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Informed consent and mental health, mainly in Spain, EU

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Abstract

Introduction: Lawfully given, informed or valid consent is considered by Spanish jurisprudence a fundamental right and entails important repercussions.

Method: Critical and theoretical examination of the matter, with special emphasis on the case of the most vulnerable people and those who require involuntary outpatient psychiatric treatment (IOT).

Results: Valid informed consent must fulfil the requirements of capacitation, willingness, information and understanding. Timely knowledge and agreement regarding by whom and how this consent must be granted are important in biomedicine and psychology in general, as well as in the specialities of psychiatry and clinical psychology in particular. It is also important to ensure valid consent for any psychotherapy, as it generally also occurs in the case of psychopharmacological treatments. This article will revise the so-named "sliding scale" to determine mental degree of competence. This concept is especially important in order to consider whether a supposed valid consent is appropriate in vulnerable people. We will talk about living will and severe mental illness concerning valid consent. The current state of psychiatric involuntary outpatient treatment in Spain will be mentioned as well as the wills of legally incapacitated individuals, elderly people or when the carer, either an individual or institution, is the main beneficiary.

Conclusions: Valid consent is necessary in every biomedical or sanitary action in general. The matter is potentially controversial if wrongful influences bear upon elderly people, incapacitated individuals and others.

Keywords: Informed consent; Valid consent; Spain; Will; Severe mental illness

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Introduction

Informed consent (IC), also known as valid or lawfully given consent, is deemed by Spanish jurisprudence a "fundamental human right" in

considering freedom a higher value in the legal system. It was defined in Spanish Act 41/2002 Regulating Patient Autonomy and Health Documentation and Information-Related Rights and Obligations as: "a patient's free, willing and conscious approval, manifested in

the full use of his or her faculties after receiving the appropriate information, so that an action affecting his or her health may take place". In the field of mental health and worldwide IC is a highly relevant, important issue.

In spite of the above, publications specialised in the issue are rather limited, quite diverse and of varying quality. IC entails significant repercussions of various types, although paradoxically on numerous occasions it is not adequately evaluated and at other times it is undertaken by physicians who are not specialists in psychiatry or psychologists specialised in clinical psychology. Both aforementioned specialisations are official qualifications awarded in Spain with validity throughout the country. Indeed, regarding psychologists there is a sole official or formal specialisation, which is precisely clinical psychology. Although many other psychologists are considered experts in diverse specialisations, this does not mean that for that reason they become formally qualified specialists. Even evaluation of the patient's mental state is undertaken in some circumstances by those who are not physicians (for example, social workers) and who themselves even use and interpret psychometric tests or trials for which they are not formally trained.

Methodology

This research has the main aim of analysing the safety, rigour and normative basis, as well as some of the practical applications, of the mental capacity to consent, especially in Spain. Due to the scarcity of suitable studies it would hardly be pertinent to conduct in that respect an orthodox review study or even an original, genuinely empirical one. Therefore, to achieve the proposed goal, we will make a critical and theoretical examination of the question, with special emphasis on patients affected by severe mental illness (SMI) and those who require involuntary outpatient psychiatric treatment (IOT).

Results

State of the question in Spain

The IC of any patient must be freely and willingly given by any user, and it is habitual as a gradual process in all health interventions. It entails notable clinical, ethical and legal dimensions, privileging the individual's autonomy and his or her right to choose. IC was introduced in Spain in the early 1990s after the duty of doctors to obtain it had been established, which we now better define as ethical responsibility. It has thus been reflected in numerous Spanish Supreme Court sentences since 2005. The minimum basic yet obligatory legal framework is Spanish General Health Act 14/1986, now replaced in this area by Spanish Act 41/2002 Regulating Patient Autonomy which partially repeals, complements and updates it. Furthermore, legislation by the different Spanish Autonomous Communities-equivalent to US states or sub-national bodies - should be borne in mind.

The IC must combine in the person granting it the requirements of capacitation, willingness, information and understanding. It is important to remark that when the IC is inadequate or wrongful it will lack legal validity throughout Spain and that, anyway, in a case of negligence by the physician who has operated, the signing of consent does not exempt him or her from responsibility [1]. It should also be added that in Spanish jurisprudence the duty of proof of the information provided to obtain the IC lies with the physician. The above is relevant in the field of mental health given that on most occasions consent is obtained verbally. There could also be various repercussions in the case of actions which were legal if dealing with an irregular IC due to incidents of annulment, among other possibilities.

Conversely, the Spanish law courts frequently hand down contradictory sentences and confrontations regarding a certain individual's capacity to grant IC. That affects both so-called *forensic physicians* (which is how certain

official government public physicians are known, who are generally not psychiatrists) and the psychiatrist or clinical psychologist specialists who appear in the same legal procedure as forensic experts (and neither do the specialist psychiatrists tend to be the public officials called *forensic physicians*). Such circumstances force the corresponding judges and magistrates to decide who of the participants is better prepared to determine formally and scientifically the mental capacitation of the charged or examined individual [2].

The IC also affects psychotherapies insofar as they are modes of treatment, which includes the need to inform truly of the scientific evidences that support the psychotherapeutic method proposed, and the possible alternative options that comprise both other psychotherapeutic and psychopharmacotherapy approaches [3-5]. It is another matter that, in general, certain doubts exist that the physicians who get trained in psychotherapy always fulfil their ethical obligations [6]. Also, as a general rule, patients' IC must be obtained when their medical records on psychotherapeutic treatments are transferred to the legal system [7].

Notwithstanding the above, it seems that most patients can sufficiently understand and comprehend the questions related to IC, except mainly if intoxication or SMI are involved [8-9]. But medical or psychological practice external to the area of mental health and in other not strictly health-related settings (such as police and public order environments) creates tensions at a bioethical level or between the principles of beneficence and duty to society [10]. Within the normative framework of deontologist-principlistpersonism, the latter duty to society is intrinsic to the principle of justice identified with the common good [11]. As well as this, insofar as refers to moribund subjects, the laws of Spanish autonomous communities governing dignified death must be taken into account. To do so, to set and develop the rights of those who face that threat, for example in the Valencian Community, Act

16/2018 on the Rights and Guarantees of Dignity for Persons in End-of-Life Care Process is in force.

For its part, the aforesaid Act 41/2002 Regulating Patient Autonomy established in Spain that any action in the area of health needs the free, willing consent of the affected person. In practice, patients' mental competence often tends to be superficially or inadequately evaluated, so that currently the old concept of shared decision-making has been revitalised [12]. But bear in mind that one is not capable or incapable in general, but in the circumscribed field of a specific action or task [13]. In like manner it should be considered that the examination of mental capacity to grant IC is a complex matter that should preferably be approached from the formally specialised area. With regards to the indispensable bioethical context it is necessary to guarantee along with IC the safeguarding of basic programmatical principles of the public health care model, which are autonomy, continuity, accessibility, understanding, fairness, responsibility and quality.

Likewise, it should be ensured that the other rights and faculties that incapacitated persons cannot exercise by themselves are made effective [14]. In any case, after the IC and before any treatment becomes effective, a period of reflection adapted to the circumstances should be allowed. Currently five exceptions to any patient's IC are allowed, which are regulated by the country's legal system: 1) When non-intervention represents a risk to public health; 2) Emergency situations in which there is no material time to obtain the IC; 3) When the patient is incapacitated to make decisions; 4) When the intervening physician uses his or her best therapeutic criteria and considers that the person could be harmed if they access the full information; and 5) When the patient presents or requests a waiver; in effect, like any other right, the right to information and treatment may be waived or accepted provided that it is not contrary to the interest and public order or harmful to third

parties. Lastly, it is necessary to leave a record where applicable of all actions taken.

For more detailed information in Spain, consult the Medical Deontological Code in its latest version proposed in 2018, as well as the *Convention on Human Rights and Biomedicine*, also known as the *Oviedo Convention*, in force in Spain since 2000. The aforesaid Medical Deontological Code specifies the duty of the pertinent medical physician of having to evaluate the patient's capacity to understand the information given so that he or she can make decisions during the IC process. For its part, the *Oviedo Convention* recognises the right of patients to information, to the IC itself and to privacy, urging for an egalitarian regulatory framework to be established in all countries. It also expressly foresees the possibility of prior instructions, upon which we will comment below.

Advance directives

When faced with hypothetical situations in the psychopathological realm, directives of prior instructions, advance directives or living wills are generically known as a "Ulysses contract" [15]. In the variously aforesaid Spanish Act 41/2002 Regulating Patient Autonomy, in addition to the concept of IC its necessary inclusion in a national register was introduced in Spain. See Royal Spanish Decree (RD) 124/2007, Ministerial Order SCO/2823/2007 and the Spanish Ministry of Health's 2019 list of autonomous communities' advance directive registers. And just for the Basque Country autonomous community, to cite an example, what is contained on advance directives in Basque Decree 38/2012 on Medical Records, Rights and Obligations of Patients and Health Professionals in the Area of Clinical Documentation.

RD 124/2007 likewise includes the possibility for the interested party to designate a representative to ensure correct compliance of his or her advance directives, as long as they comply with the *lexartis* - the name given by

Spanish jurisprudence to appropriate action on the part of professionals. If this time we take the Valencian Community as an example of one of the country's autonomous communities, here IC is determined by Valencian Health Act 8/2018, which amends Act 10/2014. In this community, IC is developed in the Comprehensive Care Plan for Persons with SMI 2018-2022 through what is termed "advance directive planning". It thus complies with the contents of the Valencian Community Mental Health Strategy 2016-2020 of the Generalitat Valenciana (Government of Valencia, ES)-the body responsible for passing local legislation.

Will granted by vulnerable persons

In regards to any patient attesting their IC-when applied specifically to last wills-it is worth recalling the "sliding scale" concept to determine the patient's mental competence, especially if he or she is particularly vulnerable [16]. This scale considers three grades of capacity that are progressively stricter depending on the consequences and risks the user's decision entails. In the first grade a minimum standard of capacity is required consisting of awareness and assent. The standard for the second grade is medium, requiring understanding and choice. The third grade requires the highest standard, consisting of appreciation of reality and rational decision, and this is the grade demanded to grant will and testament.

In particular, for the moribund person to have the recognised capacity to attest will depend, furthermore, on being free from undue influences [17,18]. And in England and Wales, also whether the 1870 Banks and Goodfellow criteria are complied with [19]. For details on the question in Spain, mainly in persons of advanced age and especially concerning possible influence of the vulnerable testator's volition, see Mesa [20]. Although the country's legislation enables persons older than fourteen years to attest, special practical importance is placed on the frequent testamentary

arrangements in favor of the person or entity who cares for the elderly or vulnerable testator.

Likewise take into account that as a general rule, except for the cases contained in the 1889 Spanish Civil Code (latest update published in 2018), any person is accorded the sufficient mental capacity at the moment of attesting, unless the contrary is demonstrated in an unequivocal, conclusive manner. In any case, final appreciation of the capacity to grant IC in a will corresponds to the judicial body upon whom exercise of jurisdictional power is incumbent. It is therefore worthwhile recalling and specifically emphasising that the notarial judgement on capacity to attest is solely a rebuttable presumption (*iuris tantum*) rather than conclusive (*iuris et de iure*) presumption, meaning it can be rebutted via irrefutable proofs. Examples of such proofs might be the forensic judgements of psychiatric physicians or clinical psychologists who are designated legal experts, as we commented in the section on the state of the question in Spain.

A specific, significant factor is whether the person granting testament suffers from SMI, a concept inherited from “*severe and persistent mental illness*” as described by the National Institute of Mental Health in Washington, US, in 1987. It is not necessary to underline the many risks that SMI may entail and which the World Health Organisation (WHO) recognised in its *Mental Health Action Plan 2013-2020*. Likewise, special mention should be made in regards to testament granted by somebody who is legally incapacitated, in the case that no specific pronouncement was made in that regard in the court decision on incapacitation. Thus, it must be especially since the entry in force in Spain in 2008 of the international tools, the United Nations’ *Convention on the Rights of Persons with Disabilities*.

Involuntary outpatient psychiatric treatment

With regard to involuntary outpatient psychiatric treatment (IOT) [11,21], it is worth recalling that it was conceived and developed through the Bellevue Pilot Project at New York’s Bellevue Hospital, United States, in 1994. The favourable experience of effectiveness found in that State seems conclusive, even if its achievements cannot overshadow its failures. The latter are mainly due to non-compliance of the court order by the interested party and the inaction of the professionals involved. Among such failures one can cite in the US the tragic homicide of K. Web dale in 1999, and the massacre perpetrated by South-Korean student Seung-Hui Cho at Virginia Tech in 2007. In Spain, had the corresponding IOT been proposed in time, it may possibly have avoided the homicides caused in Madrid, Spain, by N. Mingo in 2003 and the serious aggression against another person by the youth J. Ramos in 2005.

Although the international regulation of IOT is to date rather irregular, it generally comprises three forms: as an alternative, as a complement and as a means of avoiding involuntary psychiatric hospital admission [11]. Many psychiatrists in Spain believe that legislative regulation of IOT is necessary and that such a mode of treatment is beneficial for the patient and their family [22,23], which would legitimise the interested party’s lack of IC. Currently IOT is being applied in many western countries, almost all Anglo-Saxon or within their sphere of influence, such as the US, United Kingdom, Ontario (Canada), Australia, New Zealand and Israel, and also in other European countries like Italy, France, Portugal, Sweden, Switzerland and Germany, as well as Spain.

In Spain, in fact, IOT has been applied since 1997 in various cities. On the professional viewpoint of associations, we will mention here only the positions taken by the Spanish Association of Neuropsychiatry (AEN), opposing it, and the Spanish Society of Legal

Psychiatry, in its favour. We should recall that IOT in a patient at a specific time consists of temporarily transferring responsibility for IC to a judicial authority. In fact, IOT is generally known as “community treatment orders” or “compulsory treatment in the community” and is also known, mainly in the US, as “involuntary outpatient treatment” or “involuntary outpatient civil commitment”.

Alternatively, to IOT, in 2009 the Spanish Confederation of Families of the Mentally Ill came out in favour of the better and perhaps utopian or ideal community psychiatry, as does the aforesaid AEN. Lastly, after several failed attempts, no specific legislation exists to regulate IOT in Spain. Although it can be implemented in local programmes, in the opinion of many experts a specific legal regulation is required given that fundamental rights are restricted, such as the individual’s autonomy to grant IC. Naturally, the right to autonomy implies that the interested party enjoys sufficient discernment, intention and freedom. It is worth noting here the likewise Spanish Organic Law 5/2000 governing Penal Responsibility for Minors, which foresees IOT precisely as a measure that can be imposed, constituting a notable precedent and legal counsel to take into account for adults [5].

Conclusions

In Spain, as in other countries, IC is required for any specifically biomedical or health action in general. When dealing with an especially vulnerable individual one should bear in mind the aforesaid sliding scale of capacity to consent. Specifically, in the Valencian Community, ES, the Comprehensive Individual Care Plan 2018 is in force, which demands agreement or shared decision-making with patient, family members and physicians. The aforesaid is in complete accord with the Council of Europe’s Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, signed in Oviedo, ES, in 1997, and with the United Nations’ Convention

on the Rights of Persons with Disabilities in 2008.

Yet IC should also be obtained if advance directives are stipulated by any individual, or if he or she is receiving psychotherapy or psychopharmacotherapy, insofar as both interventions are necessarily treatments. Naturally, in the case that involuntary psychiatric hospital admissions or IOT are prescribed, such IC must be substituted for that dictated by the judicial authority. The question will be far more delicate or even conflicting if the possibility or suspicion exists that the patient has been the object of undue influences, or of dealing with wills granted by elderly people, legally incapacitated individuals, or if the beneficiaries are individuals or institutions who care for the testator.

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