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Increasing Living Kidney Donation Through Advocacy And Patient Navigation

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INCREASING LIVING KIDNEY DONATION THROUGH ADVOCACY AND PATIENT NAVIGATION

by

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A DISSERTATION

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INCREASING LIVING KIDNEY DONATION THROUGH ADVOCACY AND PATIENT NAVIGATION

RHIANNON DEIERHOI REED

HEALTH CARE ORGANIZATION & POLICY

ABSTRACT

As the prevalence of kidney disease continues to increase in the United States, the gap between the need for organs and available kidney donors is growing as well. Deceased donor organs alone are insufficient to meet this need, and transplant centers have turned their focus to living donation to address the shortage. However, the frequency of living kidney donation has been declining in the US since 2004. Changes in the health of the US population have been suggested as one possible explanation for the decline, but currently these assertions remain anecdotal. A second theory with more published evidence attributes the insufficiency of living donor kidneys to patient reluctance to reach out and ask others to become kidney donors, particularly among minorities, perhaps due to studies demonstrating increased risk of adverse post-donation outcomes. To address this concern, strategies have arisen to alleviate the transplant candidate's burden of asking for a kidney by training of advocates. Unfortunately, these strategies have failed to focus on 1) the perspective of potential living donors, 2) addressing donor comfort and confidence in the evaluation/donation process, 3) and considering actual reasons for non-donation. The aim of my dissertation is thus to describe the association between population-level factors and lower rates of living kidney donation through the use of data from the Behavioral Risk Factor Surveillance System and to analyze the effectiveness of the Living Donor Navigator program at increasing living donation at the University of Alabama at Birmingham. Herein I explore population health and socioeconomic status as potential barriers to increasing rates of living donation (paper #1), whether the Living Donor Navigator Program has achieved its goal of increasing donor approvals in a cost-effective way (paper #2), and qualitatively describe early impressions of the Living Donor Navigator Program to define core competencies and promising practices for program implementation (paper #3).

DEDICATION

In memory of Dr. Meredith L. Kilgore, whose dedication to his students and colleagues was exceeded only by his profound love for his family

ACKNOWLEDGMENTS

I have many people to thank for this amazing journey, but these words can never fully express what this experience and your roles in it have meant to me.

First I thank my committee, some of whom I have enjoyed working with closely for years and some whom I have had the pleasure of getting to know during this process. Thank you for dedicating so many hours to providing feedback, encouragement, and mentorship.

To Dr. Martha Wingate, who voluntarily stepped in at a challenging time and guided me with grace and strength: I can never thank you enough for the support you provided, both professionally and personally. The Department has been blessed to have you at its helm this past year, and I seek to follow your example of what it looks like to be a successful academic and mother.

To Dr. Stephen Mennemeyer, for graciously agreeing to shepherd me through my second paper: I have a newfound love of TreeAge thanks to your guidance and hope to continue to use my newly acquired skills to affect policy as you have done in your career.

To Dr. Jayme Locke: we have built something incredible, and I feel lucky every day that I get to work in a field that I am truly passionate about for patients who really appreciate what you do for them. Thank you for taking a chance on me five years ago. There are many more great ones to come!

To my colleagues, classmates, and friends: it truly is a team effort, and I am privileged to work and grow alongside each of you. Thank you for being collaborators, confidants, and co-conspirators on this crazy journey of life. In particular, I would like to thank Brittany Shelton, who has been going through this process as well and has provided tremendous insight, patience, and thoughtful feedback, even at the eleventh hour. I can’t think of a better person to work next to, and I know you’re right behind me!

To my parents Mark and Gwen Deierhoi, who have never doubted my ability to take on a new challenge and have provided me with unconditional love and support throughout my life: I am who I am because of you and can only hope to serve as a similar example of compassion and respect for others to my own child. I love you both so much.

To my proudest accomplishment, my daughter Ophelia: your surprise arrival and your first year on this earth have already taught me so many things. May you grow up to believe you are strong enough to accomplish anything but understand that it’s okay to stumble along the way. I will always be there to catch you and love you dearly.

And to my husband, Brandon, who has made many sacrifices as I’ve pursued this dream but has never complained and believes in me more than I can ever fully understand: thank you for giving me this experience and for loving me for me. I love you even more today than yesterday.

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COST EFFECTIVENESS OF THE LIVING DONOR NAVIGATOR PROGRAM

A QUALITATIVE ASSESSMENT OF THE UAB LIVING DONOR NAVIGATOR PROGRAM: IDENTIFYING CORE COMPETENCIES AND PROMISING PRACTICES FOR IMPLEMENTATION

INTRODUCTION

As the incidence of kidney disease continues to increase in the United States, the gap between the need for organs and available kidney donors is growing as well.[1,2] There are currently approximately 100,000 individuals on the kidney transplant waiting list, but fewer than 20,000 receive a transplant annually.[1] Deceased donor organs alone are insufficient to meet this need, and transplant centers have turned their focus to living donation to address the shortage. Superior outcomes are achieved with kidneys from living compared to deceased donors; 5-year patient survival for recipients of deceased donors in 2010 was 86.8%, compared to 93.5% among recipients of living donors.[1] Other benefits of living donor transplantation include greater flexibility in scheduling the surgery, shorter time on dialysis, and immediate functioning of the kidney.[3] However, living donor transplantation has been decreasing in the United States over the last decade, with 6,648 living donor transplants performed nationally in 2004, dropping to 5,630 in 2016 and representing less than one third of all kidney transplants (OPTN data 2017).

Despite the benefits provided to the transplant recipient, living donation is not without risks to the donor. There is an increased risk of developing end-stage renal disease, particularly among African American living donors; however, the absolute risk increase is very small and less than that of the general population (lifetime risk: 90 per 10,000 living donors vs. 326 per 10,000 among the general population).[4] As criteria for donor selection has expanded to meet the growing need for kidneys and changing health in the United States, more donors are approved with isolated medical abnormalities, such as obesity. However, there is evidence that expanding selection may have its own associated health risks. A body mass index of 30 kg/m^2 or greater at the time of donation has been shown to be associated with increased risk of end-stage renal disease, compared to donors who were normal weight.[5] There are also racial differences in outcomes among donors, with African American donors having an increased risk of hypertension (adjusted hazard ratio (aHR): 1.52, 95% confidence interval (CI): 1.23-1.88), diabetes mellitus (aHR: 2.31, 95% CI: 1.33-3.98), and chronic kidney disease (aHR: 2.32, 95% CI: 1.48-3.62) compared to Caucasian donors.[6]

In addition to the health risks associated with living donation, there are also financial disincentives. While the transplant recipient's insurance covers all medical costs associated with being evaluated for living donation and the donor surgery and hospital stay, living donors still report out-of-pocket expenses, such as childcare costs, lost wages, and travel expenses.[7] In an effort to offset these costs and remove some of the disincentives to donation, some states have instituted tax credits or deductions,[8] and recently the University of Alabama at Birmingham (UAB) implemented a policy providing for paid time off for employees who serve as living donors.[9] Some argue for compensation or reimbursement for donation-associated costs,[10,11] while others believe this is in direct contradiction with the National Organ Transplant Act of 1984, which prohibits the transfer of human organs for "valuable consideration". (NOTA; P.L. 98-507) There are also concerns that compensating donors would diminish the altruism associated with the act of living donation,[12] although empirical research has shown these concerns to be unfounded.[13] For now, there is no widely accepted best strategy for removing financial disincentives for donors.

Given concerns for peri-operative and long-term outcomes of living donors, in 2013 the Organ Procurement and Transplantation Network (OPTN) implemented policies requiring transplant centers to follow-up with living donors for a minimum of two years post-donation.[14] Despite these requirements, living donor follow-up is poor among US transplant centers.[15,16] Specifically, follow-up compliance is poorest among young, minority, and uninsured donors,[16] and interestingly, rates of living donation have decreased most among these subgroups.[17] The additional time and effort needed to follow donors, as well as the penalties associated with non-compliance, may deter transplant centers from actively pursuing strategies to increase living donation, in particular among these types of donors. Programs that focus on engaging and educating living donors about the importance of maintaining contact with the transplant center are needed and may alleviate some of the concern associated with post-donation care.

The need for living donors has led the two US transplant organizations (the American Society of Transplantation and the American Society of Transplant Surgeons) to prioritize research focused on living donors.[18] Within this agenda are strategies to address disparities in living donation, remove disincentives to donation, conduct studies of long-term outcomes of living donors, and implement programs to increase living donation in the US. Currently, there are more than 15 active NIH grants to study living kidney donation, including evaluative assessments of donor health outcomes, interventions to increase donor education, and trials to randomize donors to receive health insurance post-donation.[19]

From the perspective of the recipient, there are persistent disparities in access to living donor transplantation. For example, ESRD prevalence is approximately 3.7 times greater in African Americans than in Caucasians,[2] but African Americans are also less likely than their Caucasian counterparts to receive a transplant, either from a living or deceased donor.[20,21] Barriers to achieving living donation have already been well-described in the literature. Transplant candidates report unwillingness and reticence to discuss their need for a kidney due to embarrassment or lack of knowledge surrounding the impact to the potential donor.[22] Minorities in particular struggle with asking for a kidney.[23]

To date, several transplant centers have sought creative solutions to the need for increased living donation, engaging both the transplant candidate and potential donors. Northwestern University has implemented a culturally targeted educational website developed specifically for adults of Hispanic ethnicity undergoing dialysis called *Infòrmate*, which has not only resulted in increases in transplant knowledge (17.1% increase from pre to post-test, $p < 0.001$) but has also received favorable feedback from participants.[24] Users report the website to be “easy to navigate and understand” and “informative and helpful” and was preferable to searching multiple websites for information. Specialized topics, including immigration and financial issues, were noted as particularly informative to users.[25,26]

Another initiative to increase living donation through removal of knowledge barriers is the House Calls trial. Rodrigue and colleagues piloted this program, in which transplant candidates participated in house calls, where candidates invited friends and family into their home for an informational session with a transplant professional. This home-based educational initiative was one of three arms in a randomized controlled trial, in which participants were assigned to House Calls (a 60-90 minute session that engages the transplant candidate and their social network, conducted in the home of the candidate by a trained health educator), clinic-based education (sessions held in the transplant center), and no intervention. The House Calls group not only saw a significant increase in living donor inquiries, evaluations, and living donor kidney transplantation (LDKT), but also demonstrated increases in LDKT knowledge among participants. The house call participants were compared to the clinic-based group and to standard of care (no additional living donation education). Eighty-two percent of House Calls participants had at least one donor inquiry, while group-based and individual instruction had 61% and 47% respectively;[27] unfortunately, the use of house calls may be cost prohibitive for a transplant center, given the time involved with engaging each candidate's social network individually.

Most recently, Johns Hopkins University has demonstrated the effectiveness of its own program¸ the Live Donor Champion (LDC).[28] This program involves five informational sessions, in which transplant candidates who have not yet identified a willing living donor bring a "Champion", either a family member or friend who is willing to advocate on their behalf and share their need for a kidney transplant with the community. Each session provides both the Champion and their candidate with detailed information about kidney disease, the risks and benefits of living donation, and how best to initiate a conversation with someone about the candidate's need for a transplant. Early results from the LDC program showed an increase in knowledge and comfort in speaking about living donation, as well as an increase in the number of potential donor inquiries and subsequently the number of living donor transplants.[29] However, none of these three programs has attempted to focus on the perspective of potential living donors, address donor comfort and confidence in the evaluation/donation process, and consider possible reasons for non-donation.

Becoming a living kidney donor involves a time-consuming process of evaluation and education, not only to ensure the autonomy of the potential donor but also to confirm that the donor is both physically and mentally healthy enough to donate. Given the number of steps involved in this process, many donors withdraw from evaluation, either because they are given information that deters them from donating or they are inactivated due to failure to complete a specific test or clinic visit. While the first reason is respected to preserve autonomy, the second is a potential point of intervention in the system. As such, the LDC program has been adapted at UAB by combining it with another initiative that has shown to be incredibly successful in the UAB Comprehensive Cancer Center (CCC), the Patient Navigation program. Patient Navigators guide patients undergoing treatment for cancer through the health care system, including helping them get to their appointments, answering questions, and engaging with community and social services to meet the patient's needs. The goal of the CCC Patient Navigation program is to remove physical, emotional, social, and financial barriers to cancer care. Similarly, the Living Donor Navigator (LDN) program seeks to alleviate barriers to achieving living donor transplantation by combining the education provided to Champions with navigation provided by two non-clinical personnel. This program proposes increasing living donation at UAB in two ways: 1) improving awareness and knowledge of living donation among a group of highly motivated individuals who are personally connected to someone in need of a transplant, and 2) assisting individuals who are identified as a result of Champion community engagement through the process of evaluation and approval for living donation.

If trends in ESRD development continue in the US, the need for kidney transplantation will only increase. Therefore, identifying factors that are associated with lower rates of living kidney donation and creative strategies for increasing living donation through donor engagement are needed. This dissertation explores these issues in the following three aims:

1) To examine population-level factors associated with the rate of living kidney donation
2) To quantitatively assess the cost effectiveness of the Living Donor Navigator Program at UAB
3) To qualitatively assess barriers and promising practices for effective implementation of the Living Donor Navigator Program

While trends in comorbid disease and financial barriers have been hypothesized to be the primary cause for the decline of living donation in the US, no study to date has examined the association between center rates of living donation and population-level factors using a national survey database. Utilization of this novel data source has provided additional insight for Living Donor Navigators into the role of modifiable population factors that pose barriers to living donation. These insights can now be incorporated into classroom discussions. In conjunction with the cost effectiveness analysis and focus group data collection, these findings will allow us to improve content and delivery of the LDN program and may provide support for implementation of this program at kidney transplant centers across the country.

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POPULATION HEALTH, ETHNICITY, AND RATE OF LIVING KIDNEY DONOR TRANSPLANTATION

by

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INTRODUCTION

Although superior long-term outcomes are achieved with kidney transplantation from living donors compared to allografts from deceased donors or dialysis, living donor kidney transplantation (LDKT) has decreased since 2004 in the United States.[1] The development of new policies for donors (Organ Procurement and Transplantation Network (OPTN) Policies 14 and 18.5, Living Donation, April 2017), recent publications of negative donor outcomes,[2,3] and an aging transplant population with limited social networks may limit the pool of potential living donors.[4,5]

Another explanation may be the increasing prevalence of absolute and relative contraindications to donation, including diabetes mellitus, obesity, and hypertension.[6,7] Studies have suggested that medical conditions including undiagnosed hypertension or abnormal glucose tolerance are the most common reasons for non-donation.[8-11] A rise in unemployment and a decrease in median household income following the economic downturn of 2008 may have amplified financial disincentives to donation, such as out-of-pocket expenses and lost wages, particularly among those with low incomes already known to donate at lower rates.[5,12] Transplant candidates may be reluctant to ask individuals to donate in the current economic climate, given concerns about the potential financial impact to the living donor.[13]

While population health and financial statuses have been hypothesized as explanations for the decrease in living donation, to our knowledge, no study has examined the relationship between population health or socioeconomic status (SES) and rate of LDKT. We performed an ecological analysis using state-specific measures of population health and SES to investigate the association with transplant center rates of LDKT.

METHODS

Data sources

The primary data source was the 2015 Behavioral Risk Factor Surveillance System (BRFSS) State Prevalence and Trends Data at the Centers for Disease Control and Prevention. BRFSS is the largest continuously conducted telephone health survey system in the world, completing more than 400,000 adult interviews in the United States every year. These data include health-related risk behaviors, chronic health conditions, and use of preventive services from all 50 states, the District of Columbia, and three United States territories.[14]

The second data source was the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, wait-listed candidates, and transplant recipients in the United States; these data are submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration of the United States Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. The study was approved by the University of Alabama at Birmingham Institutional Review Board (161212003).

Study population

The unit of analysis was kidney transplant center. All United States kidney transplant centers that performed at least 10 transplants in 2015 were eligible for inclusion. One center performed more than 10 transplants in 2015 but did not list anyone in 2013-2014 and thus was excluded from the analysis, resulting in a final cohort of 213 kidney transplant centers.

Categorization of exposures

The BRFSS prevalence measures are reported at the state level and are weighted to account for the complex survey sampling design. To best define the surrounding population characteristics of a transplant center, we defined each center's ”catchment area” as the list of states from which patients were added to the waiting list at that center (Appendix A: Supplemental Methods).

Center demographic and SES indicator prevalence measures were then weighted by multiplying a given state's prevalence measure by the proportion of waitlisted patients from that state (e.g., if 80% of transplant candidates at Center A were from State A and 20% were from State B, the prevalence of obesity in State A was multiplied by 0.8 and added to the prevalence of obesity in State B multiplied by 0.2, and the resulting prevalence was assigned to the center) This was done to make a transplant center's prevalence measures look more like the patient population of the center and to account for heterogeneity within a state that is not captured by a state-level summary measure in BRFSS. A summary of the within-state variation achieved using this weighting measure is presented in Supplemental Table S1 (Appendix B).

The following population demographic and SES indicators hypothesized a priori to be associated with rate of LDKT were considered for analysis: prevalence of age ≥ 65 years, male sex, minority race/ethnicity defined as non-White (African American, Asian, Hispanic, American Indian, Native Hawaiian, other, or multi-racial), less than college education, lack of health insurance (defined as report of “no health care coverage”), annual household income < $15,000, unemployment (collapsed responses for “no work for < 1 year” and “no work for > 1 year”), no internet use in past 30 days, and not married / no partner. We considered the following population health indicators for analysis, as they are absolute and relative contraindications to living kidney donation: history of cardiovascular disease (CVD), diabetes mellitus (DM), hypertension, kidney disease, depression, poor self-rated health, obesity, and current smoking.

For center-level characteristics, we examined the absolute number of living donor transplants performed in 2015 and whether the transplant center performed incompatible kidney transplants (either blood group incompatible or donor exchange programs).[15]

Outcome ascertainment

Center rate of living donation was defined as the proportion of all kidney transplants performed at a center in 2015 that were from living donors.

Statistical analyses

Using measures of central tendency and spread, we explored the distribution of center prevalence measures by OPTN region. Given that some states only have one active transplant center, we chose to present the rate of LDKT in a heat map at the OPTN region rather than the state level, so as not to identify unique transplant centers. Prevalence measures were also described at the region level for consistency. Spearman's correlation was used to generate the correlation coefficient between covariates to assess the potential for collinearity. We also investigated the variance inflation factor (VIF) for each covariate and obtained VIFs > 10 for CVD, DM, minority prevalence, and smoking and VIFs approaching 10 for obesity, lower education, unemployment, and no internet use. As such, we chose to collapse SES and health factors into two indices.

To create the indices, prevalence measures were dichotomized into whether the center's weighted prevalence was greater than or equal to the national median of that factor (Appendix B, Supplemental Table S2). The relationship between the dichotomous factor and rate of LDKT was explored. We performed principal component factor analyses using measures with p-values ≤ 0.1 on unadjusted analyses, to confirm the communality of the measures and obtain the factor loadings for each measure to calculate weighted factor-based scores.[16,17] If a center's prevalence was greater than or equal to the national median, the factor loading was added to the total score for each index, such that a center could have a maximum score of 4.101 for the disease index and a maximum score of 3.291 for the SES index. To test internal consistency of the indices, we calculated Cronbach's alpha for each index. Given that health and SES are correlated and to determine whether there was an additive effect, the indices were cut at the median and categorized as low vs. high and further collapsed into a single measure, with the number of centers falling into each category presented in Supplemental Table S3. (Appendix B).

Living donation rate was examined for normality, and model diagnostics assessed the appropriateness of the assumption of linearity, with both assumptions confirmed.

Given the presence of more than one transplant center in some states and the potential for lack of independence of these centers, we utilized a linear mixed effects model with a random intercept for state accounting for within-state correlation to assess the association between population health and SES factors and center rate of living donation. The index and all demographic and center-level factors were considered for multivariable modeling, and the most parsimonious model was chosen by minimizing the Akaike's Information Criterion. All analyses were conducted with SAS version 9.4 (SAS Institute, Inc., Cary, NC).

Sensitivity analyses

To account for other factors of center performance that may influence volume of living donors at a center, we ran several sensitivity analyses. Given the concerns by Matar et al. that proportion of all kidney transplants done that are from living donors may not accurately measure center performance of LDKT,[18] we ran a Poisson model to estimate the rate ratio of living donor transplants per individuals on the waiting list as of January 1, 2015, as a function of population characteristics. Inferences were consistent and are reported in Supplemental Table S4 (Appendix B). We also explored the inclusion of deceased donor organs available per waiting list population, median center waiting time, waitlist additions, and total on waitlist at the beginning of the study period as covariates, and our findings were confirmed. Additional sensitivity analyses included excluding Children's Hospitals and generating a linear model with robust standard errors (R-squared=0.37). Finally, we explored different definitions of catchment area, based on distribution of donor zip code and 200-mile radius around the transplant center. All inferences were consistent.

RESULTS

Center prevalence measures by region

Among 213 centers, the prevalence of LDKT and population measures varied by OPTN region. The rate of LDKT and the number of centers within each region are presented in Figure 1. The region with the highest rate of LDKT was Region 1 with a median rate of 48% (interquartile range (IQR): 30.1-54.8), while Region 6 had the lowest rate of LDKT (19%, IQR: 16.8-29.4).

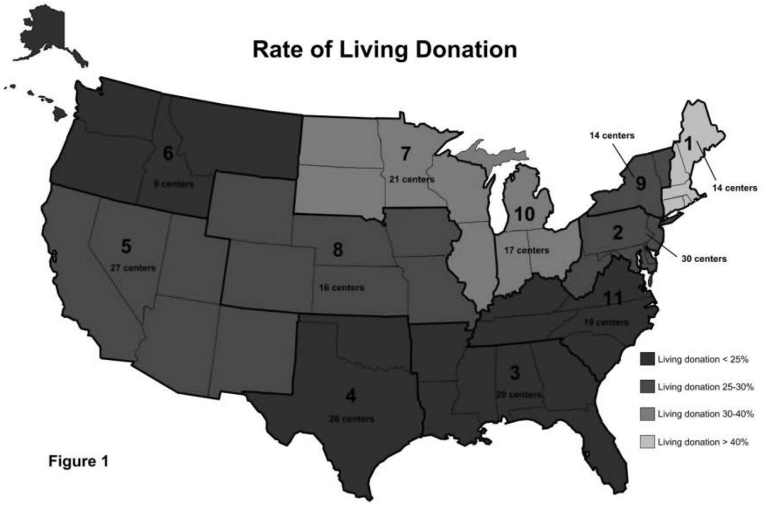

Figure 1

Note: From “Population Health, Ethnicity, and Rate of Living Kidney Donation” by R.D. Reed et al., 2018, *Transplantation*, 102(12), p. 2082. Copyright 2018 by Wolters Kluwer. Reprinted with permission.

Prevalence of minority race/ethnicity (categorized as other than White, non-Hispanic) ranged from 18% in Region 7 (IQR: 15.5-33.6) to 58% in Region 5 (IQR: 41.4-

58.1) (Table 1, Figure 2A). When examining specific groups of minority race/ethnicity, Region 3 had the highest prevalence of African Americans (AA) (median: 21%, IQR: 14.1-28.7), and Region 4 had the highest prevalence of Hispanics (median: 35%, IQR: 33.7-35.0). The prevalence of health and SES characteristics also varied by region, with the highest rates of comorbid disease and poorest SES observed in Regions 3, 4, and 11 (Table 1).

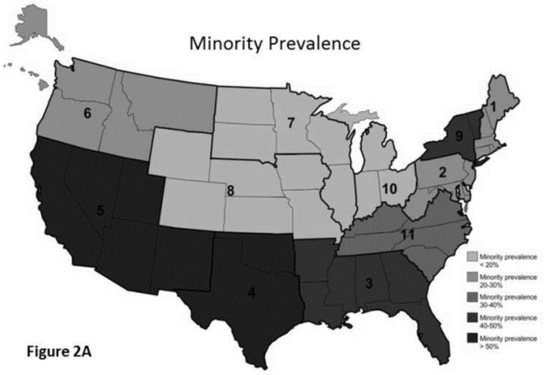

Figure 2A

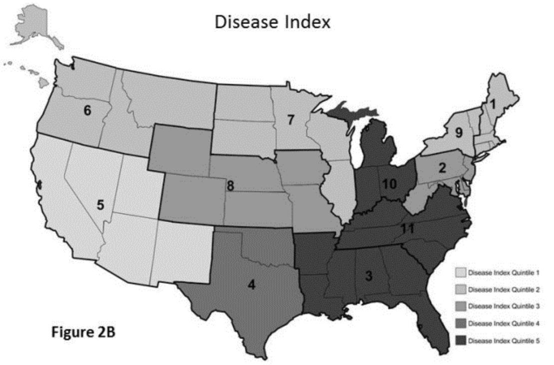

Figure 2B

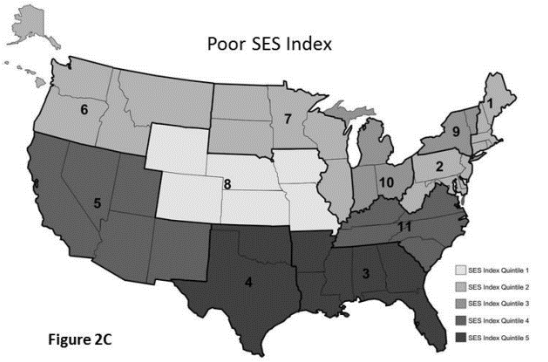

Figure 2C

Note: From “Population Health, Ethnicity, and Rate of Living Kidney Donation” by R.D. Reed et al., 2018, *Transplantation*, 102(12), p. 2084. Copyright 2018 by Wolters Kluwer. Reprinted with permission.

Association of prevalence measures and LDKT

Of the demographic factors, only high minority prevalence was significantly associated with lower rate of LDKT. High prevalence of all SES factors except marital status was negatively associated with rate of LDKT. Health factors associated with lower rate of LDKT were high prevalence of cardiovascular disease, diabetes mellitus, kidney disease, and poor self-rated health (Table 2).

Factor analysis revealed one factor for the health measures with an Eigenvalue of 3.48 (standardized Cronbach's alpha=0.92). When the health factors were collapsed into a composite measure of disease based on factor loadings, Regions 3, 10, and 11 had the highest/worst median composite score, meaning that most centers in those regions had a prevalence of comorbidities that was higher/worse than the national median (Figure 2B). The factor analysis also revealed one factor for the SES measures with an Eigenvalue of 2.37 (standardized Cronbach's alpha=0.76). When collapsed into a composite measure of poor SES, Regions 3 and 4 had the highest/worst median composite score, indicating that most centers in these regions had a prevalence of poor SES that was worse than the national median (Figure 2C).

On unadjusted analyses, we found that each one-unit increase in the composite SES score was associated with an average decrease in the rate of LDKT by 4.13 percentage points (95% confidence interval (CI): -6.1, -2.2, p< 0.001) (Table 3). Each one-unit increase in the composite disease score was associated with an average decrease of 2.45 percentage points in the rate of LDKT (95% CI: -4.0, -0.9, p=0.003). When the SES and disease scores were categorized as low vs. high and combined into one index, 69 (32.4%) centers were in catchment areas with low scores for both disease and SES indices, and 76 (35.7%) centers had high scores for both indices, with the remaining 68 centers having a high score for only one index (Supplemental Table S2).

Table 1. Prevalence measures by UNOS Region

Factor	**Region** **Median % prevalence (IQR)**										
	1	2	3	4	5	6	7	8	9	10	11
Age 65+	**20.05** (19.89-20.44)	**21.03** (19.17-21.84)	**20.67** (18.98-24.31)	**16.37** (16.31-16.49)	**17.44** (17.40-18.29)	**19.04** (18.69-20.77)	**19.40** (18.84-19.88)	**20.26** (19.30-20.58)	**19.53** (19.51-19.54)	**20.70** (20.67-20.72)	**19.81** (19.36-20.23)
Male	**48.02** (47.93-48.17)	**48.25** (48.12-48.30)	**48.30** (48.14-48.40)	**49.19** (49.17-49.20)	**49.31** (49.30-49.34)	**49.65** (49.46-50.02)	**49.18** (48.61-49.31)	**49.08** (48.77-49.53)	**47.91** (47.90-47.92)	**48.60** (48.40-48.60)	**48.14** (48.10-48.68)
Minority race/ethnicity	**23.75** (22.52-24.71)	**29.64** (21.58-41.18)	**41.30** (38.42-41.67)	**52.56** (52.23-52.80)	**57.82** (41.42-58.08)	**26.15** (21.69-27.06)	**18.31** (15.55-33.61)	**19.47** (17.90-24.89)	**41.68** (41.51-41.84)	**18.96** (17.91-22.00)	**33.01** (24.08-33.60)
Less than college education	**65.49** (64.46-67.16)	**72.10** (67.40-73.96)	**75.79** (75.34-79.83)	**76.15** (76.10-76.26)	**72.45** (72.30-74.71)	**72.26** (71.72-72.62)	**71.61** (71.07-73.82)	**74.73** (71.70-75.11)	**69.10** (69.07-69.11)	**76.42** (76.00-77.51)	**76.76** (74.98-77.98)
Lack of health insurance	**5.87** (5.34-7.35)	**8.81** (8.28-9.75)	**16.05** (14.86-16.31)	**23.16** (22.90-23.34)	**11.43** (11.40-11.54)	**10.48** (8.57-11.06)	**8.35** (7.51-9.45)	**11.29** (10.78-12.19)	**10.10** (10.07-10.11)	**9.88** (8.58-9.91)	**13.32** (10.88-14.98)
Low income (< $15,000/yr)	**8.07** (7.97-9.53)	**8.16** (7.92-8.96)	**12.08** (11.50-14.87)	**11.91** (11.90-11.98)	**15.36** (11.62-15.57)	**8.61** (8.36-10.64)	**8.70** (6.97-10.61)	**8.78** (7.77-10.53)	**11.93** (11.82-11.98)	**10.70** (10.67-11.12)	**12.27** (11.27-13.45)
Unemployment	**5.82** (5.75-6.05)	**5.83** (5.59-6.42)	**6.43** (6.38-6.92)	**5.80** (5.79-5.81)	**6.59** (5.90-6.60)	**5.58** (5.41-5.70)	**4.85** (4.30-5.58)	**4.41** (4.23-4.89)	**6.88** (6.87-6.90)	**5.33** (5.31-5.40)	**5.97** (5.73-6.52)
No internet use	**14.92** (14.81-15.74)	**18.27** (16.30-19.18)	**19.19** (18.01-23.57)	**19.10** (19.09-19.23)	**17.85** (17.30-17.90)	**12.62** (11.99-12.76)	**16.20** (15.14-16.31)	**16.02** (14.73-17.00)	**18.97** (19.92-19.00)	**17.01** (15.72-17.75)	**20.19** (19.71-21.15)
Not married or partnered	**45.51** (44.67-45.73)	**44.46** (44.38-45.19)	**46.18** (45.79-47.83)	**42.70** (42.70-42.85)	**44.20** (44.18-44.21)	**41.18** (41.08-42.86)	**42.65** (40.89-44.81)	**41.43** (41.04-42.82)	**47.73** (47.63-47.79)	**45.40** (45.28-45.41)	**44.59** (44.27-44.98)
Cardiovascular disease	**6.00** (5.97-6.06)	**6.63** (5.64-7.02)	**7.47** (7.36-8.19)	**6.12** (6.10-6.18)	**4.92** (4.90-5.16)	**5.60** (5.47-5.61)	**6.13** (5.72-6.24)	**6.25** (5.56-7.12)	**5.80** (5.80-5.81)	**7.30** (7.28-7.55)	**7.10** (7.00-8.47)

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Table 1 (cont.). Prevalence measures by UNOS Region

Factor	**Region Median % prevalence (IQR)**										
	1	2	3	4	5	6	7	8	9	10	11
Diabetes mellitus	**8.93** (8.91-9.13)	**10.28** (9.96-10.40)	**11.51** (11.29-13.03)	**11.41** (11.40-11.45)	**10.00** (9.99-10.00)	**8.42** (8.28-9.54)	**9.09** (8.53-9.93)	**9.69** (8.22-10.97)	**9.80** (9.78-9.80)	**11.00** (10.70-11.35)	**11.65** (10.70-12.79)
Hypertension	**29.88** (29.67-30.33)	**32.37** (31.73-32.92)	**36.74** (33.60-39.70)	**29.59** (29.50-29.89)	**28.51** (28.50-29.05)	**29.71** (29.41-29.94)	**30.23** (28.91-30.84)	**31.36** (28.81-33.30)	**29.35** (29.31-29.38)	**33.10** (33.08-34.29)	**35.65** (35.17-38.51)
Depression	**20.82** (20.71-21.00)	**17.26** (16.51-18.32)	**18.55** (16.58-19.87)	**16.19** (16.10-16.43)	**13.01** (12.92-18.47)	**21.03** (20.46-21.53)	**16.87** (15.63-18.55)	**19.45** (18.87-20.96)	**15.70** (15.66-15.74)	**19.67** (19.60-19.70)	**18.92** (18.69-20.68)
Kidney disease	**2.41** (2.38-2.44)	**2.56** (2.38-2.68)	**2.97** (2.84-2.99)	**2.70** (2.70-2.70)	**2.42** (2.40-2.65)	**3.09** (2.88-3.11)	**2.31** (2.14-2.60)	**2.58** (2.43-2.73)	**2.10** (2.10-2.11)	**3.21** (3.14-3.39)	**2.90** (2.78-3.23)
Obesity	**24.91** (24.50-25.31)	**29.02** (27.73-29.69)	**30.97** (26.99-34.96)	**32.41** (32.38-32.51)	**24.28** (24.20-26.18)	**26.56** (26.47-27.25)	**30.69** (28.76-30.81)	**31.97** (27.033 2.63)	**25.04** (25.00-25.07)	**31.13** (30.70-31.20)	**31.63** (30.07-33.83)
Poor self-rated health	**4.37** (3.96-4.45)	**3.65** (3.41-3.92)	**5.18** (5.09-6.70)	**5.11** (5.10-5.16)	**4.00** (4.00-4.01)	**3.78** (3.71-4.08)	**3.29** (3.09-3.64)	**4.00** (3.23-4.98)	**4.88** (4.86-4.89)	**4.90** (4.88-5.15)	**5.85** (5.68-6.82)
Smoking	**14.33** (14.01-14.74)	**16.77** (15.80-17.91)	**17.98** (15.82-21.53)	**15.27** (15.20-15.50)	**11.82** (11.70-13.25)	**15.67** (15.09-15.89)	**16.27** (15.45-17.26)	**18.01** (17.17-20.73)	**15.20** (15.19-15.21)	**20.70** (20.67-21.59)	**19.59** (18.93-22.00)

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Table 2. Estimates for relationship between center prevalence measures above or below national median and living donation rate (interpreted as: if prevalence of covariate X is above national median, the rate of living donation differs by x percentage points from centers with prevalence lower than national median)

Characteristic	Estimate	95% CI	p-value
	Unadjusted		
Demographic			
High prevalence of 65 years and older	-1.59	-7.00, 3.82	0.56
High prevalence of males	-1.41	-7.28, 4.47	0.64
High prevalence of minorities (non-White)	**-6.20**	**-11.39, -1.02**	**0.02**
Socioeconomic			
High prevalence of less than college education	**-7.38**	**-12.67, -2.10**	**0.007**
High prevalence of lack of health insurance	**-7.73**	**-12.59, -2.86**	**0.002**
High prevalence of income < $15,000/yr	**-6.60**	**-11.85, -1.35**	**0.01**
High prevalence of unemployment	**-7.30**	**-12.52, -2.08**	**0.007**
High prevalence of no internet use in past 30 days	**-7.71**	**-12.80, -2.62**	**0.003**
High prevalence of not married or partnered	-1.26	-7.31, 4.78	0.68
Health-related			
High prevalence of history of cardiovascular disease	**-6.88**	**-12.11, -1.65**	**0.01**
High prevalence of history of diabetes mellitus	**-7.11**	**-12.01, -2.20**	**0.005**
High prevalence of history of hypertension	-4.54	-9.89, 0.81	0.10
High prevalence of history of depression	-0.24	-6.06, 5.57	0.93
High prevalence of history of kidney disease	**-4.87**	**-9.89, 0.15**	**0.06**
High prevalence of obesity	-1.55	-7.05, 3.95	0.58
High prevalence of poor self-rated health	**-6.53**	**-12.03, -1.02**	**0.02**
High prevalence of smoking	-2.15	-7.65, 3.36	0.44
Center-specific			
Living donor volume	**0.24**	**0.18, 0.29**	**< 0.001**
Incompatible transplant program	**12.68**	**8.88, 16.47**	**< 0.001**

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Table 3. Factor loadings and estimates for relationship between composite SES and disease indices with rate of living donation

Characteristic	Factor loading	Estimate	95% CI	p-value
		Unadjusted		
Socioeconomic				
Less than college education	0.48746	**-4.13**	**-6.10, -2.17**	**< 0.001**
Lack of health insurance	0.37874			
Income < $15,000/yr	0.85652			
Unemployment	0.67884			
No internet use in past 30 days	0.88958			
Health-related				
Cardiovascular disease	0.90139	**-2.45**	**-4.04, -0.86**	**0.003**
Diabetes mellitus	0.88482			
Hypertension	0.90415			
Kidney disease	0.61020			
Poor self-rated health	0.83072			

Note: From "Population Health, Ethnicity, and Rate of Living Kidney Donation" by R.D. Reed et al., 2018, *Transplantation*, 102(12), p. 2085. Copyright 2018 by Wolters Kluwer. Reprinted with permission.

Centers in areas with a high prevalence of both comorbid disease and poor SES had a rate of LDKT that was 10.35 percentage points lower than centers in areas that had low scores for both disease and poor SES (95% CI: -15.95, -4.75, $p< 0.001$). Centers with a high score for only one factor did not differ statistically in the rate of LDKT from centers with low scores for both indices (Table 4).

In an adjusted model accounting for total center LDKT volume, high prevalence of age ≥ 65, high prevalence of male sex, and presence of an incompatible transplant program, the significant relationship between high prevalence of minority race and LDKT persisted, with a rate of LDKT that was on average 7.1 percentage points lower than centers in areas with fewer minorities (95% CI: -11.8, -2.3, $p=0.004$). The combined disease/SES index also remained significant, with centers with higher/worse scores for both disease and SES associated with an average rate of LDKT that was 7.3 percentage points lower than that for centers with low disease and SES scores (95% CI: -12.2, -2.3, $p=0.004$). Centers with an incompatible transplant program had a rate of LDKT that was on average 5.92 percentage points higher than centers without a similar program (95% CI: 1.82, 10.02, $p=0.005$) (Table 4).

When we used living donor transplants performed per waiting list registrants in a Poisson model as an alternative measure of center performance of LDKT, similar results were found. The rate ratio (RR) for centers with high disease and SES scores was 0.79 (95% CI: 0.65-0.97, $p=0.02$), suggesting that centers with more comorbid disease and poorer SES have a rate of LDKT per waiting list population that is 21% lower than centers in healthier areas with higher SES. Centers in areas of high minority prevalence had a RR of 0.61 (95% CI: 0.49-0.76, $p < 0.001$), indicating a 39% lower rate than areas with fewer minorities. Finally, the RR for centers with an incompatible transplant program was 1.80 (95% CI: 1.54-2.11, $p < 0.001$), demonstrating a positive association between incompatible transplantation and rate of LDKT (Supplemental Table S4).

Table 4. Relationship between center prevalence measures and living donation rate (with collapsed composite measures for disease and SES)

Characteristic	Est.	95% CI	p-value	Est.	95% CI	p-value
	Unadjusted			Adjusted		
Demographic						
High prevalence of 65 years+	-1.59	-7.00, 3.82	0.56	-3.23	-8.08, 1.62	0.19
High prevalence of males	-1.41	-7.28, 4.47	0.64	-2.66	-6.79, 1.47	0.21
High prevalence of minorities (non-White)	**-6.20**	**-11.39, -1.02**	**0.02**	**-7.05**	**-11.82, -2.28**	**0.004**
SES and Disease Combined[a]						
Low disease score, low SES score	Ref			Ref		
Low disease score, high SES score	-4.90	-13.14, 3.33	0.24	-3.91	-10.88, 3.07	0.27
High disease score, low SES score	-2.51	-9.46, 4.44	0.48	-3.65	-9.92, 2.61	0.25
High disease score, high SES score	**-10.35**	**-15.95, -4.75**	**< 0.001**	**-7.27**	**-12.23, -2.31**	**0.004**
Center-specific						
Living-donor volume	**0.24**	**0.18, 0.29**	**< 0.001**	**0.19**	**0.12, 0.26**	**< 0.001**
Incompatible transplant program	**12.68**	**8.88, 16.47**	**< 0.001**	**5.92**	**1.82, 10.02**	**0.005**

[a]Factors in the SES index (less than college education, lack of health insurance, low income, unemployment,
no internet use in past 30 days) and disease index (cardiovascular disease, diabetes mellitus, hypertension, kidney disease, poor self-rated health). Higher scores correspond with higher disease prevalence and poorer SES.

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DISCUSSION

In this ecological analysis, the first using BRFSS population health and SES measures to examine associations with center rates of LDKT, we observed a significant negative association between rate of LDKT and higher prevalence of minorities, poor SES, and comorbid disease. Centers with high scores for both disease and SES indices had LDKT rates that were on average 7.3 percentage points lower than centers serving healthier and more economically advantaged populations. Centers in areas with higher prevalence of minorities had a significantly lower rate of LDKT, 7.1 percentage points lower than the rate for centers in areas with fewer minorities. These data provide the first cross-sectional evidence that living donation is associated with population health and economic wellbeing.

Our study found a significant association between high minority prevalence and lower rates of LDKT, even after adjusting for health and SES factors. Racial disparities in LDKT are well-known.[19,20] African Americans account for 30-50% of transplant waiting lists but only 10-15% of living donors,[21] and fewer Hispanics receive LDKT than non-Hispanic whites (4% vs. 10%).[22] This disparity has been attributed to sociocultural barriers and lack of knowledge regarding risks and benefits of LDKT specific to minority populations.[23,24] Several transplant centers have initiated culturally targeted interventions among minorities and have successfully increased transplant knowledge and rate of donor inquiry.[25-27] Systematic implementation of these programs may reduce some of the racial disparity in rates of LDKT. In addition, recent studies have raised concerns about the role of Apolipoprotein L1 (APOL1) in recipients of kidney transplants from deceased AA donors.[28,29] The investigation of APOL1 among living donors has been limited.[30,31] However, concerns remain, particularly given population studies demonstrating higher rates of post-donation end-stage renal disease and mortality among AA living donors.[3,32] These data may contribute to the persistently lower rate of living donation among African Americans.

While presence of high/worse SES composite score alone was not significantly associated with lower rates of LDKT compared to centers with low scores for both health and SES, several SES score components yielded interesting findings. High prevalence of no health insurance was associated with a lower rate of LDKT, consistent with previous reports, as some centers will decline potential donors with no health insurance.[33] The association between no internet use in the previous 30 days and a lower rate of LDKT supports the hypothesis proposed by Rodrigue about limited social networks [5] Lack of internet use may be a proxy for lower access to medical care, a factor also known to be associated with lower rates of LDKT [12,34] These findings highlight the need for programs that actively engage candidate social networks to identify potential living donors, including those that engage potential donors in their homes and communities.[35,36] Additionally, the negative associations between high prevalence of lack of health insurance and high prevalence of low income with rate of LDKT further motivate discussions about testing interventions to remove or mitigate financial disincentives to living donation.[37,38]

Our study findings suggest that addressing socioeconomic disparities alone may not increase rates of living donation. While there is evidence that donor selection criteria have expanded to meet the growing organ shortage,[39,40] it has been suggested that some centers have become more reticent to accept donors in subgroups shown to be at increased risk of end-stage renal disease.[5,41] Some donor factors may be modifiable at the time of evaluation (i.e., morbid obesity), but other threats to population health, such as diabetes and hypertension, require earlier and more widespread implementation of awareness and prevention programs, particularly among children and adolescents. The

Robert Wood Johnson Foundation “Roadmaps to Health” provide strategies to improve population health that have been shown to be effective through empirical evidence,[42] including competitive pricing for healthy foods[43] and childhood obesity prevention programs,[44] which could be implemented more broadly to improve population health, thereby increasing access to living kidney donation while simultaneously decreasing the need for kidney transplantation. Additionally, community based participatory research has been used to influence policies regarding chronic disease prevention and treatment.[45] Engaging community members is essential to the success of initiatives to reduce disease prevalence and incidence.

The finding that the presence of high/worse scores for both disease and SES factors was negatively associated with rate of living donation suggests that the decline in living donation may be multi-factorial and would benefit from targeted efforts in both areas. It is also an important finding, given that nearly 36% of the US transplant centers included in our analyses were located in catchment areas defined as having high disease and poor SES scores.

Our study is not without limitations. BRFSS relies on information reported directly by a participant and thus may be subject to various sources of bias. We are not able to account for transplant staff size, which may be indicative of larger-volume centers that can perform more LDKTs. The percentage of recipients listed within a state in 2013-2014 may have differed from the fraction of the total number of recipients from that state transplanted at a center in 2015. Some LDKTs may have been performed at centers other than those that first wait-listed the recipient. Due to changes in the survey and sampling design in 2011, we cannot assess time trends to compare prevalence measures from 2004 (the peak of LDKT) and 2015, to determine if similar associations would have been seen in prior years. Additionally, BRFSS is population-level data, and as such we cannot attribute our findings to be the cause of the decline in LDKT. However, this is the first study to our knowledge utilizing this data source to examine the cross-sectional association of population characteristics with LDKT.

In conclusion, center-level variation in LDKT was associated with population characteristics and minority prevalence. Further examination of these factors in the context of patient and center-level barriers to LDKT is warranted.

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COST EFFECTIVENESS OF THE LIVING DONOR NAVIGATOR PROGRAM

by

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INTRODUCTION

While our previous work examined associations between population characteristics and living donation, we must also consider factors that influence rates of living donation from the individual perspective. Transplant candidates report unwillingness and reticence to discuss their need for a kidney due to guilt or shame about their disease and lack of knowledge surrounding the impact to the potential donor.[1] Minorities in particular struggle with asking for a kidney.[2] Solely educating the patient in need of a transplant relies on that individual to initiate all dialogues with potential donors, thus increasing the burden on the transplant candidate.[3] As such, programs are needed to increase confidence in speaking about kidney donation, not only for the transplant candidate but also for those in their social networks.

Johns Hopkins University has demonstrated effectiveness of a program called the Live Donor Champion (LDC).[4] This program involves five informational sessions, in which transplant candidates who have not yet identified a willing living donor bring a "Champion", either a family member or friend who is willing to advocate on their behalf and share their need for a kidney transplant. Each session provides both the Champion and their candidate with detailed information about kidney disease, the risks and benefits of living donation, and how best to initiate a conversation with someone about the candidate's need for a transplant. Conducted in groups of no more than 20 individuals (generally 10 candidates and their Champions), these sessions provide an opportunity for patients to learn more about their disease and why living kidney donation is their best option. These sessions are held at the transplant center, making use of existing space with which the transplant candidates are already familiar. Throughout the course of the sessions, the Champions not only gain confidence in their knowledge of living donation but also have an opportunity to share their motivation for becoming a Champion and engage with other friends and family members who provide care and support to their loved ones awaiting transplant. Early results from the LDC program showed an increase in knowledge and comfort in speaking about living donation, as well as an increase in the number of potential donor inquiries and subsequently the number of living donor transplants.[5]

However, challenges in achieving living donation are not limited to the transplant candidate. Becoming a living kidney donor involves a time-consuming process of evaluation and education, not only to ensure the autonomy of the potential donor but also to confirm that the donor is both physically and mentally healthy enough to donate. Given the number of steps involved in this process, many donors withdraw from evaluation, either because they are given information that makes them change their mind or they are inactivated due to failure to complete a specific test or clinic visit.[6,7] While the first reason is important and is respected to preserve autonomy, the second reason is a point of intervention in the system to increase the likelihood of success (achieving living donation). As such, Locke and colleagues have adapted the LDC program by combining it with another successful initiative, the Patient Navigation program created by the UAB Comprehensive Cancer Center.[8]

The Living Donor Navigator (LDN) Program partners patients seeking cancer treatments with a Navigator, a layperson who guide them through the course of their clinic visits and hospital stays, ensuring that they not only have transportation to their appointments and access to their physicians in case of questions, but also provide emotional and social support.[8] Multiple studies of this program have demonstrated increased adherence to clinic appointments, increased quality of life among patients, and decreased costs to Medicare resulting from fewer emergency room visits and hospital admissions.[9] Patient navigation is not a new concept within transplantation, as several centers have introduced their own versions of navigator programs to assist patients with access to transplantation.[10,11] However, these programs have not demonstrated sustained increases in living donor transplantation, nor have the navigators interacted with potential living donors to address donor comfort in the evaluation process. Additionally, the costs of these programs are unknown, and it is impossible to assess how resource-intensive these programs are and whether they are financially feasible at other institutions. The goal of the UAB LDN program was to achieve four additional living donor transplants in the first year of operation (the number needed for the program to break even), with the hospital covering all program expenses. As such, this study sought to examine the cost effectiveness of the UAB Living Donor Navigator program, to demonstrate success in helping our patients achieve living donor transplantation and to provide information on the program operating costs for other centers interested in starting a similar program.

METHODS

Data Sources

All data were obtained from TransChart (UAB's transplant database), transplant administration records, and the electronic medical record. These records contain the number, date, and demographics of individuals who are evaluated for kidney transplant at UAB, whether they are eligible for transplantation, are successfully transplanted (and type of transplant), and date of any deaths. TransChart also records individuals who contact UAB to become living kidney donors, whether they are screened eligible for donation, attend clinic evaluation, are approved to donate, or successfully donate a kidney.

Study Population

We used a retrospective cohort of patients who were evaluated for kidney transplant at UAB between January 1, 2016-March 1, 2018. Patients were classified by whether they participated in the LDN program. Data were gathered on donor outcomes (whether the donor was screened out, attended first clinic appointment, and was approved for donation) and patient outcomes (had a donor screened, had a donor approved for donation). The date of kidney transplant evaluation was the common starting point for study entry. Patients were excluded if they were listed for or received a multi-organ transplant (N=41), if they initiated the LDN classes prior to their kidney transplant evaluation (N=2), or if they ultimately received a living donor kidney transplant from a donor who was screened prior to the patient's evaluation date, as those donors could not be directly attributed to participation in the program (N=52). All patients evaluated beginning in February 2017 were offered the opportunity to participate in the LDN program. The final cohort was 2,004 individuals (56 of whom participated in the LDN program and 1,948 who did not participate). Donor records were excluded if the donor was screened prior to the patient's evaluation date, as it would not be possible to attribute the donor to the LDN program because they had already called in before the patient had a chance to enter the program. In the Markov model, patients entered the model upon evaluation for kidney transplant at UAB at a decision node for participation in the LDN program or in the standard of care (non-participants).

Cost-effectiveness analysis

To assess the cost effectiveness of the LDN program, two types of model parameters were necessary: 1) probabilities of each possible outcome (receipt of a deceased donor transplant, approval of a living donor, death while waiting, or continuing to wait with no approved donor) for each group (participated in LDN program vs. no participation); 2) costs associated with LDN program operation (navigator salaries, catering, printed materials). Data on initial probabilities for starting status of patients were obtained from TransChart and the electronic medical record (Table 1). Within the Markov model, absorbing states were receipt of a deceased donor kidney transplant, approval of a living kidney donor, and death. Failure of a living donor to be approved and initiation of dialysis (for those who entered the study cohort as pre-emptive patients who had declining kidney function but were not yet on dialysis) were “jump states” that sent individuals back to the beginning of the Markov node. Figure 1 contains the state transition diagram for the decision tree. Monthly status was obtained by coding mutually exclusive and exhaustive status categories, and transition probabilities were obtained by cross-tabbing these status groups in xttrans in Stata 15, using the command *fillin* to rectangularize the data (for individuals who entered an absorbing state prior to 6 months of observation time). The primary outcome was having a living donor evaluated and approved for donation. This status served as a proxy for eventual living donor transplantation, and it was assigned a utility of 1.0. The transition matrix and probabilities for each group (LDN participants and non-participants) can be found in Appendices C and D (Table S1).

Table 1. Initial probabilities used in cost effectiveness analysis for the Living Donor Navigator program

State	**Baseline Probability**
Initial status (at study entry)	
Among participants in LDN program	
Pre-emptive, not yet on dialysis	0.143
Pre-emptive and already on the waiting list	0.071
Pre-emptive and acceptable for a living donor only	0.00
Pre-emptive and not a candidate	0.018
On dialysis, not yet listed	0.411
On dialysis and already on the waiting list	0.339
On dialysis and acceptable for living donor only	0.018
On dialysis and not a candidate	0.00
Total (rounded)	1.00
Among non-participants	
Pre-emptive, not yet on dialysis	0.1812
Pre-emptive and already on the waiting list	0.02
Pre-emptive and acceptable for a living donor only	0.0026
Pre-emptive and not a candidate	0.001
On dialysis, not yet listed	0.5724
On dialysis and already on the waiting list	0.21
On dialysis and acceptable for living donor only	0.0046
On dialysis and not a candidate	0.0082
Total (rounded)	1.00

The cost-effectiveness analysis was conducted from the LDN program perspective, with annual costs obtained from the Transplant Administration office at UAB (Table 2). The annual fixed costs of program operation included salary and fringe for two Living Donor Navigators, supplies, and cell phones. The cost per class included materials and supplies and catering costs. We assumed that annual costs would be split across 100 participants, which is the maximum number of participants feasible in a given year (10 cohorts of 10 patients+10 advocates) without scaling up the program.

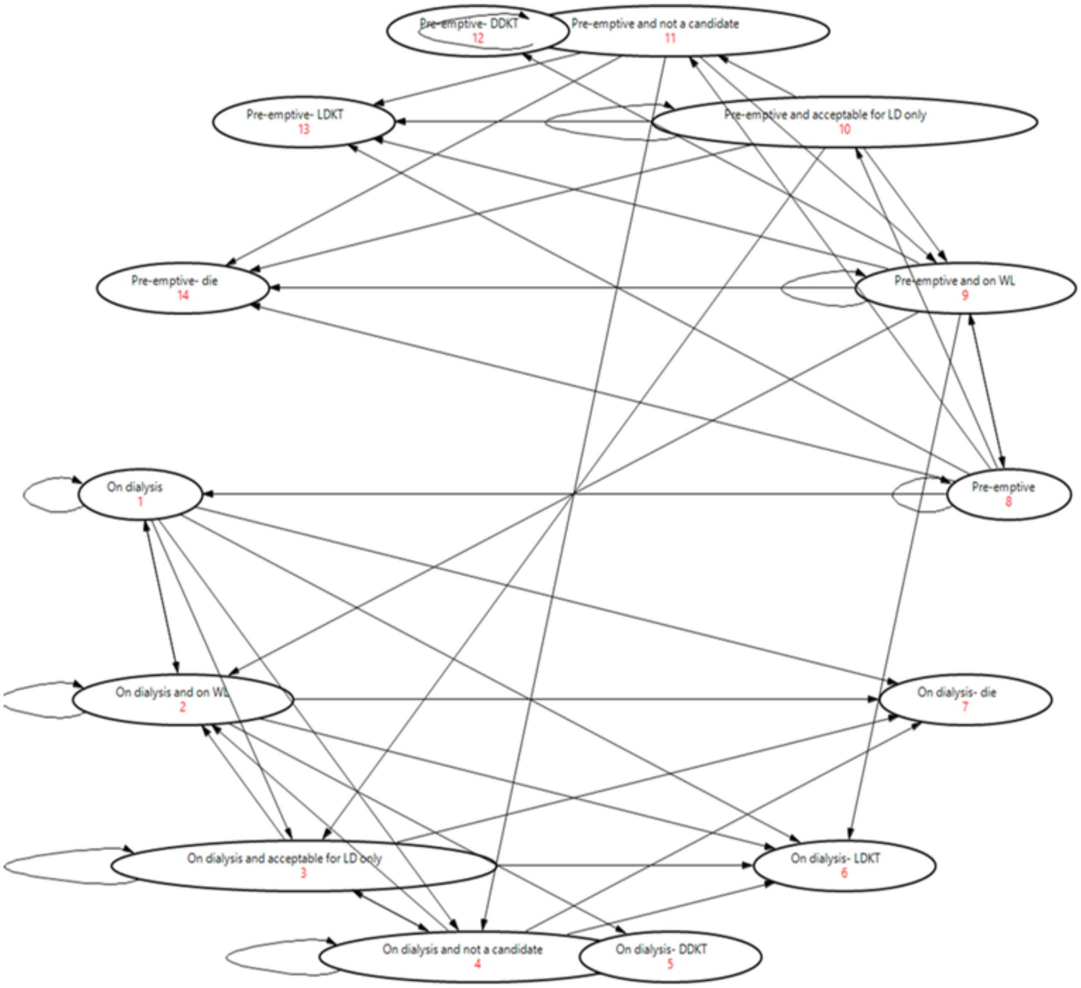

Figure 1. State Transition Diagram

Table 2. Costs associated with operation of the Living Donor Navigator program

Item	**Cost, US$**
Fixed annual costs	
Median navigator salary and fringe benefits (x2)	154,375
Supplies and cell phones	1,600
Class costs (assuming 100 participants/year)	
Catering	$9,000
Supplies/materials	$1,200
Total annual expenses	$166,175

The Willingness to Pay (WTP) threshold was set at $100,000 per living donor approved, which is a typical benchmark recommended by the Second Panel on Cost Effectiveness Analysis,[12] as well as a more context-specific threshold of $41,000 (the annual costs of the program divided by four, which is the number of living donor transplants hospital administration wanted the program to generate in the first year).

All data were entered into TreeAge Pro 2018 (TreeAge Software, Inc., Williamstown, MA) and were analyzed using a Markov model with monthly cycles and a six month time horizon. The incremental cost-effectiveness ratio (ICER) was calculated as the additional cost of participating in the LDN program compared to standard of care. The ICER was interpreted using the WTP threshold.

Due to the small number of participants in the LDN program, many initial statuses and transitions were unobserved. Therefore, one-way sensitivity analyses were performed by allowing model parameters to vary over a range of minimum and maximum values drawn from the literature. We also conducted a sensitivity analysis over a time horizon of 12 months rather than the 6 months in the base case model and restricted to those with 12-months of follow-up time available. Results of the one-way sensitivity analyses and the 12-month analysis time horizon are in Appendix D.

RESULTS

On baseline analyses using the probabilities generated from the observed cohort, 8.8% of LDN participants on dialysis and 2.2% of LDN participants who were pre-emptive had a living donor approved. Only 1.5% (on dialysis) and 1.3% (pre-emptive) of non-participants had a living donor approved. Average cost of living donor approval was

$15,106. Participation in the LDN program was more expensive but also more cost effective, as the ICER for participation in the program was $20,443/living donor (calculated by dividing the incremental cost of participation in the program ($1,661.75-$0) by the incremental effectiveness of achieving a living donor transplant (0.11-0.03). Thus, the LDN program was cost effective at a traditional WTP threshold of $100,000/living donor, as well as a context-specific threshold of $40,000 (total annual expenses divided by the number of living donor transplants the program hoped to generate in the first year).

Table 3. Cost effectiveness analysis of operating the Living Donor Navigator program

Strategy	**Cost, $**	**Incremental cost, $**	**Effectiveness (Living donor transplants)**	**Incremental effectiveness**	**ICER, $/living donors**	**Average cost-effectiveness ratio**
Do not enter LDN program	0.00		0.03			$0/living donor transplant
Enter LDN program	1,661.75	1,661.75	0.11	0.08	20,443	$15,106/living donor transplant

We performed one-way sensitivity analyses, allowing both costs of the program and probabilities of death, living donor approval, and receipt of a deceased donor transplant to vary based on probabilities obtained from the literature (Supplemental Table S2 in Appendix D). The tornado diagram in Figure S1 in Appendix D is a graphical representation of these sensitivity analyses and shows the range in ICERS resulting from allowing individual parameters to vary. The probability of being on dialysis and having a living donor approved among patients who did not participate in the LDN program was the most sensitive to variation, resulting in the largest range for the ICER ($69,827/living donor approval-$342,308/living donor approval). Using probabilities from the transplant literature, the expected value for the ICER among all of the one-way sensitivity analyses was just over $100,000/living donor approval.

DISCUSSION

We utilized a Markov model of our novel LDN program to investigate clinical outcomes, cost, and cost-effectiveness of participation in the program. In this analysis conducted from the UAB transplant program perspective, we demonstrated that the LDN program is more costly but also more effective than standard-of-care (no advocacy training or donor assistance) in generating living donor transplants. Furthermore, we demonstrated that the LDN program is cost effective at nearly any WTP threshold, to include the standard $100,000/living donor threshold described by Sanders et al.,[12] as well as a threshold based on the number of transplants anticipated to be generated in the first year.

These results are consistent with other studies of educational interventions to increase access to living donor transplantation, in that participants in the intervention were more successful at identifying living donors. The House Calls program showed a higher but non-significant likelihood of achieving living donor transplantation among participants in the home-based intervention but a significant increase in the likelihood of both donor inquiry and evaluation.[3] Results from the Live Donor Champion program reported four living donor transplants among program participants, compared to 0 in the control group.[5] However, these programs are resource-intensive and the costs are not reported. Rodrigue et al. hypothesize that both individual and group-based education are more cost-effective than the House Calls intervention but did not provide any formal analysis to support this hypothesis. As such, it is necessary to demonstrate the success of programs that are economical but also achieve the desired outcome of transplantation, to support expansion of such programs to other institutions.

While the current study only considers the operating costs of the program and does not incorporate the costs associated with organ procurement and transplantation, donor evaluation costs, reimbursements, or waitlist registration fees, the cost effectiveness estimated by the Markov model is an important finding. The Scientific Registry of Transplant Recipients (SRTR) utilizes a 5-tier performance scoring system, in which transplant centers are graded based on three metrics: transplant rate, 1-year post-transplant survival, and rate of mortality while on the waiting list.[13] With an average rate of waitlist mortality of 5-6% per year,[14] any strategy that helps patients achieve living donor transplantation will improve post-transplant survival (given the superior outcomes of kidneys from living donors) and decrease waitlist mortality.

Cost effectiveness analyses are not novel within transplantation. A 2011 study from Austria examined the cost effectiveness of pre-emptive kidney transplantation and concluded that transplantation should always be encouraged prior to initiation of dialysis.[15] A discrete event simulation (DES) study by Axelrod and colleagues explored the cost effectiveness of transplant vs. dialysis accounting for high Kidney Donor Profile Index (poorer quality) kidneys and blood and tissue group incompatibility and found that kidney transplantation is cost effective across all donor types.[16] Recently, members of our group utilized Monte Carlo simulation to explore optimal timing of treatment for hepatitis C (pre vs. post-transplant) and found that optimal timing generally favored post-transplant hepatitis C eradication.[17]An analysis of the cost effectiveness of paying living kidney donors found that this strategy translated to both cost savings and increased quality of life.[18] To our knowledge, however, this is the first study to examine the cost effectiveness of an educational intervention to increase LDKT.

Limitations to our analysis are the following: the data used to obtain probabilities for outcomes of participants in the LDN program were based on a small sample of only 56 individuals, and as such, many transitions were not observed and resulted in probabilities of zero throughout much of the decision tree. As a result, we performed several sensitivity analyses, allowing these probabilities to vary. The expected value using these probabilities exceeded the traditional WTP threshold, and model results were most impacted by changes in the probability of living donor approval among non-participants. However, although the potential for trickle-down effectiveness of the program among non-participants exists (via social media presence of the Navigators, informal conversation with patients in clinic, etc.), it is unlikely that the probability of identifying a living donor will increase substantially in this group on its own, given national trends in living donation. The findings from this analysis may not be generalizable to the national transplant population, given the heterogeneity of waiting list populations in the US. However, given that UAB has one of the largest kidney transplant waiting lists with a high minority population, we believe this study has the potential to inform transplant education at other centers with long waiting times and disparities in access to transplantation.

In addition, Markov models have no “memory” for prior conditions. The transition probabilities obtained were the average probabilities across all possible states. Given the assumptions of the Markov model, it is likely that a discrete event simulation

(DES), in which each individual entering the model is allowed to follow their own trajectory in time increments that are more granular than a monthly cycle, would more accurately capture the transitions experienced by these patients. Additionally, baseline characteristics of patients can be accounted for, rather than the model reflecting the average case. However, when the time horizon was expanded to 12-months, our inferences were confirmed, suggesting that the Markov assumption that probabilities are fixed over time is met. Future work will explore converting the Markov model to a DES model, in addition to accounting for further granularity such as dialysis modality and class attendance, to explore the impact on our findings.

The LDN program is a substantial annual investment from the perspective of the transplant center but is effective at generating living donor transplants and getting patients off the kidney transplant waiting list. More research is needed to assess whether the costs of the LDN program would be acceptable by other transplant centers, with a long-term goal of demonstrating cost effectiveness from the societal perspective to garner support from payers.

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A QUALITATIVE ASSESSMENT OF THE UAB LIVING DONOR NAVIGATOR PROGRAM: IDENTIFYING CORE COMPETENCIES AND PROMISING PRACTICES FOR IMPLEMENTATION

by

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INTRODUCTION

The average annual risk of mortality on dialysis is approximately 5%.[1] Transplantation has been shown to be superior to dialysis, not only in survival but also with regards to cognitive function and mental health.[2] However, the gap between the demand for kidneys and available deceased donor organs continues to grow, making living donation the preferred option. Unfortunately, the best strategy to increase awareness of and access to living kidney donation remains unknown. This is particularly true among racial/ethnic minority populations who have disproportionately higher rates of end-stage renal disease but lower rates of receipt of a kidney transplant and living kidney donation.[1,3-5] Some barriers relate to stigma, transplant candidates' unwillingness or reticence to discuss their need for a kidney due to guilt or shame about their disease, and concern for or lack of knowledge surrounding the impact to the potential donor.[6]

In an attempt to separate the candidate from the pressure to ask for a kidney, Johns Hopkins University had success with a program they created called the Live Donor Champion (LDC).[7] The LDC program involves six informational sessions, in which transplant candidates who have not yet identified a willing living donor bring a "Champion", either a family member or friend who is willing to advocate on their behalf and share their need for a kidney transplant with the community. Each session provides both the Champion and their candidate with detailed information about kidney disease, the risks and benefits of living donation, and how best to initiate a conversation with someone about the candidate's need for a transplant. Early results from the LDC program showed an increase in knowledge and comfort in speaking about living donation, as well as an increase in the number of potential donor inquiries and subsequently the number of living donor transplants.[8]

However, becoming a living kidney donor involves a time-consuming process of evaluation and education, not only to ensure the autonomy of the potential donor but also to confirm that the donor is both physically and mentally healthy enough to donate. Given the number of steps involved in this process, many donors withdraw from evaluation, either because they are given information that makes them change their mind or they are inactivated due to failure to complete a specific test or clinic visit.[9,10] To respond to this problem, Locke and colleagues at the University of Alabama at Birmingham (UAB) have adapted the LDC program by combining it with another successful initiative, the Lay Patient Navigation program created by the UAB Comprehensive Cancer Center.[11] In the Living Donor Navigator (LDN) program, Patient Navigators not only conduct the classes for the patients and advocates but also guide potential donors through the course of their clinic visits and hospital stays. Patient Navigators ensure that potential donors have transportation to their appointments, access to their physicians in case of questions, and provide emotional and social support, with the goal of alleviating some of the anxiety surrounding the donor process and ultimately helping to make donation successful.

The existing programs described above have been implemented with varying degrees of success, but there is a need to gain a better understanding of what recruitment techniques and approaches are most effective and under what conditions. As such, the purpose of this study was to discover areas of strength and potential improvement for the

Living Donor Navigator program at UAB and subsequently to identify Core Competencies from these areas.

METHODS

Optimal organizational/program performance requires that individual members have essential knowledge, skills, and abilities (KSA) to perform their jobs well, and further that a feedback loop exists to identify barriers and promising practices that may be of interest to those seeking to initiate similar programs. One technique for conceptualizing the needed KSAs is to identify Core Competencies that apply to all individuals with a specific job role or program goal. To systematically assess implementation factors, facilitators, and barriers to successful recruitment of the LDN program advocates, we took a Knowledge, Skills, and Abilities approach (KSAs).[12] Specifically, we conducted focus groups with advocate participants in the Living Donor Navigator program to generate themes that can identify KSAs needed for both advocates and Navigators. We focused on two organizational levels: 1) the participant level, or the advocacy training of the advocates and 2) the programmatic level, or the support role provided by the Navigators and administration of the program.

Individuals who participated in the LDN program as advocates, including patients who served as their own advocates, between April 2017 and March 2018 were eligible to participate in the focus groups (N=53). Each advocate was mailed a recruitment letter detailing the purpose of the focus group. Four focus groups were held, ranging from 40 minutes to 2 hours, with 2-3 participants in each group. Advocates were also given the option to participate by phone if they lived too far from UAB to join a focus group in person. The Institutional Review Board at UAB approved this study (Protocol 30000266).

The focus group guide was developed using the Kirkpatrick Model of Training Evaluation, which was developed in 1959 and provides strategies for trainers to objectively gauge training effectiveness.[13] The Kirkpatrick Model posits that to comprehensively assess training effectiveness, it is important to measure reaction, learning, behavior, and results. Our focus group guide included three of these four levels of evaluation; participants were asked to share their thoughts about the LDN program content and delivery (reaction), questions targeted knowledge and comfort gained through the program (learning), and other questions assessed how participants applied the information gained in the sessions (behavior). (Appendix E. Focus Group Guide). All focus group sessions were audio recorded, facilitated, and transcribed by Mrs. Reed. Field notes on group dynamics (including body language, gestures, and facial expressions) were also captured. Using thematic analysis, broad themes were identified and further classified into sub-themes, with sections of text coded into the relevant theme. Core Competencies were generated from actionable feedback in both participant and navigator-related topics, while Promising Practices were identified at the programmatic level. We believe these represent an initial look at competencies and promising practices that are crucial for program implementation and sustainability.

RESULTS

Of the 53 advocates invited to participate, 11 expressed interest in participating, 8 participated in-person, and one participated by phone, with two not arriving for their scheduled session. Participant characteristics are presented in Table 1. Participants did not differ significantly from non-participants with regards to age, sex, race, or whether they served as their own advocate.

Table 1. Demographics of Focus Group Participants

	Total participants=9
Champion characteristic	N (%)
Male sex	2 (22.2)
Race	
Caucasian	2 (22.2)
African American	7 (77.8)
Age, median (IQR)	52 (40-57)
Served as Champion for self	2 (22.2)

Four broad themes were identified: Communication, Education, Support, and Commitment. Within each broad theme at the participant level, several sub-themes arose, which we developed into core competencies. These same themes arose at the programmatic level, and we classified these as both competencies and promising practices. We selected quotations that support each competency and present them below. Some of these items may be used to improve the living donor evaluation process at the programmatic level, and we have included a process map with steps that correspond to these recommendations in Figure 1.

Core competencies for Champions identified from broad themes and sub-competencies

"Communication" was a common theme addressed by the advocate participants. From this topic, we defined **Competency 1**: comfort with identifying and communicating key information needed to gain support, awareness, and recruit/motivate donors.

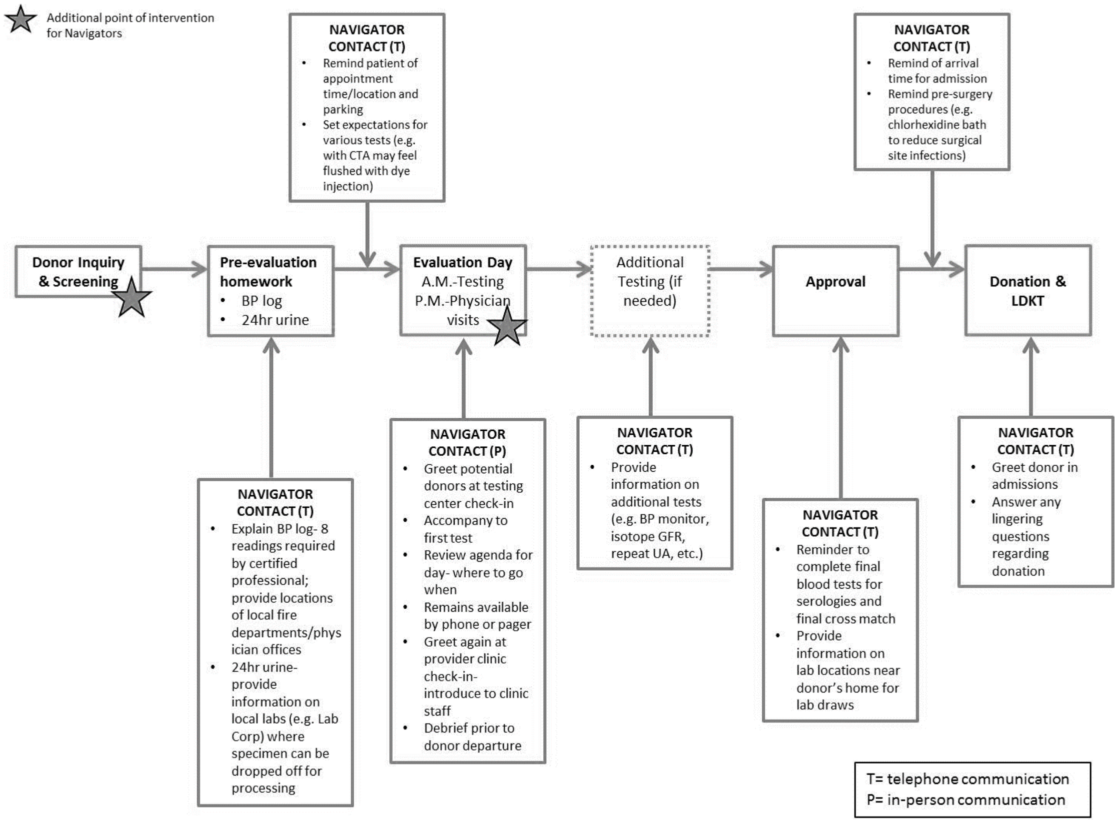

Figure 1. Process Map of Living Donor Evaluation

1) **Sub-Competency 1.1: Explain techniques to motivate potential donors without creating undue pressure.** Advocates felt it was crucial to understand how to express the need for a living donor without a sense of coercion.
2) **Sub-Competency 1.2: Identify effective methods and modalities to increase awareness of the LDN program for non-participating patients.** Several advocates indicated that they had told other patients awaiting a kidney transplant at UAB about the classes, and these individuals subsequently enrolled.
3) **Sub-Competency 1.3: Use social media as a tool to spread awareness.** All 9 participants agreed that social media platforms, such as Facebook, Instagram, and Snap Chat, were invaluable resources, and knowledge of how to use these tools

was crucial for success in identifying a living donor. They urged that this area be further covered and emphasized in the classes.

4) **Sub-Competency 1.4: Knowledge of how to engage younger individuals who are the most energetic/optimistic users of social media and most enthusiastic about donation.** Several advocates expressed that the young adults they approached were most willing to discuss the need for living donation, the most likely to indicate a desire to donate, and the most skilled at sharing the story on social media.

"Education" was a second theme commonly mentioned by participants, from which we defined **Competency 2**: have the requisite knowledge to educate potential donors about benefits of donation, how the donation system works, and alleviate fear based on the unknown aspects of donation.

Sub-competencies at the participant level were:

1) **Sub-Competency 2.1: Become familiar with risks and benefits of donation and be able to refute misconceptions.** Participants found that the program provided them with the knowledge they needed to educate others about donation and dispel common myths, and they agreed that confidence with this ability was crucial in conversing with potential donors.
2) **Sub-Competency 2.2: Share information about kidney paired donation and the UAB kidney chain.** Several advocates mentioned the UAB kidney chain as the most surprising thing they learned through their participation in the program, and they felt this is something that should be stressed by advocates as an option

for transplantation among hard-to-match candidates and those seeking to help more than their intended recipient alone.

3) **Sub-Competency 2.3: Alleviate fear (of the recipient who is unwilling to ask for a kidney and of the donor who has concerns about long-term health or finances).** When advocates were asked about common responses they encountered from individuals unwilling to be donors, they cited concerns about future health and expenses associated with the donation. A successful advocate is able to not only remove the burden of asking from the patient but also provide resources (such as the National Living Donor Assistance Center) to alleviate the fears of those who may otherwise wish to donate.

At the program level, we defined these sub-competencies:

1) **Sub-Competency 2.4: Demonstrate knowledge of the future of transplant.** Many focus group participants were interested in hearing more about future alternatives to living donation, including xenotransplantation and 3D printing. They felt that these potential options for transplantation in the future brought hope to those struggling to find a living donor.
2) **Sub-Competency 2.5: Demonstrate awareness of cultural norms/stigmas/misconceptions.** Many of the focus group participants felt that the navigators understood the disproportionate disease burden among African Americans that led to a smaller pool of potential donors, as well as the likelihood of myths and misconceptions related to donation that may arise from this donor

pool. The participants felt that in acknowledging these challenges, the navigators equipped them with tools to respond appropriately.

The third broad theme was “Support”, exemplified in the following **Competency 3**: Feel empowered with the self-confidence to perform your role as an advocate working to improve the lives of those in need. Participant-level sub-competencies identified were:

1) **Sub-Competency 3.1: Become empowered to have conversations about the need for donation and optimism about getting back to normal life post-transplant**. The focus group participants, in particular patients who served as their own advocates, agreed that the classes provided a support group that allowed them to regain some control of their lives. The patients found the classes to be a welcome reprieve from their exhausting routine of dialysis sessions, and the advocates who serve as caregivers discovered others who shared their burden.
2) **Sub-Competency 3.2: Support advocates as a force for positive societal change.** Advocates felt that in the class they were engaging in something bigger; not only were they helping their loved one (or themselves) by attempting to find a donor, but they were being equipped with tools to spread awareness to a larger audience and thus bring to light the prevalence of kidney failure.
3) **Sub-Competency 3.3: Provide a safe space to share fears and ideas.** Advocates agreed on the importance of being respectful of others in the program, holding classmates accountable for their attendance, and providing support to those who may not have been able to attend the classes.

At the program level, the sub-competencies were as follows:

1) **Sub-Competency 3.4: Provide opportunities to engage in face-to-face interaction with other advocates.** The LDN program created an unintentional geographic disparity, such that there were individuals who would have liked to participate but were unable to because of distance to UAB. When alternate models were discussed, a telehealth version was proposed, but the participants agreed that the advocates must be able to see and interact with each other for a telehealth model to succeed.
2) **Sub-Competency 3.5: Embrace social media, such as a Facebook page or newsletter for advocates to share success stories.** Most advocates felt that follow-up after conclusion of the classes in the form of a Facebook page, quarterly newsletter, or meet-ups was essential for continued success in identifying donors, as participants would feel encouraged by others who were eventually transplanted with a living donor.
3) **Sub-Competency 3.6: Demonstrate with advocates how difficult it is to ask for a kidney.** While the focus group participants acknowledged that speaking with donors would be challenging, they felt that they were not entirely prepared and would have liked the Navigators to engage them in some additional role playing activities in which they encountered more resistance from potential donors.

The final broad theme was “Commitment”, from which we developed **Competency 4**: Demonstrate commitment to actively engage in all classes and learn the skills and techniques to perform the role of an advovate. At the participant level, the sub-competencies were:

1) **Sub-Competency 4.1: Commit to regular class attendance.** Advocates agreed that attendance was important, not only for camaraderie and support but also to absorb the material and interactions provided.
2) **Sub-Competency 4.2: Contribute time and effort to enact the skills learned in class.** Those who utilized the tools provided by the LDN classes, such as finding creative solutions like bumper stickers or church bulletins, reported the most success in identifying donors.

At the program level, the sub-competencies were:

1) **Sub-Competency 4.3: Engage with faculty and staff to demonstrate commitment to their patients and donors.** Advocates agreed that participation in the surgeon/nephrologist panel by engaged and knowledgeable physicians demonstrated their commitment to the patients and the cause of living donation.
2) **Sub-Competency 4.4: Engage with navigators and share in a true passion for the advocate role.** All focus group participants felt that the navigators who taught the classes and interacted with many of them outside of the class setting were a key part of a successful LDN program, given that they demonstrated true compassion for the patients and their advocates. To succeed, an LDN program must have navigators that engender trust and buy-in from participants.

Promising practices

From these themes, (Communication, Education, Support, and Commitment), Promising Practices to improve both the role of the Navigators and program operation also emerged.

1) **Promising Practice 1. Respond promptly to donor inquiries.** Several advocates mentioned that potential donors waited weeks before receiving any acknowledgement by UAB staff of their inquiry into donation. These participants recommended that the navigators contact individuals immediately upon completion of the donor screening form to reduce delay in contact and loss of interest from the potential donor. This suggestion is indicated by a yellow star on the “Donor Inquiry & Screening” box in Figure 1.
2) **Promising Practice 2: Encourage attendance by additional advocates or donors to further spread information.** Some patients had multiple individuals who would have liked to act as advocates, but they did not think they could attend the classes. While the focus group participants agreed that the classes prepared them to discuss donation-related topics, they also believed it would be helpful for potential donors to hear the information first-hand.
3) **Promising Practice 3: Highlight the kidney paired donation program.** Similar to the participant-level competency, participants believed that the navigators should stress the KPD program and the chain as important options, even for those with a well-matched living donor. While this program is discussed by the clinical staff who evaluate the potential donor, evaluation day may also be an appropriate time for the Navigators to mention the program and some success stories to the donor, as indicated by a yellow star in the “Evaluation Day” box in Figure 1.

4) **Promising Practice 4: Make materials available prior to class for those wanting to prepare ahead of time.** While the participants found the amount of material in the course to be appropriate, some also felt that they could have more easily digested the information had they been given a chance to study ahead of the class.

5) **Promising Practice 5: Provide alternate accommodations, such as video conferencing, for those who are too far or have to miss a session due to illness.** As identified above, participants were open to alternative settings, as long as they could interact face-to-face with one another, but they felt that it was important for participants to attend all meetings.

DISCUSSION

In this qualitative study of advocates who participated in UAB's Living Donor Navigator program, we identified several broad themes of advocate feedback to the program which were further classified into competencies that could be utilized for improvement in the roles of advocate and Navigator and in program implementation. Additionally, several recommendations for promising practices were identified. The four broad themes were Communication, Education, Support, and Commitment, and each were developed into competencies, related sub-competencies, and program improvements. Most notably were themes related to interpersonal connections, support, and empathy.

The first broad theme, Communication, related to effective knowledge transfer in the delivery of the material shared in the LDN program sessions, specifically those supporting sharing of knowledge gained and to facilitate motivation of potential donors. One sub-competency identified highlighted the use of social media to reach potential donors. A 2013 study found that of 91 Facebook pages soliciting living kidney donors, 32% of pages reported having donors screened and 10% reported a live donor transplant, and the authors speculate that some of the success of social networking sites like Facebook may be due to the public and non-directed nature of the page that relieves the burden of having to ask someone in-person.[14] Kumar et al. reported a 6.6-fold increase in the likelihood of a donor inquiry for individuals using a smartphone app that helps the patient write their story and post it to Facebook.[15] By assisting patients and advocates without Facebook pages in setting up accounts and making posts, the navigators are not only highlighting the usefulness of Facebook as a tool but also equipping participants to use it to its fullest potential.

We identified engagement with young people as a second sub-competency. Advocates who participated in our focus groups believed that social media was the best arena for attracting young people, who are the healthiest and most enthusiastic about not only helping find a donor but also volunteering for donation themselves. Advocates agreed that young people were an untapped resource for those seeking a donor and recommended targeting this population due to their receptiveness and lack of fear. However, the benefits of this enthusiastic group must be weighed with the potential for long-term comorbid disease, given that the younger a donor is, the greater the lifetime risk they have of going on to develop end-stage renal disease.[16] It may be prudent for navigators to encourage advocates to seek out younger donors, while reminding donors to thoroughly discuss their risks with the clinicians evaluating them for donation.

The competencies classified into the broad theme of “Education” related to the content/material covered by the program, as opposed to the effectiveness with which they were successfully communicated. Work by our group in 2015 demonstrated that knowledge/education-related strategies were thought to be the most important tool for increasing willingness to become an organ donor.[17] Accordingly, these strategies and tools were a key component of the educational sessions. Focus group feedback from the advocates validated that the educational content of the program did provide the needed tools, prepared them to share information about the need for living donation, and was especially impactful for individuals who were not aware of the practice of living donation. The advocates were also impressed by the kidney paired donation program and the ongoing kidney chain and believed these programs should be highlighted more by the navigators, even for donors who are a match to their recipient. At the programmatic level, advocates agreed that good navigators must demonstrate appropriate sensitivity to cultural norms and stigmas that may impact someone’s willingness to be a donor or even to receive a kidney transplant. Assessments of the cultural competence of the LDN program are ongoing, the results of which will be important to demonstrate that the program can be translated to other centers with diverse patient populations.

The broad themes of “Support” and “Commitment” described the more intangible benefits of the program but were no less valuable than the comments relating to the delivery and content. Within the theme of “Support”, advocates felt that while not a formal support group, the sessions gave them an opportunity to meet other individuals who are caregivers for their loved ones on dialysis. There has been little research done on how to reduce caregiver burden in kidney disease other than through educational programs,[18] so it may be beneficial to begin administering a quality of life assessment to advocates before and after participation to ascertain whether relieving caregiver burden was an unintentional but positive consequence of the program. Advocates also stated that while they had entered the program to help their loved one find a kidney, they were also helping others awaiting transplant by sharing the need for transplantation with anyone who would listen.

At the program level under “Support”, we identified the importance of having the advocates in a classroom together. The advocates acknowledged that it was difficult to make it to all sessions, in particular if they did not live in Birmingham, and they indicated that given the opportunity to participate online, they would have done so as long as they could have been face-to-face with their classmates. They felt that seeing each other in-person kept them accountable for their attendance and efforts to find a donor. A 2014 psychology study demonstrated that students preferred an online classroom for writing activities but preferred in-person class for discussion.[19] Given the importance of role-playing activities for the session on how to ask someone to be a donor, the classroom environment for the LDN program should be maintained, but perhaps some materials and pre/post assessments can be made available online for those wishing to prepare in advance. Advocates also discussed the utility of social media at the programmatic level, which could be used to stay in contact with participants and support continued efforts to find a donor through classmate success stories. In fact, Facebook has been used previously as an online support group for liver transplant patients, and approximately

72% of participants reported that membership in the page had positively impacted their clinical care.[20]

Within the theme of “Commitment”, advocates agreed that regular attendance was important, both for receiving all class material and information and for staying engaged in the search for a living donor. Consistent attendance has been shown previously to be correlated with academic performance in the clinical setting,[21] and it will be important for us to assess whether advocates who attend all classes are more successful at identifying a living donor earlier in their search. Within the program level of this theme, advocates believed that one element of the success of the program was the selection of the instructors. Not only were they knowledgeable of the material, but they showed genuine compassion and interest in the participants of the program. This success may be attributed to the fact that the Navigators are non-clinical laypersons, and perhaps the advocates and patients feel that they relate more to them than physicians. This finding is consistent with a 2007 systematic review that demonstrated that lay-led health promotion programs can have a positive effect on patient confidence in management of chronic health conditions when compared to programs led by physicians and general practitioners.[22]

Finally, we identified some promising practices for the program from the topics discussed by advocates. These practices were related to the competencies and sub-competencies but are better classified as recommendations for improvements at the programmatic level. One of the recommendations that advocates felt most strongly about was involving the Navigators in the donor screening process, to shorten the time between when the donor completes the screening form and when they are notified if they will be moving forward in the process. One of the challenges to achieving living donor transplantation is the lengthy donor evaluation process, and advocates explained that some of the potential donors they identified lost interest after not being contacted by the transplant center. This finding is a point of intervention in the process map in Figure 1.

Our study has important limitations. The focus group participation rate was low at 17%. Mrs. Reed served as the only coder of the transcribed sessions. Additionally, the advocates may have been more willing to criticize the program if the focus groups had been moderated by someone not connected to transplantation at UAB. However, to our knowledge, this is the first qualitative assessment of a patient navigation program within transplantation and thus may serve as practical advice for those seeking to initiate a similar program at their own center, in addition to highlighting areas where we can improve our own process.

Through focus group discussions, we identified several core competencies and promising practices for the Living Donor Navigator program. These competencies can be used to assist patients in identifying their most effective advocate, to improve that advocate's engagement in the program, and to further refine educational and training preparation for advocates by the Navigators, to ensure that advocates will be successful in their role. Ultimately, these competencies can be utilized to implement this program at centers nationwide, and future research will be necessary to demonstrate the impact of the program with regards to cost and living donor transplants achieved.

Table 2. Selected Quotations to Support Sub-Competencies

Broad Theme	Sub-Competency	Quotation
Communication	1.1- Avoid creating undue pressure	"I just put it out there and not try to persuade you. That's something you have to do on your own. I'm just gonna present the information, but I'm not gonna pressure you."
	1.2- Increase awareness of the LDN program	"I told one of my, one of the accountants at work… I told him, I said, 'Get your wife outta that house… Somebody's gonna give her a kidney, 'cuz she's on dialysis right now, and you can be her donor.' And she's in the program. This program."
	1.3- Use social media	"When you make that [Facebook] page, the more people who get aware and join it, the better. 'Cuz the net gets bigger. The more people who click 'Like' or 'Share' or repost, the net just gets bigger and bigger and bigger."
	1.4- Engage younger individuals	"I just think younger children, this younger, this millennial generation, they have more, um, less apprehension about medical procedures. I think they have more of a compassionate heart. They're just, they're not- they don't have all the 'what if's' that an older person would have."
Education	2.1- Become familiar with risks and benefits	"People in my class, the like six of us that were there, I would say 5 of the 6 did not know that kidney transplant was an option."
	2.2- Discuss kidney paired donation and the kidney chain	"And if somebody finds a donor but they're not a match for So-and-so, well, 'Do you think they could match for Such-and-such?', like that's another way to reconnect in the chain."
	2.3- Alleviate fear	"People are gonna ask you. You know, 'What if something happens to me after I give my kidney?' So, you know, you have to let them know that they'll be taken care of, so I thought that was important."
	2.4- Discuss future of transplant	"And the potential of pig donors in the future and that testing. That kinda stuff made me very optimistic. I know it may be far, far in the future, but just, I know the level of desperation that my mother feels. Other people have to have that feeling, and just knowing that there's other options maybe just lurking in the future… That was good to know. That was good to hear."
	2.5- Demonstrate awareness of cultural norms	"I was noticing that most of the recipients, or potential recipients, were black. And you know, I think we lose sight of cultural norms and stuff like that affects them. It may be depression, or it may be shy, or you know, I don't talk very much. And those kinda things we need to be aware of."
Support	3.1- Become empowered to have conversations	"It's a lot easier when you have support. So not just the patient. I've been so busy supporting him, that no one was supporting me, so coming to that class let me see other people and we kinda bonded at how we need that support too."

	3.2- Support Champions as force for social change	“Maybe someone else’s journey will be easier because I, you know, we put the word out there.”
	3.3- Provide a safe space	“When I was on active duty, this one guy used this expression: ‘Cooperate and graduate’. I kinda like that. And I’m saying that to say this, by meeting and talking and stuff, it’s kind of a good thing.”
	3.4- Provide opportunities for face-to-face interactions	“It was better to come and get it here face-to-face than get it off the computer… I think it’s the emotions of the people and the camaraderie that we built in here.”
	3.5- Embrace social media for contact after the program	“I would design a [Facebook] page… and post pictures and testimonials and videos and share insight… then share those stories as they go and unfold, and then, that way we are still connected.”
	3.6- Demonstrate difficulty of asking for a kidney	“I wish I had known, um, how uncomfortable, you know, when you first do it you have to keep doing it, but when you first do it, how uncomfortable you are when you approach somebody… I think, maybe that should be taken into consideration. Personalities, different personalities, I think, will determine how a person feels about how hard they think it is.”
Commitment	4.1- Commit to regular attendance	“Come, get educated, that’s the main thing… Be present… I mean, it was shocking that when I got here, I was like, oh wow, every chair was taken. And then the second time it was literally like the six of us… I wish that you could get more people in.”
	4.2- Enact skills learned in class	“We need to get out in front and stop being so reactive. Like, I need proaction, and not just because of my husband… The sitting and talking is great, but, like, I need sitting and talking and then action.”
	4.3- Engage with faculty and staff	“When you have the surgeon come in, it really meant a lot to people in here. They really, everybody had their ducks in a row and asked the guy a lot of questions. I felt like that was one of the classes we got a lot out of.”
	4.4- Engage with navigators who are passionate about their role	“The facilitators- I appreciated their energy, their honesty, their follow-through, and just the genuine commitment and compassion that was shown through the whole class… They created a space that, to be honest, as a grown woman, is sometimes hard to find… when discussing such private topics.”

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DISCUSSION

Conclusions from Paper 1

Paper 1 of this dissertation demonstrated that there are population-level factors associated with lower rates of living kidney donor transplantation in the US. The prevalence of these factors, such as comorbid diseases that are contraindications to living donation, may lead transplant candidates to feel that the pool of potential donors is too limited and discourage them from initiating conversations within their social network. In fact, transplant candidates have reported unwillingness to ask loved ones to donate for fear of future health issues.[1,2] This concern for the donor's health may be compounded by the assumption of a limited donor pool and the enormity of the request. These findings support the need for programs that train advocates and separate the patient from the search for a donor, to relieve the patient's burden but also to expand the accessible network of individuals who can be approached by engaging the networks of the advocates. Despite being ecological data, findings from Paper 1 can be used to further motivate and refine the following aspects of the LDN program.

Navigators can encourage patients and their Champions to reach out to anyone, not just those they believe would be healthy enough to be a donor. The health index generated in this analysis included poor self-rated health, which had a negative association with living donation. This finding may suggest that individuals with health conditions that could be contraindications to donation are self-screening, because they believe they might not be good candidates. The Navigators can instruct Champions on how to respond if a potential donor thinks they may not be healthy enough to donate, encouraging the donor to let the physicians do the health screening to determine their eligibility.

Numerous studies have demonstrated that some potential living donors are excluded from donation due to newly diagnosed medical conditions that are contraindications to donation. Hoffman et al. reported that 8.5% of 762 donors evaluated at their center were found to have serious medical conditions that were previously unknown to them, several of which required immediate intervention.[3] A 2012 study reported that 14% of potential donors were found to have undiagnosed hypertension at evaluation.[4] Some individuals who may be eligible for donation may not come forward for fear of learning they have a condition previously unknown to them. As such, there may be an unintended benefit of the Navigator program if the Navigators play a role discovering unknown conditions by encouraging potential donors to follow through with their evaluation.

In this first paper, low socioeconomic status (represented by low internet use, education, and income) was negatively associated with LDKT. This low SES may translate to limited social networks and resources, and in the context of ESRD to an inability to work due to dialysis appointments. Within an already limited network are likely to be individuals with similar background and health status, restricting the pool of potential donors. The Navigators provide access to and assistance with social media tools, to help patients and their Champions spread their story, not only to their network but also to the networks of those who share their posts. Further highlighting the power of social networks and using social media to discuss transplantation will continue to enhance the effectiveness of the program and sustain the support network that patients and their Champions felt when actively participating in the classes.

Conclusions from Paper 2

This preliminary analysis of the UAB Living Donor Navigator program demonstrated the cost effectiveness of the program. This is an important finding, given the need for affordable educational programs that translate to living donor transplants. Other navigator programs have been implemented in the transplant setting but have not reported a sustained improvement compared to standard of care. Sullivan et al. performed a randomized controlled trial, in which hemodialysis facilities were randomly selected to hire a kidney transplant recipient to serve as a Navigator for patients at that facility. Primary outcomes were first visit to a transplant center, addition to the transplant waiting list, and receipt of a kidney transplant (living or deceased) in the last year of the trial, and the authors found no significant differences in either outcome for patients at intervention vs. control facilities.[5] The increased effectiveness over standard of care in our analysis may be due to the point of intervention of the LDN program, once patients are already referred to UAB for transplant, as opposed to in the dialysis center. Additionally, we might attribute the success of the program to the portion of the Navigators' roles in which they interact with any donors screened on behalf of that patient. The advocacy training of patients alone is not sufficient to achieve LDKT, given the hurdles faced by potential donors. The time spent in contact with the potential donors (on the phone, by email, in-person at clinic) is included in the Navigators' salary, and no additional expenses are incurred from this portion of the program.

For this cost effectiveness analysis, we assumed 100 participants in one year's time, which is the maximum that can be accommodated with current personnel. However, UAB has one of the largest kidney transplant waiting lists in the country, and with an average waiting time of 5-7 years, the program must be scaled up to allow more patients to benefit from the intervention. Assuming an additional navigator and 50 more participants, the cost per additional donor does not change. Therefore, it would be advantageous to hire a third navigator to expand access to this educational initiative.

Conclusions from Paper 3

Participants stated that the navigators acknowledged the burden of kidney disease is higher among minorities, and comorbid diseases are more prevalent. Understanding that poor health is associated with lower rates of living donation may further motivate Champions to go beyond their social circle; understanding the role of low SES may prompt more conversations with Navigators about assistance from the National Living Donor Assistance Center for living donors demonstrating need.

One focus group participant described a potential donor that was homosexual and was hesitant to be evaluated for donation. Reasons for healthcare avoidance in the general population include mistrust of the medical system, time and money constraints, and fear of having a serious illness.[6,7] In addition, prior negative encounters or shaming by medical professionals may contribute to avoidance of regular or needed healthcare.[8] Navigators can remind Champions and patients that the donor screening and evaluation process is entirely confidential, and recipients are not notified that they have had a donor inquire on their behalf until the donor is approved or gives permission to tell the intended recipient. This information may be helpful for Champions to share with potential donors in the course of their conversations.

In addition, there is a need for creative modalities to expand access to this educational intervention, given our predominantly rural waiting list. We are in the early stages of piloting a telehealth version of the LDN program, in collaboration with Tuskegee University, which will allow us to reach our patient population that resides in the southeastern portion of the state and is unable to travel to UAB for the four sessions. As the classes must be offered during the work day due to scheduling requirements with Tuskegee staff, attendance has been unpredictable because of dialysis sessions and poor health status. However, these limitations are not unique to the telenavigation model and have also been observed among the in-person cohorts. Previous studies of telehealth to administer interventions for various health conditions have shown mixed results,[9-12] but in general, patients have reported satisfaction with this intervention modality. One important aspect of these interventions is the inclusion of key stakeholders in the development process. As we continue with implementation of the telenavigation program, it will be important to engage participants, as we have done with these focus groups, to ensure that the program is acceptable and provides a benefit to our patients.

Another important point raised in the focus groups was that of the role of young people in helping identify a potential living donor. Young people have been reported to have the highest rates of social media engagement of any age group.[13] The familiarity of younger generations with technology and their broad social networks make them ideal

Champions, particularly with regards to the session when patients share their story on social media. The Navigators play a large role in helping them craft the story of their loved one's need for a kidney, but this also means they are responsible for ensuring that the information shared on social media is correct and non-coercive. It will be important to evaluate the content and spread of social media posts regarding the LDN program moving forward.

Policy Implications

Organ donation and transplantation are some of the most regulated aspects of the US health care system. Many of the largest developments in the field of transplantation have arisen from policy changes, most notably the coverage of all patients with end-stage renal disease under Medicare and the "Norwood Amendment" to the National Organ Transplant Act in 2007 that permitted kidney paired donation.[14]

The findings from this dissertation have important policy implications at the transplant center (local) and national level, and to a lesser extent the state level. From the center perspective, offering educational interventions to increase access to living donor transplantation creates the opportunity for more pre-emptive transplants (prior to dialysis initiation) and thus improved post-transplant outcomes and a reduced waiting list. Outcomes of pre-emptive transplantation are superior to those of patients who receive a deceased donor transplant and even those who receive a living donor kidney after dialysis initiation.[15] Among participants in the LDN program at our center, 23% were not yet on dialysis when they were evaluated for transplantation, and these patients were highly motivated to find a living donor to avoid starting dialysis. It may be worthwhile to introduce patients to the concept of the LDN program when they are seen for vascular access at an estimated glomerular filtration rate of 20-25 mL/min, as recommended by the Society of Vascular Surgery guidelines.[16] As a secondary benefit of the program, each patient transplanted with a living donor frees up a deceased donor transplant for someone who has neither a willing living donor nor the ability to participate in the LDN program.

There are also quality implications for broader implementation of the LDN program at the center level. A cross-sectional study of SRTR and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data found that patient satisfaction scores were higher among patients transplanted at higher performing centers (defined as centers with the best 1-month and 1-year patient and graft survival outcomes).[17] Conversely, a 2016 analysis combining the same data sources found significant associations between HCAHPS scores and 30-day but not 1-year transplant outcomes.[18] Further research is needed to identify patient-level measures that best correlate with transplant center performance, as well as assessment of patient satisfaction among LDN participants who have undergone transplantation.

Some states have enacted policies regarding paid medical leave or provide tax credits/ deductions to individuals who have been living kidney donors. A 2008 study found that state and federal legislation supporting living donors had a positive impact on rates of living-unrelated kidney donation, and the authors concluded that these policies reduce existing barriers to kidney donation faced by donors.[19] While this study does not specifically posit why states might be motivated to remove financial disincentives to living donation (such as lost wages and medical expenses not covered by the donor surgery), other studies have demonstrated that the rate of unemployment among those with ESRD is much higher than that of the general US population.[20,21] Additionally, the economic impact of ESRD with respect to lost productivity was conservatively estimated to be $665 million in 1994.[22] Thus, states may be motivated to incentivize living donation in order to recoup productivity losses associated with kidney disease and dialysis, with patients returning to the workforce post-transplant.

At a national level, dialysis places a tremendous burden on the healthcare system. According to USRDS, only 1% of Medicare beneficiaries have ESRD, but they account for 7% of the total Medicare budget.[23] The estimate for ESRD-associated care in 2015 was $33.9 billion, with an average annual cost of hemodialysis of $88,195.[23] As discussed previously, kidney transplantation is the preferred modality of renal replacement therapy, not only from a survival perspective but also financially. Despite the unknown costs of other educational programs (House Calls, Live Donor Champion) shown to be effective at increasing access to living kidney donation, implementation of these programs at centers across the country is likely to decrease overall ESRD-associated costs by reducing time on dialysis and improving quality of life.

Future Research Directions

As the LDN program continues to enroll patients at UAB, it will be important to monitor the outcomes of participants and perform a cost effectiveness analysis that accounts for quality of life among program participants compared to non-participants. These findings will be used to make a case for expansion of the LDN program, first to other transplant centers with similar waiting list burdens and minority populations, and eventually to all transplant centers, with the goal for the program to be covered by insurance providers as part of standard of care for transplant evaluation. Additionally, future mixed methods research will explore the cultural competency of LDN program content and delivery of this content by the Navigators, to assess why this program is so effective in a predominantly minority population. As the global burden of ESRD and the kidney transplant waiting list continue to grow, research demonstrating effective and economical programs to increase living kidney donation and reduce disparities in access to transplantation are both timely and necessary.

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APPENDIX A

SUPPLEMENTAL METHODS FROM PAPER #1

COMPLETE METHODS

Data sources

The primary data source was the 2015 Behavioral Risk Factor Surveillance System (BRFSS) State Prevalence and Trends Data at the Centers for Disease Control and Prevention. BRFSS is the largest continuously conducted telephone health survey system in the world, completing more than 400,000 adult interviews in the United States every year. These data include health-related risk behaviors, chronic health conditions, and use of preventive services from all 50 states, the District of Columbia, and three United States territories.[1]

The second data source was the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, wait-listed candidates, and transplant recipients in the United States; these data are submitted by the members of the OPTN. The Health Resources and Services Administration of the United States Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

Study population

The unit of analysis was kidney transplant center. All United States kidney transplant centers that performed at least 10 transplants in 2015 were eligible for inclusion. One center performed more than 10 transplants in 2015 but did not list anyone in 2013-2014 and thus was excluded from the analysis, resulting in a final cohort of 213 kidney transplant centers.

Categorization of exposures

The BRFSS prevalence measures are reported at the state level and are weighted to account for the complex survey sampling design. To best define the surrounding population characteristics of a transplant center, we defined each center's ”catchment area” as the list of states from which patients were added to the waiting list at that center. We utilized a kidney-only candidate's first waiting-list addition between January 1, 2013 and December 31, 2014 to account for the lag time between listing and transplantation. Of the 72,266 unique individuals listed in that time frame, 172 did not have a zip code available, and 502 were listed at centers that did not perform 10 transplants in 2015 and thus were excluded. After these exclusions, 71,592 candidates contributed geographic information.

Center demographic and SES indicator prevalence measures were then weighted by multiplying a given state's prevalence measure by the proportion of waitlisted patients from that state (*e.g.*, if 80% of transplant candidates at Center A were from State A and

20% were from State B, the prevalence of obesity in State A was multiplied by 0.8 and added to the prevalence of obesity in State B multiplied by 0.2, and the resulting prevalence was assigned to the center). The following population demographic and SES indicators were considered for analysis: prevalence of age ≥ 65 years, male sex, minority race/ethnicity defined as non-White (African American, Asian, Hispanic, American Indian, Native Hawaiian, other, or multi-racial), less than college education, lack of health insurance (defined as report of "no health care coverage"), annual household income < $15,000, unemployment (collapsed responses for "no work for < 1 year" and "no work for > 1 year"), no internet use in past 30 days, and not married / no partner. We considered the following population health indicators for analysis, as they are absolute and relative contraindications to living kidney donation: history of cardiovascular disease (CVD), diabetes mellitus (DM), hypertension, kidney disease, depression, poor self-rated health, obesity, and current smoking.

For center-level characteristics, we examined the absolute number of living donor transplants performed in 2015 and whether the transplant center performed incompatible kidney transplants (either blood group incompatible or donor exchange programs).[2]

Outcome ascertainment

Center rate of living donation was defined as the proportion of all kidney transplants performed at a center in 2015 that were from living donors.

Statistical analyses

Using measures of central tendency and spread, we explored the distribution of center prevalence measures by OPTN region. Given that some states only have one active transplant center, we chose to present the rate of LDKT in a heat map at the OPTN region rather than the state level, so as not to identify unique transplant centers. Prevalence measures were also described at the region level for consistency. Spearman's correlation was used to generate the correlation coefficient between covariates to assess the potential for collinearity. We also investigated the variance inflation factor (vif) for each covariate and obtained vifs > 10 for CVD, DM, minority prevalence, and smoking and vifs approaching 10 for obesity, lower education, unemployment, and no internet use. As such, we chose to collapse SES and health factors into two indices.

To create the indices, prevalence measures were dichotomized into whether the center's weighted prevalence was greater than or equal to the national median of that factor (Supplemental Table S1). The relationship between the dichotomous factor and rate of LDKT was explored. We performed principal component factor analyses using measures with p-values ≤ 0.1 on unadjusted analyses, to confirm the communality of the measures and obtain the factor loadings for each measure to calculate weighted factor-based scores.[3,4] If a center's prevalence was greater than or equal to the national median, the factor loading was added to the total score for each index, such that a center could have a maximum score of 4.101 for the disease index and a maximum score of 3.291 for the SES index. To test internal consistency of the indices, we calculated Cronbach's alpha for each index. Given that health and SES are correlated and to determine whether there was an additive effect, the indices were cut at the median and categorized as low vs. high and further collapsed into a single measure, with the number of centers falling into each category presented in Supplemental Table S2.

The outcome of living donation rate was examined for normality. Model diagnostics were used to assess the appropriateness of the assumption of linearity. Both assumptions were confirmed. Given the presence of more than one transplant center in some states, there was the potential for lack of independence of these centers to impact our estimates. As such, we utilized linear mixed effects model with a random intercept for state accounting for within-state correlation to assess the association between population health and SES factors and center rate of living donation. The most parsimonious model was chosen by minimizing the Akaike's Information Criterion. All analyses were conducted with SAS version 9.4 (SAS Institute, Inc., Cary, NC).

Sensitivity analyses

As a sensitivity analysis, we excluded Children's Hospitals, and inferences were consistent. To assess the robustness of our inferences, we also generated models using a linear model with robust standard errors clustering at the state. We ran a Poisson model to estimate the rate ratio of living donor transplants per log of individuals on the waiting list as of December 31, 2015. Finally, we explored different definitions of catchment area, based on distribution of donor zip code and 200-mile radius around the transplant center. Inferences were consistent.

APPENDIX B

SUPPLEMENTAL TABLES FROM PAPER #1

Table S1. Summary of within-state variation created by weighting methodology

Factor	Average within-state variation (percentage points)	Range
Age 65+	0.71	0.005-3.92
Male sex	0.22	0.00-1.60
Minority race/ethnicity	4.39	0.09-23.85
Less than college	1.59	0.01-18.9
Lack of insurance	1.11	0.05-5.02
Low income	1.1	0.03-6.47
Unemployment	0.41	0.01-5.08
No internet use	1.09	0.03-4.28
Not married	1.09	0.007-19.71
Cardiovascular disease	0.32	0.02-1.45
Diabetes	0.44	0.01-1.80
Hypertension	0.98	0.02-3.81
Depression	0.84	0.03-8.68
Kidney disease	0.14	0.001-0.63
Obesity	1.01	0.01-6.77
Poor self-rated health	0.36	0.008-1.49
Smoking	0.87	0.004-2.84
Living donor rate	27.99	0.00-57.73

Table S2. National median of prevalence measures

Factor	National median	% of centers in areas above national median
Cardiovascular disease	6.1%	54.5%
Diabetes mellitus	10.0%	60.1%
Hypertension	30.9%	47.9%
Kidney disease	2.7%	45.5%
Poor self-rated health	4.1%	56.8%
Depression	18.9%	36.6%
Obesity	29.8%	48.8%
Smoking	17.5%	34.3%
Less than college education	75.3%	38.0%
Income < $15,000/yr	10.3%	60.1%
No health insurance	10.8%	51.6%
Unemployed	5.6%	62.9%
No internet use in past 30 days	17.0%	62.4%
Unmarried / not partnered	56.4%	67.6%
Age 65+ years	20.0%	41.8%
Male	48.7%	41.8%
Minority (non-White)	26.5%	60.6%

Table S3. Categorization of centers based on combined health and SES scores

Category	N	% of centers analyzed
Low health score, low SES score	69	32.4
Low health score, high SES score	32	15.0
High health score, low SES score	36	16.9
High health score, high SES score	76	35.7

Table S4. Adjusted analyses of Poisson regression model with offset for waitlist burden

Characteristic	Rate Ratio	95% CI	p-value
	Adjusted		
Demographic			
High prevalence of 65 years and older	0.89	0.67-1.20	0.46
High prevalence of males	0.98	0.73-1.31	0.88
High prevalence of minorities (non-White)	**0.61**	**0.49-0.76**	**< 0.001**
SES and Disease Combined			
Low disease score, low SES score	Ref		
Low disease score, high SES score	0.73	0.45-1.19	0.21
High disease score, low SES score	0.83	0.62-1.10	0.19
High disease score, high SES score	**0.79**	**0.65-0.97**	**0.02**
Center-specific			
Incompatible transplant program	**1.80**	**1.54-2.11**	**< 0.001**

APPENDIX C

TRANSITION MATRIX FROM PRIMARY COST EFFECTIVENESS ANALYSES

Strategy **Enter LDN program**

Cohort State Proportions

Cycle	On dialysis	On dialysis and on WL	On dialysis and acceptable for LD only	On dialysis and not a candidate	On dialysis-DDKT	On dialysis-LDKT	On dialysis-die	Pre-emptive	Pre-emptive and on WL	Pre-emptive and acceptable for LD only	Pre-emptive and not a candidate	Pre-emptive-DDKT	Pre-emptive-LDKT	Pre-emptive-die	Payoff 1 - No Discount	Payoff 2 - No Discount
0	0.411	0.339	0.018	0	0	0	0	0.143	0.071	0	0.018	0	0	0	1661.75	0
1	0.3781575	0.3482399	0.0224388	0.0044388	0.0034917	0.0139668	0	0.1232803	0.0852527	0	0.018	0	0.0027335	0	0	0
2	0.3486878	0.3548893	0.0265229	0.0085229	0.0070786	0.0283143	0	0.1062799	0.0956886	0	0.018	0	0.0060157	0	0	0
3	0.3222107	0.359242	0.0302887	0.0122887	0.0107339	0.0429357	0	0.0916239	0.1029766	0	0.018	0	0.0096997	0	0	0
4	0.2983888	0.3615677	0.0337686	0.0157686	0.0144341	0.0577365	0	0.078989	0.1076823	0	0.018	0	0.0136643	0	0	0
5	0.2769232	0.3621131	0.0369912	0.0189912	0.0181583	0.0726331	0	0.0680964	0.1102834	0	0.018	0	0.0178101	0	0	0
6	0.2575489	0.361103	0.039982	0.021982	0.021888	0.0875521	0	0.0587059	0.111182	0	0.018	0	0.022056	0	0	0.109608158
Total															1661.75	0.109608158

Strategy **Do not enter LDN program**

Cohort State Proportions

Cycle	On dialysis	On dialysis and on WL	On dialysis and acceptable for LD only	On dialysis and not a candidate	On dialysis-DDKT	On dialysis-LDKT	On dialysis-die	Pre-emptive	Pre-emptive and on WL	Pre-emptive and acceptable for LD only	Pre-emptive and not a candidate	Pre-emptive-DDKT	Pre-emptive-LDKT	Pre-emptive-die	Payoff 1 - No Discount	Payoff 2 - No Discount
0	0.5724	0.21	0.0046	0.0082	0	0	0	0.1812	0.02	0.0026	0.001	0	0	0		0
1	0.5429034	0.2210079	0.009624	0.0157768	0.006153	0.0023543	0.0009704	0.1624893	0.029544	0.0046726	0.0025221	0.00029	0.0014386	0.0002537		0
2	0.515325	0.2300911	0.0142962	0.0230746	0.0126285	0.0047913	0.0019746	0.145778	0.0372159	0.0064557	0.003887	0.0007184	0.0032825	0.0004812		0
3	0.4895229	0.2374424	0.0186354	0.0301104	0.0193702	0.0072959	0.0030076	0.1308475	0.0432808	0.0079826	0.0051115	0.001258	0.0054495	0.0006853		0
4	0.4653656	0.243238	0.0226599	0.0368999	0.0263273	0.0098546	0.0040646	0.1175035	0.0479704	0.0092827	0.0062106	0.0018856	0.007869	0.0008684		0
5	0.4427314	0.2476394	0.0263869	0.0434575	0.0334541	0.0124553	0.0051413	0.1055731	0.0514865	0.010382	0.0071977	0.0025812	0.0104806	0.0010329		0
6	0.4215081	0.250794	0.0298327	0.0497966	0.04071	0.0150871	0.006234	0.0949027	0.0540051	0.0113041	0.0080845	0.0033277	0.0132328	0.0011807		0.028319869
Total															0	0.028319869

APPENDIX D

SUPPLEMENTAL CONTENT FROM COST EFFECTIVENESS ANALYSIS

Table S1. Transition probabilities in primary analyses

State	**Transition Probability**
Among participants in LDN program	
Pre-emptive, not yet on dialysis	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0
Living donor not approved	0.0
Acceptable for LD only	0.0
Listed for transplant	0.1379
Deemed not a candidate	0.0
Initiate dialysis	0.0
Remain pre-emptive	0.8621
Pre-emptive and already on the waiting list	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0385
Living donor not approved	0.0385
Deemed acceptable for LD only	0.0
Deemed not a candidate	0.0
Initiate dialysis	0.0385
Remain pre-emptive and on the waiting list	0.8845
Pre-emptive and acceptable for a living donor only	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0
Living donor not approved	0.0
Listed for transplant	0.0
Deemed not a candidate	0.0
Initiate dialysis	0.0
Remain pre-emptive and acceptable for LD only	1.0
Pre-emptive and not a candidate	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0
Living donor not approved	0.0
Listed for transplant	0.0
Deemed acceptable for LD only	0.0
Initiate dialysis	0.0
Remain pre-emptive and not a candidate	1.0
On dialysis	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0
Living donor not approved	0.0108
Acceptable for LD only	0.0108
Listed for transplant	0.0753
Deemed not a candidate	0.0108
Remain on dialysis	0.8923
On dialysis and already on the waiting list	
Die	0.0
Deceased donor kidney transplant	0.0103

Living donor approved	0.0412
Living donor not approved	0.0103
Acceptable for LD only	0.0
Removed from waiting list	0.0206
Remain on dialysis and on waitlist	0.9176
On dialysis and acceptable for LD only	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0
Living donor not approved	0.0
Listed for transplant	0.0
Deemed not a candidate	0.0
Remain on dialysis and acceptable for LD only	1.0
On dialysis and not a candidate	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0
Living donor not approved	0.0
Acceptable for LD only	0.0
Listed for transplant	0.0
Remain on dialysis and not a candidate	1.0
Among non-participants	
Pre-emptive, not yet on dialysis	
Die	0.0014
Deceased donor kidney transplant	0.0
Living donor approved	0.0028
Living donor not approved	0.0007
Acceptable for LD only	0.0119
Listed for transplant	0.0611
Deemed not a candidate	0.0084
Initiate dialysis	0.0183
Remain pre-emptive	0.8954
Pre-emptive and already on the waiting list	
Die	0.0
Deceased donor kidney transplant	0.0145
Living donor approved	0.0406
Living donor not approved	0.0232
Deemed acceptable for LD only	0.0
Removed from waiting list	0.0058
Initiate dialysis	0.0116
Remain pre-emptive and on the waiting list	0.9043
Pre-emptive and acceptable for a living donor only	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0161
Living donor not approved	0.0323
Listed for transplant	0.0
Deemed not a candidate	0.0
Initiate dialysis	0.0161
Remain pre-emptive and acceptable for LD only	0.9355
Pre-emptive and not a candidate	

Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0
Living donor not approved	0.0
Listed for transplant	0.0
Deemed acceptable for LD only	0.0
Initiate dialysis	0.0
Remain pre-emptive and not a candidate	1.0
On dialysis	
Die	0.0008
Deceased donor kidney transplant	0.0
Living donor approved	0.0012
Living donor not approved	0.0004
Acceptable for LD only	0.0083
Listed for transplant	0.0437
Deemed not a candidate	0.0129
Remain on dialysis	0.9327
On dialysis and already on the waiting list	
Die	0.0023
Deceased donor kidney transplant	0.0293
Living donor approved	0.0078
Living donor not approved	0.0018
Acceptable for LD only	0.0018
Removed from waiting list	0.0261
Remain on dialysis and on waitlist	0.9304
On dialysis and acceptable for LD only	
Die	0.0064
Deceased donor kidney transplant	0.0
Living donor approved	0.0064
Living donor not approved	0.0191
Listed for transplant	0.0
Deemed not a candidate	0.0191
Remain on dialysis and acceptable for LD only	0.0
On dialysis and not a candidate	
Die	0.0
Deceased donor kidney transplant	0.0
Living donor approved	0.0
Living donor not approved	0.0
Acceptable for LD only	0.0
Listed for transplant	0.0
Remain on dialysis and not a candidate	1.0

Table S2. Transition probabilities in sensitivity analyses using probabilities from the literature

State	**Transition Probability Range**	**Sources**
Death on dialysis	0.013-0.024	USRDS 2016 Annual Report[5] Robinson et al, 2014, *Kidney International*[6]
Death on dialysis among those acceptable for a living donor only	0.017-0.026	USRDS 2016 Annual Report[5] Robinson et al, 2014, *Kidney International*[6]
Death on dialysis among those not a candidate	0.017-0.026	USRDS 2016 Annual Report[5] Robinson et al, 2014, *Kidney International*[6]
Death on dialysis among those on the waitlist	0.0107-0.017	USRDS 2016 Annual Report[5] Robinson et al, 2014, *Kidney International*[6]
Death among pre-emptives	0.0007-0.013	CDC Mortality[7]
Death among pre-emptives acceptable for living donor only	0.0037-0.026	CDC Older Persons' Health[8] USRDS 2016 Annual Report[5]
Death among pre-emptives who are not a candidate	0.009-0.024	USRDS 2016 Annual Report[5] Robinson et al, 2014, *Kidney International*[6]
Death among pre-emptives who are on the waitlist	0.0107-0.017	USRDS 2016 Annual Report[5] Robinson et al, 2014, *Kidney International*[6]
Receipt of a deceased donor kidney transplant while on the waiting list	0.0017-0.0117	USRDS 2016 Annual Report[5] SRTR/OPTN 2017 Annual Data Report[9]
Receipt of a deceased donor kidney transplant pre-emptively	0.0017-0.0139	USRDS 2016 Annual Report[5] Grams et al, 2013, CJASN[10] SRTR/OPTN 2017 Annual Data Report[9]
Initiate dialysis	0.055-0.057	Ashby et al, 2007, AJT[11]
Per-person cost of the LDN program	\$1,571.75-\$2,433.63	
Among participants in LDN program		
Living donor approval among those on dialysis	0.003-0.026	Rodrigue et al, 2014, Transplantation[12], Garonzik-Wang et al, 2012, Transplantation[13]
Living donor approval among those on dialysis and acceptable for a living donor only	0.0005-0.006	USRDS 2016 Annual Report[5] Rodrigue et al, 2014, Transplantation[12]
Living donor approval among those on dialysis and not a candidate	0.0005-0.003	USRDS 2016 Annual Report[5] Rodrigue et al, 2014, Transplantation[12]
Living donor approval among those on dialysis and on the waiting list	0.006-0.026	Rodrigue et al, 2014, Transplantation[12] USRDS 2016 Annual Report[5] Garonzik-Wang et al, 2012, Transplantation[13]
Living donor approval among pre-emptives	0.0002-0.01	Mustian (unpublished data),

		Fishbane et al, 2018, CJASN[14]
Living donor approval among pre-emptives acceptable for a living donor only	0.0002-0.005	Mustian (unpublished data), Abecassis, 2008, CJASN[15]
Living donor approval among pre-emptives who are not a candidate	0.0002-0.0007	Mustian (unpublished data), Ashby et al, 2007, AJT[11] Abecassis, 2008, CJASN[15]
Living donor approval among pre-emptives on the waiting list	0.0007-0.01	Abecassis, 2008, CJASN[15] Fishbane et al, 2018, CJASN[14]
Among non-participants		
Living donor approval among those on dialysis	0.0025-0.009	Rodrigue et al, 2014, Transplantation[12], Purnell et al, 2018, JAMA[16], USRDS 2016 Annual Report[5]
Living donor approval among those on dialysis and acceptable for a living donor only	0.0005-0.005	USRDS 2016 Annual Report[5] Purnell et al, 2018, JAMA[16]
Living donor approval among those on dialysis and not a candidate	0.0005-0.0012	USRDS 2016 Annual Report[5] Rodrigue et al, 2014, Transplantation[12], Purnell et al, 2018, JAMA[16]
Living donor approval among those on dialysis and on the waiting list	0.0025-0.005	Rodrigue et al, 2014, Transplantation[12], Purnell et al, 2018, JAMA[16]
Living donor approval among pre-emptives	0.0006-0.005	Ashby et al, 2007, AJT[11] Abecassis, 2008, CJASN[15]
Living donor approval among pre-emptives acceptable for a living donor only	0.0005-0.0007	USRDS 2016 Annual Report[5] Ashby et al, 2007, AJT[11] Abecassis, 2008, CJASN[15]
Living donor approval among pre-emptives who are not a candidate	0.0002-0.0007	Mustian (unpublished data), Ashby et al, 2007, AJT[11] Abecassis, 2008, CJASN[15]
Living donor approval among pre-emptives on the waiting list	0.0007-0.01	Ashby et al, 2007, AJT[11] Abecassis, 2008, CJASN[15] Fishbane et al, 2018, CJASN[14]

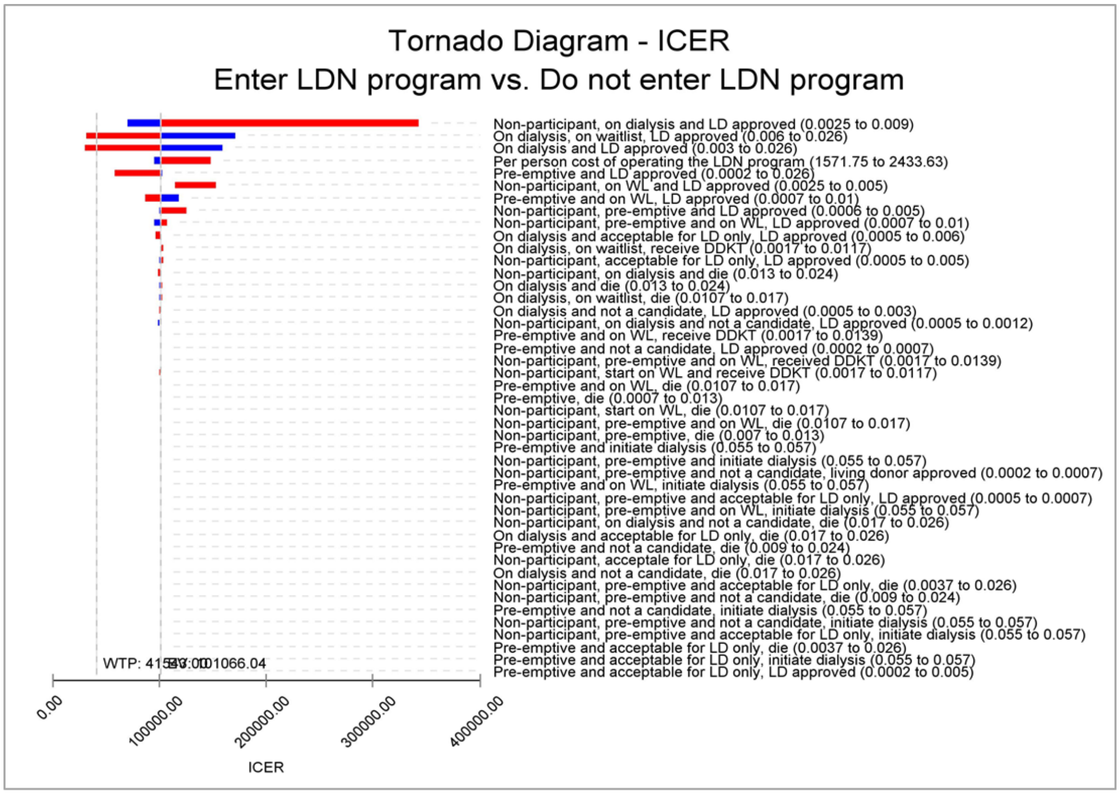

Figure S1. Tornado Diagram of One-Way Sensitivity Analyses

Table S3. Initial probabilities used in sensitivity analysis with 12-month time horizon

State	Baseline Probability
Initial status (at study entry)	
Among participants in LDN program	
Pre-emptive, not yet on dialysis	0.1163
Pre-emptive and already on the waiting list	0.093
Pre-emptive and acceptable for a living donor only	0.00
Pre-emptive and not a candidate	0.00
On dialysis	0.3953
On dialysis and already on the waiting list	0.3721
On dialysis and acceptable for living donor only	0.0233
On dialysis and not a candidate	0.00
Total (rounded)	1.00
Among non-participants	
Pre-emptive, not yet on dialysis	0.1834
Pre-emptive and already on the waiting list	0.0194
Pre-emptive and acceptable for a living donor only	0.0019
Pre-emptive and not a candidate	0.0006
On dialysis	0.5882
On dialysis and already on the waiting list	0.1952
On dialysis and acceptable for living donor only	0.0038
On dialysis and not a candidate	0.0075
Total (rounded)	1.00

Table S4. Cost effectiveness analysis of operating the Living Donor Navigator program with 12-month time horizon

Strategy	Cost, $	Incremental cost, $	Effectiveness (Living donor transplants)	Incremental effectiveness	ICER, $/living donors	Average cost-effectiveness ratio
Do not enter LDN program	0.00		0.02			$0/living donor transplant
Enter LDN program	1,661.75	1,661.75	0.08	0.06	29,859	$21,663/living donor transplant

APPENDIX E

FOCUS GROUP GUIDE

Focus Group Guide for discussions with Champions who participated in the Living Donor Navigator Program at UAB

I. INTRODUCTION

My name is Rhiannon Reed. I am working with Dr. Jayme Locke at the University of Alabama at Birmingham (UAB) on a study aimed at understanding your thoughts on your participation as a Living Donor Champion in the Living Donor Navigator Program at UAB. We would like to talk to you about your attitude and impressions about this program. The information that you provide will be used to inform efforts to strengthen and improve how we conduct this program. As, you learned during the consent process, this discussion will take around one and a half hours. Please remember not to discuss anything from this group discussion afterwards with other people outside of this group. If you have questions on other topics, we can assist you to find answers after the group discussion is over.

(Confirm that all participants have consented to the audio recording of the discussion and only start the tape recorder AFTER the introductions part of the discussion. This guide includes the topics to be covered and questions that may be helpful in facilitating the discussion. You do NOT have to ask all the questions or follow the order given in the guide. Major topic areas are indicated in **Bold**.)

II. INTRODUCTIONS

First let's get acquainted. Let's go around the circle and each person can introduce herself/himself. You can tell us your first name (or name you would like us to use during this focus group discussion) and anything else about yourself that you would like to share with the group. (Members of the research team should also introduce themselves. If the group agreed to the tape recording, you may start recording after this section of the discussion.)

III. DISCUSSION TOPICS

- **Living kidney donation**
    - What was the most surprising thing you learned about living donation after participating in the Living Donor Navigator program?
    - What are some of the benefits of living donor transplantation?
    - What are some of the risks of living donor transplantation?
    - What were the most frequent reasons or barriers you heard from people who did not want to become living kidney donors?
        - Follow-up: How important is that barrier?
        - Follow-up: How did you respond to that barrier?

- **Participation as a champion**

  - Why did you become a Living Donor Champion?
    - Probe: Why did you think your loved one needed/could use a Champion?
  - Since your participation, how frequently do you speak with others about living kidney donation or your loved one's need for a kidney transplant?
  - What kinds of groups or individuals did you speak to about living kidney donation or your loved one's need for a kidney transplant?
    - Follow-up: What kinds of groups or individuals did you find were more receptive/open to the idea of living kidney donation or your loved one's need for a kidney transplant?

- **Delivery of the program**
  - What did you enjoy most about your participation as a Champion in the Living Donor Navigator Program?
  - In thinking about the Living Donor Navigator Program at UAB, we would like to get some feedback on the program: please tell me your thoughts on the content/material covered in the program.
    - Probe: Was there too much/too little?
    - Other probe: What would be the ideal format of the program?
  - What topics do you know now that you wish you had learned about in the program?
  - Do you have any advice for future Champions that will help prepare them for having conversations about living kidney donation?
  - If this class was offered online, would you have chosen to participate?
    - Follow-up: Why or why not?

IV. CLOSING

Thank you very much for your time. Your responses will be very helpful for improving the Living Donor Navigator Program for future Champions at UAB.

APPENDIX F

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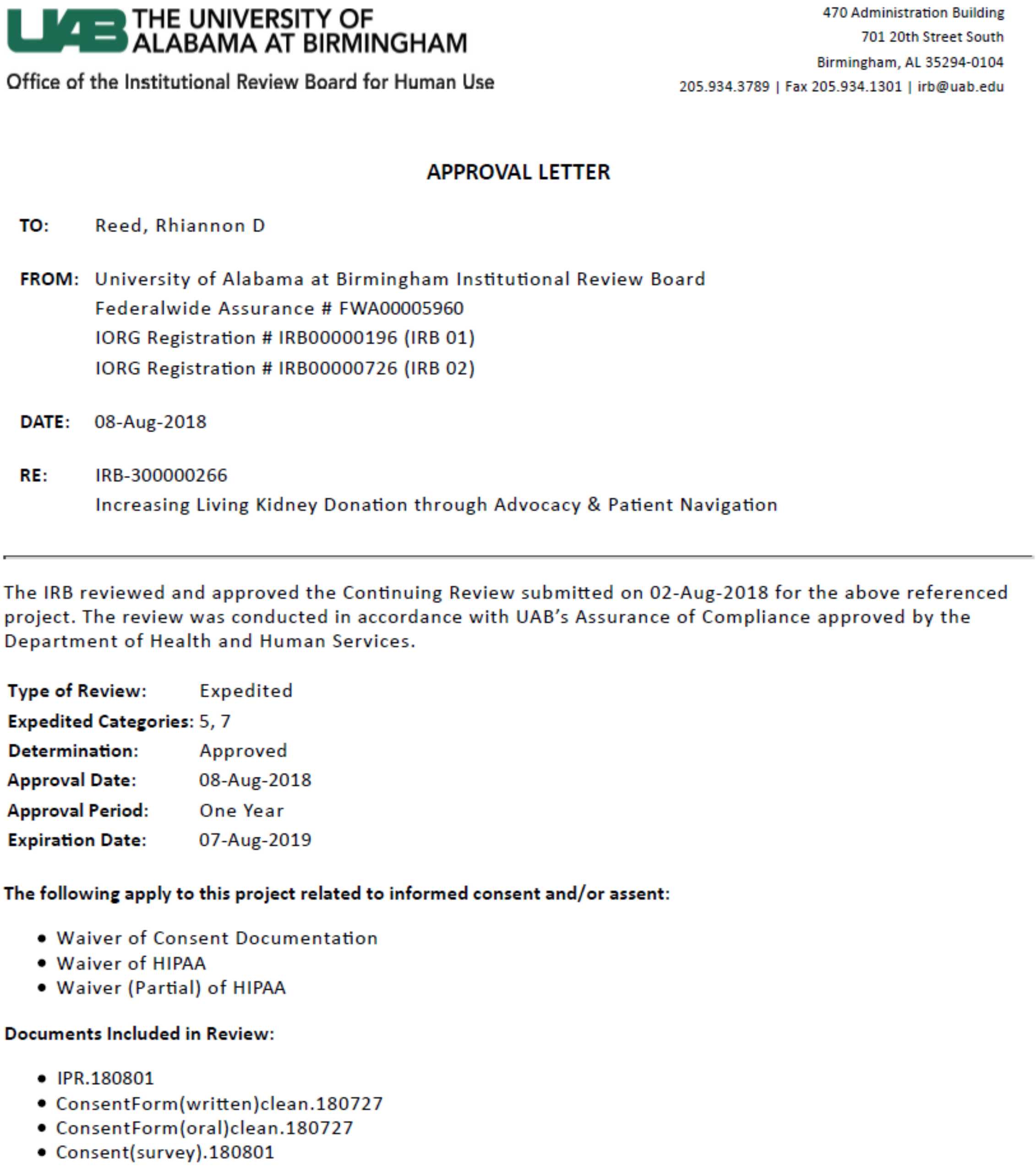
APPENDIX F

IRB APPROVALS



THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 | irb@uab.edu

APPROVAL LETTER

TO: Reed, Rhiannon D

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 08-Aug-2018

RE: IRB-300000266
Increasing Living Kidney Donation through Advocacy & Patient Navigation

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The IRB reviewed and approved the Continuing Review submitted on 02-Aug-2018 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

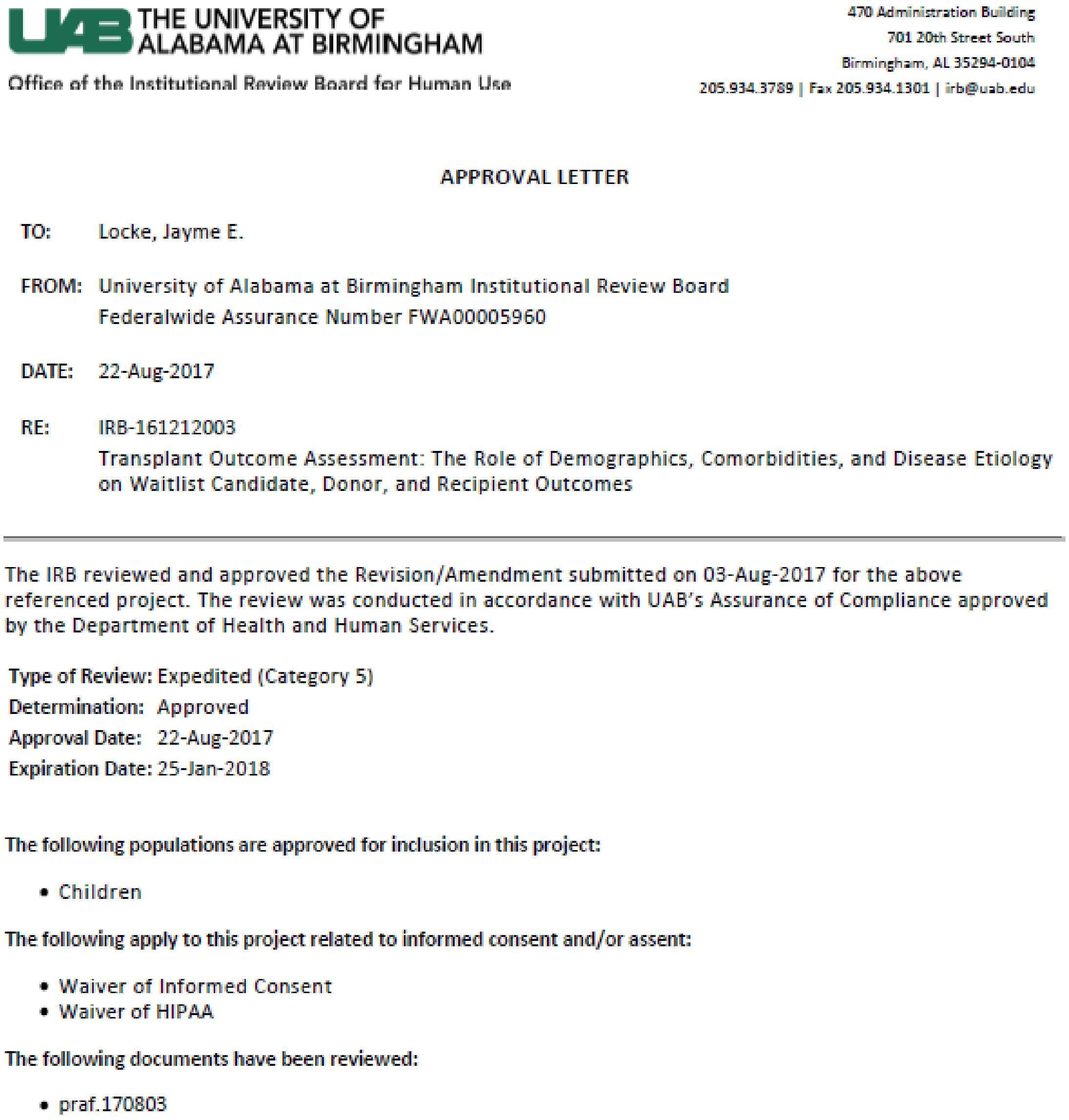
Type of Review:	Expedited
Expedited Categories:	5, 7
Determination:	Approved
Approval Date:	08-Aug-2018
Approval Period:	One Year
Expiration Date:	07-Aug-2019

The following apply to this project related to informed consent and/or assent:

- Waiver of Consent Documentation
- Waiver of HIPAA
- Waiver (Partial) of HIPAA

Documents Included in Review:

- IPR.180801
- ConsentForm(written)clean.180727
- ConsentForm(oral)clean.180727
- Consent(survey).180801



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APPROVAL LETTER

TO: Locke, Jayme E.

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance Number FWA00005960

DATE: 22-Aug-2017

RE: IRB-161212003
Transplant Outcome Assessment: The Role of Demographics, Comorbidities, and Disease Etiology on Waitlist Candidate, Donor, and Recipient Outcomes

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The IRB reviewed and approved the Revision/Amendment submitted on 03-Aug-2017 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review: Expedited (Category 5)
Determination: Approved
Approval Date: 22-Aug-2017
Expiration Date: 25-Jan-2018

The following populations are approved for inclusion in this project:

- Children

The following apply to this project related to informed consent and/or assent:

- Waiver of Informed Consent
- Waiver of HIPAA

The following documents have been reviewed:

- praf.170803

Project Revision/Amendment Form

Form version: June 26, 2012

In MS Word, click in the white boxes and type your text; double-click checkboxes to check/uncheck.

- **Federal regulations require IRB approval before implementing proposed changes. See Section 14 of the IRB Guidebook for Investigators for additional information.**
- **Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the Investigator's Brochure, questionnaires, surveys, advertisements, etc.). See Item 4 for more examples.**

1. Today's Date	August 2, 2017

2. Principal Investigator (PI)

Name (with degree)	Jayme Locke, MD MPH	**Blazer ID**	jlocke
Department	Surgery	**Division (if applicable)**	Transplantation
Office Address	LHRB 748	**Office Phone**	205-934-2131
E-mail	jlocke@uabmc.edu	**Fax Number**	205-934-0320

Contact person who should receive copies of IRB correspondence (Optional)

Name	Rhiannon Reed	**E-Mail**	rdeierhoi@uabmc.edu
Phone	205-996-2894	**Fax Number**	205-934-0320
	Office Address (if different from PI)	**ZRB706A**	

3. UAB IRB Protocol Identification

3.a. Protocol Number	X161212003
3.b. Protocol Title	Transplant Outcome Assessment: The Role of Demographics, Comorbidities, and Disease Etiology on Waitlist Candidate, Donor, and Recipient Outcomes

3.c. Current Status of Protocol—Check ONE box at left; provide numbers and dates where applicable

☐	**Study has not yet begun**	**No participants, data, or specimens have been entered.**	
☒	**In progress, open to accrual**	**Number of participants, data, or specimens entered:**	SRTR: 1,550,417 UNOS: 1,550,417 USRDS: 2,709,247 UHC: 11,499
☐	**Enrollment temporarily suspended by sponsor**		
☐	**Closed to accrual, but procedures continue as defined in the protocol (therapy, intervention, follow-up visits, etc.)**		
	Date closed:	**Number of participants receiving interventions:**	
		Number of participants in long-term follow-up only:	
☐	**Closed to accrual, and only data analysis continues**		
	Date closed:	**Total number of participants entered:**	

4. Types of Change

Check all types of change that apply, and describe the changes in Item 5.c. or 5.d. as applicable. To help avoid delay in IRB review, please ensure that you provide the required materials and/or information for each type of change checked.

☐ **Protocol revision (change in the IRB-approved protocol)**
In Item 5.c., if applicable, provide sponsor's protocol version number, amendment number, update number, etc.

☐ **Protocol amendment (addition to the IRB-approved protocol)**
In Item 5.c., if applicable, provide funding application document from sponsor, as well as sponsor's protocol version number, amendment number, update number, etc.

☒ **Add or remove personnel**
In Item 5.c., include name, title/degree, department/division, institutional affiliation, and role(s) in research, and address whether new personnel have any conflict of interest. See "Change in Principal Investigator" in the IRB Guidebook if the principal investigator is being changed.

- ☒ **Add graduate student(s) or postdoctoral fellow(s) working toward thesis, dissertation, or publication**
  In Item 5.c., (a) identify these individuals by name; (b) provide the working title of the thesis, dissertation, or publication; and (c) indicate whether or not the student's analysis differs in any way from the purpose of the research described in the IRB-approved HSP (e.g., a secondary analysis of data obtained under this HSP).

☐ **Change in source of funding; change or add funding**
In Item 5.c., describe the change or addition in detail, include the applicable OSP proposal number(s), and provide a copy of the application as funded (or as submitted to the sponsor if pending). Note that some changes in funding may require a new IRB application.

☐ **Add or remove performance sites**
In Item 5.c., identify the site and location, and describe the research-related procedures performed there. If adding site(s), attach notification of permission or IRB approval to perform research there. Also include copy of subcontract, if applicable. If this protocol includes acting as the Coordinating Center for a study, attach IRB approval from any non-UAB site added.

☐ **Add or change a genetic component or storage of samples and/or data component—this could include data submissions for Genome-Wide Association Studies (GWAS)**
To assist you in revising or preparing your submission, please see the IRB Guidebook for Investigators or call the IRB office at 934-3789.

☐ **Suspend, re-open, or permanently close protocol to accrual of individuals, data, or samples (IRB approval to remain active)**
In Item 5.c., indicate the action, provide applicable dates and reasons for action; attach supporting documentation.

☐ **Report being forwarded to IRB (e.g., DSMB, sponsor or other monitor)**
In Item 5.c., include date and source of report, summarize findings, and indicate any recommendations.

☐ **Revise or amend consent, assent form(s)**
Complete Item 5.d.

☐ **Addendum (new) consent form**
Complete Item 5.d.

☐ **Add or revise recruitment materials**
Complete Item 5.d.

☐ **Other (e.g., investigator brochure)**
Indicate the type of change in the space below, and provide details in Item 5.c. or 5.d. as applicable.
Include a copy of all affected documents, with revisions highlighted as applicable.

▶

5. Description and Rationale

In Item 5.a. and 5.b, check Yes **or** No **and see instructions for** Yes **responses.**
In Item 5.c. and 5.d, describe—and explain the reason for—the change(s) noted in Item 4.

☐Yes ☐No **5.a. Are any of the participants enrolled as normal, healthy controls?**
If yes, describe in detail in Item 5.c. how this change will affect those participants.

☐Yes ☐No **5.b. Does the change affect subject participation, such as procedures, risks, costs, location of services, etc.?**
If yes, FAP-designated units complete a FAP submission and send to fap@uab.edu. Identify the FAP-designated unit in Item 5.c.
For more details on the UAB FAP, see www.uab.edu/cto.

5.c. Protocol Changes: In the space below, briefly describe—and explain the reason for—all change(s) to the protocol.

▶ We would like to request the use of data collected under this protocol for doctoral dissertation research. The analyses proposed for the dissertation fall under the scope of the originally approved protocol. A memo from the PI permitting the use of this data for dissertation research is included with this amendment. The individuals who will use this data for their dissertations are already approved on the protocol and are:

▶ Rhiannon Reed, MPH: Working title: “Increasing Living Kidney Donation through Advocacy and Patient Navigation”

▶ Brittany Shelton, MPH: Working title: “Three Papers on Kidney Transplant Outcomes among Vulnerable Populations.”

5.d. Consent and Recruitment Changes: In the space below,
(a) describe all changes to IRB-approved forms or recruitment materials and the reasons for them;
(b) describe the reasons for the addition of any materials (e.g., addendum consent, recruitment); and
(c) indicate either how and when you will reconsent enrolled participants or why reconsenting is not necessary (not applicable for recruitment materials).

Also, indicate the number of forms changed or added. For new forms, provide 1 copy. For revised documents, provide 3 copies:
- **a copy of the currently approved document (showing the IRB approval stamp, if applicable)**
- **a revised copy highlighting all proposed changes with "tracked" changes**
- **a revised copy for the IRB approval stamp.**

▶

Signature of Principal Investigator____________________ Date 8/3/17

FOR IRB USE ONLY

☐ Received & Noted ☐ Approved Expedited* ☐ To Convened IRB

Signature (Chair, Vice-Chair, Designee) Date

DOLA __________________

Change to Expedited Category **Y / N / NA**

*No change to IRB's previous determination of approval criteria at 45 CFR 46.111 or 21 CFR 56.111