

Documenting Informed Consent for Research Participants with Schizophrenia

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Problem: Although the ability of persons with schizophrenia to provide informed consent continues to be debated, we must embrace the challenge of conducting the research needed to advance knowledge for evidence-based practice while upholding our ethical obligation to protect vulnerable persons.

Evidence: We examined the acceptability, feasibility, responses and correlates of a group of outpatients with schizophrenia to a tool designed to measure comprehension before obtaining informed consent to participate in a larger study.

Strategy: Because consent research is limited in persons with schizophrenia, our findings will inform researchers and clinicians who wish to help patients make meaningful treatment decisions.

Practice Change: We used the Evaluation to Sign Consent Form (ESC, DeRenzo, Conley & Love, 1998) to document comprehension before obtaining consent in 29 schizophrenia outpatients. ESC addresses orientation, study risks, study activities, study withdrawal and emergency procedures.

Evaluation: Outcomes included subject responses to ESC items.

Results: All subjects demonstrated comprehension using the ESC. Twenty-three subjects (79%) correctly answered all items. Six subjects required prompts on at least one item, two subjects required prompts on 2 items. Most subjects requiring prompts were male ($n = 5$) and Caucasian ($n = 4$). A significant relationship was observed between living arrangement and the need for prompts ($\chi^2 = 9.4$, $p = 0.24$). Possible explanations are executive functioning deficits and/or severity of symptoms, both of which are associated with difficulties in community living.

Recommendations: We found persons with schizophrenia willing to respond to questions documenting comprehension, and the majority of our sample did so without difficulty. Psychiatric nurses should consider documenting comprehension with the ESC due to its availability, time efficiency and utility.

Bibliography: DeRenzo, E.G., Conley, R.R., & Love, R. (1998). Assessment of the Capacity to give consent to research participation. *Journal of Healthcare Law and Policy*. 1(1), 66-87.