

Transplant Summit 2018
Breaking through Regulatory Barriers to Unleash Transplant Innovation

Speakers will be added as confirmed.

Thursday, February 8, 2018

1:45 PM

Welcome Remarks

*Anil Chandraker, MD, FAST, Brigham and Women's Hospital and
Kenneth Newell, MD, PhD, FAST, Emory University*

2:00 - 3:30 PM Session 1 – Xeno Shark Tank *

The clinical implementation of xenotransplantation is an emerging/re-emerging area of interest. While the potential impact on access to available organs is considerable there are significant barriers (real and perceived) to innovation. In this session leaders in the field will present and discuss the current state of clinical xenotransplantation.

Goals:

- 1) To familiarize the audience with recent innovations in the field of xenotransplantation as it applies to potential clinical trial translation.
- 2) To identify the barriers to proceeding with a clinical trial using xenogeneic donors. Barriers would include regulatory concerns, identification of the correct target population/organ type islet, kidney, heart etc

3:45 PM

Break

4:00 - 5:30 PM

Session 2 - Defining True Innovation: Lesons from Transplantation's Past

During its first several decades transplantation presented daunting challenges that required truly innovative solutions. As the field has matured much of what is billed as a major innovation is actually a minor refinement of established practice. The aim of this session is to set the stage for CEOT 2018 by defining true innovation through examples from the past. I line with this year's theme this session will focus on changes in policy and oversight and consider how these changes affect the field's ability to develop and apply innovative practices.

Goals:

- 1) To distinguish between truly transformative innovation and iterative progress
- 2) To use examples of past innovation to define how the regulatory/oversight landscape has changed over time
 - What unmet clinical needs drove these innovations?
 - Who or what group created the innovative solution?
 - What regulatory landscape or oversight governed these innovations?
 - What is the landscape is for a comparable intervention today

5:45 – 7:00 PM Poster & Welcome Reception

Frank Lloyd Wright Salon G

Friday, February 9

7:00 – 8:15 AM

Satellite Symposium (TBD)

8:15 AM

Break

**Continuing education credit offered. See separate packet.*

†No continuing education credit offered.

Friday, February 9

8:30 – 10:30AM

Session 3: Select one of three sessions

Option One: “OPTN/UNOS Policies and organ utilization: Necessary & Beneficial, or Obstacles to Growth & Innovation?”*

This session will explore innovative way that UNOS can more effectively fulfill its mission to increase the number of organs transplanted and a safe and efficient manner. Because kidney transplantation represents the largest number of organs transplanted, policy and allocation innovations for this organ will be discussed, however links to other solid organs will be made as appropriate.

Goals: At the end of the session the learner will:

- 1) Be able to describe the role of UNOS in the develop, implementation and oversight of deceased donor organ allocation.
- 2) Be able to understand the full complexity of deceased donor allocation.
- 3) Be able to teach other about alternative methods to allocate deceased donor organs.

Session 3, Session 5 and Session 6: The Thoracic Tracks

Options Two & Three: Heart & Lung Track*

Frank Lloyd Wright Salon A & D

The thoracic tracks for CEOT 2018 are designed to provide in-depth discussions and expert experience related to the use of novel strategies for the treatment of end-stage heart and lung failure, including regulatory and ethical considerations and risks and benefits of the innovations currently being pursued.

Heart Track:

Goals:

Session 3: Rise of the Machines: Regulatory Considerations in MCS Therapy

- 1) Identify and discuss the guidelines for appropriate referral for and use of mechanical circulatory support, including short-term support, durable devices and destination therapy.
- 2) Identify and appropriately assess the risks and benefits of the various types of mechanical circulatory support for patients with end-stage heart failure, including specific sub-populations.

Session 5: Alternatives to Heart Transplantation: Overcoming Barriers to Success

- 1) Understand and discuss the potential, limitations and challenges of alternatives to heart transplantation, including xenotransplantation and stem cell therapy
- 2) Understand and discuss the potential, limitations and challenges of novel strategies to expand the donor heart pool, including DCD heart donation and ex-vivo donor heart perfusion.

Lung Track:

Goals:

Session 3: The Evolution of Lung Support Devices: Regulatory Considerations in Lung Transplantation

- 1) Identify and discuss the risks and benefits of lung support devices and their utility as a bridge to transplantation
- 2) Identify and discuss the risks and benefits of novel devices/strategies to optimize donor lungs prior to transplantation

Session 5: Trials, Tribulations and Triumphs in Lung Transplant Innovations

- 1) Understand and discuss the potential, limitations and challenges of alternatives to lung transplantation, including xenotransplantation and the artificial lung
- 2) Understand and discuss the potential, limitations and challenges of novel strategies to expand the donor lung pool, including ex-vivo donor lung perfusion.

**Continuing education credit offered. See separate packet.*

†No continuing education credit offered.

Friday, February 9

Session 6: Case Studies in Thoracic Transplantation: Integrating Innovation

- 1) Understand and apply the guidelines for novel therapies in thoracic transplantation, including the use of extended criteria donor organs and device support.
- 2) Understand and apply the guidelines for novel strategies to optimize donor organs, including ex-vivo perfusion.

10:30 AM **Break**

11:00 – 12:30 PM **Session 4: Congressional Keynote**

12:45 – 2:00 PM **Satellite Symposium† (TBD)**

2:00 – 4:00 PM **Session 5: Select one of three sessions**

Option One: Program-Specific Reports: Past, Present and Future. Where do we go from here?*

The session will first review the history of quality oversight in solid organ transplantation and review current quality metrics and ongoing updates to program specific reports. Speakers will then discuss ideal quality metrics from the perspective of different stakeholders in transplantation including regulatory agencies, payers, patients and transplant providers. The session will conclude with a roundtable discussion addressing commonalities in stakeholder perspectives and practical steps towards evolving oversight in this field.

Goals:

1. To describe the history and components of current metrics in solid organ transplantation
2. To explain different stakeholders' views of potential improvements in quality oversight
3. To summarize steps to implement changes in the current process for quality oversight.

Option Two: Heart *

Frank Lloyd Wright Salon A

Option Three: Lung *

Frank Lloyd Wright Salon D

Saturday, February 10

7:00 – 8:15 AM **Satellite Symposium**

8:15 AM **Break**

8:30 – 10:00 AM **Session 6*: Select one of three sessions**

Option One: Clinical therapeutics to improve patient outcomes: The tribulations of trials in transplantation*

Frank Lloyd Wright E

The success of highly efficacious “contemporary” immunosuppression in improving transplant outcomes over the past two decades has hindered the development of clinical trials aimed at therapeutic advancement. This session, anchored by a panel discussion of key stakeholders, will provide an in-depth examination of these roadblocks, what our currently perceived needs are, and potential strategies that can be implemented going forward to circumvent this impasse.

**Continuing education credit offered. See separate packet.*

†No continuing education credit offered.

Saturday, February 10

Objectives:

1. Describe the current barriers faced in performing clinical trials to evaluate therapeutic advances to improve outcomes
2. Discuss unmet needs for which clinical trials in transplantation are currently needed
3. Propose innovative clinical trial design approaches to use in organ transplantation

Option Two: Heart*

Frank Lloyd Wright Salon A

Option Three: Lung*

Frank Lloyd Wright Salon D

10:00 AM	Break
10:30 – 12:00 PM	Session 7: Approaches to Facilitating the Approval of New Therapeutics in Transplantation *
12:15 PM – 1:30 PM	Satellite Symposium (TBD)
1:30 – 3:00 PM	Session 8: Out of Synch: How can factors that drive OPO and Transplant Center practice be aligned to increase the number of patients who receive a transplant*

The current system of deceased organ donation is insufficient to meet the need for organ transplantation. To what extent regulatory and financial constraints limit the current system is widely debated. This session will review the impact of regulatory and financial considerations on transplantation from the perspective of the OPO, transplant center, CMS and UNOS.

Goals:

- 1) To familiarize attendees with the regulatory and financial drivers of OPO and transplant center practices that limit opportunities for transplantation
- 2) To understand the impact of regulatory and financial drivers on transplantation
- 3) To discuss potential changes to the system to increase transplantation

3:00 – 3:30 PM	Summary Heart/Lung Track
3:30 - 4:00PM	Summary and Next Steps
4:00 – 4:15 PM	Closing Anil Chandraker, MD, <i>Brigham & Women's Hospital</i> Kenneth A. Newell, MD, PhD, <i>Emory University School of Medicine</i>
5:00 PM	Poolside Reception Paradise Pool

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