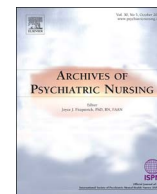




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## Decision-making Capacity for Treatment of Psychotic Patients on Long Acting Injectable Antipsychotic Treatment

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### ABSTRACT

**Objective:** Providing informed, consent requires patients' Decision-Making Capacity for treatment. We evaluated the Decision Making Capacity of outpatients diagnosed with schizophrenia and schizoaffective disorder on treatment with Long Acting Injectable Antipsychotic medication.

**Method:** This is a retrospective, cross-sectional, correlational study conducted at two Depot Clinics in Athens, Greece. Participants included 65 outpatients diagnosed with schizophrenia and schizoaffective disorder on treatment with Long Acting Injectable Antipsychotics.

**Results:** Over half of the participants showed poor understanding of the information given regarding their disease and treatment (Understanding subscale), however > 70% seemed to comprehend the relevance of this information to their medical condition (Appreciation subscale). Moreover, half of the participants reported adequate reasoning ability (Reasoning subscale), whilst patients who gained > 7% of their body weight scored statistically significantly higher in the subscales of Understanding and Appreciation.

**Conclusion:** Our results suggest that there is a proportion of patients with significantly diminished Decision Making Capacity, hence a full assessment is recommended in order to track them down. Further research is needed to better interpret the association between antipsychotic induced weight gain and Decision Making Capacity in patients suffering from schizophrenia or schizoaffective disorder.

### Introduction

Law and medical ethics call for informed consent to be obtained from all patients before treatment initiation (Berg, Appelbaum, Lidz, & Parker, 2001). In recent decades, the law in many countries gives people with mental disorders the right to give or withhold consent for their treatment (Hale, 2010), but mental health law allows and regulates the non-consensual treatment of mental disorders (Garani-Papadatos & Ploumbidis, 2005).

Providing informed consent, requires the patient's Decision-Making Capacity (DMC) for treatment (Hellenic Republic Ministry of Health and Welfare Health, 2005). In certain cases, patients lack capacity to make a decision about their treatment. Determining, therefore, whether patients have the capacity to consent to treatment is considered critical in striking a balance between respecting patients' autonomy whilst

protecting those with cognitive impairment (Appelbaum, 2007).

In patients with schizophrenia, decision-making may be affected by cognitive as well as other factors related to the core symptoms of psychosis (American Psychiatric Association, 1994). A substantial heterogeneity in DMC has been demonstrated in the literature and it has been suggested that a diagnosis of schizophrenia does not necessarily render the patient incapable of making treatment decisions (Jeste, Depp, & Palmer, 2006).

In one of the largest and most well-conducted studies, the MacArthur Treatment Competence Study (Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso, Appelbaum, & Hill-Fotouni, 1997; Grisso, Appelbaum, Mulvey, & Fletcher, 1995), Appelbaum, Grisso and colleagues examined the ability of psychiatric inpatients (hospitalized for schizophrenia or depression) and medically ill inpatients (hospitalized for angina), as well as those of healthy, non-hospitalized

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community controls, to make treatment-related decisions. Overall, the patients with schizophrenia performed poorly on measures of understanding, appreciation, and reasoning compared to the other groups. Moreover, schizophrenia patients often exhibit deficits on measures of DMC compared to controls (Owen et al., 2008).

Nevertheless, the majority of patients hospitalized with schizophrenia performed adequately on any particular measure of decision making ability, and about half did well on all the measures combined. When patients with schizophrenia performed poorly, they usually had more severe psychiatric symptoms, especially disturbances of thought and perception (e.g., disorganized thinking and delusions) (Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso et al., 1997; Grisso et al., 1995).

The aim of this study was to evaluate the DMC of outpatients with schizophrenia on treatment with Long Acting Injectable (LAI) antipsychotic medication. More specifically, the objective of this study was to investigate the level of treatment DMC of the above population using the Greek version of the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) tool, which has been recently translated and validated by Bilanakis, Vratsista, Kalampoki, Papamichael, and Peritogiannis (2013) and also to explore its correlation with other demographic or clinical variables.

## Method

### Study design, setting and sample

A retrospective, cross-sectional, correlational study was conducted from September 2014 to September 2015 at two psychiatric outpatient settings in the region of Athens, Greece. In particular, at the Depot Clinic of Agioi Anargyroi Hospital, Department of Psychiatry and at the Depot Clinic of Byron-Kaisariani Community Mental Health Centre. The target population was all adults using the aforementioned services due to the symptoms of psychosis.

DMC for Treatment was measured and evaluated using the MacCAT-T scale (Bilanakis et al., 2013) for all patients receiving a LAI antipsychotic for at least 26 months. Written informed consent was obtained in order to review patients' medical records. Educational background was not a variable assessed in term of the participants' ability to better perform on the MacCAT-T scale. We correlated three domains namely, adherence to injectable treatment, BPRS scores and weight gain to scores on the MacCAT-T (Bilanakis et al., 2013) scale. All information from the medical records was then compiled for all patients in the study sample.

Depot Clinics Protocol in Greece requires information such as adherence, psychopathology and weight to be documented at the medical record of each patient on therapy with a LAI antipsychotic at every visit.

Inclusion criteria comprised participants being a) at least 18 years old, b) having a diagnosis of schizophrenia, or schizoaffective disorder as established by the structured clinical interview for DSM-IV, c) having been prescribed LAI antipsychotic medication for at least 26 months, regardless of other concomitant medication (Benzodiazepines, sleeping pills and anticholinergics) and initiation time of psychotropics and d) being adherent to treatment, attending at least 90% of the scheduled appointments. Adherence rates were calculated by attendance to scheduled appointments for injection. Patients who missed up to three scheduled appointments, < 10%, were included in the adherent group.

Exclusion criteria were intellectual disability, less than six years of main stream education and unwillingness to participate. There were no exclusion criteria in terms of other concomitant antipsychotic medication or with regard to type, dose schedule or time of onset of the LAI antipsychotic medication. Analyses were restricted to patients who were fully communicating a choice (maximum scores on the ability to express a choice subscale of the MacCAT-T).

Overall patients that accepted to participate in our study had

received a LAI antipsychotic for at least a 26 month period (intervals ranging from two to four weeks) regardless of their previous medication status. Sample size was determined to be up to 63 participants, according to desired statistical power, statistical significance ( $\alpha = 0.05$ ) and the tables of Cohen (Burns & Grove, 2001).

Following complete description of the study to the participants, written informed consent was obtained. Ethical approval for the study was granted by the Research and Ethics Committee of Kapodistrian University of Athens, Faculty of Nursing.

Of the 75 patients eligible to participate in our study, written informed consent was obtained by 68 patients. 3 patients were excluded from the study due to poor adherence. A total of 65 patients were included in our study and their medical records were reviewed.

### Data collection and measures

Data collection was achieved through patients' medical records that were assessed by two researchers (MN, KP) who are both trained Mental Health Nurses. Adherence was assessed based on the attendance or not of patients for their injection on their scheduled appointment. The BPRS (Paneras & Crawford, 2004) scale was the scale used at both Depot Clinics for the assessment of patient's psychopathology and scores were recorded on monthly bases for each patient. Participants' weight was also recorded on a monthly basis, and patients with over 7% weight gain, were recorded as weight gainers.

The Greek version of the MacCAT-T scale was used (Bilanakis et al., 2013), for the assessment of treatment DMC. Since prolonged exposure to available LAI antipsychotic medication is associated with weight gain (Bak, Fransen, Janssen, Os, & Drukker, 2014), our population's weight was assessed. Patients who gained > 7% of their body weight were recorded as weight gainers (Lieberman et al., 2005).

The BPRS scale is one of the most frequently used instruments for evaluating psychopathology in patients with schizophrenia (Paneras & Crawford, 2004). BPRS cutoff scores were calculated based on the criteria of Panera and Crawford (Paneras & Crawford, 2004). The BPRS includes 18 items that address somatic concern, anxiety, emotional withdrawal, conceptual disorganization, guilt feelings, tension, mannerisms and posturing, grandiosity, depressive mood, hostility, suspiciousness, hallucinatory behaviours, motor retardation, uncooperativeness, unusual thought content, blunted affect, excitement, and disorientation (Bell, Milstein, Beam-Goulet, Lysaker, & Cicchetti, 1992). Total scores range from 18 (normal, not at all ill) to 126 (among the most extremely ill patients) (Paneras & Crawford, 2004). A mean BPRS total score of 26 monthly visits was calculated.

The validity and reliability of the Greek version of the MacCAT-T had been tested in a sample of psychiatric inpatients and the results on the rating of MacCAT-T demonstrated excellent interrater reliability, suggesting that this tool is a practical, reliable, and valid instrument that can provide a standardized measure for assessing treatment decision capacity in Greek psychiatric patients, and can be used for evaluation in clinical practice (Bilanakis et al., 2013).

The MacCAT-T (Grisso et al., 1997) is the most widely used questionnaire for the assessment of the DMC. It is a semi-structured interview, usually requiring about 15 to 20 min to be completed plus 2–3 min to be rated by a trained clinician. This tool provides information to patients relevant to their illness, the nature of treatment options and the risks and benefits of each option. Moreover the tool guides the clinician through a disclosure of patients' own disorders and treatment options. Questions to the patient require feedback, and this is used to assess the degree to which patients understand the information (Understanding) and recognize (Appreciating) the relevance of the information for their own situation. In this way the clinician is subsequently led to recognize of the logical process by which the patient has taken the decision to be treated (Reasoning). Finally, the patient is asked to state a treatment choice, according to everything that has been considered (Expressing a choice) (Grisso et al., 1997). The MacCAT-T

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