Emergency Care Research Networks

Hypothetical
Cardiac Biomarker/Intervention
Expert Panel Discussion
Objectives

- Discuss optimal
  - Structure
  - Function
  - Evaluation

Of a hypothetical network to be used to:

Test the feasibility and utility of a Novel biomarker in acute cardiac care
Panel Membership

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Assumptions: Biomarker

• Biomarker X is:
  – Rapidly available (bedside testing)
  – Promising in single site pilot testing
  – Identifies a subset of patients with Acute Coronary Syndrome who derive particular benefit from Intervention Y
Assumptions: Intervention Y

- Intervention Y is:
  - Given at or near balloon opening time in MI
  - Implementation requires multidisciplinary team
  - Decreases reperfusion injury
  - Must be available 24 hours a day
- Outcome includes:
  - Major adverse cardiac events 30d and 6 months
  - Imaging: echo and functional MR
Assumptions: Secondary Outcomes

• Blood draw and storage for:
  – Gene expression and inflammation mediator levels
  – Possible subgroup analysis
  – Hypothesis generation/pilot data for future grants
Study design

- Patients with positive Biomarker X
- Within 2 hours of onset of pain
- Have intervention Y
- Strict inclusion criteria
- Elevated adverse events if not meeting Inclusion Criteria
- Randomized Controlled Trial: blinded
Discussion Stimulus Questions

- **Function**: what should this Network be able to do well?
  - Enrollment standardized
  - Randomization
  - Generalizable
  - Outcome determination: accurate/standardized
Discussion Stimulus Questions

• **Functions**: What are the general and specific needs that must be accounted for in study design?
  – Central Randomization
  – DSMB
  – Monitoring
  – Electronic CRF
  – EMS involvement
  – Multi-center
Discussion Stimulus Questions

- **Structure**: given the above functional needs that may impact structural design, what are the considerations about optimal structure?
  - CTSA vs. Disease Network
  - Difficulty in establishing network de novo
  - Not all sites may have CTSA
  - Which may optimize different functional goals (ie centralized image interpretation, outcome determination etc.)
Discussion Stimulus Questions

• **Evaluation**: How should this Network be Evaluated?
  – Time to all sites with IRB approval
  – Time to all sites enrolling
  – Time to 50% enrollment done
  – % of sites meeting enrollment goals
  – # of patients with all data complete per time
  – % of patients enrolled per all screened
  – Manuscripts
  – Subsequent grants
  – Junior investigator development
  – Does the intervention have a positive c effect?