Introduction
The Pancreas Transplantation Committee Medical Urgency Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 11/20/2020 to discuss the following agenda items:

1. Overview of Project
2. Review and Discussion: Medical Urgency Criteria
3. Next Steps

The following is a summary of the Workgroup’s discussions.

1. Overview of Project

The Workgroup reviewed the goal of the Medical Urgency project, which is to evaluate and discuss criteria that should be considered medically urgent as it pertain to pancreas candidates. The following is the definition and goal of the medical urgency attribute in the pancreas continuous distribution model:

Medical Urgency: Amount of risk to a candidate’s life or long term health without receiving an organ transplant

Goal of Medical Urgency: Prioritize sickest candidates first to reduce waiting list mortality

Summary of discussion:
There were no comments or questions.

2. Review and Discussion: Medical Urgency Criteria

The Workgroup reviewed the potential medical urgency criteria suggested by the Pancreas Continuous Distribution Workgroup. The following were the suggested criteria:

- Hypoglycemic Unawareness
- Type I vs. Type II diabetics
- Pancreas Donor Risk Index (PDRI)
- Cardiac Autonomic Neuropathy

Summary of discussion:
The Workgroup Chair suggested starting discussions by identifying other criteria, if there are any, which should be considered medically urgent before the Workgroup prioritizes which criteria should be weighed more than others.

A member stated that medically urgent situations happen occasionally in children. For example, there have been a few children transplanted who have kidney failure from a non-diabetes cause and they wanted to receive a pancreas transplant along with a kidney transplant. The member continued explaining that, currently, there’s no priority given to those children in allocation – the child gets the
same amount of allocation points as an adult for a pancreas and gets extra priority for the kidney as a child. The member explained that, in this situation, it’s uncommon for the pancreas to follow the kidney for a pediatric patient. A member emphasized that while these situations don’t happen often, the Workgroup clearly wants to create some type of significant priority system for children that have diabetes and may need either a pancreas alone or a kidney-pancreas (KP).

A member inquired if the criteria will simply be binary (yes or no) or will they be gradated. So, if a patient has hypoglycemic unawareness but they’ve had six episodes in the last year, do they receive more medical urgency than if they’ve have one episode in a year? Or if a patient has diabetic ketoacidosis monthly for 12 months is that more significant than one episode in the last 12 months? Members agreed that this was something to consider. A member inquired whether the patient with hypoglycemic unawareness must have a censor or a pump in order to provide proof of the episodes.

A member stated that there’s a medical urgency escape clause for patients on dialysis with lack of access and that lack of access is very subjective. The member pointed out that in some ways the Workgroup be specific, but the Workgroup shouldn’t make this more difficult for patients. For example, some patients may not have an endocrinologist that can work with centers and doesn’t have access to the same technology. However, a member stated that for kidney dialysis access in particular centers are starting to ask for more imaging reports or documentation of those objective findings that go then to the overall diagnosis.

A member noted that it would be worthwhile for the Workgroup to think about whether there’s guidance that they can provide about what usual definitions of hypoglycemic unawareness are to help provide some standardization, even if it’s not hard criteria. Members agreed that that would be appropriate to define the criteria once the Workgroup decides on the criteria to be included in medical urgency.

A member expressed concern that medical urgency is such a broad term and the Workgroup needs to determine other issues that the patient has because those may add to their urgency. For example, the member assumed that complications among children with Type I diabetes differ in comparison to adults with Type I diabetes.

Members agreed with considering pediatrics as a criteria in pancreas medical urgency. Members also mentioned that this is consistent with how continuous distribution is going in other organ’s models and consistent with the Workgroup’s charge to think about the immediate risk of death, the risk of long-term complications, and the length of time over which those long-term complications can happen.

A member inquired about pulmonary considerations because there is some precedent for simultaneous lung-pancreas transplant. A member stated that from the lung side, they use the lung allocation score (LAS) as their medical urgency criteria, which weighs the risk of death on the waiting list and the risk of death after the transplant and the risk of death on the waiting list gets weighed twice as heavily as post-transplant mortality. A member suggested that this should be considered as part of pancreas medical urgency.

Members agreed with analyzing risk of death on the wait list against post-transplant mortality. A member mentioned that part of the charge of this Workgroup is to figure out what factors should go into a potential pancreas allocation score and how to measure the factors in order to get reliable data.

A member suggested that, once the Workgroup defines certain criteria to be included in medical urgency, then they can request any available data on the impact of the criteria that should be considered.
The Workgroup Chair inquired if there were any other criteria the Workgroup thinks should be considered. A member suggested considering access to technology as a medical urgency criterion.

A member inquired if there are other reasons that exogenous insulin don’t work or cause bad reactions in patients. A member stated that there used to be resistance to insulin but now with all the designer insulins they think it’s more uncommon.

Another member suggested including total duration of diabetes in pancreas medical urgency. The member stated that, for example, children get priority because they’re younger and have a longer life span, but also because they would have to live with diabetes for longer. A member noted that a patient who has had prolonged amount of diabetes may have worse outcomes in the end, so the problem is that organs are being allocated to patients who may not have a long post-transplant expected life.

A member countered that, if a patient has had a longer duration of diabetes, then that patient may have a higher risk of death on the wait list and asking them to wait another 4 or 5 years may be detrimental.

A member noted that the pancreas transplant wait time, on average, is not very long; so, there are some elements in pancreas that aren’t quite as pronounced as the long waiting times for kidney. However, members weren’t sure if United Network for Organ Sharing (UNOS) has the data regarding total duration of diabetes.

A member inquired if medical urgency is separate from when we assign priority points in the pancreas continuous distribution model because these criteria are specific things that would denote a patient needs to rise to the top of the pancreas list, while attributes, like age, will get points allocated to their total score. UNOS staff stated that this is pretty similar to what the Kidney Transplantation Committee just did with their medical urgency – identifying medically urgent candidates based on certain criteria, assuming they would be the sickest candidates.

A member inquired if prioritization meant adding more points to a candidate’s allocation score. UNOS staff stated that prioritization would be adding more points and offered to send examples of what the Kidney Transplantation Committee will be implementing with their medical urgency criteria.

Members agreed to add the following to their medical urgency criteria: children, access to technology, and total duration of diabetes.

**Hypoglycemic Unawareness**

A member stated that hypoglycemic unawareness is really profound and some patients don’t come out of it, some have minor problems, and most do well if they have access to medical care. A member mentioned that the Workgroup doesn’t have data regarding the absence of medical care in the presence of hypoglycemic unawareness. For example, if a patient lives far away from a medical center and their family doesn’t know how to take care of the hypoglycemic unawareness then that becomes a comorbidity. A member noted that there isn’t data about what happens to hypoglycemia unawareness in the city or in the suburbs, or if a patient lives far away from a medical center. A member stated that it would be useful to see what data UNOS has.

A member suggested breaking down hypoglycemic unawareness into the following:

- Frequency of episodes
- Patient’s ability to take care of their diabetes
  - Level of education
  - Management
  - Supervision
A member emphasized the importance of looking at psychosocial and medical aspects of management of a hypoglycemic unawareness and break it down into how often and how severe is it. In addition, for example, consider how active the patient is because if they are active then they are likely to have more incidences of hypoglycemia at work or while driving.

Members agreed that the concept of defining hypoglycemic unawareness is appropriate and mentioned that the American Diabetic Association Workgroup may have the up-to-date definition of hypoglycemia.

A member inquired whether any other member’s centers have standardization for hypoglycemic unawareness. A member mentioned that there’s a center that sends out a standardized survey for all of their pancreas evaluations; however, it’s not universally done so it’s something that would have to be added and unduly instituted as a requirement.

A member inquired which of the following has the worst long-term outcomes: to have hypoglycemic unawareness and so many episodes per month or to be so afraid of hypoglycemic unawareness that it runs high all the time. A member suggested that inviting an endocrinologist to join the Workgroup may be beneficial.

A member noted that, in regards to episodes of hypoglycemic unawareness, just having one episode might be fatal, so more episodes might not equate to a higher medical urgency.

A member mentioned that their center doesn’t quantify hypoglycemic unawareness and just asks it as a binary question. A member stated that if this is going to be a valuable mechanism to use in medical urgency then the Workgroup shouldn’t minimize that one episode of hypoglycemic unawareness can be significant; however, one episode a week has got to be worse than one episode a year.

A member suggested that the Workgroup should consult with an endocrinologist to provide additional insight. Another member agreed on the point made about limited access to continuous glucose monitoring because that could potentially segue into the hypoglycemic unawareness in regards to complications.

A member mentioned that the easier the Workgroup makes medical urgency to apply, the easier it will be applied in organ allocation, so the ease of applicability will make medical urgency a worthwhile tool.

Type I vs. Type II diabetics

Member stated that some Type II diabetics behave like Type I diabetics, even though their c-peptides may be high.

A member inquired whether the Workgroup should look at complications versus etiology. A member stated that the complication may be more accurate in terms of the diabetic patient’s actual urgency.

Pancreas Donor Risk Index (PDRI)

There were no comments.

Cardiac Autonomic Neuropathy

A member stated that, from their understanding, this criteria would include orthostatic hypotension and just hypotension in general.

3. Next Steps

UNOS staff stated that they will create a spreadsheet that includes the criterion along with their official definitions and share it with the Workgroup for feedback. UNOS staff will also reach out to research staff and see what data is currently available for the Workgroup.
UNOS staff will put a call out for an endocrinologist to consult and possibly come discuss Type I vs Type II diabetes.

There were no additional comments or questions. The meeting was adjourned.

**Upcoming Meetings**

- December 18th, 2020 (Teleconference)
Attendance

- **Committee Members**
  - Antonio di Carlo
  - Anita Patel
  - Earl Lovell
  - Emily Perito
  - Ken Bodziak
  - Rachel Forbes
  - Todd Pesavento
  - Wayne Tsuang
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Nick Salkowski
- **UNOS Staff**
  - Joann White
  - Leah Slife
  - Nag Thu Thu Kyaw
  - Rebecca Brookman
  - Ross Walton
  - Kerrie Masten
  - Nicole Benjamin