Actas Dermosifiliogr. 2014;105(6):569–573

ACTAS Dermo-Sifiliográficas

Full English text available at www.actasdermo.org

CONSENSUS DOCUMENT

Informed Consent in Dermatology: An Update☆

F. Valcuende Cavero,[a,*] M. Iglesias Valcuende,[b] R.M. Diaz Diaz[c]

[a] *Sección de Dermatología, Hospital de la Plana Vila-Real, Castellón, Spain*
[b] *Abogada, Castellón de la Plana, Comunidad Autónoma de Valencia, Spain*
[c] *Sección de Dermatología, Hospital Universitario Infanta Sofía, San Sebastián de los Reyes, Madrid, Spain*

Received 10 January 2013; accepted 18 November 2013
Available online 11 June 2014

KEYWORDS
Informed consent;
Consent forms;
Informing patients;
Legislation and jurisprudence

Abstract Spanish legislation recognizes patients' right to be informed about various aspects of their illness and to make autonomous decisions regarding diagnosis and treatment. As dermatologists, we need to become familiar with this legislation, heed its stipulations, and implement them in our practice.

PALABRAS CLAVE
Consentimiento;
Documento;
Información;
Legal

Actualización del consentimiento informado en dermatología

Resumen La legislación de nuestro país reconoce que el paciente tiene derecho a ser informado sobre los distintos aspectos de su enfermedad y a su autonomía en la toma de decisiones relativas al diagnóstico y tratamiento de la misma.

Como dermatólogos tenemos la obligación de conocer, respetar y ejecutar dicha normativa en nuestra labor asistencial.

Introduction

The Spanish Constitution establishes the right to freedom as the highest value of the legal system, and Article 10.1 states that personal dignity and the free development of the individual together constitute the foundation of political order and peace in society.[1]

The judicial system upholds the Constitution by defending the need for informed consent and recognizing the individual's right to autonomy in making life choices from among the alternatives a physician presents, selecting according to his or her own interests and preferences.[2]

Brief Review of the History of Informed Consent

Informed consent was introduced into Spanish medical practice in 1986 with the passage of General Health Law

☆ Please cite this article as: Valcuende Cavero F, Iglesias Valcuende M, Diaz Diaz R. Actualización del consentimiento informado en dermatología. Actas Dermosifiliogr. 2014;105:569–573.

* Corresponding author.
E-mail address: f.valcuende@homail.com (F. Valcuende Cavero).

1578-2190/$ - see front matter

14/1986 of April 25.[2] The relevant passages are paragraphs 5 and 6 of Article 10. The concept of the patient's right to choose from among the treatment options available was derived from Anglo-American customs that had not yet been incorporated into Spanish medicine: practice at the time was paternalistic, centered mainly on the authority of the physician, who made decisions about treatment that affected the patient's health and safety.[3]

Given the ambiguity about informed consent in General Health Law 14/1986, its application spread slowly in the midst of much debate; complaints sometimes culminated in court cases and judgments against physicians. Article 10.5 (later superseded by Law 41/2002) stipulated that information about the patient's condition must be ''complete and continuous'' and include ''diagnostic and prognostic information and treatment alternatives.'' Court rulings later clarified those statements and the concept of informed consent gradually took root as society came to understand that a patient who sought medical care forfeited neither personal dignity nor inherent rights to liberty or, more specifically, self-determination in relation to health. These are the very rights guaranteed by the Spanish Constitution. In other words, the patient has a right to know the medical diagnosis, its implications, and the treatment options so that he or she can decide what steps should be taken.

In the interest of clarity and establishing the basis for these principles in law, the Spanish parliament passed Law 41/2002 (Basic Regulations on Patient Autonomy and Rights and Obligations With Regard to Clinical Information and Records) on November 14, 2002.[4]

Definition of Informed Consent

Spanish Law 41/2002[4] defines informed consent as ''the acceptance of a medical act affecting health given freely, voluntarily, and consciously by an adequately informed patient with full use of his or her faculties'' (Article 3). The law recognizes the principle of respect for patient autonomy when regulating both informed consent and so-called advance directives. This law clarifies the legal status and rights and obligations of health care professionals and citizens; it reinforces the right to protection of health recognized under the Spanish Constitution. Specified is the requirement that all health care givers not only perform their procedures correctly but also inform, keep clinical records, and respect the choices the patient has made freely and voluntarily. The text of the law states that consent must be given in writing in the following cases:

1. Surgical procedures
2. Invasive diagnostic and therapeutic procedures
3. Generally speaking, a procedure involving substantial risk or prejudice and foreseeable negative consequences for the patient's health

The treating physician will provide the patient with the following information before consent is documented in writing:

1. Risks relevant to the patient's personal or professional circumstances
2. Probable risks under normal circumstances
3. Contraindications

In addition to the basic requirements established under Spanish law, some of Spain's autonomous communities have passed legislation of their own, even before Law 41/2002 took effect. These additional statutory laws reconcile the patient's essential right to autonomy with specific rights granted within certain jurisdictions:

1. In Law 21/2000 of December 29, the Catalan parliament established the patient's right to be informed, to give informed consent, and to formulate advance directives.[5]
2. In Galicia, Law 3/2001 of May 28 regulated informed consent and clinical records kept on patients.[6]
3. In Navarre, Foral Law 11/2002 of May 6 stated the rights of patients to establish advance directives as well as to be informed and obtain clinical records.[7]
4. In the Autonomous Community of Valencia in 2003, Law 1/2003 of May 6 covered the rights of patients and the provision of information in that community, stating that informed consent must be obtained at least 24 hours before a procedure.[8]

Informed Consent in Dermatology

As dermatologists we might be tempted to feel that our conversation with a patient during a clinical visit sufficiently ensures that the patient has freely and knowingly accepted a surgical procedure. However, while dialog is necessary, it is not sufficient for legally documenting informed consent, given that the law stipulates that consent be given in writing. That stipulation must be interpreted literally.

A medical act, in legal terms, is a work contract: the physician agrees to do everything possible to the best of his or her knowledge in accordance with good, current medical practice (a concept often referred to as *lex artis*). Acts seeking to promote or restore health are termed curative medicine and jurisprudence distinguishes them from acts in so-called satisfactive medicine; the patient undergoes satisfactive medical treatment voluntarily for reasons other than improving health. Procedures to enhance appearance or to ensure birth control are examples of satisfactive medical acts. In dermatology we perform procedures of both types.

In the practice of satisfactive medicine, the law considers that even when the patient's request for treatment might be taken to reflect consent for an intervention, it would not be sufficient to confirm knowledge of the procedure's results and risks. In satisfactive medical or surgical interventions, there is great need to inform the patient about risks, the possibility that the hoped-for outcome may not be achieved, and what postprocedural care and actions might be required to ensure success.[9] These circumstances lead us to the conclusion that while both curative and satisfactive medicine require informed consent before any medical or surgical act takes place, the scope of information the patient must receive when seeking treatment that is not strictly required to cure an illness is much greater if the individual is to be in a good position to judge whether the intervention is in his or her best interests or not.[10]