Preliminary CEoT Program

Thursday, February 8, 2018

1:45 PM
Welcome Remarks
Frank Lloyd Wright Salon EF
Anil Chandraker, MD, FASN, FAST, FRCP, Brigham and Women's Hospital
Kenneth Newell, MD, PhD, FAST, Emory University

2:00 - 3:30 PM
Session 1: Xenotransplantation, Are We Finally Ready? A Field, Challenging and Challenged by Regulation
Moderators: Andrew Adams, MD, PhD
James Allan, MD, MBA, FAST

2:05 PM We Are Ready for Prime-Time, Invest Today!
Joseph Tector, MD, PhD

2:30 PM We're Close but We Need to Consider the Following Issues Before Sinking in Your Money
Andrew Adams, MD, PhD

2:55 PM Hold on Here, Your Money Might be Better Invested Somewhere Else
Allan Kirk, MD, PhD

Panel Discussion

Session Description:
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.

Session Objectives:
1) To recognize recent innovations in the field of xenotransplantation as it applies to potential clinical trial transplantation
2) To identify the barriers to proceeding with clinical trial using xenogeneic donors, including regulatory concerns, identifying the appropriate target population and organ type (e.g. islet, kidney, heart)

3:45 PM
Break

**Continuing education credit offered. See separate packet.*
†No continuing education credit offered.

4:00 - 5:30 PM
Session 2: Defining True Innovation - Lessons from Transplantation's Past
Moderators: Kenneth Newell, MD, PhD, FAST
Anil Chandraker, MD, FASN, FAST, FRCP

4:05 PM Innovation in Surgical Technique – Living Donor Liver Transplantation
Jean Emond, MD

4:20 PM Innovation in Immunosuppression
Arthur Matas, MD

4:35 PM Innovation in Organ Donation
Darren Malinoski, MD

4:50 PM Innovation in Regulatory Framework – the National Academy of Science Study
Alexandra Glazier, JD, MPH

Panel Discussion

Session Description:
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. In 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.

Session Objectives:
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 for a comparable intervention today?

5:45 – 7:00 PM
Poster & Welcome Reception - Frank Lloyd Wright Salon G

Friday, February 9, 2018

7:30 – 8:15 AM
Continental Breakfast

8:30 – 10:30 AM **Session 3: Select One of Three Sessions**

Option One: OPTN/UNOS Policies and Organ Utilization - Necessary and Beneficial, or Obstacles to Growth & Innovation? *
Frank Lloyd Wright EF
Moderators: Richard Formica, MD

Session 3, Option One, cont.

Deceased Donors Starting Living Donor Chains

8:30 AM The Rationale and Potential Benefit for Using Deceased Donors to Start KPD Chains
Nicole Turgeon, MD

8:40 AM The Legal and Regulatory Issues Posed by Using Live Donors to Start KPD Chains
David Klassen, MD

8:50 AM Panel Discussion

Session 3, Option One, cont.: New Paradigms for Allocating Organs - When Should Utility Override Equity?

9:00 AM European Perspective on Expedited Allocation
Axel Rahmel, PhD

9:10 AM US Perspective on Expedited Allocation
Darren Stewart, MS

9:20 AM Proposing a New Paradigm -Less Choice, More Allocation
Jesse Schold, PhD, M. Stat, M.Ed

9:30 AM Panel Discussion

Option One, cont.: Re-Envisioning OPTN/UNOS

10:00 AM People and Data
Brian Shepard, MBA

10:10 AM Changing OPTN/UNOS Implementation Policies and Practices: Supporting Innovation in a Structured Environment
Richard Formica, MD

10: 20 AM HRSA Role as a Force Innovation in Transplantation
Melissa Greenwald, MD

10: 30 AM UNOS Labs: Leveraging Behavioral Science to Improve Organ Allocation
Darren Stewart, MS

Session Description:
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.

Session Objectives:
1) To describe the role of UNOS in the develop, implementation and oversight of deceased donor organ allocation.
2) To describe the full complexity of deceased donor allocation.
3) To offer alternative methods for allocating deceased donor organs.

8:30 – 10:30AM Session 3: Select One of Three Sessions
Option Two, **Heart Track: Rise of the Machines - Regulatory Considerations in MCS Therapy***
Frank Lloyd Wright Salon AB
Moderators: Liviu Klein, MD
Rondalyn Ford-McLean, MD

8:30 AM LVADs as Destination Therapy- When Best Practice Criteria Meets the Real World
Farooq Sheikh, MD

8:45 AM The Total Artificial Heart – What Metrics Should be Met for Standard Use? For Future Technology?
Francisco Arabia, MD

9:00 AM ECMO and Short Term Support - Utilization Guidelines and Impact of the New Heart Allocation System
Jeffrey Teuteberg, MD

**Continuing education credit offered. See separate packet.*
†No continuing education credit offered.

9:15 AM MCS Complications-Understanding Risks and Rewards in the Context of Appropriate Use Benchmarks
Liviu Klein, MD

Session 3, Option Two, cont.

9:30 AM DEBATE:
Innovation in MCS Technology is Helped by Regulation
Palak Shah, MD

Innovation in MCS Technology is Hindered by Regulation
O.H. Frazier, MD

10:00 AM The Cost of Success vs the Cost of Failure – Financial Considerations in Advancing Innovation
Simon Maltais, MD

Session Description:
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.

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

8:30 – 10:30AM **Session 3: Select One of Three Sessions**

Option Three, Lung Track: The Evolution of Lung Support Devices - Regulatory Considerations in Lung Transplantation*
Frank Lloyd Wright Salon CD
Moderators: Sangeeta Bhorade, MD
Christopher Wigfield, MD

8:30 AM DEBATE:
ECMO as a Bridge to Transplant Should be Exempt from 1 Year Mortality Outcomes in Lung Transplant
– Con
Charles Hoopes, MD
– Pro
Duane Davis, MD

9:10 AM DEBATE:
Ex Vivo Lung Perfusion is an Essential Tool for Donor Optimization
– Pro
Shaf Keshavjee, MD
– Con
Thomas Egan, MD, MSc

9:50 AM The Regulatory Imperative – Impact on the Practice of Lung Transplant
Christopher Wigfield, MD

10:05 AM Regulatory Realities – Redefining Benefit of Lung Transplant in the Current Era
Gundeep Dhillon, MD, MS

Session Description:
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.

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Session Objectives:
1) To identify the risks and benefits of lung support devices and their utility as a bridge to transplantation
2) To discuss the risks and benefits of novel devices/strategies to optimize donor lungs prior to transplantation

10:30 AM
Break

11:00 – 12:30 PM
Session 4: Congressional Keynote
Invitations will be extended to:
Congresswoman Jaime Herrara Beutler (R-WA),
Congressman Kevin Yoder (R-KS) and
Congresswoman Diana DeGette (D-CO)

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?*
Frank Lloyd Wright EF
Moderators: Jesse Schold, PhD, M. Stat, M. Ed
John Gill, MD, MS

2:05 PM The Past
Bertram Kasiske, MD

2:20 PM The Present
Jon Snyder, PhD

2:40 PM The Future – What Would an Ideal Report Card Look Like?
Melissa Greenwald, MD
Jon Friedman, MD
Luke Preczewski
Jesse Schold, PhD, M.Stat, M. Ed

Panel Discussion

Session Description:
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.

Session Objectives:
1) To outline 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.

2:00 – 4:00 PM **Session 5: Select One of Three Sessions**

Option Two, Heart Track: Alternatives to Heart Transplantation - Overcoming Barriers to Success*
Frank Lloyd Wright AB

Session 5, Option Two, Cont.

Moderators: Joren Madsen, MD
Shelley Hall, MD

2:00 PM DCD Heart Donation – Understanding the Regulatory and Ethical Issues
Val Jeevanandum, MD

2:20 PM Xenotransplantation – Promise and Pragmatism
Robin Pierson, MD

Session 5, Option Two, cont.

2:40 PM Whole Organ Engineering – Science and Sensibility
Doris Taylor, MD

3:00 PM Stem Cell Therapy – Engineering Process
Rachel Smith, PhD

3:30 PM Ex Vivo Heart Perfusion – Removing Time and Distance Barriers
Abbas Ardehali, MD

Session Objectives:
1) To discuss the potential, limitations and challenges of alternatives to heart transplantation, including xenotransplantation and stem cell therapy
2) To 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.

2:00 – 4:00 PM Session 5: Select One of Three Sessions

Option Three, Lung Track: Trials, Tribulations and Triumphs in Lung Transplant Innovations
Frank Lloyd Wright CD
Moderators: Martin Zamora, MD
Duane Davis, MD

2:00 PM Cell Free DNA and Other Immune Monitoring Techniques in Lung Transplantation – Are We There Yet?
David Neujhar, MD

2:20 PM Controlled Donation After Determination of Circulatory Death (cDCDD) – Improving Yield
Martin Zamora, MD

2:40 PM Xeno Lung Transplantation – The Path Forward
Agnes Azimzadeh, PhD

3:00 PM Extracorporeal Lung Support – A Bridge Too Far?
Jonathan D'Cunha, MD

3:20 PM The Artificial Lung – Can it be Realized?
Williams Federspiel, PhD

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

Saturday, February 10, 2018

7:00 – 8:15 AM
Satellite Symposium

8:15 AM
Break

8:30 – 10:00 AM Session 6: Select One of Two Sessions

Option One: Clinical Therapeutics to Improve Patient Outcomes - The Tribulations of Trials in Transplantation*
Frank Lloyd Wright EF
Moderator: Roy Bloom, MD
Roslyn Mannon, MD

8:30 AM Tracking Transplant Treatment Trials - Where Are We and What are the Barriers
Roy Bloom, MD

9:00 AM Victims of Success- Do We Still Need Clinical Trials and If So, What are Our Needs?
Robert Gaston, MD

9:30 AM Can We Get There? Re-Thinking Clinical Trial Design
Jesse Schold, PhD

9:45 AM Panel Discussion
Renata Albrecht, MD
Peter Maag, PhD
Kevin Campbell

Session Description:
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.

Session Objectives:
1) To describe the current barriers faced in performing clinical trials to evaluate therapeutic advances to improve outcomes
2) To discuss unmet needs for which clinical trials in transplantation are currently needed
3) To propose innovative clinical trial design approaches to use in organ transplantation

8:30 – 10:00 AM Session 6: Select One of Two Sessions

Option Two: Case Studies in Thoracic Transplantation - Integrating Innovation
Frank Lloyd Wright AB
Moderators: Jon Kobashigawa, MD
Nicholas Braus, MD

**Continuing education credit offered. See separate packet.*
†No continuing education credit offered.

Session 6, Option Two, Cont.

8:30 AM Extended Criteria Heart vs Destination LVAD
Marvin Slepian, MD

8:45 AM Hep-C Heart and Lung Transplantation
Shelley Hall, MD
Luke Cunningham, MD

9:00 AM Ex Vivo Lung
Jon D'Cunha, MD
Lara Schaheen, MD

9:15 AM Ex Vivo Heart
Jason Smith, MD
Christopher Burke, MD

9:30 AM DCD Lung
Martin Zamora, MD
Nicholas Braus, MD

Session Objectives:

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

10:00 AM
Break

10:30 – 12:00 PM
Session 7: Approaches to Facilitating the Approval of New Therapeutics in Transplantation *
Frank Lloyd Wright EF
Moderators: Kenneth Newell, MD, PhD, FAST
Anil Chandraker, MD, FASN, FAST, FRCP

10:30 AM Low and Not So Low Hanging Fruit – New Study Endpoints and Biomarkers
Ulf Meier-Kriesche, MD

10:50 AM Regulatory Approaches to Facilitating the Use of Therapies Approved for Other Indications in Transplantation
Mark Stegall, MD

11:10 AM PROs – New Opportunities to Measure Something That Matters to Patients
Stephen Joel Coons, PhD

Panel Discussion

Session Description:
This session will focus on next steps to focus on advancing the field. New study endpoints and biomarkers will be discussed as a new way to determine the success of a therapy. Additionally, off label drug will be explored from a regulatory perspective. Finally, patient reported outcomes will be offered as a new opportunity for collecting data points that have direct value and meaning to the patients will be offered as a way to look beyond the current SRTR data set.

Session Objectives

1) To describe new study endpoints and biomarkers as alternate means to measure success
2) To outline the regulatory approaches to facilitating the use of therapies approved for other indications in transplantation
3) To discuss the use of patient reported outcomes as valuable data points in transplantation

SATURDAY, FEBRUARY 10

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*
Frank Lloyd Wright EF
Moderators: John Gill, MD, MS
Dave Foley, MD, FACS

1:30 PM Critique of the Current OPO Performance Metrics and Proposed Improvements:

Characteristics of an Optimal OPO Metric
David Goldberg, MD, MSCE

My Pick for A New OPO Metric
Charlie Alexander, RN, MSN, MBA, CPTC

1:45 PM Regulatory and Financial Considerations That Impact OPO Performance – What Changes Would Increase Transplantation?
Kevin O'Connor, MS, PA

2:00 PM Regulatory and Financial Considerations That Impact Transplant Center Practice – What Changes Would Increase Transplantation?
Matthew Cooper, MD

Session 8, cont.
2:15 PM Reaction to the Proposed Solutions
Brian Shepard, MBA

2:30 PM Panel Discussion
Jon Snyder, PhD

Session Description:
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.

Session Objectives:
1) To explain the regulatory and financial drivers of OPO and transplant center practices that limit opportunities for transplantation
2) To describe 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
Session 9: Summary Heart/Lung Track
Frank Lloyd Wright AB
Jon Kobashigawa, MD
Sangeeta Bhorade, MD

3:30 - 4:00PM

**Continuing education credit offered. See separate packet.*
†No continuing education credit offered.

SATURDAY, FEBRUARY 10

Session 10: Summary and Next Steps
Frank Lloyd Wright EF
Anil Chandraker, MD, FASN, FAST, FRCP
Kenneth Newell, MD, PhD, FAST

4:00 – 4:15 PM
Closing
Frank Lloyd Wright EF
Anil Chandraker, MD, FASN, FAST, FRCP
Kenneth Newell, MD, PhD, FAST

5:00 PM
Poolside Reception - Paradise Pool

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