Chapter 2

LITERATURE REVIEW

The aim of this project is to quantify perceived patient barriers which may interfere with completion of the required patient evaluation in the pre-transplant stage and to formulate a concise list of recommendations for future programming. As an integral piece of a kidney transplant program evaluation, a patient survey was conducted to enumerate perceived barriers in the ESRD patient population referred for evaluation to a large Midwestern health system’s kidney transplant program. This work will provide direction to tailor evidence based interventions and patient support programming to meet patient identified needs. To provide a foundation for this inquiry, a review of pertinent literature was completed.

Search Methods

Databases Accessed

The Cumulative Index of Nursing and Allied Health Literature (CINAHL complete), PubMed, and Google Scholar were searched using the terms *kidney transplant* AND *barriers* AND *waitlist*. The search was then expanded to include *health literacy*, *access to kidney transplantation*, *end stage renal disease*, and *pre-transplant evaluation*. Articles were then hand searched for additional references.

Inclusion and Exclusion Criteria

Inclusion criteria were determined before the search process and included studies published in the English language, focused on patients greater than or equal to 18 years of age, and on patients diagnosed with ESRD. Inclusion was also limited to studies that provided details on outcome measurements and statistical results of data analysis. An exception was qualitative studies, which were included if details were provided regarding the qualitative data analysis.
Fourteen research based articles, all of which met the inclusion criteria, are included in this review.

**Review of Identified Barriers**

There is much in the literature regarding the relatively low number of people with ESRD who are waitlisted for a kidney transplant. Yuan, Bohen, and Abbott (2012) identified the most significant barrier to being waitlisted for kidney transplant as the pre-transplant evaluation process. Less than 15% of people with ESRD have received a transplant due to failure to complete the required screenings. It also has been noted that minorities and women more often struggle with the demands of the pre-transplant evaluation (Alexander & Sehgal, 1998; Sullivan et al., 2012; Weng, Joffe, Feldman, & Mange, 2005). Other barriers identified include concern of failing the required medical tests, fear of the transplant surgery, financial concerns regarding required post-transplant medications, and reduced health literacy (Grubbs, Gregorich, Perez-Stablre, & Hsu, 2009; Kazley et al., 2014; Kazley, Simpson, Chavin, & Baliga, 2012).

**Failure to Complete the Pre-Transplant Evaluation**

The pre-transplant evaluation involves a comprehensive list of tests that each transplant candidate must complete. A psychosocial screening, chest x-ray, electrocardiogram, and numerous blood and urine tests (to include, but not limited to, blood chemistry, complete blood count, antibody serology, and human leukocyte antigen [HLA] typing) are examples of the required exams and are usually performed during the pre-transplant evaluation visit (Weng et al., 2005). In addition, transplant centers require all patients to complete routine annual preventive screenings such as a mammogram, a Papanicolaou screen or prostate exam, and, if applicable, a colonoscopy. Other biomedical tests (e.g. cardiac clearance, computerized tomography) may be
ordered based on an individual’s physical exam, prior medical history, and the required surgical consult (Weng et al., 2005).

The purpose of this evaluation is to ensure that the limited number of kidneys available for transplant are placed into patients who are well positioned - physically, psychologically, and financially - for a successful outcome (Kazley, Hund, Simpson, Chavin, & Baliga, 2015). However, the burden of test completion, including the necessary time and expense, may cause patients to rethink the advantages of transplant and abort the evaluation process. Illustrating this phenomenon, Kazley et al. (2012), as a component of their larger study of barriers ESRD patients face when referred to a transplant center for evaluation, tracked the progress of all patients referred to their transplant center in 2010. There focus on five stages of the evaluation process revealed the following: 1,428 patients were appropriately referred to the center, 846 attended a required education class, 508 participated in a physician evaluation, 428 completed all required testing and were reviewed by the transplant committee for listing, and finally, 339 patients were added to the wait list. These data demonstrates a 29.5% success rate.

**Single center study in a southern state.** Kazley et al. (2012) focused their study on patients referred for pre-transplant evaluation between December 2009 and June 2011. The study sample included 127 dialysis patients who were referred, but, for a variety of reasons, failed to complete the required screenings. For example, some did not attend transplant education, some began the required testing but failed to finish, and some self-selected out of the evaluation process by requesting that their file be closed. Patients who met the inclusion criteria were identified by the research team and approached by the nursing staff as they reported for care at the vascular access clinic. If willing, the patients then completed a survey as a part of the clinic visit. The study survey, developed by a group of researchers and practitioners, was pilot
tested before being used on the study subjects; however, no reliability or validity data were reported.

For the 83 patients (a 65% response rate) who completed the study survey, 59% were female and 79% were African American, ranging in age from 20 to 78 years. Descriptive analyses (frequencies, means, ranges and standard deviation) and chi-square were used to analyze the data. Barriers such as feeling that failure of the required medical testing was probable (18.1%), fear of the transplant surgery (15.7%), and not being able to afford post-transplant medications (14.5%) were most prominent and linked to patients dropping out of, or never beginning, the evaluation process. Recommendations from this study include the use of a patient navigator to assist patients through the maze of the pre-transplant evaluation process and the required follow-up testing, and a revision of pre-transplant education focusing on the areas of concern voiced by the study respondents.

Limitations of this study include it being conducted at a single transplant center which serves an entire southern state. It would be difficult to apply the study findings to more populated urban settings. Additionally, the researchers appeared to make some conclusions in areas not specifically assessed. For example, a conclusion that patient-perceived barriers may have been the result of miscommunication from providers, inaccurate information received from fellow ESRD patients or friends and relatives, or a lack of functional health literacy was offered; however none of these items were assessed in the survey employed in this study. Nonetheless, this study supports findings of other studies which also address the phenomenon of patient barriers to kidney transplantation.

**Evaluating attendance versus nonattendance for scheduled transplant evaluation.** In a cross-sectional study employing a convenience sample of 104 adult ESRD patients, Dageforde,
Box, Feurer and Cavanaugh (2015) sought to explore the differences between patients who attended an initial pre-transplant evaluation appointment and those who, although scheduled for an appointment, did not attend. The sample of patients were from a single transplant center, referred for evaluation between November 2012 and December 2013, and were matched for status of attendance: 52 who attended a pre-transplant evaluation and 52 who did not. The respondents were all English-speaking adult ESRD patients above 18 years of age, and were matched for race in order to explore elements other than race which might be associated with attendance. The total sample was 61% male, 41% white, with a median age of 52 years (no further descriptive information was provided). The aim of this study was to examine individual motivation and other factors which could influence a patient’s decision to attend the initial pre-transplant evaluation. The study survey was administered via a structured telephone interview using Likert-style scaled questions and open-ended questions. The survey was created by the researchers, with the Brief Health Literacy Screen developed by Chew, Bradley, and Boyko (2004) embedded within it. No validity or reliability data were offered for the overall survey, although the Brief Health Literacy Screen has been independently validated by Chew et al. (2007).

The researchers compared characteristics such as socioeconomic and demographic data, health literacy, understanding of the pre-transplant evaluation, and general concerns about the transplant process. Using chi-square analysis, Fisher exact tests, t tests, and multivariate logistic regression, the differences between the group that attended the pre-transplant evaluation appointment and those that did not attend were examined. Findings indicated that patients who reported as scheduled to the pre-transplant evaluation appointment had a higher level of understanding of the pre-transplant evaluation and the transplant process over those who did not
attend the evaluation appointment \((p \leq 0.005)\). For those who did not attend, the significant findings were that they were more likely to have been evaluated at another transplant center \((p = 0.029)\) and on active dialysis \((p = 0.008)\). The attendee group demonstrated greater trepidation regarding the living donor process over those who did not attend \((p = 0.038)\); however, no further explanation is offered as to why this was so. There were no statistically significant differences found between groups for demographic data (i.e. age, race, gender, or education), income or insurance, miles from the transplant center, or length of wait time for the evaluation appointment.

The researchers also found that concerns regarding transplantation may factor into ESRD patients’ capacity to participate in the pre-transplant evaluation process. These concerns may take the form of psychological issues, ability to comply with required post-transplant self-care (including financing the transplant and the costs of required lifelong medications), and past encounters with the medical community. Recommendations included raising awareness of patient concerns that may be preventing participation in the evaluation process and designing interventions to assist patients in verbalizing and working through these issues.

This study was conducted at a single center and the small sample was one of convenience, making generalities to another setting difficult. However, the survey the researchers created was comprehensive and included questions addressing not only transplant related barriers but also health literacy, thus making it an attractive tool for use in assessing patient perceived barriers in other transplant programs.

**Race versus insurance status as a barrier.** Schold et al. (2011) also sought to understand the barriers to evaluation faced by ESRD patients. Using a convenience sample of 3029 adult patients referred to a single transplant center, the sample of this study consisted of
adults, of which 70% were between 40 to 69 years of age, 56% were White, and 59% were male. Additionally, 53% had commercial health insurance at referral and 85% had no history of previous transplant. The aim of the study was threefold: to identify variables linked with advancement toward waitlisting; to highlight specific steps in the process where barriers were evident and to identify causes of these barriers; and to attempt to examine patient characteristics for previously unexplained relationships to other variables. Data were derived from a database internal to the transplant center.

Multivariate and nested logistic regression were used to analyze the data. For the model predicting likelihood of a pre-transplant evaluation from referral, adjusted odds ratios (AOR) and a 95% confidence interval (CI) were computed. The study found that ESRD patients age 30 to 39 (AOR = .90, 95% CI = 0.61 to 1.33) were more likely than those age 70 and over (AOR = 0.19, 95% CI = 0.13 to 0.29) to receive a pre-transplant evaluation. Besides older age, other findings indicated that a primary diagnosis of diabetes and/or hypertension, lower economic standing, and non-commercial insurance status were negatively associated with access to and completion of evaluation and wait-listing. Additionally, 56% of the referred patients completed a pre-transplant evaluation; 27% were placed on the kidney transplant wait list and 16% ultimately received a new kidney from a deceased or living donor. For patients not moving forward with the pre-transplant evaluation, documented reasons included medical issues (31%), patient refusal to participate (23%), insurance or other financial concerns (16%), and death before the evaluation could be completed (12%).

Interestingly, Schold et al. (2011) found that when covered by commercial insurance, there was no appreciable difference for African Americans compared to Whites (AOR = 0.93, 95% CI = 0.72 to 1.19) progressing to evaluation and wait list; however, when covered with
noncommercial insurance (i.e. Medicare or Medicaid), African Americans were less likely to be evaluated and wait listed when compared to Whites (AOR = 1.47, 95% CI = 1.07 to 2.01). In the final regression model, adjusting for median income, type of health insurance, and distance to the transplant center, this study found that African American status was no longer a significant barrier to evaluation and waitlisting. This is an important finding as the literature generally supports a long-standing claim that African Americans are disadvantaged when seeking kidney transplantation (Alexander & Sehgal, 1998). Schold et al. concluded that noncommercial insurance status may play a larger role than race or ethnicity when considering the participation rate for pre-transplant evaluation and eventual waitlisting, pointing toward financial burdens over race.

The study recommendations were to further explore the barriers lower socioeconomic ESRD patients face and what may be needed in terms of programming and support to successfully access transplant services. Moreover, factors such as the number of clinical comorbidities or contraindications to transplant, provider clinical reasoning, patient-provider relationships, and logistical variables (e.g. transportation needs, distance to the transplant center) also need to be considered when exploring barriers to the pre-transplant evaluation.

This single center study found a significant difference in insurance status as a way of explaining racial disparities in accessing transplant services, with lower socioeconomic standing adding to the racial imbalance. However, health literacy status and level of formal education might also play a role in this sample of ESRD patients’ pursuit of transplantation – neither of which were addressed in this study. A major limitation was that the data were collected from an existing database and what was not contained within it (e.g. current employment status, current income, and a more complete listing of patient comorbidities) could not be analyzed. However,
the findings are a notable addition to the understanding of barriers ESRD patients face, and shed light on the importance of insurance status.

**Psychological Concerns Regarding Transplantation**

There are several psychological barriers cited in the literature that may prevent forward movement in the evaluation process. A frequently cited concern, ranging from 18% to over 40% of respondents, involves a fear of not passing the required medical tests (Dageforde, Box et al., 2015; Kazley et al., 2012). This fear may be the culmination of self-doubt, accumulation of false, misguided information from well-meaning acquaintances, or misunderstood information from medical providers (Kazley et al., 2012). Fearful anxiety regarding the transplant surgery is another often cited emotion, noted as a barrier to evaluation in 40% to 50% of study respondents (Coorey, Paykin, Singleton-Driscoll, & Gaston, 2009; Dageforde, Box et al., 2015; Kazley et al., 2012).

**Psychological barriers: long term dialysis versus transplant recipients.** Coorey, Paykin, Singleton-Driscoll and Gaston (2009) conducted a study which aimed to compare the barriers and attitudes toward early or preemptive transplantation (transplantation before the onset of dialysis) between patients who had received a transplant over those who remained on long term dialysis. The researchers constructed a 28-question survey designed to elicit information on pre-transplant education, psychosocial issues, and financial concerns. Using the National Kidney Foundation’s (NKF) database as the source for recruiting sample respondents, this study stands apart due to its national focus. Randomly selecting every tenth name on the list, 3,586 surveys were sent by either regular mail or email – in accordance with the NKF’s recorded contact preference for each person. The 417 eligible surveys returned represented a response rate of 12.4%. Chi-square and independent group t tests were used to analyze the data. An option was
also available to input free text comments and 85% of study respondents did so, many providing insight into strongly held emotional concerns. For example, 56% of free text respondents detailed emotion-based barriers that contributed to a delay in pursuing a pre-transplant evaluation. Concerns that the transplant surgery, if successful at all, would fail to provide an increase in physical wellbeing or quality of life, as well as fear of the long-term effects of immunosuppressant therapy were noted. A general lack of understanding of the benefits of transplant, which may have alleviated some of these fears, was also noted prompting many respondents to indicate that if they had a more accurate understanding of the benefits of transplant, they would have actively engaged in the pre-transplant evaluation process much sooner. Finally, 60% of respondents who had not yet received a transplant believed that transplantation was an option of last resort, only to be considered after the failure of all other treatment modalities.

Although this study had a national focus, the sample was generated from patients who self-selected to join the National Kidney Foundation database and thus may not reflect the greater ESRD patient population. Additionally, the response rate of those surveyed was a low 12%. However, the study findings were able to shed some light on the fears and concerns of pursuing a kidney transplant. Whether based in rational or irrational beliefs, these concerns need to be addressed in order to assist moving patients forward armed with an accurate understanding of treatment options.

**Financial Concerns**

Consideration of an ESRD patient’s health insurance status is a required step in the pre-transplant evaluation process. Because a kidney transplant requires lifelong immunosuppressant therapy and medical follow-up, the ability of a patient to afford required long term care is
essential information. Patients without sufficient health insurance are less likely to be added to
the transplant wait list than those who are deemed to have adequate resources (Laurentine &
Bramstedt, 2010). In many cases, this restriction raises ethical dilemmas that need to be
addressed.

**The ethics of transplant affordability.** Laurentine and Bramstedt (2010) performed a
review of all cases ($n = 218$) referred to the ethics committee of a large western medical center
from 2007 to 2009. Their findings demonstrated that 27% of cases were related to
transplantation and that of these cases, 40% concerned the inadequate “economic, financial, or
insurance-related” resources of potential transplant recipients (Laurentine & Bramstedt, 2010,
p.180). Of these cases, sixteen documented reduced transplant medical services due to
inadequate finances or limits of health insurance. An additional two cases, involving patients
who had received a kidney transplant, dealt with the individual’s inability to continually access
required immunosuppressant medications. The harsh reality of these cases led these researchers
to conclude that “one of the most difficult and essential roles of bioethicists is to balance the
beneficent desire to help all patients with the economic pragmatism that allows ethical allocation
of scarce and expensive technologies like transplantation” (Laurentine & Bramstedt, 2010,
p.185). Therefore, health insurance status plays a large role in an ESRD patient’s ability to
access transplantation services. Financial screening of each potential transplant recipient usually
occurs before patients are allowed access to the pre-transplant evaluation.

A weakness of this single-center review is that it only involved cases sent to the ethics
committee and may not represent all patients who sought services or who experienced restricted
access to transplant services due to limited financial means. It also may not be generalized to
other transplant centers due to the small number of cases reviewed.
The financial concerns of patients. A narrowly focused study by Ganji et al. (2014) considered the financial impact of kidney transplantation on recipients and their families. In light of the fact that most ESRD patients have Medicare as a primary insurer, these researchers noted that Medicare patients remain responsible for up to 20% of the costs of the transplant, a significant burden for those without supplemental coverage. Additionally, if not otherwise Medicare eligible (i.e. over age 65 or classified as disabled), Medicare coverage for ESRD patients will only extend 36 months after a successful kidney transplant.

Employing a structured qualitative methodology, these researchers conducted four small group interviews involving a total of 23 pre-transplant patients and family members, a majority of whom were at least 60 years of age. The overall sample was comprised of 13 African Americans and 10 non-African Americans. The sessions were conducted by trained moderators using a standard set of open-ended questions to stimulate discussion. Topics covered included the level of understanding of what insurers would cover over the transplant continuum and the amount of financial burden a patient might expect to assume. All sessions were audio recorded and transcribed verbatim. The transcriptions were then examined for themes and subthemes using inductive analysis.

In the beginning of the group interviews, patients and family members often remarked that they had a reasonable understanding of the financial intricacies of the transplant process; however as group discussions ensued, it became clear that many questions and misunderstandings remained. Findings indicated that patients and their families were confused regarding how to calculate what insurance would cover and what would remain their responsibility. Furthermore, patients noted that until services were rendered and bills received, it is virtually impossible to estimate what the financial liability might be. Patients were also
Concerned about future insurability if they should receive a transplant and lose their Medicare coverage. This concern has been somewhat mitigated by the mandate of the Patient Protection and Affordable Care Act of 2010, 2015 (2016) which prohibits the use of “preexisting condition exclusions or other discrimination based on health status” (§2704).

Recommendations from this study include enhancement of financial education and support in pre-transplant visits. A comprehensive national health insurance policy, which encourages and supports kidney transplant recipients over time, was also recommended.

Through the focus group sessions, this study added a rich dialogue to the understanding of the financial barriers and concerns ESRD patients and their families encounter while trying to make the best decisions regarding short and long-term treatment options. It also highlighted where insurance reforms and patient education in the pre-transplant period need to focus. A limitation of the study was its small sample size and single-center focus.

**Personal income and transplant affordability.** Coorey et al. (2009) also included questions regarding financial concerns in their study. Not unexpectedly, over 79% of patients with incomes less than $50,000, indicated concerns over escalating transplant related health care costs, while 62% were concerned with the costs of long-term medication therapy, and 40% were stressed over the general financial obligations for the transplant surgery. Furthermore, patients on long term dialysis had a median income of $19,000 while the median income of those who had received kidney transplant was $59,600 – quite a sizeable difference. Other studies also addressed financial worries and reported that between 14.5% and 60% of respondents struggled with being able to afford the transplantation surgery, the life-long immunosuppressant medications required post-operatively, or both (Dageforde, Box et al., 2015; Kazley et al., 2012).
Health Literacy

Health literacy is defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (Ratzan & Parker, 2000, p.vi). Additionally, the IOM (2004) advocates for increased attention to quality in health care, stating that patient “safety, patient-centered care, and equitable treatment” (p.12) can only be achieved if a patient understands the information providers are trying to impart. Those with limited health literacy may be hindered in the understanding of written health information, when speaking with health professionals, and negotiating the health care system in general (Grubbs et al., 2009). Moreover, low health literacy has been shown to correlate with diminished self-care capacity and compromised patient outcomes (Dageforde et al., 2014). This limited understanding may be interpreted as patient disinterest in the transplantation process on the part of the ESRD providers, leading to fewer referrals for evaluation (Grubbs et al., 2009).

Health literacy status as a barrier to referral for pre-transplant evaluation. In a study involving 62 hemodialysis patients receiving services at five dialysis centers in an urban area of a western state, Grubbs et al., (2009) found that low health literacy was associated with decreased referral for pre-transplant evaluation. The aim of the study was to assess health literacy as it related to being wait-listed for a kidney transplant. The study sample was 41% male and 72% African American, with a mean age of 52.4 years. A majority of respondents had Medicare and Medicaid insurance coverage. Each participant began by completing a self-administered Test of Functional Health Literacy in Adults, followed up by an interview using a standardized questionnaire. One investigator conducted all the interviews. Using Cox proportional hazard modeling this study found that approximately 32% of respondents had
insufficient health literacy with lower levels in patients 65 years and older. Insufficient health literacy was also associated with an annual income of less than $30,000 and completion of formal education equal to or less than a high school diploma. Of the 62 study respondents, 75% received a referral to a transplant center for evaluation. Of the patients referred, the overall mean time from dialysis onset to referral was nearly 18 months. However, for those deemed to possess adequate health literacy, the mean time to referral dropped to 15.3 months while those with inadequate health literacy had a mean referral time of nearly 24 months.

Recommendations from this study are to create multimedia education sessions which could meet the needs of patients with various levels of health literacy. Another recommendation, which may be a challenge in the face of tight health care finances, is to allow ESRD patients who are in the evaluation stage to experience a short overnight stay in order to facilitate the completion of all required testing. This would alleviate the need for repeated trips to the health care facility for those who may find it a challenge. A limitation of this one-center study was the small sample size and the timing of the assessment, which took place after referral for evaluation, allowing for possible change in health literacy status related to the transplant process. However, findings of this study in examining health literacy specifically in the ESRD patient population provides an opportunity for transplant centers to review their own procedures for assessing the health literacy levels of their educational materials and presentations.

Health literacy assessment tools. In another study, Kazley, Hund, Simpson, Chavin, and Baliga (2015) hypothesized that higher health literacy would equate to increased access to the national kidney transplant wait list, and higher odds that a patient would receive a kidney transplant. The study sample consisted of 92 ESRD patients – 65% African American, 51% male, 42% married, and with a mean age of 53.52 years. Government sponsored health plans
(Medicare and/or Medicaid) were the primary source of health insurance and 25% of respondents were also covered by a private source of secondary insurance. Additionally, 58% of the sample obtained wait list status and 39% received a kidney transplant. A study coordinator met privately with each participant, administering three health literacy assessment tools: the Rapid Estimate of Adult Literacy of Medicine - Transplant (REALM-T), the Newest Vital Sign (NVS) assessment, and the Decision-Making Capacity Assessment Tool (DMCAT).

Descriptive analysis, univariate analysis, and multivariate logistic regression were used to examine the data. Multivariate analysis found a positive, significant correlation for each assessment tool and the likelihood of accessing the kidney transplant wait list. Odds ratios were as follows: REALM-T (1.044), NVS (1.672) and DMCAT (1.408). These findings support the hypothesis that health literacy impacts the likelihood of being added to the wait list for a kidney transplant. Interestingly, in all of the regression models, being married was found to be a positive and significant predictor of transplant wait list access, reinforcing the role support systems play in the transplant process.

Recommendations from this study included assessing transplant patients for health literacy status and tailoring education and supporting materials to the level appropriate for the patient. Also recommended was the use of patient navigators to assist patients along the transplant continuum of care. A weakness of this study was the assumption that being married was a predictable source of support. Without assessing the quality of the marriage, this seems to be an unsupported conclusion. Another weakness is the statement, made several times throughout the article, that health literacy influenced or predicted kidney transplant outcomes. This study did not address transplant outcomes, rather it assessed health literacy as a predictor of access to the transplant wait list – two very different concepts. Despite these limitations, this
study offers further understanding of the role health literacy plays in navigating the complex path toward kidney transplantation. It also offers evidence to support the consideration of any of the three most popular health literacy assessment tools for use with this population.

Summary

The literature review findings validate that patients may experience system as well as self-imposed barriers when considering kidney transplantation. These barriers include fear of failing the required medical tests, fear of the transplant surgery, financial concerns, and reduced health literacy. To mitigate these barriers, these fears need to be acknowledged and systems should be designed to assist patients with the complex decision to either move forward with a kidney pre-transplant evaluation or to continue with long-term dialysis.