What could we do with a “Comparative Effectiveness” (CER) ARC?

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Overview

• What is CER?

• How could an ARC promote CER at BUSM?

• Examples: What could we do with a CER ARC?
Comparative Effectiveness Research (CER)

- Clinically relevant, real-world research

“inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care”
CER Simplified

1. What is the problem/disease of interest?
2. What are health care providers/systems currently doing for this problem?
   – i.e., Practice pattern variation
3. Which practice pattern results in best outcome for this problem?
   – Systematic reviews, observational studies, RCTs
4. CER for best method to implement evidence!
How could an ARC help?

- Establish a virtual home for CER at BUSM
How could an ARC help?

- Establish a virtual home for CER at BUMC
How would an ARC help CER@BU?

• **Consolidate** ➔ increase efficiency/productivity
  – Databases, programmers, mentors

• **Collaborate** ➔ increase significance & innovation
  – More disciplines and care settings
  – More cross-fertilization of methodologies

• **Catalyze** ➔ increase funding
  – Nimble response to *changing priorities*
What specifically could a CER ARC do?

• Discussion potential directions today

• Develop novel CER program:
  1. Studies optimal processes of care
  2. Innovates methodology
  3. Provides a complementary site for CER training
• Real World=Processes of Care

• What are most effective ways of managing complex conditions in complex patients across multiple sites and providers?
An example proposal...

Comparative effectiveness of processes of care among critically ill patients
Why ICUs may be good place to start

• Manage patients with multiple comorbidities, new organ failures across multiple locations
  – Inclusive of multiple specialties
  – Yet specific population of interest...

• High Stakes
  – Unfortunately, most mortality and most $$$
  – Life vs Death; Quality of Life vs. Quality of Death
The ICU is a hard place for traditional RCTs

- Time sensitive
- Volatile
- Patient can’t consent
- At BMC 10% with NO ONE to represent them!
Need new methods to improve ICU

• Novel Effectiveness RCT designs
  – ‘Learning hospital’
    • Consent
  – Cluster-randomized trial
    • May not require consent
    • $$ $$

• Better Observational Designs
  – Require better data
  – Better methodology
A Case for Studying Severe Sepsis

1 million admissions 2011
1 in 4 die in-hospital
$18K/hospitalization

Infection

SEPSIS

Systemic Inflammatory Response Syndrome
1. fever/hypothermia
2. leukocytosis/leukopenia
3. tachypnea
4. tachycardia

Severe Sepsis

Acute Organ Dysfunction
A Case of Severe Sepsis

ER: RUQ pain
- Labs, Antibiotics, Surgery consult

ICU
- Central IV, Pressors, Mechanical Ventilation

Intervent Radiology
- Gall bladder drain, develops MI, Delirium

ICU
- Renal, Cardiology, GI, Psych Consult, family mtg

ICU
- Dialysis, Endoscopy

ICU
- Palliative Care consult, family mtg

Medical Floor
- Comfort care
ICU=Multiple Stakeholders

• In that 1 severe sepsis case alone:
  – 4 sites of care
  – 9 specialties
  – 6 procedures
Why study Severe Sepsis?

We are doing better.

Walkey AJ et al. Under review.
We are doing better?

• How? Why?

• 20 years, 36 Multicenter RCTs of novel sepsis treatments, 30000 subjects, $100s millions

  – None have yielded a new effective treatment
Better *Processes* of Care?

What are we doing that is working?

Can we do *more* of it?

Where should we target QI funds?
Better processes? Practice make perfect.

Walkey AJ et al. Under review.
What are they doing that works?

Walkey AJ et al. Under review.
Specific Potential Project Examples

• Compare outcomes associated with process of care variation in severe sepsis:
  ➔ timing/utilization of antibiotics, fluids
  ➔ timing/utilization of procedures
  ➔ high utilizer vs. low utilizer hospitals
Develop Related Methodology

• Novel data sets
  – EPIC or i2b2 critical care

• How best to deal with?
  – Variable ICD-9 validity
  – DNR status in administrative data
  – Hierarchical data structures
Other areas leveraging BUMC strengths

• Different processes at “Safety Net Hospitals”? — Different outcomes?

• CER drug/ETOH abuse
  • How does ICU survival bend life trajectory of substance abusers?
  • What processes/treatments are associated with better outcomes?
Summary: CER ARC

Enhanced Faculty Recruitment → Greater Collaboration → More Efficient Resource Use

Wider Institutional Recognition → Improved Trainee Involvement → Expanded Funding opportunity

Methodologic Advances → Enhanced Faculty Recruitment
Conclusion

• ARC=Complementary nidus of CER research @BU

• Example Proposal: Critical Care Processes
  – Further discussions today

• Hope to attract diverse stakeholders with interest in developing:
  • Content
  • Methodology
  • Training