Downstairs, Upstairs, and Beyond: Conducting Transdisciplinary Research at the ED-ICU Interface

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May 16, 2019
Disclosures

• No COI to declare for this presentation

• Funding (EM & CCM overlap)
  • NIH/NHLBI Award #1K23HL130648 (current)
  • NIH/NHLBI Award #1K12HL109005: Mount Sinai Emergency Medicine Research Career Development Program (completed)

• Site PI, NIH/NHLBI U01 Prevention and Early Treatment of Acute Lung Injury (PETAL): Montefiore/Mount Sinai Clinical Center for the PETAL Network

• Scientific Advisor/Consultant for Mount Sinai Data Warehouse / Department of Scientific Computing

• Mentor Backgrounds: EM, CCM, Palliative care, Health services research, Operations research, Operations management, Health care delivery science, Cognitive science
The evolving schema of research

Single disciplines

Multi-disciplinary

Interdisciplinary

Transdisciplinary
Transdisciplinary research

“Transdisciplinary research represents a promising approach for advancing knowledge translation in relation to complex, multifactorial health problems that often exceed the capacity of any single discipline.”

– Archibald et al, BMJ Open 2018

1 Archibald MM, Lawless M, et al. BMJ Open 2018;8: e021775
ED-ICU Interface

Triage → ED Course → Wait for ICU bed → ICU Course → Ward Course → Home or ECF

DC
Process & outcome metrics

- Patient-centered outcomes
- Care delivery metrics
- ED care significantly contributes to downstream outcomes

Figure 1: Odds of persistent organ dysfunction and/or death with increasing wait time for admission

\[ \text{OR} = 1.77 (95\% \text{CI } 1.07, 2.95) \text{ per log 10 hour increase} \]

Figure 2: Range of tidal volume settings (Cc/kg IBW) through ED and early ICU course

1 Mathews KS, Durst MS, Vargas-Torres C, et al. CCM 2018
Data sources & resources

- Operationalize your problem of interest with a transdisciplinary team
- Leverage existing efforts and infrastructure
  - Hospital performance dashboards & quality metrics
  - Informatics & Data Warehouse
  - CTSA & clinical analytics
- Define and utilize common data elements to all disciplines
Panel for today

- **Kusum Mathews** – IM trained, PCCM fellowship, MS in Clinical Research (EM K-12)
  - MICU 25% / Research 75%

- **Mahshid Abir** – EM trained, MS in Health Services Research (RWJ Scholar)
  - ED 20% / Research 80%

- **Thomas Terndrup** – EM/PEM trained, Physiology fellowship
  - ED 30% / Research 70%

- **Ani Aydin** – EM trained, Shock-Trauma fellowship
  - ED 30% / SICU 40% / Med Director of Crit Care Transport Program 30%
Essential Building Blocks for Inter-Disciplinary Research: Methods & Partnerships

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Director | Acute Care Research Unit
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Disclosures

• No conflicts of interest to disclose

• The Acute Care Research Unit is supported by University of Michigan Department of Emergency Medicine and funds from grants and contracts:
  • NIH
  • RWJF
  • Michigan Medicine
  • MidMichigan Alpena
ACUTE Care Research Unit
Unifying the Delivery of Acute Care Along its Continuum
Acute Care Delivery: Clinical and Research Silos

• Acute care delivery in the US occurs in the Ambulatory, Pre-Hospital, Emergency Department, and Inpatient settings

• Both clinical care and research in these care delivery sites largely occur in silos
Inter-disciplinary health services research across the care continuum can produce insights and strategies to improve outcomes through informing policy and practice.

- Access
- Costs
- Utilization
- Transitions
- Effectiveness
Key Ingredients for Inter-disciplinary Research Across the Care Continuum

- Multi-Care Delivery Site
- Multi-Stake-Holder
- Mixed-Methods
- Multi-Organizational
Methods Toolkit for Inter-disciplinary Research

- Quantitative methods
- Qualitative methods
- Mixed methods
- Community-/stakeholder-based participatory research

https://www.google.com/search?q=mixed+research+methodology&rlz=1C1GCEA_enUS844US844&source=lnms&tbm=isch&tbs=isch&sa=X&ved=0ahUKEwiXlOOGA9DvAhXogKkLHRw0Af0Q_AUIDigB
Putting Together the Team

• Key collaborators
  • Methods experts
    ▫ Quantitative
    ▫ Qualitative
    ▫ Mixed
  • Content experts
    ▫ Condition
    ▫ Population-Specific
    ▫ Care-Delivery Setting
  • Stakeholders
    ▫ Community
    ▫ Government
    ▫ Providers

Inter-Stakeholder Relationships
ED Physicians
EMS Providers
Hospital Care
Inpatient
Ambulatory Care
Pre-Hospital Care
Emergency Department
ACUTE CARE CONTINUUM
Transitions of Care
Community
Hospital Administrators
Projects

Patient-centered Interventions to Reduce Acute Care Use

Real-time Surveillance System for Opioid Overdose

Evaluating Best Practices for EMS Oversight

Evaluating the Social Needs of Acute Care Super-Utilizers

Acute Care Delivery Redesign
Transdisciplinary Clinical Trials

Peter Hou, MD

Division of Emergency Critical Care Medicine
Department of Emergency Medicine
Disclosures

• No COI to declare for this presentation

• Co-PI, NIH Acute Lung Injury Group of New England (ALIGNE) Clinical Center (CC) for the NHLBI Prevention and Early Treatment of Acute Lung injury (PETAL) Network

• Member, PETAL Network Steering Committee

• Site-PI, NIH Procalcitonin Antibiotic Consensus Trial (ProACT)

• Site-PI, NIH Protocolized Care for Early Septic Shock (ProCESS)

• Site-PI, United States Critical Illness and Injury Trial Group (USCIITG) Lung Injury Prevention Study (LIPS) Investigator
Setting Up The Project

Governance: Stakeholders

• DEM Chair/Vice-Chair/ Director of Research; Research Manager/Coordinators; Grant Administrator; Nursing Director/Educator;

• ICU Directors/Nursing Directors/Educators

• Hospital IRB Chair/Research Management

• Hospital Information System

• Hospital Lawyer
Setting Up The Project

Budget: Agreement

• Be EXPLICIT on the MONEY flow
  • (for who/what, why, when, and how)
• Create a "Profit & Loss" balance sheet
• Are you and/or transdisciplinary team allowed to create a sundry fund?
• What is your research buy-down process?
Setting Up The Project

Governance Model: Surgical ICU Translational Research

- Departments of Anesthesia/Surgery/ Medicine/Emergency Medicine
- Sundry Fund – clinical revenue “surpluses"
  - Hired 1 biostatistician/3 research coordinators
- Supported staff’s and fellows’ research and fellows’ and residents’ education
Setting Up The Project

Governance Model: Brigham Critical Care Research Collaborative & Consortium

• Divisions of Emergency and Pulmonary Critical Care Medicine (6 Co-Is, 1 Post-doc)

• Funding from PETAL Network trials funnels through the Dept of EM
  • Hired 2 ICU research coordinators
  • Subcontracted ED research coordinators
Setting Up The Project

Research Pearls/Pitfalls:

• Plan for meeting/not meeting projections
  • Timeline
  • Deliverables (i.e., subject enrollment, f/u)
  • Budget (black, neutral, red)

• Contingency plan when your department is meeting/not meeting its budget
Transdisciplinary clinical trials: Running the project(s)

May 16, 2019

Thomas E. Terndrup, MD, Professor
Department of Emergency Medicine
Ohio State University, College of Medicine
Prior Team Science participation
(no other declared COI)

• Post-doctoral Scholar, Respiratory Physiology, Dartmouth SOM
• Public Access to Defibrillation (NHLBI), PI Alabama & Syracuse
• Resuscitation Outcomes Consortium (NINDS, NHLBI), PI Alabama
• Health Care Facilities Partnership (ASPR, DHHS), PI, Pennsylvania
• Rural Embedded Assistance for Community Health (PaDOH), PI
• ProCESS trial (NIGMS), local PI, Penn State
• ProACT trial (NIGMS), local PI, Ohio State
• PETAL network (NHLBI), clinical center PI, Ohio
Running the Project: & doing well!

• Funding & Collaborators
  • Driven by ENROLLMENT & interdisciplinary relationships
  • Some infrastructure & expect constrained funding

• Pragmatic clinical trials
  • Important, straightforward questions, few exclusions, phenotype physiologic
    • Seek clinical equipoise for interventional designs
    • Ensure adequate support, PRIOR to study
  • Sponsors looking for efficient designs

• Where are we bending the scientific acute care curve?
  • Sepsis, lung injury, respiratory failure, emergency oncology, pediatrics, resuscitation, injury, public health, mental illness, others
What’s going on out there?

• **Networks:**
  - PAD, ROC, NETT, *United States Critical Illness* and Injury Trials Group *Critical Illness* Outcomes Study (USCIITG-CIOS), PECARN, Strategies to Innovate Emergency Care Clinical Trials Network (SIREN), PETAL, LITES (Linking Investigators in Trauma and Emergency Services), CONCERN

• **Structure:**
  - Office of Emergency Care Research (NINDS), CTSI/NCATs, Trial Innovation Network, Network-of-Networks (*Resilience Intelligence Network*)

• **What other opportunities are probable?**
  - Focus on efficiencies clinical research design – common controls for multiple interventions
  - CTSA – TIN, RIC, technology vouchers

• **What challenges must be met to increase progress on human health?**
  - Infrastructure, mission priority, best questions/hypotheses
  - Set author and contributor ship EARLY.
Potential pitfalls & suggestions

• Unable to recruit
  • Determine why
  • Educate, address equipoise, go to bedside, support coordinators
  • Anticipate trials where clinical passion and conventional wisdom present
  • Over-estimates of ability to participate

• Budget does not support required efforts
  • Seek clarity
  • Reach out locally for cooperation & engagement

• Some important opportunities can not be completed
  • Prioritizing IT needs
  • Cooperation and potential trial conflicts addressed in advance
Why should I participate?

• Curiosity & improve scientific basis for emergency care
• Research support & expand network
• Academic recognition
  • Authorship -
  • Contributor ship
  • Does your leadership recognize this?

• Questions?
Thank You

Thomas.Terndrup@osumc.edu
Multi-author group publications

• When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication.

• All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete conflict-of-interest disclosure forms. Some large multi-author groups designate authorship by a group name, with or without the names of individuals. When submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists, and clearly identify the group members who can take credit and responsibility for the work as authors.

• The byline of the article identifies who is directly responsible for the manuscript, and MEDLINE lists as authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators.
Non-author Contributors

• Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. “Clinical Investigators” or “Participating Investigators”), and their contributions should be specified (e.g., “served as scientific advisors,” “critically reviewed the study proposal,” “collected data,” “provided and cared for study patients”, “participated in writing or technical editing of the manuscript”).

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National Center for Advancing Translational Sciences (NCATS)

• NCATS' mission is to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

• NCATS is improving health through smart science. The goal is to get more treatments to more patients more quickly. The Center develops, demonstrates and disseminates innovations that reduce, remove or bypass system-wide bottlenecks in the translational process. NCATS focuses on what is common across diseases and collaborates with other government agencies, including other NIH ICs; industry; academia; and patient support organizations.
The Clinical and Translational Science Awards (CTSA) Program supports a national network of medical research institutions — called hubs — that work together to improve the translational research process to get more treatments to more patients more quickly. The hubs collaborate locally and regionally to catalyze innovation in training, research tools and processes.

CTSA Program Clinical Studies

• Through CTSA Program hubs, NCATS supports activities to test and develop innovative approaches to barriers in clinical research. One example is the efficient recruitment of research participants and institutional review board (IRB) approvals for multisite clinical trials. Ongoing approaches include the following:
  
  • The Trial Innovation Network is a collaborative initiative composed of three key organizational partners:
    • Trial Innovation Centers
    • Recruitment Innovation Center
    • CTSA Program hubs
  
  • NCATS’ vision for the Trial Innovation Network is to address critical roadblocks in clinical trials and to accelerate the translation of novel interventions into life-saving therapies. Features will include a single-IRB system, master contracting agreements, quality-by-design approaches and a focus on evidence-based strategies to recruitment and patient engagement.

  • The NCATS Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Platform is a single-IRB reliance platform for multisite clinical studies. The goal is to provide flexible resources that investigators nationwide can use to harmonize and streamline IRB review for their own multisite studies. The platform is based on the successful experiences of NIH central IRB initiatives and on a CTSA Program demonstration project using a single-IRB reliance model called IRBrelly. The NCATS SMART IRB Platform is designed to be a flexible option that can be used to set up a central IRB for a network of many studies or a single IRB for one multisite study.

  • These and similar activities are intended to improve the quality and speed of clinical research in the CTSA Program network for a broad range of research studies, with the ultimate goal of bringing more evidence-based treatments to more patients more quickly.