

Introduction

- ▶ Recent empirical ethics research underscores similarities in decision-making capacity between medically ill and mentally ill research subjects.
- ▶ There is substantial overlap between mentally ill and non-mentally ill subjects in many aspects of informed consent, including motivation, willingness, therapeutic misconception, executive dyscontrol, and congnitive impairment.
- ► The debilitating nature of illness in general raises concerns with the decision-making of patients across diagnoses.
- ► General and mental health functioning may consequently have an impact on decision-making in general.
- ▶ Diagnosis is not an adequate basis for challenging decision-making capacity, so investigators and IRBs can benefit from information on factors beyond diagnosis that identify subjects at increased risk for impaired capacity.

Methods

Subjects

- 52 mentally ill subjects:45 stable inpatients
- 7 outpatients from a site with greater ethnic diversity
- Met DSM IV-R criteria for either schizophrenia or schizoaffective disorder

51 medically ill subjects:

- From a single medical school diabetes clinic
- Diagnosed with Type 1 or Type 2 diabetes mellitus

57 comparison subjects:

- No acute or chronic condition
- Likely to match patients in age, education and ethnicity

No significant differences between groups in sex, college education, ethnicity, length of illness. Mentally ill subjects scored lower on the MMSE than the other groups. Mean score on the PANSS was 64.6, (sd = 14.94, median = 62; above average impairment).

Measures

MacArthur Competence Assessment Tool – Clinical Research (MacCAT-CR)

- Adapted to an hypothetical outpatient antibiotic trial
- Randomized, blinded, non-life-threatening risks
- Probing strategies made explicit to improve subject performance

SF-36 (Short Form-36) health-related quality-of-life tool

MMSE (Mini-Mental State Examination)

PANSS (Positive and Negative Syndrome Scale, mentally ill subjects only)

Background Information Form (demographics, prior research, length of illness, view of prognosis)

Resulte

Diagnosis and MacCAT-CR scores

Mentally ill subjects scored lower than the other two groups on all subscales (Table 2)

77% of mentally ill subjects scored 23 points or higher on the 26 point Understanding scale

80.8% of mentally ill subjects scored 6 or more points on the 8-point Reasoning subscale

69.2% of mentally ill subjects scored 4 or more points on the 6-point Appreciation scale

And 88.5% of mentally ill subjects scored 2 out of 2 points on the Choice subscale

These are scores achieved by over 98% of comparison subjects. Diabetic subjects scored comparably with comparison subjects on all subscales but Appreciation, where they scored lower.

Bivariate Associations Between MacCAT-CR & Demographic Variables

MacCAT-CR scores were not significantly associated with age, ethnicity, sex, or number of years ill.

Level of education was significantly correlated with scores on the Understanding, Appreciation, and Reasoning scales among all groups considered together, and among mentally ill subjects.

Prior research experience was associated with higher Appreciation scores among all groups taken together.

For all groups taken together, higher MMSE scores correlated with higher Understanding, Appreciation, Reasoning, and Choice scores (Table 3).

PANSS subscale scores for mentally ill subjects correlated strongly with lower MacCAT-CR scores

- Positive Symptoms correlated with lower Appreciation and Reasoning:
- Negative Symptoms correlated with lower Understanding and Appreciation;
- General Symptoms correlated with lower scales across the

SF-36 Scores

For all subjects regardless of group, higher SF-36 scores on Physical Functioning and Role-Emotional correlated significantly with higher scores on MacCAT-CR Understanding, Appreciation, and Reasoning.

Among mentally ill subjects, SF-36 Physical Functioning correlated with MacCAT-CR Understanding, Appreciation, and Reasoning.

Stepwise Regressions

In all final models, three variables – MMSE scores, SF-36 Physical Functioning scores, and schizophrenia/schizoaffective diagnosis – accounted for 57% of the variance in MacCAT-CR scores in Understanding, 48% of the variance in Appreciation, and 37% of the variance in Reasoning.

Higher MMSE and physical functioning scores were associated with higher scores on each MacCAT scale.

A Direct Comparison of Research Decision-Making: Mentally ill, Medically ill, and Non-ill Subjects

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Table 1.

Table 3.

Demographics and MMSE for the three groups

	Disorder	Subjects	Diabetes	Difference	P
Age Mean (SD) Median	n = 52 37.79 ^a (11.67) 38.5	n = 57 41.04 ^{a,b} (13.16) 41	n = 51 47.00 ^b (16.61) 48	$F_{(2,157)} = 5.80$.004
Ethnicity White African American Hispanic Native American	n = 52 80.8% (42) 9.6% (5) 7.7% (4) 1.9% (1)	n = 57 71.9% (41) 19.3% (11) 7.0% (4) 1.8% (1)	n = 51 88.2% (45) 5.9% (3) 3.9% (2) 2.0% (1)	Overall, $\chi^{2}_{(6)} = 5.99$ White vs other, $\chi^{2}_{(2)} = 4.50$.42 .11
Gender Females Males	n = 52 23.1% (12) 76.9% (40)	n = 57 42.1% (24) 57.9% (33)	n = 51 35.3% (18) 64.7% (33)	$\chi^2_{(2)} = 4.48$.11
Education Less Than BA BA or More	n = 51 84.3% (43) 15.7% (8)	n = 57 86.0% (49) 14.0% (8)	n = 51 70.6% (36) 29.4% (15)	$X^2_{(2)} = 4.26$.12
Length of Illness in Years	n = 51 16.79 (11.89)	n = 21 13.19 (11.47)	n = 51 17.00 (9.54)	$F_{(2,120)} = 1.01$.37
Perceived Prognosis Stable or Getting Worse Getting Better	n = 51 72.5% (37) 27.5% (14)	n = 23 91.3% (21) 8.7% (2)	n = 51 74.5% (38) 25.5% (13)	Overall $\chi^2_{(2)} = 3.38$.18
MMSE Mean (SD) Median	n = 45 27.29 ^a (2.95) 28	n = 57 28.56 ^b (1.34) 29	n = 51 28.41 ^b (1.46) 29	$F_{(2,152)} = 5.91$.003

Note: Means with different superscripts differ significantly, per Tukey HSD follow-up contrasts at the .005 level.

		MacCAT_CR Understanding	MacCAT_CR Appreciation	MacCAT_CR Reasoning	MacCAT_CR Expressing a Choice
			Among Al	l Subjects	
	r	.687	.597	.488	.267
MMSE	p	≤.0005*	≤.0005*	≤.0005*	.001*
	n	151	153	153	153
			Among Menta	lly Ill Subjects	
MMSE	r	.802	.718	.547	.262
	p	≤.0005*	≤.0005*	≤.0005*	.083
	n	45	45	45	45
		0071 1			

Correlations of MMSE with MacCAT-CR Scales

Table 2. MacCAT-CR Scores for the Three Groups.

MacCAT-CR Scale	Schiz/ SchizoAff Disorder	Comparison Subjects	Diabetes	Test of Overall & Pair-wise Group Differences
Understanding	n = 52	n = 57	N = 49	Overall: Kruskal-Wallis $\chi^2_{(2)} = 22.34$, $p < .001*$. Mental Illness vs Diabetes: Mann-Whitney U z = -4.14, $p < .001*$. Mental Illness vs Controls: Mann-Whitney U z = -3.66, $p < .001*$.
Mean (SD)	22.42 (6.03)	25.46 (1.16)	25.47 (1.42)	
Median	25	26	26	
Appreciation	n = 52	n = 57	N = 51	Overall: Kruskal-Wallis $\chi^2_{(2)} = 29.82$, $p < .001*$. Mental Illness vs Diabetes: Mann-Whitney U z = -2.90, $p < .004*$. Mental Illness vs Controls: Mann-Whitney U z = -5.28, $p < .001*$. Diabetes vs Controls: Mann-Whitney U z = -3.11, $p < .002*$.
Mean (SD)	4.35 (1.91)	5.81 (0.64)	5.43 (0.90)	
Median	5	6	6	
Reasoning	n = 52	n = 57	N = 51	Overall: Kruskal-Wallis $\chi^2_{(2)} = 25.38$, $p < .001*$. Mental Illness vs Diabetes: Mann-Whitney U z = -4.18, $p < .001*$. Mental Illness vs Controls: Mann-Whitney U z = -4.04, $p < .001*$.
Mean (SD)	6.50 (2.31)	7.77 (0.54)	7.82 (0.43)	
Median	7	8	8	
Expressing a Choice Mean (SD) Median	n = 52 1.83 (0.51) 2	n = 57 2.00 (0) 2	n = 51 1.98 (0.14) 2	Overall Kruskal-Wallis $\chi^2_{(2)} = 9.72$, $p < .01$. Mental Illness vs Diabetes Mann-Whitney U z = -1.94 , $p < .052$. Mental Illness vs Controls. Mann-Whitney U z = -2.62 , $p < .009$.

Difference is significant at a .005 level.

Table 4. Hierarchical linear regression analyses.

Dradiating MacCAT CD Understanding

Predicting MacCAT-CR Understanding						
	Cummulative R ²	R ² Change	F	P		
SF-36 Physical Functioning	.106	.106	$F_{(1,147)} = 17.36$	<.001		
MMSE	.499	.393	$F_{(1,146)} = 114.60$	<.001		
Schiz/ SchizoAff diagnosis	.536	.037	$F_{(1,145)} = 11.62$.001		
		Predicting Ma	acCAT-CR Appreciation	n		
SF-36 Physical Functioning	.125	.125	$F_{(1,149)} = 21.34$	<.001		
MMSE	.402	.276	$F_{(1,148)} = 68.34$	<.001		
Schiz/ SchizoAff diagnosis	.487	.085	$F_{(1,147)} = 24.44$	<.001		
		Predicting M	IacCAT-CR Reasoning			
SF-36 Physical Functioning	.096	.096	$F_{(1,149)} = 15.90$	<.001		
MMSE	.276	.180	$F_{(1,148)} = 36.70$	<.001		
Schiz/ SchizoAff diagnosis	.373	.097	$F_{(1,147)} = 22.85$	<.001		

Discussion

- ▶ In this direct comparison of schizophrenia/schizoaffective, medically ill, and non-ill subjects, cognitive capacity, physical functioning, and a diagnosis of mental illness had the greatest impact on decision-making capacity. These influences were most evident among subjects diagnosed with schizophrenia/schizoaffective disorder.
- ► Level of education also made a substantial impact on diverse elements of decision-making.
- ▶ Physical and emotional health may have an impact on research decision-making across diagnostic groups.
- ► That length of illness had no discernible effect on decision-making scores offers some hopeful data on the vulnerability of chronically ill patients.
- ► As may be expected, prior research experience appears to correlate with better appreciation for the differences of research from clinical care.
- ▶ 69-89% of schizophrenia/schizoaffective subjects attained decision-making scores achieved by most comparison and medically ill subjects, underscoring the capacities of subjects with even significant mental illness. Nonetheless, mentally ill subjects demonstrating psychotic symptoms will require attention to both the positive and negative thought processes that affect their decision-making.
- ▶ Cognition, education, and psychosis remain important factors in decision-making capacity, but future research should consider that physical and emotional functioning may also have an effect among different populations. Regardless of diagnosis, common vulnerabilities should encourage the continued attention of investigators and IRBs to the full range of variables affecting research decision-making.

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