UPDATE IN RADIOLOGY

Autonomy, consent and responsibility. Part 1: Limitations of the principle of autonomy as a foundation of informed consent

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Abstract   Legal recognition of patient’s rights aspired to change clinical relationship and medical lex artis. However, its implementation has been hampered by the scarcity of resources and the abundance of regulations. For several years, autonomy, consent, and responsibility have formed one of the backbones of the medical profession. However, they have sparked controversy and professional discomfort. In the first part of this article, we examine the conceptual and regulatory limitations of the principle of autonomy as the basis of informed consent. We approach the subject from philosophical, historical, legal, bioethical, deontological, and professional standpoints. In the second part, we cover the viability of informed consent in health care and its relationship with legal responsibility.

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PALABRAS CLAVE
Derecho de autonomía; Derechos del paciente; Consentimiento informado;

Autonomía, consentimiento y responsabilidad. Parte 1: limitaciones del principio de autonomía como fundamento del consentimiento informado

Resumen   La consolidación legislativa de los derechos del paciente introdujo modificaciones en la relación clínica y en la lex artis, pero su implantación progresa con dificultades en un entorno sanitario muy condicionado por la escasez de los recursos y la abundancia de las normas. Desde hace algunos años, la autonomía, el consentimiento y la responsabilidad forman...
uno de los ejes vertebradores de la profesión médica. Sin embargo, son objeto de controversia y causan malestar profesional. En la primera parte de este artículo examinamos las limitaciones conceptuales y normativas del principio de autonomía como fundamento del consentimiento informado, abordadas desde una perspectiva filosófica, histórico-jurídica, bioética, legal, deontológica y profesional. En la segunda parte analizamos la viabilidad del consentimiento informado en la medicina asistencial y su relación con la responsabilidad jurídica.

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Introduction

It is said that something needs to change so that everything remains the same. Perhaps that is what has happened with informed consent (IC). Thirty-eight years after the publication of the Belmont Report there are still doubts about the actual capacity of IC to ensure the patient's autonomy. Everything seems to indicate that the standards intended to eradicate paternalism have not fully reached their goal. As a matter of fact, they have not prevented the increase of lawsuits, of defensive medicine and professional dissatisfaction. The physician’s attitude may have ruined some good purposes. Without ruling out this hypothesis, we will try to explore others. Our goal is to examine the conceptual and normative limitations of the principle of autonomy as the foundation of IC.

The interruption of Hippocratic tradition

The Hippocratic Oath, paradigm of the self-normative tradition of the medical profession, has had a lasting influence. Hippocratic medicine was respectful of the patient’s dignity, but at the same time it was snobbish and very paternalistic. Sheltered by this tradition, the physician has practiced for a long time regardless of the patient’s desires and not very conditioned by the law. The traditional physician’s moral prestige and his dedicated service vocation seemed enough to vouch for his conduct. However, this situation has changed.

The scientific breakthroughs of the previous century arouse great expectations as well as social alarm. Ideological pluralism contributed to a gradual demystification of the medical profession. The welfare state promoted public health that understood health as perfect physical, mental and social wellbeing. In this context, the interruption of bioethics, since the 1970s, proved decisive for the legislative development of the patient’s rights.

Thus emerges a more regulated medicine integrated in a healthcare organization that protects health with criteria of universality. The clinical relation is humanized. Control elements are introduced that modify or replace the relationship of trust. The new medical act needs to be beneficial, necessary, consensual, safe and fair. It must have quality and seek satisfaction. In view of an adverse result, risk materialized as damage becomes the axis of procedural debate, which stimulates defensive medicine.

The patient has become both the user of public services and the consumer of health products. They intend to enjoy the health the law guarantees for them. In turn physicians long for a more spontaneous medicine. They practice with a sense of resignation, conditioned by the lack of resources and the overabundance of rules. Skeptical of the formidable proposals of academic ethics, they wonder whether they are being asked too much. They resist where possible, being the IC one of the stages of such resistance.

Autonomy as a philosophical concept

Autonomy is a basic concept of the legal organization and ethical foundation of liberal and democratic societies. It originates in the moral and political philosophy of the West. It is associated with terms such as liberty, independence, willingness, authenticity and responsibility. It is part of the educational, bioethical and medical language. The autonomous individual is aware of his/her own purposes and capable of exercising his/her own will. He/she makes decisions based on his/her own needs and takes responsibility for it.

Autonomy can be understood as the capacity to act with independence, the possibility of acting with willingness or the right to decide freely. To Kant, autonomy is rational self-government through universal moral regulations. In Milis, autonomy seeks the utmost well-being, it entails sovereignty and is identified with an absence of coercion. Autonomy can be a praiseworthy aspiration or a reputable capacity. It can work as an instrument, but it is also an end in itself that is worth guarding.

The notion of autonomy is controversial. Its dominating meaning prioritizes individual rights, avoids personal ties and tends to radicalism. Many authors are suspicious of this autonomy or believe it is improbable. Some claim that emotions disqualify it. Still others believe that it is a myth or a fiction, an expression of magical voluntarism or outdated liberalism. Many author think it is no compatible with justice, solidarity or trust.

Autonomy as a legal structure

Autonomy becomes a procedural argument in the early decades of the 20th Century in the United States. The US Constitution and its amendments recognize the individual’s right to self-determination. In this context, there is a
number of lawsuits due to physical damages derived from medical acts that would prove decisive for the juridical design of IC. Three essential prerequisites are three: capacity, information and willingness.42

In several pioneering judicial resolutions legal liability is attributed to the physician who does not inform the patient truthfully or does not obtain his/her consent properly. Nevertheless, first it must be proven that lack of information deprives the patient of the opportunity to reject the treatment. The first convictions of this kind are based on the falsehood of the information, on its biased character, on abuse or aggression, understood as injury to bodily inviolability.42

The first jurisprudential consideration of the patient’s autonomy establishes that “every adult human being in his/her right mind has the right to determine what is to be done with his/her own body”. The historical quote by Judge Cardozo is indicative of the legal reasoning that takes autonomy from political philosophy to clinical medicine.41 Acknowledging the right to privacy and confidentiality occurs in parallel, more or less at the same time, through different ways.42

For some judges, the jurisprudential origin of IC reflects a situation of normative void that fostered the physician’s impunity. The IC contributes legal language and rationality, that is why it is (in procedural terms) more comfortable than the expert’s report. On the other hand, some physicians claim that the jurisprudential origin of IC represents a failure of the traditional self-normative mechanism. To them the IC is seen as an aggression that interrupts the good historical relationship between physicians and judges.39,40

**Autonomy as a principle of bioethics**

The boom of bioethics is due to a social climate of distrust in the traditional powers. In the United States, the cradle of bioethics, the historical context is marked by the Vietnam War and the Watergate scandal.41 The exposure of some regrettable episodes with respect to research on humans unleashes social alarm. From the Nuremberg Code (1947), the Declaration of Helsinki (1964) and the Belmont Report (1978) a new applied ethics emerges: bioethics.44,45

Bioethics studies human conduct in biomedicine in view of moral values and principles.46 It is multidisciplinary and it aspires to have an influence on the different strata of medical ethics (deontological, professional and personal strata).46 The principles of autonomy, welfare, justice and non-maleficence became the essential premises of healthcare medicine.44 In operative terms, bioethics can prioritize the principles or focus on the methods and their consequences.45

To bioethics, the autonomous individual “acts freely in keeping with a plan chosen by himself, just as an independent government manages its territories and establishes its policies”.44 Bioethics turns autonomy understood like this into a moral requisite of the medical act and proposes IC as the ideal procedure to ensure it. Since the 1980s, autonomy has become the leading principle of bioethics, for countless reasons that involve unexpected paradoxes.

**Reasons for leading autonomy**

Autonomy enjoys huge ideological appeal.47-51 No one wants to be left behind in the rejection of paternalism. The problem is that an autonomy that is too powerful denies the possibility of any forms of residual paternalism, which can prove useful when the perfect autonomy is impossible or undesirable.48,49 That is why some authors demand the return of a weak or gradualist paternalism within the clinical relation, taking into consideration that the current autonomist model has failed.48,52

Autonomy triumphs because its content is intuitive.38,39 Deciding whether the medical act is respectful of the patient’s autonomy is easier than evaluating its scientific-technological rigor or its degree of justice. Autonomy can be condensed in a few elementary rules, which seem to be conceived to become part of a legal text. However, the apparent simplicity of these rules conceals, as we will see, enormous application difficulties.

Autonomy is well-liked because it incorporates a control mechanism into the traditional clinical relation,20,21 but its impact on trust is not insignificant; in fact, it is not likely IC will manage to replace it. In practice, autonomy coexists with suspicion and can promote defensive medicine.37 It is usually believed that “trust is good, but control is better”. It does not really happen like this in medicine. Although no one denies the need for control in clinical relation, trust within it is essential.

The hegemony of autonomy ultimately reflects the difficulties existing to reach a consensus on any other hierarchy of bioethical principles.41 In any case such a dominating autonomy can have negative consequences for the patient if the probability for justice and welfare ever become materialize. Although autonomy is not expressly against them, it can distract the attention they deserve.50

**Autonomy as a denial of vulnerability**

Today’s present society worships the individual’s autonomy and disregards acknowledgment of their vulnerability. Today’s coexistence guidelines revolve around the myth of the autonomous adult, who is eager to maximize his/her options in a vital trajectory confined to choices and exchanges. This sociological trend ignores the fact that human beings are vulnerable upon birth and continue to be so, to a greater or lesser degree, throughout their lives.53

**Autonomy as a free choice**

Autonomy understood as freedom of choice among several available options makes sense in a clinical trial, in which two treatments are offered, a traditional and an innovating one. But freedom of choice is more unlikely in healthcare medicine, in which there are many simultaneous processes with multiple people in charge. The weight of choice is reduced within a rigid, complex healthcare organization. IC is an institutional offer rather than a medical one, with little room for actual individual autonomy.50
Limitations of autonomous language

Some physicians do not feel comfortable within legal procedures articulated with cold contractual language. After all, the autonomist language reflects the philosophical-juridical origin of IC. It is consistent with the existence of contrasting interests, but it is perhaps alien to the physician’s traditional commitment. Without the need to ignore the demands of that commitment, some physicians are skeptical about the patient’s capacity for autonomy and do not feel reflected in the autonomist jargon.

Difficulties of autonomy outside the original context

The right to autonomy originates in political philosophy and it aspires to govern clinical reality. Nevertheless, disease is not the ideal condition in which to exercise autonomy. On the other hand, autonomy looks appealing in the academic debate, but it stumbles on obstacles in healthcare medicine. Finally, autonomy originates in a concrete philosophical-legal tradition, but it tends to adopt different meanings when it operates in different cultures and traditions.

The autonomy of Spanish legislation

In Spain, the legal recognition of the patient’s autonomy is recent. The record shows it can be found in the Ley (Act) 14/1986, from April 25, General de Sanidad, and the third-generation rights collected in the Convention of Oviedo, ratified in Spain in 2000. As a result of the latter, Ley (Act) 41/2002 emerges on November 14, this act is the basic regulatory law (LBR) regulating the patient’s autonomy and his/her rights and obligations when it comes to clinical information and documentation.

In its article 2.1, the LBR indicates that human dignity and the respect for autonomy of the patient’s will and privacy must guide medical conduct with respect to information and documentation. Even though autonomy is considered the essence of human dignity, the LBR is based on both in a separate and explicit way. However, the European Court of Human Rights and the Constitutional Court link the right to self-determination with the fundamental right to physical integrity.

The LBR regulates the right to information on health, the right to privacy (understood as confidentiality) and the right to autonomy. It also regulates, in a more or less detailed manner, the previous instructions, the medical history and the discharge summary. It refers to the portfolio of services and the free choice of physician and center. But it puts special emphasis on the IC turning it into legal requirement of all medical act (Table 1).

Duty to inform and right to consent

The LBR regulates healthcare information (Art. 4), epidemiological information (Art. 6) and information as an IC requirement (Art. 8). It establishes that verbal information prior to the IC is precisely the healthcare information. This way it indicates that the main purpose of healthcare information is autonomous decision-making. This appreciation conveys an excessively instrumental view of clinical information. This vision seems to ignore the prevailing experience in many patients who are in general anxious to know, but not always willing to decide.

Article 4.1 establishes that healthcare information must be provided verbally, recording it on the medical history. The patient has the right to know (a) all the information available, (b) the purpose and nature of each intervention, their risks and consequences, and (c) the information fitting his/her own needs. The third criterion seems to be the most subtle of them all but the existence of several criteria can make the physician’s work harder and it contrasts with the closed nature of the forms.

Article 8.2 prescribes written IC for invasive procedures that presuppose risks. However, all the procedures are more or less invasive and entail some kind of risk. It is likely for this vague prescription of the LBR to promote generalization of written IC. On the other hand, article 10 indicates that written IC is especially recommended in procedures of unprecedented results. This warning underscores without any apprehension the legal-strategic importance of IC that can lead to misunderstandings.

Article 10.1 establishes that before the written IC, information should be provided about the relevant or important consequences that the intervention originates with safety and the possible risks in normal conditions, in conformity with experience and science or directly associated with this type of intervention. This detailed statement disturbs physicians and lawmakers because it does not clarify what are the odds of risk materialization on which informing is legally binding.

Article 2.3 guarantees the right to decide among several choices though in practice the patient is usually given one single option. In any case, the patient cannot choose a procedure without the doctor’s indication since it would infringe the principle of scientific autonomy and would be contrary to lex artis. The patient cannot demand an option not included in the services portfolio available either. Even though both assumptions limit the patient’s actual autonomy the LBR does not talk about them in detail.

Patient’s capacity and willfulness

The patient’s right to autonomy is limited by circumstances that prevent autonomy or prioritize other rights. The patient’s capacity is one of the IC requirements. It is so established in the LBR, whose article 9.3 provides for IC by proxy in case of physical incapacity, mental incapacity, legally modified capacity or situations where the patient is not of legal age. However it does not specify what criteria should be used for the assessment of such capacity.

Article 8.1 grants the patient the right to refuse to receive information. However, the patient who refuses to receive information cannot avoid undergoing IC. In conformity with the LBR, the patient cannot waive granting or refusing consent. In other words, he/she cannot give tacit consent. This obligation of self-determination contrasts with the genuine objective of IC: promoting autonomy.
Table 1  Informed consent in Ley (Act) 41/2002 of November 14, the basic law regulating the patient’s autonomy and the rights and obligations on information and clinical documentation. 56

| Definition                                                                 | A patient’s free, voluntary and conscious agreement, expressed in full possession of his/her faculties after receiving proper information so that there can be an action that affecting his/her health (Art. 3). The patient or user has the right to decide freely, after receiving proper information, among the clinical options available (Art 2.3) 
| Foundations                                                               | Dignity of human beings (Art. 2.1). Respect to autonomy of their will (Art. 2.1) 
| Indications of verbal informed consent                                    | All acts in a patient’s health environment need to have the free and voluntary consent of the affected party, once the information stipulated in Article 4 has been received and they have considered the choice particular to this case (Art. 8.1). As a general rule, the consent shall be verbal (Art. 8.2) 
| Indications of informed written consent                                  | It will be presented in writing in the following cases: surgery, invasive diagnostic and therapeutic procedures and, in general, the application of procedures that encompass risks or disadvantages with a notorious or foreseeable negative repercussion on the patient’s health (Art. 8.2) 
| Information prior to verbal informed consent                             | Patients have the right to know all the information available, except for the cases excluded by the Law (Art. 4.1). It shall be provided verbally recording it in the medical history (Art. 4.1). The information includes, at least, the purpose and nature of each intervention, its risks and consequences (Art. 4.1). The patient will receive the information in an understandable manner and based on their needs and it shall help them make decisions (Art. 4.2) 
| Information prior to written informed consent                            | Enough information about the application procedure and its risks (Art. 8.3). Relevant or important consequences that the intervention originates when it comes to safety (Art. 10.1.a). Risks associated with the patient’s personal or professional circumstances (Art. 10.1.b). Probable risks in normal conditions, according to experience and the state of science or those directly associated with the type of intervention (Art. 10.1.c). Counter-indications (Art. 10.1.d) 
| Information rejection                                                    | When the patient explicitly expresses his/her wish not to be informed, such will shall be respected without detriment to obtaining his/her prior consent to the intervention (Art. 9.1) 
| Revoking the informed consent                                            | The patient can freely revoke his/her informed consent in writing at any time (Art. 8.2) 

Article 8.5 allows the patient to revoke the consent granted, but article 21.1 warns that refusing the procedure offered can lead to forced discharge. Although it mentions the possibility of offering alternative procedures, the LBR does not detail the conduct that should be demanded from the physician when the patient does not grant his/her consent. It is paradoxical that a law that is meant to ensure the patient’s autonomy pays so little attention to the rights of disagreeing patients.

The importance of medical judgment

The LBR grants a determining role to the physician’s own judgment.56,57 The physician must decide if he/she is to guarantee the information or just contribute to it. He/she must assess whether the patient understands and what risks he/she should know. They must decide how much time in advance to inform and whether it should be done in writing or not. They must know when the IC can be omitted and provide alternatives for disagreeing patients. In short, they must make one decision after the other, gauging their possible medical-legal repercussion in all of them. We should ask ourselves whether the importance the law attributes to the physician’s own judgment is compatible with promoting the patient’s autonomy, or whether it reinforces the validity of traditional paternalism.

The reach of health legislation

The patient’s autonomy is regulated by many other State and autonomic laws, in a context of rapid expansion of health law, marked by doctrinal and jurisprudential controversies.63 On the other hand, acknowledging rights without the provision of the necessary resources to ensure their exercise can be deceiving.63 In any case the overabundance of detailed rules in an environment as changing as health environment increases the probabilities that they will soon be obsolete.63
Table 2  Informed consent in the medical deontological Code of the Collegiate Medical Organization. 54

| Definition | The physician shall respect the patient’s right to decide freely, after receiving proper information, about the clinical options available (Art. 12.1). |
| Foundations | Respect human life and the person’s dignity and look after health (Art. 5.1). Understanding and trust is required between the physician and the patient (Art. 8.2). The patient’s convictions shall be respected (Art. 9.1). The physician shall act with gentleness, correctness and tact while being respectful of the patient’s privacy (Art. 9.2). Information is not a bureaucratic act, but a clinical one (Art. 16.1) |
| Indications of the information | It is the physician’s duty to respect the patient’s right to be informed at each and every stage of the medical process (Art. 12.1). The physician shall offer an honest, proper explanation of their mistakes (Art. 17.1) |
| Content of the information | The information shall be enough to make decisions (Art. 12.1). It shall be conveyed in an understandable manner, with veracity, impartiality and prudence (Art. 15.1) |
| Indications of written consent | When the measures proposed presuppose a significant risk for the patient, the consent shall be obtained in writing (Art. 16.2) |
| Information rejection | The physician shall respect the patient’s right not to be informed recording it in the medical history (Art. 15.2) |
| Consent rejection | The physician shall respect the patient’s partial or total rejection of a diagnostic test or treatment. The patient shall be informed in an understandable, precise manner about the consequences that can result if they insist on their refusal, keeping record in the medical history |

Autonomy of deontological code

The rights linked to the patient’s autonomy are also described in the Deontological Code (DC) though in a peculiar way. 54 The DC, a legal prerogative of the Organización Médica Colegial (Collegiate Medical Organization), contains ethical rules inherent to the practice of the medical profession. Because the level of diligence that should be demanded from the physician is uncertain and hard to judge from out of the profession, it is accepted that professionals should define it themselves before society 40-43 (Table 2).

Deontological code and Hippocratic tradition

The DC currently in force, published in 2011, declares that it is in favor of health-care quality and continuous improvement. It defends self-regulation and admits to be in debt of the historical service vocation toward patients and society. It points out that altruism, honesty, veracity, empathy and loyalty define the good doctor and promote the patient’s trust. 64 This vocabulary has elements from the traditional clinical relation – rich in human touch while portraying a slightly idealized image of today’s physicians.

Deontological code and bioethical principles

The DC assumes bioethical principles but will not mention them. Welfare is implicit in the respect for life. Non-maleficence underlies in avoiding harm. Justice is present in the prohibition of any kind of discrimination. Finally, respect for autonomy is recognized in the defense of the patient’s dignity, decisions and convictions. In any case, information and the achievement of consent are deontological precepts linked to acknowledging the patient’s dignity, not their autonomy.

Deontological code and legislation

Successive versions of DC are getting longer and longer all the time showing the growing complexity of medicine. The DC recognizes the legal system, but it is not a law. It aspires to improve assistance, while the law intends to regulate it. The DC is binding and failure to comply with it can be considered an indisciplinary act. However, it has little punitive power. It manifests its will to fight against the laws that oppose its precepts. It describes the medical act as a lawful act. It turns medical duties into deontological precepts. It insists on duty, responsibility and quality, but it does not mention excellence, professionalism or lex artis. 64

The DC indicates the obligation of informing and obtaining consent, but it does not mention the legal procedure intended to comply with such precepts. The DC establishes that the patient must be provided with the information necessary to make decisions, just as the LBR stipulates. However, the DC puts emphasis on the need to inform gently and carefully, and it opposes the excesses that the law might embrace. It warns that consent must be verbal and never bureaucratic, stressing the need for written consent when there are significant risks, just as the LBR does. 64
DC indicates the need to report the medical errors, something the LBR omits. Consent by proxy and the limits of consent are described in terms similar to those of LBR. The DC is right when it points out that the patient’s rejection should not result in a demand alien to the medical indication. Finally, DC protects the patient’s refusal to receive the information. However, it is more explicit than the LBR when it describes the attitude that is to be demanded from the physician when the patient refuses.64

The importance of deontological code

Some physicians consider that DC is essential while others just ignore it.65 Some authors suggest that DC is nothing but a legitimizing discourse intended to protect the physician from the growing medical-legal uncertainties.68 Few lawmakers question its legitimacy, but forced association and its scarce disciplinary effectiveness have limitations.69 On the other hand, DC understood as a mandatory moral code poses questions. As Victoria Camps claims, referring the problems of applied ethics to precept codification is not the best way to underscore the place that deliberation and caution should occupy in it.45

Autonomy and professionalism

Respect for the principle of autonomy is also an essential ingredient of the medical profession. This is how US professionalism understands it, whose foundation dates back to 2002.70 Professionalism includes the principle of autonomy among its guiding principles, along with those of justice and welfare. On the other hand, professionalism understands IC as one of the responsibilities linked with the commitment to honesty with the patient. Both principles and responsibilities of professionalism are shown in the DC, the LBR and the rest of our legal system. However, professionalism has the advantage of its global claims and has been endorsed by over a hundred scientific organizations.

Anyway no code guarantees professionalism.71 The physician seeks excellence with professional acts with the force of his/her determination from an ethical point of view more personal that official. Only with it, is it possible to show a voluntary and sufficiently vigorous adherence to the existing legal, deontological and professional rules that are not always coherent.46

Conclusions

Thirty eight (38) years ago Vaccarino said that the legal modifications of IC confuse the physicians and stretch out the forms without improving the patients’ autonomy.72 His observation has not lost an inch of validity, which in turn reinforces doubts about the feasibility of autonomy and the consistency of its rules. It is undeniable that the notion of autonomy has a credible core that deserves all of our respect,95 even though it does not enjoy unanimous approval.96 But around this powerful central idea there is a weaker, more questionable incidental plot that is usually affected by its relation with clinical reality. We will go back to this point in the second part of this article, where we will also analyze the legal consequences of violating the principle of autonomy.

Ethical disclosures

Protection of people and animals. The authors declare that no experiments with human beings or animals have been performed while conducting this investigation.

Confidentiality of data. The authors confirm that in this article there are no data from patients.

Right to privacy and informed consent. The authors confirm that in this article there are no data from patients.

Conflict of interests

The authors declare no conflict of interests.

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