Evaluation of Utilizing Household Support as a Potential Risk Screening Tool for Medication Compliance for Adults with Type 2 Diabetes Mellitus

LPO 8800 – Statistical Project

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INTRODUCTION

In the United States, over 10% of adults have been diagnosed with Type 2 diabetes mellitus (T2DM) with the highest rates of T2DM concentrated in the southeast.[1] Despite high morbidity and mortality rates associated with medication noncompliance, approximately one third of US adults with T2DM are not compliant with their medication regimen, and it is estimated that the total cost of T2DM noncompliance costs up to approximately one billion dollars per year in the US alone.[2,3] The physical barriers to medication compliance can increase with age and increased physical limitations. In focus groups, adults with T2DM have reported that opening medication bottles, filling syringes, injecting medication, and picking up prescriptions from the pharmacy are all physical tasks that can be barriers to medication compliance.[4] Due to the frequent occurrence of these tasks, the availability of support on an ongoing basis can become important to medication compliance as physical limitations increase. Informal supporters, such as family members or friends, may play an important role in addressing these physical barriers for to medication compliance if they are frequently available to the adult experiencing these barriers.[4]

Medication noncompliance is associated with a range of factors. Medication adherence has been shown to decline in the presence of life stressors, such as financial stress.[2] Although many socioeconomic factors influence overall health, several factors are thought to play a more significant role in medication compliance and may attenuate the relationship between informal support and medication compliance. These factors include education attainment, employment status, household income and factors influencing health care costs (including health insurance coverage).[5,6] The complexity of a medication regimen (i.e. bolus insulin use and more medications) is likely also associated with poorer medication compliance. The proportion of

individuals with diabetes is highest in adults with the lowest levels of education.[1] These individuals may receive higher levels of informal support than their peers, however. Lower levels of education attainment and advanced age are associated with greater levels of involvement from informal health supporters.[7] It is likely that this greater level of informal support is indicative of higher baseline needs for assistance with navigating the complex medical system and with following medical recommendations (i.e. correctly taking medications at the frequency and in the amounts directed by a medical provider). Overall, social determinants of health have been identified as significant factors in T2DM self-care.[6]

Research Question, Hypothesis and Policy Area

This analysis explores the following question: Is informal support associated with improved medication compliance for adults in the United States with Type 2 diabetes mellitus (T2DM)? It is hypothesized that informal support, as measured by the number of household members self-reported through the Southern Communities Cohort Study (SCCS) baseline survey, will be positively associated with medication compliance as self-reported on the same survey.

The literature is mixed regarding the relationship between the involvement of informal supporters and T2DM medication compliance for older adults. Several previous studies with primary focuses other than evaluating medication compliance found no connection between informal support and compliance.[5,7,8] These findings may at least be partially explained by the enrollment criteria used for these specific studies, which limited participation to adults with "poorly controlled" T2DM.[5,7,8] Although this criteria were necessary to support the main areas of focus of these studies, it likely screened out or truncated the range of supporter-participant dyads who were *successful* at T2DM management, disproportionately representing neutral or harmful

dyads and likely significantly biased results toward the null. Researchers who have found a significant positive impact of informal support on medication compliance enrolled participants with all levels of diabetes control, representing the true spectrum of participant-supporter dyads.[6,9] These studies, however, used specialized screening surveys to assess informal support which may be difficult to administer in a non-research setting.[6,9]

Constructs of informal support that are relatively easy to collect in clinical settings may provide benefit in developing medication noncompliance risk screening tools appropriate for these settings. These types of tools may inform how Medicaid *home and community based services (HCBS)* funds are allocated to support training of and/or direct payment to informal supporters providing care for older adults with T2DM.

Overview of Findings

Overall, the results of this analysis provide neither compelling evidence for or against the relationship between informal support and medication compliance, however, they do provide insights into the limitations of specific ways of evaluating the constructs of informal support and medication compliance. Although household size is administratively simple to ask in a clinical setting, it likely does not provide enough insight into the level of informal support received by the patient. As such, it was a very poor predictor of medication compliance. Participants reported an unusually high level of medication compliance compared to generally accepted ranges of likely noncompliance in the general US population.[2] This may suggest that social desirability bias played a role in reported levels of compliance. Although this is a limitation, it likely represents the same bias that occurs when patients are asked about their medication compliance by their medical provider. Further research should identify easily assessed constructs of informal social support and should utilize objective tools, such as bloodwork or claims data, to an additional means of validating self-reported medication compliance.

METHODS AND ANALYSIS

Study Population

Baseline survey data from the Southern Communities Cohort Study (SCCS) was used for this analysis. Eligibility criteria for this study included being an adult age 40 to 79 at enrollment and living in one of twelve southeastern states. Over 85 percent of participants were recruited at community health centers, and this recruitment strategy resulted in a participant pool that had higher rates of advanced age, low-income and African American racial identity than is represented in the general population.

There were 32,158 participants in the baseline SCCS survey dataset. Participant data was included in this analysis if it met specific criteria. First, participants had to self-report affirmatively that they had been told by a medical provider that they had ever had T2DM (n=8,810). Second, they needed to respond affirmatively that they were supposed to take medication for T2DM (7,568 affirmative responses; 4 missing) and then report their level compliance with taking their medication as directed (7,543 reporting compliance level; 25 missing). Finally, participants were excluded if they failed to provide information regarding their household size because this explanatory variable could not be derived from other sources (7,400 meeting all eligibility criteria; 143 missing household size response).

Analysis - Characteristics

Individual Characteristics

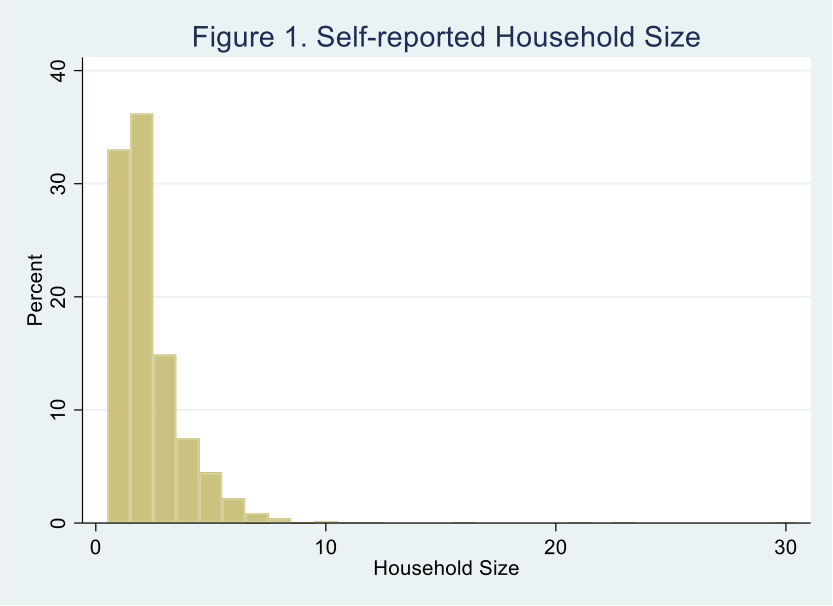
As seen in Table 1, the average age of participants was 62 years old with a standard deviation of 6.41 years. Median age was 61 years old. Females were overrepresented and comprised 68.61% of the participant pool. Participants were typically not employed (76.43%), which is unsurprising considering that this participant pool likely includes many retirees. Over 20% of participants reported an education level of at least some college or higher. Over 16% of participants reported completing less than 9 years of schooling. 77.46% of participants reported

having insurance coverage through commercial, Medicare and/or Medicaid plans. Almost 22% of participants reported having no insurance coverage, which may be of concern considering the high costs often associated with the management of T2DM.

Table 1 – Participant Demographics	
No. Baseline Participants	**32,158**
No. Meeting Eligibility Criteria for Analysis	**7,400**
No. of Diabetes Medications per Participant	**1.31 ± 0.73 (min: 0; p25: 1; p50: 1; p75: 2; max: 6)**
Reported Insulin Use	No: **4,492 (60.70%)** Yes: **2,315 (31.28%)**
Medication Compliance (Over Previous 3 Months)	**3.84 ± 0.49 (min: 0; p25: 4; p50: 4; p75: 4; max: 4)** 0 = Never: **27 (0.36%)** 1= Rarely: **33 (0.45%)** 2= Sometimes: **143 (1.93%)** 3= Most of the time: **695 (9.39%)** 4 = All the time: **6,502 (87.86%)**
Household Size	**2.30 ± 1.55 (min: 1; p25: 1; p50: 1; p75: 3; max: 30)** Lives Alone: **2,445 (33.04%)** Lives with Others: **4,955 (66.96%)**
Enrollment Age (Years)	**62.00 ± 6.41 (min: 50; p25: 57; p50: 61; p75: 66; max: 79)**
Sex	Male: **2,323 (31.39%)** Female: **5,077 (68.61%)**
Employed	No: **5,656 (76.43%)** Yes: **1,693 (22.88%)** Missing: 61 (0.82%)
Household Income	Less than $15,000: **4,509 (60.93%)** At least $15,000 but less than $25,000: **1,433 (19.36%)** At least $25,000 but less than $50,000: **842 (11.38%)** At least $50,000 but less than $100,000: **399 (5.39%)** $100,000 or more: **81 (1.09%)** Missing: 136 (1.83%)
Education Level	Less than 9 years: **1,206 (16.40%)** 9-11 years: **1,764 (23.84%)** 12 years, completed high school, or GED: **2,158 (29.16%)** Vocational, technical, or business training: **371 (5.01%)** Some college or junior college: **1,116 (15.08%)** Graduated from college: **439 (5.93%)** Graduate school (up to and including a Master's degree): **219 (2.96%)** Graduate school beyond a Master's degree (include doctors, dentists, lawyers, PhDs): **87 (1.18%)** Missing: 40 (0.53%)
Insurance Coverage	No: **1,624 (21.95%)** Yes: **5,732 (77.46%)** Missing: 44 (0.60%)

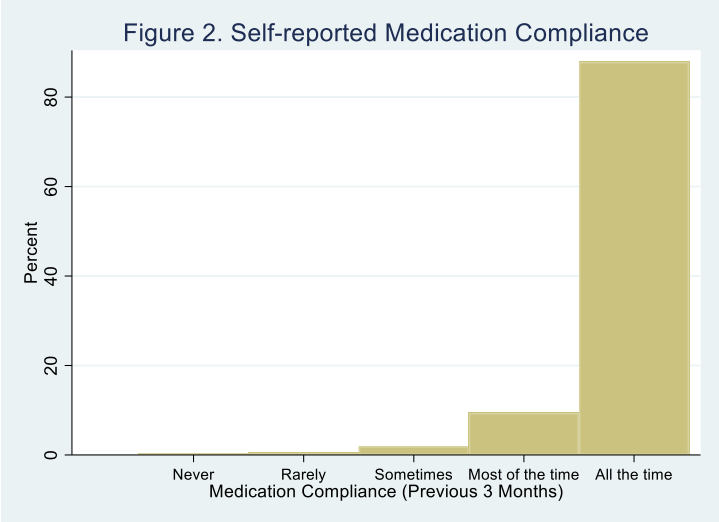
Household Characteristics

As people age, they often live with fewer individuals due to children moving out of the home or a life partner no longer being in the home due to divorce, death or movement to a nursing home. Additionally, many individuals never live with others throughout their lifetime. It is therefore unsurprising that over 33% of participants reported living alone. The average household size was 2.3 (including the participant) with a standard deviation of 1.55. At the 50th percentile, household size was 1, indicating the possibility of a right skew due to being lower than the mean. At the 75th percentile, household size was only 3 individuals. The maximum household size was 30 individuals, however. Although 30 may seem like an unrealistic household size, it is reasonable to believe that some individuals in this participant pool lived in institutional settings (i.e. communal assisted living, nursing home, etc.) and felt that inclusion of "housemates" best represented their living situation. Figure 1 shows the distribution of household size and the almost negligible number of individuals trailing off into a long right skew. Less than 1% of individuals reporting living in a household of 7 or more members. Household income was also very right skewed, with over 80% of individuals reporting less than $25,000 per year. Just over 1% of individuals reported a household income of $100,000 or more.



Medication Characteristics

Participants were generally prescribed two or fewer medications for their T2DM with a mean of 1.31 and standard deviation of 0.73 medications. The maximum number of diabetes medications reported was 6. Participants reported that at least one of their medications was insulin 31.28% of the time. As seen in Figure 2, participants reported very high medication compliance compared to previous literature.[2] On a five-point scale of compliance ranging from zero indicating "never" to 4 indicating "all the time," participants reported average medication compliance of 3.84 (SD: 0.49) over the previous three months prior to evaluation. The median for medication compliance was 4, which is higher than the mean as anticipated in a left-skewed distribution. This very left skewed variable included 87.86% of participants reporting compliance "all of the time." Additionally, another 9.39% of participants reported compliance "most of the time." It is likely that participants over reported medication compliance. This may be due to believing this response was a socially desirable answer, especially in a community health clinic setting, despite anonymity of responses. As such, the following analysis considers both the responses in their literal sense and also uses responses indicating some level of non-compliance ("never" to "most of the time" responses) as a subgroup analysis to see of participants willing to indicate a level of noncompliance showed different trends than those reporting always being compliant. Cumulatively, 12.14% of total participants indicated a level of compliance at "never" to "most of

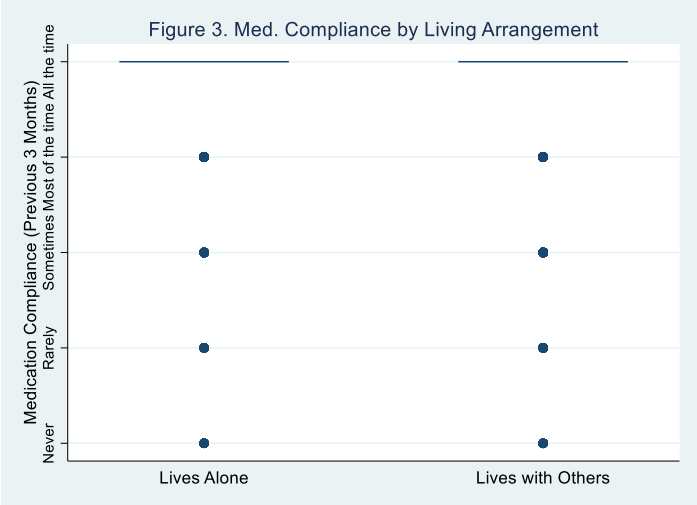


the time," and this group was also left skewed. It is unsurprising, however, that medication compliance would be left skewed in a participant pool recruited at community health clinics as these individuals are maintaining at least a low level of health care seeking behavior.

Analysis – Explanatory and Response Variables of Interest:

Household Size and Medication Compliance

As stated previously, medication compliance was very left skewed. Concerns arose after determining the level of left skew that there would not be enough variation is this variable to understand the relationship between household size and medication compliance. Figure 3 is a boxplot indicating that responses of any level of compliance below "all of the time" were statistical outliers in this dataset, both for participants living alone and for those who lived with others. Figure 4 shows that lower levels of compliance are still statistical outliers, even when responses are truncated to only participants indicating "never" to "most of the time" levels of compliance.



Transformation of the medication compliance variable was considered. Although transformation may have helped to address some of the skewness of this variable, from a practical standpoint the very small range of a high

frequency of responses limits the utility of this variable, regardless of transformation. It was decided that interpretability of a transformed variable would challenging and may be a barrier to fruitful discussion across disciplines about whether this construct is appropriate for use in a clinical screening tool.

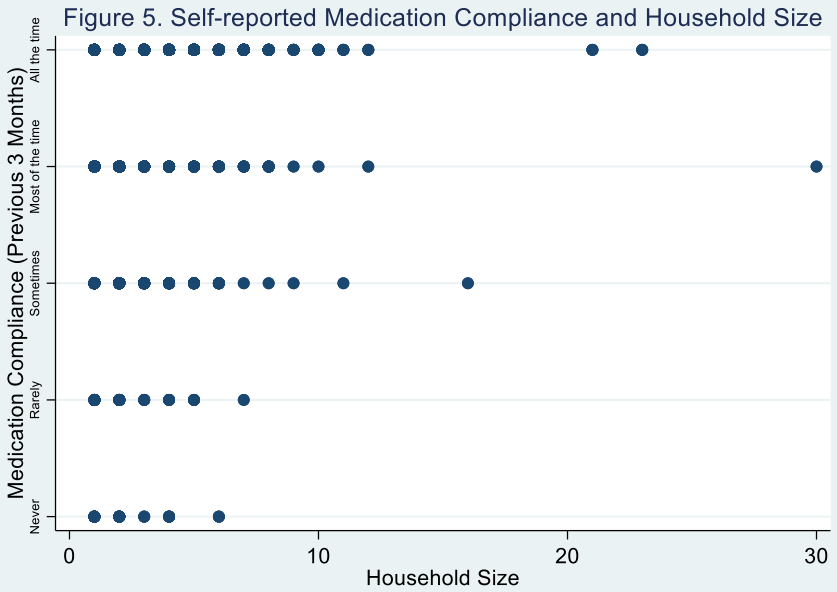
Pearson correlation coefficients were calculated for the range of covariates against both the explanatory and response variable of interest and can be seen in Table 2. This analysis was performed both for the full range of reported medication compliance and for the truncated range excluding "all the time" responses. The magnitude of correlation for all variables was very low. Correlations tended to be similar in the full range and truncated analyses, and although some correlations moved from negative to positive or vice versa, the magnitude of these correlations made these changes in direction negligible from a practical standpoint. For instance, a -0.1027 correlation between enrollment age and household size changed to a +0.0066 correlation, but from a practical standpoint, a 0.0066 positive correlation does not reflect a meaningful difference from zero.

Table 2 – Correlations Between Main Variables of Interest

	Full Range of Reported Med. Compliance		Med. Compliance Excluding "All the Time" Responses	
	Medication Compliance	**Household Size**	**Medication Compliance**	**Household Size**
Medication Compliance (Over Previous 3 Months)	1.0000		1.0000	
Household Size	-0.0335	1.0000	-0.0225	1.0000
No. of Diabetes Medications per Participant	0.0100	-0.0093	0.1533	-0.0449
Reported Insulin Use	-0.0234	0.0115	-0.0868	0.0299
Enrollment Age (Years)	0.0871	-0.1027	0.0495	0.0066
Sex	0.0040	-0.0128	0.0728	0.0562
Employed	0.0096	0.0071	0.0137	0.0145
Household Income	0.0217	-0.0053	-0.0100	0.0085
Education Level	0.0049	-0.0036	0.0580	-0.0583
Insurance Coverage	0.0056	0.0074	0.0873	0.0173

The direction of several correlations, despite their weak level of correlation, are still of interest. Of greatest interest is that household size and medication compliance were negatively correlated across both the full and truncated analyses. Although this correlation is very weak, it may indicate that household size is not protective against medication noncompliance (positively associated with medication compliance) or that household size is not an adequate construct for the evaluation of informal support related to mediation compliance. Figure 5 is a scatterplot of the relationship between household size and medication compliance. Due to the strong unimodal nature of the data, this scatterplot may obfuscate the "top loaded" weight of the relationship. When Figures 2, 3 and 5 are considered together, it is clear that the relationship between these two variables is likely strongly influenced by the range of household sizes reported by participants indicating compliance "all the time" or "most of the time." Also of interest is the negative correlation between insulin use and medication compliance. Although this correlation is very weak, it is consistent with reports from focus groups that insulin compliance is more challenging than oral medication compliance.[4] It is therefore unsurprising that individuals taking insulin reported lower levels of compliance.

Figure 5. Self-reported Medication Compliance and Household Size



After review of these variables, a bivariate regression was performed for the relationship between household size and medication compliance for both the complete and truncated range of medication compliance responses. The results of these two regressions are presented in Table 3.

Table 3 – Bivariate Regression of the relationship between Household Size and Medication Compliance

	Full Range of Reported Med. Compliance	Med. Compliance Excluding "All the Time" Responses
Medication Compliance and Household Size	-0.0108 (0.0037)*	-0.0068 (0.0122)
Constant	3.8644 (0.0103)*	2.6938 (0.0378)*
R-squared	0.0011	0.0003
N	7,400	898
Standard error in parentheses, *p<0.01		

The results of these two regressions show similar results. The constant for both regressions represents the predicted level of medication compliance if household size were zero. A household size of zero has no real-world interpretation because a household size of one indicated that the participant lived alone. Table 4 was constructed to show real-world examples of how this regression analysis would predict medication compliance if it were to be used as a risk prediction tool in a clinical setting. For the full range and truncated range regressions, each household member decreases the predicted compliance rating by 0.0108 points and 0.0068 points respectively. Not only is this value very small, it leads to non-meaningful changes in predicted scores when considering the possible ranges of household size. At one household member (indicating that the participant lives alone), the full range regression predicts a score of 3.8536 for mediation compliance. At 30 household members (indicating that the participant lives with 29 other people – an extreme outlier), the regression predicts a score of 3.5512. Although these values differ, they both fall between self-reported values indicating compliance levels closer to "all the time" than "most of the time." The R-squared values for both regressions further underscore why household size would have limited utility as a risk prediction construct for

medication compliance. The amount of variation of predicted medication compliance from mean medication compliance that is explained by household size is virtually non-existent (0.11% and 0.03% for the full and truncated range regressions respectively). Taken in its entirety, these regression models are good examples of times when a slope and/or coefficient may be statistically significant but not practically significant.

Table 4 – Predicted Medication Compliance Values for Levels of Household Size

	Full Range of Reported Med. Compliance	Med. Compliance Excluding "All the Time" Responses
Zero Household Members (Theoretical)	3.8644	2.6938
One Household Member (Lives Alone)	3.8536	2.6870
Two Household Members (Lives with One Other Person)	3.8428	2.6802
Six Household Members (Lives with Five Other People)	3.7996	2.6530
Thirty Household Members (Lives with 29 Other People)	3.5512	2.4966

DISCUSSION

Although the results of this analysis do not provide compelling evidence for or against the relationship between informal support and medication compliance, it does provide a fruitful exploration of the challenges that must be overcome when designing a risk prediction tool that is both easy to administer and robust against social desirability bias. Self-reported medication compliance was likely higher than true compliance, supporting the exploration of using medical claims data to evaluate medication adherence patterns (i.e. whether a prescription was picked up at the pharmacy) to validate self-reported measures of compliance. Many electronic medical records are being linked with pharmacy and insurance claims to provide real-time information regarding adherence. Although a question about household size requires no special training to administer, it is likely too limited of a construct to fully appreciate the range of sources of informal support available to an individual. From a practical standpoint, the construct used to

evaluate informal support must be able to explain variation in medication compliance scores for it to serve as a component of a risk prediction tool. In situations where medication compliance is self-reported, household size may not explain enough of the variability to be of use, though this may differ in situations where medication compliance scores have a more normal distribution of values. From a research standpoint, continued effort should be made to create a rapid assessment of informal support that is valid across a range of T2DM self-care behaviors, especially medication compliance. From a clinical standpoint, medical practitioners should be careful with how they interpret self-reported medication compliance and consider the use of probing questions and/or objective lab/claims data to substantiate self-reported information.

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