



CSRC Think Tank: Shock III: Advancing Pragmatic Priorities & Pathways in Shock Research

Gaylord National Convention Center
201 Waterfront Street
National Harbor, MD
February 22, 2020

8:00 – 8:05 Welcome & Introductions: Mitchell Krucoff, MD (Duke)

8:05 – 8:55 Session 1: Cardiogenic Shock in 2020 and Beyond.

- Overview of Shock 1 and Shock 2: **Marc Samsky MD (Duke)** 10 min
- FDA Perspectives: Priorities for 2020 **Bram Zuckerman** 10 min
- AHA Shock initiative: **Mariell Jessup, MD** (10 min)
- Dealing with Safety in High Risk Populations: Insights from DES/PAD. **Mitchell Krucoff, MD (Duke)** (10 min)

8:55 – 10:00 Session 2: Shock Research Network. How can we rapidly identify and triage patients with shock?

Moderators: *William O'Neill, MD (Henry Ford Health System) and Andrew Farb, MD (FDA)*

- Are shock teams and networks necessary? What are the priorities and minimum requirements for a "Shock Team/Network?" **Navin Kapur, MD (Tufts)** (5 min)
- An ELSO view **Ryan Barbaro, MD (University of Michigan)** (5 min)
- Industry: Is Shock Network Research attractive? **Zhen Zhang, MD (Abbott)** (5 min)
- NIH Perspective: **George Sopko, MD** (5 min)

Moderated Discussion (45 min): Lead Discussants **Nader Moazami, MD (New York University); Seth Bilazarian, MD (Abiomed)**

10:00-10:10: Break

10:10 – 11:15 Session 3: Informed Consent. Who? When? Where? Case Examples

Moderator: *Fernando Aguel, MS (FDA); Judith Hochman, MD (New York University)*

- Informed consent solutions for shock trials of devices: FDA view **John Sapirstein, MD (FDA)** (5 min)
- What strategies are used in Europe? **Alastair Proudfoot, MD (St Bartholomew's Hospital)** (5 min)

Moderated Discussion (45 min): *Lead Discussants: Jason Katz, MD (Duke)*

11:15 – 12:30 Session 4: Are current shock definitions adequate? What core data do we need?

Moderators: *Ron Waksman, MD (MedStar) and Ileana Pina, MD (FDA)*

- Adopting Key Variables from SCAI definitions: **Timothy Henry, MD (Christ Hospital)** (5 min)
- Key predictive model variables often missed in clinical practice: **William O'Neill, MD (Henry Ford)** (5 min)
- Updates on Shock-ARC: **William Abraham, MD (Ohio State)** (5 min)
- NIH Perspective **Patrice Desvigne-Nickens, MD** (5 min)

Moderated Discussion (40 min): *Lead Discussants: Ernest Spitzer, MD (Cardialysis)*

12:30-13:15: Lunch

13:15-14:35 Session 5: Shock Priority Clinical Trials

Moderators: *Sunil Rao, MD (Duke) and Fernando Aguel, MS (FDA)*

- The intensivist perspective: Trial priorities for MCS in the ICU? **David Morrow, MD (Harvard)** (5 min)
- The interventionalist perspective: STEMI-Shock: What would the first randomized question be? **Holger Thiele, MD (University of Leipzig)**(5 min)
- The HF perspective: Where do inotropes fit in? **Nasrien Ibrahim, MD (Mass General Hospital)** (5 min)
- Percutaneous vs. ECMO trials: do we need different centers? **Jacob Schroder, MD (Duke)** (5 min)
- PCI VS CABG- **Nathaniel Smilowitz, MD (New York University)** (5 min)
- INTERMACS: Success Story or Lessons Learned? Mandatory registry participation. **Patrice Desvigne-Nickens, MD (NIH)**(5 min)
- Industry Perspective: **Seth Bilazarian, MD (Abiomed)** (5 min)

Moderated Discussion (45 min): *Lead Discussants Andrew Althouse, PhD (Pitt); Eric Chen, MS (Abbott)*



CARDIAC SAFETY
RESEARCH CONSORTIUM

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14:30 – 16:00 Session 7: Next Steps to Advancing Pragmatic Priorities & Pathways in Shock Research

Moderator: Mitchell Krucoff, MD (Duke), Bram Zuckerman, MD (FDA)

Summaries from the Day (no slides):

- Shock research centers network: **William O'Neill, MD** (Henry Ford) (5 min)
- Shock nomenclature & definitions: **Ron Waksman, MD** (MedStar) (5 min)
- Resources for Shock Network Research: **Sunil Rao, MD** (Duke) (5 min)
- Shock Priority Clinical Trials: **Fernando Aguel, MS** (FDA) (5 min)
- Trial/Registry/Claims Data- **Mauro Moscucci, MD, MBA** (FDA)

Moderated Discussion (40 min): Lead Discussants: **William Abraham, MD** (Ohio State), **Judith Hochman, MD** (New York University), **Holger Thiele, MD** (University of Leipzig)

Closing Comments
