



**Kidney Transplant Program
Children's National Hospital**

SUBJECT: Selection Criteria and Evaluation Process for Transplant

PROCEDURE: KI.102

DATE EFFECTIVE: 06/26/2007

PAGE: 1 of 6

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POLICY: Patients will be evaluated under the direction of a transplant physician. Pre-transplant education will be offered to patients and their families by members of the transplant team. All potential transplant recipients will be selected based on medical indications and contraindications. All patients and families will be treated fairly and equally regardless of their age, race, ethnicity, orientation, disability, sexual orientation or any other unique attributes and none of these affect selection criteria. This is consistent with the hospital's anti-discrimination policy.

PURPOSE: To ensure that the transplant patient is medically and surgically suitable for transplant and to educate patients and their families about organ transplantation so that they can make an informed decision about transplantation

PROCEDURE

INDICATIONS FOR KIDNEY TRANSPLANT

1. Patient with ESRD on chronic dialysis and younger than 19 years of age.
 - a. Patients ≥ 19 years old, will be referred to an adult transplant center unless there are extenuating circumstances requiring evaluation at Children's National.
2. Chronic kidney disease with estimated GFR of less than $20\text{ml}/\text{min}/1.73\text{m}^2$ as measured by appropriate formula.
 - a. For patients < 18 years old updated Schwartz equation will be used for creatinine measured by enzymatic method calibrated to IDMS. MDRD equation will be used for patients > 18 years of age.
3. Patients with a GFR $> 20\text{ml}/\text{min}/1.73\text{m}^2$ can be referred for pre-transplant evaluation. They can proceed with work up and can be listed as status 7 and will be made active upon reaching a GFR of $\leq 20\text{ ml}/\text{min}/1.73\text{m}^2$. Patients can be made status 1 with GFR $> 20\text{ml}/\text{min}/1.73\text{m}^2$, if there is clinical indication for early transplant.

ABSOLUTE CONTRAINDICATIONS TO KIDNEY TRANSPLANTATION

1. Current acute infection (may be considered for transplant once infection is resolved).
2. Untreated malignancy
3. Patients with Oxalosis and other genetic disorders may not be a candidate for kidney transplant alone and might benefit from multi visceral transplant. Genetic input would be sought.
4. Life-limiting co-existing medical conditions: advanced cardiac, pulmonary, neurologic or other systemic disease.
5. Pregnancy
6. Persistent vegetative state
 - a. A vegetative state is considered persistent if it is present for > 1 month and can be defined as "a

- clinical condition of unawareness of self and environment, in which the patient breathes spontaneously, has a stable circulation, and shows cycles of eye closure and opening [that] may simulate sleep and waking" [Working Group of Royal College Physicians, "The Permanent Vegetative State," The Journal of the Royal College of Physicians 430 (1996):119-21].*
- b. Neurology and ethical consults will be sought to consider the child's quality-of-life issues within the context of an overall treatment plan. (Recovery of consciousness from a posttraumatic persistent vegetative state is exceedingly rare after 12 months and from a non-traumatic persistent vegetative state after 3 months in both adults and children).

RELATIVE CONTRAINDICATIONS TO KIDNEY TRANSPLANTATION

Relative contraindications are medical conditions or factors that have the potential to significantly diminish the likelihood of a successful transplant. The presence of one or several relative contraindications may exclude a patient from transplant candidacy at the current time. However, due to the highly complex medical situations of each potential transplant patient, each child will be assessed individually with regard to these concerns. Some relative contraindications are reversible or temporary and may only affect candidacy for a limited period of time. Relative contraindications to kidney transplant at Children's National are listed and described below.

1. Etiology of ESRD:

- a. Active autoimmune disease such as systemic lupus erythematosus or anti- glomerular basement (GBM) disease, or Membranoproliferative Glomerulonephritis (MPGN).
- b. Recurrent early Focal Segmental Glomerulosclerosis (FSGS) in a previous transplant which was refractory to therapy leading to graft failure in less than 3 years.

2. Chronic Infections:

- a. Hepatitis B virus: seek input from GI and ID to see if it can be successfully treated.
 - b. Hepatitis C virus: Patient to be referred to GI and ID to see if it can be successfully treated. Chronic, active hepatitis and advanced cirrhosis are contraindications to renal transplant alone. In the absence of these, attempts to be made to clear the virus prior to transplant with therapy. However, failure to clear the virus in itself is not a contraindication to kidney transplant alone.
 - c. HIV infection - Patient may be considered for transplant if:
 - i. HIV viral load is less than 50 copies measured by ultrasensitive PCR
 - ii. CD4 >200/ul in the previous 16 weeks
 - iii. Absence of opportunistic infections
 - iv. Stable antiretroviral regimen for the preceding 3 months (in consultation with the SIS clearance).
 - d. MAI, BKV: appropriate work-up and advance planning in consultation with ID.
 - e. Other infection but not limited to those mentioned above: Appropriate work up and advance planning in consultation with ID.
3. **History of malignancy:** The patient must complete a period of mandatory remission prior to transplant as determined with input from hematology/oncology and consistent with AST guidelines.
 4. **Chronic ventilator dependency:** Each case will be considered on case by case basis with input from the pulmonologist.
 5. **TPN dependence:** Consider if suitable for intestinal transplant in conjunction with kidney

transplantation

6. **Nutritional concerns:** The aim is to optimize the nutrition status to improve post- transplant outcomes and decrease complications related to transplant.
 - a. *Obesity:* Morbidly obese patients (BMI Z score ≥ 3.0) are poor candidates for transplantation and will be encouraged to lose weight prior to transplant. Evidence of weight loss trend or commitment to weight loss may be acceptable.
 - b. *Malnutrition:* Weight for length z score less than or equal to -2.0 (children up to 24 months) and/or body mass index (BMI) (children older than 24 months) z score is less than or equal to -2.0 on a standard growth chart.
 - c. Deceleration of growth velocity across two major percentile lines and/or decrease of more than 2 standard deviations on a CDC or WHO growth chart over a period of 3 to 6 months.
 - d. Evidence of protein malnutrition
7. **Patient size:** Age <1 year and Weight <10 kg: Child can be referred for transplant evaluation and can start work up process but would not receive transplantation until child is at least over a year old and weighs more than 10 kg. In rare instances, with the surgeon's approval, transplant can be undertaken between the weights of 9-10 kg.
8. **Psychosocial concerns:**
 - a. Lack of family support or adequate home supervision.
 - b. Adherence: Serious concerns regarding the ability of the patient to adhere successfully to the post-transplantation medical routine, as evidenced by:
 - i. Documented evidence of major non-adherence to medical management in the past that has been unresponsive to attempted intervention on the part of the medical team
 - ii. Documented evidence of inability to cope effectively with surgeries or major medical interventions.
 - c. Inability to access necessary medical resources and medical management in the future as evidenced by psychosocial barriers such as lack of insurance, unstable housing, unreliable transportation.
 - d. Parent/guardian with cognitive/psychiatric impairment that is severe enough to limit comprehension of patient's medical regimen. Alternate care arrangements/support will be explored before the child is excluded for transplantation.
 - e. Patients with CKD/ESRD who are receiving care at Children's National will be considered for transplant per CMS/UNOS guidelines as long as adequate post-transplant follow up and care can be ensured. A follow up of 1-year post- transplant at Children's National is strongly recommended.
 - f. In case, the child is determined not to be suitable for transplant at the present time, the reason for deferral and the time period after which the child can be reconsidered for transplant should be documented in the medical record. Family would receive notification of this and would be asked to call the transplant coordinator/physician to discuss and clarify if need be.

TRANSPLANT EVALUATION PROCEDURE

Evaluation in the pre-transplant clinic: All referred patients with advanced CKD/ESRD will be evaluated in the pre-transplant clinic for the purposes of assessing their suitability for kidney transplantation.

Education about transplant process: Patients and families will be educated about the surgical process of transplantation, in accordance with Children's National Hospital procedure *SO.A104P: Informed Consent for Transplant Patients*. In addition, all families will be educated about benefits of living donor transplant and Children's National Hospital's selection criteria will be provided.

Medical History: Medical history will be obtained to include the following information:

- ESRD onset and cause
- Surgical history including lines placement.
- Transfusion history
- H/O hypercoagulability in the patient and family members
- Immunization record: Age appropriate immunizations will be recommended unless contraindicated according to AJT guidelines (AJT 2013, supplement 4, volume 13, S311-317)
 - Pneumovax 23 for child over the age of 2 years, repeat once after 5 years
 - Menactra for children over the age of 2 years
- Urologic history
- Other pertinent medical history

Psychosocial Evaluation by Nephrology Social Worker: A nephrology/transplant social worker reviews any relative social history with the patient and family and identifies issues that could impact the success of a transplant from a financial, social or psychological perspective.

The social worker should evaluate the patient and family understanding of the risks and benefits of transplantation, coping abilities, and ability to adhere to the medical regimen. The evaluation may further include topics such as: family structure, family emotional support system, adaptation to illness, and general level of functioning. In addition, mental health history and history of substance abuse by either the patient or primary care provider should be recorded. These evaluation topics will illustrate each patient's ability to tolerate a transplant procedure and comply with post-operative treatment. The psychosocial evaluation will aid the medical staff with their overall consideration of whether the patient would benefit from the transplant, in light of the patient's other medical conditions or disabilities.

The psychosocial evaluation will be documented in the patient's electronic medical record and will be valid for 1 year. If patient is not transplanted within 1-year period, an addendum should be attached to validate the current suitability.

Laboratory Tests: Standard evaluation includes the following:

- ABO X 2.
- HLA typing, PRA, defining specific HLA antibodies (MGUH HLA Laboratory)
- Hematology and chemistries

- CBC with diff
- CMP
- Phosphorus
- PTH
- Other tests as medically indicated
- Serology tests, negative tests will be repeated at the time of transplant
 - CMV IgG
 - EBV IgG
 - Hepatitis B surface antibody, surface antigen, core antibody
 - Hepatitis C antibody, PCR if antibody +
 - HIV
 - Varicella
 - Antibodies to measles, mumps, rubella and hepatitis A, repeat after revaccination.
 - Pregnancy testing in females
- Tests for hypercoagulability
 - PT/PTT
 - ATIII activity (in case of nephrotic syndrome)
 - Factor VIII activity
 - Homocysteine
 - Other tests if needed as determined by Medical Director
 - Genetic mutations:
 - ✓ Prothrombin gene mutation
 - ✓ Factor V Leiden mutation

Radiologic/Diagnostic tests

- Chest x-ray
- Urologic history- referral to Urology for further evaluation and clearance. VCUG and urodynamic study may be ordered per urology recommendation.
- Renal ultrasound
- EKG
- Echocardiogram
- Doppler evaluation of IVC, aorta and iliac vessels in case of previous transplant
- MRI/MRV/CT angiogram: if Doppler evaluation is not deemed adequate and in repeat transplants

Consults as indicated

- Cardiology
- Dental evaluation to verify absence of infection/abscess (in children under the age of 5 years, dental clearance may be waived if no evidence of dental pathology).
- PPD or Quantiferon Gold: at the onset of ESRD, repeat as clinically indicated. If patient has positive tests without chest x-ray findings, treat in consultation with ID specialist.
 - Quantiferon Gold for only for patients > 5 years old
- Other services (as directed by the multidisciplinary care team)
- Ethics consult: Consider ethics consult in case of significant comorbidities and in case a difference of opinion exists between the health care providers and parents.

TRANSPLANT SELECTION COMMITTEE AND SUBSEQUENT FOLLOW-UP

- Following the pre-transplant evaluation and completion of necessary work-up, the potential transplant candidate will be discussed at the multi-disciplinary transplant selection committee meeting and a determination will be made as to whether to accept, deny or defer the potential candidate for kidney transplant.
- A letter of notification will be sent to the potential candidate/family to inform them of the committee's decision. A copy of the letter of notification will be placed in the candidate's medical record.
- Letters of deferral or denial will clearly state the reason the selection committee made the determination. In case of deferral, conditions to be satisfied and duration after which patient would be reevaluated will be mentioned. In case of denial or deferral, transplant coordinator and physician will make every attempt to meet with family face-to-face or by phone to explain reasons behind such a determination before sending the letter out.
- The transplant coordinator will notify the potential candidate's dialysis physician or nephrologist (if the patient has not yet entered dialysis) of the transplant selection committee's decision.
- Following completion of work-up, the chart would be reviewed; selection criteria documented in the chart; and patient will be listed on the United Network for Organ Sharing Network.

Patient can be listed status 7:

- If their estimated GFR is >20 ml/min/1.73m², can be activated once GFR is <20 ml/min/1.73m² or if clinical condition dictates transplant at GFR of >20 ml/mm/1.73m².
- Pending completion of urologic surgery and coagulation work up and made active upon completion of the same.

REVIEW/ REVISION DATES: 01/08/2012, 07/22/2012, 3/20/2013, 09/18/2013, 10/17/2013, 10/08/2015; 6/20/2016, 8/24/2016

APPLICABILITY

Areas where the policy and procedure applies: Children's Hospital. Persons to whom the policy and procedure applies: Inpatients, Outpatients

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