**Policy: Kidney/Pancreas Post Transplant: Management Protocol of the Renal Transplant Recipient (Outpatient)**

**Statement: Policy Statement:**

It is the policy of the Renal Transplant Program (Transplant Program) to closely monitor and appropriately manage the recipients who are transplanted by the Emory Transplant Program or are transferred into the Program for follow-up management.

**Background:**

During the first three months following transplantation, renal function may be quite labile. Complications resulting from mechanical factors, infections, toxic injuries, or immune mechanisms may occur, though timely intervention will often reverse or ameliorate the injurious effects of these hazards. Approximately 20% of patients will experience an episode of transient dysfunction. Contributing causes may include acute rejection, tacrolimus or cyclosporine nephrotoxicity, or anatomical problems with the transplant.

The majority of rejection episodes occur within the first three months post transplant. Therefore, the risk of a rejection episode is greatest in the early post-transplant course. After the three-month milestone is reached, acute rejection is relatively uncommon and most often precipitated by infection or an inadequate amount of immunosuppression. Several stages of effective management are therefore apparent: 1) immunosuppression should be greatest during the first three months, 2) clinic visits should be frequent to optimize therapeutic interventions, 3) an extensive database should be established to facilitate clinical decision-making, and 4) therapeutic intervention should proceed in a timely and logical manner.

The achievement of three months of uncomplicated and favorable renal function represents an important milestone for the transplant recipient. Most patients with renal allografts lost to irreversible acute rejection will have incurred a severe rejection episode within this period, and conversely, most recipients who have not been subjected to an episode of rejection can be expected to have a favorable prognosis. The management strategy for the period between 3 -12 months is vigilance for the occurrence of rejection, with a greater emphasis placed on the long-term consequences of immunosuppression and other toxicities related to these therapies. Infection, liver disease, malignancy (especially skin, cervical, and lymphoid neoplasms) and steroid induced complications are all potential hazards. Long term, after twelve months, cardiovascular disease supersedes infection, malignancy, and liver disease as the leading cause of mortality in patients with extended renal allograft function.

**Scope/Procedure:**

During the first year post-transplant the recipients are followed directly by the Program’s surgeons, nephrologists, and transplant coordinators in the Emory Transplant Clinic. After Year 1, the quarterly physician visits alternate between the patient’s primary care physician and the Program. By Year 2, the Program instructs transplant recipients to be seen quarterly by their local physician (if available) with annual visits to Emory. The patients are advised to have laboratory reports faxed to Emory, when performed by a laboratory in their local community. The Program reviews faxed reports with adjustments made and conveyed to the patient and primary physician as indicated.

**Administrative Responsibility**

Post-transplant management of the transplant patient is a multi-disciplinary effort performed collaboratively by the Program’s surgeons, nephrologists, transplant coordinators, mid-level practitioners, social workers and nutritionist in conjunction with the patient’s primary care provider. During the first three months post transplant, the Renal Transplant Program surgeons, Department of Surgery, Transplant Services provide the primary management of the renal transplant recipients. After three months, the transplant nephrologists, Division of Internal Medicine, Transplant Nephrology, assume the primary post-transplant management. Depending on the medical and surgical needs of the post-transplant patient and physician coverage of the Transplant Clinic, medical and surgical coverage may deviate as necessary. In those instances when patients are scheduled for laboratory work at Emory or locally, and not seen by a Program physician, laboratory reports are reviewed by a transplant coordinator daily with adjustments to immunosuppressive medications made per protocol (see Adjustments to Immunosuppressive Medications Protocol). Transplant social workers and a nutritionist are available for consultation should the transplant recipient, their family or the Program request such.

**General Guidelines for Post-Transplant Patient Management**

**First Three Months**

o **Communication**

To meet the regulatory requirements of the United Network for Organ Sharing (UNOS) the Transplant Recipient Registration form will be
submitted electronically via UNet at the time of the patient’s discharge from the hospital.

Communication with the transplant recipient’s primary physician is an integral step in building the collaborative health care team that will
manage the post-transplant recipient long-term. At the time of discharge for the transplant admission, a copy of the hospital’s discharge
summary with an accompanying letter should be sent to the patient’s primary care physician. Another letter describing the patient’s progress
should be sent following the 2- month clinic visit.

o **Post-Transplant Education**

During the first clinic visit post-transplant discharge, the patient should receive a copy of *Your Pathway to Healing: What to Expect after Your Kidney Transplant,* a patient transplant management tool. The clinic nurse or transplant coordinator will review the pathway with the transplant
recipient and answer any questions. Also at that time, the patient should be informed that the transplant social worker and nutritionist are
available for outpatient consultations in the transplant clinic, throughout their transplant course, should s/he request one.

o **Clinic Visits**

The initial 3 months of post-transplant appointments will be coordinated by the post-transplant program staff prior to the patient’s discharge from the hospital. This appointment schedule will reflect the appointments that will occur with both the surgeon and for lab only visits as is directed by the *Post Transplant Management Protocol*. The patient will be provided with the Kidney Post-Transplant Appointment Patient Letter (see attachment #2) that will include the specific appointment schedule obtained from the IDX system. This letter will added to OTTR It will be the responsibility of the post-transplant coordinator/post-transplant coordinator team to ensure that the patient receives the post transplant appointment letter and the Post Transplant Patient Care Calendar (see attachment #3) prior to the patients discharge from the hospital.

After discharge post transplant, patients with functional renal allografts should have laboratory parameters (SMA 18, CBC, urinalysis, and tacrolimus or cyclosporine levels) checked twice weekly and seen at least weekly for complete physical examinations in the Emory Transplant Clinic. Incisional staples are generally removed by the 14th post-operative day. This schedule should be maintained during the first eight weeks following transplantation.

During the period from 8 - 12 weeks post transplant, the interval between physician visits may be lengthened to 2 - 4 weeks, depending upon the stability of the patient’s course. An intervening rejection episode or other significant complication will require restitution of a schedule of more frequent visits.

o **Immunosuppressive Management**

Prednisone is maintained at 20 mg every AM for the first four weeks post transplant. Cellcept dosage during this period should also be unchanged (usually 1000 mg twice a day) unless reduction is mandated by excessive myelosuppression (WBC < 4,000) or significant gastrointestinal intolerance. The dosage of tacrolimus (Prograf) established at the time of hospital discharge (usually 0.1-0.2 mg/kg/day) may often need adjustment in the first six weeks. A tacrolimus level of 10 - 15 ng/mL measured by whole blood monoclonal ROA is targeted in the early post-transplant period. The short-term effects of tacrolimus-induced toxicity are generally reversible. Overt toxicity or evidence of profound immunosuppression may require a step-wise and carefully monitored reduction in dosage.

During the period from 6 - 12 weeks post transplant, small reductions in the recipient’s immunosuppressive medications are continued. Prednisone is usually tapered by 2.5 mg reductions every week until a maintenance dose of 10 mg/day is reached. Tacrolimus dosages continue to be titrated to maintain a patient’s level between 10 - 15 ng/mL depending upon the patient’s clinical course. Changes in Cellcept are infrequent and are only decreased in response to adverse effects.

o **Alloantibody Monitoring**

Alloantibody levels should be monitored routinely on all transplant recipients at 1, 3, 6 and 12 months post transplant as well as annually thereafter. Specific tests to be performed should be determined by the Emory HLA laboratory directors, dependent on the patient’s past antibody history, and may include 1) a flow cytometry screen on beads, or 2) detection of donor specific antibodies on donor cells by flow cytometry and cytotoxic methods. (See Post Renal Transplant Alloantibody Monitoring Protocol).

Additionally, blood alloantibody tests should be performed at the time of all allograft biopsies to evaluate allograft dysfunction. As above, specific tests to be performed should be determined by the Emory HLA laboratory directors, contingent on the patient’s past antibody history. These data should be used in conjunction with the results of the biopsy to determine appropriate therapy. Recipients with evidence of humoral rejection should be considered for plasmapheresis therapy.

o **Infection Prophylaxis and Monitoring**

Because of the potential for opportunistic infections in the immunocompromised patient, prophylactic therapies are initiated at the time of transplant or during the transplant admission:

Valcyte 450 mg daily or Cytovene 1000 mg tid is ordered for the first 3 months post transplant as prophylaxis against cytomegalovirus (CMV), unless patient is considered low risk i.e. a CMV antibody negative patient receiving a CMV negative organ.

Bactrim SS daily for the first 6 months is given as prophylaxis against pneumocystis carinii pneumonia (PCP). For patients on Rapamune, prophylaxis is continued indefinitely. If a patient is allergic to Bactrim, prophylaxis with either Dapsone or inhaled Pentamidine will be prescribed as appropriate.

With the use of potent immunosuppressive agents such as tacrolimus, mycophenolate mofetil (MMF), and sirolimus, there have been increasing reports of polyomavirus allograft nephropathy (PVAN) in renal transplant recipients. The histology of PVAN is characterized by mononuclear inflammatory infiltrates and tubulitis, which mimic acute cellular rejection. Recognition is critical since the proper therapy is reduction, rather than enhanced immunosuppression. The protocol to monitor polyoma virus at Emory is to order a Polyoma BK Virus PCR at 1, 2, 3, 4, 5, 6, 9 and 12 months post-transplant with confirmatory biopsy of the graft and reduction of immunosuppression as indicated. (See Post Renal Transplant Polyoma Virus Protocol).

o **Immunizations**

Renal transplant recipients are at increased risk for more severe clinical illness caused by infections but have a decreased protective response to many vaccines. With the exception of the live virus vaccinations, transplant patients can and should receive the same immunizations as non-transplant patients.

In general, patients should wait for at least 6 months after transplantation or after an episode of acute rejection before administering any vaccine.

o **Cardiovascular Risk Reduction**

Cardiovascular disease (CVD) is the leading cause of death in patients with long-functioning renal transplants, accounting for nearly 40% of deaths in this population. Cardiovascular risk factors after renal transplantation include age, tobacco use, family history, diabetes, hypertension, hyperlipidemia, preexisting left ventricular hypertrophy, prior rejection episodes and cumulative doses of corticosteroids. The incidence of new CVD events has been reported to be as high as 15.8% in transplant recipients without prior CVD and up to 23% in all renal transplant patients.

To encourage health and fitness, transplant recipients should be referred to the Intervent Cardiovascular Risk Reduction program at 1-month post transplant.

Individuals who smoke should be encouraged to enroll in a smoking cessation program of behavior modification and/or nicotine patch therapy.
The following levels should be used as target goals to reduce the cardiovascular risk factors in this patient population:

BMI < 25
Cholesterol < 200
Blood Pressure 120-120/75-85

o **Bone Disease Management**

*Renal Osteodystrophy.*It is estimated that osteoporosis may be present in up to 60% of renal transplant recipients, frequently developing within the first 18 months of transplant. Causes of osteoporosis include the use of corticosteroids, use of calcineurin inhibitors, hypogonadism, hyperparathyroidism, cigarette smoking, and insufficient dietary calcium intake. Prevention of transplantation osteoporosis begins soon after transplantation with measurement of bone density, thyroid function tests, and serum calcium, vitamin D, parathyroid hormone and testosterone levels. Treatment for osteoporosis and low bone mass should commence soon after transplantation and continue over the long term.

*Prevention.* All transplant recipients should receive Oscal D or Caltrate D, 2 tablets nightly, unless they are hypercalcemic, hypophosphatemic, or on oral phosphate supplementation. Parathyroid hormone (PTH) levels should be ordered monthly for the first 3 months post transplantation, then quarterly until one year post transplantation; then, annually thereafter. If PTH levels remain elevated 12 months post transplantation, a parathyroidectomy should be considered.

*Screening.* Measurement of bone density (DEXA scan) should be performed at one month post transplantation and then every six months for the first 2 years post transplantation. After 2 years post transplantation, DEXA scans should continue to be performed annually.

*Treatment of Osteoporosis and Osteopenia.* A DEXA scan T score of -1.0 to -2.0 in any tested area is indicative of borderline low bone mineral density (BMD). Therefore, patients with T scores of -1.0 to -2.0 should be placed on prophylactic therapy of Fosamax 35 mg po once a week. If the BMD continues to decrease on subsequent DEXA scans, the Fosamax dose should be increased to 70 mg po once a week. A DEXA scan T score of < -2.0 in any tested area is indicative of abnormally low BMD or osteoporosis and such patients should receive Fosamax 70 mg po once a week.

*Mineral-Electrolyte Abnormalities (Ca, Phosphorus, Magnesium and Bicarbonate*):

Blood work including minerals and electrolytes should be ordered with each transplant clinic visit. Treatment includes:

*Hypophosphatemia* – Treatment is K-Phos Neutral 250 mg tablet 3 times daily, titrated with laboratory results. With treatment, hypophosphatemia usually resolves 1 to 2 months post- transplant.

*Hypercalcemia* – Is usually asymptomatic. Calcium levels should be monitored in conjunction with parathyroid hormone (PTH) levels. If hypercalcemia persists with elevated PTH levels, a parathyroidectomy should be considered.

*Hypomagnesemia* – Treatment is Magnesium Oxide 400 mg daily, titrated with laboratory results.

*Metabolic Acidosis (low bicarbonate)* – Treatment is Sodium Bicarbonate 650 mg 3 times daily, titrated with laboratory results.

o **Anemia and Erythrocytosis Management**

*Anemia Management:* Erythropoietin production by the transplanted kidney is often delayed for up to 30 days following successful renal transplantation, so full correction of anemia may not occur for 2 to 3 months post surgery. Virtually all clinical studies have shown increased benefit for targeting hemoglobin levels between 11 and 12 g/dL by supplemental Epoetin therapy.

In order to detect the cause of anemia that may not be due to Erythropoietin deficiency, an anemia evaluation should consist of:

Hemoglobin (Hgb)
Red blood cell indices
Reticulocyte count
Iron parameters
o Serum iron
o Total iron binding capacity (TIBC)
o Percent transferring saturation
o Serum ferritin
A test for occult blood in stool

Refer to the Anemia Management Protocol for administration of Epoetin guidelines.

*Erythrocytosis Management:* Erythrocytosis is defined as a hematocrit (Hct) > 51% and occurs in 5 – 17% of renal transplant recipients within 2 years of engraftment. Because of an increased risk of thromboembolic complications when the Hct is greater than 55%, a target Hct of < 55% is paramount and a Hct of < 50% is desired.

Therapies should be tailored to the individual transplant recipient and are generally
instituted when the Hct is greater than 50% and may include 1) serial phlebotomies to maintain Hct < 50%, ACE inhibition, Angiotension II Receptor Type I Blockade, or Theophylline administration. See Post Transplant Erythrocytosis Management Protocol for a detailed description of each therapeutic option.

o **Malignancies of the Skin**

The most common malignancies in the renal transplant population are carcinomas of the skin and lip. Risk factors for skin cancer include immunosuppressive therapy, sun exposure/ultraviolet radiation and infection with human papilloma-virus. A comprehensive dermatology examination to screen for skin cancers should be done between 1 – 2 months post transplant, at the twelve (12) month transplant anniversary and annually thereafter. Additionally, during routine transplant visits, physicians should be mindful of the increased risk for squamous cell carcinoma and malignant melanoma. Biopsies of any suspicious lesions should be performed. Multiple lesions should be referred for a formal dermatologic surveillance.

**Three to Twelve Months Post Transplant**

o **Communication**

To maintain compliance with UNOS policy, Transplant Recipient Follow-up forms should be submitted to UNOS at the 6 and 12 - month Transplant Clinic visit and annually thereafter.

Letters regarding the recipient’s post-transplant progress should be mailed to the recipient’s primary care physician after the 6 and 12 – month clinic visit and annually thereafter.

o **Clinic Visits**

During the period from 3 – 6 months post transplant the interval between physician visits may be further lengthened to every 4 – 8 weeks. Laboratory work should be checked every 2 weeks. Complications or reevaluations following changes in medications may require shorter intervals of follow-up.

After 6 months, the patients will be seen by a physician generally every 3 months, with laboratory work checked monthly.

o **Patient Education**

At the 9 - month clinic visit, the recipient should be provided a copy of the *Renal and Pancreas Transplant Programs’ Disease Prevention Management and Routine Screening Guidelines* which is reviewed with him or her by the transplant coordinator. This education tool reminds the patient of the need for on-going heath screenings and the role of the primary care physician in those screenings.

To assure compliance with the Centers for Medicare and Medicaid Services’ End-Stage Renal Disease (ESRD) regulations, at their annual clinic visits, patients should be asked to complete a self-assessment relative to their diet as well as social service needs, to be forwarded to the transplant dietician and social worker respectively for review and appropriate action.

o **Immunosuppressive Management**

During the period from 3 - 6 months post transplant, further tapering of immunosuppressive therapy will proceed to achieve maintenance regimes:

Prednisone 10 mg daily
Tacrolimus target levels 10 - 15 ng/ml)
Cellcept 1000 mg twice a day

These are average dosages or target levels. **I**ndividual differences should be expected. Patients with a history of rejection episodes will generally require a slower tapering schedule. The tapering of these medications should proceed in a step-wise fashion, and generally no more than one immunosuppressive medication should be reduced at any given step. There is an attendant risk of precipitating a rejection episode whenever any of these medications is reduced. Therefore, the patient should be reevaluated within 7 - 14 days, after such a change has been made.

From 6 - 12 months post transplant,immunosuppressive medications are generally tapered to maintenance: Prednisone 10 mg qd and Tacrolimus target levels between 8-12 ng/ml, with an attempt to maintain Cellcept 1000 mg bid. There is no means to identify recipients who have developed complete immunological tolerance to their allografts; so all renal transplant recipients should receive some maintenance therapy as long as their graft is functional.

Immunosuppressive medications may require periodic adjustment as in the case of stress-related increases in steroids or immune-related decreases (i.e., certain infections, chronic liver disease, neoplasia, progressive renal insufficiency). Initiation of certain medications may alter the metabolism of immunosuppressive medications and therefore dictate dose adjustments.

o **Cardiovascular Risk Reduction**

Increased total cholesterol concentrations with an excess of low-density lipoprotein (LDL) fraction and increased triglyceride levels are common in transplant recipients and may affect over 60% of the patients. Factors that may contribute to hyperlipidemia include immunosuppressive medications, obesity, diet, genetic causes, hyperglycemia, and lack of exercise, poor renal function, and proteinuria.

At 3 months and 12 months post transplant, as well as subsequent annual visits, a lipid profile should be ordered.

Also at 3 months, aspirin prophylaxis therapy should be considered.

If adjustment of the immunosuppressive regimen, diet, and exercise are not successful in reducing lipid levels, drug treatment, such as HMG CoA reductase inhibitors, should be initiated.

o **Bone Disease Management**

As initiated post transplant, all transplant recipients should continue Oscal D or Caltrate D, 2 tablets nightly, unless they are hypercalcemic, hypophosphatemic, or on oral phosphate supplementation.

Parathyroid hormone (PTH) levels should be ordered at 3, 6, 9, and 12 months post transplant; then, annually thereafter. If PTH levels remain elevated 12 months post transplantation, a parathyroidectomy should be considered.

Measurement of bone density (DEXA scan) should be performed at 6, 12, 18, and 24 months post transplant; then, annually thereafter. As noted previously, a DEXA scan T score of -1.0 to -2.0 in any tested area is indicative of borderline low bone mineral density (BMD). Therefore, patients with T scores of -1.0 to -2.0 should be placed on prophylactic therapy of Fosamax 35 mg po once a week. If the BMD continues to decrease on subsequent DEXA scans, the Fosamax dose should be increased to 70 mg po once a week. A DEXA scan T score of < -2.0 in any tested area is indicative of abnormally low BMD or osteoporosis and such patients should receive Fosamax 70 mg po once a week.

o **Immunizations**

Toxoid vaccines can be resumed at 6 months post transplant; however, no live attenuated vaccines. Vaccines may be administered if the patient has a normal white blood count; has not had a recent rejection, viral or bacterial infection; or, is not allergic to egg products.

Recipients should have a routine annual vaccination against influenza and receive the pneumococcal vaccine every 5 years.

o **Disease Prevention Screenings**

Routine health screening is important for the early detection and treatment of disease. It is recommended that transplant recipients have the following health screenings performed as indicated during routine visits with their primary care physician or health care provider.

*Diabetes Mellitus* – The most common cause of ESRD leading to transplantation in the US is diabetes mellitus. It is also one of the most important risk factors associated with post-transplant cardiovascular disease. Risk factors associated with the development of post-transplant diabetes mellitus include: weight gain, older age of the recipient, the immunosuppressive drugs used, race of the recipient, and a family history of adult-onset diabetes. All transplant recipients should be screened for diabetes mellitus with fasting plasma glucose levels being drawn with routine laboratory tests.

Because of the importance of optimal glycemic control to prevent the long-term complications of diabetes, Hgb A1C should be monitored every 3 months on all diabetic renal transplant recipients. For patients who are not achieving optimal glycemic control, an endocrinology referral with additional diet and self-glucose monitoring education and/or medication management may be indicated.

Diabetic recipients should been seen by an ophthalmologist for vision screenings every 6 months with a dilated eye examination being performed annually.

*Cancer* - Annual cancer screenings are essential for the prevention or early detection of malignancy. Annual screenings for skin (see above), breast, and cervical, prostate, and colorectal cancer are recommended for this at-risk post-transplant population. The guidelines for cancer screenings as established for the general population should be used for the transplant population as well.

*Cervical Cancer* - Women > 18 years should have annual pelvic exams and Papanicolaou smears.

*Breast Cancer*- Women > 40 years of age should have a mammogram with or without self-exam every year. Baseline mammography is recommended between the ages of 35 - 39 years.

*Testicular Cancer --* All men > 15 years of age should perform monthly testicular self-examinations to check for unusual masses or lumps in the testicles. Any masses or lumps should be reported to their primary care physician.

*Prostate Cancer - –* Men should have an annual digital rectal exam (low sensitivity). All men > 50 years of age should have a serum prostate-specific antigen (PSA) test every year to screen for prostate cancer.

*Colorectal Cancer* - There is an increased incidence of colon cancer in transplant recipients more than ten years post transplant. Recipients > 50 years should have fecal occult blood testing annually with a flexible sigmoidoscopy or colonoscopy every 5 years.

*Vision Screening* - Prednisone can cause changes in eyesight and contribute to the development of cataracts or glaucoma. Annual vision screening by an ophthalmologist should be performed to test for these conditions.

*Dental Care* - Unless emergent, dental visits should be avoided until the recipient is 6 months post transplant and then resumed semi-annually. Dental management of post-transplant recipients requires consideration of the possible hematological and cardiovascular side effects of the prescribed medications. Therefore, standard dental prophylaxis is indicated prior to even routine dental maintenance. Prophylaxis includes Amoxicillin 2 Grams orally 1 hour prior to the procedure; or, if allergic to Penicillin, Clindamycin 600 mg orally 1 hour prior.

**Long term Post-Transplant Management**

o **Physician Visits**

Following the first year post transplant, the frequency of physician visits will vary depending on allograft function, and complications related and unrelated to the transplant. Transplant recipients should, however, be scheduled and seen by a physician at least quarterly.

From 13 - 24 months, after the Year 1 Transplant Clinic visit, the transplant recipients should be seen by their primary care physician at 15 and 21 months (if available), returning to the Emory Transplant Clinic at 18 and 24 months.

After the second year anniversary, recipients should be seen by their primary care physician (if available) quarterly, returning for an annual physician visit at the Emory Transplant Clinic at their annual transplant anniversary.

o **Laboratory Work**

From 13 - 24 months, laboratory work should be drawn, monitored and reviewed by the Transplant Program every six weeks with adjustments of immunosuppressive dosages made per protocol.

After the second year anniversary (24 months), laboratory work should be drawn, monitored and reports reviewed by the Transplant Program every three months with adjustments of immunosuppressive dosages made per protocol.

List of Supporting Emory Transplant Program Documents:

1. Your Pathway to Healing: What to Expect after Your Kidney Transplant
2. Adjustments to Immunosuppressive Medications Protocol
3. Post Renal Transplant Alloantibody Monitoring Protocol
4. Post Renal Transplant Polyoma Virus Protocol
5. Post Renal Transplant Bone Disease Management
6. Anemia Management Protocol - 2D Transplant Clinic
7. Post-Transplant Erythrocytosis Management Protocol - 2D Transplant Clinic
8. Renal and Pancreas Transplant Programs’ Disease Prevention Management and Routine Screening Guidelines
9. Emory University Hospital Renal Transplant Protocol Summary for Healthcare Providers

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Last Review Date: 03/02/04, 2/6/07, 6/4/08

Approved by: Renal Transplant Leadership Group

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Approval Date: 12/09/03, 03/02/04, 2/6/07, 6/4/08