Marian University
Leighton School of Nursing

Doctor of Nursing Practice
Final Project Report for Students Graduating in August 2019 and May 2020

Expanding Renal Transplant Selection Criteria to Include HIV Infected Candidates

Smyrna Rivera Hatfield

Marian University

Leighton School of Nursing

Chair: Cathryn Baack, PhD, APRN, FNP-C

Signature

Organizational Liaison: Cara Crone, MSN, AGACNP-BC, CCTC

Cara Crone, AGACNP-BC

Signature

Date of Submission: August 18, 2019

Table of Contents

Abstract

Background and Review of Literature: Renal transplantation has a significant survival benefit over dialysis and is the recommended treatment modality for ESRD in the eligible HIV infected candidate. However, there are multiple disparities in accessing renal transplant among this group including restrictive selection criteria as determined by individual transplant centers. Only 20% of potentially eligible HIV infected candidates progress towards activation to the renal transplant waiting list in comparison to 73% of their non-HIV infected counterparts.

Purpose: Ensure equitable access to renal transplant by modifying the existing selection criteria at a faith-based institution to include eligible HIV infected candidates for renal transplantation.

Methods: A single center, prospective observational cohort study was conducted to determine the influence of modifying selection criteria to include eligible HIV infected individuals with ESRD in reducing disparities for access to renal transplantation. As the theoretical framework, Lewin's Change Management model served to assess organizational readiness and permanency of selection criteria modification.

Implementation Procedure: 329 dialysis units were notified in writing of the modified selection criteria with instructions on referring patients for renal transplantation. A comparative analysis of the volume of HIV infected ESRD patient referrals, evaluations, listings and transplants six months prior to and three months post intervention was performed.

Conclusions: Six HIV infected patients with ESRD were referred for renal transplantation postintervention which correlated to a 200% increase by volume. 33% advanced to the evaluation phase. None of the participants were activated to the waiting list or received a transplant. Additional observation is warranted to establish the efficacy of modifying selection criteria in increasing the access of HIV infected ESRD patients to renal transplantation.

Keywords: renal transplant, HIV infection, end stage renal disease

Expanding Renal Transplant Selection Criteria to Include HIV Infected Candidates

Introduction

This project is submitted to the faculty of Marian University Leighton School of Nursing as a partial fulfillment of degree requirements for the Doctor of Nursing Practice, Family Nurse Practitioner track. The aim of this project is to reduce disparities among HIV infected individuals with renal disease in accessing renal transplantation by modifying selection criteria. An emphasis is placed on the efficacy of performing renal transplantation among this patient population based on survival benefits and favorable outcomes. The project will involve the modification of the existing selection criteria policy at a faith-based institution, St. Vincent Hospital and Health Services (INSV), to include eligible HIV infected candidates. Intended consequences would encompass an increased volume of HIV infected candidate referrals, evaluations, listings and eventual transplants. Long term goals include meeting transplant center requirements to participate in the Organ Procurement Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) HIV Organ Policy Equity (HOPE) Act Variance which allows the transplantation of HIV infected donor organs to HIV infected recipients.

Background

According to the Centers for Disease Control and Prevention (CDC) (2019), it is estimated that the prevalence of HIV in the United States is 1.1 million with almost 40,000 newly diagnosed cases annually. Due to recent advancements in highly active antiretroviral therapy (HAART), the life expectancy of HIV infected individuals has increased, with successive progression towards chronic illnesses, predominantly renal disease (Wright & Gill, 2015). As reported by the United States Renal Data System (USRDS) (2018), 1.5% of individuals with ESRD are infected with HIV. Furthermore, HIV nephropathy is a leading

etiology of renal failure among African Americans (Locke et al., 2015a; Sawinski & Bloom, 2014).

HIV infected patients with ESRD have a 19-fold increased mortality rate in comparison to non-HIV infected ESRD patients (Locke et al., 2017a). Conversely, HIV infected renal transplant recipients demonstrate a 79% lower risk of mortality at five years when compared to those who remain on dialysis (Apewokin, Madan, Restrepo, Hemmige, & Arora, 2018). Multiple large cohort studies have presented favorable outcomes among HIV infected renal transplant recipients, including equivocal patient and graft survival rates (Nashar & Sureshkumar, 2016). Therefore, renal transplantation in the eligible HIV infected candidate is considered a superior treatment modality for ESRD when compared to dialysis (Querido et al., 2015; Sawinski & Bloom, 2014).

Despite evident survival benefits and acceptable outcomes, multiple disparities in accessing renal transplant among HIV infected candidates persist (Baisi et al., 2016; Cohen et al., 2019; Halpern, Asch, Shaked, Stock & Blumberg, 2005). Sawinski et al. (2009), found that only 20% of potentially eligible HIV infected candidates progressed towards activation to the renal transplant list in comparison to 73% of their non-HIV infected counterparts. Once activated to the waiting list, barriers remain, as the likelihood of receiving a first kidney offer and undergoing transplantation is reduced (Cohen et al. 2019). It is postulated that these inequities exist in part due to unsubstantiated claims shared by 88% of transplant centers who cite "concerns of accelerated progression to AIDS, the potential for unacceptable complication rates and anticipation of limited recipient survival" (Cohen et al., 2019, p. 7). Moreover, Halpern et al. (2005) found that 67% of transplant surgeons were unwilling to perform transplantation for HIV infected candidates despite the acknowledgement of equivocal patient survival rates.

Problem Statement

Due to recent advancements in HAART and newfound knowledge of HIV pathogenesis and immunology, HIV infected renal transplant recipients demonstrate a significant survival benefit in comparison to utilizing dialysis as a treatment modality for ESRD (Malet et al., 2015). Furthermore, HIV infected renal transplant recipients exhibit acceptable patient and graft survival rates that are equivocal to their non-HIV infected counterparts, despite higher rates of acute rejection (Locke et al., 2014).

However, transplant centers have traditionally excluded HIV infected ESRD patients as renal transplant recipients based on concerns for increased mortality rates, risks of HIV-associated complications and poor utility of organs as a scarce resource (Cohen et al., 2019; Halpern et al., 2015). As a result, HIV infected ESRD patients are subjected to inequity when accessing renal transplantation based on restrictive selection criteria among transplant centers.

The existing selection criteria will be adjusted to remove HIV infection as an absolute contraindication and allow HIV infected ESRD patients with stable CD4+ T-cell counts and nondetectable viral loads to be considered for renal transplantation. In doing so, equitable access to renal transplant for eligible HIV infected ESRD patients is safeguarded as those individuals meet criteria to begin the process for undergoing renal transplantation.

Organizational "Gap" Analysis of Project Site

HIV infected ESRD patients are ineligible for renal transplantation at INSV based on absolute contraindications as outlined in the existing selection criteria policy. Reasons cited included the lack of an established protocol for donor and recipient selection criteria, immunosuppressive induction, maintenance therapy regimens and posttransplant monitoring, in addition to potential for drug interactions between antiretroviral and immunosuppressive

therapies with subsequent graft failure. As a result, this institution does not meet the minimum requirements to participate in the HOPE Act variance which allows for the transplantation of organs from HIV infected donors to HIV infected candidates under approved research protocols (OPTN, 2019).

The root cause of the gap within INSV is partially attributed to the lack of an established policy and protocol specific to (a) donor and recipient selection criteria; (b) immunosuppressive induction therapy; (c) maintenance therapy regimens; (d) posttransplant monitoring. Additional contributing factors include a lack of knowledge and skill as this institution has never performed renal transplantation with an HIV infected patient. However, Locke et al., (2015a) states that "center-level experience or consortium participation is not necessary to achieve excellent outcomes" among HIV infected renal transplant recipients (p. 1). Nevertheless, according to Nashar and Sureshkumar (2016), "a close collaboration between infectious disease specialists and transplant professionals is mandatory in order to optimize transplantation outcomes in these patients" (p. 300). While INSV often consults with infectious disease physicians trained in the management of transplant recipients, this professional relationship should be strengthened in preparation for performing HIV infected renal transplantation to prevent acute rejection and viral load replication.

Review of the Literature

HIV nephropathy is a predominant etiology of ESRD, especially among African Americans (Locke et al., 2015a). The USRDS (2018) reported that the prevalence of HIV has stabilized at 1.5% in hemodialysis patients and increased to almost 1% in renal transplant recipients. Prior to the introduction of highly active antiretroviral therapy (HAART), HIV infection was considered an exclusion factor for renal transplantation due to "potential risks of

chronic immunosuppression on a background of HIV-related immune dysfunction" (Sawinski & Bloom, 2014, p. 619). Between 1987 and 1997, HIV infected renal transplant recipients experienced a mortality rate up to 50% within two years post-transplant (Sawinski & Bloom, 2014). Five-year posttransplant patient and graft survival rates were 71% and 44%, respectively (Sawinski & Bloom, 2014). The availability of HAART, in combination with advanced knowledge related to the pathophysiology of HIV, led to the initiation of large cohort trials specific to HIV infected renal transplant recipients (Locke et al., 2015b).

The National Institute of Health (NIH) trial consisted of 150 HIV infected renal transplant recipients and demonstrated favorable outcomes despite higher incidences of acute rejection (Stock et al., 2010). These findings demonstrated efficacy in performing renal transplantation as the preferred treatment for ESRD among HIV patients (Vicari et al., 2016; Wright, 2016). Despite publications reflecting survival benefits and equivocal outcomes, multiple barriers delay or inhibit HIV infected candidates from accessing renal transplant (Locke et al., 2017b). For instance, the ongoing shortage of suitable organs can limit renal transplantation as an option (Muller, Barday, Mendelson, & Kahn, 2016). Efforts to address the organ shortages resulted in legislation through the HOPE Act which legalized transplantation from HIV infected donors to HIV infected recipients in the U.S. (Shaffer & Durand, 2018). However, stringent enrollment criteria limit transplant centers from participating in this open variance (Jackson & Cameron, 2017).

Epidemiology

According to the CDC (2019), there are currently 1.1 million known cases of HIV in the U.S with the primarily affected group consisting of young, African American males. Upon the introduction of HAART, the lifespan of HIV infected individuals has increased as mortality rates

due to chronic illnesses, such as ESRD, have exceeded opportunistic infections (Locke et al., 2015b; Mori, Grossi & Durand, 2019). The third cause of ESRD among African Americans is HIV nephropathy (Locke et al., 2015b). The USRDS (2018) notes a prevalence of 1.5% of ESRD patients infected with HIV. Renal transplantation is considered the preferred treatment option for eligible HIV infected candidates based on comparable patient and graft survival rates to non-HIV infected recipients. (Apewokin et al., 2018; Locke et al., 2015b).

Disparities in Accessing Renal Transplantation

Transplant center specific barriers.

Despite documented success rates, there are disparities among HIV infected candidates in undergoing renal transplantation (Cohen et al., 2019). HIV infected ESRD patients have been traditionally excluded as candidates for renal "transplantation due to the concern for worsening infections and rejection", poor utility of organs, and maleficence towards the intended recipient (Nasahr & Sureshkumar, 2016, p 301). In 1997, a survey of 148 transplant centers revealed that 88% did not believe that HIV infected candidates should receive a transplant even when asymptomatic (Cohen et al., 2019). An additional survey conducted in 2005 disclosed that 67% of transplant surgeons are unwilling to perform transplant on an HIV infected candidate despite recognition of equal patient survival rates (Halpern et al., 2015). HIV candidates are less likely to be activated to the renal transplant waitlist (Cohen et al., 2019; Nashar & Sureshkumar, 2016). Candidates who progress to listing experience lengthened time intervals to receive their first organ offer and to undergo transplantation (Cohen et al., 2019). HIV infected candidates are also subjected to higher mortality rates while listed in comparison to their non-HIV infected counterparts (Nashar & Sureshkumar, 2016). Furthermore, HIV infected candidates have a

reduced likelihood of receiving a living donor renal transplant and experience prolonged waitlist times, partially due to organ shortages (Cohen et al., 2019; Locke et al., 2017b).

Organ shortages.

According to the OPTN (2019), there are currently 95,046 patients on the renal transplant list. The Scientific Registry of Transplant Recipients (2019) revealed the national median time to transplant as 61.8 months with 23.4% of listed candidates receiving a renal transplant within 3 years. HIV infected renal transplant candidates have a significantly longer wait until their first organ offer and to transplantation (Cohen et al., 2019; Nashar & Sureshkumar, 2016). The utilization of HIV infected organs "was banned in 1988 through an amendment to the National Organ Transplantation Act" (Jackson & Cameron, 2017, p.65). Fortunately, changes in legislation through the HOPE Act have legalized transplantations from HIV positive deceased donors to HIV positive recipients in the U.S. as of 2013 (OPTN, 2019). The HOPE Act is expected to expand the donor pool by approximately 500 to 600 per year in the U.S. and reduce wait times for HIV infected candidates as well as those not infected with the virus (Muller, Barday, Mendelson, & Kahn, 2016).

At the present time, specific transplant hospital criteria must be met to qualify for participation in the open variance of the HOPE Act including an (a) "established program for the care of individuals infected with HIV; (b) study team consisting of (at a minimum) a transplant surgeon, a transplant physician, and an HIV physician; (c) transplant physician and HIV physician collectively must have experience with at least five HIV-negative to HIV-positive transplants with the designated organ(s) over the last four years" (OPTN, 2018, para. 5). Once the preceding requirements are met, "transplant hospitals must notify the OPTN Contractor in writing that they intend to participate in an institutional review board (IRB) approved research

protocol" (OPTN, 2018, para. 9). In order to maintain eligibility, transplant hospitals must submit data safety monitoring reports at designated intervals and reapply for IRB approval upon expiration (OPTN, 2018).

Locke et al. (2015b), noted that center level experience in performing HIV infected renal transplants was not a prerequisite to achieve favorable outcomes. Nevertheless, the legality of transplanting HIV infected organs into HIV infected recipients remains contingent upon approval to participate in the HOPE Act research trials (Jackson & Cameron, 2017). In effort of reducing disparities among HIV infected candidates for accessing renal transplant, some members of the transplant community have proposed "that the HIV Organ Policy Equity act can be widened to allow centers to use HIV-positive donors outside of research protocols" (Jackson & Cameron, 2017, p. 73).

Immunosuppression regimens.

HIV infected renal transplant recipients require dual therapy consisting of immunosuppressive and antiretroviral medications to prevent rejection of the allograft and viral replication (Wright, 2016). Immunosuppressive therapy has not been shown to accelerate the progression of HIV infection, rather demonstrate antiretroviral effects that serve to stabilize HIV viral loads (Cohen et al., 2019; Nashar & Sureshkumar, 2016). However, obstacles in selecting immunosuppressive regimens remain "including choice of immunosuppression drugs, drug-drug interaction and heightened risk of infections" (Nashar & Sureshkumar, 2016, p. 301). Therefore, transplant specialists must be knowledgeable of the immunological processes associated with HIV infection and the pharmacodynamics of immunosuppressive medications to achieve favorable outcomes (Locke et al., 2014).

The NIH trial consisted of a prospective, nonrandomized study among 150 HIV infected candidates who underwent renal transplantation between November 2003 and June 2009 (Stock et al., 2010). Participants were carefully selected to meet specific criteria which included (a) CD4+ T-cell counts >200 cells per cubic milliliter; (b) nondetectable HIV-1 RNA levels (<50 copies per milliliter); (c) stable antiretroviral regimen at least 16 weeks prior to transplantation; (d) meet center-specific selection criteria for renal transplant HIV-related criteria; (e) absence of a history of chronic intestinal cryptosporidiosis, primary central nervous system lymphoma, progressive multifocal leukoencephalopathy or visceral Kaposi's sarcoma (Stock et al., 2010).

The participants were found to have 1 and 3-year patient survival rates at 94.6% and 88.2% with correlating graft survival rates at 90.4% and 73.7% respectively (Stock et al., 2010). These rates were similar to patient and graft survival rates among non-HIV infected renal transplant recipients despite higher incidences of acute rejection (Stock et al., 2010). Furthermore, HIV infection remained managed as evidenced by stable CD4+ T-cell counts and reduced incidence of adverse events associated with HIV infection (Stock et al., 2010).

The results of this trial served as a catalyst for the enhancement of immunosuppressive regimens specific to HIV infected renal transplant recipients in lieu of higher than expected episodes of acute rejection (Bossini, et al. 2014; Haas, et al., 2015). Locke et al. (2014) conducted a comparative retrospective analysis of the immunosuppression regimen and occurrence of acute rejection among 516 HIV infected and 93,027 non-HIV infected renal transplant recipients from 2003-2011. Consistent with the outcomes depicted within the NIH trial, Locke et al. determined that HIV infected renal transplant recipients "had a 1.77-fold higher risk of acute rejection at 1 year compared with their HIV-negative counterparts" (p. 448). Acute rejection was more evident among transplant recipients that either did not receive anti-thymocyte

globulin as induction therapy or included sirolimus for maintenance therapy (Locke et al., 2014). Therefore, Locke et al. recommended that immunosuppression regimens include anti-thymocyte globulin as an induction therapy, with the avoidance of sirolimus-based maintenance therapy.

However, Malat et al. (2018) proposed an alternate immunosuppressive course of therapy to include basiliximab, high-dose steroids, and intravenous immunoglobulin during induction with tacrolimus, mycophenolate and a steroid taper as maintenance therapy. An emphasis was placed on the management of HAART with integrase inhibitors as an alternate to protease inhibitors and non-nucleoside reverse transcriptase inhibitors to minimize drug interactions with maintenance therapy consisting of calcineurin inhibitors. This protocol was utilized for 120 HIV infected renal transplant recipients at Hahnemann University hospital resulting in superior outcomes as reflected by 1-year patient and graft survival rates at 100 % and 3-year patient and graft survival rates at 100% and 96% respectively, despite a 55% rejection rate (Malat et al., 2018). While the variability of immunosuppressive regimens among transplant centers remains broad, favorable outcomes in the presence of higher acute rejections rates are a universal occurrence (Bossini, et al. 2014; Haas, et al., 2015; Nunes et al., 2014).

Evidence Based Practice: Verification of Chosen Option

Renal transplant is the preferred treatment modality for ESRD among HIV infected patients (Querido et al., 2015; Sawinski & Bloom, 2014). Therefore, the renal transplant selection criteria at a faith-based institution will remove HIV infection as an absolute contraindication and include eligible HIV infected ESRD patients as potential transplant recipients.

Conclusion

Outcomes associated with HIV infected renal transplant cases prior to the availability of HAART were dismal (Sawinski & Bloom, 2014; Wright, 2016). Transplant centers traditionally refused to perform renal transplant among HIV candidates based on reduced patient and graft survival rates as well as duties towards safeguarding the utility of scarce organs (Nashar & Sureshkumar, 2016). Advancements in HAART and further comprehension of the pathogenesis of HIV prompted transplant specialists to revisit renal transplantation as a treatment option for ESRD among HIV infected candidates (Locke et al, 2014). Multiple studies demonstrated comparable outcomes despite higher incidences of acute rejection (Locke et al., 2014, Malet et al., 2018; Stock et al., 2010). Nevertheless, barriers in HIV infected candidates accessing renal transplant remain, particularly transplant center exclusion criteria and organ shortages (Cohen et al., 2019). In 2013, the HOPE Act "reversed the federal ban on considering HIV positive donors and authorized clinical research in the area of transplantation from HIV positive organ donors" (Nashar & Sureshkumar, 2016, p. 305). This legislation is expected to expand the donor organ pool with subsequent reductions in wait times for all renal transplant candidates (Muller, Barday, Mendelson, & Kahn, 2016). However, transplant center participation is subject to stringent requirements and IRB approval (Jackson & Cameron, 2016; OPTN, 2018).

Theoretical Framework

Kurt Lewin's change management model often serves as a foundational model for organizational change and consists of three phases (a) unfreezing; (b) changing; (c) refreezing (Hussain et al., 2016; Syed et al., 2018; Mind Tools, 2019) (see Appendix A). This model demonstrates the process of change which includes establishing the necessity for change,

transitioning towards the preferred change and cementing the change as standard practice (Mind Tools, 2019).

Overview of Phases

Unfreezing.

The unfreezing phase begins with an analysis of the organization to determine what changes are necessary in addition to presenting rationales to justify those changes (Mind Tools, 2019). The aim of the unfreezing phase is to create an awareness of current practices that jeopardize the success of the organization and introduce new methods of mutual benefit (Mind Tools, 2019). An emphasis is placed on the significance of the proposed change to garner support from organizational leaders and employees (Mind Tools, 2019). The general concept of the unfreezing phase is that the willingness to accept the change is contingent upon the perceived necessity and importance of the intended change (Mind Tools, 2019). Open communication is imperative during the unfreezing phase as reservations and concerns must be managed to ensure progression towards changing (Syed et al., 2018).

Changing.

Lewin recognized that change is a process in which the organization transitions from disadvantageous to constructive behaviors (Syed et al., 2018). Considered the most challenging stage, the changing phase consists of implementing the desired change (Mind Tools, 2019). However, effective communication and preparation conducted within the unfreezing phase, ensures that employees are properly educated and vested in the change (Mind Tools, 2019; Syed et al., 2018). It is during this phase that employees must be reminded of the benefits associated with the change and allowed the opportunity to become active participants, which promotes a sense of empowerment (Mind Tools, 2019).

Refreezing.

In the final stage of Lewin's change management model, actions are taken to "anchor the changes into culture" by identifying factors that both support and obstruct the permanence of change (Mind Tools, 2019, para. 22). It is during this phase, that changes are accepted as the standard of practice and become commonplace (Mind Tools, 2019). However, the risk for reverting back to previous methods exists and efforts to ensure the sustainability of the change become paramount (Mind Tools, 2019). Mechanisms to safeguard the longevity of change may include the development of a reward system to reinforce changes, as positively rewarded behaviors are often repeated (Mind Tools, 2019).

Application of Conceptual Framework in DNP Project

Unfreezing.

HIV infected individuals with ESRD have traditionally been excluded in consideration for renal transplantation at St. Vincent Hospital and Health Care Center (INSV) based on absolute contraindications as outlined within selection criteria policy. This serves as a barrier for HIV infected individuals in accessing renal transplantation as the preferred treatment option for ESRD (Cohen et al., 2019). INSV is a faith-based institution which upholds Franciscan values including service of the poor and integrity (St. Vincent, 2018). Service of the poor consists of providing holistically benevolent care to all individuals, particularly those suffering socioeconomic and health disparities while integrity ensures that the behaviors and messaging within the institution are consistent with their standards of accountability (St. Vincent, 2018). Denial of this indigent population for transplant specific health care services is in misalignment with the aforementioned core values, thus validating the imminent need for modification of selection criteria policy. Amending the existing selection criteria to include eligible HIV infected

candidates for renal transplant also functions as a competitive advantage to local transplant centers that are active participants within the HOPE Act trials.

During the unfreezing phase, objectives are "to identify and win the support of key people within the organization" by presenting "the issue as one of organization-wide importance" (Mind Tools, 2019, para. 20). Pertinent stakeholders, such as hospital administration, transplant physicians, transplant surgeons and HIV infectious disease physicians must acknowledge the negative impact of existing practices within the institution as (a) disadvantageous contributions to health disparities among HIV infected candidates; (b) divergence from established core values; (c) competitive disadvantage to local transplant centers.

Lastly, open communication is imperative to manage concerns related to the survival benefit and outcomes associated with HIV infected renal transplantation as this is a common source of angst shared by multiple transplant centers (Nashar & Sureshkumar, 2016). These unsubstantiated reservations may be counteracted by providing education and literature that reflect successful experiences over lengthy time spans in multiple clinical settings.

Changing.

Throughout the changing phase, effective communication remains a hallmark of the successful transition from the planning to implementation stage (Mind Tools, 2019). Stakeholders and staff personnel are reminded of the benefits associated with changing the selection criteria policy and the manner in which those changes affect the organization. For instance, updates on the progress of altering the selection criteria policy with subsequent increases in the volume of referrals, evaluations, listings and transplants are to be presented in monthly quality assurance and process improvement conferences. Those collaborative meetings

allow for additional open discussion to identify unforeseen obstacles and circumstances or dispel rumors.

Employee engagement consists of staff participation throughout the development of policy and protocols in the form of a task force. Further involvement of personnel in the change process includes designating a HIV champion who serves as a supportive resource for staff members.

Refreezing.

The refreezing phase is considered the terminal stage within Lewin's change management model where the change is accepted as status quo (Mind Tools, 2019). However, it is also during this phase that the change is evaluated for effectiveness and the necessity for modifications is analyzed (Mind Tools, 2019). For instance, the revised selection criteria policy may prove stringent and continue to exclude HIV infected individuals as candidates for renal transplant. Sawinski et al. (2009), found that 80% of HIV infected candidates evaluated for renal transplantation failed to progress to listing, predominately due to an inability to obtain CD4+ T-cell counts > 200 cells per cubic milliliter. Therefore, staff must identify factors that contribute to noncandidacy for the implementation of investigatory and optimization practices prior to determining ineligibility, such as a simple blood draw to assess CD4+ T-cell counts. Candidates with viral loads exceeding the qualifying threshold would be referred to an infectious disease physician for management of HAART.

Actions to sustain the change include the establishment of a reward system as positive reinforcement encourages the continuation of desired behaviors (Mind Tools, 2019). Designating internal benchmarks based on the volume of eligible HIV infected candidates provides staff with

a tangible goal. Steps towards achieving these goals may be celebrated at selected intervals, particularly at the time of qualification for participation in the HOPE Act variance.

Goals, Objectives and Expected Outcomes

Specific aims include reducing disparities experienced by HIV infected ESRD patients in accessing renal transplantation through modification of the existing selection criteria policy at INSV to include eligible HIV infected candidates. Quantifiable outcomes are reflected by an increase in the volume of patient referrals, evaluations and waiting list activations. Eventual desired outcomes include performing HIV infected renal transplantation and ultimately meeting transplant center requirements to participate in the HOPE Act variance.

Project Design/Methods

A single center, prospective observational cohort study will be conducted to determine the influence of adjusting selection criteria policy to include eligible HIV infected individuals with ESRD in reducing disparities for access to renal transplantation. A subcommittee consisting of pertinent stakeholders including transplant surgeons, transplant physicians, infectious disease HIV specialists and transplant pharmacists will then develop policy in accordance with institutional guidelines. The amended policy will include an individualized protocol for recipient selection criteria consistent with the existing literature and evidenced based practices related to HIV infected renal transplantation a) CD4+ T-cell counts >200 cells per cubic milliliter; b) HIV RNA viral loads < 50 copies per milliliter (see Appendix B). Immunosuppressive induction, maintenance therapies, and post-transplant monitoring will not be developed as the existing protocol for non-HIV infected recipients is to be utilized. Upon modification of the preexisting selection criteria, 329 referring dialysis units will be notified in writing of as confirmation of comprehension to the new inclusion standards (see Appendix C).

As the theoretical framework, Lewin's Change Management model will serve to facilitate the stages of organizational change and permanency of selection criteria modification. A comparative analysis of the volume of referrals, evaluations, listings and transplants pre and post intervention will be performed to establish the efficacy of including eligible HIV infected ESRD patients within selection criteria policy as an assurance of equivocal access to renal transplantation among this population.

Project Site and Population

Setting.

The project was conducted at the renal transplant program with INSV located in Indianapolis, Indiana. The renal transplant program obtained UNOS approval in October of 2008 and performed its first renal transplant surgery in January of 2009. To date, INSV has performed close to 500 renal transplant surgeries. According to the SRTR (2019), their renal transplant program exhibits higher than expected outcomes and is ranked among the top 20th percentile of transplant centers in the U.S.

According to the USRDS (2019), the prevalence of ESRD is approximately 34,205 cases within Network 9 (a) Indiana; (b) Ohio; (c) Kentucky. Network 9 has a total of 30,877 cases of HIV infected individuals (CDC, 2019). In 2017, Indiana ranked 18th among states based on the incidence of HIV with 517 newly diagnosed cases (CDC, 2019).

Stakeholders.

Moran, Burson and Conrad (2017) emphasize the significance of identifying stakeholders to guarantee the success of a Doctor of Nursing Practice scholarly project. According to Nashar and Sureshkumar (2016) "a close collaboration between infectious disease specialists and

transplant professionals is mandatory to optimize transplantation outcomes" among HIV infected renal transplant recipients (p. 300).

Therefore, key stakeholders have been recognized as (a) transplant surgeons; (b) transplant nephrologists; (c) infectious disease physicians; (d) transplant pharmacists. Additional stakeholders include clinical transplant coordinators, quality transplant coordinators, dialysis unit staff members, such as nephrologists and social workers, histocompatibility and immunology specialists, hospital administrative personnel, and medical assistants.

Transplant surgeon.

Vondran et al. (2017) recognizes the significance of the interdisciplinary relationship between transplant surgeons and nephrologists as a contingency for the successful care of transplant recipients. In accordance with OPTN (2019) bylaws, renal transplant surgeons must demonstrate competency in the (a) management of patients with end stage renal disease; (b) selection of appropriate recipients for transplantation; (c) donor selection; (d) histocompatibility and tissue typing; (e) immediate postoperative patient care; (f) use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression; (g) differential diagnosis of renal dysfunction in the allograft recipient; (h) histological interpretation of allograft biopsies; (i) interpretation of ancillary tests for renal dysfunction, (j) long-term outpatient care" (p. 74).

Transplant nephrologist.

The American Society of Nephrology (ASN) (2019) illustrates the clinical expertise of a transplant nephrologist as an "in-depth application of immunology, nephrology, and general internal medicine with strong elements of ethics in medicine" (para. 2). This foundational knowledge promotes an understanding of the association between immunosuppressive therapy,

allograft rejection, and the risk for infections including the advancement of HIV disease (Locke et al., 2014). Furthermore, transplant nephrologists are proficient in various realms of internal medicine including the pathogenesis of infectious diseases and neoplasms associated with the use of immunological agents (ASN, 2019). Characteristic responsibilities of the transplant nephrologist parallel the transplant surgeon competencies as outlined within the OPTN bylaws and include the "manipulation of antibody and T cell-mediated injury using proven and novel immunosuppressive strategies" (ASN, 2019, para. 2; OPTN, 2019).

Infectious disease physician.

The American College of Physicians (ACP) (2019) defines "infectious disease medicine as the subspecialty of internal medicine that focuses on diagnosing and managing" complex infectious disease processes, particularly HIV (para. 1). Infectious disease physicians have a comprehensive understanding of viral pathogenesis and immunological agents (ACP, 2019). More specifically, transplant infectious disease physicians collaborate with transplant programs to provide (a) patient care in the clinical setting; (b) educational support and physician training; (c) expertise in the development of guidelines to prevent and manage infections (Mount Sinai, 2019).

Transplant pharmacist.

Transplant pharmacists deliver pharmacological expertise to transplant recipients by ensuring the safety, efficacy and cost effectiveness of immunosuppressive regimens (OPTN, 2019). Transplant pharmacists collaborate with transplant "physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel" as a member of the multidisciplinary team (OPTN, 2019, p. 71). They contribute to performance improvement initiatives, which guarantees that the standard of care reflects clinical current guidelines

(University of Kansas Hospital, 2019). Transplant pharmacists conduct patient-specific medication profiles to develop individualized immunosuppression regimens and titrate medication dosages based on immunological response and renal or hepatic insufficiency (UKH, 2019).

Clinical transplant coordinator.

According to the OPTN (2019), the clinical transplant coordinator is "a designated member of the transplant team, working with patients and their families to coordinate care, beginning with the evaluation for transplantation and continuing through and after transplantation" (p. 62). The clinical transplant coordinator serves as the gatekeeper between the patient and additional transplant team members (OPTN, 2019). The clinical transplant coordinator provides direct patient care in the form of conducting interviews with prospective transplant recipients and determining eligibility criteria to undergo transplantation (OPTN, 2019). Collaborate in the development of protocols and guidelines for patient management.

Quality coordinator.

In accordance to OPTN (2019) bylaws, "transplant hospitals must develop, implement and maintain an ongoing, comprehensive and data driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives" (p. 57). The transplant quality coordinator aides in implementing quality improvement and patient safety initiatives while establishing adherence to legislative and regulatory bodies including the Centers for Medicare and Medicaid Services, OPTN/UNOS and the Joint Commission (North American Transplant Coordinators Organization, 2016).

SWOT analysis: internal analysis. (see Appendix D).

Strengths.

Equivocal outcomes.

INSV boasts higher than expected outcomes as reflected by patient and graft survival rates of 99.2% and 99.2% at 1-year and 89% and 88.9 % at 3-years, respectively (SRTR, 2019). While these rates are representative of non-HIV infected renal transplantation, it is expected that these outcomes would not greatly deviate among HIV infected renal transplant recipients. There is substantial evidence to support the safety and efficacy of performing renal transplantation among HIV infected ESRD patients, independent of the level of transplant center experience specific to HIV positive renal transplantation (Locket et al. 2015a). Furthermore, HIV infected renal transplant recipients demonstrate equivocal patient and graft survival rates to non-HIV infected renal transplant recipients (Sawinski & Bloom, 2014).

Demand.

INSV has historically denied HIV infected ESRD patients for renal transplant, with redirection to a local transplant center that provided this service. The demand for HIV infected ESRD patients is further reflected through the epidemiology of HIV and ESRD. The USRDS (2019) reports a prevalence of 34,205 combined cases of ESRD in the states within Network 9 (a) Indiana; (b) Kentucky; (c) Ohio. According to the CDC (2019), there was an estimated 30,877 cases of HIV within the same network. The state of Indiana ranked 18th in the U.S. for the volume of newly diagnosed HIV cases in 2015 (CDC, 2019). HIV nephropathy is a leading a cause of ESRD among African Americans and correlates to 1.5% of ESRD patients (CDC, 2019). Revisiting previously denied cases may serve as an igniting force to immediately serve this indigent population.

Organizational support.

Recent aims within INSV are directed towards increasing the volume of renal transplant procedures performed annually. The hospital strives to practice in alignment with its core values and recognizes that excluding HIV infected ESRD patients as candidates for renal transplant was not in accordance with its mission to be of service to those most in need (St. Vincent, 2018). Therefore, the transplant center envisions performing HIV infected renal transplantation as serving two purposes.

Weaknesses.

Center experience.

INSV has never performed renal transplantation with a HIV infected patient which may be perceived as a lack of clinical expertise and raise concerns for the likelihood of less than desirable outcomes. However, (Locke et al., 2015b) found that center level experience was not a prerequisite for favorable outcomes among HIV infected renal transplant recipients. The renal transplant program at INSV has been in existence for over 10 years and has completed almost 500 renal transplants to date (SRTR, 2019). Transplant center specific outcomes are higher than expected and the program ranks in the top 20th percentile among all transplant centers within the U.S. (SRTR, 2019).

The transplant professionals within the program possess a wealth of knowledge and proficiency in managing renal transplant recipients. The board-certified transplant nephrologist was previously employed at a transplant center that performed HIV infected renal transplants. It was during this time that he was responsible for the medical care of those individuals. The infectious disease physician has a PhD in immunology and serves as the director of the cardiac transplant infectious disease program at INSV. The transplant surgeon is accredited by the

American Society of Transplant Surgeons and the transplant pharmacist completed a solid organ transplant and immunology residency. The transplant nephrologist, surgeon and pharmacist all meet OPTN requirements to participate in a renal transplant program.

HOPE Act.

Additional weaknesses identified included ineligibility for the transplant program to participate in research trials through the HOPE Act variance. Transplant centers are required to present collective experience among a transplant surgeon, transplant physician and HIV physician for a total of 5 HIV infected renal transplant recipients over the past 4 years (OPTN, 2018). As a result, HIV infected renal transplant candidates initially activated to the waitlist with INSV will not be eligible for HIV positive donor organs. This serves as an additional disparity for HIV infected ESRD patients due to lengthened waitlist times and an increased mortality rate while listed (Cohen et al., 2019). At the present time, the median wait time to renal transplant at INSV is 55.7 months (SRTR, 2019).

SWOT analysis: external analysis.

Opportunities.

Reduce disparities.

Modifications to the selection criteria policy reduce disparities among HIV infected ESRD patients by granting access to renal transplantation. This ensures equity among HIV infected ESRD patients and is alignment with the hospital's core values of service to the poor and integrity.

Enhance partnerships.

Expanding the selection criteria to consider a larger pool of ESRD patients for renal transplantation serves to strengthen the professional relationship between the transplant program

and referring providers. Dialysis units are regulated by CMS to facilitate the referral of ESRD patients to a transplant program for consideration of renal transplant as an alternate treatment modality (OPTN, 2019). Acting as an inclusive transplant center, with less stringent selection criteria may serve as a simplified means for dialysis units to meet CMS guidelines.

Increased revenue.

According to Bentley and Phillips (2017), the estimated billed charges per renal transplant was $414,800 which included the costs of procurement, hospital admission, physician consultation, outpatient visits and immunosuppressant medications. In consideration for the reduced conversion rate of eligible HIV infected ESRD patients that progress to listing, the financial benefits of performing HIV infected renal transplants may not be significant in small quantities (Sawinski et al., 2009).

Threats.

Acute rejection.

HIV infected renal transplant recipients have an increased risk for acute rejection (Stock et al. 2010). While acute rejection can threaten the longevity of the allograft, the literature does not support the incidence of acute rejection in the HIV infected renal transplant recipient as contributive to reduced graft survival rates (Stock et al, 2010).

Competitive marketplace.

There is external competition with a local transplant center that has performed HIV infected renal transplants and is an active participant in the HOPE Act variance. Therefore, HIV infected ESRD patients may forgo their pursuit of renal transplant with INSV to avoid potentially extended waitlist times attributable to organ shortages. Transplant centers enrolled in the HOPE Act are granted access to HIV positive donor organs (OPTN, 2018). This results in a

larger donor pool for the patients activated to their list and potential for shortened waitlist times (Muller, Barday, Mendelson, & Kahn, 2016).

Measurement Instruments

In order to measure the outcomes of this DNP Project, the volume of HIV infected ESRD patient referrals, evaluations, listings and transplants six months preintervention and three months postintervention was retrieved from the electronic health record to conduct a comparative analysis.

Data Collection Procedures

Data collection consisted of an internal audit of the transplant center specific electronic health record, Organ Transplant Tracking Registry (OTTR), to retrieve the volume of HIV infected ESRD patient referrals, evaluations, listings and transplants six months prior to and three months after selection criteria policy revision. Inclusion criteria for subject participation included patients referred to INSV for renal transplantation from September 1, 2018 to June 1, 2019 with a medical diagnosis of HIV. This data was exported to an encrypted Excel spreadsheet void of patient identifiers and protected health information.

Ethical Considerations/Protection of Human Subjects

The Marian University Internal Review Board (IRB) determined that this project was exempt from full Human Subject review. Written communication from the Marian University IRB can be reviewed in Appendix E.

All participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other guarantees, protects the privacy of patients' health information (Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 2013). Additionally, the DNP student and practice personnel who carefully

conducted this project followed the *Standards of Care* for practice in a transplant center. All information collected as part of evaluating the impact of this project was aggregated data from the project participants and did not include any potential patient identifiers.

The risk to patients participating in this project was no different from the risks of patients receiving standard transplant care. Participant confidentiality was assured by coding the participants using individual identification numbers. The list of participants and their identifying numbers were kept as electronic files, only accessible to the project coordinators. All electronic files containing identifiable information were password protected to prevent access by unauthorized users and only the project coordinator had access to the passwords.

Data Analysis and Results

A total of eight HIV infected patients with ESRD were referred to INSV in consideration for renal transplantation over a nine-month time span. Data analysis consisted of basic descriptive statistics used to quantify the volume of patient referrals, evaluations, listings and transplants six months preintervention and three months postintervention. Six HIV infected patients with ESRD were referred for renal transplantation postintervention which translates to a 200% increase by volume. 33% of the referred patients advanced to the evaluation phase. However, none of the participants progress to waiting list activation or received a transplant over the course of this project (see Appendix F).

Internal bench marks within INSV note that the average duration of the referral to waiting list activation phase exceeds 4.7 months. According to SRTR (2019), the median wait time from waiting list activation to transplant at INSV is 55.2 months. Considering the prolonged time frames in which potential transplant recipients navigate the referral, evaluation, listing and transplant phases, additional observation to determine the efficacy of adjusting the selection

criteria in reducing disparities among HIV infected ESRD patients to access renal transplantation is warranted.

Conclusion

HIV infected renal transplant recipients demonstrate a significant survival benefit over remaining on dialysis as a treatment modality for ESRD and yield similar outcomes when compared to non-HIV infected renal transplant recipients. However, some transplant centers unfoundedly exclude HIV infected ESRD patients for renal transplantation through prohibitive selection criteria.

Modifying the existing selection criteria at INSV to include eligible HIV infected ESRD patients was intended to ensure equitable access to renal transplantation among this group. However, due to prolonged lengths of time required to navigate the phases of transplantation, additional observation is warranted to truly establish the efficacy of modifying selection criteria towards increasing the access of HIV infected ESRD patients to renal transplantation.

References

American College of Physicians. (2019). *Infectious Disease.* Retrieved from https://www.acponline.org/about-acp/about-internal-medicine/subspecialties/infectious-disease

American Society of Nephrology. (2019). *Residents: Career profiles.* Retrieved from https://www.asn-online.org/education/training/residents/profile.aspx?p=wiseman

Apewokin, S., Madan, R., Restrepo, A., Hemmige, V. S., & Arora, S. (2018). Clinical and health care utilization outcomes of kidney transplantation in HIV-positive recipients: A nationwide analysis from 2008-2013. *Transplantation Proceedings, 2018*(50), 3361-3366. doi:10.1016/j.transproceed.2018.08.002

Baisi, A., Nava, F., Baisi, B., Rubbiana, E., Guaraldi, Benedetto, F. D.,...Cappelli, G. (2016). Kidney transplantation in HIV-infected recipients: Therapeutic strategy and outcomes in monocentric experience. *Transplantation Proceedings, 2015*(48), 333-336. doi:10.1016/j.transproceed.2015.12.038

Bentley, T. S. & Phillips, S. J. (2017). *2017 U.S. organ and tissue transplant cost estimates and discussion.* Retrieved from http://us.milliman.com/uploadedFiles/insight/2017/2017-Transplant-Report.pdf

Bossini, N., Sandrini, S., Casari, S., Tardanico, R., Maffeis, R., Setti, G.,...Cancarini, G. (2014). Kidney transplantation in HIV-positive patients treated with a steroid-free immunosuppressive regimen. *Transplant International,* 27(2014), 1050-1059. doi:10.1111/tri.12377

Centers for Disease Control and Prevention. (2019, April 12). *HIV/AIDS: Statistics overview.* Retrieved from https://www.cdc.gov/hiv/statistics/overview/index.html

Cohen, J. B., Locke, J. E., Shelton, B., Reed, R. D., Mustian, M., MacLennan, P.,...Sawinski, D.

(2019). Disparity in access to kidney allograft offers among transplant candidates with human immunodeficiency virus. *Clinical Transplantation, 2019*(33:e13466), 1-9. doi:10.1111/ctr.13466

Haas, J., Singer, T., Mowak, K., Brust, J., Gottmann, U., Schnulle, P.,...Benck, U. (2015). Renal transplantation in HIV-positive renal transplant recipients: Experience at the Mannheim University hospital. *Transplantation Proceedings, 2015*(47), 2791-2794. doi:10.1016/j.transproceed.2015.09.06

Halpern, S. D., Asch, D. A., & Shaked, A, Stock, P. G., & Blumberg, E. (2005). Determinants of transplant surgeons' willingness to provide organs to patients infected with HBV, HCV or HIV. American Journal of Transplant, 5(6), 1319-1325. Retrieved from https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1600-6143.2005.00812.x

Hussain, S. T., Lei, S., Akram, T., Haider, M. J., Hussain, S. H., & Ali, Muhammad, A. (2016). Kurt Lewin's change model: A critical review of the role of leadership and employee involvement in organizational change. *Journal of Innovation & Knowledge, 3*(2018), 123-127.

Jackson, K. R., & Cameron, A. (2017). Transplantation of the patient with human immunodeficiency virus. *Advances in Surgery, 51*(2017), 65-76. doi:10.1016/j.yasu.2017.03.005

Locke, J. E., Gustafson, S., Mehta, S., Reed, R. D., Shelton, B., MacLennan, P. A.,...Segev, D. L. (2017b). Survival benefits of kidney transplantation in HIV-infected patients. *Annals of Surgery, 265*(3), 604-608. doi:10.1097/SLA.0000000000001761

Locke, J. E., James, N. T., Mannon, R. B., Mehta, S. G., Pappas, P. G., Baddley, J. W,...Segev,

D. L. (2014). Immunosuppression regimen and the risk of acute rejection in HIV-infected kidney transplant recipients. *Transplantation, 4*(97), 446-450. doi:10.1097/01.TP.0000436905.54640.8c

Locke, J. E., Mehta, S., Reed, R. D., MacLennan, P., Massie, A., Nellore, A., Durand, C., & Segey, D. L. (2015b). A national study of outcomes among HIV-infected kidney transplant recipients. *Journal of the American Society of Nephrology, 6*(9), 2222-2229. doi:10.1681/ASN.2014070726

Locke, J. E., Mehta, S., Sawinski, D., Gustafson, S., Shelton, B. A., Reed, R. D.,...Segey, D. L. (2017a). Access to kidney transplantation among HIV-infected waitlist candidates. *Clinical Journal of the American Society of Nephrology, 12*(3), 467-475. doi:10.2215/CJN.07460716

Locke, J. E., Reed, R. D., Mehta, S. G., Durand, C., Mannon, R. B., MacLennan, P.,...Segev, D. L. (2015a). Center-level experience and kidney transplant outcomes in HIV-infected recipients. *American Journal of Transplant, 15*(8), 2096-2104. doi:10.1111/ajt.13220

Malat, G. E., Boyle, S. M., Jindal, R. M., Guy, S., Xiao, G., Harhay, M. N.,...Doyle, A. M. (2018). Kidney transplantation in HIV-positive patients: A single-center, 16-year experience. *American Journal of Kidney Disease, 73*(1), 112-118. doi:10.1053/j.ajkd.2018.02.352

Mind Tools. (2019). *Lewin's change management model: Understanding the three stages of change.* Retrieved from https://www.mindtools.com/pages/article/newPPM_94.htm

Miro, J. M., Grossi, P. A., & Durand, C. M. (2019). Challenges in solid organ transplantation in people living with HIV. *Intensive Care Medicine, 2019*(45), 398-400. doi:10.1007/s00134-019-05524-1

Moran, K., Burson, R., & Conrad, D. (2017). *The doctor of nursing practice scholarly project: A framework for success* (2nd ed.). Burlington, MA: Jones & Bartlett Learning.

Mount Sinai. (2019). *Mount Sinai transplant infectious diseases program.* Retrieved from https://www.mountsinai.org/patient-care/service-areas/infectious-diseases/transplant-infectious-diseases-programs

Muller, E., Barday, Z., Mendelson, M., & Kahn, D. (2016). Renal transplantation between HIV-positive donors and recipients justified. *South African Medical Journal, 102*(6), 497-498.

Nashar, K., & Sureshkumar, K. K. (2016). Update on kidney transplantation in human immunodeficiency virus infected recipients. *World Journal of Nephrology, 5*(4), 300-307. doi: 10.5527/wjn.v5.i4.300

North American Transplant Coordinators Organization. (2016, November 16). *Transplant quality coordinator-Licensed.* Retrieved from http://natco1.org/Professional-Development/documents/ABCCreative-TransplantQualityCoordinator11-16-2016.pdf

Nunes, A. T., Pereira, L., Cerqueira, A., Bustorff, M., Sampaio, S., Ferreira, I.,...Pestana, M. (2014). Renal transplantation in human immunodeficiency virus-positive patients: A report of four cases. *Transplantation Proceedings, 2014*(46), 1718-1722. doi:10.1016/j.transproceed.2014.05.030

Organ Procurement and Transplantation Network. (2018). *HOPE Act.* Retrieved from https://optn.transplant.hrsa.gov/learn/professional-education/hope-act/

Organ Procurement and Transplantation Network. (2019). National data. Retrieved from https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

Organ Procurement and Transplantation Network. (2019b). Bylaws: Membership and personnel

requirements for kidney transplant programs. Retrieved from https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Appendix_E

Querido, S., Machado, D., Silva, F., Nolasco, A., Sampaio, S., Cruz, P.,... Weigert, A. (2015). Renal transplantation in HIV-infected patients: The first Portuguese review. *Transplantation Proceedings, 2015*(47), 946-949. doi:10.1016/j.transproceed.2015.03.029

Sawanski, D., & Bloom, R. D. (2014). Current status of kidney transplantation in HIV-infected patients. *Current Opinion in Nephrology and Hypertension, 2014*(23), 619-624. doi:10.1097/MNH.0000000000000071

Sawinski, D., Wyatt, C. M., Casagrande, L., Myoung, P., Schroppel, B., DeBoccardo, G.,...Murphy, B. (2009). Factors associated with failure to list HIV-positive kidney transplant candidates. *American Journal of Transplant, 9*(6), 1467-1471. doi: 10.1111/j.1600-6143.2009.02637

Scientific Registry of Transplant Recipients. (2019). *St Vincent Hospital and Health Care Center (INSV).* Retrieved from https://www.srtr.org/transplant-centers/st-vincent-hospital-and-health-care-center-insv/?organ=kidney&recipientType=adult

Shaffer, A. A., & Durand, C. M. (2018). Solid organ transplantation for HIV-infected individuals. *Current Treatment Options in Infectious Diseases, 10*(1), 107-120. doi:10.1007/s40506-018-0144-1.

Stock, P. G., Barin, B., Murphy, B., Hanto, D., Diego, J. M., Light, J., ... Roland, M. E. (2010). Outcomes of kidney transplantation in HIV-infected recipients. *The New England Journal of Medicine, 363*(21), 2004–2014. doi:10.1056/NEJMoa1001197

St. Vincent. (2018). *About us.* Retrieved from https://www.stvincent.org/About-Us

United States Renal Data System. (2018). *2018 annual data report.* Retrieved from https://www.usrds.org/adr.aspx

University of Kansas Hospital (2019). *Clinical pharmacist-Solid organ transplant job.* Retrieved from https://lensa.com/clinical-pharmacist-solid-organ-transplant-jobs/kansas-city/jd/4e8212b725b54e7777f474ac5fe31143#description

Vican, A. R., Spuldero, F., Sandes-Freitas, T. V., Cristelli, M. P., Requiao-Moura, L. R., Reusing, J. O.,...Manfro, R. C. (2016). Renal transplantation in human immunodeficiency virus-infected recipients: A case–control study from the Brazilian experience. *Transplant Infectious Disease, 2016*(18), 730-740. doi: 10.1111/tid.12592

Vondran, F. W. R., Wintterle, S., Brasen, J. H., Haller, H., Klempnauer, N., Ritcher, F.,...Schiffer, M. (2017). Abdominal surgery meets nephrology: important nephrological aspects before and after kidney or liver transplantation. *Zentralblatt Fur Chirurgie 142*(2), 180-188. doi: 10.1055/s-0035-1557918

Wright, A. J., & Gill, J. S. (2015). Kidney transplantation in HIV-infected recipients: Encouraging outcomes, but registry data are no longer enough. *Journal of the American Society of Nephrology, 26*(9), 2070-2071. doi: 10.1681/ASN.2015010059

Wright, L.S. (2016). Kidney transplantation in patients with human immunodeficiency virus infection. *Nephrology Nursing Journal, 43*(2), 143-148.

Appendix A

Kurt Lewin's Change Management Model

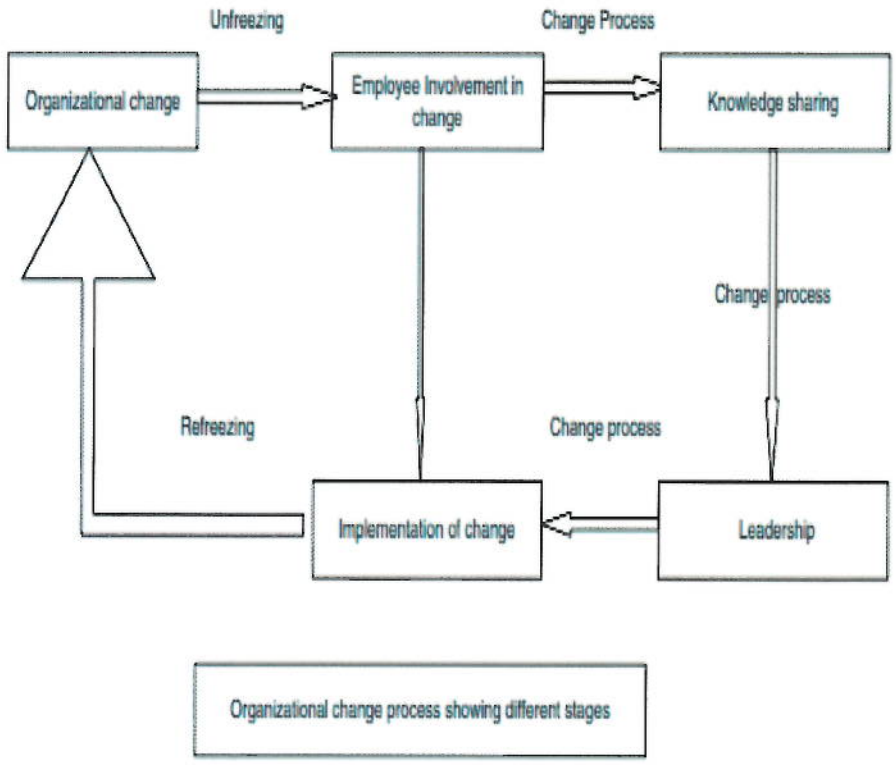


Fig. 1. Model of organizational change shows the Kurt Lewin's three steps model: *Note*: The arrows show different stages of Kurt Lewin's three steps model and not the relationship between variables.

Appendix B

Renal Pancreas Selection Criteria

Current Status: Active PolicyStat ID: 5838281

St. Vincent INDIANAPOLIS

Origination: 08/2014
Last Approved: 03/2019
Last Revised: 03/2019
Owner: Jenny Hoyer: Transplant Quality RN
Department: Renal / Pancreas Transplant Program
References:
Applicability: St Vincent Indianapolis Hospital

RENAL / PANCREAS TRANSPLANT SELECTION CRITERIA

PURPOSE

To define indications and contraindications(absolute and relative) for renal/pancreas transplantation

POLICY

St. Vincent Renal/Pancreas Transplant Program will have detailed and in writing indications and contraindications for transplant. These will be provided to all transplant recipient candidates

INDICATIONS

Kidney Alone:

A. Regularly administered dialysis for ESRD

-OR-

A. Chronic Kidney Disease stage IV or greater

Simultaneous Kidney-Pancreas:

A. Regularly administered dialysis for ESRD

-OR-

A. Chronic Kidney Disease stage IV or greater

-AND-

Type I Diabetics

A. On insulin and fasting C-Peptide less than 2ng/ml

B. BMI less than or equal to 30

Type II Diabetics

A. On insulin and fasting C-Peptide less than 10ng/ml

B. BMI ≤ 28

C. Age ≤ 45

O. Insulin requirements ≤ 1unit/kg/day (max 100 units/day)

Absence of contraindications as outlined in the selection criteria unless an exception has been collectively agreed upon per the Transplant Committee. Potential benefits of transplant outweigh the potential risk as determined by the Transplant Committee

ABSOLUTE CONTRAINDICATIONS:

A. Age less than 2 years and/or size < 10 kg.

B. Active infection

C. Active malignancy

D. Active psychosis or untreated mental health disorder

E. Untreated or active substance abuse including but not limited to illicit drugs or alcohol

F. Documented non-compliance

G. HIV positive with positive viral load and/or CD4 count ≤200

H. High probability of peri-operative mortality

I. Diagnosis of cirrhosis, chronic liver disease, or active hepatitis

J. Severe or diffuse atherosclerotic or coronary artery disease and/or disease not amenable to surgical repair, bypass grafting, or angioplasty

K. LVEF ≤ 30%

L. Morbid Obesity (BMI > 39.5)

M. Severe Pulmonary Hypertension (RVSP ≥60 mmHg)

N. Severe Pulmonary Disease as evidence by requiring any supplemental oxygen or FEV1 of 50% or less predicted by ATS

O. Anatomy that makes transplantation technically impossible

P. Patient decision

Q. Patient does not meet any established indication for transplant following completion of evaluation. Patient will be followed by their nephrologist

RELATIVE CONTRAINDICATIONS:

A. Inability to cooperatively work with any of the transplant team members or failure to comply with testing requirements

B. Moderate coronary artery disease

C. Moderate pulmonary disease

D. Moderate pulmonary hypertension (RVSP ≥ 40 mmHg)

E. Moderate vascular disease: coronary, cerebral, or peripheral

F. LVEF ≤ 40%

G. Renal disease with significant recurrence potential to cause graft loss

H. Frailty

I. Multiple previous abdominal surgeries

J. Excessive abdominal adipose tissue

K. Significant gastrointestinal disease, uncontrolled gastroparesis, or chronic diarrhea

L. Repeated non-adherence to medical regimen

M. Psychosocial / financial situation causing an inability to achieve adequate post-transplant follow up care

N. Latent Tuberculosis (patients who have undergone 2 months of treatment may be listed prior to completion of at least 9 months of treatment)

COMMITTEE NAME/APPROVED DATE

Medical Executive Committee 1/2019

Policy and Procedure Committee 12/2018

Renal and Pancreas QAPI Committee 11/2018

Attachments:

Acceptance Criteria
Non-acceptance Criteria

Approval Signatures

Step Description	Approver	Date
Final Approver	Eleanor Wessels: Polaystat Admin Quality Consultant	03/2019
	Erica Wehrmeister: Chief Operating Officer	03/2019
	Islam Gronefin: Program & Surgical Director	02/2019
	Erica Season: Director - Transplant Services	01/2019
	Jenny Hoyer: Transplant Quality RN	01/2019

Applicability

St.Vincent Indianapolis Hospital

Appendix C

Letter to Referring Providers

St. Vincent INDIANAPOLIS

A member of ASCENSION

Core Values
We are called to

Service of the Poor
Generosity of spirit, especially for persons most in need

Reverence
Respect and compassion for the dignity and diversity of life

Integrity
Inspiring trust through personal leadership

Wisdom
Integrating excellence and stewardship

Creativity
Courageous innovation

Dedication
Affirming the hope and joy of our ministry

St. Vincent Abdominal Transplant Services
8402 Harcourt Road, Suite 500
Indianapolis, IN 46260
(317) 338-6701 Main
(317) 808-6998 Fax
stvincentcare.com/indianapolis

St. Vincent Abdominal Transplant Services UPDATES!

NEW Dedicated Referral Fax Number
Please utilize **317.808.6998** for any referral communications or submissions. This electronic fax number is checked multiple times per day by our dedicated referral staff members.

NEW and IMPROVED Referral Check List
The attached referral check list needs to be filled out in its entirety to expedite your patients through the process. Please **discard** any previous referral check list you may have at your facility or office.

Recipient Selection Criteria
We have made significant changes to increase access to transplant for many of your patients including those with HIV. Please note the attached criteria for additional details.

New Outreach Opportunities
In-Person Referral Days
Shadowing opportunities

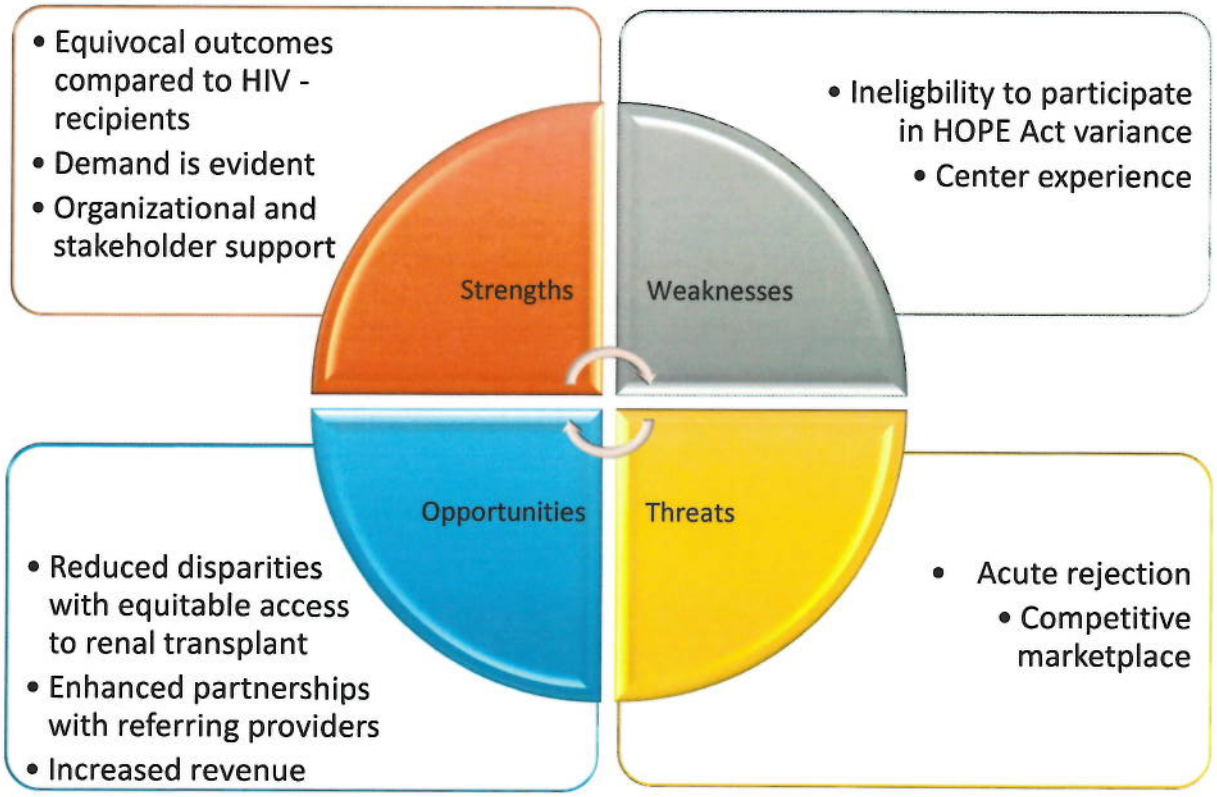
Please contact a member of the St. Vincent Abdominal Transplant Team at 317.338.6701 to request additional information or to schedule an Outreach Opportunity for your center or staff!

Sincerely,

St. Vincent Abdominal Transplant Services

Appendix D

SWOT Analysis



Appendix E

Marian University Instititional Review Board

MARIAN UNIVERSITY
Indianapolis ®

Institutional Review Board

DATE: 4/25/2019

TO: Smyrna Rivera Hatfield

FROM: Marian University IRB

RE: IRB Protocol #B19-009

TITLE: Renal Transplantation in HIV Seropositive Recipients from HIV Seropositive Donors

SUBMISSION TYPE: New Project

ACTION: Determination of Exempt Status

DECISION DATE: 4/24/2019

The Institutional Review Board at Marian University has reviewed your protocol and has determined the procedures proposed are appropriate for exemption under the federal regulations. As such, there will be no further review of your protocol and you are cleared to proceed with your project. The protocol will remain on file with the Marian University IRB as a matter of record. Please be mindful of the importance of reporting only de-identified, HIPAA-compliant information about the patient in any exhibit or publication.

Although researchers for exempt studies are not required to complete online CITI training for research involving human subjects, the IRB recommends that they do so, particularly as a learning exercise in the case of student researchers. Information on CITI training can be found on the IRB's website: http://www.marian.edu/academics/institutional-review-board.

It is the responsibility of the PI (and, if applicable, the faculty supervisor) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. Any procedural modifications must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project. Please contact Dr. Karen Spear at (317) 955-6115 or kspear@marian.edu if you are unsure whether your proposed modification requires review. Proposed modifications should be addressed in writing to the IRB. Please reference the above IRB protocol number in any communication to the IRB regarding this project.

Karen L. Spear

Karen L. Spear, Ph.D., Interim Chair, Marian University Institutional Review Board

Appendix F

Volume of HIV Infected Patient Referrals, Evaluations,

Listings and Transplant Pre and Post Selection Criteria Modification