Inpatient Depression Screening for Patients After Kidney Transplantation

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Abstract

Although the incidence of depression seems to improve with the transition from dialysis to kidney transplantation (KT), depression still remains prevalent, with rates between 20-60% documented in the literature. Depression in patients after kidney transplantation has been associated with non-adherence, increased transplant specific morbidities and mortality, and significant negative outcomes such as graft loss and patient death. There is limited research on the prevalence of depression, associated risk factors, and how to identify depression in the KT population. The literature shows that most patients after KT are not being routinely screened for depression**.** This purpose of this study is to increase early recognition of depressive symptoms in patients after KT by implementing a process improvement intervention to screen patients after KT on admission to an inpatient transplant unit. A retrospective chart review was performed to evaluate a baseline for the current evaluation of depression in this setting during the 30-day period prior to study intervention. Of the 24 patients included in the retrospective chart review, there is no evidence that depression was evaluated in 62.5% of patients. For the study intervention, 13 participants were included. The PHQ-2 and PHQ-9 screening tools were used to assess for depressive symptoms in participants on their admission to a transplant-specific unit at a large medical center, over a 30-day period. The exact Chi-square test was used to analyze the PHQ-2 scores, comparing those with PHQ-2 scores of zero with those PHQ-2 scores greater than 0. The following factors were found to be trending towards statistical significance: age, employment status, a rejection episode and living habitation status. While the screening tool intervention did not identify any positive PHQ-2 scores, it does provide a feasible way to improve evaluation of depressive symptoms in patients after KT.

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Introduction and Background

In 2014, almost 80,000 patients underwent kidney transplants worldwide (Srifuengfung et al., 2017). As kidney transplantation (KT) has become the leading treatment for end-stage renal disease (ESRD), the number of KTs performed annually in the United States continues to increase. This therapy attempts to eliminate the need for dialysis, and improve overall outcomes for ESRD patient population. Since the first successful KT surgery in the United States in 1954, transplantation has seen huge advancements, from improved surgical techniques to more effective immunosuppressive therapy, allowing graft and patient survival to steadily improve. Nationally, the KT survival rate is estimated at 89% at 1 years, and 76% at 5 years (Gorevski et al., 2013).

However, despite these advancements in transplantation and improved overall outcomes, adjusting to the realities of living as an immunosuppressed transplantation patient is difficult. Patients face a host of challenges, ranging from managing their complex medication regimens, frequent blood monitoring, and clinic visits. This can be both overwhelming and demanding for patients and their families. The physical and emotional stressors during the recovery period include learning to navigate through the potential complications associated with recovery from transplantation (Dew et al., 2015). This includes medication side effects, and the new risk of infection, rejection, and malignancy.

Compounding the stressors related to the life of a patient after transplantation may be a history of depression before transplant, which puts them at even greater risk of ongoing depression after transplantation. Depression is linked to poor behavior choices, poor diet and exercise, and substance abuse. Depressed patients may have diminished social support, social isolation, and sleep disturbances. Despite psychiatric evaluations as part of the pre-

transplantation evaluation, clinically significant depression and anxiety are seen at significantly higher prevalence rates in post-transplantation patients than in the general population. These rates are equal or higher than those seen in similar chronic disease populations. One study found transplantation patients have a depression or anxiety rate of up to 62%, compared to 3-10% seen in general population, and 10-40% in patients with other chronic diseases, such as arthritis, cancer, lung disease, heart disease, and diabetes (Dew et al., 2015). Literature suggests that 10-20% of all KT patients experience moderate to severe depression (Dobbels et al., 2008).

Depression has been strongly associated with non-adherence. In 2004, the estimated cost for treatment of non-adherence in kidney transplantation patients in the United States was approximately $100 million a year (Cukor et al., 2009). Non-adherence has been identified as the primary cause of graft failure, and if a patient is non-adherent, graft failure is seven times more likely (Gorevski et al., 2013). In various medical conditions, patients with depression are up to three times more likely to be non-adherent than those without depression (Cukor et al., 2009). In KT patients, one study cited that 22.6% of KT patients were non-adherent, causing late acute rejection in 21% of these patients compared to only 8% of rejection in those who were adherent (Gorevski et al., 2013). The cost of non-adherence after transplant is very high. Often expensive diagnostic procedures are required, as well as rejection therapies that can cost thousands of dollars per medication. Exploring the link between depression and adherence is necessary in this transplant population. A large amount of responsibility is placed of a KT recipient, from maintaining complex medication regimens with regular dose adjustments, frequent appointments and blood analysis, and the expectation to call the transplantation center for assessment with new symptoms. If a patient has certain depressive symptoms, it could make these responsibilities very difficult to sustain in the long term. Despite all the advances in

transplantation technology, patients may experience more graft loss and higher mortality related to depression than is acceptable.

Purpose of the Study

Although depression seems to improve with the transition from dialysis to KT, it remains prevalent, with rates between 20-60% seen in the literature. Depression in post-KT has also been associated with non-adherence, increased transplant-specific morbidities and mortality, and significant negative outcomes for KT patients. There is limited research on the prevalence of this depression, risk factors for depression, the potential outcomes, and the ways to reverse the trends. Research shows that most KT patients are not being screened for depression, therefore limiting early recognition and treatment (Veater & East, 2016).

The purpose of this study is to increase recognition of depression in patients after kidney transplantation by implementing a process improvement intervention to screen patients on admission to an inpatient transplant unit. The primary objective is to enhance recognition of depression in patients after kidney transplantation, with the secondary objective of analyzing the demographic and clinical variables in this sample that correlate with depression.

At this study setting at the time of study implementation, patients after KT were not being routinely screened for depression during their inpatient hospital admission. The transplantation social work team screens post-KT patients as part of the outpatient transplant clinic visit but these patients are not screened routinely as inpatients. Lack of inpatient screening creates a gap in the assessment and identification of depression for admitted transplant patients, as their mental health is often overlooked while managing acute medical problems.

Research Questions

1. Does the implementation of depression screening for patients after kidney transplantation on admission to an inpatient transplantation unit, using the PHQ-2 and PHQ-9 screening tool, increase recognition of depression?
2. Of the identified patients with depression, do the following demographic and clinical factors correlate with higher rates of depression: being unmarried, living alone, being unemployed, having a deceased donor versus a living donor, graft failure after transplant, a rejection episode, and delayed graft function?

Review of the Literature

The studies included in this review discuss many different aspects of depression in relation to post-KT patients. The following topics were included, in order to fully evaluate the literature on this topic: 1) comparison of depression rates between dialysis patients and those post-KT, 2) comparison of depression rates between deceased and living donor recipients, 3) prevalence and/or risk assessment of depression in post-KT patients, 4) assessing non-adherence in relation to depression in post-KT recipients, 5) assessing effects of depression post-KT on mortality and morbidity, and overall outcomes.

Comparing Depression Rates between Dialysis Patients and Kidney Transplant Patients

The purpose of evaluating depression in both end-stage renal disease (ESRD) patients and those post-KT patients is to analyze the risk factors identified in these patient populations. The following eight studies compare depression rates between those that are on dialysis awaiting transplant, and those who are post-KT. A cross sectional study in Turkey by Akman et al. (2004) compared rates of depression between 3 groups; waitlisted patients, post-KT patients, and post-KT patients who have returned to dialysis after chronic allograft loss. In utilizing the Beck

Depression Inventory Scale (BDI), they found significantly lower depression rates in post-KT patients compared to those post-KT that returned to dialysis (p= 0.003). Depression rates were also lower for those on a transplant waitlist than those who had been transplanted but had graft failure, even though both groups were on dialysis. Authors found an association between the length of graft survival and depression in this group, concluding that the longer the graft survived less depression was experienced. This suggests that returning to dialysis correlated to higher depression rates. The results suggest that patients post-KT are at particularly high risk for depression when graft failure leads to a return to dialysis. The authors also found that married individuals in all groups had less depression (p< 0.03). This may indicate that marriage can act as a protective factor for depression, likely related to increased social and emotional support. The authors also concluded that placing a patient on the transplantation waitlist seemed to decrease the incidence and severity of depression in ESRD patients, as it "may provide higher quality of life and better outcomes" (Akman et. al, 2004, p. 113) long term.

Andrade, et al. (2015) assessed differences in hopelessness, suicide ideation, and depression in a cross-sectional study in Brazil. This study compared 50 patients on dialysis, and 50 post-KT recipients using the BDI Scale, the Beck Scale for Suicide Ideation, and Beck Hopelessness Scale. These authors found no significant difference in hopelessness, suicide ideation and depression symptoms between these two groups. However, there was a higher prevalence of depressive symptoms and suicide ideation in the dialysis patient group. When analyzing patients after KT, those receiving transplants from deceased donors had increased depression symptoms compared to those who had received transplants from living donors (p= 0.042). In both patients undergoing dialysis and patients post-KT, unemployment (p= 0.027) and being unmarried (p=0.07) correlated to increased depression risk compared to the patients who

were working and married. This study excluded any patients who required hospital admissions for complications within the preceding four months, patients with known poor compliance, and ones with clinical instability. These exclusion criteria may have prevented the ability to capture depression in the study population, as the exclusions are possible risk factors for depression. However, depression rates in both groups were seen to be "markedly higher" than those in the general population (Andrade, et al., 2015, p. 61). This study highlighted that both groups had a high risk for depression, and that close assessment and monitoring is likely indicated in the populations.

In a prospective cohort study in the United States by Christensen and researchers (2000), patients receiving dialysis before transplantation were compared to patients after kidney transplantation. The patients post-transplantation were evaluated prior to transplantation, and then again after transplantation to assess whether there was any change in their depression after the transplantation intervention. Using the BDI scale, depression scores decreased for patients from the pre-transplant phase to post-transplant. However, there was no significant difference between the two groups (dialysis patients and those who had received a transplant). The study focused on how patient coping mechanisms affected depression and found that patients with a high preference for health-related information had lower rates of depression than those who had lower preference for information. These results, therefore, suggest that patient coping ability and health education may affect depression rates after transplantation.

Corruble and others (2011) examined whether having depression symptoms pre-transplant was predictive of outcomes post-transplant, particularly graft failure and mortality rates at 18 months post-transplant. This prospective longitudinal cohort study took place among three transplant centers in France. They utilized the short BDI and State Trait Anxiety Inventory

(STAI) as instruments. This study included patients either liver or kidney transplantations (excluding recipients with combined kidney-liver transplantations). The authors found that over half (56%) of participants reported depressive symptoms while on the transplantation waitlist. Patients with depressive symptoms had the following risk factors: being younger, female, living alone, smoking cigarettes daily, lower educational status, under employment, and engaging in less leisure activity (Corruble et al., 2011). Interestingly, the authors found patients that reported depression pre-transplantation were found to have a three to four-fold decrease in risk for graft failure and mortality 18 months post-transplantation (similar in both liver and kidney transplantation populations). While this finding is inconsistent with other findings in the literature, the researchers hypothesized that patients expressing depressive symptoms pre-transplantation may be better equipped to cope with the significant stressors post-transplantation (Corruble et al., 2011). It is also possible that those with depression were in denial, and thus more likely to also deny relevant physical symptoms, leading to poorer outcomes (Corruble et al., 2011).

A cross-sectional comparison study by Kovacs and researchers in Hungary (2011), assessed sleep, depression, and health related quality of life (HRQoL) between patients on dialysis and patients post-KT. The authors utilized the Kidney Disease Quality of Life-Short Form (SF-12) tool to assess HRQoL, the Center for Epidemiologic Studies Depression Scale (CED-S) to assess depression, and the Athens Insomnia Scale (AIS) to assess sleep. The study showed that patients post-KT had significantly better health-related quality of life than those on the transplantation waitlist. Both clinically diagnosed depression and depressive symptoms were associated with impaired health related quality of life.

In a study by Muller and others (2015), the prevalence of depression and anxiety were compared between patients before and after KT in a cross-sectional study in Lithuania. They utilized the Hospital Anxiety and Depression Scale (HADS-D/A), SF-12 to assess health-related quality of life, as well as the Resilience Scale, and Coping Self-Questionnaire. No significant differences in prevalence of depression or anxiety were identified between pre and post-transplant groups. They did not find any significant differences in terms of resilience and coping between groups. In the post-transplant group, living alone was noted to be correlated with increased depressive symptoms. Although there was no difference in depression between the two groups, the authors observed higher rates of depression in those groups than in other disease groups.

A cross sectional study in Turkey by Ozcan et al. (2015) compared cognitive symptoms and symptoms of anxiety and depression among patients post-KT, those on hemodialysis (HD), and those on peritoneal dialysis (PD). They used the HAD assessment for depression and anxiety, and Brief Cognitive Scale Examination (BCSE). Patients post-KT had significantly lower levels of anxiety and depression than those on dialysis (both HD and PD). They also had better cognitive scores ($p< 0.001$).

Another study was conducted in Hungary by Szeifert and researchers (2010) who compared depressive symptoms between waitlisted dialysis patients and those patients post-KT, in an observational cross-sectional study. The Center for Epidemiological Studies Depression Scale (CES-D) was used, with findings showing a 33% prevalence of depression in the waitlisted group, compared with 22% in patients post-KT ($p= 0.002$). The authors also found the following to be significant and independent predictors of depression among the transplant patients: number of comorbidities, estimated glomerular filtration rate (GFR), perceived financial situation, and

marital status (Szeifert et al., 2010). Depression was also found to be higher in women, those working less than part-time, and those unmarried ($p < 0.001$). They also found that as estimated GFR (indicator of worsening renal function) decreased depression scores increased ($p = 0.02$).

The studies included in this review compared depression between those persons receiving dialysis and those who had received a transplant. Many studies found being married was associated with lower rates of depression, as well as being employed. Risk factors identified included being on dialysis (whether pre- or post-transplant), smoking, lower socioeconomic status, and living alone. All the above studies found depression scores to be better or equal after transplantation when compared to rates of depression in dialysis patients.

Comparing Depression between Deceased Donor and Living Donor Recipients

Two studies were included that specifically assessed depression rates based on donor status. Schlebusch and researchers (1989), an older study from South Africa, compared depression rates between deceased donor recipients and living donor recipients. It utilized *BDI* to assess 30 deceased donors and 10 living donors. This sample distribution may indicate that there were fewer living donors being utilized when this study was conducted. The authors found no statistically significant difference between these transplant recipient groups. However, the findings did show that 20% of participants had some degree of depression. Lower rates of depression were seen in patients that were at least a year post transplantation.

Virzi and researchers (2007) performed a prospective cross-sectional study in Italy that evaluated anxiety and depressive symptom frequency and prevalence, specifically in living donor recipients and their donors. They used the Hamilton Rating Scare for Depression, Hamilton Anxiety Scale, Self-Rating Anxiety Scale, and Short Form Health Survey (SF-36) to assess health-related quality of life. Patients were assessed at one-month pre-transplant, and six months

post-transplant. Depression rates deceased for living donor recipients from pre-transplant to the post-transplant period. Their health-related quality of life also improved.

There are few studies that compare rates of depression between those who receive living donors and those of deceased donors. Two studies reviewed here are from countries outside of the United States. More studies are needed on this topic, as it could be helpful to understand if there were a significant difference in depression rates between deceased donors and living donor recipients, especially within the United States.

Prevalence and Assessment of Risk Factors of Depression in Kidney Transplant Recipients

Most of the studies reviewed focus on evaluating the prevalence and risk factors of depression among patients who had received KT, comprised of seven studies and one literature review. One cross sectional comparison study in Lithuania by Kusleikaite et al. (2007) examined factors affecting quality of life (QoL) in patients with KT, and the association between QoL and depression. The SF-36 and BDI were utilized. The authors found that 20% of participants had BDI scores over 15, indicating at least mild depression. There was an inverse correlation between depression scores and quality of life. Patients with higher depression scores were significantly older ($p < 0.05$), had higher serum Cr levels ($p < 0.05$) (Kusleikaite et al., 2007).

In a study conducted in Spain by Pérez-San-Gregorio and researchers (2013), patients with KT were evaluated for anxiety and depression during the initial transplant hospitalization (once out of ICU) and again 12 months post-transplant. This study also evaluated liver transplant patients on the same basis. The HADS and BCSE tools were used in this cross-sectional study. Results found that patients with KT were more anxious during initial hospitalization than at 12 months post ($p = 0.001$). Patients after KT were found to be more anxious than patients after liver transplantation during this hospitalization as well. There was no

statistically significant effect seen in terms of depression over time. The results suggest that patients who had received KT need more emotional support during the initial transplant recovery phase while in the hospital.

Spencer and researchers (2011) conducted a clinic audit in a transplant center in the UK to evaluate if depression screening was being done by clinicians at an outpatient transplant clinic, and to confirm depression rates within this population. The audit revealed that rates of screening were poor, particularly by the nephrologists. It found that 22.4% of patients had significant depressive symptoms, using *BDI* scores greater than or equal to 16. The most predictive factor for those with significant depressive symptoms was found to be a reported history of depression. Often this historical depression had not been identified in the patient's chart. While this was a small audit at a single center, it suggests that depression is being under-screened, therefore under- detected and under-treated.

In a Thailand study by Srifuengfung et al. (2017), prevalence and risk factors for depression in patients with KT was evaluated, as well as the link to comorbidities and functional disabilities. The study utilized the Charlson Comorbidity Index (CCI), Patient Health Questionnaire (PHQ-9), and the World Health Organization Disability Assessment Scale (WHODAS). The authors found that 12.9% of patients had depression. Patients with depression had higher comorbidity scores ($p < 0.01$) and higher disability scores ($p < 0.01$). Given that this was a study in Thailand, it is possible that Asian norms and culture may have affected the reporting of depression in this study (Srifuengfung et al., 2017).

In a prospective study in the United States by Stanfill et al. (2016), the association between demographic characteristics, weight change, and depression was explored post-KT. The CES-D was used at the time of transplant, six months post, and 12 months post-transplant. Of

the 47 participants, 62% reported depression at time of transplant, which decreased to 47% at six months, and 49% at 12 months post-transplant. Older patients were found to have higher rates of depression. No significant difference was identified between those who gained weight and depression scores. The authors concluded that patients with KT are at higher risk of depression. Patients after KT are also at high risk for significant weight gain post-transplantation, especially within the first year. This study identified an association between clinical depression and weight gain as well. This can lead to worsening cardiovascular status and increased rates of diabetes. Excessive weight gain has been associated with depression rates, with a 50 % increase in depression in overweight people over their lifetime than the general population (Stanfill et al., 2016). The results stress monitoring importance for both depression and weight gain post-transplantation.

A study conducted in Japan by Tsunoda and researchers (2010), assessed risk factors of depression after KT. This retrospective cohort study used the Zung Self-rating Depression Scale (SDS) to evaluate participants. The authors found depression prevalence in patients post-KT to be 41.4%. Patients with depression were more likely to not have a regular income, a lack of desire for a KT, and an episode of rejection. Those living alone were 2.51 times more likely to be depressed that those living with others ($p < 0.05$). The researchers identified no difference in depression scored between living and deceased donor recipients. This study excluded patients post-KT who visited the Department of Psychiatry after transplantation, and therefore may have missed some patients with depression.

In a study by Weng and colleagues (2009), a cross sectional survey in Taiwan was performed to examine the effects of self-efficacy and self-care on depression post-KT. The BDI, Self-Care Self-Efficacy Scale, and Kidney Transplantation Self-Care Behavior Scale were

utilized. The authors found 32.8% of participants had mild to severe symptoms of depression. Self-care behaviors and self-efficacy had a direct negative effect on depressive symptoms, which was able to explain 23% of the total variance. The authors concluded that self-efficacy is a "modifiable determinant of depressive symptoms" (Weng et al., 2008, p. 1787). They recommended boosting patients' beliefs in their abilities for self-care, as it could lead to decreased depression rates, and positively influence their psychological state (Weng et al., 2008). They endorsed promoting goal-setting, coaching patients, and teaching stress management skills (Weng et al., 2008). Of note, this study takes place in Taiwan, where only 2,750 KT cases were performed from 1967 to 2005 (Weng et al., 2008).

A literature review was conducted by Veater and East (2016) who examined twelve research studies regarding prevalence, detection, and the impact of depression on patients post-KT. This review concluded that patients after KT have less depression that those on dialysis; however, it is still more prevalent than that of the general population. There is also evidence for association between depression and mortality. The review concluded that while routine screening is highly recommended, it is rarely put into practice. The review found increased awareness of depression in this population to be essential, to allow for early identification and treatment.

In summarizing the above articles regarding prevalence and risk factors in depression there were consistent findings. Depression in patients with KT was estimated from 12% to as high as 62% in one study (Stanfill et al., 2016). Increased depression rates were seen in older patients, those with worsened renal function, delayed graft function, lack of regular income, an episode of rejection, and those living alone. The results suggest that social determinants and

social support might be a large contributing factor. It should also be noted that, excepting one study, all of the studies took place internationally.

Non-adherence in Relation to Depression Post Kidney Transplant

Two studies examined the relationship between non-adherence and depression in patients post-KT. Cukor et al. (2009) conducted a prospective cohort study in the United States to determine whether depressive affect is a significant predictor of self-reported medication adherence in patients receiving dialysis and patients post-KT. The BDI and Medication Therapy Adherence Scale were utilized. The authors found that compared to patients who had received transplants, the dialysis cohort was significantly more depressed ($p < 0.001$). Patients with higher depression scores had significantly lower adherence to medications ($p = 0.001$), in both dialysis and transplant patients. Patients on dialysis reported less medication adherence than transplant patients ($p= 0.002$). The authors found that transplant patients with "perceived control over their outcome" were less depressed than those who "attributed their health outcomes to chance" (Cukor et al., 2009, p. 1224). Clinical depression was associated with significantly less medication adherence. These results illustrate that depression is a significant predictor for non-adherence, and that the level of depression correlated with the level of non-adherence.

In a cross-sectional study by Gorevski et al. (2013) in the United States, patients with liver and kidney transplantations were assessed for the association of personality, depression, and quality of life (QoL) for the association with medication adherence. This study used the Immunosuppressive Therapy Adherence Scale (to measure compliance), the NEO Five-Factor Inventory Scale (to measure personality), the PHQ-9 (to measure depression) and the SF-36 (to measure HRQoL). In a sample of 86 participants with KT, 60% had minimal to mild depression, and 9.8% had severe depression scores. The authors found an association between depression

and adherence with immunosuppressive medications in patients post-KT. Those that scored higher on the depression scale were more likely to be non-adherent. The authors identified that 43% of patients with KT were non-adherent.

These two studies show a strong association between depression and non-adherence. They appeared to correlate in intensity as well. The more severe the depression score, the worse the non-adherence. This non-adherence could lead to increased healthcare cost with expensive interventions to treat rejection, but more importantly, decreased graft survival and even patient death.

Depression and Risk for Post-Transplantation Morbidity and Mortality

Four studies and one systematic review and meta-analysis were included on the topic of depression in relation to its risk for morbidity and mortality among post patients with KT. Dobbels et al. (2008) performed a retrospective observational study in America of 47,899 patients with KT (transplanted from 1995-2003). The patients were analyzed based on Medicare billing codes. This study measured the cumulative depression incidence over the first three years of post-transplant. Depression was identified in 3,360 patients, with a cumulative incidence of 5.05% at one year, 7.29% at two years, and 9.10% at three years post-transplant. Of the patients that showed post-transplant depression, 18.6% had evidence of depression in the six months prior to transplant. Depression was associated with a two-fold greater risk of graft failure, increased risk of returning to dialysis and death with a functioning graft. The authors identified the following factors associated with more depression: being Caucasian, female, diabetes as the primary cause ESRD, Rapamycin use, anti-thymoglobulin as induction therapy, donors over age 65, marked obesity, and antigen mismatch (Dobbels et al., 2008). They also found that patients 65 years or older were 14% less likely to be depressed than younger patients. There was no

difference in depression rates identified between deceased and living donor recipients. The authors concluded that depression is greatly correlated with negative outcomes for patients (Dobbels et al., 2008). One limitation of this study is that depression had to be noted in a Medicare claim for it to be identified, which may mean that not all depressed patients were represented in this study.

Rocha et al. (2001) performed a cross-sectional study in Brazil comparing outcomes in patients post-KT with and without depression (based on *BDI* scores). The scores were compared over a four-month time period. Results showed increased rates of depression in patients that had delayed graft function ($p = 0.05$). Depression was significantly higher in patients that had to return to dialysis ($p = 0.002$). Patients with depression had a higher incidence of chronic allograft nephropathy. Overall, "negative results" (Rocha et al., 2001, p. 3424), defined by adding up all negative outcomes listed in the study, were significantly more frequent in patients with depression. Therefore, the study findings showed a strong association between moderate to severe clinical depression and negative outcomes post-transplant.

A prospective cohort study by Novak et al. (2010) in Hungary analyzed whether depressive symptoms are independent predictors of mortality in patients with KT. This study used the CES-D to measure depressive symptoms in 840 patients post-KT, over a five-year period. The authors found the depression prevalence to be 22%, noting that only 2% of the patients were on antidepressants. A higher mortality was noted in patients with depression. Depression scores were significantly predictive of death-censored graft loss (nonfatal graft failure). Higher rates of depression were identified in this study among women, those with worse renal function, more self-reported comorbidities, and lower serum albumin. Patients with depression had significantly worse survival chance that those without depression, as analyzed by

the *Kaplan-Meier* survival plot (used to estimate survival over time). The results suggest that depressive symptoms are independent predictors of mortality in this population.

In a prospective cohort study in Netherlands by Zelle and colleagues (2012), recipients of KT were assessed for depression determinates, and the association with cardiovascular, all-cause mortality (any cause of death) and graft failure. The *Depression Subscale of Symptoms Checklist* (SCL-90) was utilized. The authors found that 31% of participants in this study scored positive for depression. The following were identified as independent variables associated with depression: being medically unfit to work, proteinuria, lower physical activity level, and longer time dialysis on before transplant. Depression was strongly associated with increased with cardiovascular risk ($p = 0.004$), increased all-cause mortality ($p < 0.001$), and increased graft failure.

Dew et al. (2015) conducted a systematic review and meta-analysis, analyzing 27 studies of patients post-transplant. Out of the 27 studies, five examined the association between depression post-KT and common transplant-related morbidities. The analysis found that depression increased the relative risk of mortality by 65%, with the risk of being similar in all transplant organ types. Depression was also associated with an increase death-censored graft loss.

In the before-mentioned studies, depression was shown to be strongly associated with an increased risk of mortality, up to 65% in one study. Outcomes for patients with depression were worse than those without depression. Depression was associated with greater risk of graft failure, and a return to dialysis (Dobbels et al., 2008). Depression was also associated with increased cardiovascular risk, and mortality (Zelle et al., 2012). There is evidence to show that

patients with depression, post-KT, have significantly worse outcomes, and increased morbidity and mortality.

Depression Screening Recommendation

The US Preventive Services Task Force (USPSTF) analyzes the benefits and potential risks of specific preventive care practices and it provides official recommendations. In the most recent update (Siu et al., 2016), the evidence relating to screening for depression in adults (without related signs or symptoms) was reviewed. Based on this analysis, the *USPSTF* recommends screening all adults for depression, with "adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up" (Siu et al, 2016, p. 380). The USPSTF states that screening improves the "accurate identification of adult patients with depression" (Siu et al, 2016, p. 380), as well as better clinical outcomes. There was convincing evidence that treating adults (and older adults) for depression identified through screening decreased clinical morbidity as well (Siu et al., 2016). Their evidence found that patients with chronic illness were at an increased risk for depression. In terms of potential harms for screening adults for depression, the USPSTF found these harms to be "small to none" (Siu et al., 2016, p. 380). Therefore, the USPSTF recommends all adults be screened for depression, regardless of their risk factors.

Summary of the Literature

Depression in patients after KT was estimated to be from 12% to as high as 62% in one study (Stanfill et al., 2016). The literature identified the following demographic factors as significant predictive factors for depression in this population: age, gender, marital status, employment status, social support or lack thereof, living situation, and employment status. The following clinical factors were found to be significant predictive factors in the literature: graft

failure leading to dialysis, number of comorbidities, renal function (either measured with estimated GFR or Cr clearance), rejection episode, and delayed graft function.

Depression is a significant predictor for non-adherence, with the level of depression correlating with the level of non-adherence. Clinical depression was associated with significantly less medication adherence. Many patients that could be thriving with a successful functioning kidney graft lose their graft due to rejection caused by non-adherence to necessary treatment. Depressive symptoms were also shown to be independent predictors of graft loss and mortality in the population. The literature identified that patients with depression post-KT had significantly higher mortality and negative outcomes (Zelle et al., 2012).

Gaps in the Literature

This review of literature analyzed many topics in relation to depression post-KT, including comparison between depression rates among patients receiving dialysis and patients with KT, comparison of depression rates in deceased and living donors, prevalence rates and risk factors for depression in patients after KT, non-adherence and how it related to depression in the KT populations, and risk of mortality and morbidity in depressed patients with KT. However, there are still significant gaps in the literature. There is a lack of randomized control trials on the subject of post transplantation depression. Few studies were conducted at more than one practice setting. Also, most of the studies—22 out of the 26 included in this literature review—were from countries other than the United States. This includes three studies from Brazil, three from Hungary, two studies from Turkey, two studies from Lithuania, two studies from Brazil, and one each from France, South Africa, Italy, Spain, United Kingdom, Thailand, Japan, Taiwan, and the Netherlands. Global transplantation practices and prevalence may be substantially different from those in the United States. There were few studies with robust data from large multi-center

studies within the United States. No studies that evaluated the predictive factors for depression post-KT in an American transplantation center were identified in this literature search. Therefore, there is a need for more research from the United States to better describe and understand the effects of depression in patients after KT in this country.

Theoretical framework

The Chronic Care Model (CCM) was chosen as the theoretical framework for this study because patients with depression who have undergone kidney transplantation have distinctive needs related to the long-term nature of depression and ESRD. After a kidney transplantation, patients have unique social, psychological, physical, and emotional implications related to their new health status and their ability to cope with their transplantation over their lifespan. The chronicity of end-stage renal disease that leads to transplantation and its many complications requires effective long-term patient management. Transplantation and depression are chronic conditions, defined as a condition that requires ongoing adjustments for the patient and continued interaction with the healthcare system (Wagner et al., 1996). The CCM was developed by Ed Wagner and his colleagues in the 1990s, to describe the basic elements necessary to improve health systems and optimize care at the community, organization, practice and patient levels specifically in terms of the unique needs of those with chronic conditions (Wagner et al., 1996). The aim of the CCM is to "transform the daily care for patients with chronic illnesses from acute and reactive to proactive, planned, and population-based" (Coleman, et al., 2009).

The Chronic Care Model

The Chronic Care Model (CCM) has often been applied to the chronic disease of depression. McEvoy & Barnes (2007) applied the CCM to elderly persons with depression. The author found strong evidence that showed when CCM was adopted it significantly improved

outcomes of depression management in older adults (McEvoy & Barnes, 2007, p. 235). Many influential programs have incorporated the CCM into their program approach; specifically, the Improving Mood Promoting Access to Collaborative Treatment (IMPACT) program, the Prevention of Suicide in Primary Care Elderly Collaborative Trial (PROSPECT), and the Program to Encourage Active and Rewarding Lives for Seniors (PEARLS) (McEvoy & Barnes, 2007). Randomized controlled trials assessing the IMPACT program's use of the CCM showed 50% of patients reported substantial improvement in depression symptoms, less functional impairment, and significantly greater quality of life (McEvoy & Barnes, 2007). In randomized controlled trials at multiple centers that analyzed PROSPECT, those receiving interventions based on CCM found decreased depression symptoms at a greater degree and developing over a shorter period than those receiving usual care (McEvoy & Barnes, 2007). In studies analyzing the PEARLs intervention, a randomized controlled trial also found significant decrease in depressive symptoms, as well as an increase emotional and functional well-being (McEvoy & Barnes, 2007).

The Chronic Care Model Framework

The CCM has served as a theoretical framework by researchers to develop processes and outcomes that improve care of patients with chronic illness. In order to intervene in chronic illness providers must use a holistic approach, including the patients' psychosocial, lifestyle, and physical needs (Fiandt, 2006). This framework is comprehensive, taking a multisystem approach, recommending interventions at the patient, provider, and system level (Fiandt, 2006). It encompasses six distinct concepts (Figure 1) as "modifiable components of healthcare delivery" (Fiandt, 2006, p. 1): delivery system design, patient-provider relationship, decision support, information systems, community resources, and healthcare organization. Some of these

concepts address "practice strategies", while others are "specifically patient centered" (Fiandt, 2006, p. 1). The CCM concepts can be addressed individually or together. The CCM is applied to the identification of depression in patients post-KT in multiple ways, as described below.

Delivery system design. The delivery system design of the CCM was adopted as the focus of management for patients with depression post-KT. The CCM shifts the emphasis from reactive care to planned care with sustained follow-up (McEvoy & Barnes, 2007). It advocates for screening of high-risk populations, through a team-based approach. Screening patients post-KT for depression aims to identify depression earlier in the population, which will enable earlier intervention and prevention of complications before the sequela of negative outcomes can occur, such as non-adherence and increased mortality. Once identified, care providers would be encouraged to implement multidisciplinary care interventions, as described by the CCM.

Patient-provider relationship. The CCM model stresses the concept of the patient-provider relationship, and the need to encourage patients to be engaged as active partners in the management of their disease, as well as developing new skills and lifestyle changes (McEvoy & Barnes, 2007). Self-advocacy and partnering with healthcare providers are both crucial to any post-transplant patient's recovery. Patients after KT receive extensive teaching regarding medications, necessary lab work, and recognition of complications of infection and rejection, and necessary lifestyle modifications. In assessing for depression, the screening also assesses the patient's ability to manage and cope with the new aspects of their life post-transplant. Patients with depression may be less likely to engage and actively participate in their own health maintenance, which is a key piece to their lifelong management.

Decision support. The CCM encourages utilizing evidence-based protocols to enhance decision-making among members of the healthcare team. It specifically advocates incorporating

"brief screening and assessment tools, such as the Patient Health Questionnaire- 9*"* (McEvoy & Barnes, 2007, p. 235) to identify when intervention may be needed. This study utilized this screening tool to identify depression, and then analyze the data in relation to depression and post-kidney transplant patients in order to better understand the predictive risk factors. This study analyzed demographic and clinical factors seen as predicative for high rates of depression from the review of literature, to highlight patients at highest risk. This study was conducted based on knowledge obtained from the extant literature on this topic, as recommended by the CCM.

Information systems. The concept of information systems describes the importance of collecting relevant data in order to monitor and track patient progress (McEvoy & Barnes, 2007). The study of depression in patients post-KT conducted by the author collected information on inpatients post-KT and assessed depression prevalence in the population. Information systems played a large role in the ability to access, assess, and statistically analyze the data collected.

Community resources. The CCM highlights the necessity of linking patients with wider community networks. This study assessed patients' support systems, as they relate to depression. Based on the literature, signs of reliance on community resources such as social support, being engaged in work, and living with someone has shown to reduce depression in the post-KT population. Additional study of how these community support systems relate to depression in this patient population is necessary.

Healthcare organization. The final concept involved in the CCM model is the healthcare organization. This multifaceted concept analyzes barriers to implementing the CCM effectively. Potential barriers to adopting the CCM included the following: lack of proper resources (both financial and in terms of personnel), cultural resistance to change, poor planning and lack of leadership support (McEvoy & Barnes, 2007). In order to implement this process

improvement study and intervention, buy-in from the transplantation provider team, including staff nurses, physicians, nurse practitioners, and other healthcare professionals was required. The results of this study may play a role in understanding the problem in one institution, providing a basis for what changes need to occur.

CCM framework summary. All concepts of the CCM play a role in the framework of the process improvement intervention. Each element was utilized in the design of the study. This is a multifaceted model, with many steps needed to fully improve the chronic condition of depression in the chronic illness population of patients post-KT. The study screened for depression (the concept of decision support) to collect demographic and clinical data (the concept of information support) in an organized manner. Focus on screening in high-risk patients post-KT, and sustained follow-up (the concept of delivery system design), in a patient-focused way that engages the individual to encourage better self-management (the concept of patient-provider relationship), were central to the study intervention. The implementation of screening for depression required support from stakeholders, including healthcare providers, and nursing staff (the concept of healthcare organization).

Overview of the Problem and Restatement of Purpose

The literature has shown high rates of depression in patients that are post-KT. This high rate of depression correlates to high rates of non-adherence, which can lead to rejection, and increased morbidity and mortality in these patients. The consequences of depression in this patient population can be devastating for their organ survival and overall patient wellbeing. Research shows that most post-KT patients are not being screened for depression, therefore limiting early recognition and treatment. The purpose of this study is to increase recognition of depression in patients post-kidney transplantation by implementing a process improvement

intervention to screen all patients post-kidney transplantation on admission to an inpatient transplant unit. The primary objective is to enhance recognition of depression in this post-kidney transplant inpatient population, with the secondary objective of analyzing the demographic and clinical variables in the sample that correlates with depression.

Methods

This process improvement study was designed to answer the following two questions:

1. Does the implementation of depression screening in patients post-kidney transplantation on admission to an inpatient transplantation unit, using the PHQ-2 and PHQ-9 screening tool, increase recognition of depression?
2. Of the identified patients with depression, do the following demographic and clinical factors correlate with higher rates of depression: being unmarried, living alone, being unemployed, having a deceased donor versus a living donor, graft failure after transplant, a rejection episode, and delayed graft function?

Definition of Terms

Deceased donor recipient is a deceased donor is defined by the World Health Organization as "a human being declared, by established medical criteria, to be dead and from whom cells, tissues or organs were recovered for the purpose of transplantation" (World Health Organization, "Global Glossary of Terms and Definitions on Donation and Transplantation," 2009, p. 9). Therefore, a deceased donor recipient is a person who received a transplantation from a deceased donor.

Living donor recipient is a living donor is defined by the World Health Organization as "a living human being from whom cells, tissues or organs have been removed for the purpose of transplantation" (World Health Organization, "Global Glossary of Terms and Definitions on

Donation and Transplantation," 2009, p. 12). Therefore, a living donor recipient is a person who received a transplant from a living donor.

Delayed graft function - The official definition is disputed, however, in most of the literature this acute kidney injury immediately post-KT is defined as the need for dialysis within seven days of the transplant (Siedlecki, et al., 2011).

Research Design

This study was a process improvement (PI) intervention. It included a retrospective chart review to establish the evaluation of depression prior to intervention, and then implementation of depression screening tools, PHQ-2 (and PHQ-9 when indicated), through a convenience sampling. It also included statistical analysis to assess correlation of demographic and clinical factors with depression among study participants.

Description of Setting

This study was conducted at a large academic health center in Central Virginia that serves a large catchment area. The comprehensive transplantation center at this hospital has been performing kidney transplantations for over 50 years (beginning in 1967), and averages over 100 kidney transplants yearly. The center performs both deceased and living donor kidney transplants. The Transplantation Service Line Administer and Transplantation Unit Manager granted approval and provided support for the study at this transplant center setting. The study took place on the transplant-specific, 13-bed acute and intermediate care unit. This unit was opened as a transplant-specific unit in January of 2018.

Description of Sample

The sample was obtained through convenience sampling. The same inclusion and exclusion criteria were used for both the retrospective chart review and the study sample. There

were 24 patients included in the retrospective chart review. For the screening intervention, 13 participants consented to participant in the study, based on the following criteria. One patient participated twice, on different admissions, and was treated as a unique subject in the data analysis. This gave the study a sample size of 14. Seven other patients met the inclusion criteria but declined to participate. Inclusion criteria for depression screening intervention included the following:

- Age 18 years or older
- Post-KT transplant readmission, regardless of time from transplant
- Admitted only to specific transplant unit (acute and intermediate care unit)
- Transplant surgery service as primary team
- Kidney-alone transplant
- Failed grafts
- Same patient could be screened multiple times if there were multiple readmissions during study timeframe (each admission would be considered a unique identifier with a unique participant number)

Exclusion criteria included the following:

- Pediatric or adolescent patients
- Any history of simultaneous other organ transplantations
- Pre-transplant patients, who have not yet received kidney transplant (active and inactive on the transplant waitlist)
- New post-operative kidney transplant patients, who had received their kidney transplant during the admission during the time of the study

- Admission location on any units other than the transplant-specific unit (including intensive care units, other intermediate care units, or other acute care units), unless patient transferred to the transplant-specific unit
- Patients on any other service lines, other than the transplant surgery service, unless patient transferred to the transplant surgical service
- Non-English-speaking patients
- Visual impairment preventing completion of form
- Inability to read the consent form
- Cognitive impairment with an inability to give consent

The rationale for excluding certain types of patients post-KT is as follows. Patients who have had any other organ transplantation (whether simultaneous or before or after kidney transplantation), such as kidney-liver transplantation, kidney-pancreas transplantation, or kidney-heart transplantation were excluded. The present PI study focused solely on kidney-alone transplantation, as other organ transplantations have unique considerations and variables that could have complicated this study. Patient who are new post-operative transplant patients, who received their kidney transplantation on this admission, were also excluded. These patients receive very high doses of steroids, are recovering from major surgery, and are adjusting to a lot of changes both physically and psychologically during this initial transplant admission. They are typically only inpatient for three to five days post-operatively. Therefore, those undergoing transplantation during this admission were excluded as these variables could skew depression screening.

Measures

Many different instruments were used in the literature to screen for depression in patients after kidney transplantation. The Patient Health Questionnaire-2 (PHQ-2) and Patient Health Questionnaire-9 (PHQ-9) were chosen for this scholarly project because these instruments were already in use by the transplantation social work team in the outpatient setting at this health system for patients post-KT. The social work team found this tool easy to use for both the patients and staff. By using this tool in this project, it made it possible to provide continuity from the screening already in place for these patients outpatient, and the intervention of this study.

Symptoms of depression were assessed using the PHQ-2. The PHQ-2 is the first two questions of the Patient Health Questionnaire-9 (PHQ-9), and was used as the initial screening for depressive symptoms. The stem question is "over the past two weeks, how often have you been bothered by any of the following problems?" with the first question assessing for "little interest of pleasure in doing things" (Kroenke et al., 2003, p. 1285). Question two is the stem question and "feeling down, depressed, or hopeless" (Kroenke et al., 2003, p. 1285). The response and corresponding score for each of these items are "not at all" (score of 0), "several days" (score of 1), "more than half the days" (score of 2), and "nearly every day" (score of 3) (Kroenke et al., 2003, p. 1285). The scores, therefore, can range from 0-6. Scores of three or more correlate to having a major depressive episode, with sensitivity of 83% and specificity of 92% (Thibault & Steiner, 2004). It is recommended that scores of three or above be further evaluated using the PHQ-9. The PHQ-2 is displayed in Figure 2.

The PHQ-2 instrument was chosen for this study as it is brief, which encourages completion by patients, and provides low participation burden for patients and staff. This is also

the depression screening tool that is already in use by the transplant social work team at this transplant center outpatient clinic. This allowed for continuity from outpatient to inpatient assessment, and consistency in how depression was evaluated. A study by Kroenke et al. (2003) provides strong evidence for validation of the PHQ-2, as a brief measure for screening depression. The study included a sample of 6,000 patients, from 15 clinics throughout the country, and established a strong association between PHQ-2 scores and depressive symptoms (Kroenke et al., 2003). Although the PHQ-2 is utilized, and validated, the PHQ-9 is still the preferred instrument, as it is more comprehensive and provides criteria for diagnosis of depressive disorders (Kroenke et al., 2003).

The PHQ-9 is a depression screening tool, modified from the full PRIME-MD diagnostic tool for common medical disorders, that utilizes a 9-item questionnaire. It includes the nine symptom components necessary for diagnosing depressive disorder using the DSM-IV (Kroenke et al., 2003). Major depressive disorder can be diagnosed if five or more of the criteria for depressive symptoms is present for at least "more than half of the days" in the past two weeks, and once symptom includes "depressed mood" or "anhedonia" (Kroenke et al., 2003, p. 1285). If two, three, or four depressive symptoms have been present for at least "more than half of the days" in the past two weeks, including "depressed mood" or "anhedonia," "other depressive disorder" can be diagnosed (Kroenke et al., 2003, p. 1285). If "thoughts that you would be better off dead or hurting yourself in any way" is present, regardless of duration, the diagnosis criteria for depressive disorder is met (Kroenke et al., 2003, p. 1285). The tool provides a total score between 0-27. Depression severity is scored as follows: 0-4 equals none, 5-9 is mild, 10-14 is moderate, 15-19 is moderately severe, and 20-27 is severe. Therefore, a score of five or above

indicates some depressive symptoms. This is a validated tool with 61% sensitivity and 94% specificity in adults (Maurer, 2013). The PHQ-9 screening tool is displayed in Figure 3.

Procedures

A retrospective chart review was conducted to assess the evaluation for depression prior to this study intervention. This included patients that were readmitted to the transplant-specific unit in the 30-day period prior to study intervention (October 2018-November 2018). Of the 56 patients that were readmitted during this timeframe, 24 patients met this study's inclusion criteria (as listed above). This retrospective chart review was conducted to provide a baseline number of patients who were identified as having depressive symptoms prior to this study's intervention. Information relating to depression was searched in the medical record, to assess if depression was evaluated during the admission, and if depression was identified.

The study investigator provided a brief education session to the inpatient transplant team on the following topics: depression in post-kidney transplant population, the *PHQ-2* and *PHQ-9* depression screening tools, the study design, and inclusion and exclusion criteria. This took place at the transplant nurse practitioner team staff meeting, prior to study implementation. An opportunity for concerns and questions was provided.

The research team was composed of transplantation nurse practitioners who volunteered to complete Collaborative Institutional Training Initiative (CITI) training, which is required by the Institutional Review Board (IRB) to ensure an adequate understanding of protection of human subjects (see Appendix D for documentation of confirmation of training) and assist in the study. This team consisted of the main study investigator (the doctoral student), four transplant nurse practitioners, and one transplant-specific clinical nurse specialist (CNS). The study took place over a 30-day period, from November to December 2018. The study investigator rounded

on the transplant-specific unit at least 3 days a week. Members of the research team conducted a daily assessment to determine which patients met study inclusion criteria and ensure eligible patients were solicited for study participation. The research team discussed participation in the study with all patients who met the criteria. Those patients who agreed to participate were provided an opportunity to review and sign the IRB-approved informed consent (Appendix A), and copies of the consent were offered to the participant. The research team member then provided the PHQ-2 screening tool and demographic form (Appendix B) to participants. The PHQ-2 screening tool was self-administered by the participant, not by the research team or a family member. If the participant was unable to complete the screening tools, the research team made other attempts to complete the screening at a different time. Each patient's clinical condition, comfort, and competing clinical procedures and treatments were always considered a priority. It took each participant about 10 minutes to complete the consent, PHQ-2, and demographic form. The study investigator then scored the PHQ-2 screening tool. If participant scored a three or above of the PHQ-2, then the PHQ-9 screening tool was provided to the participant by the study investigator.

The research team members placed all consent forms, completed screening tools, and demographic forms in an envelope, which was placed in a secure designated area in the study investigator's office on the transplant unit. Each participant was assigned a study ID number, and all identifying patient information was secured.

If the PHQ-9 screening identified a score of five or more, indicating depressive symptoms, this information was to be relayed to the transplant inpatient team within 24 hours for further investigation. This was to allow the transplant team to decide about the need for a psychiatry consult, or further treatment intervention. As part of the transplant team, social work and

pharmacy were to be given this information, so they could provide further assessment/intervention as well. If the patient were to indicate any thoughts regarding suicidal ideation on the screening tool, the study investigator was to provide immediate notification to the transplant team and follow medical center policy for suicide risk assessment and treatment. An explanation of this was provided to the participants on the consent form.

For all patients that completed a PHQ-2 screening form, the following clinical information was obtained from the electronic medical record: a) date of kidney transplantation, b) type of donor, c) whether the graft had failed, d) history of, or current, rejection episode, e) history of delayed graft function, f) documented non-adherence (such as medication non-adherence, or missed appointments or lab visits). These clinical factors were chosen based on the literature, which showed a high association with depression risk in this population. This information was obtained through electronic medical record chart review, and patient information was de-identified prior to being included in a secure dataset, where only participant numbers were used.

Protection of Human Subjects

IRB approval from this academic medical center was obtained prior to beginning this study (Appendix C). This IRB approval ensured the protection of human subjects in accordance with IRB and institutional standards. The retrospective chart review was granted a waiver of consent by the IRB. Informed written consent was obtained from all participants in the prospective study intervention. The IRB determined that this protocol met the criteria of minimal risk to participants. There was a plan in place to provide appropriate intervention and management, to include psychiatry consult and social work consult, in case depressive symptoms were identified during the study. Patient confidentiality was ensured, as all patient information

was de-identified and securely stored in an approved location. All findings were reported only at an aggregate level.

Data Analysis Plan

All data was analyzed using SPSS, Version 25. Descriptive statistics including frequencies and percentages were used to assess the retrospective data related to the following categories: history of depression, use of antidepressant medications, evidence of evaluation for depression, and if patient was identified as depressed. Descriptive statistics were also performed to analyze the data collected on the study participants. The PHQ screening scores, demographic factors, and clinical factors were analyzed. The exact 2-sided Chi-square test was used to examine the relationship between the PHQ-2 scores and each of the demographic and clinical factors. Statistical significance with p value of < 0.05 was used.

Results

Retrospective Chart Review

The study investigator conducted a retrospective chart review, in order to assess the number of patients identified with depression prior to the study's screening intervention. All the patients that were admitted on the transplant unit in the 30-day period, prior to the study intervention, were evaluated for inclusion in the retrospective chart review. The same inclusion criterion for the screening intervention (as above) was used to determine which patients would be included in the chart review. Of the 56 patients admitted to the transplant unit from October to November 2018, 24 patients met the criteria for inclusion. Demographic information was not accessed for these patients. Only data relating to "depression" was searched in their medical record. While searching this information, three categories of information were provided: 1) history of depression noted in the chart, 2) antidepressant medications, 3) any evaluation of

depressive symptoms in the medical record during the current admission. Table 1 displays the results of this retrospective chart review.

History of depression. Of the sample of 24 patients, 41.7% of these patients had a history of depression (n = 10). The remaining 58.3% of the patients did not have a history of depression (n = 14).

Taking antidepressants. This refers to patients who had antidepressants on their current medication list or was documented in a provider's note that they were taking an antidepressant. This revealed that 29.2% of the patients were recorded as taking antidepressants (n = 7). There were no records of antidepressant use for the other 70.8% (n=17).

Evaluation of depression. This category assessed whether there was evidence of an evaluation for depression during the current admission (in the 30-day period that was being assessed). Of the 24 charts that were reviewed, there was no evidence that depression had been evaluated in the documentation for the admission in 62.5% of the patients (n = 15). Of the 24 patients that were reviewed, nine patients (37.5%) had "depression" marked as negative in the review of systems section of the transplant note. There was no evidence that an evaluation for depression of the other 15 (62.5%) had been done during the current admission. The review of systems is a standard form used to document patient's self-reported symptoms, in response to prompts given by the provider. None of these reviews of systems contained information to determine the basis upon which the conclusion that the patient was not depressed was made.

Study Sample Demographics Data

The screening tool intervention was administered during 14 admissions to patients satisfying the inclusion criteria during the study period. There were 13 unique participants, since one participant had two admissions during the study period and received the screening

intervention each time. All data from the two admissions for this participant, including the PHQ-2 score, were the same, except possibly for Habitation Status, which was recorded as living with a "roommate" one time and living with someone "other" than spouse, significant other, roommate, parents, or adult children, the second time. Due to the strong dependency between the data from the two admissions, only data from the second admission for this participant were included in the tables and analyses, leaving an analysis sample of 13 for the study. The study included a demographic form (Appendix B) that was completed by participants. It solicited the following information: age, gender, marital status, living situation, employment status, and whether the participant had any hobbies. The demographic results are shown in Table 2.

Age and gender. All the participants were between the ages of 36-80, with no one in the '18-25,' 26-35'' or '80 or above' age range. The age range '36-50' represented 46.2% of the participants (n = 6), while the '51-65' age range was 30.8% (n = 4), with the remaining 23.1% representing the '65-80' age range (n = 3). The sample consisted of 46.2 % males (n = 6) and 53.8% females (n = 7).

Marital status. One participant missed answering this question on the demographic form. This missing value was excluded from this section's data and data from 13 participants was analyzed. Participants that reported being single were 38.5% of the sample (n = 5). Those reporting being married were 38.5% (n = 5), with 7.7% having a significant other (n = 1), and another one (7.7%) being a widow/widower. One additional participant (7.7%) missed answering this question on the demographic form.

Habitation status. This demographic question assessed who, if anyone, the participant lives with. Participants who reported living with a spouse made up 46.2% of the sample (n = 6). One participants reported living with a roommate (7.7%), while 15.4% reported living alone (n =

2). Another 15.4% reported 'living with other' (n = 2). One participant reported living with a significant other (7.7%), and one reported living with adult children (7.7%). No one reported living with his or her parents.

Employment status. Participants who reported being employed full-time were 30.8% of the sample (n = 4). Participants that were employed part-time were 7.7% (n = 1). Retired participants made up 30.8% (n = 4) of the sample, with 30.8% of participants reporting being unemployed (n = 4).

Hobbies/special interests. This demographic assessed whether the participants had any hobbies or special interests, which was answered with a "yes" or "no." Participants that reported they had hobbies represented 76.9% of the sample (n = 10), with 23.1% reported having no hobbies (n = 3). There was also a "fill in the blank" for patients to list their hobbies. The following were examples of hobbies that participants listed: "hunt, fish, golf", "reading, writing, weight training, jogging, dancing", "sports spectator, beach visits, old cars", "sewing", "art, drawing, fishing", "volunteer, puzzles, TV, crafter", "couponing, yard", "thrift store", "crafts", "travel", "bingo", "choir", and "granddaughter. "

Study Sample Clinical Data

Clinical data was also obtained about each participant, through a chart review completed by the study investigator. This clinical data is detailed in Table 3. If a participant had a history of a previous kidney transplant, the clinical data was used for their most recent kidney transplant.

Time since transplant. Each participant's transplantation date was divided into three categories of time since their transplant: 'less than six months', 'six months to one year', and 'over one year from transplantation'. Participants that were less than 6 months from transplant were found to be 61.5% of the sample (n = 8). Those with transplants between '6 months - 1

year' ago represented 7.7% (n = 1) of the participants, and those that were a year post transplant were 30.8% of the sample (n = 4).

Donor status. Participants that received a kidney transplants from deceased donors represented 92.3% of the sample (n = 12). Participants that received kidney transplants from living donors represented 7.7% of the sample (n = 1).

Graft failure. Participants that had a functioning kidney transplant graft represented 92.3% of the sample (n = 12). Participants that had a kidney transplant graft that had failed were 7.7% of the sample (n = 1).

Rejection. This category assessed whether the participant had a current, or history of, rejection episode in their current kidney transplant. Participants who had no known rejection episodes represented 76.9% of the sample (n = 10). Those who had an episode of rejection made up 23.1% of the sample (n = 3).

Delayed graft function. This category assessed whether a patient's kidney transplant had a documented delayed graft function (DGF). Participants without DGF made up 69.2% of the sample (n = 9), while those with a history of DGF represented 30.8% of the sample (n = 4).

Non-adherence. This category explored whether participants had any documentation in their chart describing the participant as being non-adherent or non-compliant, either in terms of medication administration or missed labs or appointments. Participants that did not have any documented non-adherence made up 92.3% of the sample (n = 12). Those with documented non-adherence were only 7.7% of the sample (n = 1).

Comparing PHQ-2 Scores

None of the 13 study participants scored above three on the PHQ-2 screening tool. Only scores of three or above are considered a positive screening, indicating that major depressive

disorder is likely. Positive scores require follow-up with the PHQ-9 screening tool. However, since no participants scored positive for the PHQ-2, none of them were screened using the PHQ-9. Since no participants were positive for depressive symptoms that would be considered a major depressive disorder, it was not possible to compare the demographic and clinical factors of patients with a positive PHQ-2 score, and those with a negative PHQ-2 score. Therefore, the data was analyzed comparing participants with scores of zero, and those participants scoring greater than zero (which in this case was also fewer than three). The scores of one or two imply the participant reported depressive symptoms for at least several days within the last two weeks. There were three participants that scored higher than a zero, on the PHQ-2, which is 23.1% of the sample. The other 76.9% of the participants (n = 10) scored a zero on the PHQ-2 screening tool.

Risk Factors from Study Data

In order to assess the demographic and clinical risk factors related to depression, the PHQ-2 scores were compared using the following two groups: 1) PHQ-2 scores of zero 2) PHQ-2 scores greater than zero. An exact 2-sided Chi-square statistical analysis was performed, comparing these PHQ-2 scores groupings to each demographic and clinical characteristics. None of the characteristics were found to have a statistically significant relationship with PHQ-2 scores. However, four characteristics were found to be trending towards statistical significance (as shown in Table 4). While a 3-category age variable tested independent of PHQ-2 score (p = .192), all three participants with a positive PHQ-2 score were in the 36-50 years old range. A test of a 2-category age variable (36-50 years; older than 50) comparing PHQ-2 found some evidence of a relationship (p = .070). Participant's employment status was also trending towards statistical significance (p = .105), as those participants that were employed part-time or currently

unemployed had higher PHQ-2 scores. Participant's rejection history (at least one current or historical rejection episode) was also trending towards statistical significance (p = .108). Habitation status was also found to be trending towards statistical significance (p = .080), with participants who lived with a roommate, adult child, or alone having higher PHQ-2 scores. The other variables were not found to be trending towards statistical significance (as shown in Table 5). However, with a small sample size of 13, lack of statistical significance is not evidence of a lack of relationship.

Discussion

It is well documented in the literature that there are difficulties in recruiting participants into studies related to depression (Hughes-Morley et al., 2015). In a systematic review and meta-synthesis by Hughes-Morley et al. (2015), many studies agree that depression studies encounter unique challenges related to participant recruitment. One such challenge relates to the nature of being depressed, in that patients who are depressed are less likely to be engaged and less likely to participate in research trials. Symptoms of depression, "such as lack of concentration and confidence and low motivation" were found to be participation barriers (Hughes-Morley et al., 2015, p. 280). Other studies have found that patients often declined participation if they were feeling well, for fear that participation could disrupt their current ability to cope, and cause them to deteriorate (Hughes-Morley et al., 2015). Therefore, patients who are depressed could be less likely to consent to participation in a study in general, especially one that specifically focuses on depression. This may be a barrier to obtaining accurate representation of depressed patients in studies relating to depression. In this study intervention, it is possible that patients that may have screened positively for depression chose not to participate in the study because they were depressed. Their depressive symptoms could have made them less interested in sharing in the

research. They might not have wanted to acknowledge to themselves, or their family, or healthcare team, that they are depressed. Therefore, it is possible that of the patients who had declined participation in the study, seven in total, there would have been some that would have screened positive for depressive symptoms. A participation bias could have existed which may skew the results.

There were no patients that were found to exhibit symptoms of depression documented in the retrospective chart review, prior to the implementation of the screening tool. This part of the study was designed to give a baseline for the number of patients identified without using a screening tool. The data shows that in over half of the patients (62.5%), there was no evidence to suggest they were even being evaluated for depression. Of the patient's that had depression marked as 'negative' in their chart (37.5%), it was done as part of the "review of systems" in their daily note, and it is unclear if a standardized assessment was done to evaluate these patients as 'negative'. This may have been a very cursory assessment, where the provider simply asks the patient if they feel depressed. In practice, not all the "review of system" questions get asked, and it is possible the provider may not have asked the patient about depressive symptoms and simply assumed based on interactions with the patient. The retrospective chart data shows that most patients are not being fully evaluated for depression, even with a history of depression and antidepressant use, which suggests that they may, in fact, have had depressive symptoms that were not acknowledged.

The screening tool did not identify any patients with depressive symptoms in this PI study. However, it is possible that the limited sample size, and study participation bias as discussed above, could have limited the ability to represent the full potential of the screening implementation. The screening tool used here provides a standard way to ensure that depressive

symptoms are being more fully evaluated for every inpatient admission, which the retrospective data shows is not currently taking place. The PHQ-2 consists of a two question assessment, which if found to have a positive score should be followed up with the nine question PHQ-9 screening tool. These screening tools can be completed independently by patients, and do not take long to complete. The screening tool could be given to patients as part of the standard work upon admission to the transplant unit, and recorded by the nurse into the electronic medical record. This would allow their scores to be tracked at every outpatient visit (the current standard) and during inpatient admissions as well. Ideally, patients would be re-screened every week while inpatient, as their clinical condition could affect their level of depressive symptoms.

While this study's screening tool did not identify any patients with a major depression disorder, when the PHQ-2 scores were compared, there were some variables that were trending towards statistical significance. Age, employment status, history of a rejection episode, and habitation status were all found to be characteristics that affected PHQ-2 scores. All of the participants with a positive PHQ-2 were between the ages of 35 and 50 years old. None of those participants with a positive PHQ-2 were living with a spouse or significant other. None of those participants with a positive PHQ-2 were employed full-time. Only 20% (n = 2) of those with a PHQ-2 of zero were unemployed, while 67% of those with a positive PHQ-2 were unemployed. Only 10% (n = 1) of those with a PHQ-2 of zero had a current episode or history of previous rejection in their current kidney transplant, while 67% (n = 2) of those with a positive PHQ-2 had current or previous rejection. The other variables of being unmarried, having a deceased donor versus a living donor, graft failure after transplant, and delayed graft function were not found to be associated with higher PHQ-2 scores. However, the small sample size limited the power of the study to detect such relationships.

Strengths and Limitations of Study Design

The process improvement intervention in this scholarly project has many strengths and limitations. The PI study was designed using a validated theoretical framework, the Chronic Care Model. The tools for measurement, PHQ-2 and PHQ-9, are both validated measurement tools. There was a low participant burden, as the screening tool and demographic form had very few questions and could be completed in about 10 minutes (when including the time for the informed consent process). This would make implementation of this screening tool feasible and sustainable for use by the transplant unit staff. The screening tool is designed to be self-administered; and the training to use the tool with patients is straightforward and brief. This tool could also be easily applied to patients who had other organ transplants, as it is not designed specifically for patients after kidney transplantation.

The PI scholarly project's limitations are several. The PI study was conducted at a single transplant center, on a single unit that was transplant-specific. There were no pre- and post-intervention measurements of the screening tool itself. The retrospective chart review was used to provide a pre-intervention baseline; however, there was not a direct comparison between depression rates pre-intervention and post-intervention. The small sample size was a limiting factor in this study, as it is difficult to find statistically significant data with such a small sample. A small sample size can reduce the power of the study and increase the level of error in the results. The short time frame of the study impacted the sample size as well. This study used convenience sampling, which can lead to sample bias and make the results less generalizable.

Nursing Practice Implications

There are many implications for nursing practice as a result of this process improvement intervention. This project increased awareness of depression in this patient population among

the transplant team members, and the patients. It has improved the transplant team's focus on the patient's psychosocial needs that may have been previously was overlooked in the setting of their complex medical complications. This awareness could lead to earlier identification of depression in patients post-kidney transplantation patients. The transplant unit is currently planning implementation of the depression screening tool as a standard of care for all post kidney, liver and pancreas transplant patients on inpatient admission. This would enhance the evaluation of depression and provide ongoing depression assessment for patients during the inpatient stays. As the same screening tools are used at outpatient clinic visits in this patient population, it will be possible to track patients' scores and potentially intervene earlier.

The study contributes to the literature on depression in the post kidney transplant population, particularly in the United States. This study supports the need for future research on this topic. In order to better understand the benefits of depression screening in this population, and the associated risk factors, the screening tool should be in place for a longer period, with a large sample size. More research is needed in large transplant centers in the United States, to better analyze the prevalence of depression in the population. The implementation of routine screening will hopefully lead to improved recognition of depression in the study population and ultimately, early and effective treatment of depression.

Products of the Scholarly Practice Project

The scholarly practice project contributed a sustainable, valuable, and relevant intervention for the study transplant center. A method for implementation of screening for depression for patients after kidney transplantation that can easily be administered during inpatient admissions. The process can also be easily applied to patients with other transplanted organs, such as liver transplantation patients. The depression screening tool provided continuity

in assessment between outpatient and inpatient transplant patients. Upon implementation of the screening tool as a standard of care, the transplant center plans to collect data over a six-to-twelve-month period, to analyze and assess the impact the tool is providing for patients who had undergone transplants.

The final report of this scholarly work will be submitted to Libra, University of Virginia's scholarly repository. The completed manuscript of the project will be submitted for publication in *Progress in Transplantation*, a peer-reviewed journal for the North American Transplant Coordinators Organization (NATCO). This study will be submitted to the Virginia Council of Nurse Practitioners (VCNP) organization, as a poster presentation at their annual conference, to take place in spring of 2020.

Conclusion

Depression is a common and significant problem among patients after kidney transplantation. The consequences can be detrimental to the patient's quality of life, and longevity of their transplanted kidney. Existing inpatients are not being adequately assessed for depression, leading to possible delays in diagnosis and treatment, which could be avoided if depression were identified earlier. This study proposes the implementation of the PHQ-2 screening tool in an inpatient transplant unit, to better identify patients with depressive symptoms. While patients in this study were not identified as needing further screening for a depressive disorder, the implementation of the screening tool may still prove to be beneficial to identify patients at risk for depression. As recommended in the USPSTF, all adult patients should be screened for depression, especially those with chronic illness. Therefore, this quality improvement study bolsters the need and awareness for routine screening implementations, with the hope of improving patient outcomes through early recognition and treatment of depression.

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Tables

Table 1. *Retrospective Chart Review Depression Findings*

Characteristic	n= 24	%
History of Depression		
Yes	10	41.7
No	14	58.3
Taking Antidepressant		
Yes	7	29.2
No	17	70.8
Depression Identified During Current Inpatient Admission		
No evidence of evaluation	15	62.5
Negative for depression in review of system	9	37.5
Positive for depression in review of system	0	0
Documentation of depression found in chart	0	0

Table 2. *Demographic Data from Sample*

Characteristic	n= 13	%
Age Range (years)		
18-25	0	0
26-35	0	0
36-50	6	46.2
51-65	4	30.8
65-80	3	23.1
80 or above	0	0
Gender		
Male	6	46.2
Female	7	53.8
Marital Status		
Married	5	38.5
Single	5	38.5
Significant other	1	7.7
Widow/widower	1	7.7
Missing	1	7.7
Habitation Status		
Spouse	6	46.2
Significant other	1	7.7
Roommate	1	7.7
Parents	0	0
Adult children	1	7.7
Alone	2	15.4
Other	2	15.4
Employment Status		
Employed full-time	4	30.8
Employed part-time	1	7.7
Retired	4	30.8
Currently unemployed	4	30.8
Hobbies		
Yes	10	76.9
No	3	23.1

Table 3. *Clinical Data from Sample*

Clinical Characteristic	n= 13	%
Time Since Transplant		
Less than 6 months	8	61.5
6 months- 1 year	1	7.7
More than 1 year	4	30.8
Donor Type		
Deceased donor	12	92.3
Living donor	1	7.7
Graft Failure		
Yes	1	7.7
No	12	92.3
History of or Current Rejection		
Yes	3	23.1
No	10	76.9
Documented Delayed Graft Function		
Yes	4	30.8
No	9	69.2
Documented Non-adherence		
Yes	1	7.7
No	12	92.3

Table 4. *Patient Characteristics with Evidence of Relationship with Positive PHQ-2*

Characteristic	PHQ-2 > 0 n = 3	PHQ-2= 0 n = 10	*p*-value*
	n (%)	n (%)	
Age Range (years)			.070
36-50	3 (100.0%)	3 (30.0%)	
Older than 50	0 (0.0%)	7 (70.0%)	
Employment Status			.105
Employed full-time	0 (0%)	4 (40.0%)	
Employed part-time	1 (33.3%)	0	
Retired	0 (0%)	4 (40.0%)	
Currently unemployed	2 (66.7%)	2 (20.0%)	
Rejection Episode			.108
Yes	2 (66.7%)	1 (10.0%)	
No	1 (33.3%)	9 (90.0%)	
Habitation Status			.080
Spouse	0 (0.0%)	6 (60.0%)	
Significant Other	0 (0.0%)	1 (10.0%)	
Roommate	1 (33.3%)	0 (0.0%)	
Adult Children	1 (33.3%)	0 (0.0%)	
Alone	1 (33.3%)	1 (10.0%)	
Other	0 (0.0%)	2 (20.0%)	

*Exact 2-sided Chi-square, *p*-value is significant at 0.05 level.

Table 5. *Patient Characteristics Lacking Evidence of Relationship with Positive PHQ-2*

Characteristic	*p*-value*
Gender	1.000
Marital Status	.318
Hobbies	1.000
Time Since Transplantation	.608
Donor Status	1.000
Graft Failure	.231
Documented Delayed Graft Function	1.000
Documented Non-adherence	.231

*Exact 2-sided Chi-Square, *p*-value is significant at 0.05 level.

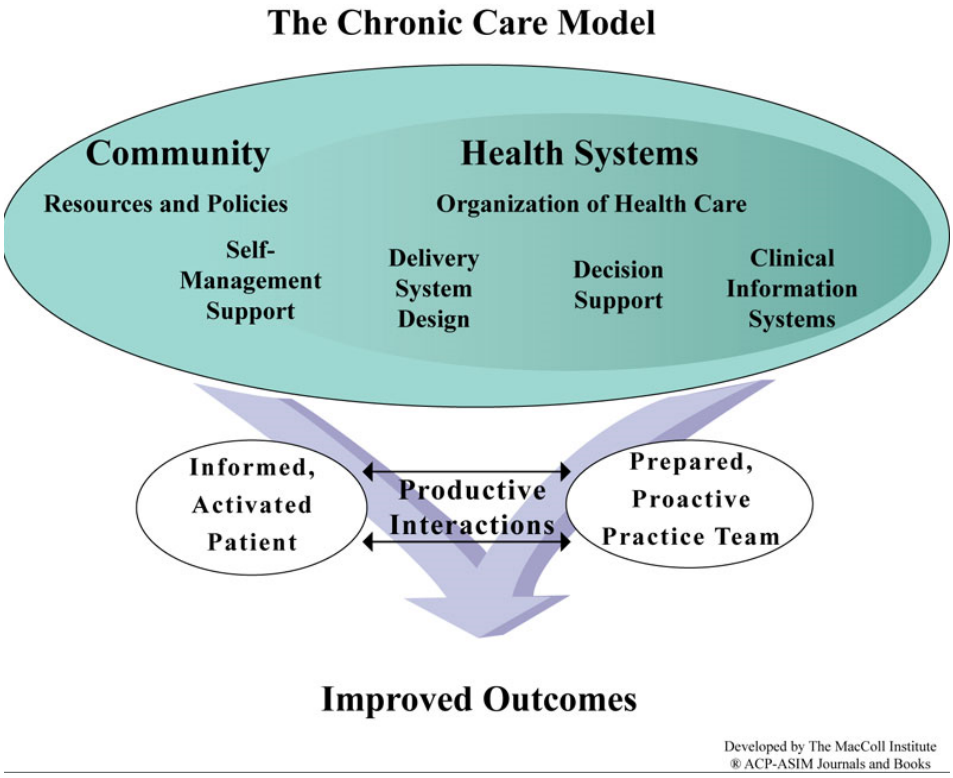

Figure 1. The Chronic Care Model
"Copyright 1996-2018 The MacColl Center. The Improving Chronic Illness Care program is supported by The Robert Wood Johnson Foundation, with direction and technical assistance provided by Group Health's MacColl Center for Health Care Innovation"

Patient Health Questionnaire-2: Screening Instrument for Depression

OVER THE PAST TWO WEEKS, HOW OFTEN HAVE YOU BEEN BOTHERED BY ANY OF THE FOLLOWING PROBLEMS?	*NOT AT ALL*	*SEVERAL DAYS*	*MORE THAN ONE-HALF THE DAYS*	*NEARLY EVERY DAY*
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3

Figure 2. PHQ-2
Created from: Maurer, D. M. (2013). Screening for depression. *American Family Physician,* 139-144.

Patient Health Questionnaire-9: Screening Instrument for Depression

OVER THE PAST TWO WEEKS, HOW OFTEN HAVE YOU BEEN BOTHERED BY ANY OF THE FOLLOWING PROBLEMS?	*NOT AT ALL*	*SEVERAL DAYS*	*MORE THAN ONE-HALF THE DAYS*	*NEARLY EVERY DAY*
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Trouble falling or staying asleep, or sleeping too much	0	1	2	3
Feeling tired or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
	Total:	____+	____+	____

Figure 3. PHQ-9
Created from: Maurer, D. M. (2013). Screening for depression. *American Family Physician,*139 144.

Appendix A

IRB Approved Consent Form for Participation in Study

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:	Dr. Kenneth White, PO Box 800826 3105 Claude Moore Nursing Education Building (434) 924-0091

Introduction:

We invite you to be part of a research study at UVa Medical Center, as part of a nursing doctoral study (through University of Virginia School of Nursing).

What is the purpose of this form?

This form will provide you with information about this research study. Before you decide to participate, we want you to know about what is involved in the study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

It is important for you to know that you do not need to join this study. Your relationship with your transplant team, and other health care providers, will not be affected by your decision to participate or not participate.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is not funded.

Why is this research being done?

This research study is being done as part of a requirement for a nursing doctorate program. The purpose of this study is to identify feelings of depression in patients that have had a kidney transplant. The hope is to recognize these feelings early, so that patients can get the help they need. Other

research has shown an association with depression in some patients who have had kidney transplants. Depression can make taking medications more difficult, as well as caring for yourself once you have a transplanted kidney.

You are being asked to be in this study because you have had a kidney transplant. You must be able to read and write in English to participate in the study, and you will need to complete these forms yourself.

Storing of Data:

We will keep the records of tis study confidential. We will not tell anyone your name is in the study. Only the people working on the study will know your information. This information and screening results will be kept in a secure location within UVa, and not shared outside of this institution.

What will happen if you are in the study?

If you agree to be in this study, you will sign this consent form before any study related procedures take place.

STUDY PROCEDURES

- Complete consent after explanation by researcher, and opportunities to ask questions about the study.
- Complete a separate Personal Information (Demographic) form.
- Complete a 2 - question form, *Patient Health Questionnaire-2 (PHQ-2)* screening tool. This is a form to screen for feelings of depression, rather than an absolute diagnosis. This form should be completed by you, not the researcher or family member. Someone from the research team will be available to answer questions.
- It is possible that the researcher will ask you to fill out one other form called the *Patient Health Questionnaire-9 (PHQ-9)* if you score a certain number on the first (PHQ-2) form.
- If the scores on the *PHQ-9* indicate a possible depression that requires further attention, the researcher will alert your Transplant Team who may decide to set up an additional referral.
- The demographic form and PHQ-2 screening tool should only take between 5-10 minutes to complete. If you are asked to also complete the PHQ-9 screening tool, it should only take an additional 5-10 minutes to complete. These forms will be given to you in your hospital room, after consent has been signed. These forms are being given for research purposes, and will not be part of your medical record.
- Your medical history will be reviewed in the computer chart.

During this study, you will be asked to fill out a personal information (demographic) form. This form will ask you about:

- age
- gender
- marital status

- living situation
- employment status
- hobbies and special interests

During this study, you will be asked to fill out questionnaires, or screening tools. These questionnaires will ask you about:

- your moods
- your level of pleasure or enjoyment in doing things
- ability to sleep
- energy level
- appetite
- depressed feelings

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You should be completely truthful in answering personal information (demographic) form and study screening questionnaires.
- Follow all instructions given.
- These forms should be completed yourself, not by legal guardians or family members.

How long will this study take?

Your participation in this study will require the time it takes to complete the personal information (demographic) form and questionnaires. Each form should take about 5 minutes. You will be given the forms on the day you have completed the consent. You may be asked to complete an additional questionnaire a few days later, depending on your responses to the first questionnaire. Completing all of these forms should take about 15-20 minutes total. There are no additional procedures, visits or study follow-up. Given you are in the hospital, if you are unable to fill out the forms when the study team comes by (related to not feeling well, or tests and procedures your medical team has scheduled), they will come back at a later time that day or the next.

Risks from Completing Questionnaires

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and move on to the next question
- Some of the questions asked may make you angry, emotionally upset or stressed out not or at a later time. If this occurs, you may contact the following person for help: Anna Tate, (703) 862-3074*.* If you do not wish to answer a question, you may skip it and go to the next question.

- There could be a risk of discomfort that may occur as a result of participation. If you do not wish to answer a question, you may skip it and move on to the next question.

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?
You may or may not benefit from being in this study. Possible benefits could include: recognizing depressed feelings, for which your transplant team could provide you with additional support**.** In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?
You do not have to be in this study. The care you receive from your transplant team and other healthcare providers will not be affected if you decide not to participate in this study.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.

If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?
You will not get any money for being in this study.

Will being in this study cost you any money?
Being in this study will not cost you any money.

What if you are hurt in this study?
If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?
You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)

- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Kenneth White
Address: PO Box 800826 3105 Claude Moore Nursing Education Building
Telephone: (434)924-0091

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908

Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Consent

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Appendix B

Demographic Information Form

ID NUMBER_____

PERSONAL INFORMATION (DEMOGRAPHIC) FORM

Please circle the answers or fill in the blank:

1. AGE:
   a. 18-25
   b. 26-35
   c. 36-50
   d. 51-65
   e. 65-80
   f. 80 or above

2. GENDER:
   a. Male
   b. Female

3. What is your marital/partner status?
   a. Married
   b. Single
   c. Significant Other
   d. Widow/widower

4. Who do you live with?
   a. Spouse
   b. Significant Other
   c. Roommate
   d. Parent/parents
   e. Adult Children
   f. Alone
   g. Other: _____

5. What is your employment status?
   a. Employed full time
   b. Employed part time
   c. Retired
   d. Currently unemployed

6. Do you have any hobbies or special interests that you engage in?

a. Yes
b. No

7. Please list your hobbies and/or special interests:

_____

Appendix C

IRB Approval

ASSURANCE FORM
University of Virginia
Institutional Review Board for Health Sciences Research
HIPAA Privacy Board

IRB - HSR # 21071

Event:	Type:	Sponsor(s): / Sponsor Protocol #:
Approval New Protocol - Expedited	Protocol	Principal Investigator: Kenneth White

Title: Implementing Inpatient Depression Screening for Post-Kidney Transplant Patients

Assurance: Federal Wide Assurance (FWA)#: 00006183 **IRB#00000447**

Certification of IRB Review:
The IRB-HSR/HIPAA Privacy Board abides by 21CFR50, 21CFR56, 45CFR46, 45CFR160, 45CFR164, 32CFR219 and ICH guidelines as compatible with FDA and DHHS regulations. This activity has been reviewed in accordance with these regulations.

Event Date: 10/22/18
Protocol Expiration Date: 10/21/19
Number of Subjects: 45
HSR Protocol Version Date: 10/15/18

UVA Site Only
IRB Application Date: 10/15/18
Data Security Plan Date: 10/15/18

Current Status: Open to enrollment

Consent Version Dates:
Adult Consent -- 10/16/18

Committee Members (did not vote):

Comments: The IRB determined the protocol met the criteria for approval per the federal regulations and was approved. It is open to enrollment.

The purpose of this study is to enhance recognition of depression in this post- kidney transplant inpatient population.

The study will involve participants to complete questionnaires. A retrospective chart review will be conducted to determine depression symptoms in this population for baseline comparison.

There is no outside sponsor for this study.

N=45 participants (25 for chart review and 20 prospective) Ages=18 years of age and greater

The following documents were submitted with this protocol:
1. Tate Demographic Form 10-4-18
2. Tate PHQ-2 10-4-18
3. Tate PHQ-9 10-4-18

This study is not regulated by the FDA as it does not involve research on a drug, biologic or device.

No additional committee approvals are required

No compensation

REGULATORY INFORMATION:

The IRB determined this protocol met the criteria of minimal risk.

Protocol Expedited by Category #5: Research involving materials (data, documents, records or specimens) that have been collected solely for non-research purposes (such as medical treatment and/or diagnosis).

Protocol Expedited by Category #7: Research on individual or group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focu group, program evaluation, human factors evaluation, or quality assurance methodologies.

This protocol has been granted a Waiver of Consent to identify potential subjects via 45CFR46.116.

Prospective portion:
This protocol has been granted a Waiver of Consent via 45CFR46.116 to contact potential subjects by direc contact by a person who is their health care provider. Direct contact may include phone, letter, direct email or potential subject approached at UVa by a person is their health care provider. Phone, letter or emails will be approved by the IRB-HSR prior to use.

Written consent will be obtained for this study. The consent form signed will have a non-expired IRB-HSR approval stamp.

Chart review portion:
This protocol has been granted a waiver of consent under 45CFR46.116 for the main study.

This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for the main study.

The following HIPAA identifiers will be collected: Name, elements of date, age over 89, MRN.

The minimum necessary PHI to be collected includes: demographics, depressive symptoms identified.

Subjects may not be contacted by any method (email, phone, in person etc.) to obtain more information for this study without additional IRB-HSR approval.

No identifiable health information will be taken or shared outside of the UVa HIPAA covered entity.

PLEASE REMEMBER:
* If an outside sponsor is providing funding or supplies, you must contact the SOM Grants and Contracts Office/ OSP regarding the need for a contract and letter of indemnification. If it is determined that either of

these documents is required, participants cannot be enrolled until these documents are complete.
* You must notify the IRB of any new personnel working on the protocol PRIOR to them beginning work.
* You must obtain IRB approval prior to implementing any changes to the approved protocol or consent form except in an emergency, if necessary to safeguard the well-being of currently enrolled subjects.
* If you are obtaining consent from subjects, prisoners are not allowed to be enrolled in this study unless the IRB-HSR previously approved the enrollment of prisoners. If one of your subjects becomes a prisoner after they are enrolled in the protocol you must notify the IRB immediately.
* You must notify the IRB-HSR office within 30 days of the closure of this study.
* Continuation of this study past the expiration date requires re-approval by the IRB-HSR.

The IRB-HSR official noted below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.

Name: Amy E. Blackman, MSN, RN, CCRC Title: Member, Institutional Review Board for Health Sciences Research Phone: 434-924-9634 Fax: 434-924-2932	Name and Address of Institution: IRB for Health Sciences Research University of Virginia, PO Box 800483 Charlottesville, VA 22908 **OR** IRB for Health Sciences Research One Morton Drive, Suite 400 Charlottesville, VA 22903
Approval: Approved by Amy E. Blackman, MSN, RN, CCRC From IP Address: 172.28.22.76	Date: 10/22/18 at 01:51 PM

Appendix D

Confirmation of Research Team Training

UNIVERSITY of VIRGINIA

Office of the Vice President for Research
Institutional Review Board for Health Sciences Research

Confirmation of Training in Human Subject Protection

HSR # : 21071 **Title :** Implementing Inpatient Depression Screening for Post-Kidney Transplant Patients

This is a certificate confirming that the following personnel have completed University of Virginia Research Training, an on-line tutorial that reviews the core concepts for the responsible conduct of research in a way that is consistent with federal and university requirements. Following each topic summary, the investigator must correctly answer the test question before being allowed to continue. This training is required every three years.

Name	Training	Last Trained	Expires
Melinda L Bowles-Childress	HSR	(HSR CITI - All Researchers) 15-Jan-18	15-Jan-21
Amy L Roman	HSR	(HSR CITI - All Researchers) 24-Feb-16	24-Feb-19
Suzanne Queheillalt	HSR	(HSR CITI - All Researchers) 25-Jan-16	25-Jan-19
Kenneth R White	HSR	(HSR CITI - All Researchers) 13-May-17	13-May-20
Shawn M Floyd	HSR	(HSR CITI - All Researchers) 10-Jan-18	10-Jan-21
Lara Myers	HSR	(HSR CITI - All Researchers) 10-May-18	10-May-21
Anna L Tate	HSR	(HSR CITI - All Researchers) 21-Jul-18	21-Jul-21

10/16/2018

Richard Stevenson, MD
Chair, Institutional Review Board for Health Sciences Research
(UVA IRB)

Date

Inpatient Depression Screening for Patients after Kidney Transplantation

Anna La Monica Tate, MSN, AGACNP-BC, PCCN

University of Virginia, School of Nursing

Charlottesville, Virginia

Kenneth R. White, PhD, AGACNP-BC, ACHPN, FACHE, FAAN

Abstract

Introduction: Depression in patients after kidney transplantation (KT) is documented in the literature to be between 20-60%. This has been associated with non-adherence, increased transplant specific morbidities and mortality, and significant negative outcomes such as graft loss and patient death. There is limited research on the prevalence of depression, and associated risk factors. The literature recommends routine screening of these patients, but that it rarely is put into practice. Research Question: Does implementing a process improvement intervention to screen inpatient admissions for depression increase early recognition of depressive symptoms in patients after KT? Design: A retrospective chart review evaluated the baseline for the current evaluation of depression in this setting during the 30-day period prior to study intervention. For the study intervention, 13 participants were included. The *PHQ-2* and *PHQ-9* screening tools were used to assess depressive symptoms when patients were admitted to a transplant unit, over a 30-day period. Results: Of the 24 patients included in the retrospective chart review, 62.5% of patient's chart showed no evidence of evaluation for of depression. The exact Chi- square test was used to analyze the PHQ-2 scores, comparing those with PHQ-2 scores of zero with those PHQ-2 scores greater than zero. The following factors were found to be trending towards statistical significance: age, employment status, a rejection episode and living habitation status. Discussion: While the screening tool intervention did not identify any positive PHQ-2 scores, it does provide a feasible way to improve evaluation of depressive symptoms in patients after KT.

Introduction and Background

In 2014, almost 80,000 patients underwent kidney transplants worldwide (Srifuengfung et al 788). Since the first successful KT surgery in the United States in 1954, transplantation has seen huge advancements, from improved surgical techniques to more effective immunosuppressive therapy, allowing graft and patient survival to steadily improve. Nationally, the KT survival rate is estimated at 89% at 1 years, and 76% at 5 years (Gorevski et al. 301). However, despite these advancements in transplantation and improved overall outcomes, adjusting to the realities of living as an immunosuppressed transplantation patient is difficult. Patients face a host of challenges, ranging from managing their complex medication regimens, frequent blood monitoring, and clinic visits.

Compounding the stressors related to the life of a patient after transplantation may be a history of depression before transplant, which puts them at even greater risk of ongoing depression after transplantation. Despite psychiatric evaluations as part of the pre-transplantation evaluation, clinically significant depression and anxiety are seen at significantly higher prevalence rates in post-transplantation patients than in the general population, or in similar chronic disease populations. One study found transplantation patients have a depression or anxiety rate of up to 62%, compared to 3-10% seen in general population, and 10-40% in patients with other chronic diseases, such as arthritis, cancer, lung disease, heart disease, and diabetes (Dew et al. 988). Literature suggests that 10-20% of all KT patients experience moderate to severe depression (Dobbels et al. 819).

Depression has been strongly associated with non-adherence. In 2004, the estimated cost for treatment of non-adherence in kidney transplantation patients in the United States was approximately $100 million a year (Cukor et al. 1223). Non-adherence has been identified as the

primary cause of graft failure, and if a patient is non-adherent, graft failure is seven times more likely (Gorevski et al. 301). In various medical conditions, patients with depression are up to three times more likely to be non-adherent than those without depression (Cukor et al. 1223). In KT patients, one study cited that 22.6% of KT patients were non-adherent, causing late acute rejection in 21% of these patients compared to only 8% of rejection in those who were adherent (Gorevski et al. 301).

In patients after KT, depression was shown to be strongly associated with an increased risk of mortality. Outcomes for patients with depression were worse than those without depression. Depression was associated with greater risk of graft failure, and a return to dialysis (Dobbels et al. 819). Depression was also associated with increased cardiovascular risk, and mortality (Zelle et al. 1033). There is evidence to show that patients with depression, post-KT, have significantly worse outcomes, and increased morbidity and mortality.

Purpose of the Study

The purpose of this study is to increase recognition of depression in patients after kidney transplantation by implementing a process improvement intervention to screen patients on admission to an inpatient transplant unit. The primary objective is to enhance recognition of depression in patients after kidney transplantation, with the secondary objective of analyzing the demographic and clinical variables in this sample that correlate with depression.

Research Questions

3. Does the implementation of depression screening for patients after kidney transplantation on admission to an inpatient transplantation unit, using the PHQ-2 and PHQ-9 screening tool, increase recognition of depression?

4. Of the identified patients with depression, do the following demographic and clinical factors correlate with higher rates of depression: being unmarried, living alone, being unemployed, having a deceased donor versus a living donor, graft failure after transplant, a rejection episode, and delayed graft function?

Methods

Research Design

This study was a process improvement (PI) intervention. It included a retrospective chart review to establish the evaluation of depression prior to intervention, and then implementation of depression screening tools, PHQ-2 (and PHQ-9 when indicated), through a convenience sampling.

Description of Setting

This study was conducted at a large academic health center in Central Virginia. The center performs both deceased and living donor kidney transplants. The study took place on the transplant-specific, 13-bed acute and intermediate care unit.

Description of Sample

The sample was obtained through convenience sampling. The same inclusion and exclusion criteria were used for both the retrospective chart review and the study sample. There were 24 patients included in the retrospective chart review. For the screening intervention, 13 participants consented to participant in the study, based on the following criteria. Seven other patients met the inclusion criteria but declined to participate. Inclusion criteria for depression screening intervention included the following:

- Age 18 years or older
- Post-KT transplant readmission, regardless of time from transplant

- Admitted only to specific transplant unit (acute and intermediate care unit)
- Transplant surgery service as primary team
- Kidney-alone transplant
- Failed grafts

Exclusion criteria included the following:

- Pediatric or adolescent patients
- Any history of simultaneous other organ transplantations
- Pre-transplant patients, who have not yet received kidney transplant
- New post-operative kidney transplant patients, who had received their kidney transplant during the admission during the time of the study
- Admission location on any units other than the transplant-specific unit
- Patients on any other service lines, other than the transplant surgery service
- Non-English-speaking patients
- Visual impairment preventing completion of form
- Inability to read the consent form
- Cognitive impairment with an inability to give consent

Measures

Symptoms of depression were assessed using the PHQ-2. The PHQ-2 is the first two questions of the Patient Health Questionnaire-9 (PHQ-9), and was used as the initial screening for depressive symptoms. Scores of three or more correlate to having a major depressive episode, with sensitivity of 83% and specificity of 92% (Thibault and Steiner 1101). The PHQ-2 is displayed in Figure 1. The PHQ-2 instrument was chosen for this study as it is brief, which encourages completion by patients, and provides low participation burden for patients and staff.

Although the PHQ-2 is utilized, and validated, the PHQ-9 is still the preferred instrument, as it is more comprehensive and provides criteria for diagnosis of depressive disorders (Kroenke et al. 1284).

The PHQ-9 is a depression screening tool, modified from the full PRIME-MD diagnostic tool for common medical disorders, that utilizes a 9-item questionnaire. It includes the nine symptom components necessary for diagnosing depressive disorder using the DSM-IV (Kroenke et al. 1284). Depression severity is scored as follows: 0-4 equals none, 5-9 is mild, 10-14 is moderate, 15-19 is moderately severe, and 20-27 is severe. Therefore, a score of five or above indicates some depressive symptoms. This is a validated tool with 61% sensitivity and 94% specificity in adults (Maurer 139). The PHQ-9 screening tool is displayed in Figure 2.

Procedures

A retrospective chart review was conducted to assess the evaluation for depression prior to this study intervention. This included patients that were readmitted to the transplant-specific unit in the 30-day period prior to study intervention. Of the 56 patients that were readmitted during this timeframe, 24 patients met this study's inclusion criteria. Information relating to depression was searched in the medical record, to assess if depression was evaluated during the admission, and if depression was identified.

The study intervention took place over a 30-day period. Members of the research team conducted a daily assessment to determine which patients met study inclusion criteria and ensure eligible patients were solicited for study participation. Consented participants were provided the PHQ-2 screening tool and demographic form by the research team. The PHQ-2 screening tool was self-administered by the participant. Each patient's clinical condition, comfort, and competing clinical procedures and treatments were always considered a priority. It took each

participant about 10 minutes to complete the consent, PHQ-2, and demographic form. The study investigator then scored the PHQ-2 screening tool. If a participant scored a three or above of the PHQ-2, then the PHQ-9 screening tool was provided to the participant by the study investigator.

For all patients that completed a PHQ-2 screening form, the following clinical information was obtained from the electronic medical record: a) date of kidney transplantation, b) type of donor, c) whether the graft had failed, d) history of, or current, rejection episode, e) history of delayed graft function, f) documented non-adherence (such as medication non-adherence, or missed appointments or lab visits). These clinical factors were chosen based on the literature, which showed a high association with depression risk in this population

Protection of Human Subjects

IRB approval from this academic medical center was obtained prior to beginning this study. This IRB approval ensured the protection of human subjects in accordance with IRB and institutional standards. The retrospective chart review was granted a waiver of consent by the IRB. Informed written consent was obtained from all participants in the prospective study intervention. The IRB determined that this protocol met the criteria of minimal risk to participants. There was a plan in place to provide appropriate intervention and management, to include psychiatry consult and social work consult, in case where depressive symptoms or suicidal ideations were identified during the study. Patient confidentiality was ensured, as all patient information was de-identified and securely stored in an approved location. All findings were reported only at an aggregate level.

Data Analysis Plan

All data was analyzed using SPSS, Version 25. Descriptive statistics including frequencies and percentages were used to assess the retrospective data and the data collected on

the study participants. The PHQ screening scores, demographic factors, and clinical factors were analyzed. The exact 2-sided Chi-square test was used to examine the relationship between the PHQ-2 scores and each of the demographic and clinical factors. Statistical significance with *p* value of < 0.05 was used.

Results

Retrospective Chart Review

Of the sample of 24 patients, 41.7% of these patients had a history of depression (n = 10). There were 29.2% of the patients that were recorded as taking antidepressants (n = 7) on their current medication list. Nine patients (37.5%) had "depression" marked as negative in the review of systems section of the transplant note. There was no evidence that an evaluation for depression of the other 15 (62.5%) had been done during the current admission.

Study Sample Demographics Data

The screening tool intervention was administered during 14 admissions to patients satisfying the inclusion criteria during the study period. There were 13 unique participants, since one participant had two admissions during the study period and received the screening intervention each time. Due to the strong dependency between the data from the two admissions, only data from the second admission for this participant were included in the tables and analyses, leaving an analysis sample of 13 for the study. The study included a demographic form that was completed by participants. It solicited the following information: age, gender, marital status, living situation, employment status, and whether the participant had any hobbies. The demographic results are shown in Table 1. All the participants were between the ages of 36-80, and the age range '36-50' represented 46.2% of the participants (n = 6). The sample consisted of 46.2 % males (n = 6) and 53.8% females (n = 7). In terms of marital status, participants that

reported being single were 38.5% of the sample (n = 5). Those reporting being married were 38.5% (n = 5), with 7.7% having a significant other (n = 1), and another one (7.7%) being a widow/widower. One additional participant (7.7%) missed answering this question on the demographic form.

Participants were asked with whom, if anyone, the participants lived. Participants who reported living with a spouse made up 46.2% of the sample (n = 6). One participants reported living with a roommate (7.7%), while 15.4% reported living alone (n = 2). Another 15.4% reported 'living with other' (n = 2). One participant reported living with a significant other (7.7%), and one reported living with adult children (7.7%). No one reported living with his or her parents.

Participants who reported being employed full-time were 30.8% of the sample (n = 4). Participants that were employed part-time were 7.7% (n = 1). Retired participants made up 30.8% (n = 4) of the sample, with 30.8% of participants reporting being unemployed (n = 4). Participants that reported they had hobbies represented 76.9% of the sample (n = 10).

Study Sample Clinical Data

Clinical data was also obtained about each participant, through a chart review completed by the study investigator. This clinical data is detailed in Table 2. If a participant had a history of a previous kidney transplant, the clinical data was used for their most recent kidney transplant. Participants that were less than 6 months from transplant were found to be 61.5% of the sample (n = 8). Those with transplants between '6 months - 1 year' ago represented 7.7% (n = 1) of the participants, and those that were a year post transplant were 30.8% of the sample (n = 4). Participants that received a kidney transplant from deceased donors represented 92.3% of the sample (n = 12). Participants that had a functioning kidney transplant graft represented 92.3% of the sample (n = 12). Participants who had no known rejection episodes represented 76.9% of the

sample (n = 10). Participants without delayed graft function (DGF) made up 69.2% of the sample (n = 9). Participants that did not have any documented non-adherence made up 92.3% of the sample (n = 12).

Comparing PHQ-2 Scores

None of the 13 study participants scored above three on the PHQ-2 screening tool. Only scores of three or above are considered a positive screening, indicating that major depressive disorder is likely. Positive scores require follow-up with the PHQ-9 screening tool. However, since no participants scored positive for the PHQ-2, none of them were screened using the PHQ-9. Since no participants were positive for depressive symptoms that would be considered a major depressive disorder, it was not possible to compare the demographic and clinical factors of patients with a positive PHQ-2 score, and those with a negative PHQ-2 score. Therefore, the data was analyzed comparing participants with scores of zero, and those participants scoring greater than zero. The scores of one or two imply the participant reported depressive symptoms for at least several days within the last two weeks. There were three participants that scored higher than a zero, on the PHQ-2, which is 23.1% of the sample.

Risk Factors from Study Data

In order to assess the demographic and clinical risk factors related to depression, the PHQ-2 scores were compared using the following two groups: 1) PHQ-2 scores of zero 2) PHQ-2 scores greater than zero. An exact 2-sided Chi-square statistical analysis was performed, comparing these PHQ-2 scores groupings to each demographic and clinical characteristics. None of the characteristics were found to have a statistically significant relationship with PHQ-2 scores. However, four characteristics were found to be trending towards statistical significance (as shown in Table 3). While a 3-category age variable tested independent of PHQ-2 score (p =

.192), all three participants with a positive PHQ-2 score were in the 36-50 years old range. A test of a 2-category age variable (36-50 years; older than 50) comparing PHQ-2 found some evidence of a relationship ($p = .070$). Participant's employment status was also trending towards statistical significance ($p = .105$), as those participants that were employed part-time or currently unemployed had higher PHQ-2 scores. Participant's rejection history (at least one current or historical rejection episode) was also trending towards statistical significance ($p = .108$). Habitation status was also found to be trending towards statistical significance ($p = .080$), with participants who lived with a roommate, adult child, or alone having higher PHQ-2 scores. The other variables were not found to be trending towards statistical significance.

Discussion

It is well documented in the literature that there are difficulties in recruiting participants into studies related to depression (Hughes-Morley et al. 274). Many studies agree that depression studies encounter unique challenges related to participant recruitment (Hughes-Morley et al. 274). In this study intervention, it is possible that patients that may have screened positively for depression chose not to participate in the study because they were depressed. Therefore, it is possible that of the patients who had declined participation in the study, seven in total, there would have been some that would have screened positive for depressive symptoms.

There were no patients that were found to exhibit symptoms of depression documented in the retrospective chart review, prior to the implementation of the screening tool. This part of the study was designed to give a baseline for the number of patients identified without using a screening tool. The data shows that in over half of the patients (62.5%), there was no evidence to suggest they were even being evaluated for depression. Of the patient's that had depression marked as 'negative' in their chart (37.5%), it was done as part of the "review of systems" in

their daily note, and it is unclear if a standardized assessment was done to evaluate these patients as 'negative'. The retrospective chart data shows that most patients are not being fully evaluated for depression, even with a history of depression and antidepressant use, which suggests that they may, in fact, have had depressive symptoms that were not acknowledged.

The screening tool did not identify any patients with depressive symptoms in this PI study. However, it is possible that the limited sample size, and study participation bias as discussed above, could have limited the ability to represent the full potential of the screening implementation.

While this study's screening tool did not identify any patients with a major depression disorder, when the PHQ-2 scores were compared, there were some variables that were trending towards statistical significance. Age, employment status, history of a rejection episode, and habitation status were all found to be characteristics that affected PHQ-2 scores. The other variables of being unmarried, having a deceased donor versus a living donor, graft failure after transplant, and delayed graft function were not found to be associated with higher PHQ-2 scores. However, the small sample size limited the power of the study to detect such relationships.

The PI scholarly project's limitations are several. The PI study was conducted at a single transplant center, on a single unit that was transplant-specific. There were no pre- and post-intervention measurements of the screening tool itself. The retrospective chart review was used to provide a pre-intervention baseline; however, there was not a direct comparison between depression rates pre-intervention and post-intervention. The small sample size was a limiting factor in this study, as it is difficult to find statistically significant data with such a small sample. This study used convenience sampling, which can lead to sample bias and make the results less generalizable.

Conclusion

Depression is a common and significant problem among patients after kidney transplantation. The consequences can be detrimental to the patient's quality of life, and longevity of their transplanted kidney. Existing inpatients are not being adequately assessed for depression, leading to possible delays in diagnosis and treatment, which could be avoided if depression were identified earlier. This study proposes the implementation of the PHQ-2 screening tool in an inpatient transplant unit, to better identify patients with depressive symptoms. While patients in this study were not identified as needing further screening for a depressive disorder, the implementation of the screening tool may still prove to be beneficial to identify patients at risk for depression. This process improvement study bolsters the need and awareness for routine screening implementations, with the hope of improving patient outcomes through early recognition and treatment of depression.

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Tables

Table 1 Demographic Data from Sample

Characteristic	n= 13	%
Age Range (years)		
18-25	0	0
26-35	0	0
36-50	6	46.2
51-65	4	30.8
65-80	3	23.1
80 or above	0	0
Gender		
Male	6	46.2
Female	7	53.8
Marital Status		
Married	5	38.5
Single	5	38.5
Significant other	1	7.7
Widow/widower	1	7.7
Missing	1	7.7
Habitation Status		
Spouse	6	46.2
Significant other	1	7.7
Roommate	1	7.7
Parents	0	0
Adult children	1	7.7
Alone	2	15.4
Other	2	15.4
Employment Status		
Employed full-time	4	30.8
Employed part-time	1	7.7
Retired	4	30.8
Currently unemployed	4	30.8
Hobbies		
Yes	10	76.9
No	3	23.1

Table 2 Clinical Data from Sample

Clinical Characteristic	n= 13	%
Time Since Transplant		
Less than 6 months	8	61.5
6 months- 1 year	1	7.7
More than 1 year	4	30.8
Donor Type		
Deceased donor	12	92.3
Living donor	1	7.7
Graft Failure		
Yes	1	7.7
No	12	92.3
History of or Current Rejection		
Yes	3	23.1
No	10	76.9
Documented Delayed Graft Function		
Yes	4	30.8
No	9	69.2
Documented Non-adherence		
Yes	1	7.7
No	12	92.3

Table 3 Patient Characteristics with Evidence of Relationship with Positive PHQ-2

Characteristic	PHQ-2 > 0 n = 3	PHQ-2= 0 n = 10	*p*-value*
	n (%)	n (%)	
Age Range (years)			.070
36-50	3 (100.0%)	3 (30.0%)	
Older than 50	0 (0.0%)	7 (70.0%)	
Employment Status			.105
Employed full-time	0 (0%)	4 (40.0%)	
Employed part-time	1 (33.3%)	0	
Retired	0 (0%)	4 (40.0%)	
Currently unemployed	2 (66.7%)	2 (20.0%)	
Rejection Episode			.108
Yes	2 (66.7%)	1 (10.0%)	
No	1 (33.3%)	9 (90.0%)	
Habitation Status			.080
Spouse	0 (0.0%)	6 (60.0%)	
Significant Other	0 (0.0%)	1 (10.0%)	
Roommate	1 (33.3%)	0 (0.0%)	
Adult Children	1 (33.3%)	0 (0.0%)	
Alone	1 (33.3%)	1 (10.0%)	
Other	0 (0.0%)	2 (20.0%)	

*Exact 2-sided Chi-square, *p*-value is significant at 0.05 level.

Patient Health Questionnaire-2: Screening Instrument for Depression

OVER THE PAST TWO WEEKS, HOW OFTEN HAVE YOU BEEN BOTHERED BY ANY OF THE FOLLOWING PROBLEMS?	*NOT AT ALL*	*SEVERAL DAYS*	*MORE THAN ONE-HALF THE DAYS*	*NEARLY EVERY DAY*
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3

Figure 1. PHQ-2
Created from: Maurer, Douglas M. "Screening for depression." *American Family Physicians* (2012): 139-144.

Patient Health Questionnaire-9: Screening Instrument for Depression

OVER THE PAST TWO WEEKS, HOW OFTEN HAVE YOU BEEN BOTHERED BY ANY OF THE FOLLOWING PROBLEMS?	*NOT AT ALL*	*SEVERAL DAYS*	*MORE THAN ONE-HALF THE DAYS*	*NEARLY EVERY DAY*
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Trouble falling or staying asleep, or sleeping too much	0	1	2	3
Feeling tired or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
	Total:	____+	____+	____

Figure 2. PHQ-9
Created from: Maurer, Douglas M. "Screening for depression." *American Family Physicians* (2012): 139-144.