

---

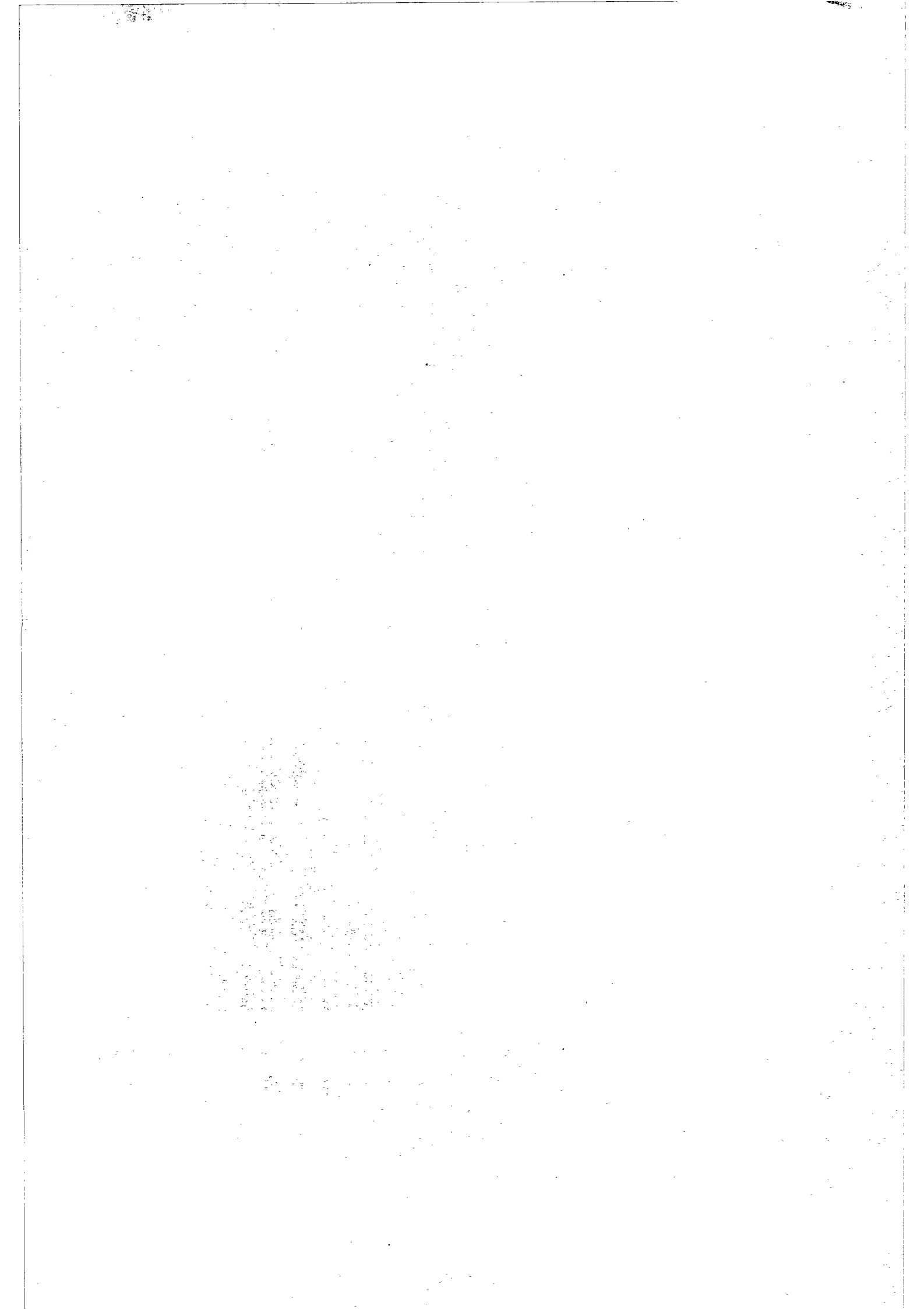
**Patients' Rights Development  
in Europe  
December 1998**

**Dimo Iliev and Mikko Vienonen**



**Health Services Management (HMA)  
Health Care Systems**

---



---

# Patients' Rights Development in Europe

By

*Dimo Iliev and Mikko Vienonen*

Introduction .....	3
The review .....	4
Global developments .....	4
Patients' rights development in selected European countries .....	5
Patients' rights legislation in force .....	6
Legislation on patients' rights under preparation .....	8
National Charter or code of patients' rights .....	10
Patients' rights incorporated in various legal texts .....	11
Patients' rights explicitly defined in health service legislation and institutional charters .....	12
Discussion .....	14
Conclusions .....	17
Appendix 1 .....	18
Chronological list of major international and national developments in patients' rights ....	18
Appendix 2 .....	20
Synopsis of laws and draft laws on basic patients' rights .....	20
Austria .....	20
Belarus .....	20
The Czech Republic .....	21
Estonia .....	21
Finland .....	21
Georgia .....	23
Hungary .....	23
Iceland .....	24
Ireland .....	25
Israel .....	25
Lithuania .....	26
The Netherlands .....	26
Russian Federation .....	28
Slovakia .....	28
Turkey .....	29
United Kingdom .....	29
Uzbekistan .....	30
Appendix 3 The development of patients' rights on the European scene .....	31
References .....	32

---



# Patients' Rights Development in Europe

December 1998

Dimo Iliev and Mikko Vienonen



World Health Organization  
Regional Office for Europe

**Abstract**

The promotion of patients' rights, being a dynamic process, is difficult to monitor. Medical progress and the concomitant challenges to the rights of patients, combined with changes in society and countries' legal frameworks, necessitate an assessment of the experience gained in promoting these rights. Existing instruments dealing with patients' rights then need revision and updating to ensure that they are constantly protected and respected, and to prevent their violation. A further challenge will be to monitor and assess the real implementation of patients' rights in day-to-day practices at country level. The theory which is spelled out in charters and legal texts may provide an idealized picture of reality at institutional level and in patients' histories. In future reviews, this aspect would need to be further elaborated.

**Keywords**

**Patient advocacy  
Legislation, Medical  
Europe  
Europe, Eastern**

**© World Health Organization**

All rights in this document are reserved by the WHO Regional Office for Europe. The document may nevertheless be freely reviewed, abstracted, reproduced or translated into any other language (but not for sale or for use in conjunction with commercial purposes) provided that full acknowledgement is given to the source. For the use of the WHO emblem, permission must be sought from the WHO Regional Office. Any translation should include the words: *The translator of this document is responsible for the accuracy of the translation.* The Regional Office would appreciate receiving three copies of any translation. Any views expressed by named authors are solely the responsibility of those authors.



The 1997 review looked at and emphasized the stages in the development of patients' rights throughout the European Region. The use of this approach allowed the identification of four main groups of countries, classified according to the different points they have reached in legislating on patients' rights:

1. Countries with patients' rights legislation in force;
2. Countries with patients' rights legislation before Parliament;
3. Countries with patients' rights legislation in preparation;
4. Countries with patients' rights charters; and
5. Countries with patients' rights incorporated in different legal texts.

The 1998 review was based on a different approach. In addition to reviewing new developments in the field, it looked into the legal strategies applied in countries. The combination of these two approaches provided additional insight into the following two questions:

- Where do European countries stand on their way towards achieving patients' rights?
- What have they done or what are they planning to do to legislate and promote patients' rights?

## **The review**

Three methods were used to collect the relevant data. First, available legal texts or published documents on patients' rights were analysed. Second, a questionnaire was sent to 22 Member States to identify the countries where a law on patients' rights had been passed since the end of 1995 and those where such a law was under preparation. The purpose was to ascertain the contents of actual and draft patients' rights legislation, and the legal means available in the absence of such legislation. Third, a telephone survey of officers responsible for legal affairs was conducted in the ministries of health in selected countries, based on the questionnaire sent out to the other Member States. Both the questionnaire and the telephone survey were used for retrieving coherent information from some countries. In total, the review included 29 countries.

## ***Global developments***

At both the national and the international levels, there is a clear tendency towards legislating on patients' rights. Since the end of the Second World War, a growing number of international organizations have produced declarations, charters or more binding legal documents, such as conventions and treaties, on human rights and health, evoking patients' rights (Annex 1). The current trend stems from a concern that human rights are not always respected in the health care sector and that the latest, accelerating developments in health care technology have made protecting them even more difficult.

In November 1996, the Committee of Ministers of the Council of Europe, following Opinion No. 198 of the Parliamentary Assembly, adopted the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. The Convention was solely opened to signature in Oviedo on 4 April 1997. By 4 April 1998, 22 Member States of the Council of Europe had signed the Convention and two

## Introduction

During the last decade, the issue of patients' rights has absorbed increasing attention at the national and international levels. Many countries in Europe and elsewhere have incorporated certain social and patients' rights into their health care legislation. Usually the social rights related to health care are spelled out in the countries' constitutions or basic laws. The social rights set the general framework for laying down further legal provisions addressing specific patients' rights. Because patients are reliant on the health care system and health care professionals, and therefore potentially vulnerable, they need mechanisms to promote and protect their rights (1). Patients' rights are the special guarantees designed to ensure that human rights and freedom are respected in the field of health care. Along with the patients' vulnerable position, two other factors drive the move towards enforcing patients' rights. First, recent extraordinary developments in medical science may have serious ethical as well as physical implications for human beings. Second, many countries in the WHO European Region are undertaking action to contain costs and to ration health care delivery while holding a general political commitment to maintain and improve equity in health. It is therefore necessary to reinforce basic human rights with a set of specific rights reflecting the particular circumstances of the health care sector.

The WHO Regional Office for Europe has developed a systematic approach to the issue of patients' rights. Studies on this topic were carried out at the beginning of the 1990s and published in the book *The rights of patients in Europe* (2). A European Consultation on the Rights of Patients was held in Amsterdam in March 1994. The Consultation endorsed the principles of the rights of patients in Europe (3), which laid down the framework for developing patients' rights at the level of their daily lives. In 1996, the Regional Office held a Conference on European Health Care Reforms in Ljubljana, Slovenia. One of the issues stressed was citizens' choice and patients' rights in the context of health care reforms. A review analysing the trends in and prospects for the development of patients' rights in Europe was issued as part of the background documentation for the Conference (4), followed by a further elaborated version in 1998 (5).

Providing up-to-date information on patients' rights development will help empower governments, national legislators and other actors to implement these rights and to choose techniques to promote them. The WHO Regional Office for Europe has therefore set up a Network on Patients' Rights and Citizens' Empowerment. In August 1997 the Network held its first meeting in Gothenburg, Sweden. Participants from 11 countries attended and several other countries had expressed the wish to come on board. The second meeting of the network was held in Canterbury, United Kingdom, in July 1998 and participants from 20 western and eastern European countries attended.

Changes in national legislation on patients' rights are difficult to monitor on a regular basis and are only sporadically reported in the relevant literature. This makes the monitoring process difficult and does not allow countries to learn from each others' experience. The Health Care System programme of the Regional Office for Europe therefore decided to make an annual review of patients' rights development in as many European countries as possible. The aim is to document recent developments and announce them to the wider public, as well as reflecting the progress achieved in some countries. The first review was carried out in the spring of 1997 (6).

had already ratified it. The Convention is the first internationally binding legal text addressing bioethical issues. It seeks to protect human beings against the possible misuse of new biological and medical techniques by safeguarding fundamental human rights and freedoms.

An additional Protocol to the Convention on the Prohibition of Cloning Human Beings was prepared. The Protocol was opened for signature on 12 January 1998 in Paris. It will enter into force after five ratifications by signatories, including at least four Member States of the Council of Europe. By 5 May 1998 the Protocol had been signed by 22 Member States of the Council of Europe. Further, the Council of Europe has set up two working parties to prepare additional protocols to the Convention on Genetics and Embryo Research.

WHO expressed concern about the implications of cloning for the respect of human integrity and dignity. At the request of the World Health Assembly in May 1997, WHO set up a Scientific and Ethical Review Group to address the issue of human cloning. During its one-hundred-first session, the WHO Executive Board recommended to the Fifty-first World Health Assembly the adoption of a resolution on the ethical, scientific and social implications of cloning in human health (7). Following the Executive Board recommendation, the Fifty-first World Health Assembly adopted resolution WHA51.10 on ethical, scientific and social implications of cloning in human health (8), which reaffirms "that cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity". It also urges WHO Member States to take action to prohibit cloning for this purpose.

Finally, the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted on 11 November 1997 a Universal Declaration on the Human Genome and Human Rights. The Declaration aims to ensure full respect for human dignity, freedom and rights in the application of genetics and human genome research. It spells out the rights of the people concerned to consent, receive or refuse information on genetic examination, to have genetic data held confidential and to receive just reparation for damage sustained as a direct and determining result of an intervention affecting his or her genome.

### ***Patients' rights development in selected European countries***

Some countries have adopted new legislation on patients' rights, while others have revised and updated existing legal texts. The countries addressed in this study are likely to use three main tools to promote patients' rights: a specific law, the incorporation of a set of patients' rights into existing legislation regulating the overall functioning of the health care system, and a charter (Table 1).

Countries embarking on specific laws did so to bring together separate components of patients' rights in different pieces of legislation; these had turned out to be difficult to find, and patients in particular did not know about them. The group of countries with patients' rights incorporated in various texts is the biggest of the other three groups in Table 1. This practice should be understood as a preliminary stage to the framing of a specific law. In fact, the countries with specific laws previously had specific patients' rights provisions in various laws. Similarly, countries that have drafted charters on patients' rights have brought various legislative regulations under one umbrella. The adoption of a charter, instead of a separate law, is more appropriate to some countries' legislative structures and legal traditions.

**Table 1.** Main tools for promoting patients rights in selected European Member States (as by October 1998)

Law in force	Law in preparation*	Patients' rights incorporated in various legal acts	Patients' Charter
Denmark	Belarus	Austria	France
Finland	Estonia	Bulgaria	Ireland
Greece	Georgia	Czech Republic**	Portugal
Iceland	Norway	France**	United Kingdom
Israel	Russian Federation	Germany	(Czech Republic)***
Lithuania	Turkey	Hungary	(Slovakia)***
Netherlands		Poland	(Sweden)***
		Slovakia**	
		Slovenia	
		Spain	
		Sweden	
		Uzbekistan	

\*Law before the Parliament or under ministerial preparation.

\*\*Some countries are difficult to classify in one category only, as they both have a patients' rights charter and patients' rights laws incorporated into various legal acts.

\*\*\*Patient charters exist but not at national level.

### *Patients' rights legislation in force*

In the legal system in **Denmark**, patients' rights are embodied in a variety of legislations. In 1997, however, the Ministry of Health set up a drafting group, which worked throughout the year. The Ministry of Health submitted the draft law prepared by the group to the Parliament on 26 March 1998. According to the parliamentary rules, a draft law in Denmark has to be discussed three times before a final vote takes place. The law was passed in October 1998 with immediate implementation.

**Finland** was the first country in Europe to enact a law on patients' rights: the Act on the Status and Rights of Patients was passed in 1992 (Appendix 2) and enforced on 1 March 1993 (4). The need for such a law was first discussed in the early 1980s. The Act laid down provisions covering patients' rights to:

- good health care and treatment when needed;
- access to treatment;
- information and self-determination;
- emergency treatment.

The Act also addresses the status of minor patients, through a provision requiring that the opinion of a minor patient (under the age of 18) on the treatment he or she receives be assessed, taking into account his or her age and level of development. Another provision addresses the powers of patients' representatives in certain situations.

Further, the Act provided for new rights associated with a complaint procedure and the patients' ombudsman. Patients not satisfied with the treatment they receive may lodge a complaint to the director responsible for health care in the establishment in question. On an upper level, the patient can refer the matter to the National Board of Medicolegal Affairs or

the provincial government. A patient treated in a public health care establishment can also address a complaint to the Chancellor of Justice of the State Council. The Chancellor is in charge of supervising public servants and the way they respect regulations. According to the Act on the Status and Rights of Patients, a patient ombudsman shall be appointed for every health care establishment. The ombudsmen do not have the duties of lawyers, and their status as employees of health care establishments has weakened their role.

In 1996, the Ministry for Social Affairs and Health assessed the experience gained in implementing the Act. Its report concluded that the Act was influencing positively the overall functioning of the health care system, making people more aware of their rights in using the health care services and affecting the attitudes of health care professionals (9). The younger generations of health professionals already appeared to be more willing to adopt new behaviour towards their patients. However, the authors of the report criticised the Act's handling of the question of informed consent as vague. Two issues, patients' access to information and right to self-determination, were identified as needing further consideration.

In **Greece**, patients' rights are indirectly addressed in the Code on the Practice of Medicine of 1939 and the Regulation of Medical Deontology of 1995. Both texts obligated physicians to provide treatment in full respect of patients' dignity and religious freedom, and to respect medical secrecy. In 1992, the Act on Modernization and Organization of the Health System (No. 2071/92, section 47) directly provided patients' with rights to physical security, information and freedom of choice, and the right to complain. The law was enforced in August of 1997 after a ministerial decision. Since then patients' offices have been established in each hospital where patients' can address their complaints. An all-party parliamentary committee has given an opinion, following which a charter addressing the rights of patients will be drafted.

**Iceland** adopted an Act on the Rights of Patients on 17 May 1997. The Act entered into force on 1 July 1997 (Annex 2) and ensured specific rights for patients in accordance with general human rights and human dignity, thus strengthening their legal status regarding health services and support to the confidential relationship which must exist between patients and health workers.

The Act also provides for the rights of sick children. Information concerning children below the age of 16 should be given to their parents, although the children should receive information appropriate to their age and development. Further, children over 12 years old have to be consulted regarding consent to health care. The Act requires that sick children be spared unnecessary tests and procedures and permits the presence of their parents and other close relatives.

One year after the law drew in force, the Ministry of Health and Social Security had noticed a general positive reaction to the law – although no research has been done on the matter. Discussion took place regarding the importance of financing to ensure the effectiveness of the law.

The Ministry is now looking into material to introduce the new law effectively. Information will be published for health professionals, stressing out the main points of the law and answering some practical details. Lectures to introduce this material to health professionals are scheduled. A booklet and a poster emphasizing the main points of the law and would be

distributed to all citizens are under preparation. The Ministry is also looking into ways of including patients' rights in the curriculum of health professionals education.

In 1996, **Israel** and **Lithuania** enacted patients' rights legislation (Annex 2). The Act on Patients' Rights, defining the physician-patient relationship, came into force in Israel on 12 August 1996. Its provisions are being implemented in health care establishments throughout the country. In September 1996, **Lithuania** adopted a Law on Patients' Rights and Injury to Patients. This was not, however, the first legal instrument dealing with patients' rights in the country. Patients' rights are mentioned in the Health System Law, the Health Service Institutions Law and the Health Insurance Law which was implemented in October 1997.

**The Netherlands** adopted the Medical Contract Law in 1995 (Appendix 2) on the recommendation of the advisory committee of the National Council for Public Health (10). The Law contains provisions on informed consent, information, access to and retention periods for medical data, and confidentiality. Subsequently a second Act on Complaints was passed, complementing existing legislation and providing for complaints procedures.

The different approaches in Finland and the Netherlands stem from the structures of their health care systems, the first being a tax-based municipal system and the second insurance based. According to the Medical Contract Law, patients' rights become part of the contract established between the patient and the provider of health services. The Law strengthens the legal position of the patient by bringing his or her rights into the civil code.

#### *Legislation on patients' rights under preparation*

In **Belarus**, **Estonia**, **Georgia**, **Norway**, **the Russian Federation** and **Turkey** draft laws have been prepared and are being put before the respective parliaments.

In **Belarus**, the 1996 Law on Health refers to a set of patients' rights (Appendix 2). A draft law on patients' rights was discussed in the Ministry of Health and put before Parliament in November 1997, but still awaits discussion.

The Ministry of Social Affairs in **Estonia** submitted a draft law on patients' rights to Parliament for a first reading in December 1996 (Annex 2). The law passed the first reading but Parliament decided to postpone the second reading and vote, as a law regulating the medical profession was being prepared. The provisions of the two laws should be congruent, so action on the patients' rights bill was expected to continue after the bill on the medical profession reaches Parliament. By mid-1998, however, neither had yet become law.

In 1996, the Ministry of Health and Social Affairs in **Norway** set up a drafting group to prepare a draft law on patients' rights. The draft was circulated for discussion in various ministries and a wide range of lay organizations. It was then debated in three months of public hearings organized in the summer of 1997. The hearings focused on the second chapter of the draft law, referring to material patients' rights. These pertain to rights to health services, a second opinion, free choice of hospital, home and nursing care, and psychiatric health services.

The results of these discussions were reflected in an amended draft law due to be discussed by the government before the end of 1998. The government will then submit a proposal to Parliament. The latter will hold debates on the draft in the beginning of 1999 and is expected to vote it into law in the course of that year. The law will not come into force, however, before 1 January 2000. The draft law on patients' rights in Norway is part of a legislative package to regulate the overall functioning of the health care system. Three other draft laws are also being examined and considered, addressing:

- health personnel;
- specialised health care; and
- psychiatric health care.

Patients' rights in **the Russian Federation** are mainly incorporated in the Foundations of the Russian Federation Law on Protection of Citizens' Health. In recent years, however, a whole series of laws and legally binding enactments in which patients' rights are reflected have been adopted in the sphere of medical and sanitary legislation<sup>1</sup>.

Special sections in the "Principles of the legislation of the Russian Federation on the protection of the health of the citizens" are devoted to the rights of citizens and groups in the population. This is the first broad expression of patients' rights, including the rights to information on one's state of health, to choose a physician and a treatment establishment, to consent to and to refuse medical intervention, and to be seen by a clergyman for the purpose of religious rites in hospital.

In the Russian Federation, a specific law on patients' rights, based on the 1994 WHO principles of patients' rights in Europe, was drafted in 1995 and is still before Parliament (Appendix 2). The draft law stems from the existing legislation of the Russian Federation, especially the laws mentioned above; it underpins the heightened responsibility of the authorities at all levels and of local government bodies to implement the state guarantees in the sphere of health care. The individual rights of the patient include the right to life, personal integrity, the confidentiality of information, self-determination, respect for religious belief, etc.

In **Georgia** and **Turkey**, discussions are pointing towards the preparation of such legislation on patients' rights.

In December 1997, the Parliament of **Georgia** voted on the Health Care Law, which includes a separate chapter on patients' rights. Chapter 2 contains ten articles pertaining to patients' rights to health care, informed consent, a second opinion and refusal to receive medical information, and the rights of incapable or mentally disabled patients (Appendix 2). Despite the patients' rights provisions of the health care law, Georgia is strongly committed to designing a separate law dealing with the issue. Work on a draft law started in May 1996. A special working group was set up and the first draft was discussed by the Council of the Health Minister and by various other ministries and departments. International experts from

---

<sup>1</sup> These include the "Principles of the legislation of the Russian Federation on the protection of the health of the citizens", the Federal Law of the Russian Federation, including those on the wellbeing of the population, medical insurance, psychiatric care, transplants of human organs and tissues, the donation of blood and blood components, and the prevention of the spread of HIV infection.

WHO, the Council of Europe and Canada provided advisory support to the drafting group. The draft law was to be submitted to Parliament in September 1998.

In **Turkey**, the Ministry of Health has prepared a draft law on patients' rights (Appendix 2), which was opened to public discussion in spring 1998. The Chamber of Physicians, the general public, the press and several academicians have expressed their opinions on the draft law. An amended second draft was expected to be submitted to Parliament in the course of 1998. The draft law contains 52 articles with provisions for:

- justice in health care;
- patients' information;
- patients' rights protection;
- informed consent;
- protection of people participating in medical trials; and
- applications of the law.

#### *National Charter or code of patients' rights*

**France, Ireland, Portugal and the United Kingdom** have approached the issue of patients' rights in similar extra-parliamentary ways. The British, French, Irish and Portuguese governments have promulgated patients' charters.

In **France**, the concept of patients' rights was first recognized in 1936 by a Supreme Court judgement in the case of Mercer. The Court ruled that the relationship between a physician and a patient constituted a contract for health care, according to which the patient had the right to expect treatment reflecting scientific progress at the time and the physician became responsible for his or her patient. The first French text dealing with patients' rights as such was a ministerial circular (ministerial note laying down instructions) dated 20 September 1974, which introduced a Charter for Hospitalized Patients, focusing on inpatients. This Charter, however, concentrates on the obligations of health care establishments, rather than the rights of patients within them. Thus, although it remains the first comprehensive text dealing with patients' rights in France, the Charter has limited efficiency and is narrow in scope.

The Charter was revised and a new version issued on 6 May 1995, emphasizing at the outset that public hospital services must be accessible to all, particularly the most vulnerable patients. To ascertain the level of satisfaction with the health care services, patients are required to comment on their stays in health care establishments. A copy of the Charter must be given to every patient admitted for treatment in any health care establishment.

In **Ireland** a Charter of Rights for Hospital Patients was published in 1991. The objectives of this charter were to ensure that the health service becomes more responsive to the needs of individual patients and that there is a code of practice available which sets out what patients have a right to expect when they make use of hospital services. The government was firmly committed to raising standards in hospitals and to guaranteeing that everybody, irrespective of income, will have access to high quality medical care.

In **Portugal** a patients' rights charter was drafted by the Directorate General for Health and issued in 1997 by the Ministry of Health as National Charter. Its adoption is presently in

force. The majority of the rights listed in this charter are also promoted by civil, penal and traditional health care legislation, which makes patients' rights defensible in court.

The commitment to patients' rights in **the United Kingdom** is enshrined in the Patients' Charter (England, Wales, Scotland and Northern Ireland have separate charters), which is part of the Citizens' Charter initiative. The government first issued the Patient's Charter in 1991 to create a better National Health Service (NHS). The Charter (12) lays down ten rights and ten national standards (Appendix 2) that are not legal rights but reflect the aim of the NHS to provide additional services to its users, "as circumstances and resources allow". In 1995 a revised version of the Charter was issued, extending its coverage to dental, ophthalmological and community pharmaceutical services.

#### *Patients' rights incorporated in various legal texts*

**Austria, Bulgaria, The Czech Republic, France, Germany, Slovakia, Slovenia, Spain and Uzbekistan** have incorporated regulations on patients' rights into different laws and regulations governing their health sectors. All these countries have constitutional principles laying down rights related to health care. In the majority of cases, the constitutions provide for social rights such as health protection and access to health care services, the right to receive health care services and the right to equal treatment regardless of sex, race, ability to pay or other social denominators. In many countries of central and eastern Europe and some countries of central Asia, a movement began in the mid-1990s towards incorporating a set of specific patients' rights into legislation regulating health care systems.

In **Austria**, patients' rights are laid down in different laws regulating the overall functioning of the health care sector. In 1992 the Austrian Federal Ministry of Health and Consumer Protection drew up a patients' rights charter, but it was not implemented. One year later, an amendment was made to the Federal Hospital Act, adding a list of patients' rights (Appendix 2). The list contains provisions on the rights to health care, physical security, freedom of choice, information and privacy. It starts by providing each person with the right to receive the best health care and treatment currently available, regardless of age, income or social position.

The right to health care stems from the entitlement of Austrian citizens to health insurance, which covers more than 99% of the population. Insured people are entitled to medical aid, hospital care, medication, medical auxiliaries, home nursing services, psychotherapy, medical rehabilitation and ergotherapy. While people in Austria may choose among the general practitioners (GPs) working in private practices, they do not enjoy the same free choice among practitioners working in public hospitals.

**Bulgaria** has no specific law on patients' rights but principally includes them in the Bill on Public Health, which was first promulgated on 8 November 1973 and has been amended several times since (most recently in March 1997). According to the law, the rights to which patients are entitled are more social than individual.

In addition to its Charter for Hospitalized Patients, **France** has enacted several laws addressing patients' rights and referring to patients' participation in biomedical research, hospital management and the ethical implications of medical technology. Finally, in 1996 the

Social and Economic Council adopted an opinion on the Evin report on patients' rights, strongly recommending that they be given high priority in national legislation.

In the **Czech Republic**, patients' rights are contained in two documents: the Code of Patients' Rights, prepared by the Central Ethical Commission set up by the Ministry of Health and approved by the Ministry on 25 February 1992 (Appendix 2), and the Ethical Code of Physicians, prepared by the Conference of the Czech Chamber of Physicians in November 1992, which lays down physicians' duties and indirectly addresses patients' rights.

In **Germany**, provisions in constitutional law deal with patients' rights and refer to the right to life and to physical integrity. Patients' rights are also enshrined in the 1983 health insurance law and in the Social Code. Nevertheless, the Advisory Council recommended in 1992 that existing provisions be brought together in a patients' rights charter.

**Slovakia** has no law on patients' rights; but patients' rights are included in the Act on Health Protection of People, the Act on Health Care (Appendix 2) and the Act on Therapeutical Order. The Association of Hospitals of Slovakia has prepared a strategic document, a Charter on Patients' Rights, which is awaiting government consideration. The Charter contains 15 patients' rights and it is based on the WHO Declaration on the Promotion of Patients' Rights in Europe (3), as well as the charter of patients' rights drafted by David Andersen in 1971 in the United States. Some of the articles of the Charter represent rights that are not established by law but could be applied in health care institutions. Following the publication of the Charter, a media campaign started in several local journals, reflecting the reactions of the public and the medical profession. The results of this campaign will probably mark the way for patients' rights development in Slovakia.

In **Slovenia**, the need for patients' rights legislation has been considered, but no law has been passed or prepared. Nevertheless, such rights are included in other legislation, recommendations of the Slovene Consumer Association and regulations of the Institute of Health Insurance. A draft law on patients' rights is under discussion with health care users and providers.

In **Spain**, patients' rights are dealt with in the 1986 General Law on Public Health and in the 1994 Charter of Rights and Duties of Patients. In addition, the General Council of the Medical Order of Spain has recognized patients' rights in Chapter III of the Code of Deontology.

In **Uzbekistan** article 24 of the 1996 Bill on Protection of the Health of Citizens lays down several provisions for patients' rights (Appendix 2).

#### *Patients' rights explicitly defined in health service legislation and institutional charters*

The **Hungarian** Parliament adopted a new law in May 1997 on the handling and protection of medical data. This lays down rules about patients' rights to have access to medical data, and prohibits the transfer of medical data to certain persons and bodies. Although the option of drafting a law on patients' rights was discussed, the final decision was to incorporate them in a special chapter in a law on health care. In 1997 the Ministry of Welfare drafted an Act on Health Care (Act 154/97), which was submitted to Parliament in the summer of 1997 and passed in December. Chapter 2 is devoted to patients' rights (Appendix 2).

In Hungary, patients who are incapable or are under the age of 18 must be involved in their treatment, and their opinions are to be taken into consideration in the treatment process. Further, the Act on Health Care makes provisions for living wills and spells out the right to refuse treatment. Patients may decide whether to prohibit an autopsy or a postmortem use of tissues and organs for medical or research purposes.

Patients' rights in **Poland** are mainly embodied in the constitution and in legal documents forming the corpus of the civil law: the Civil Code, the Public Health Institutions Act, the Medical Practitioners' Act, the Nurses' and Midwives' Act, the Medical Ethics Code, and the Nurses and Midwives' Ethics Code. There have been project-type attempts to establish a national patients' rights charter but this initiative never went further than some institutional charters. The Public Health Institutions Act was updated in 1997 and chapter on patients' rights was incorporated. A draft law on patients' rights was submitted to Parliament at the end of 1997, but did not come to a vote as the Government had changed in the meantime.

Meanwhile, the Medical Chamber, which has been obliged by law to draft a Medical Ethics Code, has included a set of patients' rights in it. The Chamber of Nurses and Midwives and several patients' organisations decided to launch educational activities (seminars, public hearings and debates) to make people more aware of their rights as patients.

Presently Poland can be classified among those countries like Hungary and Sweden where patients' rights are quite comprehensively been incorporated in existing and newly updated health sector legislation. Nevertheless, the present government in Poland (September 1998) is planning to draft a separate law on patients' rights in the near future (possibly in 1999 and/or 2000).

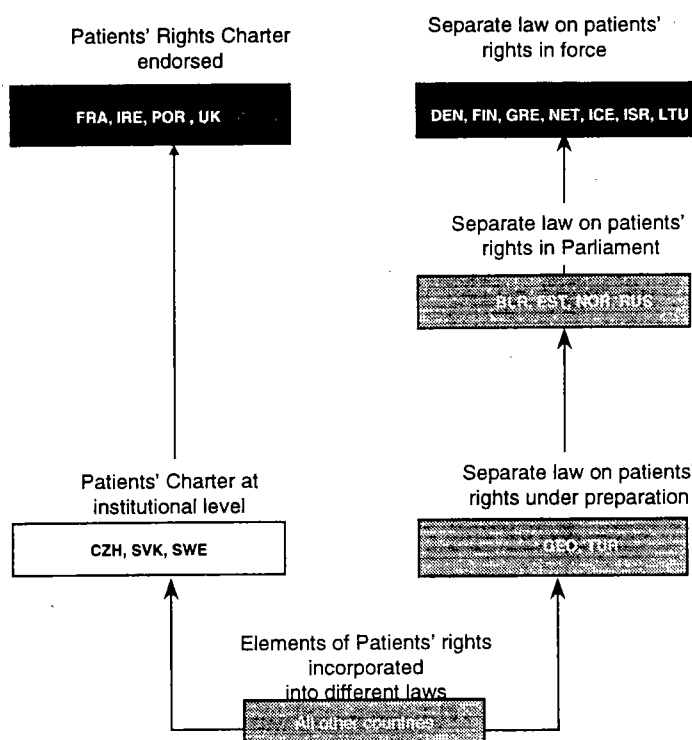
In **Sweden**, patients' rights are promoted in two different ways, which makes it somewhat difficult to allocate this country to one of the identified groups of strategies for promoting patients' rights. Patients' rights pertaining to information, consent, care and treatment are embodied in the Health and Medical Services Act, and in the Health and Medical Personnel Duties Act. Specific provisions for consent given by a legal representative are laid down in the Code on Parents, Guardians and Children. The rights to confidentiality and privacy are spelled out in the Secrecy Act and the Health and Medical Personnel Duties Act. Along with the existing legislation, the Federation of County Councils has issued a Charter that contains several principles based on existing legislation and agreements between the Federation of County Councils and the State for promoting patients' rights. This document has been distributed to all county councils with the purpose that the councils should – although on a voluntary basis – build their patients' rights policies according to the principles set out in this document. However, the charter was not designed for providing any legal rights defendable in court, and could not therefore be considered as a national charter.

In November 1997, a parliamentary commission had suggested that provisions specific to patients' rights be consolidated and several amendments be made on existing laws regulating the health care system in general. The proposal was reviewed by the government who proposed several amendments focusing on the patient, such as the right to choose between different methods of treatment and the rights to a second opinion for patients with grave diseases. The proposal was to be read by the Parliament in Autumn 1998.

## Discussion

International initiatives addressing patients' rights have conveyed a strong message to countries in the WHO European Region. Member States have shown a positive response in their moves towards developing such rights. Figure 1 illustrates the common patterns discernible in these moves. The line on the left follows the process of endorsement of a patients' rights charter, which can either take place at the countrywide level or result from initiatives at the institutional level by competent authorities, physicians' associations or other institutions dealing with health matters. The line on the right indicates the steps towards elaboration of a law on patients' rights.

**Figure 1.** Patterns of patients' rights development in Europe



As per October 1998

The recent developments described in this document show that most countries have followed the path marked out at the Amsterdam Consultation on Patients' Rights in 1994 and have incorporated the principles for promoting patients' rights (3) into their legislation. As to matching the Amsterdam principles with national law, countries refer to human rights and values in health care in their constitutions. Different legal instruments in Member States provide for the rights to information, consent, confidentiality and privacy, and care and treatment. Patients are directly entitled to these rights in countries with a specific patients' rights law. In other countries, different pieces of legislation lay down patients' rights in the form of obligations incumbent upon physicians.

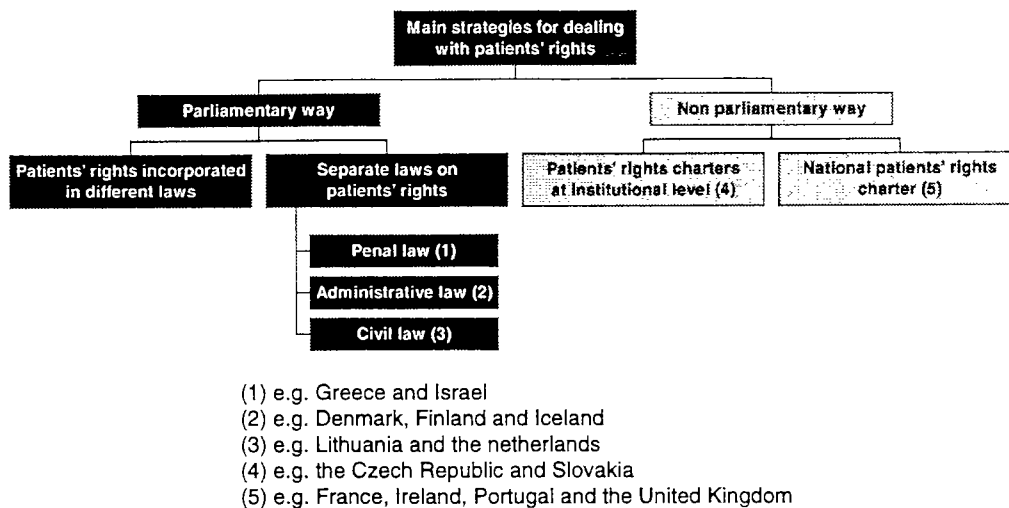
As to the right to consent, the relevant Amsterdam principle (3) states that "the informed consent of the patient is a prerequisite for any medical intervention". Nevertheless, in some countries consent appears to be limited to cases of organ removal and sophisticated

operations. Appendix 3 illustrates the development of patients' rights in selected European countries.

Creating patients' rights legislation is a long process involving different partners and going through different stages. An initiative to lay down provisions specific to patients' rights might originate from a large range of official institutions or civil societies. In the health care field, this is usually the ministry or department in charge of health matters, but in some cases the ministry of justice or social affairs could also propose patients' rights legislation.

In their commitment to create legislation on patients' rights, European countries seem to use three main strategies (Figure 2). The first strategy is not to legislate on patients' rights directly (13). In this case, development follows the rulings of the courts and is vulnerable to the hazards inherent in each individual situation dealt with. Countries opting for this alternative rely on the law of precedent. The second strategy consists of democratically creating patients' rights legislation, using parliament and national legislative procedures. The outcome is either a separate law on patients' rights or a set of rights incorporated in different laws. In both cases the national legislator, parliament, has the last word.

Figure 2. Main legal strategies for patients' rights in Europe



There are three legislative techniques for dealing with patients' rights in a separate law, and they all refer to the nature of the law (Fig. 2): administrative, civil or penal. The civil-law option provides a contractual model of horizontal relationships between the health care provider and the patients (14). Countries such as the Netherlands and Lithuania have used this option in their laws on patients' rights. Similar types of relationship between patients and their health care providers exist under the regulations governing the delivery of GP health services in France. In these three countries, a patient who has a claim against a physician would be referred to a civil court.

Using administrative law to spell out patients' rights creates another type of relationship, described in the literature as vertical: it is usually established between the government, as the ultimate organiser of the health care system, and the patients (14). This approach is applied in countries with national health care systems, such as Finland, Iceland and Denmark. Within the context of administrative law, the government has a major role in protecting and promoting patients' rights. Nevertheless, administrative law prohibits patients from taking direct legal

action against health care providers. Care providers act on behalf of the health care establishments in which they perform their duties. In case of a lawsuit, the litigants would therefore be the patient and the health care establishment, not the individual physician.

A combined situation exists in France, where the legal instruments governing the relationships between patients and health care providers depend on the type of health care provider. In case of disrespect of the patients' rights by a GP, the patient may undertake legal action according to the civil law, submitting the matter to the civil courts. If the patient claims that a doctor working in a public hospital has transgressed his or her rights, the matter is referred to the administrative court. The administrative court makes its decision according to the prescriptions of administrative law. If the evidence reveals that the patient's rights were transgressed, the court rules that the hospital should pay reparation. Using the administrative-law method, however, does not prevent the patient from seeking reparation under civil law.

Finally, the third strategy is the use of non-parliamentary means, as in countries with patients' rights charters. The distinguishing feature of the method is that the law is not used and the process of drafting a charter does not require the involvement of parliament. This usually implies that the competent ministry drafts the charter. In France, Ireland, Portugal and the UK, charters were adopted at the national level and apply to all health care establishments. In other countries, such as the Czech Republic and Slovakia, patients' charters are promoted at the institutional level. This means that a health care establishment elaborates on its own charter based on the provisions of legislation.

From the practical point of view, the non-parliamentary procedures take less time than legislative procedures, but their results are not legally binding. Thus, patients' rights in a charter cannot be defended in court.

The analysis of patients' rights distinguishes between social and individual rights (10, 13, 14). The former refer to a set of rights collectively enjoyed, such as the right to receive or to have equal access to health care. The latter are more readily expressed in absolute terms and are inherent in the individual as a human being. Although a great majority of European countries are committed to a wide-ranging set of social rights, current tendencies may endanger this commitment. The need to contain costs has led to a narrowing of the scope of collectively financed health care services and the exclusion of increasing numbers of people from formal health care provision, while the scarcity of resources is forcing countries to make patients share the costs, either officially through co-payments or unofficially through under-the-table payments. These two trends underline the fact that the provision of social rights reflects what is possible in a given country at a particular time, whatever the country's commitment to them may be.

Even so, central and eastern European countries are making real advances in introducing new individual rights relevant to information, consent, confidentiality and privacy, and care and treatment, while others are moving towards reviewing and reinforcing existing individual patients' rights. Instruments designed to promote patients' rights need to be revised and updated in the light of the experience gained in implementing them, in order to reflect the rapid changes taking place in the health care sector.

## Conclusions

The Amsterdam Consultation on Patients' Rights in 1994 and the Ljubljana Conference in 1996 strengthened the movement towards the further development and true implementation of patients' rights, even in countries where the issue had not previously received much attention. A motivating factor has been the desire to clarify patients' rights in one law. Three Member States (Denmark, Iceland and Lithuania) have enacted laws on patients' rights since the Ljubljana Conference, and two (Estonia and Norway) are likely to do so in the near future. Three others (Hungary, Poland and Sweden) have included patients' rights in different instruments regulating the functioning of their health care systems. Nevertheless, difficulties in monitoring developments in this area highlight the need for countries to discuss and agree on the criteria for evaluating them.

As to the legal strategies applied, the countries analysed in this review rely on three main strategies: the first is not to create patients' rights provisions. The use of a parliament's legislative function to spell out patients' rights constitutes the second strategy, which usually culminates in a specific law. The third strategy is the use of non-parliamentary means, which leads to drafting a patients' rights charter. The choice depends on a country's legal traditions and probably reflects political priorities. Drafting a law on patients' rights requires more time and resources, so that countries engaged in other reforms often prefer to incorporate a set of rights into their existing legislation, rather than creating new laws. When these are set out in one legal document, however, it is much easier both for beneficiaries to know their rights and for those rights to be monitored and revised.

The promotion of patients' rights, being a dynamic process, is difficult to monitor. Medical progress and the concomitant challenges to the rights of patients, combined with changes in society and countries' legal frameworks, necessitate an assessment of the experience gained in promoting these rights. Existing instruments dealing with patients' rights then need revision and updating to ensure that they are constantly protected and respected, and to prevent their violation.

## Appendix 1

### *Chronological list of major international and national developments in patients' rights*

<u>Year</u>	<u>Event</u>
1944	<b>The Medical Care Recommendation</b> adopted by the International Labour Organization
1945	(Recommendation # 69 – Section IV – Philadelphia)
1948	<b>Universal Declaration of Human Rights</b> adopted by the United Nations' General Assembly
1973	<b>Patients' Bill of Rights</b> issued by the American Hospital Association
1974	<b>Charter of Patients' Rights and Duties</b> issued in France
1974	<b>Hospital Patients' Charter</b> issued in France
1976	<b>Recommendation on the Rights of the Sick and Dying</b> adopted by the Parliamentary Assembly of the Council of Europe
1979	<b>Charter of the Hospital Patient</b> adopted by the Hospital Committee of the European Community
1979	<b>Provision on Patients' Rights</b> included in the Framework Hospital Code of the German Democratic Republic
1980	<b>Recommendation concerning the patient as an active participant in his own treatment</b> adopted by the Committee of Ministers of the Council of Europe
1981	<b>Declaration of Lisbon on the Rights of the Patient</b> adopted by the World Medical Association
1984	<b>A European Charter on the Rights of Patients</b> adopted as a resolution by the European Parliament
1985	<b>Recommendation on legal duties of doctors vis-à-vis their patients</b> drafted by the Committee of Ministers of the Council of Europe (note: not adopted)
1986	<b>Patients' Rights</b> enumerated in General Health Law, Spain
1989	<b>Charter of Rights and Duties of Patients and Users of the Basque Health Service</b> promulgated by the Basque Autonomous Community, Spain
1991	<b>Circular on Physicians' Duties on Patients' Rights</b> issued in Denmark (replaced in 1992)
1991	<b>Patients' Charter</b> issued by the UK Government
1992	<b>Act on the Status and Rights of Patients</b> promulgated in Finland
1993	<b>Provision of "patients' rights"</b> included in the accreditation manual for hospitals issued by the Joint Commission on Accreditation of Health Care Organizations, United States
1994	<b>WHO Declaration on the Promotion of Patients' Rights in Europe</b> endorsed by 34 Member States of the WHO European Region
1994	<b>Medical Contracts Act (on patients' rights)</b> promulgated in the Netherlands
1995	<b>Revised Hospital Patients' Charter</b> issued in France
1995	<b>Revised version of the Declaration of Lisbon on the Rights of the Patient</b> adopted by the World Medical Association
1996	<b>Patients' Rights Act</b> promulgated in Israel





<u>Year</u>	<u>Event</u>
1996	<b>WHO Ljubljana Charter on Reforming Health Care</b> emphasizing citizens' voice and choice, endorsed by almost all WHO Member States of the European Region
1996	<b>Equity and patients' rights in the context of health reforms</b> addressed in the Council of Europe fifth Conference of European Health Ministers in Warsaw
1996	<b>Law on Patients' Rights and Injury to Patients</b> promulgated in Lithuania
1996	<b>Convention on Human Rights and Biomedicine</b> adopted by the Council of Europe
1997	<b>Bill on the Rights of Patients</b> promulgated in Iceland
1997	<b>Convention on Human Rights and Biomedicine</b> opened for signature in Oviedo by the Council of Europe
1998	<b>Law on the rights of patients</b> passed in Denmark

## Appendix 2

### ***Synopsis of laws and draft laws on basic patients' rights***

#### *Austria*

Patients' rights are enshrined in an amendment to the Federal Hospital Act of 1993. The main patients' rights are:

- the right to health care under the health insurance system;
- the right to physical security (physicians and other health care personnel have the duty to provide health care services according to the state of the art);
- the right of free choice (people have free choice of a GP but not in public hospitals; patients may refuse treatment);
- the right to information (patients have to be informed about their health status, diagnostic possibilities, the available therapeutic methods, and treatment risks and benefits; patients may refuse to receive this information but they are required to state their refusal clearly; physicians may withhold information in cases where the information could harm the patient);
- the right to private life (strong provisions are made for the respect of patient's privacy, personal data and consent; exceptions are provided in cases of dangerous transmittable diseases, information to public prosecutors and criminal investigations); and
- the right to complain (mediation boards are established on a voluntary basis by the local chambers of physicians; patients have the possibility to complain in civil courts in cases of injuries and damages).

#### *Belarus*

The main patients' rights spelled out in the Law on Health (18 June 1996) refer to:

- the right to receive health care services free of charge in public health establishments;
- the right to free choice of physician;
- the right to information about health status;
- the right of hospitalized children under the age of 14 to be accompanied by their parents; and
- the right to receive emergency health care services in any health care establishments.

### *The Czech Republic*

The Code of Patients' Rights (25 February 1992) states that patients are entitled:

- to respectful and professional treatment given by qualified workers;
- to know who is in charge of them, to respect for their privacy and to the presence of their own families;
- to be informed, so as to be able to make proper decisions regarding the health care provided;
- to refuse treatment under circumstances laid down by law;
- to respect of their privacy and to give or withhold consent to students' participation in the curative process;
- to confidential medical records and the designation of a person to have access to them;
- to continuity of treatment after discharge;
- to be informed when the physician will use non-standard or experimental treatment and to refuse to participate in any stage of an experiment (informed consent is necessary for participation in research into therapies);
- when dying, to respectful care, taking account of personal wishes in accordance with the law; and
- to know (and required to respect) the internal order of the health care establishment where treatment is provided.

### *Estonia*

The main patients' rights enshrined in the draft law on patients' rights submitted to Parliament are:

- the right to be treated and to medical aid;
- the right to receive emergency treatment and aid;
- the right to obtain information;
- the right to declaration of will; and
- the right to consent to organ and tissue removal for transplant and scientific research purposes.

### *Finland*

The Act on the status and rights of patients (1992) sets out the following patients' rights.

#### **Chapter 1 deals with general provisions**

- Section 1 deals with the application of the Act.
- Section 2 sets out the definitions of a patient, health care and medical care, health care professionals, a health care unit and patients' documents.

**Chapter 2 covers the rights of patients**

- Section 3 lays down the right to good health and medical care and related treatment of patients. Patients' entitlement extends to the limits of the available resources.
- Section 4 defines the right to access to treatment. If a person cannot be given treatment, he or she must be referred to treatment elsewhere or to be given explanation of the waiting for treatment.
- Section 5 provides for the right to information. Information shall not be given against the will of the patient or when such an information might cause him or her harm. The information must be provided in a way enabling the patient to understand it, and interpretation should be provided, if possible.
- Section 6 prescribes the patient's right to self determination.
- Section 7 lays down the conditions for treatment of minor patients. Their opinion about the treatment they receive has to be taken into account, according their age and development.
- Section 8 refers to emergency treatment.
- Section 9 spells out the right to be informed and the powers of the patient's representative.

**Chapter 3 covers complaints and the patient ombudsman.**

- Section 10 provides for the complaints' channels.
- Section 11 introduces a patient ombudsman for each health care establishments (or unit, in terms of the law).

**Chapter 4 deals with patient's documents.**

- Section 12 describes how the patient's documents are to be kept and refers to administrative regulation.

Section 13 covers the confidentiality of information: communication of data concerning the patient is prior to his or her consent. The Section provides for three exemptions: communication of data to legal and civil authorities entitled to receive information by virtue of the law, to another health care establishment, and to close family member if the patient is unconscious or there is no reason to believe that the patient would forbid this.

**Chapter 5 contains miscellaneous provisions.**

- Section 14 prescribes penal punishment in case of breaking the secrecy obligation.
- Section 15 regulates the right of appeal.
- Section 16 states that a decree will lay down more precise provisions for the implementation of the Act.
- Section 17 covers the Act's entry in force.

### *Georgia*

Chapter 2 of the Health Care Law (December 1997) spells out the following patients' rights.

- Article 5 sets down the right to receive health care services and medical aid in Georgia under the existing regulations.
- Article 6 prohibits any discrimination based on race, sex, religious convictions, political and other views, ethnic and social origin, property or title status, place of residence, disease and sexual orientation.
- Article 7 makes provisions for the right to receive understandable and comprehensive information and to seek a second opinion.
- Article 8 lays down provisions regulating the patient's participation in biomedical research. A verbal informed consent is the necessary condition for the patient's participation in the medical educational process.
- Article 9 states that patients have the right to refuse any kind of medical intervention, and to participate in biomedical research and education activities. Exceptions are outlined in Article 75.
- Article 10 spells out the right of patients to a living will, termination of treatment and resuscitation.
- Article 11 prescribes for the giving of consent by a legal representative when the patient is unable to express consent.
- Article 12 requires that urgently needed medical interventions on mentally disabled and irresponsible patients can be performed only in the patient's interest.
- Article 13 permits the provision of medical care in prisons, including in cases of hunger strike, subject to the patient's consent.
- Article 14 gives the patient the right to choose and change his or her doctor and health care establishment according to the insurance agreement.

### *Hungary*

Chapter 2 of the Act on Health Care (1997) gives everyone the right:

- to receive medical treatment that respects human dignity;
- to make decisions regarding treatment modalities;
- to obtain information concerning himself or herself and to give informed consent;
- to refuse medical treatment; and
- have access to medical records.

### *Iceland*

The fundamental provisions of the Act on Patients' Rights, passed by the Icelandic Parliament in May 1997, are as follows.

- In Chapter I, Article 3 refers to the quality of the health service. It lays down the right to equal health services, to the best available treatment at each time and to continuous treatment. Access to information on the rights of patients is dealt with under Article 4, which states that the Ministry of Health and Social Security shall ensure that the information concerning patients' rights, patients' associations and social security schemes is available and made accessible to patients;
- Chapter II, on information and consent, contains provisions for information on health and treatment, and the relevant exemptions from this principle. The duties of health workers faced with patients refusing treatment and exemptions from consent to treatment are set out in Articles 8 and 9. Articles 10 and 11 deal with consent to scientific research and participation in the teaching of students.
- Chapter III, on confidentiality and professional secrecy, prescribes the rights to confidentiality and professional secrecy and the relevant exemptions in Articles 12 and 13.
- Chapter IV, on handling of information in clinical records, lays down the specific rights to access to clinical records (Article 14) and to comment on information in the clinical record (Article 16).
- In Chapter V, on treatment, Article 17 stresses the patient's right to respect for human dignity. Article 18 deals with waiting times for treatment, and gives the patient the right to know the reasons for delay, as well as the estimated waiting time. Articles 20 and 21 prescribe the right to an empowered choice of health worker and declares the patient responsible for his or her own health. Article 22 lays down provisions for admission and discharge of patients. Articles 23 and 24 give dying patients the rights to an easing of their suffering and the presence of their family and friends, and deal with their treatment.
- Chapter VI describes special rules on sick children. It makes provisions for sick children as regards information on their health and treatment, consent to treatment and other topics.
- Chapter VII, on the right to complain, specifies the rules allowing patients to complain about their treatment.

*Ireland*

The Charter of Rights for Hospital Patients (1991) list 12 rights putting the patient first.

1. Access to hospital services in emergency cases or to be put on a waiting list in admission to hospital cannot take place immediately;
2. The right to receive out-patient appointment within reasonable time;
3. The right to be treated in a courteous manner at all times by every member of the hospital staff;
4. The right to receive visits from relatives and friends, including children;
5. The right to be treated with respect for religious and philosophical beliefs;
6. The right to privacy, especially when the nature of the clinical condition of the patient is being discussed;
7. The right to be informed of the name of the consultant under whose care a patient is being placed and the right to be informed of the nature of the illness or condition in understandable language;
8. Treatment should only be given to a patient with his/her informed consent or, in the case of a child, with the consent of a parent or guardian;
9. The right to total confidentiality in respect of the medical records;
10. The right to refuse to participate in the teaching of medical students and to take part in any clinical trials or research concerning the use of new drugs or medical devices;
11. The right on discharge from the hospital to be informed of the nature of the condition and the treatment received while in hospital
12. The right to complain about any aspect of hospital service and have the matter referred to the hospital's Complaints Committee if the complaint is not satisfactory resolved.

*Israel*

The Act on Patients' Rights (1 May 1996) is divided into nine chapters dealing with specific issues.

- Chapter 1 sets out the aim of the Act: to establish the rights of every person who requests or receives medical care, and to protect his or her dignity and privacy.
- Chapter 2 deals with the definitions of several terms used in the text.
- Chapter 3 is on the right to medical care. It regulates the delivery of medical care in non-urgent and urgent circumstances, prohibits discrimination among patients, entitles the patient to obtain a second opinion, and ensures the continuity of medical care and respect for the patient's dignity and privacy.
- Chapter 4 provides for informed consent to medical care. The Act determines the extent of the information to be given to patients, and exceptions to the rule.
- Chapter 5 covers medical records and medical information, setting out a framework for the obligation of staff to maintain the confidentiality of information concerning patients.

- Chapter 6 regulates the setting up of different committees and rules for their procedures. An Investigative Committee inquires into a patient's complaints or exceptional incidents in the giving of medical treatment. A Control and Quality Committee evaluates and improves the quality of medical care. An Ethics Committee puts the Act into effect, and has different duties from the ethical committees of each health care establishment.
- Chapter 7 covers the responsibility for the observance of patients' rights in a medical facility, providing for an ombudsperson.
- Chapter 8 provides for the Act to apply to the security forces.
- Chapter 9 contains miscellaneous provisions.

### *Lithuania*

The law on Patients' Rights and injury to Patients (September 1996) consists of four parts and 25 articles.

- Part I covers general provisions, defines of the terms used in the law and sets out the purpose of the Law.
- Part II lays down the rights to health care (Article 3), to accessible health care (Article 4), to choice of provider of health care services (physician or nursing staff member) and establishment (this choice might be limited in accordance with other legal provisions—Article 5), to information (Article 6), to participation in the process of teaching and scientific research (participation in scientific research is subject to the patient's consent; specific legal provisions laid down in other laws regulate this issue—Article 7), to refuse treatment (Article 8), to complain to an administrative staff member of the health care institution or to lodge a complain before the Ministry of Health and courts (Article 9) and to the inviolability of personal privacy (Article 10).
- Part III is on patients' documents, and provides for the keeping of medical records and documents concerning patients and sets out the circumstances in which patients may have access to these and the conditions for the use of the information contained in patients' documents for scientific research and student instruction.
- Part IV describes the grounds for and procedure in the case of compensation for injury to patients, defines injury to patients, and the ways it should be assessed, provides for compulsory insurance of physicians and other care providers against compensation for possible injury to patients, and sets out the procedure regulating the payment of compensation to injured patients

### *The Netherlands*

The Medical contract law(1994) brings the following patients' rights to the civil code.

- Article 446 gives definition of the medical contract. The contract is established between the care provider and the principal (the patient) for carrying out medical actions directly affecting the person of the principal or of a particular third party.
- Article 447 prescribes that a minor who has attained the age of 16 shall be competent to enter into a treatment contract.
- Article 448 lays down provisions on the right to information. The care provider shall inform the patient clearly and, if requested, in writing of the proposed examination, state of health and treatment. Patients under the age of 12 are to be provided with understandable information. The care provider may withhold information from the patient only if its provision would manifestly cause harm to the patient. The withheld information should be given to the patient when there is no longer a danger of causing him or her harm.
- Article 449 says that, if the patient has expressed a wish not to be informed, this is to be respected.
- Article 450 provides for consent. If the patient has not attained the age of 16 but is over 12, the consent of his or her parents is required.
- Article 451 gives the patient the right to request a written description of the treatment to which he or she has consented.
- Article 452 requests the patient to cooperate to the best of his or her knowledge with the health care provider.
- Article 454 spells out the rights to data protection and confidentiality. The care provider shall keep all data concerning the course of the patient treatment in a file. The patient may add statements to the file regarding the documents mentioned.
- Article 455 gives the patient the right to ask for a deletion of files related to his or her treatment. Exemptions are granted for documents whose retention may reasonably be assumed to be of considerable importance to a person other than the patient.
- Article 456 gives permission to patients to request copies of the documents referred to in article 454.
- Articles 457–459 regulate access to patients' documents, and list the people to whom such access might be given. Article 458 lays down provisions for using information concerning the patient for statistical and research purposes. Article 459 stipulates that only the patient can observe the process carried out by the care provider.
- Articles 462–464 deal with liability of the health care establishment in which the treatment is provided.
- Article 465 lays down provisions for treatment of patients below the age of 12 and the conditions in which their parents should be consulted.
- Article 466 stipulates that, if there is no time to request the permission referred to in Article 465, the treatment should be performed to prevent serious harm to the patient.
- Article 467 regulates the use of anonymous substances or parts secreted from the body for medico-statistical or other medico-scientific research purposes. Such use is allowed if the patient has not objected and the research is carried out with due care.

### *Russian Federation*

The draft law on the rights of the patient spells out the following patients' rights.

#### **Chapter I deals with general provisions.**

- Article 1 defines the scope and purpose of the law.
- Article 2 introduces the key concepts used in the law (patient, rights, medical care, consent, etc.).
- Article 3 spells out the basic principles for giving effect to the rights of the patient.
- Article 4 refers to the existing legislation of the Russian Federation on the rights of the patient.
- Article 5 recalls the international agreements relevant to patients' rights.

#### **Chapter II describes the rights and obligations of the patient.**

- Article 7 lists the rights of patients to: accessible medical care guaranteed by the state, respectful and humane treatment, relief of the pain associated with illness and/or medical intervention, assured quality of care, informed free choice of physician, medical establishment and medical insurance organization, voluntary medical insurance, confidentiality of information, compensation for damage to health in the rendering of medical care and for moral damage, and the exercise of religious rites including the making available of a separate room;
- Article 8 spells out the rights of a patient hospitalised without his or her agreement and article 9 sets the restrictions on the patient in the provision of medical care.
- Article 10 Lists the obligations of the patient to maintain of his or her health status.

#### **Chapter III guarantees the basic rights of the patient.**

- Articles 11–14 make provisions for state guarantees of the rights of patients to accessible medical care without payment, high-quality medical care, information in the provision of medical care and to confidentiality of information.
- Articles 15–17 lay down the right of the patient to give voluntary informed consent and to refuse the actions of medical workers and other persons involved in the provision of medical care.
- Articles 18 and 19 prescribe the rights to compensation for damage to health and for moral damage.

### *Slovakia*

According to the Act on Health Care (No. 277/1994), patients have rights:

- to health care provision;
- to choose a physician and health care establishment, with the exception of people doing military service or in prison;
- to physical and mental integrity;
- to be informed about their health status, treatment and prognosis and to the confidentiality of all medical records (although the physician decides on the content of the information);
- to refuse health care with the exceptions provided for in the Act;

- to be relieved from pain;
- to informed consent to any medical intervention- patient refuses an intervention he/she is bound by a written statement; treatment may be applied without seeking the patient's consent in conditions spelt out by the Act; and
- to gain access to and to comment on their medical records.

### *Turkey*

The draft law on patients' rights contains the following legal provisions.

- Articles 6–14 cover justice in health care, including the rights to be informed, to choose and change health care setting, to choose and change physician and to receive necessary diagnosis and treatment; and the ban on euthanasia.
- Articles 15–20 cover patients' information, including the rights to be informed about one's health status, to ask for information, to gain access to and correct medical records, and to refuse to be informed.
- Articles 21–23 deal with patients' rights protection, including the right to respect of confidentiality.
- Articles 24–31 cover informed consent, including the rights to consent to organ and tissue removal, and to refuse treatment.
- Articles 32–36 provide protection for people participating in medical trials, including the right to consent participation and the rights of minors.
- Articles 37–41 cover miscellaneous rights, such as those to security in health care establishments, to attend religious services and to carry out religious rituals.
- Articles 42–49 describe the applications of the law.

### *United Kingdom*

The rights included in the 1991 Patients' Charter<sup>2</sup> are:

- to receive health care on the basis of clinical need, regardless of ability to pay;
- to be registered with a GP;
- to receive emergency medical care at any time;
- to be referred to a consultant and to receive a second opinion under particular circumstances;
- to an explanation of any treatment proposed;
- to have access to health records;
- to choose whether to participate in medical research and student training;
- to information on local health services (quality standards and waiting times);
- to admission for treatment within two years from registration on a waiting list;
- to receive a full and prompt written reply to complaint.

---

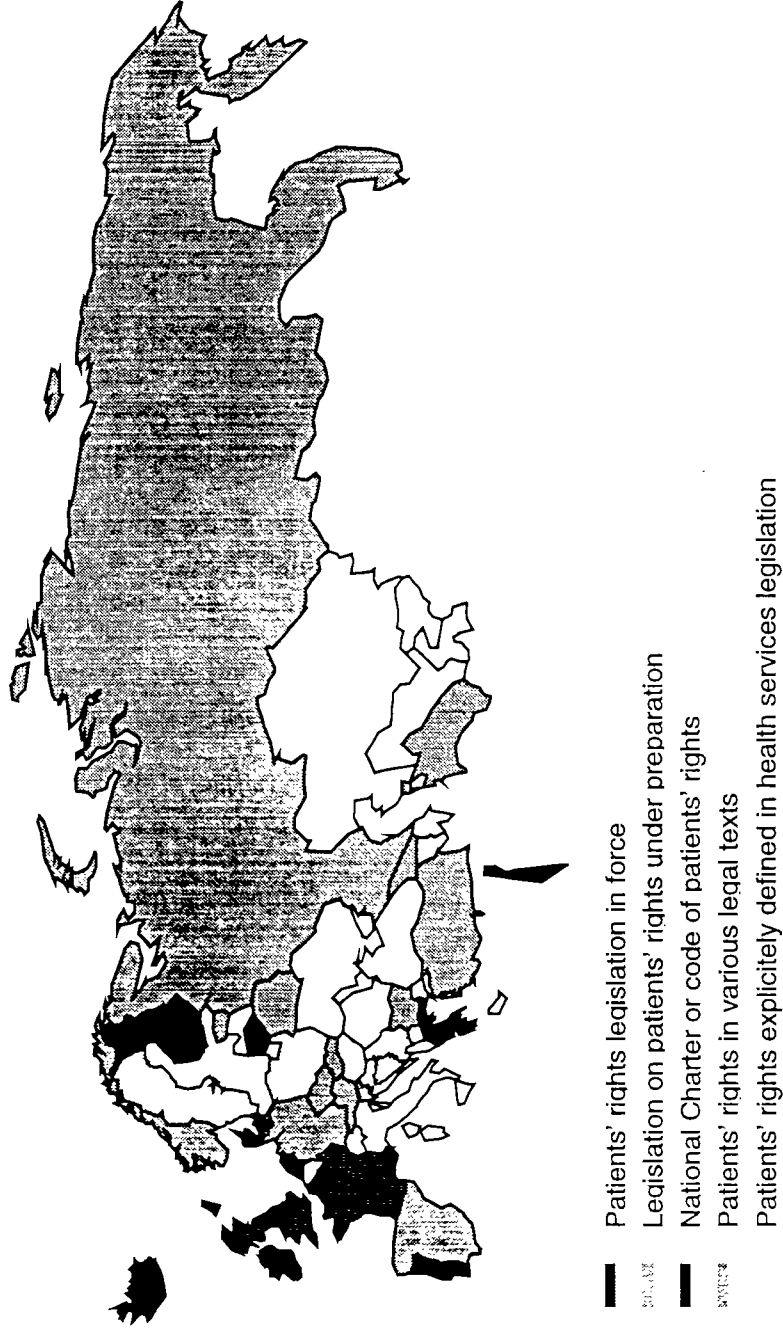
<sup>2</sup> The 1995 revision of the Patients' Charter was not available when this review was carried out.

*Uzbekistan*

Article 24 of the Bill on Protection of the Health of Citizens (14 September 1996) spells out the following patients' rights:

- to respectful and humane care from health care personnel;
- to the choice of physician and health care establishment;
- to request consultation with other physicians and specialists;
- to keep confidential all information and data about their reasons for requesting health care services, their health status, medical condition and diagnosis;
- to consent to and to refuse any medical intervention;
- to receive any information related to their rights, duties and health status, and to designate a representative for this purpose;
- to receive health care services within the framework of the voluntary health insurance system; and
- to have access to a lawyer or other legal representative for defence of their rights.

### Appendix 3 The development of patients' rights on the European scene



## References

1. Conseil économique et social. *Les droits de la personne malade*. Paris, Rapport, 1996, 189.
2. Leenen, H. et al. *The rights of patients in Europe*. Deventer, Kluwer, 1993, p. 189.
3. *Declaration on the Promotion of Patients' Rights in Europe*. Copenhagen, WHO Regional Office for Europe, 1994 (document ICP/HLE 121).
4. Vienonen, M., ed. *European health care reforms. Citizens' choice and patients' rights*. Copenhagen, WHO Regional Office for Europe, 1996, p. 133.
5. Saltman, RB, Figueras, J and Sakellarides, C (eds) (1998) *Critical challenges for health care reform in Europe*. Buckingham: Open University Press.
6. Iliev, D. and Vienonen, M. *Patients' Rights in Europe as at June 1997*. Copenhagen, WHO Regional Office for Europe, 1997.
7. Executive Board 101<sup>st</sup> session. Geneva, 19–27 January 1998. Resolutions and decisions. Annexes. Geneva, World Health Organization, 1998 (document EB101/1998/REC/1).
8. World Health Assembly resolution WHA51.10 on the ethical, scientific and social implications of cloning in human health. *World Health Organization—Organisation Mondiale de la Santé*. 1998 (<http://www.who.ch/wha-1998/listang.htm>).
9. Hannikainen, P. et al. Three years in force: has the Finnish act on the status and rights of patients materialized? Helsinki, Ministry for Social Affairs and Health, 1996, p. 17.
10. Markenstein, L.F. The codification in the Netherlands of the principal rights of patients: a critical review. *European journal of health law*, 2: 33–45 (1995).
11. Birmontiene, T. Patients' rights legislation in Lithuania. *European journal of health law*, 3: 85–94 (1996).
12. Department of Health. The patient's charter. London, HM Stationery Office, 1991, p. 6.
13. Wijnberg, B. Patients' rights and legislative strategies. *Medical law*, 12: 137–140 (1993).
14. Leenen, H.J.J. The rights of patients in Europe. *European journal of health law*, 1: 5–13 (1994).



