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Personal Viewpoint

A Call for a National Transplant Surgical Quality Improvement Program

M. J. Englesbe, S. J. Pelletier, S. Kheterpal, M. O'Reilly and D. A. Campbell, Jr.*

Departments of Surgery and Anesthesia, Transplant Services, University of Michigan Health System, MI, USA
**Corresponding author: D. A. Campbell, Jr., darrellc@med.umich.edu*

The severity of illness in transplant patients and the complexity of transplant operations results in significant postoperative morbidity and mortality. Remarkable efforts have been made by transplant physicians to study and improve organ allocation, graft and patient survival, immunosuppression and the long-term management of post-transplant complications. Less effort has been spent studying the actual transplant operation and systems of acute transplant care. The National Surgical Quality Improvement Program (NSQIP) has provided a standardized approach to quality improvement and has demonstrated significant potential for a reduction in postoperative morbidity and mortality in other surgical disciplines. Medical centers are under increasing pressure to measure surgical quality and the nexus of transplant surgical quality improvement should not lie in the hands of CMS or JACHO, but rather it should be created and developed within the transplant community. The time has come for a national transplant surgical quality improvement program based on the NSQIP infrastructure. Such a proactive approach toward quality improvement from the transplant community is an excellent investment for patients, providers and health care payers.

Key words: Morbidity, quality improvement, surgical complications

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Introduction

Few health care disciplines are analyzed as rigorously as organ transplantation in the United States. Based on massive data collection efforts and state-of-the-art scientific analysis, the Scientific Registry of Transplant Recipients (SRTR) provides the analysis of national organ allocation and outcomes data to the Organ Procurement and Transplantation Network (OPTN). The OPTN develops policy for organ allocation throughout the country, and significantly influences national and international direction. Transplant physicians and surgeons have pioneered these data systems, and can be justifiably proud of the effort.

But the data systems as they exist should not be viewed as a foundation for transplant quality improvement. They focus primarily on allocation of scarce resources, something quite different. Because the standardized mechanisms for reporting transplant complications do not exist, important questions about transplant surgical quality remain unanswered. While the requirement for reporting of information is already onerous, the reporting and collection of data for quality improvement could be performed by the transplant community by adopting a standardized approach to quality improvement, using a quality reporting infrastructure based on the National Surgical Quality Improvement Program (NSQIP). The NSQIP, now implemented in 128 VA hospitals and an increasing number of private sector hospitals, could be adapted to fit the transplant community quality improvement needs. Such a system will likely be an attractive investment for payers, since there are significant cost savings associated with a reduction in surgical complications.

Our Quality Improvement System Needs Improvement

What is currently missing, and what could be provided by NSQIP, is an infrastructure, which would permit the comparative evaluation of surgical quality. The first step in a national quality infrastructure includes defining and standardizing comorbid conditions and postoperative complication endpoints. An accurate (prospective) method for collecting the data points must be established. When this is accomplished, a risk adjustment model can be devised and tested. Finally, a workable model for auditing and testing of inter-rater reliability is necessary. Using this standardized approach, the national comparison of institutional surgical quality becomes feasible. (Table 1) When variations in risk-adjusted outcomes are identified, the "best practices" in the better performing hospitals can be identified and disseminated. Using this approach, quality might be improved. The VA hospital system saw a 27% reduction in mortality and a 45% reduction in morbidity over the 10-year interval that NSQIP was operational (1).

Patient and graft survival are standardized well in transplant outcomes reporting. The glaring deficiency involves

Table 1: Five key elements to the success of the transplant NSQIP (adapted from (1,4))

1. Concrete end points (short-term graft function, 30-day survival, etc.)
2. Standardization of definitions and terms
3. Prospective data collection
4. Sophistication of the data collectors
5. Mechanism for risk adjustment

surgical complications. The rates of surgical complications between institutions cannot be measured and compared for the following reasons. First, the identification of postoperative events is poor. In most institutions, identification of complications is done retrospectively, and may even use computerized administrative billing data sets. Billing data does not distinguish comorbid conditions present at the time of admission from complications occurring following surgery. As a result, a ventilator-dependant liver transplant candidate with pulmonary edema might mistakenly be characterized by administrative data as having postoperative pneumonia. In a recent study, data collected prospectively by a trained nurse reviewer were compared to data obtained in the same patients using an administrative data set (2). Using the VA Patient Treatment File (PTF), a large administrative data set, ICD-9CM codes for the preoperative risk variables used in NSQIP were found in only 45% of cases. Postoperative occurrences measured by NSQIP data collectors were found in only 41% of the PTF reviews. Sensitivity and positive predictive value of the administrative data were poor, averaging 0.175 and 0.186, respectively. Sensitivity and positive predictive value should be $\geq$0.90 to justify substituting ICD-9CM codes for prospective NSQIP evaluations done by nurse coordinators.

A second deficiency in transplant outcomes reporting is the risk adjustment methodology. Risk adjustment is poor because we have not fully identified, defined and ranked comorbid conditions preoperatively, nor have we defined the surgical complications of interest postoperatively and the interval at which they should be measured. The center-specific reports (CSRs) from the SRTR provide vast amounts of high quality risk-adjusted data focusing on: mortality on the list, graft function and mortality following transplant. Despite this, in the current system an obese, alcoholic, smoker with a previous coronary artery bypass grafting and a portocaval shunt has exactly the same risk profile for liver transplant as a thin woman with primary biliary cirrhosis and no other illnesses. In order to develop a meaningful risk adjustment system, in this example, the definition for "alcoholic" must be discussed and standardized, likewise for "smoker," "CABG," "obese," and "portocaval shunt." Similarly, surgical complications of interest also need to be targeted and defined, and a measurement end point, for example 30 days, decided upon. In the NSQIP system a data definitions committee meets regularly and rigorously defines variables. This attention to detail is difficult and time consuming, but essential to the process.

A final point is that the reliability of the data must be repeatedly confirmed. This is crucial because any quality reporting system will ultimately fail if participants lose faith in the validity of the data. In the NSQIP system, nurse data collectors are regularly tested for their understanding of the definitions used, and each program is regularly audited by an independent nurse team for accuracy. Few quality improvement initiatives place this much emphasis on the reliability of the data.

Success of NSQIP in the VA and Private Sector

Significant improvements in the surgical care of veterans have been made since the inception of the NSQIP. For example, the Salt Lake City VAMC was noted to be a high outlier for morbidity in general surgery related to postoperative wound infections in 1996. The surgical group describes how the feedback they received was used to critically assess their care processes, determine root causes and development care protocols to improve outcomes (3). Based on NSQIP feedback, wound complication rates dropped from 5.5% to 2.9%. The national data are also impressive. Between the beginning of NSQIP data collection and 2002, the 30-day mortality postoperative in the VA system has decreased by 27% while the 30-day postoperative morbidity rates have dropped by 45% (4). Most importantly, the NSQIP has been accepted by regional VA surgical leaders and administrators as a non-threatening, valid and constructive means to improve upon the surgical care of patients in the VA medical system.

The American College of Surgeons (ACS) has identified the NSQIP as one of its priorities for American surgery. Led by Tom Russell, the Executive Director of the ACS, and Scott Jones, Director of Quality of Optimal Patient Care for the ACS, the Board of Regents have supported a plan to expand the NSQIP, now called the ACS–NSQIP, to private sector hospitals. Currently 80 hospitals, nationally, are fully enrolled or in the process of enrollment. Many surgical specialties are considering the ACS–NSQIP structure for their own quality initiatives.

Focus on System and not the Surgeon

We do not advocate that the transplant surgical quality improvement project function as a surgeon report card. The compendium of site visits and studies performed by the NSQIP have concluded that quality surgical care is primarily a function of well-coordinated systems of care (4). In addition, this initiative would be a peer-controlled program, which will require the cooperation of transplant surgeons. Directing the focus of the project at individual surgeon outcomes would undoubtedly alienate the most important participants in the project. We propose that no surgeon-specific data be transmitted to the central database.

Similarly, it may not be fair to compare a program that does 300 transplants a year to a program that does 30. Smaller programs are at significant risk for variable annual outcomes. With the exception of a small steering committee, center anonymity must be assured. The success of the initiative depends on the participation of a diverse complement of centers. The surgeons participating in the program must embrace the project as an opportunity to improve the care of transplant patients in the United States and elsewhere. If the program is viewed as a threat, it will have less chance of success.

Financial Implications and Data Burden

The data burden and cost of reporting outcomes are significant and currently lie heavily on the shoulders of the individual transplant centers. Per the Department of Health and Human Services, the data submitted to the OPTN by the OPOs and transplant hospitals is considered mandatory under 121.11(b) (2) of the "OPTN final rule." Though this reporting is burdensome and expensive, the transplant community and our patients have greatly benefited from the analysis of this data by UNOS and the SRTR and the subsequent policy and practice changes.

Hospitals and medical centers also bear the burden of massive amounts of data reporting (much of it regarding "quality measures") required by JCAHO (Joint Commission on Accreditation of Hospital Organizations) and CMS (Center for Medicare Services). The nexus of transplant surgical quality improvement should not lie in the hands of CMS or JACHO; it should be created and developed within the transplant community. Certainly most transplant physicians would agree that the transplant community understands the complexities of transplant care better than the government.

Hospital administrators and insurance providers are well aware of the high cost of surgical complications. In one study, median hospital costs were lowest for patients without complications (4487 dollars) compared with those with minor (14 094 dollars) and major complications (28 356 dollars) ($p < 0.001$) (5). In the VA system, reductions in post-surgical pneumonias alone (exclusive of other complications) have resulted in annual savings of $9.3 million (6,7). Improvements in post-operative morbidity stand alone as sufficient benchmarks. Nonetheless, it translates into reduced length of stay and increased patient satisfaction. Insurance carriers will look favorably upon centers with a commitment to quality improvement and cost reduction. In addition, participation in voluntary programs may reduce third party regulation and oversight. Characterization of patient acuity and exemplary outcomes will provide leverage for transplant center negotiations with hospital administration and insurance companies.

In summary, efforts to improve transplant surgical quality need to develop within the transplant community, or they will likely be imposed in a less effective manner by third parties. The cost of the program will be relatively small compared to the potential benefits to our patients and savings to the payers.

Our Proposal

We propose a transplant NSQIP pilot program to start with several transplant programs in the United States.

Step 1. Center Recruitment: We plan to recruit several North American transplant centers to participate in a pilot program (estimate approximately 3 to 5 centers).

Step 2. Data selection and standardization: Determination of the variables and end points to be collected in the

Table 2: Data points for pilot liver transplant NSQIP

Demographics—age, sex, race, SS#, address, estimated annual income, insurer type.
Surgical profile—etiology of liver failure, procedure, previous abdominal surgery, TIPS, transplant number, admission status, level/experience of surgeons in the OR, level/experience of anesthesia in the OR.
Preoperative data—MELD, height, weight, DM, smoking, functional status, hepatic (varices, amount of ascites, history of SBP, etc.), renal (dialysis, creatinine 3 months ago, creatinine at transplant, edema, etc.), pulmonary (hepato-pulmonary syndrome, etc), neurologic (grade of encephalopathy, etc.), cardiac (pulmonary HTN, previous MI, etc.), nutrition (muscle wasting, etc.), body habitus (breadth of rib margin, etc.) and lab values.
Donor data—age, height, weight, sex, preservation fluid/volume of flush (HTK/UW), pressors, hemodynamic measures, percent fat in liver (on biopsy), date admission to hospital, date donation, cause of death, donor following cardiac death technique, recovery times and lab values.
Intra-operative data—ASA, Mallampati, lines places, PA pressures, OR times, fluids and transfusions, (serial measures of MAP/PA pressures/coagulation profiles/blood gases), type of incision made, bypass used, cava technique (piggyback, bicaval, side to side), hepatic artery technique, portal vein technique, revascularization times, bile duct technique, drains/stents left in place, reperfusion hemodynamic data, method of reperfusion, cardiac echo used, other infusions used and intra-op occurrences.
Postoperative data—pressors, transfusion quantity in the ICU, reoperations, hepatic (bile leak/stricture/location/management, hepatic artery thrombosis/stenosis and management, caval stenosis/management, primary non-function/relisting, portal vein complications, recurrent ascites/management) respiratory (date extubation, pneumonia, etc), renal (dialysis, creatinine trends, diuresis), infectious (locations and organisms, sepsis, antibiotics), neurologic (stroke, delirium, tacrolimus toxicity), cardiac (myocardial infarction, arrhythmia, etc.), nutrition (enteral nutrition started), immunosuppression regimen, retransplant, death, discharge, functional status trends.

Table 3: Data points for pilot kidney transplant NSQIP

Demographics—age, sex, race, SS#, address, estimated annual income, insurer type.
Surgical profile—etiology of renal failure, previous surgery, transplant number, level/experience of surgeons in the OR, level/experience of anesthesia in the OR.
Preoperative data—height, weight, DM, smoking, functional status, renal (dialysis, time on dialysis, type of dialysis, preop urine output, etc.), hepatic (synthetic dysfunction), pulmonary (COPD/steroids, etc.), vascular (PVOD, amputations, previous revascularization), neurologic (previous stroke, etc.), cardiac (ejection fraction, CAD, inducible ischemia, previous MI, previous revascularization, etc.), nutrition (muscle wasting, etc.) and lab values.
Donor data—height, weight, sex, race, right/left kidney, preservation fluid/volume of flush (HTK/UW), living donor (relationship, procurement technique, medical history), deceased donor (pressors, hemodynamic measures, biopsy results if applicable, date admission to hospital, date donation, cause of death, donor following cardiac death technique, expanded criteria donors, medical history), recovery times and lab values.
Intra-operative data—ASA, Mallampati, lines places, OR times, fluids and transfusions, serial measures of MAP and blood gases, revascularization times, bladder anastomotic technique, stent placed and reason, drains, reperfusion hemodynamic data, diuretics used, immunosuppression, IVF volume infused prior to reperfusion, mean intra-op blood glucose, single/multiple artery/vein, side placed and intra-op occurrences.
Postoperative data—ICU admission, immunosuppression (drugs used, mean levels, calcineurin delay/induction), reoperations, renal (dialysis/delayed graft function, creatinine trends, diuresis volume, foley removal, stent removal, urinary leak, stricture, infection and management), respiratory (date extubation, pneumonia, etc.), endocrine (daily mean glucose), infectious (locations and organisms, sepsis, antibiotics), neurologic (stroke, delirium, tacrolimus toxicity), cardiac (myocardial infarction, arrhythmia, etc.), death within 30 days, technical graft loss, discharge date, functional status trends.

Table 4: Data points for pilot pancreas transplant NSQIP

Demographics—age, sex, race, SS#, address, estimated annual income, insurer type.
Surgical profile—procedure (SPK, PAK, PTA), previous surgery, transplant number, level/experience of surgeons in the OR, level/experience of anesthesia in the OR.
Preoperative data—height, weight, DM duration, insulin dose, smoking, functional status, endocrine (number/severity of complications of DM, hypoglycemic unawareness, admissions/ER visits for hypoglycemia), renal (dialysis, time on dialysis, type of dialysis, preop urine output, etc.), hepatic (synthetic dysfunction), pulmonary (COPD/steroids, etc.), neurologic (previous stroke, etc.), vascular (PVOD, amputations, previous revascularization), cardiac (ejection fraction, CAD, inducible ischemia, previous MI, etc.) and lab values.
Donor data—height, weight, sex, race, preservation fluid/volume of flush (HTK/UW), pressors, hemodynamic measures, date admission to hospital, date donation, cause of death, donor following cardiac death technique, medical history, recovery times and lab values (Hb_{A1c}, Amylase).
Intra-operative data—ASA, Mallampati, lines places, OR times, fluids and transfusions, serial measures of MAP, glucose and blood gases, revascularization times, arterial anastomotic site (Y graft length), vein anastomotic site (vein graft used), duodenal anastomotic site, reperfusion hemodynamic data, immunosuppression, IVF volume infused prior to reperfusion, mean intra-op blood glucose, side placed, and intra-op occurrences.
Postoperative data—ICU admission, immunosuppression (drugs used, mean levels, calcineurin delay/induction), reoperations, endocrine (daily mean glucose), renal (dialysis, creatinine trends), respiratory (pneumonia, etc.), infectious (locations and organisms, sepsis, antibiotics), neurologic (stroke, delirium, tacrolimus toxicity), cardiac (myocardial infarction, arrhythmia, etc.), death within 30 days, technical graft loss, discharge date, functional status trends.

transplant NSQIP will be an arduous effort requiring the cooperation of a variety of transplant physicians. Obviously, the clinical variables of interest will vary depending on patient age and failing organ. The data points must focus on the system of care, not simply the transplant operation. Medical, surgical, anesthetic and critical care data points will be included. Potential data points are detailed in Table 2 for liver transplantation, Table 3 for kidney transplantation and Table 4 for pancreas transplantation. Depending on the expertise of the pilot centers, small bowel, lung and heart transplant data points may be included.

Step 3. Hire a nurse reviewer: For a hospital or transplant center to join, a nurse reviewer would be required. These nurses must be highly qualified with significant clinical experience. The nurses undergo a rigorous training period focusing on standardization of data definitions and are subject to frequent audits to assure uniformity of data collection standards and methods.

Step 4. Establish a web-based data portal: The flow and accuracy of data will be continually monitored and continuous database for data entry and retrieval would be available. Center-specific data are always available to members of the transplant team at that specific center. This will significantly aid participating centers in internal quality assurance efforts. A web-based infrastructure for data management already exists with the ACS–NSQIP and could be adapted to the transplant NSQIP.

Step 5. Issue reports: Periodically, a comprehensive report will be released comparing the risk-adjusted surgical outcomes of all participating centers in a blinded fashion. The center will be able to compare its profile with other institutions and national averages. Every effort will be made to make the raw data available to affiliated and non-affiliated researchers for analysis.

Step 6. Issue quality improvement action plans: The data will then be used for quality improvement action plans. Centers with outstanding improvements in care or outstanding baseline care will be asked to share their "best practice initiatives." The majority of the resources of the

program will eventually be devoted to dissemination of specific systems of medical, surgical, anesthetic and critical care that optimize quality transplant care. These action plans offer a unique venue for a multidisciplinary approach to complex transplant patients.

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