PATIENT RIGHTS IN THE EU

SPAIN

EUROPEAN ETHICAL - LEGAL PAPERS N° 15
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Sarah Defloor
Herman Nys
Kris Dierickx
Tom Goffin

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Within the Centre for Biomedical Ethics and Law of the Catholic University of Leuven - one of the leading bioethical and legal research centres in Europe - we are involved as coordinator, partner or participant in different European research projects. Biomedical ethics and law are rapidly evolving disciplines. Although there exists already a great number of specialized peer reviewed journals and series of books in both disciplines we felt a growing need for a medium through which the results of our research can directly be presented to the research community and the interested community at large. To meet this need we decided to start the *European Ethical-Legal Papers*. Such papers will also contribute to the transparency we owe to society that finances our research efforts. We also hope that it will contribute to the discussion and the exchange of information and ideas among researchers in Europe and elsewhere.

Herman NYS  
Professor Medical Law

Kris DIERICKX  
Associate Professor Medical Ethics
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EuroGentest is a five-year EU funded program that aims to develop the necessary infrastructure, tools, resources, guidelines and procedures that will lead to the establishment of harmonized, qualitative genetic testing services in Europe. Within EuroGentest we are dealing with the ethical and legal issues of genetic testing. Harmonization of the technical aspects of genetic services in Europe requires a legal and ethical framework that respects cultural, religious, philosophical and other domestic characteristics of a given country and its population(s), but at the same time conforms to basic and universally accepted human rights. To continuously supervise the legal and ethical developments regarding the promotion and protection of the rights of patients and users of health services and to make the results of our research publicly available, is a permanent challenge. This publication in the European Ethical-Legal Papers aims to contribute to it.

Opened for signature more than 10 years ago (in Oviedo, Spain, on 4 April 1997), the European Convention on Human Rights and Biomedicine is now becoming increasingly important as a standard to evaluate the efforts and the progress made by the Member States of the European Union to promote and protect the rights of patients and users of health services. In this fifteenth issue we present the results of this evaluation for Spain, one of the EU Member States that have ratified the Convention.

The content of this publication will be as follows.
In an introductory chapter we briefly will describe Spain with respect to some of its main features related to its political and legal background and its health care system.
This will be followed by an encompassing overview of the rights of patients in Spain. In a first paragraph the legal status of the Biomedicine Convention will be situated against the background of Spanish constitutional law. Then we will turn to a description of the national legislation on patient rights. Many different enumerations of patient rights exist. Since we are particularly interested in the way the
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Biomedicine Convention has been received by the Member States of the European Union, we will follow the structure of the Convention. The right to informed consent (articles 5, 6, 8 and 9 of the Convention) will come first, followed by different aspects of the right to private life and the right to information (article 10 of the Convention) such as: patient rights regarding the medical file, the right to medical secrecy/confidentiality and the right to privacy and protection of private life. This part of the analysis will end with the right to complain in case of unlawful infringement of a patient right (article 23 of the Convention) and the right to compensation for undue damage (article 24 of the Convention). In the next chapter we will look at the rights of patients as users of genetic services: are the rights of patients complemented by more specific rights for users of genetic services? (articles 11 and 12 of the Convention). With some concluding remarks we will finish this paper N° 15 of the Ethical-Legal Papers.

Without the help of Mayte Requejo Naveros (Associate Professor of Criminal Law, Law School, Complutense University of Madrid) we could not have accomplished this work. She provided us with valuable information on the status of patient rights in Spain and answered our questions accurately and patiently. In the footnotes we refer to the information provided by her as “personal communication of”. The possible mistakes and wrong interpretations are our responsibility. We are also aware of the limitations of this endeavor not the least because of differences in languages. Nevertheless we hope that this publication will stimulate the discussion on the promotion and protection of patient rights in Spain. Therefore we welcome all reactions on www.cbmer.be.

Leuven, March 2008

*The research for this publication was supported by the Eurogentest Network of Excellence of the EU, FP6 – 512148 and its coordinator Prof. Dr. J.J. CASSIMAN*
II. BRIEF DESCRIPTION OF SPAIN

§ 1. Political and legal system

The Kingdom of Spain is a constitutional monarchy and is organized as a parliamentary democracy. Since 1975 King Juan Carlos I is the chief of state. Although the King of Spain today exercises little real power over the Spanish politics, he is regarded as an essential symbol of Spain.

The Council of Ministers (or Consejo de Ministros) is the supreme executive body in Spain. The Council is headed by the President of the Government, which is the equivalent to a Prime Minister. He is elected by the National assembly and nominated by the King. The President of the Government designates the rest of the Council and he can also assign various vice presidents, although this is not mandatory. The President of the Government directs the activities of the Council as a whole. The leader of the majority party or the leader of the majority coalition following the legislative elections is usually proposed to be President of the Government by the Monarch and is elected by the National Assembly. There is also a Council of State that is the supreme consultative organ of the Council of Ministers. However, its recommendations are non-binding.

The legislative power on the national level is vested in the bicameral National Assembly or General Courts (or Cortes Generales), which consists of the Congress of Deputies (or Congreso de los Diputados) and the Senate (or Senado). The Congress of Deputies has 350 members who are elected by popular vote on block lists by proportional representation. The Senate consists of 259 seats of which 208 are directly elected by popular vote and the other 51 are appointed by the regional legislatures. The members of the Congress and the Senate serve concurrent terms of 4 years. In practice, the position of the Senate is rather weak. It can make changes or refuse laws, but the Congress is capable to ignore these amendments. With few exceptions, it is the Congress that approves every law.
The Spanish judicial branch is composed of different courts depending on what is to be judged and on the jurisdictional order. The Supreme Court is the highest judicial body in Spain for all matters not pertaining to the Spanish Constitution. The role of the judiciary branch is governed by the General Council of the Judiciary of Spain.

The Constitutional Court of Spain is the highest judicial body with the power to rule on the constitutionality of laws, acts or regulations set forth by the national or the regional parliaments. It also may rule on the constitutionality of international treaties before they are ratified, if requested to do so by the government, the Congress of Deputies or the Senate. The Court consists of 12 magistrates who serve a nine-year term.

The Spanish nation is a decentralized country and is organized in the form of a so-called State of Autonomies (or Estado de las Autonomías). Spain is administratively subdivided into 17 Autonomous Communities (or Comunidades Autónomas). All of the Autonomous Communities have their own elected parliaments, governments, public administrations and budget. The Spanish Constitution lays out the competences that are exclusively the responsibility of the central state or of the Autonomous Communities, and those that are shared between the two.¹

§ 2. Health care system

The Spanish Constitution of 1978 guarantees the right to health care and health protection.² According to article 43 the public authorities have to organize and watch over public health by means of preventive measures and the necessary benefits and services. The law has to establish the rights and duties in this respect.

The Spanish health care system is a totally decentralized system. Following the decentralization of the Spanish nation, different health care powers have been transferred to the regional level. The

² English version of the Spanish Constitution available on http://servat.unibe.ch/icl.
decentralization reform was completed in 2002 and resulted in the governance of the system being decentralized to all 17 Autonomous Communities.³

Although the Autonomous Communities enjoy considerable legislative freedom and autonomy with regard to health care policy, the central government has retained the responsibility for certain strategic areas. The central government not only has the power to promote coordination and cooperation in the health sector, but also the power to ensure that the quality of all services is guaranteed and to ensure that equity with regard to access to health care exists throughout the national territory.⁴ It also has certain competencies concerning international health, financing the system, definition of the benefits packages, undergraduate education and postgraduate medical training, pharmaceutical policies, research and high-level inspection.

The Spanish Ministry of Health and Consumer Affairs plays the most significant role in determining the health care policy at central level. The Ministry is the key authority responsible for coordinating public health and health care services, drafting health policy and any basic enabling legislation required.⁵ It guarantees the effective right of all inhabitants to health protection.

All 17 Autonomous Communities have important legislative and implementation powers in the fields of public health, community care and most social services.⁶ There is no hierarchy between the central

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government and the regional government in matters that have been transferred.7

The General Health Care Act of 1986 outlines the main principles for the Spanish National Health System. This system is created from the social security health services and provides universal coverage with free access to health care. It is publicly funded and has a regional organizational structure.

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III. GENERAL PATIENT RIGHTS

§ 1. Legal status of the Convention on Human Rights and Biomedicine

Spain has participated very actively in the elaboration and approval of the European Convention on Human Rights and Biomedicine. The Convention was opened for signature by the Member States of the Council of Europe in the city of Oviedo in Spain. Spain has signed the Convention on 4 April 1997 and has ratified it on 1 September 1999. The Convention entered into force on 1 January 2000.

According to article 96 (1) of the Spanish Constitution international treaties that are concluded in a legally valid way become part of the internal legal order once officially published in Spain. Their provisions may only be abolished, modified or suspended in the manner provided for in the treaties themselves or in accordance with general norms of international law. Consequently, the Convention has a superior force to any national legislation and is directly applicable in Spain.

Notwithstanding the direct applicability of the Convention, the ratification of the Convention encouraged a reform of the existing legislation on health care. A reform was necessary not only because some aspects of the existing legislation were in contradiction with the Convention, but also because some of the new rights provided for in the Convention were not yet acknowledged in the Spanish health care legislation.

The Convention on Human Rights and Biomedicine was implemented in Spain in November 2002 through the Basic Law 41/2002 on the

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Autonomy of the Patient and the Rights and Obligations with regard to Information and Clinical Documentation (hereafter: the Patient Rights Law). The Exposition of Reasons (Explanatory Memorandum) of this Basic Law refers to the Convention as the main source of the Law: “(...) Finally, emphasis may be placed on the special relevance of the Convention of the Council of Europe for the protection of human rights and the dignity of the human being with regard to the applications of biology and medicine (Conventions on the rights of man -sic- and biomedicine), signed on 4th April 1997, which came into force in the Kingdom of Spain on 1st January 2000. This Convention is a major initiative: in fact, unlike the various earlier international declarations, it is the first international instrument having a binding juridical nature on the countries signing it. Its special value lies in the fact that it establishes a common framework for the protection of human rights and human dignity in the application of biology and medicine. The Convention deals explicitly, at length and with considerable extent, with the need to acknowledge the rights of patients, among which it highlights the right to information, informed consent and the privacy of information relating to the health of persons, with the aim of achieving a standardization of legislations in this field in different countries. In this regard, it is highly advisable to bear the Convention in mind when it comes to tackling the challenge of regulating such important questions.”

Spain has made several restrictions based on article 26 of the Convention. The Patient Rights Law contains such restrictions for reasons that concern the public health or the health of a patient. That is the case with the right to information and the right to informed consent. On the one hand, the doctor is allowed -with regard to the right to information- not to inform the patient if he thinks it can be prejudicial to his health. The right to informed consent on the other hand, can be limited in order to preserve the health of the patient, the health of third parties and the public health.

§ 2. National legislation on patient rights

The primary legal sources of patient rights at national level in Spain are the General Law on Public Health of 1986 and the Patient Rights Law of 2002. In addition, the General Council of the Medical Order of Spain has recognized patient rights in the third chapter of the Code of Deontology.¹²

The General Health Law of 1986 lays down a series of rights and duties of patients. However, due to a growing awareness of patient rights that had been distinguished by several legal initiatives at national and international level such as the Convention, the patient rights guaranteed by the law of 1986 became insufficient.

In 2002 the Basic Law 41/2002 on the Autonomy of the Patient and the Rights and Obligations with regard to Information and Clinical Documentation was passed in the Spanish Parliament. This Patient Rights Law entered into force on 16 May 2003.

The Patient Rights Law has partially repealed the General Health Law of 1986, particularly as regards the provisions on patient rights. The Exposition of Reasons (Explanatory Memorandum) to this Law states the following: “(...) this Law completes the provisions enunciated by the General Health Act as general principles. In this regard, it reinforces and provides special treatment for the right to autonomy of the patient. In particular deserving of special mention is the regulation on prior instructions which, in accordance with the criterion set down in the Oviedo Convention, considers the wishes of the patient stated in advance within the scope of informed consent”.¹³

According to the first article of this Patient Rights Law the purpose of this law is to regulate the autonomy of the patient and the rights and obligations with regard to information and clinical documentation of patient, users, professionals as well as public and private health centers and services.

§ 3. Right to informed consent

Article 5 of the Biomedicine Convention:

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
The person concerned may freely withdraw consent at any time.

The right to informed consent is extensively regulated in chapter 4 of the Patient Rights Law of 2002, which is entitled “Respect for the autonomy of the patient”.

A. Right to informed consent as a basic requirement

The right to informed consent is included as one of the basic principles of the Patient Rights Law. According to the second paragraph of article 2 of this Law all actions within the scope of health require in general the prior consent of patients or users of health services. The consent must be obtained once the patient has received prior information and shall be given in writing when a law provides this. The third paragraph determines that the patient has the right to decide freely between the clinical options available, once he has received proper information. All professionals involved in care activities are obligated not only to perform their techniques correctly, but also to comply with the duties of information and clinical documentation. They are also obligated to respect the decisions taken freely and voluntarily by the patient (article 2 (6)).

The third article of the Patient Rights Law defines an informed consent as the free, voluntary and conscious decision of a patient, stated in the full use of his faculties after receiving proper information, so that an action concerning his health can be undertaken.
In addition to these general provisions, the informed consent is extensively dealt with in the fourth chapter of the Patient Rights Law, which regulates the autonomy of the patient. According to the first paragraph of article 8 any action regarding the health of a patient requires the free and voluntary consent of the concerned party, once the patient has assessed the options inherent to the case and after he received the information provided for in article 4 which regulates the right to health care information.

B. Contents of information preceding informed consent

The first paragraph of section 4 stipulates in broad terms that patients have the right, by virtue of any intervention in the scope of their health, to learn any information available on their health, with the exception provided for by law. Such information includes at least the purpose and nature of each intervention, its risks and consequences. According to article 4 (2) clinical information has to be truthful, it has to be communicated to the patient in a manner that is comprehensible and suited to his needs and it has to help him take decisions in accordance with his own free will. The Patient Rights Law defines clinical information as any data -regardless its form, kind or type- permitting knowledge to be acquired or enlarged on the physical state and the health of a person, or the way of preserving, caring, improving or retrieving it.

Article 10 (1) contains more specific conditions regarding the contents of information preceding informed consent. In accordance with this article the physician has to provide the patient with the following basic information prior to obtaining written consent:

a) relevant or important consequences;

b) risks related to the personal or professional circumstances of the patient;

c) probable risks under normal conditions, in accordance with the experience and state of the science, or directly related to the type of intervention;

d) contraindications.

With regard to the specific risks that have to be communicated to the patient, the prevailing opinion in legal scholarship is that the
information preceding an intervention must encompass both the typical and the personalized risks. The typical risks can be described as those risks which, according to the current state of scientific knowledge, can usually be expected. The personalized risks are those risks that result from the individual pathology of the patient and from the relevant personal or professional circumstances.

The Supreme Court on the other hand, has judged in several decisions that remote risks also have to be communicated to the patient as long as they can result in serious harm.

As a general rule it can be stated that information shall be provided orally with a note being made in the clinical record (article 4 (2)). The Patient Rights Law does not state in which cases the information must be given in writing. According to REQUEJO it is arguable that the information must be given in writing in those cases in which the consent must be given in writing (see infra § 3 C).

In accordance with the first paragraph of article 9 a patient may waive the right to be informed, without prejudice to the obtaining of the prior consent for an intervention. This waiver of information shall be noted in a document. However, the Patient Rights Law contains certain limitations to this right not to be informed, as there is the interest of the health of the patient, the health of third parties or the community or the therapeutic demands of the case. According to REQUEJO such broad limitations to the right not to be informed may arguable dilute the effect of its acknowledgement.

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There is no specific provision in the Patient Rights Law concerning the burden of proof of the fact that information preceding consent was given or not. With regard to the legal obligation to obtain informed consent, the prevailing opinion is that the lack of proof that information was supplied by the physician and that consent was given by the patient is to the detriment of the defendant, regardless the form in which the information was supplied and the consent was given.\textsuperscript{18}

The consolidated opinion of the Spanish Supreme Court is based on the principle that the burden of proof must lie upon the party who can have easier access to evidence. In addition, imposing a negative proof on the defendant is considered as a serious barrier which could infringe upon the constitutional right to effective protection by the courts.\textsuperscript{19}

C. Form of informed consent

The Patient Rights Law establishes as a general rule that the informed consent must be given orally (article 8 (2)). The requirement of an oral informed consent has been welcomed by practitioners and scholars as the General Health Law of 1986 required a written consent in all cases. However, this was not workable in practice and was even unnecessary in many health care processes.\textsuperscript{20}

According to article 2 (2) of the Patient Rights Law the consent has to be given in writing in cases provided for by law. This provision is elaborated in article 8. The second paragraph of this article stipulates that consent has to be given in writing in case of surgical operation, invasive diagnostic and therapeutic procedure, and in general when the application of procedures implies risks or drawbacks having a notable and foreseeable negative repercussion. In accordance with article 8 (3) the written consent of the patient shall be necessary for


each intervention listed in the second paragraph. The written consent has to contain sufficient information on the application procedure and on its risks. The physician has to assess the need for a written consent on the basis of the degree of incertitude as regards the result of the intervention (article 10 (2)).

D. Exceptions to the requirement of informed consent

**Article 8 Biomedicine Convention**

*When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.*

The Patient Rights Law establishes two exceptions to the requirement of informed consent. According to article 9 (2) the physician shall in the first place be able to conduct clinical interventions which are essential for the health of the patient without the informed consent of the patient in case there exists a risk for public health. In the second place the informed consent does not have to be obtained when there is an immediate serious risk for the physical or mental integrity of the patient and it is not possible to obtain his consent, consent of the family or the consent of persons tied to the patient for *de facto* reasons.

E. Refusal and withdrawal of consent

The Spanish Patient Rights Law acknowledges the right of patients to refuse a medical treatment. In accordance with article 2 (4) all patients or users of health care services have the right to refuse treatment, except in the cases determined by law. The denial of treatment has to be noted in writing.

The patient can freely revoke his consent in writing at any moment (article 8 (5)). The withdrawal of consent has to be done in writing in
all cases, also in the cases where consent has been given orally. As it was not contemplated in the General Health Law of 1986, this provision was introduced by the Patient Rights Law following the Biomedicine Convention.

F. Previously expressed wishes

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**Article 9 Biomedicine Convention**

*The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.*

The introduction at state level of a regulation concerning previously expressed wishes in article 11 was one of the most important innovations of the Patient Rights Law. Not taking into account the regulations of the Autonomous Communities, it was the first time in the Spanish legal system that the previously expressed wishes were regulated.

By means of the document of prior instructions, a capable and free person who is of age (18 years), can declare his will in advance as regards the care and treatment of his health or the destination of his organs or his body in case of death, so that his wishes are complied with at the moment he is not capable of expressing his will personally (article 11 (1)). According to NAVARRO-MICHEL an advance directive may express the preference to have treatment abstained (if not applied yet) or withdrawn (if treatment was already started), or it may express the patient’s wish to exhaust every possible medical

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treatment. The first paragraph of article 11 also foresees the possibility to designate a representative to act as an intermediary with the physician or the medical team in order to fulfill the patient’s will.

With regard to the form of the document, the Patient Rights Law only provides that it must be in writing. It leaves the imposition of other requirements to the regulations of the Autonomous Communities. The laws of the Autonomous Communities establish two ways of granting the document of prior instructions, namely before a notary (without witnesses) or in the presence of three witnesses of legal age and with legal capacity.

In accordance with article 11 (3) advanced directives that are contrary to the legal system, the lex artis or those who fail to correspond to the factual situation foreseen by the interested party at the moment of giving the instructions, shall not be applied. The patient’s clinical record shall contain a reasoned statement related to the factual situation.

The legal system exception refers to previous expressed wishes that may be contrary to any Spanish Law. The legal provisions generally alluded to are the ones related to the protection of the right to life and more precisely those referred to euthanasia. In particular, the fourth paragraph of article 143 of the Spanish Criminal Code punishes actions of active euthanasia. The lex artis exception refers to situations in which the advanced directives go against the rules of medical good-practice.

According to article 11 (4) the prior instructions shall be able to be freely revoked at any moment, with a note being made of this in writing.

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The Patient Rights Law contains two provisions aiming to secure the efficacy of prior instructions. Article 11 (2) stipulates in the first place that each provider of health care services has to lay down an appropriate procedure in writing to guarantee compliance with the previously expressed wishes. In order to ensure that the advanced directives have efficacy throughout the whole country, article 11 (5) states that a national register has to be created within the Ministry of Health and Consumption.

G. Informed consent in case of minor patients

<table>
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<tr>
<th>Article 6 Biomedicine Convention</th>
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1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

According to article 315 of the Spanish Civil Code the legal age of majority is 18 years. However, a minor who is emancipated or has reached the age of 16 has attained the age of medical majority. Article 9 (3) c) of the Patient Rights Law stipulates that consent by representation cannot be granted in case of minors who are neither incapable nor incapacitated but who are emancipated or who are more than 16 years of age. However, it became clear in a study of PÉREZ-

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CÁRCELES and others that the parents of minor patient are still informed in a lot of cases.\textsuperscript{29}

Nevertheless, in case of interventions that involve serious risks - according to the judgment of the physician - the parents must be informed and their opinion must be taken into account. In addition to this exception, the Patient Rights Law also determines that the voluntary interruption of pregnancy, the practice of clinical trials and the practice of assisted human reproduction techniques are subject to specific regulation and to the general regime of legal age (article 9 (4)). As stated above, this is also the case for an advanced directive. According to article 11 (1) only persons who are of age are allowed to express their wishes through a document of prior instructions (see §3 F).

When the minor patient is under age and is neither intellectually nor emotionally capable of understanding the scope of the suggested intervention, the informed consent must be given by the patient’s legal representative (article 9 (3 c)). The minor must be heard if he is more than 12 years old.

In accordance with the fifth paragraph of article 9 the representative has to give his consent in accord with the circumstances, in proportion to the needs of the patient, at all times in favor of the patient and with respect to his personal dignity. To the degree possible, the patient has to participate in the decision-making process throughout the health care process.

\textsuperscript{29} M.D.PÉREZ-CÁRCELES, J.E.PEREÑIGUEZ, et al., "Primary care confidentiality for Spanish adolescents: fact or fiction?", \textit{Journal of Medical Ethics} 2006, N° 32, 332.
H. Informed consent in case of incapacitated adults

**Article 6 Biomedicine Convention**

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure.

When the attending physician is of the opinion that the patient is not capable of taking a decision or his physical or mental state does not allow the patient to appreciate his situation, the consent must be granted by a legal representative (article 9 (3) a)). According to article 11 (1) a person who is of age, capable and free can designate a representative to act as an intermediary with the physician or the medical team in order to fulfill the patient’s will. If the patient has no legal representative, the consent shall be granted by a member of his family or by a person tied to the patient for de facto reasons.

Regarding the information preceding the consent, the same rules that apply in case of minor patients are applicable. Article 5 (1) stipulates that the patient is the one who has the right to information. A member of his family or persons tied to the patient for de facto reasons may also be informed to the degree that the patient gives his permission in an explicit or tacit manner. The patient has to be informed, even in cases of incapacity, in a manner that is adjusted to his possibilities of comprehension. Moreover, the legal representative must also be informed. When the attending physician is of the opinion that the patient lacks the capacity for understanding the information due to his physical of mental state, the information must be made available to family or persons tied to him for de facto reasons.
§ 4. Right to information about his or her health

A. Right to information about his or her health as a basic requirement

Spanish health law provides the right to information about his health as a right independent of the right to informed consent. As opposed to the General Health Law of 1986, the Patient Rights Law provides a detailed and extensive regulation of the right to information about his health. The Law substantially improved the existing legal framework and introduced significant innovations. The Patient Rights Law differentiates two types of health information, namely health care information (article 4) and epidemiological information (article 6). Health care information is defined as any information regarding one’s health, whereas epidemiological information refers to the health problems of the community when they imply a risk for the public health or for the patient’s individual health.

According to article 4 (1) patients have the right, by virtue of any intervention in the scope of their health, to know any information available on their health, unless otherwise provided for by law. As a general rule, the information has to be given orally. This new provision resolves one of the major problems created by the General

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Health Law, which required that information was given orally and written. This rule was in practice impossible to comply with.\textsuperscript{31} According to article 4 (2) clinical information has to be truthful, it has to be communicated to the patient in a manner that is comprehensible and suited to his needs, and it has to help him to take decisions in accordance with his own free will. The Patient Rights Law defines clinical information as any data -regardless its form, kind or type- permitting knowledge to be acquired or enlarged on the physical state and the health of a person or the way of preserving, caring, improving or retrieving it. The physician responsible for the patient and all other attending professionals have to guarantee that the patient’s right to health care information shall be complied with (article 4 (3)).

In accordance with article 5 (1) the person who has the right to be informed is the patient. Members of his family or persons tied to him for \textit{de facto} reasons must also be informed to the degree that the patient permits this either in an explicit or a tacit manner. The patient has to be informed, even in cases of incapacity, in a manner that is adjusted to their possibilities of comprehension. Moreover, the legal representative must also be informed (article 5 (2)) . When the attending physician is of the opinion that the patient lacks the capacity to understand the information due to his physical or mental state, the information must be made available to family or persons tied to him for \textit{de facto} reasons (article 5 (3)).

B. Right not to know

According to the first paragraph of article 4 all persons have the right not to be informed. Although certain Autonomous Communities already recognized this patient right, it was the first time that the right not to be informed was acknowledged at state level, thereby guaranteeing its protection throughout the Spanish territory.\textsuperscript{32}


The right not to be informed is also recognized within the framework of informed consent (article 9 (1) - see §3 B). The Patient Rights Law provides in this context certain limitations to the exercise of the right not to know, which are the health of the patient, the health of third parties, the health of the community or the therapeutic demands of the situation.

C. Therapeutic exception

The fourth paragraph of article 5 establishes an exception to the right of information. This exception is called the state of therapeutic necessity and is also known as the therapeutic exception. According to this article the right of the patient to health information can be limited by the accredited existence of a state of therapeutic necessity. Therapeutic necessity can be defined as the power of the physician to act professionally without informing the patient in advance when the knowledge of the patient’s actual situation could cause serious harm to his health, due to objective reasons. When this situation arises, the physician has to make a motivated note of the circumstances in the clinical record and he has to communicate his decision to members of the patient’s family or to persons tied to him for de facto reasons.

§ 5. Patient rights regarding the medical file

**Article 10 Biomedicine Convention**

1. Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

As opposed to the General Health Law of 1986, which contained only a restricted regulation, patient rights regarding the medical file are extensively regulated in the fifth chapter of the Patient Rights Law.

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A. Right to a medical file

In accordance with the first paragraph of article 15 of the Patient Rights Law all patients or users of health care services have the right for a record to be kept -in writing or in the most suitable technical medium- of the information gathered during all their provided health care services. The clinical record is defined in article 14 (1) as the set of documents related to care processes for each patient, with an identification of the doctors and other professionals who have intervened. This provision also stipulates that the aim of a clinical record is to obtain the maximum degree of integration of the health data of the patient, at least in each health centre. The medical file has to be elaborated by the professionals who are directly involved in the treatment (article 15 (3)).

Each health centre has to file the clinical records of its patients in such a way that their security, their correct keeping and the possibility of retrieval of information are guaranteed (article 14 (2)). According to article 15 (4) the clinical record has to be kept in accordance with the criteria of unity and integration in order to facilitate the best and most appropriate knowledge of the patient’s health care data by physicians. The medical file of a patient has to be kept for an appropriate time which has to be at least five years starting from the date of discharge in each process of medical care (article 17 (1)).

B. Contents of the medical file

According to the first paragraph of 15 of the Patient Rights Law the medical file has to include all information considered to be significant for the truthful and updated knowledge of the health condition of the patient. This general formulation is elaborated in the second paragraph of article 15 which determines the contents of the medical file in a more detailed manner. In accordance with this provision the minimum content of the medical file shall be as follows:

a) documentation relating to the clinical-statistical sheet;

b) authorization for admission (only required in case of hospitalization or if so provided);
c) report for emergency (only required in case of hospitalization or if so provided);
d) anamnesis and physical exploration;
e) the evolution;
f) medical orders;
g) the inter-consultancy sheet;
h) reports on complementary explorations;
i) informed consent (only required in case of hospitalization or if so provided);
j) the anesthesia report (only required in case of hospitalization or if so provided);
k) the surgery report or delivery register (only required in case of hospitalization or if so provided);
l) the pathological report (only required in case of hospitalization or if so provided);
m) the evolution and planning of nursing care;
n) the therapeutic application of nursing;
o) the graph of constants (only required in case of hospitalization or if so provided);
p) the clinical report for discharge (only required in case of hospitalization or if so provided).

C. Right to access and copy the medical file

i. Right to access the medical file

The Patient Rights Law regulates the right to access the medical file in article 16 which is entitled “Users of the clinical record” (see infra §6) and article 18 regarding the rights relating to the medical file.

The right of the patient or his duly accredited representative to access his medical file is guaranteed by article 18. According to the first paragraph of this provision the health care centers have to regulate the procedures which enable the patient to exercise this right. The right to access the medical file can not be exercised to the prejudice of a third party’s right to confidentiality of his data noted in the medical file for the therapeutic interest of the patient, nor to the prejudice of the right to confidentiality of the subjective annotations made by the professionals who elaborate the clinical record (article 18 (3)).
ii. Right to copy the medical file

According to article 18 (1) the patient not only has the right to access the medical file, but also the right to copy it.

iii. Post mortem access by relatives

In accordance with article 18 (4) the clinical record of a deceased patient may be accessed by family members or persons related to the patient by de facto reasons, unless the patient has expressly prohibited such access and this was duly accredited. This provision also stipulates that a third party may access relevant data of the medical file when his health is at risk. However, it is not clear whether such access can only be granted when the clinical record belongs to a deceased patient or whether such access can be extended to the clinical record of any patient.34

The right to access the medical file can not be exercised by family members or third parties when it concerns subjective annotations made by the professional who elaborated the clinical file or when the obtained information would affect the privacy of the patient or would be harmful to third parties.

D. Right to correction, erasure and/or demolition

The Patient Rights Law does not contain specific regulations on the right to correction, erasure and/or demolition of the medical file.

§ 6. Right to medical secrecy/ confidentiality

**Article 10 Biomedicine Convention**

1. *Everyone has the right to respect for private life in relation to information about his or her health.*

The obligation to respect medical secrecy is both laid down in article 199 (2) of the Spanish Criminal Code and in the Patient Rights Law. According to article 7 of this Law all persons have the right for the confidential nature of the data regarding their health to be respected. No one may access that data without prior authorization pursuant to the law. Health care centers have to adopt the appropriate measures to guarantee these rights.

Article 16 regulates the access by health care professionals and of those persons who -although not being health care professionals- carry out their tasks in the context of health care.\(^{35}\) According to the first paragraph of this provision the health care professionals who conduct the diagnosis or treatment of the patient, have access to the clinical record as a fundamental instrument for the proper care of the patient. Each health care center has to establish the methods which allow access at all times to the clinical record by the professional caring for the patient (article 16 (2)).

The management and the administration personnel of the health care center may only access data of the medical file related to their own functions (article 16 (4)). Furthermore, the patient’s medical file may also be accessed by health care personnel who carry out functions of inspection, evaluation, accreditation and planning in the performance of their functions (article 16 (5)). According to article 16 (6) all personnel who access the data of a medical file during the course of their work, have to maintain confidentiality.

According to article 16 (3) access to the clinical record for judicial or epidemiological purposes or for purposes of public health, research or teaching is governed by the provisions of the Organic Act 15/1999 on

the Protection of Personal Data (see §7), the General Health Law of 1986 and other regulations regarding each individual case.

According to a study of PÉREZ-CÁRCELES and others however, almost all family doctors provide information to family members.\textsuperscript{36}

\textbf{§ 7. Right to privacy/ protection of private life}

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\textbf{Article 10 Biomedicine Convention}\
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1. \textit{Everyone has the right to respect for private life in relation to information about his or her health.} \\
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Article 18 of the Spanish Constitution guarantees the right to personal and family privacy of Spanish citizens. It states "the law shall restrict the use of data processing in order to protect the honor and the personal and family privacy of citizens, as well as the full exercise of their rights". This provision was further elaborated by the Organic Law 15/1999 on the Protection of Personal Data.\textsuperscript{37} The right to privacy also benefits from an extensive protection both in criminal and civil laws.\textsuperscript{38} Title X of the Spanish Criminal Code covers criminal offences against privacy. Civil protection of the right to privacy is granted by the Organic Law 1/1982 on the Civil Protection of the Right to Honor, Privacy of the Person and the Family and Reputation.

The Patient Rights Law does not provide for the right to privacy or the right to the protection of the private life as a patient.

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\textsuperscript{36} M.D.PÉREZ-CÁRCELES, J.E.PEREÑIGUEZ, et al., "Balancing confidentiality and the information provided to families of patients in primary care", \textit{Journal of Medical Ethics} 2005, 533.
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A. Processing of data concerning health

The processing of personal data is regulated by the Organic Law 15/1999 on the Protection of Personal Data. According to article 3 (a) of this Law personal data is defined as any information concerning an identified or identifiable natural person. The processing of data is defined by (c) of the same article as operations and technical processes, whether or not by automatic means, which allow the collection, recording, storage, adaptation, modification, blocking and cancellation, as well as assignments of data resulting from communications, consultations, interconnections and transfers.

Personal data which refers to health is in accordance to article 7 (3) considered to be data with special protection. It may be collected, processed and assigned only when -for reasons of general interest- the data subject has given his explicit consent or it is provided for by law. The personal data concerning health may also be processed when this is necessary for purposes of preventive medicine or diagnosis, the provision of medical care or treatment, or the management of health care services. Such data processing has to be effected by a health professional who is subjected to professional secrecy or by another person who is also subjected to an equivalent obligation of secrecy.

Article 8 of the Organic Law 15/1999 on the Protection of Personal Data is entitled “Data on health”. According to this provision public and private health care institutions and centers and the corresponding professionals may process personal data relating to the health of persons consulting them or admitted to them for treatment, in accordance with the provisions of the central or regional government legislation on health care.

B. Right to access and right to receive a copy

The Organic Law on the Protection of Personal Data contains in title III several provisions concerning the rights of the data subject. Article 15 guarantees his right to access and his right to receive a copy. According to the first paragraph of this provision the data subject has the right to request and obtain free of charge information on his
processed personal data, on the origin of such data and on their communication or intended communication. The information may be obtained by simply displaying the data for consultation or by providing the processed data in writing, in a copy, fax or photocopy - whether certified a true copy or not-, in a legible and intelligible form and without using keys or codes which require the use of specific devices (article 15 (2)). The right to access may only be exercised at intervals of not less than twelve months, unless the data subject can prove a legitimate interest in doing so in which case it may be exercised earlier.

C. Right to correction, erasure and/ or demolition

Personal data has to be erased when it has ceased to be necessary or relevant for the purpose for which it was obtained or recorded (article 4 (5)). If the personal data recorded prove to be inaccurate or incomplete, it shall be erased and officially replaced by the corresponding rectified or supplemented data, without prejudice to the rights granted to data subjects in article 16. This provision guarantees the data subject the right of rectification or cancellation. According to article 16 (1) the person or body responsible for the processing (defined as the controller in article 3 (d)) is obligated to implement the right to rectification or cancellation of the data subject within a period of ten days. Rectification or cancellation shall apply to data whose processing is not in accordance with the provision of the Organic Law 15/1999 on the Protection of Personal Data and, in particular, when such data are incorrect or incomplete (article 16 (2)). After being cancelled, the data shall be blocked and shall be maintained solely at the disposal of the public administrations, judges and courts for the purpose of determining any liability arising from the processing and for the duration of such liability. When the liability expires, the data shall be deleted (article 16 (3)). If the rectified or cancelled data have previously been communicated, the controller has to notify the person to whom they have been communicated of the rectification or cancellation (article 16 (4)).
§ 8. Right to complain and to compensation

A. Right to complain

**Article 23 Biomedicine Convention**

*The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.*

The right to complain is not provided for by the Patient Rights Law. However, the General Health Law of 1986 pays specific attention to complaint and suggestion procedures (article 10 (12)). The regulation recognizes the right of any citizen to issue a complaint, but also guarantees the protection of patient rights.\(^{39}\) In practice, all health service centers in the Autonomous Communities should have guidelines stating the rights and obligations of the users of health care services, the available services at the center, their characteristics and the procedure for submitting suggestions or complaints.\(^{40}\)

The Spanish Ombudsman is the high commissioner of the Parliament. He protects and defends basic rights and public freedom on behalf of citizens.\(^{41}\)

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B. Right to compensation

**Article 24 Biomedicine Convention**

*The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.*

Spanish health care legislation does not contain any specific provisions concerning the right to compensation. Consequently, the general provision with regard to breach of contract (articles 1101 and following of the Civil Code), liability in tort (articles 1902 and following of the Civil Code) or article 28 (2) of the General Consumers Protection Act will be applied. According to MARTÍN-CASALS and others the general rules of causation are still applied to medical malpractice cases in a very strict way, whereas the Spanish courts seem willing to give an increasing role to arguments that serve the goal of facilitating the proof of the physician’s fault.42

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IV. RIGHTS OF USERS OF GENETIC SERVICES

§ 1. Introductory remark

Genetic testing in Spain is mainly regulated by the legal framework that applies to health services as a whole, as there is at present no specific legal framework concerning genetic testing in Spain.\textsuperscript{43} Consequently, the regulations on patient rights are \textit{mutatis mutandis} applicable as rights of users of genetic services. The European Convention on Human Rights and Biomedicine has in accordance with the Spanish Constitution a superior force to any national legislation and is directly applicable in Spain (see III §1). As a result of this direct applicability, the provisions of the Convention related to genetic services can be applied.

A. Right to informed consent

The right of a patient to consent to diagnostic procedures (such as genetic tests) is one of the basic patient rights in Spain. According to the second paragraph of article 2 of this Law all actions within the scope of health require in general the prior consent of patients or users of health services. The consent must be obtained once the patient has received prior information and shall be given in writing in the events provided for by law. Article 3 of the Patient Rights Law defines an informed consent as the free, voluntary and conscious decision of a patient, stated in the full use of his faculties after receiving proper information, so that an action concerning his health can be undertaken.

In addition to these general provisions, the informed consent is profusely dealt with in the fourth chapter of the Patient Rights Law, which regulates the autonomy of the patient. According to the first

\textsuperscript{43} X., "Spain", in L. MATTHIESSEN - GUYADER (ed.), \textit{Survey on national legislation and activities in the field of genetic testing in the EU Member States}, European Commission, 2005, 56.
paragraph of article 8 any action regarding the health of a patient requires the free and voluntary consent of the concerned party, once the patient has assessed the options inherent to the case after he received the information provided for in article 4 which regulates the right to health care information. The patient can freely revoke his consent in writing at any moment (article 8 (5)).
The Patient Rights Law also acknowledges the right of patients to refuse a medical treatment in article 2 (4), unless otherwise provided for by law.

B. Right to information

Spanish health law provides the right to information about his health as a right independent of the right to informed consent. According to article 4 (1) all patients have the right to know any information available on their health, unless otherwise provided for by law. The information has to include at least the purpose and nature of each intervention, its risks and consequences. According to the first paragraph of article 4 a patient also has the right not to know.

C. Right to privacy

The right to personal and family privacy is guaranteed by article 18 of the Spanish Constitution. However, the Patient Rights Law does not provide for the right to privacy or the right to the protection of the private life as a patient.
The processing of personal data is regulated by the Organic Law 15/1999 on the Protection of Personal Data.

§ 2. Prohibition of discrimination on grounds of genetic heritage

Article 11 Biomedicine Convention

*Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited*
Although there is -besides the directly applicable article 11 of the Convention- no explicit prohibition of discrimination on grounds of genetic heritage, the general principle of non-discrimination is guaranteed by the Spanish constitutional law. The first article of the Constitution stipulates the following: “Spain constitutes itself into a social and democratic state of which advocates liberty, justice, equality and political pluralism as the superior values of its legal order”. The basic principle of equality is elaborated in article 14. According to this provision all Spanish citizens are equal before the law, without any discrimination for reasons of birth, race, sex, religion, opinion or any other personal or social condition or circumstance.

§ 3. Use of predictive genetic tests

**Article 12 Biomedicine Convention**

*Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.*

No explicit regulations on the use of predictive genetic tests exists in Spanish medical law. The lack of national legislation however does not mean that the use of predictive genetic tests is not regulated since article 12 of the Biomedicine Convention is directly applicable.
1. Spain has signed the *Convention on Human Rights and Biomedicine* on 4 April 1997 and has ratified it on 1 September 1999. The Convention entered into force on 1 January 2000. Spain has made several restrictions based on article 26 of the Convention for reasons that concern the public health or the health of a patient.

2. According to the Spanish Constitution the Convention on Human Rights and Biomedicine has a superior force to any national legislation and is *directly applicable* in Spain.

3. The primary legal sources of *patient rights at national level* in Spain are the General Law on Public Health of 1986 and the Patient Rights Law of 2002. The latter has partially repealed the General Health Law of 1986, particularly as regards the provisions on patient rights.

4. The right of a patient to *informed consent* is one of the basic patient rights in Spain. The consent must be obtained once the patient has received prior information. This information has to be truthful, has to be communicated to the patient in a manner that is comprehensible and suited to his needs and has to help him take decisions in accordance with his own free will.

5. The Patient Rights Law establishes as a general rule that the informed consent must be given *orally*, unless otherwise stipulated by law.

6. A capable and free person of age (18 years) can declare his will in advance as regards the care and treatment of his health or the destination of his organs or his body in case of death by means of the *document of prior instructions*, so that his wishes are complied with at the moment he is not capable of expressing his will personally.

7. Spanish health law provides *the right to information* about his health as a right independent of the right to informed consent. The
patient also has the right not to know. The right of the patient to health information can be limited by the accredited existence of a state of therapeutic necessity.

8. The patient or his legal representative have the right to access the medical file. The right to access the medical file cannot be exercised to the prejudice of a third party’s right to confidentiality of the data noted in the medical file for the therapeutic interest of the patient, nor to the prejudice of the right to confidentiality of the subjective annotations made by the professionals who elaborate the clinical record.

9. The processing of personal data is regulated by the Organic Law 15/1999 on the Protection of Personal Data.

10. Spain has no specific law on genetic testing. The regulations on patient rights are mutatis mutandis applicable as rights of users of genetic services. As a result of its direct applicability, the provisions of the Convention related to genetic services are applicable.
VI. BIBLIOGRAPHY


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