Managing Long-Term Outcomes for Kidney Transplant Patients: An Integrated Needs Assessment

Transplant Specialists

April 20, 2012

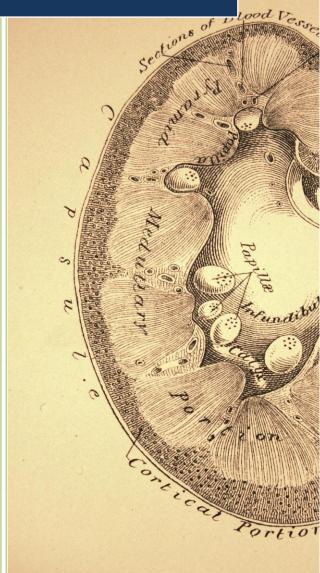












Executive Summary

Since the first successful kidney transplant between identical twins in 1954, surgical techniques, pharmacotherapy, and organ donor registries have improved, making renal transplant the therapy of choice for a growing number of individuals.

Short-term care of kidney transplant patients focuses on suppressing the immune system to prevent the body from rejecting the new organ. This necessitates strong immunosuppressive medication that leaves the patient vulnerable to infection. Over time, the drug dosage is lowered and the risk of infection lessens, but kidney transplant recipients must take immunosuppressive medication for the rest of their lives. These drugs have serious adverse effects, including cancer, diabetes, bone disease, hypertension, dyslipidemia, and many other medical conditions. Physicians who manage the long-term care of kidney transplant patients must identify treatment that maximizes kidney function and averts rejection while simultaneously minimizing the risk of short- and long-term adverse effects.

In the United States, the increasing population with end-stage renal disease, better survival rates among transplant recipients, and advances in surgery and medicine that make transplant an increasingly viable option all contribute to the growing number of individuals living with a donor kidney. Increasingly, transplant specialists—together with community nephrologists, urologists, surgeons, and other health care professionals—are expected to actively participate in the longitudinal management of kidney transplant recipients. Consequently, communication, coordination of care, delineation of roles and responsibilities, and effective referral procedures are key issues in the management of transplant patients.

This integrated needs assessment was designed to:

- Identify and quantify the attitudes and educational and behavioral needs of nephrologist transplant specialists surrounding the care of patients with kidney transplants.
- Assess current clinical performance to assure long-term graft and patient survival.
- Identify learning preferences, including educational interventions, preferred by transplant specialists.
- Quantify the forces, attitudes, and barriers to practice improvement and the corresponding readiness of physicians to change.

Addressing gaps surrounding the management of the kidney transplant patient requires a multifaceted evaluation of the forces that impact patient care so appropriate educational strategies can be designed. Identifying variables that impact physician behavior is key to meeting educational challenges and

capitalizing on learning opportunities. This needs assessment project integrates data from the following sources to identify opportunities for physician education:

- Survey and analysis of clinical literature surrounding post-graft management and chronic care of kidney transplant patients.
- Review of relevant clinical guidelines on kidney transplant care.
- In-depth interviews with stakeholders, including transplant surgeons, nephrologists, urologists, and associated health care professionals.
- Analysis from a validated assessment tool completed by more than 200 specialists. The tool
 assessed clinician treatment behavior, perceived competency, barriers to care, clinical
 knowledge, and educational preferences.

This targeted report presents specific qualitative and quantitative findings from the transplant specialists (nephrologists with specific training in transplant medicine, most of whom practice in the transplant center setting).

This needs assessment was funded through an educational grant from Pfizer Medical Education Group. The project was completed using a collaborative process between the participating organizations; no one member could have completed this rigorous analysis without the challenge and support of the others. This spirit of collaboration should continue with continuing medical education professionals designing education and interventions to improve the ongoing care of kidney transplant patients.

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Needs Assessment Overview

The behavior of physicians and health care professionals depends not only on skill and knowledge, but also on the clinical environment and the forces at play within that environment. For physicians and health professionals to change, systems and stakeholders must also change. This needs assessment was designed to:

- Identify barriers to best practice at individual and system levels
- Develop tools to assess the knowledge, attitudes, and practice gaps of transplant specialists
- Assess the knowledge, skill, and/or attitude gaps of transplant specialists related to the care of the kidney transplant patient
- Determine how various factors, including systems factors, work together to accelerate or impede clinician adherence to best evidence
- Identify optimal change strategies and the resources to close the identified gaps

Research Questions

The following questions regarding the care of kidney transplant patients were addressed during this study:

- How are physicians and health care professionals managing patients through the life of the graft compared to consensus statements and standards of care?
- How do clinicians perceive their own care of kidney transplant patients?
- What gaps in knowledge, attitude, skills, and behavior exist that can be addressed through education?
- What are the most appropriate formats for educational interventions?

Stakeholders

This larger needs assessment project focused on three populations: community nephrologists, transplant specialists (primarily nephrologists who practice at transplant centers), and transplant surgeons—including urologists, nephrologists and general surgeons—who manage care of kidney transplant patients. Transplant coordinators and nurses who work with these patients were also included in the qualitative components of the needs assessment in order to provide a broader perspective of the physician needs.

This report presents quantitative and qualitative needs assessment results from the transplant specialist group, as well as touching on comparisons and interactions between the three target groups. Specific results for community nephrologists and transplant surgeons, as well as a comprehensive project report, are available as separate documents.

Needs Assessment Methodology

To identify the educational strategies needed to close the gaps in care, we first performed a thorough and detailed review of evidence-based literature, observational studies, guidelines, consensus statements, and research initiatives surrounding the care of kidney transplant patients. **Table 1** outlines various clinical guideline statements consulted during this process.

Guideline Title	Organization	Year(s) of Publication
Caring for Australasians with Renal Impairment (CARI) Transplantation Guidelines ⁱ	Australian and New Zealand Society of Nephrology (ANZSN), Board of Kidney Health Australia (KHA)	2005-2010 (various)
KDOQI Guidelines for CKD Care and Dialysis Care ⁱⁱ	National Kidney Foundation Kidney Disease Outcome Quality Initiative (NKF KDOQI)	2000-2009 (various)
KDIGO Guideline for the Care of the Transplant Patient ⁱⁱⁱ	Kidney Disease: Improving Global Outcomes (KDIGO)	2009
Guidelines on Renal Transplantation ^{iv}	European Association of Urology	2003 (full-text update 2009)
Immunosuppressive therapy for renal transplantation in adults ^v	National Institute for Clinical Excellence (NICE)	2004
European Best Practice Guidelines for Transplantation ^{vi, vii}	European Renal Association, European Dialysis and Transplant Association	2000 (Part 1) ; 2002 (Part 2)
United Kingdom Guidelines for Living Donor Kidney Transplantation ^{viii}	British Transplantation Society, the Renal Association	2000

Table 1: Clinical Guideline Documents for Kidney Transplantation and Disease

Of these documents, the main evidence-based comprehensive clinical guideline for the ongoing care of kidney transplant patients is a 2009 publication from *Kidney Disease: Improving Global Outcomes* (KDIGO). Results from 3,168 randomized control trials, 7,543 cohort studies, and 1,609 reviews informed the *KDIGO* recommendations, while previous publications on long-term management—such as part two of the European Best Practice Guidelines for Renal Transplantation, released in 2002—were based primarily on expert opinion.¹²

After the literature assessment was complete, we employed a number of distinct needs assessment techniques to identify gaps and determine the barriers to providing optimal patient care. These techniques included in-depth interviews with stakeholders, focus groups with target audiences, a Change Readiness Inventory® (CRI), a knowledge assessment tool, and a practice assessment tool.

Individually, each needs assessment component provides a unique perspective into the actual and perceived needs of clinicians as well as their barriers to best practice. Moreover, the systematic and integrated evaluation of all needs assessment components identifies and validates knowledge, attitudes, competencies, current clinical practices, and external systems barriers.

All needs assessment methods were designed to reflect the diversity of the practice settings in which care is provided. The provider-focused needs assessment methodology described below provides a multi-dimensional perspective on educational needs; results may be used to inform the development of educational interventions and encourage maximal impact on educational, behavioral, and clinical outcomes.

Qualitative Assessment

Interviews

To better target the needs of the learner, sixteen in-depth interviews were conducted with transplant specialists. They served to identify key issues and influences on clinical behavior, patient management, and educational needs. The interviews also helped identify touch points in the diagnosis, treatment, and long-term management of the kidney transplant patient as well as explore practice management issues that impact therapeutic decision-making. Thirty interviews were also conducted with other stakeholders who work with transplant specialists to provide care to kidney transplant patients, including community nephrologists, transplant surgeons, urologists, and transplant coordinators.

Project partners used the resulting information gathered through the literature review to create an interview guide that was then reviewed by a clinical expert. The interviews were conducted by telephone and lasted approximately one hour; participants were compensated for their time. Researchers used existing partner relationships to access interview participants.

Focus Groups

Project partners conducted and moderated focus groups in order to better understand the influence that each stakeholder group has on the clinical approach to and the long-term management of kidney transplant patients. This approach allowed researchers to discuss the topic areas of the one-on-one interviews in a group setting and develop the assessment tools for the quantitative phase of research. Three of the six focus groups incorporated transplant specialists:

- Two focus groups were conducted with mixed-specialty teams affiliated with specific transplant centers in Detroit, MI (March 2011) and Birmingham, AL (April 2011). These teams included community nephrologists, transplant surgeons, transplant coordinators, and transplant specialists (nephrologists).
- One focus group, were conducted in conjunction with the American Transplant Congress (May 2011), consisted of transplant surgeons and specialists.

These sessions served to revise and validate the practice assessment and knowledge assessment questions.

Quantitative Assessment

Information from the interviews and focus groups aided in developing and refining the online assessment tool, consisting of three distinct sections. Each section provided valuable quantitative information and, cumulatively, allowed analysis on the perceived and actual needs of the learners. The three sections of the assessment are highlighted below:

- Change Readiness Inventory® (CRI): The CRI measured attitudes, perceived needs, and barriers in clinical practices. The clinical competencies section was developed in cooperation with clinical experts from the American Society of Transplantation, referencing current literature. This section was used to establish the perceived needs of the target audience.
- Knowledge and Practice Assessment tools: These tools were designed to assess current
 knowledge and actual clinical behavior related to the long-term care of kidney transplant
 patients. The tools assessed a comprehensive baseline of physicians' knowledge and clinical care
 behavior in the management of immunosuppressive therapy as well as the recognition and
 treatment of common co-morbidities in transplant patients. The knowledge and practice
 assessment tools provided a self-report of clinicians' attitudes and behaviors surrounding the
 delivery of care and collected details regarding specific treatment modalities and reasons for
 treatment choices. Results present a quantitative measure of clinician's knowledge and skill
 gaps.
- Educational Preferences Assessment: The final portion of the quantitative survey assessed educational preferences. Questions were designed to determine the best formats in which to present educational activities. This helps to identify the preferred topics, design, learning format, and platform for the target learner groups. From this information, educational planners may design interventions that provide the greatest potential to impact clinical practice and patient health.

Specific survey questions were developed by Healthcare Performance Consulting, the American Urological Association, and the American Society of Transplantation. Items were reviewed by clinical experts and validated with a sample of the target audiences. The survey was posted online and a link was disseminated via email to members of the three target audiences.

The survey was distributed to community nephrologists recruited through ResearchNow (an online panel provider with a validated clinical panel) and transplant specialists recruited through the membership of the American Society of Transplantation. A total of 197 surveys were distributed and 146 were returned, for a response rate of 74 percent. The transplant specialist group consisted of nephrologists with additional training in transplant medicine. All respondents were further screened to ensure that they matched the target audience and provided care to kidney transplant recipients.

The complete text of the survey can be viewed in Appendix 1 (page 34).

Qualitative Results

The in-depth interviews and focus groups were designed to assess key issues and influences on the complex management of kidney transplant patients. The interviews identified numerous challenges in coordinating the care of patients throughout their transplant journey, from the community nephrologist's initial referral to a transplant center, to the subsequent transition of the patient back to the community nephrologist, to the continuing care of the patient for ongoing primary care issues.

Stakeholders stated that the management of kidney transplant patients is challenging, time-consuming, and often requires a great deal of communication and coordination of care. Major challenges include managing immunosuppressive therapy, managing co-morbidities that often worsen after transplant, patient adherence and compliance issues, and monitoring and screening for signs of organ rejection, cancer, infections, and osteopenia. The issues that were discussed were consolidated into key themes, exemplified by direct quotes gathered from interviewees.

Key Themes from the Interviews

Coordination and Continuity of Care

Care must be carefully coordinated between the community/referring nephrologist and the transplant center both before and after the transplant. A number of challenges, both systemic and personal, affect this coordination of care. Communication between various physicians who care for the patient is, at times, sub-optimal. Often, reports such as doctor visits, labs, or screenings are not communicated in a timely manner between the primary care physician, community nephrologist, and transplant center. For the first three months after transplant, patients are seen primarily by the transplant specialist and surgeon; after three months, care is typically transitioned to the community nephrologist and/or the primary care physician and other specialists.

Ideally, the transplant centers would see patients quarterly for one year post-transplant and once a year thereafter; in actuality, this schedule varies widely. Patient distance from the transplant center, access to a community nephrologist, and patient preference play a role in how post-transplant care is provided. Patients located far from the transplant center may not return as frequently. Ideally, the nephrologist monitors kidney function and frequently co-manages co-morbidities with a primary care provider or other specialist(s). However, some patients do not have access to a community nephrologist, and are cared for by a primary care provider; other patients who see a community nephrologist may or may not have a primary care doctor as well. Either one may manage cancer screenings, monitor for osteoporosis and risk of infections, and provide appropriate vaccinations. The transplant center most often manages any changes to immunosuppression, but relies on the community nephrologist or primary care provider to communicate lab results or other patient data.

Busy community nephrology practices may lose track of transplant patients after a period of time. Patient and family education is crucial to ensure that patients get the appropriate screenings and are alert to additional risks for illness and disease, such as osteoporosis, certain cancers, and infection. Patient understanding that immunosuppression places them at greater risk for these conditions contributes to their motivation and adherence to appointments and medication regimens.

The development of protocols and communication strategies to identify a lead physician in ordering surveillance testing would benefit providers and patients. Up-to-date patient information should be shared in a timely manner.

"Patient management post-transplant is the art and science of medicine – the challenge of balancing immunosuppression efficacy versus side effects, toxicity and patient tolerance."

Patient Diversity

Kidney transplant candidates represent a broad spectrum of patients: from relatively healthy to those with multiple co-morbidities and chronic diseases; from wealthy to poor; and from motivated to unmotivated. The ages of transplant patients range from teens to seniors, each presenting unique needs and challenges. Generally, younger patients tend to be less adherent. Pre- and post-transplant patient assessments by health care team members attempt to identify specific patient management issues.

Management of Co-Morbidities and Complicated Drug Regimens

Interviewees across all specialties note the many challenges in managing the multiple co-morbidities seen in transplant patients. Some of the most common co-morbidities include diabetes, kidney disease, hypertension and hyperlipidemia. Because most of these are treated with medication, the potential for drug interactions with immunosuppressive therapy is a major concern. Interviewees are apprehensive about pharmacies making generic substitutions, especially for immunosuppression medications that they feel may not be therapeutically equivalent. Interviewees also indicated that this switch confuses patients, since the pills may be a different color and shape. When asked about educational needs, participants listed 'improving their ability to manage multiple co-morbidities' and 'recognizing the signs and symptoms of drug interactions' as areas of interest.

"Pharmacy can change immunosuppression meds to generic willy-nilly, and it can be a problem for patients to recognize pills."

Patient Adherence

Clinicians across all specialties agree that patient adherence (patient compliance) is an important, challenging, and time-consuming issue that affects all members of the health care team (transplant surgeon, nephrologist, coordinator, social worker, pharmacist, community nephrologist, and primary care physician). The complexities involved in managing the transplant patient present a challenge to patient adherence. Numerous financial issues play a role as well, including loss of a job and/or changes in insurance coverage, the costs of multiple medications, the costs associated with numerous doctor and lab appointments, and periodic visits to the transplant center. According to the clinicians, taking time off work to go to doctors' appointments, traveling to the transplant center, and transportation costs all were of concern to patients as well. Furthermore, patients may lose Medicare and/or Medicaid coverage at three years post-transplant.

Motivating patients to follow long-term, complex treatment plans is also a challenge. While younger patients and teens are often less adherent, family members play an integral part in ensuring that patients of all ages follow physician recommendations. If adherence is a concern, drug levels may be periodically checked to detect if the patient is taking his or her medications as prescribed. Some patients develop a strong, supportive relationship with the dialysis center staff and experience feelings of loss following transplant, which may affect adherence as well. Patients who are doing well post-transplant may skip follow-up appointments, lab work, and medications; though some can tolerate this, others will get into trouble. Frequently, patients are evaluated by a social worker pre-transplant to determine the likeliness of compliance post-transplant (e.g., was the patient compliant with dialysis, doctor's appointments, and lab work?).

Educational needs in this area include developing processes to educate patients and family members on the importance of long-term adherence and establishing communication guidelines, protocols, and adherence monitoring strategies. Helping patients access community resources that cover medication costs may also have a positive impact on patient adherence.

"Compliance with medications long-term can be challenging. Patients who are doing well may skip doctors' appointments, lab work, and meds: some will get by, and some will run into problems."

Treatment Protocols and Guidelines

Treatment protocols and recommendations for patient follow up are developed by transplant teams (transplant surgeons and transplant specialists at each transplant center) and are based on clinical evidence from the literature as well as transplant center experience. Whenever possible, the transplant team develops standing orders and then customizes treatment based on individual patient needs. National guidelines are used to manage multiple co-morbidities, although most accepted national

guidelines for chronic disease and co-morbid conditions are not specific to transplant patients. AST, *KDIGO* and KDOQI guidelines were mentioned as providing useful general recommendations for patients with chronic kidney disease, although there are fewer evidence-based guidelines specifically for transplant patients. Some clinicians were not aware of specific guidelines for transplant patients.

Interviewees report that they rely heavily on teamwork to develop and update protocols. Typically, protocols are reviewed on an annual basis or when there is a change in leadership at the transplant center, and revised as needed. Educational needs in this area include developing a mechanism to educate community nephrologists and primary care providers (PCPs) on any protocol changes. Because community nephrologists and primary care clinicians may care for patients from multiple transplant centers with varying protocols, communication is vital to maintaining optimal patient care.

Immunosuppression and the Use of Steroids

The transplant team usually takes the lead in managing immunosuppression. The use of steroids varies among transplant centers. Most transplant centers use steroid minimization, rapid tapering, or steroid-free protocols (except for patients with underlying conditions, such as lupus). Centers report no change in patient outcomes with steroid minimization. Interviewees agree that it is a challenge to balance the risk for toxicity (over-immunosuppression) with the risk of rejection (under-immunosuppression). Patients who receive multiple transplants represent additional challenges, as they develop more antibodies and have a greater risk for graft rejection; therefore, every effort is made to encourage the first kidney transplant to last as long as possible. Most transplants are successful for at least five years. Years five to 10 post-transplant are often more difficult due to the long-term effects of immunosuppression and worsening co-morbidities. A transplant lasting 10 to 15 years is considered a very good result.

"Managing the risk of toxicity due to over-immunosuppression vs. the risk of rejection due to under-immunosuppression is complex. A kidney transplant survival of five to 1 years is considered good."

Identifying potential drug interactions is a continual process. Risk factors and signs and symptoms of rejection must be frequently monitored (e.g., trends in creatinine levels, ultrasound if obstruction is suspected, biopsy if there are concerns about rejection, testing for BKV and CMV).

Interviewees expressed an interest in education related to best practice protocols, case studies on managing immunosuppression in first-time and repeat transplant patients, and how to manage adverse events related to over- or under- immunosuppression. Information on best practices and results for various steroid use protocols (steroid free, steroid minimization, and rapid tapering) would also be valuable.

"There is consensus that avoiding or minimizing steroids is the right approach due to side effects and aggravating comorbidities, though there is variation on how this is done."

Most Recent Changes in Clinical Practice

When asked about recent changes in their practice, transplant specialists and surgeons stated that they were using fewer steroids, increasing testing for BKV (due to an increase in prevalence), and seeing more generic medication substitutions, especially the use of more generic immunosuppression agents. Educational needs cited included helping community nephrologists and primary care providers identify the signs and symptoms of rejection and determining course of action when creatinine levels are rising. Best practices and case studies on when to do biopsies would also be helpful.

Educational Opportunities for Transplant Center Physicians

Educational topics directed specifically toward transplant center physicians, including surgeons and specialists, may include:

- Managing chronic co-morbidities in the transplant patient
- Best practices and case studies on immunosuppression and steroid use
- Managing drug interactions
- Improving processes and communication with referring physicians, both pre- and posttransplant

Transplant Center Focus Groups

The focus groups allowed researchers to specifically target individual clinician groups to confirm interview findings and further explore the unique educational needs and opportunities of each specialty.

Focus groups assessing transplant center staff revealed that systemic issues related to coordination of care are particularly troublesome. While transplant center clinicians have electronic health records available to them, the community physician may not, or electronic systems may not integrate.

Regardless, communication and coordination is burdened by the need to record, review, and manage records that are partially on paper and partially electronic. Transplant coordinators spend hours a day pulling together patient information that would ideally be gathered by a system.

Additional issues identified included:

- Inadequate staffing to manage the patient load. Transplant coordinators may be responsible for up to 700 patients and cannot adequately monitor and oversee that number.
- Increasingly shrinking resources for providing care to patients who cannot afford it.

- Substitution of generic medications increases patient confusion, decreases adherence, and confuses assessment of efficacy.
- Community nephrologists, primary care physicians, and other specialists who care for kidney transplant patient have conflicting wishes about "who takes care of what." It is difficult for the transplant center clinicians to balance the differing needs and desires. As an end result, clinical responsibilities tend to be handled on a case-by-case basis.

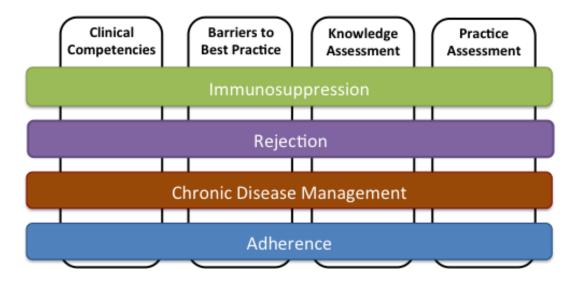
Quantitative Results

Development of the Quantitative Survey Instrument

After all in-depth stakeholder interviews and focus groups were complete, project partners performed a careful review and analysis of all available data in order to create a framework for a qualitative physician survey. Researchers determined that the most relevant issues in patient care could be categorized into four overarching themes:

- 1. Selection and management of immunosuppression therapy,
- 2. Risk and detection of graft rejection,
- 3. Chronic care of the kidney transplant patient (including management of co-morbidities and chronic disease), and
- 4. Patient adherence to therapy.

All sections of the quantitative survey were designed to collect further data in each of these four topics, as illustrated in the following graphic. Throughout this document, charts and items that relate to each topic will be color-coded according to the graphic below: *immunosuppression* is green, *rejection* is purple, *chronic disease management* is maroon, and *adherence* is blue.



The individual quantitative assessment tools—which assessed competency, barriers to best practice, knowledge, and practice—were combined into a single survey in order to define relationships between knowledge, clinical practices, competencies and barriers. The relationship between these items is shown below in **Table 3**. While some items overlap and correlate, they may be grouped into 4 basic categories: Immunosuppression, Rejection, Chronic Care, and Patient Adherence. The groups and related charts will be color-coded throughout this report to reflect this correlation. Qualitative findings and educational implications also fall neatly within these categories, and will be organized and color-coded accordingly.

Competencies	Barriers	Knowledge Questions	Practice Questions
	Immunosuppression		
C1select an effective immunosuppressive drug regimen that attains adequate protection of the kidney allograft against rejection. C2minimize short- and long-term adverse side effects of immunosuppressive medications. C3identify potential interactions between immunosuppressive agents and other medications.	B1. I do not always have access to the patient information that I need to make the best decision about patient management. B3. We are not able to utilize the best therapies due to cost constraints. B4. Many patients cannot afford the treatments that will keep them healthy. B6. Primary care physicians are not adequately trained to manage the complexity of a transplant patient.	K1,K2,K3, K4,K7	P1, P2, P3
	Rejection		
C4identify risk factors for acute rejection. C5detect signs and symptoms of acute graft rejection by monitoring creatinine levels. C6 attain an allograft biopsy to determine if rejection is occurring.	B1. I do not always have access to the patient information that I need to make the best decision about patient management. B2. Access to the transplant center is limited. B4. Many patients cannot afford the treatments that will keep them healthy. B6. Primary care physicians are not adequately trained to manage the complexity of a transplant patient. B8. There is too much of a delay between when a patient first shows elevated creatinine and when they return to the center for appropriate testing and management.	K5	P3
	Chronic Care		
C7coordinate with other specialists or primary care physicians to manage co-morbid conditions (diabetes, hypertension, cardiovascular disease). C8use screenings to detect cancer in the transplant patient. C9 monitor as appropriate for osteoporosis (calcium serum levels, phosphorus, bone-mineral density, and plasma intact PTH). C10mitigate risk of infection by appropriate use of prophylactic antibiotic, antiviral and antimycotic treatment. C11appropriately vaccinate six months post-transplant using inactive vaccines.	B1. I do not always have access to the patient information that I need to make the best decision about patient management B2. Access to the transplant center is limited and causes problems. B6. Primary care physicians are not adequately trained to manage the complexity of a transplant patient. B7. There is insufficient staff in our practice/facility to be able to support transplant patients as well as we should. B8. There is too much of a delay between when a patient first shows elevated creatinine and when they return to the center for appropriate testing and management. B9. Coordination of care for co-morbid conditions causes problems.	K6, K8, K9, K10, K11, K12	P5, P6, P7, P9, P10
	Adherence		
C12identify risk-factors for non-adherence to medication regimens. C13effectively communicate risks of non-adherence to patients and family	B4. Many patients cannot afford the treatments that will keep them healthy. B5. Patients are not honest with me about adherence to their treatments	No related knowledge questions	P8

Table 3: Relationships Between Competencies, Barriers, and Knowledge/Practice Questions (Immunosuppression, Rejection, Chronic Care, Adherence)

Demographics

The assessment was distributed to three target specialties: community nephrologists, transplant surgeons, and transplant nephrologists. Responses were distributed evenly between the three specialty groups (Figure 1, below).

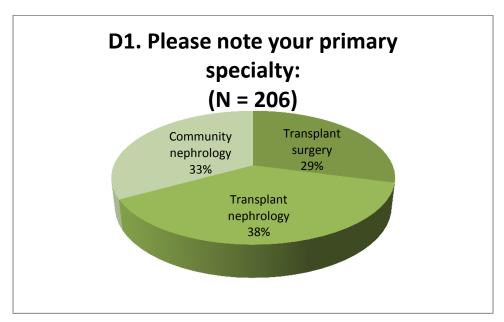


Figure 1: Primary Specialty

Of 206 total respondents, 78 identified themselves as transplant nephrologists (referred to in this document as transplant specialists). The charts presented in this document graphically illustrate the responses of these 78 individuals. Select charts are included in this section; additional charts may be viewed in Appendix 2 (page 41).

Responses indicate that transplant specialists have varying patient loads; the most common number of patients seen per week is 11-25 (46% of respondents) (Figure 2).

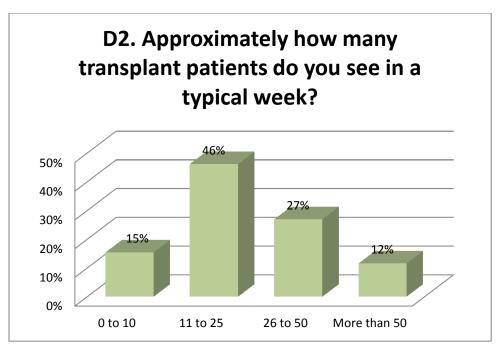


Figure 2: Patients Seen in a Typical Week

Change Readiness Inventory® - Perceived Needs and Barriers

The competencies are a series of statements that represent the abilities needed to successfully manage kidney transplant patients. These competencies were developed from clinical guidelines, current literature, and expert opinion. Physicians were asked to consider the following statements, then indicate both their *present* and *desired* levels of ability (from 1=low to 5=high) in performing each task.

Please rate your *present* and *desired* ability to:

- C1. Select an effective immunosuppressive drug regimen that attains adequate protection of the kidney allograft against rejection.
- C2. Minimize short- and long-term adverse side effects of immunosuppressive medications.
- C3. Identify potential interactions between immunosuppressive agents and other medications.
- C4. Identify risk factors for acute rejection.
- C5. Detect signs and symptoms of acute graft rejection by monitoring creatinine levels.
- C6. Attain an allograft biopsy to determine if rejection is occurring.
- C7. Coordinate with other specialists or primary care physicians to manage comorbid conditions (diabetes, hypertension, cardiovascular disease).
- C8. Use screenings to detect cancer in the transplant patient.
- C9. Monitor as appropriate for osteoporosis (calcium serum levels, phosphorus, bone-mineral density, and plasma intact PTH).
- C10. Mitigate risk of infection by appropriate use of prophylactic antibiotic, antiviral and antimycotic treatment.
- C11. Appropriately vaccinate 6 months post-transplant using inactive vaccines.

- C12. Identify risk-factors for non-adherence to medication regimens.
- C13. Effectively communicate risks of non-adherence to patients and family.

*Immunosuppression, Rejection, Chronic Disease, Adherence

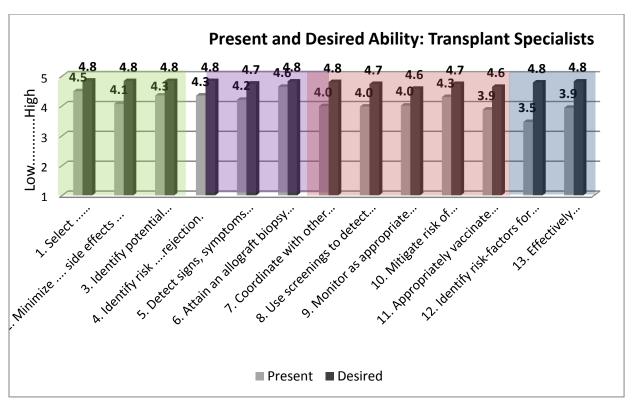


Figure 17: Transplant Specialist Present and Desired Competencies (*Immunosuppression, Rejection, Chronic Disease, Adherence*)

Figure 17 shows transplant specialists' average rating of their own present and desired abilities. The average *desired ability* ratings range from 4.6–4.8, averaging 4.8 on a one to five scale. This is similar to what is often seen for the average of desired clinical competencies, with little variability. This reflects a high and consistent desire to excel in every area of managing the transplant patient. The average *present ability* was 4.1 on the five-point scale, with a range of 3.5 to 4.6. There is greater variation in the present abilities as compared to the desired abilities, as is common with self-rated competencies.

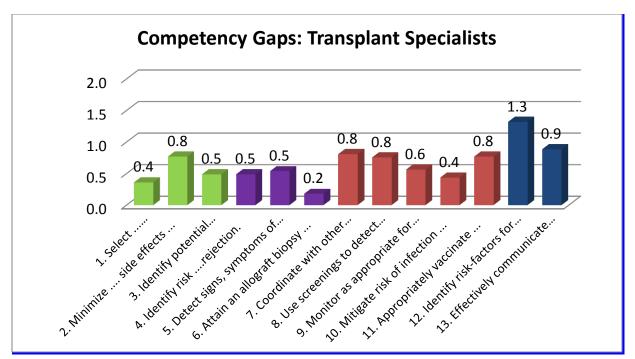


Figure 18: Transplant Specialist Competency Gaps (Immunosuppression, Rejection, Chronic Disease, Adherence)

The *perceived need* of each competency is the difference, or gap, between physicians' ratings for *present* and *desired* levels of ability. In other words, this number represents the difference between "what is" and "what ought to be." A gap of 0.5 is presumed to be important, with gaps of 1.0–2.0 considered ideal for clinician education. A gap smaller than 0.5 indicates low motivation to learn and change, while a gap higher than 2.0 may represent a level of change that the physician believes to be unattainable or impractical.

The average gap, or perceived need, of this competency set is 0.6 (Figure 18). The individual gaps for each competency ranged from 0.2 to 1.3. Ten of 13 gaps are over the 0.5 level and should be carefully considered for educational interventions. Only one gap is in the ideal range between 1.0 and 2.0 (C12. Identify risk-factors for non-adherence to medication regimens). The second highest gap also relates to adherence (C13. Effectively communicate risks of non-adherence to patients and families). Physicians realize that change is needed in adherence-related competencies and are highly motivated to make practice changes in this area.

Barriers to Best Practice

Barriers are real or perceived issues that may prevent physicians from applying best practices. Knowledge of the nature and magnitude of these barriers helps educational designers address them within the scope of the interventions, and in doing so, encourage change in physician performance as

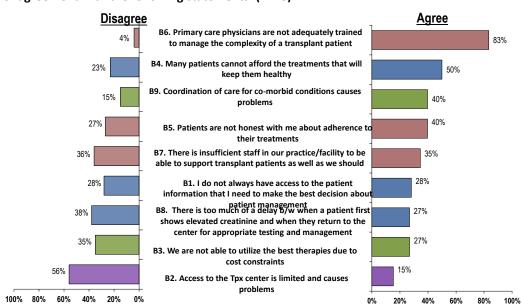
well as change in knowledge and skill. These barriers were derived from expert opinion, data from the in-depth interviews, and literature on physician change.

The next set of statements represents barriers to best practice when managing transplant patients. Please rate each statement according your level of agreement as to whether the item represents a barrier to effective management of transplant patients. (1=Strongly Disagree, 5=Strongly Agree)

- B1. I do not always have access to the patient health information that I need to make the best decisions about patient management.
- B2. Access to the transplant center is limited.
- B3. I am not able to utilize the best therapies due to cost constraints.
- B4. Many patients cannot afford the treatments that will keep them healthy.
- B5. Patients are not honest with me about adherence to their treatments.
- B6. Primary care physicians are not adequately trained to manage the complexity of a transplant patient.
- B7. There is insufficient staff in our practice/facility to be able to support transplant patients as well as we should.
- B8. There is too much of a delay between when a patient first shows elevated creatinine and when they return to the center for appropriate testing and management.
- B9. Coordination of care for co-morbid conditions causes problems.

*Immunosuppression, Rejection, Chronic Disease, Adherence

Figure 19 shows the list of statements arranged in order of respondents' highest perceived barriers. The bars to the right represent the percentage of respondents rating the barrier high (four or five on the five-point scale), indicating agreement. The bars to the left represent the percentage of respondents rating the barrier low (one or two), indicating disagreement.



Using a 1 to 5 scale, where 1 is strongly disagree and 5 is strongly agree, please rate your level of agreement with the following statements: (n=78)

Note: Agree represents those respondents answering a 4 or 5 on a 5-point scale where 5 is strongly agree and 1 strongly disagree. Disagree represents those respondents answering a 1 or 2 on the same 5-point scale.

Figure 19: Transplant Specialist Barriers to Best Practice (Immunosuppression, Rejection, Chronic Disease, Adherence)

Barrier B6, *Primary care physicians are not adequately trained to manage the complexity of a transplant patient*, had both the highest percent of agreement and the lowest percent of disagreement. This barrier stands out as a strong impediment to best practices in caring for kidney transplant patients. The next highest barrier, B4, represents a cost constraint: *Patients cannot afford the treatments that will keep them healthy*. A large group (23 percent) of respondents indicated disagreement with this statement. This may reflect centers with more support personnel (transplant coordinators, social workers) who are often able to find sources of free or low-cost medications for patients.

A high percentage of respondents also strongly agreed with Barrier 9, Coordination of care for co-morbid conditions causes problems and Barrier 5, Patients are not honest with me about adherence to their treatments. These barriers emerged as common themes during the interviews.

Knowledge Assessment Questions

The Knowledge Assessment portion of the survey consisted of 14 questions designed to assess knowledge that is directly related to the clinical competencies. Each question relates to a specific clinical competency. The full text of the knowledge assessment questions is available in Appendix 1 (page 34).

Transplant specialists are highly knowledgeable in immunosuppression and rejection. The only questions that posed any difficulty were those related to chronic disease (Figure 20).

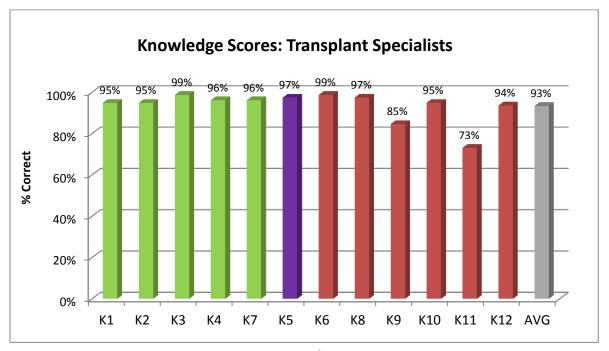


Figure 20: Transplant Specialist Knowledge Scores (*Immunosuppression, Rejection, Chronic Disease, Adherence*)

Practice Assessment Questions

The practice assessment questions were designed to assess actual clinical practices of the respondents. The results may be compared to best practices to establish real needs and their relationships to perceived needs and knowledge gaps. Responses to select practice questions are shown below, with the remainder appearing in Appendix 2 (Page 41).

Transplant specialists were asked to indicate the percentage of their patients that see a community nephrologist outside of their institution. Only a quarter of respondents estimated that more than 50 percent of their patients see a community nephrologist (Figure 21). This is important because interviewees indicated that, while they encourage patients to have a community nephrologist, many do not. Chronic care issues that would be managed or coordinated by a community nephrologist must then be managed by the transplant center.

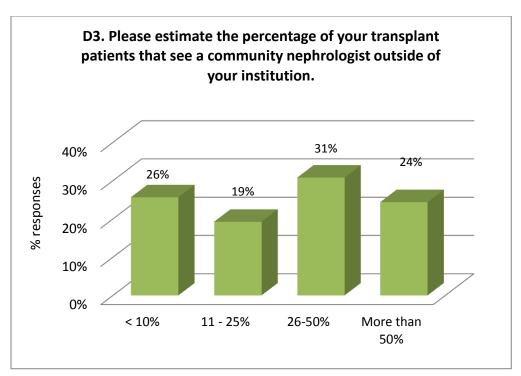


Figure 21: Transplant Specialist Estimates of Patients with a Community Nephrologist

When asked to rate their responsibility in a variety of preventive care issues (P5, Figure 22), transplant specialists varied in their responses. They rated responsibility for hypertension management highest (4.5 on a scale from one to five), followed by lipid management (4.0). They expressed the lowest level of responsibility for cancer screening, which rated at 3.4 on the five-point scale.

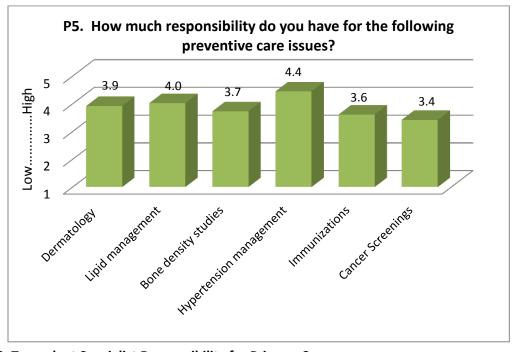


Figure 22: Transplant Specialist Responsibility for Primary Care

Vaccinations are a fundamental part of the preventive care that is crucial to maintaining good health. They are particularly important with the transplant population due to immunosuppression. While most transplant specialists indicate that they administer influenza vaccines, far fewer indicated that they administer pneumonia, hepatitis B or Tdap vaccines (Figure 23).

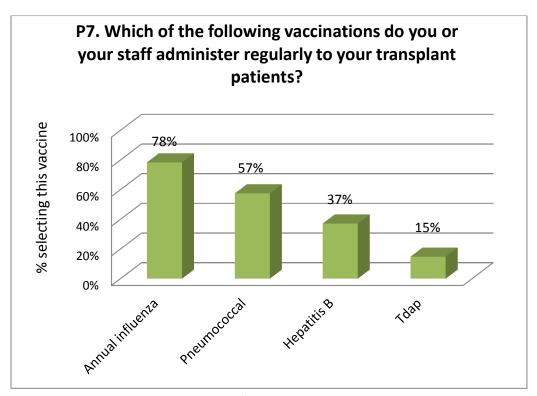


Figure 23: Transplant Specialist Responsibility for Vaccinations

Because transplant recipients are at higher risk for bone disease, respondents were asked which monitoring methods they routinely use. Although there were a variety of responses, most respondents use methods in accordance with existing guidelines (Figure 24).

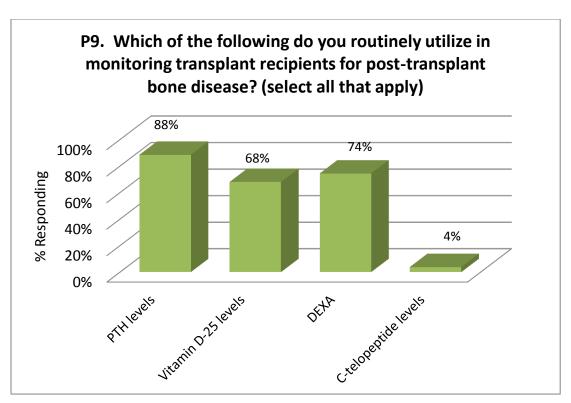


Figure 24: Transplant Specialist Bone Disease Monitoring Methods

BK viremia is of particular concern in transplant patients and has been more prevalent in recent years. Although KDIGO recommendations call for monthly screenings for three to six months post-transplant and every three months afterward for the first year, only 32 percent of respondents follow this schedule (Figure 25). Many of the "other" responses were in compliance with or more rigorous than the recommended schedule. However, 12 percent indicated that they screen *only if there is evidence of graft dysfunction*.

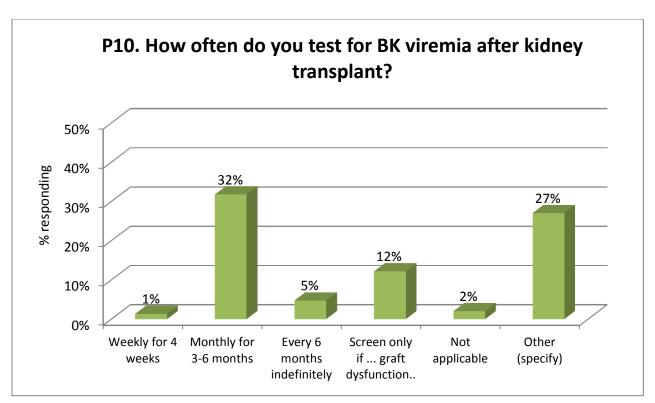


Figure 25: Transplant Specialist Monitoring for BK Viremia

Educational Preferences

Survey respondents were asked a series of questions about their educational preferences. While it is important to consider their preferences to encourage participation in educational activities, educational preferences do not necessarily follow educational needs.

Transplant specialists were asked in which areas they believed the current body of knowledge and literature is inadequate to guide them in best practices (Figure 26). Twenty-six percent feel that the current body of knowledge and literature is adequate, which may represent a barrier to participation in CME and should be considered when planning and promoting CME activities. Fifty-three percent selected *co-morbid conditions*; these specialists may appreciate exposure to the most recent evidence-based data on co-morbidities in transplant patients.

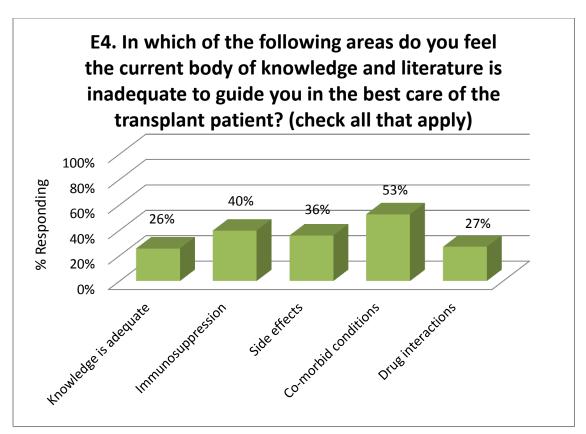


Figure 26: Transplant Specialist Knowledge and Literature

Respondents were presented a list of topics related to management of kidney transplant patients and asked to indicate up to three activities that they were most likely participate in (Figure 27). The choices available to participants were:

- 1. Immunosuppression update
- 2. Drug-drug interactions in the kidney transplant patient with chronic disease such as hypertension and diabetes.
- 3. Managing adverse effects of immunosuppression
- 4. Appropriate monitoring of the kidney transplant patient
- 5. Titration of immunosuppression therapy
- 6. Managing chronic conditions such as hypertension and diabetes in the kidney transplant patient
- 7. Screenings and tools for preventive care in the transplant patient
- 8. Increasing adherence in the transplant patient
- 9. Other

The most frequently selected topics were:

- Immunosuppression update
- Titration of immunosuppression therapy
- Appropriate monitoring of the kidney transplant patient

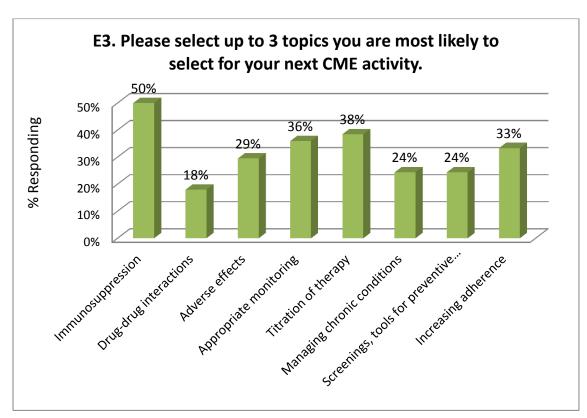


Figure 27: Transplant Specialist Topics for Next CME Activity

When asked to rate the importance of various attributes of educational activities, responses showed little difference between them (Figure 28).

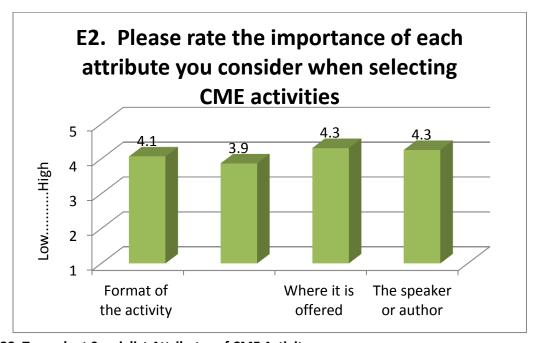


Figure 28: Transplant Specialist Attributes of CME Activity

The survey also queried learners about the format of their most recent educational activity (Figure 29). This provides a rough indication of the type of activity in which transplant specialists are most likely to participate. Transplant specialists overwhelmingly indicated state and national society meetings, with 54 percent of responses. All other categories of educational activity were selected much less frequently.

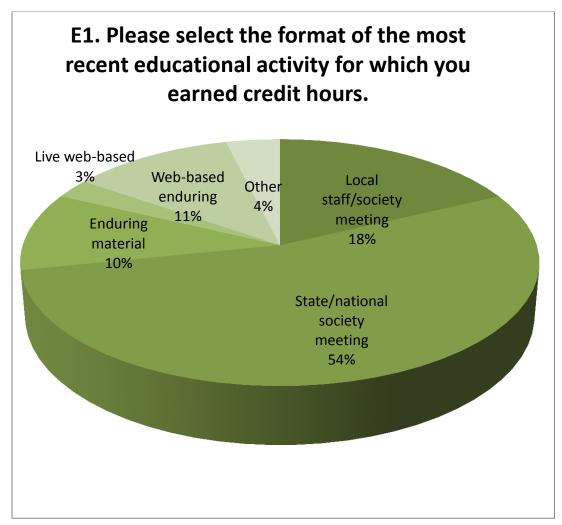


Figure 29: Transplant Specialist Most Recent Educational Activity

Implications for Continuing Education

Table 4 summarizes the findings for transplant specialists in terms of each of the four assessment categories.

Topic	Perceived Need	Knowledge Gap	Practice Gaps	Barriers
Immunosuppression	Minimize side effects Detectacute rejection	No	No	Multiple protocols Cost of medications Adherence to regimen
Rejection	Detectacute rejection	No	No	Cost of medications Adherence to regimen
Chronic Care	Coordinate with other specialists. Use screenings Monitor for osteoporosis Appropriately vaccinate	Yes	Yes	Adherence to regimen Coordination of care Management of co- morbidities
Adherence	Identify risk-factors for non- adherence Effectively communicate risks of non-adherence	No	Yes	Cost of medications Adherence to regimen

Table 5: Transplant Specialists: Summary of Findings (*Immunosuppression, Rejection, Chronic Disease, Adherence*)

Immunosuppression and Rejection

Transplant specialists are well versed in immunosuppression. They perceive that they are quite competent and desire to be highly competent managing immunosuppression. Their highest perceived needs relate to minimizing side effects. Education on immunosuppression should focus on new developments, therapies, and regimens. Knowledge-based educational formats will be sufficient to attract participation and engage these specialists.

Transplant specialists can play an important role in providing best standards of care to community nephrologists, and, ultimately, the primary care community.

Transplant specialists have important perceived needs in the detection of acute rejection and will respond well to educational topics in this area.

Chronic Care

As the expert in transplant medicine and immunosuppression, the transplant specialist holds the key role in ensuring overall appropriate management of kidney transplant patients. Competency gaps indicate that they perceive need in patient chronic disease management. Interventions can be designed and implemented to facilitate better coordination of care. Tools and processes may be developed to ensure that patients undergo appropriate monitoring, screening, testing and follow-up care. Processes and systems can be implemented to ensure that the right information reaches the appropriate clinician at the most opportune time.

These tools, resources, systems, and processes must be driven by the transplant center. Community nephrologists, primary care physicians, and other specialists all have their own ways of working with patient information; therefore, the onus falls upon the transplant center to develop and implement a cohesive system.

Transplant centers can play a significant role in developing tools and resources that enhance coordination of care for patients who are transitioning from care managed in the transplant center to care managed within the community nephrology or primary care setting. Creating processes to share and coordinate care—and developing tools, resources, and education to facilitate those processes—should help to improve management of chronic disease in these patients.

Adherence

Allograft rejection is sometimes related to adherence issues. Perceived needs and barriers related to adherence were rated highly by community nephrologists, transplant specialists and transplant surgeons. All are aware of the role that adherence plays in the success of immunosuppression, organ rejection, and chronic care management. They report that adherence is closely linked to socioeconomic factors and recognize the unique adherence risks in young adult populations due to resistance and in the older populations due to confusion and the multiplicity of medications. Adherence should be addressed in all educational activities as a key factor in allograft survival. Tips and tricks to increase adherence should be part of the common curriculum of managing the transplant patient. This should include the identification of risk factors for non-adherence, the communication of health risks to patients and caregivers, and the signs and symptoms of non-adherence.

The cost of care emerged as a key factor influencing patient adherence. Physicians in the community may not be well connected to resources that provide medications and care for those who cannot afford it. Some aspect of educational activities should focus on the identification and use of available resources so that they are accessible to community physicians as well as transplant centers.

Educational Attributes

Transplant specialists are most attracted to live specialty meetings at the state or national level. They will also participate in other formats for topics related to new immunosuppression therapies, minimizing side effects, and increasing patient adherence.

Appendix 1: Quantitative Assessment Tool

Thank you for your willingness to participate in this assessment. It should take you less than 10 minutes. This will help AST and other organizations to plan and implement effective medical education activities. Your responses to this survey are entirely confidential, and no personally identifiable information will be collected. Please click Continue to get started.

information will be collected. Please click Continue to get started.
Practice Profile
D1. Please note your primary specialty: Transplant surgery
 Transplant nephrology Community nephrology Other (please specify)
 D2. Approximately how many kidney transplant patients do you see in a typical week? 0 - 20 21 - 40 41 - 60 More than 60
D3. Please estimate the percentage of your transplant patients that see a community nephrologist outside of your institution.
• Less than 10%
• 11-25%
26-50%More than 50%
D4. Please select your type of practice
• Solo
Single specialty groupMulti-specialty group
 Multi-specialty group Hospital transplant center
Other

Clinical Competencies

The next series of items represents clinical competencies related to management of the transplant patient. Please rate your Present Ability in the left-hand column, and your Desired Ability in the right-hand column.

Present Ability[Low,High]

	1	2	3	4	5
C1. Select an effective immunosuppressive drug regimen that attains adequate protection of the kidney allograft against rejection.					
C2. Minimize short- and long-term adverse side effects of immunosuppressive medications.					
C3. Identify potential interactions between immunosuppressive agents and other medications.					
C4. Identify risk factors for acute rejection.					
C5. Detect signs and symptoms of acute graft rejection by monitoring creatinine levels.					
C6. Attain an allograft biopsy to determine if rejection is occurring.					
C7. Coordinate with other specialists or primary care physicians to manage comorbid conditions (diabetes, hypertension, cardiovascular disease).					
C8. Use screenings to detect cancer in the transplant patient.					
C9. Monitor as appropriate for osteoporosis (calcium serum levels, phosphorus, bone-mineral density, and plasma intact PTH).					
C10. Mitigate risk of infection by appropriate use of prophylactic antibiotic, antiviral and antimycotic treatment.					
C11. Appropriately vaccinate 6 months post-transplant using inactive vaccines.					
C12. Identify risk-factors for non-adherence to medication regimens.					
C13. Effectively communicate risks of non-adherence to patients and family.					

34 Appendix 1

Barriers

The next set of statements represent barriers to best practices when managing transplant patients. Please rate each statement according your level of agreeement as to whether the item represents a barrier to effective management of patients in pain.

Please indicate your level of agreement to the following statements: (1= strongly disagree, 5=strongly agree)

Barrier Questions (B1 – B12)	Strongly Disagree1	2	3	4	Strongly Agree5
B1. I do not always have access to the patient health information that I need to make the best decisions about patient management.					
B2. Access to the transplant center is limited.					
B3. II am not able to utilize the best therapies due to cost constraints.					
B4. Many patients cannot afford the treatments that will keep them healthy.					
B5. Patients are not honest with me about adherence to their treatments.					
B6. Primary care physicians are not adequately trained to manage the complexity of a transplant patient.					
B7. There is insufficient staff in our practice/facility to be able to support transplant patients as well as we should.					
B8. There is too much of a delay between when a patient first shows elevated creatinine and when they return to the center for appropriate testing and management.					
B9. Coordination of care for co-morbid conditions causes problems.					

Practice Assessment

A1.

	Very	2	3	4	Very
	Uncomfortab				Comfortable
	le 1				5
How comfortable are you in monitoring immunosuppression?					

P5. How much responsibility do you have for the following preventive care issues?

	No responsibilit y 1	2	3	4	Complete responsibilit y 5
Dermatology consultations	O				
Lipid management	O				
Bone density studies					
Hypertension management	O				
Immunizations					
Cancer Screenings: colonoscopy,mammogram, PSA, etc.					

P6. In your transplant recipients, which strategy is used for post-transplant CMV?

- Prophylaxis with acyclovir or valganciclovir depending on donor/recipient serologies
- Preemptive therapy: initiate antiviral medication if laboratory evidence for CMV replication
- Treatment only, based on disease.
- Other

P7. Which of the following vaccinations do you or your staff administer regularly to your transplant patients?

- Annual influenza
- Pneumococcal
- Hepatitis B
- Tdap
- Other

P8. Please select up to 3 measures you rely on the most to monitor adherence to therapy. Select no more than 3 measures.

- Self-reported adherence
- Compliance with routine laboratory testing
- Blood medication levels
- Attendance at clinic visits
- Prescription refill records
- Other

P9. Which of the following do you routinely utilize in monitoring transplant recipients for post-transplant bone disease? (select all that apply)

- PTH levels
- Vitamin D-25 levels
- DEXA
- C-telopeptide levels

P10. How often do you screen for BK viremia after kidney transplant? Weekly for 4 weeks

- Monthly for 3-6 months
- Every 6 months indefinitely
- Screen only if evidence of graft dysfunction present
- Not applicable
- Other (specify)

Knowledge Assessment

K1. You are seeing a 36-year-old 8 months out from a deceased donor kidney transplant. You note that there is significant albuminuria. Which of the following medications could be contributing to this?

- Tacrolimus
- Cyclosporine
- Azathioprine
- Sirolimus

K2. Which of the following medications is most likely to contribute to a patient's dyslipidemia?

- Sirolimus
- Tacrolimus
- Mycophenolate Mofetil
- Belatacept

K3. Which of the following medications would preclude the use of allopurinol for hyperuricemia?

- Azathioprine
- Mycophenolate mofetil
- Cyclosporine
- Tacrolimus

K4. You would like to start a kidney transplant patient on clarithromycin. What will happen to the blood level of tacrolimus if the dose is not changed?

- The tacrolimus level will increase
- The tacrolimus level will decrease
- There will be no change
- Tacrolimus has to be stopped as it is contraindicated with clarithromycin

K5. A 68-year-old white male who received a kidney transplant from his wife 10 years ago for end stage renal disease due to polycystic kidney disease has had diarrhea for the past three days. He did not take his medications for two of those days. Presents to you feeling light headed. Blood pressure seated was 126/76, and on standing 90/55. Laboratories reveal a creatinine of 2.6 (baseline 1.5). What would you do?

- Give intravenous fluids and biopsy immediately to exclude rejection.
- Encourage oral fluid intake and biopsy immediately to exclude rejection.
- Give intravenous fluids and biopsy only if creatinine does not decrease the following day
- Proceed with a biopsy to exclude concomitant rejection even if the creatinine decreases the following day.
- Other (specify) _____

K6. John receives a kidney transplant and requires anti-hypertensive therapy post-transplant. Which of his pre-transplant anti-hypertensive medications would be expected to increase tacrolimus levels?

- Diltiazem
- Carvedilol
- Lisinopril

K7. Which of the following medications has the strongest association with the development of post-transplant diabetes?

- Sirolimus
- Tacrolimus
- Mycophenolate mofetil
- Cyclosporine

K8. Which is the leading cause of death in the transplant recipient?

- Malignancy
- Cardiovascular disease
- Infection
- Cerebrovascular disease

K9. For the kidney transplant recipient, what cancer has the risk most similar to the age- matched general population?

- Kidney
- Colon
- Non-melanoma skin
- Lymphoma

K10. Which is the correct virus-associated malignancy pair?

- BKV-bladder cancer
- HHV-6-Kaposi sarcoma
- EBV-Post transplant lymphoproliferative disease
- CMV-colon cancer

K11. The agent used for pneumocystis prophylaxis with the highest propensity for hemolytic anemia in select individuals is:

- Dapsone
- TMP/SMX
- Pentamadine
- Atovaquone
- •

K12. Mark is a 65 year old male who wishes to update his immunizations. He asks if he should avoid any of the following. Which of the following would you tell him is/are UNSAFE? (select all that apply)

- Injected influenza
- Varicella zoster
- Tetanus
- Pneumovax

Educational Preferences

- E1. Please select the format of the most recent educational activity for which you earned credit hours.
 - Local staff/society meeting
 - State/National society meeting
 - Enduring material (print journal, monograph, etc.)
 - Live web-based presentation
 - Web-based enduring activity (no live component)
 - Other

E2. Please rate the importance of each attribute you consider when selecting CME activities?

	Not Important 1	2	3	4	Very Important 5
Format of the activity (presentation, interactive small group, live webinar, self-study, etc.)					
Number of hours required to complete the activity					
Where it is offered (on-line, local meeting, national meeting, etc.)					
The speaker or author of the activity					

- E3. Please select up to three (3) topics you are most likely to select for your next CME activity.
 - Immunosuppression update
 - Drug-drug interactions in the kidney transplant patient with chronic disease such as hypertension and diabetes.
 - Managing adverse effects of immunosuppression
 - Appropriate monitoring of the kidney transplant patient
 - Titration of immunosuppression therapy
 - Managing chronic conditions such as hypertension and diabetes in the kidney transplant patient
 - Screenings and tools for preventive care in the transplant patient
 - Increasing adherence in the transplant patient

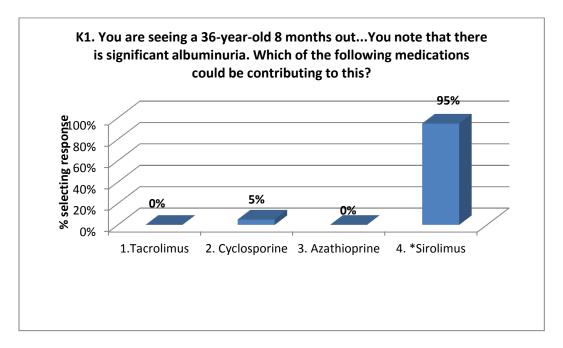
•	Other	

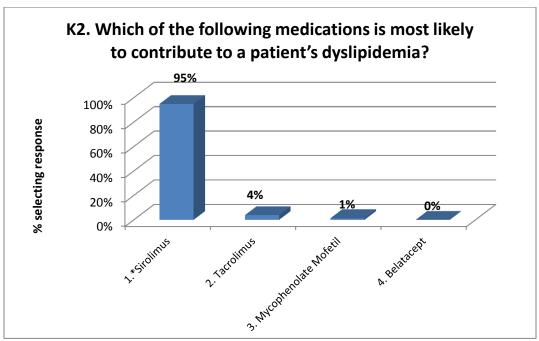
E4. In which of the following areas do you feel the current body of knowledge and literature is inadequate to guide you in the best care of the transplant patient. (check all that apply)

- The current body of knowledge and literature is adequate to guide me in all of these areas.
- Immunosuppression
- management of side effects
- co-morbid conditions
- · drug interactions

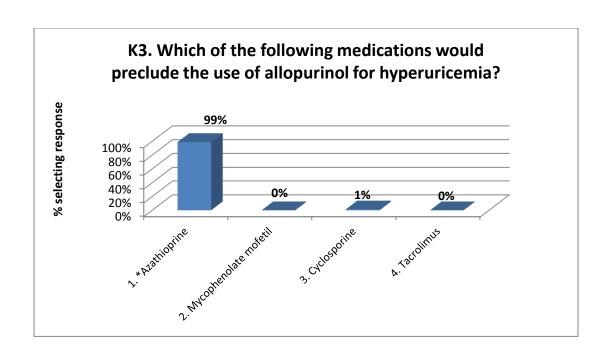
This completes the survey. Thank you for your participation. Please click on Submit below to record your responses.

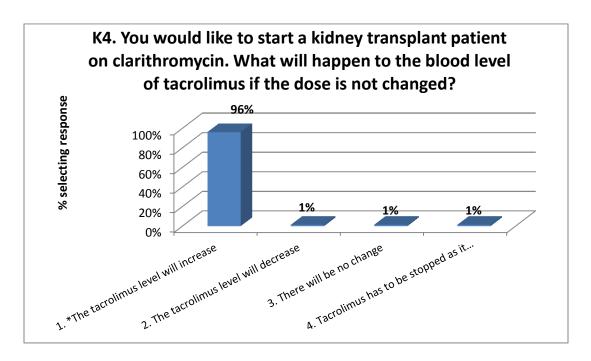
Appendix 2: Additional Data Charts

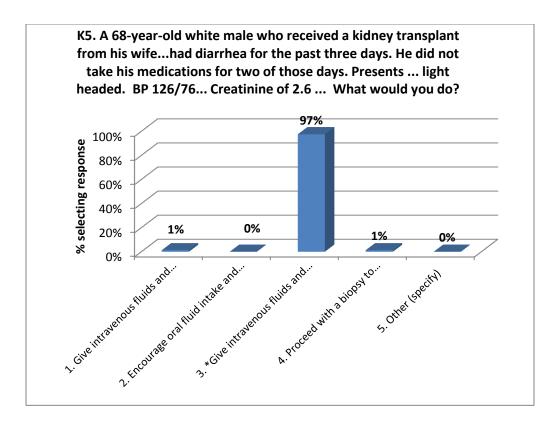


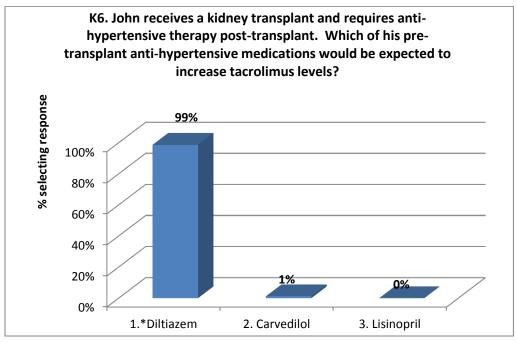


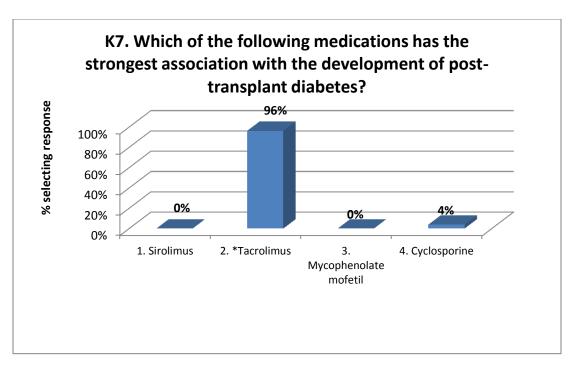
40 Appendix 2

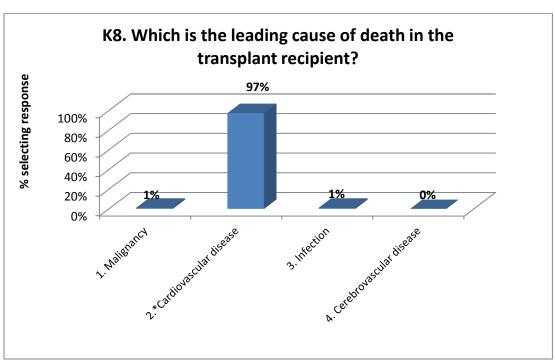


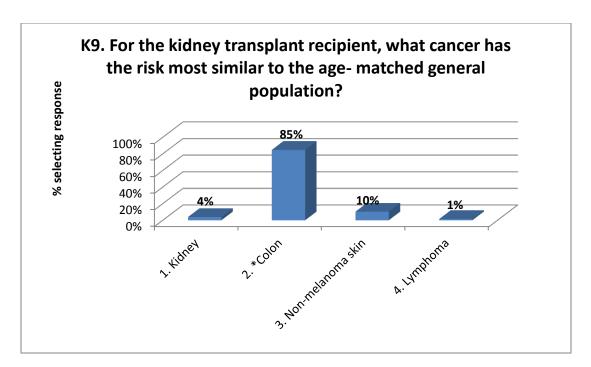


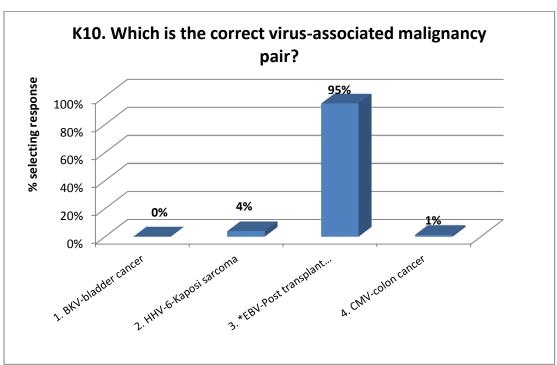


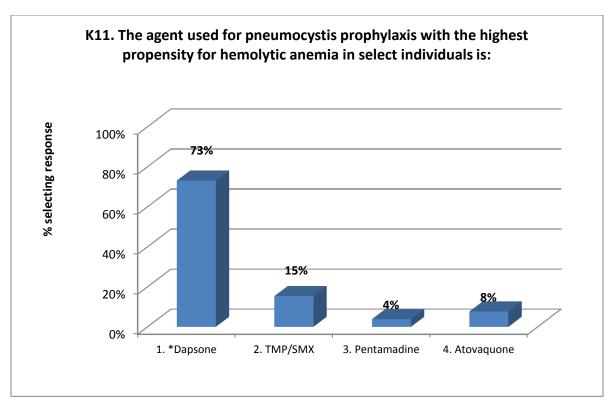


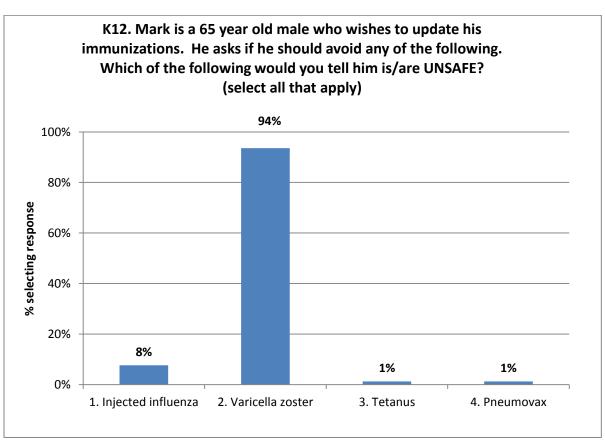


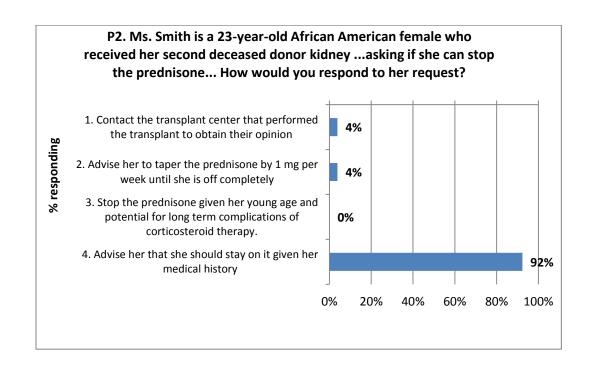


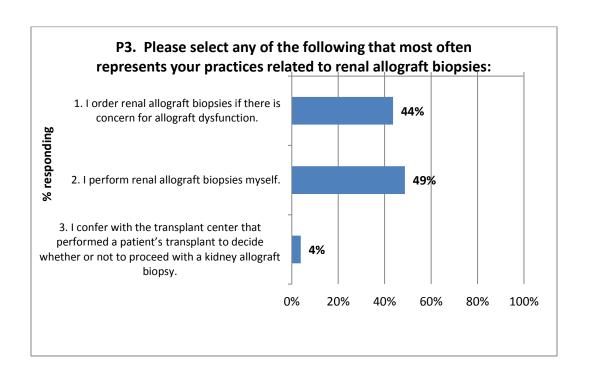


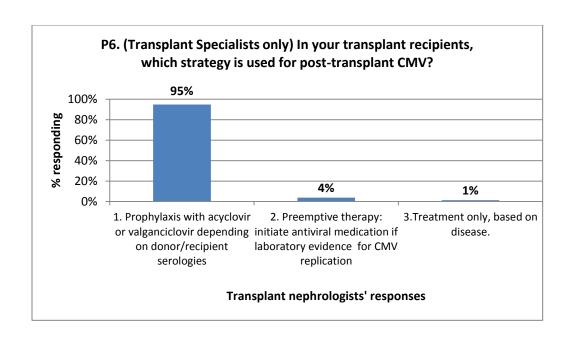


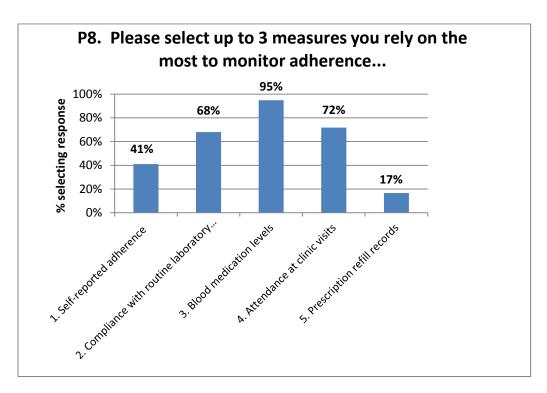












Appendix 3: References

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48 Appendix 3

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