Creation of a Translational Science Platform to Foster a Learning Health Care System within the Vanderbilt University Medical Center Enterprise

CTSA/VICTR Initiative

PCC and CEG Engagement
Interaction and Information Flow Goal – Working toward Enhanced Integration
CTSA Learning Health Care System “Platform”

Studies run through reusable platform

TRANSLATIONAL SCIENCE PLATFORM

STUDY SPECIFIC TAILORING

Pragmatic Research Studio
protocol customization
endpoint selection

CREATE REUSABLE FIXED INFRASTRUCTURE

institutional and regulatory policy, master protocols
clinical decision support, clinical registries
real-time EHR data capture with coupled REDCap support
expert cores, studios, standing DSMB

Scientific Review
LHS Council

Intervention 1

Intervention 2

Intervention n

Improved Outcomes?

NO
Publish
De-implement

YES
Implement
& Publish

Studies run through reusable platform

Improved Outcomes?

NO
Publish
De-implement

YES
Implement
& Publish

Studies run through reusable platform

Improved Outcomes?

NO
Publish
De-implement

YES
Implement
& Publish
How do we achieve this at VUMC?

CTSA Priority Score: 12

Achieves grant funding for all supportive personnel effort (e.g. coordination, evidence synthesis, regulatory)

- promote discovery as routine course in health care delivery
- encourage innovation and ideas from all clinical areas
- support and develop research endeavors to answer real world questions
- enhance quality and safety
- embrace change implementation
Informed Consent

• Waiver of Informed Consent considered when:
  – Minimal Risk
  – Waiver does not adversely affect the rights or welfare of the participants
  – Consent Impracticable
  – When appropriate, participants will be provided with additional pertinent information after participation
Learning System in Action at VUMC

Meaningful research can be operationally OVERLAID
And without delaying implementation

Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

Chlorhexidine Bathing and Health Care–Associated Infections
A Randomized Clinical Trial

Michael J. Noto, MD, PhD; Henry J. Domenico, MS; Daniel W. Byrne, MS; Tom Talbot, MD, MPH; Todd W. Rice, MD, MSc; Gordon R. Bernard, MD; Arthur P. Wheeler, MD

Design

- **Design**: cluster randomized, multiple crossover trial
- **Setting**: five VUMC ICUs from July 2012 through July 2013
- **Participants**:
  - **Inclusion**: all patients admitted to participating ICUs
  - **Exclusion**: burns, TEN/SJS, known chlorhexidine allergy
- **IRB approval with waiver of consent**
Intervention

• All patients bathed daily with no-rinse cloths:
  – impregnated with chlorhexidine
  – without chlorhexidine

• All other infection control procedures were performed according to usual practice of each ICU for the duration of the study
Prespecified primary outcome

• Composite rate of healthcare-associated infections
  – CLABSI
  – CAUTI
  – *C. difficile* infection
  – VAP

• All outcomes used existing hospital mechanisms for data collection

• Infection-related outcomes adjudicated by infection control personnel
  – Blinded to treatment assignment
  – Used CDC-NHSN definitions
Control

Chlorhexidine

Units randomized to bathing sequence

10,783 patients admitted

Cardiovascular

Medical

Neuro

Surgical

Trauma

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

9,340 intention to treat population

0 met exclusion criteria

1443 admitted during washout excluded

Chlorhexidine n=4448

Control n=4852

Control n=2126

Control n=2327

Control n=1723

Chlorhexidine n=1272

Chlorhexidine n=1892

Control n=2327

Chlorhexidine n=1892
Cardiovascular Medical Neuro Surgical Trauma

10,783 patients admitted

Units randomized to bathing sequence

0 met exclusion criteria

Control Chlorhexidine Control Control Chlorhexidine

Chlorhexidine n=1723 Chlorhexidine n=1272 Chlorhexidine n=2126

Control n=2327 Control n=1272 Control n=2126

Chlorhexidine n=1892 Chlorhexidine n=1723 Chlorhexidine n=2126

Control n=2327 Control n=1723 Control n=2126

1443 admitted during washout excluded

9,340 intention to treat population

Chlorhexidine n=4448 Control n=4852
Control

Chlorhexidine

Units randomized to bathing sequence

0 met exclusion criteria

Cardiovascular

Medical

Neuro

Surgical

Trauma

10,783 patients admitted

Chlorhexidine

n=1892

Control

n=2327

Chlorhexidine

n=1723

Control

n=1272

Chlorhexidine

n=4448

Control

n=4852

9,340 intention to treat population

1443 admitted during washout excluded
10,783 patients admitted

Units randomized to bathing sequence

0 met exclusion criteria

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

9,340 intention to treat population

1443 admitted during washout excluded

Chlorhexidine n=4448

Control n=4852
Control

Chlorhexidine

Units randomized to bathing sequence

0 met exclusion criteria

Cardiovascular

Medical

Neuro

Surgical

Trauma

10,783 patients admitted

Control

Chlorhexidine

Control

Control

Chlorhexidine

Control

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

Chlorhexidine

Control

9,340 intention to treat population

1443 admitted during washout excluded

Chlorhexidine n=4448

Control n=4852
10,783 patients admitted

Units randomized to bathing sequence

0 met exclusion criteria

Cardiovascular Medical Neuro Surgical Trauma

Control Chlorhexidine Control Chlorhexidine Chlorhexidine Control Chlorhexidine

Chlorhexidine n=1892 Control n=2327 Chlorhexidine n=1723 Chlorhexidine n=1272 Control n=2126

1443 admitted during washout excluded

9,340 intention to treat population

Chlorhexidine n=4448 Control n=4852
Cardiovascular  Medical  Neuro  Surgical  Trauma

10,783 patients admitted

Units randomized to bathing sequence

0 met exclusion criteria

Control

Chlorhexidine
n=1723

Control

Chlorhexidine
n=1272

Control

Chlorhexidine
n=2126

Chlorhexidine

Control

Chlorhexidine
n=4448

Control

Chlorhexidine
n=4852

2-week washout

1443 admitted during washout excluded

9,340 intention to treat population

Chlorhexidine
n=4448

Control
n=4852
10,783 patients admitted

Units randomized to bathing sequence

- Control
- Chlorhexidine (n=1272)
- Control (n=2126)
- Chlorhexidine (n=2327)
- Control (n=4852)
- Chlorhexidine (n=4448)

0 met exclusion criteria

Cardiovascular: 1443 admitted during washout excluded

Medical

Neuro

Surgical

Trauma

9,340 intention to treat population
Control Chlorhexidine n=1723

Units randomized to bathing sequence

Chlorhexidine Chlorhexidine Control Control Chlorhexidine Control

Control Chlorhexidine Control Chlorhexidine Control Chlorhexidine Control

Chlorhexidine n=1892 Control n=2327 Chlorhexidine n=1723 Chlorhexidine n=1272 Chlorhexidine n=2126

9,340 intention to treat population

10,783 patients admitted

0 met exclusion criteria

1443 admitted during washout excluded

Chlorhexidine n=4448 Control n=4852
10,783 patients admitted

Units randomized to bathing sequence

0 met exclusion criteria

Cardiovascular
Medical
Neuro
Surgical
Trauma

Control
Chlorhexidine
Chlorhexidine
Control
Chlorhexidine
Control
Chlorhexidine
Control
Chlorhexidine

Control
Chlorhexidine
Control
Chlorhexidine
Control
Chlorhexidine
Control
Chlorhexidine

Chlorhexidine
n=1892

Control
n=2327

Chlorhexidine
n=1723

Control
n=1272

Chlorhexidine
n=2126

Chlorhexidine
n=4448

Control
n=4852

9,340 intention to treat population

1443 admitted during washout excluded
Chlorhexidine Bathing and Health Care–Associated Infections: A Randomized Clinical Trial

MJ Noto and coauthors

Chlorhexidine Bathing and Health Care–Associated Infections: A Randomized Clinical Trial

Published online January 20, 2015

Available at jama.com and on The JAMA Network Reader at mobile.jamanetwork.com
Conclusion

These findings do not support daily bathing of critically ill patients with chlorhexidine.
Balanced Crystalloids versus Saline in the Intensive Care Unit: The SALT Randomized Trial

Matthew W Semler, Jonathan P Wanderer, Jesse M Ehrenfeld, Joanna L Stollings, Wesley H. Self, Edward D Siew, Li Wang, Daniel W Byrne, Andrew D Shaw, Gordon R. Bernard, Todd W Rice, and for The SALT Investigators and the Pragmatic Critical Care Research Group

Am J Respir Care Med. 2016. DOI: 10.1164/rccm.201607-1345OC
The Challenge:

• Enroll >5,000 ICU patients
• Control delivery of a time-sensitive intervention
• Collect patient-level fluid, lab, outcome data
The Challenge:

- Enroll >5,000 ICU patients
- Control delivery of a time-sensitive intervention
- Collect patient-level fluid, lab, outcome data

Traditional Approach:
- Half a decade
- Hundreds of personnel
- Dozens of centers
- Millions of dollars
The Challenge:

- Enroll >5,000 ICU patients
- Control delivery of a time-sensitive intervention
- Collect patient-level fluid, lab, outcome data

Traditional Approach:
- Half a decade
- Hundreds of personnel
- Dozens of centers
- Millions of dollars

Alternative Approach:
- Novel study structure
- Informatics-enhanced:
  - Intervention
  - Data collection
### Study Structure

#### Cluster - Randomized
Each ICU randomized to a Fluid Group ("NS" vs. "balanced")

#### Multiple - Crossover
1 month blocks, 11 crossovers (one year) → 8,000 patients

<table>
<thead>
<tr>
<th></th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2015</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2016</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2017</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MICU</strong></td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
</tr>
<tr>
<td><strong>Neuro</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CVICU</strong></td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
</tr>
<tr>
<td><strong>Trauma</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SICU</strong></td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
</tr>
<tr>
<td><strong>ED</strong></td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
</tr>
</tbody>
</table>
## Study Structure

**X = Normal saline, Y = ‘balanced’ (Plasmalyte or LR)**

<table>
<thead>
<tr>
<th></th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MICU</strong></td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
</tr>
<tr>
<td><strong>Neuro</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
</tr>
<tr>
<td><strong>CVICU</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
</tr>
<tr>
<td><strong>Trauma</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
</tr>
<tr>
<td><strong>SICU</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
</tr>
<tr>
<td><strong>ED</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
<td>X</td>
<td>Y</td>
</tr>
</tbody>
</table>
Delivery of the Intervention

Pharmacy stocks unit preferentially with assigned fluid
Delivery of the Intervention

8T3 is enrolled in the SALT trial.

VUMC is comparing the use of normal saline (NS) with lactated ringer’s (LR) and plasma-lyte (FLA) in ICU patients. Patient [redacted] has been assigned to receive NS for all isotonic fluid orders, unless a contraindication is present.

If a contraindication to NS is present, please select from the list below to order off-study IV fluid. Otherwise, please select option 1 to order NS.

Select an option below:

1. Order normal saline bolus
2. Bypass due to specific attending request
3. Exit Without Ordering

Pharmacy stocks unit preferentially with assigned fluid.
Delivery of the Intervention

8T3 is enrolled in the SALT trial.

VUMC is comparing the use of normal saline (NS) with lactated ringer’s (LR) and plasma-lyte (FLA) in ICU patients. Patient __________ has been assigned to receive NS for all isotonic fluid orders, unless a contraindication is present.

If a contraindication to NS is present, please select from the list below to order off-study IV fluid. Otherwise, please select option 1 to order NS

Select an option below:

1. Order normal saline bolus
2. Bypass due to specific attending request
3. Exit Without Ordering

If assigned to Normal Saline, can bypass for:
- specific attending request

If assigned to Balanced Fluid can bypass for:
- hyperkalemia
- brain injury
- specific attending request

Pharmacy stocks unit preferentially with assigned fluid
MEASUREMENTS AND MAIN RESULTS: Patients assigned to saline (n=454) and balanced crystalloids (n=520) were similar at baseline and received similar volumes of crystalloid by 30 days (2,715 ± 4,073 mL vs 3,157 ± 5,069 mL; P = 0.40). MAKE30 did not differ between groups (24.7% vs 24.6%; P = 0.98).
Video vs. Direct Laryngoscopy in Critically Ill Patients

Patient Level Randomization LHS Project designed by Pulm/CC trainee
Study Design (Fellow Project)

• Open-label, parallel-group, randomized trial
Study Design (Fellow Project)

- Open-label, parallel-group, randomized trial
- Video Laryngoscopy vs. Direct Laryngoscopy
Study Design (Fellow Project)

- Open-label, parallel-group, randomized trial
- Video Laryngoscopy vs. Direct Laryngoscopy
- Inclusion:
  - 18 or older
  - being intubated by PCCM fellow
Study Design (Fellow Project)

• Open-label, parallel-group, randomized trial
• Video Laryngoscopy vs. Direct Laryngoscopy
• Inclusion:
  – 18 or older
  – being intubated by PCCM fellow
• Exclusion:
  – awake intubation
  – too emergent to open study envelope
  – specific laryngoscope required
Video Laryngoscopy Improves Glottic Visualization

* *p = 0.001*
Video Laryngoscopy did not Increase First Attempt Success

% Successful on First Attempt

- Direct: 65%
- Video: 68%

$p = 0.683$
Video Laryngoscopy Does Not Decrease Time to Intubation
Randomized Trial of Video Laryngoscopy for Endotracheal Intubation of Critically Ill Adults

David R. Janz, MD, MSc; Matthew W. Semler, MD; Robert J. Lentz, MD; Daniel T. Matthews, MD; Tufik R. Assad, MD; Brett C. Norman, MD; Raj D. Keriwala, MD, MPH; Benjamin A. Ferrell, MD; Michael J. Noto, MD, PhD; Ciara M. Shaver, MD, PhD; Bradley W. Richmond, MD; Jeannette Zinggeler Berg, MD, PhD; Todd W. Rice, MD, MSc; for the Facilitating Endotracheal Intubation by Laryngoscopy technique and apneic Oxygenation Within the ICU Investigators and the Pragmatic Critical Care Research Group

*See also p. 2106.

1Department of Medicine, Section of Pulmonary and Critical Care Medicine Louisiana State University School of Medicine, New Orleans, LA.
2Division of Allergy, Pulmonary and Critical Care Medicine, Department of Medicine, Vanderbilt University School of Medicine, Nashville, TN.


Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal’s website (http://journals.lww.com/ccmjournal).

Supported by a National Heart, Lung, and Blood Institute (NHLBI) T32 award (HL087738). Data collection utilized the Research Electronic Data Capture (REDCap) tool developed and maintained with Vanderbilt Institute for Clinical and Translational Research grant support (U11 TR000446 from NCATS/NIH).

Dr. Janz received support for article research from the National Institutes of Health (NIH). Drs. Semler, Lentz, and Shaver received support for article research from the NIH. Their institutions received funding (Investigators conducting this study were supported by a National Heart, Lung, and Blood Institute [NHLBI] T32 award [HL 087738]). Dr. Norman

Objective: To evaluate the effect of video laryngoscopy on the rate of endotracheal intubation on first laryngoscopy attempt among critically ill adults.

Design: A randomized, parallel-group, pragmatic trial of video compared with direct laryngoscopy for 150 adults undergoing endotracheal intubation by Pulmonary and Critical Care Medicine fellows.

Setting: Medical ICU in a tertiary, academic medical center.

Patients: Critically ill patients 18 years old or older.

Interventions: Patients were randomized 1:1 to video or direct laryngoscopy for the first attempt at endotracheal intubation.

Measurements and Main Results: Patients assigned to video (n = 74) and direct (n = 76) laryngoscopy were similar at baseline. Despite better glottic visualization with video laryngoscopy, there was no difference in the primary outcome of intubation on the first laryngoscopy attempt (video 68.9% vs direct 65.8%; p = 0.68) in unadjusted analyses or after adjustment for the operator’s previous experience with the assigned device (odds ratio for video laryngoscopy on intubation on first attempt 2.02; 95% CI, 0.82–5.02, p = 0.12). Secondary outcomes of time to intubation, lowest arterial oxygen saturation, complications, and in-hospital mortality were not different between video and direct laryngoscopy.

Conclusions: In critically ill adults undergoing endotracheal intubation with video laryngoscopy compared with direct intubation, there is.
A Pragmatic, Randomized, Controlled Trial Examining the Efficacy of a Hospital Discharge Follow-up Phone Call Program

Maya Yiadom, MD
Principle Investigator
Study Procedure

Cohort Identification

Stephen Pert

- Daily business objects reports every weekday morning for ~6-9 months
- All inpatient status hospital discharges that occurred the previous 24 hrs (or 72hrs on Mondays)
  - Encounter number
  - MRN
  - Admit date
  - Discharge date
  - Name
  - All phone numbers available
  - Street address
  - City, state
  - Zipcode
- Sent, every week day, to a “Randomization Nurse” via RedCap

Business Intelligence Analyst
Department of Finance
Study Procedure

Intervention Delivery/Exposure

Phone Call Program

Phone Call Nurse will:

- Place a call within 3 days of discharge
- Repeat calls made (3 calls max) for up to 7 days post discharge
- Make call guided by semi-structured script
  - Screen for new symptoms
  - Review understanding of discharge meds
  - Review understanding of follow-up appt
  - Identify need for intervention
  - Interventions provided
- Document
  - Call outcomes in Starform
  - Reasons patients are “unreached”
  - Call attempts

Sarah Marlow, RN
Operations Systems Engineer
Discharge Phone Call Program
Study Procedure

Post Enrollment Covariate Data Collection

• Research Derivative Team

Dikshya Bastakoty
VICTR Data Analyst

Emily Bruer
Translational Research Data Coordinator
Research Derivative

Kevin Cox
Research Derivative
Post Enrollment Covariate Data Collection

- Research Derivative Team
- CCSIR will pull covariates

Sunil Kripalani, MD
Director, Center for Clinical Implementation Sciences Research (CCISR)

Kathryn Goggins
Research Program Manager, Center for Clinical Implementation Sciences Research (CCISR)
REDCap Data Base Management

- Build study REDCap Database
- Receive data pulls from, Finance, RD and CCQIR
- Import data from Starpanel “data dumps”
- Alert team to data integrity and quality issues that may produce “bias” or “missingness”
- Basic level data cleaning
- Export data for biostatistical analysis
Interim Analysis

Interim Analysis

• **Safety Officer:** Tina Hartert, MD
  Asst. Vice President for Translational Science

• **Blinded Statistician:** Li Wang, MS
  VICTR Biostatistician II

• **Blinded Results Review:** Select VUMC Executives
  - Mitch Edgeworth, MBA
    Chief Executive Officer
  - Jerry Hickson, MD
    Chief Quality, Patient Safety, and Risk Prevention Officer
  - Robin Steaban, RN
    Associate Chief Nursing Officer
Study Procedure

Results Review and Interpretation

• Results Review and Interpretation: Study Team

Maya Yiadom  Hank Dominico  Dan Byrne  Michelle Hasselblad

Neesha Choma  Sunil Kripalani  Frank Harrell

Sara Marlow  Cheryl Gatto  Gordon Bernard
Results Dissemination

- VUMC Leadership
- Adult Enterprise Quality Committee
- Poster/Abstract Presentation
- Manuscript publication
CTSA Learning Health Care System “Platform”

CREATE REUSABLE FIXED INFRASTRUCTURE
- institutional and regulatory policy, master protocols
- clinical decision support, clinical registries
- real-time EHR data capture with coupled REDCap support
- expert cores, studios, standing DSMB

STUDY SPECIFIC TAILORING
- Pragmatic Research Studio
  - protocol customization
  - endpoint selection

STUDIES run through reusable platform

Improved Outcomes?
- NO: Publish De-Implement
- YES: Implement & Publish

Scientific Review
LHS Council

Intervention 1
Intervention 2
Intervention n
<table>
<thead>
<tr>
<th>Title</th>
<th>Idea and Protocol</th>
<th>Regulatory IRB/CT</th>
<th>Launch and conduct</th>
<th>Interim analysis</th>
<th>Enrollment end</th>
<th>Final analysis and close out</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMART – ICU Fluids – Semler (N=10,000, 24 months)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharge Phone Calls – Yiadom (N=3556, 6 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>September 2017</td>
<td></td>
</tr>
<tr>
<td>AKI Model Peds – Van Driest (N=10,000, 12 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>November 2017</td>
<td></td>
</tr>
<tr>
<td>COMPASS – PC – Karlekar/Ely (N=400, 24 months)</td>
<td></td>
<td></td>
<td></td>
<td>review after 30 pts enrolled and tracked for 6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU Recovery Program – Bloom/Stollings (N=550, 6 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procalcitonin PEDS – Banerjee (N=210, 12 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Precautions – ICU – Huerta (N=2000, 8 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSP – MS – Bagwell (in development)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** = estimated enrollment target from ClinicalTrials.gov where registered or study protocol if not yet underway

- **HARD STOP**
- **IN PROCESS**
- **COMPLETE**
Questions?