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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

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Bioética; Ley; Código deontológico; Profesionalismo 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. © 2016 SERAM. Publicado por Elsevier España, S.L.U. Todos los derechos reservados.

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). 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. ¹⁶ 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. ^{17–19} 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. ¹⁹⁻²¹ The welfare state promoted public health that understood health as perfect physical, mental and social wellbeing. ²² In this context, the irruption 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.²³ The new medical act needs to be beneficial, necessary, consensual, safe and fair. It must have quality and seek satisfaction.²⁴ In view of an adverse result, risk materialized as damage becomes the axis of procedural debate, which stimulates defensive medicine.²⁵

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. ^{26,27} Skeptical of the formidable proposals of academic ethics, they wonder whether they are being asked too much. ²⁸ 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. ²⁹ 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.²⁹

Autonomy can be understood as the capacity to act with independence, the possibility of acting with willingness or the right to decide freely.²⁹ To Kant, autonomy is rational self-government through universal moral regulations.³⁰ To Mills, autonomy seeks the utmost wellbeing, it entails sovereignty and is identified with an absence of coercion.^{31,32} 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.²⁹

The notion of autonomy is controversial.³³ 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.³³⁻⁴¹

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

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