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Informed Consent in Older Medical Inpatients: Assessment of Decision-Making Capacity

Porrino P, Falcone Y, Agosta L, Isaia G, Zancocci M, Mastrapasqua A, Isaia G, Bo M

To the Editor: Lack of education, cognitive decline, polytherapy, comorbidities, acute medical illness, and hospitalization can limit the ability to understand medical information and impair decision-making capacities[1-4] in older adults, making questionable the reliability of informed consent. Physicians usually informally assess decision-making capacity, which remains the criterion standard in clinical practice, although a standardized test such as the Mini-Mental State Examination (MMSE) has been shown to perform reasonably well in the assessment of decision-making capacity when compared with expert evaluation. The current hypothesis-generating study assessed the prevalence of effective understanding of informed consent documentation of older medical in-patients and whether the MacArthur Competence Assessment Tool for Treatment (MacCAT-T)[3, 5] may support clinical evaluation of decision-making capacities.

This study was conducted over a 2-month period on Italian-speaking individuals aged 75 and older consecutively admitted to an acute geriatric ward. Exclusion criteria were refusal to participate, history of dementia, severe visual, and hearing or cognitive impairment. Italian was used for consent forms and tests. Information was recorded on clinical and demographic variables—including education—and cognition (MMSE),[6] depression (Geriatric Depression Scale),[7] and function (activities of daily living, instrumental activities of daily living)[8, 9] were evaluated using standardized scales. Decision-making capacity was assessed using the MacCAT-T,[3, 5, 10] a semistructured interview that measures four abilities related to decision-making capacity: understanding of the disorder and its treatment, appreciation of the disorder and its treatment, reasoning, and ability to express a choice. Responses are rated for quality of response (adequate = 2, partial = 1, inadequate = 0). The method provides summary ratings for each ability (0–6 for understanding, 0–4 for appreciating, 0–8 for reasoning, and 0–2 for expressing a choice).

An expert geriatrician (MZ) invited each participant to read carefully the informed consent document attached to the medical chart regarding personal data handling; participants were then invited to rate their degree of understanding of the document (yes, no, I don't know, I don't want to answer). A senior qualified geriatrician (MB) investigated participants' true understanding of the document, which was rated good when the participant understood the document completely, poor when the participant understood the document partially, and null when there was no evidence that the participant understood any part of the document.

The Student *t*-test was used to correlate the understanding of consent with continuous variables and the chi-square test for categorical variables; multivariate analysis and logistic regression were used to identify independent associations using SPSS package for Windows version 18 (SPSS, Inc., Chicago, IL).

Of 234 individuals consecutively admitted, 45 declined to participate, and 43 were excluded, leaving a sample of 146 (mean age 81.2 ± 6.3 , 52.1% female), 57.5% of whom had elementary education (1–5 years), 21.9% intermediate education (6–8 years), 13.7% upper-intermediate education (9–12 years), and 6.8% university education. MacCAT-T scores demonstrated good performance in more than half of subjects in the area of expression and reasoning, and almost all subjects performed well in expression of choice. One hundred fourteen participants (78.2%) said that they understood the informed consent document, 20 (13.6%) said that they did not understand it, and 12 (8.2%) expressed some doubt. After individual interviews, 42 participants (28.6%) were found to have really understood, and 104 (71.4%) were found not to have understood the document completely. Participants who did not really understand the document were older, more cognitively impaired, more depressed, and less likely to be functionally independent; had worse awareness of their health status; and were less able to reason about different treatments than those who understood. No significant relationship between education level and understanding was observed. Only MacCAT-T scores in the area of reasoning about therapy (risk ratio (RR) = 2.42, 95% confidence

interval (CI) 1.26–4.64, $P = .008$) and appreciation of clinical disorder (RR = 0.16, 95% CI 0.07–0.36, $P < .001$) were independently associated with understanding of informed consent (Table 1).

Table 1. Variables Associated with Physician-Assessed Understanding of the Informed Consent Document

Variable	Risk Ratio (95% Confidence Interval)	P-Value
MacArthur Competence Assessment Tool for Treatment		
Reasoning about therapy	2.42 (1.26–4.64)	.008
Appreciation of clinical disorders	0.16 (0.07–0.36)	<.001
Mini-Mental State Examination	1.58 (0.93–2.66)	.09
Geriatric Depression Scale	0.88 (0.54–1.43)	.600
Age	1.22 (0.66–2.28)	.53
Activities of daily living	0.78 (0.40–1.51)	.45

Although the majority of older medical in-patients said that they understood informed consent, only one-third of them actually did; the MacCAT-T interview may support the clinical evaluation, which is considered the standard for assessing decision-making capacity, although it is subjective and strongly dependent on the specific clinical attitudes and specialty of the physician. Therefore, it might play a role in assisting physicians not routinely involved in the management of older adults in assessing decision-making capacities in individuals with borderline cognitive performance or with mild to moderate cognitive impairment.

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