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ABSTRACT

Purpose: Ethical and legal recognition of patient autonomy and rights is a reality in Spain. Together with informed consent, advance directives and advance care planning have also played a major role in bringing about this situation. This paper aims to provide a description and critical analysis of their ethical and legal framework, concept, grounds, purpose and requirements under Spanish law, and to show that the appropriate way to understand and implement advance directives is to integrate them into the broader process of advance care planning, combining its legal, ethical and clinical dimensions. Materials and methods: Descriptions, arguments and conclusions presented in this paper are based on a review of legislation, case law and scientific bibliography.

Conclusions: Spanish legal norms on advance directives represents a step forward in the consolidation of autonomy as a core of doctor-patient relationship and in the guarantee of patients, healthcare professionals and health institutions’ rights and duties. Moreover, it guides professionals and eases decision-making process in healthcare. Finally, it improves the quality, humanisation and justice of Spanish health system. Key words: advance care planning, advance directives, autonomy, clinical decision-making, end-of-life, patient rights, Spain

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INTRODUCTION

Ethical and legal recognition of patient autonomy and rights is nowadays a reality in Spain. Together with informed consent, advance directives and advance care planning have also played a major role in bringing about this situation. The aim of this paper is to provide a description and critical analysis of their ethical and legal framework, concept, grounds, purpose and requirements under Spanish law [1-5] and to show that the appropriate way to understand and apply advance directives and their like is to integrate them into the broader process of advance care planning, combining the legal dimension with the ethical and clinical ones.

The protection of patient autonomy as a right in Spain began with the Spanish Constitution of 1978. This has neither a right to autonomy nor a general right of liberty. This does not have a right to informed consent either, but informed consent is an expression of and based on the basic right to physical and moral integrity [6].

Furthermore, the Spanish Constitution includes a catalogue of fundamental rights and liberties which support and develop patient autonomy: human dignity and free development of personality [7], the right to life [8], the freedom of conscience – ideological and religious freedom [9] and other fundamental rights and liberties, such as the right to health protection [10].

Its first significant legislative development was the General Health Act (Act 14/1986, of 25 April 1986), recognising the patient’s right to autonomous decision-making –to be informed and to choose among different treatments- as consent [11], but only for the present, without regulating advance directives.

A second step consolidating and enhancing patient autonomy came from the Council of Europe’s Convention on Human Rights and Biomedicine (Convention of 4th April 1997, ratified by Document of 23rd July 1999), for the protection of human rights and dignity of the human with regard to the applications of biology and medicine (Convention on human rights and biomedicine), a kind of bioethics Constitution whose most eminent legislative development is Act 41/2002, of 14 November, regulating patient autonomy, and rights and obligations regarding clinical information and documentation. For the first time in Spanish legal system, the Convention on Human Rights and Biomedicine introduces the institution of advance directives [12]. Following the example of the Convention and some Autonomous Communities’ laws which preceded it, the Act 41/2002 regulates advance directives for the entire State [13].

In a third stage of increasing patient autonomy, the creation and regulation of the national Registry of advance directives (See Royal Decree 124/2007, 2 February, regulating the national Registry of advance directives and the corresponding personal data file) and other options of advance care planning deserve a special mention in national area. In Autonomous Communities the legislative development of advance directives ensued, setting out legal concepts and clinical situations in order to specify the scope of patient autonomy and advance care planning [14].

LEGAL FRAMEWORK

The legislative scene of advance directives in Spanish Law is difficult to summarise [15]. Besides the State regulation, applicable on the entire Spanish territory, all Autonomous Communities possess their own regulation of advance directives [16], resulting in a huge normative body which contains diverse institutions of advance care planning [17].

This normative heterogeneity is both quantitative and qualitative. On one hand, neither the State nor the Autonomous Communities have regulated the question with similar extension and detail. On the other hand, the quality is unequal: there are laws that appropriately guide the clinical decision-making, as well as imprecise, confused and also contradictory laws. Moreover, the legal accuracy and the terminology are varied. Finally, some contents of a suitable legal development are still pending, because of a defective previous regulation.

State Legislation

Advance directives are a recent legislative phenomenon in Spanish Law. The first legal regulation which was directly applicable was article 9 Convention on Human Rights and Biomedicine, signed 4 April 1997 and in force in Spain since 1 January 2000 (Article 9. Previously expressed wishes, "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 need to establish and clarify this regulation and guarantee the autonomy and rights of the patient, amongst other reasons, led to the enactment of Act 41/2002, of 14 November, whose article 11 is the basic and common regulation of advance directives for the entire Spanish territory (Article 11. Advance directives, “1. For the advance directives document, a person who is of age, competent and free states in advance his or her will regarding healthcare and treatments or, after his or her death, the destination of his or her body or organs, with the aim that his or her will will be complied when he or she is no longer competent to express them personally. The person who issues the document can appoint a proxy who, in the event, acts as an interlocutor with the doctor or medical team to ensure that advance directives are complied with. 2. Each health service will regulate the correct procedure so that, if the case arises, compliance with everyone’s advance..."
Advance directives are guaranteed. Advance directives must always be set down in writing. 3. Advance directives which are contrary to the norms of the legal order or to the lex artis shall not be applied, nor those which do not correspond with the previous statement of the interested party at the time of issuing them. The patient’s clinical history shall include a reasoned record of the notes related to these considerations. 4. Advance directives can be freely revoked at any time recording it with a written statement. 5. In order to ensure in the entire national territory the efficacy of advance directives expressed by patients and formalised in accordance with the legislation of the respective Autonomous Communities, the national Registry of advance directives will be created within the Ministry of Health and Consumer Affairs, which will be governed by the norms determined by regulation, with prior agreement of the Inter-territorial Council of National Health System*). Later, according to article 11.5, and again after Autonomous Communities’ legal norms, the national Registry of advance directives was created [18]. Finally, two special laws have regulated the use of advance directives in their respective areas, widening its content and allowing the patient to decide on the use of his reproductive material [19] and on obtaining or analysing his or her biological samples after he has died [20].

Autonomous Communities’ Legislation
Regional legislation on advance directives preceded national legislation. From the end of the year 2000 [21], many legal norms have been enacted, leading to the current complicated and huge normative body. Such variety complicates the knowledge of legal regulation even though at the time it contributes to complete the national legislation and define the characteristics of advance directives.

Case Law
There is little Spanish case law on advance directives. Most court rulings concern the content of advance directive documents and in particular their validity, applicability and efficacy, whilst the rest focus on the concept itself and the requirements governing their validity.

The ruling 160/2010 of 2 June 2010 of Tenerife Provincial Court – section 3 [22], regarding the use of reproductive material of a deceased husband to inseminate his wife, correctly states that a typed letter signed by the deceased husband cannot be deemed an advance directive [23]. As far as content is concerned, the topic that has given rise to the largest number of court rulings is the decision by Jehovah’s Witness patients to refuse blood transfusions. An early ruling of Ciudad Real Provincial Court of 31 December 2001 [24] examines article 9 Convention on Human Rights and Biomedicine, and concludes that its invocation would require legislative development (at that time, there was no national nor Autonomous Community legal norms applicable to the case), and that article 9 Convention does not establish a link with the previously expressed wishes but simply requires “taking into account”. Therefore, the Court rejects the appeal to the previous judicial decision authorising blood transfusion to the patient. The three remaining cases, the rulings of Guipúzcoa Provincial Court (section 2) of 22 September 2004 [25] and of 18 March 2005 [26], and of Lleida Provincial Court (section 1) N. 28/2011, of 25 January 2011 [27] adopt a different way of reasoning. They recognise the validity and priority of a Jehovah’s Witness’ opposition to a blood transfusion included in his advance directives document, in the first case in opposition to the medical doctors request of judicial authorisation to carry out a blood transfusion, and in the second case after the judge a quo’s decision authorising the blood transfusion. The judgment 353/2010 of 8 October of A Coruña Provincial Court (Section 5) [28] deals with the designated proxy in an advance directive, and concludes that this designation provides a strong argument for choosing him/her for the guardianship, as does judgment 82/2012 of 27 February of the Asturias Provincial Court (Section 5) [29], which also encompasses the capacity test as a requirement for appointment of a proxy.

Judgment 385/2012 of 16 April of the High Court of Justice of Asturias (Administrative Appeals Chamber, Section 1) [30] confirmed the legality of a clause on euthanasia and assisted suicide contained in an advance directive document, considering that this directive, drafted in a conditional sense and subject to what would be permitted by the legislation in force at the time of its application, is by no means illegal, but rather a case of subjection to the law. This judgment also deals with another issue, that of the formal and procedural requirements governing an application for an advance directive document to be included in the Register.

CONCEPT
Advance care planning
Advance directives are the most important legal instrument of advance care planning, but only a part of it [31-35]. Advance care planning is a wider and overall continuous process which includes a host of dimensions (clinical, cultural, familiar, social, psychological, emotional) to improve the quality of care and decisions at the end of life, enhancing communication among the patient, the healthcare professionals (doctors, nursing, psychologists...), relatives and other close people, and guaranteeing the respect of patient’s autonomy, values and rights.

The Spanish legal system contains a legal definition of the “advance planning of healthcare decisions relating to the process of dying and death”: “processes concerning reflection and
communication between health professionals, patients and their relatives that help to improve the moral quality of a person’s decision-making during the process of dying and death, taking into account, amongst other criteria, the advance directives or any other such document forming part of his or her history of values” [36]. The advance planning of decisions has been defined in the clinical sphere as a voluntary process of communication and deliberation between a competent person and the healthcare professionals involved in his or her care regarding the values, wishes and preferences that the former would like to be taken into account with regard to the health care he or she will receive as a patient, essentially during the end-of-life period [37,38].

Advance directives

Advance directives develop the general theory of informed consent and enhance autonomy. They are a singular specification because consent and the faculty of autonomous decision-making are protected like prospective or ad futurum autonomy. Unlike current informed consent, which is granted for an immediate or almost immediate action or intervention, advance directives consist of two moments: the moment of issue, which coincides with the patient’s competence to take autonomous decisions, and the moment of application, which occurs later when the patient lacks the competence to decide autonomously.

Taking into account the legal definition ex article 11.1 Act 41/2002 as well as the national and regional legal norms, a more precise and comprehensive legal concept of advance directives can be proposed (Advance directives are the free, voluntary and informed expression of a competent person (who is of age) on his or her preferences of healthcare and treatments; and/or the designation of a proxy who acts as an interlocutor with the healthcare professionals and contributes to the interpretation, respect and compliance of his or her instructions and wishes; and/or the expression of his or her personal values, preferences and objectives; and/or, after death, the destiny of his or her body and/or organs and/or tissues, and/or the use of his reproductive material, and/or the prohibition to obtain and analyse his or her biological samples. The advance directives are issued with the aim of being respected and complied in the event that the patient cannot longer express his or her will autonomously, and must be set down in writing and issued in compliance with the legal procedure).

Conceptual clarifications

Three issues need a further commentary. Firstly, the host of legal denominations of advance directives, especially in Autonomous Communities’ legislation, generates legal uncertainty and insecurity. However, for the variety of terminology does not imply conceptual or semantic variety, the different denominations must be understood as different ways to formulate the same reality or concept. Therefore, the national and regional norms must be interpreted in the same way and referred to a single institution [39].

Secondly, the rather common conceptual confusion between advance directives and the advance directives document can potentially lead to a misinterpretation and to an unsuitable application, with harm to patient’s rights and autonomy and lack of protection to healthcare professionals. A formal and documentary expression of advance directives is required, but which actually matters is not the document but the decisions expressed within it. The advance directives document supports and expresses patient’s will, resulting from a process of reflection and dialogue with healthcare professionals on how the patient wants to be treated when he can no longer make autonomous decisions. And furthermore, advance directives must be understood as a part of the broader advance care planning process.

Thirdly, it is important to differentiate between the Spanish legal concept of advance directives and the original North American one [40], in particular with regard to an aspect that influences their validity and efficacy. In the USA advance directives can be either oral (the most common case) or written, whilst in the case of Spain their validity requires them necessarily to be given in writing, following one of the established procedures (article 11.2 Act 41/2002). If this is not done it should be talked of suggestions or opinions whose content may be of equal or even greater relevance for advance planning and clinical decision-making, although they cannot be considered to constitute legally valid advance directives, but merely criteria that can serve as guidelines for a proxy decision. Both are representations of a patient’s autonomous power to decide, but only those decisions regarding health care or medical intervention that have been recorded in writing and conveyed in accordance with a legally established procedure can be considered as advance directives within the Spanish legal system.

Thus, when there are valid applicable advance directives there is no need neither for surrogate decision-making nor proxy decisions. On the other hand, statements or wishes that are not legally deemed to constitute advance directives will be a decisive element in the proxy decision-making process, in accordance with the so-called subjective standard, or, when applicable, the substituted judgment or best interest criteria. In Spanish legal system the subjective standard does not refer to advance directives but to the surrogate or proxy decision-making that will serve to put into practice the wishes expressed by a patient, either orally or in writing, other than the health or care-related decisions he or she may have included in an advance directives document.
To sum up, therefore, the patient decision-making process is essentially subject to three requirements: information, voluntariness and competence (articles 1-11 Act 41/2002). With particular regard to the latter, we can determine three different settings or ways in which it can be exercised: (1) decisions made when competent concerning the present moment (informed consent: articles 2-3 and 8-10); (2) decisions made when competent concerning a time of future incompetence (advance directives: article 11); (3) decisions made when incompetent (surrogate or proxy decision: article 9). Respect for patient autonomy requires recognition of these three settings and their internal hierarchy. It is neither ethically right nor legally lawful to apply an advance directives document (2) whilst a patient enjoys sufficient competence to make autonomous decisions and express his or her informed consent (1); nor is it to request a decision from a patient’s proxy (3) whilst the former maintains his or her capacity to make autonomous decisions (1) or has previously let his or her wishes be known in the form of an advanced directives (2).

To ignore this normative setting is to perpetuate a paternalistic idea of doctor-patient relations and the decision-making process.

**JUSTIFICATION AND PURPOSE**

From an ethical point of view, the justification of advance directives is the principle of respect for autonomy, which has led to a new model of doctor-patient relationship, decision-making and definition of health. In Spain, a patient’s right to take autonomous decisions on his own life and health and on the treatments he wishes to receive belongs to the basic right to physical and moral integrity (article 15 Spanish Constitution; Judgment of Spanish Constitutional Court 37/2011, of 28 March) and is legally recognised. This patient’s right co-exists with a duty of healthcare professionals to know, respect and apply advance directives (articles 2.6 and 11 Act 41/2002).

As an instrument of advance care planning, advance directives have different aims and purposes. An immediate purpose is to strengthen the patient’s right to express his will in advance, widening the scope of informed consent; advance directives provide greater knowledge of, and control over, his end-of-life period. Moreover, they are a relevant assistance in interpreting the patient’s directives and guiding clinical decision-making when the patient can no longer express his will in an autonomous way. They allow forecasting future situations and planning healthcare in an integral and continuous way, reduce the risk of wrong decisions and provide legal certainty. Finally, advance directives contribute to reduce stress and to improve patient’s well-being and also that of the professionals and relatives involved in healthcare [41-46].

**WHO CAN ISSUE THE DOCUMENT?**

“A person who is of age, competent and free...” is the answer of article 11.1 Act 41/2002 to the question on who can issue a document of advance directives. Here, there are two elements of the theory of informed consent and also of advance directives: competence and voluntariness. To these a third basic element must be added: information.

Article 11.1 requires that the person who issues the advance directives is competent and legally of age. He must be at least 18 (article 12 Spanish Constitution), the age from when he is considered (*iuris tantum* presumption) competent (articles 315 and 322 Spanish Civil Code). Some regional legal norms set exceptions to being of age and allow certain minors to issue advance directive documents: a mature minor, an aged 16 and above individual who has intellectual and emotional competence to understand the purpose and consequences of the intervention (article 9.3c Act 41/2002), and the under 16 year old minor who is emancipated by his legal parents or a judicial decision (articles 314-321 Civil Code) or the minor from the age of 14 when emancipated through marriage (articles 46 and 48 Civil Code) [47].

The reference to the patient’s liberty or free character (article 11.1 Act 41/2002) means voluntariness and refers to guaranteeing that the decision-making process takes place without coercion, intimidation or any other unlawful influence. Thirdly, and even when it is not included as a legal requirement in article 11.1 Act 41/2002, information must be considered a further requirement for the valid issue of advance directives, in order to avoid other defect of consent: error about the object (articles 1265 and 1266 Civil Code), and to control own decisions. Despite this, the patient has the right that his wish not to be informed will be respected (articles 4.1 and 9.1 Act 41/2002). Information must be truthful and be communicated to the patient in a comprehensible way and suited to his needs, and it shall help him to express in advance his wishes regarding his care (article 5 Convention on Human Rights and Biomedicine; articles 2.3, 4.2 Act 41/2002).

Issuing an advance directive is so personal that can only be exercised by the right-holder, i.e. the patient. This is not a right which can be exercised by a proxy or third party. When a patient is incompetent to make his own decisions it cannot be used an advance directive (whereby a competent patient takes an autonomous decision which will be applied when he is no longer able to do so: article 11 Act 41/2002) but rather a substitute or surrogate decision-making (whereby a surrogate takes a decision on behalf and for the benefit of the incompetent patient: article 9 Act 41/2002).
Conflicts of interest

None.

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REFERENCES

6. Article 15 and Judgement of Spanish Constitutional Court 37/2011, of 28 March.
7. Article 10.1.
8. Article 15.
9. Article 16.
10. Article 43.
11. Article 10.
12. Article 9: “previously expressed wishes”.
13. Article 11.
16. The Spanish State is made up of seventeen Autonomous Communities and two Autonomous Cities (articles 137 ff. CE). Each Autonomous Community has authority to legislate in health matters, including advance directives (article 149 CE).
19. Act 14/2006, 26 May, on techniques of assisted human reproduction (Article 9.2).
21. The first Autonomous Community was Catalonia: Act 21/2000, 29 December, on information rights concerning health, patient’s autonomy and clinical documentation, article 8.
23. See also a case on post mortem use of deceased couple’s reproductive material in the Ruling N. 164/2011 of 12 July of Barcelona Provincial Court (section 18) [JUR2011]373587.
24. [Tirant TOL 142.031.
36. Aragon: Act 10/2011, of 24 March, on the rights and guarantees of the dignity of a person during the process of dying and death, article 5.1.
39. Spanish legal norms on advance directives comprehends the following denominations:
deseos expresados anteriormente (Convention on Human Rights and Biomedicine); instrucciones previas (Act 41/2002, Asturias, Canaries, Castile and Leon, Galicia, La Rioja, Madrid, Murcia); voluntades anticipadas (Aragon, Balearics, Cantabria, Castile-La Mancha, Cataluña, Navarre, Basque Country, Valencia); expresión anticipada de voluntades (Extremadura); manifestación anticipada de voluntad (Canaries); voluntad expresada con carácter previo (Cantabria); voluntades previas (Cantabria); voluntad vital anticipada (Andalusia, Balearics); testamento vital (Andalusia, Valencia).

40. The North American experience began with the living will and then extended the possibilities of advance care planning to other instruments such as Do-Not-Resuscitate orders, powers of attorney, advance directives, advance treatment directives or advance directives for health care. On how this process evolved in the USA see Olick RS. Taking advance directives seriously. Prospective autonomy and decisions near the end of life. Washington D.C.: Georgetown University Press; 2001.


47. See Andalusia, Aragon, Navarre, Valencia.