Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients

OPTN Vascularized Composite Allograft (VCA) Transplantation Committee
Purpose

- Pursue additional data collection to measure and evaluate uterus transplant outcomes
- Solicit community input in this unique area of data collection
Uterus Registrations and Transplants

Uterus Candidate Registrations in the U.S.

Year of Listing
- 2016
- 2017
- 2018
- 2019

New Registrations
- 0
- 2
- 4
- 6
- 8
- 10
- 12
- 14
- 16

Uterus Transplants in the U.S.

Year of Transplant
- 2016
- 2017
- 2018
- 2019

Number of Transplants
- 0
- 2
- 4
- 6
- 8
- 10
- 12
- 14
- 16

- Uterus Deceased Donor
- Uterus Living Donor

8 births as of January 17, 2020
Scope

- Safety monitoring and improving transplant outcomes
- Within the purview of the OPTN Final Rule § 42 CFR 121.11(b)(2)
- Not a change to OPTN policies or data submission – gathering input
- Feedback sought on
  - Data elements to be reported
  - Timing of data reporting
Input

- OPTN Committees
  - Ethics
  - Data Advisory
  - Pediatrics

- Subject Matter Expert Stakeholder Organizations
  - American Academy of Pediatrics
  - Society for Assisted Reproductive Technology
  - Society for Reproductive Surgeons
  - Transplant Pregnancy Registry International (Gift of Life International)
Data

- Current voluntary data collection

<table>
<thead>
<tr>
<th>Neonate status date (last time infant was seen by the program)</th>
<th>Neonate status (alive/deceased)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate gestational age (week or weeks/days)</td>
<td>Neonate APGAR scores (one and five minute)</td>
</tr>
<tr>
<td>Neonate delivery weight</td>
<td>Neonatal complications at birth (yes/no)</td>
</tr>
</tbody>
</table>

- Possible additions

| Neonate delivery length | Neonate length of stay |

- Other data that should be included?

- Are there any barriers to mandating this data reporting?
Feedback request

- What data, if any, should transplant programs be required to report at birth on infants born to uterus recipients?
- What data, if any, should transplant programs be required to submit as follow-up on children born to uterus recipients?
  - Developmental milestones?
- How long after birth should the OPTN require transplant programs to report data on the child?
- What would be the challenges that this type of data requirement would present?
  - What’s the best balance between burden and usefulness?
  - Additional consent or regulatory concerns?
Questions