



Diminished capacity to make treatment decision for COVID-19 vaccination in schizophrenia

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Received: 20 December 2021 / Accepted: 11 April 2022 / Published online: 30 April 2022
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Abstract

Recent evidence suggests that people with schizophrenia are at high risk for severe COVID-19 and should be prioritized for vaccination. However, impaired decision-making capacities could negatively affect the uptake of COVID-19 vaccination in this population. Capacity to consent to COVID-19 vaccination was assessed in 80 outpatients with schizophrenia. Using the MacArthur Competence Assessment Tool for Treatment, 56.3% of the sample were classified as having diminished capacity to consent to the vaccination. Diminished capacity to consent to COVID-19 vaccination was associated with lower vaccination rates, poorer cognition and higher level of psychotic symptoms. Developing interventions for enhancing informed consent for vaccination is urgent within this population.

Keywords COVID-19 · Capacity to consent to treatment · Vaccine · Schizophrenia · Healthcare

Introduction

Several nationwide cohort studies and analyses using electronic health records revealed that having a mental health disorder was associated with increased and more severe COVID-19-related outcomes including mortality [1]. This was especially the case for severe mental health illnesses such as schizophrenia spectrum disorders. Consequently, individuals with schizophrenia should be prioritized in vaccine allocation strategies [2]. However, several important barriers could negatively affect the uptake of a COVID-19 vaccine in this population, including impaired decision-making capacity. Indeed, impaired decision-making ability has been repeatedly observed in people with schizophrenia. Using both experimental tasks, such as the Iowa Gambling

Task [3] and clinical tools, such as the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) or for Treatment (MacCAT-T), studies have repeatedly found altered decision-making capacities in individuals with schizophrenia, mainly due to cognitive deficits and psychotic symptoms [4, 5]. Ability to make treatment decision has been proposed as one of the most impaired decision-making capacity in schizophrenia [6]. Using instruments, like the MacCAT-T, which is considered the standard measure for assessment of capacity, it was found that 10–52% of people with schizophrenia were classified as being impaired in decisional capacity for treatment [7].

To our knowledge, no studies have explored capacity to consent to vaccination, particularly COVID-19 vaccination in people with schizophrenia. The aims of this investigation were (1) to examine the capacity to consent to COVID-19 vaccines in individuals with schizophrenia and (2) the clinical determinants of capacity to consent to COVID-19 vaccines in patients diagnosed with schizophrenia. We hypothesized that (1) a high proportion of patients will have reduced capacity to make treatment decision for COVID-19 vaccination and (2) capacity to make treatment decision for COVID-19 vaccination will be inversely related to the severity of psychotic symptoms and positively to cognitive functioning.

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Methods

Participants

We included 80 people with schizophrenia consecutively admitted to the University Department of Adult Psychiatry of Montpellier, France between April 2021 and October 2021. Participants were initially identified through regular examination of the electronic medical records and consultations with ward nursing staff. Patients were then approached for a research interview and those assenting to participate were given full details of the study. Judgments on mental capacity to participate in this study were based on a clinical assessment and a thorough review of the medical record notes.

Inclusion criteria were: (a) age between 18 and 60 years, (b) a DSM-5 diagnosis of schizophrenia, (c) adequate proficiency in French. Exclusion criteria for all participants were: (a) known neurological disease, (b) history of learning disability/developmental disorder.

Measures

Capacity to consent to COVID-19 vaccination was assessed with the French version of the MacCAT-T [8, 9]. The patient's understanding of the COVID-19 disorder and treatment-related information (Understanding) was rated from 0 to 6; appreciation of the significance of that information for the patient, in particular, the benefits and risks of treatment (Appreciation), was rated from 0 to 4; the reasoning ability of the patient (Reasoning) was rated from 0 to 8; and ability of the patient to express a choice between a vaccine against COVID-19 and an alternative treatment (Expressing a choice) was rated from 0 to 2. To reduce demands on the patient's cognitive abilities, we used the MacCAT-T in the same way as Owen et al. [7] and compared vaccine for COVID-19 to no medical treatment, i.e., we did not offer an alternative treatment. Patients were divided into two groups based on ratings on the four subscales of the MacCAT-T and on the methodology of Elzakkars et al. [10]. For every subscale, a patient could rate poor (50% or less of the maximum rating on that subscale), intermediate (51–75% of the maximum rating) or good (76–100%). If a patient had a poor or intermediate rating on one or more of the four subscales, this patient was considered as having diminished mental capacity to consent to COVID-19 vaccination.

Clinical and cognitive assessment

Symptom severity was measured using the Positive and the Negative Syndrome Scale PANSS. For this study, four of the

analytically derived PANSS factor component scores were taken into account: Total, General Psychopathology, Positive and Negative [11].

Global cognitive functioning was assessed with the Montreal Cognitive Assessment (MoCA) [12]. The MoCA is a brief measure of global cognitive function originally developed to detect mild cognitive impairment. Total score was the independent variable.

Procedure

Written informed consent was obtained from all participants prior to their inclusion in the study. Patients completed all measures in one session. All participants gave their written consent to participate. For all the participants in the clinical group, medical co-morbidities and sociodemographic data were collected from the electronic medical records. Any missing data were collected during the session where the MacCAT-T and other clinical measures were administered.

Statistical analyses

Statistical analyses were performed with the Jamovi statistical computer software [The jamovi project (2021). jamovi. (Version 1.6) Retrieved from <http://www.jamovi.org>]. Group comparison was made with the χ^2 test for nominal variables and independent *t* test for continuous variables. *P* values were 2-tailed, and significance was set at a *P* value less than 0.05. Analyses were performed using Jamovi software version 1.6.

Results

The collected sociodemographic and clinical data are reported in Table 1. As documented in Table 1, 58.8% of patients had a full vaccine status. Diminished mental capacity was observed and ranged from 8.8% for the Expressing a choice dimension to 56.3% for the Understanding dimension.

Group comparisons indicated that diminished capacity to consent to COVID-19 vaccination was related to a poorer global cognitive functioning for the Understanding (21.9 ± 4.6 vs 25.6 ± 2.7 ; Welch's $t = -4.35$; $P < 0.001$; Cohen's $d = -0.95$) and Appreciation (22 ± 5.1 vs 24.2 ± 3.7 ; Welch's $t = 1.95$; $P = 0.05$; Cohen's $d = 0.77$) MacCAT dimensions.

Higher level of psychotic symptoms, based on the PANSS scores, was related to diminished capacity to consent, specifically for the Understanding dimension (55.4 ± 10.2 vs 68.6 ± 21.8 ; Welch's $t = 2.72$; $P = 0.01$; Cohen's $d = 0.77$) and the Appreciation dimension (58.8 ± 19.3 vs 69.8 ± 13.1 ; Welch's $t = -2.32$; $P = 0.02$; Cohen's $d = 0.66$).

Table 1 Sociodemographic and clinical characteristics of the sample

Patients characteristics	Value: mean (s.d.) [range] or %			Statistics	P value
	All sample n = 80	Vaccinated n = 47	Unvaccinated n = 33		
Demographic variable					
Age	41.2 (13.2)	42.7 (12.63)	39.1 (13.97)	$t = -1.20$	0.23
Gender, female	30%	36.2%	21.2%	$\chi^2 = 2.07$	0.15
Years of education, mean	12.6 (3.16)	12.9 (3.3)	12 (2.9)	$t = -1.23$	0.22
Full vaccine status	58.8%				
Clinical variables					
Patients under treatment	100%				
Duration of the disease	16.8 (12.4)	15.8 (12.5)	18.2 (12.2)	$t = 0.77$	0.44
PANSS ^a total	62.1 (18.3)	60 (18.7)	66.2 (17.2)	$t = 1.15$	0.25
PANSS positive	13.2 (5.7)	12.9 (6.39)	13.9 (4.4)	$t = 0.62$	0.53
PANSS negative	16.3 (5.5)	15.6 (5.52)	17.6 (5.52)	$t = 1.23$	0.22
PANSS general psychopathology	32.6 (9.17)	31.5 (8.96)	34.6 (9.48)	$t = 1.12$	0.26
Montreal Cognitive Assessment	23.5 (4.3)	23.8 (4)	23.2 (4.7)	$t = -0.57$	0.56
MacCAT-T^b					
Understanding disorder	56.3% ^c	53.2% ^d	60.6% ^d	$\chi^2 = 0.43$	0.51
Appreciation	32.5% ^c	19.1% ^d	51.5% ^d	$\chi^2 = 9.26$	0.002*
Reasoning	31.3% ^c	19.1% ^d	48.5% ^d	$\chi^2 = 7.77$	0.005*
Expressing a choice	8.8% ^c	4.3% ^d	15.2% ^d	$\chi^2 = 2.88$	0.09
Co-morbidities					
Diabetes	11.2%	12.8% ^d	9.1% ^d	$\chi^2 = 0.26$	0.60
Pulmonary disease	15%	17% ^d	12.1% ^d	$\chi^2 = 0.36$	0.54
Cardiovascular disease	6.2%	8.5% ^d	3% ^d	$\chi^2 = 0.99$	0.31
One or more co-morbidities	23.8%	27.75% ^d	18.2% ^d	$\chi^2 = 0.96$	0.32

^aPositive and negative syndrome scale^bMacArthur competence assessment tool for treatment^cProportion of patients with diminished mental capacity^dProportion among patients with diminished mental capacity on MacArthur competence assessment tool for treatment* $p < .05$

As documented in Table 1, the proportion of patients with diminished mental capacity for both Appreciation and Reasoning MacCat dimensions was higher in the unvaccinated group compared to the vaccinated group (respectively, 51.5% versus 19.1%, $P = 0.002$; 48.5% vs 19.1%, $P = 0.005$).

Diminished capacity to consent to COVID-19 vaccination on Appreciation and Reasoning of the MacCAT dimensions was associated with lower vaccination rates, respectively, $P = 0.002$ and $P = 0.005$.

No relationships were found between vaccination status, demographical, clinical, global cognitive functioning, and comorbidity variables (Table 1).

Discussion

To our knowledge, this is the first study to investigate the question of capacity to consent to COVID-19 vaccine and more broadly vaccination in individuals with schizophrenia. Our results revealed that in our clinical sample, there was a high rate of reduced capacity to make decisions for COVID-19 vaccination. Most importantly, the subgroup of patients with diminished capacity to consent had a lower vaccination rate than the group with persevered capacity, suggesting that diminished capacity to consent might constitute a barrier for COVID-19 vaccination. Moreover, impaired capacity to consent was associated with higher levels of psychotic symptoms and reduced cognitive abilities which is in accordance with previous studies about decision-making capacity for other treatments such as antipsychotics [5].

Despite accumulating evidence that people with schizophrenia are at high risk for severe forms of COVID-19 and

long-term sequelae (including hospitalizations and mortality), a recent longitudinal study indicated that this population remains under-vaccinated against COVID-19 compared to the general population [13, 14]. This was the case in our study, even if firm conclusions cannot be drawn due to the small size of our population. Indeed, less than 60% of our sample of patients were vaccinated whereas around 76% of French adults had at least one COVID vaccine dose at the end of October 2021 (source ourworldindata.org). Several factors including costs, accessibility problems, and the absence of medical recommendations have been associated with lower COVID-19 vaccination rates in individuals with schizophrenia [13]. This study indicates that reduced capacity to consent to vaccination may constitute a significant barrier to an efficient vaccination program in this population.

If there is preliminary evidence of the efficiency of targeted vaccination programs for people with mental disorders, our findings are of major importance in cases of vaccine refusal [15]. From an ethical and recovery point of view, autonomy and the right to self-determination are of fundamental importance for people with severe mental disorders. Clinicians faced with a patient's refusal to be vaccinated should thus make an appropriate assessment of the individuals' decision-making capacity using tools such as the MacCAT-T. Importantly both uncertainty and unwillingness to be vaccinated against COVID-19 can be partly reduced by appropriate interventions integrating feedback, and providing clear information on the virus and disease itself [16]. In addition, interventions aiming at enhancing mental capacity for vaccination, which has been shown to be effective and feasible in this population, should be considered as a priority. Indeed, vaccination is not compulsory in France, contrarily to other medical treatments such as psychiatric medications (such as antipsychotics), and to our knowledge, this is also the case at date in other Western medical systems concerning COVID-19 vaccines [17, 18]. It is important that healthcare professionals understand the risks and benefits of COVID-19 vaccination for people with schizophrenia, so that they can support them in reaching an informed decision. Indeed, in the end, it should be left to the individual to weigh the benefits and the risks, and to give informed consent for vaccination, even in individuals with severe mental disorders [2].

Limitations

The primary limitation of this study is its relatively small sample size. Future studies should consider collecting a larger sample size to ensure a representative distribution of the population. Second, this is a single center study in a sample of French individuals with schizophrenia, which

potentially limits the generalizability of our results. Replication of the present study in other countries is needed. Another limitation is the cross-sectional design of our study. Even though we found an association between capacity to consent and lower vaccination rates in the patient group, we cannot conclude a causal relationship between these two variables. Additional studies with a longitudinal design are thus needed.

Author contributions SR and DC designed the study. ME, DC, YL, JA and PT collected the data. SB conducted statistical analyses. SR wrote the first draft of the paper. All the authors were involved in discussing the findings and writing the manuscript. They all approved its final version.

Funding This work was funded by a 2021 ANR Grant, (SCHIZO-VAC; ANR-21-COVR-0017).

Data availability The anonymised dataset is available from the corresponding author on reasonable request.

Declarations

Conflict of interest No authors declare any possible conflicts of interest.

Statement of ethics Participants in the study were treated in accordance with international ethical standards, including APA standards of ethics, and was approved by the hospital's institutional review board (IRB ID: 202100768).

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