LIVING KIDNEY DONOR DROPOUT AT THE KENYATTA NATIONAL HOSPITAL TRANSPLANT PROGRAM.

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DECLARATIONS.

This dissertation is my original work and has not been presented for any award in any other university.

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ABBREVIATIONS:

AM	Arterial Multiplicity
ANOVA	Analysis of Variation
APOL1	Apolipoprotein L - 1
BMI	Body Mass Index
BP	Blood Pressure
CMV	Cytomegalovirus
CT	Computed Tomography.
EBV	Epstein Barr Virus
eGFR	estimated Glomerular Filtration Rate
ESRD	End Stage Renal Disease.
FSGS	Focal Segmental Glomerulosclerosis
GFR	Glomerular Filtration Rate
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen
IQR	Inter Quartile Range
KDIGO	Kidney Disease: Improving Global Outcomes
KNH	Kenyatta National Hospital
KPD	Kidney Paired Donation
KPD	Kidney Paired Donation
LFT	Liver Function Tests
mGFR	measured Glomerular Filtration Rate
MRA	Magnetic Resonance Angiography
OPTN	Organ Procurement and Transplantation Network.

PSA	Prostatic Specific Antigen
SD	Standard Deviation
SPSS	Statistical Package for Social Sciences
UNOS	United Network of Organ Sharing
USA	United States of America
VM	Venous Multiplicity
WHO	World Health Organization

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ABSTRACT.

BACKGROUND.

Kidney transplantation involves transplanting a healthy kidney to a patient with ESRD. Donors can either be living or deceased. Living donation offers the advantage of optimal preparation of both the recipient and the donor and allows better logistical control. Not every potential donor that starts the evaluation process eventually donates a kidney. The reasons for this are varied and range from medical contraindications to social or ethical dilemmas.

METHODS.

We conducted a retrospective descriptive study at the Kenyatta National Hospital transplant clinic. Medical records of all living kidney donors who enrolled into the transplant program during the period from January 2010 to September 2018 were obtained. All donors that did not successfully donate to their intended recipient were segregated and data pertaining to their sociodemographic characteristics and reason(s) for exclusion were obtained and data analysed using statistical package for social scientists (SPSS) version 22.0 for windows.

RESULTS.

The study was conducted between October and December 2018. During this period medical files of 286 donors that were evaluated during the period between, January 2010 and September 2018, were obtained. A total of 121 medical records of donors who were excluded were analysed. There was a male preponderance with a male to female ratio of 1.8 :1. The mean age was 33.4 years, majority (69.3 %) had post primary education and 46.8% were siblings to their intended recipients. The donor dropout rate was 42.3%, with the most common reason for donor exclusion being a medical contraindication at 52.3%. Of these, hypertension, diabetes and renal disease accounted for 24.1%. 22.4% and 29.3% respectively. Psychosocial reasons accounted for 22.5% while those excluded because of an immunological contraindication were 7.2%. Only two donors were excluded due to a surgical contraindication. Other reasons for exclusion (19.8%) were related to the intended recipient and included, recipient demise (10 donors), severe cardiovascular disease that rendered the recipient not transplantable (9 donors) or in other cases the availability of a more suitable donor (5 donors). Majority of donors (56.4%) were excluded in the early stages of the donor evaluation process (stage 1 to stage 3). Majority of the donors (75.7%) made between one to four visits prior to exclusion, while only a minority (2.7%), made greater than 8 visits before being excluded. The mean duration of time between donor enrollment and donor exclusion was 33.7 weeks with a median of 2.5 weeks. The shortest time taken before donor exclusion was less than a week with the longest duration was almost 78 weeks.

CONCLUSION.

In this study, we report a moderate rate of living donor drop out. The main reason for exclusion was a medical contraindication, with majority having renal disease, hypertension or diabetes.

CHAPTER ONE: INTRODUCTION.

LIVING KIDNEY DONOR DROPOUT AT THE KENYATTA NATIONAL HOSPITAL TRANSPLANT PROGRAM.

1.1 BACKGROUND

As the population grows older and people live for longer, the number of new cases of chronic kidney disease (CKD) are increasing steadily. This has also been attributed to improved diagnostic techniques that are able to detect very subtle changes in kidney function and morphology, hence detecting previously undiagnosed CKD. Chronic kidney disease is defined as kidney damage present for three months or more and presents as either abnormalities in kidney structure or kidney function. Abnormalities in kidney function can present as either changes in the composition of blood, changes in the composition of urine or abnormalities in imaging tests. When kidney function continues to decline patients eventually develop end stage renal disease (ESRD) and therefore require a form of renal replacement therapy sustain their life.

The two main forms of available renal replacement therapy include long term dialysis and kidney transplantation. Kidney transplantation is a form of allograft transplant, that is, the transfer a healthy kidney from a donor of the same species into a patient with ESRD. Kidney transplantation is further classified into either deceased donor transplantation or living donor transplantation depending on the source of the donor organ. Living kidney donation over and above deceased donation, offers the advantage of longer allograft survival and being an elective procedure can be better planned for.

Living kidney donation maybe directed or non - directed. Directed living kidney donation occurs when a donor with prior knowledge and an emotional or family bond to the patient with ESRD sets out to donate a kidney to him or her. Non directed kidney donation is purely altruistic and the potential donor anonymously donates a kidney to a patient with ESRD on the transplant waiting list.

Before a living kidney donor can successfully donate a kidney, he or she has to undergo an extensive evaluation process that begins with a counselling process, followed by laboratory, and imaging tests, and ends with a discussion in a multidisciplinary team that determines if the potential donor is fit for donation or not. Not every potential donor that begins the donor evaluation process is converted into an actual donor. In as much as there may be a scarcity of organs available for transplantation as compared to the patients with ESRD its always important to ensure that any donor deemed fit to donate must have good kidney function and in overall good health. In any transplant center a fair number of potential donors fail to convert to actual donors because at any of the stages afore mentioned a donor can drop out and therefore fail to complete the evaluation process. A donor may drop out either because of medical reasons, surgical reasons, or psychosocial reasons or they just opt out of the evaluation process.

1.1.1 DONOR EVALUATION AND TRANSPLANTATION AT THE KENYATTA NATIONAL HOSPITAL.

The Transplant process begins with the identification of potential transplant candidates/recipients from the pool of ongoing dialysis patients. These are then referred to the renal counsellor who counsels the patient and his/her family on transplant process, requirements and expectations. The renal counsellor then assists the family select one or two willing donors from the pool of family members. Once preselected the donors are then referred to the transplant coordinator who with the help of the renal counsellor recruits them into the donor evaluation process.

1.1.2 LAWS AND REGULATION GOVERNING KIDNEY TRANSPLANTATION IN KENYA.

Kidney donation is legal in Kenya but only blood relatives are allowed to donate to their intended recipients (living related kidney donation). An exception is made for married couples so long as they prove they are legally married. Recently a new law, which is part of the larger Health Bill 2016, was passed by parliament on May 2015. It builds on the Human Tissue Act of 1966(reviewed in 2012). Once logistics are in place, the law will allow Kenyans or their family members, either in a written or oral statement before

witnesses to donate organs to persons or institutions of their choice upon death. This will bring into reality the long awaited cadaveric donor transplantation that will ease pressure on living related kidney donation.

1.2 PROBLEM STATEMENT.

Living related kidney donation is the main source of organs in Kenya for patients with ESRD requiring kidney transplant. Although the Kenyan community is aware of the practice of kidney donation to family members with ESRD, not all potential donors successfully complete the donor evaluation process and successfully donate to their intended recipients. Currently the actual rate of donor drop out in most transplant centers within the country is unknown, and the reasons for this drop out are also not documented. Once this information is available, and if some of the reasons for dropping out are modifiable, mechanisms can be put in place to decrease the rate of dropping out hence making more organs available for transplantation as many transplant centers battle with scarcity of available organs for transplant.

1.3 STUDY JUSTIFICATION

- Living related donation gives the best outcomes with regards to graft function and patient survival.
- In transplant centers there is good number of donors who end up not eventually donating to their intended recipients, but this number (rate of drop out) remains unknown.
- The reasons for not donating are varied, but no formal data exists in our transplant center that outlines these reasons.
- More ever such information would be invaluable in streamlining the donor evaluation process making it more efficient and cost effective.
- Such data will also be valuable in increasing access to kidney transplantation by increasing the potential donor pool as some of the reasons for donor drop out will be demystified after the audit process.

1.4 RESEARCH QUESTION.

What was the period prevalence of kidney donor drop out at Kenyatta National Hospital (KNH) transplant center, from January 2010 to September 2018 and how does it relate to the potential donors clinical and sociodemographic characteristics

1.5 OBJECTIVES:

1.5.1 BROAD OBJECTIVE

Determine the magnitude of kidney donor drop out at the Kenyatta national hospital transplant center for the period from January 2010 to September 2018.

1.5.2 SPECIFIC OBJECTIVE:

1.5.2.1 Primary:

1. To determine the rate of kidney donor drop out during the specified period.
2. To determine the reasons for kidney donor drop out during the specified period

1.5.2.2 Secondary:

1. To determine the socio demographic characteristics of donors that dropped out.
2. Determine the duration of time between donor enrolment and donor drop out
3. Determine the stage of evaluation at which the donor dropped out of the evaluation process
4. Determine number of documented hospital visits the donor made before dropping out.

CHAPTER TWO: LITERATURE REVIEW.

Data from previous studies suggests that globally the patients who have kidney failure and are receiving renal replacement therapy are over 1.4 million in number and this number is increasing by an average of eight percent annually [1]. Compared to dialysis, kidney transplantation confers a reduction in the risk of mortality, a reduction in cardiovascular events and improved quality of life for patients with ESRD [2, 3].

Two forms of kidney donation exist, living and deceased. Transplantation services are reported to be offered in almost one hundred of the World Health Organization (WHO) member states. However, the number of live kidney donors and the rates of living donor kidney transplantation vary worldwide [4- 6]. In the western world, the use of living donors has gradually increased over time although the use of organs from deceased donors for kidney transplantation is still in excess of those from live donors .However in other areas like Asia and the Arabian countries, due to cultural and religious practices, fewer organs from deceased donors have been used in kidney transplantation [7, 8].

2.1 LIVING DONOR TRANSPLANTATION.

The use of allografts from live donors confers the best form of renal replacement therapy in terms of life expectancy and quality of life to patients with ESRD. It is associated with better patient and graft survival in comparison to the use of organs from deceased donors, especially when preemptive live donor transplantation is performed. It has lower rates of acute rejection , less occurrence of delayed graft function, preempts rapidly deteriorating quality of life that may occur during chronic dialysis, and in the long haul, it is more cost-effective. [9 – 15, Table 1]

Living kidney donation is a planned process therefore it also offers the advantage of optimal preparation of both the recipient and the donor. Such scheduling and planning also allows better logistical control which helps minimize organ cold ischemia time. Recently the number of live donors willing to donate a kidney has increased, contributing to the increase of living donor kidney transplantation, probably reflecting both increased awareness of living donor nephrectomy and improved surgical techniques

which are associated with quicker recovery and lower risk of perioperative complications [Table 1]

Table1. Benefits of Live Donor compared to Deceased Donor Kidney Transplantation.

Kidneys from live donors last longer and offers greater recipient survival.[9 - 15]
In cases of immunologically incompatible transplants, planned desensitization of recipients can occur more easily. [16].
Reduces the number of patients on the waiting list for deceased donor's kidney hence reducing number of individuals on chronic dialysis.[17]
Living donor renal transplantation can be preemptive therefore more cost saving from the avoidance of dialysis [18, 19].
Because of the possibility of shorter periods spent while on dialysis patients have better post-transplant outcomes and less associated comorbidities.[20,21]
Since living kidney donation is elective, patients unsuitable for emergency surgery are optimally assessed and prepared prior to surgery.

2.2 DONOR EVALUATION PROCESS.

Before an individual can become a living kidney donor, a complete evaluation must be done that ultimately involves the entire transplant team. The Organ Procurement and Transplantation Network (OPTN)/United Network of Organ Sharing (UNOS) mandate the bare minimum tests that are required during live donor evaluation [22, Table 2]. This evaluation process aims to establish the potential donor's general health, assess kidney function, anatomy and also test if the potential donor and his/her intended recipient are immunologically compatible. The evaluation process also screens for factors that may be associated with an increased risk for potential complications to the donor that may arise

from having a single kidney. It also determines the presence of communicable diseases, and assesses any psychological risk or possibility of coercion that may preclude donation.

The total time required for all the necessary investigations and processes required to be completed before one can become an actual donor, may vary from one center to another center. The evaluation process of the live donor should as efficient as possible and it's a high priority area as elaborated at a recent consensus conference [23]. The Kidney Disease: Improving Global Outcomes (KDIGO) has published guidelines on living kidney donor evaluation. The guidelines assist transplant centers develop and follow processes that are as efficient as possible so as to satisfy the requirements of donor candidates and their intended recipients [24]. Subsequently, the United Kingdom aims that by 2020, all their potential donors be able to finish the evaluation process in a span four and a half months where possible. [25] From findings from two multicenter cohort studies, the median time taken to complete this process was 10 months but for a significant percentage of potential kidney donors this period of evaluation exceeded 16 months [26]. Sometimes there are incidental findings necessitating further examination for a detailed and complete donor work up. On other occasions, it was necessary to prolong the time taken for evaluation in order to decrease the risks to the donor or to the recipient for example for achieving desired BMI, smoking cessation and control of blood pressure [27, 28].

2.3 MULTIDISCIPLINARY SELECTION COMMITTEE.

After potential donors complete the donor evaluation process, each donor's and intended recipients case is presented to team. This multidisciplinary team comprises nephrologists, urologists, vascular surgeons, the transplant coordinator, transplant counsellor, social worker, Anesthetists, pharmacist, and nutritionist [23]. This is important in ensuring that each team member gets a chance to use his or her expertise in determining the eligibility for donation of each potential donor based on either, medical, surgical, social or mental eligibility criteria. Should the multidisciplinary team deem that the donor has a higher risk for donation compared to what is currently known and what is acceptable, they will discontinue the process and drop the potential donor despite what the he or she would

wish to do [30]. The potential donor and recipient are then informed of the decisions made at the multidisciplinary team's meeting. If the donor and intended recipient are suitable and the donation process is to proceed, a surgery date is then scheduled.

Table 2: Donor evaluation process.

• Detailed medical history
• Full physical examination including BMI
• Haemogram, clotting profile, electrolyte panel and LFTs
• Sugar levels and cholesterol levels, glycated hemoglobin, or OGTT if the risk for diabetes is high.
• Infection screen (HIV, Hepatitis B and C, Syphilis, Tuberculosis, EBV, CMV
• Blood group, HLA typing and crossmatch.
• Estimation of GFR(24 hour creatinine clearance or radioisotope scanning)
• Urinalysis and if indicated, urine culture.
• Cancer screening(PSA, pap smear, mammography or as recommended in the general population
• Renal anatomy scanning (Spiral CT or MRA)
• Stress test, Echocardiography and Electrocardiography as needed.

- Modified from Ajay et al [29]

2.4 DONOR EXCLUSION/NON DONATION/DROP OUT

Not every potential donor that starts the evaluation process eventually donates a kidney. In any transplant center there is good number of donors who end up not eventually donating to their intended recipients. The reasons for this vary because each center has a specific evaluation process and eligibility criteria. Currently there is limited long term data and no randomized controlled studies to base inclusion and exclusion criteria for potential donors on. This has also contributed to the variability in the reasons for donor exclusion among various centers. [31].They may range from medical contraindications to social or ethical dilemmas depending on the judgement of the multidisciplinary selection team. There are very few absolute contraindications to living kidney donation [Table 3]. If a potential donor is excluded from the donation process he/she should be counselled on the reason for exclusion and offered any necessary support regarding why he/ she was excluded. In some cases, the particular transplant center may inform the excluded donor that a different center may have a different evaluation process that may alter his/her eligibility making him/her suitable for donation for example if using an extended donor criteria. [32, Table 4]. This means a donor may be excluded in one transplant center but be eligible for donation in another center. However most centers use the Amsterdam guidelines for donor evaluation and follow the UNOS/OPTN policies that detail the minimum evaluation requirements for determining eligibility a potential living kidney donor [23, 32 – 33].

Table 3: Absolute Contraindications to Living Kidney Donation.

• Current malignancy or ongoing infection
• Renal stones due to a metabolic condition
• Poorly controlled blood pressure
• Gross proteinuria/ Glomerular disease / impaired GFR
• Sickle cell disease
• Bilateral renal artery stenosis.

Table 4: Potential Donor Exclusion Criteria.

• Younger than eighteen years of age or mental incapability of making an informed decision.
• Poorly controlled blood pressure or history of high blood pressure with coexistent target organ damage
• HIV infection, Diabetes Mellitus, Hepatitis B/C infection.
• Active malignancy or incompletely treated malignancy
• Presence of possible donor coercion
• Occurrence of illegal financial exchange between donor and recipient.
• Presence of acute and /or symptomatic infection.
• Mental illness requiring management prior to donation or suicidal ideation.

- Modified from Deonna RM et al [34]

Some of the key reasons pertaining to the acceptance or exclusion of potential donors are discussed below. However it important that the donor be evaluated as a whole and the presence of one risk factor be assessed while considering the presence or absence of other potential risk factors that the donor may have.

- Glomerular filtration rate (GFR).

  Specific guidelines exist as to the minimum measured glomerular filtration rate (mGFR) acceptable prior to a donor acceptance. This is to ensure that the function of the remaining kidney is expected to be more than 37.5mL/min/1.73m^2 by the time the donor gets to the age of 80 years (donor's estimated lifetime) [35, 36]. Many centers use a lower cut off for renal function, of 80mls/min per 1.73 m ^{2}. The use of one cut off value for all potential donors doesn't take into consideration that renal

function declines with age [37, 38]. Therefore, each potential donor's risk of developing ESRD post donation should be determined using the cut off value for the expected creatinine clearance based on his/her age [Table 5].

Table 5: Measured Creatinine Clearance According To Age.

Age (yr)	Mean Creatinine Clearance (ml/min per 1.73 m^2)	SD	Mean − SD	Mean − 2 SD
17–24	140	12	128	116
25–34	140	21	119	98
35–44	133	20	113	93
45–54	127	17	110	93
55–64	120	16	104	88
65–74	110	16	94	78
75–84	97	16	81	65

- Modified from Rowe et al [39]

- Age

  In majority of transplant centers, donors must be above eighteen years old though there are some situations where younger donors have been used. [40]. Transplant centers are also encouraged to be cautious when accepting donors below the age of 25 years of age. Young people though healthier, they have a longer period of time for the development of co morbidities and have an increased life time risk of kidney failure. At the time of evaluation, there may be no evidence of renal disease or even risk factors for developing the same. However, because of a longer lifetime, conditions that confer the risk of developing kidney disease may occur, for example, diabetes mellitus, high blood pressure, and obesity and subsequently end stage renal failure. This possible progress from normal kidney function to kidney failure requiring renal replacement therapy is supported by data from OPTN, which showed that majority of the donors on the transplant list were aged 18 years to 34 years and subsequently developed ESRD more than 15 years after donation[41] . Young donors could also

be under pressure to donate from a dominant relative especially if they are still financially dependent on the potential recipient [42].

On the other hand, an older cohort of donors is more likely to have a lower GFR and a more significant medical history compared to the younger donors. However when we look at intraoperative and immediate post donation outcomes like for example, length of operation time, perioperative blood loss, and the duration of hospital stay, there is no difference in data from younger donors compared to selected older donors [43–45]. Though older donors may have risk factors for developing kidney disease over time, for example high blood pressure, they are less likely to have sufficient time to enable such potential risk factors to contribute to the development of renal disease. Even if renal disease does develop, it may not have an impact on life expectancy compared to younger donors [46]

- Gender

Females who desire to have children should also be advised on the negligible but important increase in the probability of gestational hypertension and pre-eclampsia in kidney donors [47, 48]. Females who have recently undergone childbirth should also be given time for the normal pre pregnancy renal physiology to be restored, prior to being considered as donors. If available, alternative donors should be considered for donation.

- Hypertension.

Potential donors should undergo screening for high blood pressure/hypertension, which should be done with two or more measured resting blood pressure readings on more than one visit. Sometimes during evaluation of blood pressure a high reading can be obtained making the clinician worry about the possibility of white coat hypertension. In such instances the potential donor should have ambulatory blood pressure measurements done to confirm the presence of hypertension [49]. For a potential donor with mild well controlled blood pressure, the risks of donation have

not been well documented. However it is recommended that the Amsterdam guidelines on hypertension in potential donors that state that donors with blood pressure >140/90 are excluded, be followed in determining donor eligibility [33]

- Diabetes

Diabetes or pre diabetes (impaired glucose tolerance) confers a higher risk of incident diabetic nephropathy or faster progression of prevalent diabetic nephropathy in subjects living with a single kidney. All donors should have a fasting blood glucose done. Even if the fasting sugar is normal, donors with possible risk factors for developing diabetes for example those with first-degree relatives with diabetes, history of gestational diabetes, or Body mass index (BMI) greater than 30, should have an oral glucose tolerance test (OGTT) or HbA1c done. [Table 2, Table 6] [50]. Potential donors with impaired glucose tolerance may not be eligible potential donors, especially if there other risk factors for renal disease for example obesity, high blood pressure, or proteinuria.

Table 6: Diagnosis of Prediabetes and Diabetes.

	Impaired glucose tolerance/pre diabetes	**Diabetes**
Fasting blood glucose(mg/dl)	100– 125	>= 126
2 – hr. plasma glucose with 75g oral glucose tolerance test	140 - 199	>= 200
HbA1C%	5.7 – 6.4	>=6.5

- Obesity/ High BMI

  Obesity, when present maybe associated with proteinuria or high blood pressure. It may also contribute to renal disease. [51] After unilateral nephrectomy for various reasons, obese patients were more predisposed to developing proteinuria or abnormalities in kidney function [52]. A BMI of greater than 30 is also associated with increased minor wound-related surgical complications accrued from nephrectomy. [53]. BMI of greater than 35 is considered a contraindication to donating a kidney in majority of transplant centers [54] but a potential donor's muscle mass, his/her body shape, should be put into consideration while assessing the BMI. If overweight, the potential donor should be encouraged achieve target BMI prior to the donation process, and all the possible risks of being overweight should be discussed with him/her.

- Proteinuria and Hematuria

  Significant, persistent proteinuria should preclude donation. However some exceptions exist, the main one being orthostatic proteinuria. Orthostatic proteinuria can be confirmed in especially donors aged less than 30 years by the use of a split urine collection [55]. Transient proteinuria secondary to for example vigorous exercise should also be ruled out by repeat collections. Albuminuria is better measure of glomerular abnormality (compared to 24hr total urinary protein) and a daily albuminuria of 30 mg is the standard cut-off [56]. If proteinuria is greater than 300 mg or albuminuria is greater than 30 mg, such a donor is usually excluded from kidney donation, especially if there are other risk factors for renal disease.

  Isolated hematuria may be due to a urological condition (for example renal calculi or renal malignancies) or glomerular in origin. For urological causes, they can be investigated through imaging and/or cystoscopy while for glomerular causes, a kidney biopsy is needed to make a diagnosis. A histological diagnosis of IgA nephropathy as the cause of hematuria precludes donation. If the cause of hematuria is confirmed to be benign, then such a donor can be accepted.

- Renal calculi.

  A history of recurring or multiple calculi, usually, is considered as a contraindication to donating a kidney. Recurrence of renal stones after donation can obstruct the flow of urine (obstructive uropathy) in the single kidney contributing to future kidney failure. Contraindications for donation in a patient with renal stones include presence of struvite stones, cystinuria, and primary hyperoxaluria. However, 77% of United States transplant programs consider allowing potential donors with a history of renal stones to proceed with kidney donation [57].

- Anatomical Variation.

  In most centers, single renal artery/ renal vein is the preferred anatomy for living kidney donors. [58] However the presence of multiple renal vessels (arterial or venous multiplicity, AM/VM) should not be an absolute contra-indication for live kidney donation [59 -60]. Currently available data seems to suggest a favorable outcome in kidney donors with vascular multiplicity. [61 - 62]. Despite the possibility of an increased warm ischemia time, increased operation time and moderate increase in blood loss in donors with multiple renal arteries, vascular multiplicity does not seem to be a contra-indication for donation [62]. However, an increase in the incidence of urological complications after kidney transplant in donors with AM, has been reported [63].

- Immunological incompatibility.

  Previously ABO-incompatible (ABOi) kidney transplantation or transplant in a patient with an HLA reactive antibody to the donor had been considered as a contraindication to the success of kidney transplantation. However availability of Desensitization protocols has made transplantation across blood groups and in sensitized individuals feasible. Desensitization can be achieved by plasmapheresis and the use of B cell-depleting agents followed by the use of potent immune suppressive medication [64-65].

Other possible contraindications to kidney donation are ongoing smoking and other factors that may influence a potential donor's ability to make decisions (impaired cognitive function, untreated mental disorder, or ongoing substance abuse). In most transplant centers would be donors are prevented from donating if any member of the donor evaluation team confirms that there is evidence of donor coercion. In most countries payment for donation is illegal [66]. The Declaration of Istanbul on organ trafficking and transplant tourism clarifies the issues of transplant tourism, trafficking and commercialism and gives guidelines for practice in organ donation and transplantation. It outlines the circumstances under the removal of organs from a living or deceased donor are ethically unacceptable and aims at preventing unethical transplant activities [67].

2.4.1 PREVALENCE OF DONOR DROP OUT/ NON DONATION

Currently information regarding the rate and reasons for donor drop out (non donation) in various transplant centers is limited. Most of the data available is from studies done prior to the use of Kidney paired donation (KPD), and also from a time period when ABO incompatibility was the most common reason for non donation. Many of these studies are also from single center experiences with variability in inclusion or exclusion criteria and therefore cannot be generalized. Published reports show that only 10 – 20% of the potential donors who contact transplant centers proceed to actual donation. This low conversion rate highlights the complexity and rigorous process of the potential living kidney donor (Table 7).

In a retrospective study in an Irish kidney donor program by Connaughton et al, all potential donors who presented wishing to undergo donor evaluation for possible kidney donation in the period between January 2000 and march 2014, and their outcomes were analyzed. 956 potential donors for 496 recipients were analyzed. Out of these, 883 potential donors proceeded to the initial stage of assessment. The donor dropout rate at this stage was 64.2%. 614 out of 956 potential donors did not proceed for further evaluation. There after 269(28.1%) donors underwent further assessment by the multidisciplinary team. In total 93 (9.7%) donors were declined following this assessment

with 176(18.4%) donors ultimately proceeding to live kidney donation. The major reason for declining donor was a medical contraindication (n=63, 67.7%) [68]

Table 7. Prevalence of Donor Dropout in Various Transplant Centers.

Study/Type	Location	Period	Number of total potential donors	Donor dropout rate	Most common reason
Connaughton et al/ retrospective analysis	Ireland	Jan 2000 - march 2014	956	81.5%	Medical 67.7%
Moore DR	USA	2004 - 2009	706	54%	Medical 33%, 14% - undiagnosed HTN
Al - Rabadi et al/ retrospective analysis	Jordan	Jan 2008 - June 2016	642	44.2 %	Medical 63.6% renal disease – 32.9%
McCurdie et al	Cape town	39-month	117	83%	22 % Availability of another suitable donor or cadaveric donor
Lapasia JB. Et al	Stanford university, USA		484	47%	Medical reason 65.5%
Francis R et al	St George's Hospital, UK	5 years	189	82%	30% immunological incompatibility

Reasons for donor drop out or non donation in potential donors undergoing evaluation and the factors affecting non donation at the Vanderbilt University Medical Center, USA, from 2004 to 2009 were analyzed. The sample included 706 candidates and close to half

of them (46%) were allowed to proceed with the donation process. Previously unknown hypertension (14%), impaired glucose tolerance (10%), and elevated urea (9%) were the most common medical reasons for donor drop out. About 13% of potential donors had a change of mind during the evaluation process. The older potential donors were more likely were more likely not to donate and within the excluded group an advanced age was more likely to be associated with previously undiagnosed high blood pressure and an abnormal glucose tolerance test [69].

In another evaluation by Trevit et al, of 29 live donor transplants done over a 3 year period, many potential donors did not proceed to transplant. For those who had an acceptable tissue type, were blood group compatible and lymphocytotoxic crossmatch negative, they looked at the reasons for cancelling donor work up. The reasons were impaired renal function (5 potential donors)cardiac/hypertension (4 potential donors), Reno vascular (1 potential donor), cancer (1 potential donor), cross-match positive at a late stage (3 potential donors), failure to attend at clinic/change of mind (6 potential donors) and hepatitis (2 potential donors). [70]

Al - Rabadi et al also carried a retrospective audit of all living related kidney donors at King Hussein medical center, Jordan, that were evaluated from January 2008 to June 2016. From a total of 642 potential donors, 384(59.8%) successfully proceeded to donation. The most common cause for donor dropout was medical reasons with 47 potential donors (32.9%) dropping out because they had a potential risk for renal failure following donation (e.g., hematuria, proteinuria, kidney stones, multiple kidney cysts, scarred kidney, congenital malformation, a history of recurrent urinary tract infection). 30 (21%) had blood group or immunologic incompatibilities. 15 potential donors (10.5%) had a change of mind during the evaluation process, 13 potential donors (9%) had elevated blood pressure, 10 (7%) had a high body mass index, 8 (5.6%) were diabetic or pre diabetic, 7 (4.9%) were found to be unsuitable surgically, 4 (2.8%) had hepatitis B virus infection, 4 (2.8%) were pregnant, 3 (2.1%) had significant cardiovascular disease, 1 (0.7%) had an enlarged spleen and lymph node enlargement, and 1 (0.7%) had thyroid disease [71].

For centers that use both deceased donor organs and living donors, the shortage of cadaveric donors for renal transplantation has resulted in the increase of the use of living donors. McCurdie et al reviewed the outcomes of the assessments of potential living kidney donors at the department of surgery, university of Cape town. One hundred seventeen potential donors evaluated over a 39-month period were included in the study analysis. As part of the donor evaluation process, potential donors underwent clinical, blood, and radiological tests. Of the 117 potential donors, only 20 were ultimately used (conversion rate of approximately 17%). Five percent of the donors were found to have a medical contraindication to donation, during the first visit. Additionally, 25% had ABO incompatibility, following the investigations, a further 13% were dropped out, 9% had psychosocial problems, and in 4% of the cases, there were recipient related issues. Twenty-two percent of the potential donors completed the evaluation process and were found to be suitable. However they were excluded because of the availability of another live donor or because a cadaver donor kidney became available [72].

The living donor evaluation process at a single center in Stanford was audited to determine the proportion of prospective donors that actually donate, and to identify the key reasons for exclusion. In this audit, It was hypothesized that a substantial portion of prospective donors were excluded for medical reasons that had yet to be consistently associated with increased morbidity for either donors or recipients. Of the 484 prospective donors, 39 (8%) successfully donated, 229 (47%) were excluded, 104 (22%) were actively undergoing evaluation, and 112 (23%) were withdrawn before evaluation was complete. Criteria for exclusion were medical (n = 150), psychosocial (n = 22), or histocompatibility (n = 57) reasons. Of the 150 prospective donors excluded for medical reasons, 79% were excluded because of obesity, hypertension, nephrolithiasis, and/or abnormal glucose tolerance. One hundred and forty-seven (61%) intended recipients had only one prospective living donor, of whom 63 (42%) were excluded [73].

Francis R et al reported their 5 year experience of live donor transplantation at St George's Hospital, UK, with particular reference to the reasons for failure to complete the assessment and suggest pathways to improve the situation. 189 (103 female, 86 male)

potential donors entered the assessment process. 34 (18%) actually donated comprising 17 (50%) siblings, 9 (26%) parents and 8 (24%) unrelated donors. Of the excluded donors (155), forty six (30%) had blood group or immunological incompatibility and forty (27%) had a change of mind. Twenty three (15%) had a medical contraindication, mostly due to cardiovascular disease and in particular, sixteen (10%) had impaired renal function [74].

Other studies have also sought to determine if race and gender play a role in donor drop out (non donation). Reeves - Daniel et al, in their study to determine if race and gender had any effect on living kidney donation, at the Wake Forest University Health Sciences, USA, performed a retrospective review of 541 unsuccessful living kidney donations. This was to inquire into reasons for donors not donating to their intended recipients and also to look into the possibility of any differences in race and/or gender. Of the 541 unsuccessful donors, majority were Caucasians, while female donors(58.2%), compared to male donors, were more likely to result in non-donation due to an impaired renal function(7.9% Vs 0.9%) or due to a failure to successfully get to the end of the donor evaluation process (6.4% Vs 1.8%). For the African Americans (compared to Caucasians) the most common reason for exclusion was obesity (BMI >or= 32 kg/m(2); (30.4% Vs. 16.6%) or an inability to finish the donor evaluation process(12.3% Vs. 1.8%) ,whereas African Americans were less likely to be excluded because of renal stones (1.5% Vs. 7.3%).all above were statistically significant. From this evaluation we see various significant reasons for non donation existing between living African American and Caucasian kidney donors, particularly among women. Some of these were potentially modifiable reasons for non donation for example obesity and the inability to complete the donor evaluation process [75].

Lunsford et al also carried out a retrospective analysis of all potential donors referred for kidney donation between January 1, 2000 and December 31, 2004 with an aim to study the reasons for non donation and determine if there were any differences with regards to race between donors and non donors. The donor dropout rate was 30.3%. The reasons for donor drop out(n = 1,050) included, unacceptable donor health status (43.1%) and factors associated with the potential recipient (41.3%). Also 9.7% of donor – recipient pairs were

immunologically incompatible. Therefore those potential donors were also excluded. Racial disparities were also noted and showed that African Americans were more likely to be excluded because of an incompatible blood group. Non - African American donors were more likely to successfully donate (13.2% vs. 4.6%, $P<0.01$) and those who did not successfully donate were excluded because the potential recipient received an organ from another donor, either living or cadaveric (20.0% versus 7.9%). There was no racial disparity between African Americans and other races with regards to overall donor health (including diabetes and hypertension). However, following a sub analysis, there was an indication that African American donors were more likely to be excluded because of a high BMI ($P=0.01$) [76].

CHAPTER THREE: METHODOLOGY:

3.1 Study design:

Retrospective descriptive study

3.2 Study site:

The study was carried out at the Kenyatta National Hospital Transplant (KNH) Clinic.

3.3 Study population:

The study population consisted of all donors who were enrolled into the transplant program and started the donor evaluation process but dropped out or were excluded from donating to their intended recipients during the period starting January 2010 to September 2018.

3.4 Case definition:

Any potential donor who enrolled into the transplant evaluation process but never completed the evaluation process nor successfully donated a kidney.

3.5 Sampling technique:

Consecutive sampling of records of all potential donors that were enrolled into the transplant program during the period between January 2010 and September 2018 that never proceeded to donate a kidney to their intended recipient will be done.

3.6 Screening and Recruitment:

The principal investigator reviewed hospital medical records of all donors enrolled into the Kenyatta National Hospital transplant program and segregated the records of those potential donors that did not eventually proceed to donate a kidney. The records of those potential donors who did not proceed to donate were then included in to the study. They were carefully scrutinized for relevant sociodemographic and clinical data that was then entered into the study proforma.

3.7 Inclusion Criteria:

All potential donors who never proceeded to donate a kidney to their intended recipient.

3.8 Exclusion Criteria.

Donors who successfully donated a kidney.

3.9 Data Collection.

Perusal of the potential donor's medical records was done to obtain the following information which was subsequently recorded into the study proforma.

1 Donor sociodemographic factors
2 Stage at which the donor dropped out or was excluded from donation.
3 Reason (s) for dropping out/ being excluded.
4 Duration time (in weeks) between donor enrollment and donor drop out.
5 Number of hospital visits made by the donor prior to dropping out.

3.10 Data Variables.

3.10.1 Dependent Variables – These are measurable outcomes of interest that were Influenced by the independent variables. These included,

3.10.1.1. Reasons for dropping out

1. Medical/renal reason

A potential donor was considered to have a medical reason for dropping out if they had any of the following,

- Renal disease – unexplained hematuria, renal stones, congenital malformations, polycystic kidneys, proteinuria, recurrent urinary tract infections, Reno vascular disease.

- Infections that preclude donation – Hepatitis B , HIV
- Non communicable diseases : Diabetes or pre diabetes, hypertension, High BMI
- Pregnancy
- Malignancy
- Any other medical condition that would preclude donation(referred to as other medical condition).

2. Immunological reason.
   - Positive T cell cross match
   - ABO incompatibility
3. Surgical/anatomical reasons
   - Multiple renal arteries/ veins
   - Anatomical Kidney variations that preclude donation for example solitary kidney, pelvic kidney.
4. Psychosocial reasons
   - Failure to attend clinic.
   - Change of mind.
   - Ongoing abuse of alcohol or other drugs.
5. Others:

   Other reasons that don't fall under above categories, for example availability of another more suitable donor, evidence of donor coercion, recipient issues(death/ illness)

3.10.1.2. Stage at which donor dropped out –

Stages of donor evaluation were classified according to the current protocol in use at the KNH renal transplant program that is in keeping with the KDIGO guidelines for donor evaluation

Stage 1 - Psychosocial evaluation and counselling, nutritionist review.

Stage 2 - History taking, Blood grouping and baseline serology for HIV, Hepatitis

B and Hepatitis C

Stage 3 - Baseline laboratory investigations.

Stage 4 - Evaluation of renal function.

Stage 5- Imaging

Stage 6 - Tissue typing/ T cell crossmatch.

Stage 7 - Multidisciplinary team discussion

3.10.2 Independent Variables

3.10.2.1 Sociodemographic factors

- Age
- Gender
- Level of education
- Current residence (county)
- Marital status
- Occupation
- Relation with the potential recipient

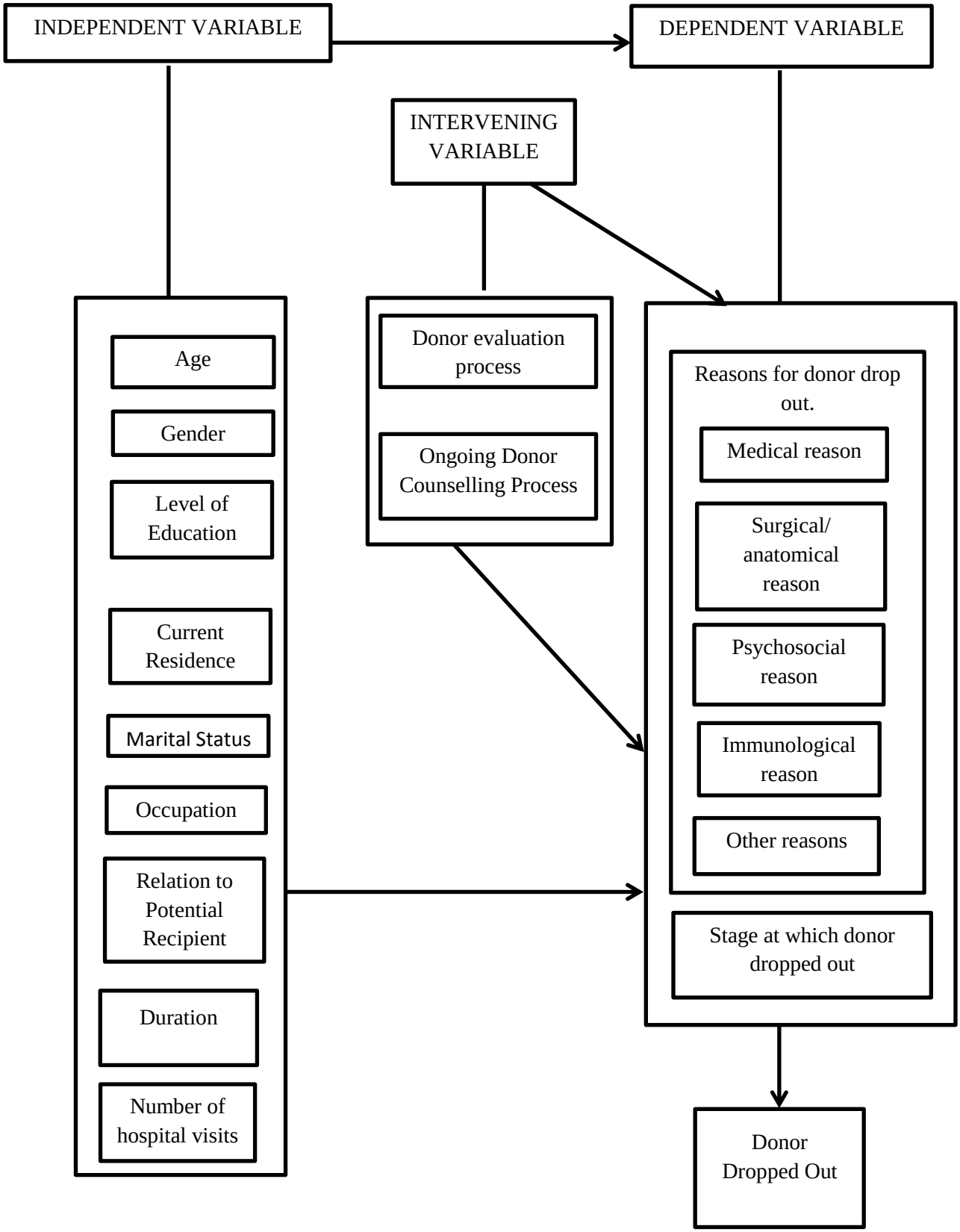
3.10.2.2 Duration –

Duration of time taken (in weeks) between donor enrollment into the donor evaluation process and donor drop out from the evaluation process.

3.10.2.3 Number of hospital visits-

Total number of documented hospital visits made by the donor prior to dropping out.

Figure 1. Conceptual Framework.



3.11 Data Management/ Data Analysis.

After recording in the proforma, data was verified, and entered into computerized data entry sheets. Analysis was done using SPSS version 22.0 for windows. Socio-demographic and clinical characteristics of the kidney donors were summarized into means or medians and percentages for continuous and categorical variables respectively. The rate of drop out was analyzed and presented as a percentage. Reasons for drop out were also presented using frequency distributions and percentages. Duration of time at drop out and the number of hospital visits were summarized into medians and interquartile ranges (IQR) while the stage of evaluation was presented using percentages.

ANOVA was used to compare means of more than two variables for example comparing the mean age of donors dropped because of the various reasons(medical, surgical, immunological, psychosocial, other reasons)

Associations that were assessed included association between selected sociodemographic characteristics, mean duration taken and mean number of hospital visits made prior to donor drop out, and the various reasons for donor drop out.

Data was presented in the form of tables, pie charts and graphs. The level of significance was set at $p< 0.05$ and a 95% confidence interval was applied to the numerical variables that are normally distributed.

Strength of association was expressed as odds ratio with a 95% confidence interval.

3.12 Ethical Consideration.

Study was carried out after ethical approval by the Kenyatta National Hospital research and ethics committee. Data collected from the patients' medical records was handled with utmost confidentiality. After the study the excluded donors' support system will be streamlined in line with the various reasons for donor exclusion to ensure that excluded donors are managed and supported accordingly

3.13 Study Feasibility and Time Frame.

Medical records of all potential donors enrolled into the transplant program since its incipience are stored at the records department of the Kenyatta national hospital renal unit. These records were easily available and were segregated to get donors who were either excluded or dropped out of the donor evaluation process, whose data was used in the research process. Since it's a period based study, all prevalent and incident cases during the specified period (January 2010 to September 2018) were studied.

The time frame for data collection, compilation and analysis was done in November 2018 while results were presented in December 2018.

3.15 Study Results Dissemination.

After data analysis, the study results were presented to the multidisciplinary selection committee/team. The team comprised of the nephrologists, urologists, vascular surgeons, transplant coordinator, social worker/psychologist/psychiatrist/counsellor Anesthetists, pharmacist, and nutritionist. These are the members normally involved in the donor selection process and are therefore also tasked with ensuring the donor evaluation process is cost effective and efficient.

CHAPTER FOUR: RESULTS.

The study was conducted between October and December 2018 at the Kenyatta National Hospital transplant clinic. During this period medical files of 286 donors that were evaluated during the period between, January 2010 and September 2018, were obtained. From these medical files, 165 medical files belonging to donors who successfully donated kidneys to their intended recipients were excluded. A total of 121 medical files of donors who started the evaluation process but either did not complete the evaluation process or did not successfully donate to their intended recipients were included into the study as the study population.

4.1 SOCIO DEMOGRAPHIC CHARACTERISTICS.

The age of the study population had a normal distribution with a mean age of 33.4 years, median of 31.0 years and a mode of 29 years. The oldest donor who was dropped was 57 years of age while the youngest was 19 years of age. 64.9 % were male while 59.5 % were married. Almost all the donors had some form of formal education with the majority (69.3 %) having attained post primary education (Table 7)

Since organ donation is usually from living related donors, first degree relatives (siblings, parents and children) formed the bulk of dropped donors with majority (46.8%) being siblings to their intended recipients. Alcohol intake was not rampant in these donors with only 1 out of 10 donors reporting alcohol intake, that was however not clinically significant (intake of less than 5 standard drinks per week). Most of the donors (95.5%) were nonsmokers (Table 8).

4.2 SELF REPORTED PREVALENT CO MORBIDITIES

At the initial stages of donor evaluation (baseline), only one donor gave a positive history of having hypertension that was well controlled on medication. None of the other donors reported to have a previous or ongoing significant medical condition (Table 9)

Table 8. Socio-demographic characteristics of the study population

Variable	Frequency (%)
Age	
Mean age (SD)	33.4 (9.1)
Media (IQR)	31.0 (27.0-40.0)
Min-Max	19.0-57.0
Mode	29
Gender	
Female	39 (35.1)
Male	72 (64.9)
Formal education	
None	2 (1.8)
Primary	27 (24.3)
Secondary	40 (36.0)
Tertiary	37 (33.3)
Missing	5 (4.5)
Marital status	
Married	66 (59.5)
Single	42 (37.8)
Divorce	1 (0.9)
Separated	1 (0.9)
Widowed	1 (0.9)
Relationship to the potential recipient	
Sibling	52 (46.8)
Parent	12 (10.8)
Friend	1 (0.9)
Child	10 (9.0)
Spouse	1 (0.9)
Cousin	11 (9.9)
Fiancé	1 (0.9)
Nephew	5 (4.5)
Niece	2 (1.8)
Uncle	3 (2.7)
Missing	13 (11.7)
Current smoker	
Yes	5 (4.5)
No	106 (95.5)
Current intake of alcohol	
Yes	11 (9.9)
No	100 (90.1)
Amount of alcohol intake (n=11)	
<5 standard drinks/week	9 (81.8)
≥5 standard drinks/ week	2 (18.2)

Table 9: Prevalence of co – morbidities in the study population

Variable	Frequency (%)
Diabetes	0
Hypertension	1 (0.9)
Hyperlipidemia	0
Stoke	0
PVD	0
Malignancy	0
Bleeding disorder	0
Psychiatric condition	0

4.3 RATE OF DONOR DROP OUT AND REASONS FOR DONOR EXCLUSION.

Out of the two hundred and eighty six donors who were evaluated during the period of interest, 121 donors did not successfully donate to their intended recipients. This translated to a donor dropout rate of 42.3%. (figure2). The most common reason for donor drop out was a medical contraindication, which accounted for 52.3% of donors who were excluded. Donors were also excluded because of psychosocial reason (22.5%) which included, failure to attend clinic, ongoing substance abuse that the donor was not willing to stop and a change of mind not to donate, during the evaluation process. Immunological contraindications to donation accounted for 7.2% of the donor dropout rate, and only two donors were excluded due to a surgical contraindication. Other reasons for non donation (19.8%) were related to the intended organ recipient and included, recipient demise (10 donors), severe cardiovascular disease that rendered the recipient not transplantable (9 donors) or in other cases the availability of a more suitable donor (5 donors) (Figure 3, Table 10)

Figure 2 Living Kidney Donor evaluation Outcomes

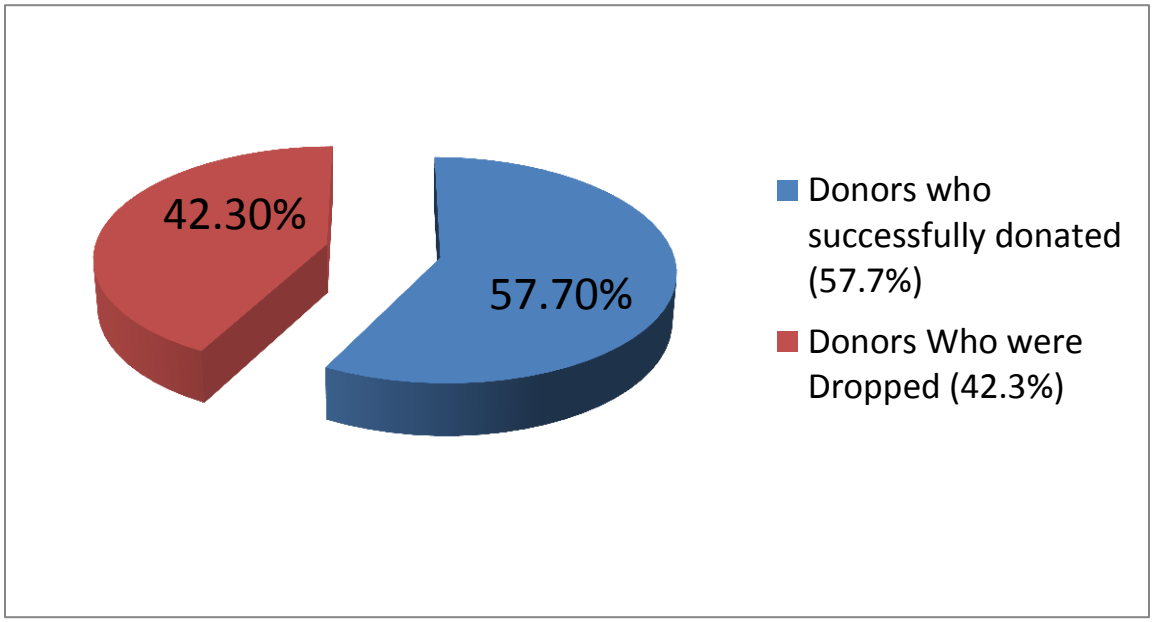


Figure 3. Documented reasons for Donor drop out.

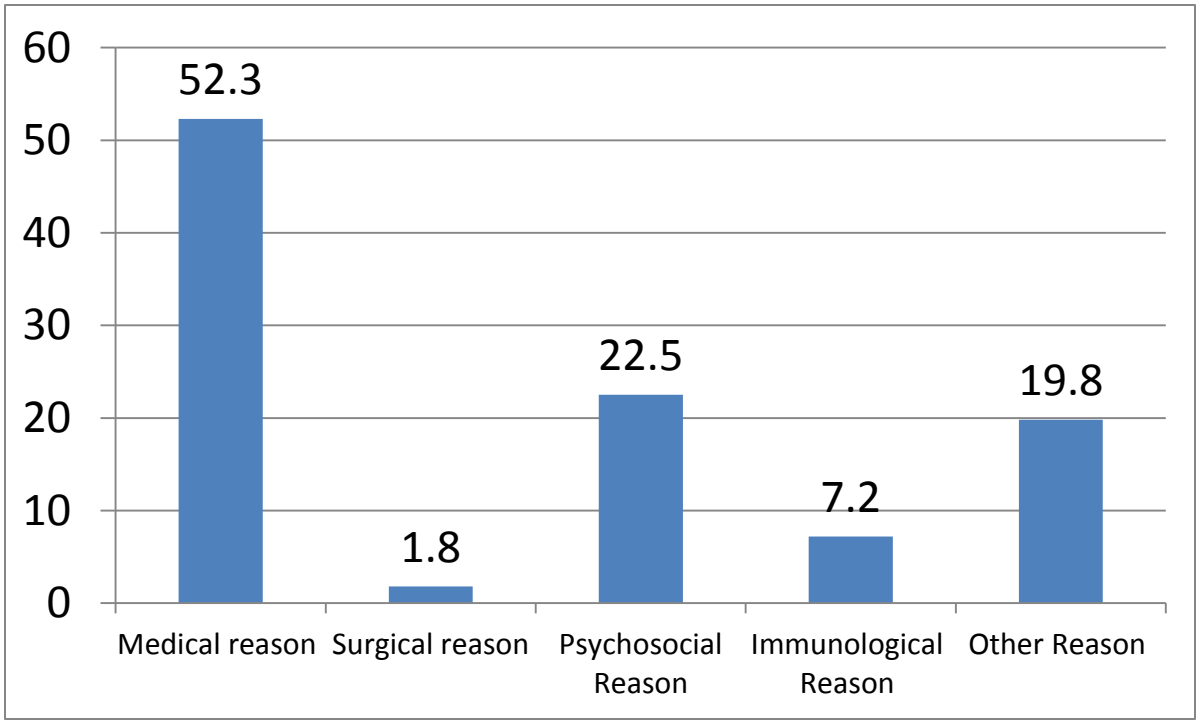


Table 10 Other reasons for donor exclusion.

Variable	Frequency (%)
Recipient death Recipient not transplantable Availability of another suitable donor	10 (41.6) 9 (37.6) 5 (20.8)

Since a medical contraindication was the most common reason for donor exclusion, the various documented medical reasons that contributed to donor drop out were analysed..

Previously undiagnosed hypertension, diabetes and renal disease accounted for 24.1%. 22.4% and 29.3% respectively (Table 11)

Table 11. Various Medical reasons for donor exclusion

Variable	**Frequency (%)**
Renal disease	**17 (29.3)**
Hypertension	**14 (24.1)**
Diabetes	**13 (22.4)**
CMV	5 (4.5)
HIV	3 (2.7)
Heart disease	3 (2.7)
Dyslipidemia	3 (2.7)
Malignancy	2 (1.8)
Pregnancy	2 (1.8)
Obesity	2 (1.8)
Peptic ulcer disease	1 (0.9)
Asthma	1 (0.9)
Hepatitis B	1 (0.9)

4.4 STAGES OF DONOR EXCLUSION.

The donor evaluation process is staged and at each stage a donor has the potential of being excluded. In this study, over half of the excluded donors (56.4%) were dropped in the early stages of the donor evaluation process that is, during baseline evaluation and prior to assessment of renal function (stage 1 to stage 3). Of these 20% were excluded in stage1, 10.9% excluded in stage 2, while 25.5% were excluded in stage 3 (Table 12)

Table 12. Stage at which donors dropped out.

Variable	Frequency (%)	95 % CI
Stage 1	22 (20.0)	13.6-28.2
Stage 2	12 (10.9)	5.5-16.4
Stage 3	28 (25.5)	18.2-33.6
Stage 4	14 (12.7)	7.3-19.1
Stage 5	13 (11.8)	6.4-18.2
Stage 6	6 (5.5)	1.8-10.0
Stage 7	15 (13.6)	7.3-20.0

4.5 HOSPITAL VISITS AND DURATION OF TIME BETWEEN ENROLMENT OF POTENTIAL DONOR AND TIME OF DROP OUT.

The efficacy of the donor evaluation process was assessed by documenting the number of visits made by donors and also the duration of time taken between donor enrollment and donor drop out. Majority of the donors (75.7%) made between one to four visits prior to exclusion, while only a minority (2.7%), made greater than 8 visits before being excluded (Table 12). The mean duration of time between donor enrollment into the transplant evaluation process and donor exclusion was 33.7 weeks with a median of 2.5 weeks. The shortest time taken before a donor was dropped during the evaluation period was less than a week with the longest duration being almost 78 weeks (one and a half years) (Table 14)

Table 13. Documented hospital visits prior to donor exclusion

Number	Frequency (%)
1-4 visits	86 (77.5)
5-8 visit	22 (19.8)
> 8 visits	3 (2.7)

Table 14. Mean duration of time (weeks) between donor enrolment and donor Exclusion.

	Mean (SD)	Median (IQR)	Min- Max
Duration in weeks	33.7 (84.8)	2.5 (0-7.0)	0 - 78.7

4.6 ASSOCIATION OF VARIABLES.

Bivariate analysis was done to explore the association between medical, surgical and psychosocial reasons for donor drop out and some selected demographic and patient characteristics.

There was no association detected between medical reasons for donor drop out and the age of donors, gender, relationship to the potential recipient, number of hospital visits made and the median duration of time taken before donor exclusion (Table 15)

Donors excluded because of other reasons (recipient death, recipient not transplantable and the availability of another more suitable donor) were less likely to be second degree relatives and this was statistically significant at a p value of 0.048. They were also more likely to be younger (30.1yeras vs 34.2 years) but this did not reach statistical significance (Table 16).

Table 15. Factors associated with medical reason for donor drop out

Variable	Medical reason		OR (95 % CI)	P value
	Yes	No		
Mean age in years (SD)	34.5 (9.7)	32.3 (8.3)		0.219
Gender				
Female	24 (61.5)	15 (38.5)	1.8 (0.8-4.0)	0.149
Male	34 (47.2)	38 (52.8)	1.0	
Relationship to potential recipient				
1st degree	33 (44.6)	41 (55.4)	1.0	0.887
2nd degree	9 (42.9)	12 (57.1)	0.9 (0.4-2.5)	0.059
Others	3 (100.0)	0	-	
Median duration (weeks) before donor drop out (IQR)	12.1 (3.0-32.0)	14.6 (0.6-39.2)	-	0.911
Number of hospital visits made	41 (48.8)	43 (51.2)	1.0 (0.1-15.8)	0.973
1-4 visits	14 (66.7)	7 (33.3)	2.0 (0.1-37.0)	0.641
5-8 visit	1 (50.0)	1 (50.0)	1.0	
> 8 visits				

Table 16. Factors associated with other reasons for donor drop out

Variable	Other reasons		OR (95 % CI)	P value
	Yes	No		
Mean age in years (SD)	30.1 (6.8)	34.2 (9.4)		0.054
Gender				
Female	7 (17.9)	32 (82.1)	0.8 (0.3-2.3)	0.716
Male	15 (20.8)	57 (79.2)	1.0	
Relationship to potential recipient	18 (24.3)	56 (75.7)	1.0	
1st degree	1 (4.8)	20 (95.2)	0.2 (0-1.2)	0.048
2nd degree	1 (33.3)	2 (66.7)	1.6 (0.1-18.2)	0.723
Others				
Median duration (weeks) before donor drop out (IQR)	21.8 (0.5-49.6)	9.0 (2.1-29.9)		0.423
Number of hospital visits made	16 (19.0)	68 (81.0)	0.2 (0-4.0)	0.315
1-4 visits	5 (23.8)	16 (76.2)	0.3 (0-6.0)	0.439
5-8 visit	1 (50.0)	1 (50.0)	1.0	
> 8 visits				

There was also nil association between psychosocial reasons for donor exclusion and donor age, gender, relationship to potential recipient, number of hospital visits made and median duration between donor enrolment and donor exclusion (Table 17)

Table 17. Factors associated with Psycho social reason for donor drop out

Variable	**Psychosocial reason**		**OR (95 % CI)**	**P value**
	Yes	**No**		
Mean age in years (SD)	35.6 (8.7)	32.8 (9.2)	-	0.185
Gender				
Female	7 (17.9)	32 (82.1)	0.7 (0.3-1.7)	0.396
Male	18 (25.0)	54 (75.0)	1.0	
Relationship to potential recipient			1.0	1.0
1st degree	59 (79.7)	15 (20.3)	1.1 (0.3-3.7)	0.902
2nd degree	17 (81.0)	4 (19.0)	0.1 (0-1.5)	0.057
Others	1 (33.3)	2 (66.7)		
Median duration (weeks) before donor drop out (IQR)	8.5 (2.3-52.1)	12.1 (2.0-27.7)	-	0.831
Number of hospital visits made				
1-4 visits	22 (26.2)	62 (73.8)	1.0	
5-8 visit	2 (9.5)	19 (90.5)	0.3 (0.1-1.4)	0.121
> 8 visits	0	2 (100.0)	-	0.999

CHAPTER FIVE: DISCUSSION.

Living donor kidney transplant offers better outcomes with regards to graft survival and function compared to deceased donor transplant. In this study we report the magnitude of living donor drop out (exclusion), and the documented reasons for donor exclusion, in kidney donors undergoing evaluation in a single national referral center in Kenya, The Kenyatta National Hospital.

The excluded donor population was fairly young, predominantly male and literate with majority having formal education. Since currently only provisions for living related donation are available and therefore only living related donors undergo evaluation for donation, this was reflected in the relationship of excluded donors to their intended recipients. Majority were first degree relatives with siblings forming the bulk of donors. Ongoing smoking and significant alcohol intake was very low in this population and so were self-reported prevalent co morbidities that have an implication on donation or are absolute contraindications to donation like diabetes, hypertension, malignancy and ongoing psychiatric conditions.

We report a lower donor dropout rate than some of the studies done in other centers that had an attrition rate of up to 83%, but also compares to some centers whose attrition rate was in the range 44.2% to 57%. Possible explanation for our lower attrition rate could be the difference in the donor evaluation process between our center and other centers. While in other centers like the Irish kidney donor program experience reported by Connaughton et al, donors are not preselected prior to initiation of the donor evaluation process, our donor population is highly preselected prior to initiation of the donor evaluation process. Education and counselling on the donor requirements and evaluation process is usually done to the patient and family prior to selection of a potential donor. With such information the family members who would be potential donors are already aware of some of the requirements and contraindications to donation even before enrolment into the transplant program. Therefore, some potential donors who are aware that they may have a contraindication to donation, eliminate themselves even prior to starting the evaluation process rendering the ones who actually do start the process less

likely to be excluded. This high preselection of our donor population would also explain why there were almost no prevalent self-reported co morbidities at the initial stages of evaluation as only one donor reported to have well controlled hypertension.

Another potential contribution to the difference in the rate of donor drop out is the type of transplant in practice in different centers. While we practice only living related donation, centers like University of Cape Town, department of surgery, as reported by McCurdie et al, practice both deceased donor and cadaveric donor transplantation. For this center the living donor dropout rate was high (83%) compared to our rate that was lower, at 42.3%). Some of their living donors (22%) were excluded not because they did not meet the criteria for donation but because a cadaveric organ or another suitable donor was available for their intended recipient.

A medical contraindication formed the bulk of our excluded donors accounting for 52.3% of the rate of donor drop out. Similarly in other published data a medical contraindication forms the bulk of donors who are excluded and this ranges from 60% - 68%. Donor evaluation guidelines in use in most transplant centers provide a framework of absolute and relative contraindication to donation and majority of them lie in the medical category. Therefore it is highly likely that if a transplant center follows these guidelines majority of the potential donors will be excluded because of a medical reason therefore explaining the similarity in these findings across different centers. The rate reported in this study is however slightly lower probably because of our highly preselected donor population as previously mentioned.

Out of the medical contraindications, previously undiagnosed hypertension, diabetes and renal disease collectively accounted for the highest percentage of reasons for non donation. This reflects the rising incidence of non communicable diseases (NCDs) as opposed to infectious conditions, in our donor population who are deemed to be potentially healthy. And considering our population was highly preselected at the onset of donor evaluation, this means that these donors were unaware that they had a condition that can potentially cause renal disease or already had renal disease yet they were willing to donate. Some of the donors excluded also had more than one incident medical

condition, for example diabetes with hypertension or hypertension with renal disease. This documentation puts emphasis on the need for transplant centers to adhere to donor evaluation guidelines and to be keen on conditions that may lead to renal disease and the possibility of ESRD in donors post donation.

Almost a third (29.3%) of donors dropped because of a medical contraindication , had newly diagnosed renal disease either in the form of decreased glomerular filtration rate, nephrolithiasis, persistent proteinuria and/ or glomerular hematuria or renal cysts. Considering that the practice in our center is that of living related donation, this may be reflective of published data that has alluded that chronic kidney disease has a familial predisposition with some conditions like polycystic kidney disease and Alports disease having a well-established pattern of Mendelian inheritance. Also genetic variants in the apolipoprotein L – 1(APOL1) confer a high risk for hypertensive nephrosclerosis and Focal segmental glomerulosclerosis (FSGS) especially in the black population.

For hypertension, literature suggests that some transplant centers do not exclude donors well controlled on less than 2 anti-hypertensives, however in our center all donors with hypertension regardless of their treatment status were excluded. This is because of paucity of data regarding the impact of donor nephrectomy on the risk of renal disease in hypertensive donors post donation, making it difficult to draw definite conclusions.

Diabetes and pre diabetes confers a higher risk of diabetic nephropathy in donors post nephrectomy compared to the general population. In our study out of the 58 donors excluded because of medical reasons, 13 were excluded because of newly diagnosed diabetes or pre diabetes. Potential donors with a family history of diabetes also have a high risk (30%) of developing diabetes over 5 years hence caution should be employed when selecting donors especially in centers that practice mainly living related kidney donation.

Psychosocial aspects of donor drop out accounted for 22% of donors excluded. The reasons included failure to attend clinic, change of mind during the evaluation process and ongoing abuse of alcohol or other drugs (without the willingness or motivation to stop). The failure to attend clinic maybe a reflection of financial constraints because a

majority of our patients have no health cover that caters for investigations, consultation charges or even travel and accommodation expenses incurred during the evaluation process and therefore have to finance their own evaluation(for both donor and recipient). This may put a heavy financial burden on them making them inconsistent in their clinic visits

Other reasons for donor exclusion included recipient related issues (recipient death during the evaluation process, severe recipient cardiovascular disease that does not allow transplantation) and the availability of a more suitable donor (in the case where a recipient had more than one potential donor and the excluded one was less suitable for example a younger female donor compared to an older male donor). In this scenario the donors were in good health and met the criteria for donation but their intended recipients were not suitable for transplantation. Cardiovascular disease remains a major known cause of death in transplant recipients and is a significant barrier to improving long term outcomes in kidney transplantation. Therefore sometimes after clinical evaluation some potential kidney transplant recipients may have such a heavy burden of cardiovascular disease that even if they were transplanted, there would not be any benefit in outcomes. For other patients the burden is so high that they are either an anesthetic risk or undergo demise even before the process of donor evaluation is completed.

Majority of the donors (77.5%) made one to four visits to the transplant clinic prior to exclusion meaning that for a majority of our cases there was no delay in determining if a potential donor was eligible for donation or not. This may reflect the efficiency of the donor evaluation process. For the ones who made more visits, it may have been necessary especially if additional investigations were required to fully establish that a potential donor was not eligible for donation. The mean duration taken before a donor was excluded was 33.7 weeks. However the median was 2.5 weeks with an inter quartile range of less than a week to 7 weeks. This shows that there were a number of donors in the upper quartile who took a significant amount of time (maximum was 78.7 weeks) before being excluded. This could reflect donors to recipients who needed additional care or a longer time to reduce their cardiovascular risk burden. This is for example in a case of optimizing dialysis in a transplant candidate to reduce severe pulmonary hypertension

with an aim of making them more suitable transplant candidates (which may not have been successful hence their donors were excluded) or donors who may have needed additional time to for example achieve suitable BMI (even if this may have not been successful hence the exclusion)

This retrospective study has its limitations in that since it was an audit of medical records, some records may have been incomplete. However we believe this may not have affected the validity of the study as any missing data did not have an impact on the achievement of the primary objectives of the study.

Secondly a direct comparison to other studies about donor evaluation may be difficult because of differences in our baseline donor population (which was somewhat preselected), and some differences in donor eligibility criteria. However despite these limitations we believe our study is important as it reflects our real experience in evaluating potential donors and we believe this can be a resource to other centers in the country doing live kidney donor assessment.

CONCLUSION.

In conclusion, we report a moderate rate of donor drop out in our transplant center. The most common reason for exclusion was a medical contraindication, with hypertension, diabetes and renal disease being the most prevalent medical conditions. A surgical contraindication was the least prevalent reason for donor drop out.

RECOMMENADTIONS

Following this study, we recommend the following:

Strengthening of the dialysis clinic (from which potential recipients are identified from). This will help in identifying potential recipients early before they develop significant cardiovascular disease that would render them otherwise not transplantable.

Follow up of donors (possibly with a phone call) who do not come to the clinic on their scheduled date of return for the next step of the evaluation process. This will enable the transplant coordinator identify donors who are taking too long to complete the evaluation process and more importantly identify the reasons why.

Counselling for donors should continue throughout the donor evaluation process. This will cater for psychosocial reasons of donor drop out for example, change of mind and ongoing substance abuse, therefore reducing the overall door dropout rate.

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APPENDIX 1 DATA COLLECTION TOOL

Serial Number

Date of enrollment into the transplant evaluation process

Socio Demographics/PATIENT DETAILS

1. Age ☐☐ yrs
2. Gender ○ Female ○ Male
3. County of Residence in last 5 yrs_____
4. Formal educational Yes ○ No ○
5. Occupation/employment _____
6. Marital status_____
7. Relationship to the potential recipient _____
8. Current Smoker ☐ Yes ☐ No
9. Current Intake of alcohol ☐ Yes ☐ No
10. If yes to above: Intake of < 5 standard units in a single day ☐ Yes
    Intake of 5 or more standard units in a single day ☐ Yes

Previous medical History at Time of Evaluation

Diabetes ☐ Yes ☐ No

☐ Diet ☐ Oral ☐ Insulin

Hypertension ☐ Yes ☐ No ☐ Don't Know

Hyperlipidemia ☐ Yes ☐ No ☐ Don't Know

Stroke ☐ Yes ☐ No

PVD ☐ Yes ☐ No

Malignancy ☐ Yes ☐ No

Bleeding disorder ☐ Yes ☐ No

Psychiatric condition ☐ Yes ☐ No

Clinical Findings

Blood pressure (mm/Hg) **Heart rate (beats/min)** **BMI**

☐☐☐/☐☐☐ ☐☐☐ ☐☐☐

Significant Physical Examination findings

Laboratory Investigations

Lab	Value	Units		Lab	Value	Units
Creatinine	_____			Uric Acid		
BUN / Urea	_____			AST		
Sodium	_____			ALT		
Potassium	_____			Albumin		
Calcium	_____			GGT		
Phosphate	_____			ALP		
Platelets				Total bilirubin		
Total WBC	_____			Total Cholesterol		
Hemoglobin				Triglycerides		
Fasting blood Glucose				HDL		
Blood group				LDL		

Urinalysis

Ph.	
Specific Gravity	
Protein	
Glucose	
Blood	
Ketones	
Pus cells	

Microscopy	

OGTT

CMV IgG Positive ◯ Negative ◯

CMV IgM Positive ◯ Negative ◯

CMV PCR

T cell crossmatch Positive ◯ Negative ◯

HLA Match

Imaging

KUB ultrasound

DTPA

Total GFR	
Left Kidney	
Right Kidney	

ECG

Echocardiography

Chest X-ray

CT Angiogram

Final Documented reason(s) for donor exclusion

Date of Donor Exclusion

Stage of donor exclusion

Number of documented hospital visits prior to donor exclusion.

APPENDIX 2: KENYATTA NATIONAL HOSPITAL - RENAL UNIT: RECIPIENT / DONOR EVALUATION FORM

RECIPIENT		
NAME…… IP NO…… AGE……SEX…… WT……HT……BMI……BP……..		
STAGE 1	Counseling Consent Nutritionist History taking	
STAGE 2	Blood group HIV HBV HCV	
	UREA CREATININE K,NA,CA,PO4 URIC ACID HB WBC, PLT, ESR FBS URINALYSIS LFT, PTH LIPID PROFILE CMV IGG /IGM	
STAGE 3	KUB U/S DOPPLER U/S OF FEMORALS/ILIACS PLAIN ABD XRAY	 RT KID LT KID
STAGE 4	HLA	A B DR DQ TCELL XMATCH
STAGE 5	CT ANGIOGRAM* CXR ECG/ECHO STOOL O/C MCU PAP/ PDT/PSA	
STAGE 6	PROPOSED DATE **(multidisciplinary team meeting)** PRE OP WORKUP	
*CT angiogram if >40years; Doppler U/S if <40years		

DONOR		
NAME…… IP NO…… AGE……SEX…… WT……HT……BMI……BP……		
STAGE 1	Counseling Consent Nutritionist History taking	
STAGE 2	Blood group HIV HBV HCV	
STAGE 3	UREA CREATININE K,NA,CA,PO4 URIC ACID HB WBC, PLT, ESR OGTT URINALYSIS LFT LIPID PROFILE CMV/ IGG/IGM	
STAGE 4	KUB U/S CHEST XRAY - DTPA	24-HR CREAT CLEARANCE RT LT
STAGE 5	HLA	A B DR DQ TCELL XMATCH
STAGE 6	CT ANGIOGRAM ECG/ECHO	
STAGE 7	PROPOSED DATE **(Multidisciplinary team meeting)** PRE OP WORKUP	
CT angiogram (aorta/iliac/femoral include venous phase)		