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Autonomy, consent and responsibility. Part II. Informed consent in medical care and in the law☆

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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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Autonomía, consentimiento y responsabilidad. Parte II. El consentimiento informado en la medicina asistencial y en la jurisprudencia

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

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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

In the first part of this article we examined the limitations of the principle of autonomy as the foundation of informed consent (IC). In second part we will approach the difficulties posed by getting IC in assistential medical care,[1] with specific references to radiodiagnosis. We will analyze the relation between IC with *lex artis* and juridical liability. We will describe the procedural significance of infringed autonomy by invalid consent. Finally, we will refer to the deficiencies that can undermine the legal validity of IC in lawsuits for professional or patrimonial liability.[2]

Informed consent in assistential medicine

Judicial-ethics and specialized training

Lack of judicial-ethics training provides confusion when it comes to the right to autonomy with the procedure ensuring it and with the document that certifies it.[3] Even knowing the judicial-ethics stipulations, the physician usually focuses on the scientific-technical aspect, seeking new challenges and professional promotion. Perhaps that is why we tend to equate scientific excellence and professionalism. However, scientific excellence is not enough to characterize the good physician.[4] On the other hand, the division of labor, inherent to specialized medicine, outlines the scope of professional duty and blurs the distribution of obligations.[5] Perhaps this is why it is difficult to determine who should be informed and on what.[6]

A matter of logistics

The deliberative process of IC takes time, peace, space and furniture. The orthodox processing of IC is incompatible with an intensive exploitation of healthcare resources.[7] However, IC can be expedited with structured interviews and audiovisual systems.[8] This is why it is surprising to find out that there are very few provisions aimed at improving information and facilitating the decision. Although it is often thought that the physician does not know how or does not want to process the IC,[9] perhaps the fact is that they do not have the means to do in a better way.

Communicative skills

Some physicians have difficulties disclosing the healthcare information in colloquial terms due to a lack of verbal skills, which is frequent in multicultural environments.[10] On the other hand, translating the medical jargon into an accessible language requires empathy and motivation, without which it is not possible to evaluate the patient's understanding. In any case, there is indeed need for tools to estimate the patient's cognitive skills and specific training in communicative skills.[11]

The sociology of risk

Society seeks security but it feels more and more insecure. The demand for protection increases the feeling of vulnerability and it in turn, greater demand. This concatenation suggests that the risk has a lot of social construct linked to the citizens' own expectations.[12] In traditional medicine, the patient would accept all dangers. The IC however transforms the danger into risk, which is assumed by both physicians and patients.[2] The IC distributes risks and liabilities between both though it not always in a balanced way.

Amount of information

The amount of information the patient is given has great legal relevance. The basic regulatory law (BRL) that regulates the patients' rights establishes that patients should be informed in a way that is adequate to their capacity for understanding, that they should be provided with all the information that they might need.[13] Nevertheless, some physicians prefer to inform the patients about everything that may influence them, whether they need it or not.[14] Having learned a lesson in lawmaking, the physician focuses on warning against the risks associated with the procedure offered. However, it is also important to fight unfounded beliefs and expectations.[14] The physician tends to overestimate the amount of information revealed. The patient, in turn, usually needs data associated with their experience of the disease.[15]

Probabilistic information

Information about the serious and exceptional risks, which is both common and controversial, will be dealt with below from a radiological and lawmaking perspective. For now, let us just say that the explanation of low-probability risks is problematic. Although diagrams and comparisons with ordinary risks are useful, many physicians that are not used to handling probabilities do no manage to transmit intelligible

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