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PANCREAS TRANSPLANTATION (DA AXELROD, SECTION EDITOR)

The Economic Aspects of Pancreas Transplant: Why Is the Organ Acquisition Charge So High?

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Abstract Pancreas transplantation in the USA has declined steadily over the past 10 years. Fewer patients are being listed as candidates, and fewer pancreata are being recovered from deceased donors. Of the donors where there is an intent to recover a pancreas for an identified recipient, some are ruled out intraoperatively, and >25 % of pancreas are discarded after recovery. Based on the current Centers for Medicare and Medicaid Services (CMS) cost-finding and reimbursement policies for organ procurement organizations (OPOs), this high level of intended for transplant but untransplanted pancreas has had the effect of substantially raising OPO pancreas organ acquisition charges (OAC). While numerous reasons for the decline in pancreas transplant volume have been posited, some have suggested that high OACs have been a significant factor. In this article, the manner in which OPO OACs are developed is reviewed in the context of CMS requirements and OPO and transplant center practices.

Keywords Pancreas · Transplant · Organ · Cost

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Introduction

Despite reasonable outcomes, pancreas transplantation from deceased donors has declined 31.5 % over the past decade. This trend has been steady for both simultaneous pancreas-kidney (SPK) and pancreas transplant alone (PTA) [Table 1]. Living pancreas donation, although never more than an occasional procedure, has essentially ceased with only one living SPK reported in the past 5 years.

The reasons for this decline are most likely multifactorial and include the following: better control of patient insulin levels with improved delivery systems, concerns about outcomes with PTA, increased interest in islet transplantation, and the economics of pancreas transplants [2].

Pancreas are recovered with the intent to transplant from a relatively small percentage of deceased donors, and, of those recovered, a significant percentage is discarded or sent to research. In the USA in 2012, there were 8144 deceased donors. Pancreata were recovered for transplantation from 1418 (17.4 %). Of the pancreas recovered, 1046 were transplanted and 372 (26.2 %) were discarded or sent for research. The most commonly reported reasons for discard were as follows: other (120), anatomical abnormalities (78), no recipient located/list exhausted (52), and poor organ function (27). Pancreata have the highest rate of discard among all organs when compared to liver (10.4 %), heart (1.1 %), lung (4.3 %), and kidney (18.6 %) [3].

Not accounted for in this analysis is the number of deceased organ donors where the pancreas was evaluated prior to recovery and deemed to be potentially transplantable, a potential recipient was identified, a surgical team was brought to the organ recovery site, and the pancreas was ruled out intraoperatively and not recovered. Specific data on organs where there was intent to recover for transplant but not actually recovered is required to be reported by organ procurement

Table 1 US pancreas transplants—deceased donors [1]

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Simultaneous pancreas kidney	603	542	466	468	434	375	349	287	242	256
Pancreas transplant alone	881	902	923	864	837	854	828	795	801	761
Total pancreas transplants	1484	1445	1390	1332	1271	1229	1177	1082	1043	1017

Source: US Organ Procurement and Transplantation Network. Available at: http://optn.transplant.hrsa.gov/converge/latestData/viewDataReports.asp,accessed Nov 2014

organizations (OPOs) to the Centers for Medicare and Medicaid Services (CMS) but is not available publically. Data from a single OPO [New England Organ Bank, unpublished data Table 2] is illustrative.

The large number of pancreas with intent to recover but not recovered, and pancreas recovered and discarded, is key to understanding why OPO organ acquisition charges (OACs) are relatively high for pancreas. The pancreas transplant rate from intended recoveries for this OPO ranged from 39–49 % during the four-year period. In contrast, the rate of transplant from intended recoveries for the other extrarenal organs was much higher for the same time period. For example, the liver transplant rate ranged from 83.3 to 91.7 %.

The Economics of Pancreas Transplantation

Comprehensive reviews of the literature on the economics of pancreas transplantation suggest there are few rigorous studies of the cost-effectiveness of pancreas transplantation [4, 5] Those studies that are available suggest that transplant center reimbursement for pancreas transplantation has been an issue since the procedure began to increase in numbers and gain traction clinically. In the early years, it was sometimes considered an investigational procedure, and insurance coverage policies were not uniform, often decided on a case-by-case basis. A comprehensive study in 1993 [6] found that private insurers were the primary source of patient coverage. For SPK, Medicare was paying for the kidney transplant portion of the hospital charges, but the pancreas transplant costs were either covered separately or simply not reimbursed. Beginning in July 1999, Medicare provided coverage for SPK for all patients with type 1 diabetes and end-stage renal disease. Not surprisingly, this change in coverage increased access to SPK for Medicare beneficiaries [7, 8].

Despite improved insurance coverage, the cost of the pancreas transplant procedure remains an issue today. Any analysis of transplant procedure cost must include the following: hospital charges (pre-, peri-, and posttransplant), professional fees for the surgeon(s) and others, and OPO pancreas organ acquisition charges. This paper is focused on OPO OACs.

How Do OPOs Establish Organ Acquisition Charges?

Each OPO in the USA establishes an acquisition charge for each type of organ. This fee is paid to the OPO by the transplanting hospital for each organ it receives. Although often referred to as a "standard acquisition charge" (SAC), it is better named an OAC as its components vary from organ to organ and from OPO to OPO. There is very little standard about it. OPOs may use somewhat different methodologies in establishing their OACs, but there are many common aspects.

OPOs are designated every 4 years by the Secretary of the Department of Health and Human Services to provide all services related to deceased organ donation for a defined geographic region of the USA, commonly known as the donation service area (DSA). Oversight of payments to OPOs is

Table 2 Single OPO pancreas recovery experience

	2010	2011	2012	2013
Organ donors	226	229	217	248
Donors to OR with intent to recover pancreas for transplant	47	64	52	54
Pancreas ruled out in OR	6	14	12	14
Pancreas recovered with intent to transplant	41	50	40	40
Recovered pancreas discarded	18	25	18	18
Pancreas transplanted(#/% of intent to recover for tx)	23/48.9%	25/39.0%	22/42.3%	22/40.7%

regulated by CMS as part of the End-Stage Renal Disease (ESRD) program. Although Medicare ESRD payments only cover renal transplants, the methodology proscribed by CMS in determining those payments impacts how the OPO charges transplant centers for all other organs in addition to kidneys. Medicare reimburses OPOs the reasonable cost of allowable services, with the definition of "reasonable" and "allowable" determined by CMS regulations and applied by private contractors (fiscal intermediaries) working under contract to CMS. Each year, OPOs are required to file a Medicare cost report that, using Medicare's cost-finding methodology, assigns costs associated with renal procurement and distribution, extrarenal procurement and distribution, and tissue recovery (This assumes the OPO also recovers tissue for transplantation which most OPOs do.).

Costs associated with a specific organ are assigned to that organ. For example, a cardiac catheterization to assess heart function pre recovery would be assigned to the heart, and a bronchoscopy would be assigned to the lungs. Costs that relate to all organs such as donor serology and NAT testing or hospital operating room charges are assigned proportionately to all organs considered for recovery on a particular donor. For many donors, costs associated with assessing a particular organ's suitability for transplant will be incurred, but the decision will be made not to recover that organ based on the clinical findings. Or an organ will be thought to be suitable for transplant, and an intraoperative finding will rule it out. However, the costs associated with assessing the organ still must be assigned to that organ's cost center.

Prior to the start of each OPO's fiscal year, an estimate is made of the number of donors that will be recovered, the number of each organ type that will be recovered, and the number that will be transplanted. As OPOs only generate payment of an extrarenal organ OAC if the organ is actually transplanted, the costs associated with organs evaluated but not recovered, and/or organs recovered and discarded also must be covered by the OAC. In addition to the direct costs associated with each organ, general costs and OPO overhead costs are assigned proportionately. This total cost for each organ is then divided by the number of that type of organ expected to be transplanted to determine the OAC for each extrarenal organ. The procedure for kidneys is the same except that the kidney OAC must be submitted to CMS for its approval.

OPO CMS Cost Reports

At the end of the OPO's fiscal year, actual costs are tallied and assigned to the appropriate organ. Indirect (overhead) costs are then assigned proportionately to each organ according to CMS rules. OPOs are then required to file a cost report with CMS which reflects the cost centers for each organ and tissue. If the OAC established for kidneys at the beginning of the fiscal year has generated less revenue than the actual calculated cost per kidney, CMS reimburses the OPO for the difference. If the revenue exceeds the calculated cost per kidney, then the OPO must refund the difference to CMS, and typically is required to lower its kidney OAC for the subsequent fiscal year. For extrarenal organs, the OPO is responsible for any differential between the revenue generated by the OAC and actual costs.

Critical to determining the amount paid by CMS is the proportion of recovered or intended to be recovered kidneys, to total organs. This is used to determine the amount of indirect cost that will be covered by Medicare and how much must be covered by extrarenal organ OACs (Note: All costs associated with tissue recovery are excluded from calculation of renal and extrarenal OACs.). Prior to 2007, Medicare only required the OPO to count extrarenal organs that actually were recovered in determining cost-sharing allocation. For example, a donor may have been evaluated for kidney, liver, heart, and lung recovery, but only the two kidneys and liver actually were recovered. In that case, two thirds of the non-organ specific costs as well as shared direct and overhead costs would be assigned to renal because only the three organs actually recovered would be counted.

Medicare recognized that the ESRD program was unintentionally subsidizing extrarenal costs and issued a ruling [9••] on December 21, 2006 that changed the cost-finding methodology to avoid "cross-subsidization" of "non-renal organs into non-Medicare patients." The key change was that "Because . . . CMS presumes an OPO intends to procure all transplantable organs, CMS will allocate the general costs across all organs (whether or not actually recovered), *unless an OPO can demonstrate that it did not intend to procure a particular organ*" (emphasis added). The CMS ruling then goes on to list the ways an OPO can demonstrate a lack of intent to recover an organ, including as follows:

- Organ ruled out based on donor history
- Organ ruled out by laboratory data and/or no recipient having been identified prior to entering the operating room for the organ recovery.

In effect, OPOs now need to declare in the donor record which organs are intended to be recovered for transplant *prior* to the start of the donor recovery operation.

Impact of the Change in CMS Cost Finding

The CMS Ruling shifted costs to any organ that was ruled out intraoperatively. Previously, only organs actually recovered were included in the cost-finding process. The change in CMS policy helped reduce, or at least moderate increases in,

the OAC for kidneys, especially as kidneys are only occasionally ruled out intraoperatively. However, OACs for all other organs increased. Pancreas cost was impacted the most due to the large number of pancreas that are ruled out during the recovery procedure, especially when added to the high pancreas discard rate after recovery. As cited in the single OPO example above, a pancreas was actually recovered and transplanted in less than 50 % of the cases where the OPO went to the operating room with the intent to transplant the pancreas. Thus, each pancreas transplanted, as required by CMS rules, had to be assigned more than double the overhead and indirect costs. Some OPOs with large pancreas transplant programs chose to moderate the impact of the change by not increasing the pancreas OAC to cover the entire cost, or made the transition over several years. However, the result of doing this is that the OACs for other extrarenal organs had to be raised above actual costs, or the OPO had to make up the difference from a margin on tissue recovery. The latter solution, while possible for many OPOs in 2007, is less feasible today as the supply of available tissue has grown and processors have reduced reimbursement and/or capped tissue donor volumes.

The impact of the change was particularly severe on islet cell transplantation where there is a "need to complete the manufacturing process for islets before suitability and transplant intent of the pancreata involved can be determined," and a patient may require islet infusions from multiple donors [10••]. Suggestions have been made as to how CMS might modify its cost-finding and reimbursement policies, but for now, pancreas recovered for whole-organ transplant are treated the same as pancreas recovered for islet cell isolation.

The "intent to recover" rule also applies to pancreas for research. If the pancreas was intended to be recovered for transplant when the recovery began, and subsequently was recovered only for research, or was recovered for transplant but ultimately discarded, the intent rule applies. If the pancreas was recovered specifically with the intent to use it in a research protocol, then it is excluded from the CMS calculation used to determine the allocation of costs to each organ.

Conflicting Incentives

Exacerbating the effect of the CMS cost-finding methodology for OPOs is the effect of conflicting incentives that CMS provides to OPOs and transplant centers in the application of performance regulations. OPOs are encouraged to recover, or at least consider for recovery, every organ where there is some potential for transplant. Transplant centers' performance is measured on the outcomes of the transplants they actually perform. While there is some adjustment for donor characteristics, most transplant centers believe the adjustment is inadequate and thus are reluctant to transplant organs where there is a higher perceived potential for graft failure. This is particularly true for pancreas where most programs have relatively low transplant volumes, and a single graft failure is more likely to put them into non-compliance.

The Advisory Committee on Organ Transplantation of the US Secretary of DHHS formally recognized this conflict in their Recommendation 55 of August, 2012:

"Due to misalignment and inconsistencies between CMS certification regulations and outcome requirements for TC and OPOS, the ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, SRTR, the OPO community, and transplant centers representatives, to conduct a comprehensive review of regulatory requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on transplant centers and OPOs. These revisions will include, but not be limited to, improved risk adjustment methodologies for transplant centers and a statistically sound method for yield measures for OPOs. The ACOT recommends that this review be completed within one year and action taken within two years [11]."

To date, no adjustment has been made in the OPO or transplant center performance metrics.

Conclusion

OPO pancreas OACs are high due to the following:

- The disparity between the number of organ donors where there is an intent to recover a pancreas for transplant at the start of the recovery operation, and the number of pancreas actually transplanted
- CMS cost-finding methodologies for OPOs that require the assignment of full overhead and indirect costs to all extrarenal organs where there was an intent to recover the organ for transplant, even if the organ was not actually recovered
- CMS performance metrics for OPOs and transplant centers that encourage OPOs to recover every organ possible for transplant, but also encourage transplant centers to be cautious in the organs they actually transplant to avoid being penalized for poor patient outcomes

Compliance with Ethics Guidelines

Conflict of Interest Richard S. Luskin, Dara L. Washburn, and Susan Gunderson declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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