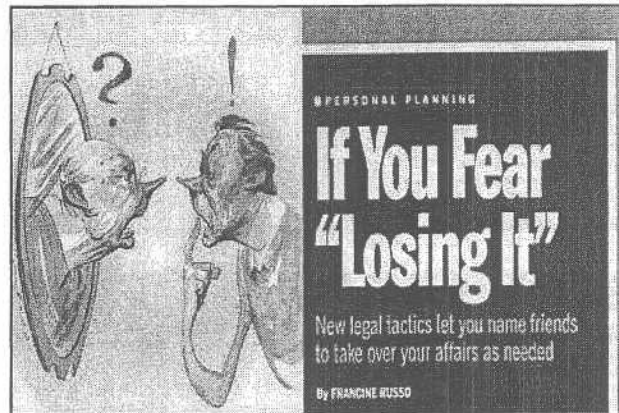


Decision-Making Capacity Assessment and Surrogate Consent

Daniel Marson, J.D., Ph.D.
Associate Professor of Neurology
Associate Director, Alzheimer Disease Research Center
University of Alabama at Birmingham
Birmingham, Alabama USA
dmarson@uab.edu

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“As our society ages, clinical assessment of higher order functional capacities has become increasingly important. In areas like financial capacity, medical decision making capacity, medication compliance, and driving, society has a strong interest in accurately discriminating intact from impaired functioning.”

Marson et al. (2000) *Archives of Neurology*, 57: 877-844

Questions

- What is decisional capacity?
- Are there different types of decisional capacity?
- How does one clinically assess decisional capacity?
- Can one use objective instruments to assess capacity?
- How consistent are clinicians in judging capacity?
- What cognitive (and emotional) functions are associated with loss of decisional capacity?
- How is decisional capacity lost over time?

Outline

- Capacity/Competency Concepts
- The Challenge of Assessing Capacity
- Medical Decision Making Capacity (MDC)
- Assessing MDC in Alzheimer's Disease
- Research Consent Capacity
- Assessing Research Consent Capacity in AD
- Surrogate or Proxy Consent to Research Participation
- Future Developments

Capacity Concepts

Capacity Concepts

■ What is a legal competency?

"A threshold requirement, imposed by society, for an individual to retain decision making power in a particular activity or set of activities."

Capacity Concepts

■ Capacity versus competency:

- ◆ Related but not interchangeable terms
- ◆ Capacity/incapacity:
 - + denotes a clinical status determined by clinician
 - + clinical competency judgments
- ◆ Legal competency/incompetency:
 - + denotes a legal status determined by a judge
 - + involves consideration of non-clinical factors

Capacity Concepts

■ Multiple competencies:

- ◆ not a unitary concept or construct
- ◆ "competency to do what?"

Capacity Concepts

Civil competency issues in clinical practice:

- ◆ manage financial affairs
- ◆ enter into contracts
- ◆ make a will
- ◆ consent to medical treatment
- ◆ consent to research participation
- ◆ execute advance directives
- ◆ live independently
- ◆ select living situation
- ◆ driving

Capacity Concepts

■ Capacity is a medical-legal construct:

- ◆ hypothesized condition that cannot be directly observed
- ◆ only behavioral signs, indications observable, measurable

Capacity Concepts

■ Legal presumption of competency:

- ◆ normal adult achieving age of majority presumed competent
- ◆ burden of proof lies with party alleging person is incompetent

Capacity Concepts

Diagnosis does not constitute incompetency

What does a diagnosis of vascular dementia tell you about a person's capacity to drive?

Relevant to issue of driving capacity

But not determinative of driving capacity issue

Have to examine functional abilities constituent to driving

Capacity Concepts

Cognitive impairment does not constitute incompetency

What does a MMSE score of 22 tell you about a person's capacity to make medical treatment decision for herself?

Relevant to issue of consent capacity

But not determinative of consent capacity

Examine functional abilities constituent to consent capacity

Capacity Concepts

■ Competency can be intermittent:

- ◆ competency status can fluctuate over time
- ◆ competency can be lost and later restored
- ◆ intermittent nature of competency varies across conditions
- ◆ contrast schizophrenic patient and AD patient

Challenges in Assessing Capacity/Competency

Challenges in Assessing Competency

■ Capacity assessment poorly understood area of practice

■ Many knowledge gaps for clinicians:

- ◆ lack of conceptual knowledge of capacity (Marson & Harrell, 1996)
- ◆ little or no formal assessment training (Marson et al. 1994)
- ◆ few standardized, capacity specific measures (Marson et al. 1995)

Challenges in Assessing Competency

■ Problems with clinician capacity assessments:

- ◆ confuse mental status and competency (McKinnon et al. 1989)
- ◆ rely on clinical impressions and MMSE scores to make judgments of competency (Marson et al. 1994)
- ◆ fail to accurately assess capacity in older adults (Finen et al. 1990)

Research Question

“How consistent are experienced physicians in judging the medical decision making capacity of dementia patients?”

Consistency of Competency Judgments

■ Subjects:

- ◆ 16 older controls
- ◆ 29 patients with mild AD (MMSE ≥ 20)

■ Physicians:

- ◆ 5 medical center MDs
- ◆ 2 neurologists, 2 geriatricians, 1 geriatric psychiatrist
- ◆ older adults 80% of practice
- ◆ average of 67 competency cases handled per physician

Consistency of Competency Judgments

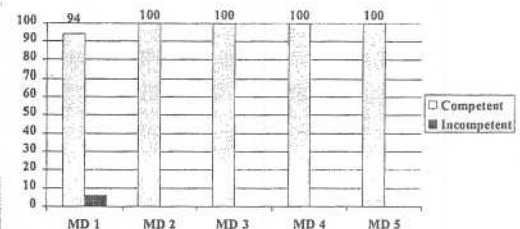
■ Procedures:

- ◆ All subjects administered a competency interview focusing on medical decision making capacity
- ◆ Interviews videotaped
- ◆ Each physicians individually reviewed videotapes
- ◆ Blinded to subject dx and NP test performance
- ◆ Competency judgment: competent or incompetent?

Physician Competency Judgments (%)

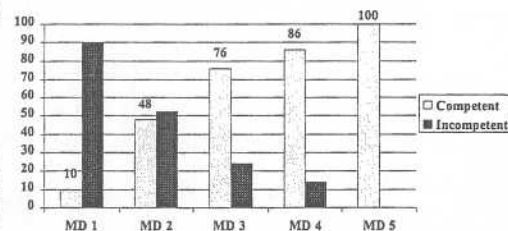
Normal Controls [n=16]

Marson et al. 1997 JAGS



Physician Competency Judgments (%)

Mild AD Patients [n=29]



Marson et al. 1997 JAGS

Consistency of Competency Judgments

Results:

judgment agreement high for controls (98%, $k=1.0$)

judgment agreement low for AD patients (56%, $k=.14$)

real difference in competency judgment reliability

across control and AD groups

Research Question

"If they first receive training in competency assessment, how consistent are experienced physicians in judging the medical decision making capacity of dementia patients?"

Consistency of Competency Judgments

Subjects:

- ◆ 10 older controls
- ◆ 21 patients with AD (mild and moderate)

Physicians:

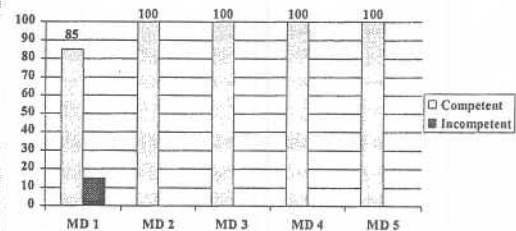
- ◆ 5 medical center MDs
- ◆ Training: judgments on five defined consent abilities
- ◆ then made overall competency judgment

Standards for Capacity to Consent

- S1: capacity simply to "evidence" a treatment choice
- S3: capacity to "appreciate consequences" of choice
- S4: capacity to provide "rational reasons" for choice
- S5: capacity to "understand" treatment situation, treatment choices, respective risks/benefits
- [S2]: capacity to make the "reasonable" treatment choice (when alternative is manifestly unreasonable)

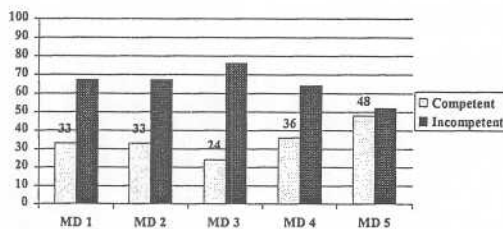
Physician Competency Judgments (%)

Normal Controls [n=10] *JAGS Marson et al. 2000*



Physician Competency Judgments (%)

AD Patients [n=21]



Marson et al. 2000 JAGS

Consistency of Competency Judgments

Results:

- agreement high for controls (95%, $k=1.0$)
- agreement good for AD patients (76%, $k=.48$)
- *competency assessment training enhances clinicians' judgment consistency

Challenges of Assessing Competency

- Capacity assessments are challenging
- But the assessment process can be improved:
 - ◆ sound conceptual understanding of capacity assessment
 - ◆ knowledge of existing empirical research
 - ◆ developing new research capacity studies
 - ◆ capacity assessment training and experience
- Ongoing challenge: moving from a finding of performance impairment to a categorical judgment
- Discriminating competency from incompetency?

Medical Decision Making Capacity (Treatment Consent Capacity)

Capacity to Consent to Treatment

- Capacity to consent to, or refuse, treatment
- Specific competency under the civil law
- Crucial element of informed consent doctrine:
 - ◆ Informed
 - ◆ Voluntary
 - ◆ Competent: mental and emotional capacity to consent
- Implicates issues of professional liability

Capacity to Consent to Treatment

- “Medical” competency:
 - ◆ Issue arises in medical setting
 - ◆ Involves a health care decision maker
 - ◆ Decisions rarely subject to judicial review
- Important issue in managing dementia patients

Functional Abilities Related to Treatment Consent Capacity

- “evidencing” a treatment choice
- “appreciating” personal consequences of choice
- providing “rational reasons” for treatment choice
- “understanding” treatment situation and choices
- making “reasonable” treatment choice [discredited]

Consent Capacity and Dementia

Potential impact of dementia on consent capacity:

- ◆ learning/retaining new medical information
- ◆ understanding simple medical concepts
- ◆ recalling relevant historical information: values, experiences
- ◆ impairment of reasoning and judgment
- ◆ expressing preferences and choices
- ◆ distortion of treatment situation/choices (delusions, confabs)
- ◆ vulnerability to undue influence and coercion

Assessing Medical Decision Making Capacity in Alzheimer's Disease

Research Question

"Could a psychometric instrument be developed to measure loss of treatment consent capacity in patients with dementia?"

Consent Capacity Instrument

Capacity to Consent to Treatment Instrument (CCTI)

- Psychometric measure
- Evaluates the five consent abilities
- Two specialized clinical vignettes:
 - ◆ Hypothetical cardiac and neoplasm conditions
 - ◆ Treatment alternatives with risks/benefits
 - ◆ Presented simultaneously orally and in writing
 - ◆ Questions examine each consent ability
- Scoring system: performance score and capacity outcome

Standards for Capacity to Consent

S1: capacity simply to "evidence" a treatment choice

S3: capacity to "appreciate consequences" of choice

S4: capacity to provide "rational reasons" for choice

S5: capacity to "understand" treatment situation, treatment choices, respective risks/benefits

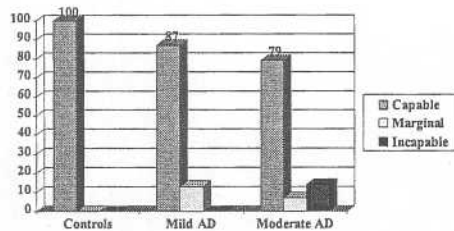
[S2]: capacity to make the "reasonable" treatment choice (when alternative is manifestly unreasonable)

CCTI Video

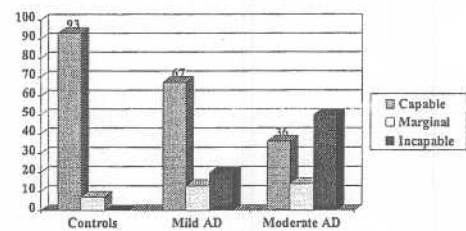
CCTI Performance by LS and Group

	N	S1 Evidence Choice	S3 Appreciate Consequences	S4 Rational Reasons	S5 Understand Choices
		0-4	0-10	0-12	0-70
Controls	15	4.0 (0.0)	8.7 (1.2)	10.3 (3.8)	58.3 (6.6)
Mild AD	15	3.9 (0.4)	7.1 (2.0)	6.1 (3.4)	27.3 (9.6)
Mod AD	14	3.6 (0.9)	5.9 (2.7)	2.3 (2.4)	17.9 (10.6)

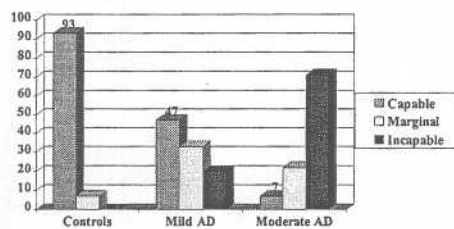
CCTI Capacity Outcomes (%)
S1: Evidencing a Treatment Choice



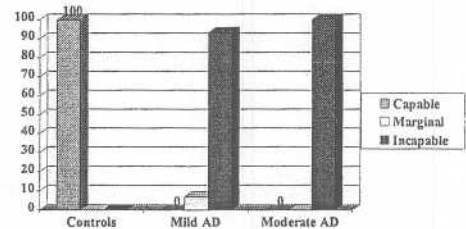
CCTI Capacity Outcomes (%)
S3: Appreciate Consequences of Choice



CCTI Capacity Outcomes (%)
S4: Rational Reasons for Choice



CCTI Capacity Outcomes (%)
S5: Understand Treatment Situation/Choices



Summary of CCTI Study Findings

Mild AD patients performed adequately:

- ♦ evidencing a choice (S1)
- ♦ making reasonable choice (S2)
- ♦ appreciating consequences (S3)

Mild AD patients had difficulty:

- ♦ providing reasons for choice (S4)
- ♦ understanding and recalling treatment information (S5)

Mild AD patients may lack competency to consent

Neuropsychological Predictors of Medical Decision Making Capacity in Alzheimer's Disease

Neuropsychological Predictors of CCTI Performance for AD Patients [n=29]

S5: Understanding Treatment Situation and Choices

	r	p	Adj R ²	p
DRS Conceptualization	.81	.0001	.70	.0001
Boston Naming Test	.72	.0001	.11	.001
WAIS-R Comprehension	.72	.0001		
WAIS Similarities	.67	.0001		
DRS Initiation/Persev	.64	.0002		

Neuropsychological Predictors of CCTI Performance for AD Patients [n=29]

S4: Providing Rational Reasons for Treatment Choice

	r	p	Adj R ²	p
DRS Initiation/Persev	.60	.0005	.36	.0008
CFL	.57	.002		
Tokens	.48	.01		
DRS Attention	.46	.01		
Trails A	-.45	.02		

Neuropsychological Predictors of CCTI Performance for AD Patients [n=29]

S3: Appreciating Consequences of Treatment Choice

	r	p	Adj R ²	p
Trails A	-.58	.001		
WAIS-R Comprehension	.56	.002		
DRS Conceptualization	.50	.006		
CFL	.48	.009	.58	.0001
Simple auditory compreh	.45	.01		

Neuropsychological Predictors of CCTI Performance for AD Patients [n=29]

S1: Evidencing a Treatment Choice

	r	p	Adj R ²	p
Simple auditory comprehen	.66	.0001	.44	.0001
Boston Naming Test	.62	.0003		
WAIS Similarities	.54	.003		

Summary of NP Models for CCTI

- S1: Evidencing Choice- simple auditory comprehension
- S3: Appreciate Consequences- ECF /expressive (CFL)
- S4: Reasoning- ECF /expressive/semantic (DRS Initiation)
- S5: Understanding- abstraction (DRS Conceptualization)
semantic knowledge (Boston Naming)
[*immediate and delayed recall?]

Marson et al. 1995 Archives of Neurology
Marson et al. 1996 Neurology

Capacity to Consent to Research Participation

Capacity to Consent to Research

- Capacity to consent to/refuse research participation
- Emerging as specific competency under the civil law
- Not all states have laws or regulations addressing:
 - ◆ capacity to consent to research
 - ◆ proxy consent to research participation
 - ◆ research on people with mental/cognitive impairment
- Topic that is receiving increased state attention

Capacity to Consent to Research

- Related but distinct from treatment consent capacity
- Arises in a research as opposed to treatment context
- "Therapeutic misconception"
- Risks/benefits different from than treatment situation
 - ◆ placebo assignment
 - ◆ no treatment effect
- IRB oversight of research consent process/procedures
- Capacity more focused on a written consent form
- Reading comprehension of greater importance

Capacity to Consent to Research

- Similar conceptual framework to informed consent:
 - ◆ Informed
 - ◆ Voluntary
 - ◆ Competent
- Same conceptual approach to assessment:
 - ◆ Still examine same set of functional abilities
- Similar challenges in:
 - ◆ distinguishing intact from impaired abilities
 - ◆ translating findings into categorical judgment

Functional Abilities Related to Research Consent Capacity

- "evidencing" a research participation choice
- "appreciating" personal consequences of choice to participate or non participate in research
- providing "rational reasons" for participation or non-participation
- "understanding" research protocol and procedures

Assessing Research Consent Capacity in Alzheimer's Disease

Assessing Research Consent Capacity

- Recent study of research consent capacity in AD patients
Kim et al. *American Journal of Psychiatry* 2001; 158:712-717
- McArthur Competence Assessment Tool: semi-structured interview for research consent capacity
- 37 mild/moderate AD patients; 15 older controls
- 3 expert clinicians were criterion standard
- Instrument: 84% of AD pts incapable on at least one ability
- Clinicians: 62% of AD pts incapable on at least one ability

Capacity to Consent to Research

- Conclusion: Even mild AD patients may have impaired research consent capacity
- How to differentiate capable from incapable subjects remains challenging despite use of standardized tools
- Our methods of assessment are improving!
- But our understanding of the line between competence and incompetence remains fuzzy

Approaches to Assessing Research Consent Capacity

- Ultimately consent capacity is a clinical judgment
- Needs to have the proper conceptual basis
- It can be based on variety of information sources:
 - ◆ Clinical interviews with the patient and family
 - ◆ Interview/checklist approach
 - ◆ Use of specific capacity measures
 - ◆ Use of capacity sensitive neuropsychological test measures
- Judgment needs to be documented

Competency Assessment Checklist

Surrogate or Proxy Consent to Research Participation

Proxy Consent to Research Participation

- Starting point for IC: Consent of research subject
- If subject is incapable, then proxy consent is needed for subject to participate in research
- Who can legally provide such proxy consent?

Proxy Consent to Research Participation

- Still unclear:
 - ◆ Few states have enacted specific laws or regulations governing proxy consent to research
 - ◆ Existing laws focused on MI/MR protections as opposed to dementia research needs
 - ◆ California recently enacted a statute in this area
 - ◆ Some states use proxy hierarchies for treatment consent
 - ◆ In states like New York, currently no guidance

Proxy Consent to Research Participation

- Past practice: Family caregiver gives proxy consent through practice of “dual consent”
 - ◆ Strong moral basis for this
 - ◆ Knows well the subject’s values and preferences
 - ◆ Provides “substituted judgment” for incompetent person
- ◆ Dual consent approach:
 - + consents from both caregiver and subject with dementia
 - + proxy consent built into informed consent process

Proxy Consent to Research Participation

- Problem: Family caregiver may not be subject’s legally authorized representative (LAR)—practice violate state law?
- Problem: Dual consent approach may avoid issue of actually evaluating subject’s competency, before seeking proxy consent
- Problem: Caregiver proxy consent does not address ethical issue of risk-benefit analysis for research participation?
 - ◆ What is level of risk to incompetent participant?
 - ◆ Minimal? Slightly more than minimal? More than minimal?
 - ◆ Is there any direct benefit to the incompetent participant?
- *Regulatory changes on the horizon

California Statute on Research Proxy

- California proactively addressed many of these issues in a law approved in September 2002. [Handout]
- Prior California law prohibited subject’s involvement in any research without their informed consent
- New statute authorizes proxy consent for research:
 - ◆ Institution has IRB assurance under HHS regulations
 - ◆ Institution obtains informed consent in accordance w regulations
 - ◆ Limited to studies of cognitive impairment, lack of capacity, or serious or life threatening diseases and conditions of participants
 - ◆ Subject does not dissent
 - ◆ Proxy decision maker must have “reasonable” knowledge of subject

California Statute on Research Proxy

- Establishes a proxy hierarchy for decision making
- Statute represents a significant effort and accomplishment on the part of universities and state dementia research groups
- One unaddressed issue pointed out by some bioethicists
- Statute empowers designated proxies to consent to research on behalf of incompetent subject, but does not address the cost-benefit analysis ethical concern raised
- Question: Should proxies under the statute have full authority to enroll incompetent dementia patients in research that involves greater than minimal risk and has no direct benefit?

Future Developments

- Greater federal regulation of research involving noncompetent adult research subjects
 - ◆ National Human Research Protections Advisory Committee
 - ◆ Examining issues of informed and proxy consent in cognitively impaired populations
 - ◆ Issuing a report to OHRP
- Greater IRB scrutiny of informed consent process with cognitively impaired patients
 - ◆ Investigators need to establish process for evaluating consent capacity
 - ◆ Documentation of evaluation beyond possessing a written consent form

Future Developments

- Greater attention to state laws/regulations related to proxy consent for research
 - ◆ Potential danger of research shutdown
 - ◆ Proactive approach like that of California indicated
 - ◆ What are your state laws (if any) regarding proxy consent?
 - ◆ What is the definition of a LAR in your state?
- More research studies that examine these issues and provide valuable empirical data on informed and proxy consent in dementia populations

Collaborators

Department of Neurology

Randall Griffith, Ph.D.
Katherine Belue, B.S.
Anna Sicola, B.S.
Sara Krzywanski, M.S.
Edward Zamrini, M.D.
Lindy Harrell, M.D., Ph.D.

Department of Biostatistics

Alfred Bartolucci, Ph.D.
Nickie Burst
Lisa Irby

Department of Education

Scott Snyder, Ph.D.

Department of Psychology

Virginia Wadley, Ph.D.

National Institute on Aging

Alzheimer's Disease Research Center (Harrell, PI)

A Longitudinal Study of Loss of Financial Capacity
in Alzheimer's Disease (ADRC Project 2) (Marson, PI)

Physician Judgments of Competency in AD
(Pilot Grant) (Marson, PI) (1994)

National Institute of Mental Health

Studies of Financial Capacity in Alzheimer Disease
(1 R01-55247-A2) (Marson, PI)

Alzheimer's Association

The Competency of Alzheimer Patients to Make
Informed Treatment Decisions (PRG91-122)

Longitudinal Studies of Loss of Competency in
Alzheimer's Disease (IIRG93-051)