

Defining high risk in adult kidney transplantation

Background—Because identifiable factors contribute to allograft loss, and because no consensus has been reached on the definition of high risk, an interdisciplinary group of nurses, physicians, pharmacists, and social workers was convened in May 2008.

Objective—Participants sought to reach consensus about the current state of science and best practices related to the definition and management of high-risk kidney transplant recipients.

Methods—An expert facilitator with extensive experience in leading consensus teams guided consensus-building activities, which included discussion and small-group work.

Results—This consensus group conceptualized the definition of the “high-risk” kidney transplant recipient and provided information to guide the multidisciplinary team in their assessment of these patients before and after transplant. Three key areas, which were conceptualized as independent scales, had a substantial impact on outcomes: (1) transplant recipient medical factors, (2) donor and recipient immunological factors, and (3) transplant recipient psychosocial factors. Though depicted separately, alteration of a specific risk on one scale could influence some risk factors on another scale. In addition, the kidney allograft itself must be considered in the assessment of high risk.

Conclusions—The continuum of risk described here should be useful to transplant clinicians in their assessment of high-risk adult kidney transplant patients, may aid centers in developing a more complete definition of high risk, and may lead to risk-reduction efforts. (*Progress in Transplantation*. 2009;19:252-258)

High Risk Renal Transplant Consensus Group

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With advances in medical, immunological, and psychosocial management of adult kidney transplant recipients, the concept of the high-risk recipient has also evolved. Although most transplant centers have developed criteria to define high risk, some may not include certain variables. A broader understanding of risk factors may enable practitioners to better assess which patients will and will not benefit most from a kidney transplant so that risk-reduction interventions can be initiated. Because identifiable factors contribute to allograft loss, and because no consensus has been reached about the definition of high risk,¹ an interdisciplinary group of nurses, physicians, pharmacists, and social workers was convened at a hotel neighboring Dulles International Airport near Washington, DC. Participants sought to reach consensus regarding the current state of science and best practices related to the definition and management of the high-risk kidney transplant recipient. An expert facilitator with extensive experience in leading consensus teams guided

consensus-building activities, which included discussion and small-group work.

We undertook the consensus conference scope of work with several assumptions. First, we assumed a spectrum of risk for kidney transplant recipients; that is, not all transplant candidates share equal risk. Second, deliberations also took into account the center-specific imperatives that affect recipients at nearly every juncture; for example, centers performing kidney transplantation have protocols derived from center experience as well as accepted practices and regulations. Third, we were cognizant that any conclusions or recommendations might be applied differently at various centers throughout the United States and in other countries. Fourth, we focused on adult high-risk kidney transplant recipients, realizing that pediatric kidney transplantation has unique risks, some of which differ from adult transplantation. Finally, the intent was to highlight issues that could be managed by transplant nurses working in conjunction with the transplant team.

The definition of risk and the modeling of risk concepts emerged with emphasis on clinical applicability and understanding. Thus, high-risk recipients are subject to medical, immunological, and psychosocial factors that may significantly decrease graft survival when compared with regionally acceptable graft outcomes. These 3 factors seemed to be best conceptualized by using 3 independent scales. Though depicted separately, alteration of a specific risk on one scale could influence some risk factors on another scale. Figure 1 delineates our risk factor model, with each of the 3 scales having multiple components, the most important of which were further refined by the group. Application of such a model may assist transplant practitioners in evaluation, selection, and management of patients. Should scoring and validation evolve, it may be possible to tabulate a composite risk that would allow more reliable prediction of both desirable and undesirable outcomes for kidney transplant candidates.

Although the consensus conference was designed to identify issues related to care of high-risk kidney transplant recipients, we agreed that an additional risk factor was brought suddenly to every recipient: that is, the transplanted organ itself. Certainly, the use of an expanded-criteria donor kidney added risk to any transplant case. We recognized the advantage of a living donor or an anatomically normal, standard-criteria deceased donor kidney in reducing risk. Of course, all recipients come to transplant surgery with definable risks that may or may not be altered by the source or condition of the donor organ. Therefore, we identified circumstances of the donor such as age, cause of death, prior cancer, presence of other diagnoses such as diabetes, and body mass index (BMI), which are critical to assessing recipients' outcomes.

Additionally, we discussed circumstances of procurement and preservation such as duration of cold ischemia time, procurement injury, and warm anastomotic time, all of which may relate to graft function. Despite this recognition of the situations related to

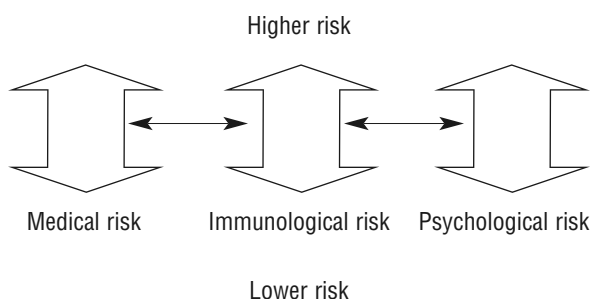


Figure 1 Three types of factors are critical to assessing high-risk kidney transplant recipients. These factors include medical, immunological, and psychosocial circumstances. Each may be relatively higher or lower in significance for any given recipient and situation.

Table Medical risk factors

Cardiovascular disease
Obesity
Diabetes mellitus
Peripheral vascular disease
Hepatitis C
Advanced age
HIV infection
Focal segmental glomerular sclerosis
Race/ethnicity
Hyperlipidemia
Anemia
Time on dialysis
Infectious disease history

donation and the organ transplanted, we agreed that the patient presents to the transplant team for implantation of any organ that is deemed suitable for that patient. Consequently, we decided to seek consensus on the risk factors related to the recipient and not the risk factors related to the transplanted organ.

Medical Risk Factors

We identified and discussed many medical risk factors, some of which are listed in the Table. Ultimately, the 4 medical risk factors deemed most important to evaluate before transplant were cardiovascular disease, obesity, diabetes mellitus, and peripheral vascular disease, problems that are universally evaluated before proceeding with transplantation.²⁻⁶ Each may have a profound effect on any recipient before and after a kidney transplant.

Cardiovascular disease is the No. 1 risk for increased mortality in adult kidney transplant recipients.⁷ We noted the importance of performing routine cardiac screening along with assessing the patient's medical history and performing a physical examination, electrocardiography, and chest radiography during virtually all transplant evaluations for risk stratification, and we agreed that dobutamine stress echocardiography may be the first test to rule out ischemic heart disease in any patient with further cardiac risk. If the results indicate cardiovascular disease, the potential recipient is referred for a cardiology consultation and possible cardiac catheterization. Revascularization with stenting or coronary artery bypass grafting may be indicated, and those procedures should be performed before the kidney transplant in order to limit kidney and cardiac complications after transplant.⁷ Cardiac screening is especially important for patients more than 50 years of age and patients with a history of dia-

betes, cardiac event, hypercholesterolemia, or smoking.⁸ We agreed that cardiac exclusion criteria for kidney transplantation are an ejection fraction less than 30%, inoperable coronary artery disease (high-grade stenosis), severe cardiac valvular disease, and severe pulmonary hypertension.

Even though transplantation can be beneficial in slowing the advancement of cardiovascular disease, ongoing cardiac care after transplantation is crucial.⁹ For example, immunosuppressive management that includes steroid withdrawal may reduce cardiac risks by decreasing the effects of diabetes, hypertension, and hyperlipidemia. Using statins, anticoagulation therapy, antiplatelet therapy, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, β -blockers, and smoking cessation may all be part of treatment to avert cardiovascular events after a kidney transplant.^{7,10}

Addressing obesity to minimize risks is important during all phases of transplantation. The World Health Organization defines obesity as a BMI (calculated as weight in kilograms divided by height in meters squared) greater than 30,¹¹ and we agreed that patients with a BMI of greater than 40 should be considered ineligible for transplant.¹² We further defined a potential recipient with a BMI of 35 to 40 as high risk. Yet obesity is a modifiable risk factor that should be addressed through behavioral change before transplant. Several interventions that should be implemented include counseling with a registered dietitian on weight-reduction diet and exercise, enrollment in a formal weight-loss program, and referral for bariatric surgery if indicated. The potential recipient may need changes to the dialysis treatment regimen, which might include a change from peritoneal dialysis to hemodialysis.

Postoperatively, obesity is associated with wound complications such as infection, dehiscence, delayed healing, and hernia, as well as emergence of diabetes, hyperlipidemia, hypertension, and deep vein thrombosis. Obese patients also have a higher incidence of delayed graft function, graft loss, and chronic allograft nephropathy.^{12,13} Long-term care should include immunosuppression considerations such as steroid avoidance in conjunction with nutrition, exercise, and behavior modification, which may decrease the risks associated with elevated BMI in the postoperative phase.¹⁴

Diabetes mellitus is the most common cause of chronic kidney disease. Its associated comorbid conditions (eg, cardiovascular disease, infection, neuropathy, and nephropathy) place the potential recipient at risk for suboptimal graft outcomes. The pretransplant assessment of diabetes self-care and adherence may include collaboration with the endocrine team to achieve an acceptable hemoglobin A1C level, weight loss to a BMI goal of less than 35, and appropriate

education of the patient about all aspects of diabetes care. A history of diabetes certainly does not exclude patients from transplant unless instability near the time of surgery with recent diabetic ketoacidosis or infection is suspected.

Most important was the consensus that blood glucose and overall diabetic management was an ongoing process in the preoperative, perioperative, postoperative, and chronic long-term phases of transplant care. Strategies to reduce the risks associated with diabetes include exercise, nutritional management, smoking cessation, monitoring of hemoglobin A1C level, selection of immunosuppressive agents, and avoidance of steroids.¹⁵ The preceding strategies may also be considered in patients without preoperative diabetes, as several immunosuppressants pose a risk to development of posttransplant diabetes.¹⁵

Peripheral vascular disease (PVD), which may be aneurysmal, calcific, or occlusive, is the fourth severe medical risk factor that ultimately may affect graft survival.¹⁶ Once PVD is suspected, the following studies should be considered to screen preoperatively in determining the extent of PVD: focused physical examination of proximal and distal pulses, duplex ultrasound of abdominal and iliac vessels, and unenhanced computed tomography of the abdomen and pelvis to determine presence of calcific PVD. Once identified, treatment options to reduce risk of PVD, such as smoking cessation, exercise, diet modification, pharmacological agents, and careful management of contributing disorders such as hypertension and hyperlipidemia, should be implemented. Vascular surgery consultation may be recommended to determine if operative intervention is indicated.¹⁷ We agreed that the following would exclude an individual from transplantation: severe uncorrected carotid stenosis, ulcerative plaques or aneurysms in central vessels (aorta, carotid arteries, iliac vessels), claudication or rest pain in the lower extremity, and severe vascular stenosis. The transplant team should work closely with the referring nephrologist and others to address any symptomatic or severe PVD before transplant.

After transplant, the ongoing medical management to control PVD risks is similar to treatment in virtually all settings for transplant recipients. These universal goals are easily stated and include blood pressure control, weight and dietary management, sound treatment of metabolic problems such as diabetes or dyslipidemia, and attention to concepts of a healthy lifestyle. However, these goals are not always easy to achieve. The posttransplant immunosuppression protocol may worsen hypertension and metabolic derangements even in the face of normal kidney allograft function. But, with sound evaluation before transplant, the care of PVD after transplant should usually result in stable and successful long-term outcomes.

Immunological Risk Factors

Immunological risk for adult kidney transplant recipients actually begins before transplantation and extends for the life of the patient or the allograft. With the exception of identical twin transplantation, the risk for rejection is virtually ever-present and depends on the prior immunological experience of the recipient (sensitization), compatibility of the kidney donor with the recipient, and posttransplant events that may activate the immune response.

In the immunological evaluation before transplantation, matching is of paramount importance and involves 3 areas of assessment. ABO/blood type matching is virtually the same as with banked blood in that blood type O is the universal donor and blood type AB is the universal recipient. Thus, a donor with blood type O is compatible with a person of any other blood type, whereas a donor of blood type A is compatible with anyone having a blood type of A or AB and a donor of blood type B is compatible with anyone having blood type B or AB. The AB donor may be considered only to donate to an AB recipient. In recent years, the subtype of A termed A2 has been determined as similar to that of persons having blood type O, although only 10% to 20% of persons with blood type A have this subtype. Thus, subtyping of an A donor that indicates that the donor is "A sub 2" may permit donation to a recipient of any blood type.

Human leukocyte antigen (HLA) matching is the second common type of matching in kidney transplantation. Determined by the 6 antigens deemed important to initiate an immune response, the perfect HLA match is a 6-antigen match. A donor-recipient pair sharing no similar antigens would be a 0-antigen match.

Finally, the most important matching determination is the final cross-match, which involves the potential use of several laboratory tests performed immediately before transplantation. These tests can determine the degree of reactivity or sensitization that a potential recipient may have to a donated organ. Thus, a positive cross-match can be used to predict that a recipient would react and reject a donor organ whereas a negative cross-match would indicate that the recipient is not responsive to the particular antigens of the donor and would not have an immediate rejection episode or hyperacute rejection.¹⁸

Circumstances before transplantation that may cause a recipient to be cross-match positive (incompatible) with a particular donor include a history of pregnancy, transfusion, previous transplant, or other event that caused the potential recipient to produce antibody against antigens that may be present on the donor organ. The degree of this response, or the strength of preformed antibody, can be measured by testing through panel reactive antibody (PRA) titers. The percent PRA is a measure of a potential recipient's

level of sensitization against a group (panel) of donor antigens. Thus, the PRA reflects the percentage of the general population that a potential recipient may have made antibodies against (become sensitized), and would, theoretically, reject. A patient with a high PRA value is far more likely to mount a brisk rejection against any organ than a patient who has 0% PRA.¹⁹

Donor and recipient compatibility in kidney transplantation, therefore, includes determination of suitable matching studies as well as the degree of sensitization of the recipient, particularly if that recipient has preformed antibodies against specific donor antigens. Highly compatible, well-matched donors and recipients would share the same blood type, HLA antigens, and have a negative cross-match, thus enjoying a low immunological risk. Although HLA antigen compatibility has become less important with modern post-transplant immunosuppression, the need for an ABO-compatible organ and a negative cross-match remain apparent in most cases. Even with a negative cross-match, a relatively high immunological risk occurs when the recipient has demonstrated a high PRA and there is a 0% or low HLA match in the donor-recipient pair.²⁰

In recent years, transplantation with donor organs of incompatible blood type or positive donor-recipient cross-match has been successfully performed. Such attempts almost always involve modification of the recipient through immunological manipulation and monitoring before transplant and most often occur with the living donor circumstance. The living donor who is initially incompatible with the recipient is an available source of kidney replacement for the period of time that it may take to "desensitize" the potential recipient. Thus, managing the sensitized patient with a living donor who is either blood-type or cross-match incompatible may be undertaken, although this portion of clinical transplantation can still be experimental. In any event, the recipient may benefit from immune system modification (Figure 2) using pretreatment with immunoglobulin, plasmapheresis, or other methods.²¹

The algorithm for desensitization of persons without a living donor is similar, except that any deceased donor transplant is unplanned by the very nature of deceased donor organ allocation. Thus, the optimal time to initiate desensitization therapy is likely to be after the patient has demonstrated a high PRA for some time, is approaching the "top of the waiting list," and is otherwise in stable health. Such determinations are, by their nature, center specific.

Desensitization protocols may or may not be experimental, depending on a host of circumstances, and consequently, may or may not require approval of the institutional review board. Nonetheless, conferees understood the general utility of attempting to prepare highly sensitized patients for the chance at a kidney

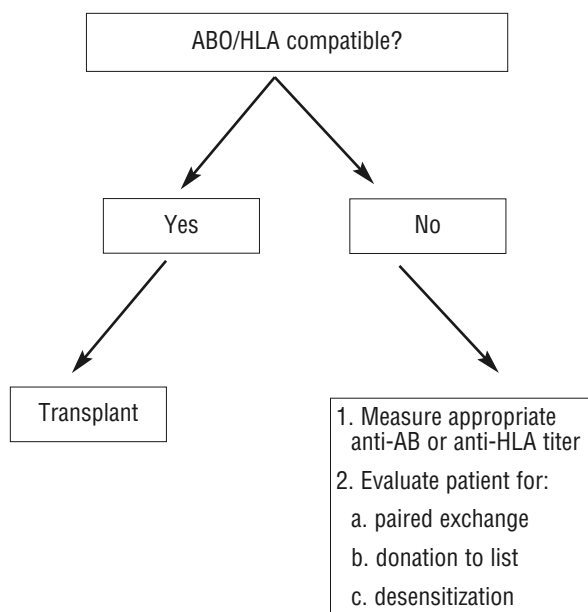


Figure 2 Treatment algorithm for sensitized patients with living donors.

Abbreviation: HLA, human leukocyte antigen.

transplant and agreed that an increasing number of centers may soon undertake such treatment plans. Use of desensitization protocols may become more important as the paired kidney exchange programs grow, and living donors absolutely incompatible with their recipients may still donate in other ways, enabling ultimate transplantation to an intended recipient.²² Still, high immunological risk remains with recipients who continue to produce high levels of antibody, have many positive cross-matches with a number of different donors, and who may not be suitable for desensitization before transplantation.

The sensitivity and specificity of immunological testing are also changing. A negative complement-dependent cytotoxicity cross-match before transplantation signifies the lack of significant anti-HLA donor-specific antibody (DSA) in the recipient that would pose a risk for hyperacute rejection. Many centers have embraced more sensitive assays such as flow cytometric cross-matching and single-antigen flow bead analysis to identify DSA specificity. In sensitized patients, these newer tests for presence of DSA should probably be considered.

The ABO-incompatible recipient must have an anti-AB isoagglutinin titer drawn to determine the level of risk for an antibody-mediated rejection. The recipients with low titers are more likely to be successfully desensitized before transplantation. Titer levels are center specific; however, in general, titers less than or equal to 1:16 have been considered safe for transplantation.

Several treatment options are available for successful desensitization, including intravenous administration of immunoglobulin (IVIg), plasmapheresis, rituximab, mycophenolate mofetil, calcineurin inhibitors, and splenectomy. No one strategy or combination of therapies is optimal. Most successful programs incorporate a combination of IVIg and plasmapheresis to remove DSA before transplantation.²³ Rituximab and splenectomy have longer term risks to recipients but may play a role. Most strategies for sensitized living-donor recipients involve pretreatment with a combination of therapies that may be center specific. After the transplant, isoagglutinin or cross-match titers are followed, and recipients may continue desensitizing therapy while allograft biopsies guide long-term care.

In the posttransplant period, the immune system may be activated by suboptimal immunosuppressive therapy, infections that activate an immune response, and certain viruses that are associated with allograft rejection. Sensitized recipients must maintain a fine balance between too much immunosuppression and not enough. Obviously, suitable immunosuppressive monitoring must be part of every posttransplant follow-up treatment plan. The presence of any infection should alert all to careful monitoring and management of any immunosuppressed transplant recipient. Finally, specific viruses such as cytomegalovirus and the BK virus may not only alter the immune response (or be present because of immunosuppression), but may be associated with clinical treatment plans that place the patient at risk for loss of the transplanted organ.

Psychosocial Risk Factors

Although many intrinsic personal factors and extrinsic socioeconomic circumstances may interact and coalesce to determine a transplant recipient's psychosocial risk profile, we opined that 4 psychosocial variables play a major role in determining kidney transplant success or failure. All agreed that compared with more objective medical and immunological risks, psychosocial risks may be more subjective, making quantitative judgment more difficult. Although psychometrically sound assessment tools are available for assessing psychosocial factors, few transplant teams regularly use these tools, and subjective assessment by trained observers appears to be the standard of care. The 4 variables important in psychosocial risk are adherence to treatment protocols, ability to understand the transplant center system of care, active psychiatric diagnosis, and financial resources or support. Any one of these variables could create a situation that dooms an organ transplant.

Vigilant patient self-care and monitoring is required for the life of the transplanted organ. During the immediate postoperative period, patients are asked

to follow fairly strict discharge instructions and monitoring, regularly attend posttransplant appointments, and routinely submit blood samples. A recent meta-analysis indicates that medication nonadherence is especially high in kidney transplant recipients.²⁴ Predicting which transplant candidates will follow posttransplant recommendations remains a challenge, and very few studies have systematically examined interventions to improve adherence in adult kidney transplant recipients.²⁵

Factors related to the transplant team and center, and to the healthcare system, may also play an important role in supporting transplant recipients and their families.²⁴ We recognized that a disparity exists between how transplant professionals view access to care within a center, and how that center might be perceived by patients and their families. Thus, adherence includes patient self-management, attending clinic appointments, following through with necessary insurance paperwork, and trying to comply with healthy behaviors such as exercise and diet. Treatment recommendations come from professionals who are comfortable with their work place; yet, the transplant clinic may be a strange and even threatening place to the patient. Transplant professionals' expectations and communication of adherence to specific treatment plans could influence patients' behavior. The impact of factors related to the healthcare center and team on psychosocial risk, especially adherence, should be examined by transplant center leaders through quality improvement efforts that ensure that an easily navigated experience awaits all patients.

Strong evidence suggests that the presence of psychopathology, especially mood disorders including depression and anxiety, is linked with poorer outcomes in kidney transplantation. Research has found higher rates of depression associated with increased graft failure, return to dialysis therapy, and death with a functioning graft.^{26,27} Other studies suggest that although depression was not a solitary predictor of mortality, it was a strong predictor for poorer perceived quality of life.²⁸ Patients with mental health disorders seem to have greater difficulty in navigating the transplant system, adhering to necessary treatments, and coping with complications. Although symptoms of anxiety seem to diminish after successful transplantation (compared with their dialysis patient counterparts), symptoms of depression may remain, prompting considerations of intervention.²⁹

Little research is available to evaluate the role of other psychiatric diagnoses, such as psychotic disorders (eg, schizophrenia) and substance abuse disorders, although psychiatric factors may have an impact on long-term kidney transplant outcomes. Nevertheless, studies of the value of anxiety and depression screening in kidney transplant candidates are needed.

Transplant social workers, along with their dialysis social worker counterparts, may be in ideal positions to implement assessments that ultimately could lead to treatment of psychopathology and improvement in patients' well-being and quality of life.²⁶

Unfortunately, little published research has examined the role of access to health insurance and other financial resources on kidney transplant outcomes. A consensus was reached that adequate health insurance coverage was a major determinant in candidacy and risk in kidney transplantation. Although each transplant program may develop its own center-specific requirements for insurance coverage before proceeding with transplantation, we agreed that patients who are uninsured are not deemed acceptable until health insurance coverage is secured in many cases. What is more debatable among and within transplant programs is how to determine candidacy of underinsured patients, such as those with only 80% coverage for prescription drugs. Many had observed patients discontinuing or reducing the dose of immunosuppressants because of cost. Patients and their families living at lower income levels are also more likely to have difficulty in returning to the transplant center for regular monitoring and may avoid attending medical appointments in order to prevent additional copayments even with insurance coverage.

Future Work

We established that much work remains to be accomplished in identifying best practices in management of high-risk transplant patients. The 2 age extremes for transplant patients are particularly challenging. Pediatric and adolescent transplant patients and the growing number of older transplant recipients have unique management issues. Future consensus conferences could address the best practices with these groups.

Conclusions

The consensus group defined the high-risk adult kidney transplant recipient and assessed information to guide a multidisciplinary team in its assessment of such patients before and after transplantation. Three key areas were agreed to have a substantial effect on outcomes: (1) transplant recipient medical factors, (2) donor and recipient immunological factors, and (3) transplant recipient psychosocial factors. In addition, the kidney allograft itself must be considered in the assessment of risk. The continuum of risk described in this article should be useful to transplant clinicians in the assessment of transplant recipients and may aid centers in developing a more complete definition of high risk. Further research is warranted to better understand how medical, immunological, and psychosocial factors combine to affect outcomes in adult kidney transplantation.

Acknowledgments

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