Assessing Decisional Capacity in Neuroscience Research

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Overarching Principles of Capacity Assessment

- Potential research participants are entitled to a presumption of capacity.
- Deprivation of decision-making 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 (Karlawish 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)
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.
References - 1

- Appelbaum PS, Roth LH. Competency to consent to research: a psychiatric overview. Arch Gen Psychiatry 1982;39:951-8.
References - 2


