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The Reality of Transplantation: Clinical and Operational Issues for Kaiser Permanente

Historical Insight

Clinical transplantation of organs became a reality in 1954, when the first renal transplant between identical twins was successfully performed in Boston. Kidney transplantation provided the foundation necessary to proceed with other types of extrarenal transplants. Since that time, many have contributed to transplantation advances, although during the 1960s and 1970s, transplantation was considered experimental and "taboo" in both public and private sectors. Spending time and money on this research was considered inappropriate when its efficacy and outcomes had yet to be established.

Traveling fast forward through the 1980s and into the present, we find that organ transplants have become the preferred option for treating thousands of patients suffering from end-stage failure of vital organs. Growth of transplantation has paralleled development of increasingly potent and effective immunosuppressive agents, improved methods of organ preservation, and great innovation in surgical techniques. Miraculous advances have made it possible to successfully engraft in humans all the vital vascular organs as well as bone marrow and stem cells. Hundreds of thousands of lives have been touched by this gift of life.

Change and Challenges

Change comes fast as researchers continue to explore newer, more effective strategies for providing organs to a population segment which relies on technology to endow each person with new

life. That same change impacts the strategy necessary to wage war on cancer and to provide lifesaving bone marrow (BMT) and peripheral blood stem cell (PBSC) transplantation. The rapidly evolving state of the art and the growing pains experienced by all segments of the health care industry continue to pose a unique challenge to health plans providing transplant services to members.

The challenge for transplantation is not yet over; in a way, organ transplantation has become a victim of its own success as the demand for donor organs continues to drastically outweigh the supply. The United Network for Organ Sharing (UNOS) Scientific Registry data, as of August 31, 2001, reflected that more than 78,189¹ men, women, and children are on the UNOS national transplant waiting list and that every 18 minutes, a new name is added.¹ This crisis has caused the transplant community to push the outer limits of the potential donor pool, including performing living unrelated or stranger transplants. The ethical and financial implications for society of this type of live donation have yet to be sorted out. Additional information and statistics on the National Organ Transplant Wait List can be found on the UNOS Web site at: www.unos.org.

Kaiser Permanente Accepts the Challenge

In response to both solid organ and BMT/PBSC transplants becoming a community standard of care, Kaiser Permanente (KP) modified its benefit structure to move trans-

plantation from experimental to the standard of care for many disease-specific diagnoses. The clinical and consumer demand for transplant services continues to rise, seemingly unabated. With this move came the reality that this patient population requires a more advanced system of case management to ensure access, to provide oversight of clinical care, to ensure internalization of pre- and post-transplant services whenever possible, to develop and deliver patient education, and to develop lines of communication with Centers of Excellence (COE), many of which are outside KP service areas. The confluence of both clinical and financial forces drives the need for case management of transplant services.

Centers of Excellence in the national community are defined by Kaiser Permanente (KP) National Transplant Network (NTN)'s Quality, Resource, and Risk Management Program as facilities and medical professionals specializing in specific types of organ or bone marrow/stem cell transplant.

Because quality and access remain a priority, KP has elected a more efficient use of the health care resources dedicated to transplant services and has developed a single delivery system designed to improve the standard of care for members. This move from multiple delivery systems to a single system was a new direction for KP which required alignment of both financial incentives and administrative capabilities to improve health outcomes.

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Some benefits attributed to moving from multiple contracting systems to a single system have been increased access to quality providers, improved outcomes through reduction of variability, and ability to track performance change in utilization and outcomes coupled with reduction in expenses related to transplant services (primarily due to ability to negotiate cost-saving contracts). In addition, savings have been realized in administrative support systems and by consolidating strategic planning efforts.

Administrative Leadership

Administrative oversight of KP's NTN is accomplished through the National Transplant and Contracting Services (NTACS) department. NTACS provides leadership, coordination, and oversight to NTN and its provision of transplant services programwide to ensure exemplary performance is achieved.

The value that NTN brings to KP is the ability to operate as one entity with national providers and integrated systems, by which adequate volume can be offered to leverage opportunities. Realizing a long-term vision of common business processes, performance metrics, and technology support where multiple systems existed previously was, and is, a challenge which continues to confront KP as it moves to integrate best practices and uniformity into its national network.

The goal of NTN is to provide members with access to a network of transplant programs located at premier medical centers, where successful outcomes are predictably high. NTN is dedicated to assuring continued access to premier transplant programs which meet or exceed NTN's stringent site selection criteria and which are known

nationally for their respective transplant expertise. To ensure that this goal is continually achieved and exceeded, NTN has developed national standards, policies, and benchmarks to oversee the quality monitoring process, to monitor access to services, and to formally review and adopt new technology recommendations.

NTN currently consists of 23 transplant COE and 83 transplant programs for solid organ and bone marrow or stem cell transplantation for both adult and pediatric patients, excluding kidney transplantation which is not within the scope of NTN.

Service Delivery

NTN has implemented a transplant support structure based on assigning transplant nurse coordinators affiliated in three regional hubs to achieve economy of scale for transplant case management. These hubs are the nucleus of case management experienced by KP members receiving transplant-related services. Case managers located at these hubs deliver services consistently and thoroughly, an accomplishment which avoids service duplication and inappropriate medical services delivery while ensuring effective communication for monitoring patient progress and data coordination. As KP's transplant patients have been more mobile in seeking transplant services, NTN's case management model has transformed to successfully provide, often by telephone, an interregional model for clinical management and care coordination.

A KP member identified as a potential candidate for transplant services is referred by his or her local Permanente Medical Group (PMG) through an NTN hub to a contracted COE for evaluation. The referral and case management of

the patient starts when the patient's care path at the COE begins until they return home to the care of the local PMG physician. The hubs also are responsible for identifying and reporting on quality issues of morbidity, mortality, and service delivery for KP members throughout the transplant experience.

KP National Governance

NTN is governed by a national advisory board which sets policies, standards, and criteria. This advisory board is multidisciplinary and includes KP multiregional physician representation. Clinical management is provided by clinical management subcommittees according to transplant type and consists of PMG physician specialists from across the program who establish and regularly review patient and site selection criteria as well as COE outcomes data for NTN. Many dedicated PMG physicians believe in the value that NTN brings to the program and to KP members. These physicians continue to spend many hours improving the level of NTN's performance by developing quality review programs as well as patient and site selection criteria and by being available daily to ensure that KP members receive the highest quality of transplant care available.

Quality: The Core Programs

NTN's quality program is its foundation. The first national quality program within KP, NTN's quality program sets extremely high standards for other programs to follow. The Quality Improvement Committee (QIC) is both multidisciplinary and multiregional in reporting both to the Quality Health Improvement Committee (QHIC) and the Medical Directors' Quality Committee (MDQC). The NTN



quality program's objectives are to provide a quality care experience to KP members and to improve the clinical outcomes and health status of KP membership through ensuring that contracted providers meet all necessary requirements of the NTN program. NTN's interregional model for clinical management and care coordination has been successful in decreasing variation in practices, improving levels of performance at COE, and lowering costs associated with transplantation.

The quality program consists of eight separate and distinct programs:

- Site selection process, criteria and site visits;
- Quality, Resource, and Risk Management (QRRM) Screening Program;
- Significant events management;
- Annual COE outcomes survey, Quality Review Corrective Action Plan (QRCAP) and COE inactivity policy;

- Utilization management;
- Satisfaction surveys;
- Patient performance status; and
- Internal performance monitors.

Current Transplant Referral Census

Table 1 represents the number of KP members referred for both solid organ and for BMT/PBSC transplantation, number of actual transplants, and number of KP members still on the UNOS organ wait list as of December 31, 2000. Also shown is a breakdown of the solid organ census by organ type. These statistics represent only members who were referred through and managed by an NTN hub. Data have not been captured for members who were not managed through a hub.

KP experienced a 32% increase in solid organ transplant referrals in 2000, compared with 1997, and only a 5% increase in number of members actually receiving trans-

plants. The increase in referrals for transplant is directly related to advances in technology, increase in indications, and decrease in contraindications. This relation is important to KP because the need for services required to care for this specific patient population having transplants continues to increase with the number of patients requiring transplantation both before and after the transplant event. This increasing need will continue to require additional physician, nursing, and administrative staff to care for and provide services to this segment of our membership.

What is Unique About NTN?

The health care marketplace is currently an arena of intense competition based on quality of care, case-specific volume and outcomes, and cost. Identifying quality measures among programs instead of selecting solely on pricing is evidence of the injection of

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Transplant Type	Referrals			UNOS listed			Transplanted			Died waiting		
	SCAL	NCAL	CEAST	SCAL	NCAL	CEAST	SCAL	NCAL	CEAST	SCAL	NCAL	CEAST
Heart	55	95	20	18	8	8	16	12	5	6	1	2
Heart/Lung	2	6		1	0		0	1		0	1	
Liver	190	178	63	136	6	29	40	44	16	11	34	5
Liver/LDLT			1			2			1			
Liver/Kidney			1			0			0			
Lung	21	11	20	16	15	13	4	4	10	0	6	3
PAK/PTA			1			0			0			
PTA		3	1		1	1		1	0		0	
SPK	17	21	17	N/A	12	9	7	8	5	N/A	1	
Small Bowel	1	0		0			0	0		0	0	
Total	286	314	124	171	112	62	67	70	37	17	43	10

	Referrals	Transplants	UNOS wait list
BMT/PBSC	479	218	NA
Solid Organ	724	174	345

SCAL means KP Southern California Service area; NCAL means Northern California service area; CEAST = all regions outside California. LDLT = Living donor liver transplant; PAK/PTA = pancreas after kidney transplant or pancreas transplant alone; SPK = simultaneous pancreas/kidney transplant; UNOS = United Network for Organ Sharing.



Permanente Medicine into NTN's contracting efforts and network of providers.

NTN has shared with the program performance measurement results and improvement data through annual outcomes surveys and the development of long-term relationships for transplant services. The Network produces annual report cards, which are annually distributed to all contracted COE. An additional note here is that the COE have stated that all of their contracted payers require them to provide data; however, KP is the only payer which provides them with a report card. Figure 1²

represents a sample blinded report card provided to a COE.

Annual statistical surveys of volumes and survival outcomes are measured for all COE participating in NTN, and results are compared with national data provided by UNOS, the International Bone Marrow Transplant Registry (IBMTR), and the Autologous Bone Marrow Transplant Registry (ABMTR). Under the umbrella of NTN Quality, Resource, and Risk Management programs, statistical survey results as well as any quality issues are identified, and action is taken. In addition, regular transplant program reviews, including site visits when

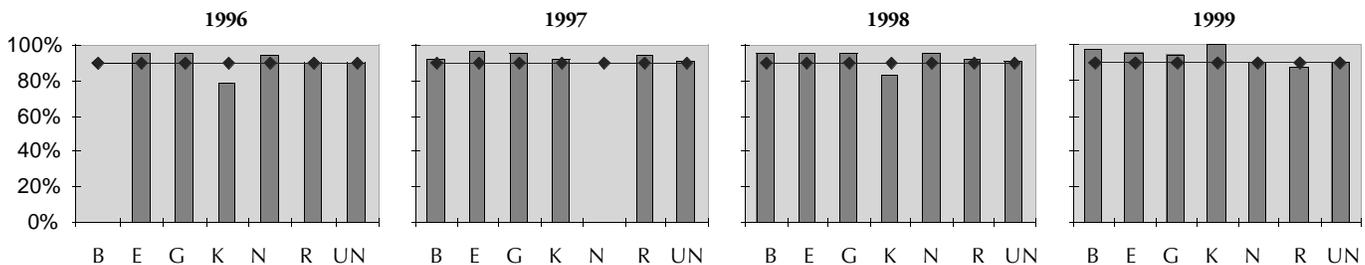
indicated, are completed by hub medical directors, transplant coordinators, PMG physician specialists, and contract administrators. However, fragmentation of KP's clinical and cost data systems presents a challenge to developing programwide reporting and predicting trends to accurately assess KP's transplant experience.

Advances in Technology —Where Do We Go from Here?

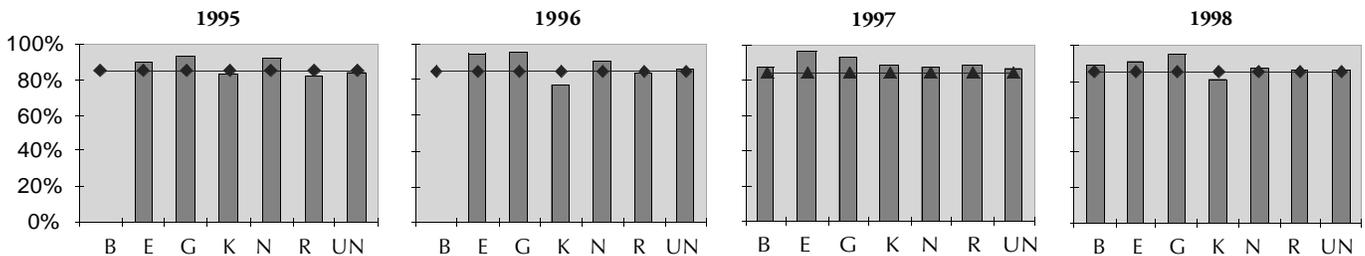
Small Bowel Transplantation

The tremendous strides made in transplantation since the 1950s provide excitement for what the

Three-Month Patient Survival Rate Comparison



One-Year Patient Survival Rate Comparison



- Extracted from NTN's year 2000 Annual Outcomes Survey, representing three-month and one-year survival rates for NTN contracted liver programs.
- An alpha character represents each program.
- UN represents UNOS.

Figure 1. Kaiser Permanente (KP) National Transplant Network (NTN) survey results from each participating center of excellence's liver program show 1996-1999 liver transplant outcomes measured against KP minimum criteria (horizontal line, graph) and against criterion established by United Network for Organ Sharing (UNOS). (Reproduced with permission of the author and publisher from: Kaiser Permanente of California. National Transplant and Contracting Services. National Transplant Network (NTW): annual Centers of Excellence (COE) outcomes report, 1998-1999. [Oakland (CA): National Transplant and Contracting Services, Kaiser Permanente of California; [2000].)²

future of transplantation will look like. Recent advances in transplant procedures include small bowel and small bowel-liver transplants in which patients with intestinal failure are treated with a therapy which has demonstrated improved quality of life.³ More than 80% of these patients have been able to discontinue their use of total parenteral nutrition and to resume unrestricted oral diets.

Pancreas Transplantation

Another area of advancement is seen in pancreas transplantation, performed either simultaneously with a kidney, after the kidney, or alone, which has demonstrated success in achieving insulin independence for patients. Early financial analysis is demonstrating the cost benefits of these procedures. The attractive option of transplanting a kidney (from a living donor) followed by a cadaver pancreas (pancreas after kidney, or (PAK)) is now a reality and is an option for certain uremic, diabetic patients.⁴ NTACS is currently negotiating with two renowned centers in developing a contractual relationship to make this service available to our members. Several KP members have already received this procedure.

Islet Cells

KP has also been introduced to an alternative treatment for Type 1 diabetes—transplantation of pancreatic islets: transplanting only the insulin-producing islet cells from the pancreas.⁵ In addition, PMG physicians have reviewed the possibility of referring a pediatric, nondiabetic patient with severe, chronic pancreatitis for islet cell extraction and reinfusion (islet autograft).^{6,7} The potential advantages with islet cell

transplants include a less invasive procedure, less immunosuppression required, fewer complications, overall lower costs, and wider application.

Heart Transplantation

The future of heart transplantation may be the total artificial heart. Mechanical cardiac support technology, specifically ventricular assist devices (VAD), have been used as a bridge to transplantation.⁸ Clinical trials have been initiated to evaluate VAD as destination therapy.⁹⁻¹² VAD has advanced to the point where patients can be ambulatory and managed from home while they wait for their transplants. To date, KP has only supported VAD as a bridge to transplant, but as clinical trials progress, we may need to rethink the long-term viability of VAD. Until the organ donor crisis is resolved, about one fourth of patients waiting for a heart transplant will die before an organ is available.

Lung Transplantation

Although the number of lung transplant procedures performed annually remains small compared with most other types of transplant procedures, advances in technology continue.¹ Within the past five years, living lobar transplants have been successfully performed with survival outcomes similar to those with cadaveric transplants.¹³ This transplant is primarily performed for patients with cystic fibrosis, although other diagnoses are being considered. The procedure requires two living donors, each of whom donates a lobe of his or her lung, thus providing enough tissue mass for the recipient. This procedure was originally considered because of the critical shortage of available donor organs.

Liver Transplantation

In the past two years, an intense national controversy has occurred about distribution and allocation of donor livers. UNOS has implemented some policy changes to address the issue of providing livers to the sickest patients, but opportunities for improvement still exist. Numerous advances in liver transplantation have been made in the past few years to address the donor shortage. These include living-related transplants (adult donor to pediatric recipient), reduced size grafts, and cadaveric split transplants.¹⁴ In the split procedures, the donor liver is separated to perform two transplants, one for an adult patient and one for a pediatric patient. In the past 18 months, living donor adult-to-adult liver transplant procedures also have been performed.¹⁴ To date, limited data are available to evaluate efficacy and to monitor donor complications, but a registry has been established by the American Society of Transplant Surgeons (ASTS) to track the increasing number of these liver transplant procedures.¹⁵

Bone Marrow Transplant or Peripheral Blood Stem Cell Replacement

BMT/PBSC has developed extensively in the past two decades. Both autologous and allogenic transplants have experienced increased application because of improving rates of long-term disease-free survival, an increase in availability of donors, and improved medications. Currently, there is a shift from marrow to PBSC.^{16,17} One of the benefits to PBSC is that general anesthesia is not required during harvesting. Because of success of the National Marrow Donor Program (NMDP),



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more than four million persons are registered as volunteer donors.¹⁸ Although minority donors are still needed, patient population requiring BMT is not faced with the critical issue of donor availability, which faces patients awaiting solid organ transplantation.

Within the past year, one of the newest protocols in this field has surfaced—the nonmyeloablative transplant regimen.^{19,20} This regimen is a form of allogeneic transplant designed to exploit a graft vs tumor effect without using intensive toxic conditioning regimens.^{19,20} This mode has enabled older patients or those with comorbidity to be considered as potential transplant candidates. The future of BMT/PBSC may include protocols for the treatment of autoimmune diseases such as multiple sclerosis and rheumatoid arthritis. Monitoring these clinical trials will be necessary to assess safety and efficacy.

Live Donation

With the increasing number of KP members who will be referred for transplant services comes the creation of a donor patient population made up of both KP and non-KP persons. As we monitor the technological advances in the area of living donations, we realize a new set of issues to be resolved and managed, ie, defining benefits for the living donor—both in length of time and breadth of coverage. Currently there are five types of living organ donors: genetically related, emotionally related, Good Samaritan donors, donors-at-large, and vendors. We have much to learn about the psychosocial aspects surrounding the decision to become a living donor. We may find it prudent to study donor outcomes on a psychosocial as well as a medical level.

Conclusion

We are faced with the issue of determining what these advances mean to KP and to NTN, especially because we are already experiencing an increased number of referrals for all types of transplantation. Traditionally, KP has focused on protecting patients' interests and ensuring the delivery of quality patient care. Through the development of national programs such as NTN, KP continues to advance further toward providing health care quality. Through continued dissemination of information and with collaboration among clinicians and nonclinicians, we will all gain a better understanding of the wide range of both clinical and operational issues now injected into the complex reality of transplantation. ❖

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Support Good Quality Care

Our goal is to provide the best quality care our members can afford, and to support good quality care by conducting medical research and teaching.

*Sidney R Garfield, MD, founder The Kaiser Permanente Health Plan.
This "Moment in History" quote collected by Steve Gilford, KP Historian*