

Ethical issues arising in research with people with mental health conditions

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Case study

Research ethics challenges in a first episode of psychosis clinic in Latin America

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Description of the research project

Psychotic disorders produce substantial morbidity and mortality, having a devastating effect on patients and their families.¹ Early intervention in these patients improves response to treatment and long-term global functioning.^{2,3} Consequently, early intervention in first-episode psychosis (FEP) has become a public health priority.^{2,4} However, in low-and-middle-income countries (LMICs), the implementation of early intervention services face difficulties such as scarce resources, weak infrastructure, absence of mental health policies, lack of healthcare workforce, and stigma.^{5,6}

In 2014, we began a cohort of FEP patients attending our clinic to contribute to meaningful clinical knowledge in this area and obtain resources to offer the best available clinical care. So far, we have conducted clinical studies on metabolic syndrome and healthy lifestyle,⁷ neuroimaging,⁸ treatment resistance,⁹ social determinants of mental health,¹⁰ epidemiology,¹¹ public policies,⁶ among others.

This case report shares the potential benefits of research for clinical practice in a Latin American setting and exposes ethical issues arising when working with vulnerable populations, such as difficulties in decisional capacity.

Background

Chile has a mixed public-private health service, with around 80% of the population attending the public health system. The Chilean General Guarantee in Health Law took effect in 2005 and ensures rapid access to standardized treatments and financial support for 80 prevalent conditions, including psychotic disorders.^{4,11}

Our program is based at the Instituto Psiquiátrico Dr. J. Horwitz, the largest psychiatric hospital in Santiago, the capital. With 22 inpatient beds and ambulatory services, the Early Intervention Program treats FEP patients between 16 and 30 years. It is a tertiary care center, and patients are usually referred from the emergency department or associated community health services. Our FEP patients frequently need initial inpatient care as they typically present with severe symptoms (mean duration of untreated psychosis is 10.8 (SD 1.2) months). During their hospitalization (mean 32 days), patients are treated by a multidisciplinary team of psychiatrists, psychologists, social workers, occupational therapists, and nurses. In addition, families participate through periodic meetings and a structured psychoeducation program. When patients are capable of consent (usually a few days before discharge), we offer them and their families to participate in our follow-up study cohort. If they consent to participate, we make additional sociodemographic and clinical evaluations, cognitive tests (MATRICS), a blood sample for DNA analysis, and a structural MRI, with a one-year ambulatory follow-up. If they do not consent to participate, they continue treatment as usual in our ambulatory clinic or community center. Considering the number of patients attended, ours is the most extensive first

psychotic episode program in the country. To date, we have recruited 132 FEP patients in our follow-up cohort.

Ethical issues

Autonomy and decision-making capacity

A person's capacity to make judgments regarding medical decisions or participate in research is fundamental to the ethical principle of respect for autonomy and is an essential component of informed consent. Impairments in this capacity are a concern in patients with severe psychiatric disorders like the ones we usually treat in our clinic. For instance, a review of 12 studies of patients with schizophrenia found impaired performance in 10-52% of the sample, compared to 0-18% in controls.¹² This impairment was more frequent on hospitalized patients, patients with greater cognitive impairment, and more negative symptoms.¹² On one hand, this study shows a substantial heterogeneity among people with schizophrenia and non-psychiatric controls, and on the other hand, it suggests that schizophrenia does not impair a person's decisional capacity as a rule.

Decision-making capacity involves different components; the most frequently agreed upon include:

1. Understanding or comprehending the meaning of the relevant information, including benefits and risks.
2. Appreciation of how the information applies and is relevant to one's own condition and situation.
3. Reasoning with the information provided or comparing options based on the person's values and beliefs. In other words, the ability to weigh risks and benefits and consequences of the decision.
4. Evidencing or expressing clearly a choice.

Some patients clearly lack decisional capacity (i.e., patients with severe thought disorders or cognitive impairment, severe brain damage, advanced stages of dementia). The problem is developing a consistent notion of decisional capacity in persons with some but not all mental capacities. We cannot fail to protect someone that cannot decide individually, but, on the other hand, we cannot exclude her from her right to decide on her own if she has decisional capacity.¹³ We are morally committed to imposing minimal restraints on individual choice.¹³ Also, a person deemed incompetent to decide or underaged does not mean that her current values or preferences need not be considered. When this is the case, patients are always asked for an informed assent, and their preferences and values are regarded.

In addition, there is consensus that decisional capacity may vary within a single individual over time. Also, it should be assessed relative to a specific decision at a particular time and context.¹⁴ Considering this, we decided to ask for consent to participate in our cohort the days before discharge, when the patient's decisional capacity is at its most. First, the treating physician decides when the patient has appropriate decisional capacity. Then, she explains the study to the patient and caregivers and asks for informed consent. This kind of approach permits a more comprehensive clinical and decisional capacity evaluation from our standpoint. In addition, the existence of a therapeutic relationship allows the patient and caregivers to ask questions openly in a protected and trustful environment. On the other hand, it has some risks, such as a less systematic evaluation than using standardized instruments and risks of coercion.

One of the most widely used instruments to help clinicians assess decisional capacity is the MacCAT-T.¹⁵ It is based on the four abilities mentioned earlier. However, critics of this instrument agree that this model evaluates abilities necessary for capacity, but they question if these are always sufficient. They cite other important capacities such as the subject's emotions, values, and the authenticity of a subject's choice.¹³ Emotions seem an essential issue to consider in our patients, as there is evidence that depressed patients weigh risks and benefits differently, and they may score well on the MacCAT-T, for instance.^{13,16}

Another relevant challenge faced by our team is the risk of coercion. As exposed earlier, patients are invited to participate in the cohort by their treating physicians. In addition, they are offered resources such as a cerebral MRI or cognitive evaluation that otherwise, they would not be able to access. To minimize this risk, we make clear that they will always receive treatment according to the Chilean General Guarantee in Health Law. In addition, we inform the family or other caregivers. Another relevant aspect we acknowledge is that there are no financial incentives for the investigators, although academic or personal incentives may influence them.

Finally, although there are degrees of capacity and we should aim at maximizing a person's chance of deciding for herself when speaking about a particular decision, there is a need to decide binarily. That is, we need to define who has the final decision-making authority, to avoid endless controversy and discussion.

Conclusions and recommendations

In conclusion, a patient cannot be declared incompetent based on her diagnosis. We should aim to protect a person's decisional capacity and assess it relative to a specific decision and context. This is not always easy, and there are associated risks, such as failure to protect patients that cannot decide individually, or on the contrary, excluding them from their right to decide. Also, we should aim to reduce behaviors that may undermine voluntariness, such as coercion.

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