

Uterus Transplantation Intersociety Roundtable
Chicago, Illinois
April 21, 2016

Summary

A Roundtable to discuss the development of uterus transplantation in the United States was convened under the sponsorship of the American Society for Reproductive Medicine (ASRM) in collaboration with the American Society of Reconstructive Transplantation (ASRT) on April 21, 2016, in Chicago, Illinois. Invitees included the leadership of the major professional societies and organizations involved in transplantation in the United States and two active US uterus transplant programs.

Goals of the Roundtable

The new frontier of uterus transplantation has been proven successful with reports of live births from a Swedish team at the University of Gothenburg. Several US programs are actively preparing to perform this procedure, and one center very recently performed a uterus transplantation from a deceased donor. To be successful, this procedure requires an intense collaborative effort among many different subspecialists encompassing obstetric and gynecologic surgery, reproductive medicine, traditional transplant surgery and medicine, organ procurement organizations (OPOs), and a host of supporting subspecialists. Professional societies in these various subspecialties play a crucial role in shaping best practices, endorsing and supporting responsible innovations, insisting on professional standards, and providing a forum for education and open display of results. As uterus transplantation is already a reality in the US, and there is a known and quickly growing interest from both potential recipients and programs interested in establishing uterus transplantation, the time is right to convene a Roundtable of leaders in the field of solid organ transplantation and reproductive medicine and surgery, as well as the professional societies they represent, to establish a collaborative process that will allow this innovative field to move forward responsibly.

Chairs of the Roundtable

Sue McDiarmid, MD – President, American Society of Radiologic Technologists (ASRT), and Chair of the Vascularized Composite Allotransplantation (VCA) Organ Procurement and Transplantation Network/United Network of Organ Sharing (OPTN/UNOS) Committee

Owen Davis, MD – President, American Society for Reproductive Medicine (ASRM)

Attendees:

Gordon Bowen – CEO, American Organ Procurement Organization (AOPO)

Christos Coutifaris, MD, PhD – Vice-President, ASRM

Tommaso Falcone, MD – Co-Director, Uterus Transplant Program, Cleveland Clinic

Goran Klintmalm, MD, PhD – Chairman and Chief, Baylor Simmons Transplant Institute, Baylor

Scott Levin, MD – Chair-Elect, VCA UNOS/OPTN Committee

Dianne McKay, MD – American Society of Transplantation (AST)

Charlie Miller, MD – President, American Society of Transplant Surgeons (ASTS)

Samantha Pfeifer, MD – Chair, ASRM Practice Committee, Society of Reproductive Surgeons

Richard Reindollar, MD – CEO, ASRM

Andy Tzakis, MD – Co-Director, Uterus Transplant Program, Cleveland Clinic

Stefan G. Tullius, MD, PhD – Chief, Brigham and Women's Hospital

Jessica Goldstein, RN – Education Program Coordinator, ASRM

Dr. McDiarmid opened the Roundtable by introducing Dr. Owen Davis, President of ASRM.

The ASRM Perspective

Presentation: Dr. Davis, President, ASRM

Dr. Davis presented indications, alternatives, and estimated need for uterine transplantation and anticipated important questions to be answered.

He discussed the five live births reported to date from the Swedish program at the University of Gothenburg under the leadership of Dr. Mats Brännström who reported the first live birth following uterus transplantation in September 2014. Indications for the uterus transplantation procedure were congenital absence of the uterus in four patients and following hysterectomy for cervical cancer. All the infants were delivered by cesarean section. Maternal complications included preeclampsia and prematurity. In general terms, Dr. Davis noted that the risks of uterine

transplantation include surgical/anesthetic risks to two people if using a living donor, risk of rejection, and potential risks to the fetus from prematurity and anti-rejection medications. The cost of a uterine transplant is not yet known.

The main indication for uterus transplantation is congenital absence or other congenital malformation of the uterus, which has an incidence of approximately 1:5,000. Other indications include loss of the uterus from either benign or malignant tumors, postpartum complications, or irreversible acquired uterine injury (for example, radiation, adhesions, and inoperable fibromas)

The alternative to uterine transplantation is gestational surrogacy, in which a pregnancy is carried by a woman other than the intended parent. There were approximately 3,400 gestational carrier (GC) cycles (not patients) performed in the United States in 2013 (the latest year for which statistics were currently available). A total of 57% of GC transfers result in live birth, and they account for approximately 2.5% of all in vitro fertilization (IVF) cycles in the US. The cost of a GC cycle in the United States is approximately \$100,000–\$150,000, which includes the procedure, legal, and agency fees, and payments to the GC. The risks of gestational surrogacy are the risks associated with IVF, routine risks of pregnancy, and legal risk.

The question arises, in the context of adoption, if GC cycles are safe, well established, and effective, why perform uterine transplantation?

- Religion: Some faiths do not permit gestational surrogacy, but will permit transplant. Uterine transplantation represents the only religiously acceptable path to parenthood for women who have congenital or acquired absence of the uterus. Examples of communities that do not allow GCs are some sects of ultraorthodox Judaism and Sunni Islam.
- Legislative barriers: In some jurisdictions, there are legal bans on gestational surrogacy for either altruistic or commercial reasons, or both.
- Personal fulfillment: Some women have a personal desire to carry a pregnancy and have children that are biologically related to them.
- Decision-making ability: Relinquishment of potentially important decisions occurs once a pregnancy is established in a GC. The use of a GC takes away a multitude of decisions about pregnancy from intended parents.
- Ethical issues: Some have a conscientious objection to expose another to the risks of gestational surrogacy if there is an alternative where the intended parent may assume all risks.

In the evaluation of gestational surrogacy versus uterine transplantation, the following questions must be considered:

- What is the relative cost difference?
- What is the risk to all parties? Is uterine transplantation riskier?
- What are the challenges of GC pregnancies that are not present for uterine transplant–recipient pregnancies?
- Is it ethical to perform this procedure when it is not essential to vital function, especially when alternatives are available to most?
- What kind of psychological evaluation is needed?

Dr. Davis noted that the tone of the ASRM membership toward this procedure is mixed. Mats Brännström, MD, PhD, spoke at the ASRM 2014 Annual Meeting to great accolade. However, ASRM members continue to ask why would this be done in the US where there are few legislative barriers for gestational surrogacy?

Important Questions to be Addressed:

1. What key health professionals should be involved in uterus transplantation?
Patients enter the system with reproductive surgeons/IVF doctors, and are screened and referred to transplant surgeons. Patients return to reproductive surgeons/IVF doctors for IVF and are also seen by maternal fetal medicine (MFM) physicians for pregnancy counseling before transplantation.
2. What is the projected/expected need/use (in numbers)?
Unknown at this point
3. How should this procedure be regulated and incorporated into the tissue procurement system?
Vascularized composite allotransplantation (VCA) was brought under the Organ Procurement and Transplantation Network/United Network of Organ Sharing (OPTN/UNOS) regulatory framework to provide the infrastructure and framework to standardize the process for vascularized allograft as is done for organ transplants (for example, heart and liver). While the “Guidance Document for VCAs from Living Donors” developed by the OPTN/UNOS VCA Committee (OPTN, June 2, 2015) provides general guidance relevant to living-donor uterus transplantation, it does not establish specific policies for uterus transplantation from living donors. It is critical for reproductive surgeons

(and ASRM as the umbrella organization) to be familiar with and understand the process of obtaining informed consent and rules for living-donor safety.

4. Will this be offered to the transgender community?

Scientifically, it is preferable to perform this procedure initially on the least complicated patients—those with absence of a uterus and normally functioning ovaries. Once the procedure has become well established and comparatively routine and surgeons are experienced with the techniques and care involved, individuals with more complex medical, endocrine, or surgical needs could be considered. Barriers to care for more complex patients (including transgender, disorders of sexual development, and other medical conditions) should be published, along with medical rationale for not treating these groups in the initial stages of this surgery’s development. The necessary milestones for expanding patient selection to these groups should be delineated.

5. How is it possible to move this field forward and procure additional research resources?

Actions to consider include:

- Add ASRM representation to the UNOS VCA Committee
- Advocate for National Institutes of Health (NIH) funding of VCA
- Advocate for a consensus conference with Society of Maternal Fetal Medicine (SMFM) representation

6. What are some financial obstacles?

Initial clinical protocols supported by institutions will not be sustainable. It will become necessary to bridge the gap between institutional support and a patient’s ability to afford the procedure. Insurance coverage will vary in the United States from state to state and policy to policy. In order for insurance companies to support uterine transplantation, it will be necessary to demonstrate success and fill a medical need. Currently, 40% of the need for IVF is unmet due to financial barriers. This is likely to be compounded by this more expensive and more complex surgical procedure. As an example, Dr. Klintmalm, representing the program at Baylor, noted that patients must prove financial ability to cover the cost of IVF to participate in the uterus transplant program. Though the procedure currently is covered largely by the institution, potential transplant candidates must be available for frequent monitoring, able to bear the financial costs of medications, etc. In the Baylor experience, approximately 20% of those screened for uterus transplant were able to bear the financial and psychological costs and have adequate social support. The need is potentially significant; those able to access this treatment are few.

Dr. Owen proposed a guidance document that would:

- Discuss need and projected future need
- Create indications based on research to date
 - Include relative contraindications
 - Include absolute contraindications
- Outline the future of uterine transplantation
 - Needed research
 - Milestones in development
 - Future applications
- Other
 - Address barriers, with expense being first
 - Recommendations should be predicated on patient safety
 - Note that research is crucial for future applications
 - Research is complicated due to the fact that reproductive systems are species specific
 - Non-human primates are the closest equivalent animal model with inherent research issues such as cost and length of trial needed

The Role of UNOS/OPTN in Oversight of Uterus Transplantation

Presentation: Dr. Sue McDiarmid, President of ASRT and Chair of the UNOS/OPTN VCA Committee

In July 2013, the United States Secretary of Health and Human Services amended the National Organ Transplant Act (NOTA) of 1986 to designate VCAs as organs. The definition of a VCA as an organ required that all nine criteria published in the Final Rule were fulfilled. As such, a uterus fulfills the criteria for a VCA and therefore comes under the oversight of the OPTN, and subject to the policies and bylaws outlined below. This legislation required the development of policies and bylaws specific for VCA that were aligned with the provisions of NOTA and therefore similar to those for traditional organ transplantation.

OPTN and UNOS convened a multidisciplinary VCA Committee to spearhead developing the first policies relevant to VCA to meet the implementation date of July 3, 2014, for the Final Rule. The policies that have been developed and the necessary bylaw changes include:

- Approval of the definition of a VCA as set out in the Final Rule
- Acceptance of the requirements for OPTN/UNOS membership for VCA programs
- Specific policies for the authorization of potential donors of VCAs
- Allocation algorithms for VCA donors
- Mandatory data submission requirements
- Guidance documents for the donation and authorization process, and for potential VCAs from living donors

The OPTN/UNOS Board approved the initial policies and bylaw changes in June 2014 to meet the deadline for implementation of the Final Rule. Since then, further modifications of the first policies and bylaws have occurred which are also described.

(Citations of OPTN/UNOS reference documents provided at end of summary)

Membership Requirements for Uterus Programs

The first VCA membership requirement bylaw required that the VCA program must be located in a hospital that was a member of the OPTN/UNOS and have an approved traditional solid-organ transplant program. As well, the application required a letter of intent that stated that the local OPO would provide VCA organs, and identified the surgical, medical, and administrative directors who would be responsible for the VCA program. The letter of intent had to be signed by the surgical and medical directors and the chief administrative officer of the institution. It is important to note that the first VCA Membership Bylaws did not contain any training or experience requirements for VCA program key personnel. The membership requirements were passed by the Board in June 2014 with the provision they would sunset in September 2015 so that the Committee could develop more specific requirements.

In the intervening year the VCA Committee worked diligently on improved VCA membership requirements, aligning new proposals with established OPTN/UNOS membership criteria for

traditional solid-organ programs that emphasize objective credentialing standards and training and experience requirements for both the medical and surgical leaders of traditional transplant programs. The committee felt it was essential to apply to the new and innovative field of VCA the same standards of all other organ transplant programs. The overarching intent of such standards has always been to promote patient safety by establishing minimum requirements to be met by the medical and surgical leaders of transplant programs, and subject to accountability and oversight by the OPTN/UNOS.

The VCA Committee chose to develop specific criteria for the three VCAs most commonly performed at that time in the United States: upper limb, head and neck, and abdominal wall. A fourth category of “other” also was described to encompass other VCAs not yet commonly performed (for example uterus vascularized joints, larynx). For all four categories, a VCA program needed to identify 1) a program director, 2) a primary reconstructive transplant surgeon, and 3) a primary transplant physician responsible for the medical management of the patient. Specific requirements were established for the primary reconstructive transplant surgeon for upper limb, head and neck, abdominal wall, and the category of other, respectively. These included board certification requirements and documentation of fellowship training, where available in associated disciplines, and documentation of relevant experience.

At present a uterus transplant program must fulfill the requirements under the “Other” VCA pathway and are summarized below:

Board Certification

- American Board of Medical Specialties or foreign equivalent in a specialty relevant to the VCA type

Experience

- Independent surgical practice in the specialty over a consecutive 5-year period
- Observation of at least two multi-organ procurements
- Preoperative evaluation of at least three potential VCA transplant patients

Program Infrastructure

- Multidisciplinary surgical team including other specialists necessary to perform the VCA transplant
- Member with extensive microvascular experience
- Demonstrated planning for the type of VCA transplant

Documentation

- Letter from hospital identifying type(s) of VCA
- Letter signed by presiding institutional executive
- Identification of team members and their roles
- Logs documenting cadaveric rehearsals

VCA and Deceased-Donor Uterus Allocation

From its inception, the VCA Committee adopted a strong mandate to increase access to all VCA organs. Therefore, the VCA Committee decided to establish an allocation policy that would allow the broadest sharing of deceased donors within the limits of cold ischemia time as individually judged by accepting surgeons. (The limits of cold ischemia times are not yet known for VCAs and may differ among VCAs). The policy, therefore, proposed allocating donor organs based on compatible blood type and physical characteristics (when appropriate), with the first level of allocation being to regional programs followed by offers to all programs nationally. The usual algorithm of offering local donors to local candidates first was discarded in the interest of increasing access to and broader sharing of VCA grafts. The Committee considered prioritization based on other factors such as sensitization, zero Australian Bleeding Disorders Registry (ABDR) match, and geographic parameters to limit ischemia time, but found there was insufficient data to justify adding these elements into current policy. Data to be collected will help inform decisions for future VCA allocation policies.

The initial VCA organ allocation system was first approved in June of 2014 and reapproved by the OPTN/UNOS board unchanged in June of 2015.

Uterus Transplantation and Living Donors

In the amendment to the Final Rule, the nine criteria defining a VCA made no distinction as to the donor source. Therefore, the criteria listed also could be applied to a graft from a living VCA donor. The possibility of a living VCA donor was addressed by the US Secretary of Health and Human services in public comment, who opined that oversight of living donors, regardless of the organ, comes under the auspices of the OPTN. The VCA Committee was aware of the successful use of living donors in the Swedish Gothenburg program, and also was required to respond to

objections made to the concept of a living-donor VCA following the public comment period for the VCA definition process. The Committee declined to recommend prohibiting living VCA donation, as this prohibition would require a change to the Final Rule as noted above.

The VCA Committee carefully considered these comments and sought collaboration with the UNOS/OPTN Living Donor Committee and OPTN/UNOS Ethics committees to develop a guidance document with the specific purpose of educating the transplant community and general public about the concept of a living donor VCA, and under what circumstances this might occur. Uterus transplantation was used as an example of successful application of living donation to the field of VCA, but rather than develop specific criteria for living-donor uterus transplant programs, the guidance document addressed general considerations regarding the VCA types that might be considered suitable from a living donor, the principles of protecting donor safety, recommendations for informed consent process, medical and psychosocial evaluation of living VCA donors, and criteria for living VCA recovery programs. While the VCA Committee felt that it was too early to develop specific policy and bylaws governing living-donor VCA, the guidance document is closely modeled on the current living-donor policy that covers all other living donors, but to date specifically excludes VCA living donors. The VCA Committee was aware of the precedent for developing guidance documents in the field of living kidney and liver donation. This approach is well-established within the OPTN/UNOS as an appropriate mechanism to educate, provide specific and detailed guidance, and request important information to better inform the future development of appropriate policies.

VCA Deceased-Donor Authorization Policy

The VCA Committee felt strongly that separate authorization for VCA donation should be obtained. A policy requiring a separate authorization specific for a VCA donation did not violate the Uniform Anatomic Gift Act which permits consideration of a further gift, therefore allowing OPOs to seek authorization for VCA donation separately in the setting of a potential donor's premortem authorization for organ donation on a general registry. The policy also did not conflict with state laws or the efforts of the donation community. The authorization requirement stated that "recovery of a vascularized composite allograft for transplant must be specifically authorized from individual(s) authorizing donation whether that be the donor or a surrogate donation decision maker consistent with applicable state law." The specific authorization for VCA must be documented by the host OPO.

The Committee felt strongly that education of OPO staff, donor hospital staff, requestors, and general public was essential to ensure full understanding of the request for VCA donation and that consent would not be assumed unless specifically documented by the potential donor. As well, it was emphasized strongly that approaching a family for authorization of VCA donation should not jeopardize their authorization for life-saving solid-organ donation. These principles were formalized in a guidance document for VCA deceased-donor authorization that was approved in December 2014 and is now posted on the OPTN website.

The OPOs also have an important responsibility in order to participate in the donation process. OPOs must ensure that their staff has access to the UNOS Secure Enterprise website to obtain the OPTN VCA candidate list. (VCA candidates while listed with UNOS are not yet part of the standard transplant candidate listing system.) If a suitable donor becomes available, they must obtain and document separate authorizations for procuring the VCA. VCA grafts can only be allocated from the VCA candidate list according to the rules of VCA allocation. The OPOs also are required to record refusal and bypass reasons similar to those for traditional solid-organ transplantation, and this data must be completed and returned to the OPTN through the secure email site.

Data Collection and Submission Requirements for VCA

Under the Final Rule that regulates NOTA, one of the requirements of the OPTN is to maintain and operate a data collection system for all organ transplant candidate recipients and donors in the United States. This data is to be used to respond to public data requests, provide data to OPTN members, analyze transplant outcomes, and provide data necessary to make changes in policy. The VCA Committee felt strongly that not only was a centralized data collection system a requirement to be in compliance with the requirements of the OPTN contract, but that it was essential to support the scientific advancement of VCA transplantation in the United States. Accordingly, the VCA Committee adopted, with necessary modifications, the same data submission requirements for other non-VCA organs. As well, unique data elements specific for VCA were added to the requirements. The rationale for the proposal's stipulation for detailed data collection was to answer critical questions, currently unknown, that will guide the development of VCA transplantation. These include essential information on patient safety and outcome, patient and graft survival, and functional restoration in VCA recipients.

The data elements that were retained for VCA, and are currently collected for other organs, include demographic information, insurance and payment information, functional status, diagnosis, medical condition, infection detection, previous or de novo malignancy, patient and graft survival, acute rejection, and immunosuppression. The important new data elements were related to specific VCA organ function. Currently, objective measures of function are in place for upper extremity and face transplantation. At present, there are no specific outcome measures in place for uterus transplantation. The proposal for data collection for VCA went out for public comment in the fall of 2014 and were presented and approved by the OPTN/UNOS Board on June 1, 2015.

Dr. McDiarmid concluded her remarks noting the following:

- Programs interested in uterus transplantation in the United States have expanded in number at a higher rate than expected.
- Currently, there are three authorized programs and more on the horizon.
- If the number of uterus transplants increases, as now seems imminent, the VCA UNOS/OPTN Committee will need to consider developing more specific membership criteria for uterus transplant programs, particularly addressing the expertise requirements of the multidisciplinary team members, and to develop specific data collection elements relevant to uterus transplant outcomes.
- The VCA Committee in conjunction with the Living Donor and Ethics committees may need to reconsider specific policy for living-uterus donation.

The Special Role of the OPO in Uterus Transplantation

Presentation: Mr. Gordon Bowen, President, American Organ Procurement Organization

Mr. Gordon began his presentation with an overview of the role of the OPO in deceased-donor organ recovery and how the uterus, now designated as an organ, was subject to all the same processes as are in place for organ procurement in general. Mr. Gordon specially addressed the vital role the OPO has in the authorization (consent) process for all organ donors. Mr. Gordon brought forward several specific points in regard to consent:

- The importance of the UNOS/OPTN policy that authorization for any VCA must be separately obtained from that of traditional lifesaving organs, and the importance to the OPO of the guidance document developed to assist in this process.
- Consent/authorization documents and processes for VCA do not distinguish between whether the procedure is under a research or routine protocol.
- There is a separate institution-specific consent for the recipient at the recipient hospital.
- American Organ Procurement Organization (AOPO) can provide assistance (via documents) to assist with institutional review board (IRB) approval where needed.

Presentation: Building a Uterus Transplant Program: Perspectives from the Cleveland Clinic Program: Dr. Andy Tzakis and Dr. Tommaso Falcone

The Cleveland Clinic program performed the first uterus transplant in the United States in February 2016.

The program's founders, Drs. Andy Tzakis and Tommaso Falcone, described the process that went into creating the program and the clinical course and outcome of the first recipient of a uterus transplant in the United States.

The Cleveland Clinic made an early decision to use only deceased donors. Prior to inception of the clinical trial, Dr. Tzakis performed more than 12 "rehearsal" deceased-donor uterus procurements. He stressed the importance of this experience and highlighted several important lessons learned from deceased-donor uterus procurement.

- Ischemia time is a critical component of success.
- Candida infections need to be prevented.
- Meticulous ligation of pelvic vessels needs to be performed to avoid bleeding from the organ after transplant.
- Management of the vagina at procurement is critical, as significant bleeding can occur after reperfusion.

The Cleveland Clinic program went on to develop their clinical trial protocol. IRB approval was obtained over the course of 12 months. Institutional support was provided for 10 transplants, and financial support was limited to that of the institution.

The program published the steps in developing their uterus transplant program in 2016: Flyckt RL, Farrell RM, Perni UC, Tzakis AG, Falcone T. Deceased donor uterine transplantation: innovation and adaptation. *Obstet Gynecol* 2016;128(4):837-42. The article emphasized the development of a well-functioning multidisciplinary team, application of a robust informed consent process, use of a deceased-donor protocol, and ethical considerations.

The multidisciplinary team consisted of a:

- Transplant surgeon
- Gynecologic surgeon
- Reproductive endocrinologist
- High-risk obstetrician
- Anesthesiologist
- Transplant psychiatrist
- Infectious disease specialist
- Social worker
- Patient advocate
- Research nurse or coordinator

During program development, 250 reproductive-aged candidates contacted the institution of which 239 were screened over 7 months. The characteristics of these candidates were also been published: Arian S, Glyckt R, Farreoo R, Falcone T, Tzakis A. Characterizing women with interest in uterine transplant clinical trials in the United States: who seeks information on this experimental treatment? *Am J Obstet Gynecol* 2017;216(2):190-1.

First Case Synopsis: The first potential recipient was identified on September 15, 2015. A deceased donor became available on February 24, 2016, and the uterine transplantation was performed. The immunosuppression protocol consisted of antithymocyte globulin (ATG) induction followed by a standard triple therapy protocol (tacrolimus, mycophenolate mofetil, and steroids). Initially, the patient did well after transplant except for some manageable bleeding. On postoperative day 12, the patient developed hypovolemia and was taken to the OR where an arterial anastomosis disruption from Candida infection was identified that necessitated graft removal.

Lessons Learned

Drs. Tzakis and Falcone emphasized several key points which they consider as unanticipated contributors to the graft loss:

- An open vagina for a relatively long time during transportation
- Long cold ischemic time
- The need for vaginal preparation of donor and recipient
- Need for more thought about donor screening protocols (organisms, etc.?)
- How does a program respond to an adverse event such as this without overreacting in future protocol changes?

Presentation: Building a Uterus Transplant Program: Perspectives from the Baylor Program: Dr. Stefan Tullius and Dr. Goran Klintmalm

The Baylor program for uterus transplantation was developed from an IRB-approved protocol. The IRB-approved protocol allows the performance of 10 uterus transplants in women affected by absolute uterine infertility. The transplants can be performed with both living and deceased donors. Prior to IRB approval, the protocol was discussed and approved by the Baylor University Medical Center Ethics Committee and by the Medical Board. The uterus transplant team was assembled with existing faculty of the Baylor University Medical Center. The core Team includes four transplant surgeons, two gynecologists, two obstetricians, one IVF gynecologist, one dedicated neonatal intensivist, one psychologist, and one clinical nurse coordinator. Dedicated radiology and pathology support was also included. Selection of the recipient and donor candidates was conducted according to the inclusion criteria specified in the IRB-approved protocol and ratified by the members of the uterus transplant team in appropriately structured multidisciplinary meetings.

The Baylor team formed a close collaborative relationship with the Swedish team led by Professor Mats Brännström, including visits to the Swedish program, and on-site visits to Baylor by Professor Brännström . Results of the Swedish team's pre-clinical trial research and animal models were part of the process that informed the training of the Baylor team. Six "rehearsal" deceased-donor uterus procurements also were performed in collaboration with the local OPO. Funding for the Uterus Transplant Project were secured through the Baylor Foundation and the Baylor University Medical Center. All cost to date has been monitored with the aim of assessing the average cost of uterus transplantation.

- **Dr. Tullius specifically commented on challenges in funding these procedures:**
 - Uterus transplant has the potential for greater volume than other VCA surgeries.
 - Additional funding is critical for growth of the field.
 - Ethical training funding is needed.
 - Without funding, this procedure will remain out of reach for most.
 - The Department of Defense might be of assistance to fund genitourinary VCA.
 - Action to consider: Produce a white paper to solicit opportunities for funding and increase accessibility and availability.
 - An NIH U01 grant application is currently underway at Baylor.

Steps Forward

Leaders of the representative societies contributed ideas about how to continue to move the process of uterus transplantation forward.

- There is a compelling need for guidance documents (published data are too limited for guidelines or policy) to be developed by the relevant subspecialists to assist in setting standards for the development of uterus transplant programs and to coordinate best practices for all aspects of the procedure.
- There was a unified opinion that such guidance documents would require the input of the ASRM.
- The American Society of Transplant Surgeons (ASTS) leadership committed to help coordinate this process and contribute the specific expertise of the traditional solid-organ transplant community. Specifically, the ASTS offered to:
 - Provide a framework around which the specialists can do the work
 - Provide a place for these multidisciplinary teams to meet
 - Facilitate reciprocal presentations at each other's meeting to encourage collaboration and insight
- ASRT leadership noted that this society has committed membership from both the reconstructive transplant surgical perspective (including uterus transplant program surgeons and physicians) and the traditional solid-organ transplant community, and as such would be able to help create bridges of collaboration essential to this process.
- UNOS/OPTN leadership offered that the VCA Committee would actively consider what amendments to the current policies/bylaws that govern VCA may need to be considered to assist in the development of the field. In particular:

- Develop specific membership requirements for uterus transplant Programs in regard to standards of expertise for the surgeons and physicians leading the programs, consistent with all other solid-organ transplant programs. Specific membership standards may be an important next step to ensure transparency and appropriate oversight of uterus transplant programs.
- Develop specific data elements unique to uterus transplantation that fulfill mandated data submission requirements for all organ transplantation in the United States.
- Engage the UNOS/OPTN Donor Transmitted Disease Committee to assist with:
 - How to screen potential uterus donors
 - Infectious disease–related exclusion criteria
 - Treatment algorithm for donors who test positive for various infectious diseases
- The ASTS leadership noted that this society has an Advisory Council for VCA. Special considerations for uterus transplantation should be an important mission of this group’s further work, and the membership of the Advisory Council should be reviewed to ensure adequate representation for uterus transplantation within the membership.
- The AOPO leadership confirmed that this organization is ready to assist in any considerations regarding deceased-donor uterus consent processes and special procurement procedures, including education of their community in the unique aspects of uterus procurement procedures, in particular managing the coordination of the multiple donor-procurement teams likely to be present for life-saving organ procurements. For AOPO consideration, the following comments were made:
 - Are drug overdose victims acceptable donors?
 - What is a “low-risk” donor?
 - Guidelines for differentiating between high- and low-risk donors are needed with treatment algorithms.

Final Comments from ASRM Leadership:

- There are fundamental differences between the transplant and reproductive disciplines.
- ASRM must educate and provide a liaison to collaborate with the transplant community to move this field forward.
- This effort requires champions from both the transplant community and reproductive medicine community representing the various stakeholders.

- The proceedings of this Roundtable should be summarized in written format and used as a first intersociety initiative to bring coordinated efforts to assist the progress of the complex field of uterus transplantation.

The meeting was adjourned at 3:30 p.m. with thanks to all participants.

OPTN/UNOS Reference Documents:

Final Rule Amendment for VCA: 42 CFR Part 121, as amended July 3, 2013.

Guidance Document: VCAs from Living Donors

<http://optn.transplant.hrsa.gov/resources/by-organ/vascular-composite-allograft/vcas-from-living-donors/>

Accessed December 4, 2015.

Guidance Document: VCA Guidance Document VCA Authorization

http://optn.transplant.hrsa.gov/media/1137/vca_donor_guidance.pdf

Accessed December 4, 2015.

Summary prepared by S.V. McDiarmid, MD, with special thanks to Richard Reindollar, MD, ASRM CEO, and Jessica Goldstein, RN, ASRM Education Program Coordinator