Rivista di psichiatria 2023; 58: 241-248

Psychiatric advance directives (Ulysses Contract): the need for a specific law and a criteria proposal for its introduction

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Summary. Aim. Advance healthcare directives in the psychiatric field raise more concerns and controversies compared to their use in other medical branches. We discuss the role of advance directives in this field and suggest a criteria proposal for the settlement of a comprehensive regulation on the matter. **Methods.** We analyse the existing law and discuss the ethical points in the Italian context and, in comparison, with the United Kingdom context. **Results.** Numerous studies have highlighted that psychiatric patients experience advance directives as an instrument to participate in therapeutic decision-making. Regarding the usefulness of advance directives, Italy and the United Kingdom did not approve deontological rules or laws. The United Nations Commission states that, based on the principles of the Convention on the Rights of Persons with Disabilities, it is necessary to respect the spatient's will, even if it is biased by psychic disorders. **Conclusions.** The Convention does not consider advance directives; instead, they just suggest using some support to have the patient regain their competence. In case this is unsuccessful, it is necessary to appoint a substitute decision-maker to express, even in the light of the advance directives, the will that the patient would have expressed if he had been competent.

Key words. Psychiatric advance directives, informed consent, self-determination, living will.

Direttive anticipate psichiatriche (Contratto di Ulisse): la necessità di una legge specifica e una proposta di criteri per la sua introduzione.

Riassunto. Scopo. Le direttive anticipate di trattamento in ambito psichiatrico sollevano maggiori preoccupazioni e controversie rispetto al loro utilizzo in altre branche mediche. Nel presente manoscritto, gli autori discutono il ruolo delle direttive anticipate in questo campo e suggeriscono una proposta di criteri per la definizione di una normativa completa in materia. **Metodi.** Analisi comparativa delle normative esistenti e dei documenti di bioetica in Italia e nel Regno Unito. **Risultati.** Numerosi studi hanno evidenziato che i pazienti psichiatrici vivono le direttive anticipate come uno strumento per partecipare al processo decisionale terapeutico. Per quanto riguarda l'utilità delle direttive anticipate, l'Italia e il Regno Unito non hanno approvato norme o leggi deontologiche. La Commissione delle Nazioni Unite afferma che, in base ai principi della Convenzione sui diritti delle persone con disabilità, è necessario rispettare la volontà del paziente, anche se influenzata da disturbi psichici. **Conclusioni**. La Convenzione sui diritti delle persone con disabilità non prende in considerazione le direttive anticipate, ma si limita a suggerire l'utilizzo di un supporto per far sì che il paziente riacquisti la propria capacità. In caso di insuccesso, è necessario nominare un fiduciario che esprima, anche alla luce delle direttive anticipate, la volontà che il paziente avrebbe espresso se fosse stato competente.

Parole chiave. Direttive anticipate psichiatriche, consenso informato, autodeterminazione, testamento biologico.

Introduction

The Advance Directive is a document through which a subject, in full possession of his mental faculties, expresses to a third party (relative, friend, physician) his will on whether or not to undergo given treatments, his preference regarding the assumption of drugs, therapeutic procedures, and hospitalisations in case of the insurgence of a disease that results in the impossibility of making a conscious choice[1].

The fundamental bioethical principle of autonomy concerns the right of an adult to make treatment decisions after being fully informed and without interference[2]. This principle, which is historically related to the revolution of medical ethics after the devastating consequences of Nazi doctor experiments, carried out in the name of scientific research, is covered by many international documents (Nuremberg Code, Convention on Human Rights and Biomedicine, Charter of Fundamental Rights of the European Union) concerning the provision of informed consent and compliance with the patient's wishes as prerequisites to the delivery of health care[3].

From a bioethical perspective, advanced healthcare directives are based on two theoretical considerations. The first is that technological progress in the biomedical field has changed the meaning and process of death by medicalising it; the second is that informed consent is the document that legitimises the physician's activity. This means that in the event of loss of capacity, there is an urgent need to reconstruct consent to prevent physician activity from being illegitimate[4]. In this vein, advance directives are a tool for obtaining informed consent and individual freedom in situations close to the end of life that would otherwise have escaped patient control.

Advance directives are applied especially to patients suffering from recidivist-remittent psychiatric disorders or subject to re-intensification within chronic progress with possible spontaneous or treatment-induced symptomatic attenuations, which may result in loss of clarity of thought and rational ability of the patient milder than what happens, for example, in patients with advanced dementia. These patients have lost not only their ability to take action or understand, but also their ability to communicate with the environment. In light of such consideration, the psychiatric disorder that can be more directly applied to advance directives is certainly bipolar disorder, in the inter-critical phase of which the patient can recover a full ability of thought and judgment and can therefore give consent to possible treatments, as well as an anticipated adhesion to future treatments in case of relapse in critical clinical conditions. Nevertheless, even patients with schizophrenia, in the possible case of at least partial symptomatic relapse, can sometimes express anticipated adhesion to treatments in the case of possible reintensification of the disorder. For these psychiatric patients, self-binding directives, also known as "Ulysses Contracts", have been expressed[5].

The use of PADs is mainly debated, and globally, it is ruled differently based on the approach legislatures have chosen to recognise the wishes of persons with mental illness. During the 1990s, some countries debated the opportunity to recognise psychiatric advance directives (PADs). The US has recognised these tools since early this period, while New Zealand and Scotland in 1999 and 2003, respectively. In Australia, some changes are happening due to the revision of mental health laws by many jurisdictions (i.e., New South Wales and Northern Territory have completed this review, while further works are even conducted in Western Australia, South Australia, Queensland, Tasmania, ACT, and Victoria). However, to date, only the ACT and the Victorian Review formally supported the recognition by the legislation of the Advance Directives[6]. In Europe, the situation is quite complex since not all UE countries recognise these tools' use for mental health. Spain and France do not have a specific framework in this matter, whereas other countries have introduced this option only for specific pathologies or with peculiarities regarding their legal validity[7,8]. In 2008, the Netherlands introduced a law, successively amended, on self-binding directives[9]. Germany recognised advance directives in 2009 for somatic and mental healthcare, though there are no specific provisions on the self-binding directives[10].

The present manuscript discusses the role of PADs in the psychiatric field, considering the absence of comprehensive regulation and the unanimity of views on the matter, and suggests a criteria proposal for the settlement of a new law.

Ulysses Contract in psychiatric patients with relapse

The definition recalls the episode of the Odyssey in which Ulysses – who wanted to hear the Sirens sing without being bewitched by their voice – asked his mate Eurylochus to tie him to the mast and put wax in his crew's ears so that they could not hear the sirens sing and could not untie him until they had overtaken the place where they lived, not even if he had asked them persistently[11].

A psychiatric patient with remitting relapsing disorder is like Ulysses and is aware that his condition can come back alternatively, thus temporarily compromising their ability to decide.

Therefore, he is aware that, to improve, he needs to be helped by others, that is, doctors, trustees, and relatives. He can ask for help through PAD. PAD is a deed through which the patient admits that he or she needs other people and "gives" them his will, asking them to take it into action in the future when he cannot support it. By signing a contract, the patient chooses to responsibly reduce his autonomy for the sake of his own and those of his family. In such light, which could lead him to act dangerously for his health, they would choose to anticipate their free will and, like Ulysses, tell the physician their will, that is, they could decide not to interrupt therapy, even if they should implore him to do so in the future, or they could participate in clinical studies regarding experimental treatments, as well as choose the structure to be hospitalized[12].

The self-binding directive allows the use of previous experience with the disease to describe the first symptoms of the onset of the acute stage and consent to specific treatments in advance. When it comes to treating, patient competence can be severely reduced by mental disease, and, still, there may not be conditions for involuntary treatment.

The Ulysses Contract binds the patients when the insurgence of the disease does not allow them to decide what is best to do. Therefore, it is an agreement between the arranging party and the addressees, which becomes effective if and when the disease compromises their ability to decide.

PADs are legal instruments that allow competent people to document their instructions or preferences for future mental health treatments and to appoint a proxy decision maker, whose task is to interact with doctors and relatives during the spiralling of the patient[13].

According to Daverio, this possibility represents an occasion for a more crucial familiar involvement on the one hand. However, on the other hand, it shows the difficulty in determining that this person(s) is the trustee of patient interests[14].

The Ulysses Contract, in addition to protecting the autonomy of the psychiatric patient, must be considered an instrument of support for a vulnerable condition: the psychiatric patient is not autonomous but instead experiences difficulties and, therefore, the contract represents actual treatment.

Therefore, the Ulysses Contract is not just an expression of their wishes. However, it is a way to allow the patient to express his will and develop a relationship in treatment based on trust and cooperation between the physician and the patient[15]. This makes the physician-patient relationship not paternalistic, but it is a relationship in which the physician assumes responsibility for the patient's fragility, explains the treatments that he will undergo in case of an outbreak of disease, and must ensure that the patient understands everything. The patient, aware that the condition makes them fragile, trusts the physician so that they both become active parties in the therapeutic path[16,17].

This was confirmed by research edited by Gergel et al. that included 565 people (154 men, 400 women, 11 transgender or other), mainly white and British: 82% approved self-binding directives. Among these, 89% explained their choice, stating that relapse of the disease causes distorted decision-making processes[11]. Only 12% of the participants refused the self-binding directives. This refusal was motivated by logistic concerns, the value of their thinking process in the event of illness, and a potential violation of human rights. Only 7% gave answers, which indicated ambivalence due to logistic preoccupations with the writing and fulfilment of self-bonding directives.

Therefore, a significant positive aspect of PADs is that they improve the patient's autonomy and active participation in the treatment. They also promote empowerment, defined as the continuous ability of groups or individuals to act by themselves to obtain greater control over their lives[18].

Furthermore, in evidence-based terms, PAD would lead to minor hospitalisation and minor use of involuntary psychotherapy compared to those patients who have not written PAD[19], other than a minor tendency to violent behavior[20].

The reduction in coercive measures is significant. If the patient knows that they have accepted such interventions by arranging them with the physicians, they accept them more willingly, which would be much more difficult if they were forced[21].

However, the criticalities are also meaningful. First, it is necessary to avoid using the authorisation given to buying the PAD too broadly. The fact that the latter allows for treatment, notwithstanding the present denial, does not mean that the treatment is always legitimate: the same treatment allowed by the PAD must be fully evaluated and justified before it is carried out. Furthermore, it is essential to consider whether the intervention strengthens the person's self-realisation and is proportional to the negative aspects of the treatment. It is essential to keep in mind that mental illness does not necessarily imply incompetence[22]. The Italian National Committee for Bioethics stated that in treating psychotic patients, there are still issues of responsibility and self-determination that should even be valued in terms of competence[23].

The main criticality of PAD is determining whether a patient can make a given decision. Consequently, only a patient who underwent total remission of the disease can sign a PAD. Proving that a patient with mental disorders request is truly a free and conscious choice is particularly complicated because the presence of a mental disorder does not automatically imply a loss of capacity, even if there is a strong possibility that this can influence the patient's decision-making process. For psychiatric patients, Buchanan developed the concept of competence, which includes a series of capabilities (informability, cognitive ability, and decision-making)[24]. There is no unanimity of thought about the conditions necessary to consider a patient competent. According to the General Medical Council, a person has the ability if he can understand the relevant information for decision-making, he can retain this information and use it to decide and even communicate the decision (§ 83)[25]. A more restrictive approach belongs to those who state that decision-making understands the elements of the decision, chooses, argues about its consequences, and appreciates its implications. That is, the subject must be able to apply the information to his situation, evaluate the options available, and assess the consequences for himself and others, motivating the choices logically and clearly without being influenced, that is, based on their values[26]. The intention of the notion of competence is fundamental because it affects the possibility of applying PADs in cases in which they would be extremely useful, that is, those cases in which, when treatment is deemed necessary, the incompetent patient expresses a will that is incompatible with PADs.

The actual verification of competence is carried out at different stages of the disease and allows the protection of self-determination and personality development of seriously impaired patients in the looser framework of protection of the dignity and identity of the subject without using the incapability category. Focusing on the real decision-making capacities of the patient allows us to overcome the capacity/incapacity dichotomy and describe the patient's condition more adequately.

Therefore, being capable patients means understanding the health problem the physician presents, processing the information received, evaluating the advantages and disadvantages, and making a rational decision on the therapeutic recommendation[27]. Therefore, ensuring that the request made by a patient with mental disorders is a free and conscious choice is a challenging task for a psychiatrist because the presence of a mental disorder does not automatically imply loss of capacity, even if there is a high risk that this may influence the patient's decision-making process. To address this problem, various assessment scales have been suggested for the level of patient decision-making competence, such as the MacArthur Competence Assessment Tool for Treatment, which allows the physician to assess if the patient is "capable". The development of patient responses allows the physician to assess the patient's condition, overcoming the idea of being capable/incapable[28,29].

General discipline of advance directives in laws and deontological codes in Italy and in the United Kingdom. Their insufficiency to protect the psychiatric patient

The advance directive consists of the patient's decision to continue or interrupt a specific future treatment in the circumstances indicated by them if, when the time comes to carry out it, they lack the capacity to express their will (sect. 24[1])[25].

The advance directive cannot influence the physician's choice if an underage person or an incompetent adult writes it. (sect. 24[1])[25].

In contrast, the directive is valid even if the settlor is not prepared to specify the treatment and the circumstances to which their decision refers (sect. 24[2])[25].

As for the outcomes of the advance directive, when this is valid and applicable, it is effective just as if it was the manifestation of a present will (sect. 26[1])[25] and excludes the physician's responsibility for the damage derived from the patient as a result of compliance with his directive (sect. 25[1])[25].

The advance directive is not valid in three cases that exclude one another. The first concerns the patient who has withdrawn his decision when he was still capable. The second occurs when the patient, after choosing the advance directive, gives a trustee a proxy with the power to give or deny consent to the treatment referred to in the advance directive. The third case occurs when the patient makes decisions completely incompatible with the advance directive.

The advance decision is not applicable if the patient is capable when treatment becomes necessary (sect. 25[3])[25].

Even when the patient is incompetent at the time of treatment, an advance directive cannot be applied in case a) the treatment is not the one specified in the advance directive; b) the circumstances of the actual case do not correspond to the ones specified in the advance directive; c) there are serious reasons to believe that there are circumstances not foreseen by the patient at the time of the advance decision, and which would have influenced their decision had they foreseen them (sect. 25[4])[25].

Advance directives can be revoked or modified at any time, provided that the settlor is capable (sect. 24[3])[25]. The termination does not need to be in written form (sect. 24[4])[25].

Law no. 219/2017 foresees two paths through which the patient can formalise his choices in both health and end-of-life, i.e., advance directives on treatment and planning of treatment. Advance treatment directives (DATs) are the tool through which a person of age, able to understand and act, foreseeing his possible incapacity to self-determination, and after acquiring adequate medical information on the consequences of his choices, can express «his will on treatments, as well as consent or refusal on diagnostic check-ups or therapeutic choices and on single treatments»[30]. Through DAT, the patient can appoint a trustee of age and be able to understand and act on his behalf with the physician and with medical structures (article 4).

Therefore, even if not directly directed to psychic patients, DATs can allow the patient with relapse to specifically decide what therapies or treatments they intend to undergo, especially in the acute phase of the disease (i.e., neuroleptic, anti-psychotics, long-acting or depot drugs, place of possible hospitalisation, drug or physical enclosure, etc.). In such cases, advance directives should contain a detailed description of the disease and report symptoms during the acute and preceding phases. In this case, DATs would be considered an authentic moment of awareness and insight into the disease. For directives to enhance the patient's self-determination and decision-making capacity, the latter must have the possibility of imagining a possible crisis and its solution. Furthermore, PADs could speak to the patient, who becomes the protagonist of their therapeutic path, thus overcoming the paternalistic idea that the patient is dependent on the physician's decision.

Article 5 of law decree no. 219/17 is dedicated to shared panning of treatment. It envisages the possibility of defining the plan of therapy shared between the patient and the physician on the outcome of a chronic and invalidating disease characterised by relentless disease with an unfavourable prognosis. The physician must comply with the planning agreed with the patient in case the latter cannot give their consent or is in a state of incapacity. Therefore, this instrument works as an alternative to DAT[31], as, in this case, the disease must already be present. On the other hand, the object of DATs exists regardless of the presence of the disease and allows the interested party to express his will in the future in the case of the disease. Therefore, shared treatment planning requires immediate consent to specific treatments and information on possible developments in the disease and possible additional treatments. Even if these provisions are complete and further analysed, the Mental Health Act and Italian law cannot face the safeguard issues posed by mental illness.

None of these two instruments provided for by Italian law corresponds to a PAD. Shared treatment planning is for a patient who already has the disease at the time of planning. However, in case this is a psychiatric disease, the applicability of shared planning can be heavily conditioned by the seriousness of the disease: in case of a low level of competence of the patient, there is no possibility of starting an actual shared path. Surely, suggesting PAD to a diseased patient could be helpful to make them feel involved and experience treatment in a less traumatic way. However, this is not the right path to protect patient self-determination. Even advance directives, as provided by Italian law, do not correspond to a PAD. The latter implies the implementation of treatment based on anticipated consent, despite the present refusal. Therefore, it needs specific information on the disease and its treatment in accordance with all the requirements of valid consent. Italian law does not thoroughly highlight this aspect, which generically requires information without specification on its origin and contents. Therefore, there is no guarantee that the choice expressed in an advance directive result from an actual relationship between the subject and a specialist of the treatment specified in the provision.

The results of the Mental Health Act are even less pertinent, as it conceives advance directives as an instrument to refuse treatment in advance. On the contrary, the usefulness of PADs lies mainly in anticipated acceptance (i.e., there is no need to wait for the appointment of a proxy by a judge) of a treatment that cannot be accepted and cannot be carried out compulsorily due to a lack of provisions.

Furthermore, for all countries in which, as in Italy with article 32 of the Italian Constitution, it is necessary to have a law to restrict a patient to undergo treatment, the lack of a law on PADs is, per se, a fact that prevents the use of PADs to overcome the present refusal of an incompetent patient. Their results show that PADs can only be used as instruments to increase the possibility that the patient, after the physician has reminded them of PADs, decides to confirm the same will. Deontological codes try to provide for the lack of applicable provisions, even if only partially, because they do not deal with PADs directly. The Italian code states that: a) the physician takes into account written, undersigned, and dated declarations regarding advance treatment statement, signed by a competent person and following medical intelligence that can be documented; as a consequence, it is necessary to document the information to verify its correctness; b) advance treatment statement proves freedom and awareness of choice on diagnostic procedure and/or therapeutic intervention that the patient wishes or does not wish to carry out in case of severe or total compromise of cognitive and evaluative faculties which impedes expressing present will; therefore, if the choice must be a conscious one, the information must be detailed and specialistic like in the cases of present consent on the one hand and, on the other, with advance directive it is not only possible to refuse, but also to ask for treatment, and total loss of cognitive faculties is not necessary to do so; c) in considering the advance treatment statement, the physician verifies their logical and clinical consistency with the present condition and acts accordingly, in respect of the dignity and quality of life of the patient, clearly expressing it in the documentation; the physician cannot therefore breach the advanced statement.

The United Kingdom's deontological code considers a situation even more similar to that of the PADs. These are cases in which it is predictable that, at the time of future treatment, the patient will find it more challenging to make a decision, that is, because he is afraid, confused, or experiences situations that restrict his capacity or pressure (§ 32).

The physician should anticipate such circumstances and discuss them with the patients in advance, if possible, so that when the time comes to decide, the patients have already had the opportunity to consider the relevant information (§ 33).

Discussing the options in advance does not eliminate the need for another meeting immediately before treatment or at regular intervals as treatment and therapy progress. Although there is an ongoing assistance plan, or if the patient has chosen in advance, the physician must explain the possible options in case these are changed, or the patient has changed mind (§ 34).

Furthermore, according to the General Medical Council (2020), the physician must encourage patients to express their will in advance if they suffer from progressive, affecting diseases (§ 35).[25]

The information provided by both deontological codes is applicable even in the case of PAD. However, the psychiatric disease frequently poses a problem that is less frequent in previous directives related to other pathologies. On average, advance directives are applicable in situations that hinder patient awareness. On the contrary, the emergence of mental illness does not hinder the patient from expressing his will, even if it sometimes biases his competence. Consequently, a question is posed to the physician (that deontological codes do not seem to tackle) on the best practise in case of divergence between PAD and the present will.

According to the United Nations Committee on the Rights of Persons with Disabilities, competency assessment and substitute decision-making are discriminatory practises against people with mental disabilities[32]. The will of a person must always be respected, even if that person is incompetent, that is, when a psychic disorder alters his will.

Consequently, the present will always prevail over the will formalised in the PAD. This is legally effective only in two cases: a) the patient is incapable of expressing any will, that is, advanced dementia; b) the patient is in a deep confusional state, and his will cannot be understood univocally, like in the case of moderate dementia. In the acute phase of mental illness, the patient is materially incapable of expressing his choices without ambiguity. According to the Committee, this choice results in the annulment of the previous PAD, even if this was expressed when the patient was competent.

The thesis sustained by the Committee implies that PAD is inapplicable just in those cases in which it would prove more useful, i.e. those cases in which the patients express a non-free will but are biased by disease, that leads them to make a choice non-compatible with the choice made when they were fully competent. These patients no longer have the option to control the disease.

Furthermore, the Convention on the Rights of Persons with Disabilities does not seem to justify the conclusion reached by the Committee. First, the Convention deals with the protection of people with mental disabilities. However, it does not consider whether the disease should be respected to the extent that it should not be treated or administered as a less effective therapy.

The Convention only states that people with disabilities have the same legal capacity as others in all aspects of life and that if the legal capacity is to be limited, the respect of rights and choices of the person must nevertheless be guaranteed (Article 12). The point, though, is actually what will be to be respected: Is it the previous, but free and conscious, or is it the present will be biased by the disease?

Second, giving prevalence to the will expressed in PADs does not imply discrimination. As article 2 of the same Convention states, in fact, discrimination based on disability is defined as any distinction, exclusion, or restriction based on disability that has the aim or effect of compromising or undoing recognition, entitlement, and exercise based on the principle of equality, all human rights and fundamental liberties, be they political, economic, social, cultural, civil, or other. However, in the cases examined, limiting the present will to give prevalence to PAD has neither the aim nor the effect of harming patient rights. In contrast, it aims to protect free and conscious will. Another position sustains the so-called combined supported decision-making: In case of divergence between PAD and the present will of an incompetent patient, physicians must support the patient if there are reasons to believe that decision-making incompetence can be overcome, that is, by interrupting the examination to give the patient some time to distract, rest, or talk to a trusted person.

If the support tools allow the patient to regain competency, they will express a valid present will to confirm or revoke PAD.

If the patient remains incompetent, despite support, substitute decision-making is necessary. It must be carried out not according to the best interest standard but according to the substituted judgment standard. The first balances the concern for the patient's health with the concern for his freedom based on concrete cases. The second guarantees that a trustee expresses the same will as the patient had they been competent. Hence, PAD can become effective with a substituted judgment standard.

Naturally, caution must prevail. First, the present will not be ignored and put aside. The patient who cannot give valid consent must participate in substitute decision-making within the limits of his capacity. Their presence should be carefully considered, provided that this does not have the same value as the current will be expressed by a competent patient[33].

Second, it must be considered whether the clinical and factual situation foreseen in the PAD corresponds to the actual one. However, even if this is lacking, the trustee, who must know the patient thoroughly, is the best to state what their will would have been had he been competent. Therefore, the freedom of self-determination is more safeguarded with respect to the best interest standard.

For both physicians and the appointed trustee, it should be understood that the tools adopted must: a) not be too restrictive to allow PAD; b) ensure that the benefits expected to exceed the risks and the responsibilities for the patient. Resorting to physical violence must be the last resort, to be used only in case less restrictive therapies prove useless, and a condition presents as in letter b) mentioned above. Even the European Convention on Human Rights (1950) allows detention, as in Article 5, but uses the word "alienated" to indicate a passive subject, thus hinting that these severe cases justify the limitation of liberty. Furthermore, it ratifies both the right to file an appeal to the court to make a decision in the short term and the right to liberation and economic compensation if detention occurs in breach of Article 5[34].

In Italy, the use of substitute decision-making to apply a PAD against the present will of the incompetent patient clashes with decree no. 833/78, still in force. This states that the compulsory medical treatment of a psychiatric patient requires, other than the provisions of law, compliance with a procedure that includes a favourable opinion of two physicians and the validation of a judge. Nevertheless, during practise, treatment is often carried out even without following this procedure, but rather with the presence of a proxy decision maker called a support administrator: if the judge appoints them to give consent to medical treatments, physicians can treat the patient regardless of their present refusal (law no. 4/2004). Thus, the implementation of law decree no. 4/2004 seems to allow physicians to consider PAD, but it reduces the guarantee for psychiatric patients regarding the law of 1978. This is even more serious, as such guarantees correspond to those imposed by the Convention on the Rights of Persons with Disabilities (2014).

The latter states that measures that limit legal capacity must: a) respect the will and choices of the person; b) be free from possible conflicts of interest and undue influences; c) be proportionate and appropriate to the patient's condition; d) be applied for the shortest possible time; e) be subject to periodic review by a competent, independent, and impartial authority of a judiciary board (art. 12, co. 4). This affirms the need for a specific legal intervention to provide physicians with clear factual indications.

Conclusions

The PAD represents an effective instrument to involve the patient in the therapeutic process and to encourage his adherence to therapy even when their competence fails due to relapse.

The general discipline of advance directives offers a useful basis for indicating how to behave even with PADs. However, the psychiatric disease requires the regulation of some specific issues that cannot be included in general provisions. Among other questions, we need to consider the following. Can a general practitioner or clinical psychologist evaluate competence? Is it strictly necessary for a psychiatrist to do this? How long can therapy with a self-binding directive last? Does the prosecutor need to be informed about the drawing of a self-binding directive? Is an authorisation by the judge necessary to administer therapy allowed by a self-binding directive refused? Should such treatment only be administered to prevent the risk of self- or hetero-detrimental conduct, or should it be assisted all the same? What are the correct mechanisms to use after dismissal to monitor compliance with patient rights? But in general, is it necessary to be competent to annul a self-binding directive, or does the refusal of the incompetent patient invalidate the PAD?

In this sense, the guidelines suggested by the United Nations Committee significantly reduce the usefulness of PADs. It seems preferable to adopt support tools that help the patient recover their competence. It would be appropriate to have the support of a team of specialists and the patient's family so that, through constructive dialogue, they can make the best decision for the patient. Dialogue with the family and reference to PAD would avoid regression to medical paternalism.

If the patient does not recover his competence, it is necessary to resort to a substitute decision-maker who expresses what the patient's will would be, where possible. It is understood that, in case of refusal, treatment can be forced after having complied with the specific guarantees provided by the law and the European Convention for Persons with Disabilities.

Conflict of interests: the authors have no conflict of interests to declare.

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