

**OPTN/UNOS Pancreas Transplantation Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, MO**

**Jonathan Fridell MD, Chair
Jon Odorico MD, Vice Chair**

Contents

Action Items	2
1. Proposal to Require the Collection of Serum Lipase for Pancreas Donors	2
Committee Projects	2
2. Proposal for the Definition of Pancreas Graft Failure	2
3. Pancreas Underutilization	3
4. Review of Pancreas Primary Physician and Surgeon Bylaws	4
5. Pancreas as a Part of a Multivisceral Transplant	4
Committee Projects Pending Implementation	4
6. Changes to Pancreas Allocation System	4
Implemented Committee Projects	5
Review of Public Comment Proposals	5
7. Proposal to Allow Collective Patient and Wait Time Transfers (Operations and Safety Committee)	5
8. Proposal to implement pre-transplant performance review by the Membership and Professional Standards Committee	6
9. Data Collection and Submission for Vascularized Composite Allografts (VCA Committee)	7
Other Committee Work	7
10. Abstracts for ATC 2015	7
Meeting Summaries	7

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This report reflects the work of the OPTN/UNOS Pancreas Transplantation Committee during the June 2014 – November 2014 period.

Action Items

1. Proposal to Require the Collection of Serum Lipase for Pancreas Donors

[Public Comment: March 14 - June 13, 2014](#)

The Committee proposes to make serum lipase a required field in order to make electronic pancreas offers and to program a new field in DonorNet® where OPOs will report the upper limit of normal of the laboratory's normal serum lipase reference range (**Exhibit A**).

RESOLVED, that modifications to Policy 2.11.E (Required Information for Deceased Pancreas Donors) and related modifications in DonorNet® making serum lipase a required field including the required upper limit of normal , as set forth in Exhibit A, are hereby approved effective pending programming and notice to the OPTN membership.

Committee Projects

2. Proposal for the Definition of Pancreas Graft Failure

Public Comment: [September 29 - December 5, 2014](#)

Board Consideration: June, 2015 (Estimated)

Currently, there is no nationally and consistently utilized definition specifically for how to identify and document pancreas allograft failure. Pancreas transplant programs reporting when a pancreas graft failed varies due to this lack of a standard definition. As a result, the inconsistent data limits the ability to analyze and compare pancreas programs' outcomes nationally.

The purpose of this proposal is to draft policy that defines for transplant professionals when pancreas allograft failure occurs and how to document the pancreas graft failure event to the OPTN. The proposal achieves this purpose by drafting policy for when a pancreas graft failed, updating Tiedi® help documentation of how to document pancreas graft failure, and updating the graft status section in the pediatric and adult pancreas and kidney-pancreas Transplant Recipient Registration and Transplant Recipient Follow-Up forms.

The Pancreas Transplantation Committee (the Committee) understands the essential and urgent need to measure, and thereby more consistently manage outcomes. Although the proposed changes are a significant step forward in the effort to consistently identify and document pancreas graft failure on a national basis, the Committee acknowledges the proposed language has room for growth. Currently, the OPTN policy requirements for reporting pancreas graft failure do not consistently coincide with all current, clinical

definitions of pancreas graft failure. Nor does OPTN policy identify all potential scenarios for when pancreas graft failure may occur. As such, the Committee decided to respond to the imminent need with this proposal and believes this proposal is a significant first step in achieving consistent identification and documentation of pancreas graft failure throughout the U.S. In turn, this proposal creates a foundation on which pancreas transplant programs outcomes may be monitored.

This proposal also includes the Pancreas Committee's C-peptide Data Collection Study, which the Pancreas Committee previously reported the preliminary findings of this study in its June 2014 report to the OPTN Board. The details of these findings of the C-peptide Data Collection study are located in the fall 2014 public comment proposal, [Proposal for the Definition of Pancreas Graft Failure](#).

3. Pancreas Underutilization

Public Comment: January, 2015 (Estimated)

Board Consideration: June, 2015 (Estimated)

The goal of the Pancreas Underutilization project is to determine why there is a decline in the number of pancreas transplants and why a significant number of transplantable pancreata are not transplanted. The Committee is studying what may explain the trends in volume of pancreas transplants. This investigation involves literature review, analyzing trends in OPTN data, and conferring with outside experts on the subject. The Committee is discussing everything from organ offer to implantation. This project entails a broad look into allocation challenges, facilitated pancreas allocation updates, and issues from procurement to implantation (e.g., technical challenges, communication challenges, and best practices).

The Committee has been investigating the reasons behind increasing trends in pancreas discards. Preliminary observations are:

- Pancreas transplant activity peaked in early 2000s and has been on the decline since approximately 2005. Transplant activity, as investigated by the committee, includes annual metrics of waiting list size, volumes in registrations added, and the number of transplants.
- The decline has not been driven by the decrease solely in pancreas transplants or rise in pancreas discards.
 - Overall waiting list size and annual additions to the waiting list have both steadily decreased, which shows doctors aren't considering patients for pancreas transplants as much as they used do
 - An increase in diabetic kidney recipients who are not added to pancreas waiting list nor receiving pancreas transplant with kidney

Based on the research reviewed thus far and the Committee's discussions surrounding the potential reasons for pancreas underutilization, the Committee believes the pancreas transplant community will benefit from a guidance document on the best practices for how to effectively utilize pancreas and kidney-pancreas waivers. Further, the Committee continues to review the results of outstanding data requests and will draft a manuscript to publish its investigation findings.

The Committee is also analyzing and updating the facilitated pancreas allocation policy. The Committee is currently drafting updates to the facilitated pancreas allocation policy, which includes adding the following information to the policy:

- Create qualifying criteria for transplant hospitals to participate in facilitated pancreas allocation
- Create monitoring mechanism or review system to assess whether participating transplant hospitals are correctly utilizing facilitated pancreas allocation
- Update time requirements associated with facilitated pancreas allocation
- Remind pancreas transplant hospitals of the facilitated pancreas allocation option

4. Review of Pancreas Primary Physician and Surgeon Bylaws

Public Comment: August, 2015 (Estimated)

Board Consideration: December, 2015 (Estimated)

The Joint Societies Working Group (JSWG) identified and included this project as part of their review and the JSWG is still reviewing this project. The project is on hold for the Pancreas Committee until the JSWG provides the Pancreas Committee its recommendations.

5. Pancreas as a Part of a Multivisceral Transplant

Public Comment: August, 2015 (Estimated)

Board Consideration: December, 2015 (Estimated)

The problem this project aims to solve is a discrepancy in reported data and lack of policy surrounding multivisceral transplants. Specifically, the inconsistencies between transplant hospitals and OPOs when reporting how a pancreas is transplanted, and whether the pancreas counts as a transplanted organ, during multi-organ transplantations that include liver and intestinal organs en bloc. This inconsistency in reporting creates data discrepancies and inconsistent practices for post-transplant follow-up.

The Pancreas Committee does not have any updates on the Pancreas as a Part of a Multivisceral Transplant project since the June 2014 Board Report.

Committee Projects Pending Implementation

None

6. Changes to Pancreas Allocation System

Public Comment: March 19 – July 16, 2010

Board Approval: [November 8, 2010](#)

Implementation Date: October 30, 2014

The changes to the pancreas allocation system will be implemented on October 30, 2014. The major changes to the pancreas allocation system creates are:

- *Qualifying Criteria:* Creating qualifying criteria for kidney-pancreas candidates to accrue waiting time

OPTN/UNOS Pancreas Transplantation Committee

- *Combined Match-run*: Places kidney-pancreas candidates, pancreas candidates, and islet candidates on a single, combined, match-run
- *Kidney follows pancreas through local classification*: Directs OPOs to allocate kidneys and pancreas, when both are available, to kidney-pancreas candidates, through the new classification tables in *Policy 11.5.F Deceased Donors 50 Years Old and less with a BMI Less Than or Equal To 30 kg/m²* and *Policy 11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m²*.local classification, before allocating the kidneys on the kidney match-run

The Committee support staff and Committee leadership worked closely with the implementation team to assist and advise, as needed, with programming changes, education efforts, and communication outreach in preparation for the changes to the pancreas allocation system.

The Committee will begin reviewing data to assess the impact of the changes beginning April 2015.

Implemented Committee Projects

None

Review of Public Comment Proposals

7. Proposal to Allow Collective Patient and Wait Time Transfers (Operations and Safety Committee)

The Pancreas Committee supports the Proposal to Allow Collective Patient and Wait Time Transfer overall. However, the Pancreas Committee asked for clarifications (which were answered during the presentation) and made suggestions.

The Pancreas Committee members expressed concern over when the accepting center is responsible for the candidate information. As a suggestion, the proposal and presentations should be clear about when the accepting center is responsible for the transferred candidates' information. Further, the Pancreas Committee pointed out that the accepting hospital does not know if the candidate information is up to date upon candidate transfer.

Questions from Pancreas Committee

- **How long will the OPTN have to review the applications?**
The Operations and Safety Committee representative and support staff explained there is not a set time-frame for which the applications will be reviewed and completed, but the review will be timely.
- **When the accepting program accepts a large batch of transfers (for ex. 400 – 500 patients) the accepting program will need time to review the candidates' information – which is allotted for in the proposal. However, the candidates' data, at the time of transfer, may be inaccurate. As such, will the accepting program be held accountable for inaccurate data that was previously entered by the closing program? Or will the accepting program only be held accountable for inaccurate information after the accepting program has had time to review the candidates' records?**

The Operations and Safety Committee representative and support staff explained that the accepting program will be held accountable for candidate information after the patient is transferred to the accepting program.

- **May a patient opt-in or opt-out of the transfer? May the patient decide to which center they will be transferred?**

The Operations and Safety Committee representative and support staff explained that the closing center has to notify the patient of his options regarding the transfer.

The proposal sought feedback on two specific questions

- **Should a deadline be proposed to complete full evaluations including post-transfer reporting done every 90 days until evaluations are complete?**

A Pancreas Committee member explained that patient evaluations vary amongst transplant programs. As such, a complete update on all patients may take a long time depending on the accepting transplant programs patient review protocol. The member explained that it may take a couple years to complete evaluating all patients based on the current patient review protocol at an accepting transplant center. If the Operations and Safety Committee wants the patients to be initially reviewed by the accepting transplant program, within a set time, then the proposal needs to explicitly state this expectation.

As a point of clarification and recommendation, the proposal should state time limits for the accepting center to review active status patients.

- **Expectations about the receiving transplant program communicating active versus inactive status to candidates?**

The Pancreas Committee recommended that patients should be transferred as inactive, where it would be the closing center's responsibility to notify patients that they are inactive pending evaluation at the accepting center. At the very least, regardless of whether the closing program or accepting program changes the patients' status, the patient needs to know of the transfer, status re-evaluation, and potential status change.

8. Proposal to implement pre-transplant performance review by the Membership and Professional Standards Committee

Approximately half of the Pancreas Committee members supported this proposal, the other half opposed the proposal.

Questions from Pancreas Committee

- **A Pancreas Committee member asked for clarification regarding whether pre-transplant variables will be looked at in conjunction with post-transplant variables.**

MPSC support staff explained that both will be looked at together – looking at the big picture view of programs performance pre and post-transplant.

- **Is the MPSC expecting more programs to be identified or less programs to be identified for review?**

MPSC support staff explained that there is expected to be slightly more programs identified for review using this assessment.

- **Is there a plan to offer programs annual reports of their performance?**

MPSC support staff explained that the vision is for programs to receive routine reports of where they stand in comparison to other programs. The Pancreas Committee supported the use of routine reports so that a program will have an idea of how they are performing.

- **When will pre-transplant pancreas modeling with CPM go into effect?**

MPSC support staff explained that those models currently don't exist, so it would be difficult to predict when the pre-transplant pancreas models, utilizing CPM, would go into effect. As of right now, MPSC is evaluating how the tool works for only liver and kidney programs.

A Pancreas Committee member recommended that rather than creating a pre-score, the MPSC create a whole-picture score that includes all transplant activity, specifically (1) transplant rate, (2) mortality on the wait list, and (3) post-transplant activity.

The Pancreas Committee pointed out that a center may not be in control of caring for patients pre-transplant. In this situation, the center should not be held accountable.

9. Data Collection and Submission for Vascularized Composite Allografts (VCA Committee)

The Pancreas Committee supports the Data Collection and Submission Requirements for Vascularized Composite Allografts proposal. Notably, the committee supports reporting data from all the proposed data points.

Other Committee Work

10. Abstracts for ATC 2015

The Committee plans to submit two abstracts for ATC in 2015. One abstract will be about the Committee's c-peptide data collection study associated with the Definition of Pancreas Graft Failure project and the second abstract will be about the Committee's research on the Pancreas Underutilization project.

Meeting Summaries

The committee held meetings on the following dates:

- June, 2014
- August, 2014
- September, 2014
- October, 2014

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=69>

Proposal to Require the Collection of Serum Lipase for Pancreas Donors

Table of Contents

Sponsoring Committee: Pancreas Transplantation Committee 2

Summary and Goals of the Proposal: 2

Background and Significance of the Proposal: 2

Supporting Evidence and/or Modeling: 3

Expected Impact on Living Donors or Living Donation: 3

Expected Impact on Specific Patient Populations: 4

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule: 4

Plan for Evaluating the Proposal: 4

Additional Data Collection: 5

Expected Implementation Plan: 5

Communication and Education Plan: 5

Compliance Monitoring: 6

Policy or Bylaw Proposal: 7

Public Comment Responses 8

 1. Public Comment Distribution 8

 2. Primary Public Comment Concerns/Questions 8

 3. Regional Public Comment Responses 9

 4. Committee Public Comment Responses 9

 5. Individual Public Comment Responses 10

Post Public Comment Consideration: 11

Title: Proposal to Require the Collection of Serum Lipase for Pancreas Donors**Sponsoring Committee: Pancreas Transplantation Committee****Summary and Goals of the Proposal:**

The Committee proposes to make serum lipase a required field in order to make electronic pancreas offers. Currently, serum lipase is an optional field in DonorNet® that is not required in order to make electronic pancreas offers. The purpose of making serum lipase values a required field is because serum lipase values are a direct indicator of pancreas function and quality. As such, the serum lipase values assist in making an informed decision regarding electronic pancreas offers.

The proposal also proposes to create a new field in DonorNet® where OPOs will report the upper limit of normal of the laboratory's normal serum lipase reference range (i.e., maximum normal value or highest reference value). The reason for programming this new field is because laboratories' measurement ranges vary for serum lipase. As a result, a serum lipase value may have two different meanings at two different laboratories. This results in varying "normal" serum lipase values across the country. This new field will provide a reference point regarding the serum lipase value to the physician making the decision whether to accept the pancreas.

Background and Significance of the Proposal:

Policy 2.11.E (Required Information for Deceased Pancreas Donors), lists the information that is required for deceased pancreas donors. This list of information only applies to potential pancreas donors and currently does not include serum lipase values, but does include serum amylase values. In comparison to serum amylase analysis, the Committee believes that serum lipase analysis is more sensitive and specific, and thus a better indicator of pancreas quality. Physicians need to know the pancreas' quality when determining whether to accept or decline the offered pancreas. Since the Committee supports that serum lipase values are medically accepted as a direct measure of the donor's pancreas function and quality, serum lipase values serve as vital elements for the transplant physician to make an informed decision about the pancreas offer.

Currently, serum lipase is a requested field in DonorNet® that is not required in order to make electronic pancreas offers. Committee members reported that during pancreas allocation, some OPOs do not provide a serum lipase value, which, in turn, makes assessing pancreatic quality an unnecessary challenge. (See *Supporting Evidence And/Or Modeling*, below.) As such, this proposal proposes to make the serum lipase values a requirement to make electronic pancreas offers.

Hospitals and laboratories vary in the range of serum lipase values reported. As a result, a serum lipase value may have two different meanings at two different laboratories. Reference information is required in conjunction with reporting the serum lipase values. This results in varying "normal" serum lipase values across the country. As such, this proposal includes creating a new field where the OPO will report their lab's upper limit of normal (i.e., maximum normal value or highest reference value) on the serum lipase reference range, in addition to the serum lipase value. This will provide a reference point to further interpret the serum lipase value for pancreatic quality. As such, the upper limit of normal is a vital addition to the reported serum lipase value.

Supporting Evidence and/or Modeling:

Currently, members report serum lipase values in DonorNet® for approximately 99% of pancreas donors (defined as pancreas recovered for transplant). Members report serum lipase values in DonorNet® for approximately 79% of non-pancreas donors (pancreas not recovered). Overall, members report serum lipase values 83% of the time in DonorNet® (all donors). On the DDR, OPOs report serum lipase values for approximately 97% of pancreas donors recovered but not transplanted, 99% of transplanted pancreas donors, and for approximately 6% of non-pancreas donors. OPOs report serum lipase values on 24% of all DDRs. There are 17% (and 21% of non-pancreas donors) of donors that did not have serum lipase values entered into DonorNet®. This means that at least 17% of all donors did not have serum lipase values available at the time of any organ offer.

Figure 1 shows the number of deceased donors recovered in the US from 2010-2012 by whether or not their pancreas was recovered or transplanted and whether or not lipase was recorded on the DDR or if they have ever had a value entered in DonorNet®.

Lipase Field	Donor Pancreas Disposition						Total	
	Not Recovered		Transplanted		Recovered but Not Transplanted			
	N	%	N	%	N	%	N	%
DDR								
No Lipase on DDR	18261	93.46	36	1.04	37	3.07	18334	75.72
Lipase Recorded on DDR	1278	6.54	3430	98.96	1170	96.93	5878	24.28
Total	19539	100.00	3466	100.00	1207	100.00	24212	100.00
DonorNet								
No Lipase on DonorNet	4011	20.53	38	1.10	16	1.33	4065	16.79
Lipase Recorded on DonorNet	15528	79.47	3428	98.90	1191	98.67	20147	83.21
Total	19539	100.00	3466	100.00	1207	100.00	24212	100.00

Figure 1. Based on OPTN data as of November 29, 2013. Data subject to change based on future data submission or correction.

Expected Impact on Living Donors or Living Donation:

There is no expected impact on Living Donors or Living Donation.

Expected Impact on Specific Patient Populations:

This proposal has a potential impact on patients seeking a pancreas or kidney/pancreas transplant. This proposal creates a potential positive impact on pancreas and kidney/pancreas candidates in that, ideally and ultimately, the patient will receive a higher quality pancreas.

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:

This proposal's expected impact on OPTN key goals and strategic plan is that the proposal provides a better understanding of the donor's pancreas quality so that transplant programs can make better decisions regarding the suitability of the graft for each individual potential pancreas recipient.

This proposal also supports the OPTN key goals and strategic plan by potentially increasing the number of transplants through an increase in the number of organs transplanted per donor and reducing the percentage of recovered organs not transplanted (i.e., reducing the number of discards). The proposal supports this goal by potentially reducing the number of pancreatic discards by matching more compatible pancreas donors to pancreas recipients. Another OPTN Strategic Plan Goal this proposal supports is to improve post-transplant survival with increased patient and graft survival rates and reduced re-transplants rates due to more medically compatible pancreata allocated to donors.

The last goal that this proposal supports is the efficient management of OPTN resources. As an abnormal lipase may be an indicator of poor pancreas quality or inflammation, this information will assist decision makers in determining the suitability of the pancreas for transplantation prior to procurement. As a result, the decision makers' knowledge of abnormal serum lipase values may eliminate wasted resources (OPO SAC fees, flight costs, staff time, etc.) by preventing the allocation and placement of a pancreas that is ultimately discarded.

This proposal also promotes §121.4 of the Final Rule, which states: "(a) The OPTN Board of Directors shall be responsible for developing policies within the mission of the OPTN including (1) Policies for the equitable allocation of cadaveric organs in accordance with §121.8." Specifically, this proposal promotes § 121.8 of the Final Rule, which states: "Allocation of organs. (a) Policy development. (2) Shall seek to achieve the best use of donated organs; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement." Lastly, this proposal supports §121.7, which states: "(b) Offer of organ for potential recipients. (3) An organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital," and furthers the OPTN Strategic Plan of improving survival for patients post-transplant and increasing the number of transplants.

Plan for Evaluating the Proposal:

The Committee proposes requiring the collection of serum lipase for all pancreas donors to increase pancreas utilization. Starting one year after implementation, the Committee will see if increased collection of serum lipase is associated with increased pancreas utilization. This analysis will occur annually to see if this trend continues or takes time to affect utilization. The evaluations may continue up to three years to monitor these trends after implementation. Deceased donors in a similar length time frame can be compared before and after the policy to examine any change in utilization. Metrics that illustrate pancreas utilization will be used, including the number of pancreata offered, accepted, recovered, and discarded.

Additional Data Collection:

This proposal will require additional data collection in DonorNet®. OPOs will be required to input serum lipase values for all pancreas offers. In addition, OPOs will have to input a laboratory’s upper limit of normal of their own corresponding serum lipase reference range.

This proposal coincides with the following Principles of Data Collection: (1) develop transplant, donation, and allocation policies, and (2) fulfill the requirements of the Final Rule. The intended use of these data is to better assess pancreatic quality for all pancreas offers.

Expected Implementation Plan:

This proposal will be submitted to the Board of Directors in November 2014. If approved, this proposal will require additional programming in DonorNet®. The policy will become effective upon programming implementation.

Prior to programming, OPOs will be responsible for reading and understanding documentation that explains that serum lipase and the upper limit of normal will become required fields.

Communication and Education Plan:

Upon Board approval, several communications channels will be used to inform transplant professionals (specifically, OPO and kidney/pancreas transplant center personnel) about the requirement to collect serum lipase for all pancreas donors. DonorNet® currently contains a field for serum lipase, and research shows that most OPOs already record the information in UNetSM, so this change would not be significant enough to require extensive notification, UNetSM training, or special education sessions.

The first notification of this change will be sent to members through the policy notice in December 2014, 30 days after approval by the board.

System notices will be sent to DonorNet® users to provide advance notice of the change before the requirements are programmed. Lastly, the help documentation in DonorNet® will be updated to explain that serum lipase is a required field as well as provide guidance for what the upper limit of normal field aims to capture and how to complete the upper limit of normal field in conjunction with the serum lipase value.

The table below outlines the proposed communication and education activities.

Communication Activities			
Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice (summary of all policy changes approved by the board in a PDF format)	Transplant Community	Electronic	December 2014 (or 30 days after board approves the change)

System Notice	UNet SM users	Through UNet SM	In accordance with programming schedule

Compliance Monitoring:

At OPOs, site surveyors will continue reviewing a sample of deceased pancreas donor records for documentation of serum amylase.

At OPOs, site surveyors will begin reviewing a sample of deceased pancreas donor records for documentation of serum lipase.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 At a meeting of the OPTN/UNOS Board of Directors convened on November 12, 2014 in St. Louis, the
2 following resolution is offered.

3
4 *A resolution to require the collection of serum lipase for pancreas donors.*

5
6 Sponsoring Committee: Pancreas Transplantation Committee

7
8 **RESOLVED, that Policies 2.11.E Required Information for Deceased Pancreas Donors are modified**
9 **as set forth below, are hereby approved, effective pending programming and notice to OPTN**
10 **membership.**

11
12 **2.11 Required Deceased Donor Information**

13
14 **2.11.E Required Information for Deceased Pancreas Donors**

15
16 The host OPO must provide *all* the following additional information for all deceased donor
17 pancreas offers:

- 18
19 1. Donor name
20 2. Donor ID
21 3. Ethnicity
22 4. Weight
23 5. Date of admission for the current hospitalization
24 6. Alcohol use (if known)
25 7. Current history of abdominal injuries and operations including pancreatic trauma
26 8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average
27 urine output, and oliguria
28 9. Current medication and transfusion history
29 10. Pertinent past medical or social history including pancreatitis
30 11. Familial history of diabetes
31 12. Insulin protocol
32 13. Indications of sepsis
33 14. Serum amylase
34 15. Serum lipase
35 ~~15~~6. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens.
36 The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.

37 #

Public Comment Responses

1. Public Comment Distribution

Date of distribution: March 14, 2014

Public comment end date: June 13, 2014

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	26	17 (65.38%)	N/A	5 (19.23%)	4 (15.38%)
Regional	11	11 (100%)	N/A	0 (0%)	0 (0%)
Committee	19	1 (5.26%)	N/A	1 (5.26%)	17 (89.47%)

2. Primary Public Comment Concerns/Questions

Overall, there was significant support for this proposal as evidenced by all regions in favor of the proposal, the majority of individuals in support of the proposal, and support from all professional societies except for AOPO opposing part of the proposal (the professional societies responses are shown in the “Individual Public Comment Responses” section below).

The primary public comment concern was from the OPO Committee and OPO community. The OPO community is concerned that not all OPOs will be able to produce a serum lipase value in time for an electronic pancreas offer. According to an OPO Committee member there are OPOs that are geographically located in remote areas and do not have the means to produce a serum lipase value in time to make an electronic pancreas offer. As an example, the OPO Committee member explained that some OPOs located in remote areas of Texas will not be able to always comply with the proposal’s requirement.

OPO community members also explained that OPOs do not have the authority over when a lab will produce the lab values. As such, they felt the OPO should not be held responsible for producing lab values at a certain time. In this case, even OPOs who typically are able to produce lipase values on their donors will sometimes have circumstances when the lipase value is unavailable.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	13 yes, 0 no, 0 abstentions		In person
2	3/28/2014	27 yes, 0 no, 0 abstentions		In person
3	5/30/2014	16 yes, 0 no, 1 abstention		In person
4	5/9/2014	20 yes, 4 no, 1 abstention		In person
5	6/12/2014	18 yes, 6 no, 4 abstentions		In person
6	5/16/2014	35 yes, 4 no, 0 abstentions		In person
7	5/9/2014	18 yes, 0 no, 0 abstention		In person
8	4/4/2014	14 yes, 0 no, 1 abstention		In person
9	5/21/2014	15 yes, 0 no, 0 abstentions		In person
10	5/15/2014	10 yes, 1 no, 6 abstentions		In person
11	5/30/2014	24 yes, 0 no, 0 abstentions		In person

4. Committee Public Comment Responses

Organ Procurement Organization (OPO) Committee:

The Committee discussed this proposal following a presentation by a member of the Pancreas Transplantation Committee. The Committee noted that not all donor hospitals have the ability to perform serum lipase testing. Although the data presented by the Pancreas Committee shows that serum lipase is reported on the DDR 99% of the time for pancreas donors, it does not address the timeliness of the testing. The proposal makes serum lipase a required field in DonorNet® in order to make electronic pancreas offers. However, if serum lipase testing is not locally available or the test results are delayed for whatever reason, the ability to allocate the pancreas becomes difficult under the proposed policy.

The Committee discussed several other concerns:

- Is there scientific data to show how deceased donor serum lipase relates to pancreas graft survival?
- One of the purposes of the proposal is to promote a more efficient allocation system. However, Committee members argued that requiring serum lipase before making organ offers will make organ allocation less efficient.
- Because of the timing issues, it might be difficult for OPOs to comply with these new requirements.

- Does the data show that requiring serum lipase will lead to more pancreas transplants? If serum lipase is not available are the pancreata still being transplanted?
- Is it known why 1% of serum lipase results were not reported? Was it due to lab results being received later or unable to obtain at all?

Recommendations from the OPO Committee:

- Make serum lipase a desired test when available. One option is to require the tests be sent but organ offers can be made before test results are received.
- Support the creation of a new field in DonorNet® where OPOs will report the upper limit of normal (i.e. maximum normal value or highest reference value) of the laboratory's normal serum lipase reference range.
- Wait for information from the Pancreas Underutilization Subcommittee to determine impact on pancreas utilization.
- Make the Pancreas Committee aware that requiring serum lipase results before making pancreas offers will create logistical challenges for the OPOs.

Patient Affairs Committee:

The Committee received the presentation on Serum Lipase and voted with minimal discussion. (Support – 15, Abstain – 1, Against – 0)

5. Individual Public Comment Responses

Comment 1:

Vote: Oppose

Date Posted: 06/13/2014

AOPO appreciates the work of the committee, and we do support reporting via DonorNet® the upper limit of normal for the laboratory's lipase reference range. However there are other areas of concern. There may be geographic impediments for laboratory testing that reduce the efficiency of allocation for some OPOs. Holding up pancreas allocation until serum lipase results are available, will create logistical challenges for OPOs.

Comment 2:

Vote: Oppose

Date Posted: 05/28/2014

This will place a burden on [sic] the OPO to report the [sic] hospital specific upper limit of normal on a lab. Tx center have never called previously for such results. This will also require significant reprogramming of OPO EMR.

Comment 3:

Vote: Oppose

Date Posted: 06/13/2014

We are concerned with our ability to meet this requirement 100% of the time (either not able to report at all or much later in the donation process because its a send-out lab); concern that the requirement might make process less efficient; concern over lack of data to support that this change will in fact lead to more transplanted pancs. Recommend making serum lipase a desired test when available. One option is to require the tests be sent but organ offers can be made before

test results are received. Support the creation of a new field in DonorNet where OPOs will report the upper limit of normal (i.e. maximum normal value or highest reference value) of the [sic] laboratorys normal serum lipase reference range. Wait for information from the pancreas utilization subcommittee to determine impact on pancreas utilization. Make the Pancreas Committee aware that requiring serum lipase results before making pancreas offers will create logistical challenges for the OPOs.

Comment 4:

Vote: Support

Date Posted: 06/17/2014

ASTS supports this proposal which would require the collection of serum lipase for pancreas donors.

Comment 5:

Vote: Support

Date Posted: 06/13/2014

NATCO supports this proposal as written.

Comment 6:

Vote: Support

Date Posted: 06/16/2014

Overall this is a well-written proposal. Serum lipase levels are crucial to the assessment of the pancreas donor. These levels must be interpreted in the context of baseline laboratory ranges, and therefore, the requirement to report the upper limit of normal is necessary. The AST is in complete support of this proposal.

Post Public Comment Consideration:

After public comment, the Pancreas Transplantation Committee made several attempts to address the OPO Committee's concerns and questions about the serum lipase proposal. The Pancreas Transplantation Committee leadership worked with the OPO Committee leadership to address and brainstorm potential solutions to the OPO Committee's concerns. In addition, the Pancreas Transplantation Committee Chair reached out to two OPO Committee members to directly address their concerns about the proposal. Finally, the Pancreas Transplantation Committee presented a post public comment follow-up presentation to the OPO Committee on September 23, 2014. The paragraphs below expand upon OPO Committee's major concerns and provide the Pancreas Transplantation Committee's response.

The Pancreas Transplantation Committee leadership also worked with the OPO Committee leadership to address the OPO Committee's concerns about the proposal. The OPO Committee leadership recommended that serum lipase could remain a required field as long as there was a guarantee that OPO's who could not produce the serum lipase value in time for the electronic pancreas offer would not be cited for policy non-compliance. The OPO Committee leadership suggested one of the following solutions as part of that guarantee:

- GGT: Monitor serum lipase fields similar to how gamma-glutamyl transferase (GGT) was formerly monitored.

- Preferred Field: Make serum lipase a “preferred” field similar to how some of the thoracic fields are preferred fields.
- Letter: Draft a letter, from the Pancreas Committee leadership and OPO Committee leadership, that explains both committees recognize that some OPOs are located in geographically remote locations and cannot provide a serum lipase value in time to make an electronic pancreas offer. The letter will further explain that the remotely located OPOs should not be “dinged” in the event they are cited for a policy noncompliance regarding the required serum lipase field.

Unfortunately, none of the suggested solutions are feasible for the following reasons:

- GGT: The Department of Evaluation and Quality (DEQ) stopped monitoring GGT in 2005 (approximately). When DEQ monitored GGT they monitored the field to ensure that the GGT value was provided. There is no known history of GGT being monitored, by the OPTN/UNOS, in any unique or exceptional manner.
- Preferred Field: OPTN/UNOS does not identify fields as “preferred.” Instead, fields are monitored if they are required by policy. There are, however, thoracic fields that are *required if requested* (see [Policy 2.11.C Required Information for Deceased Heart Donors](#) and [Policy 2.11.D Required Information for Deceased Lung Donors](#)). Since they are only required under certain conditions, DEQ does not monitor these fields. Keep in mind that for these fields to be required, the member has to make the request for the information (e.g., as applied to the serum lipase scenario, the pancreas surgeon would have to call the OPO and request the OPO to provide the serum lipase value for each pancreas offer).
- Letter: DEQ’s monitoring is based on requirements as they are reflected in policy language, and reports compliance or potential noncompliance to the MPSC. The MPSC can always consider circumstances when deciding whether or not to take action against a member, but it is based on the medical judgment of the members of the MPSC. In general, the preference is that OPTN/UNOS only make requirements that can be applied uniformly.

An OPO Committee member pointed out that her practice reviewed the European P-PASS score (which includes amylase and lipase) and concluded that the P-PASS score impacts pancreas acceptance, but that subsequent studies have not shown that the P-PASS score impacts graft survival. Further, the OPO Committee member pointed out that the newer PDRI¹ (pancreas donor risk index) does not include lipase/amylase as pancreas donor risk factor². Therefore, the OPO

¹ PDRI was developed by Axelrod/Melcher (J Surg Res. 2013 Aug;183(2) App to reality: snapshot validation of the US Pancreas Donor Risk Index in a UK center. Mittal S1, Sharples E, Lee F, Reddy S, Sinha S, Friend P, Vaidya A).

² This OPO Committee member also pointed to the following abstracts in her practices’ discussion on pancreas enzymes donors, which the member noted were focused on amylase:

- Transplantation, Volume 75, Issue 8, 27 April 2003, Pages 1271-1276 Underutilization of pancreas donors (Conference Paper) Krieger, N.R.a, Odorico, J.S.ab, Heisey, D.M.a, D’Alessandro, A.M.a, Knechtle, S.J.a, Pirsch, J.D.a, Sollinger, H.W.a a Division of Organ Transplantation, Department of Surgery, Univ. of Wisconsin Medical School, Madison, WI, United States b Department of Surgery, Univ. of Wisconsin Hosp. and Clinics, H4/756 Clin. Science Center - 7375, 600 Highland Ave., Madison, WI 53792, United States (2) Transplant Proc. 1998 Mar; 30(2):276-7.
- Donor factors affecting outcome after pancreas transplantation. Odorico JS, Heisey DM, Voss BJ, Steiner DS, Knechtle SJ, D’Alessandro AM, Hoffmann RM, Sollinger HW.
- Diabetes. 1989 Jan;38 Suppl 1:1-3. Influence of serum amylase and plasma glucose levels in pancreas cadaver donors on graft function in recipients. Hesse UJ, Sutherland DE.

Committee member believed that serum lipase is not as direct of an indicator of pancreas quality as presented in the proposal.

In response, the Pancreas Transplantation Committee explained that the P-PASS score was designed to predict the likelihood for acceptance of a pancreas allograft, so it reflects features of an entire donor population and specifically analyzed factors that would impact on the transplantability of the pancreas. These characteristics include Age (y)*, BMI (kg/m²)*, ICU stay (d), Cardiac arrest (min), Sodium (mmol/L), Amylase (U/L), Lipase (U/L), (Nor) adrenaline or dobuta-/dopamine. According to the P-PASS scoring system, lipase is actually a factor that helps predict the likelihood of transplanting a pancreas allograft. The P-PASS was not designed to predict subsequent pancreas allograft failure. Since the P-PASS score was associated with a decreased likelihood of actually transplanting the pancreas, and graft failure is limited to the pancreas grafts that were actually transplanted, the transplanted population only reflects the pancreas grafts with the best P-PASS scores. As such, it is not surprising that the P-PASS score does not predict subsequent graft survival.

The PDRI, on the other hand, was designed to identify factors associated with increased risk of graft failure after pancreas transplantation and, therefore, it was based exclusively on pancreas transplants that were actually performed.³ The PDRI excludes all pancreas allografts that did not appear transplantable. Donor characteristics for the PDRI include Gender, Age, Black race, Asian, BMI, Height, Cause of death: CVA/stroke, Pancreas preservation time (h), DCD, and SCr > 2.5. Note that the donor characteristics do not include lipase. As indicated from the P-PASS score, lipase is a strong predictor of whether or not a donor pancreas will be transplanted. This introduces a selection bias in that only the transplantable allografts were implanted. The pancreas allografts from donors with abnormal lipase values were less likely to be transplanted. This is why, once a pancreas has been deemed suitable for transplantation, the lipase is no longer a feature that helps predict subsequent failure. The conclusion that can be drawn from the P-PASS and PDRI scoring systems is that lipase is an important characteristic for predicting suitability of a pancreas allograft for transplantation, but once the pancreas is transplanted, lipase is no longer an important factor for graft survival.

A second OPO Committee member was concerned about how OPOs located in geographically remote areas would comply with the proposal's requirement to produce serum lipase in time for the electronic pancreas offer. In response, the Pancreas Transplantation Committee offers a "best practices" solution. The "best practices" solution applies to OPOs who either cannot produce the serum lipase value in time for the electronic pancreas offer because the OPO is in a remote geographic location, or to OPOs who have no control over when the lab will produce lab results. For these OPOs the Pancreas Transplantation Committee recommends that when the OPO is unable to produce the serum lipase value in time for the electronic pancreas offer, that the OPO upload a letter from the lab director into the donor file. The letter should explain that the lab does not produce serum lipase results in time for the OPO's electronic pancreas offer. In an effort to mitigate additional burden on the OPO, the letter may be a generic letter that is not donor specific. In the event the OPO's audit includes a review of the donors' record where the OPO was unable to produce the serum lipase value in time for the electronic pancreas offer, the OPO may point to the lab letter as justification for the non-compliance. However, it is important to note that this is only a "best practice" solution that the Pancreas Transplantation Committee supports in the event of an OPO's non-compliance due to circumstances outside of the OPO's control, and not a

³ PDRI was developed by Axelrod/Melcher (J Surg Res. 2013 Aug;183(2) App to reality: snapshot validation of the US Pancreas Donor Risk Index in a UK center. Mittal S1, Sharples E, Lee F, Reddy S, Sinha S, Friend P, Vaidya A).

guaranteed dismissal of policy non-compliance. The Membership and Professional Standards Committee reviews non-compliance situations on a case-by-case basis.

After discussing all of the feedback, the Committee unanimously supported a motion to submit the Proposal to Require the Collection of Serum Lipase for Pancreas Donors to the Board of Directors. (10 support, 0 oppose, 0 abstentions)

In light of the discussions between the Pancreas Committee and OPO Committee, the Pancreas Committee also drafted and approved a secondary policy proposal that includes an exception to the serum lipase requirement. While the Pancreas Committee prefers the version of the proposal that was released for public comment, the Committee requests that the Board of Directors consider the below proposal if the Board of Directors does not support the initially proposed serum lipase requirement language (see the resolution language in the “Policy of Bylaw Proposal” section).

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

2.11 Required Deceased Donor Information

2.11.E Required Information for Deceased Pancreas Donors

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

1. Donor name
2. Donor ID
3. Ethnicity
4. Weight
5. Date of admission for the current hospitalization
6. Alcohol use (if known)
7. Current history of abdominal injuries and operations including pancreatic trauma
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
9. Current medication and transfusion history
10. Pertinent past medical or social history including pancreatitis
11. Familial history of diabetes
12. Insulin protocol
13. Indications of sepsis
14. Serum amylase
15. Serum lipase
- 15~~6~~. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens. The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.

If serum lipase results are not available at the time of the pancreas offer because the laboratory could not provide the results prior to the pancreas offer, the host OPO must do both of the following:

1. Report to the OPTN Contractor that the serum lipase results were not available at the time of the pancreas offer.
2. Provide serum lipase results to the transplant hospital as soon as they become available.