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PAPER

PSYCHIATRY; PATHOLOGY AND BIOLOGY

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Assessment of the Capacity to Express Informed Consent for Organ Donation in Patients with Schizophrenia

ABSTRACT: In Italy, the "silent-consent" principle of donor's willingness regulates organ donation for postmortem transplantation, but civil incompetence excludes it. We investigated decisional capacity for organ donation for transplantation of 30 controls and 30 nonincompetent patients with schizophrenia as related to clinical symptoms, cognition, and functioning. Assessments were carried out through the Competence for Donation Assessment Scale (CDAS), Brief Psychiatric Rating Scale (BPRS), Scale for the Assessment of Positive Symptoms (SAPS), Scale for the Assessment of Negative Symptoms, Life Skills Profile (LSP), Raven's Colored Progressive Matrices (RCPM), Wisconsin Card Sorting Test, Rey RI, Rey RD, and Visual Search. Patients and controls differed on the CDAS Understanding and Choice Expression areas. Patients showed significant inverse bivariate correlations between CDAS Understanding and scores on total BPRS, LSP self-care scale, and RCPM cognitive test. Our results show that decisional capacity for participating in research does not predict decisional capacity for postmortem organ donation in patients with schizophrenic or schizoaffective psychosis; hence, before judging consent for donation, patients must be provided with enhanced information to better understand this delicate issue.

KEYWORDS: forensic science, organ donation, schizophrenia, MacArthur Competence Assessment Tool for Treatment, informed consent, ethics, transplantation

The rules of organ donation are based on informed consent and on the willingness of the potential donor to donate his/her organs after death. These rules are strictly related to the principle of autonomy/self-determination of rational adult human beings and to the value of altruism and respect for people (1,2). Laws at this respect vary widely among the various countries (3–5) and so do practices regarding presumed consent for organ donation and transplantation. This variation reflects the lack of consensus on what should be termed donation and indicates the need for deeper awareness of the ethical meaning of organ transplantation and brain death (6).

Current Italian legislation follows the Law 91 of April 1, 1999 on Organ Donation and Transplantation Number, adhering to the principle of "silent-consent." This means that if a person who is capable to express valid consent does not specifically oppose donation of his/her organs while still in life, her/his organs may be used for donation after death. This is similar to the presumed consent system that is successfully applied in Spain and is currently supported by the Prime Minister of the United Kingdom. The same system has been enforced in some US states but is gradually withdrawn and revised in most of them. In Italy, a Donor Card, on which everyone should provide her/his consent or no consent for organ donation in case of death, has been mailed to all people registered in the National Health System (7).

Nevertheless, the principle of "silent-consent" has still to be enforced because of lack of application of the ministerial directives. Hence, temporarily, the declaration of willingness of organ donation is regulated by the principle of explicit consent or dissent; however, if the person did not provide in the past an explicit consent or dissent, his/her relatives can refuse organ donation upon his/her death (7). Minor age and civil incompetent people are excluded by law from the procedure of willingness declaration. An incompetent person for the Italian Law is comparable to the "incapacitated person" of the Utah Code Section 75-1-201. Patients with mental illness, especially patients with schizophrenia, do not receive special attention by the legislator.

In Italy, interdiction is equivalent to complete loss of civil rights. It is important to highlight, however, that the vast majority of legal actions to obtain interdiction for one person are promoted to protect personal property, and only rarely for strictly medical reasons (8).

Ethical problems arise from the fact that some people, especially those with schizophrenia, but also those with eating disorders, with somatic delusions (9), or some persons with delusional depression like Cotard's syndrome, have problems with the perception of their own body. These problems might ultimately affect their competence and capacity to give free, informed consent for organ donation. Ethical problems are boosted by the lack of clear-cut scientific knowledge regarding brain death; its identification with

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the individual's death has engendered considerable international debate (1,10–13).

The purpose of this study was to evaluate the capacity to express informed consent for one's own organ and tissue donation after death according to regulating laws in a sample of patients with schizophrenia or schizoaffective disorder.

Materials and Methods

Assessment of Capacity to Give Informed Consent

Many recent studies on decisional capacity in people with mental illness used the MacArthur Treatment Competence (MacCAT-C), which has been specifically developed by Grisso, Appelbaum, and their collaborators to assess the capacity of a person to express informed consent for medical treatment (14). These studies used a Clinical Research version (MAcCAT-CR) to assess the capacity of mentally ill patients who were going to enter or stay in clinical trials. Two studies focused on patients with depression (15,16), two on patients with Alzheimer's disease (17,18), one was limited to forensic patients (19), but most focused on the competence of patients with schizophrenia (16,20–28). Another study using the MacCAT-C examined acutely ill patients with psychosis, finding no significant differences among patients with schizophrenia, schizoaffective disorder, and bipolar disorder, and stressing the importance of cognitive impairment in reducing capacity (29). This tool is easy to adapt to the purpose of every single trial (15). To achieve our aim, we adapted the Italian version of the MacArthur Competence Assessment Tool for Treatment scale (MacCAT-T) (14,30) to suit the purpose of assessing the competence of the subgroup of patients with schizophrenia to assess decisional capacity in the specific area of organ donation after death. This adaptation we called the Competence for Donation Assessment Scale (CDAS).

Competence for Donation Assessment Scale (CDAS)

Before assessing our sample, we carried out a preliminary investigation using the CDAS in a sample of patients with schizophrenia, with other psychiatric disorders, and mentally healthy controls. In adapting the assessment tool, based on observations carried out in our sample, we modified or deleted some of the original MacCAT-T questions to fit the purpose to understand competence for donation (see Appendix); the final form of the CDAS and our preliminary validation results were submitted to a panel of magistrates, forensic psychiatrists, transplant surgeons, and statisticians, who found the new tool to possess sufficient content validity. The scale was submitted to 20 medical students. Inter-rater agreement (93%) and internal consistency (Cronbach's alpha = 0.97) were considered acceptable.

The MacCAT-T assesses patient's competence to make treatment decisions by examining their capacities in four areas, i.e., understanding information relevant to their condition and the recommended treatment, reasoning about the potential risks and benefits of their choices, appreciating the nature of their situation and the consequences of their choices, and expressing a choice. Our scale, like the MacCAT-T, consists of four areas assessing the ability level in the following areas, considered as important to express a valid consent in clinical and research practice, i.e., Understanding, Appreciation, Reasoning, and Choice Expression.

Patients

We recruited 36 consecutive patients with DSM-IV (31) schizophrenia or schizoaffective disorder from two psychiatric outpatient services in Rome, Italy, asking them to enter in our study. Thirty-one civil nonincompetent patients (22 men and 9 women) gave free, informed consent. Consent was obtained after assessing the patients with the Italian version of the MacCAT-CR (30). Medication status was not considered as an inclusion criterion; however, all patients were receiving classical or atypical antipsychotic drugs during the 6-month period preceding their evaluation. Exclusion criteria were >55 years of age, chosen to minimize the risk of age-related cognitive impairment, as well as comorbidity with premorbid mental retardation, substance use/abuse, cerebral vascular disease, or exogenous toxic states that *per se* could impair cognitive abilities.

We used 30 consecutive users of an out-patient radiology service (19 men and 11 women) as a control group. Exclusion criteria, other than the above, were past or current psychiatric disorder. The study has been approved by the ethics committee of the ASL RMD, Rome.

Clinical and Functional Assessment

Patients were assessed by specifically trained psychiatrists and psychologists, who carried out psychiatric interview and diagnosed them according to the DSM-IV criteria. To evaluate patient's clinical status, we used the Italian version (32) of the following scales:

- Brief Psychiatric Rating Scale, 4.0 version (BPRS 4.0) (33), a routinely used scale in clinical and research practice to assess psychopathology; total scores constitute a measure of severity of the psychiatric disorder.
- Scale for the Assessment of Positive Symptoms (SAPS) (34), a 34-item scale developed by Andreasen to assess positive symptoms of schizophrenia, and which consists of four subscales, i.e., hallucinations (H), delusions (D), bizarre behavior (BB), and formal thought disorder (FTD).
- Scale for the Assessment of Negative Symptoms (SANS) (35), a 25-item scale by the same investigator, assessing negative symptoms of schizophrenia; its five subscales are affective flattening (AF), alogia (A), avolition/apathy (AP), anhedonia/asociality (AN), and attention impairment (AI).
- Life Skills Profile (LSP). This 39-item scale is used to assess the life skills of patients with schizophrenia (36). Each item is rated 1–4, with 1 at the negative extreme and 4 at the positive one. Total score ranges 39–156; the individual score of each subscale (self-care [SC], nonturbulence [NT], socialization [S], communication [C], responsibility [R]) is also rated.

Cognitive Assessment

A trained research psychologist (Ad.B.) administered a cognitive test battery to patients to assess cognitive impairment.

The test battery included the following things:

- Raven's Colored Progressive Matrices (RCPM) (37). This test has been included in a Neuropsychological Test Battery by Miceli and colleagues (38,39). They used a modified version in which possible answers are presented vertically, to minimize visuo-spatial inattention effects. The assessed cognitive functions are predominantly visuo-spatial skills. Unlike performance on Raven's Progressive Matrices, patients with right hemisphere lesions tend to commit more errors, compared to those with left hemisphere lesions. The tool provides a valid measure of cognitive efficiency; low performance reliably indicates cognitive impairment.
- Spinnler's Attention Matrices (Visual Search) (40). This test consists in projecting 16 figure-stimuli on a screen. The score takes

into account both time needed to complete the test and number of errors. This is an attention test; its aim is to assess selection ability in a visual search situation.

- Rey's 15-word list (41). This test assesses the immediate recall (IR) (cutoff, 28.53) and delayed recall (DR) (cutoff, 4.69) ability of 15 words, providing a measure of verbal memory (42).
- Wisconsin Card Sorting Test (WCST) (43). This test assesses predominantly executive functions (mainly, cognitive flexibility-set shifting), and it is particularly sensitive to frontal lobe dysfunction (44).

The scales were completed by a trained research psychiatrist (MCDM), under the supervision of a senior forensic research psychiatrist (SF).

We first provided information on the law regarding consent for organ donation and on the brain death concept. This was followed by a structured interview investigating the four areas of decisional capacity. The score for Understanding ranges from 0 to 10, for Appreciation, 0–2, for Reasoning, 0–6, and for Choice Expression, 0–4. Total score could be obtained by adding the scores of the specific areas; it ranges from 0 to 22. However, differently from the MacArthur Competence Assessment Tools, we did not calculate the total score, because deficits in just one subscale might immediately translate into incompetence, despite such deficits could not be detected in other subscales (45).

Statistics

The Statistical Package for Social Sciences (SPSS) version 11.0 (46) was used for statistical analysis. Descriptive statistics was used to assess socio-demographic data and baseline scores. Student's t test was used to compare variables such as age, education, and scores on the CDAS.

We also analyzed bivariate Pearson correlation coefficients among all considered variables, including clinical symptoms and functioning (BPRS, SAPS, SANS, and LSP) and cognitive outcomes (Visual Search, Rey RI, Rey RD, WCST, and RCPM), as well as the CDAS. As multiple correlations were performed, to reduce the probability of obtaining significant results by chance, we set statistical significance at $p < 0.01$.

TABLE 1—*Comparison between the groups of patients and controls using Student's* t *test concerning sociodemographic characteristics and competence measures.*

Group	*N*	Mean	Standard Deviation	Standard Error	*t*	*p*(*t*)
Age						
Controls	30	37.03	11.01	2.02	0.09	0.93
Patients	30	36.57	7.29	1.33		
Educational level						
Controls	30	11.40	3.86	0.71	1.53	0.13
Patients	30	10.07	2.78	0.51		
Understanding						
Controls	30	10.00	0.00	0.00	3.59	0.00
Patients	30	8.50	2.29	0.42		
Appreciation						
Controls	30	1.90	0.30	0.06	1.65	0.11
Patients	30	1.67	0.71	0.13		
Reasoning						
Controls	30	5.13	1.10	0.20	0.67	0.50
Patients	30	4.90	1.54	0.28		
Choice expression						
Controls	30	3.80	0.49	0.09	2.11	0.04
Patients	30	3.43	0.82	0.15		

Results

Thirty-one patients gave their consent for the study, but one was excluded because he was not able to complete the interview, thus leaving an overall sample of 30 patients (9 women and 21 men). Mean age was 36.57 (SD = 7.29). Education years were 10.07 (mean; SD = 2.77) (Table 1). Baseline scores of questionnaires related to both clinical symptoms and cognitive assessment are listed in Table 2.

Mean age in the control group (11 women and 19 men) was 37.03 (SD = 11.04) and education years were 11.40 (mean, SD = 3.86) (Table 1). The two groups did not differ for composition by gender nor for age or educational level.

Among the 30 patients who obtained a maximum score on the Understanding area of the MacCAT-CR, only 12 (40%) had a maximum score on the CDAS-U.

As shown in Table 1, the two groups were homogeneous with respect to scores on the CDAS Appreciation and Reasoning subscales. However, controls scored significantly higher than the patients with schizophrenia or schizoaffective disorder on the CDAS understanding and choice expression subscales (Table 1).

In the patient group, Pearson's bivariate correlation analysis showed high inter-correlations among the questionnaires used in our research and their own global scores.

SAPS scale correlations ranged from $r = 0.66$ to 0.89 SAPS H and SAPS D, respectively, with their total scores (SAPS Total, $p < 0.01$). SANS scale correlations ranged from $r = 0.72$ to 0.86, respectively, between SANS AN and SANS A with their total score (SANS Total, $p < 0.01$). Correlations within the LSP scale ranged from $r = 0.69$ (between LSP SC and LSP total score) to $r = 0.84$ (between LSP S and LSP total score), $p < 0.01$.

TABLE 2—*Baseline scores of clinical and cognitive scales of the 30 patients with schizophrenia or schizoaffective disorder.*

Variables	Range (min –max)		Mean (M)	Standard Deviation (SD)
Clinical				
Brief Psychiatric Rating Scale total score	38	90	53.23	13.84
SAPS H	0	21	3.57	5.69
SAPS D	0	23	7.80	6.81
SAPS bizarre behavior	0	15	4.37	3.89
SAPS formal thought disorder	0	32	9.53	9.24
SAPS total score	0	77	25.27	20.81
SANS affective flattening	0	24	10.83	7.75
SANS A	0	22	6.70	5.39
SANS avolition/apathy	0	16	7.33	4.75
SANS anhedonia/asociality	0	20	9.50	5.25
SANS attention impairment	0	11	5.17	3.43
SANS total score	6	77	39.53	21.99
LSP self-care	17	46	33.17	5.99
LSP nonturbulence	28	48	40.30	5.06
LSP S	8	23	14.50	3.77
LSP C	12	24	19.70	3.23
LSP R	12	20	17.23	1.99
LSP total	84	151	124.90	15.03
Cognitive				
Visual search	27.25	53.75	41.79	5.90
Rey RI	13	56	32.90	9.06
Rey RD	0	11	6.07	2.87
Wisconsin Card Sorting Test	0	6	3.07	2.50
Raven's Colored Progressive Matrices	16	32	26	4.94

LSP, Life Skills Profile; SANS, Scale for the Assessment of Negative Symptoms; SAPS, Scale for the Assessment of Positive Symptoms.

Clinical Symptom Outcome and Decisional Capacity

Several significant correlations were found in the exploratory analysis between the subscales of our CDAS and the other scores of the questionnaires used to assess the levels of symptoms, namely BPRS, SAPS, SANS, and the level of functioning, LSP (see supplementary Table S1).

The Understanding subscale of the CDAS highly correlated inversely ($p < 0.01$) with total BPRS score ($r = -0.49$) and positively with LSP SC ($r = 0.53$). Further strong inverse correlations were observed between the Reasoning subscale and SANS AN ($r = -0.49$, $p < 0.01$) and the Choice Expression subscale and SANS AN ($r = -0.57$, $p < 0.01$).

Cognitive Outcomes and Decisional Capacity

A strong trend toward correlation was found between the RCPM score and the Understanding area of the CDAS ($r = 0.576$, $p < 0.05$). Other results were not significant.

Discussion

In this study, we focused on the competence for giving free informed consent for postmortem organ donation of patients with schizophrenia who were competent for giving consent to research and found that many patients who were competent for research were not competent for giving consent to organ donation. We found capacity for giving consent for postmortem donation to be affected by positive and negative symptoms, life skills and cognitive factors.

The patients we enrolled were all followed up by their treating doctors, who participated in this study; they also were not acutely ill, as they were seen as outpatients. These facts may account for the high rate (97%) of patients who gave valid informed consent for research. However, among these patients, only 40% were able to understand properly the problems and the meaning of donating one's own organs for transplantation after death. This might be taken to mean that understanding may be hampered by increasing difficulty and complexity of the concepts involved and is task-specific. The difference in consent for postmortem organ donation from other informed consents is also indirectly acknowledged by the Neuroscience Institute of Schizophrenia and Allied Disorders (NISAD), which collects brains postmortem for schizophrenia research; in fact, the NISAD does not recruit donors but rather accepts volunteers after a complex and confirmatory consent process (47).

Scores on the CDAS Understanding and Choice Expression subscales show a higher degree of impairment in psychotic patients, when compared with healthy controls. We found a significant inverse correlation between severity of symptoms, as measured with the BPRS (total score), and scores on the CDAS areas Understanding, Appreciation, and Choice Expression. This finding matches other studies that found a relationship between impaired decisional capacity and severity of psychopathology (see reference 26 for a review), although most recent studies found a lower impact of the extent of symptoms compared to cognitive impairment (20,25,29,48).

We observed that the more the patient has anhedonia and asociality, as resulting from the scores on the respective subscales of the SANS, the more his/her reasoning abilities fail (score on the CDAS Reasoning), and the more are his/her choosing and decisional abilities impaired (as shown by scores on the CDAS Choice Expression). This is a finding heretofore unreported in literature.

Self-caring ability (as measured with the LSP scale) was found to correlate positively with understanding capacity, i.e., the poorer the patient's SC, the slower is understanding of relevant data and the higher the decision-taking impairment.

Several studies investigated decision-taking capacity in psychiatric patients as far as clinical treatments are concerned (49). Cohen and co-workers (16) found that patients with schizophrenia performed worse than patients with depression in decision-taking to participate in research and patients with depression performed worse than healthy controls. This finding suggests a negative influence of disease on decisional processes.

Our data only partially agree with those of Grisso and Appelbaum (50). These investigators found that patients with schizophrenia and lower performance in understanding and reasoning measures tended to have more severe psychiatric symptoms, especially thought disorder. This led them to hypothesize a negative influence of symptom severity on decision performance. Their data support interdependence between symptom severity and decisional capacity.

Howe and colleagues (29) found the Positive and Negative Syndrome Scale (PANSS) positive symptom subscale scores to be correlated inversely with the Understanding area of the MacCAT-T only, while we found the BB subscale of the SAPS to be inversely correlated with both Understanding and Appreciation subscales of the CDAS. Differences in the instruments used may account for the differences; however, both the above study and ours point at the involvement of positive symptoms in the reduction of decisional capacity. Candilis and colleagues (51) recently found the Positive, the Negative, and the General Psychopathology scores of the PANSS to correlate with the degree of impairment of decisional capacity in patients with schizophrenia.

We found a highly significant positive correlation between cognitive abilities, as assessed through RCPM, and understanding capacity, but no significant correlation between understanding capacity and the other cognitive tests used in this study.

Patients with schizophrenia showed deficits in semantic memory, being slower in understanding and learning (52). The use of cued methods has been shown to increase understanding in a sample of patients with schizophrenia (53). The use of powerful means of communication, like multimedia, and additional information may be used to increase their competence in expressing free consent. Although the role of multimedia presentations in enhancing the expression of consent to research is controversial, patients with cognitive problems, such as most patients affected by schizophrenia or schizoaffective disorder, may benefit from their use (54). This could be extended to providing the patient with additional information on the aims of the trial, whatever its nature. Patients with schizophrenia who accept to participate in research projects are eager to be informed on the study's outcomes (55).

Cognitive impairment correlates inversely with decisional capacity in patients with schizophrenia when the most stringent criteria of the MacCAT-CR are applied (at least 18 on the Understanding subscale and at least five on the Appreciation subscale, as well as at least six on the Reasoning subscale) (28). Gurrera and colleagues (56) found neuropsychological performance to predict all four dimensions of competence in patients with mild to moderate dementia. We found a correlation between understanding capacity and cognitive performance on Raven's progressive matrices, but dissimilarly from Gurrera and colleagues (56), we did not find a correlation between neuropsychological performance and the MacCAT-related CDAS dimensions in our study. We used different tests than those used by Gurrera's group (56) and we investigated a different population, so it is possible that the discrepancy between our results and theirs could reside in differences in tests and populations; however, it is also

possible that, as they acutely observed in their sample, "Relationships between elemental cognitive function and decisional capacity may differ in individuals whose decisional capacity is impaired by other disorders, such as mental illness."

Our data show that it is not possible to determine *a priori* the competence for organ donation to transplantation of a patient with schizophrenia or by using indirect assessment tools. Understanding in one area may not translate into understanding in other areas, and sometimes it is worth investigating the meaning of the patient's sentences, as this may shed new light to the patient's reasoning processes. Hence, laws based on silent-consent may in fact violate the freedom of choice of severely ill psychiatric patients. In these patients, competence of understanding relevant information is the most impaired and is related to the severity of both psychopathology and cognitive changes. We suggest that research investigators should either know the patient to be assessed from before, or they first consult the specific patient's psychiatrist(s) or general practitioner(s) before performing evaluation.

We support that cognitive and symptomatic improvement, along with providing clear information which should focus specifically on similar patients, could improve their understanding ability. In addition, we may expect improvement of overall decision competence. Carpenter and Conley (57), who pay less attention to symptom expression, advocated focusing on cognitive impairment and the need to overcome it. Our findings agree with those of Grisso and Appelbaum (50), who suggested to provide additional explanations to patients with schizophrenia that show initial understanding deficits. They observed that these patients showed a higher level of understanding information about treatment after having received additional information about the same treatment.

We agree with Cohen et al. (16), who state that it is not possible to avoid an individualized evaluation of specific decision competence, despite patients with severe mental disorder, even in their acute state, were found to have capacity for expressing valid consent for research. Taken together, our data support that patients with schizophrenia, despite preserving competence in one field, for example, participating in research, may present deficits in other fields, such as competence for donation. For example, one of our patients with DSM-IV schizophrenia, characterized by severe paranoid symptoms, was not declared civil incompetent. He believed he was possessed by the devil, which was tormenting him with voices and inflicting him atrocious pain. This patient stated he would be delighted to donate his organs after death, because donation would probably free him from the sufferance that otherwise would continue also after death. It is obvious that his wish to donate was based on some lack of understanding of the basic principles underlying postmortem organ donation, and this could be detected only after individually focused investigation. Similar case reports and editorials are found in literature (58–60). Hence, this specific competence should be adequately searched before applying the "silent-consent" principle to patient populations that may have their judgment impaired. We therefore recommend to thoroughly investigate patient motivations, going beyond merely filling-out a rating scale.

Future Directions

We found that impaired understanding, as assessed through the CDAS, is related with poor decisional capacity in people with schizophrenia and impaired cognition affects decisional ability in these patients. Our results, with all the limitations related to a small sample, suggest that the ongoing regulations, based on the "silent-consent" principle for organ donation, do not take into account individual differences in patients with schizophrenia. In fact, current legislation requires people with specific problems to show the same competence for consent expression as healthy individuals. Instead, the former would rather need special help and specific guidance to express a truly free and informed consent.

To address the special issues created by the mismatch between capacity to give informed consent for participating in research and capacity to give consent for organ donation, it could be useful to compare in future studies the testamentary capacity of patients. Testamentary capacity deals with a postmortem scenario, so it may constitute a useful paradigm to compare with the capacity to give consent for postmortem organ transplantation, which is in fact a biological testament.

Another way to approach this delicate issue, should the patient be incapacitated to provide informed consent for organ donation, is to rely on family surrogate consent. In a recent survey of mature American citizens, a large proportion agreed that family surrogate is an adequate strategy for providing experimental subjects for dementia studies (61). People affected by dementia are likely not to be able to provide informed consent for participating in research; this would constitute a barrier for future research. It is up to society to decide whether it is ethical to surrogate consent to care givers for areas, such as postmortem organ donation, in which people with full capacity in other areas show incapacity to give consent. However, the respect of individual freedom should be guaranteed in any decision a legislator might take. Future research should consider first decisional capacity-aiding programs, like psycho education and multimedia information, to assess whether the incapacity to understand a given area of discussion, hence to make a decision, is transient or persistent. This implies longitudinal, prospective designs for future studies, with testing and retesting subjects who participate in programs and their nonintervention controls.

Another issue that deserves to be settled is whether decisional capacity has to do with insight/awareness. Intuitively, we are prompted to believe that it has, but research on this topic is currently scanty, with one group of investigators supporting an association (62) and another finding no correlation (26). Both these groups used MacArthur instruments to measure capacity, but the first used a semi-structured interview to assess insight, while the second used a self-rated scale; however, their sample differed for age, that could partly account for the discrepancy. Further research is warranted to obtain sound data on the association between insight/awareness and decisional capacity. Another measure that needs to be tested for association with decisional capacity could be treatment adherence/compliance. One study found an association between the Appreciation subscale of the MacCAT-T and medication adherence behavior (63), but further research is needed.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Pearson's bivariate correlations.

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Appendix

Competence for Donation Assessment Scale (CDAS)

Preliminary inquiry—1st part. Assessment of knowledge of the April the 1st Law number 21.

- Do you know the new Law 21/1999 on transplantation entails the application of the "silent-consent" criterion? Do you know what that means?
- Do you know how to express your will on your organ and tissue donation after your death? Do you know whether you may change your mind about it and how you may do that?
- Do you know which is the role of your relatives or of people living with you, with respect to the decision on donating your organs after your death, according to the aforementioned law?
- According to you, death corresponds to brain death? What does this mean?
- Do you know who pays for the transplantation?

2nd part. Information

- The Law 91/1st April 1999, referring to the "silent-consent" criterion, thus reports: "...the citizens are required to declare their own free will as to the post-mortem donation of organs and tissues of their own body, and are informed that their failure to express their will shall be considered as consent to donation…", within 90 days from the notification of the request.
- The same Law establishes that to express his/her will, the citizen may fill out the mailed form and bring it always with him/her or communicate his/her choice to the local public health unit or to his/her family physician. Furthermore, it provides that the citizen may change his/her opinion at any instance and communicate it to the local public health unit or to his/her family physician, or through his/her written declaration that his/her relatives may exhibit during the phase of death certification.
- Relatives and people living with the person in question are not required to give consent for donation of organs and tissues of the deceased person, as the ultimate decision is up to the person in question.
- Before initiating the transplantation procedure, it is necessary to ascertain that the person is dead. It is scientifically ascertained that there is only one death, and this is brain death and consists in ceasing all brain functions; in fact, the diagnosis is formulated by a group of specialists working in a public structure, but independent from the group that will carry out the transplantations; the former group will decide after an observation period of at least 6 h (for adults). Finally, it is the magistrate who will provide authorization for carrying out transplantation.
- The cost of transplantation is supported by the National Public Health System and buying or selling organs or tissues are severely punished by the Law.

Competence for Donation Assessment Scale (CDAS)

Name (initials):	Age:	Physician:
Date:	Service/Unit:	

Understanding of the topic

Provide information and ask whether there are any questions

- "Could you please now explain, with your own words, what did I say about the Law that regulates the consent to organ donation?"
- Control (if needed)
- Repeat information and enquiry (if needed).

Communication	Person's response	Score
Meaning of the "silent-consent" principle		
Procedure for declaration of will		
Relative's role		
Meaning of brain death		
Transplantation costs		

Evaluation

Ask: "You may decide to express explicit consent or dissent to organ donation; or you may decide not to express any opinion at all or you may not decide, which are equal to consent—we will speak later about that. What do you believe is the right thing to do?"

☐ Consent ☐ Dissent ☐ Silence ☐ Undecided

Control: "So you think it is fair to donate/not donate organs, do you? Why do you think this is the best decision for you?"

Person's explanation	Score

i. Choice expression and reasoning

Choice expression: "Please, let's review your possible choices. First, to give explicit consent; second, to give explicit dissent; third, to avoid expressing your will, which is the same as giving consent; fourth, remain in doubt and not to provide any decision, which is also the same as providing consent. Which one of these options appears to suit you best? What do you think you will most probably do?"

Choice

Do you believe that (cite the person's choice) would be best? Please, tell me what makes you think this choice is better than the others.''

Control: discuss the explanation to explore reasoning processes.

Person's explanation	Score
Consequential	
Comparative	
Consistency (logical)	

ii. General consequences

Question 1: ''Which consequences would your choice have on your life and after your death?''

Consequence 1	Score

Question 2: ''Now, let's consider the other choices. Which consequences would each choice have on your life and after your death?''

Consequence 2	Score

Consequences (total) ☐

Final Choice

Ask: ''At the beginning of our conversation you had chosen (mention the person's first choice). What do you think now, after we discussed everything? Which is your final choice?''

Choice	Score

iii. Logical consistency of the choice

Interviewer's explanation	Score

iv. Summary of Competence for Donation Assessment Scale (CDAS) scores

Total score-Understanding (0–10) ☐

Total score-Evaluation (0–2) ☐

Reasoning

Consequential ☐

Comparative ☐

Logical consistency ☐

Total score-Reasoning (0–6) ☐

Total score-Choice expression (0–2) ☐