Maine Medical Center
Maine Transplant Program
Policies and Procedures
Selection Criteria for Transplantation and Living Kidney Donation

Purpose

To define the process by which the Inclusion and Exclusion Criteria for Kidney Transplantation and Living Kidney Donation is developed and implemented in accordance with relevant clinical practice guidelines, hospital institutional policy, and regulatory requirements.

Policy

It is the policy of the Maine Medical Center that formal hospital approved Inclusion and Exclusion Criteria will be developed and utilized in a consistent, fair, and non-discriminatory manner to select candidates and living donors who are most suitable for transplantation and kidney donation. These Criteria will be evidence based, and utilized uniformly in the selection of candidates and living kidney donors.

Procedures

1. Transplant Program medical leadership will be responsible for the development of Inclusion and Exclusion Criteria using knowledge of clinical research, practices, and outcomes.

2. Inclusion and Exclusion Criteria will clearly define all factors that are considered in determining suitability for transplantation or living donation. Groups or individuals of groups will not be excluded from consideration without clinical support for the exclusion.

3. For candidates that are placed on the transplant program’s waiting list outside of the Inclusion Criteria, documentation will be included in the Committee note to support the exception.

4. Specific Inclusion and Exclusion Criteria will be formally codified in a Policy and Procedure and publicly available on the Program’s website and on the MMC Policy and Procedure.

5. Inclusion and Exclusion Criteria will be available upon request by referring physicians and dialysis centers.

6. The Criteria will be approved by the Maine Medical Center Institutional Policy Review Committee. Any changes in the Criteria will be also be approved by this Committee.

7. Inclusion and Exclusion Criteria will be reviewed by the Transplant Quality Assessment and Performance Improvement (QAPI) Committee at least every three years.

Appendix A: Inclusion and Exclusion Criteria Kidney Transplant
Appendix B: Inclusion and Exclusion Criteria Living Donor

References: Centers for Medicare and Medicaid Services, 2019 Organ Transplant Program Interpretive Guidelines 482.90
Maine Medical Center
Policies and Procedures
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Director

Original Date: 10/11/2019

11/11/19
Date
Maine Medical Center
Transplant Program
Policies and Procedures
Inclusion and Exclusion Criteria for Kidney Transplantation

Purpose

To define the inclusion & exclusion criteria for kidney transplantation.

Policy

Organ transplantation is associated with risks due to anesthesia, surgery and immunosuppression. It is our policy to offer transplants to those candidates most likely to benefit while minimizing the risk of adverse effects and poor outcomes. The Maine Transplant Program selection criteria are therefore defined below:

Indications for transplantation:

1. ESRD (on dialysis) or eGFR<20mls/min.
2. Patient understanding of the risks and benefits associated with ESRD treatment options including dialysis and transplantation
3. Patient understanding of the essential nature of long-term immunosuppressive medications and the associated risks of serious complications including infection, malignancy and cardiovascular disease (further characterized in the “Kidney Recipient Consent for Surgery”)

Absolute Contraindications:

1. Metastatic Cancer
2. Serious conditions unlikely to be improved by transplantation as life expectancy can be finitely predicted such as:
   - Congestive Heart Failure with EF<40%
   - Active coronary artery disease not amenable to revascularization
   - Advanced COPD (hypercarbia, FEV/FVC< 80% and FEV1 < 50%, Chronic O2 use)
   - Severe pulmonary hypertension
   - Cirrhosis with portal hypertension
   - Dementia
   - Physical disability sufficiently severe to require long term skilled nursing facility placement
3. Chronic liver disease as evidenced by:
   - Decompensated liver disease
     i. Encephalopathy
     ii. Coagulopathy: INR>1.8
     iii. Hypoalbuminemia: Albumin <3.5
   - Portal Hypertension
     i. Ascites
     ii. Varices
     iii. Portal gastropathy
     iv. Splenomegaly
   - Advanced stage fibrosis
     o Cirrhosis
4. Ongoing or recurring infections
5. HIV/AIDS related complications
   • Untreated HIV viremia
   • CD4<200
   • AIDS defining diagnosis
6. Active substance abuse (see policies “Recreational Drug Use Policy” and “Narcotic Use Policy”).
7. Demonstrated patient non-adherence as evidenced by:
   • Non-attendance at dialysis or clinic visits
   • Persistent, excessive fluid weight gain
   • Persistent hyperphosphatemia (>7)
   • Persistent hyperkalemia (>6)
   • Persistent hyperparathyroidism (PTH>500)
8. Inability to tolerate immunosuppression
9. Morbid Obesity (BMI>37, see “Obesity Policy”)
10. Prior early graft failure from either:
    • Recurrence of a primary kidney disease or
    • De novo allograft disease associated with a high risk of graft failure.
11. Inadequate health care insurance
12. Inability to travel to and attend clinic after transplantation.
13. Uncontrolled psychiatric disorders.

Modifiable risk factors to be addressed prior to transplantation

1. Coronary Heart Disease – Minimum criteria include:
   • EF to exceed 40%
   • Asymptomatic
   • Revascularization as clinically indicated
   • Compliance with medical regimen
   • Tobacco cessation
2. Peripheral Vascular Disease – Minimum criteria include:
   • Free of active infection, ulceration and rest pain
   • Revascularization as clinically indicated
   • Tobacco cessation
3. Cerebrovascular Disease – Minimum criteria include:
   • Non critical carotid artery disease
   • Revascularization as clinically indicated
   • Tobacco cessation
4. Peptic Ulcer Disease – Minimum criteria include:
   • Asymptomatic
   • No recent bleeding (<6 mos)
   • On PPI or H2 blocker therapy
5. Chronic Lung Disease – Minimum criteria include:
   • Needs to be supplemental O2 free
   • Negative CT chest if age>55 and tobacco use exceeded 30 pack years
- FEV/FVC > 80% and FEV1 > 50%
- Tobacco cessation

6. Chronic active hepatitis B/C – Minimum criteria include:
   - No evidence of cirrhosis on liver biopsy
   - No evidence of hepatocellular carcinoma on imaging
   - Needs to be actively seeing hepatology
   - Needs to be adherent with regimen
   - Hepatitis B Viremia needs to be controlled with therapy
     - HBV: lamivudine/adevirov/entecavir
   - Hepatitis C treatment may be recommended either before or after transplantation

7. Malignancy – Minimum criteria include:
   - Needs to be in full remission confirmed with current appropriate imaging
   - Minimum duration depends on type of malignancy – refer to MTP policy “Malignancy Prior to Transplantation” for specific requirements

8. Obesity – Minimum criteria include:
   - BMI>30-37 is regarded as a risk factor for complications (see “Obesity Policy”).
   - Patient may be advised to reduce weight
   - May be an absolute contraindication if numerous other issues co-exist.

9. Physical Disability
   - Regarded as a risk factor for complications
   - The patient must be able to attend clinic post surgery
   - Rehabilitation may be indicated before a decision can be made about a debilitated individual’s candidacy for transplantation

10. Diabetes Mellitus – Goals include:
    - Needs to check finger stick sugars at least twice a day
    - HbA1c level less than 8%
    - Tobacco cessation

11. Psychiatric Disorders (defined by the presence of psychiatric diagnoses or Rx psychototropic medications) – Minimum criteria include:
    - Consultation with psychiatry at MMC is REQUIRED in order to manage peritransplant issues
    - Symptoms must be adequately controlled with appropriate medication for at least 6 months
    - Patient must have an ongoing relationship with a local psychiatric care provider
    - Patient must be adherent to their psychotropic medications

12. Malnutrition – Minimum Criteria include:
    - Needs dietary intervention for Albumen < 3.5g/dl
    - Minimum Albumin to exceed 3g/dl

13. Sustained suboptimal adherence with CKD/ESRD care defined by the following parameters for 3 or more months:
    - Uncontrolled Hyperparathyroidism defined as PTH>500ng/ml
    - Uncontrolled hyperphosphatemia defined as Phos persistent >7 mg/dl
    - Uncontrolled hyperkalemia defined as K persistently >6meq/l
• Excessive fluid weight gain between dialysis treatments defined as >3kg wt gains
• Persistently uncontrolled hypertension defined as greater than 150/90 at then end of dialysis treatments
• Premature signing off dialysis treatments
• Dialysis non attendance

The individual risk factors described may increase the risk of complications, graft failure and death after transplantation although may not be permanent barriers to transplantation. Regardless, such issues need to be optimized prior to transplantation in order to enhance post transplant outcomes. The presence of multiple such risk factors may collectively exclude a patient from transplantation.

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Director

5/17/18
Date

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Inclusion Criteria

1. Voluntary and appropriate altruistic motivation,
2. Normal renal function (creatinine clearance above 85 ml/min on two separate occasions)
3. Donor capable of understanding "Living Donor Evaluation Consent" which reviews risks associated with donation and complications

Absolute Contraindications

1. Is both less than 18 years old and mentally incapable of making an informed decision* (Age 18-24 requires documentation that the donor's maturity level has been addressed)
2. Diabetes Mellitus (either by fasting glucose, 2 hr GTT or HbA1C > 6.5%)
3. Stage 1 CKD as evidenced by unexplained proteinuria or hematuria
4. Hypertension
   a. HTN uncontrolled with a single medication
   b. HTN with end-organ damage (LVH by ECHO, microalbuminuria, retinopathy)
   c. HTN under age 50
   d. HTN in minority populations
   e. HTN with other cardiovascular risk factors (dyslipidemia, tobacco use, overweight, family history or cardiovascular disease)
5. History of nephrolithiasis with large stone burden (5 mm), abnormal metabolic profile (serum or urine) or age below 40
6. Active malignancy, or incompletely treated malignancy*
7. History of cancer within last 5 years (other than minor skin malignancies)
8. History of melanoma at any time
9. Active substance abuse including heavy ongoing alcohol use
10. Morbid obesity (BMI > 35 mg/m²)
11. Coronary artery disease or valvular heart disease associated with increased risk of surgery
12. Major neurological conditions (e.g., cerebrovascular accident, multiple sclerosis)
13. Connective tissue diseases (e.g., lupus erythematosus, scleroderma)
14. Hematological conditions (sickle cell anemia, thalassemia)
15. Significant liver disease with synthetic and functional abnormalities
16. Psychosocial Issues
   a. Psychiatric illnesses that prevent the donor from understanding the process of informed consent and risks associated with surgery
   b. Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality*
   c. Evidence of suicide risk*
   d. High suspicion of donor coercion*
17. Infectious conditions that not only pose an increased risk for donor, but might be transmissible to the recipient through donation
   a. Hepatitis C antibody positivity
   b. HIV, unless the requirements for a variance are met, according to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* 
   c. Hepatitis B antigen positive
   d. Untreated TB
18. Evidence of acute symptomatic infection (until resolved)*American Society of Anesthesiologists Physical Status (ASA PS) score 3 or greater
19. High suspicion of illegal financial exchange between donor and recipient
20. Pregnancy in last 6 months, or plan to become pregnant in next 6 months
21. Any disease requiring treatment with renal toxic medication
22. Refusal to consent for blood products

Relative Contraindications
1. Glucose intolerance (either by elevated fasting glucose, 2 hr GTT or HbA1C)
2. Chronic pain which requires treatment with non-steroid anti-inflammatory drugs
3. Certain malignancies > 5 years in remission — Will be reviewed case by case basis
4. Hepatitis B core Antibody positive
5. Evidence of atherosclerosis on angiogram
6. Steatohepatitis
7. Heavy tobacco use with pulmonary function test abnormalities
8. History of thromboembolic disease (pulmonary embolism, deep vein thrombosis)
9. Peripheral vascular disease, aortic atherosclerosis, aortic aneurysm
10. For females only: Inability to stop hormone replacement therapy or hormonal contraception
11. Other medical conditions, that in the opinion of the donor advocate and/or transplant surgeons,
   place the donor at an unacceptable risk for medical problems either during surgery or short-term and
   long-term post donation.

*Items that are asterisked are stated in the exclusion criteria for all living donors per UNOS Living Donation
  policy 14.4.D

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2/13/19

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