

## The Importance of Reporting Negative Findings:

Results from a Pilot Study on the Role of Social Support in Transplant Adherence

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*Social support is associated with adherence to medical treatments (Chisholm-Burns, Spivey, & Wilks, 2010). This is the first study to explore social support and adherence 6 weeks post-kidney transplant. Fifty-eight adult deceased-donor kidney transplant recipients participated in the study. Social support was assessed using the Modified Social Support Survey; adherence was defined as the proportion of appointments kept, immunosuppressant blood values, and the Immunotherapy Barrier Scale. Measures were completed at transplant, and at 2, 4, and 6 weeks post-transplant. Data were analyzed using linear mixed models with random effects for person. Variance in participants' adherence was hypothesized. However, all participants were adherent; no statistically significant relationship between adherence and social support was identified. Immediately following transplant, qualitative or mixed-method approaches may give better insight into facilitators of adherence.*

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### INTRODUCTION

Prevention of graft loss in kidney transplant patients is the primary goal of the transplant team. Extant literature supports the association of social support and adherence to medical treatments across populations and diagnoses, including organ transplant (Chisholm-Burns, Spivey, & Wilks, 2010). Thus, an important aspect of psychosocial candidacy for transplant is a robust and reliable social support plan (Coffman, 2010; DiMatteo, 2004). The level and quality of transplant candidates' social support is weighed carefully by the transplant team, and social workers in particular, before approving a patient for transplant. In kidney transplantation, social support post-transplant has been shown to have an impact on adherence, which is directly related to return to dialysis, re-transplantation, and morbidity and mortality of transplant recipients (Chisholm-Burns et al., 2010; Coffman, 2010; Denhaerynck et al., 2005; Stille et al., 2010). Conversely, inadequate social support post-transplant impacts adherence, health-related quality of life, and can lead to graft loss, and even death (Muehrer & Becker, 2005).

Previous studies have examined social support during the post-transplant period typically beginning at around 3 or more months post-transplant (Hilbrands, Hoitsma, & Koene, 1995; Nevins, Krause, Skeans, & Thomas, 2001; Vlamincx et al., 2004). However, the 6 weeks immediately following transplant surgery require a high level of consistent, practical, and emotional social support. Because these first few weeks are medically critical and psychosocially demanding, understanding social support during this time period may be crucial to post-transplant success. Yet, little is known about the role of social support in adherence within the first 6 weeks following transplant, because extant literature does not explore this time period.

Given the gap in knowledge and the importance of this time period, research is needed to explore how social support, comprised of both practical and emotional support, impacts adherence in the first 6 weeks following transplant. Greater information about the role of social support in adherence during this early post-transplant time period may provide further insights into how best to prevent graft loss. Therefore, the overall goal of this study was to examine the role of social support in the initial 6-week period following kidney transplantation, and whether it was associated with greater adherence to the post-transplant regimen. How predictors of social support, such as gender and caregiver relationship, and whether geographical distance from the transplant center, and ability to financially meet daily needs affected adherence were also explored (Sholz et al., 2012).

### METHODS

In this study, we used a longitudinal cohort design. There are no agreed-upon gold-standard questionnaires for measuring patient adherence, and there are a number of validated questionnaires available to choose from (Fairman & Motheral, 2000). The use of self-report measures to identify non-adherence are advantageous for obtaining information from the patient's perspective. In adherence research, the patient's viewpoint is recognized as an important component of information for understanding perceived barriers, attitudes, and behaviors associated with adherence (Fairman et al., 2000).

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### Sample

Adults aged 18 and older, with the ability to speak and read English, who successfully (i.e., the graft is functioning during the transplant admission) received a deceased donor kidney transplant at the academic hospital transplant center were eligible to participate in this study. Exclusion criteria included individuals who had previously undergone transplant, because they had prior experience with the post-transplant regimen, or were multiple-organ transplant recipients (e.g., combined kidney/pancreas transplant recipients), and those who experienced kidney graft loss during the transplant admission and required immediate return to dialysis. Individuals who were not able to provide informed consent due to mental status changes were also excluded.

Severity of disease was not controlled for in the design of the study because people actively listed for transplant were required to meet specific medical and functional status criteria, such as end-stage renal disease diagnosis with a glomerular filtration rate (GFR) of  $\leq 20$  and the ability to complete activities of daily living. Given that the transplant listing process eliminates people who are either too well or too ill for transplant, participants had a relatively similar severity of disease. The researchers were also part of the participants' care teams. To minimize potential conflict and risk of coercion, researchers ensured that potential participants were aware they did not have to join in the study and that their decision to participate or not would not impact the services or the care they received from the social work staff, and that their survey responses would not be shared with the treatment team or entered into the medical record.

### Recruitment

First-time adult recipients of deceased donor kidney transplants were recruited to participate in this prospective, longitudinal cohort study from February 8, 2013 through January 15, 2015. One hundred forty-three people met eligibility criteria. Eighty-eight were approached; 28 declined to participate. Reasons for declining included not feeling well enough, or being too overwhelmed with post-transplant healthcare needs to participate. A total of 60 participants were recruited and consented during the post-transplant hospital admission. Upon further review, 2 participants did not meet inclusion criteria, resulting in a total of 58 participants. Basic demographics, including age, gender, nationality, living arrangement, marital status, employment status, level of education, adequacy of income to meet basic needs, and travel time from home to the transplant center were collected at the time of consent.

### Ethics Approval

Ethics approval was given by the University of Michigan Institutional Review Board (approval number HUM00059851). Participation was voluntary. All participants signed a written informed consent form.

### Study Outcomes and Measures

The primary outcome measurement of this study was adherence to post-transplant medication regimen. Adherence was assessed by the proportion of post-transplant appointments kept, and whether immunosuppression medication blood levels were within targeted ranges. Patients were typically required to have frequent follow-up appointments with the transplant team, weekly for the first month, and bi-weekly for second and third months. However, the exact number of appointments varied from person to person, based on the person's health status, and distance from the hospital. Thus, it was decided that in this study that the proportion of appointments kept, rather than the frequency of appointments, would be the best indicator of adherence.

Per renal transplant protocol at our academic medical center, lab values for tacrolimus and cyclosporine were taken twice a week for the first 90 days post-transplant, and were recorded in the medical record. Tacrolimus levels should have been between 8 and 12 ng/mL. For desensitized patients tacrolimus levels should have been between 10 and 12 ng/mL. Cyclosporine levels should have been between 250 and 300 ng/mL for the first 30 days and between 200 and 250 ng/mL for days 31–60. Any deviations from target tacrolimus or cyclosporine levels were noted in the electronic medical record. Typically, during this time period, ongoing adjustments to drug dosages at the direction of the medical team were needed while patients were reaching a therapeutic level. These adjustments were not unexpected and may have been unrelated to adherence. Variations in blood values of this type were not viewed as non-adherent. It was expected that deviations not explained by these anticipated adjustments would indicate that medication was not taken regularly or as prescribed, and therefore would be a clinical indicator of non-adherence.

Self-reporting of adherence was measured by the Immunotherapy Barrier Scale (ITBS) (Chisholm, Lance, Williamson, & Mulloy, 2004). The ITBS is a 13-item Likert scale used to assess the self-reported perceptions of participants' adherence to post-transplant medications. It has been validated in the post-kidney transplant population (Chisholm et al., 2004; Constantiner & Cukor, 2011). Responses were scored from 1, "strongly disagree" to 5, "strongly agree." The total score was comprised of two subscores measuring uncontrollable factors (i.e., not intentional or a result of the respondent's own doing), and controllable factors (i.e., the respondent's intentional deviation from regimen). A higher score indicates poorer adherence.

The primary predictor of interest in this study was social support. We used the Modified Social Support Survey (MSSS) which is an 18-item Likert scale measure of functional social support (Sherbourne & Stewart, 1991). It represents four dimensions of support: emotional/informational, affectionate, positive social interaction, and tangible, which yield four subscale scores that are combined for the total score. Responses are scored from 1, "strongly disagree"

to 5, “strongly agree.” Each of these scores range from 0 to 100, with higher scores indicating greater perceived support. The MSSS survey has been shown to be valid and reliable in populations of chronically ill people (Sherbourne et al., 1991).

Basic demographic information was collected, including age, gender of participant and caregiver, relationship of the primary caregiver to participant (i.e., spouse, family member, non-family member), distance from participants’ home to the transplant center, and financial status (assessed using the question: “Do you have enough money to meet your daily needs?”) (World Health Organization, 2004).

#### Data Collection Procedures

Self-report measures were administered to participants during the initial transplant admission (MSSS only), and at 2, 4, and 6 weeks post-transplant (MSSS and ITBS). These assessment points are important, as kidney transplant recipients are expected to have 24-hour caregiver support for the 2 weeks following surgery, and transplant recipients are generally on driving restriction until 4 weeks post-transplant, and are expected to have transportation from an identified support person. The entire time period (0–6 weeks post-transplant) is important, as transplant recipients are typically expected to have the most intense and frequent follow-up. Participants were contacted within a 1- to 3-day window, around the 2, 4, and 6 week follow-up assessments. Throughout the study, social work services were provided at standard levels of care, with no change in the frequency of social work contacts or the number or intensity of services provided. Post-transplant appointments were obtained from the medical record, as were the immunosuppression medication blood level values.

#### Statistical Analysis

Descriptive analyses were used to describe demographic characteristics and study outcomes. Linear mixed modeling (LMM), with random effects per person and repeated effects for time (data collection period), was used to test the relationship of social support and adherence, accounting for the effects of time, gender, gender of caregiver, and relationship to caregiver (family or spouse vs. non-family). To determine optimal covariance structures for each analysis, the Swartz’s Bayesian Criteria was used to the best model fit; these are reported in Table 2 and 3 footnotes (Raftery, 1995). IBM SPSS version 22.0 (IBM Corp., 2013) was utilized for statistical analysis.

## RESULTS

### Participant Characteristics

Fifty-eight deceased donor kidney transplant recipients participated in the study. The attrition rate was 24.1% over the study. They were evenly distributed by gender. Participants reported 2 to 50 people in their social circle, with a mean of 8 people. Most, 86.2% participants, reported they had enough money to meet their daily needs.

**Table 1. Participant demographics (N=58)**

<b>Sex</b>	31 (53.4%) male 27 (46.6%) female
<b>Age</b>	Ranged between 29 – 73 years old Mean age of 57 years
<b>Distance from medical center</b>	50% ≤ 100 miles
<b>Caregivers</b>	30 cared for by spouse/ significant other 24 cared for by other family members 4 cared for by non-family members

### Medication and Appointment Adherence

All participants were adherent, in terms of medication and appointments kept, without variation in adherence levels, during the time period studied. The total number of clinic appointments, with the transplant surgeon or transplant team across all participants was 495 within the 6-week time period, with a total of 493 (99%) appointments kept. Appointments ranged from 3 to 5 per participant, with a mean of 4 appointments per person in 6 weeks. Across all participants, the total number of immunosuppressant blood level values recorded was 641; with 2–3 blood values recorded each week per participant within the 6-week time period. Participants were within the immunosuppression target range 60% of the time. Participants had contact with transplant nurses on average every other day during the 6-week time period of the study to discuss their blood levels and make medication adjustments. Each contact was documented in the medical record. Review of medical record documentation revealed that although immunosuppressant blood levels were not within range 40% of the time, participants seemed to be taking their medications as prescribed. As these conversations were self-reported, there was no way to determine whether being out of the target range was really the result of anticipated dosage adjustments or if nonadherence was actually the cause. Because no variance in adherence to medications and appointments was identified, we did not test the relationship of these factors with social support. The lack of variance made assessing the original hypothesis impossible.

### Self-reporting of Adherence

In terms of self-reported adherence, perceived social support had an impact on participants’ perceptions of adherence to post-transplant medications. Participants who perceived social support to be high (high MSSS total scores) also reported higher perceptions of adherence to post-transplant medications (low ITBS total scores; see **Table 2**).

**Table 2. Perception of adherence (ITBS total score) and perceived social support (MSSS total score)**

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						LB	UB
Intercept	23.31	5.33	67.15	4.37	0.00	12.66	33.96
Week 2 (vs. week 6)	1.00	1.06	56.03	0.95	0.35	-1.11	3.12
Week 4 (vs. week 6)	0.31	0.96	74.63	0.33	0.75	-1.60	2.23
Female vs. Male	0.56	1.47	45.64	0.38	0.70	-2.39	3.52
Spouse vs. non-family caregiver	6.27	3.87	48.47	1.62	0.11	-1.50	14.04
Family caregiver vs. non-family caregiver	5.13	3.84	47.25	1.33	0.19	-2.60	12.86
<b>Total social support (MSSS total)</b>	<b>-0.11</b>	<b>0.05</b>	<b>96.92</b>	<b>-2.21</b>	<b>0.03</b>	<b>-0.22</b>	<b>-0.01</b>

Covariance structure: First order autoregressive ITBS = Immunotherapy Barrier Scale, MSSS = Modified Social Support Survey

We explored the relationship between perceptions of adherence (ITBS total score) and two sub-scores from the MSSS, tangible and emotional/informational. These two sub-scores were chosen above and beyond the other sub-scores, as it was thought that, alongside emotional/information support, tangible support may have the most impact on adherence during this time period. In particular, tangible support was chosen because during the first 6 weeks post-transplant, there are a greater number of tangible needs requiring

a high level of commitment from caregivers. Due to the greater number of tangible needs during this time period, we expected perceived tangible support to have a greater impact on perceptions of adherence. However, statistical analysis revealed that higher perceived emotional/information support is significantly related to higher perceptions of adherence to post-transplant medications, rather than tangible support (see Table 3).

**Table 3. Perception of adherence (ITBS score) and perceived emotional and tangible support (MSSS sub-scale score)**

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						LB	UB
Intercept	23.22	5.87	75.07	3.96	0.00	11.53	34.90
Week 2 (vs. week 6)	0.86	1.06	54.95	0.81	0.42	-1.26	2.98
Week 4 (vs. week 6)	0.41	0.98	73.52	0.42	0.68	-1.54	2.37
Female vs. Male	0.43	1.44	43.61	0.30	0.77	-2.47	3.33
Spouse vs. Non-family caregiver	4.82	3.77	45.36	1.28	0.21	-2.77	12.42
Family caregiver vs. Non-family caregiver	3.86	3.78	44.96	1.02	0.31	-3.76	11.48
<b>Total social support (MSSS total)</b>	<b>-0.11</b>	<b>0.05</b>	<b>96.92</b>	<b>-2.21</b>	<b>0.03</b>	<b>-0.22</b>	<b>-0.01</b>
<b>Tangible support (MSSS subscale)</b>	<b>0.01</b>	<b>0.05</b>	<b>122.44</b>	<b>0.25</b>	<b>0.80</b>	<b>-0.09</b>	<b>0.12</b>
<b>Emotional support (MSSS subscale)</b>	<b>-0.11</b>	<b>0.05</b>	<b>125.30</b>	<b>-2.22</b>	<b>0.03</b>	<b>-0.21</b>	<b>-0.01</b>

Covariance structure: First order autoregressive ITBS = Immunotherapy Barrier Scale, MSSS = Modified Social Support Survey

## DISCUSSION

We expected that a greater perceived social support would be positively and significantly associated with participants' ability to keep post-transplant appointments and take their medications. However, we found a lack of variability in adherence, with all participants 100% compliant. Although the association between perceived emotional support and self-reported adherence from the ITBS scale mirror results from previous studies, showing that perceptions of adherence are high for transplant recipients who perceive social support to be high (Chisholm-Burns et al., 2010), no statistically significant relationship was found between social support, and medication and appointment adherence as we defined it in this study.

A lack of significant findings is often viewed as disappointing by researchers, and as undesirable by journal editors, as the preference and publication bias for positive results is well-known throughout the history of science (Matosin, Frank, Engel, Lum, & Newell, 2014). However, scientific thinking and future studies may be improved through the inclusion and reporting of non-significant and/or negative findings (Matosin et al., 2014). Reporting these types of findings is a valuable part of analyzing and validating current thinking, and necessary for a more complete scientific understanding (Matosin et al.). With this aim in mind, the non-significant findings from our pilot study are reported here.

The general lack of support for the relationship between social support and adherence in the acute post-transplant period in this study suggests that other factors likely play an important role in adherence during the 6-week period immediately following kidney transplantation. One such factor may be that in large, highly structured transplant programs the process for screening patients and assessing whether they have the appropriate level of caregiving is well established, leading to a pool of participants who are highly adherent, at least initially. Immunosuppressant medications may not have been an informative indicator of adherence because they required many adjustments to be made by participants at the direction of their physician or nurse, often multiple times per week. These adjustments in the initial post-transplant period may be due to individual variation in absorption and metabolism of the medication. Minor adjustments to find the right dose to produce the desired blood level in a particular individual are not necessarily indicative of a lack of adherence, but rather an expected adjustment process. Given the variability in blood level values during this time period, participants' ability to communicate effectively with their providers regarding these changes, and their ability to follow directions regarding medication management, may be better indications of their capacity to adhere, than the blood level value itself. Future studies of adherence in the 6 weeks post-transplant may need to account for medication adjustments to more accurately account for what is actually occurring in regards to variations in immunosuppressant blood values.

Existing evidence shows that education, and reinforcement of the medication regimen by social work and other clinic staff is important, especially when patients are unsure about their medication regimen, which can lead to non-adherence (Srinivas & Shoskes, 2010). Anecdotal comments from this study are consistent with previous findings, and also suggest that education is important. Standardized measures showed that participants had no concerns about taking immunosuppressant medications. Despite these scores, anecdotal comments from participants to researchers and other staff suggested that a portion of them did not understand when to take their medications and could not tell if the medications were helping. Participants' anecdotal comments, and the observations of the researchers may have implications for all members of the transplant team when working with recipients in the 6 weeks following transplant. For example, telephone contacts between nursing staff and patients are frequent during this time period. This appears to be an opportunity to reinforce medication and post-transplant education and the importance of adherence. This may be an opportunity for transplant centers to have a more formal approach to conversational content in these already occurring interactions. A more formalized approach may have implications for staffing, hiring, and training.

There continues to be a great need for psychosocial research studying patients' attitudes and perceptions regarding their perceptions of managing everyday life and the role of social support (Vermeire, Hearnshaw, Van Royen, & Denekens, 2001). Patients' own beliefs and lived experiences are important for determining adherence (Vermeire et al., 2001). Anecdotally, while most participants in the study reported perceptions of high emotional support on the MSSS, they sometimes reported differently in conversations with transplant clinic nurses and social workers as recorded in the medical record. These comments, often informal, suggest that support provided by the transplant team may have contributed to participant's overall perceptions of social support (Denhaerynch et al., 2005). While social support has long been known to improve adherence, the quality, duration and frequency of interactions between the patient and doctor also appear to be related to adherence (Vermeire et al., 2001). In this study, adherence could have been impacted by the patients' relationships with the transplant team, particularly the clinic nurse, given the frequency of interaction between them. Future studies should account methodologically for these different sources of support and explore how they each contribute to adherence.

## STRENGTHS AND LIMITATIONS

Targeting an early period post-transplant addresses an important gap in the literature. Also, collecting data via mobile phone may have increased the likelihood of participants responding, as it allowed for rapport building between the interviewer and participant, and did not rely on participants remaining at the same address during the study (Freedman, Thornton, & Camburn, 1980; Johnson et

al., 2015). The literature suggests that recall for time spans greater than 3 months is difficult for respondents, and is therefore not recommended. Asking patients to think back over the most recent two weeks likely helped to improve recall (Chisholm et al., 2004).

In addition to the lack of variance in adherence outcomes, there are several limitations to this pilot study. The sample is small and from a single institution. Recruitment was also a challenge, as some potential participants could not be approached due to the timing of the transplant (e.g., weekends), and availability of the researchers (e.g., work schedules, time off). It is possible that, with a larger sample or multiple study sites, there could be greater variability in adherence. The researchers were also members of the healthcare team, which could have influenced participants to underreport nonadherence. Engagement by participants during this time period may be high given the recentness of the transplant, and frequent contact with transplant team; non-adherence to medications and appointments may be more clearly discernible further out from transplant. Some unknown or unaccounted factors could also have influenced the outcome. One such unanticipated factor that was not controlled in this study was the transition to a new electronic medical record, which occurred part way through the study. This change may have impacted the ability to track missed appointments if the cancelled or missed appointment data did not transfer accurately from one system to the next.

#### FUTURE DIRECTIONS

There were several lessons from this study that will help to inform and shape future research in the area of social support and adherence in the immediate post-kidney transplant period. Anecdotal comments provided by participants and caregivers during our study indicated that patients' lived experiences of adhering to medications and appointments in the first 6 weeks post-transplant may be different from what they reported on the MSSS and ITBS measures. Using standardized measurement tools may not fully capture all that is occurring during this important time period. Given the lack of statistically significant results, but important anecdotal information, the next step in our research will be to use a qualitative approach to more fully understand the lived experience of adherence, and the role of social support in the post-operative period. This will help to inform the design of future quantitative studies. In addition, we will continue to examine the impact of social support on adherence and outcomes at 3 months, 6 months, and 1 year post-transplant to assess whether the trajectory demonstrated in the initial post-transplant phase will remain the same or change over time, and at what point in time that change takes place. It is possible that even those lacking adequate social support may have been able to manage well for 6 weeks due to the limited time span and the overall trajectory may change with time.

This study utilized a combination of self-reporting tools and non-self-reporting measures. In the literature, self-report

measures and diaries of medication adherence are usually concordant with non-self-report measures, such as blood or metabolic testing (Garber, Nau, Erickson, Aikens, & Lawrence, 2004). Given the lack of variance in adherence found here, different outcomes or approaches to data collection may be indicated, such as a more formal examination of phone calls or interview-based measures. In the adherence literature, interview-based measures do not perform as well as standardized measures, and are less likely than self-report measures or diaries to result in information about adherence (Garber et al., 2004). However, future studies exploring the role of social support in adherence during the first 6 weeks post-transplant may want to use a combination of interviews and non-self-report measures. While interviews may not give particularly useful information about adherence, they may be able to give meaningful insights into patients' lived experiences of the post-transplant period and their understanding of the medical regimen. This combination of assessment tools in future studies may allow for greater discovery and more fully reveal outcomes related to the phenomena being studied.

Lastly, future studies should carefully consider how to interpret immunosuppressive medication levels during this time period, as they run the risk of false negative results. Additionally, future studies may want to account for home care nursing visits, emergency room visits, and hospital readmissions, as these may also reveal information about adherence during this time period. Further research is also needed regarding the impact of frequent interactions by professional providers to ascertain how professional support is incorporated into participants' perceptions of overall social support, as well as its effect on adherence.

#### CONCLUSION

Reporting non-statistically significant findings with reflections on the ways in which research methodology could be improved is a key aspect of improving and guiding future research. In transplant, early identification of nonadherence may help prevent future graft loss. For well-established transplant programs, it is not surprising that adherence is high in the first 6 weeks post-transplant. Standardized self-reporting scales may be limited in fully capturing patients' experiences of social support and medication adherence immediately after transplant. Utilizing immunosuppressant blood level values and appointment attendance rates may also fail to reveal which patients could be at risk for non-adherence during this time period. Self-reported measures, while informative about the ways in which perceived social support may impact perceptions of adherence, may not always provide enough information about the behaviors or attitudes which may be indicative of future non-adherence. Qualitative or mixed-method approaches in the 6 weeks post-transplant may be more useful in this inquiry and better capture the nuances and depth of patients' experiences immediately following transplant. Gathering in-depth data in this manner may help identify which factors contribute

to or are indicative of non-adherence later in the post-transplant period. Early identification of these factors could give providers guidance regarding prevention and early intervention for barriers to adherence.

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