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?