13 *Patients' rights: from recognition to implementation*

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Introduction

Patients' rights can be seen as a precondition to empowering people and moving to health systems that are more person-centred. They provide a foundation for citizens to be considered as actors in control of their own health care delivery process.

Increasingly, the challenges and potential solutions that health systems are facing are explored through a patients' rights lens. Changes, such as the rapid ageing of the population and the rising burden of chronic conditions (including mental health problems), along with scientific and technological developments as well as cultural preferences, are creating new questions that are often debated within the context of fundamental rights, including self-determination, dignity and equality. The growing complexity of health care together with innovations in the fields of medicine (e.g. precision medicine) and of information and communication technology (ICT) (e.g. e-health), along with an increased focus on quality and safety, are likely to impact patients' rights, especially with regard to privacy and equity. These elements require the development of coherent strategies around citizens' involvement and patients' rights with respect to health and social care. The notion of patients' rights reflects a shift towards a more equal relationship between the individual service user and the provider, such that the provider acts as a clinical expert in support of a more active patient, based on increased patient autonomy and better communication (Emanuel and Emanuel, 1992) (*see* Chapter 2).

The formulation of patients' rights can also help to grow awareness. For patients, this includes a more active role in their own care, while for providers it involves greater understanding of the impact of interventions on patients. It can also guide and steer policy-makers in reforming health systems by recognizing the potentially vulnerable position of patients due to information asymmetry, but also due to the

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sometimes critical and intimate context, which requires a great deal of trust between patients and caregivers.

This chapter analyses the relevance and usefulness of patients' rights for achieving broader health system objectives of person-centredness and patient empowerment. It begins by presenting a conceptual framework looking at different aspects of patients' rights, followed by an assessment of the state of patients' rights and their enforcement systems in various countries. This also highlights some national examples of good practice. Drawing on the existing evidence about the actual use of patients' rights and their impacts on outcomes at individual, organizational and system levels it then develops some policy lessons for further promoting, defining and implementing patients' rights.

The chapter draws on a mapping exercise that was conducted in 2015 and funded under the EU health programme. The project explored the situation in 30 European countries (28 EU Member States plus Norway and Iceland) using a survey of national patients' rights experts (European Commission, 2018).

Defining patients' rights

Historically, the notion of patients' rights is firmly rooted in the recognition of the inherent dignity of all human beings and their equal and unalienable rights, such as the Universal Declaration of Human Rights (UDHR) and other sources of international law. Given the particularly vulnerable position of people when seeking health care, it was considered important to specify these basic rights in the care setting. Clearly, basic rights such as the right to be free from cruel, inhuman or degrading treatment (Article 5 UDHR) or the right to privacy (Article 12 UDHR) have a special meaning when transferred to a care context. Patients' rights are primarily addressed to health professionals (and caregivers more generally), who have a duty to respect the basic human rights of the people they treat or care for in all circumstances. This is essentially based on bioethical principles as expressed in the Hippocratic Oath (Will, 2011). However, patients' rights also cover more systemic factors and state responsibilities in the organization and delivery of care. State parties have three types of obligation: to respect human rights themselves, to protect against violations by third parties, and to fulfil the conditions for their realization

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(Office of the United Nations High Commissioner for Human Rights, the World Health Organization, 2008).

Some commentators distinguish individual rights 'as a patient' from the collective and social rights 'to become a patient'; the latter refer to issues of coverage, access and entitlements (Nys & Goffin, 2011). Individual patients' rights and social rights are considered to be different in nature, although the right to medical care is also enshrined as a fundamental human right (Article 25 UDHR). Individual rights aim at protecting the individual sphere, whereas social rights, such as the right to health care, are to safeguard the participation of people in social benefits (Leenen, 1994). Patients' rights prevent society from unlawfully intruding into a person's private sphere, while access rights to health care require governments to work towards their full realization in accordance with resource constraints.

In a similar way, patients' rights are distinguished from the concepts of patient safety and quality of care. Indeed, the right to medical treatment that is safe and of high quality is seen to be part of a consumer protection framework. Some argue that violations of standards of quality and safety should be interpreted differently from a breach of human rights, the only exception being where maltreatment by a health care provider is systemic (Ezer & Cohen, 2013).

The need for better legal protection of patients was prompted by evidence demonstrating variation in medical practice associated with variations in health outcomes, along with evidence of adverse events and medical errors. It also highlighted the importance of informational and procedural rights, often referred to as consumer-oriented rights, although they clearly have a human rights component as well.

While human rights are universal, indivisible, interdependent and interrelated, social and consumer rights leave more room for national variation, determined by social, economic and cultural factors. However, even if social and consumer-oriented patients' rights have different origins and address different needs and expectations, they cannot be completely separated from the human rights framework. This is illustrated by the fundamental right to "the enjoyment of the highest attainable standard of physical and mental health", which was first internationally recognized by the 1946 Constitution of the World Health Organization (WHO). This human right to health is generally defined in broad terms, ranging from rights related to broader health determinants to the right

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to medical care and access to health services. It also includes more typical patients' rights, such as the right to be free from non-consensual medical treatment, the right to seek, receive and impart information and ideas concerning health issues, or the right to have personal health data treated with confidentiality (Office of the High Commissioner for Human Rights, 2000). It also includes collective citizens' rights such as the participation in health-related decision-making at national and community levels. The involvement of citizens at a systems level is expected to help reduce the gap between theory and practice in individual patients' rights (Hart, 2004).

Overall, then, these rights are complementary and interdependent (Roscam Abbing, 2014). Patients' rights can only be fully accomplished in an environment that ensures that the care provided meets high standards of quality and safety, and that has put mechanisms in place for redress or compensation where standards are not being met. A strong patient voice and the promotion of patients' rights are also considered important for maintaining a focus on quality, especially in times of increased financial pressures (OECD, 2017).

European frameworks for patients' rights

Patients' rights are mainly determined at the national level and to some extent reflect differences in national contexts, especially where this concerns ethical questions, such as around the beginning and end of life. However, supra-national frameworks, such as the aforementioned UDHR and, within Europe, the European Convention on Human Rights (1950), play a role in influencing national legislation, as do more recent policy concerns, such as growing migration, increased mobility of patients and the need for cross-national cooperation in health care as well as the internationalization of medical research (Roscam Abbing, 2004).

Within the European context, several developments have contributed significantly to promoting patients' rights legislation in European countries (Leenen, Gevers & Pinet, 1993). These include the 1994 Amsterdam Declaration on the promotion of the rights of patients in Europe. It was a first attempt to formulate a consistent set of patients' rights that should apply irrespective of the characteristics of a country's health system or specific circumstances of patients. The Declaration sought to enhance awareness among citizens about their (active) role in

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health care, to strengthen collaboration and trust between patients and providers, and to support policy-makers in developing patient-centred policies (Table 13.1). This vision of strengthening citizens' voice and choice in health care was later reasserted in the Ljubljana Charter on Reforming Health Care (1996).

This was followed, in 1997, by the European Convention on Human Rights and Biomedicine (Oviedo Convention) (Council of Europe, 1997). While primarily intended to protect human dignity against misuse of biological and medical advances, it also contains general patients' rights (Table 13.1). These rights can be directly invoked in countries that have ratified this convention, provided they are unconditional and sufficiently precise (Nys & Goffin, 2011).

Within the EU, the issue of patients' rights in the context of EU integration was pursued as early as 1984, when 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 the Active Citizenship Network, a group of European civic organizations, launched a European Charter of Patients' Rights, which contains 14 specific patients' rights and three additional active citizenship rights (Box 13.1). This initiative was inspired by the Charter of Fundamental Rights of the EU that was adopted in Nice in 2000. Mainly drawing on the right to health care (Article 35 of the Charter of Fundamental Rights of the EU), the focus was on access to high quality health care, which was seen to be of particular importance in the context of EU enlargement and increasing mobility in health care. Since 2007 an annual European Patients' Rights Day has been organized to increase awareness about the importance of patients' rights.

Another example of a voluntary arrangement developed by civil society is the European Cancer Patients' Bill of Rights that was launched by the European Cancer Concord initiative in 2014. Motivated by the substantial differences in cancer incidence and mortality between countries in Europe, the charter provides three main rights: the right to accurate information and pro-active involvement, the right to timely and appropriate specialized care underpinned by research and innovation, and the right to be treated in health systems that ensure improved outcomes, patient rehabilitation, best quality of life and affordable health care (Lawler et al., 2014).

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Box 13.1 The European Charter of Patients' Rights

1. Right to preventive measures
2. Right of access
3. Right to information
4. Right to consent
5. Right to free choice
6. Right to privacy and confidentiality
7. Right to respect of patients' time
8. Right to the observance of quality standards
9. Right to safety
10. Right to innovation
11. Right to avoid unnecessary suffering and pain
12. Right to personalized treatment
13. Right to complain
14. Right to compensation

Rights of active citizenship

- Right to perform general interest activities
- Right to perform advocacy activities
- Right to participate in policy-making in the area of health

Source: Active Citizenship Network, 2002

In 2011 the EU adopted and implemented the Directive on the application of patients' rights in cross-border health care, which essentially focuses on social and consumer patients' rights in the context of cross-border health care (Table 13.1).

Among the four frameworks reviewed here, only the Biomedicine Convention and the EU Directive are legally binding. Yet all four influenced the promotion and development of patients' rights in Europe, as noted earlier. While there are slight differences in the formulation of these rights, with an emphasis on certain dimensions, there is relative consensus on the core elements of patients' rights. Specific patients' rights that are aimed at protecting specific patient groups (e.g. minors, those with disabilities or those with mental health problems) or people in specific circumstances (e.g. clinical trials, genetic testing) are omitted from the assessment presented in Table 13.1.

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Table 13.1 *Patients' rights as defined under four different European frameworks*

Human rights categories	WHO/Europe Amsterdam Declaration (1994)	Council of Europe Biomedicine Convention (1997)	Active Citizenship Network European Charter of Patients' Rights (2002)	EU Directive on the application of patients' rights in cross-border health care (2011)
Right to respect, dignity, integrity and non-discrimination	Respect (1.1) Integrity and protection (1.3) Respect of values, convictions and culture (1.5, 1.8) Dignity in treatment and dying (1.8, 5.11) Support of family, relatives and friends (5.9) Non-discrimination (6.2)	Protection of dignity and identity, non-discrimination, respect of integrity (1) Primacy of the interest and welfare of the human being (2)		Non-discrimination with regard to nationality (4.3)
Right to privacy and confidentiality	Respect of privacy (1.4, 4.6–8) Confidentiality and protection of personal information (4.1) Access to medical file (4.4) and control over personal and medical data (4.5)	Respect for private life in relation to personal health information (10.1)	Confidentiality of personal information and protection of privacy (6)	Union provisions on the protection of personal data (4.2.e) Access to (written or electronic) medical record (4.2.f and 5.d)

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Table 13.1 *(cont.)*

Human rights categories	WHO/Europe Amsterdam Declaration (1994)	Council of Europe Biomedicine Convention (1997)	Active Citizenship Network European Charter of Patients' Rights (2002)	EU Directive on the application of patients' rights in cross-border health care (2011)
Right to liberty and self-determination	Self-determination (1.2) Information (2) • Health services (2.1) • Health status (2.2) • Treatment options (2.2) • Second opinion (2.7) • Health providers (2.8) Informed consent (3.1)	Free and informed consent (5) Information about health (10.2)	Information regarding health status, health services (3), treatment options (4) Informed consent (4) Free choice (5)	Information • on quality and safety standards and guidelines (4.2.a) • on providers (incl. availability, quality and safety, prices, authorization or registration status, professional liability protection (4.2.b and 6.3) • on treatment options (4.2.b) • on rights and entitlements to cross-border care (5.b and 5.4) • on patients' rights, complaints procedures and mechanisms for seeking remedies, dispute settlement (6.3)

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Right to health	Protection of health and pursuit of highest attainable level (1.6) Access to health services (5.1) • Equity and non-discrimination (5.1, 5.5) • Quality of care (5.3) • Continuity and cooperation (5.4) • Choice (5.6) • Social care (5.7) • Relief of suffering (5.10) and humane terminal care (5.11)	Equitable access to health care of appropriate quality (3) Observance of relevant professional obligations and standards (4)	Preventive measures (1) Equal access to health services (2) • Respect of patients' time (7) • Observance of quality standards (8) • Safety (9) • Access to innovation (10) • Avoidance of unnecessary suffering and pain (11) • Personalized treatment (12)	Care in accordance with the standards and guidelines on quality and safety laid down by the Member State of treatment (4.1.b) Non-discrimination • scale of fees (4.4) • medical follow-up (5.c) Reimbursement of cross-border health care (7–9) • same level of reimbursement (7.2.4) and transparent mechanism for calculation (7.2.6) • applicable limitations, conditions, eligibility criteria, formalities can only apply if justified by overriding reasons of general interest (7.2.7–9) • prior authorization cannot be refused if treatment cannot be provided domestically within a medically justifiable time-limit (8.5) • fair, transparent and swift administrative procedures (9)

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Table 13.1 *(cont.)*

Human rights categories	WHO/Europe Amsterdam Declaration (1994)	Council of Europe Biomedicine Convention (1997)	Active Citizenship Network European Charter of Patients' Rights (2002)	EU Directive on the application of patients' rights in cross-border health care (2011)
Right to remedy		Judicial protection against unlawful infringement (23) Fair compensation for undue damage (24) Application of appropriate sanctions (25)	Complain and receive feedback (13) Sufficient and swift compensation in case of harm caused by treatment (14)	Transparent complaints procedures and mechanisms to seek remedies in case of harm (4.2.c) Systems of professional liability insurance, or equivalent (4.2.d) Procedures for appeal and redress in case of non-respect of entitlement rights (5.b)
Right to participation, representation and collective action	Representation at each level of the health system (5.2)		Perform general interest and advocacy activities for the protection of patients' rights (part III) Participate in health policy-making (part III)	

Types of patients' rights

Drawing on the comparison of patients' rights frameworks in the preceding section, we identify 13 core patients' rights that can be clustered into six categories: self-determination, confidentiality, access to health care, choice, information and redress (Table 13.2). These rights require specific action or measures for implementation, while others, such as the right to respect a patient's integrity, do not necessarily require a particular translation but are more reliant on attitudes within health care settings. Similarly, the right to collective participation and action is not included in this list as it is considered a fundamental citizens' right that transcends the position of a particular individual, although it plays an important role in helping to implement individual patients' rights (Hart, 2004).

Table 13.2 *Clusters of core patients' rights as identified from four patients' rights frameworks*

Self-determination	1. The right to (informed) consent
	2. The right to participate in (clinical) decision-making/to choose treatment options
Confidentiality	3. The right to data confidentiality
	4. The right to access one's medical record
Access to health care	5. The right to benefit from medical treatment according to needs
	6. The right to safe and high-quality treatment received in a timely manner
Choice	7. The right to choose a health care provider
	8. The right to a second opinion
Information	9. The right to information about one's health
	10. The right to information about health care providers
	11. The right to information about rights and entitlements
Redress	12. The right to complain
	13. The right to compensation

Several of these rights are interconnected. Thus, informational and procedural rights ('information' and 'redress') cut across the various clusters as they support the implementation and protection of other rights.

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For example, the right to information about one's health is intrinsically connected to the right to informed consent. Informed consent is also linked to the right to a second opinion, which at the same time can be considered as a right 'derived' from the right to choose one's provider. Provider choice in turn is supported by the right to information about health care providers. The right to access medical records can also be seen as an informational right. While it serves as a way to control confidentiality and accuracy of personal data, it is also an important lever to evaluate if the right to safe and high-quality treatment was violated and to exercise the procedural right to complain or to claim compensation in case of any harm. Finally, the right to participate in clinical decision-making is perhaps seen less as a traditional right but rather as an extension of the right to informed consent.

Mapping the implementation of patients' rights in EU Member States

EU Member States have taken different approaches to implementing patients' rights, reflecting differences in health systems as well as countries' legislative traditions (Roscam Abbing, 2014). Most European countries have brought together all general patients' rights into one dedicated law (Hart, 2004). Finland, the Netherlands and Hungary were among the first to develop such a unified law, followed by a second group of countries which were inspired by the Council of Europe's Biomedicine Convention. More recently, countries such as Germany and Denmark have consolidated or coordinated their existing framework, while others introduced relevant legislation following public pressure (e.g. Portugal) or examples from neighbouring countries (e.g. Luxembourg). At the time of writing, Bulgaria and Italy were the only countries that had yet to implement a special law or charter on patients' rights.

The most important initial driver of the development of patients' rights legislation was the fundamental rights movements of the 1970s, which was accompanied, in some countries, by the development of health law as a separate legal discipline (e.g. the Netherlands, Norway, Slovenia). Among countries in central and eastern Europe, the political transition of the early 1990s promoted patients' rights legislation (den Exter, 2002). As noted earlier, civil society, especially patients' organizations, also played an important part in placing patients' rights on the political agenda (e.g. France, Romania), while more recently media

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coverage of patients' rights violations has helped to increase awareness of this issue.

The adoption of special patients' rights laws typically meant an important shift towards a more patient-oriented approach, not only with respect to formulating more detailed rights but also in terms of improving transparency and enhancing awareness. At the same time, other legislation (such as civil, criminal, disciplinary or administrative law) will still apply, in particular as far as procedural patients' rights are concerned, such as the right to compensation, which is often enforced through traditional legislation governing breach of duty of care or negligence.

As countries pursue different routes, and do so at a different pace, any attempt to classify or map approaches will intrinsically be limited (Nys & Goffin, 2011). Concerning special patients' rights laws, countries use different approaches to enforcement: legal, quasi-legal and moral rights (Fallberg, 2000) (Table 13.3).

- ***Legal patients' rights*** are well-defined, actionable rights based on the (horizontal) relationship between the provider and the user of health services. Taking the contractual nature of this relationship as the legal basis, some countries have formalized this as a specific 'sui generis' contract to distinguish it from other contractual forms; examples include the Netherlands (Table 13.3). Other countries have also taken a private law approach to adopting directly enforceable patients' rights laws, with countries such as Germany, Portugal and Spain classifying it as a generic service contract (Barendrecht et al., 2007).
- ***Quasi-legal patients' rights*** refer to (vertical) obligations imposed on health care providers by public or administrative law or legally binding codes of medical duty. Finland led the way with an act rooted in the Nordic legal tradition of obligations (rather than rights) defined in the context of the 'social contract' between the state and its citizens (Fallberg, 2000). Elsewhere, enforcement relies more on public sector regulation, such as in France and Greece (Table 13.3). In contrast to the legal patients' rights approach, quasi-legal rights imply that any direct civil action taken by the individual in case of violation of rights would be subject to a prior sanction taken against the provider. Also, in countries that have implemented a legal patients' rights framework, but where this framework does not contain specific sanctions or enforcement mechanisms, then these rights could be classified as quasi-legal by nature. This is, for example, the case in Scotland.

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Table 13.3 *Mapping national approaches according to their enforceable character and type of legislation*

	Legal patients' rights		**Quasi-legal patients' rights**	**Moral patients' rights**
	horizontal / private		***vertical / public***	
	'Sui generis' private contracts	***Generic private contracts***		
Special patients' rights law	Netherlands (1994) Estonia (2001) Lithuania (2001) Slovakia (2004)	Hungary (1997) Belgium (2002) Spain (2002) Poland (2009) Latvia (2010) Czech Republic (2011) Germany (2013) Luxembourg (2014)	Finland (1992) Iceland (1997) Norway (1999) France (2002) Romania (2003) Croatia (2004) Greece (2005) Slovenia (2008) Cyprus (2005) Portugal (2014) Denmark (2014) Sweden (2015)	Austria (2002) United Kingdom (England) (2009) Ireland (2012) Malta (2016)
Patients' rights split across different pieces of legislation	Bulgaria, Italy			

Source: adapted from Nys & Goffin, 2011

- ***Moral patients' rights*** rely on soft law, non-legally binding documents such as patient charters or codes of conduct. This is mostly the case in countries that operate a public health service as the concrete realization of the state's duty to provide medical treatment to its citizens. Here, patients' rights tend to be included in non-binding charters and they tend to have a 'declaratory' function through formulating citizens' legitimate expectations vis-à-vis the state and its agents, and they are aimed mainly at preventing any violation through raising awareness among patients and providers. At the same time, in some countries such charters can have quasi-legal power, such as the NHS Constitution in England, or in Austria agreements between the federation and individual states that establish patients' rights charters. These are, however, not legally binding on health care providers.

Table 13.3 summarizes national approaches to patients' rights legislation across 30 countries in the EU and the European Economic Area. Further detail on individual countries' approaches is provided in the Should this be cited as Appendix 13.1?.

The inclusion of countries in a particular category does not reflect the strength of patients' rights enforcement. In practice, legal rights are not necessarily more enforceable than quasi-legal or moral rights. Several countries with quasi-legal approaches, such as the Nordic countries, have elaborate dispute settlement mechanisms in place, including no-fault patient injury compensation schemes. Also, the NHS Constitution in England is enforced through the regulation of fundamental standards set out in the health and social care legislation. Here, the Care Quality Commission, the independent regulator of all health and social care services in England, can sanction any breaches of the requirements through NHS staff (Care Quality Commission, 2015).

The nature of individual patients' rights

If patients' rights are to contribute to more person-centred health systems, decision-makers need to ensure their implementation as enforceable legal rights that enable people to exercise these rights. Not linking patients' rights legislation to actual enforcement mechanisms and procedures reduces related laws and frameworks to mere declarations or principles with little practical use and usefulness. This section explores how countries in Europe had defined and implemented patients' rights. It is structured according to the three clusters of the 13 core patients'

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rights we identified earlier in this chapter: self-determination and confidentiality; access and choice; and information and redress. We examine each cluster in turn.

Self-determination and confidentiality

All EU Member States have developed (or are developing) a legal approach to defining and implementing the traditional rights to self-determination and confidentiality, including the right to informed consent, to participate in clinical decision-making, to data confidentiality and to accessing one's medical record. These rights are often protected by multiple mechanisms.

Most countries have implemented strong mechanisms to protect the right to consent as it is fundamental to respecting a person's autonomy (Buelens, Herijgers & Illegems, 2016). There can be considerable variation in the way consent should be given (written, oral, implicit), although certain practices in place in some countries do not appear to be compatible with how informed consent is generally understood. For example, in Latvia, several hospitals require patients to sign a general consent form upon admission, which commits individuals to agree to any treatment recommended by the treating clinician. In practice this means that the consent given takes the form of a contractual obligation, that is, the patient can only be admitted to the hospital upon giving consent in advance. This further implies that the individual patient is being denied the right to be informed about alternative treatment options. This observation highlights the need for greater emphasis on self-determination in some European countries.

More generally, there is a growing perception that informed consent as a concept may be outdated in that it tends to overly rely on the notion of the patient as a passive recipient to whom certain information must be disclosed. Some commentators have argued for the development of a new ethical and legal standard that prioritizes patient autonomy in decision-making and which has been described as 'informed request' (Moulton et al., 2013). The right to actively take part in decisions about treatment options has so far been formally recognized in a limited number of countries, such as Finland, Germany, the Netherlands, Norway and Sweden.

In most countries the right to privacy and confidentiality is perhaps even more strongly protected than the right to informed consent, with

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various civil, criminal and constitutional protections in place, including complaint and redress mechanisms and penalties for violation of confidentiality and data protection. However, there have been instances where privacy and confidentiality have been violated despite new legal safeguards. Examples include lack of privacy during physical examination or inadequate protection of individual patients' health records. More systematic violations of confidentiality include the treatment of certain groups of people such as ethnic minorities, people with infectious disease or with substance abuse problems, and sex workers, with instances documented in a number of central and eastern European countries in particular that have been brought before the European Court of Human Rights (Talbot, 2013). Whether such cases point to weaknesses in legislation or lack of legal protection remains difficult to assess with certainty, however. There remains a small number of countries that do not specifically guarantee the right to privacy or confidentiality; instead, this right tends to be covered by data protection legislation.

The right to access one's own medical record is strongly provided for in most countries included in our review, although in some countries hospitals appear to restrict access in practice, through for example, charging administrative fees for people wishing to exercise this right. This right is crucially linked to the right to information while also serving as a means to monitor whether the right to privacy is being upheld.

Access and choice

The right to access medical care is intrinsically linked to the degree to which countries provide for universal coverage. It is for this reason that this right is generally addressed outside special patients' rights laws. Yet as we have seen in the Introduction to this book, there remain gaps in health care coverage in a number of European countries, with evidence of an increase in the gaps following the global financial crisis of 2007–8 as indicated by rising levels of unmet medical need in some countries (Reeves, McKee & Stuckler, 2015).

The right to receive safe and high-quality treatment in a timely manner is generally expressed as an obligation of the provider to adhere to a certain standard of care. The notions of 'standard of care' and 'adherence' are, however, not well defined in relevant legislation, ranging from 'meeting certain patients' expectation' to 'adhering to the current scientific medical knowledge'. Several countries have

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specified the right to receive treatment in a timely manner, with, for example, Denmark, Finland and Sweden defining maximum waiting times guarantees. Within the European Union, people are entitled to receive treatment in another EU Member State where that treatment cannot be guaranteed domestically within medically justifiable time limits (Palm & Glinos, 2010). This entitlement was reaffirmed in the aforementioned EU Directive on the application of patients' rights in cross-border health care.

The ability to choose a health care provider is increasingly acknowledged as a patients' right, although countries vary in the extent to which this right is realized. Provider choice can form an intrinsic value of the health system, or serve as a means to increase efficiency and improve quality and patient satisfaction (*see* Chapter 8). Under Directive 2011/24/EU, patient choice of provider is, within limits, extended to health care providers in another EU Member State irrespective of whether or not the provider in question is contracted by the publicly funded health system in that Member State. This can increase pressure on Member States to extend choice options and also allow reimbursement for non-contracted providers domestically. However, as shown in Chapter 8, provider choice can form an important source of inequity, especially for people living in rural and remote areas, and more importantly perhaps, for those who do not have the means to express choice and act upon it.

The right to a second opinion is less universally accepted, with only a small majority of countries having formally and unconditionally recognized this right. This implies that related costs will be covered under the publicly funded health system. In countries that do not permit free choice of provider, the right to a second opinion is often subject to strict rules and conditions, typically through strictly defined referral pathways requiring the explicit approval of the treating physician. Some countries only permit one referral per treatment or care process (Estonia, Norway, Slovenia, Spain) or a second opinion is limited to certain providers, usually public or contracted providers, or providers within the same provider organization (Slovenia), providers that are listed for a given pathology (some Italian regions), or as selected by the treating physician (Poland). In Estonia and Italy, a second opinion may also be obtained from a non-contracted provider or a provider

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outside the country, while elsewhere the right is restricted to certain (mostly life-threatening) conditions (Denmark, Italy, Spain, Sweden). In Denmark, the Health and Medicines Authority can establish a special second opinion panel for people with serious illness to assess the patient's eligibility for experimental treatment at a private hospital in Denmark or elsewhere, with the treating physician responsible for the final decision. In Italy, patients with a (suspected) rare disease can be evaluated by experts from the National Network for Rare Diseases, and this may include seeking scientific advice from outside Italy. Overall, clinicians tend to have a high level of discretion in deciding whether the patient will be able to exercise their right to a second opinion. In Poland, the right to a second opinion is framed as a right of appeal to a medical opinion or decision, which is to be filed to a Medical Commission operated by the Patient Rights Ombudsman's 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 two met the formal requirements and were forwarded to the Commission.

Information and redress

Informational rights are key to enable people to make informed decisions about their own care and to enforce other patients' rights. Their enforcement requires procedural rights that ensure the provision of *ex-ante* information to enable people to exercise their rights and *ex-post* information that involves redress procedures in case of violation of these rights. One major challenge in the delivery of health care more generally, and the clinician–service user relationship specifically, remains the imbalance of knowledge, frequently referred to as information asymmetry (*see also* Chapter 4). It is against this background that enhancing access to information about health and health care is seen as a priority in many health systems in order to help people make informed decisions. Within the EU context, the aforementioned European Directive on the application of patients' rights in cross-border health care emphasizes the need to improve information for cross-border patients, through, for example, establishing national contact points.

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The right to information has three dimensions:

- ***The right to information about one's health*** is instrumental to the right to consent and the right to participate in (clinical) decision-making more broadly. Countries vary in terms of the content of information that should be provided and its dissemination. Typically, information should address the effectiveness, benefits and risks of any proposed treatment as well as alternative options, and it should be provided in a way that is understandable and suited for different people's needs, but this raises some practical and ethical issues (Entwistle et al., 1998). Importantly, the right to information also includes a right not to know, which needs to be respected where this is the individual's expressed preference (Laurie, 2014).
- ***The right to information about health care providers*** is instrumental for people to be able to exercise their right to provider choice. There are many challenges to realizing this in practice, such as the nature of the data and information that should be provided, approaches to data collection and validation, as well as their source and format (*see also* Chapter 7). Many countries have established an obligation for providers to publish information about various aspects, ranging from basic information about certification to practice to data about the quality of care provided, along with outcomes. A number of countries have invested in centralized web-portals to provide information about providers, but as discussed in Chapters 4 and 9, the evidence about the use and usefulness of this information by the public remains inconsistent.
- ***The right to information about rights and entitlements*** is instrumental to enforcing other patients' rights. Providing accurate and transparent information about citizens' rights and entitlements is part of good governance and is seen as a way to empower the public to access social services and demand the protection of their rights (Office of the United Nations High Commissioner for Human Rights, 2007). Governments have invested in improving access to information and reducing the administrative hurdles for people to claim and obtain the services to which they are entitled, including through central contact points, hotlines, web-portals, etc. The aforementioned EU Directive on cross-border health care specifies that the information provided should be easily accessible and made available by electronic means. It should include objective information about administrative procedures. While these provisions have been formulated in the context of cross-border care, people living in countries that have yet to establish public information systems may benefit, too.

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Redress is the most critical aspect in the enforcement of patients' rights. It covers the whole spectrum of instruments to settle disputes that may arise in the context of the patient–provider relationship. Disputes not only result from harm inflicted on the patient, but also from their rights being violated, expectations unmet or miscommunication. We have noted earlier that as effective sanctions are lacking in many settings, redress is often regulated under more traditional legislation covering breaches of duty of care and negligence ('tort law').

Professional liability regulations provide a strong incentive for providers to act cautiously and they also provide for fair compensation for patients who have suffered harm. Yet reliance on professional liability also has several flaws. Patients seeking compensation carry the burden of proof, including the need to provide evidence of damage incurred as well as evidence demonstrating negligence (fault) on the part of the provider and of the causal link between the provider's action and incurred harm. Countries such as Sweden, Finland, Denmark, Norway, Iceland, France and Belgium have developed no-fault compensation schemes which grant financial compensation for medical injury without the need for the patient to establish evidence of negligence. While the modalities differ, no-fault out-of-court compensation systems are generally seen to be more fair and efficient, with some evidence pointing to reduced health care costs as a result of clinicians reducing the practice of defensive medicine (Vandersteegen et al., 2015). Relevant schemes may also benefit health systems more broadly by enhancing transparency around adverse events.

Redress based on medical malpractice is, however, not suited to address breaches of statutory rights which do not necessarily cause physical harm. Countries have thus developed alternative dispute resolution mechanisms that seek to prevent litigation through establishing complaint and mediation procedures. Several countries have introduced independent mediators, such as ombudsmen (Mackenney & Fallberg, 2004) or mediation councils, which act at provider level (e.g. Belgium, Finland), regional level (e.g. Norway, Slovenia), national level (e.g. Greece, Malta, Poland), or simultaneously at all levels (e.g. the UK). Outcomes range from out-of-court settlements, administrative or disciplinary sanctions, to explanations or apologies. The latter is typically done through providing a report to the complainant following an internal investigation by the health care provider or institution. If the outcome is not satisfactory, the patient can still decide to initiate a legal

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procedure. In order to address inequalities in the use of redress mechanisms, patients can be assisted or represented by patient advocates or patients' organizations, who sometimes act as their legal representative in court (Belgium, Estonia, France, Hungary, Italy).

Complaints are most commonly triggered by concerns about the quality of care, in particular safety, including poor communication, staff attitudes and undignified service. Complaints data, where collected systematically, can help steer quality improvement initiatives, although the evidence of impact of such systems remains weak (Pedersen et al., 2013). Complaints procedures can also contribute to monitoring the implementation of patients' rights. For example, Bulgaria, Greece, Hungary and Malta have introduced special patients' rights committees inside or outside the health ministry, which are tasked with monitoring the situation and advising on any changes. At the international level, monitoring mechanisms for individual and social human rights also contribute to the implementation of patients' rights. One example is the 1997 Biomedicine Convention described earlier, which can involve the European Court of Human Rights in giving advisory opinions on legal questions concerning the interpretation of the Convention, and the Court can also act directly if patients' rights that fall within the remit of the European Convention on human rights are being violated.

Conclusions and policy lessons

Patients' rights in Europe have become more widely acknowledged and accepted. The consolidation of patients' rights and their enforcement is expected to help raise awareness, to empower patients, and to guide policy-makers to support the achievement of broader health system objectives. However, evidence that patients' rights achieve any of these goals is generally lacking. In the Netherlands, an evaluation of the law on patient contracts (ZorgOnderzoek Nederland, 2000) found that the patient's perspective was taken into account and that a fear of legalizing the doctor–patient relationship proved to be unfounded (Leenen, 2001). An assessment of the implementation of the 2015 Patient Act in Sweden showed little evidence that it had improved the legal position of patients (Vardanalys, 2017) (*see also* Chapter 3). This was mainly because enforcement mechanisms were found to be inadequate and efforts at the various levels in the health care administration to implement the Patient Act had been limited. More generally,

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shortcomings in the implementation of a patients' rights framework could lead to reduced confidence in the health system, while also increasing inequalities where the mechanisms introduced only benefit that part of the population that is better able to take advantage of new opportunities afforded.

Increasingly the concept of patients' rights is interpreted in a broad sense; this includes the basic individual patients' rights rooted in human rights frameworks and the rights that are more closely linked to social and consumer protection frameworks. We find that fundamental patients' rights appear to have become well-established in most countries in Europe, while the implementation of consumer-oriented rights lags behind. The broader interpretation of patients' rights also includes greater attention to quality and safety in the health sector, and the responsiveness and efficiency of public services more broadly.

A broader notion of patients' rights that integrates these various dimensions is likely to help advance the notion of the patient as an individual who needs to be protected from unlawful intrusion into their personal sphere to an informed and active partner in the health care system. This increased recognition is reflected by recent moves in some countries such as Norway, which revised its Patients' Rights Act in 2011, to also include users of care services. Similarly, the 2014 reform of long-term care in the Netherlands explicitly includes stipulations on the participation and shared decision-making of service users.

However, while progress has been made, the implementation of patients' rights in European countries requires further development. A major challenge remains enforcement, with lack of awareness among different stakeholders seen as a major barrier towards achieving the intended aims of legislative frameworks. Effective complaints and mediation procedures as well as systematic monitoring of patients' rights compliance are important instruments to increase their impact on individuals and the system as a whole. International efforts can play an important role, such as the 2011 European Directive on cross-border care, which prompted several EU Member States to update their patients' rights legislation, at least the procedural rights around information and redress. Also, more effective European mechanisms for monitoring patients' rights development and compliance with the relevant international frameworks could help to support their further development, as well as the promotion of good practices in raising awareness and enforcing patients' rights nationally.

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Appendix 13.1 *Patients' rights legislation in European countries*

Country	(Main) legal source	Category (*)	General comments and highlights
Austria	"Agreements on guaranteeing patients' rights" concluded between the Bund (Federal Republic) and the respective Länder (states)	IV	• The division of power between Federal and State level, lack of transparency and the more traditional approach to health care are hampering the development and enforcement of patients' rights. • Nine Federal States have so far concluded non-binding Patients' Rights Charter agreements: Burgenland, Carinthia, Lower Austria, Upper Austria, Salzburg, Styria, Tyrol, Vorarlberg and Vienna. • Next to rights drawn from constitutional, civil, criminal or administrative law, laws regulating different professions in the health care sector and 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).

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Belgium	Law of 22 August 2002	II	• The law of 22 August 2002 on the rights of the patient is mainly focused on traditional patients' rights as it derived from the discussion on the ratification of the Biomedicine Convention in the 1990s. • In 2014 the right to receive limited information about the health care provider (insurance and registration status) was included, also under the impulse of the patients' rights directive. • For its enforcement, patients are referred to standard liability procedures (civil, criminal, disciplinary). • The patients' rights law also grants the right to a complaints and mediation procedure. All hospitals are required to appoint an ombudsman. The law also established a central liability for hospitals.
Bulgaria	Health Act (2004)	V	• Patients' rights are still rather in the stage of awareness raising. There is no special law on patients' rights. • In 2009 the Public Council on the Rights of the Patient was established, an advisory and monitoring body within the Ministry of Health that is mandated to monitor and analyse all activities related to patients' rights and support the development of patients' rights legislation. • Complaint procedures are established at various levels of the health system.

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Appendix 13.1 *(cont.)*

Country	(Main) legal source	Category (*)	General comments and highlights
Croatia	Patients' Rights Protection Act (2004)	III	• The Patients' Rights Protection Act provides for the establishment of a commission for the protection of patients' rights. • Apart from the criminal act that contains provisions about malpractice, enforcement is a weak point. • Within civil society the Croatian Association for the Promotion of Patients' Rights is pushing for the further improvement of patients' rights.
Cyprus	Safeguarding and Protection of Patients' Rights Law 1(I)/2005	III	• The law on the safeguarding and protection of the rights of patients (2005) includes 17 patients' rights and a mechanism for monitoring and resolving patients' complaints about patients' rights violations. • Enforcement of patients' rights still remains an important challenge, which is related to the subsisting paternalistic doctor–patient relationship that translates into relatively low awareness and sensitiveness levels among citizens.
Czech Republic	Act no. 372/2011 Coll. on Health Care Services	II	• The Health Care Services Act clearly defines the basic rights and obligations of each party and includes complaints procedures for patients and relatives as well as sanctions for providers. • The Act also sets adjusted monitoring and (quality) control requirements targeted at improvements in patient safety and the quality of care. • Additionally, a Specific Health Services Act (2011) specifies patients' rights related to specific situations such as sterilization, in vitro fertilization and organ donation.

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Denmark	Consolidating Health Act no.1202 (2014)	III	• In 2011 the National Agency for Patients' Rights and Complaints was established as an independent government institution. • The Patient Insurance Scheme grants no-fault compensation in case of harm caused from medical treatment in the health system. • In case patients cannot be treated in a regional hospital within two months they can benefit from an extended free choice of hospital. In 2013 a waiting time guarantee was also introduced for diagnostic assessment based on a referral by a General Practitioner.
Estonia	Law of Obligations Act 2001 (chapter 41 'Contract for provision of health care services')	I	• Estonia is still in the early phase of developing a comprehensive framework on patients' rights. • The Estonian Patients Advocacy Association (EPAA) counsels and represents patients in mediation. Formal complaints can be lodged with the Health Care Quality Expert Commission, which acts under the Minister of Social Affairs as an independent and consultative body.

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Appendix 13.1 *(cont.)*

Country	(Main) legal source	Category (*)	General comments and highlights
Finland	Law No. 785 (1992) on the status and rights of patients	III	• Patients' rights are seen as essential in protecting the confidential relationship between patient and health care provider. • Each health care facility employs a patient ombudsman, whose duty is to inform patients of their rights and assist them, if necessary, in submitting a complaint, appeal or claim for indemnity. The most serious complaints are brought before the National Authority for Medico-Legal Affairs (NAMLA). • The 1987 Patient's Injury Act (amended in 1999) established a no-fault compensation scheme for unforeseeable injuries resulting from medical treatment or diagnosis. The scheme is managed by the Finnish Patient Insurance Centre. Unexpected adverse effects caused by pharmaceuticals (including from clinical trials) are covered under the Finnish Pharmaceutical Insurance Pool, a voluntary insurance taken by pharmaceutical companies operating in Finland.

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France	Act No. 2002-303 concerning the rights of patients and the quality of the health system (incorporated in the Code of Public Health)	III	• The Patients' Rights and Quality of Care Act established patient complaint and compensation procedures. Following the scandal of blood contaminated by HIV, a no-fault compensation scheme was introduced for all infections contracted through medical activities. For other therapeutic hazards, patients are compensated by their health insurance fund through the National Office for the Compensation of Medical Accidents. • Patients' associations have played an important role in the development of patients' rights. They also sit on hospital administrative committees and on research ethics committees. They can represent individual patients in court and before the Commission for indemnification.
Germany	Patients' Rights Act (2013) (*Patientenrechtegesetz*)	II	• To increase their transparency and consistency, patients' rights, which were formerly dispersed over various laws, were re-edited in the special Patients' Rights Act (2013). • A mandatory complaint management system was introduced for hospitals, but other institutions and health service providers have also started to use them on a voluntary basis as part of their quality management programmes. • A Charter of Rights for People in Need of Long-term Care and Assistance was developed in 2003 with the support of the Federal Ministry of Family Affairs, Senior Citizens, Women and Youth, and the Federal Ministry of Health.

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Appendix 13.1 *(cont.)*

Country	(Main) legal source	Category (*)	General comments and highlights
Greece	Law No. 2071/92 as amended by the Law of 17 July 1997 Law I. 3418/2005 on the Code of Medical Ethics	III	• The legal approach to patients' rights in Greece is still in the early stages of development. The status of enforcement still remains weak but recently case-law before the courts started to emerge. • Even if non-binding, the opinions and recommendations of the Hellenic National Bioethics Commission, established in 1998 as an independent advisory body of experts under the jurisdiction of the Prime Minister, are considered influential enough to fill any gaps in the legislation. • Also control mechanisms and institutions were created to support patients' rights implementation, e.g. the Ombudsman's office and the Office of Patient Rights in the Ministry of Health.
Hungary	Health Act CLIV (1997) Chapter II (Rights and obligations of patients) and Chapter VI (Rights and obligations of health care workers)	II	• The law also provides for non-litigious resolution of disputes between patients and health care 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 all play a key role in the enforcement of patients' rights.

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Iceland	Act on the Rights of Patients No. 74/1997.	III	• The Patients' Rights Act is 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, which also includes continuity of service and cooperation between all health care practitioners and institutions involved in their treatment. • In 2000 a Patient Insurance Scheme was established to compensate patients for any physical or mental damage in connection with health services.
Ireland	National Healthcare Charter 'You and Your Health Service' (2012)	IV	• 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. • The Human Rights Commission, established under the Human Rights Commission Act of 2000 and charged with promoting and protecting human rights as defined both in the Constitution and in international agreements to which Ireland is a party, is an important advocate for patient rights. • The National Healthcare Charter, established by the Health Service Executive and the Department of Health, sets out what users of health and social care services can expect from the Health Service, without calling them rights, as part of an exercise to improve its quality.

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Appendix 13.1 *(cont.)*

Country	(Main) legal source	Category (*)	General comments and highlights
Italy	Law establishing the National Health Service (833/1978)	V	• Patients' rights are mostly derived from the constitutional right to health and the general principles of dignity, solidarity, autonomy and professionalism that underpinned the institution of the National Health Service. • Several initiatives at national and local level aim at raising patients' rights awareness. In 1980 Cittadinanzattiva, one of the largest Italian citizens' associations, created the Tribunal for Patient Rights (Tribunale per i diritti del malato), a network of citizens and professionals organized in local sections, to collect complaints from users of health care services and undertake action for patient participation in health care policy.
Latvia	Law on Patients' Rights (2010)	II	• 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. Despite a poor knowledge about patients' rights, they attract a lot of media coverage and public interest. • In practice, the main institution dealing with patients' rights is a non-governmental organization called the Patient's Ombudsman, which assists patients in mediation with providers. Formal patient complaints can be filed to the Health Inspectorate, under the Ministry of Health. • Since 2014 a Medical Treatment Risk Fund has been in place within the National Health Service to provide compensation in case of harm caused to a patient's life or health.

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Lithuania	Law on the Rights of Patients and Compensation for the Damage to their Health No I-1562 (1996), included in Civil Code (2001)	I	• Patient complaints can be lodged at the provider level, or at the level of the Ministry of Health (the Commission on Evaluation of the Damage Caused to Health of Patients). The State Consumer Rights Protection Authority, which coordinates the activities of state institutions with regard to consumer protection, has a special division for paid medical services.
Luxembourg	Law of 24 July 2014 relating to the rights and obligations of the patient	II	• The special law was inspired by the patients' rights law in Belgium and France and was to some extent induced by the EU Directive on cross-border care.
Malta	National Patients' Charter of Rights and Responsibilities (2016)	IV	• The obligation to issue a Patient Charter was set out in the Health Act of 2013. • The Charter introduces a waiting time guarantee (maximum 18 months) that would give a patient the right to obtain treatment from a local private provider or in another European country in accordance with the Maltese Cross-Border Healthcare Regulations, under the Health Act. • In the interests of patients' rights, the Government established three commissioner functions: the Commissioner for Health, the Commissioner for Mental Health and the Commissioner for the Elderly. These officials act as ombudsmen in dealing with grievances and concerns from the public in their respective areas.

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Appendix 13.1 *(cont.)*

Country	(Main) legal source	Category (*)	General comments and highlights
Netherlands	Medical Treatment Contract Act (1994)	I	• There is an elaborate system of complaints, mediation and compensation. In 2016 a new Patients and Clients Rights Act was adopted containing new rules aimed at ensuring good and effective complaints and disputes management in health care as well as promoting quality of care. • With the 2006 health care reform, the Dutch health care 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 health care provider.
Norway	Patients' Rights Act No. 63 (1999)	III	• The Patients' Rights Act has been amended several times. The heading of the Patients' Rights Act was revised in 2011, adding "users of care services". In 2013 the Patients' Rights Act was amended to simplify the priority-setting process for specialized health care. The severity of the condition will only be used to determine the maximum waiting time. • Every county must have a Health and Social Services Ombudsman (POBO), who assists users of care services with information, advice and guidance. • The Norwegian System for Patient Injury Compensation (NPE) instituted by the Patient Injury Act (2001) handles compensation claims for patients who have sustained an injury while accessing statutory as well as private health care services. Its binding decisions can be appealed to the Patients' Injury Compensation Board.

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Poland	Act of 6 November 2008 on Patients' Rights and Patients' Rights Ombudsman	II	• The Law on Patients' Rights and the Patients' Rights Ombudsman gathered all dispersed patients' rights in one well-defined legal act and established the post of Patient Rights Ombudsman. All patients' rights regulations are to be interpreted in compliance with the Polish Constitution of 1997. • The Office of the Patient Rights Ombudsman, a central government authority appointed by the prime minister, acts independently of the Minister of Health and the President of the National Health Fund, aiming to ensure that patients' rights are protected and providing support in exercising those rights. Nevertheless, the state of enforcement of patients' rights is still considered to be weak in reality.
Portugal	Law no. 15/2014 on the rights and duties of the Health Care System beneficiaries	III	• Despite growing attention and monitoring by the regulatory health authorities, the level of implementation at the level of health care institutions still seems weak. Also the judicial system seems to be hesitant in sanctioning patients' rights violations and enforcing medical liability.

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Appendix 13.1 *(cont.)*

Country	(Main) legal source	Category (*)	General comments and highlights
Romania	Law 46/2003 related to patients' rights	III	• Given the poor patients' rights knowledge among the population and the fragmentation in complaint and redress procedures, enforcement remains weak. However, media reports about shortcomings in the health system, including poor conditions and cases of neglect in long-term and mental care facilities, have stirred the public debate. It also encouraged citizens to set up or join patients' organizations that provide counselling, support and practical guidance (even to seek treatment abroad).
Slovakia	Act No 576/2004 Coll. on health care, health care-related services and on the amendment and supplementing of certain laws	I	• Complaints about inadequate care can be lodged with the Health Care Surveillance Authority, an independent body which has become a credible advocate of patients' rights. • A non-governmental organization called the Association of Protection of Patients' Rights also deals with patients' rights.
Slovenia	Patients' Rights Act No. 15/2008	III	• General awareness among patients, doctors and other medical professionals is still quite low. Also the enforcement of patients' rights is weak but improving gradually. • In 2002 the ombudsman for patient rights was appointed for a period of six years. This person, however, is only responsible for the population of the eastern part of the country. • The nongovernmental Slovene Consumer Association is involved in the development of legislation relating to patients' rights, patient satisfaction and quality of health care services.

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Spain	Basic Law 41/2002 on the Autonomy of the Patient and Rights and Obligations with regard to Clinical Information and Documentation	II	• Within the framework of Basic Law 41/2002, all Autonomous Communities have developed their own Patients' Rights and Duties Charters, in some cases as part of the regional health act. • Regions have established specific structures and procedures to monitor and enforce patients' rights and deal with complaints through Patient Support Services (Servicios de Atención al Paciente) or User Complaint Units (Unidades de Atención al Usuario). • Most regional health systems have also introduced a patients' ombudsman. Their reports have a certain influence in safeguarding patients' rights due to their impact in the media.
Sweden	Patient Act (2015)	III	• The idea of the Patient Act was to gather all statutes regarding patients into one single law in order to improve transparency to care providers, patients and their family members. • The Patient Act needs to be interpreted along with other relevant acts and frameworks, e.g. the Health and Medical Services Act, the Patient Safety Act and the Patient Data Act. • Since 1997 a no-fault patient injury insurance scheme compensates any person suffering an injury in connection with medical or dental care in Sweden under the terms of the Patient Injuries Act.

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Appendix 13.1 *(cont.)*

Country	(Main) legal source	Category (*)	General comments and highlights
United Kingdom	NHS Constitution for England (based on Health Act 2009) Scotland: Patient Rights Act (2011)	IV	• The NHS Constitution for England, which is regularly updated, outlines the principles and values of the NHS, as well as the rights and responsibilities of patients and NHS staff in England. • The Scottish Charter of Patient Rights and Responsibilities was published in 2012, after legislation required it. Wales introduced the idea of a charter for patients' rights as early as 2007, but to date one has not been published. There is no charter in Northern Ireland. • Patients who want to file a complaint can get assistance from the Patient Advice and Liaison Service (PALS), which is located in all hospitals in England. They can also contact their local Healthwatch branch, a statutory body established under the Health and Social Care Act 2012 and hosted by the Care Quality Commission. Complaints that cannot be solved at the provider level can be addressed to the Parliamentary and Health Service Ombudsman.

Note: (*) I = 'sui generis' private contract legal rights model; II = generic private contract legal rights model; III = vertical quasi-legal rights model; IV = moral rights model; V = split rights model

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