

Introduction

While there exists an extensive literature on the parameters of proper informed consent in clinical research where human subjects are either included or excluded on the basis of symptoms often identified in patients whose diagnosis is consistent with psychosis, those questions pertinent to the parameters of proper informed consent for such persons are fundamentally unclear. Few research subjects are properly evaluated on the existing criteria for medical and legal consent so long as the patient agrees to proposed treatment plans¹.

In addition to a lack of proper consent screening, patients with psychotic diagnosis' are exposed to further improper treatment due to a lack of understanding on their disorder, and the influences that potential delusions and hallucinations can have on the recovery process as early as the consent evaluation. As many as 98% of schizophrenic patients suffer from cognitive impairment, however, it does not lend itself to a strict diagnostic criteria². This then raises the question of what part of psychosis lends itself directly to a diagnosis, and how this symptom or feature might be better identified, both in cases of medical consent and the court of law. The evaluation of this question came down to one word: ability.

Methods

Prior to beginning research there existed:

- Little solid development on definitions of psychosis and medical consent.
- Virtually no research on the relationships between psychosis and consent.
- No available literature review or database on current developments in this research.

Due to this lack of information, the vast majority of research was centered on creating a comprehensive literature review on what already existed to serve as a foundation for the continuation of this work. For the literature review, information was gathered from a variety of sources, including the DSM-5, physician handbooks, and psychosis-centered case studies conducted within recent years. Once a throughout literature review had been composed and revised by multiple sources, attention was turned to analyzing existing evaluation tools to spark the development of a more effective alternative.

Table 1. Current Evaluation Tools of Medical Consent Comparison³

Tool	Domain	Description	Utility
Mini-Mental State Exam (MMSE)	Attention, Orientation, Memory, Language processing	<ul style="list-style-type: none"> • Brief screening tool • Assesses many cognitive abilities necessary for higher-level cognitive processes (e.g., making an informed consent decision) 	Indicates whether or not a patient needs further screening of cognitive capacity
MacArthur Competence Assessment Tool for Treatment (MacCAT-T)	Understanding, Appreciation, Reasoning, Ability to express a choice	<ul style="list-style-type: none"> • Interactive interview • Uses hypothetical medical situations (e.g., amputation) to model consent process • Allows relevant domains to be discussed between provider and patient 	Demonstrates level of cognitive capacity through the use of hypothetical situations presented from a first-person perspective, as if the patient was making a decision related to his or her own care
Hopemont Capacity Assessment Interview (HCAI)	Understanding, Appreciation, Reasoning, Ability to express a choice	<ul style="list-style-type: none"> • Interactive interview • Uses hypothetical medical situations (e.g., eye infection, intervention related to heart and lungs) to model consent process • Allows relevant domains to be discussed between provider and patient 	Demonstrates level of cognitive capacity through the use of hypothetical situations (e.g., eye infection) presented from a third-person perspective, as if the patient was making a decision related to someone else's care
Capacity to Consent to Treatment Instrument (CCTI)	Understanding, Appreciation, Reasoning, Ability to express a choice	<ul style="list-style-type: none"> • Interactive interview • Uses hypothetical medical situations (e.g., brain cancer, cardiac surgery) to model consent process • Allows relevant domains to be discussed between provider and patient 	Demonstrates level of cognitive capacity through the use of hypothetical situations (e.g., brain surgery) presented from a first-person perspective, as if the patient was making a decision related to his or her own care

Results

Gained from this ten-week study were:

- An extensive understanding of current literature.
- A composed review of standing literature for future publication.
- A comprehensive knowledge of current evaluation tools for both psychosis and medical consent.
- An early understanding of laws on insanity pleas and how they relate to cases of psychosis.
- A grasp on the psychotic experience through the eyes of the caretaker via an interview with physicians in the STEP program.

What these results led to was:

- Plans to create a more effective and patient-centered evaluation tool.
- Awareness of need for universal definitions of psychosis, medical consent, and legal consent.

Future Development

- Publishing review of current literature to establish a clear definition of both consent and psychosis, as well as their relationship.
- Formatting of a new psychosis and consent assessment tool to decrease physician bias in evaluation process.
- Studying psychotic patients' personal experiences with the mental health system to improve outside understanding, with permission of IRB review.

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References

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