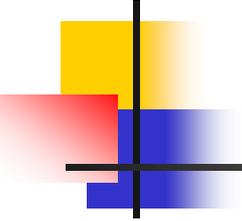


Assessing Decisional Capacity in Neuroscience Research

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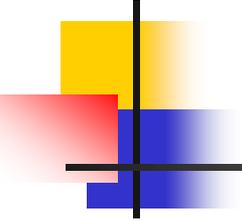
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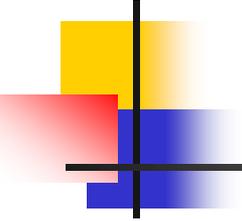
Overarching Principles of Capacity Assessment

- Potential research participants are entitled to a presumption of capacity
- Deprivation of decisionmaking power due to impaired capacity involves a significant loss of rights—hence assessments should be done with great care
- Efforts should be made to ameliorate deficits, when possible, before concluding person is incapable



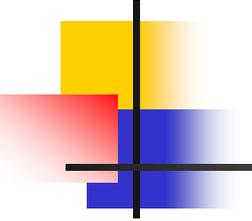
Need for Individualized Assessment

- Diagnosis not good predictor of degree of capacity, e.g.,
 - Of 90 subjects with severe mental illness, 25% were deemed incompetent by experts (Kim et al., BJP, 2007)
 - Only 47% of 59 patients with mild-moderate AD judged competent by 2/3 psychiatrists (Karlavish et al., AJGP, 2008)
- Nor are standard assessment tools
 - In 37 patients with mild to moderate AD those scoring ≤ 19 were unlikely to have capacity, whereas those scoring ≥ 26 were highly likely to be competent—but MMSE not helpful in intermediate range (Kim & Caine, Psychiatr Serv, 2002)



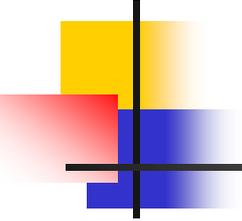
Approaches to Assessing Impaired Capacity

- Screening increasingly prevalent in studies of higher risk (e.g., DBS) or with more impaired participants (e.g., schizophrenia)
- Can be done with:
 - Clinical interview—but reliability a problem and impairment underestimated (Marson et al., JAGS, 2000; Raymont et al., Lancet, 2004)
 - Symptom measures (e.g., MMSE, BPRS)—but poorly predictive
 - Competence screening instruments (Dunn et al., 2006)



Assessment Tools Based on Elements of Decisional Capacity

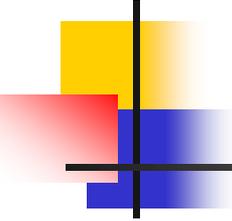
- Evidencing a choice
 - Does the person have the ability to express a stable choice about research participation?
- Understanding disclosure of information
 - Does the person understand the disclosed information about the nature of the research project, procedures, risks/benefits, alternatives?



Elements of Decisional Capacity - 2

- Appreciation of the nature of the situation and its consequences
 - Does the person have the ability to appreciate the effects of a decision about research participation on his/her own situation?
- Reasoning (ability to weigh risks and benefits)
 - Does the person have the ability to compare alternative options in light of their risks and benefits?

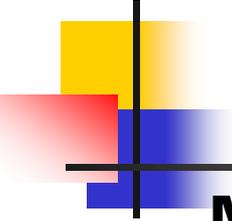
(Appelbaum & Roth, 1982)



Assessment Tools – MacCAT-CR

- Most widely used — >50 published studies
- Assesses understanding, appreciation, reasoning, and choice
- Series of disclosures followed by questions and reasoning tasks
- Takes approximately 15-20 minutes
- Provides quantitative scores, but not competent/incompetent decision

(Appelbaum & Grisso, 2001)



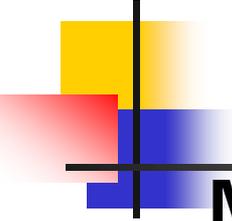
MacCAT-CR Understanding

MacCAT-CR Disclosure

U-1 (ii) Disclosure (Procedures of Project)—

Patients who agree to be in this study will do the following things:

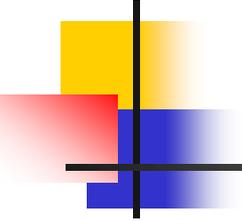
- First, they will stop all medications for schizophrenia for 2 weeks; this is called the washout period
- Second, after the washout period, they will receive either the new medication or the old medication for 8 weeks; this is called the treatment phase of the study
- Altogether, the study lasts 10 weeks; 2-week washout and an 8-week treatment phase



MacCAT-CR Understanding

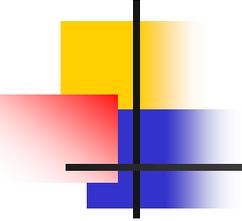
MacCAT-CR Questions

- “Do you have any questions about what I just said?”
- “Can you tell me your understanding of what I just said?”
- If subject fails to mention spontaneously, ask
 - “How long will the research study last?”
 - “What will happen to your medication at the beginning of the study?”
 - “What medication will you receive in the study?”



Understanding - Scoring

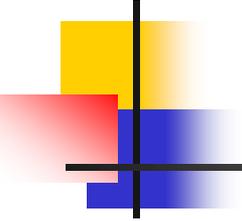
- 2 Subject recalls content of item and offers fairly clear version.
- 1 Subject shows some recollection of item content, but describes in a way that renders understanding uncertain, even after efforts to clarify
- 0 Subject does not recall, is clearly inaccurate, or seriously distorts meaning



Assessment Tool - UBACC

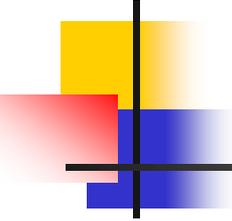
- 10-item scale—5 mins. to administer
- Inquires about understanding, appreciation, and reasoning
- Good interrater reliability
- Moderate (0.3-0.5) item correlations with MacCAT-CR subscales
- 9 published studies

(Jeste et al., AGP, 2007)



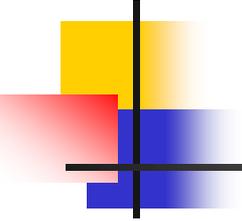
UBACC Sample Questions

- Understanding: What is the purpose of the study that was just described to you?
- Appreciation: Do you believe this is primarily research or primarily treatment?
- Reasoning: What makes you want to consider participating in this study?
- Scoring: 0-2



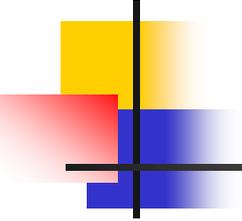
Use of Screening Instruments

- Thresholds can be set based on data from similar populations or *a priori* judgments
- Degree of capacity required will vary depending on study's complexity and risk
- Failure can trigger clinical evaluation and/or remediation
- Retesting after remediation allows participation for those able to improve performance
- But investigator should be permitted to exclude even subjects who pass the screen



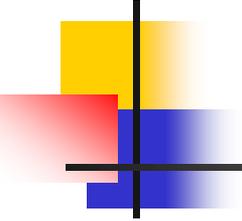
Who Should Do the Screening?

- NBAC (1999) suggested independent evaluation—but that carries costs in time and money
- Use of objective measures may allow clear documentation of decisions and obviate the need for outside assessor



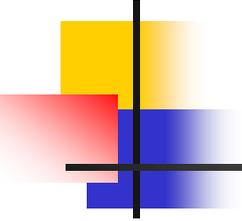
Conclusions

- Neuropsychiatric illness may lead to decisional impairment, but is neither a necessary nor sufficient condition for incapacity
- Screening for incapacity can be done reliably and validly, with acceptable cost
- Desire to protect incapable subjects must be balanced against interest in allowing people to make their own decisions whenever possible



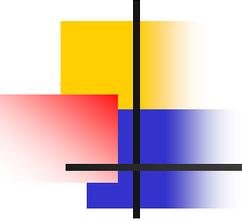
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