OPTN Pancreas Transplantation Committee
Meeting Summary
June 2, 2025
Conference Call

Dolamu Olaitan, MD, Chair
Ty Dunn, MD, MS, FACS, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Cisco Webex teleconference on 06/02/2025 to discuss the following agenda items:

1. Welcome and Updates
2. Discussion: Medical Urgency Criteria – Voting Item
3. Presentation: SRTR update on kidney-pancreas candidates in PSR pretransplant metrics

The following is a summary of the Committee's discussions.

1. Welcome and Updates

Staff shared the results of the new meeting series for the 2025-2026 committee meeting cycle. Staff stated the new series would be sent out shortly.

2. Discussion: Medical Urgency Criteria – Voting Item

The Committee discussed and finalized the criteria for pancreas medical urgency and voted on the finalized criteria.

Summary of presentation:

The Committee reviewed previous discussions and the criteria that have been proposed, comparing three options ranging from most restrictive to least restrictive. The Committee also discussed adding a provision for early graft failure as a medical urgency criterion.

Summary of presentation:

The Chair presented a brief outline of the previous discussions on the medical urgency definition and criteria. They reaffirmed the central goal of ensuring the sickest candidates on the pancreas waiting list are prioritized to reduce waiting list mortality. The Chair noted there was previous consensus from the Committee regarding those candidates who receive kidney medical urgency status should also qualify for pancreas medical urgency. There was additional consensus affirmed for including the HypoA-Q IA (Hypoglycemia Awareness Questionnaire Impaired Awareness) subscore of 12 or greater and based on feedback from the Winter 2025 Public Comment update, there was agreement to include the Clarke Score (4 or higher).[1]

The Committee reviewed the three medical urgency definition and criteria options.

[1] Continuous Distribution of Pancreata, Winter 2025 https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-pancreata-winter-2025/

Option 1:

Medical urgency definition points are awarded based on the candidate having impaired awareness of hypoglycemia or an early graft failure as defined below.

To qualify for medical urgency points the candidate must be:

1. An active candidate
2. Accruing waiting time, according to Policy 11.3: Waiting Time

And meet one of the following criteria:

1. Candidate meets criteria for Kidney medical urgency (see policy 8.4.A.i)
2. Candidate is seeking retransplant after suffering from early pancreas graft failure (and the pancreas was removed within 14 days of the transplant). The candidate will retain medical urgency points for 6 weeks following explant of graft
3. Has impaired awareness of hypoglycemia as defined by one of the following criteria:
    a. HypoA-Q IA subscale of 12 or more, or
    b. A Clarke score ≥4, or
    c. Continuous Glucose Monitor (CGM) data over past 6 months identifying patients at high risk based on time below hypoglycemic range:
        i. 9% or more of time <70 mg/dl
        ii. 4% or more of time <60 mg/dl
        iii. 2% or more of time <54 mg/dl, or
    d. A recorded severe hypoglycemic event in the past 6 months (a Level 3 as defined by the American Diabetes Association with supporting documentation), or
    e. Past 6 months: Diabetic Ketoacidosis (DKA) (with supporting documentation), or
    f. Severe Cardiac Autonomic Neuropathy (such as a referral from cardiologist with proven documentation), or
    g. Exocrine Insufficiency with supporting documentation.

Option 2:
[…]
And meet one of the following criteria:

1. Candidate meets criteria for Kidney medical urgency (see policy 8.4.A.i)
2. Candidate is seeking retransplant after suffering from early pancreas graft failure (and the pancreas was removed within 14 days of the transplant). The candidate will retain medical urgency points for 6 weeks following explant of graft, or
3. Has impaired awareness of hypoglycemia as defined by one of the following criteria:
    a. Continuous Glucose Monitor (CGM) data over past 6 months identifying patients at high risk based on time below hypoglycemic range:
        i. 9% or more of time <70 mg/dl, or
        ii. 4% or more of time <60 mg/dl, or
        iii. 2% or more of time <54 mg/dl, or
    b. A severe hypoglycemic event (Level 3 as defined by the American Diabetes Association, with supporting documentation) in the past 6 months with one of the following:
        i. HypoA-Q IA subscale of 12 or more, or
        ii. A Clarke score ≥4

Option 3:
[…]
And meet one of the following criteria:

1. Candidate meets criteria for Kidney medical urgency (see policy 8.4.A.i)
2. Candidate is seeking retransplant after suffering from early pancreas graft failure (and the pancreas was removed within 14 days of the transplant). The candidate will retain medical urgency points for 6 weeks following explant of graft
3. Has impaired awareness of hypoglycemia as defined by one of the following criteria:
    a. Continuous Glucose Monitor (CGM) data over past 6 months identifying candidates at high risk based on time below hypoglycemic range:
        i. 9% or more of time <70 mg/dl, or
        ii. 4% or more of time <60 mg/dl, or
        iii. 2% or more of time <54 mg/dl, or
    b. A severe hypoglycemic event (Level 3 as defined by the American Diabetes Association, with supporting documentation) in the past 6 months and one of the following:
        i. HypoA-Q IA subscale of 12 or more, or
        ii. A Clarke score ≥4
    c. Or, Diabetic Ketoacidosis (DKA) (with supporting documentation) within the past 6 months and one of the following:
        i. HypoA-Q IA subscale of 12 or more, or
        ii. A Clarke score ≥4
    d. Or, Severe Cardiac Autonomic Neuropathy (with a referral from cardiologist with supporting documentation) and one of the following:
        i. HypoA-Q IA subscale of 12 or more, or
        ii. A Clarke score ≥4
    e. Or, Exocrine Insufficiency with supporting documentation and one of the following:
        i. HypoA-Q IA subscale of 12 or more, or
        ii. A Clarke score ≥4

Summary of discussion:

The Committee voted to use medical urgency definition option 2 as revised and discussed during the committee call:

To qualify for medical urgency points the candidate must be: […]

And meet one of the following criteria:

1. Candidate meets criteria for Kidney medical urgency (see policy 8.4.A.i)
2. Candidate is seeking retransplant after suffering from early pancreas graft failure (and the pancreas was removed within 14 days of the transplant). The candidate will retain medical urgency points for 6 months following explant of graft, or
3. Has impaired awareness of hypoglycemia as defined by one of the following criteria:
    a. CGM data over past 6 months identifying patients at high risk based on time below hypoglycemic range:
        i. 9% or more of time <70 mg/dl, or
        ii. 4% or more of time <60 mg/dl, or
        iii. 2% or more of time <54 mg/dl, or

b. A severe hypoglycemic event (Level 3 as defined by the American Diabetes Association, with supporting documentation) in the past 6 months with one of the following:
    i. HypoA-Q IA subscale of 12 or more, or
    ii. A Clarke score ≥4

A member asked for clarification on item 2, which concerns candidates seeking a retransplant after early pancreas graft failure. They inquired whether this criterion applies in addition to the proposed medical urgency or if it serves as an independent pathway. The Chair clarified that this is an independent criterion, meaning candidates do not need to have qualified for medical urgency under other criteria to be considered. The member then questioned whether CGM data would be validated, noting that the other options, HypoA-Q IA and Clarke score, are both established tools for diagnosing impaired awareness of hypoglycemia (IAH) while CGM data is not traditionally used that way. The Chair explained that when CGM data falls within the proposed thresholds, it has been clinically validated by endocrinologists as a reliable indicator of IAH. The Vice Chair agreed with the members' observations, emphasizing that even patients who have access to advanced diabetes technology and are actively engaged in their care can still experience significant challenges. They stressed that the proposed CGM thresholds offer an objective, evidence-based way for these patients to qualify. The Vice Chair also acknowledged that not all patients have access to such technology and underscored the importance of carefully considering all qualification pathways.

A representative of the Scientific Registry for Transplant Recipients (SRTR) said that CGM data and records of severe hypoglycemic events are the most reliable ways to assess patient risk. They emphasized that clinical decisions should focus more on the actual health risks such as life-threatening hypoglycemia rather than relying only on scores that measure a person's awareness of those episodes. They noted that some endocrinologists are moving in this direction, prioritizing documented episodes over subjective self-assessments. They added that candidates who experience early graft failure often have excellent outcomes with a quick retransplant. They noted that based on their experience and published data, if a graft fails in the first 14 days, it is often due to technical failure and the optimal window for retransplant is typically within 1-10 days, or up to 2 weeks. If that window is missed, surgeons often wait until 6-12 weeks, when the surgical area is safer to operate on. They recommended extending the proposed 6-week medical urgency status window to 3 months after pancreatectomy, to allow more clinical flexibility and improve outcomes for these higher-risk patients. The Vice Chair agreed, stating they had similar views regarding the time frame and felt it often depends on individual clinical decisions. Other members voiced their agreement with a minimum 3-month window although one noted that some patients still have significant adhesions even after 3 months, and it might be better to wait longer in those cases. A 6-month window was recommended, as it was pointed out only a small number of patients would qualify this way and that would leave greater flexibility in clinical judgement.

The Committee discussed the need to clarify the wording and structure of the medical urgency criteria. One member pointed out that while the main focus is impaired awareness of hypoglycemia, some of the conditions listed as options, like diabetic ketoacidosis (DKA), cardiac autonomic neuropathy (CAN), and exocrine insufficiency, are not directly related to impaired awareness. Other members agreed and it was noted that in Medical Urgency Definition - Option 2, those conditions are not included as criteria. Another member raised two concerns: the need for clear guidance on what documentation is required, and the issue of equity in access to CGMs, since not all patients will have access to such technology. The Chair acknowledged both concerns and explained that the proposed criteria of the HypoA-Q IA subscore

and the Clarke score were included to address this equity issue and offer multiple qualification pathways. It was also clarified that severe hypoglycemic events at Level 3 (as defined by the American Diabetes Association [ADA]) is documentable through hospital or ER records. The Chair reminded the Committee that the medical urgency definition has been discussed and reviewed since 2021. While it may not be perfect, the initial version will be reviewed and improved as needed. They highlighted that a clear and supportable definition is needed so the Committee can move forward with voting, as the medical urgency criteria will be a key part of the composite allocation score of CD.

A representative from the SRTR raised a concern that some candidates might not meet the first two qualifications, being an active candidate and accruing waiting time, because their estimated glomerular filtration rate (eGFR) is above the threshold of 20, which is the current threshold for kidney transplantation. They noted that this could exclude some candidates with severe hypoglycemia unawareness, particularly those with Type 1 diabetes and rapidly declining kidney function. The representative suggested these candidates should be allowed to accrue waiting time even if they do not yet meet the eGFR threshold. It was acknowledged that this would require a separate policy change as it falls outside the current scope of the continuous distribution framework. The Chair agreed that this issue is important and worth considering for a future policy update, especially as it could help support timely living donor transplants. Staff also clarified that the “active candidate” and “accruing waiting time” language was not what was being voted on at this time, the primary focus is on the criteria and the policy language will be refined before the final proposal.

A member asked whether candidates need to meet all three CGM thresholds to qualify or if meeting one was enough. It was clarified that meeting any one of the thresholds would be sufficient. The member then raised a concern about how the thresholds reflect different levels of risk, as time spent below 54 mg/dL may indicate a higher mortality risk than time spent below 70 mg/dL. The Chair explained that while mortality data is limited regarding the CGM thresholds, the cutoffs are evidence based, have been independently verified in a variety of studies, are endorsed by the ADA and already integrated into most CGM systems. The Chair also noted that should patients set their CGM alarms higher than 90 mg/dL due to fear of hypoglycemia, these patients could still be captured under the other criteria. The Chair reminded the Committee that the data collected through the medical urgency applications would be reviewed every 6 months to ensure it can be improved and revised as needed.

Members voted on whether to move forward with option 1, 2, or 3.

Option 1: 2 votes

Option 2: 13 votes

Option 3: 1 vote

A member shared that they supported for Option 2 as there is no clear evidence showing that conditions like exocrine insufficiency, cardiac dysfunction, or DKA improve with pancreas transplant or are medically urgent. They also raised concerns that these criteria could lead to the system being misused and emphasized that the criteria should focus on the most life-threatening conditions. Another member expressed support for Option 3, noting that it would allow for broader enable data collection on all the conditions discussed by the Committee and provide flexibility to refine or expand the criteria in the future. It was clarified that centers would still be able to request medical urgency for candidates who did

not meet the criteria, as the proposed future Pancreas Review Board would have discretion to approve such cases in exceptional or life-threatening circumstances.

Members agreed that starting off with more narrowly defined, evidence-based criteria, with the option to expand later, would a more cautious and effective approach. It was also noted that having clear, objective standards will likely help build community support and reduce pushback.

Next steps:

Staff will update the early graft failure timeline from 6 weeks to 6 months reflective of Committee feedback. The Committee will review potential medical urgency attribute weights on the UNOS developed dashboard.

3. Presentation: SRTR update on kidney-pancreas candidates in PSR pretransplant metrics

A representative from the SRTR updated the Committee on changes being made to the program specific reports (PSRs) regarding reporting of kidney-pancreas (KP) pretransplant metrics to the OPTN Membership and Professional Standards Committee (MPSC). These changes are scheduled to go live in July 2025.

Summary of presentation:

The representative highlighted kidney-pancreas candidates will now be included in:

- Kidney pre-transplant metrics
- Pancreas pre-transplant metrics
- In addition to their own KP-specific report

This change brings KP candidates under MPSC oversight for pre-transplant mortality, which it did not have previously. Additionally, these changes align with how the reporting of other multi-organ candidates (kidney-liver, heart-lung) are handled.

KP candidates will continue to receive separate risk adjustments, and the expected outcomes are based on national KP data, not on kidney- or pancreas-alone data.

The pancreas report has a more noticeable impact as KP candidates make up a majority of pancreas listings. Some programs will see rate ratio shifts but the overall effect is neutral.

Summary of discussion:

The Chair expressed concern that while there is substantial data on outcomes like mortality and graft failure for kidney candidates, there is no equivalent for pancreas candidates. They were unsure how the upcoming changes would account for that gap. The SRTR representative explained that this update currently only addresses the pretransplant metrics, not graft failure. It will now include deaths of patients on the waitlist for KP transplants in the three reports, but it does not capture the post-transplant graft failures or deaths.

The Vice-Chair asked for clarification on how the system handles patients who are initially listed for a KP and end up receiving a living donor kidney and then continue to wait for a pancreas-alone transplant. The representative explained that this situation would be recorded as multiple listings. The KP listing would be considered complete once the kidney transplant occurs and would be included in the relevant reports. A new listing would then be created for the pancreas-alone transplant, with its own timeline and outcomes tracked separately from the point of kidney transplant.

Another SRTR representative asked how outcomes are tracked for patients listed for both kidney-alone and KP, specifically in the event of death. They wanted to know whether these would be counted once or twice and how is the risk is adjusted. The presenting representative clarified that these patients are treated as a single individual in the data. Their outcomes will appear on all three reports, but any risk adjustment is based on their KP status, not kidney alone.

A question was raised about how the system handles patients who are active on the kidney waitlist but inactive on the KP waitlist, such as those who may need to lose weight before being eligible for a KP. It was confirmed that as long as the KP listing is still ongoing, these patients are still counted and adjusted as KP candidates. If they are removed from the KP list and then relisted as kidney-alone candidate, their data is adjusted as kidney-alone with the relevant comorbidities.

The Vice Chair asked as to how long a patient is included in the KP report if they are removed from the KP list but remain on the kidney list and then eventually pass away. It was clarified that KP candidates are tracked for a full 2 calendar years. Even if they are removed from the KP list during that period, they will still be followed through that window. If they receive a kidney transplant, any follow-up is paused to avoid capturing post-transplant deaths. However, if the patient dies while waiting for a kidney-alone transplant during that 2-year period, the death would still appear in the KP report.

The Vice Chair also asked about a more complex case: if a patient is listed for a KP transplant, receives a living donor kidney, then experiences a major health event and is switched to a pancreas-alone listing, but is later removed from the list for being to ill to proceed, would a death during the 2-year window show up in the pancreas report. The representative affirmed that the only place the death would be reported is the pancreas-alone report.

Another SRTR representative added that in this case, the patient effectively be counted twice: once as a post-transplant death in the kidney data and once as a pretransplant death for the pancreas-alone data. A concern was raised that this could discourage the use of simultaneous pancreas-kidney (SPK) transplant. However, it was noted that this issue falls outside the scope of the current changes, which are focused on the pretransplant metrics. The overlap was explained as a result of tracking both pre- and pos-transplant outcomes across different pathways.

Next steps:

Staff will share the slides with the full committee following the conclusion of the meeting.

Upcoming Meetings

- July 8, 2025

Attendance

- **Committee Members**
  - Asif Sharfuddin
  - Colleen Jay
  - David Lee
  - Dean Kim
  - Diane Cibrik
  - Jason Morton
  - Jessica Yokubeak
  - Mallory Boomsma-Kempf
  - Muhammad Yaqub
  - Patrick McGlone
  - Neeraj Singh
  - Oyedolamu Olaitan
  - Shehzad Rehman
  - Stephanie Arocho
  - Rupi Sodhi
  - Girish Mour
  - Todd Pesavento
  - Ty Dunn
- **SRTR Representatives**
  - Bryn Thompson
  - Grace Lyden
  - Jon Miller
  - Raja Kandaswamy
- **UNOS Staff**
  - Stryker-Ann Vosteen
  - Dzhuliyana Handarova
  - Lindsay Larkin
  - Ross Walton
  - Keighly Bradbrook
  - Asma Ali