Evolution of quality at the Organ Center of the Organ Procurement and Transplantation Network/United Network for Organ Sharing

One of the goals of the Organ Center of the Organ Procurement and Transplantation Network/United Network for Organ Sharing is to increase the efficiency of equitable organ allocation in the United States. Recognizing the ever-growing need for organ donors and transplants, leaders at the Organ Center increased its commitment to quality improvement initiatives through the development of a quality management team in 2001. The Organ Center began to focus on ways to capture data on processes and pinpoint areas for improvement. As the collection and analysis of data evolved, the Organ Center embraced formal quality standards, such as improvement cycles. Using these cycles, the Organ Center has seen significant improvement. One initiative involving lifesaving heart, lung, and liver placement showed success by doubling the Organ Center's organ placement rate. Another project involving the validation of donor information demonstrated that the accuracy of organ allocation can be improved by 5% on a consistent basis. As stewards for the gift of life and leaders in organ allocation, the Organ Center uses continuous quality improvement to achieve the goal of increasing the efficiency of equitable organ allocation.
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From its early beginnings in 1982 as the Kidney Center, the Organ Center of the Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS) has grown to provide service for the 50 states and the Commonwealth of Puerto Rico. As more organs were successfully transplanted, the name was changed from the Kidney Center to the Organ Center in 1984. The Organ Center has provided continuous service for the past 27 years.

The Organ Center is housed within UNOS, a nonprofit organization that operates the OPTN by contract with the Health Resources and Services Administration, within the federal Department of Health and Human Services. UNOS was awarded the OPTN contract in 1986 and has remained the contractor through a number of competitive renewals. Under the OPTN contract, UNOS maintains the national computerized database of the transplant candidate waiting list and organ-matching system that comprises UNet and DonorNet.[1]

Available 24 hours a day, 365 days a year, the Organ Center assists the US transplant community by

- Placing deceased donor organs for transplantation
- Arranging transportation for shared organs
- Providing resource support to the US transplant community about national organ sharing policies and processes
- Running and transmitting the computerized donor/recipient match results[1]

The Organ Center is staffed by 17 full-time organ placement specialists, 1 data and operations specialist, and 3 managers. The Organ Center workday is divided into two 12-hour shifts and is typically staffed with 3 organ placement specialists per shift and 1 additional organ placement specialist on call. Having two 12-hour

shifts allows donor and organ placement information to be transferred among staff only twice per day, limiting the opportunity for miscommunication.[2] An electronic shift report ensures that all placement efforts are communicated to the next shift. All phone calls that come through the Organ Center are digitally recorded for quality assurance.

In 2001, a quality management team was formed at the Organ Center. The team's primary mission is to audit 100% of donor cases at the Organ Center, ensuring adherence to OPTN/UNOS policies and Organ Center procedures. The team is housed in the Evaluation and Quality Department within UNOS, separate from the Organ Center to avoid any conflict of interest. The quality management team provides bimonthly updates to Organ Center management and staff on donor case performance. These updates are used by management to monitor both the individual and organizational trends. Since the inception of the quality management team, the allocation of more than 50 000 unique, donated organs has been reviewed for accuracy. The current quality management team consists of 4 staff members.

Another effort to ensure quality began in June 2004 when the Organ Center and the quality management team, along with several other departments at UNOS, became International Organization for Standardization (ISO) 9001:2000 certified—a certification specific to quality management systems.[3] The most recent ISO surveillance audit was in July 2008 and resulted in a perfect audit score. Together, the Organ Center and quality management staff have more than 130 years of transplant experience, and several staff members each have more than a decade of experience.

Improvement Initiatives for the Organ Placement Process

Before the current method of organ placement via electronic organ offer notification through DonorNet, Organ Center staff telephoned transplant centers to inform them of an organ offer. Organ Center staff either verbally reviewed a donor chart with on-call transplant center staff or faxed the donor chart to the center. This process could be extremely lengthy. In 2005, the Organ Center made 42 900 unique organ offers to transplant centers in 17 122 hours of total organ placement time for an average rate of 2.5 organ offers per organ per hour.

One of the initial organ placement quality improvement activities attempted to maximize the opportunity for organ acceptance by increasing the numbers of offers made for lifesaving organs—hearts, lungs, and livers. In October 2005, the Organ Center, using the Plan-Do-Study-Act (PDSA) model, began a series of PDSAs that tested several placement strategies to evaluate whether offer rates for these organs could be increased[4] (Figure 1). Some of the placement strategies included tandem placement—where more than 1 staff person would make organ offers and case-load balancing—where the placement work load would be rebalanced if possible to allow 1 staff person to be solely devoted to a single case and not other tasks.

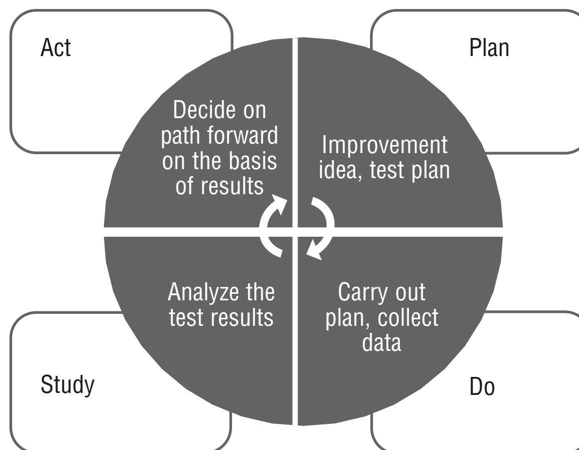

Figure 1 Plan-do-study-act (PDSA) cycle.

Worksheets for heart and lung placement were created as an additional placement efficiency tool. These forms included all the key organ-specific elements most likely to be relayed verbally to a transplant center in the course of a heart or lung offer. Rather than having several different pages of donor information, these 1-page forms centralized all pertinent information. The forms allowed more efficient organ offers and provided expeditious exchange of information between Organ Center shifts, allowing uninterrupted organ offers.

Before implementing these quality improvement tools in November 2005, the mean organ offer rate for lifesaving organs was 2.4 offers per hour. Within the first 60 days of implementation of the improvement model, the rate more than doubled to 5.5 organ offers per hour, and by 120 days the organ offer rate reached 6.1 offers per hour. The most successful strategy was case-load balancing, which allowed 1 staff member to work solely on the lifesaving organ placement.

A year later, a data analysis was performed for equal time periods before and after the quality improvements had been implemented. The analysis revealed increases in the organ offer rate for lifesaving organs, the number of lifesaving organ placement referrals, and the number of organ procurement organizations (OPOs) that referred lifesaving organs to the Organ Center. The number of OPOs that used the Organ Center for at least 1 lifesaving organ placement increased 63% in the period after the improvement model was implemented. During that period, the number of organ placements for lifesaving organs increased 121%

while the total number of organ offers increased 332% because of the combination of more organs and a faster organ offer rate. Additionally, the analysis revealed an increase in the successful placement of organs from 4% before to 8% after implementation of the improvement model, thus increasing lifesaving transplantation rates.

With the implementation of DonorNet electronic organ offer notifications in April 2007, OPOs were required to enter donor information electronically and transplant centers were required to review donor data electronically.[5,6] Since the speed of telephoned organ offers was no longer a limiting factor, the Organ Center shifted its quality improvement focus to donor data.

A clinical data grid was created that Organ Center staff used on each case before placement. The grid consisted of key data elements related to donors that had been verbally communicated as part of the organ offer before DonorNet. The grid included donation after cardiac death (DCD) status, positive results of serologic tests, and cultures positive for various microorganisms. Organ Center staff would check the grid to verify that applicable data were accurate, entered electronically, and did not solely exist in a DonorNet attachment because such attachments could not be viewed from commonly used mobile devices. If any data point was inaccurate or not entered electronically, it was updated or corrected by the OPO before the Organ Center made any attempts at placement. This preplacement quality check of clinical donor data ensured that each transplant center reviewing an organ offer had the same set of key donor data elements available.

During routine quality management reviews of donor cases, many of the errors identified were found to have been "inherited" from the OPOs when the case was turned over to the Organ Center (eg, an HLA error identified on a kidney match). A preliminary study conducted in May and June 2007 on 291 individual donor cases indicated that 3.7% of cases had discrepant donor data on the organ-specific match. Such errors required the match to be reinitiated to ensure accurate allocation of the organ. Additionally, in 6.8% of those cases, discrepant donor data were found that did not affect the match for the organ that the Organ Center was placing, but would affect screening or matching for other organs.

Validation of organ-specific match and key donor data before placement decreases the number of errors found during postplacement audit. Thus a match grid review was implemented as part of the donor case preparation before placement attempts. The match grid is a tool that identifies, by organ, which donor data fields affect match screening or sorting, requiring accuracy before placement. The grid is required to be reviewed before placement and is retrospectively audited for accuracy.

The initiative for monitoring the quality donor data began in October 2007. The goal was to improve the equity of the organ allocation system by identifying, documenting, and correcting DonorNet donor data entry errors before organ placement is attempted. Organ Center staff began reviewing and comparing current donor data, donor data used at the time of the match, and all attachments housed within DonorNet for data inconsistencies. In each case where incorrect data point(s) were found, the OPO was notified in real time. When a match was found to be incorrect, the OPO was responsible for correcting the data and the match would be reinitiated before any attempts were made to place an organ, ensuring proper allocation of organs.

A database was developed to capture this data by donor-, OPO-, and data-specific fields. Within the first month, the Organ Center staff recorded 14 "saves" by identifying incorrect match-related donor data and correcting the match before organ placement. In the first 6 months, Organ Center staff were consistently finding that more than 5% of the matches submitted for organ placement were run with incorrect match– related donor data. Additionally, in almost 15% of cases, the Organ Center identified incorrect donor data points that were not related to the match, or match-related donor data points that were associated with organs the Organ Center was not asked to place. In total, more than 20% of cases placed through the Organ Center had incorrect donor data that either directly affected the match the Organ Center used for placement, affected another organ-specific match, or potentially affected a transplant center's ability to accurately consider an organ offer.

Eighteen months of data collection indicates that of 7846 matches from which the Organ Center was asked to place organs, more than 5% (412) had donor data errors that required correction and a reinitiation of the match run before organ placement (Figure 2). The impact of incorrect data fields on the number of candidates on a match (a strong indicator of the effect the data had on screening candidates) was analyzed. The analysis demonstrated that 70% of the matches had differences in the number of candidates when the matches were rerun with the correct data. The number of candidates affected by the incorrect data points varied widely—from a difference of 0 candidates to a difference of more than 8000 candidates. The most common data errors identified were laboratory values, such as serum level of creatinine for kidney match screening, which accounted for 44% of the total of incorrect donor data points found. Height and weight errors comprised 13%, HLA errors were 13%, and donor DCD status accounted for 4% of the errors found.

More than 14% (1169 of 7846) of the donor cases handled by the Organ Center had at least 1 error in an

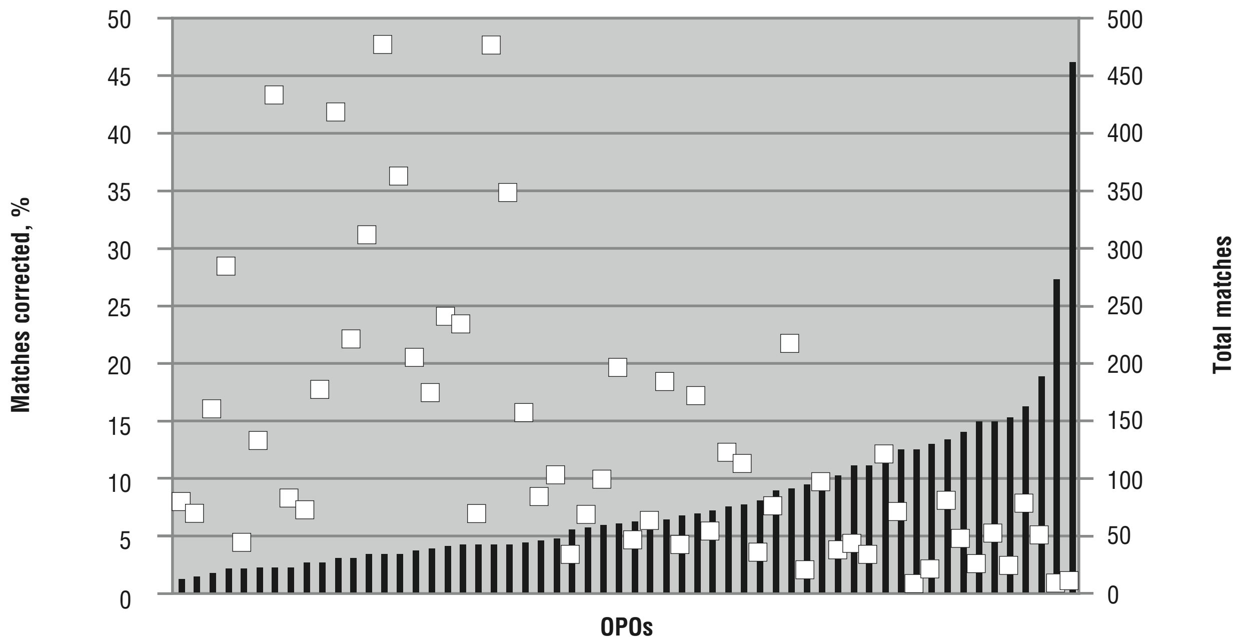

Figure 2 Percentage of matches corrected and total matches by organ procurement organization (OPO). All matches were corrected before organ placement. Each bar represents 1 OPO and is the percentage of matches corrected for that OPO. Boxes represent number of matches. (For example, the OPO at the far left has had 81 matches through the Organ Center with 1 match that had an incorrect match data point identified. The OPO at the far right has had 13 matches through the Organ Center with incorrect data points identified on 6 of those for a 46% rate of match data points identified and corrected by the Organ Center.)

online donor data point identified that did not directly affect the match from which the Organ Center was asked to place organs. Of those 1169 donor data errors, approximately 30% potentially affected another organ match (eg, a donor hospital error identified on a kidney match that does not affect kidney matching or sorting, but could have affected matching or sorting on the heart or lung match because of the role of distance in those matching algorithms). This finding indicates that potentially another 4% of organ matches had donor data errors that were not corrected before placement.

In summary, the donor data quality monitoring initiative resulted in more than 400 "saves" by correcting donor data errors before the Organ Center attempted placement. These corrections enable correct screening and sorting of potential matches, ensure the reliability of the key donor data that transplant teams use to accept or decline an organ offer, and increase the accuracy of the allocation system for all candidates.

Quality Assurance Activities Related to ABO Blood Group

Before the June 2004 implementation of the OPTN/UNOS policy requiring double verification of the transplant candidate's blood group,[6] subsequent to a February 2003 unintentionally ABO-mismatched organ transplant, the Organ Center provided several levels of ABO quality assurance.

Currently, the Organ Center monitors a daily report that identifies transplant candidates who are listed at different centers and have a different ABO reported. This report is generated on the basis of the social security numbers of the transplant candidates. Organ Center staff place same-day phone calls to transplant centers to notify them of the discrepancy to increase awareness and improve patient safety. Causes of the ABO discrepancies identified have ranged from human entry errors in verification of the blood types, "ambiguous" blood types (eg, one candidate was multilisted after a bone-marrow transplant because he had seroconverted to the donor ABO), and errors in data entry of the social security number resulting in inaccurate ABO/candidate associations.

The existing protocol at the Organ Center, instituted in January 2004, required the use of the aviation alphabet (eg, A, Alpha; B, Bravo; O, Oscar), when verbally communicating blood type. This protocol was instituted to reduce the chance of a miscommunication about the ABO typing of a donor or candidate.

Since March 2004, the Organ Center has been using standardized written communication to help an OPO add a donor or verify a donor's blood type. Having OPOs complete and submit the donor's information in writing reduces the chance of miscommunication in relaying information over the phone. Additionally, a hard copy of the donor's ABO typing must be included with the written communication if the Organ Center is to enter or verify the donor's blood type. In order to be acceptable, the ABO source document must include a

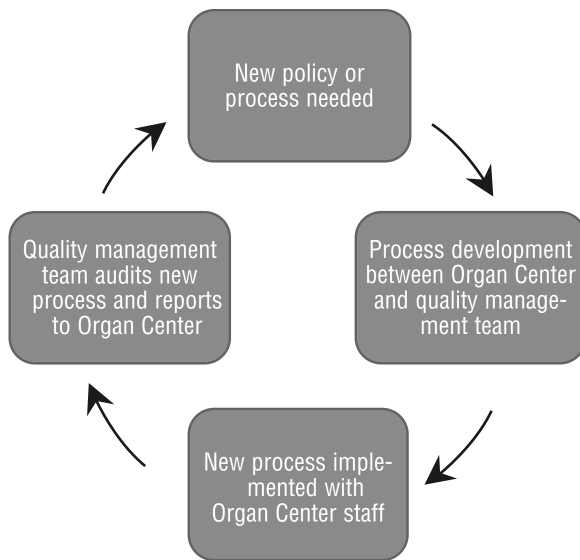

Figure 3 Organ Center's proactive cycle for process improvement.

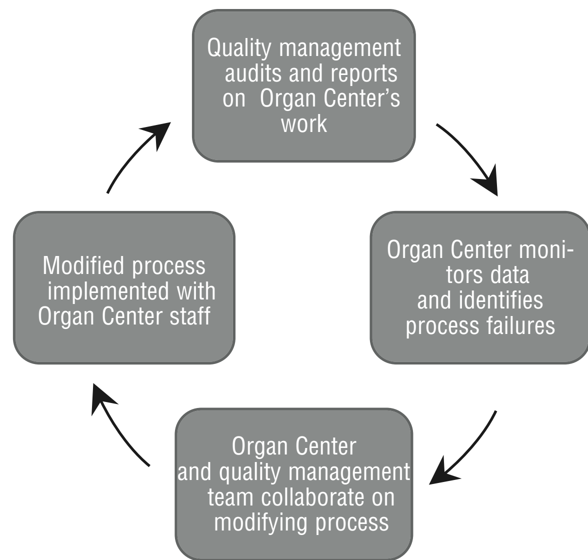

Figure 4 Organ Center's retrospective cycle for process improvement.

donor identifier (eg, donor name or UNOS donor ID number) as well as clearly documented ABO type. Before adding or verifying an ABO, the Organ Center staff will enter donor information, print the data entered, and communicate back to the OPO coordinator to review. If the data are accurate, the coordinator will sign and resubmit the data, at which point the Organ Center will complete the online verification. This provides yet another level of review, further reducing the risk of inaccurate data being entered into the system.

Quality Improvement Initiative for Organ Transportation

One of the Organ Center's roles is to assist transplant centers and OPOs with the prompt and efficient transport of organs from the donor site to the transplant center. In 2008, the Organ Center assisted with the transportation of more than 3200 organs (approximately 9 organs daily).

Beginning in May 2005, the Organ Center began collecting transportation failure and transportation "near miss" data. These data are reviewed by OPTN/UNOS committees as they consider organ wastage issues. Delays of 2 hours or more from the original estimated organ arrival time were categorized as "near misses" because of the potential that additional cold ischemic time may make an organ unacceptable to the transplant center. Transportation failures were defined as organs that did not make it to the original intended transplant center or that arrived at the intended destination but were delayed enough to be unacceptable for transplantation.

The tracking mechanism relied on Organ Center staff and/or OPTN/UNOS members to report transportation problems or delays to Organ Center management. With this passive mechanism of reporting, transportation failures and near misses were reported on less than 0.5% of all transportations arranged by the Organ Center. Beginning in June 2008, a quality improvement initiative was implemented with the goal of collecting more accurate data in this area. Rather than relying on a passive reporting mechanism, Organ Center staff began retrospectively reviewing each Organ Center transportation arrangement for any delays or problems.

Through the first 9 months of this more active approach of monitoring, transportation failures have been recorded on 1.4% of all shipments, and near misses have been recorded on 2.8% of all shipments. The improved monitoring revealed 3 primary reasons for failures and near misses: (1) human errors resulting in misroutings or delays by couriers or airline/airport personnel, (2) flight delays primarily due to aircraft mechanical issues and weather, and (3) human errors related to handling or labeling of the organs by OPO staff. The data show that transportation failure and near misses may have been underreported previously. The improved accuracy of these data is vital to policy development activities, such as kidney paired-exchange donations, in order to adequately assess the risk of shipping a live donor kidney.

Continuous Process Improvement

The Organ Center has developed 2 methods of process improvement, a proactive cycle and a retrospective cycle (Figures 3 and 4). The proactive cycle

allows Organ Center management and the quality management team to collaborate prospectively on new processes for Organ Center staff as a result of changes to OPTN/UNOS policies or programming modifications in UNet. The retrospective cycle involves reviewing Organ Center data on current processes in an effort to improve those processes.

An example of using the proactive cycle is how the Organ Center prepared for changes to the OPTN/UNOS policy concerning the sharing of 0 mismatched organs. On August 18, 2008, a policy modification was implemented that changed the way these organs were offered. This modification eliminated the minimum number of hours of required offers and replaced it with a minimum number of offers, in addition to other modifications. The Organ Center worked with quality management in the preceding weeks to evaluate the current processes and revise them to ensure adherence to the policy modification. Staff at the Organ Center were trained on 7 revised processes related to the allocation of 0 mismatches. Case audit data, as it related to 0 mismatch organ allocation, were compared for the 6-month period before and after policy modification. The data revealed that 0 mismatch organ allocation error rates were recorded in a very low number of cases (0.06%) in both time periods, demonstrating a successful transition from one process to another using the proactive improvement cycle.

An example of the retrospective cycle relates to the renal minimum acceptance criteria that the Organ Center uses for screening purposes during kidney placements. In early 2008, quality management audit reports revealed an increase in procedural errors by Organ Center staff in the use of this tool. Organ Center management, in conjunction with the quality management team, reviewed the process and made modifications. A training module was developed, and each staff member received training on the revised process. Case audit data revealed a 50% decrease in the error rate related to the minimum acceptance criteria when comparing the 6-month periods before and after process modification; indicating a successful application of the retrospective process improvement cycle.

Conclusion

Quality improvement has evolved in the past decade in the OPTN/UNOS Organ Center. Many of the Organ Center's quality improvement initiatives were started by simply collecting and analyzing data. Initial PDSA cycles were small in effort and yielded minor improvements in efficiency and accuracy. As more data were analyzed and Organ Center processes were modified, a positive trajectory of quality improvement occurred. Today the Organ Center continually reviews each process from organ placement to transportation for improvement potential via the retrospective and proactive cycles. Data are collected and analyzed in various ways and are used to benchmark each change and improvement. The Organ Center strives to achieve the highest work quality by providing accurate and efficient services for the transplant community focused on patient safety and stewardship of the gift of life made possible by donors and their families.

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