cross-border patients. There are fines for illegal processing of data (Code of Administrative Offences) as per the Law on Legal Protection of Personal Data. (ranges from 104 to 289 Euros.)

The right to access/amend records is protected by Article 6.735 of the Civil Code of Lithuania, Article 7 of the Law on the Rights of, the Order of the Minister of Health of 1 July 2011 No V-658 on the Implementation of the Right of the Patient to Get Acquainted with Information in Medical Records. Written requests are required, and data released within 10 days. No relevant case law exists, and there are no specific enforcement remedies.

Quality & safety

The Lithuanian Law on the Rights of Patients and Compensation for the Damage to their Health determines that the patient shall have the right to high quality health care services. The same law provides the following definition of high quality health care services: accessible, safe, efficient health improvement, disease prevention, diagnostic, patient treatment and nursing services which are provided to an appropriate patient at an appropriate time and place by an appropriate health care professional or a team of health care professionals according to the level of modern medical and nursing science and good practice, taking into account the service provider's possibilities and the patient's needs and expectations by satisfying or exceeding them. Health care service providers and health care specialists (broadly

speaking) must obtain a license in order to perform their activities. The licenses issued for health care institutions are registered in the special public register. The work of health care specialists (broadly speaking) is also regulated by the laws, namely, special medical standards approved by the Minister of Health which are special legal provisions that are supposed to regulate doctor activities in treating a disease or a group of diseases. These medical standards include the professional, qualification requirements for each of health care specialists, their working field, etc.

In practice, timely treatment is a problematic aspect in Lithuanian health care system. In order to provide solutions, the Minister of Health adopted an order. It imposes a duty on health care service providers to provide information about the waiting lines for the appointments with various health care specialists. This information should be provided to the Territorial Health Insurance Fund. However, the mentioned Order does not provide information about the acceptable or waiting times for the appointment with the doctor.

The Commission set for cross-border care can refuse to issue the prior authorisation in the following cases: 1) when the requirements set in Article 20(2) of the Regulation (EC) No 883/2004 of the European Parliament and the Council of 29 April2004 on the coordination of social security systems are not met or 2) or if the same treatment can be provided timely Lithuania, according to a person's health status and the expected course of the disease.

In the majority of cases the quality of treatment provided by the health care specialists and their responsibility are challenged in the courts. The Supreme Court of Lithuania has established the criteria according to which the actions of health care professionals/physicians have to be evaluated and also stated that not only the legal acts regulating the activity and practice of particular health care specialists has to be taken into account but also the provisions of professional ethic of health care specialists.

As regards the quality of the health care service, it can be challenged according to the procedure set in Articles 23 and 24 of Law on the Rights of Patients and Compensation for the Damage to Their Health.

Choice

The right to choose a health care professional and health care institution is stated as a basic principle of the health system (Article 49(3) Law on Health System of Lithuania No I-552 of 19 July 1994) and a patient right (Article 4 of the Law on the Rights of Patients and Compensation for the Damage to Their Health). However, when exercising this right of free choice the patient's right to receive free of charge health care may be restricted in accordance with the procedure established by legal acts. In practice, free choice is limited to health care institutions and health care specialists belonging to the Lithuanian National Health System. The procedure for choosing a health care professional shall be established by the head of the healthcare institution. Since 2001 patients need to register with a GP or a primary care institution but they can change every six months (Order of the Minister of Health No 583 of 9 November 2001 on Regulation of Enrolment of Persons to the Primary Health Care Institutions). Except for dermatologist/venereologist and psychiatrists, patients need a signed referral by their GP to access specialist care free of charge. Patients can also opt to consult private providers or seek specialist care without referral but in that case they

will pay the fee. This also counts for the patient seeking a second opinion from another specialist of the same professional qualification. In reality, the formal choice of primary and secondary care providers depends on actual availability and is sometimes rather theoretical, especially in rural areas.

The National Health Insurance Fund (NHIF) and the State Health Care Accreditation Agency provide information about providers, including information on waiting times. Also providers present their services on web site but many of these websites are not very suitable and useful for helping patients to make an informed choice. NGOs and patient associations are particularly active in this field and competent to provide objective information to patients.

LUXEMBOURG

General context

The development of patients' rights in Luxembourg started with the Law of 28 August 1998 on hospitals, which defined a catalogue of patients' rights applicable in the case of hospital care. In 2005, the Deontological Code of the Medical Profession, which is legally binding, recognized main patients' rights to be observed by all medical doctors. While this was followed by other healthcare professions, these obligations were still essentially provider-oriented and very well known by the patients. Inspired by the patients' rights law in Belgium and France – and to some extent also the Directive on cross-border care - the law of 24 July 2014 relating to the rights and obligations of the patient was finally adopted. Next to these patient rights, which are now generally well-established, also some more consumer-oriented rights with a long tradition in Luxembourg (e.g. second opinion, free choice of provider) are well accepted and enforced. Informational rights are more weakly enforced and there is only very limited transparency about quality of care.

Self-determination & confidentiality

Article 8 of the Patient Rights Law enshrines the right to information about one's health, the right to informed consent and the right to participate in decision making. This new law anticipates "a collaborative model of healthcare delivery". In theory, consent should be express but in practice it is often implied. The burden of proof that consent was properly obtained lies on professionals, and doctors strongly oppose this; "proof can be provided by any means and establishes a rebuttable presumption in favor of the documentation contained in the patient file." Comprehensive information including all options must be provided and the right not to know must be respected. Patients can be more passive if they wish and are entitled to choose third persons to aid in decision-making. No special provisions for cross-border patients, with information provided in one of three official languages, but translations are permitted. There is some evidence that patients receive less information than patients elsewhere in EU. In terms of enforcement, there are no specific remedies.

The right to privacy is protected by the Patient Rights Law, by the Constitution, the law concerning protection of private life, and the data processing law. Article 3 of the Patient Rights Law protects principles of "of respect for the patient's private life, of privacy, of confidentiality as well as of religious and philosophic convictions." Explicit

consent is required for sharing of data. Luxembourg is about to launch a new eHealth records system, and is taking part in the EXPAND cross-border project. The aim is to make cross-border patient data sharing more efficient. Breach of confidentiality is a criminal offence under article 458 of the Penal Code.

The right to access and amend records is protected by Article 16 of the Patient Rights Law. Copies of records are available, and a fee is sometimes required. Personal notes from doctors can be exempted from disclosure. Any access request must be granted within 15 days.

Quality & safety

According to the patient rights law, patients have the right to a safe and quality treatment and an equal access to health care. The Health Scientific Council issues recommendations for good medical practice standards. For hospital services, each hospital has a Quality Evaluation Committee which assesses how well the hospital functions and the quality of its services. Patients are thus generally not well informed about the quality achieved and are not able to detect where quality might be lacking There is no national organism defining today acceptable waiting times for a treatment or matters concerning periodization.

In practice, prior authorization is granted very largely (in over 90% of requests) and – although not formally foreseen in legislation – de facto granted if a specific treatment could be provided under better conditions abroad.

Choice

The right to free choice of provider is enshrined in article 19 of the Luxembourg Social Security Code and article 5 of the patient rights law, which specially stresses that the initial choice may be modified at any time. Luxembourg patients are very much attached to the principle of free patient choice, which applies not only to the primary health care provider but also to secondary care. A reference physician model ("médecin référent") was introduced as a soft gatekeeping model by the 2010 healthcare reform law but this is not mandatory and only serves as guidance. Given the limited size of the country, choice is sometimes limited in some specialties. In practice, however, Luxembourg generously allows access to healthcare abroad.

The patient rights law created a patient information and mediation service that should have become operational since May 2015 (www.mediateursante.lu). It is open to both domestic and cross-border patients and provides general information as mentioned in Directive 2011/24. Next to a health portal under the direction of the Ministry of Health (www.sante.lu) a web directory of all licensed healthcare providers and their right to provide service is available (www.esante.lu). It will be further enhanced with a geo-localization feature and information about languages and accessibility for persons with disabilities will be added. Providers are legally required to provide information on quality and safety of healthcare if available, including the number of medical procedures treated and the number of incidents (Article 8 (4) subparagraph 5 of the PRL). An important challenge is that there is no consistency in the availability, readability and objectivity of information provided due to the lack of an agreed, visible and applied national information strategy. Especially information on the quality of health services is poorly available to the public and information about medical errors is mostly not accessible at all. Consolidated objective data about outcomes is partly

accessible through the "carte sanitaire", a publication that serves as a tool for the strategic orientation of the hospital sector. Furthermore some data about general patient satisfaction or other outcomes is publicly available through the annual reports of the main hospitals. However, these data are controlled by the providers and not necessarily comparable between providers. Patients are thus generally not well informed about the quality level achieved and where quality might be subject to caution.

MALTA

General context

Malta doesn't seem to have a patients' rights framework. Only some special laws cover certain aspects like the legal acts on data protection or health care professions. The recent Health Act states that a patients' rights Charter should be developed but this is not yet implemented. The cross-border care Directive may have had some influence in this respect.

Self-determination & confidentiality

The right to consent is recognized in the Health Act and in the Civil Code. Written consent is required for procedures, but verbal consent sufficient for out-patients and general consultations. There are no specific information requirements and the reasonable person standard is used (although not required in law). The Health Act and the Patients' Rights Charter enable patient participation. The cross-border treatment of patients law is still being drafted as a bill; it was originally to be added to the health act but it is still to be implemented due to delays. Enforcement is via the Ombudsman for Patients' Rights or recourse to the courts.

The right to privacy is stipulated in the Data Protection Act, which imposes a legal obligation with some exceptions (danger to others, under Mental Health Act). Patients are usually informed about datasharing but it is only implied that consent should be sought. There are not yet any cross-border patient provision and there is no health related data protection case law. Enforcement is via the Data Protection Act or the constitution.

The right to access records is stipulated in the Data Protection Act and in the Health Act (Article 28). Records are usually accessed indirectly through a doctor or lawyer. Data can be corrected or erased but not added to. There is no right to a copy, although they are sometimes provided. No cross-border patient provisions yet. Enforcement via Data Protection Commissioner or courts.

Quality & safety

Quality and safety is not yet specified in Maltese law. There are no defined waiting times. People can write to consultants through their GPs. Patients with more severe diseases are given priority; urgent cases such as cancers are treated immediately. This has its toll on waiting lists. For a review of a certain decisions patients can write to the Ombudsman.

Choice

Free choice of healthcare in Malta mainly relates to the private sector, which accounts for about two-thirds of the workload in primary care. Most patients choose their own private family doctor and are willing to pay out-of-pocket because it offers greater convenience and better continuity of care. They can also self-refer to any private specialist of their choice. The state primary health-care system is offered mainly through eight public health centres and local health clinics. These services are free of charge but choice of the individual doctor is limited. The same applies for secondary care. People have access free-of-charge to out-patient or in-patient specialist care in public hospitals but need a doctor's referral (either from a public or private provider). A preference for a particular specialist can be specified in the referral but waiting time for an appointment depends on the urgency of the case. Since 2009 under the "Pharmacy of Your Choice" scheme patients government-procured pharmaceuticals are also supplied through private retail pharmacies and patients can collect their medicines from any pharmacy of their choice.

Under the supervision of the Medical Council, providers are required to provide information to patients. However, there are no legal requirements to publish data on performance, waiting times and prices. The right to second opinion is not formally stated in the law.

NETHERLANDS

General context

The Netherlands were the first European country to codify patients' rights as part of a medical treatment contract between patient and healthcare provider within its Civil Code. The Medical Treatment Contract Act that entered into force on 1 April 1995 was the result of a movement that started already in the 1960s with the establishment of health law as a new legal discipline, later followed in 1983 by the enactment of two new constitutional rights to privacy and physical integrity. The Dutch legal framework that is completed by other general and specific legal norms, also leaves room for the development of instruments of professional self-regulation. More recently, a draft Clients' Rights Care Bill is being discussed containing rules aimed at ensuring a good and effective complaints and disputes management in healthcare as well as promoting the quality of care. With the 2006 healthcare reform the Dutch healthcare system assigned a more significant role to patients with greater opportunity for them to influence the quality of services and a more pronounced right to receive information needed to make an informed choice of healthcare provider.

Self-determination & confidentiality

The right to consent is enshrined in Article 7:448 in conjunction with Article 7:450 of the Act on the Medical Treatment Contract as part of Book 7 of the Dutch Civil Code, which entered into force on 1 April 1995. Right to consent generally recognized as following from the constitutional right to physical integrity, protected by Article 11 of the Dutch Constitution. Consent to treatment is separate from consent to enter into a treatment contract. Other specific laws are also relevant (Organ Donation Act, and the Medical-Scientific Research with Human Subjects Act.). Written consent is not required

unless the patient requests it, although the practitioner may wish to obtain written consent for surgery etc. Consent can be presumed for non-invasive actions. Information can be provided verbally but must be given in written form if requested and must include what the "reasonable" patient would wish to know. Written information can never replace the requirement of verbal information; written information is then always provided in addition to the verbally provided information. There is a right not to know (Article 7:449 of the Act on the Medical Treatment Contract). Dutch government policies 'strive' towards patient participation. No specific cross-border patient provisions but translations must be provided to meet information criteria. Useful evidence is available in the Evaluation of the Act on the Medical Treatment Contract, which was performed in 2000. There is a large body of case law. Enforcement is via a complaints officer, complaints mediator, or healthcare institution complaints committees as regulated by the Clients' Right of Complaint (Care Sector) Act, and health professional disciplinary courts.

The right to privacy is protected by Article 10 of the Dutch constitution and by civil, criminal and administrative law, as well as various professional codes (not only doctors have an obligation to respect confidentiality). Key protections are present in Article 7:457 of the Act on the Medical Treatment Contract, Article 88 of the Individual Healthcare Professions Act, and Article 272 of the Dutch Penal Code. The Personal Data Protection Act is also relevant. There are no specific cross-border patient provisions. In addition to the aforementioned enforcement options, the Dutch Data Protection Authority has powers (see Chapters 8 (Legal protection) and 9 (Supervision) and 10 (Sanctions) in the Dutch Personal Data Protection Act.)

The right to access records is guaranteed by Chapter 6 of the Personal Data Protection Act, with copies available subject to a fee. Patients can add notes of their own to medical records. No specific cross-border patient provisions.

Quality & safety

In the Netherlands, the laws relevant in the area of quality and safety of healthcare in general are the Care Institutions Quality Act and the Individual Healthcare Professions Act. Both Acts, together with the Act on the Medical Treatment Contract, could be seen as the core of the (quality) legislation in the area of Dutch health law. In addition, standards and guidelines on quality and safety of healthcare are also reflected in other, more specific laws, as well as in documents of professional elf-regulation Regarding the Care Institutions Quality Act and the Individual Healthcare Professions Act, the Dutch legislator has set general standards, with broad outlines that leave room for self-regulation. As such, both Acts place great responsibility on healthcare professionals and health institutions to ensure the delivery of appropriate and high-quality care. Directly related to quality healthcare is the general provision in the Act on the Medical Treatment Contract requiring the healthcare provider to act as a competent care provider and in doing so to comply with the responsibility emanating from the medical professional standard.

The individual patient/ citizen should contact their own health insurer with a request for information about conditions to grant or refuse prior authorization for cross-border care.

Choice

The right to have choice and to information that supports making informed choices was one of the "seven consumer rights in health care" that the Dutch government wanted to strengthen in its 2008 programme presented to Parliament. The right to free choice of provider in the Netherlands is derived from the right to self-determination and relevant constitutional rights. In practice, the Dutch health system attributes a gatekeeping function to primary care physicians. Patients have to register with a GP and need a referral to obtain out-patient or in-patient specialist care. In principle they can freely choose their GP and can switch to a new one without restriction. However, GPs have the right to refuse a patient, e.g. when they already have too many patients on their list or when the patient lives too far from the practice. Choice can also be restricted by the health insurer. When choosing their health insurer, citizens can either opt for an in-kind policy, which guarantees them free-of-charge health services from providers who have been contracted by the health insurer, or they can choose a restitution policy, which allows them to maintain free provider choice but limits reimbursement to a maximum level. Of particular importance is Article 13 of the Health Insurance Act (entered into force in 2006), which prescribes that if in the context of an in-kind policy the insured decides to choose a non-contracted provider health insurers are also required to reimburse the services. In this case the insurer can determine the level of reimbursement but according to Dutch jurisprudence it should be sufficiently high that it remains a financially feasible option for the patient. (so-called "hindrance criterium"). The Dutch government has proposed to abolish the insurers' obligation to reimburse non-contracted care, at least for secondary care, which would limit free choice of provider. In an advice to the First Chamber the highest administrative court has found this proposal consistent with European law, i.e. the Directive 2011/24. Also in long-term care patients can either opt to receive benefits in kind from contracted providers or receive a personal care budget with which he or she can individually purchase care from professional organizations, but also from family or other non-professionals.

Healthcare providers are obliged to make information available about the services they provide and their performance (Article 38, Paragraph 4 of the Dutch Healthcare Market Regulation Act). Also Article 10 paragraph 1 of the proposed Quality, Complaints and Disputes Care Bill 1 imposes an information obligation upon the healthcare provider. This information concerns at least the tariffs and the quality of the services provided and should be provided in such a way that these data are easily comparable for consumers. Providers are also obliged to publish their tariffs for non-contracted care. They are also legally bound to transfer information about the quality of care to the Quality Institute for Healthcare, which is responsible for providing clear and reliable information to patients, providers and insurers. Various web sites present information to patients to make an informed choice of the provider, including the governmental National Health Care Institute (www.kiesbeter.nl) as well as the Dutch Patients' and Consumers' Federation (www.zorgkaartnederland.nl). The Dutch Association of Hospitals (NVZ) has developed the Quality Window that since May 2014 provides hospital and rehabilitation centre scores and data on indicators like waiting lists, credentials and patient experience.

The right to a second opinion is derived from the free choice of provider. It is seen as part of the healthcare provider's information duty to inform about 'other possible methods of examination or treatment' (Royal Dutch Medical Association). Except for a

second opinion about work incapacity, it is covered by statutory health insurance under the same conditions. This often means that a referral will be needed.

NORWAY

General context

Norway has a Patients' Rights Act (No. 63) since 1999. This was the result of a process that started already in the 1970 when the traditional provider-oriented approach gradually changed through media reports (e.g. the so-called "Reitgjerdet" case about unlawful detention in a psychiatric hospital), landmark decisions by the Supreme Court and the institution of health law as a separate legal discipline. As the health care in Norway is mainly publicly funded and provided by public entities, the Public Administration Act also plays an important role. This may have hampered the development of more consumer-oriented rights, even though the heading of the Patients' Rights Act was revised in 2011, adding "users of care services". Next to specific legislation on relevant issues such as patient injury, medical research, the Criminal Code as well as the 1999 Human Rights Act (No. 30) that incorporates various international human rights treaties, are also important sources.

Self-determination & confidentiality

The right to informed consent is expressed as a general rule in the Patients' Rights Act, section 2-1. Specific laws also apply, for example the Mental Health Care Act, cf. sect. 2-1). In some areas consent is regulated separately (i.e. the Health Research Act (20 June 2008 No. 44) sect. 13 (medical research) and the Biotechnology Act sect. 2-5 (medically assisted reproduction). There are no formal requirements for an "ordinary" consent. In certain contexts particular laws require written consent (such as the Biotechnology Act (5 December 2003 No. 100) sect. 5-4 (genetic testing) and the Mental Health Care Act sect. 2-2 (consent to being withheld in a psychiatric hospital for a limited time). Patient must have received the necessary information concerning his or her health condition and the content of the health care, including choice of treatment. Invasive treatment may be given when consent cannot be obtained if in best interests and consent would have been probable. There is a right not to know genetic information about oneself. The Patients' Rights Act focuses on the right to participation. Cross-border patients have a right to translations according to the Act. Compensation for violation of rights is available.

The right to private life has been protected in the constitution (section 102) since 2014. The right to protection of medical records grew from pharmacy regulations and is also protected by the Patients' Rights Act. There is a legal obligation under the Health Personnel Act to protect records, with violations punishable by up to three months in prison. Transgressions are also punishable via the Penal Code by up to 3 years' incarceration. There are no specific cross-border patient provisions. There have been several privacy cases in the Supreme Court.

The right to access records on request is laid down in the Patients' Rights Act and Health Personnel Act. Copies are available for EUR 10. "Shadow" health records are not permitted. There are specific procedures for altering and removing health data. There are no specific cross-border patient provisions.

Quality & safety

The time dimension is two-folded in the specialized health care sector. If a patient is referred by a general practitioner to specialized health care, the patient has the right to an assessment within 30 days (to be reduced to 10 days by law 21 June 2013 No. 79, this part of the amendment yet not in force), cf. the Patients' Rights Act sect. 2-2. If the disease is life threatening, the patient has the right to a swifter assessment, and some patients groups are have shorter, specific time limits. This regime does not apply to emergency health care. An evaluation shall be made of whether the patient has a right to necessary health care, and if so a time limit for the provision of health care shall be set.

Health personnel shall conduct their work in accordance with the requirements to professional diligence and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general, cf. the Health Personnel Act sect. 4. Health personnel must be authorized or have a license.

For many groups of diseases the Directorate of Health has issued clinical guidelines. Quality indicators and waiting times are published on public web sites. Providers of health services are under an obligation to conduct internal controls. The main responsibility to monitor patient safety and quality policy is vested to the Norwegian Board of Health Supervision and is also responsible for administrative sanctions of health personnel.

Waiting times for specialized health care services shall according to the Patients' Rights Act be set according to the patient's individual needs. The three main factors for prioritization are the severity of the disease, the expected treatment outcome and cost. The patient has a right to appeal decisions on assessment on specialized health care.

If the regional health enterprise has not ensured that a patient has received necessary health care according to the individual time limit, the patient obtaining an explicit authorization from the competent body (e.g. statutory health insurer, health authority) in order to get statutory reimbursement for healthcare services provided in another Member State than the state of affiliation is entitled to immediate health services, also outside the realm, The foreign health care provider must be authorized in the country where the treatment is taking place, and be a specialist in the field, if this is required for national treatment.

The Norwegian Board of Health Supervision is regularly making investigations on the matter, and whether specialized health care is provided timely and of sufficient quality is often a topic discussed in mass media.

The Patients' Rights Act sect. 2-2, paragraph 2 stipulates that a patient that is considered to be entitled to necessary health care shall be notified on the outcome and the fixed time limit. This notification shall also include information about the possibility to appeal.

Choice

The Patients' Rights Act sections 2-4 establish the right to free choice of provider. The patient's choice of his or her general practitioner is also guaranteed by Regulation No. 843 (29 August 2012). Based on the RGP scheme introduced in 2001 people register with a regular GP of their choice, provided this GP still has available capacity. They can only change GP twice a year. Access to free-of-charge specialized health services (inpatient or outpatient) is subject to referral from a GP. Upon referral patients can freely choose the institution as long as it is either owned by a regional health authority or is contracted by. In some cases hospitals can refuse to admit patients coming from other regions in order to prioritize patients from the hospital's own region. Recently, an amendment to the Patients' Rights Act and the Specialist Health Services Act was approved in Parliament to extend choice of hospitals. This will give patients the right to seek treatment in all approved hospitals, public and private and treatments will be refunded according to fixed rates set in regulations.

Although there are no specific legal requirements on clear and objective information about providers, the Health Directorate takes a leading role. The Norwegian information service "Fritt sykehusvalg Norge" (Free Hospital Choice Norway) provides up-to-date relevant information to patients about the different hospitals, including patient's rights, waiting times and quality information. Also information on quality indicators is made available (https://helsenorge.no/kvalitetsindikatorer). In addition the Norwegian Patient Organization" (www.pasient.no)) and various individual providers inform patients about available services. Patients who have received a referral may obtain information from the free hospital choice telephone service about waiting times for privately practising specialists within their home region.

The right to a second opinion is also recognized by the Patients' Rights Act. However, a referral from a GP is need and it is only allowed once for the same condition. Patients can freely choose from which provider they want to receive a second opinion within the limits as described above.

POLAND

General context

It took a long time of institutional and mental acceptance for Poland to move away from the provider-oriented approach that was mainly based on the Professions of Physician and Dentist Act (1996) and the binding rules contained in the Code of Medical Ethics (1993). The new basic legal fundament of patients' rights is the Act of 6 November 2008 on Patients' Rights and the Patient Ombudsman (Journal of Laws 2009, No. 52, item 417 and No. 76, item 641). It contains a mix of fundamental and more consumer-oriented rights and introduces the notion of "collective patients' rights", modelled after the notion of "consumer collective rights". All patients' rights regulations are to be interpreted in compliance with the Polish Constitution of 1997. The rights-based approach facilitates the enforcement of the rights through a private law remedy, in particular compensatory remedy, based on the Civil Code. Despite of the presence since 2005 of a central body responsible for patients' interests - the Patient Rights Ombudsman - in the Polish Ministry of Health, the state of enforcement of patients' rights is still considered to be weak in reality.

Self-determination & confidentiality

The right to consent is laid down in the Physicians Act of 1996 (articles 32–35) and in the Patient Rights Act of 2008. Although the rules contained in the two Acts are almost identical, there are slight inconsistencies between them and the Patient Rights Act is the prevailing document. Consent can normally be oral but written consent is required for surgery (though the law is unclear on the consequences of lack of written consent). Article 34 of the Patient Rights Act states that "a physician may perform an operation or apply a treatment or diagnostic method that creates an increased risk for the patient only after having obtained the latter's written consent." Burden of proof that consent was obtained rests with the doctor. Information is stipulated in the Patient Rights Act to include "health condition, diagnosis, suggested and possible diagnostic and treatment methods, foreseeable consequences of their application or omission, results of treatment and prognoses." Patients should be participants in decision-making and have a right not to know. In practice, patients sign a case history after a brief initial examination, which gives general consent despite the treatment not being known yet. Patients should therefore be consented again for specific treatment. Damages can be sought for violations stipulated in the Patient Rights Act. Of note is the high rate of consent violations in psychiatric hospitals: "violations of the consent requirements (procedure of admittance) were found in about 10% of all reported violations, while the patients' right to information on planned therapeutic procedure was violated in 22% of cases."

The right to privacy is protected by the constitution (article 47), articles 13-14 of the Patient Rights Act, and art. 40 sec. 1 of the Physicians' Act. It also includes a right to respect of dignity when health services are provided, and a right to die in peace and with dignity. Confidentiality is protected by civil and criminal law, with exceptions listed in articles 14 sec. 240 and article 40 sec. 2 2 of the Physicians Act. No major problems regarding right to privacy, although "around 8% of all complaints to the Patient Rights Ombudsman related to the violation of this right in 2013".

There is a constitutional right to access records. Access is granted directly by practitioners or institutions. Medical records and documents (including prescriptions) that are attached to the request for reimbursement of cost of cross-border services must be accompanied by an official translation into Polish. A process of digitalization of records is underway. In the past, hospitals have hindered access to records. Complaints relating to record access should be made via the Ombudsman.

Quality & safety

According the Patient Rights Act patients are entitled to 'health care services which meet the requirements of medical science and, in cases of limited availability of provision of treatment, to honest medical procedure based on medical criteria and determining the sequence of access to those services.' Two major factors that determine the quality of health care services are i) the diligence of medical professionals and ii) the quality and technical standards of appliance.

There is no licencing or approval system. The entity wishing to perform medical activity must be entered in a register kept by the voivode (the head of the provincial authorities) or another competent body (medical/professional chambers – as regards individual and group practices of physicians, nurses, midwives, dentists and pharmacists). If a person who sets up a health care entity fulfils all the requirements,

the voivode may not refuse to register the entity. Act on Accreditation in Health Care was passed, defining accreditation rules and procedures. The law followed the 1998 national accreditation programme for hospitals, implemented by the Centre for Quality Monitoring in Health Care. The accreditation process is voluntary. The Centre has developed accreditation standards with regard to the functioning and provision of health care.

As regards the quality and standards of healthcare services the two main regulatory bodies are the Ministry of Health and the National Health Fund. Due diligence and quality of treatment provided by medical personnel is controlled by professional chambers, which are charged with the enforcement of vocational (disciplinary) liability.

The Act on Health Care Services Financed from Public Resources prescribes detailed rules on waiting lists. The maintenance of the waiting lists is an obligation of the service providers, and it is monitored very closely by the National Fund. A patient cannot challenge decisions about waiting times.

Prior authorisation can be refused if the healthcare service (incl. healthcare provider) sought will expose the patient to a significant patient-safety risk that cannot be balanced by potential benefits flowing form the receipt of the healthcare.

In recent years substantial activities have been undertaken in the area of quality control, including HTA and the introduction of accreditation standards for hospitals and primary care. Nevertheless, standards of care are still missing in many areas of care (e.g. rehabilitation), making it difficult to assure and monitor quality of care. As regards timely access to health care, both the two Ombudsmen (the Civic Rights Ombudsman and the Patient Rights Ombudsman) and the Supreme audit Office have repeatedly reported that in many specialised outpatient and inpatient or clinics the waiting time for medical advice or service is too long.

Choice

The free choice of a healthcare provider is stipulated in articles 28-31 of the Act on Health Care Services Financed from Public Resources (2004). It applies to all providers at all levels and without geographical restrictions, including a primary care physician (nurse and midwife), a specialist (outpatient and inpatient), a hospital and a dentist (dental clinic). However, choice is limited to providers who were contracted by the National Health Fund (NFZ) (except for hospital emergency care). Patients need to register with a GP, usually within their region of residence. They can change twice a year free of charge, but every next change is subject to a fee of 80 PLN unless the change is due to special reasons (e.g. the change of residence). A referral from a primary care physician (or another specialist) is usually needed to access specialist and hospital care but exceptions are made for certain specialist types and certain conditions (e.g. HIV, tuberculosis). Physician can only refuse a patient if there is no emergency or risk and if he points at real alternatives by another doctor or in another hospital. He also needs to motivate this refusal in a written medical record and report to his supervisor if he is employed or on call. In reality, the right to choose is often theoretical and clearly hampered by the limited financing. According to the annual reports of the Patients' Rights Ombudsman and the Civic Rights Ombudsman it seems that choice is mainly based on a waiting time.

The right to information to enable patients to make decisions about accessing health services is expressed in the Patients' Rights Act. The main sources of information are the NFZ and health care providers. The NFZ obliges each contracted health care provider to display specific information in their facilities. They also need to a NFZ sign at an accessible and clearly visible spot on the outside of the building to inform patients that the institution provides health care services within the public system of health care insurance (2004 Law on Health Care Services Financed from Public Sources and by the NFZ). The NFZ itself also provides comprehensive information on its website, including waiting times for elective care and quality certificates held by the health care facilities. Monthly updated information on waiting lists is obtained from all contracted health care providers and is available for various types of service. Information on quality certificates (in particular, accreditation certificates) held by health care providers is available through the Health Care Units Register (RZOZ) and the Centre for Quality Monitoring in Health Care (CMJ). Apart from the voluntary accreditation system, there is no comprehensive information system on the quality of inpatient care in Poland. In recent years, voluntary hospital rankings have occasionally been published by some newspapers (e.g. Wprost, Rzeczpospolita) with the support of the CMJ and the Society for the Promotion of Quality.

The right to a second opinion is stated in Article37 Physicians Act: in case of diagnostic or therapeutic doubts, the physician, on his own initiative or at the patient's (or legal representative's) request shall consult an appropriate specialized physician or organize medical consultation if he deems it justified in the light of art of medicine's requirements. The consultant's opinion has an advisory character and the treating physician is still responsible for the whole treatment (art. 53 of Code of Ethics). This second opinion or medical council also applies to services of nurses and midwives. The decision to consult lies with the treating provider and a patient cannot freely choose the specialist who will be asked for a second opinion. If the request for a second opinion is denied that provider has to make an annotation in the patient's medical file. Following the ECtHR judgment in Tysiac v. Poland (app. No. 5410/03) of 20 March 2007, the 2008 Patients' Right Act also included a right to second opinion Articles 31–32 PRA) framed as a right to object to a medical opinion or a medical decision. This medical appeal, including a written motivation referring to legal norms that have been impacted by the challenged opinion or decision, is to be filed within thirty days to the Medical Commission operated by the Patient Rights Ombudsman office. This Commission consists of three physicians, two of which must be specialists in the branch of medicine pertinent to the case, selected from a special list and appointed by the Ombudsman. The Commission takes a decision within thirty days on the basis of the medical records and any necessary examination. No appeal is possible, neither by a patient nor by the Ombudsman. In 2013, 28 objections were filed but only 2 met the formal requirements and were processed to the Commission

PORTUGAL

General context

Patients' rights are of growing importance in Portugal, also due to increasing interest from the media in cases of medical malpractice. A special law on the rights and duties of the Health Care System beneficiaries was adopted in 2014 (Law no. 15/2014), which is complemented by professional ethical codes and administrative rules from the

General Health Administration. Despite the growing attention and monitoring by the regulatory health authorities the level of implementation at the level of healthcare institutions may still seem weak. Also the judicial system seems to be hesitant as to sanctioning violations of informed consent or enforcing medical liability. A similar reluctance is observed about applying consumer protection law to healthcare situations.

Self-determination & confidentiality

The right to consent is anchored in the constitutional right to physical and psychological integrity and in the Basic Law of Health Care. Verbal consent is more common, but such consent should always be recorded in records. Several situations require written consent, including voluntary termination of pregnancy; realization of invasive procedures in pregnant women, voluntary sterilization, medically assisted procreation (MAP); the installation of anticonception devices, blood and organ donation, research, off-label prescriptions and many others. There is a right to be informed about one's condition, possible treatment plans and the expected development of one's situation. There is a right not to know. The general rule is that the patients should be encouraged to participate in decisions regarding their health. There are no specific cross-border patient provisions. In terms of enforcement, there are no specific procedures; lawsuits and disciplinary action are the only avenues of recourse.

A right to privacy is the established in Article 26 of the Constitution and in Article 80 of the Civil Code; the Personal Data Protection law is also relevant, as are various specific laws (Law on Clinical Trials, Law on Medically Assisted Procreation, Law on Personal Genetic Information and Medical Information, and others). There is a legal obligation to respect confidentiality, which flows from article 195º of the Portuguese Criminal Code. The Ethics Code of the Medical Association (article 85th and following) also imposes responsibilities. There are no specific cross-border patient provisions.

The right to access records is present in soft law, in the Oviedo Convention (which is applied in Portugal as national law), the Law on Protection of Personal Data and the Law on Personal Genetic Information and Health Information. In private health care units, there is an indirect access system to records (via practitioner), whereas in public health care units, there is a direct access system. In the public sector the Law on Access to Administrative Documents applies and in the private sector the Law on Personal Genetic Information and Health Information and the Law on Protection of Personal Data) apply. There are no specific cross-border patient provisions.

Quality & safety

The guarantee of quality is, from the very beginning, constitutionally granted at the subparagraph (d) of paragraph 3 of article 64 of the Constitution of the Portuguese Republic which establishes that in order to ensure health protection, the state should regulate and supervise business and private forms of medicine, articulating them with the national health service, in order to ensure adequate standards of efficiency and quality in the institutions of public and private health. There are very clear rules regarding the licensing of private healthcare units since 2009. The Decree-Law no. 279/2009 establishes the legal regime of opening, modification and operation of these units. In procedural terms, the opening and operation of private healthcare units depends on the registration in the Regulatory Authority of Health and the license

issued by the Regional Administration of Health that through the licensing and the subsequent supervision control the quality of the provided healthcare.

In accordance with Law 15/2014 the user/patient of health services is entitled to receive the healthcare he/she needs in a promptly way or in a period of time considered clinically acceptable.

If the healthcare abroad in question can be provided in Portugal within a useful term from a clinical point of view, having regard to the state of health and the probable evolution of the patient disease. he patient is exposed to a safety risk that may not be considered acceptable, having regard to the potential benefit of cross-border healthcare for the patient; be If there is a reasonable certainty to conclude that the population is exposed to a considerable safety risk as a result of cross-border healthcare; c If the healthcare in question are administered by a healthcare provider that will inspire serious and specific concerns regarding to compliance with the standards and guidelines of healthcare quality and patient safety;

Besides possible complaints to the Health Regulatory Authority and the General Inspection of Health Activities, as well as disciplinary procedures and lawsuits there are no specific procedures.

Choice

Patients have the right to choose services and healthcare providers depending on existing resources in accordance with the rules of organization (Article 2 of Law no. 15/2014 and the law on Foundations of Health). This right is also considered as a fundamental principle of the relationship between the patient and the practitioner in the Code of Ethics of Medical Association (art 40). While choice of provider is greater for those covered by a health subsystem or private health insurance, patients in the national health service (NHS) have to register with a GP either in a public primary care centre or in a private providers contracted by the NHS. Their choice is limited to the available providers within a geographical area based on their residence. People may change GPs at any time if they apply in writing, explaining their reasons, to the Regional Health Authority's board (RHA). For secondary specialist care a referral is needed. In practice, patients bypass their GP by visiting emergency departments. Frequently, there is a delay in obtaining a consultation depending on the specialty. Just as free choice the right to second opinion, although included in the Charter of Patient Rights and Duties of the General Directorate for Health (point 7), remains rather theoretical. As a way to increase choice for patients in the NHS the "dental voucher" was established in 2008 specifically designed for dental care, where the public sector is residual. Pregnant women have access to three "dental vouchers", which give them the right to schedule a dentist appointment. The elderly are entitled to two of these vouchers per year. They were the first groups to benefit from this measure, and since then it has been expanded to children with DMFT in permanent teeth, when referred by their primary care physician.

While there is no specific legal obligation the Health Regulatory Authority and the General Inspection of Health Activities provide some information on healthcare provider, including information on available services and reports on quality of care. Data on the waiting times for specialist care and diagnostic services are not available. The Ministry of Health also developed a health portal in 2011 and since 2007 an NHS

call centre ("Saúde 24") was. Also patients' organizations play an important role in informing and guiding patients.

ROMANIA

General context

Within the context of the Law no. 95/2006 that regulates the functioning of the statutory health system, the Law no. 46/2003 defines the patients' rights. Other relevant provisions can be found in specific acts on mental health, data protection etc. Governmental decisions or orders further organize specific aspects such as the access to medical records, patients' feedback mechanisms in public hospitals, membership in hospital Boards of Ethics. Enforcement follows the more traditional way determined by disciplinary, administrative, civil, or criminal law. However, given the poor patients' rights knowledge among the population and the fragmentation in complaint and redress procedures, enforcement remains weak. Shortcomings of underfunded public healthcare system, including the poor conditions and cases of neglect in long term and mental care facilities (covered by media reports, but also the ECtHR's Judgement on Campeanu) have stirred the public debate. It encouraged patients to set up or join patients' organisations that provide counselling, support and practical guidance (even to seek treatment abroad).

Self-determination & confidentiality

The right to informed consent is provided for in the Health Law and the Patient Rights Law. Written consent is normally required except for simple observations. Patients are entitled to information on "diagnosis, the nature and the purpose of the treatment, the risks and the consequences of the suggested treatment, the feasible alternatives to the treatment, the risks and their consequences, the expected evolution of the condition in the absence of treatment". The right not to know applies in two circumstances: when information could cause suffering or when another person is appointed to receive the information. Patients can discuss alternative treatments but there is no right in law to participate. There are no cross-border patient provisions except translation. A national Survey on the quality of healthcare services and perceived corruption was conducted in 2013-14: "28% of them report having to follow the treatment or the procedure imposed by the medical personnel, without being informed of alternatives." Complaints are made via professional colleges or Malpractice Commissions.

The right to privacy is defined in Chapter IV, Law 46/2003; Article 21 reads "all information regarding the patient's condition, the results of investigation, the diagnosis, the expected evolution, the treatment, personal data, are confidential even after the patient's death". All healthcare personnel have an obligation to maintain confidentiality. Law 95/2006, Article 872 states that cross-border patients are entitled to respect for their private lives with regard to the processing of personal data.

The right to access records is provided in Article 24, Law 46/2003. Access is via a doctor, with time limits for direct access. Electronic access is possible online using national health insurance card and a pin code. There is also a right to add, correct, erase or destroy data. Access not reported to be a difficulty in survey. For cross border

EU patients, the right to access medical records held in Romania is provided for in article 872, Law 95/2006. Cross-border patients have a right to a copy or e-copy.

Quality & safety

The Patient's Rights Law provides in Article 2 that patients have the right to receive the highest attainable quality treatment, available according to the available human, financial and material resources. The timely provision of healthcare as a right not expressly stated as an independent right, but it is done indirectly but via guidelines laying down procedures for assessing "reasonable delay" by the doctor.

Hospitals must obtain a sanitary authorization prior to commencing their activities, and subsequently they have a delay of five years for obtaining the accreditation from the National Authority for Healthcare Quality Management, that enables them to enter contract with Health Insurance Houses and provide services covered from the health insurance funds Exhaustive and detailed safety protocols and clinical guidelines for diagnosing, treating and prevention measures are published through orders by the Ministry of Health, upon the recommendation of specialised commissions, or professionals' associations or societies. Professional competence and fitness to practice is certified and monitored by Colleges. The national framework contract for the provision of services covered by public health insurance funds and the implementation methodological norms sets out activity thresholds: maximum number of consultations which can be given by doctors within a limited time, the duration of the consultations. The minimum number of personnel / shift /section /unit, their required qualifications, and working times are regulated through orders issued by the Ministry of Health, observing the units types.

Acceptable waiting times for treatment are individually determined by the patients' treating doctors based on their personal and health circumstances. Prioritisation of health services, including medical devices and home provided healthcare must be done in accordance with guidelines provided by the National Health Insurance House and the decentralised Health Insurance Houses. Guidelines are available for several categories of conditions and factors.

The National Health Insurance House will only grant approval of reimbursement for cross-border care if (a) no hospital can provide the services within a reasonable term and (b) the patient's state of health or treatment will not be endangered by the journey itself. In these circumstances, the safety, timeliness and quality of healthcare can be debated upon if it rests on the personal financial resources of the insured patients.

Choice

Free choice of healthcare provider is formally recognized by the statutory health insurance Law 95/2006 (Article 208.3.c) as well as the Law on Patient Rights. However, patients cannot easily exercise this in the countryside or in small cities where there's often only one family doctor or hospital. Even if there are no geographical restrictions with respect to choosing a provider, most patients' choice is limited as they will have to bear the travel costs. Patients register with the family doctor of their choice and can change every six months. Access to treatment in a public or contracted hospital is subject to the family doctor's (GP) prior referral, and this referral is indicating the unit and the specialty within which the further

investigations, treatment or rehabilitation shall be done. Referrals are valid for 30, 60 or 90 days and subsequent referrals for conditions connected to the main investigated one can be issued by the specialist doctor. The choice of the hospital does not include a guaranteed choice of physician or surgeon: specialists in certain areas of treatment are few in numbers and hospitals' sections cannot function properly due to insufficient personnel. Parallel health insurance funds (e.g. the military) tend to recommend the use of associated hospitals.

Healthcare providers have an obligation to provide information on the services they offer, including their personnel and its corresponding specialisations, fitness to practice, the prices of services that are not reimbursed by health insurance etc. Patients can also obtain individualised information regarding waiting times. Objective information is provided by the National Health Insurance Fund that centralises information on fitness to practice, sanctions and provided services. Their territorial branches can provide information on prices, waiting lists and times for treatment funded by them. Medical professionals' colleges are also under a duty to gather data and report on their members in terms of numbers, fitness to practice and sanctions applied by the Malpractice commissions. Based on statistical data from the Public Health Departmental Authorities (decentralised bodies of the Health Ministry) and quantitative indicators from the National Institute of Public Health the Ministry of Health has started to develop a performance ranking of hospitals in 2011, which can be consulted on its web site. Finally, patients' associations also inform patients on specific treatments and the providers that offer them.

Patients are entitled to seek and to obtain "another medical opinion" (article 11 Patients' Law) but in practice may be more difficult to obtain.

SLOVAKIA

General context

In 2002-2003 the project "Promotion of Patients' Rights in Slovakia" that was supported by the Dutch government and included the creation of a Patients' Rights Unit in the Slovakian Health Ministry for administrative support, lead to the adoption of Act No. 576/2004 Coll. as part of the 2004 health care reform. This special law incorporates all the usual patients' rights into the legislation. These rights are well established and citizens are well-aware of them as well as of some of the more consumer-oriented rights. The rights to second opinion and information are not legally defined.

Self-determination & confidentiality

The right to consent is stipulated in Section 6 of Act. No. 576/2004 Coll. on health care and health care-related services. Any form of consent is appropriate unless written consent is required. Patients are entitled to comprehensive information. There is no formal right not to know, but patients can refuse to be told information. Patients have right to choose between alternatives but most patients only give consent to suggested specific treatment. The burden of proof is with the health care provider.

There are no cross-border patient provisions and no specific remedies.

The right to privacy is recognized both in the constitution (general right to privacy) and in specific legislation - Act No. 578/2004 Coll. This is one of the most respected patient rights. From time to time there are leaks of health data to the media especially in cases of celebrities. Enforcement is via the Personal Data Protection Authority or the courts.

The right to directly access records is provided in the act on health care, and is only denied to patients receiving psychiatric or psychological treatment that would be adversely affected by access. There are no formal conditions for access but copies must be paid for. The right to access records is well established but providers sometimes try to restrict access.

Quality & safety

The Act on health care, health care-related services and on the amendment and supplementing of certain laws as amended provides that health care is delivered lege artis when all the medical services necessary to for identification of the disease are provided to the patient which shall ensure timely and effective treatment taking into account the present medical knowledge. All health care providers require permit. The permit has a gatekeeping function and depending on the type of provider it is issue by a self-government or Ministry of Health. The provider ensures a continual system of quality to maintain and increase the standard of quality. The system of quality is systematically documented in writing which has purpose to minimize deficiencies in provision of the health care and increase degree of satisfaction of patients while maintaining providers economic effectiveness. The provider's system of quality should apply to all activities in the medical facility which may influence the health of persons or the course of their treatment, warrant that the staffing and equipping of the medical facility corresponds at least to the requirements set out in Act on providers or in separate regulation

Waiting lists are regulated by a decree of the Ministry of Health. The decree does not define acceptable waiting times only specifies for which conditions waiting lists are created. There is no formal procedure allowing the patient to challenge the decision on waiting times.

Prior authorization for cross-border care is granted by health insurance company if the health care is covered by the scope of by public health insurance and a) disease can't be treated in the Slovak Republic within a reasonable time (usually 12 months) taking into account the current state of health of the insured person and the possible development of the disease, b) the treatment is not carried out in the Slovak Republic, c) have exhausted all treatment options in the Slovak Republic and the treatment in another Member State is expected to substantially improve health or prevent deterioration of the insured person, d) the insured person is resident in another EU member state and wishes to continue treatment, which began in the Slovak Republic, the place of residence, or e) disease requires the use of highly specialized and cost-intensive medical infrastructure or medical equipment that are not available in the Slovak Republic. The health insurance company may refuse to grant prior approval for the provision of cross-border healthcare) disease involves treatments presenting a particular risk for the policyholder or the population, taking into account the potential contribution of cross on which the insured seeks, b) the treatment is provided by a healthcare in another Member State of the European Union, which casts doubt on the credibility of quality and safety in health care provision.

Choice

The right to free choice is legally recognized (§ 11 Act. No. 576/2004 Coll.). It applies to any inpatient or outpatient health care provider. However, free choice in the context of statutory health insurance is restricted to contracted health care providers, except if the health insurance company grants a prior authorization to reimburse care provided by a certain non-contracted provider. Patients register with a GP through a written agreement for a period of at least six months, which can only be terminated in writing. The providers may not refuse patients except in specified cases, for example work overload or a conflict of interests. GPs cannot reject a patient due to work overload if the patient is a permanent resident in the physician's district or if the patient is in need of urgent care. Also for specialized care, there is a free choice of specialist. Admission to a hospital requires a referral from GP or a specialist, except for urgent care, psychiatric patients and patients in the specialist's dispensary.

Although the law guarantees all citizens the right to obtain information from the various public institutions, in practice there are often no data. Health insurance companies are obliged to publish the list of the health care providers they have contracted with. There is no specific legislation related to the collection of information related to the performance of providers, waiting times and prices. Information on quality of providers is scarce. Based on their own analysis, the privately managed health insurance company Dôvera published the first quality assessment of hospitals in 2008, followed by the state-owned General Health Insurance Company later that year. Also certain NGOs and think tanks have collected and published information on performance.

Patients are not formally entitled to a second opinion but could obtain it if they want to. There is no formal process for it.

SLOVENIA

General context

Next to the special Patient Rights Act No 15/2008 the relevant legal framework in Slovenia also includes specific provisions in the Health Services Act (which lays down individual obligations by medical professionals), the Health Care and Health Insurance Act as well as the General Practitioners Services Act (with a chapter on Interpersonal Relations between the doctor and the patient), followed by a series of acts dealing with specific issues. The enforcement of patients' rights is weak but improving gradually. The driver for patients' rights development has been essentially the introduction of health law as a legal discipline together with the ratification of the Biomedicine Convention. General awareness among patients, doctors and other medical professionals is still quite low. More recently, media reports on cases of alleged medical errors (cf. Nekrep case) are catching public attention.

Self-determination & confidentiality

The right to informed consent is rooted in the constitution (Articles 34 and 35) and specified in the Patient Rights Act (Articles 26 and 27), which "amends and upgrades" the Health Care and Health Insurance Act. The General Practitioners Services Act also

imposes responsibilities on doctors. Verbal consent is normally used, but written consent is necessary in certain cases. Patients have a right to be informed about their medical condition, the likely course and consequences of the illness or injury, the purpose, type, manner of implementation, the likelihood of success and the expected benefits and the outcome of the proposed medical treatment. A right not to know is also stipulated in the Patient Rights Act. The patient "has the right to actively participate in selecting the method of treatment after being presented with all the necessary explanations on the treatment" (Article 21). However, in practice "many problems were detected….most of them are connected to shortage of the doctor`s time devoted to conference with patients." No specific duties for cross-border patients and no specific remedies.

The right to privacy is protected by Article 35 of the constitution and the Patient Rights Act (Articles 5 and 43). A legal obligation to preserve confidentiality is imposed by Article 51 of the Health Services Act. The Patient Rights Act also imposes an obligation to identify anyone responsible for breaches. No specific duties for cross-border patients. Criminal liability is a possibility for violations.

The Patient Rights Act provides the right to access medical records if legal grounds are given, within five days. Proxies can also access on behalf of patients. There is also a right to alter records. The Healthcare Databases Act is in the process of being updated regarding the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare; it includes e-health measures. Enforcement is via the information commissioner, whose annual report provides some evidence.

Quality & safety

The Patient Rights Act guarantees the right to adequate, quality and safe healthcare. Receiving treatment in a timely manner is a principle that is protected in a special patient right, defined as a right to due consideration of patient`s time. The patient has the right to adequate, quality and safe healthcare in accordance with the medical doctrine meaning that care as responsive to the patient's needs and in line with the capabilities of the Slovenian healthcare system. As a systemic law, the Health Services Act and the General Practitioner Services Act are key in judging the quality of the performance of the core provider of healthcare activities – the physician. The legislation provides a specific system of appraisal which serves as the ground to award, extend or revoke licences for independent performance of healthcare activities. The licence needs to be renewed every seven years. Tasks relating to that are entrusted to the Medical Chamber of Slovenia.

The Patient Rights Act tasks its performers to ensure the shortest waiting times possible, while balancing between the available finances and the (reasonable) waiting period. If a patient must wait for the service for longer than three months, he or she has the right to request a check-up at the physician who referred him or her to the service.

A reason for refusal is the fear that a patient will be, with sufficient certainty, exposed to safety risk that could not be understood as acceptable. Nevertheless the possible advantages of proposed healthcare service should also be taken into consideration. A prior authorization will also be denied if the public would be, in case of approval, with sufficient certainty exposed to safety risk or in case the healthcare service will be executed by a provider for which there are serious and concrete concerns regarding

respecting of standards and guidelines of quality, safety and supervision over healthcare services.

Many problems were noticed regarding the exercise of the right in practice. One of the most problematic ones is the issue of long waiting time for all kinds of first medical examinations on secondary and tertiary level.

There is a special misdemeanour procedure for remedies in case of violation of some of the regulations regarding the question on managing the waiting lists. In case healthcare provider doesn`t keep waiting lists in accordance with prescribed standards, it can be charged with a fine of 400 – 4.100 EUR.

Choice

The right to choice of provider is one of the 14 explicitly listed patients' rights in Article 5 of Patient Rights Act. However, it is not an absolute right as it is linked in practice to the capabilities and norms within a healthcare network. Services are only covered if the provider is contracted by the Health Insurance Institute of Slovenia (HIIS). Every Slovene citizen has the right to choose one personal physician (GP or paediatrician) as well as a personal gynaecologist and dentist without administrative and/or territorial constraints. Patients can change their choice at any time, while physicians can only reject a patient for specific and well-grounded reasons which have to be communicated in writing to the patient within eight days. The majority of providers at the primary care level are contracted by the HIIS and are still employed in health centres, while a smaller group of them work in private practices. The personal physician acts as a gatekeeper for specialist services and refers the patient to a particular outpatient specialist or to hospital diagnostics and treatment. However, the patient ultimately decides which specialist provider to turn to, provided he has a contract with the HIIS. For patients suffering from a chronic disease which requires long-term treatment by certain specialists, the personal physician can transfer some of his authority to the consulting specialists or hospital. The latter has to report back on a regular basis to the personal physician about the patient's progress.

In accordance with the Patient Rights Act providers should ensure that patients are properly informed of who they are, what is their professional and (or) scientific title, what services they offer and their time availability, and which laboratory and other providers they collaborate with. Patients should also be informed in advance about the costs of treatment if it is not fully covered by statutory health insurance (Article 25 of Patient Rights Act). The Medical Chamber of Slovenia has an online application named "Public search for doctors", which helps patients to identify doctors or dentists who are specialized in a certain field of medicine. They can also check whether a certain doctor has a valid license for the healthcare services he/she provides. Data on a quality of doctors is only accessible in a limited way: in the year 2009 the Medical Chamber of Slovenia for the first time granted the awards for the best doctors on certain fields of medicine. The Slovenian Code of Medical Deontology prohibits any direct or indirect advertising or publicity (Article 10). The National Institute of Public Health next to its duty to inform and educate public in the field of public health also has an obligation to collect and publish statistical data on waiting periods. According to Article 15 Patients' Rights Act, a patient has the right to be informed about the reasons for the waiting time and has additionally the right to the insight of the waiting list, of course with certain limitations needed for the protection of personal data of other patients.

The right to a second opinion is formally recognized in Article 5 and 40 of Patient Rights Act. While it is unlimited for private patients, for patients with statutory health insurance it is subject to certain conditions. It only applies to secondary or tertiary care, it can only be exercised once for the same health condition or anticipated procedures, it requires a prior discussion between the treating doctor and patient. In principle the second opinion should be given by a doctor in same institution, only if this is not possible the patient may be referred to another institution.

SPAIN

General context

Spain started to legally define patients' rights already in its General Health Law 14/1986. It took until 2002 however before a special patients' rights law was adopted: the Basic Law 41/2002 on the autonomy of the patient and the rights and obligations with regard to clinical information and documentation. This followed the ratification in 1999 of the Biomedicine Convention. Also the Spanish General Council of the Medical Order recognized patients' rights in the third chapter of the Code of Deontology. Also the Law on data protection and the Criminal Code, which addresses specific violations such as confidentiality and unconsented access to clinical records, are part of the legal framework. Consumer-oriented patients' rights have been the object of a much more recent development in the Spanish legal system and as a consequence there are still many issues that remain unsettled. The implementation of the cross-border Directive is considered an important driver in that respect.

Self-determination & confidentiality

The right to informed consent is considered one of the basic principles in the Patients' Rights Law. Article 8 of the law states that informed consent must be given verbally, but in certain cases such as surgery, written consent is required. The information provided should be comprehensive, and it should be provided in writing when consent will be obtained in writing. Specifically, information should cover: "Relevant or important consequences; risks related to the personal or professional circumstances of the patient; probable risks under normal conditions, in accordance with the experience and state of the science, or directly related to the type of intervention; and counter-indications." There is no specific right to participate, though it is implied in article 2.3 of the Patients' Rights Law. No legal attention has yet been paid to cross-border patient issues. The enforcement avenues depend on the context: in the private sphere, the Civil Code applies. In the public context, Law 30/92 on Public Administration and Common Administrative Procedure applies.

The right to privacy is both specific and broad, being grounded in both the Patients' Rights Law and the Constitution. A legal obligation to respect confidentiality is present in civil, criminal and administrative laws. Article 6 of Royal Decree 81/2014 on cross-border health care establishes that in order to facilitate health care, the right to privacy regarding personal and health data protection shall be guaranteed according to Organic Law 15/1999 on the Protection of Personal Data and the Patients' Rights Law. No reform is currently planned. The PRL refers to General Health Law 14/1986 with regard to infringements of rights.

The right to access records is provided in Article 15 of the Patients' Rights Law (also to proxies and heirs). Access to records is via hospitals and staff, and copies are available for no fee. Articles 5 and 6 of the Royal Decree on Cross-Border Health Care provide that in order to facilitate healthcare, patients shall be supplied with a copy, in adequate support, of the clinical record and results of the diagnostic tests and therapeutic procedures. Violations are punishable with fines via the General Health Law of up to EUR 300,000.

Quality & safety

Article 4.b of the Law on the Cohesion and Quality of the National Health System recognises the right to receive healthcare in the Autonomous Community of residence within a maximum time frame, in accordance with implementing regulations. In this respect, the Royal Decree 605/2003 establishes the criteria, indicators and minimum and common requirements regarding information about waiting lists in external care, diagnostic and therapeutic tests and surgical interventions in centres of the National Health System. Most healthcare professions are regulated by professional bodies. Moreover, in the public healthcare system, healthcare providers must be public servants or assimilated to public servants. Article 60 of the Law on the Cohesion and Quality of the National Health System establishes the Agency for the Quality of the National Health System, which is related to the Ministry of Health and which is in charge of elaborating and maintaining quality and safety rules, indicators, clinical practice and assistance guides, good practices records and adverse situations records. The Agency is advised by scientific societies and experts, based on national and international experience. Article 61 of the same law provides that the Ministry of Health and the Autonomous Communities must periodically elaborate quality plans which must contain the priority quality objectives for the relevant period.

Although Royal Decree 605/2003 lays down some general criteria, it is up to the Autonomous Communities to establish waiting times depending on the type of health care. Implementing rules differentiate between surgical interventions, first external consultations and certain diagnostic or therapeutic tests. Depending on the specific Autonomous Community, the typical waiting time is between 90 and 180 days for surgical interventions, 30 to 50 days for first external consultations and 30 days for tests. If waiting times are exceeded or close to their end, most Autonomous Communities allow the patient to ask to receive health care in another center of his/her choice in the relevant Autonomous Community.

A cause for refusal is where the patient will, accordingly to a clinical evaluation, be exposed with reasonable certainty to a risk (incl. healthcare provider) that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare.

Choice

The right to free choice of healthcare provider is established by the General Health Law 14/1986 (Article 10.13 and Article 14). The implementing rules are contained in Royal Decree 1575/1993 on free choice of healthcare provider in primary healthcare. Royal Decree 8/1996 regulates the free choice of doctor in specialised care centres of the National Health Service (SNS). However, there is some regional variation in the degree of patient choice as Autonomous Communities have developed their own norms, with some having integrated also private providers in their public network of

healthcare provision (e.g. Catalonia) or lifting geographical restrictions (e.g. Madrid). GPs play the gatekeeper role in the SNS. Choice of GP and pediatrician (for users under 14 years old) is restricted to those available in the relevant health area, but in cities of more than 250K inhabitants, this is extended to GPs and pediatricians across the city. Access to specialist care requires referral, except for emergencies. For the most advanced health services and interventions in tertiary care hospitals access is subject to a referral by another specialized health care services rather than a GP. The possibility to choose a specialist and hospital is relatively less developed. Patients may choose their provider only for certain medical specialties. Change is only possible after one year, unless the SNS authorizes based on legitimate reasons.

The National Health Service has to give to the users sufficient information for them to exercise their right to free choice. Each center must provide information and documentation that allows users to know which doctors can be chosen, places and times for consultations and, if applicable, waiting times, as well as any other information that may be of interest for the user to exercise his/her right (Article 8 of Royal Decree 8/1996). The Basic Act 41/2002 on Patient Autonomy, Rights and Duties on Information and Clinical Documentation further elaborated those rights related to information and clinical documentation within the SNS. Rules governing information on providers are laid down by the different Autonomous Communities.

Patients in the SNS are entitled to a second opinion (Article 4.a of Law 16/2003 on the Cohesion and Quality of the National Health System). However, this right is restricted to defined illnesses or therapeutic situations and can only be requested (in writing) once in each care process. Furthermore, the second opinion has to be issued by a physician acting within the same Autonomous Community of residence of the patient. The implementing provisions are adopted by the different Autonomous Communities.

SWEDEN

General context

For a long time there was no specific law regulating patients' rights in Sweden, as opposed to Nordic countries. Instead, different rights for patients, such as patient choice or the right to information, were incorporated in other legislation and are formulated in policy agreements between the state and the county councils. Regulations were mainly targeted at the behaviour of personnel and only indirectly at patients' rights. The 1982 Health and Medical Services Act defined the county councils' responsibility to provide all their citizens with high-quality health care services. In 1999, patients' rights in the health care system were further strengthened. The revised Act ordered the county councils' obligations to improve individualized information, increase opportunities to choose between alternative treatments and ensure the right to a second opinion when suffering from a life-threatening or other particularly serious disease or injury. Moreover, every county council and municipality was to establish a patients' committee to support and help individual patients and contribute to quality development in the health care system.

On 1 January 2015 a new Patient Act entered into force. This law aims to strengthen and define the position of patients and to promote patient integrity, self-determination and participation. Many of the provisions in the new law are derived from other statutes, while some have been adjusted and some are new. The idea of the Patient Act is to gather all statutes regarding patients in one, single law to make it clear to

care providers, patients, and family what applies in the area. The law extends and clarifies the current information duty towards patients, expands the patient's ability to receive a second opinion and increase choice of publicly financed primary care and outpatient specialist care throughout the country.

Self-determination & confidentiality

The right to consent is explicitly stated in Chapter 4 Section 2 of the Patient Act (2014:821), though it is also protected by constitutional law, the Health and Medical Services Act, and the Patient Safety Act. No specific form of consent is mandated. There is a right to comprehensive information in oral or written form including treatment options and a right not to know. No specific duties for cross-border patients. Enforcement is via administrative, penal or tort law.

The right to privacy is regulated by Chapter 25 Section 1 of the Public Access to Information and Secrecy Act (2009:400) for public healthcare and Chapter 6 Section 12 first paragraph, and Section 16 of the Patient Safety Act (2010:659) for private healthcare. Public healthcare personnel must respect confidentiality. The regulations governing confidentiality in private healthcare are less clear. Case law appears to primarily address issues concerning (wrongful) disclosure of health data to authorities such as the Police Authority, the Swedish Migration Board, and Swedish Social Insurance Agency. Enforcement is again via administrative, penal or tort law.

The right to access medical records is governed by Chapter 2 Section 1 of the Freedom of the Press Act. In public healthcare, a request should be made to the doctor in writing or orally, and information must be provided as soon as possible. Access can be to the physical record, or to a transcription. There are no fees for access, but a small fee for copies. Recourse in cases of rights violations are via the Health and Social Care Inspectorate, the Parliamentary Ombudsman, or the Swedish Data Protection Authority.

Quality & safety

The right to safe and quality treatment is stipulated in many various acts, such the Health and Medical Services Act (1982:763) and the Patient Safety Act (2010:659). According to Section 2a of the Health and Medical Services Act health care must be carried out so that it meets the demands of good care. The Swedish quality assurance system is complex and contains many actors. Public institutions include the Health and Social Care Inspectorate, the National Board of Health and Welfare, the Medical Responsibility Board and Patients´ Advisory Committee.

A health care guarantee is regulated in Chapter 2 Section 3 of the Patient Act, Section 3 g of the Health and Medical Services Act and Ordinance (2010:349) on healthcare guarantee.

The health care provider: Providers' has the overarching responsibility for patient safety as well as quality assurance. Section 31 of the Health and Medical Services Act (1982:763) stipulates that the quality of health care shall be guaranteed and systematically and continuously developed. According to Chapter 3 Section 5 of the Patient Safety Act severe adverse events must be reported to the Health and Social Care Inspectorate (called "lex Maria reports"). If a provider does not fulfill its duties, the Health and Social Care Inspectorate (IVO) can require the provider to take

appropriate measures and in very severe cases IVO has a legal possibility to close the provider's health care activity

The heath care personal shall perform his/her work in accordance with scientific knowledge and approved experience. All health professionals have a duty to report to the health care provider if a patient in connection with health care is struck by, or exposed to, the risk of serious injury or illness. If a health care professional does not fulfill his/her duties, several measures can be taken such as a probationary period, a restraint of the right to prescribe medicine and the revocation of a license.

The National Board of Health and Welfare (Socialstyrelsen): The National Board of Health and Welfare has responsibility for the issuing of statutes and national guidelines. The goal of these guidelines is to contribute towards patients receiving a high standard of medical care.

The Health and Social Care Inspectorate (IVO): IVO is a government agency responsible for supervising health care. Its supervision remit covers the processing of complaints concerning, for example, the reporting of irregularities in health care (lex Maria reports).Primarily the health care providers, who are supervised by the Health and Social Care Inspectorate.

A health care guarantee means that a patient shall receive healthcare within a certain period of time. This is regulated in Chapter 2 Section 3 of the Patient Act, Section 3 g of the Health and Medical Services Act and Ordinance (2010:349) on healthcare guarantee. The health care guarantee indicates the frame of time within which a patient shall be offered care from the county council or the region. However, it does not regulate whether care shall be provided or what type of care a patient shall receive. Note: Emergency care is not tied to the health care guarantee.

From the time it is decided that a patient should be seen by a physician for a first visit at the district health care clinic, or alternatively, make a visit or receive a treatment within specialized care, the health care guarantee indicates how long, at the longest, a patient shall be required to wait. If it is not possible to receive care or treatment at the health care facility where a patient has sought care within the designated time frames, a patient shall be offered an appointment or treatment at another health care facility. It is possible that a patient can be referred to another health care facility in another region or under the jurisdiction of another county council.

If healthcare providers do not properly respect the right to safe and quality treatment received in I timely manner, this omission may result in critical statements/decisions taken by the Health and Social Care Inspectorate.

Choice

Since the 1st of January 2015 patients have the right to choose any outpatient health centre or clinic without geographical restriction, as long as it is run by - or has an agreement with - the county council or region (Chapter 9 Section 1 of the Patient Act). The patient is entitled to have a fixed medical contact at this health centre (Section 5 second paragraph Health and Medical Services Act and Chapter 6 Section 3 of the Patient Act). Since primary care has no formal gate-keeping role and county councils or regions have their own referral procedures, patients are mostly free to consult specialists directly, depending on where they live or want to receive care. Patients can

also freely choose any hospital. In any case, based on the care guarantee that was introduced in 2005, patients are entitled to access to care within maximum waiting times (cf. The so-called "0–7–90–90" rule meaning instant contact for consultation; GP within 7 days; specialist within 90 days; treatment after diagnosis within 90 days) which apply throughout the whole country and include all elective care in the county councils (Chapter 2 Section 3 of the Patient Act, Section 3 g of the Health and Medical Services Act and Ordinance).

Patients are entitled to receive all necessary information adapted to their particular circumstances and capabilities (e.g. age, maturity, experience, language background) to choose their healthcare provider (Chapter 3 Section 2 of the Patient Act). This also includes information on when he or she can expect to get treatment within the context of the care guarantee. All county councils and regions provide information about how and where to seek care through their websites. There are also several national projects aimed at improving the access and use of information for patients and citizens. The initiative 1177.se is a collaborative project between all county councils and regions in Sweden. Next to the website it also comprises a 24/7 phone line 1177, with medical staff available to give advice about medical conditions and where or at what level to seek care if necessary. Information about waiting times is compiled by the Swedish Association of Local Authorities and Regions (SALAR) and published as a database (www.vantetider.se). Developments in the Swedish health system towards choice and privatization have also increased the need for information on performance and differences in quality and patient satisfaction between providers. Since 2006 the National Board of Health and Welfare and SALAR collaborate to develop an annual comparison and ranking across county councils (Öppna jämförelser), including a comparison of hospitals based on some 50 indicators. Also private initiatives were developed to provides citizens and patients with comparative information about providers, such as the one financed by the Confederation of Swedish Enterprises (www.omvard.se), which is partly based on information collected through National Patient Surveys, which are conducted every two years.

Patients in Sweden have a right to a new medical evaluation (a second opinion) if they have a life-threatening or highly serious disease or injury (Chapter 8 section 1 first paragraph of the Patient Act and Section 3a second paragraph of the Health and Medical Services Act) and if the healthcare provider is a county council or region (Chapter 1 Section 2 second paragraph of the Patient Act). The county council is obliged to pay for a new medical evaluation and travel, even if the second doctor is in another county. If the doctor recommends an alternative treatment the treatment will only be covered if it is . justified on the basis of scientific evidence and clinical experience, and it is reasonably priced in view of the particular illness or injury involved.

UNITED KINGDON

General Context

It is only very recently that the UK has adopted an approach to patient rights whereby patients can see their rights set out in a codified, user-friendly form. Under the Health Act 2009, the "NHS Constitution" (The Constitution) and the "Handbook to the NHS Constitution" (The Handbook) must be published by the Secretary of State. These

publications are the codification of patient rights within the Law - the Health Act 2009 does not create the rights or even give the content of the Constitution - but for the patient (and NHS staff) they are the first comprehensive expression of the rights, expectations and duties that operate within the NHS. The Constitution and Handbook have four parts. The first two outline seven principles and six core values upon which the NHS is built. Part three outlines first the seven areas of rights and pledges that the patient can enjoy and the responsibilities owed to the NHS by patients and the public. Part four outlines NHS staff members' rights and pledges to them, and their responsibilities.

This brings together two lines through which patient rights have developed in the UK. The first line relates to the more traditional rights - the rights relating to the definition of the relationship between the carer and the patient within the consultation or treatment room. The second line relates to the more modern, consumer-style rights about access and choice within the broader provision of healthcare.

The more traditional rights had their origin in the medical professions themselves. It concerns the quality of care and the nature of the doctor-patient interaction - adherence to professional norms, being registered as a suitably qualified practitioner, etc. This starts in the self-regulation of the (Royal) Colleges (for physicians and surgeons from the 15th and 16th centuries), with the twin elements of registration and definition of professional standards. These bodies remain strong and have been added to with colleges of medical specialisms and other health professions.[15] The Medical Act 1853 created the General Medical Council (GMC) with the mandate to create a compulsory register of doctors. Under the Act, to practice medicine with the claim to being 'a doctor', one must be registered. Further, the GMC was charged with setting the standards for medical education, regulating University courses and requirements for admission to the profession. The GMC, whilst a statutory body, has a very strong professional self-regulatory element. Section 35 of the Medical Act 1983 gives the GMC power to determine, 'in such manner as the Council think fit, advice for members of the medical profession on standards of professional conduct or on medical ethics'. The subsequent sections of that Act concern the powers of the GMC in regulating 'fitness to practice' and 'professional conduct' of doctors. The GMC publishes a number of codes of guidance to practitioners, particularly "Good Medical Practice" (GMP)[16] and the various specific advice. This is the core of (traditional) patient rights in the UK; it is enforced on practitioners through the requirement to follow the professional standards as a continuing condition of registration, and that registration is compulsory to be able to claim to be a professional medical practitioner (and thereby gain access to mainstream employment).[17]

Alongside this traditional patient rights have two other origins: further statutory requirements, and the Common Law. English Law is Common Law - i.e. its origins are

[15] See, for example, Royal College of Physicians (established, 1518); Company of Barber-Surgeons (1540, splitting into Royal College of Surgeons in 1754); British Medical Association (1832); Royal College of Nursing (1916). A number of specialisms also have their own bodies, for example, the Royal College of General Practitioners (1953).

[16] http://www.gmc-uk.org/guidance/index.asp This code and the further explanatory notes, via the website, is supported by case studies and education materials that readers can use to develop their understanding of the concepts.

[17] This rather obtuse wording is because it is not compulsory to register to offer medical services; it is a criminal offence to make a false claim or pretend to be a professional practitioner (see, for example, Medical Act 1858, s. 40).

in judge-made Law. From the mid-19th century, this has accommodated the more democratic aspect of Parliament-made Law, in statutes. The Medical Acts are a good example of this; from the 1980s, and particularly post-2000, there have been more statutory codifications and original Acts in the area of standards and quality in the NHS (which will be referred to in the text below). Judge-made Law has also contributed to the development of actions for compensation (the Tort of medical negligence) and to the definition of standards (for example, in informed consent), and in relation to criminal Law. These developments (from the 19th and 20th century) have in some cases (but not all) been incorporated into Acts of Parliament, and have influenced the developments of the Codes of Guidance.

Whereas traditional patient rights are well established in UK Law, albeit in a number of sources, the new, or consumer, patient rights (dealing more overtly with patient choice in a market) are more difficult to identify. The UK famously developed the National Health Service as part of the Welfare State under the National Health Service Act 1946 (NHS Scotland, 1947 and NHS Northern Ireland, 1948). Before this, the provision of health was a mixture of private, charitable and local government provision, where the right to health was entirely based upon the ability to pay at the point of use, or upon a local charitable opportunity. The National Health Service nationalised much of health care (the hospitals, the expectation of provision and cost), making health a right for all citizens (based on a universal "National Insurance" payment and underpinned by taxation), free at the point of use. This right remains at the heart of the majority of NHS provision, and it remains a strong part of the cultural identity of 'Britishness'. [18]

The idea of consumer medicine has some traction in current political discussions. However, patients remain in a 'doctor-patient' relationship in the NHS with and expectation that the NHS will address any health problem. There is no clearly defined 'basket of goods' to which individuals are entitled. Rather, entitlement is to all health care with regulation in two ways: first by waiting lists and budgets; second by approval of therapies for use in the UK by the National Institute for Health and Care Excellence (NICE). NICE operates with an element of economic effectiveness as well as clinical effectiveness. Waiting lists and budget are the most interesting element in terms of patient expectations and rights. Individuals interact with the institution of the NHS. Waiting times and budgets are more political questions than rights questions. Increasingly, expectations of being seen within a particular time are more common as part of the political drive for efficiency in the NHS, but they are more difficult to exercise as hard legal rights to timely healthcare. The NHS is rooted in collectivism, and this is reflected in the approach that is taken towards the 'new' or consumerist patient rights. Further, there is an alternative for those who can afford which acts as a self-help against individually unacceptable waiting times, in the parallel provisions of 'private healthcare' in the UK. Alongside the NHS, there are private providers who offer services paid at the point of use. Often, because of the deal struck by the doctors with the Government in the initial creation of the NHS in the 1940s, the doctors also work within the NHS (and are therefore regulated in terms of traditional patient rights in the same, professional, way); other health workers, for example nursing staff, working within the private system (for example, in private hospitals) again have to be registered in their profession and are subject to that professional regulation. Thus, the

[18] Timmins, N. (1995) The Five Giants: A Biography of the Welfare State London: Harper Collins.

patient right to choice operates with a two-tier way: within the NHS, there are opportunities for second opinions and a choice of doctor, but this is subject to waiting times and what one might describe as 'soft rights' of general practitioner (GP) referral; the greater choice operates for those who can afford additional health insurance, but this tends to operate in the middle ground of care - not at the GP level or at the emergency or highly expensive, technical care (e.g. oncology), but at the realm of more routine operations (e.g. hip replacements, etc.).[19]

The Constitution starts with the six core values and seven principles that frame the NHS. The values are "working together for patients", "respect and dignity", "commitment to quality of care", "compassion", "improving lives", and "everyone counts". The handbook explanations of the values stress the primacy of the patient and the coordination of the various elements of the service to serve the needs of the patient. There is a commitment to respect and dignity, to excellence, and to just delivery of services. Interestingly, questions of efficiency and value for money do not appear in the values; these appear in the principles. Whereas the values point to the quality and manner of care, the principles point more to access. Thus the principles are that: "the NHS provides a comprehensive service available to all", "access to NHS services is based on clinical need, not on an individual's ability to pay", "the NHS aspires to the highest standards of excellence and professionalism", "the NHS aspires to put patients at the heart of everything it does", "the NHS works across organisational boundaries and in partnership with other organisations in the interest of patients, local communities and the wider population", "the NHS is committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources", and "the NHS is accountable to the public, communities and patients that it serves". These values and principles are expressed through rights and pledges to patients in the areas of: access; quality of care and environment; nationally approved treatments, drugs, and programmes; respect, consent and confidentiality; informed choice; involvement in your healthcare and in the NHS; and, complaint and redress.

The right of access to healthcare

This has been to a large extent covered in the discussion of the origin of the NHS above. However, the Constitution includes a number of rights that make rights to access explicit, and that connect those rights to broader issues of equality. Therefore, in the first and second principles, the duties expressed in the Equality Act 2010 are made explicit for the NHS: there can be no discrimination by virtue of "age, disability, race, gender or gender reassignment, sexual orientation, pregnancy and maternity, religion or belief, or marital or civil partnership status"[20]; 'health inequalities' must also be alleviated. Further, unless specifically addressed by statute,[21] individuals are entitled to the benefit of a "comprehensive health service designed to secure improvement (a) in the physical and mental health of the people of England, and (b) in the prevention, diagnosis and treatment of illness" and provided "free of charge"

[19] Propper, C., (2000) "The demand for private health care in the UK." Journal of Health Economics 19(6): 855–876.
[20] The Handbook, p. 20, derived from the Equalities Act 2010. The provision must also comply with the Human Rights Act 1998.
[21] See the rules relating to prescription, dental and opthalmic services, and for 'overseas visitors', under the National Health Service Act 2006 (as detailed in The Handbook, pp 18 and 19).

(commonly understood as 'free at the point of use').[22] Further, under the Constitution, the right of access includes a right to expect a local assessment of health needs and a planning of the service accordingly.

As indicated above, in a system that aims to offer a fully comprehensive health care, rather than a limited range of core services, but that has finite resources, waiting times become one of the key measures for providers to regulate access to the service (in conflict with successive Governments in broad conflicts over funding levels). The Constitution outlines the rights to access within defined acceptable waiting times. There is a general right to start "consultant-led", "non-urgent" treatment within 18 weeks of referral; oncology patients have rights to be seen and to start treatment much more quickly - for example, to be seen within two weeks from a GP referral where cancer is suspected. (The Handbook, p. 27) Medical factors, for the patient's welfare, can extend these time-limits.

It is interesting, given the comprehensive and rather collectivist approach of the NHS, there is no corresponding duty owed by the patient to take responsibility for his or her own health. The first 'responsibility' that the Constitution places upon the patient is, "Please recognise that you can make a significant contribution to your own, and your family's, good health and wellbeing, and take personal responsibility for it." (The Handbook, p. 86) This is explained in the Handbook as follows, "You have a role to play in staying healthy...You can ask about what support you might be offered in managing your condition yourself or changing to a healthy lifestyle stopping smoking, reducing weight, taking up exercise or reducing excessive alcohol consumption."[23] There is no sanction attached for failure to take this responsibility.

The Constitution explicitly refers to the right to seek health care in other jurisdictions under the EU Regulation 883/2004 and Directive 2011/24/EU. The National Contact Point[24] has largely been constructed to assist out-going patients (NHS patients going abroad), with country-by-country explanations; in-coming patients have information on the NCP, but might also need to access, for example, the "NHS Choices" portal for broader detail of patient rights.[25]

Self-determination and confidentiality

Patients have the right to informed consent in UK Law. "You have the right to accept or refuse treatment that is offered to you, and not to be given any physical examination or treatment unless you have given valid consent. If you do not have the capacity to do so, consent must be obtained from a person legally able to act on your behalf, or the treatment must be in your best interests." (The Handbook, p. 51) This has been developed over a long period in the Common Law. Its origins are in Tort and Criminal Law relating to assault and battery. In relation to competent adults, cases have defined the extent of the right, and the corresponding duties of practitioners. Particularly, two cases are landmarks: Bolam v. Friern Hospital Management Committee [1957] 1 WLR 582 and Sidaway v. Board of Governors of the Bethlem Royal Hospital [1985] AC 871. The practical detail of informed consent is explained in

[22] National Health Service Act 2006, s. 1.
[23] Ibid.
[24] http://www.nhs.uk/NHSEngland/Healthcareabroad/Pages/Healthcareabroad.aspx
[25] http://www.nhs.uk/choiceintheNHS/Rightsandpledges/Pages/Rightsandpledgeshome.aspx

the GMP supplements the NHS Choices website "Consent to Treatment"[26], and the GMC supplement to GMP "Consent: Doctors and Patients Making Decisions Together"[27] These make clear the distinction between the information required, the consent, and the evidencing of consent. Implied consent is discussed only in relation to organ donation, and then only as a possible future option.

Children of the age of 16 and 17 are presumed to have competence to make their own medical decisions like adults (and in the same way it is a rebuttable presumption). Those under the age of 16 are subject to the decision making of their parents or guardians. However, under the decision of Gillick v. West Norfolk and Wisbeck Area Health Authority [1986] AC 11 a child is entitled to make decisions for him- or herself where the medical practitioner (and ultimately a court, where the judgement of the doctor is challenged) judges the child to be competent to make that particular decision. "Gillick competence" is a situation-dependent judgement; the child does not have to show general competence. Adults who do not have competence are represented by guardians, or where no such person is appointed the doctor "they must consult with family members and other interested people where possible. For serious medical treatment decisions, if there is no family available with which to consult, they must consult an independent mental capacity advocate (an IMCA)."[28]

There is a distinction in English Law between medical confidentiality and privacy. The distinction is in no small part because the Common Law did not recognise privacy as a right, and it is introduced into English Law directly by the Human Rights Act 1998, and before that only indirectly by reference to the European Court of Human Rights.[29] Medical records, which must be created and kept by the practitioner, are regulated under Statute by the Data Protection Act 1998 (and previously by the Access to Medical Reports Act 1988 and the Data Protection Act 1984). The 1998 Act follows the European Directive on the processing of personal data (95/46/EC). There is, in the background of the early Law, a more protectionist position; the right to access one's data was not immediately forthcoming, with a sense of the record being owned by the practitioner or the NHS, and the information being of a specialist nature from which a patient might need to be protected. The presumption today is that a patient must have access to his or her medical data.

Under the Constitution there are a number of rights relating to patient confidentiality and privacy, particularly around their personal data. As a patient, you have the right: "of access to your own health records and to have any factual inaccuracies corrected." (The Handbook, p. 54); "to privacy and confidentiality and to expect the NHS to keep your confidential information safe and secure." (p. 55); "to be informed about how your information is used" (p. 57); "to request that your confidential information is not used beyond your own care and treatment and to have your objections considered, and where your wishes cannot be followed, to be told the reasons including the legal basis" (p. 58). There are corresponding duties on doctors in both the Constitution and the GMC's GMP. There is also a pledge that the NHS "commits to ensure those

26 http://www.nhs.uk/conditions/consent-to-treatment/pages/introduction.aspx

27 http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

[28] The Handbook, p. 51, following the Mental Capacity Act 2005.

[29] For key cases in the development of confidentiality and privacy are Attorney-General v Guardian Newspapers (No 2) (the Spycatcher case), [2004] UKHL 22 and Campbell v Mirror Group Newspapers [1990] 1 AC 109

involved in your care and treatment have access to your health information so they can care for you safely and effectively", "to anonymise the information collected during the course of your treatment and use it to support research and improve care for others," and "where identifiable information has to be used, to give you the chance to object wherever possible" (pp. 60–61), and "to share with you any correspondence sent between clinicians about your care" (p. 62). The second of these pledges is fascinating. In many jurisdictions, this would be contentious (and indeed, the response to the "Care. Data" initiative indicates that it is controversial for many in the UK). However, here, the use of personal data, albeit anonymised is presumed to be acceptable, and presented as a positive 'good' for the patient. This positive presentation of medical research continues in the pledge "to inform you of research studies in which you may be eligible to participate" (p. 61). Point 50 of the GMP requires that a registered practitioner "must treat information about patients as confidential. This includes after a patient has died."

Quality and safety

One of the first, and oldest, mechanisms for ensuring quality is registration of practitioners with the obligation as part of the registration that the applicants have successfully completed prescribed study. This is a measure found in the earliest colleges of physicians and of surgeons, and it is formalised as the main duty of the General Medical Council from the Medical Act 1853. Today, that initial validation and the regulation of providers of medical education remains a major duty on the GMC. Equally, today practitioners undergo a rigorous revalidation process every five years, requiring a self-prepared, reflective portfolio, evidencing the candidate's continuing education, 'quality improvement activity', significant events, colleagues' and patients' feedback, 'review of complaints and compliments'.[30] The portfolio forms the basis of an assessment with the candidate. This has been developed in no small part because of the scandals that medical practice has undergone in recent years, for example, the actions of the GP Shipman, and the practices in Alder Hey Hospital and Bristol Royal Infirmary.[31]

Under the Constitution, the "commitment of quality of care" is one of the core values and the third principle is that "the NHS aspires to the highest standards of excellence and professionalism". These are translated into a number of rights (and corresponding duties). Patients have "the right to be involved, directly or through representatives, in the planning of healthcare services commissioned by NHS bodies, the development and consideration of proposals for changes in the way those services are provided, and in decisions to be made affecting the operation of those services", and there is a corresponding pledge to provide patients (and the public) with information to enable them to participate in such discussions. (The Handbook, p. 71–72) Patients "have the right to be treated with a professional standard of care, by appropriately qualified and experienced staff, in a properly approved or registered organisation that meets required levels of safety and quality." (p. 33) Further, patients "have the right to be treated with a professional standard of care, by appropriately qualified and experienced staff, in a properly approved or registered organisation that meets required levels of safety and quality." (p. 36) This has corresponding pledges in

[30] http://www.gmc-uk.org/RT__Supporting_information_for_appraisal_and_revalidation__DC5485.pdf_55024594.pdf

[31] See, for example, Dixon-Woods, M., Yeung, K., Bosk, C L., (2011) "Why is U.K. medicine no longer a self-regulating profession? The role of scandals involving "bad apple" doctors." Soc Sci Med. 73(10): 1452–9.

relation to standards of hygiene and "to identify and share best practice in quality of care and treatments." (pp. 39–41) Patients "have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you." (p. 44)

Choice

A patient has a right to choose a GP practice (and a doctor within that practice): this choice is honoured in all but exceptional circumstances, including the patient's misconduct or a 'breakdown in the doctor-patient relationship', but the NHS Commissioning Board has a duty to assist in finding an alternative.[32] Likewise, with the exception of mental health, emergency, maternity care and oncology services under the two-week referral time, a patient has the right to choose the NHS provider of outpatient, consultant-led care.[33]

This is a right under the Health and Social Care Act 2012 as a duty on the NHS Commissioning Board, expressed as follows: "Where a range of potentially suitable treatments or forms of healthcare is available, an adult, competent person has the right to receive the information they need in order to decide their preference. NHS staff will involve you in discussions to decide, with you, on the right choice for you. If you wish, this can include your family and carers". (The Handbook, p. 69) Further, as a patient "[you have] the right to be given information about the test and treatment options available to you, what they involve and their risks and benefits." (The Handbook, p. 53) These rights are reflected in the GMC's "Good Medical Practice", where the first two points of GMP are "1. Patients need good doctors. Good doctors make the care of their patients their first concern: they are competent, keep their knowledge and skills up to date, establish and maintain good relationships with patients and colleagues, are honest and trustworthy, and act with integrity and within the law. 2. Good doctors work in partnership with patients and respect their rights to privacy and dignity. They treat each patient as an individual. They do their best to make sure all patients receive good care and treatment that will support them to live as well as possible, whatever their illness or disability." Point 49 requires that registered practitioners "must work in partnership with patients, sharing with them the information they will need to make decisions about their care,15 including: a) their condition, its likely progression and the options for treatment, including associated risks and uncertainties; b) the progress of their care, and your role and responsibilities in the team; c) who is responsible for each aspect of patient care, and how information is shared within teams and among those who will be providing their care; d) any other information patients need if they are asked to agree to be involved in teaching or research". Point 51 requires that registered practitioners "must support patients in caring for themselves to empower them to improve and maintain their health. This may, for example, include: a) advising patients on the effects of their life choices and lifestyle on their health and well-being; b) supporting patients to make lifestyle changes where appropriate". Point 68 requires the registered practitioner to GMP 68 "be honest and trustworthy in all your communication with patients and colleagues. This means you must make clear the limits of your knowledge and make

[32] The Handbook, p. 63 and 64, referencing the National Health Service Act 2006, National Health Service (General Medical Services Contracts) Regulations 2004 and National Health Service (Personal Medical Services Agreements) Regulations 2004.
[33] The Handbook, p. 65, referencing National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012.

reasonable checks to make sure any information you give is accurate". There is an expectation under the Constitution that medical practitioners "should aim to involve patients, their families, carers or representatives fully in decisions about prevention, diagnosis, and their individual care and treatment." (The Handbook, p. 133)

3.3 Enforcement – a country by country review

The following pictures are taken from the reports of the Country Experts. In the main they are using the words of those experts, consolidated from a number of separate questions. Where an opinion is expressed about the effectiveness of the system, for example, this is the opinion of the particular country expert. In the main, the experts completed the questionnaire as requested. Some, however, departed slightly from that format. Equally, some gave very detailed answers which have been presented in full, almost as case studies. Hence, the balance between the different country reports is not equal.

In relation to **Cross-border health care**, there must be a presumption that unless otherwise stated, the general domestic Law applies and that no special provisions are made for those exercising their rights under the Directive. In some cases, country experts pointed this out.

Criminal Law This survey or report does not systematically address the criminal procedures including, for example, manslaughter, assault, battery, molestation, sexual molestation, causing bodily harm, duress, and causing unlawful detention, relating to a failure of informed consent of other criminal liability. This is more a State investigation and punishment issue which is indirectly interesting for patient rights in terms of the environment that it creates for the health carer to follow the Law in relation to informed consent, but it is not directly on the point about the enforcement of patient rights for the individual patient. Further, the effectiveness of the preventive impact of the criminal Law requires a very different questionnaire to a different sample of professionals in comparison with that required to illicit information about the enforcement of patient rights at the individual level. We are reminded by the German expert that there might be situations where the breach of, for example, the right to informed consent, is justified in the public interest.

The Italian expert provided a detailed example of how criminal liability might be addressed.

> In general terms, the state of the art for the criminal relevance regarding the lack of informed consent is summarized by a Supreme Court decision, rendered in a plenary session (no. 2437 del 2009). The Court ruled on the two most suitable incriminating rules that would apply to the lack or invalidity of consent to treatments (610 Criminal Code: private violence; and 582 Criminal Code: personal injury). On the former, it excluded the potential of that particular legal provision to encompass the conduct. On the latter, the court ruled that lack (or invalidity) of duly informed consent may lead to criminal sanctions unless there is a 'favourable outcome' understood as the appreciable improvement of the health condition of the patient, in relation not only to the typical rules of medical science, but also to the possible alternatives considered alongside any manifestation of will either positively or indirectly expressed by the patient.

Data Protection Further, all European Union and European Economic Area Member States are required under Directive 95/46/EC to have provisions in relation to breach of duties concerning the processing of personal data. This requires that there is a Supervisory Authority for personal data processing in place, and that specific

procedures are in place for the processing of sensitive personal data such as medical data (particularly Article 8). There are duties to allow access to personal data, to require rectification of personal data, and to have a civil and criminal structure in place for investigate breaches and to impose measures to redress breaches should they be found to have occurred. As this is a standard requirement for all the jurisdictions, it will not be repeated for each country hereunder. However, where specific divergence from those standard requirements are noted in a country report, they are reported in this country-by-country report.

Broader considerations Other Law is in force that relates to patient rights. The Swedish expert pointed to two examples that are useful at this point:

> The Medical Products Agency (Läkemedelsverket) is a government agency responsible for the regulation and monitoring of pharmaceuticals and herbal remedies in addition to other medicinal products - Medicinal Products Act 1992:859. A patient can contact the Medical Products Agency if he or she has a complaint about a pharmaceutical product. For more information: https://lakemedelsverket.se/english/overview/About-MPA/
>
> If a patient feels that he or she is subject to discrimination from the healthcare services on the basis of gender, gender identity, gender expression, ethnic origin, religion or other beliefs, sexual orientation, disability or age, he or she can report this to *the Equality Ombudsman* (Diskrimineringsombudsmannen). The Equality Ombudsman is a government agency. The Equality Ombudsman can pursue a complaint through court or reach a settlement between the claimant and defendant. For more information: http://www.do.se/en/
>
> If a patient is injured as a result of medication, then he or she should contact the Pharmaceutical Insurance (LFF). The Pharmaceutical Insurance covers everyone who has been treated with prescribed pharmaceutical products or pharmaceuticals purchased from a legitimate dealer in Sweden. It also extends to include patients who received their pharmaceuticals at a hospital. For more information: http://lff.se/a-unique-type-of-insurance/for-patients/

AUSTRIA

There is a Civil Law Right to Complain about breaches of medical contracts. Civil court proceedings are available for breach of contract and in tort Law. Where a patient cannot afford representation, a legal-aid lawyer can be provided.

Administrative court proceedings for the more structural aspects of the system - for breaches of procedural duties in the provision of health care to the individual.

Patient Ombudsmen, Arbitration Boards at the Medical Chambers of the Federal States, and Patient Compensation Funds, provide mechanisms to explore out of court settlements of disputes and the Federal State has a duty to provide these 'alternative dispute resolution' services.

Patient Representatives are established to represent patients in disputes, even offering to negotiate with insurers on their behalf. Patient Advocates represent psychiatric patients.

Tortious liability in Civil Law is based on establishing fault. Where fault cannot be established, Patient Compensation Funds provide (partial) compensation. Where liability is established against an individual physician outside a hospital, but the compensation cannot be paid, a fund of the Austrian Medical Chamber is established (by subscription by all independent physicians) since 2006 to address this unmet need. - Leischner A, Zeinhofer C, Lindner C, Kopetzki C, *Medical Law in Austria*, Kluwer Law International BV (NL), 2011, at p 110-111

> See, Helmut Koziol, *Basic Questions of Tort Law from a Germanic Perspective*, Jan Sramek Verlag, Wien, (2012) www.jan-sramek-verlag.at/fileadmin/user_upload/Koziol_BasicQuestions_ePDF_HighResOpen_FINAL.pdf

Cross-border enforcement issues

The National Contact Point shall consult cross-border patients.

BELGIUM

The Right to Complain is a specific right under the Patient Rights Law. A complaint must be registered with the relevant Ombudsperson's office. In addition to a preventive (preventing complaints and preventing the shortcomings that gave rise to them) and mediating function, the ombudsperson also has a twofold informative function: to provide information about alternate possibilities for dealing with a complaint in the event that mediation fails and to provide information about the organization and functioning of the ombudsperson's office itself. Under the hospital legislation every hospital must appoint an ombudsperson.

A Federal Ombudsperson service for patient rights has been established at the Ministry of Public Health. This service is responsible for handling complaints of patients concerning the exercise of their rights, granted by the Law on Patient Rights, by referring patients to the appropriate local ombudsperson. The complaint is treated by the Federal Ombudsperson service if there is no appropriate local ombudsperson. It

concerns, for example, GPs, dentists, pharmacists, independent nurses and physiotherapists.

Civil court proceedings for negligent breach of duty of care to the patient (not contract law)

Administrative Law does not provide specific sanctions in relation to patient rights (e.g. failure to give adequate information to ensure informed consent). In the informed consent example, the patient must establish the negligence of the health carer.

Patients can make a complaint to the provincial disciplinary councils. These bodies cannot compensate; the investigation is about professional fitness to practice rather than redress for breach of patient rights. The councils have disciplinary powers over professionals. Reflecting the seriousness of the proceedings, the professional accused has a number of due process safeguards to protect him or her - Crown Order, 6-02-1970.

There is no assistance in the patient rights law available to the patient.

Compensation

As the civil liability system was found inappropriate as a compensation mechanism in the context of medical malpractice (e.g., risk of so-called defensive medicine; liability risks that can no longer be insured, prejudice to confidentiality and trust between patient and physician) the law of 15 May 2007 was meant to introduce a system of compensation of medical damage based on solidarity instead of liability. The inspiration came from the Scandinavian so-called no-fault (although it is more correct to use the term no blame) insurance schemes. The act of 15 May 2007 was characterized by the following elements: no proof of negligence was required; the individual civil liability of the physician was to be abolished and he or she could no longer be sued by the patient before a civil judge except in case of intentional or serious error; for certain types of damages thresholds and caps were planned; compensation of the damage was to be paid by a fund which was to have been financed by the State and the health care professionals. However, the entrance into force of this act had been postponed several times because of doubts as to its financial viability, and it was finally repealed by the law of 31 March 2010 regarding the compensation of damage due to health care (Moniteur belge, 2 April 2010). This latter act which entered into force on 1 September 2012 contains a system inspired by the French regime embedded in the 2002 Act which combines in a rather unique way the classic liability system as a rule with compensation of very severe damage caused by an unavoidable risk and based on national solidarity with the victim. The law is applicable to damage caused by a fact that happened after 2 April 2010 (Article 35,§ 2).

The law organizes a Medical Accidents Fund with three goals: compensating (very) severe health damage not caused by a fault, intervening as mediator between patient and insurer and compensating as substitute with recourse against the failing insurer.

Cross-border enforcement issues

No specific provisions apply.

BULGARIA

There is no specific right to complain. However, complaints about breaches of patient rights can be made to the Health Insurance Fund, to Medical Audit Agency and Bulgarian Medical Union. The legislation also contain **Codes of professional ethics** issued by Bulgarian Medical Union, sanctioned by the Minister of Health in year 2000, amended in 2013 and the Code of professional ethics issued by the Union of Dentists in Bulgaria - Guilds of Doctors and Dentists Act. Further, the law contains a Code of ethics of the masters of pharmacy. The Medical Guilds have arbitration committees and an Ombudsman; there is no healthcare ombudsman outside the Guilds. In 2009 the Public Council for the Rights of the Patient was established under the Minister of Health. It has a wide stakeholder membership, and is an advisory board to the Minster in relation to all aspects of patient rights.

Medical Audit Agency can impose fines for the breach of patient rights, e.g. in relation to the provision of adequate information for informed consent). The Professional Guilds also have powers in relation to breaches of patient rights.

Cross-border enforcement issues

No specific provisions apply. Pursuant to Art. 80f Health Insurance Act persons who exercise cross-border health services rights shall be entitled to have reimbursed their healthcare in the Member State of treatment to the extent of costs that National Health Insurance Fund or the Ministry of Health would have paid for the relevant healthcare in Bulgaria, but not more than actual costs.

The right to reimbursement does not apply to healthcare provided to compulsorily insured persons in the Republic of Bulgaria hospitals established in its territory that are not contracted to provide medical care with the National Health Insurance Fund and are not financed or subsidized with funds from the budget of the Ministry of Health.

Croatia

The right to complain is seen as a right to the protection of legal rights - Health Protection Act. Complaints must be addressed by providers without delay, with a requirement to provide a written answer within 8 days. If the outcome is not satisfactory for the patient, he or she may pursue the complaint further through the Ministry of Health, Croatian Medical Chamber or through the Courts.

There is a right to sue both the health carer and the institution within which the care is provided for damages in civil Law for a breach of a patient's rights (e.g. to informed consent) - Civil Obligations Act and Patients' Rights Protection Act. This is through an action in the Misdemeanour Court. Actions before the Croatian Medical Chamber (professional sanctions) are also possible.

The right to compensation is formally recognized as a specific patient's right - Patients` Rights Protection Act, Art. 29 - where it is stipulated that patients have right to claim damage in accordance with regulation of obligatorily law. The right to

compensation is stipulated in article 1046 and 1100 of *Civil Obligations Act.* Patients whose rights are violated can also seek compensation through criminal court case.

CYPRUS

There is no right to complain *per se*. However, the Law protects the rights created under the Law - Patient Rights Act. These include a **statutory duty to assist patients in making complaints**, to **investigate fully the complaint without delay**, and to **inform the patient of the reasoned outcome as soon as it is reached**. State hospitals are obliged to have a Patients' Rights Officer. The same Law requires the creation of a Complaints Examination Committee and a National Bioethics Committee both with power to hear complaints within the scope of their jurisdictions - Patient Rights Act. The CEC hears disputes in the public sector that are not resolved by the PROs, and can hear first instance complaints in the private sector.

Private hospitals do not have to give assistance to complainants, but must provide accurate information; public hospitals are obliged to assist patients.

Cross-border enforcement issues

One of the duties of the National Contact Point is to help the patients with their complaints procedure - Cross Boarder Health Law, Article 8(3)(d).

CZECH Republic

There is a right to complain - Act no. 372/2011 Coll., on Health Care Services. Breaches, for example of the right to information in relation to informed consent, can constitute "moral damage" and are actionable as such for financial damages. Providers must accommodate complaints and adjudicate on them. Patients can also pursue their complaints through Regional Offices, the Ministry of Health, health insurance funds, professional organizations (e.g. the Czech Medical Chamber), and the Ombudsman. Where these mechanisms are not successful in resolving the complaint, there are appeal structures and the patient can resort to the Civil or Administrative Counts. The right to compensation is not a patient right, but rather is a broader right, concretely in the Act no. 89/2012 Coll., Civil Code, as amended.

Cross-border enforcement issues

No specific provisions apply.

DENMARK

The right to complaint is recognized as a specific patient right in the Act on Complaints and Compensation within the Health Care Services (Consolidating Act no. 1113 of 7 November 2011 Act on Complaint and Compensation). In cases of a breach of patient rights, the patient can make a complaint to the National Agency for Patients' Rights and Complaints (Patientombuddet) - http://www.patientombuddet.dk. Complaints about specific professionals can be made to Disciplinary Boards, who assess

professional competence issues. They can issue 'criticisms' or 'serious criticisms' against the professional. Further sanctions are only available through the jurisdiction of the Danish Health and Medicines Authority. Complaints can also be made to the secretariat about the general standard of care given by a provider. A first offer for dialogue will be made as a way of seeking resolution. If this fails or is not undertaken (it is not compulsory) the process moves to a formal complaint. Under the Act on Complaints and Compensation, a complaint must be made within 2 years of the patient becoming aware of the reason for complaint with an absolute deadline of 5 years from the actual incident itself.

Complaints must be heard in the general administrative Law duty towards openness and awareness towards citizens. Patients must be informed of their rights in relation to making complaints. In the private sector, however, these rights and duties are much more restricted.

Regions employ Patient Councilors who assist patients in making complaints. NGO support is also available.

For compensation, there is a special no-fault compensation system for patients, which is regulated by the Act on Complaints and Compensation within the Health Care Services (Consolidating Act no. 1113 of 7 November 2011 Act on Complaint and Compensation). Information (in English) about the scheme is available on this website http://patienterstatningen.dk

Cross-border enforcement issues

There are no special procedures for cross-border patient rights enforcement. The domestic provisions are used.

ESTONIA

No information available

FINLAND

There is a right to complain to the health carer or institution providing the health care - Patient Rights Act (particularly s. 10). The patient may also make a complaint to the Supervisory Authority or to the Parliamentary Ombudsman. Submitting a complaint to the health carer or institution does not limit the patient's right to make a further complaint to the supervisory authority or ombudsman. A right to redress for breaches of the duty of care is provided in Civil Law - Patient Injury Act 585/1986, and the Act of Torts 412/1974. The process also allows the authorities to address questions of continuing fitness to practice of the health carers involved. Patient Ombudsmen must be appointed in 'health care units'. These Ombudsmen must provide patients with some assistance in complaining. See https://www.finlex.fi/fi/laki/kaannokset/1992/en19920785.pdf.

Compensation is available through the Patient Injury Act (585/1986) The Act is not translated to English unfortunately, but Patient Insurance Centre (www.pvk.fi/en)

provides information in English. The patient may also claim compensation through a civil law procedure under Tort Liability Act (412/1974) or in connection of penal law case - https://www.finlex.fi/fi/laki/kaannokset/1974/en19740412.pdf

Cross-border enforcement issues

The national focal point must produce information about patient rights and procedure to appeal and complain - Act on Cross-border Health Care, s. 24. The same procedures apply as in all health care.

FRANCE

The right to complain is established in Loi 2002/303. Every victim of a medical accident must be informed - Article L1142-4. Complaints commence with a letter of complaint to the health care provider (e.g. hospital). This starts an administrative inquiry. Mediation is available to seek a resolution of the complaint at this stage with compensation given by the insurance company (a legal requirement for health practitioners and institution - Loi 2002/303). Compensation is awarded on the basis of fault, where it is not agreed, it is ultimately established in a particular case by Civil or Criminal Courts. Every victim of a medical accident must be informed of the same - Article L1142-4. The patient has the right to ask for compensation the Commission of Indemnification (CCI) when he or she is considered the victim of a medical accident, a iatrogenic accident, a nosocomial infection, a vaccination accident, an accident in biomedical research (Article L1142-5). The procedure is free and quick (6 months to get an offer of compensation). This procedure can be started at the same time as the complaint before the courts. If the CCI considers that the damage is a consequence of a fault, the case will be sent to the Court, if there is no fault the indemnification will be given by the ONIAM www.oniam.fr . This office is funded by the state, on the principle of solidarity to compensate the damages resulting of medical accidents (no fault compensations system). Beyond these provisions, under Civil Law patients have rights to bring an action for breach of duties where there is damage. Equally, actions might be brought for violations of the Deontology Code.

In hospitals there are commissions for patients' rights. This is a kind of mediation. The commission informs the patient of the rights and the processes that could be used, conciliation, submission to the CCI, or action in justice. Each year the commission provides a report to the administration of the establishment. Family members can do the process when the patient is not able (incompetent, minor, deceased patient)

The right to compensation is found in Loi 2002-303 of 4 March 2002 setting up Art. L1142-4 in the public health code (CSP)

Cross-border enforcement issues

The general law applies without difference.

GERMANY

The right to complain is considered under the general Civil Law, and the general right to complain about the breach of the so called "Behandlungsvertrag", a contract between patient and provider. Such complaints are then heard under the general Civil Law procedures and rules. Complains about the provider are checked like any other civil struggle by the court and prosecutors. There are also institutions (Schlichtungsstellen für Arzthaftpflichtfragen) specialized on mediation between patients and providers.

Compensation is provided in the general Law (BGB), as follows:

> Section 253: Intangible damage
>
> Money may be demanded in compensation for any damage that is not pecuniary loss only in the cases stipulated by law.
>
> If damages are to be paid for an injury to body, health, freedom or sexual self-determination, reasonable compensation in money may also be demanded for any damage that is not pecuniary loss.
>
> Section 823: Liability in damages
>
> A person who, intentionally or negligently, unlawfully injures the life, body, health, freedom, property or another right of another person is liable to make compensation to the other party for the damage arising from this.
>
> The same duty is held by a person who commits a breach of a statute that is intended to protect another person. If, according to the contents of the statute, it may also be breached without fault, then liability to compensation only exists in the case of fault.

Cross-border enforcement issues

The general Law applies.

GREECE

A breach of patient rights can be raised as a complaint in administrative Law at the health Ministry's **"Office of Patient Rights"** or before the **Ombudsman (**Law 2477/1997, 3094/3003). It can also be brought as an action for compensation in Civil Law (medical liability) or administrative Law. The provider must answer the complaint - Law 2071/1992.

Cross-border enforcement issues

Cross-border patients may file complaints to the Ministry's Office for Patient Rights - article 4 para 2 d of l. 4213/2013. This does not exclude them from submitting applications through the general Law, for example, to the Ombudsman's office.

HUNGARY

Patients have the right to complain to the health care provider (including the right to make a written complaint to the supervisory body of the health care institution). A complaint must be answered with a written report within 10 days - Health Care Act. Exercising this right does not prejudice the patient's rights to use other legal avenues to seek redress; the health care provider or supervisory body must advise the patient of this. The health care provider must have detailed rules concerning the making of complaints; the details of any particular complaint must be kept for 5 years. Breaches of patient rights may give rise to actions for damages, or in less serious cases to a complaint to and action by the **Patients' Rights Advocate.**

At the beginning of the 1990s it became clear in Hungary that the empowerment of patients can be best achieved if fundamental patients' rights are implemented. At that time, the Committee of Ministers of the Council of Europe developed a set of guidelines for the member states on how to create structures for citizens and patient participation in decision-making processes in the health care system. In Hungary, the patients' rights advocacy system was introduced in 1997 with the hope that basic rights would be observed in daily practice. The patients' rights advocate protects the patients' rights based on Article 30 of the Health Care Act. His/her main duty is to provide information on patients' rights and to enforce them. The tasks of the patients' rights representative include especially the following: to provide assistance in accessing medical documentation and in questions related to medical documentation; to help patients in articulating their complaints and, based on a written authorization received from the patient, initiate investigation at the director of the health care provider institution or at the maintaining body of the institution, or—in cases relating to the treatment of the patient—initiate the procedure at the competent authority and represent the patient throughout the procedure; to inform the health care workers on the regulations referring to the rights of patients or the amendments to these, as well as on the enforcement of the rights of patients in the health care provider institution. Thus, the patients' rights representative may only proceed in individual cases within the framework of an authorization received from the patient and may initiate private complaints based on the permission of the patient. The patients' rights representative has to alert the health care provider's director or the supplier of the health care provider about the unlawful practices and other omissions connected to the functioning of the health care provider institution as noticed throughout their activity, and make suggestions for their termination. If the problem persists, the patients' rights representative has the right to take the complaint to the competent authority, organ or person. The patients' rights representative gives special consideration for the protection of the rights of patients who are exposed because of their age, physical or mental disability, health condition or social status. The patients' rights representative has the right to enter the territory where the health care provider functions, to have access to relevant documentation and to formulate questions to the employees of the health care providing institution. The patients' rights representative is obliged to keep the medical secrets relating to the patient, and to process the patient's personal data in accordance with the relevant laws. The patients' rights representative cannot have employment contract with the health care providers where the patients they represent are being treated. The patients' rights advocates and representatives now work within the framework of the National **Center for Patients' Rights, Children's Rights, and Documentation** (OBDK).

Compensation: damage resulting from health services is compensated according to the provisions of the Hungarian Civil Code (Act V of 2013). Title XXVI of the Civil Code on General Provisions and Common Rules on Liability for Damages is also applicable to damages caused by health care providers. Under this Title, Sections 6:518 to 6:534 provide general rules on the unlawfulness of torts, the extent of liability, the mode and due date of compensation, etc.

Cross-border enforcement issues

Complainants may opt for different channels of legal recourse (below) besides the healthcare provider and its financing organization (GYEMSZI):

The **National Center for Patients' Rights, Children's Rights, and Documentation** (OBDK) can be contacted in case of questions regarding patients' rights (in case of **any violation of patient rights**). The OBDK assist the complainant in finding the patient rights advocate assigned to the healthcare provider at issue, who then will help put together the complaint and to file it through the appropriate channels. The OBDK houses and operates the national bureau of complaints.

The **Office of the Chief Medical Officer** (OTH) can be contacted with (primarily medical-professional) service-related issues. The OTH operates a system of specialized physicians in every specialty field. The OTH conducts an official inquest and issues and order then informs the complainant on the result.

Complainants may file a claim in civil litigation (**in a court of law**) against the healthcare provider. The court may establish the liability of the institution and may oblige the institution to pay damages.

The Authorities above may also have competence to decide on compensation claims arising out of cross-border care.

ICELAND

Patients have a right to complain (in writing, clearly stating the cause of the complaint) about breach of the duty of care owed to them - Patient Rights Act. Complaints about medical service should be directed to the management of the health care provider; to the Medical Director of Health where the complaint relates to specific treatment. The Medical Director has powers in relation to the investigation, particularly to call for expert examination of the patient and to hear evidence in the case. Staff or health institutions must provide "guidance to a patient, or a relative, who wishes to put forward comments or make a complaint. Furthermore, the management of a health institution is obliged to investigate notifications from staff who believe that the rights of patients are being infringed on. A patient shall receive a reply to his/her comments and complaints in writing at the earliest opportunity." Patient Rights Act, Article 29. No legal-aid or legal representation is available.

Other options, potentially pursued simultaneously or subsequently to the complaints procedure before the Medical Director of Health, consist of a) a criminal investigation for criminal medical negligence, c) claiming compensation under the no-fault

compensation scheme established by the Act on patient insurance no. 111/2000, c) pursuing a tort (fault-based) claim before the courts.

There is a special Act establishing a no-fault compensation scheme, Act on patient insurance no. 111/2000. There is a statutory limit on compensation amounts under the Act, and patients also have recourse to the general legal framework to seek compensation for acts in tort.

Cross-border enforcement issues

No specific provisions apply.

IRELAND

Patients have a right to complain - Health Act 2004, part 9. They also have the right to complain to the Medical Council and the Ombudsman - under the Medical Practitioners Act 2007 and Ombudsman Act 1980 (respectively). Breaches of patient rights can give rise to actions for personal injury (negligence) for damages in the Civil Counts. Complaints can also be made for breach of professional standards to the professional bodies. A complaint can also be made through the internal procedures of the Health Service Executive - Health Act 2004.

Public health care providers are under a duty to respond to complaints within 30 days of receipt of the complaint. Advocacy services are available to assist patients. Compensation is only available through Court actions. There is no 'right to compensation' per se. There is a right of access to justice through the court system as a result of which, if the plaintiff is successful in establishing negligence, compensation may be awarded.

Country expert comments on the efficiency of the system:

> The main challenge is for patients to understand the mechanism for making a complaint and the appropriate body to which to refer a complaint. The complexity of the healthcare system can be difficult for patients to navigate and sometimes they send their complaints to the wrong organization. A very useful website was launched to assist patients in this regard http://www.healthcomplaints.ie/. It sets out a pathway for persons who want to make a complaint and provides assistance in advocacy etc. Sometimes patients misunderstand the nature of the complaints process e.g. they think that the regulator will 'fix' their problem with their doctor, or get them the procedure they want. The job of the regulator is to act in the public interest to ensure the fitness to practice of practitioners on the register – it is not a private dispute resolution mechanism as such. Patients also sometimes use the complaints mechanism as a prelude to litigation as the investigation (which is free of charge) will enable them and their legal advisors to get access to the explanations and defence of the practitioner. They can then use this information as a basis for legal action for compensation.

Cross-border enforcement issues

No specific provisions apply. To comply with Article 4(2)(*d*) of the CBD all doctors will be required by law (Medical Practitioners Amendment Bill 2014) to ensure that they have adequate indemnity insurance.

ITALY

Patients have a right to complain under the Carta dei Servizi Sanitari (Charter of Healthcare Services) - Act 273/1995. There is a presumption of patient-centricity in the service, requiring an agreement between the patient and the provider; the general expectations of the Charters can be set regionally. For instance, according to the Tuscan Charter of Healthcare Services report 2014 all the Tuscan ASL have a protocol for complaints management, and encourage information on the right to complain in their website, through brochures, posters, etc. Pursuing these complaints procedures does not prejudice or preclude the use of other mechanisms.

Tortious liability for breach can arise in a complex way in Italian civil Law. For example, a breach of the right to informed consent can constitute a breach of a duty concerning information and autonomy, but also a question in relation to the duty of a medical practitioner to treat the patient - Supreme Court (*ex ultimis* Cass. 2854/2015). See, G. Comandé, *Medical Law in Italy*, Wolters Kluwer, 2014, 192 ff.

Worked example on informed consent and tortious liability in Italian Law:

> "In relation to the eventual compensation of damages ensuing from a violation of the right to informed consent, it is important to distinguish between two hypothetical situations: (1), where the violation only infringes upon the right to self-determination with reference to one's own health and (2) a situation where an actual damage to the health of the patient has been caused (i.e., where an impairment of physical or mental health can be causally linked to the lack of consent). In the former situation, the patient can claim only non-economic damages for such an infringement. In the latter case, if the patient shows that s/he would not have undergone the treatment – upon receiving full information of the risks – and it can be demonstrated that the risks s/he was not informed of actually materialized, s/he can recover full economic and non-economic damages (Cass. 2847/2010)."

There are some mediation services offered by providers. These are offered following consideration of the formal letter of complaint. Complaints are explained in the Ministry of Health Guidelines for Adverse Events (2011) and the "Manuale di formazione del governo clinico: la sicurezza dei pazienti e degli operatori" (2012).

Cross-border enforcement issues

Article 5 Act 38/2014 states that the patient who suffers damage as a result of healthcare services received in Italy by healthcare providers operating in the Italian territory has the right to bring the ordinary remedies provided for a national.

The National Contact Point website is in both in Italian and in English and provides the basic information.

LATVIA

No information available

LITHUANIA

Patients have a right to complain in signed writing - Law on the Rights of Patients and Compensation for Damage to their Health, Art. 23. The patient must lodge the complaint not later than one year after s/he becomes aware that his or her rights have been violated and not later than three years after the date of the violation of those rights. Where the first decision does not resolve the complaint, patients can appeal to a number of bodies, depending on the particular case: the National State Insurance Fund or its Territorial branches, or the State Health Care Accreditation Agency. These institutions act more like an arbiter in the appeal. The patient can also pursue an action for breach in Civil Law. The right to compensation is established by Articles 6.247- 6.250 of Civil Code of Lithuania, Article 23 of Law on the Rights of Patients and Compensation for the Damage to their Health.

Country expert comments on the efficiency of the system:

> To the best of our knowledge, there is no case law where the right to complain attributed to the patients is challenged directly, i.e. the restrictions or limits of this right. This question was indirectly raised and analyzed by the Supreme Administrative Court of Lithuania in the following cases: case No AS-602-2-14 of 18 January 2014 in the context of determining whether the person who filed a complaint to the competent authority had the right to do so, case No I-671-121/2014 of 6 January 2014 where the claimant challenged the fact that the on Law on the Rights of Patients and Compensation for the Damage to Their Health does not foresee the requirements for complaints (particularly to the form and annexes to complaints) which can be filed to the national competent authorities acting as appeal institutions and due to this the competent authority can restrict and impede the right to complain by asking to provide the same documentation several times. According to the publicly available information, namely the sociological survey made by "Baltijos tyrimai" in 2007, 70% of respondents were familiar with the right to complain and the content of this right.
>
> There are constant discussions on this topic in the public and media, several amendments of the laws are currently negotiated in the Parliament of Lithuania, and including the one on the compensation to patients for damages causes to their health (turn form insurance to special fund is proposed). To be more precise, the amendment of the Law on the Rights of Patients and Compensation for the Damage to Their Health was registered on 11 December 2014. This amendment aims at changing the instruments and ways of how the compensation for damage to patients' health is made. It also aims at including

the compensation without previous acknowledgment of the "guilt" made by the health care provider or its employees (health care specialists). In other words the proposed model does not include the evaluation of "guilt" in cases the damage is made to patients' health. Please note, that at the current stage the Government of Lithuania did not accept this amendment of the Law on the Rights of Patients and Compensation for the Damage to Their Health by on 25 March 2015 by Order No 297 of the Government of Lithuania.

Cross-border enforcement issues

No specific provisions apply.

LUXEMBOURG

There is no specific right to complain directly recognized as a patient right in medical law. Generally, complaints can be made to the patient information and mediation service that can be contacted to help resolve all complains; the complaints structure is open to patients and healthcare professionals, is free and is confidential. The mediator has no adjudication power - Patient Rights Law. Every hospital provides a department dealing with patient complaints. Patients can also bring their complaint before the competent deontological order, for example the "College of Physicians" ("Collège médical"). Finally an action for damages can be granted according to Civil Law rules, before a Civil Court.

Hospitals are under a duty to investigate complaints made against them. The approaches vary, with some using mediators. There is a movement to increase the availability of mediation, and to ensure a degree of due process in mediation - Patient Rights Law, 2014. An NGO - "Patiente Vertriedung a.s.b.l." - is available to assist patients in the complaint process.

Compensation may be sought according to civil law rules. In general, the relationship between a patient and a healthcare provider is of a contractual nature, although this is not always the case. Liability can thus be both in tort and in contract. It is always based on the Civil Code.

Cross-border enforcement issues

No specific provisions apply.

MALTA

NO information available

THE NETHERLANDS

There are various ways in the Netherlands, both informal and formal, of dealing with complaints about the performance of healthcare providers and claims for compensation or damages. In addition to the role and supervision of the Dutch Healthcare Inspectorate on the basis of the Care Institutions Quality Act, these ways include a complaints officer or complaints mediator, healthcare institutions' complaints committees - Clients' Right of Complaint (Care Sector) Act. There are also health professional disciplinary courts (five Regional and one Central) - Individual Healthcare Professions Act. Civil liability for breach of patient rights and breach of the duty of care can also be pursued through the Civil Courts. Redress can also be sought through the health insurers and dispute committees. It should be noted that the proposed Quality, Complaints and Disputes Care Bill, presently being discussed in the Dutch Parliament (Upper Chamber), may bring some changes to this situation. The Dutch National Contact Point provides information about the procedures.

There are three possible options available to patients in the Netherlands seeking to claim compensation for damage caused by a health professional: patients can contact the professional's insurance company, file a claim with the Conciliation Board, or initiate a civil law procedure.

> See L. Bongers and D. Townend (2014) "The Implementation of the Directive on the Application of Patients' Rights in Cross-border Healthcare in the Netherlands" *European Journal of Health Law* 21(1): 65–78.

Cross-border enforcement issues

No specific provisions apply.

NORWAY

Citizens can appeal "individual [administrative] decisions" - Public Administration Act, § 2a and 28. The Patients' Rights Act states that the Public Administration Act shall not apply to administrative decisions made pursuant to Chapter 2 in the Patients' Rights Act (thus including decisions on necessary health care). However, the Patients' Rights Act has a separate regime for complaints; partly reintroducing the procedural requirements that are lacking due to the no appliance of the Public Administration Act (see also sect. 7-6 on the application of the Public Administration Act). Sect. 7-2 has provisions on complaints and sect. 7-4 has provisions on the right to request for assessments of possible breach of duty. A complaint must be submitted in writing, s. 7-3. The complaint should state the details of the complaint and provide necessary additional information. There are time limits for submitting requests (four weeks) and complaints (three weeks), s. 7-5. The Patient can make a complaint to the Patient Ombudsman under the Patient Rights Act chapter 8. Complaints can also be considered by one of the 19 County Governors. The Ombudsmen and County Governors have more informal procedures (e.g. oral complaints). County Governor and National Board of Health Supervision decisions can be challenged under Administrative Law procedures in the Courts.

The Norwegian Board of Health Supervision produces annual reports as well as reports on selected topics (see https://helsetilsynet.no/no/Norwegian-Board-of-Health-

Supervision/Publications/, where summaries in English are available). Topics in recent report have included health services for elderly, long term use of antibiotics and strengthened involvement of patients and their next of kin.

The rights to compensation regulations are found in the Patient Compensation Act (15 June 2001 No. 53).

Cross-border enforcement issues

There are separate complaints' procedures for cross border patients in regulation 22 November 2010 No. 1466 sect. 10 and 11. The complaint body is the Norwegian Health Economics Administration (https://helfo.no/english, with some information in English). The appeal body is the Norwegian Directorate of Health (and some decisions may even be reviewed by a separate administrative court). See http://www.npe.no/en/Patient/How-do-I-claim-compensation/ for a brief presentation in English on access to compensation; the forms etc. are only available in English.

POLAND

There is no explicit right to complain in the Law. However, the right can be inferred from art. 2 of the Patient Rights Act which creates a statutory duty on public health care authorities (the National Health Fund), the providers of healthcare services, persons performing medical professions and other persons assisting in the provision of healthcare services in relation to the enforcement of patients' rights. Complaints to providers can be rather informal in process terms and have to be investigated. Complaints can be made to the National Health Fund where there is a contractual relationship between the parties.. Complaints can also be made to the Patient Rights Ombudsman (or the Ombudsmen for the patients of psychiatric hospitals) (now totalling some 60,000 per year. Complaints against medical personnel can also be made to the relevant medical chamber. Complaints against specific doctors are considered in the Medical Chambers (professional bodies) and by the Supreme Medical Court of Physicians' Professional Liability - Act of 2-12-2009 on Chambers of Physicians. Complaints must be made within 3 years of the event in question. The action can result in a number of fitness to practice outcomes, but not in compensation or direct remedy for the patient. That is only available in the Courts. Appeals on administrative grounds from the professional count are by cassation to the Supreme Court.

A breach of certain patient rights duties, for example relating to informed consent, can be actionable even where the practitioner has performed the medical procedure with due diligence. The claim for damages for non-pecuniary loss is available - Patient Rights Act.

The general right to compensation was first envisaged in 1997 by the revision of the Medical Care Establishment Act and then transferred to the 2008 Patients' Rights Act. Art. 4 of the PR Act provides for compensation in the case of violations of rights envisaged in the Act: "A person harmed by a negligent breach of patient rights may claim pecuniary compensation for moral damage in an action based on art. 448 of the civil code ("In the case of infringement of personal interests, the court may award an injured person an adequate sum as compensation for non-pecuniary loss or, if he so

demands, award an appropriate sum for a designated social purpose, irrespective of other means necessary to eliminate the effects of the damage caused".) (art. 4 sec 1). In a case of breach of the right to die in dignity, a spouse, the next of kin or a guardian may claim a sum of money to be paid for the benefit of a charitable institution (art. 4 sec 2). As Poland belongs to the group of systems where damages for non-pecuniary loss may be awarded in specific cases only, the above provision introduces a specific legal avenue for seeking pecuniary remedies by patients' whose rights were infringed. Moreover, there are also specific entitlements to compensation scattered over other medical laws

Cross-border enforcement issues

No specific provisions apply.

PORTUGAL

Under the Law, there is no specific right to complain, only general rights under the Law. Patients and patient organizations or similar bodies can also make complaints and suggestions about the quality of health care, made to the "Patient's Office" (Gabinete do Utente). The Office receives these complaints (and comments) and must respond in a timely fashion, including any information about the follow-up to their suggestions and complaints - Charter of Rights and Duties of the General Health Directorate. Article 9 of Law No. 15/2014, which consolidates the rights and obligations of users of health services, provides that the user of health services has the right to complain and complain in health facilities, under the law, and to receive compensation for damages. Complaints and grievances may be present in a complaints book or informally, with a requirement for a response under the law. Health services, suppliers of goods or health services and health operators are required to have a complaints book, which can be filled in on request. Complaints can also be made to the Ombudsman.

There are general actions available in Civil Law for breaches of patient rights. Further, complaints can be made to the professional bodies. Alternative dispute resolution is beginning to be seen, particularly in relation to appeals.

Cross-border enforcement issues

No specific provisions apply.

ROMANIA

No information available.

SLOVAKIA

Patients have a right to complain to the health care provider. The management of the facility must investigate the complaint and the patient must be given information about the result of investigation. Complaints related to professional or ethical behaviour may also be made to the relevant professional chamber. The professional licensing authority has the power to investigate and where necessary punish breach of obligation when it has jurisdiction over the providers.

Patients also have the right to complain to the Health Care Surveillance Authority (HCSA), and independent legal entity established by the Act No. 581/2004 Coll. The Authority has public administration duties, relating to surveillance over health insurance companies, public health insurance and over the provision of health care. The HCSA must investigate the complaint and give notice of the result of the investigation to the patient. It may initiate a procedure leading to the cancellation of the permit for the health care facility or cancellation of the license of the health care professional by the respective chamber.

The right for compensation is a specific right codified in Civil Code, s. 444 The details how lump sum damages are calculated is set out in Act No. 437/2004 Coll. on Compensation for Suffered Pain.

Cross-border enforcement issues

No specific provisions apply.

SLOVENIA

The right to complain is formally recognized as a specific patient right - Patient Rights Act, Art. 5. The Patient Rights Act introduces a special right of the patient regarding the dealing with a violation of his/her rights. The act gives the patient who believes his/her rights laid down in this act have been violated the right to be dealt with in the following procedures:

- Procedure of the s. c. first hearing of the violation of patient's rights at the responsible person of the provider of healthcare services, based on the patient's oral request or request in writing (Articles 56 to 63);
- Procedure of the s. c. second hearing of the violation of patient's rights at the Commission of the Republic of Slovenia for the Protection of Patient's Rights, also based on the patient's oral request or request in writing (Articles 64 to 79). This procedure also includes a procedure of mediation.

Article 58 of Patient Rights Act contains the so called mandatory announcements which means that every provider of healthcare services must assure that all of the important data on the possible exercise of the right to complain are published on a conspicuous part of the waiting room (or on usual bulletin board of a hospital). The requirement applies to the name, contact details and workplace of a person authorized for receiving the first request for protection of patient rights, to the data on a manner of filing the request and the time of its admission and to the name and contact details of the closest patient`s rights representative. The possibilities of representation and other possible help from him or her should be explained too.

The Act points out that its provisions that govern the procedures to protect the rights of patients in no way encroach in regulations that guarantee supervision over professionalism of health services as well as do not infringe on regulations that deal with health insurance violations. Article 48 of the act lays down the general procedural principles, which are summarized in nine basic items:

a) Informing and supporting the patient; b) Simple, transparent, quick and efficient solving of the issue; c) Free advice and aid of the patient's rights representative; d) Impartial and fair treatment; e) Adequate and ongoing recording of procedural activities by the participants; f) Solving and closing the procedure where the cause for it arose; g) Oral procedure, in general; h) Exclusion of the public; i) Options for peaceful problem solving. Regarding the question of the capacity to sue and be sued in procedures dealing with patient rights, the patients who do not have disposing capacity use *mutatis mutandis* those provisions of this act that determine a special manner to enforce the rights of such patients. When children's parents are deciding on launching a procedure, consensus is not needed. The demand for launching procedures can also be filed by the immediate family or people close to the patient, if the patient agrees. Immediate family can also demand the procedures to be launched after the patient's death. Patients who do not have disposing capacity have the right that their cooperation is ensured to the largest extent possible and their opinion, if they are able to express it and if they understand its meaning and consequences, considered in procedures on violation of their rights. The act introduces an institution of the patient's rights representative. The representative's core function is to provide basic information to the patient, provide expert aid and give substantiated guidelines in exercising the rights of patients in healthcare, health insurance and provision of healthcare services. The representative can address proposals, opinions, criticisms or recommendations to the providers of healthcare services, who are obliged to discuss and reply to them. The provider of healthcare services must also give the representative access to all data that he required for his/her activities. The patient's medical records and other data are made available to the ombudsman pursuant to the patient's written consent. The representative's activities are not paid for by the patient and are confidential. The representative is not paid for his or her work. Every province as a rule names one representative, appointed by the province's representation body after a public call for bids. The representative is located in the province's capital. The province provides the necessary conditions for the representative's activities. The representative is entitled to a reward and reimbursement of costs. S/he is appointed for a five-year term and can be reappointed. The candidate must, apart from the general requirements, have a university diploma and at least ten years of experience in the field of law, healthcare, consumer protection or patient's rights. The representative requires written authorization by the patient for his or her activities. Should s/he assess that the patient's claim is manifestly unfounded, s/he is not required to accept the authorization for representation. The act also gives certain powers regarding the protection of patient's rights to the human rights ombudsman. The human rights ombudsman should, in the scale of his legal tasks, also monitor the situation in the field of enforcement of patient's rights and, on the basis of such monitoring, request that the responsible national bodies, local community bodies and holders of public powers provide for the conditions for effective enforcement of this act. The ombudsman appoints one of his or her substitute to deal with the field. The important general principle is the assurance that exercising the rights regarding violation of the patient's rights under this act is not a precondition for demanding a potential judicial protection. Patients have free access to it at any time they decide to.

Regular courts guarantee the protection of general rights to patients, while the protection of rights stemming from health insurance can be requested with the specialized Labour and Social Court. Regular courts give the patient the possibility to enforce his/her damage claims in line with the general rules of the law of obligations. The criminal court allows the patient to enforce the protection of his key rights and values, protected by the Penal Code of the Republic of Slovenia. These include criminal acts, such as dereliction of medical help in contrary to professional duty, malpractice, prohibited acts by the doctor regarding organ transplants etc.

The right to compensation is not formally recognised as a specific patient right as they are otherwise defined in Article 5 of Patient Rights Act. The issue of compensation for the damages is arranged in the general provisions of Slovenian civil law, in the Code of Obligations (OG RS, No 97/2007 (UPB1). Two key principles of the law of obligations provide the basis for liability for damages - *neminem laedere*, the principle that prohibits causing damages and from which we deduce the non-contractual responsibility for compensation; and the principle of *diligence*, which is used for contractual responsibility for the compensation. Discerning between liability due to a breach of contract or a wrongful act is not of key importance in Slovenian law, as substantial differences among the two of them do not exist.

Country expert comments on the efficiency of the system:

> In Slovenia the Ministry of Health regularly publishes annual reports on a status regarding protection of patient rights. The latest available report is The State Report on Status of Patient Rights for the Year of 2013. It includes the reports of all of the Slovenian patient`s rights representatives (we have 12 representatives at the moment – April 2015) and also the report of the Commission of the Republic of Slovenia for the Protection of Patient's Rights. Patient`s rights representatives dealt with 6.611 complaints of patients (which was a 5,8% increase compared to a year before). Patients most usually complained because of allegedly violated: a) Right to an adequate, quality and safe healthcare; b) Right to due consideration of the patient's time; c) Right to free choice of the physician and the provider of healthcare services and d) Right to information and participation of patient in treatment procedures. Commission of the Republic of Slovenia for the Protection of Patient's Rights received only 9 demands for second hearing of the violation of patient's rights in year 2013. It was by half less than in a year 2012. The reduction of the number of demands for a second level hearing showed that there was an important increase of obtained solutions already on the first level and that the Slovenian patient`s rights representatives solved majority of patients` complaints with informal mediation. For more details see: http://www.mz.gov.si/si/delovna_podrocja/pacientove_pravice/porocila_o_stanju_na_podrocju_varstva_pacientovih_pravic/, 22. 4. 2015.
>
> Another important report is also the regular annual report of the human rights ombudsman. In every report, beside other fields of work of ombudsman, also the field of patient rights is covered. The latest available report is for the year 2013 and there we can find some opinions and suggestions of ombudsman regarding the improvement of the situation on the field generally and also a brief presentation of the discussed individual complaints by patients. The main issues in complaints regarding the right to complain were two: first was the

human resource problem that prevented the (current, updated) dealing with complaints before the Commission of the Republic of Slovenia for the Protection of Patient's Rights and the second was the problem of cessation of work of one of patient's rights representative due to financial difficulties of Ministry of Health. For more details see http://www.varuh-rs.si/fileadmin/user_upload/pdf/lp/Devetnajsto_redno_letno_porocilo_Varuha_CP_RS_za_leto_2013.pdf, 22. 4. 2015.

Regarding reform initiatives I should mention the suggestion of the human rights ombudsman that there is a need for reform of Patient Rights Act regarding the question of its adaptation to foreign patients who don`t speak Slovenian language. Namely, until now the corresponding demands of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare have not been met yet.

Cross-border enforcement issues

There are no specific provisions, but the human rights ombudsman acknowledged the need for reform of Patient Rights Act regarding the question of its adaptation (in all possible ways) to foreign patients who don't speak Slovenian language.

SPAIN

General Health Law recognizes the right of any citizen to issue a complaint, and guarantees the protection of patients' rights. A distinction must be drawn as to whether the health care is provided within a public or private setting. In private health provision, complaints can be made through the Civil Law and the damages provisions in the Civil Code. Public provisions of health care complaints are dealt with under Law 30/92 on Public Administration and Common Administrative Procedure. Further, actions can be brought for breaches under the Patient Rights Law with fines under the General Health Law, classifying breaches as 'minor', 'serious' and 'very serious'. The right to compensation works through the application of the general Law. Operating differently between the private and public sectors, as follows: If the liability has taken place in the private system, the Spanish Civil Code applies. Articles 1101 et seq. regulate compensation for breach of contract and articles 1902 et seq. regulate tort liability. Regarding the public healthcare system, article 106.2 of the Spanish Constitution provides that citizens are entitled to compensation for any damage to their rights and property, provided that such damage arises from the normal or abnormal functioning of public service. This provision is developed by Law 30/1992 (see above) and Royal Decree 429/1993 laying down the procedure for claiming damages from the Administration.

Complaint procedures are subject to implementing regulations adopted by the Autonomous Communities. Generally speaking, patients have a relatively easy access to complaints procedures, mainly thanks to the complaint forms that can be downloaded from the hospitals websites. However, patients lack visibility on how the procedure works, how decisions are adopted and how to challenge those decisions.

Cross-border enforcement issues

No specific provisions apply.

SWEDEN

Patients have a specific right to complain about a healthcare related injury or experienced deficiencies in patient safety in connection with care or treatment provided by a healthcare provider or healthcare personnel - Patient Safety Act. The Complaint is made to the Health and Social Care Inspectorate (Inspektionen för vård och omsorg, IVO). The IVO has disciplinary power over providers and professionals. Under the Law of the Patients' Advisory Committee (1998:1656) all county councils must establish a *Patients' Advisory Committee*. The Committee is a central independent authority. A patient can contact the Patients' Advisory Committee if he or she wants to make a comment or complaint relating to his or her treatment, patient fees, diagnosis or medication. The Patients' Advisory Committee has no disciplinary powers but can help the patient to receive proper information and give advice on what to do next. There are no costs associated with filing a complaint with the Committee. See http://www.1177.se/Other-languages/Engelska/Regler-och-rattigheter/Om-man-inte-ar-nojd-med-varden/#section-1.

Breaches of patient rights can be actionable in Tort Law (medical negligence - Tort Liability Act 1972:207. However, this is difficult, for example, in relation to a breach of the duties relating to informed consent.

In Administrative Law, complaints can be brought before the IVO - Patient Safety Act. The Parliamentary Ombudsman (Riksdagens ombudsman) can also hear complaints against public authorities or public officials. (https://www.jo.se/en/About-JO/)

Since 1975 Sweden has had a patient insurance system to compensate patients for health-related injuries. The system was initially based on a voluntary patient insurance solution, but in 1997 it was replaced by the Patient Injury Act (1996:799). In accordance with the Patient Injury Act, any person who suffers an injury in connection to health, medical or dental care in Sweden, can receive compensation, as long as the other provided conditions are met (Section 6 of the Patient Injury Act).

Cross-border enforcement issues

No specific provisions apply.

UNITED KINGDON

The Handbook to the NHS Constitution, pp. 85–92, outlines the rights to complain and to redress. There are **rights to complain to the NHS providers** (from the immediate carer to the institution providing the structure of the care) – Local Authority Social Services and National Health Service Complaints England Regulations 2009 and NHS Bodies and Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch) Regulations 2012. The complaint must be acknowledged within three working days and "investigated properly". The complainant

must be informed of the options for the conduct of the complaint, and the likely timeframe for the completion of the process. Throughout the process the complainant must be informed of the progress of the complaint, and any outcome of the investigation of the complaint. This provides a statutory 'internal' complaints procedure.

Complaints can also be made to the Parliamentary and Health Service Ombudsman – Health Service Commissioners Act 1993. The most formal options for complaints are through Judicial Review of administrative actions and made to the High Court. Here the question concerns, essentially, the reasonableness of the decision that is made and the procedural appropriateness of the decision-making. An action for medical negligence is also available, and depends upon proving a duty of care and a negligent breach of that duty (i.e. a breach that would be outside the range of actions by a similar professional that would be acceptable generally in the profession; not a 'best practice' but a sufficient practice). This requires a court action (commenced within three years), most often brought with the assistance of lawyers, often in this area working under 'no win, no fee' arrangements. Breach of statutory duty is a tort that is also available in the area, and would require similar legal assistance; it remains a back-stop action where other dispute resolution tools have failed. Negligence actions allow damages to be ordered; judicial review actions and adjudications by the ombudsman allow for remedies requiring, for example, retaking decisions with appropriate considerations. Breaches relating to the processing of personal data are made under the Data Protection Act 1998 and through the powers under the Act given to the Information Commissioner (including investigation and the ordering of damages). NHS staff can use employment Law for their complaints.

Whereas the measures described above relate to the State's mechanisms for enforcement of rights, the professional conduct of doctors can also be addressed through a complaint, largely concerning fitness to practice, against a member of a profession to the particular professional body of which s/he is a member.

Cross-border enforcement issues

No specific provisions apply.

3.4 Council of Europe activities

3.4.1 The Convention on Human Rights and Biomedicine

The most significant contribution to Patient Rights from the Council of Europe is found in the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. It establishes a number of fundamental patient rights both in relation to healthcare and where citizens are participants in biomedical or other scientific research. The principles are as follows (Article-by-Article):

The first four articles establish a general position in relation to the duties of Member States in relation to human dignity in biomedical science.

"Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Each Party [State] shall take in its internal law the necessary measures to give effect to the provisions of this Convention." (Article 1)

"The interests and welfare of the human being shall prevail over the sole interest of society or science." (2)

"Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality." (3)

"Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards." (4)

Thereafter, the Convention outlines specific aspects relating to these general principles.

Articles 5 to 9 concern Consent. In line with other international standards on consent,[34] consent must be "free and informed" on the basis of "appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks" and on the basis that it may be "freely withdrawn" at any time.

Private Life and the Right to Information (10); Genetic discrimination, predictive genetic testing and modification of human genome, restriction on sex selection (11–14); scientific research (15–18); living donor organ transplantation (19–20); prohibition on financial gain from human organs (21), restriction on use of removed human tissue (22).

[34] Helsinki Declaration; WHO (Eds.), Promotion of the Rights of Patients in Europe, Proceedings of a WHO Consultation, Published on behalf of the World Health Organization, Regional Office for Europe, in collaboration with the Health Law Section, University of Amsterdam (The Hague: Kluwer Law International, 1995)

Articles 23–25 require that MS put sanctions and compensation mechanisms in place for the infringement of rights.

Article 28 requires that "fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation".

What is not seen in the Convention is detailed pre- and proscription in relation to the rights. There is a great deal of discretion for individual Member States in the interpretation of the rights. For example, 'appropriate information' in relation to consent, or the manner in which consent is interpreted is left to the MS practice. This is, perhaps, inevitable, but it leaves the sense that the Convention is a framework of rights and expectations that have to be further articulated in practice.

3.4.2 The impact of Council of Europe Activities in their countries.

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. Indeed, one could suggest that the patient rights aspects of the Oviedo convention are drafted in such a broad way that they accommodate the range of approaches to patient rights that have emerged in the Countries of the EU and EEA. It is very difficult to say, given the wide discretion that is found in the Convention, whether the Convention itself was instrumental in producing the rights, rather than reflecting the general European environment of patient rights. The responses from the experts, indicating a relatively low level of impact of the Council of Europe activities in their jurisdictions suggests, perhaps, the latter. Likewise, in the broader areas, the EU has either assimilated the duties – with the development of the Charter of Fundamental Rights – or overtaken the duties – as in data protection.

APPENDIX

Annex 1: Survey template (Final Version)

PRE-MaX

Patients' Rights in the European Union – Mapping Exercise

Survey

Introduction

With the adoption and implementation of the Directive 2011/24/EU on the application of patients' rights in cross-border health care, the EU has not only attempted to clarify the entitlements of citizens to reimbursement for cross-border health care, it has also introduced a framework of rules to ensure a set of common values and operating principles that EU citizens would expect to find - and structures to support them - in any Member State's health system in the EU. They are considered necessary to ensure patients' trust in cross-border healthcare (recital 5), and also more broadly to establish a high level of trust between the patient and healthcare provider (recital 19). However, as has been recognised in the Council Conclusions on Common values and principles in European Union Health Systems (2006), Member States have taken different approaches in the broad area of patients' rights - some have chosen to express them in terms of the rights of patients, others in terms of the obligations of healthcare providers. Enforcement is also carried out differently across the Union.
With this mapping exercise, which was commissioned by the EU Commission's Consumers Health and Food Executive Agency (CHAFEA/2014/Health/03), we want to take stock of patients' rights (in the broadest sense) in all EU Member states as well as in Norway and Iceland. More specifically, we want to explore how the more traditional types of patients' rights are connecting to the more consumer-oriented types, and what structures, procedures and mechanisms are in place to enforce them. This work should be able to inform the activities of the National Contact Points (NCPs) that have been established as part of the cross-border care Directive.

For the sake of this mapping exercise we are considering both fundamental patients' rights as well as more consumer-oriented patients' rights (*), including procedural rights that help to enforce them. At this point we are not considering rights related to social cover for health care, neither are we regarding ethical questions. We are clustering them in the following way:

- Self-determination
  a) The right to informed consent (incl. ...)
     i) The right to information about one's health
     ii) The right to participate in (clinical) decision-making / to choice of treatment options (*)
- Confidentiality
  a) The right to privacy
  b) The right to access one's medical record
- Choice
  a) The right to choice of healthcare provider (incl. ...) (*)
     i) The right to second opinion (*)
     ii) The right to information about the healthcare provider (*)

- Quality and safety
  a) The right to safe and high-quality treatment received in a timely manner (*)
- Procedural rights
  a) The right to complain
  b) The right to compensation
  c) The right to information about rights and entitlements (*)

Practical instructions for correspondents

Please answer the questions in English.

Provide answers in the text boxes below each of the questions. Feel free to enlarge the boxes as you wish. There is **no** need to edit all your answers to a coherent report or extended summary document.

Please try to answer the questions with a broad interpretation of sources of the law, and perhaps also including soft law provision, professional regulations and standards. Where you cannot see answers, please feel free to leave the question; likewise, if you feel you can go beyond the specific question we have asked to capture the spirit of your law, please add what you feel is necessary.

Sub-questions, indicated as a, b, c, etc. are meant to specify the aspects to be covered in your answers, no detailed and long contributions on each of the sub-questions are needed.

Please provide full references to the specific national laws, regulations, acts in-text you are addressing.

In case there is any literature (in English) as well as English-language websites where we can find additional information regarding a certain patient rights aspect in your country, please provide a reference or link too.

Please hand back the document as a word file

Questionnaire

General context

Fundamentally patients' rights encompass a set of rules and principles governing the relationship between the patient and the provider. However, they can also extend to rights determining the patient's broader position within the health system.

How would you assess the legal importance of patients' rights in your country?

a. **What is the general approach taken towards patients' rights? (e.g. legal approach, awareness raising, patient-oriented, provider-oriented etc.)**

What (if any) are the main instruments or sources for defining and implementing patients' rights in your country? (e.g. special law, administrative law, criminal law, disciplinary code, charter, strategy paper etc.)

Where would you situate your country with respect to both the state of development (newly-established vs established) and of the enforcement (weak vs strong) of both (A) fundamental patients' rights and (B) more consumer-oriented patients' rights? (please mark A and B in one of the squares below)

State of development / State of enforcement	Newly-established	Well-established
Weak		
Strong		

Please explain your choice:

What are/have been the main drivers for the development of patients' rights in your country? (e.g. ratification of the Council of Europe's Convention on Biomedicine, transposition of the cross-border care Directive, national reform strategy, specific reports or scandals in the media, motivation from first principles in medicine or law, etc.). Please comment.

Individual patients' rights

Self-determination

The right to informed consent (incl. the right to information about one's health and the right to choice of treatment options/participate in (clinical) decision making)

Although informed consent is a fundamental principle for clinical decision-making, it faces many challenges in terms of putting it into practice, especially in a cross-border context.

Is the right to informed consent formally recognized[35] in your country?

a. **If so, where is it stipulated in the law?**

b. **Or is it defined through other means? (e.g. soft law)**

How is this right implemented in practice?

a. **What form does it take? (i.e. written consent required; verbal consent; non-verbal consent)**

b. **Who should prove that consent was given? (i.e. patient; provider)**

c. **Under what conditions is consent presumed?**

How is the right to information defined in this context?

a. **What are the specific requirements (e.g. form, content) for providing information preceding consent (assuming that there is no valid consent without information)?**

b. **Are patients formally entitled to be informed of alternative treatment options?**

c. **Is also a "right not to know" provided for?**

[35] This should be read broadly

Are patients formally entitled to participate (beyond the scope of consenting to a specific treatment) in the clinical decision making regarding their own health?

a. **What are the main policies/instruments to empower patients in their own treatment pathway? (e.g. health literacy)**

b. **Alternatively, are there any non-binding guidelines or best practices in this field that were developed by certain actors in your country?**

Does the law provide for any specific duties to accommodate the right to informed consent for cross-border patients? (i.e. the use of language)

a. **Alternatively, are there any non-binding guidelines or best practices in this field that were developed by certain actors in your country?**

Is there any evidence in your country of how the right to informed consent is used in practice? (e.g. research, case law)

a. **What are the main issues/challenges reported?**

b. **Is there any reform in this area underway?**

What specific procedures or remedies exist (if any) in case the right to informed consent is not properly respected?

a. **General procedural rights are to be covered under 2.2.5. Procedural rights**

Confidentiality

The right to privacy

The right to respect a patient's private life and/or the duty of medical secrecy/confidentiality in relation to health data and information are crucial elements for the trust relation between patients and providers. Differences in privacy protection legislation between Member States might be an obstacle to patient mobility and impede continuity of care.

Is the right to privacy formally recognized36 in your country as a specific patient right or is it embedded as a broader right (e.g. in constitutional law)?

a. **If so, where is it stipulated in the law?**

b. **Or is it defined through other means? (e.g. soft law)**

How is this right exercised in practice in relation to health data?

a. **Does a legal obligation exist to respect the secrecy/confidentiality of health data? (e.g. in criminal law; civil law; public (administrative) law; disciplinary law)? Does this apply only to physicians? Are there any exceptions allowed? (i.e. overriding reasons)**

b. **Is the patient's consent required to process/transfer health data in the context of delivering health care? (i.e. explicit; implied; presumed under certain circumstances)**

c. **What mechanisms/policies are currently in place to ensure safe processing of patients' health data?**

Does the law provide for any specific duties regarding privacy protection and data processing for cross-border patients? Alternatively, are there any non-binding guidelines or best practices in this field that were developed by certain actors in your country?

Is there any evidence in your country of how the right to privacy is used in practice? (e.g. research, case law)

a. **What are the main issues/challenges reported?**

b. **Is there any reform in this area underway?**

[36] This should be read broadly

What specific procedures or remedies exist (if any) in case the right to privacy is not properly respected?

a. **General procedural rights are to be covered under 2.2.5. Procedural rights)**

b. **If the specific measures here are the same as those outlined in one of the previous questions (e.g. XII), please just cross-reference or mention any difference from that approach (or specific application of those rules) for this right here.**

The right to access one's medical record/data

Beyond the scope of information provided to operate consent to clinical decisions, everyone is entitled to know any information collected about his or her health. This is mostly operationalised through the right to have access to one's medical record. This right is key to "enforcing" other patients' rights (i.e. privacy, quality and safety, compensation, etc.), including to ensuring continuity of care. This is also why the Directive 2011/24/EU *guarantees this right for cross-border patients.*

Is the right to have access to one's medical record formally recognized[37] in your country?

a. **If so, where is it stipulated in the law?**

b. **Or is it defined through other means? (e.g. soft law)**

How is this right implemented in practice?

a. **How is access organized? (e.g. directly or indirectly with the help of a health care practitioner)? Is it subject to certain modalities (e.g. time restrictions; payment of a fee)**

b. **Is the content of the medical record prescribed by law? (e.g. in a general or detailed way) Does the right to have access relate to all information or are certain elements excluded? (e.g. personal notes of the health care practitioner; data related to a third person/provided by a third person)**

c. **Is there a right to add information/documentation to the record? Is there a right to correct, erase or destroy health data in the record?**

d. **Is there a right to receive a copy of the medical record/data? Can a fee be charged for this copying?**

[37] This should be read broadly

Does the law provide for any specific duties or facilities regarding access to medical record in the context of cross-border care?

a. **Alternatively, are there any non-binding guidelines or best practices in this field that were developed by certain actors in your country?**

Is there any evidence in your country of how the right to access one's medical record/data is used in practice? (e.g. research, case law)

a. **What are the main issues/challenges reported?**

b. **Is there any reform in this area underway?**

What specific procedures or remedies exist (if any) in case the right to access one's medical record/data is not properly respected?

a. **General procedural rights are to be covered under 2.2.5. Procedural rights)**

b. **If the specific measures here are the same as those outlined in one of the previous questions (e.g. XII), please just cross-reference or mention any difference from that approach (or specific application of those rules) for this right here.**

Choice

The right to (informed) choice of healthcare provider (incl. the right to second opinion)

Choice in health care is a complex issue. It can relate to various aspects (e.g. provider, insurer, insurance plans). It can be modified in various ways (e.g. gatekeeping, financial incentives, etc.). In some countries choice is an intrinsic value of the health systems, in others it is more regarded as a tool to increase efficiency and improve quality. The right to second opinion is closely linked to the right to choose one's provider. Countries have put in place different mechanisms to enable choice. Different groups usually make a different use of choice. Information is key to making an informed choice about what healthcare provider to consult.

Is the right to (free) choice of healthcare provider formally recognized38 within your country's statutory health system?

a. **If so, where is it stipulated in the law?**

b. **Or is it defined through other means? (e.g. soft law)**

How is this right implemented in practice?

a. **Does the right to free choice apply to all or specific types of providers (e.g. primary physician, specialist, hospital)?**

b. **Is choice in any way limited or modulated? (e.g. within a geographical area, within the same hospital, restriction to change within a given time frame, gatekeeping, to a list of contracted providers, financial incentives)**

How is the right to information defined in this context?

a. **What are the specific legal requirements for providing clear and objective information about providers? Who is responsible for collecting and providing the information on**

   i. **Performance? (outcomes, quality indicators, safety standards, right/fitness to practice)**

   ii. **Waiting times?**

   iii. **Prices?**

b. **What tools/mechanisms (e.g. dedicated web sites, league tables) are available for enabling or helping patients to make an informed choice?**

c. **Which organizations play a role in providing objective information about available providers and treatments?**

d. **What information are healthcare providers allowed/obliged to provide (see also a.i-iii)?**

[38] This should be read broadly

Are patient formally entitled to a second opinion?

a. **Is it subject to any conditions, restrictions or formalities (e.g. authorisation, referral)?**

b. **Can the patient freely choose from who they can get a second opinion? Can it also include doctors in other Member States?**

Does the law provide for any specific duties regarding (informed) choice in the context of cross-border health care?

a. **Alternatively, are there any non-binding guidelines or best practices in this field that were developed by certain actors in your country?**

Is there any evidence in your country on whether/how/which individuals exercise choice? (e.g. research, case law)

a. **What are the main issues/challenges reported?**

b. **Is there any reform in this area underway?**

What specific procedures or remedies exist (if any) in case the right to choice is not properly respected?

a. **General procedural rights are to be covered under 2.2.5. Procedural rights)**

b. **If the specific measures here are the same as those outlined in one of the previous questions (e.g. XII), please just cross-reference or mention any difference from that approach (or specific application of those rules) for this right here.**

Quality and safety

The right to safe and high-quality treatment received in a timely manner

Patients have a right to expect treatments and care that are safe and of a high quality. This requires an authoritative discussion on what constitutes safe and high quality care, and bodies that can then implement and monitor the observation of these standards. Timeliness can be considered as an essential aspect of patient safety and quality. The concept of 'undue delay' has been accepted at EU level as a criterion for the right to seek treatment abroad.

Is the right to safe and quality treatment received in a timely manner formally recognized[39] in your country?

a. **If so, where is it stipulated in the law?**

b. **Or is it defined through other means? (e.g. soft law)**

How is this right implemented in practice in the patient-provider relationship?

a. **What main approach(es) is/are taken towards ensuring patient safety and quality of care in your country? Please briefly describe the policies and strategies in place and specify if they are binding or voluntary.**

   i. **structural norms (e.g. licensing/accreditation norms, activity thresholds)**

   ii. **process protocols (e.g. safety protocols, clinical guidelines, quality management)**

   iii. **outcome measurement (e.g. indicators, monitoring, reporting, publicity)**

b. **Which main bodies are responsible for implementing these patient safety and quality policies (e.g. inspections, accreditation agency, licensing bodies)?**

How is the right to timely treatment implemented in practice? (This may be in guidelines.)

a. **How are acceptable waiting times for treatment defined, and by whom? (e.g. maximum waiting times)**

b. **Is there an agreed system of prioritization for specific interventions/treatments? Are foreign patients included in these waiting lists?**

c. **How can a patient challenge decisions about waiting times?**

[39] This should be read broadly

Under what conditions is prior authorization[40] for cross-border care in your country …

a. **granted on the basis that the specific treatment could be provided under better conditions (patient safety, quality and/or timeliness) in another Member State?**

b. **refused on the basis that the patient would be exposed to an unacceptable patient-safety risk if treatment would take place in another Member State? (cf. Article 8.6 (a) Directive 2011/24/EU)**

c. **refused on the basis that the cross-border healthcare provider raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision? (cf. Article 8.6 (c) Directive 2011/24/EU)**

Is there any evidence in your country on how the right to safe and quality treatment received in a timely manner is exercised in practice? (e.g. research, case law, evaluations of legislation)

a. **What are the main issues/challenges reported?**

b. **Is there any reform in this area underway?**

What specific procedures or remedies exist (if any) in case the right to safe and quality treatment received in a timely manner is not properly respected?

a. **General procedural rights are to be covered under 2.2.5. Procedural rights)**

b. **If the specific measures here are the same as those outlined in one of the previous questions (e.g. XII), please just cross-reference or mention any difference from that approach (or specific application of those rules) for this right here.**

Procedural rights

The right to complain

In the event of a breach of rights, rights must be enforceable. The right to complain allows patients to report those breaches and to be heard. These complaints can be heard in a variety of

[40] i.e. the condition of obtaining an explicit authorization from the competent body (e.g. statutory health insurer, health authority) in order to get statutory reimbursement for healthcare services provided in another Member State than the state of affiliation..

fora, with varying degrees of formality, requiring differing responses depending on, for example, admissions of liability or requirements of negligence. We appreciate that this right is in many ways covered by the last question in each of the preceding rights, but this section is an opportunity to ensure that the issue is covered in depth.

Is the right to complain formally recognized41 in your country as a specific patient right or is it embedded in a broader right to complain?

a. **If so, where is it stipulated in the law?**

b. **Or is it defined through other means? (e.g. soft law)**

How is this right implemented in practice in the patient-provider relationship?

a. **Do providers (individual or institution) have any obligations to accommodate complaints patients may have against them?**

b. **What others instances exist for patients to make a complaint? Do these instances act as mediator between patient and provider or rather as an arbiter?**

c. **Are these complaint procedures subject to any restrictions, conditions or formalities? (e.g. type of complaints, consecutive steps to take)**

d. **How and by whom is a complaint investigated? Briefly describe the process from the first, perhaps informal complaint, to more formal disciplinary or compensatory hearings.**

e. **Is the patient given any assistance during the complaint process? Can others file complaints on behalf of the patient? (e.g. family members)**

f. **What further options are available in case the patient is not happy with the outcome of his/her complaint?**

Does the law provide for any specific duties or facilities regarding the right to complain for cross-border patients?

a. **Alternatively, are there any non-binding guidelines or best practices in this field that were developed by certain actors in your country?**

[41] This should be read broadly

Is there any evidence in your country on how the right to complain is exercised in practice? (e.g. research, case law)

a. **What are the main issues/challenges reported?**

b. **Is there any reform in this area underway?**

The right to compensation

If harm was done to patients or their rights were denied, they could claim some form of compensation (e.g. financial).

Is the right to compensation formally recognized42 in your country as a specific patient right or is it embedded in a broader right to seek compensation?

a. **If so, where is it stipulated in the law?**

b. **Or is it defined through other means? (e.g. soft law)**

How is this right implemented in practice?

a. **In what circumstances is a patient entitled to compensation?**

b. **Is the right to claim compensation subject to any restrictions, conditions or formalities? (e.g. proof of harm and liability)**

c. **What system of professional liability insurance (or similar guarantee or arrangement) exists in your country to compensate for any harm done to patients?**

d. **Besides financial compensation, what other sanctions or penalities could apply to settle a claim?**

Does the law provide for any specific duties or facilities regarding the right to compensation for cross-border patients?

a. **Alternatively, are there any non-binding guidelines or best practices in this field that were developed by certain actors in your country?**

[42] This should be read broadly

Is there any evidence in your country on how the right to compensation is exercised in practice? (e.g. research, case law)

a. **What are the main issues/challenges reported?**

b. **Is there any reform in this area underway?**

The right to information about rights and entitlements

In order to enforce their rights patients in the first place need to be informed about what their rights and entitlements are. Whereas national contact points have been established to provide cross-border patients with easily accessible information on patients' rights, procedures to file complaints and seek remedies, they can draw on information mechanisms already in place for domestic patients.

Is the right to information about rights and entitlements formally recognized43 in your country as a specific patient right or is it embedded in a broader right to seek compensation?

a. **If so, where is it stipulated in the law?**

b. **Or is it defined through other means? (e.g. soft law)**

How is this right implemented in practice?

a. **What are the specific legal requirements for providing information on rights and entitlements? Who is primarily responsible for providing the information? What mechanisms are used?**

   i. **Basket of care; conditions, criteria and formalities for statutory coverage**

   ii. **Other patients' rights**

b. **Which other actors play an important role in informing and assisting patients and citizens to enforce their rights?**

c. **How will the "National Contact Point" be used? Will the NCP also be available for domestic patients seeking information about their own jurisdiction?**

[43] This should be read broadly

Does the law provide for any specific duties regarding the use of language in this context (i.e. with respect to foreign patients or language minorities, etc.)?

a. **Alternatively, are there any non-binding guidelines or best practices in this field that were developed by certain actors in your country?**

Is there any evidence in your country on how the right to information about rights and entitlements is exercised in practice? (e.g. research, case law)

a. **What are the main issues/challenges reported?**

b. **Is there any reform in this area underway?**

Council of Europe

The Council of Europe has been a strong and important force in the development of patients' rights in Europe. As part of PRE-MaX we are assessing the impact of the Council of Europe's work. This will in part be done through a literature review of the Council of Europe's opus on patients' rights, but we are also interested to see how far the activities of the Council of Europe in relation to patients' rights have had an impact in nation states.

Has your country ratified the Biomedicine Convention? How has this been done?

Which other Council of Europe activities in relation to patients' rights have been implemented in your National Law?

What key cases have occurred in your country resulting from Council of Europe inspired legislation?

How far have decisions based on Council of Europe activities from other jurisdictions or fora been implemented and/or applied in your national Law or practice?

Thank you for your input!

Annex 2: Identified sources of the literature review

Introduction

The aim of the Literature Review was to locate published information (studies, reports etc.) on areas that would benefit from greater formal cross-border co-operation and collaboration in healthcare provision, or information that would assist in developing a methodology to investigate this.

The term cross border was included in searches in relation to quality of care; these only produced 8 relevant hits. For this work a search was carried out using PubMed and the terms health care and cross-border. Health care is used as a MESH term in PubMed, and includes delivery of health care, as well as the three words individually. Cross-border also includes "cross border" as two separate words. This search produced 498 hits, all of which were reviewed.

In addition, searching was also carried out using Google Scholar and Google. These searches began with the four words cross, border, health and care.

The types of documents included in the search results are peer-reviewed articles, journal entries and book chapters. The results are provided as tables of bibliographic information for the identified references, combining the results from the PubMed and Google searches. The results have been grouped into the following categories.

Cross-border and inter-regional projects and studies	32 results
Health care "tourism" – reproduction	32 results
Health care "tourism" – other, non-specific	16 results
Patients' rights and legal issues	42 results
Telemedicine, E-health, information exchange	19 results
Trade in health services	5 results
Other	20 results

The term health "tourism" has been used as it appears in a number of the results, but it intended to cover any travel for treatment.

Results

Cross-border and inter-regional projects and studies – 32 references

Author(s)	Bibliographic information	Title of reference	Author information (if available)
Alkerwi A, Guillaume M, Zannad F, Laufs U, Lair ML; NESCAV project group.	BMC Public Health. 2010 Nov 15;10:698. doi: 10.1186/1471-2458-10-698	Nutrition, environment and cardiovascular health (NESCAV): protocol of an inter-regional cross-sectional study	Centre de Recherche Public Santé, Centre d'Etudes en Santé, Grand-Duchy of Luxembourg. alaa.alkerwi@crp-sante.lu
Anogianakis G, Ilonidis G, Anogeianaki A, Lianguris J, Katsaros K, Pseftogianni D, Klisarova A, Temelkov T, Tatsis C	J Telemed Telecare. 2004;10 Suppl 1:4-6	The Varna-Thessaloniki telemedical collaboration in setting up a regional transborder transplantation network	Department of Physiology, Faculty of Medicine, Aristotle University of Thessaloniki, Thessaloniki, Greece. anogian@auth.gr
Brand H, Hollederer A, Wolf U, Brand A	Health Policy. 2008 May;86(2-3):245-54. Epub 2008 Feb 21	Cross-border health activities in the Euregios: good practice for better health	Institute of Public Health NRW (lögd), Westerfeldstr. 35-37, 33611 Bielefeld, Germany
Burger R, Kostera T	World Hosp Health Serv. 2010;46(4):4-6	Striking a balance between national interests and patients' needs: cross-border projects meeting European challenges	University of Applied Sciences IMC
Burnett S, Renz A, Wiig S, Fernandes A, Weggelaar AM, Calltorp J, Anderson JE, Robert G, Vincent C, Fulop N.	Int J Qual Health Care. 2013 Feb;25(1):1-7. doi: 10.1093/intqhc/mzs079. Epub 2013 Jan 4	Prospects for comparing European hospitals in terms of quality and safety: lessons from a comparative study in five countries	Centre for Patient Safety and Service Quality, Faculty of Medicine, Imperial College London, Room 508 Medical School Building, St Mary's Campus, Norfolk Place, W2 1PG London, UK. s.burnett@imperial.ac.uk

Calnan M, Palm W, Sohy F, Quaghebeur DNA	European Journal of Public Health. 1997, 7(3), 26-32. DOI: http://dx.doi.org/10.1093/eurpub/7.suppl_3.26 26-32	Cross-border use of health care: A survey of frontier workers' knowledge, attitudes and use	
Daniels-Haardt I, Verhoeven F, Mellmann A, Hendrix MG, Gemert-Pijnen JE, Friedrich AW	Gesundheitswesen. 2006 Nov;68(11):674-8	[EUREGIO-projekt MRSA-net Twente/Münsterland. Creation of a regional network to combat MRSA]. [Article in German]	Landesinstitut für den Offentlichen Gesundheitsdienst NRW, Münster, Germany. inka.daniels-haardt@loegd.nrw.de
Danne T	Dtsch Med Wochenschr. 2011 May;136(21):1135-9. doi: 10.1055/s-0031-1280526. Epub 2011 May 17	[Cross-border health care in Europe: will centers of reference for pediatric diabetes serve as a model?]. [Article in German]	Zentrum für Kinderendokrinologioe– und Diabetologie, Kinderkrankenhaus auf der Bult, Hannover. danne@hka.de
Dara M, de Colombani P, Petrova-Benedict R, Centis R, Zellweger JP, Sandgren A, Heldal E, Sotgiu G, Jansen N, Bahtijarevic R, Migliori GB; Wolfheze Transborder Migration Task Force	Eur Respir J. 2012 Nov;40(5):1081-90. doi: 10.1183/09031936.00053012. Epub 2012 May 31	Minimum package for cross-border TB control and care in the WHO European region: a Wolfheze consensus statement	World Health Organization, Regional Office for Europe, Copenhagen, Denmark
Deurenberg RH, Nulens E, Valvatne H, Sebastian S, Driessen S, Craeghs J, De Brauwer E, Heising B, Kraat YJ, Riebe J, Stals FS, Trienekens TA, Scheres J, Friedrich AW, van Tiel FH, Beisser PS, Stobberingh EE	Emerging Infectious Diseases , May 2009,Vol. 15, No. 5, 727-734	Cross-Border Dissemination of Methicillin-Resistant Staphylococcus aureus, Euregio Meuse-Rhin Region	

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Di Iorio CT, Carinci F, Azzopardi J, Baglioni V, Beck P, Cunningham S, Evripidou A, Leese G, Loevaas KF, Olympios G, Federici MO, Pruna S, Palladino P, Skeie S, Taverner P, Traynor V, Benedetti MM*	J Med Ethics. 2009 Dec;35(12):753-61. doi: 10.1136/jme.2009.029918	Privacy impact assessment in the design of transnational public health information systems: the BIRO project	Serectrix s.n.c., Pescara, Italy. tania_diiorio@virgilio.it
Doering N, Legido-Quigley H, Glinos I, McKee M, Maarse H	Health Policy and Technology. 2013, 2 (2). pp. 4-9.	A success-story in cross-border telemedicine in Europe: the use of intra-operative teleneuromonitoring during aorta surgery	
Evers S, Paulus A, Boonen A	Int J Integr Care. 2001;1:e18	Integrated care across borders: possibilities and complexities	Maastricht University, Faculty of Health Sciences, Department of Health, Organisation, Policy and Economics, PO Box 616, 6200 MD Maastricht, The Netherlands. secretariaat@beoz.unimaas.nl
Friedrich AW, Daniels-Haardt I, Köck R,	Euro Surveill. 2008 Aug 28;13(35). pii: 18965	EUREGIO MRSA-net Twente/Münsterland--a	Institute of Hygiene, University Hospital Munster, Germany.

Verhoeven F, Mellmann A, Harmsen D, van Gemert-Pijnen JE, Becker K, Hendrix MG		Dutch-German cross-border network for the prevention and control of infections caused by methicillin-resistant Staphylococcus aureus	alexander.friedrich@ukmuenster.de
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Hermans HE, den Exter A	Croat Med J. 1999 Jun;40(2):266-72	Cross-border alliances in health care: international co-operation between health insurers and providers in the Euregio Meuse-Rhine	Department of Health Policy and Management, Erasmus University Rotterdam, Room L4-85, P.O. Box 1738, 3000 DR Rotterdam, The Netherlands. Hermans@bmg.eur.nl
Houyez F, Sanchez de Vega R, Brignol TN, Mazzucato M, Polizzi A	Interact J Med Res. 2014 May 5;3(2):e9. doi: 10.2196/ijmr.2867	A European network of email and telephone help lines providing information and support on rare diseases: results from a 1-month activity survey	European Organisation for Rare Diseases (Eurordis), Paris, France. francois.houyez@eurordis.org
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Kiasuwa Mbengi RL, Baeten R, McKee M, Knai C	Facts Views Vis Obgyn. 2014;6(3):127-32	Issues arising when crossing a border to give birth: an explora-tory study on the French-Belgian border	Scientific Institute of Public Health, J. Wytsmanstraat 14, 1050 Brussels, Belgium
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Post GB	Prehosp Disaster Med. 2004 Jul-Sep;19(3):235-44	Building the Tower of Babel: cross-border urgent medical assistance in Belgium, Germany and The Netherlands	ITS, Institute for Applied Social Sciences, Nimegen, The Netherlands. B.Post@its.kun.nl
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Spyrou S, Vartzopoulos D, Bamidis P, Maglaveras N	Stud Health Technol Inform. 2008;136:653-8	Cross-border collaboration between Greece and FYROM: mobile healthcare provision	3rd Regional Healthcare Authority (Macedonia), Greece
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Berg Brigham K, Cadier B, Chevreul K	Hum Reprod. 2013 Mar;28(3):666-75. doi: 10.1093/humrep/des418. Epub 2012 Dec 6	The diversity of regulation and public financing of IVF in Europe and its impact on utilization	URC Eco Ile-de-France (AP-HP), Hôtel Dieu, 1 Place du Parvis Notre Dame, Paris 75010, France. karen.brigham@urc-eco.fr
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Blyth E	Fertil Steril. 2010 Jun;94(1):e11-5. doi: 10.1016/j.fertnstert.2010.01.046. Epub 2010 Mar 6	Fertility patients' experiences of cross-border reproductive care	Department of Social Work, School of Human and Health Sciences, The University of Huddersfield, Queensgate, Huddersfield, United Kingdom. e.d.blyth@hud.ac.uk
Collins J, Cook J	Cross-border reproductive care: now and into the future	Fertil Steril. 2010 Jun;94(1):e25-6. doi: 10.1016/j.fertnstert.2009.12.009. Epub 2010 Feb 11	Mahone Bay, Nova Scotia, Canada. johncollins@eastlink.ca
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Davies T	Fertil Steril. 2010 Jun;94(1):e20-2. doi: 10.1016/j.fertnstert.2009.11.005. Epub 2010 Jan 8	Cross-border reproductive care: quality and safety challenges for the regulator	Human Fertilisation and Embryology Authority, London, United Kingdom. trish.davies@hfea.gov.uk
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Ethics Committee of American Society for Reproductive	Fertil Steril. 2013 Sep;100(3):645-50. doi:	Cross-border reproductive care: a	

Medicine	10.1016/j.fertnstert.2013.02.051. Epub 2013 Mar 21	committee opinion	
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Forman R	Reprod Biomed Online. 2011 Dec;23(7):808-10. doi: 10.1016/j.rbmo.2011.10.002. Epub 2011 Oct 8	Cross-border reproductive care: a clinician's perspective	CRM London, 111 Park Road, London, United Kingdom. RobertForman@crmlondon.co.uk
Franklin S	Reprod Biomed Online. 2011 Dec;23(7):814-6. doi: 10.1016/j.rbmo.2011.09.016. Epub 2011 Oct 8	Not a flat world: the future of cross-border reproductive care	University of Cambridge, Cambridge, UK. sbf25@cam.ac.uk
Gürtin ZB*	Reprod Biomed Online. 2011 Nov;23(5):555-64. doi: 10.1016/j.rbmo.2011.08.004. Epub 2011 Aug 27	Banning reproductive travel: Turkey's ART legislation and third-party assisted reproduction	Centre for Family Research, Convener, Cambridge Interdisciplinary Reproduction Forum, CRASSH, University of Cambridge, Cambridge CB2 3RF, United Kingdom. zbg20@cam.ac.uk
Hudson N, Culley L, Blyth E, Norton W, Rapport F, Pacey A	Reprod Biomed Online. 2011 Jun;22(7):673-85. doi: 10.1016/j.rbmo.2011.03.010. Epub 2011 Mar 13	Cross-border reproductive care: a review of the literature	School of Applied Social Sciences, De Montfort University, 0.15b Hawthorn Building, The Gateway, Leicester LE1 9BH, UK. nhudson@dmu.ac.uk
Inhorn MC, Patrizio P	Curr Opin Obstet Gynecol. 2012 Jun;24(3):158-63. doi: 10.1097/GCO.0b013e328352140a	The global landscape of cross-border reproductive care: twenty key findings for the new millennium	Department of Anthropology and MacMillan Center for International and Area Studies, Yale University, New Haven, Connecticut 06520-8277, USA
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Rozée Gomez V, de La Rochebrochard E	Hum Reprod. 2013 Nov;28(11):3103-10. doi: 10.1093/humrep/det326. Epub 2013 Aug 13	Cross-border reproductive care among French patients: experiences in Greece, Spain and Belgium	Ined, 133 boulevard Davout, Paris F-75020, France
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Health care "tourism": other, non-specific – 16 references

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Annex 3: Identified activities from the project review

	Short Description Project
No	**1**
Name	**Monitoring Medicines**
Acronym	/
Website	http://monitoringmedicines.org/
Mission/ Objectives	Optimizing drug safety monitoring to enhance patient safety and achieve better health outcomes
Lead Partner	Uppsala Monitoring Centre, Sweden
Database/source	FP7-HEALTH
Link to patient right	Patient safety
No	**2**
Name	
Acronym	**ORCAB**
Website	http://ec.europa.eu/research/health/public-health/clinical-outcome-into-practice/projects/orcab_en.html
Mission/ Objectives	Improving quality and safety in the hospital: The link between organisational culture, burnout, and quality of care. ORCAB aims at benchmarking the organisational and individual factors that impact on quality of care and patient safety and at designing bottom-up interventions that both increase quality of care and physician well-being.
Lead Partner	Medical School Department Social Medicine, Thessaloniki, Greece
Database/source	FP7-HEALTH
Link to patient right	Quality of care and patient safety
No	**3**
Name	**EUropean Cross Border Care Collaborations Short Title: CrossEurope**
Acronym	EUCBCC
Website	http://ec.europa.eu/research/health/public-health/health-systems/projects/eucbcc_en.html OR http://www.ecabeurope.eu/

Mission/ Objectives	EUCBCC aims to facilitate a process whereby Europe's citizens can make informed choices about whether to seek health care in another Member State and, if they so choose, to ensure that the administrative and clinical processes are straightforward and ensure continuity of care. It takes as its starting point the recent draft Directive on Patients' Rights, augmented by the existing body of research on cross-border care.
Lead Partner	London School of Economics and Political Science
Database/source	FP7-HEALTH
Link to patient right	Patient informed choices on cross border healthcare

No	4
Name	**Establishment of Quality Assurances for Detection of Highly Pathogenic Bacteria of Potential Bioterrorism Risk**
Acronym	EQADeBa
Website	www.rki.de/EN/Content/Prevention/EQADeBa/ EQADeBa__node.html
Mission/ Objectives	The project, supported by the second Health Programme, aimed at improving the preparedness of laboratories designated by the authorities in EU Member States to respond to any potential bioterrorist threat or natural outbreak of diseases caused by highly pathogenic bacteria like anthrax, plague, or tularaemia. In the case of such an attack or outbreak, laboratories must be able to achieve a quick and precise diagnosis of highly potentially dangerous threats.
Lead Partner	Robert Koch Institute, Berlin, Germany
Database/source	EU Health Programme 2008-2013
Link to patient right	Quality of care / patient safety in case of emergency / prevention

No	5
Name	**Vigilance and Surveillance of Substances of Human Origin**
Acronym	SOHOV
Website	http://www.sohovs.org/soho/
Mission/ Objectives	The aim of SOHOV&S is to support EU MS in the establishment of Vigilance and Surveillance(V&S)systems for tissues and cells in transplantation and in assisted reproduction. The project will drive harmonisation in terminology, investigation approaches, facilitating communication and cross-border management of serious adverse events and reactions (SAR/E).
Lead Partner	Istituto Superiore di Sanità - ISS (Roma)

Database/source	EU Health Programme 2008-2013
Link to patient right	Safety of medical procedures and quality of donated blood, tissues, etc - Surveillance and quality
No	6
Name	**European network social inclusion and health**
Acronym	Correlation II
Website	www.correlation-net.org/
Mission/ Objectives	We aim to improve the access to and the quality of medical and social services and work for a social Europe, in which marginal and vulnerable groups have a permanent place with the same (human) rights then everyone else.
Lead Partner	De Regenboog Groep, Amsterdam, Netherlands
Database/source	EU Health Programme 2008-2013
Link to patient right	Access and quality medical care
No	7
Name	**EUropean Best Information through Regional Outcomes in Diabetes**
Acronym	EUBIROD
Website	http://www.eubirod.eu/
Mission/ Objectives	EUBIROD targets the sustainability of complex systems of health indicators requiring continuous update and regular maintenance. The project proposes an action to implement, extend, and customize the application of the BIRO technology in at least 20 European Member States. Participants will be connected through a system that will safely collect aggregated data and produce systematic EU reports of diabetes indicators.
Lead Partner	Università degli Studi di Perugia, Italy
Database/source	EU Health Programme 2008-2013
Link to patient right	(Global) Indicators
No	8
Name	**European Heart Health Strategy**
Acronym	EuroHeart (2006)
Website	http://www.escardio.org

Mission/ Objectives	The objectives of the project are to: strengthen cross-sector cooperation; obtain comprehensive comparable information on policies and actions on cardiovascular health (CVH) promotion and cardiovascular disease (CVD) prevention; improve the awareness, diagnosis and treatment of women with CVD across Europe; and achieve a level playing-field by introducing national versions of CVD guidelines.
Lead Partner	European Society of Cardiology, France
Database/source	EU Health Programme 2008-2013
Link to patient right	CVD Guidelines
No	**9**
Name	**European Heart Health Strategy II**
Acronym	EuroHeart II (2010)
Website	http://www.ehnheart.org/projects/euroheart-ii.html
Mission/ Objectives	The project recommends investing in data collection systems in order to monitor trends in CVD risk factors,mortality rates and incidence. Policy makers are also encouraged to adopt legislative measures to improve dietary standards and reduce smoking, while at the same time promoting greater physical activity. Finally, the project underlines the need for scientific and professional bodies to draw up effective strategies for implementing professional guidelines and overcoming barriers.
Lead Partner	European Heart Network, Brussels, Belgium
Database/source	EU Health Programme 2008-2013
Link to patient right	Guidelines for effective and action of quality in the field of CVD
No	**10**
Name	**Quantification of sun exposure in Europe and its effects on health**
Acronym	EuroSun
Website	http://eurosun-project.org/Home/EuroSun-introduction-background-and-objectives.html
Mission/ Objectives	EuroSun aims to monitor ultraviolet exposure across Europe and its effects on incidence of skin cancers and cataracts. E.g. Development of indicators of changing risk of melanoma and non-melanoma skin cancers and of cataracts,… Measuring the exposure of individuals and populations in Europe to UV radiation by using the data of meteorological satellites.
Lead Partner	International Prevention Research institute, Lyon, France
Database/source	EU Health Programme 2008-2013
Link to patient right	Development of Indicator

No	11
Name	**Improving access to health care for asylum seekers and undocumented migrants in the EU**
Acronym	AVERROES Network
Website	http://averroes.medecinsdumonde.org/
Mission/ Objectives	The project contributes to enhancing the European Union population's health, by improving asylum seekers' and undocumented migrants' access to health care. Médecins du Monde (MdM) aims at documenting asylum seekers and undocumented migrants' access to health care in the EU. MdM also seeks to promote these populations' right to access health care on equal terms with nationals, and a right to protection against deportation for seriously ill foreigners.
Lead Partner	Medecins du Monde, Paris, France; Brussels, Belgium and Madrid, Spain
Database/source	EU Health Programme 2008-2013
Link to patient right	Patient rights within socio economic factors

No	12
Name	**Expanded European Information System to Monitor Short and Long Term outcomes and Improve Quality of Care and Safety for Very-Low-B**
Acronym	EuroNeoStat II
Website	http://www.euroneostat.org/ --> Link expired Check: http://ec.europa.eu/chafea/projects/database.html?prjno=20081311
Mission/ Objectives	EuroNeoStat II mission or strategic goal is that all Very Low Gestation (VLGA, gestation <32 wks) and Very Low Birth Weight (VLBW, birthweight <1501 g) infant born in Europe, receive the best possible health care no matter where born by preventing existing inequalities and that all Neonatal Units use the indicators developed, to assess the quality of care provided and implement strategies to improve outcome.
Lead Partner	Fundación Vasca de Innovación e Investigación Sanitarias
Database/source	EU Health Programme 2008-2013
Link to patient right	Quality evaluation and patient registries, patient safety

No	13
Name	**Better Statistics for Better Health for Pregnant Women and Their Babies: European Health Reports**
Acronym	EURO-PERISTAT III

Website	http://www.europeristat.com/
Mission/ Objectives	The EURO-PERISTAT project's goal has been to develop valid and reliable indicators that can be used for monitoring and evaluating perinatal health in the EU. The project began in 1999 as part of the Health Monitoring Programme and has continued into a third phase, with the ultimate aim of producing a European Perinatal Health Report and establishing a sustainable system for reporting perinatal health indicators.
Lead Partner	/
Database/source	EU Health Programme 2008-2013
Link to patient right	Indicator development, patient registries, health reports
No	**14**
Name	**Information network on good practice in health care for migrants and minorities**
Acronym	MIGHEALTHNET
Website	http://mighealth.net/index.php?title=Main_Page
Mission/ Objectives	The MIGHEALTHNET project aims to stimulate the exchange of knowledge on migrant and minority health through the development of interactive data bases in each of the participating countries. These 'wikis' will contain the following sorts of data: 1. Background information concerning migrant and minority populations. 2. The state of health of migrants and minority populations. 3. The health care system and the entitlement of migrants and minorities. 4. Accessibility of health care. 5. Quality of care: 'good practices' developed to improve the matching of service provisions to the needs of migrants and minorities. 6. Achieving change: centers of expertise, general reports and policy documents, training programmes, E-mail groups, etc.
Lead Partner	National and Kapodistrian University of Athens
Database/source	EU Health Programme 2008-2013
Link to patient right	Access to healthcare, quality of care
No	**15**
Name	**European Haemophilia Network**
Acronym	EUHANET
Website	http://www.euhanet.org/

Mission/ Objectives	The objective of this project is to establish the European Haemophilia Network (EUHANET) to harmonise and improve the care received by European citizens with inherited bleeding disorders. The European Health Professionals and Patient Organisations will work together to enhance the quality of the delivered care. Criteria will be developed for the definition of levels of care provided by haemophilia centres and these will be applied to centres throughout Europe. A new public Haemophilia Central website will provide all the information relevant to patients with inherited bleeding disorders and their carers. EUHANET will also support collaboration between the expanded and developed pharmacovigilance system, the European Haemophilia Safety Surveillance System (EUHASS), and the new prospective Rare Bleeding Disorders Database (RBDD).
Lead Partner	The University of Sheffield, UK
Database/source	EU Health Programme 2008-2013
Link to patient right	quality of care, surveillance, database

No	16
Name	**An EU Rare Diseases Registry for Wolfram Syndrome, Alstrom Syndrome and Bardet Biedl Syndrome**
Acronym	EURO-WABB
Website	http://www.euro-wabb.org/en/
Mission/ Objectives	The EURO-WABB Project is a collaboration of doctors, scientists and patient support groups from all over Europe. Within the EU Health Programme 2008-2013 and its call for promoting health through the creation of new registers for rare diseases, EURO-WABB is supported by The EU Directorate General for Health and Consumers (DG-SANCO) via its Executive Agency for Health and Consumers. The overall aim is for this register to be a key instrument to increase knowledge on these rare diseases, improve the lives of affected people through better management, and to develop clinical research.
Lead Partner	University of Birmingham, UK
Database/source	EU Health Programme 2008-2013
Link to patient right	Quality evaluation, patient registries

No	17
Name	**EUROPEAN QUALITY SYSTEM INDICATORS AND METHODOLOGY ON ORGAN DONATION**
Acronym	ODEQUS PROJECT
Website	http://odequs.eu/

Mission/ Objectives	ODEQUS specific objectives were to identify Quality Criteria (QC) and to develop Quality Indicators (QI) in 3 types of organ donation: after Brain Death, after Cardiac Death and Living Donation. Those tools will be useful for hospitals self-assessment, external evaluation as well as for developing an European auditing model.
Lead Partner	Universitat de Barcelona, Spain
Database/source	EU Health Programme 2008-2013
Link to patient right	Quality indicators, quality standards,
No	**18**
Name	**Chain of Trust–Understanding patients and health professionals' perspective on Telehealth to build confidence and acceptance**
Acronym	Chain of Trust
Website	http://www.eu-patient.eu/whatwedo/Projects/Chain-of-Trust/
Mission/ Objectives	The paramount objective of the "Chain of Trust" project is to advance the empowerment of patients, health professionals and national health authorities across the EU in their understanding and effective use of telehealth services in an effort to actively contribute to the vision of high quality, patient-centred, equitable healthcare for all EU patients.
Lead Partner	European Patients' Forum - EPF, Brussels, Belgium
Database/source	EU Health Programme 2008-2013
Link to patient right	Patient rights, privacy, telemedicine
No	**19**
Name	**International Research on Quality in Healthcare**
Acronym	INTERQUALITY
Website	http://interqualityproject.eu/
Mission/ Objectives	Project Objectives: 1. To investigate the effect of different financing methods and incentives on the quality, effectiveness and equity of access to health care in four patient groups affected by: - pharmaceutical care - hospital care - outpatient care - integrated care. 2. To develop collaborative practice models of healthcare, in the context of financing treatment of chronic diseases. 3. To establish the feasibility and effectiveness of developed models in the settings of each partner healthcare system.
Lead Partner	WARSZAWSKI UNIWERSYTET MEDYCZNY, Poland
Database/source	FP7-HEALTH

Link to patient right	quality outcomes, clinical efficacy, safety, equity
No	**20**
Name	**Guiding Patients Anytime Everywhere**
Acronym	MobiGuide
Website	http://www.mobiguide-project.eu/
Mission/ Objectives	MobiGuide research's main objective is to create a scalable, secure, ubiquitously accessible, and user-friendly mobile solution for designing, deploying, and maintaining Patient Guidance Systems based on clinical guidelines and personal health records, that provide personalized evidence-based clinical recommendations, increase the patients' satisfaction and compliance to evidence-based clinical guidelines, and reduce risk to patients and healthcare costs.
Lead Partner	University of Haifa (HU), Israel
Database/source	FP7 - ICT
Link to patient right	monitoring, patient data, patient empowerment, hospital records
No	**21**
Name	**Consent in a Trial and Care environment**
Acronym	CONTRACT
Website	http://contract-fp7.eu/site/
Mission/ Objectives	CONTRACT seeks to understand the way the European Data Protection Directive and the Clinical Trials Directive have had and continue to have an impact on the success of translational research.
Lead Partner	GOTTFRIED WILHELM LEIBNIZ UNIVERSITAET HANNOVER, Germany
Database/source	FP7-HEALTH
Link to patient right	Consent, data, new alternatives for consent, ethics
No	**22**
Name	**Deepening our understanding of quality improvement in Europe**
Acronym	DUQuE
Website	http://www.duque.eu/

Mission/ Objectives	The main goal of the DUQuE project is to study the effectiveness of quality improvement systems in European hospitals. This has been done by assessing the relationship of organisational quality improvement systems/management and culture, professionals' involvement, and patient empowerment with the quality of hospital care (including clinical effectiveness, patient safety and patient involvement).
Lead Partner	FAD Avedis Donabedian University Institute,Autonomous University of Barcelona, Spain
Database/source	FP7-HEALTH
Link to patient right	Quality hospitals in Europe, quality improvements, patient empowerment
No	**23**
Name	**Using operations management to improve healthcare outcomes**
Acronym	MANAGED OUTCOMES
Website	http://www.managedoutcomes.eu/
Mission/ Objectives	This main goal can be divided in seven specific objectives: Develop more effective and efficient healthcare systems models with new a scientific approach building on service operations management. Investigate relationships among quality of care, cost, efficiency and accessibility. Develop tools, methods, and models to create more sustainable health systems to encounter universal challenges of healthcare demand. Understand the relationship between healthcare outcomes and cost-benefits using technical, allocative and economic efficiency measures of service production systems. Identify different demand segments of healthcare. Enhance cooperation between researchers in Europe to promote the integration and excellence of European healthcare systems research. Develop future European healthcare system model scenarios.
Lead Partner	AALTO UNIVERSITY, Finland
Database/source	FP7-HEALTH
Link to patient right	Quality of healthcare, accessibility
No	**24**
Name	**Improvement in Postoperative PAIN OUTcome**
Acronym	PAIN-OUT
Website	http://pain-out.med.uni-jena.de/

Mission/ Objectives	PAIN OUT is a multi-national research project that provides a unique and user-friendly web-based information system to improve treatment of patients with post-operative pain. The project offers a system for measurement and feedback of outcome quality and supports the process of decision making in order to achieve an optimized treatment of patients. From 2009-2012, it was funded by European Commission's 7th Framework Programme (Grant Agreement no. 223590).
Lead Partner	Universitätsklinikum Jena, Germany
Database/source	FP7-HEALTH
Link to patient right	Improving clinical decision making
No	**25**
Name	**Clinical decision making and outcome in routine care for people with severe mental illness**
Acronym	CEDAR
Website	http://www.cedar-net.eu/
Mission/ Objectives	**Background**: A considerable amount of research has been conducted on clinical decision making (CDM) in short-term physical conditions. However, there is a lack of knowledge on CDM and its outcome in long-term illnesses, especially in care for people with severe mental illness. Thus, this project entitled "Clinical decision making and outcome in routine care for people with severe mental illness" (CEDAR) is proposed by participants in six European countries (Denmark, Germany, Hungary, Italy, Switzerland and UK).
Lead Partner	UNIVERSITAET ULM, Germany
Database/source	FP7-HEALTH
Link to patient right	Clinical decision making
No	**26**
Name	**Promoting patient safety and quality improvement in critical care**
Acronym	PROSAFE
Website	http://prosafe.marionegri.it/

Mission/ Objectives	The project will: a. **Build a collaboration network of ICUs** for collecting and comparing clinical data for improving patient safety and quality of services. b. Develop a **web-based multilingual system** for gathering data from ICU networks. c. Permit the **analysis and comparison of clinical data through multivariable methods** and provide ICUs with tools **for identifying and eliminating weaknesses and for fostering and sharing strengths with other network members.** d. **Enhance patient safety** in terms of quality of delivered healthcare. e. **Improve outcome in ICUs** by reducing mortality and avoiding medical errors through continuous monitoring of activity. f. Introduce effective strategies of **good practice exchange** between different EU countries in the critical care domain.
Lead Partner	Mario Negri Institute for Pharmacological Research, Italy
Database/source	EU Health Programme 2008-2013
Link to patient right	Patient safety

No	**27**
Name	**Surveillance System: Occurrence of Urinary Incontinence in Women as a Consequence of Inefficient or Inappropriate Obstetric Care**
Acronym	Ob.Surve
Website	http://www.obsurve.eu/ --> Website down
Mission/ Objectives	The project aims at setting up a surveillance system to monitor the occurrence of urinary incontinence (UI) in women in the EU. The project will focus on incontinence as a consequence of inefficient or inappropriate obstetric care, with the ultimate view to formulate appropriate strategies, policies and actions to avoid these conditions, and thus improve the quality of life of particular sections of the female population.
Lead Partner	AZIENDA ULSS 20 Verona, Italy
Database/source	EU Health Programme 2008-2013
Link to patient right	Health surveillance

No	**28**
Name	**European Union Network for Patient Safety**
Acronym	EUNetPaS
Website	http://www.eunetpas.eu/
Mission/ Objectives	EUNetPaS seeks to establish an umbrella network to improve cooperation among Member States in the field of patient safety, particular with respect to culture, reporting and learning systems, and education, and thus avoid overlap and duplication of efforts.

Lead Partner	Haute Autorité de Santé - HAS, France
Database/source	EU Health Programme 2008-2013
Link to patient right	Patient safety
No	**29**
Name	**European Haemophilia Safety Surveillance System**
Acronym	EUHASS
Website	http://euhass.org/
Mission/ Objectives	EUHASS is a pharmacovigilance program to monitor the safety of treatments for people with inherited bleeding disorders in Europe. Haemophilia treatment centres report adverse events directly to the EUHASS website and regular surveillance reports are produced.
Lead Partner	The University of Sheffield, UK
Database/source	EU Health Programme 2008-2013
Link to patient right	Patient Safety and surveillance
No	**30**
Name	**Learning from International Networks about Errors and Understanding Safety in Primary Care**
Acronym	LINNEAUS EURO -PC
Website	http://www.linneaus-pc.eu/
Mission/ Objectives	The main focus of the co-ordination action is to build a network of researchers and practitioners working on patient safety in primary care the European Union.
Lead Partner	School of Community Based Medicine, University of Manchester, UK
Database/source	FP7-HEALTH
Link to patient right	Patient safety
No	**31**
Name	**Quality and safety in European Union hospitals: A research-based guide for implementing best practice and a framework for assessing performance**
Acronym	QUASER
Website	http://www.quaserproject.eu/ --> http://ec.europa.eu/research/health/public-health/clinical-outcome-into-practice/projects/quaser_en.html

Mission/ Objectives	This translational study aims to design and disseminate an evidence based guide for hospitals to implement quality and safety improvement programmes, and an evidence based framework for payers to assess and monitor the quality and safety of hospitals across the EU.
Lead Partner	UNIVERSITY COLLEGE LONDON, UK
Database/source	FP7-HEALTH
Link to patient right	Quality and safety in EU hospitals
No	**32**
Name	**European Consortium in Healthcare Outcomes and cost-benefit research**
Acronym	ECHOUTCOME
Website	http://www.echoutcome.eu/index.php/en/home.html
Mission/ Objectives	ECHOUTCOME is an interdisciplinary European research platform with the aim of assessing methodological properties of Healthcare Outcome and Cost-Benefit studies. The ECHOUTCOME consortium is composed by eight partners from 4 countries including three academic international experts in Outcome Research from, the French Scientific Society in Health Economics, the European office of one Multinational BioPharma industry, two research organisations (SME) specialized in advanced statistics and modelling and one organization specialized in international research administration. The general objective of this consortium is to study European health systems in order to assess decision making criteria in the frame of national needs and expectations across member states concerning healthcare outcomes and cost-benefit analyses Using both the descriptive and the experimental approaches, the ECHOUTCOME consortium will be able to investigate the relationship between **quality of care** with costs, efficiency and **accessibility** by indentifying and assessing existing approaches, but with the capability to develop new approaches for Decision Making purpose.
Lead Partner	UNIVERSITE LYON 1 CLAUDE BERNARD, France
Database/source	FP7-HEALTH
Link to patient right	Quality of care and accessibility
No	**33**
Name	**European Health Care Outcomes, Performance and Efficiency**
Acronym	EuroHOPE
Website	http://eurohope.info/

Mission/ Objectives	By using available databases as well as by collecting additional data on health-related quality of life measures (enabling Quality Adjusted Life Years as an outcome measure) and patient satisfaction (including expectations) the EuroHOPE project will evaluate, through a microeconomic disease-based approach, the performance of European health care systems in terms of outcomes, quality, use of resources and cost. Concentration will be on five important health problems/diseases: acute myocardial infarction, stroke, hip fracture, breast-cancer, and very low birth weight infants.
Lead Partner	TERVEYDEN JA HYVINVOINNIN LAITOS, Finland
Database/source	FP7-HEALTH
Link to patient right	patient satisfaction, quality of care

No	34
Name	**European Collaboration for Healthcare Optimization**
Acronym	ECHO
Website	http://echo-health.eu/
Mission/ Objectives	ECHO, European Collaboration for Healthcare Optimization, gathers the interests for Healthcare Performance Measurement of different Academic and Research Institutions from six European countries and an International Body for Healthcare Policy Analysis. Designed as a 48 months project, it has been conceived as a "pilot study" based on available administrative databases. It aims at describing the actual performance of six different Healthcare Systems at hospital, healthcare area, regional and country level. To tackle performance measurement in this project, two different methodological approaches will be used: [a] a population geographical-based, responding the question: Is the access to a diagnostic or surgical procedure dependant on the place where a person lives? And, [b] a provider-specific, answering the question: Is the risk for a patient to access high quality care -and have better health outcomes- different regarding the provider in which he or she is admitted? Utilization, equity in access and allocative efficiency will be analysed as performance measures in the former approach; and, healthcare outcomes and associated costs will be measures in the latter one.
Lead Partner	INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD, Spain
Database/source	FP7-HEALTH
Link to patient right	Access to health care, assessment of performance

No	35
Name	**Prevention of Hospital Infections by Intervention and Training**
Acronym	PROHIBIT

Website	https://plone.unige.ch/prohibit/
Mission/ Objectives	The aim of PROHIBIT is to understand existing guidelines and practices to prevent healthcare associated infections (HAI) in European hospitals, identify factors that enable and prevent compliance with best practices, and test the effectiveness of interventions of known efficacy. The project will employ a mixed-methods approach combining the strengths of qualitative research, survey methods, observational and experimental designs.
List of publication	https://plone.unige.ch/prohibit/publications
Lead Partner	UNIVERSITE DE GENEVE, Switzerland
Database/source	FP7-HEALTH
Link to patient right	Guidelines and best practices, evaluation of effectiveness
No	**36**
Name	**IMPROVING PATIENT SAFETY OF HOSPITAL CARE THROUGH DAY SURGERY**
Acronym	DAYSAFE
Website	http://www.daysafe.eu/
Mission/ Objectives	The general objective of the project is to improve patient safety and quality of hospital care through the promotion of DS best practices and standards. This project intends to elucidate main issues concerning ambulatory surgery, investigating DS at different levels of MSs health systems, and also offer realistic solutions, recommending evidence-based best practices and standards identified through benchmarking. This initiative aims to provide some relevant, practical and flexible answers to European health systems increasingly facing an ethical and political dilemma regarding how to assure sustainable and equitable access to safe and high quality health care
Lead Partner	Agenzia Nazionale per i Servizi Sanitari Regionali , Rome, Italy
Database/source	EU Health Programme 2008-2013
Link to patient right	Quality of care and patient safety
No	**37**
Name	**IMplementation of quality indicators in PAlliative Care sTudy**
Acronym	IMPACT
Website	http://www.impactpalliativecare.eu/
Mission/ Objectives	The overall aim of the IMPACT project was to develop optimal improvement strategies to improve the organization of palliative cancer and dementia care in Europe and to study factors influencing the effectiveness of the strategies.

List of publication	
Lead Partner	STICHTING KATHOLIEKE UNIVERSITEIT, Netherlands
Database/source	FP7-HEALTH
Link to patient right	Effectiveness of strategies, quality of care
No	**38**
Name	The **European Union Network for Patient Safety and Quality of Care,**
Acronym	PaSQ Joint Action
Website	http://www.pasq.eu/
Mission/ Objectives	The general objective of PaSQ Joint Action (JA) is to contribute to Patient Safety (PS) and good Quality of Care (QC) by supporting the implementation of the Council Recommendations on PS through cooperation between European Member States (EU MS), EU stakeholders and international organisations on issues related to quality of health care, including PS and Patient Involvement (PI). This will be done by sharing knowledge, experience and good practices with each other, the Commission and relevant European and international bodies, as well as examining transferability of these practices.
Lead Partner	French National Authority for Health (HAS)
Database/source	EU Health Programme 2008-2013
Link to patient right	implementation of good practice

Annex 4: Council of Europe activities - Tables

1.Ratification Status

The Council of Europe is the best source for this, and provides the following data on the situation

(http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=29/07/2015&CL=ENG Last visited 3 August, 2015).

Here the basic information of the table is included, with the addition of the details concerning the four Protocols to the Convention: on the prohibition on the cloning of human beings

(http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=168&CM=8&DF=29/07/2015&CL=ENG Last visited 3 August, 2015);

on the transplantation of human organs and tissue

(http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=186&CM=8&DF=29/07/2015&CL=ENG Last visited 3 August, 2015);

on biomedical research

(http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=195&CM=8&DF=29/07/2015&CL=ENG Last visited 3 August, 2015);

and on genetic testing for health purposes

(http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=203&CM=8&DF=29/07/2015&CL=ENG Last visited 3 August, 2015).

	Convention	Human Rights and Biomedicine		Protocol:	Prohibition on Human Cloning		Protocol:	Organ and Tissue		Protocol	Biomedical Research		Protocol:	Genetic Testing	
	Signature	Ratification	Entry into force	Signature	Ratification	Entry into force	Signature	Ratification	Entry into force	Signature	Ratification	Entry into force	Signature	Ratification	Entry into force
Albania	30/3/2011	30/3/2011	1/7/2011												
Andorra															
Armenia															
Austria															
Azerbaijan															
Belgium															
Bosnia and Herzegovina	16/12/2005	11/5/2007	1/9/2007	31/7/2014	4/6/2015	1/10/2015				16/12/2005	11/5/2007	1/9/2007			
Bulgaria	31/5/2001	23/4/2003	1/8/2003	23/9/2005	30/10/2006	1/2/2007	23/9/2005	30/10/2006	1/2/2007	23/9/2005	30/10/2006	1/9/2007			
Croatia	7/5/1999	28/11/2003	1/3/2004	7/5/1999	28/11/2003	1/3/2004	29/10/2003	28/11/2003	1/5/2006						
Cyprus	30/9/1998	20/3/2002	1/7/2002	30/9/1998	20/3/2002	1/7/2002				9/7/2010					
Czech Republic	24/6/1998	22/6/2001	1/10/2001	24/6/1998	22/6/2001	1/10/2001									
Denmark	4/4/1997	10/8/1999	1/12/1999	12/1/1998						25/1/2005					
Estonia	4/4/1997	8/2/2002	1/6/2002	12/1/1998	8/2/2002	1/6/2002	24/1/2002	17/9/2003	1/5/2006						
Finland	4/4/1997	30/11/2009	1/3/2010	12/1/1998	30/11/2009	1/3/2010	26/6/2006	30/11/2009	1/3/2010				27/11/2008		
France	4/4/1997	13/12/2011	1/4/2012	12/1/1998			13/12/2011						13/12/2011		
Georgia	11/5/2000	22/11/2000	1/3/2001	11/5/2000	22/11/2000	1/3/2001	25/3/2002	18/12/2002	1/5/2006	21/2/2005	8/4/2010	1/8/2010			
Germany															
Greece	4/4/1997	6/10/1998	1/12/1999	12/1/1998	22/12/1998	1/3/2001	24/1/2002			25/1/2005					
Hungary	7/5/1999	9/1/2002	1/5/2002	7/5/1999	9/1/2002	1/5/2002	4/5/2005	30/11/2006	1/3/2007	28/9/2005	30/11/2006	1/9/2007			
Iceland	4/4/1997	12/10/2004	1/2/2005	12/1/1998	12/10/2004	1/2/2005	24/1/2002	12/10/2004	1/5/2006	25/1/2005			7/7/2009		
Ireland															
Italy	4/4/1997			12/1/1998			28/2/2002			19/10/2005					
Latvia	4/4/1997	25/2/2010	1/6/2010	12/1/1998	25/2/2010	1/6/2010									
Liechtenstein															
Lithuania	4/4/1997	17/10/2002	1/2/2003	25/3/1998	17/10/2002	1/2/2003				7/3/2005					

	Convention	Human Rights and Biomedicine		Protocol:	Prohibition on Human Cloning		Protocol:	Organ and Tissue		Protocol	Biomedical Research		Protocol:	Genetic Testing	
	Signature	Ratification	Entry into force	Signature	Ratification	Entry into force	Signature	Ratification	Entry into force	Signature	Ratification	Entry into force	Signature	Ratification	Entry into force
Luxembourg	4/4/1997			12/1/1998			24/1/2002			25/1/2005			27/11/2008		
Malta															
Moldova	6/5/1997	26/11/2002	1/3/2003	12/1/1998	26/11/2002	1/3/2003	8/2/2007	5/2/2008	1/6/2008	25/1/2005	7/8/2013	1/12/2013	27/11/2008	29/4/2011	
Monaco															
Montenegro	9/2/2005	19/3/2010	1/7/2010	22/3/2010	8/12/2010	1/4/2011	9/2/2005	19/3/2010	1/7/2010	9/2/2005	12/2/2013	1/6/2013	12/2/2013	12/2/2013	
Netherlands	4/4/1997			4/5/1998			4/2/2002								
Norway	4/4/1997	13/10/2006	1/2/2007	12/1/1998	26/5/2015	1/9/2015				25/1/2005	26/5/2015	1/9/2015	26/5/2015	26/5/2015	
Poland	7/5/1999			7/5/1999											
Portugal	4/4/1997	13/8/2001	1/12/2001	12/1/1998	13/8/2001	1/12/2001	21/2/2002			4/2/2005			17/3/2015		
Romania	4/4/1997	24/4/2001	1/8/2001	12/1/1998	24/4/2001	1/8/2001	20/2/2015			17/7/2006					
Russia															
San Marino	4/4/1997	20/3/1998	1/12/1999	12/1/1998											
Serbia	9/2/2005	10/2/2011	1/6/2011				9/2/2005			9/2/2005					
Slovakia	4/4/1997	15/1/1998	1/12/1999	31/3/1998	22/10/1998	1/3/2001				25/1/2005	23/9/2005	1/9/2007			
Slovenia	4/4/1997	5/11/1998	1/12/1999	12/1/1998	5/11/1998	1/3/2001	24/1/2002	19/1/2006	1/5/2006	25/1/2005	19/1/2006	1/9/2007	25/5/2009	3/9/2009	
Spain	4/4/1997	1/9/1999	1/1/2000	12/1/1998	24/1/2000	1/3/2001	27/11/2006	22/12/2014	1/4/2015						
Sweden	4/4/1997			12/1/1998						25/1/2005					
Switzerland	7/5/1999	24/7/2008	1/11/2008	7/5/1999	24/7/2008	1/11/2008	11/7/2002	10/11/2009	1/3/2010						
The former Yugoslav Republic of Macedonia	4/4/1997	3/9/2009	1/1/2010	12/1/1998	3/9/2009	1/1/2010	15/3/2002	3/9/2009	1/1/2010						
Turkey	4/4/1997	2/7/2004	1/11/2004	12/1/1998						25/1/2005	21/9/2011	1/1/2012			
Ukraine	22/3/2002			10/4/2006			26/6/2006			26/6/2006					
United Kingdom															

2. Thematic List of Council of Europe Treaties relating to Patient Rights.

This list is from the Council of Europe's own (complete) Chronological List of Treaties

http://conventions.coe.int/Treaty/Commun/ListeTraites.asp?CM=8&CL=ENG (last visited 2 August, 2015)

Key:

No.	Treaty		
	European Convention on Human Rights		Social Security
	Convention on Human Rights and Biomedicine		Social Charter
	Data Protection		Animals
	Access to Medicines and HealthCare		Torture
	Organs, Blood, etc.		Other
	Movement of People		

(Priority regarding Patient Rights) = H (High); M (Medium); L (Low); P (Procedural)

No. = Number in chronological sequence of creation of Council of Europe Treaties

"Contribution" to patient rights

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
H	5	Convention for the Protection of Human Rights and Fundamental Freedoms	Rights to life (Article 2); no inhuman treatment (article 3) ;private and family life (8); thought, conscience and religion (9); freedom of expression (10); marry (12); effective remedy (13) - premise of human dignity, but note the derogations in the public interest (esp. in 8 and 10).	4/11/1950	3/9/1953
L	9	Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms	Right to private property (1), education (2).	20/3/1952	18/5/1954
P	44	Protocol No. 2 to the Convention for the Protection of Human Rights and Fundamental Freedoms, conferring upon the European Court of Human Rights competence to give advisory opinions	ECtHR empowered to give opinions	6/5/1963	21/9/1970
P	45	Protocol No. 3 to the Convention for the Protection of Human Rights and Fundamental Freedoms, amending Articles 29, 30 and 34 of the Convention	Amendment to powers over rejection of petitions (Treaty No. 5/ Article 29 - '5/29' herein)	6/5/1963	21/9/1970
M	46	Protocol No. 4 to the Convention for the Protection of Human Rights and Fundamental Freedoms, securing certain rights and freedoms other than those already included in the Convention and in the first Protocol thereto	Freedom of movement within territory (and freedom of exit)(2)	16/9/1963	2/5/1968
P	55	Protocol No. 5 to the Convention for the Protection of Human Rights and Fundamental Freedoms, amending Articles 22 and 40 of the Convention	Composition of Human Rights Commission	20/1/1966	20/12/1971
P	67	European Agreement relating to Persons participating in Proceedings of the European Commission and Court of Human Rights	Immunities and rights of audience before ECtHR	6/5/1969	17/4/1971

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
P	155	Protocol No. 11 to the Convention for the Protection of Human Rights and Fundamental Freedoms, restructuring the control machinery established thereby	Revision of Section 2 (procedure of the ECtHR).	11/5/1994	1/11/1998
M	160	European Convention on the Exercise of Children's Rights	Creates expectations about treatment of Children in legal proceedings - particularly about involving the child to the extent of his/her competence.	25/1/1996	1/7/2000
H	177	Protocol No. 12 to the Convention for the Protection of Human Rights and Fundamental Freedoms	"The enjoyment of any right set forth by law shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status" (1.1) "No one shall be discriminated against by any public authority on any ground such as those mentioned in paragraph 1." (1.2)	4/11/2000	1/4/2005
H	164	Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine	See section 1, above.	4/4/1997	1/12/1999
H	168	Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings	"Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited." (1.1) "For the purpose of this article, the term human being 'genetically identical' to another human being means a human being sharing with another the same nuclear gene set." (1.2) No derogation permitted. (2)	12/1/1998	1/3/2001

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
H	186	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin	"Parties to this Protocol shall protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin." (1) Chapter 2: General provisions concerning the transplant process and system Chapter 3: Removal of organs and tissue from living people Chapter 4: from deceased people Chapter 5: Implantation of an organ removed for a purpose other than implantation Chapter 6: Prohibition on financial gain Chapter 7: Confidentiality	24/1/2002	1/5/2006
H	195	Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research	Parties to this Protocol shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to any research involving interventions on human beings in the field of biomedicine. (1) Chapter 2: general presumptions: primacy of human dignity (3), freedom of science (subject to 3)(4), no available alternative (5), and justifiable proportional risk to benefit (6), approval for ethics and science (7), and scientific quality (8) Chapter 3: independent ethics committee review of protocols. Chapter 4: informed consent Chapter 5: protection of incompetent people in research Chapter 6: special research participants - breastfeeding mothers, emergency situations, prisoners. Chapter7: 'safety and supervision' Chapter 8: 'confidentiality and right to information' Chapter 9: 'research in States not party to this Protocol' Chapter 10: infringement, compensation and sanctions	25/1/2005	1/9/2007

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
H	203	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes	Purpose: protection of fundamental rights and freedoms of people in relation to (1)... "tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development (hereinafter referred to as 'genetic tests')" (2.1) Excluding: "a) to genetic tests carried out on the human embryo or foetus; b) to genetic tests carried out for research purposes." (2.2) Where: a) "'Analysis' refers to i) chromosomal analysis, ii) DNA or RNA analysis, iii) analysis of any other element enabling information to be obtained which is equivalent to that obtained with the methods referred to in sub-paragraphs a.i. and a.ii.; and, b) "'biological samples' refers to i) biological materials removed for the purpose of the test concerned, and ii) biological materials previously removed for another purpose. (2.3) Chapter 2: General principles of non-discrimination and human primacy over 'sole interest of society or science'; Chapter 3: 'Genetic services'; Chapter 4: Informed consent and counselling; Chapter 5: Incompetent people; Chapter 6: 'tests for the benefit of family members'; Chapter 7: privacy and information rights; Chapter 8: health screening programmes; Chapter 9: 'public information'.	27/11/2008	NB

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
H	108	Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data	Early response to international movement on protection of personal data. Limited to 'automated processing' (1) Established the key language - data subject, 'controller' of the data.(2) Distinguishes personal data and special personal data (particularly sensitive data) (6) Duties - process fairly and lawfully, storage, quantity of data fit for purpose only, accuracy, and presumption of deidentification where possible (5) Data security (7); Sanctions (10); Cross-border data flows (12) Mutual assistance between States (13–17); Inter-State Consultative Committee on data protection (18–20)	28/1/1981	1/10/1985
L	180	Convention on Information and Legal Co-operation concerning "Information Society Services"	"In accordance with the provisions of this Convention, the Parties shall exchange texts, where practicable by electronic means, of draft domestic regulations aimed specifically at 'Information Society Services' and shall co-operate in the functioning of the information and legal co-operation system set up under the Convention." (1.1) NB. Not telecommunications, etc. MS must designate an Information Society Services (ISS) Authority responsible for communicating Law/draft legislation on ISS (3)	4/10/2001	NB
L	181	Additional Protocol to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, regarding supervisory authorities and transborder data flows	Supervisory DP Authorities in each MS (1) Transborder data flows to non-Convention countries only where an 'adequate level of protection' is shown (2)	8/11/2001	1/7/2004

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
M	14	European Convention on Social and Medical Assistance	"Each of the Contracting Parties undertakes to ensure that nationals of the other Contracting Parties who are lawfully present in any part of its territory to which this Convention applies, and who are without sufficient resources, shall be entitled equally with its own nationals and on the same conditions to social and medical assistance (hereinafter referred to as 'assistance') provided by the legislation in force from time to time in that part of its territory." (1) "The cost of assistance to a national of any of the Contracting Parties shall be borne by the Contracting Party which has granted the assistance." (4) Section 2: Repatriation (6–10). Section 3: Residence (11–14).	11/12/1953	1/7/1954
L	14A	Protocol to the European Convention on Social and Medical Assistance	"For the purposes of this Protocol the term 'refugee' shall have the meaning ascribed to it in Article 1 of the Geneva Convention, provided that each Contracting Party shall make a declaration at the time of signature or ratification hereof or accession hereto, specifying which of the meanings set out in paragraph B of Article 1 of that Convention it applies for the purpose of its obligations under this Protocol, unless such Party has already made such a declaration at the time of its signature or ratification of that Convention." (1) "The provisions of Section I of the Assistance Convention shall apply to refugees under the same conditions as they apply to the nationals of the Contracting Parties thereto." (2)	11/12/1953	1/7/1954
M	33	Agreement on the Temporary Importation, free of duty, of Medical, Surgical and Laboratory Equipment for use on free loan in Hospitals and other Medical Institutions for purposes of Diagnosis or Treatment	"The Contracting Parties shall, provided that they have sufficient stocks for their own needs, make medical, surgical and laboratory equipment available on free loan to such other Contracting Parties as may, in exceptional circumstances, have urgent need of it; such equipment shall, upon request, be sent to the Party concerned and shall subsequently be returned." (1.1a) "Each Contracting Party benefiting under the terms of the previous paragraph shall grant all possible facilities for the importation on a temporary basis of the equipment loaned." (1.1b)	28/4/1960	29/7/1960

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
H	38	European Agreement on Mutual Assistance in the matter of Special Medical Treatments and Climatic Facilities	"The provisions of this Agreement shall apply to persons residing in the territory of one of the Contracting Parties who are eligible for compulsory or optional medical benefits: a) under social security schemes, whether general or special, contributory or non-contributory, including special schemes for civil servants or persons treated as such and schemes relating to employer's obligations in regard to medical benefits; or b) under social and medical assistance schemes; or c) under schemes of benefits for victims of war or its consequences." (1) "Each Contracting Party shall endeavour to have admitted to medical establishments or spas in its territory which can provide appropriate medical treatment any persons referred to in Article 1, for the medical treatment required which they need but which is not available in the territory of the Contracting Party where they reside, in accordance with a certificate issued by the doctor designated by the institution to which the patient is affiliated." (2)	14/5/1962	15/6/1962
H	91	European Convention on Products Liability in regard to Personal Injury and Death	Producers (including importers who rebrand products to their own name, and suppliers of unbranded products) are liable to pay compensation for death or personal injuries from defective products (3) Liability in multi-component products is each for the total (in solidum) (3.5) Contributory negligence included (4)	27/1/1977	NB
P	110	Additional Protocol to the Agreement on the Temporary Importation, free of duty, of Medical, Surgical and Laboratory Equipment for Use on free loan in Hospitals and other Medical Institutions for Purposes of Diagnosis or Treatment	The EEC by this protocol can become a contracting party to the Agreement. Now incorporated into Agreement ETS033.	1/1/1983	1/1/1985
M	129	Arrangement for the Application of the European Agreement of 17 October 1980 concerning the Provision of Medical Care to Persons during Temporary Residence	Creates competent bodies in each State and addresses information flows and certificates of entitlement to medical care.	26/5/1988	NB

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
L	144	Convention on the Participation of Foreigners in Public Life at Local Level	Extends rights of free expression, association and assembly to non-nationals of CofE States. Also ensures local representation bodies and rights to participate in local elections. (3–6)	5/2/1992	1/5/1997
M	166	European Convention on Nationality	"Each State shall determine under its own law who are its nationals." (3.1) "This law shall be accepted by other States in so far as it is consistent with applicable international conventions, customary international law and the principles of law generally recognised with regard to nationality." (3.2) Nationality based on the principles: "a) everyone has the right to a nationality; b) statelessness shall be avoided; c) no one shall be arbitrarily deprived of his or her nationality; d) neither marriage nor the dissolution of a marriage between a national of a State Party and an alien, nor the change of nationality by one of the spouses during marriage, shall automatically affect the nationality of the other spouse." (4) Applied under non-discrimination principles (5)	6/11/1997	1/3/2000
P	200	Council of Europe Convention on the avoidance of statelessness in relation to State succession	This provides for continuity of citizenship into a new State on State succession, and underlines the need to avoid statelessness (particularly 1–4)	19/5/2006	1/5/2009
L	211	Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health	This is a public health measure concerning the counterfeiting and trafficking in counterfeit medical products. (1, 3 and 4) It creates a criminal investigation and prosecution framework, including corporate liability (Chapters 2 and 3)	28/10/2011	NB
L	26	European Agreement on the Exchange of Therapeutic Substances of Human Origin	"The Contracting Parties undertake, provided that they have sufficient stocks for their own needs, to make therapeutic substances of human origin available to other Parties who are in urgent need of them and to charge only those costs involved in the collection, processing and carriage of such substances." (2) Where "therapeutic substances of human origin" are "human blood and its derivatives" (1)	15/12/1958	1/1/1959

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
L	39	European Agreement on the Exchanges of Blood-Grouping Reagents	"The Contracting Parties undertake, provided that they have sufficient stocks for their own needs, to make blood-grouping reagents available to other Parties who are in urgent need of them and to charge only those costs of collection, processing and carriage of such substances and the cost (if any) of their purchase." (2)	14/5/1962	14/10/1962
L	80	Agreement on the Transfer of Corpses	Maximum conditions and terms, including relevant documentation, required for the transfer of corpses between signatory States.	26/10/1973	11/11/1975
L	84	European Agreement on the Exchange of Tissue-Typing Reagents	"The Contracting Parties undertake, provided that they have sufficient stocks for their own needs, to make tissue-typing reagents available to other Parties who are in need of them and to charge only those costs of collection, processing and carriage of such substances and the cost (if any) of their purchase." (2)	17/9/1974	23/4/1977
P	89	Additional Protocol to the European Agreement on the Exchange of Tissue-Typing Reagents	The EEC by this protocol can become a contracting party to the Agreement.	24/6/1976	23/4/1977
P	109	Additional Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin	The EEC by this protocol can become a contracting party to the Agreement.	1/1/1983	1/1/1985
P	111	Additional Protocol to the European Agreement on the Exchanges of Blood-Grouping Reagents	The EEC by this protocol can become a contracting party to the Agreement.	1/1/1983	1/1/1985
L	216	Council of Europe Convention against Trafficking in Human Organs	Purposes: "a) to prevent and combat the trafficking in human organs by providing for the criminalisation of certain acts; b) to protect the rights of victims of the offences established in accordance with this Convention; c) to facilitate co-operation at national and international levels on action against the trafficking in human organs." (1) Creates criminal liability for illicit removal and trafficking in human organs, and illicit soliciting to procure such organs.	25/3/2015	

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
L	19	European Convention on Establishment	"Each Contracting Party shall facilitate the entry into its territory by nationals of the other Parties for the purpose of temporary visits and shall permit them to travel freely within its territory except when this would be contrary to ordre public, national security, public health or morality." (1) "Nationals of any Contracting Party shall enjoy in the territory of any other Party treatment equal to that enjoyed by nationals of the latter Party in respect of the possession and exercise of private rights whether personal rights or rights relating to property." (4) Revocable in specified circumstances (national interest, etc.) (5)	13/12/1955	23/2/1965
M	12	European Interim Agreement on Social Security Schemes Relating to Old Age, Invalidity and Survivors	Entitlement relating to "a) benefits in respect of old age;b) benefits in respect of invalidity, other than those awarded under an employment injury scheme; c) benefits payable to survivors, other than death grants or benefits awarded under an employment injury scheme." (1.1) Subject to conditions, "a national of any one of the Contracting Parties shall be entitled to receive the benefits of the laws and regulations of any other of the Contracting Parties under the same conditions as if he were a national of the latter, provided that: a) in the case of invalidity benefit under either a contributory or non-contributory scheme he had become ordinarily resident in the territory of the latter Contracting Party before the first medical certification of the sickness responsible for such invalidity; b) in the case of benefit payable under a non-contributory scheme, he has been resident in that territory for a period in the aggregate of not less than fifteen years after the age of twenty, has been ordinarily resident without interruption in that territory for at least five years immediately preceding the claim for benefit and continues to be ordinarily resident in that territory; c) in the case of benefit payable under a contributory scheme, he is resident in the territory of any one of the Contracting Parties." (2.1)	11/12/1953	1/7/1954
M	12A	Protocol to the European Interim Agreement on Social Security Schemes Relating to Old Age, Invalidity and Survivors	Makes the Interim Agreement available to refugees (2)	11/12/1953	1/10/1954

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
M	13	European Interim Agreement on Social Security other than Schemes for Old Age, Invalidity and Survivors	Agreement concerning the following benefits: "a) sickness, maternity and death (death grants), including medical benefits insofar as they are not subject to a needs test; b) employment injury; c) unemployment; and d) family allowances." (1.1) "This Agreement shall apply to schemes of contributory and non-contributory benefits, including employers' obligations to compensate for employment injuries. It shall not apply to public assistance, special schemes for civil servants, or benefits paid in respect of war injuries or injuries due to foreign occupation." (1.2) Such that "a national of any one of the Contracting Parties shall be entitled to receive the benefits of the laws and regulations of any other Contracting Parties under the same conditions as if he were a national of the latter: a) in the case of benefit in respect of employment injury, provided that he resides in the territory of one of the Contracting Parties; b) in the case of any benefit other than benefit in respect of employment injury, provided that he is ordinarily resident in the territory of the latter Contracting Party; c) in the case of benefit claimed in respect of sickness, maternity or unemployment, provided that he had become ordinarily resident in the territory of the latter Contracting Party before the first medical certification of the sickness, the presumed date of conception or the beginning of the unemployment, as the case may be; and d) in the case of a benefit provided under a non-contributory scheme, other than a benefit in respect of employment injury, provided that he has been resident for six months in the territory of the latter Contracting Party.	11/12/1953	1/7/1954
M	13A	Protocol to the European Interim Agreement on Social Security other than Schemes for Old Age, Invalidity and Survivors	Makes the Interim Agreement available to refugees (2)	11/12/1953	1/10/1954
	48	European Code of Social Security	The Code seeks to encourage the development of a minimum standard for Social Security across the Member States. It relates to the minimum provision to be expected in relation to medical care for those with a morbid condition or pregnant women (7–12); for sickness benefits generally (13–18); unemployment benefit (19–24); old-age benefit (25–30); 'employment injury benefit' (31–38); family allowances (39–45); maternity benefits (46–52); invalidity benefits (53–58); and benefits to support the survivors of a breadwinner (59–64).	16/4/1964	17/3/1968

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
	48A	Protocol to the European Code of Social Security	This protocol is designed to further a desire amongst the members to move from a minimum to the highest standard of social security.	16/4/1964	17/3/1968
	78	European Convention on Social Security	The convention builds on the European Code of Social Security to build obligations accepted by the Member States.	14/12/1972	1/3/1977
	78A	Supplementary Agreement for the Application of the European Convention on Social Security	Technical procedural provisions for the implementation and operation of the Convention.	14/12/1972	1/3/1977
	139	European Code of Social Security (Revised)	Revision of the Code to reflect changing European cultural values and expectations in relation to Social Security. (Given it is not in force, the question must be asked how far this represents shared values.	6/11/1990	NB
	154	Protocol to the European Convention on Social Security	Technical revisions.	11/5/1994	NB

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
	35	European Social Charter	Commitment to the following: "1. Everyone shall have the opportunity to earn his living in an occupation freely entered upon. 2. All workers have the right to just conditions of work. 3. All workers have the right to safe and healthy working conditions. 4. All workers have the right to a fair remuneration sufficient for a decent standard of living for themselves and their families. 5. All workers and employers have the right to freedom of association in national or international organisations for the protection of their economic and social interests. 6. All workers and employers have the right to bargain collectively. 7. Children and young persons have the right to a special protection against the physical and moral hazards to which they are exposed. 8. Employed women, in case of maternity, and other employed women as appropriate, have the right to a special protection in their work. 9. Everyone has the right to appropriate facilities for vocational guidance with a view to helping him choose an occupation suited to his personal aptitude and interests. 10. Everyone has the right to appropriate facilities for vocational training. 11. Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable. 12. All workers and their dependents have the right to social security. 13. Anyone without adequate resources has the right to social and medical assistance. 14. Everyone has the right to benefit from social welfare services. 15. Disabled persons have the right to vocational training, rehabilitation and resettlement, whatever the origin and nature of their disability. 16. The family as a fundamental unit of society has the right to appropriate social, legal and economic protection to ensure its full development. 17. Mothers and children, irrespective of marital status and family relations, have the right to appropriate social and economic protection. 18. The nationals of any one of the Contracting Parties have the right to engage in any gainful occupation in the territory of any one of the others on a footing of equality with the nationals of the latter, subject to restrictions based on cogent economic or social reasons. 19. Migrant workers who are nationals of a Contracting Party and their families have the right to protection and assistance in the territory of any other Contracting Party." (Part 1) Right to Protection of Health: MS commitment "1) to remove as far as possible the causes of ill-health; 2) to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; 3) to prevent as far as possible epidemic, endemic and other diseases." (11) Right to medical assistance regardless of means (13)	18/10/1961	26/2/1965

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
	128	Additional Protocol to the European Social Charter	Workers employment rights. Rights of elderly people (4).	5/5/1988	4/9/1992
	163	European Social Charter (revised)	Revisions to Social Charter. Addition to 11.3 of accidental injury;	3/5/1996	1/7/1999
	123	European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes	Accepts the principle that animal experimentation in science (including medicine) is acceptable within safeguards.	18/3/1986	1/1/1991
	106	European Outline Convention on Transfrontier Co-operation between Territorial Communities or Authorities	Administrative measures 'reinforce and foster neighbourly relations' for co-existence in border regions (1), including the development of cross-border regional agreements. Annexes have model agreements (NB nothing specifically on patient rights, but on local governance.)	21/5/1980	22/12/1981
	50	Convention on the Elaboration of a European Pharmacopoeia		22/7/1964	8/5/1974
	59	European Agreement on the Instruction and Education of Nurses		25/10/1967	7/8/1969
	100	European Convention on the Obtaining Abroad of Information and Evidence in Administrative Matters		15/3/1978	1/1/1983
	119	European Convention on Offences relating to Cultural Property		23/6/1985	NB
	122	European Charter of Local Self-Government		15/10/1985	1/9/1988
	134	Protocol to the Convention on the Elaboration of a European Pharmacopoeia		16/11/1989	1/11/1992
	135	Anti-Doping Convention		16/11/1989	1/3/1990
	188	Additional Protocol to the Anti-Doping Convention		12/9/2002	1/4/2004

P.	No.	Treaty	Contribution	Opening of Treaty	Entry into Force
	199	Council of Europe Framework Convention on the Value of Cultural Heritage for Society		27/10/2005	1/6/2011

3. Recommendations of the Council of Europe

Recommendation/ Report	url	date
Recommendation on Xenotransplantation	https://wcd.coe.int/ViewDoc.jsp?id=45827	19/06/2003
Recommendation on protection of human rights and dignity of persons with mental disorder	http://www.coe.int/t/dg3/healthbioethic/Activities/08_Psychiatry_and_human_rights_en/Rec%282004%2910%20EM%20E.pdf	22/09/2004
Recommendation on research on biological materials of human origin	https://wcd.coe.int/ViewDoc.jsp?id=977859	15/03/2006
Guidelines for RECs	https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=0900001680307e6c	3/12/2010
Report on Ethical Issues Raised by Emerging Sciences and Technologies Roger Strand and Matthias Kaiser (U of Bergen)	https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168030751d	23/01/2015
From Bio to NBIC Convergence: From Medical Practice to Daily Life Rathenau	https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=0900001680307575	2014
Guide on the decision-making process regarding medical treatment in end-of-life situations	https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168039e8c5	2014

4. Activity of the ECtHR

4.1 Principal CaseLaw

Area	Name		Citation
Art 8	Von Hannover n°3 V. Germany	Discussion of the proper considerations in determining Article 8 cases in domestic court	264(2013) 19.09.2013
Art 8	Case of Söderman v. Sweden	Filming in a domestic setting without consent - privacy violation given nature of the filming.	5786/08 12.11.2013
Art 8 (medical files)	Avilkina and Others v. Russia	Disclosing refusal to have blood transfusion whilst in hospital (part of medical record) breach of privacy	171(2013) 6.06.2013
Art 8 DP	Bernh Larsen Holding As and Others v. Norway	Extent of 8(2) in relation to tax authorities	080(2013) 14.03.2015
Art 8 DNA after release without charge	S. and Marper v. United Kingdom	Proportionality of retaining genetic information of a person on the national criminal data base when that person was not charged or convicted of a crime	30562/04 and 30566/04 4.12.2008
Art 8	K.U. v. Finland	Telecommunications - identifying data - confidentiality agreement in identity of telecoms user not a shield where against violation of another's privacy	2872/02 2.12.2008
Art 8	Judgment M.K. v. France	Privacy in electronic communication	120(2013) 18.04.2013

Area	Name		Citation
Art 8	Iordachi and others v. Moldova	Privacy - illegal telephone tapping - outside the scope of criminal investigation	25198/02 10.02.2009
Oviedo	Glass v. the United Kingdom	Decisions concerning a child with disabilities	61827/00 9.03.2004
Oviedo	Vo v. France	Status of the Embryo	53924/00 8.07.2004
Oviedo	Lambert v. France	Correct procedure for removing hydration and feeding from person in vegetative state	46043/14 5.06.2015

4.2 Complete lists of Judgements in ECtHR

Area	Chamber	Judgement
Data Protection	Grand Chamber	http://hudoc.echr.coe.int/eng#{"fulltext":["data%20protection"],"documentcollectionid2":["GRANDCHAMBER"]}
Data Protection	Chamber	http://hudoc.echr.coe.int/eng#{"fulltext":["data%20protection"],"documentcollectionid2":["CHAMBER"]}
Patient Rights	Grand Chamber	http://hudoc.echr.coe.int/eng#{"fulltext":["patient%20rights"],"documentcollectionid2":["GRANDCHAMBER"]}
Private life	Grand Chamber	http://hudoc.echr.coe.int/eng#{"fulltext":["private%20life"],"documentcollectionid2":["GRANDCHAMBER"]}

Annex 5: Programme of the one-day workshop

PRE-MAX

Patients' Rights in the European union – MApping eXercise

CHAFEA/2014/Health/03 concerning mapping patients' rights in all Member States in the European Union

Practical information for participants

Workshop on implementation of patients' rights

We are looking forward to welcoming you to the workshop at the UM Brussels Campus

Programme:

Workshop Day 1	**Thursday, September 10th**
12.00- 13.00hrs	Arrival and Registration plus Light Lunch
13.00- 13.15hrs	Welcome address
13.15-13.30hrs	Introductory address: meeting's objectives and methodology *(Brand)*
13.30-15.00hrs	Session 1 Patient rights law – preliminary results *(Nys/ Shaw)*
15.00 -15.30hrs	Break
15.30- 17.00hrs	Session 2 Enforcement systems *(Townend/Shaw)*
19.00 -22.00hrs	*Dinner*

Workshop Day 2	**Friday, September 11th**
09.00 -9.15hrs	Opening thoughts – reflections from Day 1 & agenda for Day 2 *(Brand)*
09.15- 10.45hrs	Session 3 Council of Europe activities *(Townend/Shaw)*
10.45-11.15hrs	Break
11.15 -12.45hrs	Session 4 The Role of the EU *(Brand/Palm)*
12.45 -13.00hrs	Preliminary Reflections on the workshop
13.00 -13.15hrs	Closing *(Brand)*
13.15 -14.30hrs	Light Lunch

Annex 6: Discussion paper D5

(D5) Discussion Paper

for the one –day workshop (Task 4) on implementation of patients' rights

CHAFEA/2014/Health/03 concerning mapping patients' rights in all Member States in the European Union

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1. Introduction

With the adoption and implementation of the Directive 2011/24/EU on the application of patients' rights in cross-border health care, the EU has not only attempted to clarify the entitlements of citizens to reimbursement for cross-border health care, it has also introduced a framework of rules to ensure a set of common values and operating principles that EU citizens would expect to find - and structures to support them - in any Member State's health system in the EU. They are considered necessary to ensure patients' trust in cross-border healthcare (recital 5), and also more broadly to establish a high level of trust between the patient and healthcare provider (recital 19). However, as has been recognised in the Council Conclusions on Common values and principles in European Union Health Systems (2006), Member States have taken different approaches in the broad area of patients' rights - some have chosen to express them in terms of the rights of patients, others in terms of the obligations of healthcare providers. Enforcement is also carried out differently across the EU.

2. Rationale and framework of the mapping

Within this context the Commission is looking for a mapping exercise of existing patients' rights in 30 countries (including the 28 EU Member States, Norway and Iceland). This study provides an overview of the various legal frameworks as well as other policy tools and mechanisms in place (or in the making) to define, implement and enforce patients' rights. More specifically it is:

(1) To carry out a review of national legislation including soft laws and draft legislation in the field of patients' rights in all EU Member States, Norway and Iceland

(2) To assess the existence and functioning of the structures, procedures and mechanisms instrumental to enforce the identified patients' rights under (1).

(3) To map Council of Europe activities in the field of patients' rights

(4) To organise a workshop to discuss the findings of above tasks with relevant stakeholders and to develop a comprehensive list of useful and achievable patients' rights

This mapping exercise is based on a solid conceptual framework to map and categorise various approaches and national strategies. We focus on three domains of patients 'rights:

- Basic individual patients' rights, such as the right to informed consent; to privacy and dignity; to access to the medical file;
- Consumer-oriented patients' rights, such as to choose one's provider, to second opinion, to safe and timely treatment (patient safety and quality of care) and the right to information of one's health
- Procedural patients' rights, such as the right to complain, to compensation, and to participate in decision-making.

Clearly, these different patients' rights cannot be totally separated from each other. Some could even be considered as 'derived' rights that help to implement and enforce other rights.

3. Preliminary findings per task

In the following sections 3.1 -3.3 the preliminary findings of the mapping exercise on patients' right in all member states of the EU, Norway and Iceland and conclusions drawn from these preliminary findings are presented. At the end of each (sub-)section a text box poses questions and statements derived from the preliminary findings which will be addressed/ put forward for discussion during the workshop. Then, Section 4 focusses on patients' rights in the cross-border setting. On the basis of the preliminary findings section 5 suggests a number of recommendations for further actions subject for discussion as well

General context

Gradually all Member States are developing a legal approach to defining and implementing patients' rights. Only a few Members States are still lacking a special law on patients' rights (Austria, Bulgaria, Ireland, Italy, Malta). However, the legal framework on patients' rights usually extends beyond the scope of a single patients' rights law. Other specific legal acts or governmental decisions addressing specific issues or aspects, the application of general principles derived from civil, criminal or administrative law, or even direct reference to the Constitution will complete the picture. Even if in most cases the adoption of a patients' rights law meant an important shift towards a more patient-oriented approach, still in many cases laws defining the obligations of health professionals or deontological codes continue to be an important source for patients' rights.

Clearly, countries like Finland, the Netherlands and Hungary belong to the patients' rights pioneers. They also represent a different approach in terms of legally defining and implementing patients' rights: the nominate contract model (Netherlands), a special patients' rights law with legally enforceable rights (Hungary) and the vertical or public model (Finland). These pioneers were followed by a next group of countries in the late 1990s and early 2000s, which often were inspired by the adoption and ratification process of the Council of Europe's Biomedicine Convention. Among the most recent group of countries introducing special patients' rights legislation, some actually consolidated or coordinated their existing framework (e.g. Germany, Denmark, Sweden) while others were pushed by increased public interest (e.g. Portugal) or inspired by patients' rights law in neighbouring countries (Luxembourg).

Whereas basic patients' rights seem to have become well-established in most Member States, this seems to be less the case for the more consumer-oriented rights. They also represent a more recent trend that is inspired by an increased attention for ensuring quality and safety in the health sector, but also more generally for 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 the Directive 2011/24/EU on the application of patients' rights in cross-border health care.

For all types of patients' rights alike the main problem remains the actual enforcement of patients' rights. At least for six countries weak enforcement was explicitly mentioned as one of the main challenges (Croatia, Cyprus, Greece, Poland, Romania, Slovenia). On the other hand, it seems that courts are increasingly engaging in this field. Also a lot of alternative enforcement mechanisms are emerging, ranging from monitoring bodies (Bulgaria), patients' rights advocates (Hungary) and

ombudspersons (Poland) to legal representation of individual patients by patients' associations (France).

3.1 Task 1 Review of national legislation in the field of patients' rights

3.1.1 Basic individual rights

All Member States are developing a legal approach to defining and implementing the basic fundamental or classic patient rights to **self-determination and confidentiality** (including the rights to consent; privacy; accessing the medical records). These rights are embedded in several individual human rights frameworks (for example the Biomedicine Convention). In a way this mapping exercise concludes that we will arrive at a minimum set of patient rights in all 30 States.

Despite a common base for basic individual rights, the rights to consent, privacy and accessing medical records are protected by ***multiple mechanisms in each member state***. The right to privacy is perhaps the most heavily protected, with strong penalties in many states for breaches of confidentiality and data protection. Most countries also have strong protections for the right to consent, with some notable exceptions such as Latvia. The right to access one's medical record is also provided for strongly in most member states, although many respondents reported that some hospitals do try to limit access in practice.

How to strengthen the awareness of basic individual rights among patients and professionals?

Good examples of translating basic individual rights in the practice in different setting (rights to consent, access to med. file, privacy)

Ways to develop more common approaches in Europe apart from the general principles

3.1.2 Consumer-oriented patients' rights

With regard to the more consumer-oriented patients' rights our mapping exercise shows that these rights are not yet formally recognized in a lot of member states in general. Some trends can be discerned.

Choice in health care is a complex issue. There is a huge variation in the way it is implemented in various health systems. In some countries choice is an intrinsic value of the health systems, in others it is more regarded as a tool to increase efficiency and improve quality. Although **free choice of provider** is often stated as a fundamental principle and patient right, necessary to protect the trust relationship between the individual provider and the patient, in practice it is often restricted by regulation and reality.

Traditionally, provider choice has been more limited in tax-based health system, with patients being registered with public primary care providers within their local community who act as gatekeepers to control access to specialised care provider. While we see in some of these systems geographical restrictions being lifted and choice being extended to private providers who are contracted by the system, in social

health insurance systems choice is sometimes reduced by more selective contracting or the introduction of (soft) gatekeeping mechanisms in primary care or for chronic patients. On the other hand, in long-term care the introduction of personalized budgets are seen as a way to increase self-determination and choice (Germany, Netherlands).

Perhaps more than regulatory restrictions, practical obstacles created by limited capacity, long waiting times and shortage of providers make choice a theoretical right, especially for people living in rural and remote areas. Often the degree of choice is balanced with the financial implications/risk patients are willing or capable to take. For instance, if patients want to choose for a more distant provider they will have to bear the travel costs. In some health systems people can opt explicitly for more extensive choice options in return for higher user charges (e.g. Denmark, Netherlands). But especially in countries with an important sector of private healthcare provision, differences in choice between public and private patients are considered an importance source of inequity (e.g. Greece).

Even if the right to second opinion is often derived from the right to free choice and has been formally recognized in a growing number of Member States, this right is often even more theoretical with procedural conditions and significant restrictions.

Despite of the fact that clear and objective information about providers and their performance is considered key to making an informed choice about what healthcare provider to consult, a unified, clear and coherent regulation is often still lacking. Increasingly, web sites are set up to provide this kind of information but there are not always well organised and targeted to patients' needs. Quality is the most wanted type of information but generally the least available.

Can a minimum degree of provider choice be agreed for all member states? How could the patients' right to freely choose one's provider be formulated in a European context?

What kind of information needs to be provided to enable choice?

Who should provide? How? In what way? What is the role of the NCPs in that respect?

How could the patients' right to a second opinion be warranted in practice? How can the EU help to ensure that patients are treated according to the best available standards and evidence?

In contrast to the concept of a right to **safe and quality treatment** many respondents refer here to the obligation of the physician, sometimes framed as a patient right, to adhere to a standard of care. In many countries *'the standard of care patients/clients are entitled to expect'* is very broadly described in various legal acts as "meeting certain patients' expectation and or "adhering to the current scientific medical knowledge". The right is embedded in the contractual relationship between provider and patient (e.g. Austria), in dedicated patient rights acts (e.g. Finland, Iceland) or can be recognized in a set of different laws (e.g. Italy) However, this remains often very broad and not further specified.

The obligation of professionals to adhere to a certain standard of care is structurally ensured by the formal recognition via licensing and accreditation of healthcare professionals in almost all countries and to a lesser degree - but increasingly - of healthcare institutions (e.g. hospitals) providing care. Poland is an exception here only providing voluntary system of accreditation.

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. Reporting publicly about outcomes is practiced in Scandinavian countries (Iceland, Norway, Denmark, Finland) but not common in many other countries. Countries which have not stipulated patient safety and quality formally include Ireland and Malta.

Implementation of patient safety and quality policies is a task often spread over various institutions in the healthcare sector including typically the Ministry of Health, professional chambers and a dedicated institute for quality.

The recognition of the right to ***treatment in a timely manner***, hence provisions on waiting times and list are to a lesser degree – compared to quality and safety - formally recognized in the 30 countries. Among the countries addressing waiting time, some have set maximum waiting times whereas other only have established criteria how waiting lists need to be established without specifying limits.

What needs to be done beyond the actions included in the2009 Recommendation for patient safety to enhance the right to safe and quality treatment?

- Who should do what?

How do national quality institutes that coordinated/ supervise domestic standards of care need to be equipped (remit, position, controls, etc.) to effectively perform checks?

What kinds of outcome indicators are needed? For whom?

European exchange of quality/patient safety indicator for x-border care needed, so that patient can decide if she/he wants to go?

Should quality of care and patient safety be approached from a consumer protection route by the EC?

3.2 Task 2 Review of enforcement mechanism for the identified patients' rights under (1)

This mapping exercise considers the enforcement mechanisms in the abstract – i.e. not how they are applied in practice (how discretions are used or the standards of evidence that are required for a successful complaint or action, or whether the system is adequately funded to make it available to patients) but the range of possibilities that are available in the Law. In this General Context section, it must be stressed that not all the mechanisms described occur in each jurisdiction.

Legal Bases range from sanctions in the criminal Law for assaults or violation of data protection rights (under Directive 95/46/EC) or in professional (contract) Law for violation of codes of practice or professional standards. Here the sanctions include imprisonment, fines, or suspension or removal of a licence to practice. Civil or tortious liability for compensation is seen through either a no-fault approach, or a fault- or negligence-based system. Administrative or constitutional Law (including human rights Law) is also used as the basis for an action, with redress being available either through the formal court structure or through more informal 'ombudsmen' or other tribunals. It is interesting that the Directive on Cross-border Patient Rights does not of itself create legal bases for redress, although in a number of jurisdictions the National Contact Point is indicated as a procedural route. The forums that are available to address breaches of patient rights are from the formal to the informal. Criminal, civil, administrative and constitutional courts are possible forums for complaint, as are professional 'courts', ombudsmen and tribunals. In the first instance, however, a complaint will be made to the health care provider, be that the professional directly dealing with the treatment or the institution within which the care is provided. Here, a range of dispute resolution mechanisms is used, again with varying degrees of formality. At this general level, however, it is very interesting to see that two of the key elements that patients making a complaint might want to see are not present in the patient rights legal landscape: explanation and apology.

Sources of the Law differ between jurisdictions. A large number of MS have specific patient rights legislation containing the right to complain. Equally, many use general Laws relating to compensation, or the general tort Law system to find a solution to the complaint. This relates most obviously to quality of care issues, and the long-established area of medical negligence – areas that have a physical or psychological damage. What is not as well established is redress for a breach of a right *per se*. This diversity in approaches to procedural rights within each jurisdiction that ensure the patient's ability to complain and 'manage' any adverse effects of their treatment, and that could make complaint difficult and unpredictable, is amplified in the cross-border situation. Take for example, the enforcement of the right to informed consent.

From the Country Correspondent reports, there are many Member State where the full range of legal remedies and mechanisms is available to a patient, i.e. the patient can pursue his or her complaint through the criminal Law, the civil Law of Tort (medical liability), through a parliamentary or health Ombudsman, and/or through a professional hearing (or that their complaint could initiate a professional action as well), and that this process might be started through an informal complain made to the health carer or the institution, or to other bodies (Austria, Hungary, Italy, Netherlands, Portugal and the UK). In other jurisdictions, the expert reports that there are no specific procedures for informed consent, but that the general Law applies, which could mean that all the above actions are available (Iceland, Latvia, Lithuania, Luxembourg, and Slovenia). In Germany, only the criminal liability was mentioned, whereas in other jurisdictions, the criminal Law was not mentioned, only the general civil Law (Belgium, Croatia, France, Norway, and Poland). It should be noted that there are variations within this civil liability. For example, the experts from Belgium and Sweden pointed to the difficulty in making a medical negligence claim for breach of informed consent regulations, and Estonia indicated that the burden of proof was on the patient. Some experts indicated the role of a National Agency for Patients' Rights And Complaints (Denmark), an Office of Patient Rights (Greece), Malpractice

Commission (Romania), or Health Care Surveillance Authority (Slovakia). What was particularly interesting in the context of the survey being about Directive and cross-border patient rights, no expert mentioned the role of the National Contact Points in this context. Further, no expert discussed how rules of which Law and which forum would apply in the international context.

What is clear is that a patient coming from outside a Member State will have a complicated and culturally different (often almost opaque) system to consider. It is unclear how far this will act as a barrier to deciding to use rights to cross-border treatment under the Directive, but it certainly raises the question of how far harmonisation of processes, or at least a strengthening of the role of the National Contact Points.

Is the range of dispute resolution mechanisms fit for purpose? In particular, is a fault-based approach to complaint or redress for mistake appropriate for encouraging good medical practice? Does fault-based dispute resolution mitigate against explanation and apology?

What is or should be the role of the National Contact Point in assisting the patient to negotiate the different dispute resolution mechanisms?

3.3 Task 3 Council of Europe activities

The Council of Europe's mandate concerns, in part, the protection of fundamental rights and freedoms of the citizens of Europe. Its 47 Member States (including all the European Union Member States) have taken direct and indirect steps to promote Patient Rights across Europe.

The starting point for Council of Europe Activities is the 1950 Convention for the Protection of Human Rights and Fundamental Freedoms (The European Convention on Human Rights), with its enforcement through the European Court of Human Rights. The convention articulates the concept of human dignity. Given its origins a lot of the Convention concerns rights relating to the rule of Law and operation of justice. However, there are key foundational rights for patient rights. Article 1 establishes the right to life. . Article 8 gives a right to Private and Family Life,. Further, individuals have the right to freedom of thought conscience and religion (Article 9), and to freedom of expression (Article 10). These rights form the beginning of rights for patients. The ECtHR has interpreted the right to private and family life in a number of medical contexts. So, patient rights stand on a platform of dignity and the specific, long-standing principle of privacy in medicine from the Convention.

The 1997 Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine contains the strongest statement of patient rights in the broader Europe. The duties flow from the Article 1 obligation that "Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine". What follows is not limited to patient rights – for example, Article 2 indicates the supremacy of human dignity over "the sole interests of society or science" – but it contains fundamental patient rights. Article 3 demands "equitable access to health care of

appropriate quality" but Parties do this "taking into account health needs and available resources". Appropriate quality is, in part, considered in Article 4, which ties health care to "relevant professional obligations and standards". Article 28 broadens the discussion about appropriate quality by requiring that the "fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation".

Article 5 of the Convention on Human Rights and Biomedicine requires Parties to require a general principle that "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it", where s/he is given "beforehand […] appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks" and that s/he can "freely withdraw consent at any time". Article 6 provides for those who are not legally competent to give consent, with provision for a guardian (be that person or other authority) to safeguard the person's Article 5 rights in his or her place. Article 6 includes the provision that "The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity"; the incompetent adult "shall as far as possible take part in the authorisation procedure". What is not clear is how the guardian has to act in making decisions on behalf of another. Articles 7 and 8 address situations where consent is not required: the treatment of the mentally ill and those in emergency situations where consent is not possible, and in both instances a measure of serious harm occurring without the intervention is required. Article 9 requires that "previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account". Article 10 establishes what again conforms to an international standard of privacy and rights to information: "1. Everyone has the right to respect for private life in relation to information about his or her health. 2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed. 3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient". Article 23 requires Parties to "provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice"; to compensate for "undue damage resulting from an intervention" (Article 24); and that sanctions be in place for infringements of Convention provisions (Article 25).

These Articles are given in some detail to show that the agreement in this area of the Convention is in line with other international instruments, particularly the Helsinki Declaration, and could be said to be international 'best practice' to ensure patient autonomy and dignity.

Whereas the Council of Europe has developed these landmark instruments in relation to biomedicine, they have not been universally accepted by the Member States. No Party has brought the Protocol on genetic testing into force, with only Moldova, Montenegro, Norway and Slovenia ratifying it. The ratification and entry into force for the other Protocols is somewhat better, but like the ratification and entry into force of the Convention itself, it is not universal amongst the Member States. There are a number of further lines of Council of Europe activity at the Treaty or Convention level

that have a bearing on Patient Rights. Data protection in Europe originates in the Council's 1981 Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. Again, the acceptance by the Members is limited.

The Country Correspondents' responses to questions about the impact of Council of Europe Activities in their countries revealed very mixed responses. In some, the impact, especially of ECtHR cases, was reported to be significant. In Austria, Council activity was said to have inspired the patient safety strategy; in Belgium, professional hearings have been made public following ECtHR jurisprudence; the VO v France decision was said to have generated discussion in Germany; the Icelandic biobanking Law acknowledges Council of Europe influences; the Norwegian legislation on biomedicine is influenced by the Biomedicine Convention; in Poland decisions concerning blood transfusions and Jehovah's Witnesses were influenced by Council activity; and in Slovenia Laws relating to assisted reproduction and transplantation of human body parts were also influenced by Council of Europe activity. Further, correspondents indicated that ECtHR decisions more generally were followed in their domestic Law (especially, as in The Netherlands, when the country was a party to the case). However, in other countries, the reported impact is quite thin. This poses the question, is this the case?

Is the objection to the Convention specific to issues in relation to research and the pharmaceutical business, or does it also concern patient rights?

Is the impact of Council of Europe activity really as varied (and in some cases limited) as correspondents indicate?

4. Preliminary findings on patients 'rights in the cross-border situation

This section highlights some of the specific issues related to the application of patients' rights in the context of cross-border patients, e.g. informed consent and access to one's medical record possibly impeded by language problems, choice of provider and information for cross-border patients, procedural rights and continuity of care.

Self-determination & Confidentiality

While in many member states no specific provisions exist for cross-border patients, the existing laws regarding informed consent, privacy or access to the medical record equally apply to all health care provided on their territory. However, for some country respondents it is clear that the cross-border situation may require some special attention. Some highlight the possibility to receive an e-copy of the medical file for cross-border patients (Estonia, Luxembourg, Romania, Slovenia). In France and Norway, mandatory translating services are covered by law with regard to cross-border patients. Finally, the EXPAND cross-border project (among others in Luxembourg) aims to make cross-border patient data sharing more efficient.

Quality and safety

Many countries foresee as a general condition to grant prior authorization for *cross-border care* that the service is part of the statutory benefit basket but cannot be provided within medically necessary time limits. Whereas in principle prior authorization cannot be granted on the basis of quality and patient safety reasons,

this seems to be a strong motivation for cross-border care. Although the Directive 2011/24.EU provides for the possibility of member states to require and refuse prior authorization for treatment by providers who would raise quality and safety concerns, none of the countries seems to have actually implemented specific regulations in that respect.

Choice

As a principle Directive 2011/24/EU extends patients' choice option 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 questions: (a) to what extent does this increase pressure on member states to extend choice options and also allow reimbursement for non-contracted providers domestically?; (b) to what extent member states are allowed to limit reimbursement for cross-border care to rates that are applicable to non-contracted providers? In countries where health insurers are traditionally bound to also reimburse (to a lesser extent) non-contracted care (e.g. Austria, Netherlands), these questions may actually lead to reductions in choice domestically.

Another issue is whether the absence of choice options domestically because the specific care or expertise is not available in the country (e.g. rare diseases) could justify to getting care and/or second opinion in another member state (see quality and safety section). Also the applicability of conditions that actually limit choice, such as referrals by a domestic provider or the requirement that first all domestic treatment options have to be exhausted, need to be questioned as to their conformity with EU rules.

What specific requirements would be needed to guarantee self-determination and confidentiality to cross-border patients? How can continuity of care and good follow-up for cross-border patients be guaranteed while respecting confidentiality and safe data sharing?

How should patients' right to safe and quality care in a timely manner be guaranteed in a EU context? Should next to the concept of "undue delay" a similar concept be needed to define a minimum standard for quality and safety?

How should provider choice be defined in a cross-border setting? What conditions limiting choice may be justified or not?

Is the information provided by the NCPs (and other relevant actors) sufficient to allow patients to make an informed choice of provider in another member state and to assess quality and patient safety aspects?

5. Next steps

In addition to the full implementation and application of the Directive 2011/24/EU the question remains to what extent the development of a European Charter of patients' rights can help to improve the position of cross-border patients and support the further development of patients' rights at national level.

Is it feasible and desirable to define a minimum set of patients' rights at EU level?

If so, what form should this take and how would the various rights need to be termed?

Should these rights apply specifically to cross-border patients or to all patients in the EU?

Should the NCPs play a role in promoting patients' rights at an EU level?

How could the enforcement of patients' rights be strengthened by the EU?

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