

Lettere al direttore

Italian Law no. 219/2017: consequences on the informed consent of the psychiatric patient and on the therapeutic privilege

Legge Italiana n. 219/2017: conseguenze sul consenso informato del malato psichiatrico e sul privilegio terapeutico

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In recent years all the factors that characterize the doctor-patient relationship have changed considerably. In fact, there has been an evolution in the bioethics and legal rules regulating medical activity and in the awareness of patients undergoing medical procedures. In particular, informed consent has assumed an increasingly central role, identified as a central and indispensable phase of medical activity. In fact, what distinguishes legitimate and illegitimate medical activity is the informed consent of the patient. Central and founding the legal basis of informed consent is the right to self-determination: no one can be obliged to a treatment against his will except by law provision (as also recited by art. 32 of the Italian Constitution). Therefore, any medical act, in the absence of the patient's consent, is unlawful.

In Italy, recently, Law 219 of 2017 (Rules on informed consent and advance healthcare directives) has been promulgated¹ and, this act, makes the role of informed consent in the doctor-patient relationship even more central. In fact, Article 1 of this law is entirely dedicated to informed consent and states that «no medical treatment may be initiated or continued unless there is free and informed consent of the person concerned, except in cases expressly provided for by law. In addition, paragraph 3 states that each person has the right to know his or her own health conditions and to be fully informed, updated and understandable about the diagnosis, prognosis, benefits and the risks of the diagnosis and health treatment indicated, as well as the possible alternatives and consequences of any refusal of, or diagnosis or renunciation of, health treatment».

After the promulgation of this law it has therefore become explicitly required by law the acquisition of an informed consent by the doctor. More than in the other medical branches, in the psychiatric field this law has important consequences in terms of the rights of the psychiatric patient and the responsibility of the psychiatrist.

The informed consent of the psychiatric patient has always been a discussed topic in the medico-legal and bioethical context. The fundamental problem of this issue is linked to the inability, presumed or actual, of the psychiatric patient to give a valid consent to medical treatments. For the validity of informed consent, the following elements are required:

ability to understand information; ability to process the information received; ability to assess all possible consequences of the choice made and the ability to communicate the decision. First, it will have to be defined when a psychiatric patient – who is not legally incompetent – can be defined as “unable to give a valid consent”. One element that has often been used to question the capability to provide informed and conscious consent is the type of diagnosis: acute psychosis², chronic psychosis³, severe depression⁴. It is understandable that there is a doubt as to the validity of a consent granted/denied by a person with delusional ideation or with depressive symptoms so serious as to compromise even the decision-making capacity⁵. Obviously, one cannot rely solely on the type of psychiatric diagnosis to understand the ability to determine oneself and to make free and conscious choices. In fact, even in the psychotic patient, there are disease-free intervals in which the subject is perfectly able to understand the information provided by the doctor and, therefore, consent to the carrying out of a certain therapeutic intervention^{6,7}. Thus, to establish the validity of a consent, it is necessary to evaluate the current conditions in relation to the disease, the developmental stage of the disease, the presence or absence of response to therapeutic strategies, the presence of critical and judgmental skills⁸. The ability of the psychiatrist to understand whether his patient has, at that moment (not in his/her medical history) the ability to fully understand the information about a given treatment is crucial. If the physician sees an inability to give consent from a psychiatric patient – not legally incapacitated/incompetent and not in emergency situations – what should he do? There are two options: to refrain from treatment or to perform an Involuntary Health Treatment (IHT). In both cases there could be important legal issues in the area of professional liability⁹⁻¹⁴. In these cases the role of the psychiatrist is very delicate because, to date, there is no objective and standardized method to safely delineate the ability to provide a valid consent of the mentally ill, therefore the assessment is completely entrusted to the individual physician who must assume responsibility for his decision with potential medico-legal consequences in case of litigation. Furthermore, in the case of the psychiatric patient, more frequently than in other

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patients, the so-called “therapeutic dependence” is frequently observed. So the mentally ill often relies on the decisions of the treating psychiatrist to identify the best therapeutic path. This certainly increases the freedom of decision-making of the psychiatrist but also increases the liability of the doctor in the context of the authorization to carry out certain treatments, with important bioethical and medico-legal implications, especially in chronic treatment. A tool that can be used in the psychiatric field is “Therapeutic privilege”, which is characterized by the physician’s choice to limit the information he provides to his patient, where full information on the mode and purpose of treatment is likely to cause damage to the patient. On the basis of Therapeutic privilege – with the risk of providing little or too much and futile information – the psychiatrist will have to use with great diligence and ability the instrument of the clinical interview using judgment and assessment of the appropriateness to provide the information omitting futile elements that could damage the patient. Obviously, this instrument is particularly debated in the bioethics and medico-legal field^{15,16}. The American Medical Association (AMA), although endorsing the use of Therapeutic privilege in cases of emergency and imminent risk to the safety of the incapable patient, stated that in cases where there is no emergency it is ethically unacceptable to withhold information without the explicit consent of the patient¹⁷. Even on the basis of Law 219/2017 it would seem that there is no margin for the use of the instrument of therapeutic privilege since Italian law has clearly made the acquisition of a complete informed consent in all medical acts (including psychiatric acts) indispensable. Consequently, the psychiatrist will have on the one hand the responsibility of having to decide whether a psychiatric patient is able or not to authorize a medical treatment (and in order to achieve this goal will not have standardized tools available) and on the other hand will have to try to obtain the informed consent of his patient informing him completely (if he does not want to use the instrument of the IHT), being always imposed by Italian law. Therefore, the Italian psychiatrist, in theory and by law, must always provide all the information on a certain treatment that, as already said, often prevent to reach the goal of protecting the health of the patient. In addition, in the event of a medico-legal dispute where there is an unlawful finding related to informed consent, the psychiatrist will have to prove why at that precise moment in the acquisition of consent he considered that his patient was able/unable to make an independent decision. This situation, apart from emergencies and needs, is particularly difficult because often the competence of a mentally ill person is blurred and fluctuating.

Also, and especially, following the entry into force of Law 219/2017, the conduct that the psychiatrist should have, within the framework of informed consent, is not yet clear. The psychiatrist, in the absence of objective tools, must define at best whether and when a mentally ill person - not legally incapable/incapacitated - is able to give a valid consent and

such a process is particularly complex. In view of the new Italian regulatory context, the medico-legal consequences of wrong choices by the physicians are certainly serious, especially if they violate the patient’s right to authorize all treatments deemed necessary.

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REFERENCES

1. Law 22 December 2017, n. 219. Rules on informed consent and advance healthcare directives. (18G00006) (GU Serie Generale n.12 del 16-01-2018). Available from: <https://www.gazzettaufficiale.it/eli/id/2018/1/16/18G00006/sg>
2. Irwin M, Lovitz A, Marder SR, et al. Psychotic patients’ understanding of informed consent. *Am J Psychiatry* 1985; 142: 1351-4.
3. Jones GH. Informed consent in chronic schizophrenia? *Br J Psychiatry* 1995; 167: 565-8.
4. Elliot C. Caring about risks. Are severely depressed patients competent to consent to research? *Arch Gen Psychiatry* 1997; 54: 113-6.
5. Bersani G, Pacitti F, Iannitelli A. “Delusional” consent in somatic treatment: the emblematic case of electroconvulsive therapy. *J Med Ethics* 2020, in press.
6. Ceccanti M, Iannitelli A, Fiore M. Italian Guidelines for the treatment of alcohol. *Riv Psichiatr* 2018; 53: 105-6.
7. Bersani G, Iannitelli A. La legalizzazione della cannabis: tra irresponsabilità politica e deresponsabilizzazione degli psichiatri. *Riv Psichiatr*, 2015, 50, 5, 195-8.
8. Zaami S, Rinaldi R, Bersani G, Marinelli E. Restraints and seclusion in psychiatry: striking a balance between protection and coercion. Critical overview of international regulations and rulings. *Riv Psichiatr* 2020; 55: 16-23.
9. Montanari Vergallo G, Zaami S, Di Luca NM, Bersani G, Rinaldi R. Italian law n. 24/2017 on physicians’ criminal liability: a reform that does not solve the problems of the psychiatric practice. *Riv Psichiatr* 2017; 52: 213-9.
10. Montanari Vergallo G, Rinaldi R, Bersani G, Marinelli E. Medico-legal notes for a new set of standards in the assessment of penal liability in psychiatry. *Riv Psichiatr* 2017; 52: 16-23.
11. Rinaldi R. Health in the 21st Century: new rights come to the fore? *Clin Ter* 2018; 169: e149-50.
12. Biondi M, Picardi A. I nuovi “casi difficili” in psichiatria. *Riv Psichiatr* 2018 53: 223-32.
13. Cioffi A, Tomassini L. Letter to the editor in response to “Is it time for international guidelines on physical restraint in psychiatric patients?”. *Clin Ter* 2019; 170: e108-9.
14. Montanari Vergallo G, Zaami S. Guidelines and best practices: remarks on the Gelli-Bianco law. *Clin Ter* 2018; 169: e82-5.
15. Edwin A. Don’t lie but don’t tell the whole truth: the therapeutic privilege - is it ever justified? *Ghana Med J* 2008; 42: 156-61.
16. Johnston C, Holt G. The legal and ethical implications of therapeutic privilege - is it ever justified to withhold treatment information from a competent patient? *Clinical Ethics* 2006; 1: 146-51.
17. Wynia M. Invoking therapeutic privilege. *Virtual Mentor* 2004; 6: 90-2.