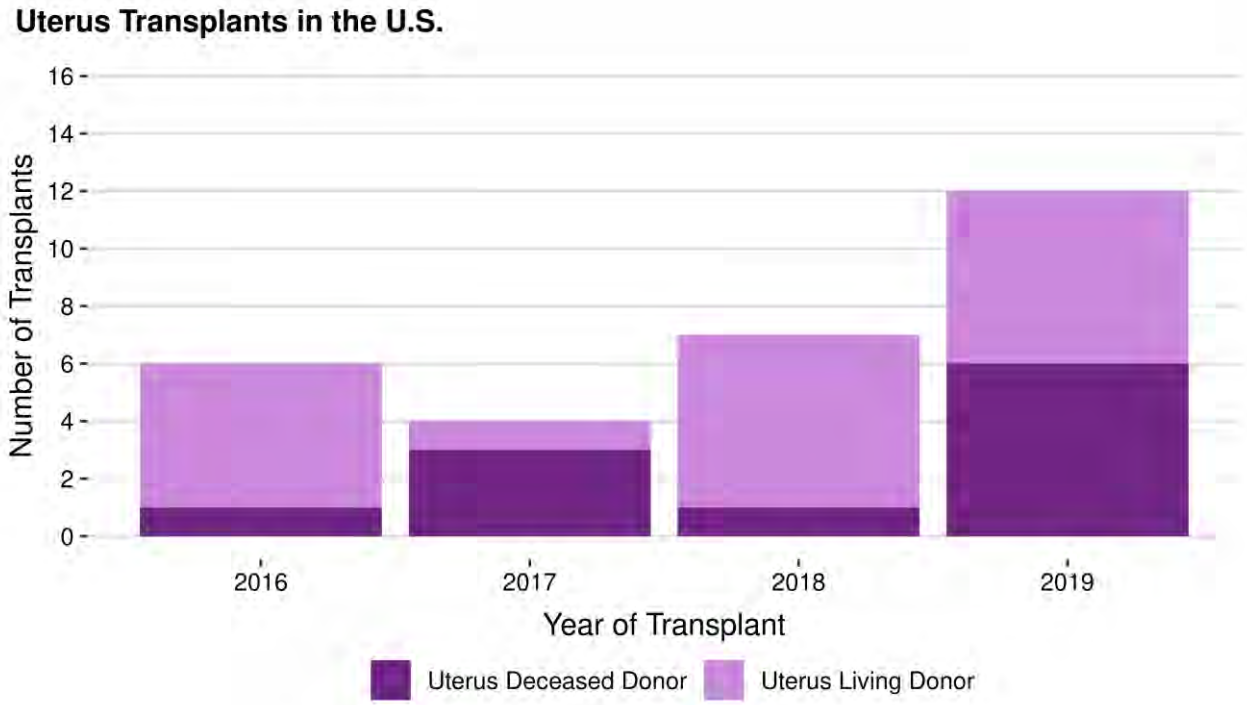
Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients

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



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

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

- 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