

At-a-Glance

Proposal to Require the Collection of Serum Lipase for Pancreas Donors

- **Affected/Proposed Policy:** Policy 2.8.E. Required Information for Deceased Pancreas Donors

Pancreas Transplantation Committee

This document proposes to make serum lipase a required field in Policy 2.8.E Required Information for Deceased Pancreas Donors, as well as required in DonorNet[®], in order to make electronic pancreas offers. Currently, serum lipase is a listed field in DonorNet[®], but is not required in order to make electronic pancreas offers. Serum lipase level(s) in deceased donors are reliable indicators of pancreas function and quality. As such, the serum lipase values assist in making an informed clinical decisions regarding electronic pancreas offers.

The proposal also proposes to create 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. 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.

- **Affected Groups**

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Data Coordinators
Transplant Physicians/Surgeons
Organ Candidates
General Public

- **Number of Potential Candidates Affected**

As of December 23, 2013, there are 1,178 candidates on the Pancreas waiting list and 2,034 candidates on the Kidney/Pancreas waiting list. Both Pancreas and Kidney/Pancreas waiting list candidates will be affected by this policy change. This policy will affect the candidate pool by requiring the collection of serum lipase values for pancreas donors. Serum lipase values assist in making an informed decision regarding pancreata quality for electronic pancreas offers.

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal 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.

Proposal to Require the Collection of Serum Lipase for Pancreas Donors

Affected/Proposed Policy: Policy 2.8.E. Required Information for Deceased Pancreas Donors

Pancreas Transplantation Committee

Public comment response period: March 14, 2014 – June 13, 2014

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 a listed field in DonorNet®, but 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 lab's 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 2.8.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, serum lipase analysis is more sensitive and specific, and thus a better indicator of pancreas quality. What this means for transplant purposes is that the physician needs to know the pancreas' quality when determining whether to accept or decline the offered pancreas. Since 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 listed field in DonorNet® but 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. As such, this proposal proposes to make the serum lipase values a requirement to make electronic pancreas offers.

OPOs report serum lipase values in DonorNet® for approximately 99% of pancreas donors (defined as pancreas recovered for transplant). OPOs report serum lipase values in DonorNet® for approximately 79% of non-pancreas donors (pancreas not recovered). Overall, OPOs 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. These numbers imply that approximately

17% of all donors (and 21% of non-pancreas donors) may not have had serum lipase values available for consideration when the OPO makes the offer for a potential transplant.

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.

- ***Collaboration***

At the Committee's October 2013 meeting, a Committee member asked if requiring the collection of serum lipase would be difficult for small OPOs. In order to further address this question, UNOS staff met with a Committee member (who is a subject matter expert on OPO operations) to discuss the OPO's perspective and to gather the OPO community input on the serum lipase project.

The Committee member reached out to colleagues at small OPOs to inquire if the requiring serum lipase values would be burdensome. The Committee members' colleagues responded that it would not be a challenge if serum lipase became a required field and noted that he supports requiring serum lipase values if the test is available. The Committee member pointed out that the qualifying factor is if the serum lipase test is available, then it should be a part of required information for organ offers. The Committee member noted that there may be exceptional cases where a hospital may put in a place-holder value for a required field because, for whatever reason, they don't collect the required field. The Committee member noted that he wouldn't want the serum lipase requirement to be a limiting factor to send notifications. The Committee member expressed a concern that requiring serum lipase for electronic notification may delay organ allocation when a hospital is waiting on the lab value. Specifically, the Committee member noted the serum lipase value shouldn't delay the electronic notifications because the OPO should be able to proceed with the organ offers in order to sift through the uninterested programs. The Committee member noted that the issue isn't surrounding the interested programs; rather, the programs that are not interested in the offer. UNOS staff pointed out that serum amylase is currently required to send an electronic offer but is not required to run a match. Further, Pancreas Committee leadership want serum lipase to follow the same programming as serum amylase, and want a serum lipase value on the electronic notifications in order to determine the quality of the pancreas. The Committee member suggested for implementation purposes, it would be easier for OPOs to phase-in the requirement. Specifically, to require the serum lipase value in policy for auditing purposes, then at a later date, make the serum lipase field required in DonorNet®.

The Committee sent the OPO Committee a memorandum that explains the serum lipase project, the benefits of the project, and how the project will affect the OPO community. The Committee asked for the OPO Committee's feedback and support of the serum lipase project.

The OPO Committee recommended keeping serum lipase as a "desired or optional" piece of information along with the ranges, where the serum lipase values may be discussed at the time of the offer rather than becoming a required field. The OPO Committee suggested that if the

transplant center has a question regarding a lipase value, the transplant center should communicate with the OPO or the on-site OPO personnel.

Specifically, regarding the frequency of lipase being documented for pancreas offers, the OPO Committee asked why serum lipase should be required when the data show the majority of OPOs report serum lipase values. Although the Pancreas Transplantation Committee understands the OPO Committee's point, labs do not report serum lipase values 100% of the time, and since the value is a direct indicator of pancreatic quality, it should be reported every time, without exception.

Specifically, regarding reporting the upper limit of normal value, the OPO Committee suggested reporting this value only if it is available. In response, the upper limit of normal value is an existing number that is associated with the serum lipase test the lab chooses to use. In other words, the upper limit of normal value is available every time the serum lipase test is performed. Since serum lipase values are a direct indicator of pancreatic quality, the serum lipase value should be reported for every offer. In addition, from a data analysis perspective, collecting information about the upper limit of normal will allow for the lipase values to be normalized and combined across OPOs with varying 'normal' ranges.

Lastly, the OPO Committee did not support another mandatory field in UNetSM, especially one that requires additional programming to add real time normal ranges for each donor. Although the Pancreas Transplantation Committee understands that this proposal creates additional responsibility for the OPO the majority of labs are already reporting the value to the OPO. Therefore, the need for the value outweighs the additional administrative burden and costs considering that serum lipase values directly reflect pancreatic quality.

- ***Alternatives considered***

The Committee considered four different options for how to achieve the serum lipase project goals. The four options are listed below.

- **Option 1:** Require serum lipase for pancreas donors in policy only and no programming changes.
- **Option 2:** Require serum lipase for pancreas donors in policy and modify DonorNet[®] to make serum lipase required to send electronic pancreas organ offers. (This is the same policy and programming requirement as serum amylase.)
- **Option 3:** Require serum lipase for pancreas donors in policy and modify DonorNet[®] to make serum lipase required to send electronic pancreas electronic organ offers and to run a match.
- **Option 4:** Require serum lipase for pancreas donors in policy and modify DonorNet[®] to make serum lipase required to send pancreas electronic organ offers and run a match and modify Waitlist to make serum lipase donor acceptance criteria fields required on the candidate required. (Note: Currently the serum lipase donor acceptance criteria fields are not required on the candidate

record. Screening on serum lipase would only happen if these fields were entered on the candidate record and also on the donor record.)

The Committee leadership met on November 20, 2013, to discuss the potential implementation options for how to collect serum lipase values. The Committee leadership reviewed and discussed the four options listed above. A member responded that Option 1 is unacceptable and Options 2-4 are acceptable. Option 1 is unacceptable because it only makes serum lipase required in policy and not in programming. As such, OPOs could still systematically make electronic pancreas offers without entering serum lipase values, which would not achieve the project's goals. Specifically, it was noted that serum lipase should have the same programming rules and requirements as serum amylase, and Option 2 allows serum lipase to have the same programming rules and requirements as serum amylase. As such, Option 2 appears to be the best option. Regarding Option 4, it was noted that Option 4 appears too complicated and includes unnecessary programming. A member noted that Option 4 could be helpful if the surgeon did not want to hear about offers with a serum lipase value over a certain amount.

- ***Upper Limit of Normal***

During the Committee's November 20, 2013, teleconference, a lengthy discussion was held, noting that variation exists with laboratories across the country on serum lipase result ranges. Specifically, laboratories vary on the top threshold value of serum lipase. As a result, the members discussed potentially programming a reference range, in addition, to requiring the collection of serum lipase values. However, they noted that a reference range may have burdensome and expensive programming costs. Further, referencing the serum lipase high value would be sufficient, since there is no concern surrounding a low serum lipase value.

During the Committee's December 13, 2013, meeting, a member pointed out that initial discussions of this proposal surrounded creating a range field that captures the lower and upper limit of a laboratory's serum lipase reference range. However, the lower range value does not have clinical significance because it does not matter if the serum lipase value is too low. If the serum lipase value is too low, the value would not be meaningful to the surgeon deciding whether to accept or decline the pancreas offer. As a result, in order to keep programming to a minimum, a member previously suggested creating a field next to the serum lipase field that shows the serum lipase range's upper limit of normal. A hospital or lab would type in the serum lipase value in DonorNet[®], then type in that hospital or lab's upper limit of normal of its normal serum lipase range.

During the Committee's December 13, 2013, meeting, the members discussed the following options for where to house the upper limit of normal field:

- **Option 1:** All laboratory upper limit of normal fields are located on the test result report that the physician references (perhaps in the laboratory attachments) when reviewing the pancreas offer. This option requires compiling a document that shows all hospital and labs upper limit of normal field for their serum lipase reference range.
- **Option 2:** The OPO enters the upper limit of normal in a "notes" section that is already located on the donor record.

- **Option 3:** The OPO enters the upper limit of normal in a field near the serum lipase field in the donor record. This option requires programming a new field in the donor record within several different sections of DonorNet®.

During the Committee's December 13, 2013, meeting, an SRTR representative pointed out that from a data analysis perspective, Option 2 would be a challenge because it is difficult to analyze texts in a "notes" field. An SRTR representative pointed out Option 3's strengths: (1) from a data analysis standpoint, if the members choose to analyze the correlation between serum lipase values and outcomes, etc., it will be easier to analyze the data with Option 3's format, and (2) from a utilitarian standpoint, it is more convenient to have the range information immediately available with the serum lipase values in the same program (as opposed to locating a separate document in the lab attachments section that contains the reference ranges). In addition, from a data analysis perspective, collecting information about the upper limit of normal will allow for the lipase values to be normalized and combined across OPOs with varying 'normal' ranges

- ***Strengths and weaknesses***

The chief strength of the serum lipase proposal is that requiring the collection of serum lipase and the reporting of the upper limit of normal field for all pancreas donors provides physicians more detailed information to make more confident clinical decisions. The intent is to lead to better outcomes, less potential for organ discards, and a more efficient organ allocation system. Further, it is currently accepted practice that serum lipase values correlate with pancreas quality. As such, requiring the collection of serum lipase and reporting the upper limit of normal allows the transplantation community to stay in step with clinical practice.

OPOs are the potentially impacted parties of this proposal. This proposal will require OPOs to report two new values, but the Committee came to the determination that it would NOT be overly burdensome for OPOs to report serum lipase and the upper limit of normal values. However, for those OPOs that upload data into DonorNet®, the systems that support this upload may need updating.

As such, this proposal will impact OPOs two-fold: (1) it will require OPOs to report serum lipase values for electronic pancreas offers, and (2) require OPOs to report the upper limit of normal of a laboratory's serum lipase normal range. Although the two requirements will create additional work and potential programming efforts for OPOs, these two requirements coincide with the need to stay in step with clinical advancements.

- ***Description of intended and unintended consequences***

The intended outcome of this proposed policy change is to increase the ability to make better decisions regarding donor pancreas quality and compatibility with potential recipients. In turn, this increases patient and graft survival and decreases pancreata discards.

The unintended consequences of this proposed policy change are to make pancreas donor acceptance criteria more complex and burdensome. However, in practice, physician's commonly require this piece of information in order to assess the quality of the deceased donor pancreas. Therefore, it is plausible, that requiring the collection of serum lipase may lead to an increase in pancreas allocation and more quality placement. Another unintended consequence is an increase on financial costs on OPOs to collect serum lipase values as well as an increase in programming costs associated with the upper limit of normal field.

The Committee plans to monitor and manage unintended consequences through project follow-up where the Committee will discuss and assess how requiring serum lipase and upper limit of normal ranges are playing out in everyday practice.

The serum lipase value we will collect has the potential to produce misleading data. In order to reduce the potential for misleading data we propose to require the collection of the upper limit of normal. In order to completely understand the serum lipase value, the physician needs to have a reference number for the OPO's upper limit of normal.

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. These numbers imply that approximately 17% of all donors (and 21% of non-pancreas donors) may not have had serum lipase values available for consideration when the OPO makes the offer for a potential transplant.

Members report serum lipase values on 24% of all DDRs. These numbers imply that roughly 17% of all donors (and 21% of non-pancreas donors) do not have serum lipase values available for consideration when making the decision to offer or place the pancreas for transplantation.

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.

Compliance with OPTN Strategic Plan and Adherence to OPTN Final Rule

This proposal supports the Strategic Plan in that it 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 Strategic Plan's goal to increase the number of transplants by increasing 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.

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

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in November, 2014. If approved, this proposal will require additional programming in DonorNet®, and 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. A link to the policy notice will be included in the December Transplant Pro e-newsletter.

We will further communicate the new information in the Transplant Pro e-Newsletter, and we will link readers to the relevant policy. 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 – Included in the monthly Transplant Pro e-newsletter sent on the 3 rd Thursday of each month	December 2014 (or 30 days after board approves the change)
System Notice	UNet SM users	Through UNet SM	In accordance with programming schedule
Brief news items on the Transplant Pro website and in the monthly e-newsletter.	OPOs, kidney/pancreas transplant centers	http://transplantpro.org	In accordance with programming schedule

Compliance Monitoring

The proposal to require the collection of serum lipase values will not affect monitoring of pancreas transplant programs.

Policy or Bylaw Proposal

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

2.8 Required Deceased Donor Information

2.8.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
16. 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*.