OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board Subcommittee
Meeting Summary
March 12, 2020
Conference Call

James Trotter, MD, Committee Chair
James Pomposelli, MD, PhD, Committee Vice Chair
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Introduction

The National Liver Review Board (NLRB) Subcommittee (the Subcommittee) met via teleconference on 3/12/2020 to discuss the following agenda items:

1. Proposed Changes to Pediatric Guidance Documents

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

1. Proposed Changes to Pediatric Guidance Documents

Members of the OPTN Pediatric Transplantation Committee presented proposed changes to the pediatric guidance document for the National Liver Review Board.

Summary of Discussion:

Members of the OPTN Pediatric Transplantation Committee presented the following data points:

- Depending on OPTN region, 25-75% of pediatric liver transplants occurred in children with active exceptions

Post-NLRB, children are less likely to have an active exception, but the percentage of those transplanted with an active exception has not changed

A Subcommittee member asked if this data could be made available in pediatric age subgroups, specifically under 2, 2-11 and 11-18 years old.

Pediatric Committee members proposed three recommendations for changes to the pediatric guidance document which were informed by a survey of the Society of Pediatric Liver Transplant Society providers and reviewers and NLRB member experience. The following are the recommendations as presented and discussed:

Recommendation 1: Clarify purpose and limitations of the pediatric guidance

- The guidance is not fully comprehensive of all situations that could be appropriate for exception points
- Importance of recognizing:
    - PELD under-estimates waitlist mortality for children
    - Access to split liver transplant (usually an adult donor) depends on the child's local MMaT, not national MPaT, and may vary significantly in different areas across the country. Reviewers should keep in mind that centers may be adjusting their request based on their local access

"Insufficient evidence," has been interpreted to mean "no exception warranted" instead of potentially intended "should be considered on a case-by-case basis, inadequate evidence exists to set specific guidelines."

Recommendation 2: Update sections of existing guidance, based on SPLIT feedback and available evidence

- Portal hypertension
    - "Varices" and "GI Bleeding" need clarification:
        - Portal hypertension should be updated so that a bleed is not necessary for exceptions, because data does suggest that 50% of life-threatening hemorrhages occur with little predictability
        - Infant with recurrent bleeding varices should be allowed exception points, regardless of transfusion requirement
        - Should remove the TIPS requirement
    - "Intractable Ascites" needs clarification. For a baby this can be a major issue:
        - affects enteral feeding tolerance
        - can lead to central line placement for TPN
        - a 1 kg weight gain in a small baby (5-6 kg) baby will likely give them respiratory distress
        - therapeutic paracentesis in extreme cases; places patient at increased risk for infection so should not be a requirement
- Failure to thrive and growth guidelines should be updated with newly available evidence
    - Compensated cirrhosis in small children (e.g. less than 10kg) that are still growing
    - Data on the risk of "frailty" in pediatric populations
- Rare tumors section needs clarification

Xanthomas, as they can be both deforming as well as have a significant impact on growth and development of motor skills

Recommendation 3: Conditions not currently mentioned in guidance

- Glycogen storage diseases, or other rare diseases are not in current guidance
- Disability leading to missed school days

Liver/kidney or liver/pancreas

The Subcommittee Chair informed the presenters that some changes that address these issues are part of the NLRB enhancements that are currently out for Public Comment. A Subcommittee member asked to compare data of waitlist candidates who have died prior to transplant to where livers were allocated and if they were offered to pediatric recipients first. Another Subcommittee member stated data from 2016 should not be used to determine what's happening today with a very different process. It was also stated in addition to guidelines changes, some requests need to be written more robustly as some are written poorly. Another Subcommittee member asked to audit exception denial reasons to see if reviewers are potentially being too conservative.

The Subcommittee Chair suggested forming a subgroup to evaluate and formalize these recommendations for future NLRB enhancements. Another Subcommittee member expressed the importance to address PELD as well. The Subcommittee Chair informed the Subcommittee there is a separate Subcommittee that will begin meeting soon to address the PELD calculation. A Subcommittee member recommended clarifying within the guidance the appropriate amount of points that should be given based on conditions as this has been a source of confusion for reviewers.

A Subcommittee member asked if there was a way to explore data on how pediatric candidates have died as those factors may be important in helping reviewers apply appropriate scoring. Another Subcommittee member suggested looking at neurodevelopmental outcomes for pre-transplant and how it affects the patient after transplant.

Next Steps:

NLRB Subcommittee and Pediatric Committee members will work to finalize recommendations for the next NLRB enhancements proposal. UNOS staff will also compile requested data for the subgroup's review.

Upcoming Meeting

- April 9, 2020