Commentary

Clin Ter 2021; 172 (5):414-419. doi: 10.7417/CT.2021.2349

Italian law no. 1/2021 on the subject of vaccination against Covid-19 in people with mental disabilities within the nursing homes

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Abstract

The Coronavirus Disease-19 (Covid-19) pandemic, in the last year, has resulted in a significant number of infections and deaths among nursing homes' residents. This phenomenon has set up the necessity to subject these patients, often suffering from mental disabilities to a vaccination against Covid-19.

However, vaccination has long been the subject of public attention, being regulated differently in many European countries. In Italy, the Ministry of Health has given priority, vaccination-wise, to health facilities' patients. The government has regulated through-law no. 1 of January 5, 2021, art. 5, the manifestation of consent to be Covid-19 vaccinated in incapacitated subjects admitted to assisted health facilities. This rule arose from the need to protect fragile individuals as well as providing real dispositions for the involved health professionals.

Nursing homes' elderly guests could be divided into four categories: a) subjects capable to express their will (affected by physical problems); b) subjects who, due to varying degrees of incapacitation, have their own legal guardian, curator or support administrator, appointed in accordance with the law; c) incapacitated subjects without legal representatives d) subjects who, pursuant to law no. 219/2017, have appointed their own trustee.

This paper provides for a clear exemplification of all the possible scenarios identified by the Italian law no.1/2021. ***Clin Ter 2021; 172 (5):e414-419. doi: 10.7417/CT.2021.2349***

Key words: *Covid-19, vaccination, law no. 1/2021, informed consent, mental disabilities, incapacitated subjects, nursing homes*

Background

The international scientific community has always guaranteed the right of protection to people who cannot give consent to medical procedures, and therefore of mentally incapacitated patients. The Oviedo Convention, signed by the European Council in 1997, establishes that, if an adult is not capable to give consent due to disability, it should be provided by the subject's legal representative (art.5). Art. 7 states the prohibition to administer any treatment to a person suffering from mental disorder in the absence of explicit consent, unless its omission would result in a serious threat to subject's health (1).

Definition of incapacity and Italian legislation

The legal capacity refers to a person's ability to understand the characteristics of a certain issue, and to make a thoughtful decision on the topic. As a consequence, the individual must have the cognitive and psychic capacities to correctly understand the surrounding reality, to organize distortion-free thoughts, to understand the meaning of his or her actions and, finally, to self-determine. Any physical or psychic impediment, momentary or permanent, which diminishes such abilities, renders the subject incapable.

The delicacy of determining the capacity degree of a person made it necessary to establish standardized methods, mostly used in hospitalized psychiatric patients, among which the MacArthur Competence Assessment Tool for Treatment (MacCAT-T), the Mini-Mental State Evaluation (MMSE) and the Wisconsin Card Sorting Test (WCST). The analysis of these tests applied to different classes of individuals opened the debate on which specific neuropsychological domains are involved in the process of giving consent, emphasizing alternatively the importance of executive functioning (2), as well as the reasoning one (3). However, the remark that different analysis methods lead to different observations suggests that mental capacity to make treatment decisions cannot be presumed, and the unpredictable overlap with capacity as measured by validated capacity assessments, points out that a revision of the latter ones is needed (4). Legally valid and officially appointed support figures become therefore indispensable, in cases where individual ability to self-determine is compromised.

In Italy, Law no. 219/2017 confirms the need to assist incapacitated individuals trough different legal figures: guardians in case of interdiction, and curators and support administrators for incapacitated subjects.

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ISSN 1972-6007

The right of the incapacitated person to informed consent in the European context

In the context of medical assistance, the ability to undertake a diagnostic-therapeutic act is subordinated to the patient's consent on any procedural process.

Informed consent's mandatory nature, in Italy, is emanated from Articles 33 and 34 of the Constitution of the Italian Republic.

In France, on the other hand, Articles 1111-2 and 1111-4 of the Code de la Santé Publique (French Public Health Code) sanction the obligation for doctors to give adequate information to the subject about his or her health conditions, and consequently, they enshrine the subject's right to freely express his or her will.

Anglo-Saxon countries have similar dispositions: the United Kingdom provides for the absence of a statute on informed consent, relying on the principle of the "Common Law".

In Germany, it is the Bürgerliches Gesetzbuch (BGB, German Book of the Civil Code) to sanction the obligation to provide adequate information, and to proceed to medical acts after obtaining valid consent. In the Netherlands, the consent to medical treatment is regulated by Law of 17 November 1994; similar indications about the medical-patient agreement are provided in the seventh book of the Burgerlijk Wetboek (BW, Dutch Book of the Civil Code) referenced to as one of the "special areas".

Consent, for its own nature, may be considered valid whenever the patient's capacity to act is confirmed. Any physical or mental defect, in fact, affecting the individual's ability to discern what is mostly right for himself, would imply lack of validity of the given consent.

This topic has aroused a strong international debate, culminating in the promulgation of the aforementioned Oviedo Convention in force within the member states of the European Union. The latter Convention came into effect in Italy by promulgating law n. 219/2017, which delegates an incapacitated person's choices to their respective legal representatives or, when appointed in an advance decision of treatment, in the person of trust. However, since the concept of individual best interest has been established as an absolute priority, a disagreement on the matter raised by doctors may result in the decision being referred to the Judge.

The French Code de la Santé Publique, however, allows an incapacitated patient to give his or her own consent when his or her legal capacity is not entirely compromised, relying on the assistance of legal representatives whenever necessary. On the other hand, the regulatory orientation towards those who are incapable of self-determination is quite similar.

The German jurisprudence, like the Italian one, protects incapable patients as well. In fact, art. 1901a of the BGB refers to the patient's right to subscribe a document of advance decisions of treatment.

Furthermore, according to art. 1901b, patients who didn't pronounce any directives should be assisted by a legal representative. In selected cases of particular complexity (Art. 1904), incapable patients should be addressed to the judgment of the specifically designated Supervisory Court.

Drafting advance treatment provisions is made even more relevant according to the legislative system of the Netherlands, pursuant to art. 450, paragraph 3 of BW, Book 7. This article provides that patients, foreseeing the possibility of losing their ability to self-determination, can subscribe a written advance treatment provision. Moreover, patients are allowed to designate a representative (art. 465 of the same book) who can act when a legal institution of protection is not yet operating. The doctor, therefore, acts in accordance with both the Advance Provision of Treatment and the legal representative, being able to disregard only those indications that fail to comply with the patient's best interest.

In particular, Switzerland has adopted a specific approach to medical decision-making: in view of the absolute non-essentiality of vaccination according to the vaccination recommendations of the Federal Office of Public Health (FOPH) and Federal Commission for Vaccination Issues (EKIF) (5), the provisions of Article 392, n. 1 Zweckverband Grossraum Braunschweig (ZGB, Administrative association for the Braunschweig area) remain in force. According to the latter, doctors cannot take any decision about the patient vaccination. In case of the absence of a legal representative and whenever the patient's best interest is concerned, the decision about patient's treatment should be taken by the KESB (Kindes- und Erwachsenenschutzbehörde, Swiss Authorities of Protection of Children and Adults).

Finally, the English context deserves a further dissertation, given the specific provisions issued by the Mental Capacity Act of 2005. This act, which indicates an incapacitated subject as someone who, through impairment or disturbance of the psychic sphere, is prevented from taking proper autonomous decisions, prioritizes the principle of protecting the best interests of each individual. This objective is pursued by the primary attempt of doctors to consider the patient's current will, by appropriate, timely and constant constraint on the therapeutic options. The supporting figures, which are specifically designated by the subject in the lasting power of attorney (LPA), are also required to protect the interests of the individual, in agreement with the doctor's indications. If required by the situation, or in case of disagreement between doctor's judgment and the representative's, one or both sides could refer the decision to the Judge.

Scientific and ethical implications by vaccination in the elderly

The main objective of modern vaccination campaigns is to achieve "herd immunity", which refers to population-level effect of individual immunity to prevent transmission of pathogens (6).

Based on the formula proposed by Fine et al. (7) for the calculation of the percentage threshold to reach herd immunity and taking into account the R0 value of Covid-19 estimated by Zhang et al. (8) being 2.27, it is estimated that 56% of the population should be immunized for the virus (9).

The limited availability of doses, contextualized in a period of epidemic characterized by high mortality, made it necessary to establish who to give priority in vaccina-

tion: from current scientific notions it is clear that the main risk factor for the development of a serious disease from a SARS-CoV-2 infection is advanced age, followed by chronic diseases, especially cardiac and respiratory ones (10). This is reflected in the epidemiology of the virus, which in Italy caused the death, by November 2020, of about 58,000 people, of which 99% over 50 and 60% over 80; this must obviously be interpreted on the basis of the fact that this class of individuals represented 26% of the total infected in the period February-May 2020 and 8% in the period June-November 2020 (11). These data, comparable to European context, meant that patients hospitalized in nursing homes were among the priority categories, as they are representative par excellence of the elderly class affected by multiple comorbidities. The scientific community has shown, based on data belonging mainly to the flu vaccination campaigns, that the immune response of elderly subjects is lower than that of younger subjects, being able to be around 17-53%, compared to 90% of the latter (12).

Therefore, not wanting to excessively overstep the topic, we intend to express the hope that this attempt to privilege the protection of the weakest categories will not be thwarted by the poor adherence to vaccination by categories less exposed to risks, as recently shown by the "No-Vax" trends, which are accused of having produced a new increase in the incidence of communicable diseases in developed countries (13).

Vaccination strategy and related consent in the European context

The international debate on incapable subjects' rights in the health context has recently been revived in the light of the vaccination campaigns against Covid-19 (14). European Member States decided to provide vaccination primarily for the most at-risk population, such as elderly institutionalized patients in long-term care facilities, which frequently are in the condition of legal incapacity or natural incapacity.

This kind of choice, which aims to protect the most vulnerable groups of the population, shows indeed a respectable effort to identify the preventive and/or therapeutic actions that best suit the needs of individual patients (15), in the perspective of a 21st century personalized medicine, according to the 4P principle (Personalized, Predictive, Preventive, Participatory) (16).

As part of the vaccination campaign against SARS-Cov2 virus, therefore, France adopted the principle of non-compulsoriness, and ruled for vaccination consultation for the elderly within residential facilities, to be carried out within 5 days of administration, in order to ensure adequate information to those patients able to express an informed consent autonomously, even when interdicted (17).

In Germany, the explanatory contribution made by the Covid-19 vaccination procedural model recently issued by the Supervisory Court in Essen (18), shows an opening towards disqualified people who retain their capacity to self-determine: they should be entitled to adequate clinical and therapeutic information in order to be able to express their personal and independent consent to the procedure.

The English model, instead, established by a recent judgment on Covid-19 vaccination (19), defines the pivotal role of individual assessment whenever a legal opinion and medical conditions are in conflict. Coronavirus vaccine was declared to be in the best interest of an 80-year-old woman with dementia and diabetes who lived in a nursing home, in contrast to her son's refusal on the matter. The woman did not have the ability to decide on her own but had previously received the flu vaccine and firmly declared to trust her doctors, who promoted Covid-19 vaccination. The decision of the Court depended on the high risk/benefit ratio expected from vaccination compared to the high intrinsic risk of serious disease.

Switzerland adopted a peculiar attitude on the matter of medical decision-making. Given the absolute non-essentiality of vaccination according to the FOPH and the EKIF (20) vaccination recommendations, the provisions of Article 392, n. 1 ZGB remain in force, i.e. doctors cannot administer a vaccine, despite the absence of representative figures and the best interest of the patient. In such cases, the decision is always referred to the Kindes und Erwachsenenschutzbehörde (KESB - Authority for the Protection of Children and Adults).

In Italy on the subject of compulsory vaccination, the Constitutional Court with the judgment n. 5 of 2018 had already ordered the *"[…] Discretion of the legislator when choosing the means by which to ensure effective prevention from infectious diseases, being able sometimes to […] calibrate measures and sanctions, in order to ensure effectiveness of the obligation. This discretion must be exercised in light of different health and epidemiological conditions established by competent authorities (judgment no. 268/2017), and the ever-evolving medical acquisitions, which must guide the legislator in his choices (constant jurisprudence of this Court since the fundamental judgment n. 282/2002) […]"*. Constitutional values involved in the issue of vaccination, in fact, are many, including the freedom to self-determination in health care, the protection of individual and collective health (protected by art. 32 Cost.), and the interests of fragile subjects.

In our country, therefore, the choice of vaccinal recommendation or obligation, are at the discretion of the legislator. The legislator, in fact, will have to strike a reasonable balance between the need to ensure effective prevention and not to affect self-determination right of individuals who do not wish to undergo health treatment.

Incapacitated subject informed consent according to Italian law no. 2019/2017

The consent to vaccination in people with mental disabilities within health facilities, is an extremely delicate question. In Italy, regulation of consent is guaranteed by law 219/2017.

According to Art. 3, the incapacitated subject has the right to exert his or her capability of understanding and decision-making. In regard to information, in line with the international trend, Law 219 establishes that the latter type of subject has the right to receive information on choices related to his health in a manner appropriate to his ability

to comprehend and self-determine. Consequently, the legislator has adopted the primary assumption of promoting an ideal relationship between the doctor and the patient, which should be founded on dialogue and respect of human rights (autonomy, freedom and liability) (21).

The same legislation states that informed consent of an incapacitated subject under Article 414 of the Civil Code is, therefore, expressed or refused by his guardian, protecting psychophysical health and wellbeing of the subject, in full respect of his dignity.

When a supportive administrator is appointed, providing for exclusive health representation, informed consent shall also be expressed or refused by the supportive administrator, taking into account the will of the beneficiary, in relation to his or her competence to stand trial.

However, the central core of the law is represented by Art. 4 which concerns advance decisions: it establishes the capability of patients to express their own wishes regarding health treatments, diagnostic tests or therapeutic choices, in anticipation of a possible future incapacity of self-determination (22).

Law no. 219/2017 also regulates the conflict of will between representative figures and doctors. In the event that the legal representative of the person or the supportive administrator, in the absence of advance decisions, refuses the proposed treatment, which is considered appropriate and necessary by the doctor, the final decision shall be left to the Court. In Italy the most critical issues on vaccination in healthcare facilities naturally invest incapable patients who, despite being incapacitated, do not have a legally appointed representative who can protect their health and their rights.

The grey area, therefore, consists of patients who are naturally incapable, without legal representation, and whose health protection, in the case of vaccination, must necessarily be combined with the profile of public health (23).

This legislative void would have induced the recourse, in individual cases, to the arbitrary judgment of the Courts, posing the risk of generating discrepancies regarding the access to treatment, as it happened in 2013 in the matter of compassionate therapy based on stem cells, to subjects at the end of life (24). The suspension of the treatment by the government, at the material time, led to different judgments by the local courts regarding the continuation of the latter, generating major difference in treatment between patients, explicitly violating the principle of justice and the equality of access to health care.

By these means, result the need and urgency to provide for incomplete legislation in the case of incapacitated patients, and the importance of protecting the health of fragile and particularly exposed subjects, in the current pandemic context, led to the enactment of the Law no. 1 of 05 January 2021.

Law No. 1 of 5 January 2021

The first paragraph of Article 1 of Law No. 1 of 05 January 2021 provides that incapacitated subjects admitted to healthcare facilities express consent to Covid-19 vaccination through their relative guardian, curator or supportive administrator, or through the trustee referred to in Article 4 of Law No. 219 of 22 December 2017. In particular, in case of interdicted patients, guardians must guide patient's decisions pursuant to art. Section 3, Law 219.

As stated by law no. 219/2017, art. 3, paragraph 4, the supportive administrator with exclusive representation, must decide involving the assisted person, in relation to his or her competence to stand trial.

Law no. 1/2021 and law no. 219/2017 are in contrast when addressing the topic of incapacitated subjects. In the first case, consent is expressed by the curator while, in the second case, by the subject himself or herself. The intention of law no.1/2021 could be interpreted as the will to entrust representatives with decision-making ability in order to speed up the decisional making process in the abovementioned cases of legally incapacitated patients.

Such an interpretation could be read as unconstitutional: *"[…] it would deprive the beneficiary who's perfectly competent to stand trial due to physical illness […] Therefore, when the supportive administrator does not have healthcare representation, only the beneficiary should decide on vaccination treatment, unless the beneficiary's psycho-physical condition has changed since the appointment of the supportive administrator […]"*.

Naturally incapacitated subjects

Art. 5, second paragraph regulates the most controversial situation, the case of hospitalized subjects, incompetent to stand trial without legal representation. The chief medical officer should, only for the purpose of vaccination, assume the role of Supportive Administrator. In particular, it is required to contact the spouse or partner of the subject and, eventually, the closest relative within the third degree. This to ensure that vaccination responds to the best option for the hospitalized person; therefore, to express in writing, in accordance with law no. 219/2017, consent to vaccination and any subsequent recalls.

In case of disagreement is provided the right to appeal to the judge pursuant to art. 3, paragraph 5 of law no. 219/2017. In no case consent to vaccination will be expressed in contrast with the will of the subject, previously expressed, or against the will of closest relatives.

Appointed supportive administrator, chief medical officer and relatives

Article 1 of Law 219 of 2017 provides that, in accordance with patient's will, his family members or partner or a trusted person may also be involved in the treatment process.

According to Law No. 1 of 05 January 2021, for guests of healthcare facilities, unable and without legal representation, similar rules apply. The chief medical officer, in fact, is required to consult in a precise hierarchical order: the spouse, the partner or the nearest relative within the third degree. In case of disagreement, the chief medical officer may appeal to the judge pursuant to art. 5, paragraph 4 of such law.

The supportive administrator with health representation, on the other hand, is not obliged to interface with relatives.

Law No. 1/2021, art. 5 provides for the judge's intervention in case of hospitalized subjects incompetent to stand trial and in the following cases:

- when the spouse or one or more of the next of kin has expressed dissent to vaccination. Recourse in this case is optional;
- when relatives are unavailable, in which case consent must be communicated immediately to the judge together with relevant documentation.

In the last case, the judge can either validate the chief medical officer's consent or reject it if it does not appear that the suitability of vaccination to protect and improve patient's health has been established (25).

- Paragraph 10 provides for a further hypothesis. In case of vaccine refusal, the spouse, or relatives can appeal to the judge.

Guidelines proposed by Court of Milan

The Court of Milan has exemplified standard situations that can be created in the case of vaccination for healthcare patients.

The simplest case is that of the patient capable to express consent. The choice on vaccination will be expressed personally by the patient, without having to activate any procedure.

The most complicated distinction is between naturally incapacitated and legally incapacitated patients.

Naturally incapable subject:

- The chief medical officer will take over the functions of Patient's Supportive Administrators but only for the purpose of vaccination. When the patient has a spouse or relative within the third degree, they should be contacted to agree on vaccination. In the case of unavailability of relatives or in the case of dissent, chief medical officer will be able to give consent asking for judge's validation.
- If the subject has drawn up the advance decision, it must be respected. If advance decision expressly contains refusal to vaccination and in the absence of the trustee, the health care provider cannot give consent to vaccination. Healthcare provider, in agreement with the trustee, may disregard advance decision if it appears to be manifestly inconsistent with, or does not correspond to, the patient's current clinical condition, or if there are treatments that were unforeseeable at the time of subscription. In the case of conflict with the trustee or in the absence of a trustee doctors may contact the Judge.

Legally incapacitated subjects:

- Legal representatives will express their wishes. But in case of supportive administrator without health representation there are two hypotheses: if the patient is still able to express consent, he will decide on the vaccine. Otherwise, the supportive administrator will have to ask the judge (according to art. 405, paragraph 4 C.C.) to authorize him to give consent to vaccination. The Court of Milan has specified that the absence of health representation of the supportive administrator cannot be validated from successive provisions of the judge. In case of unavailability of legal representatives within 48 hours, health care professionals will give consent to vaccination and afterwards request validation from the judge.

Conclusion

The greatest value of Law no. 1/2021, art. 5 is the regulation of consent to vaccination for subjects admitted to healthcare facilities, especially those incompetent to stand trial and without guardian, curator, supportive administrator and trustee.

On the other hand, it presents critical issues in the hypotheses of subject's beneficiaries of a guardian, curator, supportive administrator or trustee, in such cases it would have been preferable to refer to the discipline of Law 219/2017.

The new law of 05 January 2021 confirms two legal guidelines in our legal system: the lack of mandatory nature of vaccination, in compliance with art. 32 of the Constitution of the Italian Republic and the importance of the provisions of Law 219/2017 on the expression of consent.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. https://rm.coe.int/168007cf98. Accessed April 2021.
2. Mandarelli G, Parmigiani G, Tarsitani L, et al. The relationship between executive functions and capacity to consent to treatment in acute psychiatric hospitalization. J Empir Res Hum Res Ethics 2012; 7(5):63-70
3. Mandarelli G, Tarsitani L, Parmigiani G, et al. Mental capacity in patients involuntarily or voluntarily receiving psychiatric treatment for an acute mental disorder. J Forensic Sci 2014; 59(4):1002-1007
4. Owen GS, Richardson G, David AS, et al. Mental capacity to make decisions on treatment in people admitted to psychiatric hospitals: cross sectional study BMJ 2008; 337: a448
5. Vaccination recommendation for mRNA preparations against Covid-19 from the Federal Office of Public Health and the Federal Commission for questions on vaccination. EKIF (Eidgenössische Kommission für Impffragen) 2020
6. Smith DR. Herd Immunity. Vet Clin North Am Food Anim Pract 2019; 35(3):593-604
7. Fine P, Eames K, Heymann DL. "Herd immunity": a rough guide. Clin Infect Dis 2011; 52(7):911-6
8. Zhang S, Diao M, Yu W, et al. Estimation of the reproductive number of novel coronavirus (COVID-19) and the probable outbreak size on the Diamond Princess cruise ship: A data-driven analysis. Int J Infect Dis 2020; 93:201-204
9. Xia Y, Zhong L, Tan J, et al. How to Understand "Herd Immunity" in COVID-19 Pandemic. Front Cell Dev Biol 2020; 8:547314
10. Underlying Medical Conditions Associated with High Risk for Severe COVID-19; Centers for Disease Control and Pre-

vention. Available here: https://www.cdc.gov/coronavirus
11. Impact of the covid-19 epidemic on total mortality of the resident population in the period january-november 2020. Istituto nazionale di Statistica (ISTAT) and Istituto Superiore di Sanità (I.S.S.) 30th December 2020
12. Derhovanessian E, Pawelec G. Vaccination in the elderly. Microb Biotechnol 2012; 5(2):226-232
13. Pandolfi F, Franza L, Todi L, et al. The Importance of Complying with Vaccination Protocols in Developed Countries: "Anti-Vax" Hysteria and the Spread of Severe Preventable Diseases. Curr Med Chem 2018; 25(42):6070-6081
14. Maiese A, Russa R, Santoro P, et al. Future litigation after Covid-19 pandemic in Italy [published online ahead of print, 2020 Jul 10]. Med Leg J 2020; 25817220938004
15. La Russa R, Fineschi V, Di Sanzo M, et al. Personalized Medicine and Adverse Drug Reactions: The Experience of An Italian Teaching Hospital. Curr Pharm Biotechnol 2017; 18(3):274-281
16. Quattrocchi A, Del Fante Z, Di Fazio N, et al. Personalized medicine in psychiatric disorders: Prevention and bioethical questions. Clin Ter 2019; 170(6), pp. E421–E424
17. Campagne de vaccination contre la COVID 19 – Guide à la phase 1: Organisatione la vacciantion en EHPAD et USLD. Ministère de solidarités et de la santé 2020
18. Information des Betreuungsgerichtes Essen zu den Fragen einer Covid-19 - Impfung im Rahmen der rechtlichen Betreuung; available here: https://www.ag-essen.nrw.de/
19. Re E (Vaccine): LB Hammersmith and Fulham v W [2021] EWCOP 7
20. Vaccination recommendation for Covid-19 mRNA preparations from the Federal Office of Public Health and the Federal Vaccination Questions Commission (EKIF)
21. Caporale M. Scienze umane e bioetica nell'esperienza dei corsi integrati delle facoltà di medicina [Human science and medicine]. Med Secoli 2005; 17(1):243-249
22. Viola RV, Di Fazio N, Del Fante Z, et al. Rules on informed consent and advance directives at the end-of-life: the new Italian law. Clin Ter 2020; 171(2):e94-e96
23. "L'epidemiologia per la sanità pubblica" EpiCentro, Istituto Superiore di Sanità (I.S.S.)
24. Mandarelli G, Parmigiani G, Tarsitani L, et al. The relationship between executive functions and capacity to consent to treatment in acute psychiatric hospitalization. J Empir Res Hum Res Ethics 2012; 7(5):63-70
25. Notarnicola E, Berloto S, Longo F, et al."L'emergenza Covid-19 e l'impatto sul sistema assistenza anziani in Italia." Mecosan 2020; 113: 187-194.