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Informed Consent in Dermatology: An Update[☆]



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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.

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PALABRAS CLAVE

Consentimiento;
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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.

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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

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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 41/2002⁴ 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

Information the Patient Needs Before Giving Valid Consent

Content and Characteristics of the Information

Law 41/2002 establishing the basis for patient autonomy states that information shall at a minimum include the purpose and nature of each intervention along with its risks and consequences (Article 4.1). Article 10 further states that the basic information necessary for informed consent prior to an intervention or therapy shall include the following points:

1. The main or most important consequences the intervention will safely lead to
2. The risks related to the patient's personal or professional circumstances
3. The probable risks under normal circumstances based on experience and current scientific knowledge or directly related to the type of intervention
4. Contraindications

Thus, Law 41/2002 and jurisprudence recognize the patient's right to information that covers the following as far as possible:

1. The diagnosis of the patient's disease or lesion.
2. The prognosis the condition normally implies, with or without treatment.
3. The risks involved, especially in the case of surgery.
4. Finally, consistent with the principle of consideration of alternatives, if locally available means for treatment are inadequate, this deficit must be made clear so that the patient or relatives can choose to go to another care facility if possible.¹¹

Foreseeable or typical risks are those that are inherent to the intervention, and the law requires that the patient know about them before agreeing to incur them, even when they are rare in statistical terms.¹²

Consent hinges on being informed: the patient must be given the essential information in the most comprehensible manner possible in order to be able to freely and knowingly give consent. The information must allow the patient to form an idea of the situation and grasp the alternatives available—including nonintervention—as well as the risks associated with each alternative. Information must be explained in terms of probability, since there can be no absolute certainty about the outcome of each alternative. Explanations should be presented with common sense and the degree of detail the patient can grasp: excessive detail using terms that are too difficult to understand can overwhelm, to the extent that no clear idea forms on the basis of information either heard or read. The information must be given long enough in advance of the intervention to allow the patient to decide freely and knowingly. Some Spanish autonomous communities have stipulated that information must come at least 24 hours before the consent form is signed.

For obtaining consent to satisfactory procedures, for which we should comply not only with the substance of the physician's obligation (referring to outcomes rather than

means) but also with the duty to inform, we note that the information provided should be still more complete. Because these medical or surgical acts are not necessary for maintaining or restoring health, the patient must be all the more aware of the risks involved—whether foreseeable or inherent to the procedure or general, involving such risks as arise from any hospital intervention. The Supreme Court considers that complete information is necessary for giving informed consent or declining treatment in such cases, especially when a surgical procedure is planned, and of course information must be complete when treatment is satisfactory rather than curative, because of the supreme importance of the voluntary nature of the patient's consent.¹³

Clear and comprehensible information is the essential foundation for the patient or family's consent. Information must be complete and understandable, so that the recipient can properly integrate it into his or her existing knowledge. It must also be adequate, meaning that it is clear and precise enough to serve as the basis for agreeing to the procedure the physician or the medical service is proposing. To these requisites, we must add that our explanations must be correct, honest, and fair. If these criteria are met, voluntary consent will be informed and the patient will decide freely, as is every individual's undeniable right, according to the principle of autonomy.¹⁴

Format in Which Information Must Be Presented

As the burden of proof of having informed the patient falls to the physician in legal proceedings, jurisprudence considers that providing information in writing has evidentiary value *ad probationem*.¹³

On occasions in which a document signed by the patient contained generic recognition of having been informed, the court has interpreted that the burden of proof that no information, or adequate information, was given passes to the signer of the document.

The courts have interpreted the obligation to obtain informed consent in very broad terms, applying it to all medical acts; thus, in principle the obligation is never excluded in any case. However, there are doubts about the reach of this assumption given that many interventions involve minimal risk and the health care system would be overburdened if informed consent were obtained each time a frequent act is performed. Examples of such common acts would be the prescription of medicines, basic cleansing of wounds, vaccination against tetanus, or placing a bandage. Clearly the need for informed consent is general, but compliance will vary according to type of medical intervention. If no risk is involved, consent may be given orally in the natural course of care, without formalities. Only when the medical act is invasive and entails risk for the patient will it need to be preceded by adequately and clearly informing the patient in writing so that there is no room for doubt.¹⁰

In the actual practice of medicine in the public health service the limited amount of time we can spend with each patient is an obstacle to our compliance with these requirements. However, this difficulty does not spare us from meeting our obligation. We must use common sense and dialog with the patient to determine whether the proposed treatment has been understood, and in any case we

need to provide the explanation in writing along with the informed consent form to be signed.

Exceptions to the Need for Written Informed Consent

Exceptions to the need for written informed consent will be encountered only rarely, but it pays to summarize them here:

1. Public health risk. Spanish Organic Law 3/1986 of April 14 refers to special circumstances that threaten the public welfare and that allow the health authorities to adopt measures to detect, treat, hospitalize, or control patients in order to protect society by preventing injury or loss of life. Such measures can be adopted whenever health emergencies occur, need arises, or there is evident indication that the public health is threatened by the specific circumstances represented by a person, a group of persons, or a particular activity.
2. Imminent, grave risk to the patient's physical and psychological safety in a situation when informed consent is not feasible. Three circumstances must concur: 1) the situation must involve grave and imminent risk, 2) obtaining the patient's permission must be impossible because judgment is impaired or because the patient cannot manage to understand the importance of the intervention, and 3) the nature of the emergency precludes obtaining informed consent from the patient's legal guardians or the guardians are unknown to the health care providers.

Decisional Capacity for Consent

The patient who consents must have the capacity to do so. Capacity in this context does not refer to civil capacity but rather natural capacity. The following conditions must be met:

1. The patient must be an adult, older than 16 years of age, or an emancipated minor.
2. The physician must judge the patient capable of making decisions, that is, not to be in a physical or mental state that precludes taking responsibility for his or her situation.

Minors can also give valid informed consent to treatment without need for a surrogate, provided the minor is intellectually and emotionally able to understand the scope of the intervention.

Consent Given by a Representative on Behalf of the Patient

Minors With Insufficient Judgment (Article 9.3.a)

A minor is understood to be an unemancipated individual under 16 years of age. If the minor lacks the natural capacity to give consent, it must be given by a legal representative: a parent whose parental rights have not been terminated, a guardian or court-appointed surrogate, or the

public administration that automatically assumes guardianship of an abandoned minor.

Incapacitated Adults

When the adult lacks decisional capacity, consent must be given by the patient's legal representative: the individual who holds parental authority that has been extended or restored, the guardian, or the court-appointed surrogate. The law states, "The patient must be informed, even if incapacitated, to the extent consistent with his or her level of understanding." From this wording we infer that if incapacitated individuals must be informed as far as possible, they must also be heard to the degree that judgment allows, even if their decisions are not binding.

Patients of Advanced Age With Genuine Incapacity

Incapacity in individuals of advanced age must be assessed by the physician, who must judge, first, that no physical or mental state prevents the patient from grasping the situation (the disease and the arguments for the proposed treatment or alternatives) and, second, that the patient has minimal decisional capacity. It is the physician's responsibility to judge whether there is genuine incapacity and the reasoned decision must be explained in writing. The explanation is normally included in the informed consent form signed by the patient's surrogate. Surrogate consent can be given by a court-appointed guardian or by a relative or significant other. Such persons could be chosen according to the order of precedence used by courts: spouse, children, forebears, and siblings.

Consequence of Lack of Information: Uninformed Consent

The obligation to inform is a natural one in situations where professional services are contracted, and failure to provide information is a violation of the contractual relationship. Withholding information can establish that the physician is liable not only to civil malpractice suits but also to deontologic and administrative review. Whether or not lack of information injures the patient, failure to inform has been considered an injury in and of itself. When a conscious patient has inadequate information, consent is considered ineffective, and the courts have on occasion referred to this as uninformed consent. To the extent that inadequate information might affect consent, even though it did not affect the outcome, it is considered to constitute a grave moral injury separate and distinct from bodily injury resulting from the intervention. Thus, the patient is entitled to compensation regardless of whether medical negligence in surgery or postoperative care is demonstrated.⁹

Informed Consent Templates

Time constraints on patient visits in public health services and the need to provide complete information about procedures and their consequences in public as well as private medicine—especially in aesthetic or cosmetic procedures

in dermatology—require us to make written material available. Such material will explain the procedures and all their consequences. We also require templates of documents for the patient to sign to express informed consent. Such forms serve additionally to identify the patient or surrogate and the physician providing the information and performing the procedure, if known beforehand.

Updated templates for informed consent have been posted on the website of the Spanish Academy of Dermatology and Venereology (AEDV): www.aedv.es.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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