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*

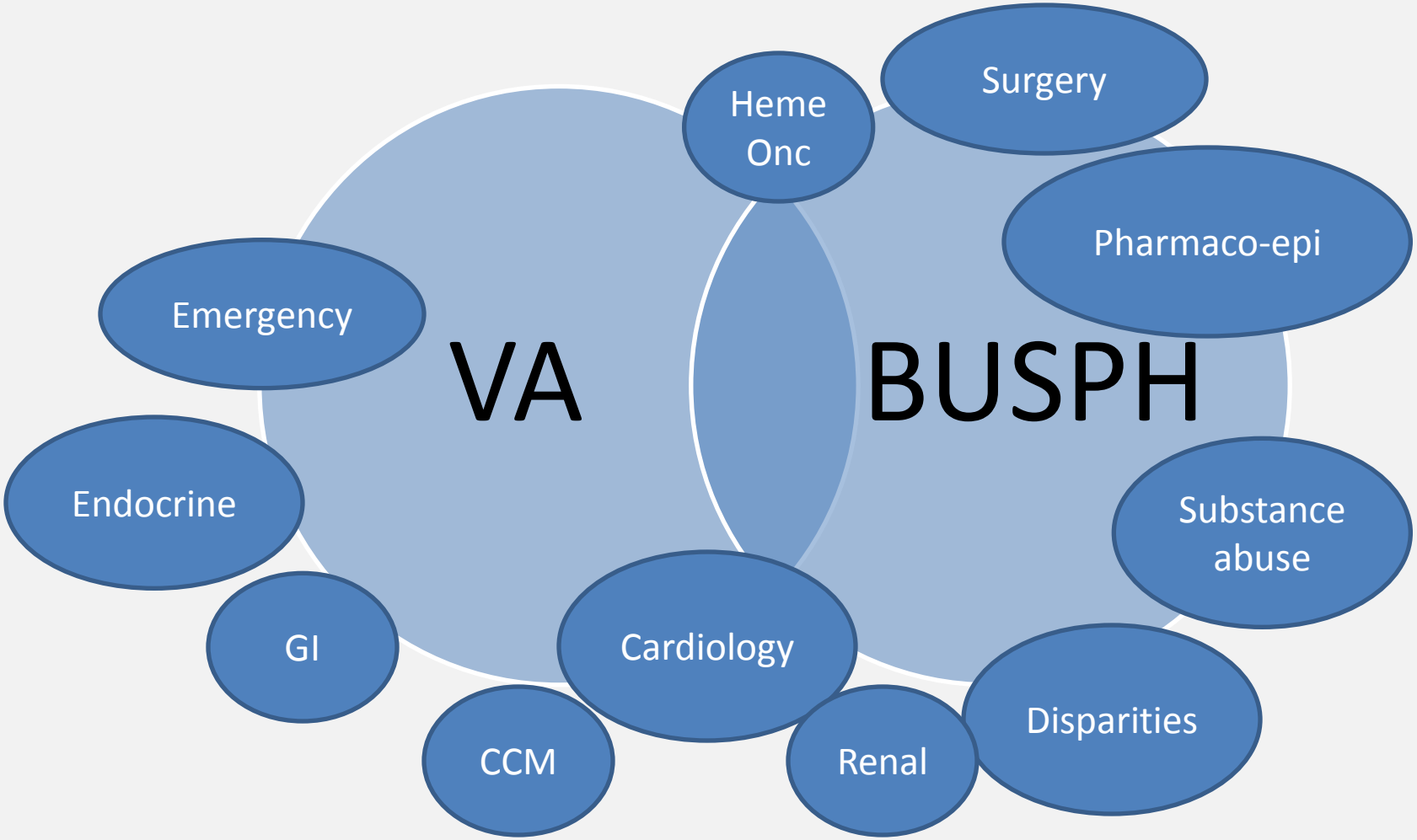
"**inform health-care decisions by providing evidence on** the **effective**ness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or **ways to deliver health care**"

CER Simplified

1. What is the problem/disease of interest?
2. What are health care providers/systems currently doing for this problem?
   - ie., 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?

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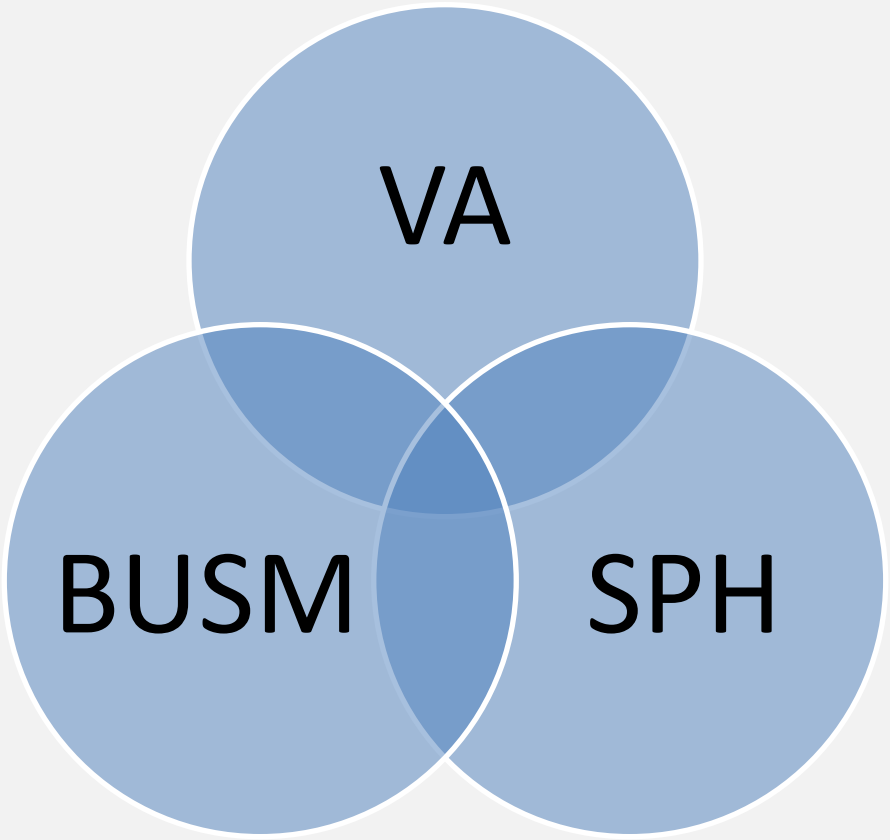


How would an ARC help CER@BU?

- **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

PERSPECTIVE

COMPARATIVE EFFECTIVENESS — THINKING BEYOND MEDICATION A VERSUS MEDICATION B

Comparative Effectiveness — Thinking beyond Medication A versus Medication B

Kevin G. Volpp, M.D., Ph.D., and Anup Das

N ENGL J MED 361;4 NEJM.ORG JULY 23, 2009

- 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…

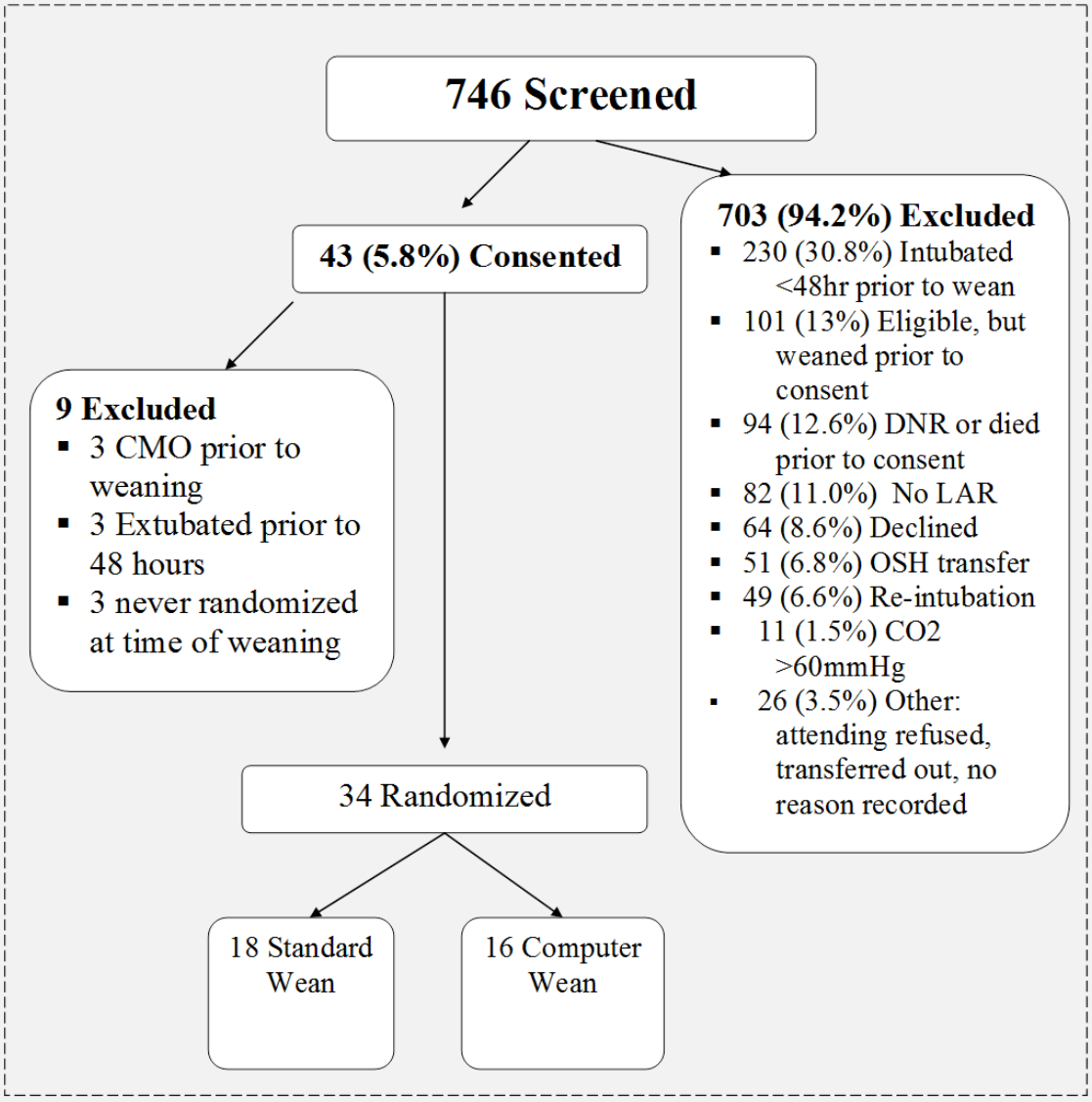
Comparative effectiveness of processes of care among critically ill patients

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

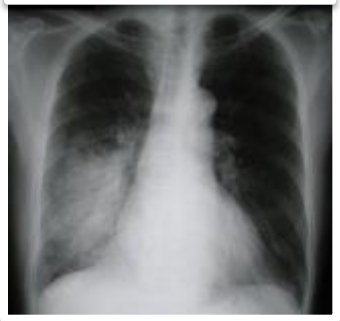
$18K/hospitalization

H-CUP

SEPSIS

Severe Sepsis

Infection



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Systemic Inflammatory Response Syndrome

1. fever/hypothermia
2. leukocytosis/leukopenia
3. tachypnea
4. tachycardia

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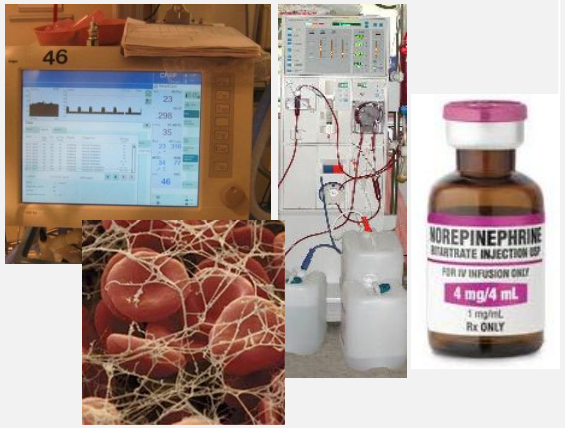
Acute Organ Dysfunction



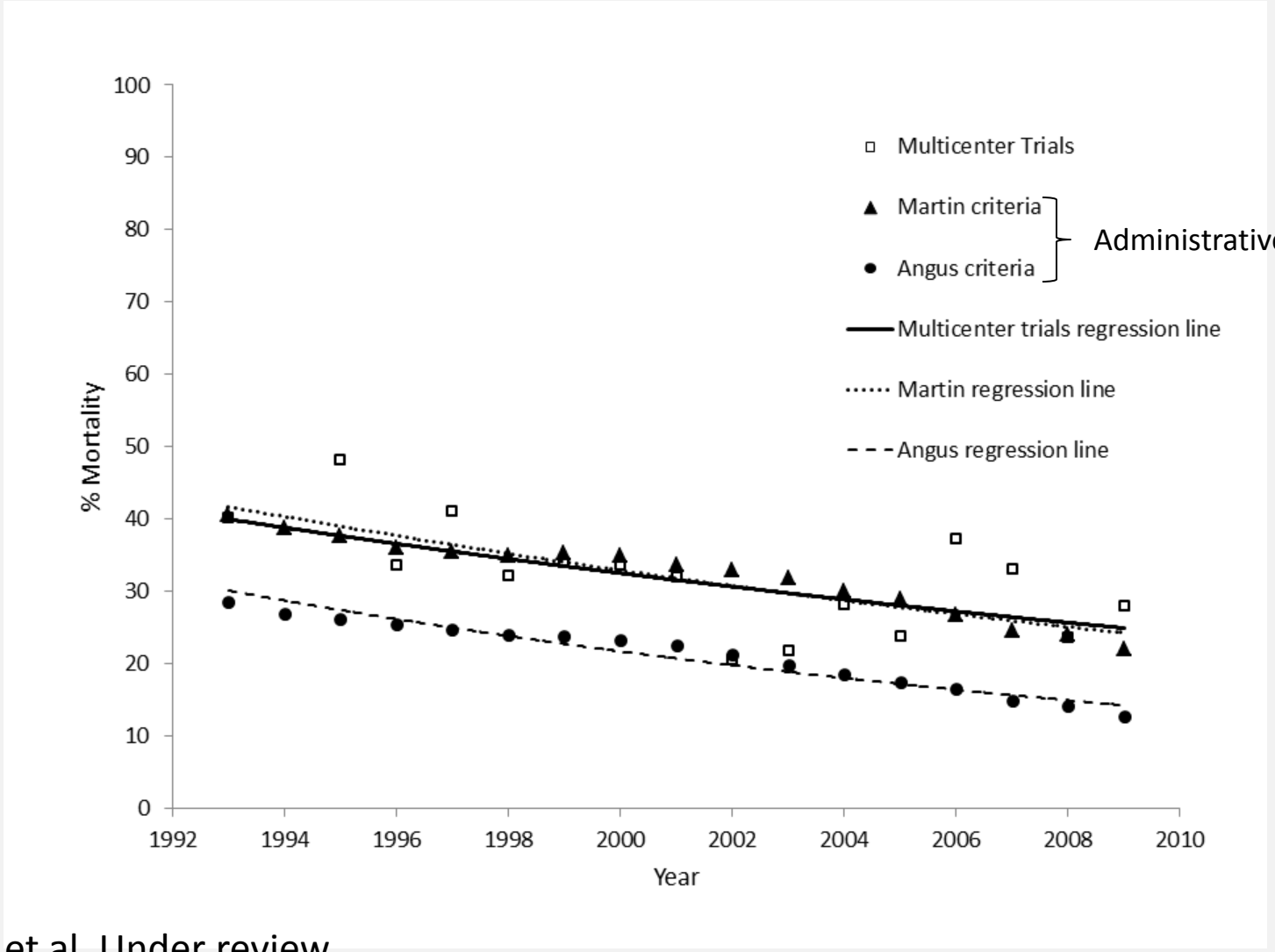
A Case of Severe Sepsis

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*

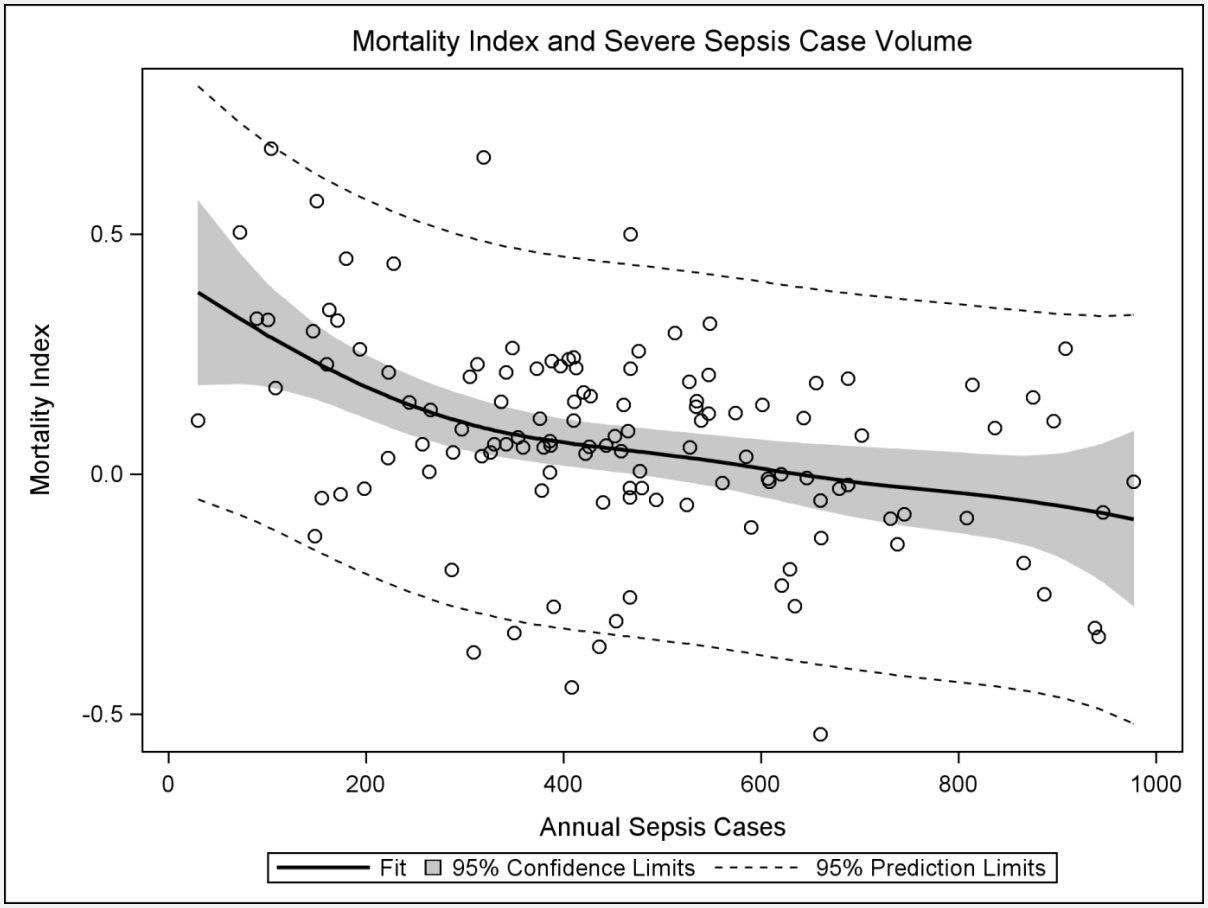
Better *Processes* of Care?

What are we doing that is working?

Can we do *more* of it?

Where should we target QI funds?

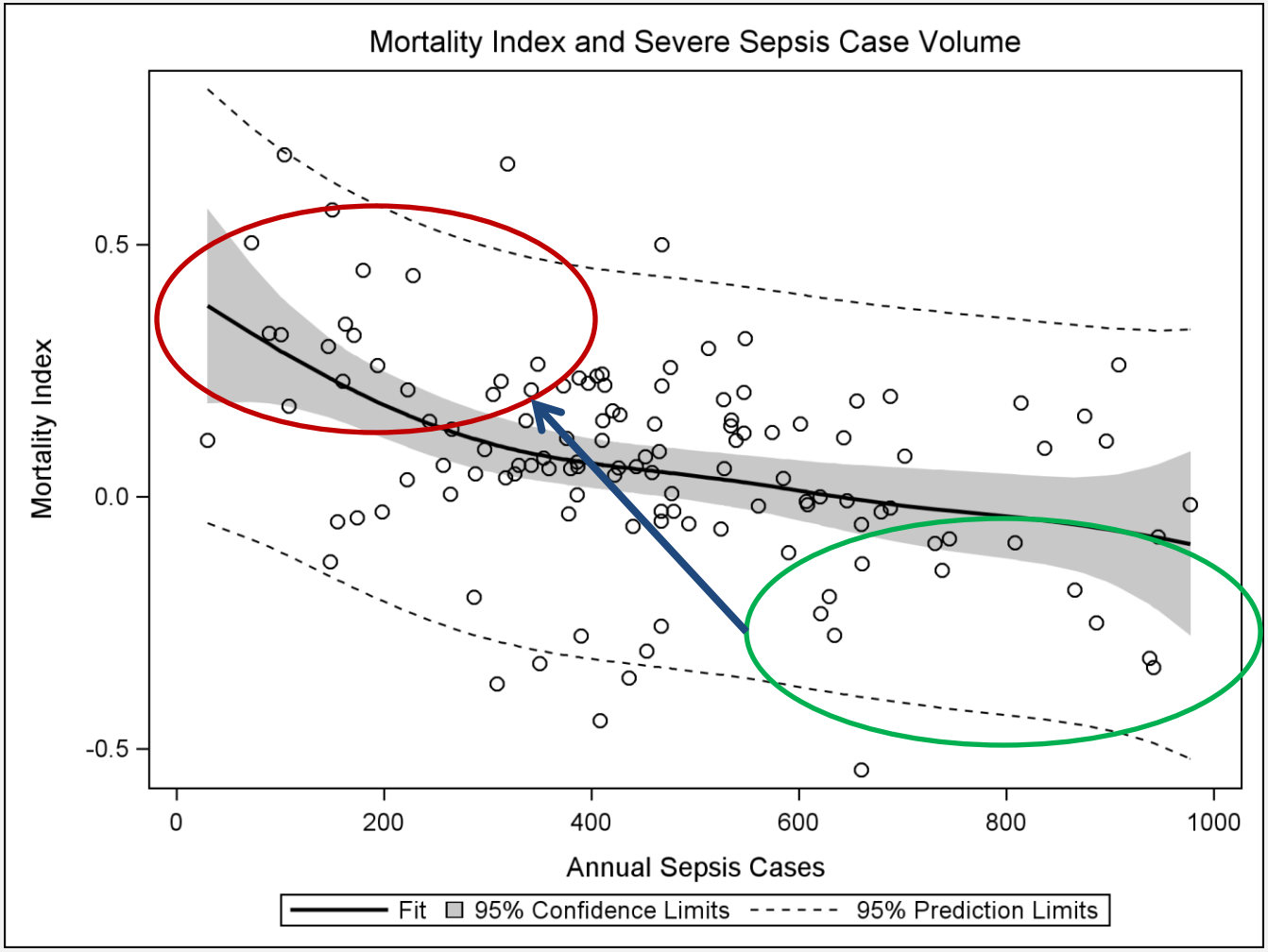
Better processes? Practice make perfect.



= US academic hospital

Walkey AJ et al. Under review.

What are they doing that works?



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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

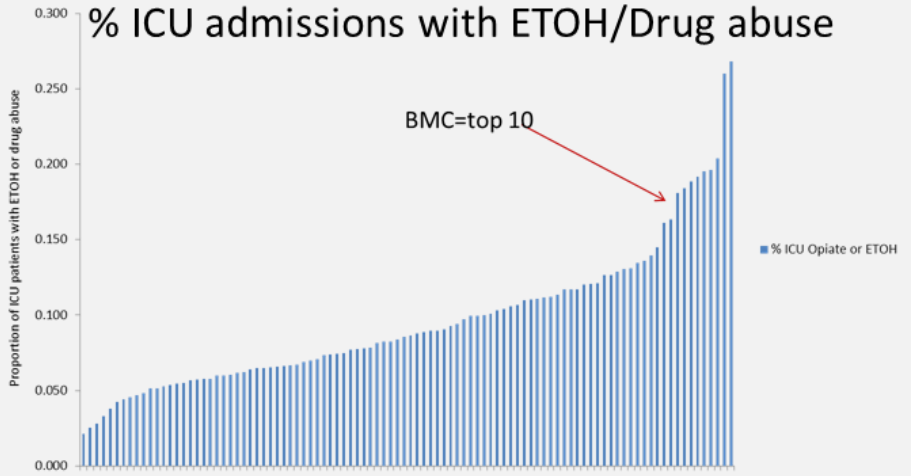
Develop Related Methodology

- 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

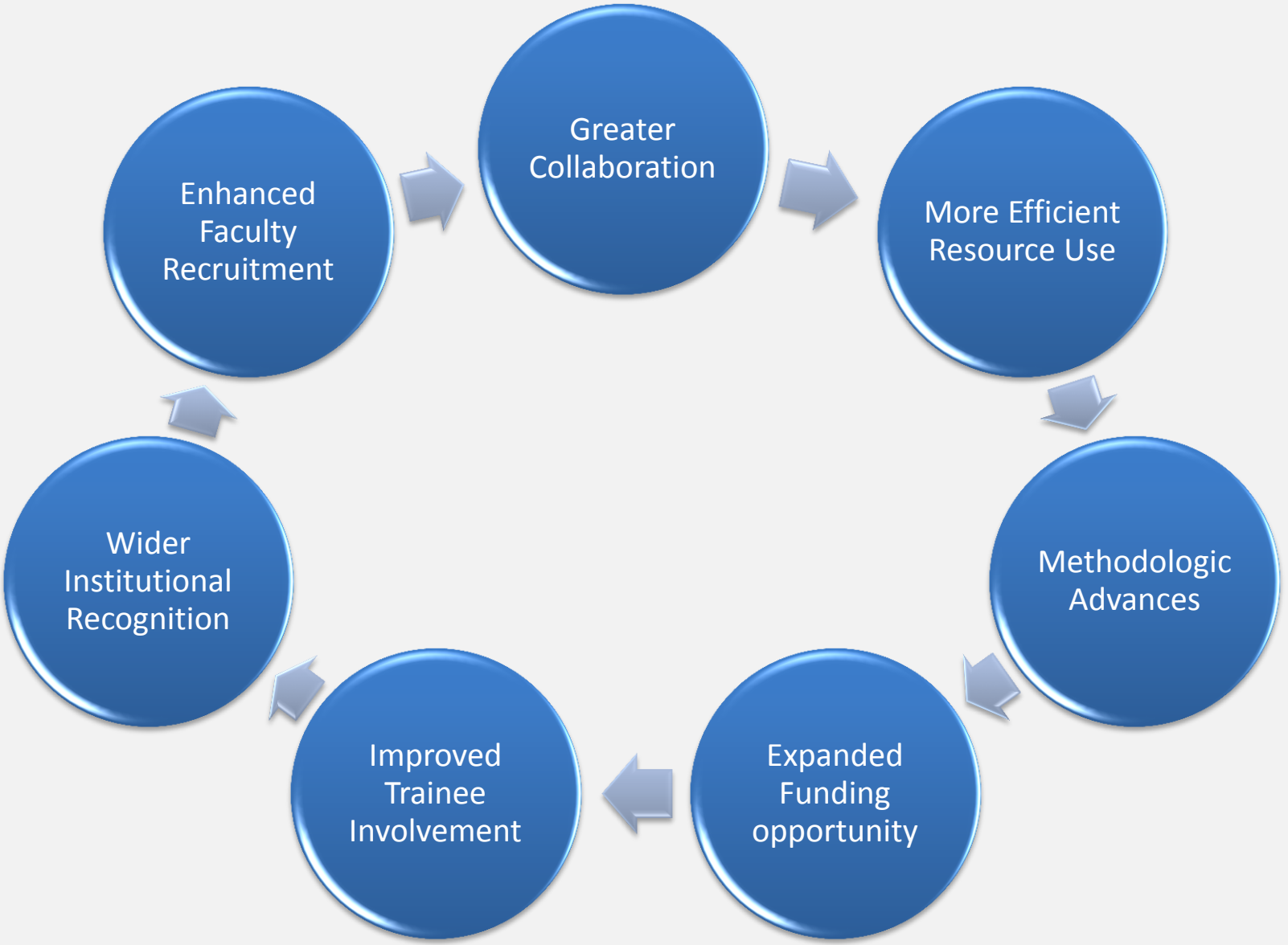
Other areas leveraging BUMC strengths

- 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



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