What is a Consensus Statement

Donald S. Likosky, PhD
Variability in Brain Injury

• Brain injury occurs among ____% of patients after CABG surgery
Brain injury occurs among ____% of patients after CABG surgery

1. <10%
2. 10-19%
3. 20-29%
4. >30%
5. Depends
Reasons Underlying this Variability

- Follow-up interval (2d – 5yr)
- Defining Decline
  - 20% decline on (20% of tests, ≥1 tests, or ≥2 tests)
  - ≥1 SD on (1 of 4 domains, ≥2 domains, ≥1 tests, ≥2 tests)
  - Paired tests
  - Z-scores
  - Correlation
  - ANOVA
Why is this important

• Results from studies are impacted, in part, by choices in
  – Design
  – Analysis
  – Reporting
• Status quo prevents comparisons across studies
• **Study Design**: Use a control or comparison group

• **Assessments**: Rey auditory verbal learning; Trail-making A; Trail-making B; Grooved pegboard

• **Timing of Assessments**: preop, Immediate postop, @ 3 mos postop

Statement was a product of panel + audience input, which was recorded
• Statement led to changes:
  – In editorial process for publications
  – To design of studies & analyses

A game changer!
CONSENSUS FORUM

Defining Incidence

John M. Murkin
Guy McKhann,
University of Western C,
Winston-Salem, North

Consensus Statement: Defining Mini Inflammatory Response to Cardiopul

R. Clive Landis, 3, Joseph E. Arowosafe, 4, Robert A. Gregory Fisher, 5, Richard A. Jonas, 6, Donald S. Likosi Stump, 7, Edward D. Verrier 8

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ABSTRACT

The lack of established cause and effect between positive medium of inflammation and adverse clinical outcomes has been responsible for longstanding efforts to improve interventions in cardiopulmonary bypass (CPB). Candidate interventions that impede preclinical trials by suppressing a given inflammatory factor might fail at the clinical trial stage because the marker of interest is not linked causally to an adverse outcome. Clinically, there exists examples in which pharmacological agents or other interventions improve clinical outcomes but for which we are unaware of any anti-inflammatory mechanism. The Outcomes consensus panel made 3 recommendations in 2009 for the conduct of clinical trials focused on the systemic inflammatory response. This panel was tasked with updating, as well as simplifying, a previous consensus statement. The present recommendations are based on the research findings in the peer-reviewed literature.

Correspondence: Dr. R. Clive Landis, Edmond Cohen Laboratory for Vascular Research, Chronic Disease Research Center, University of the West Indies, Barbados, Barbados (E-mail: RCL@cs.wisc.edu).

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The causal factors of the systemic inflammatory response to cardiopulmonary bypass (CPB) are not well identified in the early 1990s. 1. activation of complement, coagulation, fibrinolysis, and leukotriene biosynthesis; 2. production of tumor necrosis factor, interleukin-1 and other cytokines; and 3. release of neuropeptides stimulating the immune system. The pathogenesis of CPB-associated organ dysfunction is multifactorial, involving a complex interaction of metabolic, nutritional, and functional factors. It is clear that the inflammatory response is not a simple acute inflammatory reaction but rather a complex, chronic, and low-grade reaction that is associated with a variety of clinical outcomes. The consensus panel made 3 recommendations in 2009 for the conduct of clinical trials focused on the systemic inflammatory response. This panel was tasked with updating, as well as simplifying, a previous consensus statement. The present recommendations are based on the research findings in the peer-reviewed literature.

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Our goal

• Use this conference as a vehicle for having impact on the manner in which we report perfusion practices that impact RBC transfusions

• Expectation that such an effort will
  – Bring consistency in data reporting
  – Focus areas for further research
  – Draw insight into how to improve clinical outcomes