# Assessing historical compliance with medical recommendations among transplant candidates: preliminary findings

**Context**—Noncompliance with medical recommendations by transplant candidates and recipients carries serious consequences for morbidity and mortality. Few patient-specific, objective measures for assessing historical compliance exist.
**Objective**—To address this gap, a psychometric and exploratory analysis of an interview-based, global measure of clinician-rated judgment of historical compliance was undertaken.
**Methods**—All findings are based on a retrospective chart review of the medical and psychosocial evaluations of 96 consecutive potential heart transplant candidates seen at a large Southeastern academic medical center.
**Results**—Preliminary results demonstrated adequate interrater reliability and discriminant validity for the measure. Additionally, results from hierarchical multivariable regression analysis revealed years of education to be positively associated with clinician-rated judgment of historical compliance.
**Conclusions**—This study provides preliminary psychometric support for the use of a measure of historical compliance among heart transplant candidates. Findings from this study also are consistent with the literature to date and may be reflective of a psychobiological process that mediates the relationship between socioeconomic status and health outcomes. (*Progress in Transplantation.* 2010;20:47-52, 95)

**Alok Madan, PhD, MPH, Connie White-Williams, RN, PhD, Jeffery J. Borckardt, PhD, Barry K. Rayburn, MD, Beverly A. Bush, PhD, A. Hal Thurstin, PhD**
Medical University of South Carolina, Charleston (AM, JJB), University of Alabama at Birmingham (CWW, BKR, BAB, AHT)

Corresponding author: Alok Madan, PhD, MPH, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, 67 President Street, 1-South, PO Box 250861, Charleston, SC 29425 (e-mail: madana@musc.edu)

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Since the seminal efforts in the 1960s, researchers in the area of medical compliance have attempted to assess, understand, predict, and intervene with noncompliant patients.[1,2] Arguably, noncompliance with medical recommendations has greater consequences for the transplant population than for populations with other chronic medical conditions.[3] Although medical interventions and surgical procedures have improved over the decades since the earliest transplants, medical noncompliance continues to be among the few identifiable and potentially preventable causes of increased morbidity and mortality risk among transplant candidates and recipients.[4-8] Consequently, pretransplant psychosocial evaluations (including assessments of current and potential difficulties with compliance) are the norm at most transplant centers.[9]

Research suggests that difficulties with compliance before transplant are associated with noncompliance after transplant,[10] with compliance rates decreasing over time.[11,12] Methods to assess compliance, however, vary considerably from center to center,[13] and few objective measures are available to assess compliance among transplant populations. Thus valid, reliable, and easy-to-use measures of past medical compliance are needed. In this article, we present preliminary psychometric data on an interview-based, global measure of historical compliance relevant to heart transplant candidates as well as the measure's association with select demographic, medical, and psychiatric variables.

## Methods

### Participants

The study sample consisted of 96 consecutive adults (≥18 years) with heart failure who presented for consideration for heart transplantation to the University of Alabama at Birmingham's heart transplant program

between January 1, 2000, and August 31, 2003. Data from these patients were the basis of all analyses and conclusions. Participants were divided into 3 diagnostic groups based on the problems necessitating heart transplantation: ischemic heart disease (n = 49 [51%]), dilated cardiomyopathies (n = 37 [39%]), and congenital disorders (n = 10 [10%]).

### Procedure

In this retrospective analysis, individual patients' charts and medical records were reviewed as part of a larger study examining outcomes among heart transplant candidates. The charts included a self-reported personal history, an objective measure of coping and personality style (ie, *Millon Clinical Multiaxial Inventory,* 3rd edition; MCMI-III[14]), and a comprehensive psychological assessment, including a clinician-rated judgment of historical compliance. The self-reported personal history provided detailed demographic information as well as psychosocial histories. The clinician-rated judgment of historical compliance was originally designed and used as an instrument to aid with clinical decision making within the context of pretransplant psychological evaluations.

Patients' medical histories were used to establish the validity of this scale. A subset of the study sample (n = 29) was used to establish the reliability of the scale. Two separate licensed clinical psychologists rated historical compliance. The first psychologist (B.A.B.) based her ratings on a face-to-face, clinical interview with each participant. A reviewer (A.M.) deleted any identifying information about these ratings from each participant's medical record. Blinded to the ratings of the first psychologist, a second psychologist (A.H.T.) rated historical compliance on the basis of a review of the medical record.

All data were collected with full approval from the institutional review board at the University of Alabama at Birmingham. Participants' personal health information was handled ethically and in accordance with Health and Human Services regulations.

### Clinician-Rated Judgment of Historical Compliance: The Scale

Compliance was based on clinician-rated judgment of participants' self-reported history of compliance across 6 health behavior domains specific to heart failure, including (1) diet, (2) exercise, (3) medications, (4) alcohol use, (5) nicotine use, and (6) illicit drug use.

A licensed clinical psychologist rated each transplant candidate on a 9-point Likert scale from "excellent" to "poor," with intermediate levels defined as "good to excellent," "good," "moderate to good," "moderate," "fair to moderate," "fair," and "poor to fair." Excellent was operationalized as (1) no current or remote history of alcohol, nicotine, or drug use, (2) a lifelong history of positive dietary and exercise regimens, and (3) compliance with medications. Good was operationalized as (1) remote history (>6 months) of alcohol, nicotine, or drug use that has been discontinued without reoccurrence, (2) adequate diet and exercise, and (3) compliance with medications. Moderate was operationalized as (1) recent history (6 months or less) of alcohol, nicotine, or drug use that has been discontinued without reoccurrence; (2) some diet and exercise concerns, and (3) inconsistent compliance with medications. Fair was operationalized as poor compliance with specific medical instructions. Poor was operationalized as (1) current and continued alcohol, nicotine, or drug use, (2) uncontrolled obesity, (3) noncompliance with diet and exercise, and (4) noncompliance with medications.

Intermediate levels of historical compliance (good to excellent, moderate to good, fair to moderate, and poor to fair) were also created to allow for the possibility that an individual may fall between 2 major demarcations of historical compliance. For example, an individual may have had a recent history (<6 months) of nicotine use (criteria for moderate compliance) but adequate compliance with diet, exercise, and medication use (criteria for good compliance). Consequently, the individual would qualify for a clinician-rated judgment of moderate to good compliance.

### Data Analyses

Summary statistics were calculated in terms of means and standard deviations for continuous variables and in terms of frequencies and proportions for categorical variables. Group differences among the demographic, medical, and psychiatric continuous variables were examined by using the nonparametric, Kruskal Wallis test, because of the considerable difference in sample size among the 3 groups. Group differences among categorical variables were examined by using a $\chi^2$ test of independence. Ordinary least squares regression analyses were performed on standardized scores of the clinician-rated judgment of historical compliance scale and demographic, medical, and psychiatric variables to test for expected relationships among variables. Pearson product moment correlation coefficients were used to test for consistency of ratings between 2 psychologists providing scores for overlapping participants.

Hierarchical multivariable regression analysis was conducted to examine the association among demographic, medical, and psychiatric predictors and clinician-rated judgment of historical compliance. Each of these classes of variables is differentially associated with measures of compliance.[15,16] Demographic variables (block 1), cardiac disease–specific variables (block 2), and psychiatric variables (block 3) were entered as predictors into separate regression

Table 1 Demographic and medical characteristics across diagnostic group[a]

| Variable | Ischemic heart disease (n = 49) | Dilated cardiomyopathies (n = 37) | Congenital disorders (n = 10) | *P* |
|---|---|---|---|---|
| Demographic | | | | |
| Age, y | 57.1 (7.1) | 46.3 (12.0) | 39.1 (14.7) | <.001 |
| Education, y | 12.7 (2.5) | 12.9 (1.9) | 14.1 (2.2) | .1991 |
| White race, No. (%) | 44 (90) | 23 (62) | 10 (100) | .01 |
| Male sex, No. (%) | 43 (88) | 21 (57) | 3 (30) | <.001 |
| No. of caregivers | 2.3 (1.4) | 2.4 (1.5) | 3.6 (1.3) | .03 |
| Living with caregiver, No. (%) | 48 (98) | 34 (92) | 9 (90) | .3515 |
| Working, No. (%) | 8 (16) | 9 (24) | 4 (40) | .2305 |
| Medical | | | | |
| Cardiac disease duration, y | 9.7 (7.2) | 6.8 (6.8) | 34.7 (10.9) | <.001 |
| Heart failure duration, y | 2.1 (2.9) | 3.8 (4.1) | 6.8 (13.7) | .1542 |
| No. of inpatient evaluations, No. (%) | 8 (16) | 8 (22) | 3 (30) | .5755 |
| New York Heart Association class 3/4, No. (%) | 45 (92) | 32 (86) | 10 (100) | .3936 |
| Left ventricular ejection fraction | 23.1 (11.1) | 15.7 (7.8) | 40.5 (13.8) | <.001 |
| Right atrial pressure | 9.5 (5.6) | 11.1 (7.8) | 13.4 (7.0) | .1537 |
| Pulmonary capillary wedge pressure | 21.3 (8.9) | 21.6 (9.0) | 17.3 (4.9) | .3077 |
| Cardiac output | 4.5 (1.0) | 4.2 (1.2) | 5.3 (1.5) | .1070 |
| Cardiac index | 2.2 (0.4) | 2.1 (0.6) | 2.5 (0.6) | .07 |
| Pulmonary vascular resistance | 207.4 (106.4) | 242.4 (121.8) | 211.7 (114.2) | .4205 |
| Systemic vascular resistance | 1454.5 (347.7) | 1115.4 (459.0) | 1078.6 (421.7) | .08 |
| Body mass index[b] | 28.1 (6.8) | 28.0 (4.6) | 24.9 (6.1) | .2273 |

[a] Data are presented as mean (standard deviation) unless otherwise indicated.
[b] Calculated as weight in kilograms divided by height in meters squared.

models. Because of the exploratory nature of these analyses, predictor variables with *P* values less than .15 in each of the 3 independent regression models were retained for inclusion in the final model rather than the more commonly used, and more stringent, *P* values of less than .10. Results are presented in terms of standardized beta weights and associated *P* values. *R*2 is presented as the measure of strength of association, that is, explained variance.

Statistical significance was set at $P = .05$. All analyses were done by using SAS/STAT software, version 9.0 of the SAS System for Microsoft Windows (SAS Institute Inc, Cary, North Carolina).

## Results

### Sample Characteristics

Table 1 provides the demographic and disease characteristics of participants across the 3 diagnostic groups: ischemic heart disease, dilated cardiomyopathies, and congenital disorders. The study sample consisted of primarily middle-aged (mean, 51.0 [SD, 12.0] years), white (80.2%) males (69.8%) with some college education (mean 12.9 [SD, 2.3] years) and severe heart failure (90.6% New York Heart Association class III/IV; left ventricular ejection fraction: mean, 22.1 [SD, 12.5]). However, patients in the ischemic heart disease group were older ($P < .0001$), had a disproportionately larger percentage of European-Americans ($P = .0102$) and males ($P = .0001$), and had a lower left ventricular ejection fraction ($P < .0001$) than did patients in the congenital disorders group. Additionally, patients in the congenital disorders group had significantly more identified primary caregivers than did patients in either of the other 2 groups ($P = .0347$). Marginally significant differences were also observed among groups on 2 measures of cardiac efficiency (cardiac index [$P = .0673$] and systemic vascular resistance [$P = .0806$]).

Table 2 provides details of psychiatric functioning across the 3 diagnostic groups. On average, participants did not endorse clinically significant difficulty with anxiety, depression, or dysthymia as measured across the clinical syndrome scales of the MCMI-III. Only a small percentage of individuals endorsed sufficient symptoms across the 3 clinical syndrome scales consistent with an axis I disorder from the *Diagnostic and Statistical Manual of Mental Disorders* (4th edition), that is, $T \geq 85$ (3.1% = anxiety; 2.1% = depression; 1.0% = dysthymia). However, one-fourth of the study sample was prescribed an antidepressant (n = 24) and 22.9% of participants were prescribed an anxiolytic (n = 22). Additionally, 37.5% of the sample was prescribed either an antidepressant or an anxiolytic. The 3 diagnostic groups did not significantly differ across measures of psychiatric functioning on the MCMI-III clinical syndrome scales or in terms of current prescription of an antidepressant or an anxiolytic agent.

Results also revealed that the study sample's clinician-rated judgment of historical compliance

Table 2 Psychiatric characteristics across diagnostic group[a]

| Variable | Ischemic heart disease (n = 49) | Dilated cardiomyopathies (n = 37) | Congenital disorders (n = 10) | *P* |
|---|---|---|---|---|
| Psychiatric | | | | |
| Anxiety | 42.4 (31.2) | 34.3 (31.2) | 45.0 (32.8) | .4419 |
| Depression | 52.8 (18.2) | 44.3 (23.6) | 50.8 (25.7) | .3140 |
| Dysthymia | 39.9 (25.3) | 31.6 (30.8) | 30.0 (31.0) | .2796 |
| Selective seroronin reuptake inhibitor, No. (%) | 14 (29) | 7 (19) | 3 (30) | .5498 |
| Anxiolytic, No. (%) | 10 (20) | 11 (30) | 10 (10) | .3515 |

[a] Data are presented as mean (standard deviation) unless otherwise indicated.

fell within the moderate to good and good range overall (mean [SD], 6.3 [1.9] for ischemic heart disease, 6.5 [1.9] for dilated cardiomyopathies, and 7.7 [1.4] for congenital disorders). Sixty-eight percent (n = 65) of the study sample received ratings of good or better (ie, remote history of any substance use that has been discontinued without reoccurrence, adequate diet and exercise, compliance with medications), whereas only 3% received the lowest possible rating of poor (ie, active substance use, gross noncompliance with dietary and exercise requirements, and frequent and consistent noncompliance with medication doses).

### Preliminary Assumptions

Because clinician-rated judgment of historical compliance was a global estimate of the degree to which each participant historically followed medical recommendations, each participant was assumed to have been presented with specific guidelines regarding the necessity of complying with pharmacological treatments and modification of heart-unhealthy behaviors for the management of their cardiovascular disease before being evaluated for possible transplantation at University of Alabama at Birmingham's heart transplant program. Each participant most likely received variable medical recommendations pertaining to specific pharmacological treatments and modification of heart-unhealthy behaviors.

Based on national guidelines for management of patients with heart failure, pharmacological treatments were most likely patient-specific but could have plausibly incorporated the use of a number of medications, including but not limited to lipid-lowering agents, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, ß-adrenoceptor blockers, antioxidants (eg, vitamin E or beta carotene), anticoagulants (eg, aspirin), calcium channel blockers, thiazide-type diuretics, estrogen replacement therapies, and antiarrhythmic agents.[17,18] Additionally, each participant most likely received specific recommendations regarding the necessity of maintaining normal body weight (body mass index [calculated as mass in kilograms divided by height in meters squared], 18.5-24.9); eating a diet rich in fruits, vegetables, and low-fat dairy products with a reduced content of cholesterol, saturated fat, and total fat; reducing dietary sodium intake; engaging in regular aerobic physical activity (at least 30 minutes a day, most days of the week); limiting alcohol consumption (no more than 2 drinks/day); totally discontinuing nicotine use; and totally discontinuing illicit drug use.[19-22] Although participants were unlikely to have been presented with all recommendations during each medical encounter, they were most likely presented with these recommendations in aggregate during the greater than 8-year course of their medical treatment before being evaluated for possible heart transplantation at University of Alabama at Birmingham.

### Preliminary Validity and Reliability

As stated initially, there are 3 major causes of heart failure necessitating heart transplantation: ischemic heart disease, dilated cardiomyopathies, and congenital disorders. The cardiac conditions preceding ischemic heart disease, such as myocardial infarction, are often associated with poor compliance with heart-healthy behaviors for an extended period, often years. On the other hand, congenital disorders are frequently diagnosed shortly after birth and require considerable medical management after the initial diagnosis, and parental influence most likely helps maintain healthy behaviors. Results from these analyses supported this hypothesis: patients with ischemic heart disease (n = 49) were rated significantly less compliant than patients with congenital disorders (n = 10), Kruskal Wallis $\chi^2_1 = 5.12$, $P = .02$, thus establishing discriminant validity for the clinician-rated judgment of historical compliance.

Results also revealed an adequate degree of agreement between the 2 clinical psychologists' ratings of historical compliance, $r = .76$, $P < .001$, reflecting adequate interrater reliability.

### Relationships Among Predictor and Outcome Variables

The regression analyses were designed to examine the additive influence of each block of predictor

variables on the outcome variable. The demographic variables from block 1 accounted for 13.75% of the variance in clinician-rated judgment of historical compliance, but the overall effect was only marginally significant, $F_{7,88} = 2.00$, $P = .06$. Education ($\beta = .26$) and number of identified primary caregivers ($\beta = .17$) were significantly ($t_1 = 2.44$, $P = .02$) and plausibly ($t_1 = 1.66$, $P = .10$) associated with the outcome variable and were therefore retained for inclusion in the final model. The medical variables from block 2 accounted for 12.11% of the variance in clinician-rated judgment of historical compliance, but the overall effect was not significant, $F_{13,82} = 0.87$, $P = .6111$. Cause of heart failure ($\beta = -.22$) was plausibly ($t_1 = -1.74$, $P = .09$) associated with the outcome variable and was therefore retained for inclusion in the final model. The psychiatric variables from block 3 accounted for 7.42% of the variance in clinician-rated judgment of historical compliance. The overall model was not significant, $F_{5,90} = 1.44$, $P = .22$. However, dysthymia ($\beta = -.21$) was sufficiently associated with the outcome variable ($t_1 = -1.65$, $P = .10$) and was therefore retained for inclusion in the final model.

The final model of the hierarchical multiple regression included education, number of identified primary caregivers, cause of heart failure, and dysthymia as predictors. Results from the regression analysis revealed an overall omnibus effect for these 4 predictors on clinician-rated judgment of historical compliance, $F_{4,91} = 4.00$, $P = .001$. The overall model explained 14.95% of the variance in the outcome variable. Education ($\beta = .24$) was found to be the sole, significant predictor in the overall model, $t_1 = 2.48$, $P = .01$. Number of identified primary caregivers ($\beta = .16$, $t_1 = 1.62$, $P = .11$), dysthymia ($\beta = -.16$, $t_1 = -1.61$, $P = .11$), and cause of heart failure ($\beta = -.09$, $t_1 = -.91$, $P = .36$) were nonsignificantly associated with the outcome variable in the final model.

## Discussion

The scale presented was developed for use in the clinical-decision making process as part of comprehensive pretransplant psychological evaluations. Preliminary analysis of its psychometric properties revealed it to be a valid and reliable instrument for use in clinical and research settings. Results suggest that the scale can be used to distinguish heart transplant candidates with likely histories of unhealthy behaviors from those with likely histories of healthy behaviors. Additionally, results suggest that the scale can consistently provide this discrimination between clinicians.

Overall, findings from this study revealed that the study sample was rated quite highly in terms of historical compliance with heart healthy behaviors, and few patients (~3%) were rated on the low end of the scale. These findings are not completely unexpected as self-report and interviews of compliance often provide higher estimates of compliance than pill counts or electronic pharmacy records.[21,22] These findings are also in line with findings from a recent population-based, health behaviors survey in which only 5% of their study sample self-reported absolute noncompliance across recommended guidelines pertaining to physical activity, tobacco use, alcohol consumption, fruit and vegetable consumption, and dietary fat intake.[23] Although selection bias may have resulted in a truly more compliant patient population, response bias also may have contributed to a skewed clinical profile. Given the context of pretransplant psychosocial evaluations, patients had ample extrinsic motivation to minimize their degree of dysfunction and to exaggerate their self-reported histories of compliance with heart healthy behaviors.

Findings from this preliminary study also revealed that education was strongly and positively associated with overall ratings of clinician-rated judgment of historical compliance. Similar trends are evident in general, cardiac-specific populations, as well as transplant populations. For example, results from a population-based survey[23] revealed that twice as many persons with at least some college self-reported complying with all public health guidelines regarding exercise, tobacco use, alcohol use, fat intake, and fruits/vegetable consumption compared with persons with less than a high school education. Similarly, in a specific examination of patients with coronary artery disease, Harlan et al[24] found that individuals who completed college were 71% more likely to participate in cardiac rehabilitation than were such patients who completed high school only. Research has also demonstrated higher levels of education to be associated with better compliance among patients awaiting kidney transplant.[25]

The consistent positive association between greater educational achievement and better overall compliance may be a marker of limited financial resources to afford treatments (such as medications and rehabilitation programs) or lower health literacy. In fact, Dew and colleagues[26] found that lung transplant recipients who had public insurance (eg, Medicaid) had increased risk of noncompliance across multiple heath behavior domains, including medication use, diet, smoking, spirometry noncompliance, completing blood work, and monitoring blood pressure. This association may also reflect the larger association between low socioeconomic status and poor health.

Although related to other frequently used measures of socioeconomic status such as occupation and income, education has been used as a proxy for socioeconomic status, and persons with lower education tend to have worse health.[27] Poor health behaviors (eg, smoking, obesity, and low physical activity) also

tend to be more prevalent among persons with low socioeconomic status. However, this association tends to be moderate and does not explain a significant portion of the variance in the relationship between socioeconomic status and health outcomes.[28,29] Kristenson and colleagues[30] argue that psychobiological processes may mediate the relationship between socioeconomic status and health outcomes. They base their argument on the observation that persons from lower socioeconomic status backgrounds report greater environmental challenges and fewer coping resources compared with persons from higher socioeconomic status backgrounds,[31,32] leading to a lifelong history of learning the association between environmental demands and individual responses.[30] In regard to compliance with medical recommendations, this history of "acquired expectancies,"[30(p1512)] or more accurately failures, may result in little motivation to accept and implement suggested lifestyle changes (eg, discontinuation of tobacco and alcohol use), after the initial diagnosis of a cardiovascular condition. If few strategies of change have been effective in the past, there would be little expectation that newly prescribed medication regimens and/or behavioral modification programs would be effective in present or future circumstances.

## Limitations

Overall, the findings from this preliminary study fill a gap in the transplant literature by providing the requisite psychometric properties of a measure that can be used to quantify historical compliance with medical recommendations among transplant candidates. Although this is a necessary initial step in the development of the measure, the measure has a number of shortcomings that need to be addressed before its widespread use in research and clinical settings. The rating system of the scale itself could benefit from greater specification of the various categories of compliance. In the scale's present form, not all categories are sufficiently operationalized, forcing clinician judgment and resulting in potential inconsistencies over time as well as between clinicians. Terms such as "adequate" need to be better defined in a revised version of the scale, perhaps improving the test-retest and interrater reliability. Future research should examine its utility in accurately identifying individuals who develop difficulties with compliance during the post-transplant period.

## Financial Disclosures

None reported.

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