

One kidney transplant center's experience: linking process improvements and Medicare/Medicaid conditions of participation

Context—An institutional priority toward transplantation, dedicated team dynamics, aggressive clinical growth, and optimal care practices are essential for delivering exceptional care to transplant patients. The importance of multidisciplinary integration of these priorities throughout the continuum of patient care is widely recognized in the transplant arena as well as by the Centers for Medicare and Medicaid Services (CMS). In fact, it is the collaboration within these aspects of care that is necessary for certification by CMS.

Objectives—To establish institution-wide practices, systems, and mechanisms to optimize performance of transplant centers through the use of evidence-based protocols, clinical innovation, and data-driven quality improvements. To develop training programs and competency based orientation addressing the topics needed for transplant nurses, multidisciplinary caregivers, and clinical transplant coordinators who provide care to transplant patients. To comply with the CMS conditions of participation for transplant centers.

Methods—Formation of a renal transplant council and multidisciplinary care team. Flow chart of hospital course from admission to discharge, carefully examining patients' progression through the continuum of care, assessing for barriers to care and knowledge deficits of transplant practitioners.

Results—Development of multiple clinical process improvements resulting in the creation of an environment for continuous learning, optimal transplant care, and exceptional outcomes in transplantation as well as compliance with CMS conditions of participation for transplant centers. (*Progress in Transplantation*. 2009;19:326-332)

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In October 2003, the transplant medical director for St Joseph Hospital's kidney transplant program, along with the leaders of St Joseph Hospital in Orange, California, recognized the need to coordinate and improve the multiple processes involved in the care of transplant patients. As a first step, a renal transplant council was formed. On October 9, 2003, the first council meeting convened and was attended by the transplant medical director, transplant center coordinators, renal services directors and managers, as well as nursing staff and clinical educators. The aim of the council became

to foster an environment where staff is continuously educated and relationships amongst all team members are collegial and collaborative in order to reduce harm and improve outcomes for renal transplant patients.

The primary goals of the council were established purposefully in conjunction with the hospital's professional practice model, which is to achieve optimal patient outcomes through accountability, responsibility, collaboration, professional growth and development of each member of the health care team.

The council and hospital alike recognized that an institutional priority toward transplantation, dedicated team dynamics, aggressive clinical growth, and optimal care practices are essential for delivering exceptional care to transplant patients. Also recognized was the importance of developing an infrastructure and culture for attracting and retaining highly qualified staff at all levels.¹ The goals, therefore, of St Joseph Hospital's renal transplant council quickly became

1. To increase the knowledge of renal transplant care for all practitioners providing care to transplant patients by:

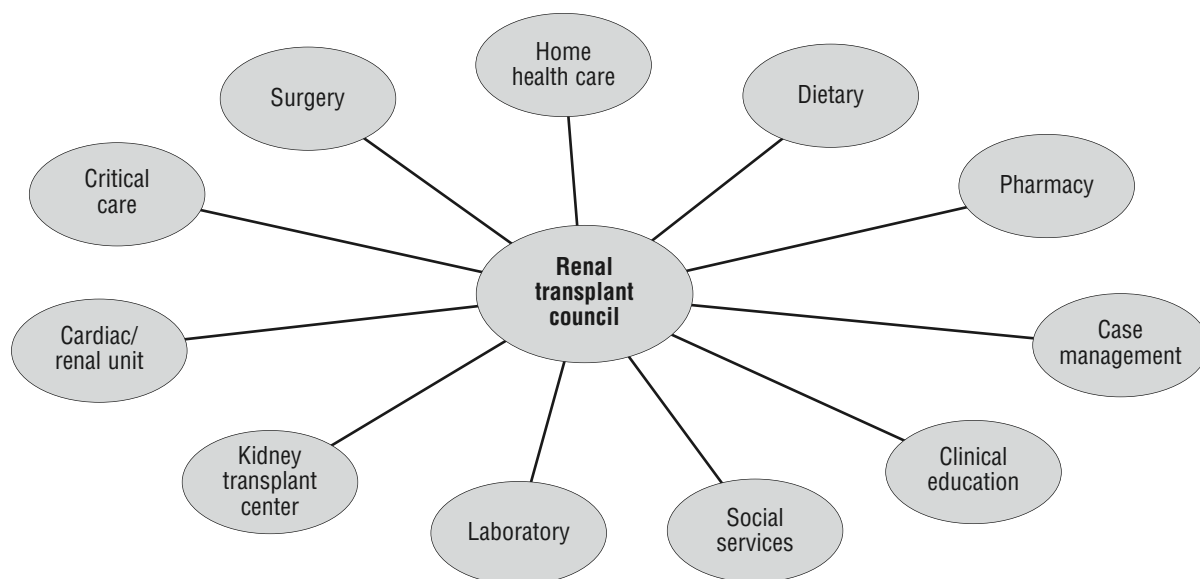


Figure 1 Renal transplant council.

- Increasing teamwork among practitioners
 - Using multidisciplinary rounds to ensure that all disciplines are aware of and on task with the daily plan of care
 - Providing staff with education and access to transplant care experts
2. To maximize patient safety by:
 - Standardizing order sets
 - Integrating evidence-based clinical practice guidelines, ongoing process analysis, and data-driven quality improvements
 3. To improve satisfaction of patients, patients' families, staff, and physicians.
 4. To obtain and maintain compliance with regulatory agency guidelines for ensuring high-quality care of transplant patients.

Beginning to Take Action Through Gap Analysis

By the end of October 2003, a gap analysis had begun in the form of flow charting the hospital course of transplant patients from admission to discharge, carefully examining patients' progression through the continuum of care: preoperative, to surgery, to post-operative, to discharge, to outpatient management; assessing for barriers to care and knowledge deficits of all practitioners involved in the care of transplant patients. During this initial gap analysis, several areas of communication and process breakdown were identified. Thus, the focus was turned to incorporating a systematic approach toward action.

With the use of the plan, do, check, act (PDCA) model, an analysis toward change and process improvement began.² Once the target areas were identified, the cycle of the PDCA model guided the council members

toward the development of specific projects. As time progressed, this type of systematic approach revealed the need to increase the number of council members in order to accomplish desired goals. Department leaders were notified and asked to look for individuals in their departments with an interest in serving on the council and representing their prospective department. Managers, clinical coordinators and staff nurses from the intensive care unit and cardiac/renal units, as well as representatives from social services, dietary, pharmacy, the operating room, and the laboratory became added members (Figure 1).

The chairpersons of the council became the nurses on the inpatient units caring for the transplant patients and living donors. Currently one of the hospital's certified clinical transplant nurses is being mentored to fill the role of chairperson. In addition, a new position was created for a registered nurse inpatient coordinator to serve as a resource, liaison, and educator to the health care team, patients, and patients' families as well as to bridge the gap between the hospital-at-large nursing units and the outpatient transplant center.

The gap analysis that began in October 2003 is an ongoing process addressing the complexity of care of transplant patients today. It is during such analyses and communication with the multidisciplinary team members that clinical process improvements are identified and courses of action are established. Established St Joseph Hospital processes for implementing change (eg, changes with medication protocols introduced to the pharmacy and therapeutics committee; new forms implementation to forms committee) and the PDCA cycle tool were used to implement ideas for improvement. When implementing practice changes at the unit level, input from key staff is obtained and carefully

analyzed by the council. From this, focus groups or task forces are formed. Research into evidence-based best practice is sought, reviewed, dissected and brought back to the council for discussion. Once accepted, education regarding the change ensues, followed by an evaluation of its effectiveness. In all, the completion of one turn through this cycle for improving processes flows right into the beginning of the next.²

Clinical Process Improvements Staff Education and Competence

To meet educational needs, transplant-specific in-service training sessions and case discussions were started. To reach the entire staff, a Renal Transplantation Education Module was developed, written by expert members of the council. Topics included in the module address immunology, pharmacology, pathways to better management, care of live donors, education of patients, and diet. At the end of the learning module, nurses are required to take a written test and score 95% or better. Those scoring less than 95% are given the opportunity to repeat the test after one-on-one discussion and review with a transplant educator and/or the inpatient coordinator.

Twice a year, a 4-hour class is offered that addresses kidney transplantation. Topics covered include information on the pretransplant workup, transplant medications, immediate postoperative care including potential complications, patient education for transition into outpatient management, and a special discussion, "Why Did the Transplant Surgeon Do That?" The latter topic has become a fun, interactive, competitive question-and-answer presentation given by the transplant nurse practitioner and inpatient coordinator. Prizes are awarded to staff members who answer the most questions correctly.

Furthermore, nursing members of the council developed a competency-based orientation checklist to ensure nursing competency in the care of kidney transplant patients. Competency-based orientation is a method that focuses on the end results of orientation: the ability of an employee to perform expected job responsibilities and move toward specialty care of kidney transplant patients. The performance criteria included in the competency-based orientation checklist are standards throughout the entire continuum of care for transplant patients that must be demonstrated for competency to be met.³ The checklist is a tool to be completed during orientation to transplant care, the period in which the preceptor and orientee review learning needs, action plans, and goals on a daily, weekly, or biweekly schedule depending on the orientee's needs. It provides continual feedback regarding strengths and areas for improvement, making both parties aware of opportunities for enhancement and ensuring the development of a proficient transplant practitioner.⁴

The competency-based orientation checklist is also used to (1) assess the skill level and readiness of the nurse to care for the transplant recipient and donor, (2) design an individualized orientation and define the level of practice required by the department, and (3) document the employee's satisfactory performance of skills.

Another tool available is the Reference Guide to Nursing Care of the Transplant Patient, which includes sections from the Transplantation Module, Kidney Transplant Recipient Framework for Continuum of Care, Pathways to Better Management, Kidney Transplant Patient Care Daily Worksheet, Guide to Educating the Kidney Transplant Patient, Discharge Instructions for the Kidney Transplant Patient, and a copy of the Transplant Diary pages that mimic those given to the patient to allow for continuity of education between the inpatient nurse and recipient.

In addition, a Kidney Transplant Nurse Pocket Guide was developed to address the needs and recommendations made by the bedside nurses to improve and expedite care of transplant patients. This guide is a useful tool that reinforces the critical concepts in the care of transplant patients such as the use of the patient diary, signs and symptoms of infection and rejection, transplant medication regimen, sample progress note documentation, special notes regarding what to report immediately to the transplant surgeon, and contact numbers for the surgeon and coordinators.

Clinical Laboratory Support

The clinical laboratory at St Joseph Hospital was involved early in the renal transplant council. The first member of the clinical laboratory team involved was the supervisor of phlebotomy, followed by the clinical laboratory scientist, the quality, safety and education coordinator, and the blood bank supervisor.

The first task that involved the clinical laboratory was to expedite patient testing, primarily the pretransplant potassium analysis used to determine if the transplant could proceed as planned or if the patient would require dialysis before transplantation. The clinical laboratory instituted a new process to place neon pink stickers on the patient's blood tubes to make them stand out among the more than 300 specimens submitted to the laboratory in the early morning hours. The goal was for the pretransplant potassium level to be measured and made available within 1 hour of receiving the sample in the laboratory. Phlebotomy supplies were made available on the nursing unit so that the nurse who started the intravenous catheter could obtain the blood samples without delay. It was soon noted, however, that obtaining blood samples while starting the intravenous catheter often produced hemolysis and required that the specimen be obtained again. A change in practice then ensued that required a phlebotomist to be available for specimen collection.

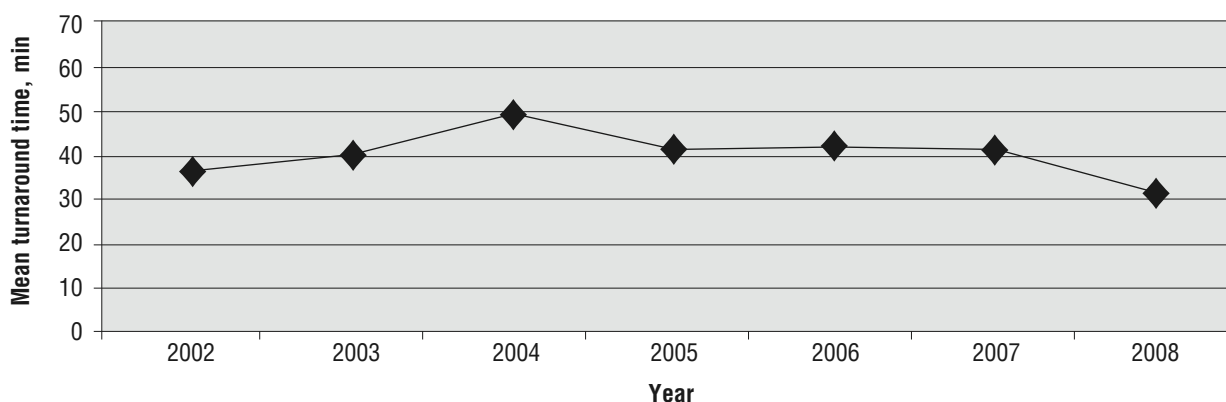


Figure 2 Laboratory turnaround times.

When a pretransplant blood sample is required, the phlebotomy team is notified and a phlebotomist is paged to respond immediately to the nursing unit for collection of a blood sample. The specimen tubes and bag are labeled with the bright pink sticker and a member of the nursing staff immediately delivers the blood by hand to the laboratory. The mean turnaround time from receipt of specimen to reporting of results since the clinical laboratory's active involvement in the process has gone from 49 minutes to 31 minutes (Figure 2).

Further, it was recognized early that errors associated with missed collection of samples for measurement of levels of immunosuppressant medications could have significant consequences, including a delay in intervention or use of an inappropriate intervention such as biopsy in a patient with transplant dysfunction ultimately due to toxic effects of medications. Therefore, an attitude of "zero tolerance" for missed laboratory tests was adopted and multilayered processes were developed to prevent such occurrences. The multilayered process is communicated on a nursing care checklist called the "Renal Transplant Patient Daily Worksheet." This worksheet consists of and documents areas of care that must be checked and initialed by the bedside nurse who is caring for the transplant patient. Some of the areas to be checked and initialed include ensuring (1) that samples for ordered laboratory tests were obtained and results were received, (2) that medications were given, (3) that education of the patient occurred with each interaction, (4) that computer orders, including laboratory tests were entered correctly, (5) that medication reconciliation by a pharmacist and a nurse was completed, and (6) that a 12-hour chart check and verbal shift change report was completed.

In addition to ensuring safe, appropriate, and timely execution of the transplant surgery event, the clinical laboratory staff was involved in preparing a section of the self-learning module developed by members of the renal transplant council. The quality assurance,

safety, and education coordinator met with the transplant surgeon and transplant coordinators to make sure that the laboratory analyses that were most critical for the kidney transplant patient were emphasized.

The blood bank supervisor and staff were involved when it became apparent that their services were needed as well. To date, the blood bank staff performs antibody titers 24 hours a day, 7 days a week.

The hematology division of the clinical laboratory further contributed by offering a CD3 test used for monitoring induction therapy with a same-day turnaround time for results. This test is offered 7 days a week.

The microbiology laboratory supports transplant patients with a special transplant protocol for urine culture testing that uses different screening procedures than the procedures used for routine specimens. Bacterial, fungal, and viral screenings are available to help with surveillance for posttransplant infection.

The anatomic pathology department contributed by developing protocols to eliminate errors in handling and processing of biopsy specimens. The implementation of these protocols guarantees same-day light microscopy on transplant biopsy specimens.

The clinical laboratory's outpatient service changed its hours of operation in the morning from 8 AM to 6:30 AM to accommodate transplant patients and ensure timely reporting of levels of antirejection drugs. The chemistry department's "run" time for cyclosporin/tacrolimus levels was moved up to 11 AM in order for results to be available to the transplant center surgeon by 1:30 PM.

It is quite apparent that each division of the clinical laboratory is involved in taking care of transplant recipients or donors during the continuum of transplantation care and contributing to a positive outcome. "Transplant patient" triggers an instinctive reaction among staff amidst the other urgent procedures received in the clinical laboratory. The staff recognizes the crit-

ical nature of what must be done to support patients and the transplant program.

Pharmacy Support

The renal transplant council recognized that drug therapy plays a significant role in improving outcomes and that medication errors could increase harm in transplant patients. Therefore, the council requested that the pharmacy department be involved in the development of processes aimed at improving the care of transplant patients.

In response, a new process was created that would help ensure accurate medication therapy. All transplant patients at St Joseph Hospital have pharmacists who are responsible for performing daily independent medication reconciliations to help ensure correct and accurate medication therapy. The pharmacists also follow the transplant patients from a clinical standpoint, to ensure that drug interactions, drug levels, and other critical factors are not overlooked.

Every day, the pharmacists generate a computer report that lists all hospitalized patients who have orders for any of the following immunosuppressive medications: cyclosporine, tacrolimus, mycophenolate, sirolimus, thymoglobulin, and daclizumab. The pharmacists obtain relevant transplant history from the chart and electronic medical record. Laboratory tests and drug therapy are evaluated to ensure that appropriate drug levels are collected, drug interactions are noted, and that proper follow-up is done. The primary focus is on immunosuppressants, corticosteroids, immune globulins, antibiotics, antivirals, and antifungals; however, all drugs are reviewed. This information is recorded on a patient-specific transplant monitoring form that was created by the pharmacy department to track drug therapy, errors, interventions, laboratory results, and any other pertinent pharmacy issues.

The pharmacists then meet with the bedside nurses every day to reconcile the medication administration record by comparing original chart orders with the patient's medication profile generated by pharmacy and nursing. The reconciliation of the medication administration record is documented as a chart order. The following day, the pharmacists continue the reconciliation from the time that the "24-hour check" was completed on the previous day.

At any point, the pharmacist will notify the transplant surgeon and/or nephrologist if a medication that interacts with an immunosuppressant is ordered and if drug levels are outside of the usual therapeutic range. The pharmacists recommend collection of samples for measurement of serum levels of immunosuppressant drug if these laboratory tests are not ordered within 48 hours of admission. When a transplant patient is discharged, the transplant monitoring form is placed in a

folder located in the central pharmacy. This step ensures continuity of records if the patient is readmitted to the hospital.

This new process has helped prevent medication errors from reaching patients, although significant data trends in error reduction have not been demonstrated. This absence of documented error reduction is largely because the incidence of capture and reporting has increased, especially during the past year when a computerized system for reporting medication errors was implemented. It is the goal of the council that future data will support how these processes do reduce patient harm significantly.

Regulatory Compliance

The formation of the renal transplant council in 2003 would prove to be a valuable asset for the transplant center. On March 30, 2007, the Centers for Medicare and Medicaid Services (CMS) of the US Department of Health and Human Services published, in the Federal Register, the "Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants."⁵ The conditions of participation became effective June 28, 2007, and transplant centers had 180 days or until December 26, 2007, to submit a request for approval under these new conditions of participation.⁵

CMS established these new Medicare conditions of participation for organ transplant programs, which detailed the requirements that must be met to be certified as a Medicare-approved transplant center.^{6,7} In short, without approval, the transplant center would lose the ability to bill Medicare for transplant services. If approved, the transplant center would be eligible for reapproval every 3 years. CMS began their survey of transplant centers in 2007 and plans to complete all surveys within 3 years.

As an unexpected benefit to the transplant center and hospital, several of the processes of the renal transplant council were directly applicable to the new CMS conditions of participation

- Condition of Participation 432.92: Organ Recovery and Receipts
 - Requires the transplant center to have a written protocol for validating donor-recipient blood type and other vital data for the deceased and living donor organ transplantation process.
- Condition of Participation 482.94: Patient and Living Donor Management
 - Requires the transplant center have written policies for patient management for the transplant and discharge phases of transplantation and under the care of a multidisciplinary patient care team.
 - Requires the transplant center have written policies for living donor management for donor

evaluation, donation, and discharge phases of living organ donation and under the care of a multidisciplinary patient care team.

- Condition of Participation 482.96: Quality Assessment and Performance Improvement
 - Requires the transplant center to develop, implement, and maintain a written, comprehensive, data-driven quality assessment and performance improvement program to evaluate the performance of all transplantation services.
 - Requires the transplant center to establish policies to address and document adverse events that occur during any phase of the transplant process.
- Condition of Participation 482.98: Human Resources
 - Requires coordination with the hospital to ensure adequate training of nursing staff and clinic transplant coordinators in the care of transplant patients and living donors.
 - Requires a multidisciplinary transplant team composed of individuals with the appropriate qualification, training, and experience in their relevant areas of specialty.
- Condition of Participation 482.98: Additional Requirements for Kidney Transplant Centers
 - Requires the transplant center to directly furnish transplantation and other medical and surgical specialty services required for the care of patients with end-stage renal disease, including inpatient dialysis services.⁶

The renal transplant council brought together the various disciplines involved in the transplant process, from the outpatient transplant team to the inpatient hospital staff. From the early concepts of collaboration and education came an invaluable forum to address and fulfill the requirements of the Medicare conditions of participation and to create an exceptional dynamic multidisciplinary patient care team for patients and live donors.

Results

Currently the council meets every other month for 1.5 to 2 hours to discuss agenda items that regularly include reports on laboratory test turn-around-times, pharmacy issues including medication errors, staff education classes, transplant activity, regulatory standards, policy and procedure implementation, and input from other disciplines. The council participants include the transplant medical director, the transplant center's nurse practitioner and coordinators, transplant inpatient coordinator, social workers, case managers, dietitians, pharmacists, laboratory personnel, dialysis staff, and nurses involved in the care of transplant patients including nurses from outpatient home health care.

The clinical process improvements established by the members of the renal transplant council have greatly

contributed to ensuring the excellent practice of patient care required daily on the transplant units. An environment for continuous learning, process improvement, and exceptional outcomes in transplantation has been created. Avoidance of medication errors, decreased laboratory turnaround times, legible physicians' orders, increased competency and confidence among nursing and clinical staff, and compliance with CMS conditions of participation for transplant centers have been addressed.

Transplant Outcomes

In the most recent report from the Scientific Registry of Transplant Recipients (SRTR) with a release date of July 2009, covering patients who received a transplant between January 1, 2006, and June 30, 2008, with 1-year follow-up, 88 consecutive adult patients who received transplants at St Joseph Hospital had 100% 1-year graft survival, compared with the 94.82% (92.62% for deceased donors, 96.74% for live donors) that would be expected on the basis of the characteristics of these patients. The *P* value of .022 indicates that this difference is significantly higher than expected. Furthermore, this most recent report is the sixth consecutive SRTR report in which patients (161 patients) receiving kidney transplants at St Joseph Hospital have been reported to have 100% 1-year graft survival. In each of these 6 SRTR reports, the 100% 1-year graft survival was significantly higher than expected on the basis of the characteristics of these patients, with a *P* value less than .05 in each report.⁸

In the most recent SRTR report with a release date of July 2009, covering patients who received transplants between January 1, 2006, and June 30, 2008, with 1-year follow-up, 100% of the 83 adult patients reported here were alive 1 year after transplant compared with 97.79% that would be expected on the basis of the characteristics of these patients. Although the *P* value of .334 indicates that the difference between these rates is not statistically significant, it should be noted that 100% of the 232 consecutive adult patients who received a transplant at St Joseph Hospital since January 1, 2001, spanning 11 consecutive SRTR reports, of which the SRTR analyzed 205 first time transplants for patient survival, were alive 1 year after transplant.⁸ This finding is statistically higher than expected, with a *P* value of less than .05 (written correspondence, Scientific Registry of Transplant Recipients, January 12, 2009).

Conclusion

The meticulous care of transplant patients is not only complex, but mandatory and attainable as well. Through the collaborative efforts of a multidisciplinary team across the continuum of care, an infrastructure

has been created to provide a path for expeditious and exceptional transplant practice and service.

The establishment of competency-based clinical standards with evidence-based continuous process improvements have contributed to excellent, efficient practice of the team providing care. The critical review and detailed analysis of the transplant process has clearly defined goals and expectations that have instilled a new dedication and commitment among the staff. The work accomplished by all of the members of the St Joseph Hospital Kidney Transplant Team and Transplant Council has and will continue to allow the institution to increase the number of kidney transplants and improve the quality of care provided to transplant recipients, donors, and their families.

Moreover, the contributions of the renal transplant council, have allowed St Joseph Hospital to maintain exceptional patient care standards and outcomes that serendipitously parallel the Medicare conditions of participation.

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None reported.

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