BEST-ICU

NIH-FUNDED STUDY

IRB# 0794-23-FB

Behavioral Economic & Staffing Strategies To Increase Adoption of the ABCDEF Bundle in the Intensive Care Unit

A Stepped Wedge Cluster Randomized Controlled Trial

National Heart, Lung, and Blood Institute

National Institute of Nursing Research

BEST-ICU

UNMC Nebraska Medicine

The Ohio State University Wexner Medical Center

Iowa Health Care

University of Wisconsin-Madison

MPIs

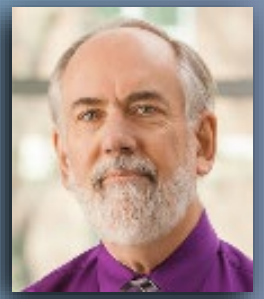
Balas

Vasilevskis

Project Coordinator

Wagner-Connolly

Co-Investigators



Campbell

Geary

Hetland

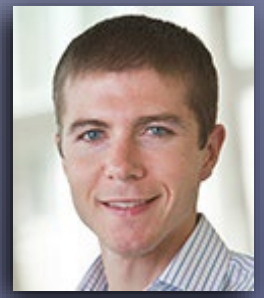
Blanchard

Circo

Liston

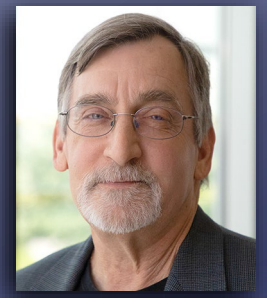
Miller

Hepburn

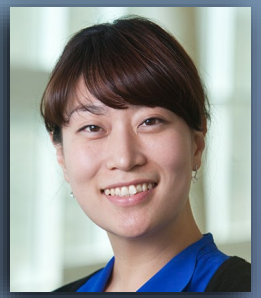


Kupzyk

Wichman



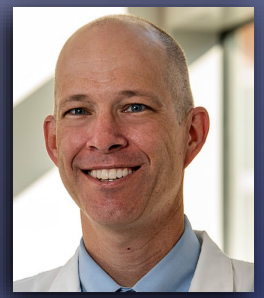
Horner



Kim

Krupp

Blum

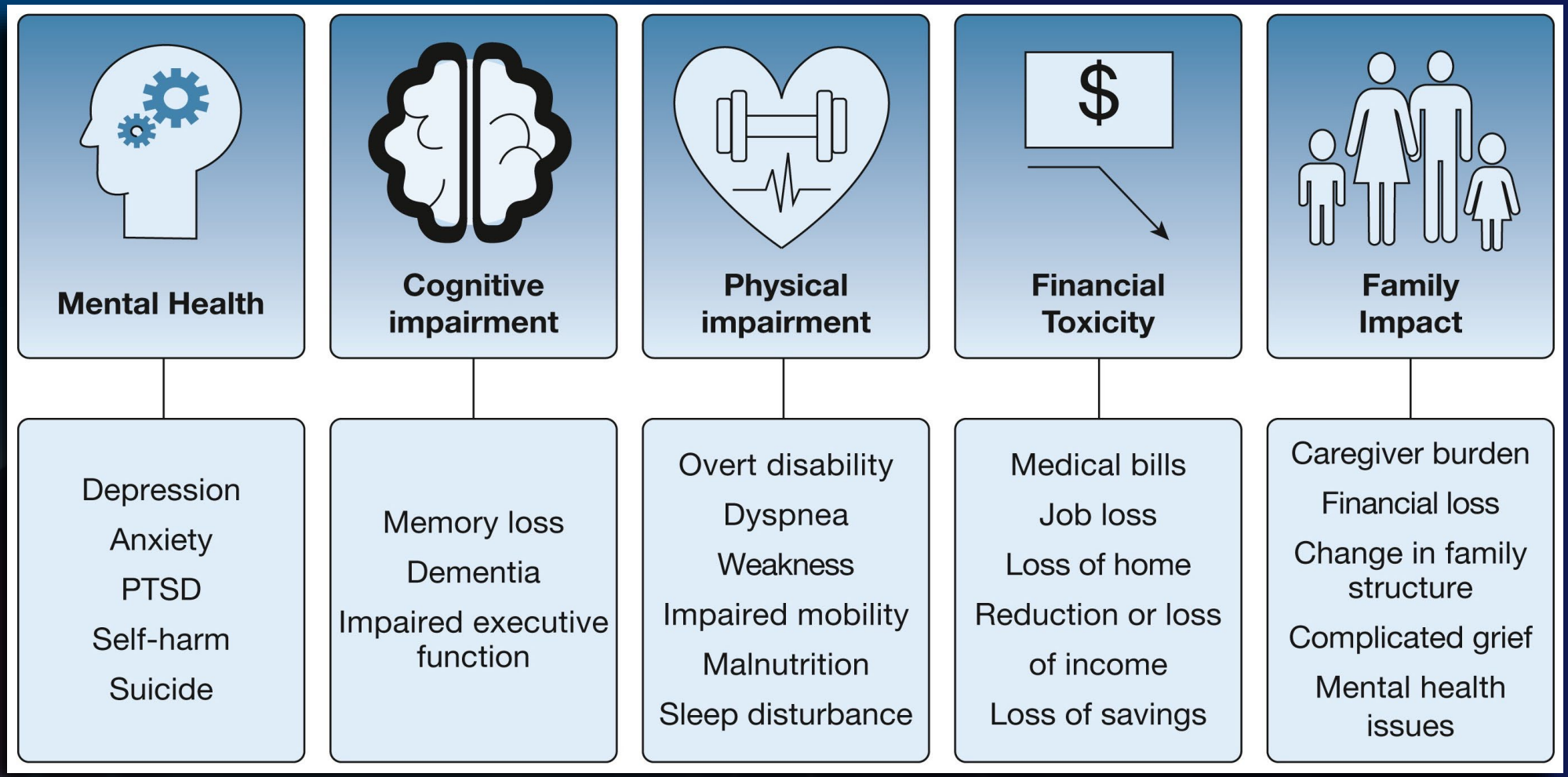


Exline

Gerlach

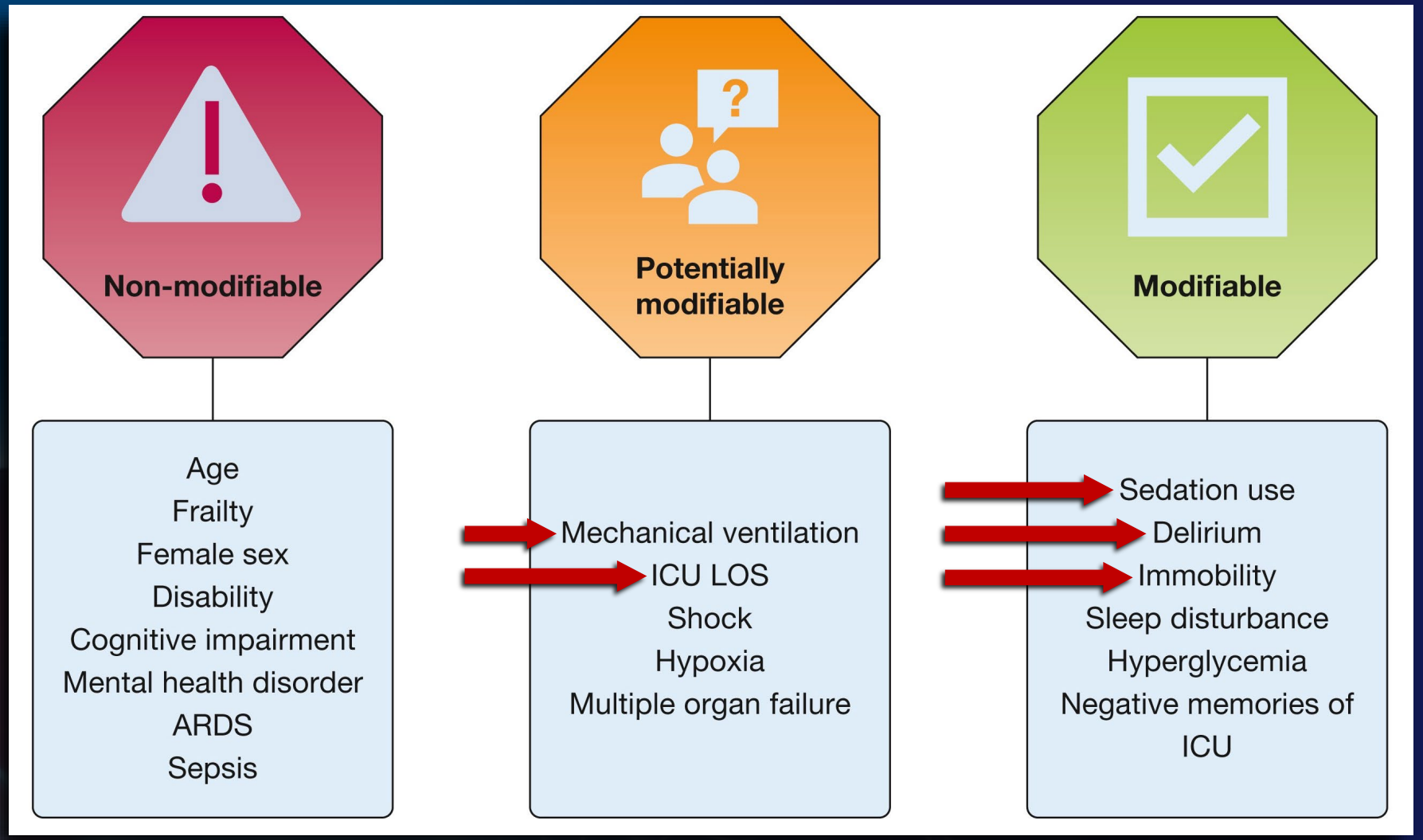
Significance: Post Intensive Care Syndrome (PICS)

Human & Financial Costs of Increasing ICU Survivorship



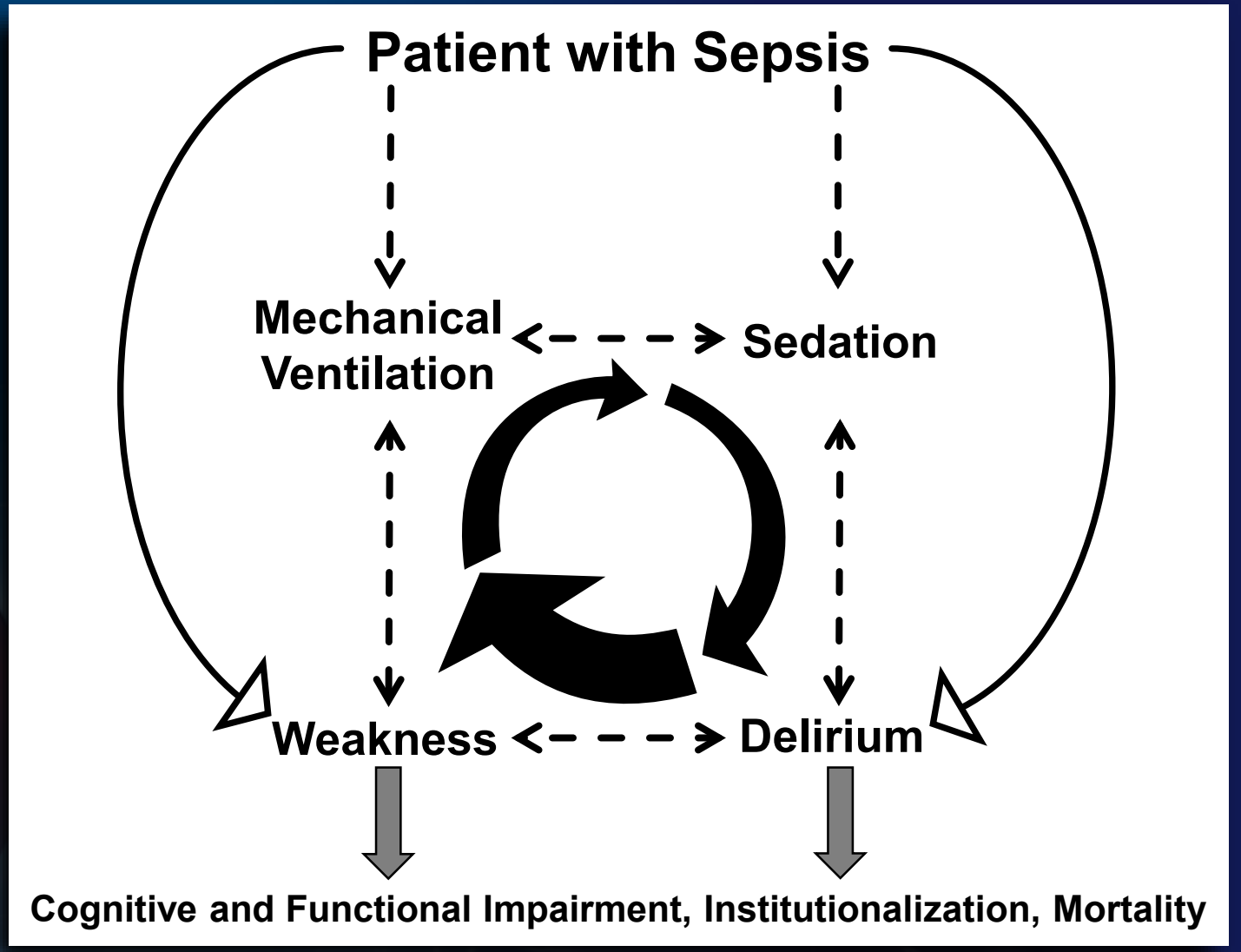
Hiser et al. Journal of Intensive Care (2023) 11:23

Conditions Associated with PICS



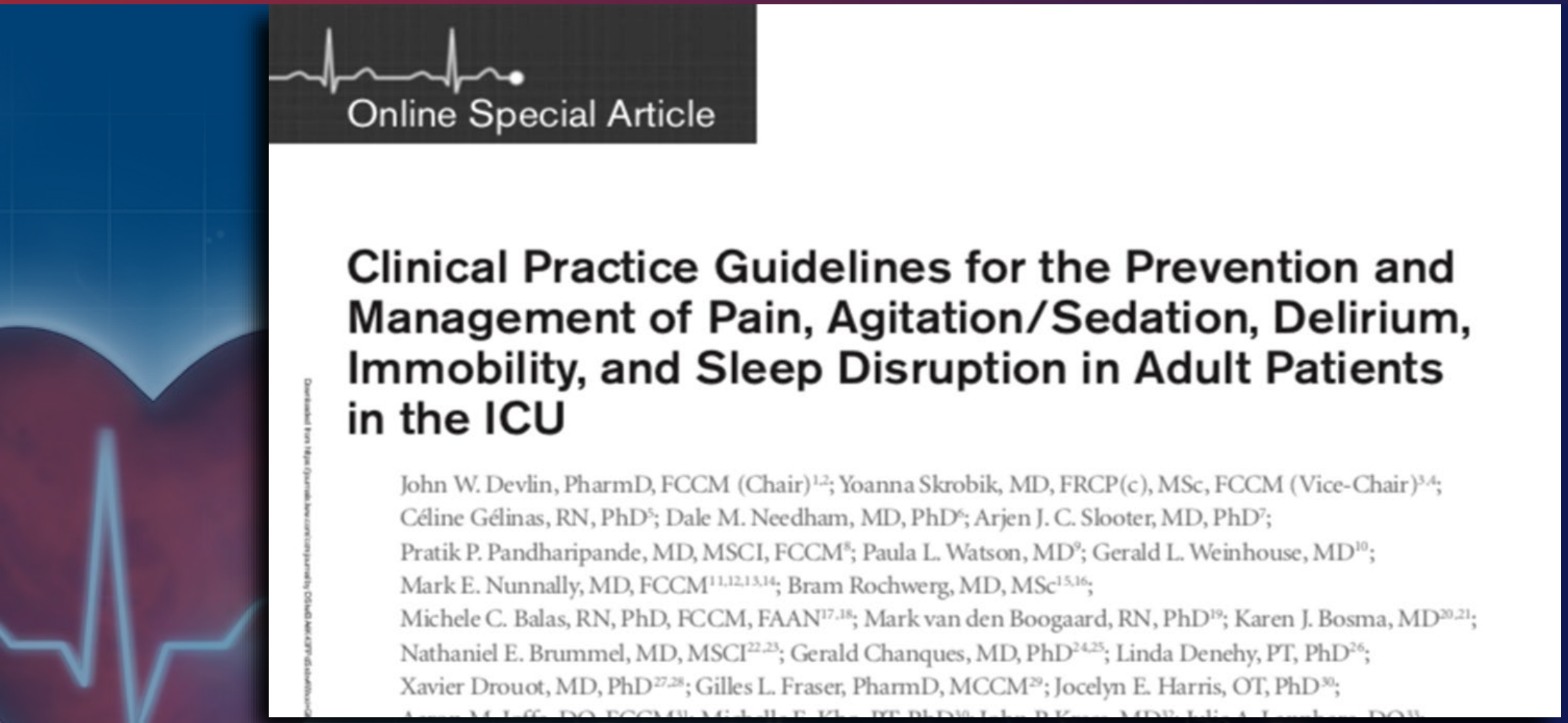
Hiser et al. Journal of Intensive Care (2023) 11:23

Modifiable Conditions Associated with PICS



Vasilevskis, E., et al. (2010) Chest.138(5): 1224–1233.

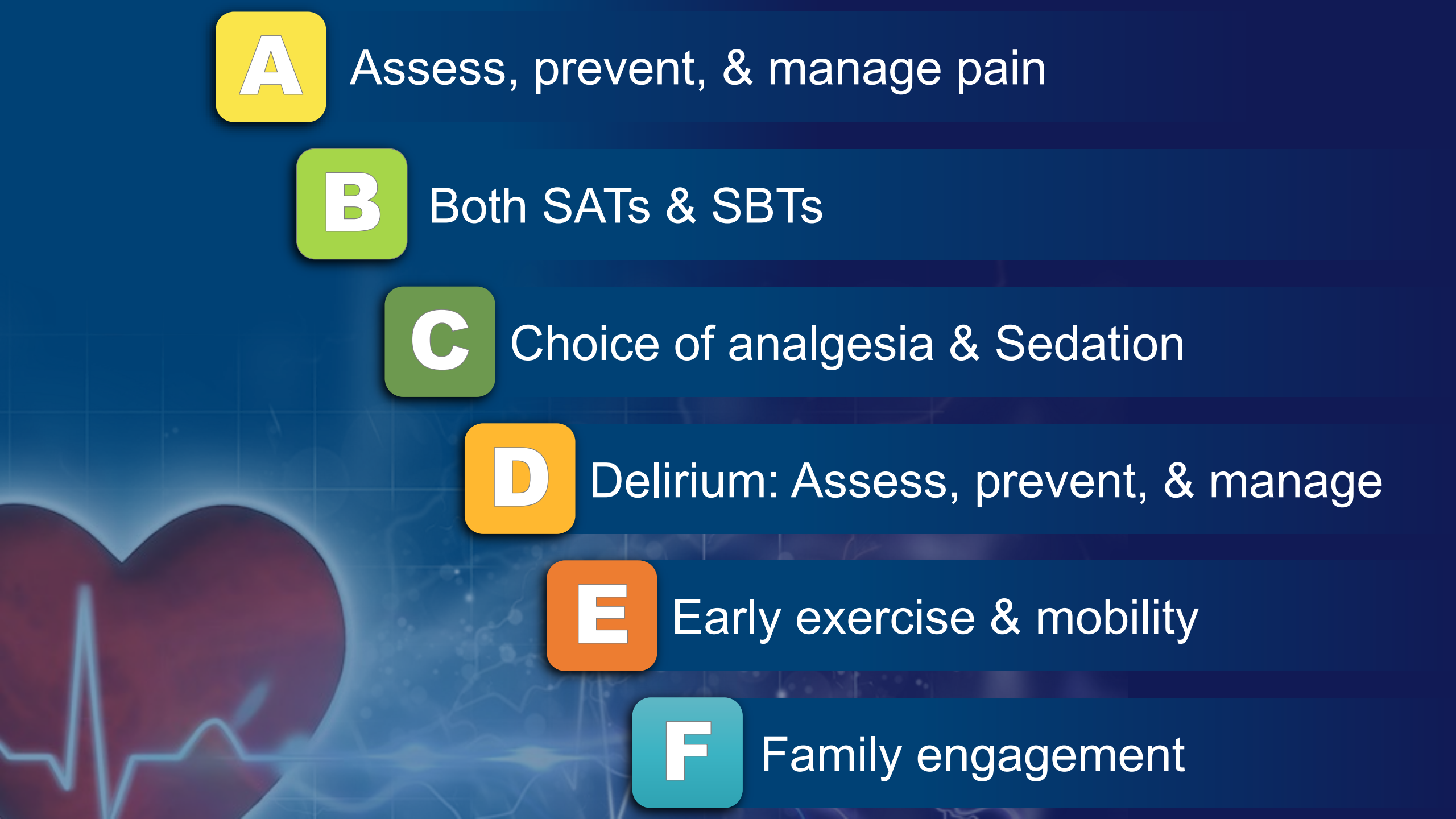
Highly Efficacious & Safe MV Liberation, Symptom Management, & Mobility Interventions Exist



Online Special Article

Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU

John W. Devlin, PharmD, FCCM (Chair)[1,2]; Yoanna Skrobik, MD, FRCP(c), MSc, FCCM (Vice-Chair)[3,4]; Céline Gélinas, RN, PhD[5]; Dale M. Needham, MD, PhD[6]; Arjen J. C. Slooter, MD, PhD[7]; Pratik P. Pandharipande, MD, MSCI, FCCM[8]; Paula L. Watson, MD[9]; Gerald L. Weinhouse, MD[10]; Mark E. Nunnally, MD, FCCM[11,12,13,14]; Bram Rochwerg, MD, MSc[15,16]; Michele C. Balas, RN, PhD, FCCM, FAAN[17,18]; Mark van den Boogaard, RN, PhD[19]; Karen J. Bosma, MD[20,21]; Nathaniel E. Brummel, MD, MSCI[22,23]; Gerald Chanques, MD, PhD[24,25]; Linda Denehy, PT, PhD[26]; Xavier Drouot, MD, PhD[27,28]; Gilles L. Fraser, PharmD, MCCM[29]; Jocelyn E. Harris, OT, PhD[30];


A
Assess, prevent, & manage pain
B
Both SATs & SBTs
C
Choice of analgesia & Sedation
D
Delirium: Assess, prevent, & manage
E
Early exercise & mobility
F
Family engagement

ABCDEF Bundle Facilitates Adoption of Multiple PADIS Practices & Improves Outcomes

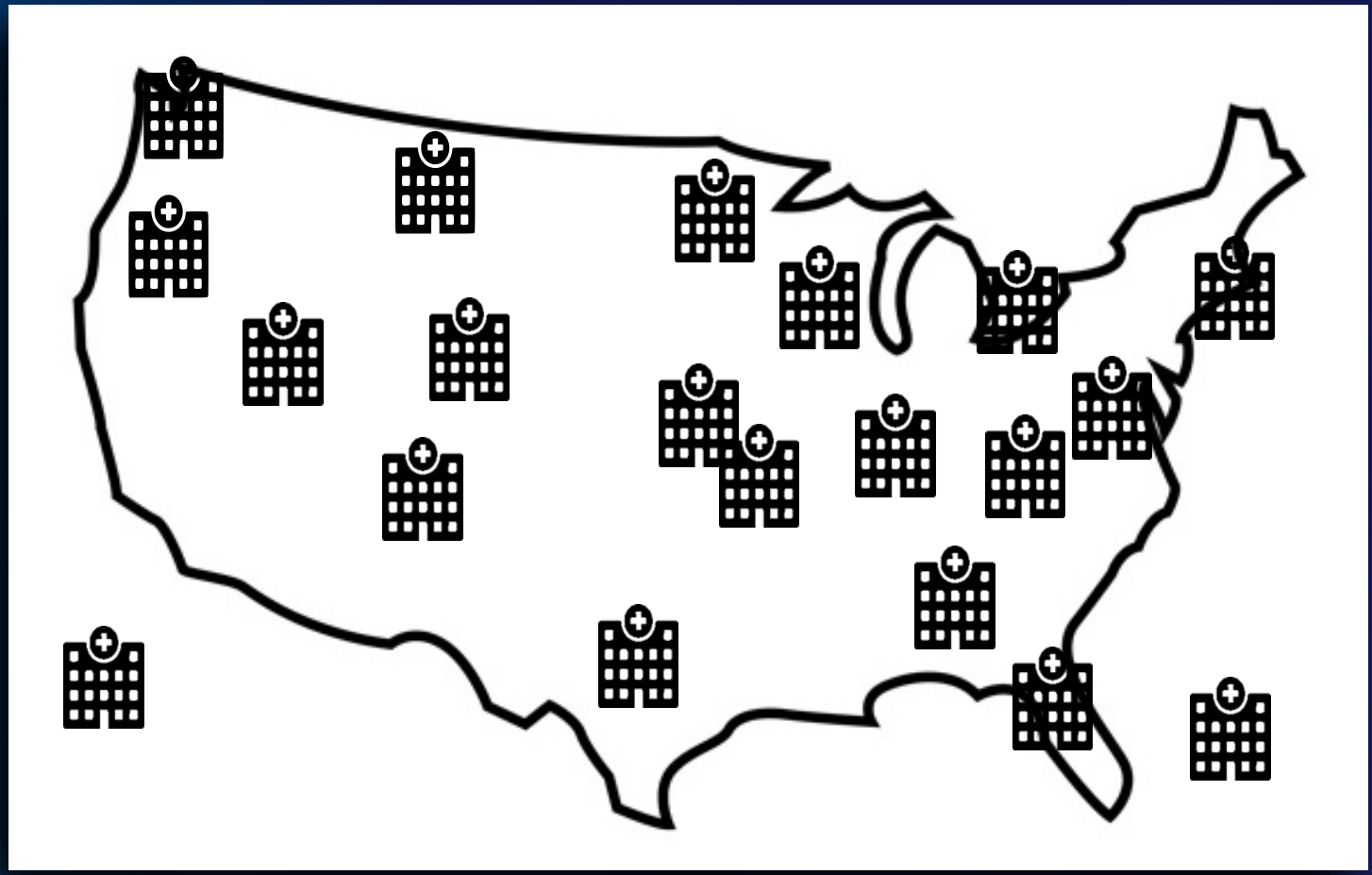
- Evidence-based, multicomponent, interprofessional approach to optimizing care of the critically ill
- Overarching goal is to maximize wakefulness & encourage cognitive & physical activity
- Applies to every ICU patient, every day, regardless of MV status or diagnosis
  - A patient simply receives every bundle element for which she/he is eligible

SCCM ICU Liberation Collaborative

Society of Critical Care Medicine

The Intensive Care Professionals

GORDON AND BETTY MOORE FOUNDATION



SCCM ICU Liberation Collaborative

Purpose: To build on the success of bundled care & bridge an ongoing evidence to practice gap, the SCCM launched the ICU Liberation Collaborative. Purpose was to foster bedside application of the SCCM's PADIS Guidelines via the ABCDEF bundle

Setting: 68 ICUs

- Diversity
  - Regional (across the US)
  - Type of ICU
  - Size of Hospital
  - Community, Academic, & VA

Patients: 15,226

- Diversity
  - 54% on MV
  - Admission diagnosis: sepsis, respiratory, neuro, cardiac

Pun B, et al., Crit Care Med. 2019 Jan; 47(1): 3–14

All eligible bundle elements performed
VS
No eligible bundle performed

Complete bundle performance

Improved Outcomes

Clinical Outcomes

Outcomes	Complete Bundle Performance*	P Value
Mechanical ventilation	0.28 (0.22–0.36)	< 0.0001
Coma	0.35 (0.22–0.56)	< 0.0001
Delirium	0.60 (0.49–0.72)	< 0.0001
Significant pain	1.03 (0.88–1.21)	0.7000
Physical restraints	0.37 (0.30–0.46)	< 0.0001

Clinical Outcomes

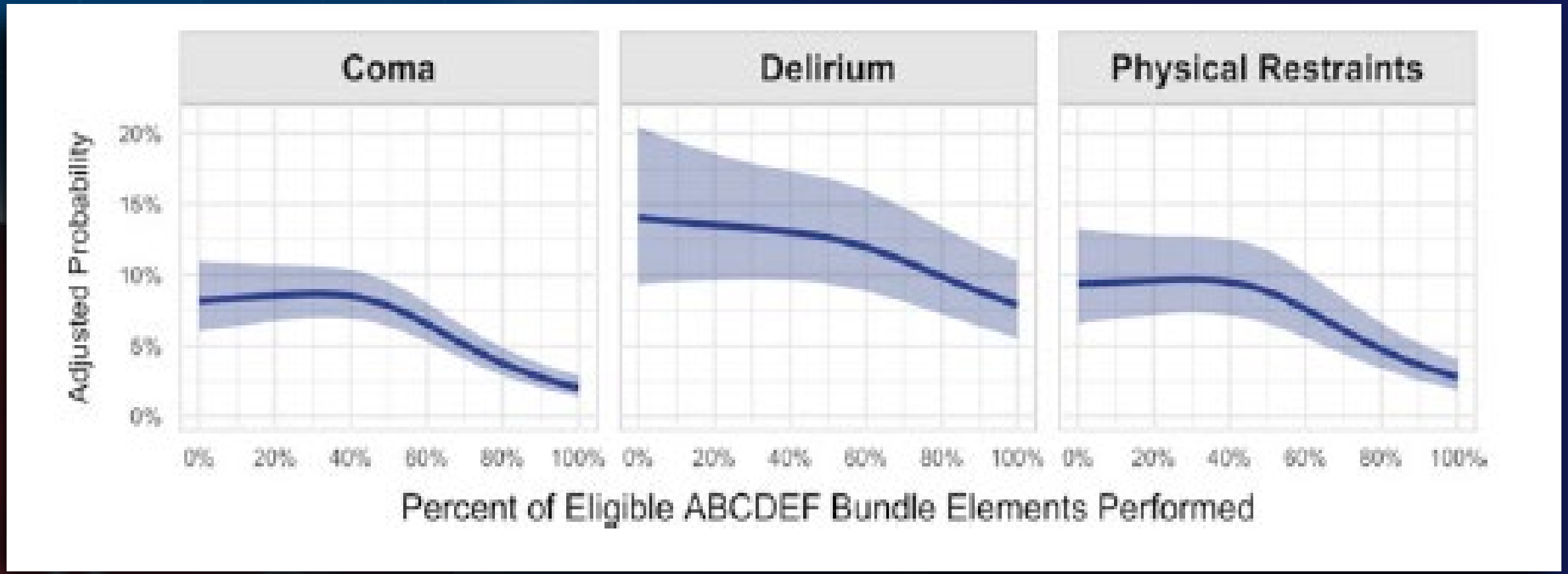
Outcomes	Complete Bundle Performance*	P Value
ICU discharge	1.17 (1.05–1.30)	< 0.004
Hospital discharge	1.19 (1.01–1.40)	< 0.033
Death	0.32 (0.17–0.62)	< 0.001
ICU readmission	0.54 (037–0.79)	< 0.001
Discharge destination	0.64 (0.51–0.80)	< 0.001

Percent eligible bundle elements performed

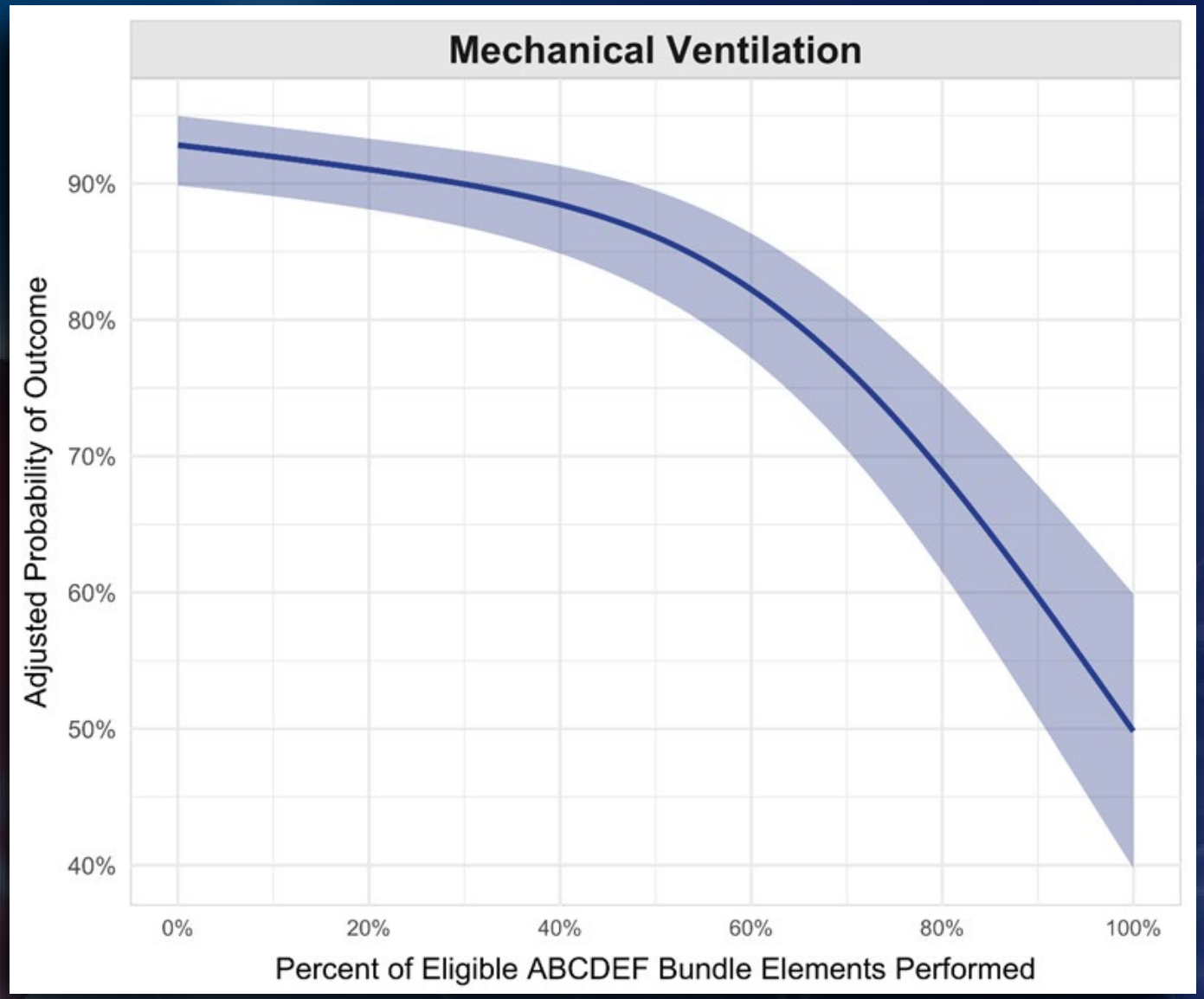
Partial bundle performance

Improved Outcomes

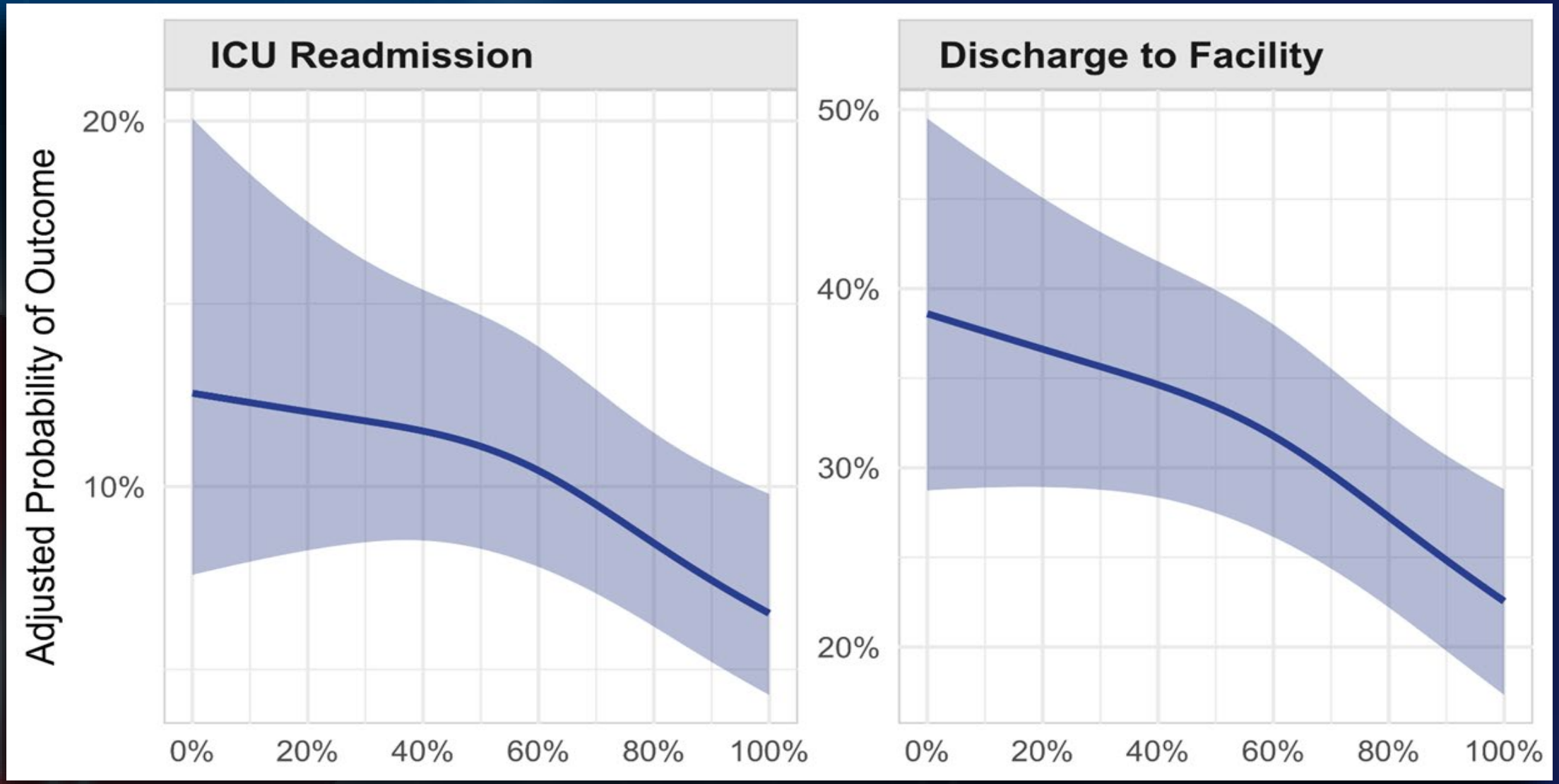
Clinical Outcomes



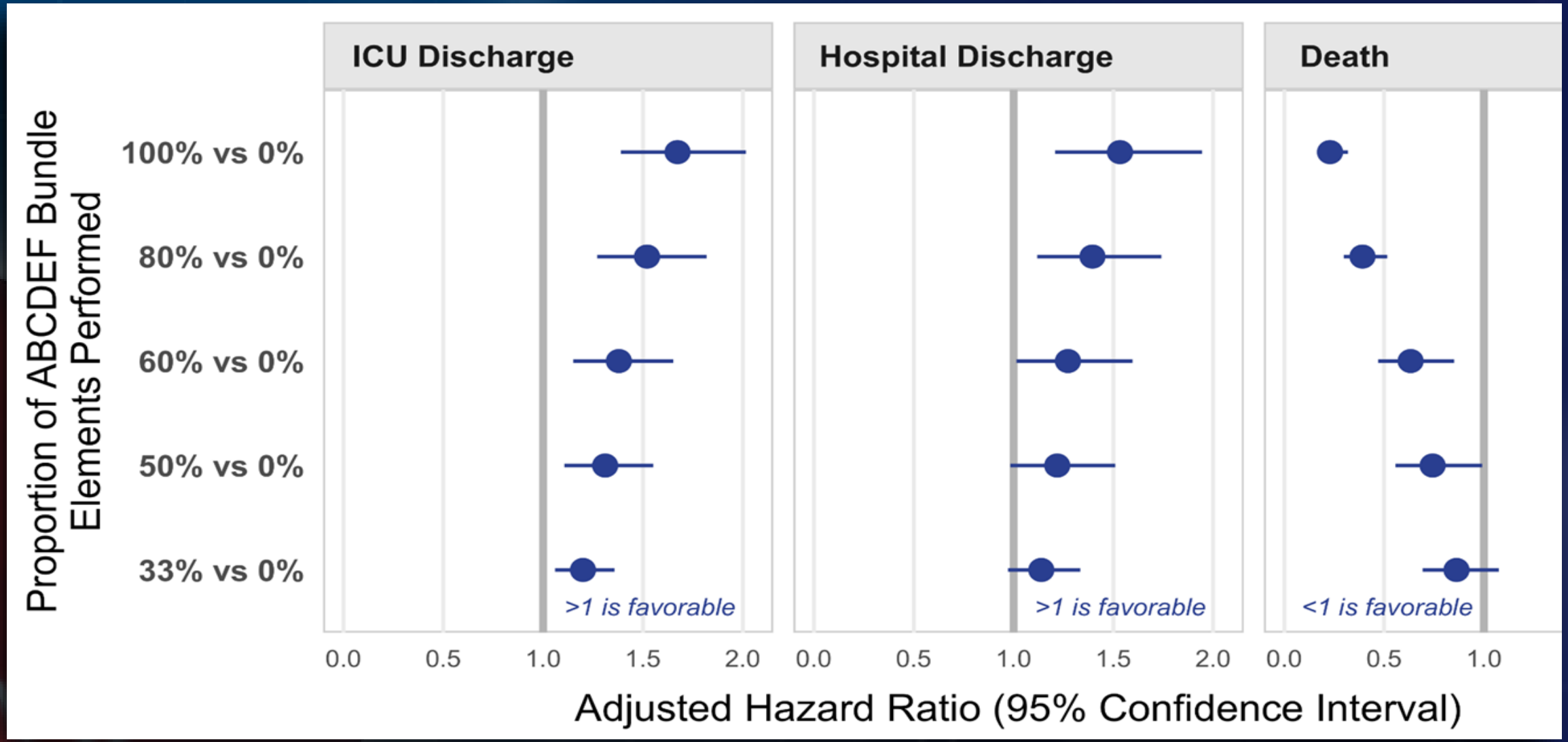
Clinical Outcomes



Clinical Outcomes

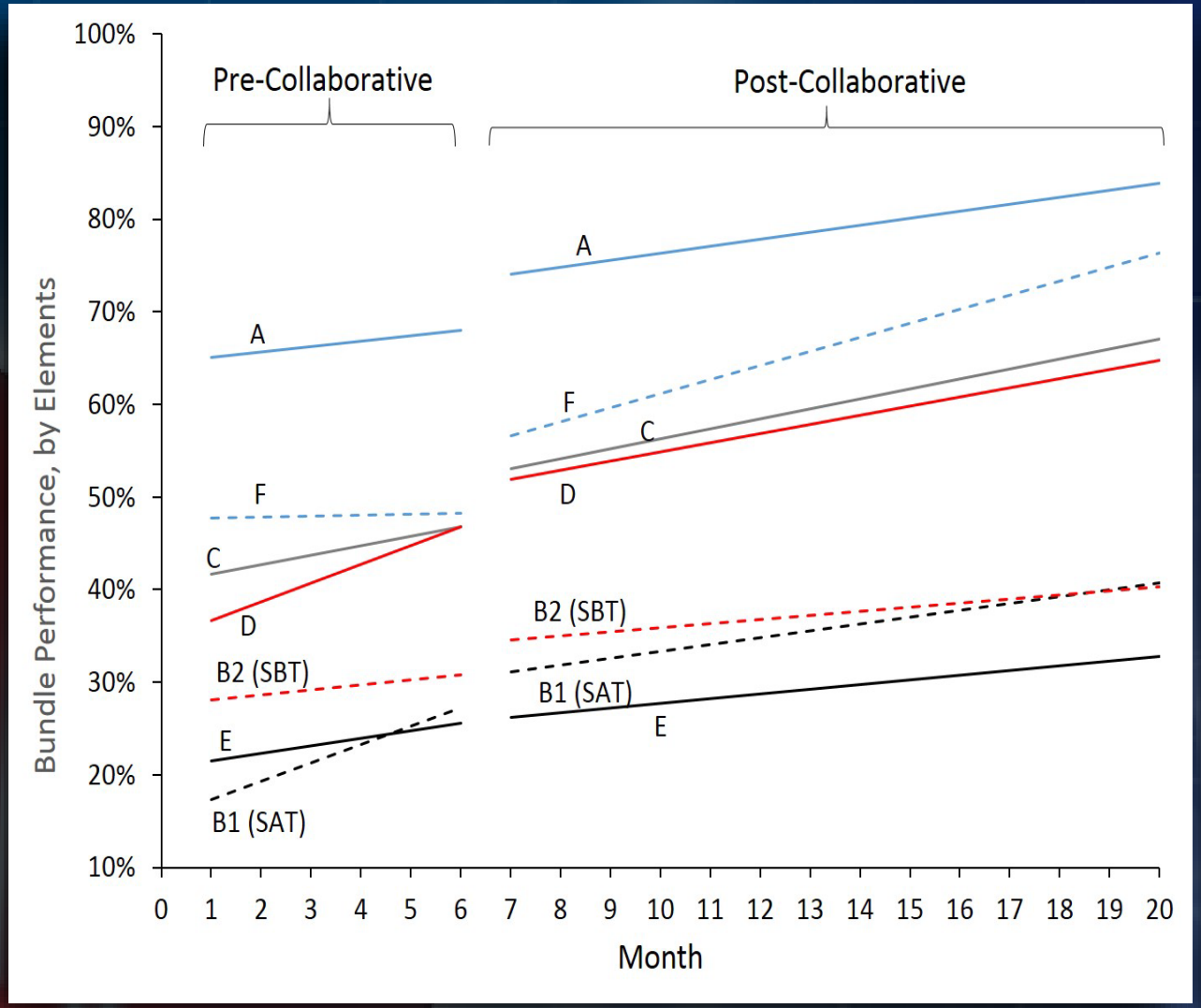


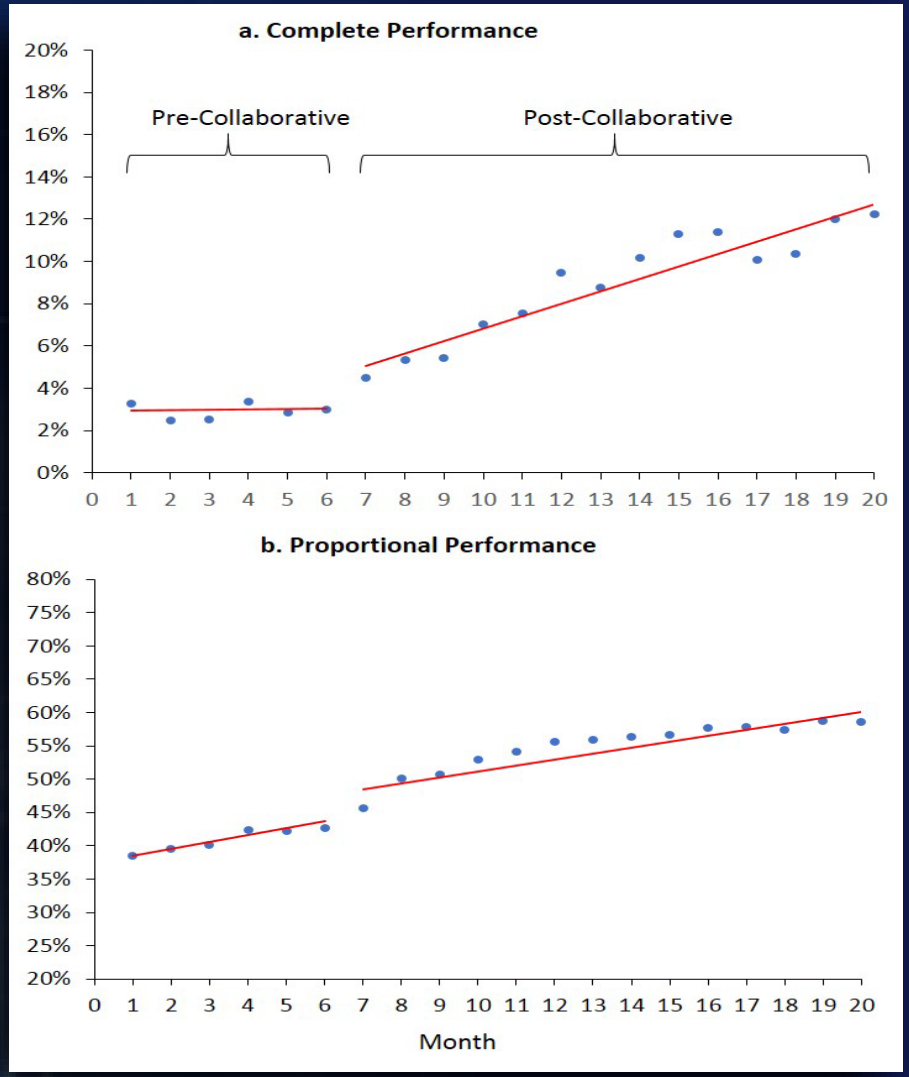
Clinical Outcomes



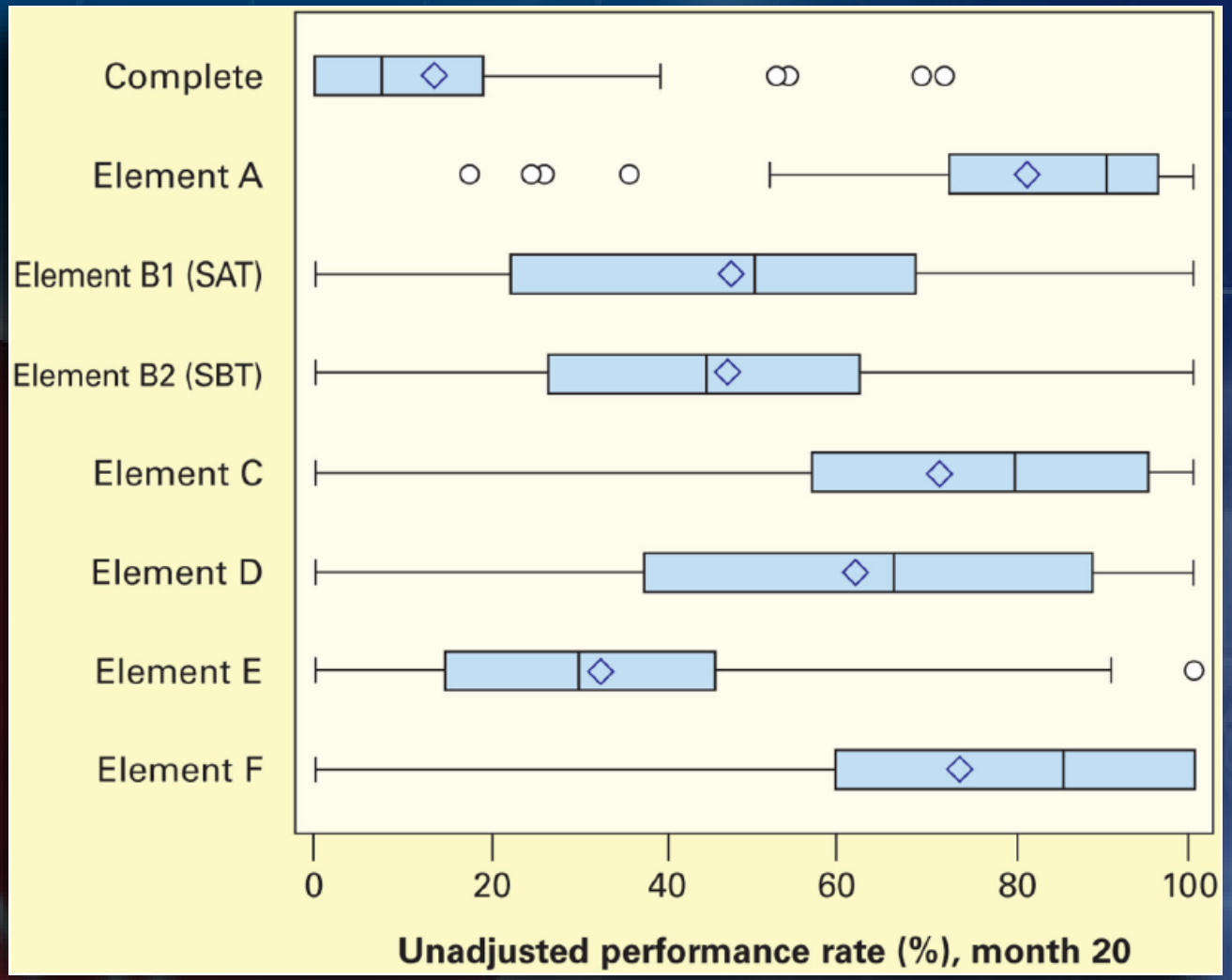
Implementation Gaps: Continual Low Bundle Adoption

National Heart, Lung, and Blood Institute





Implementation Gaps: High Variability



Implementation Gaps: Numerous & Complex

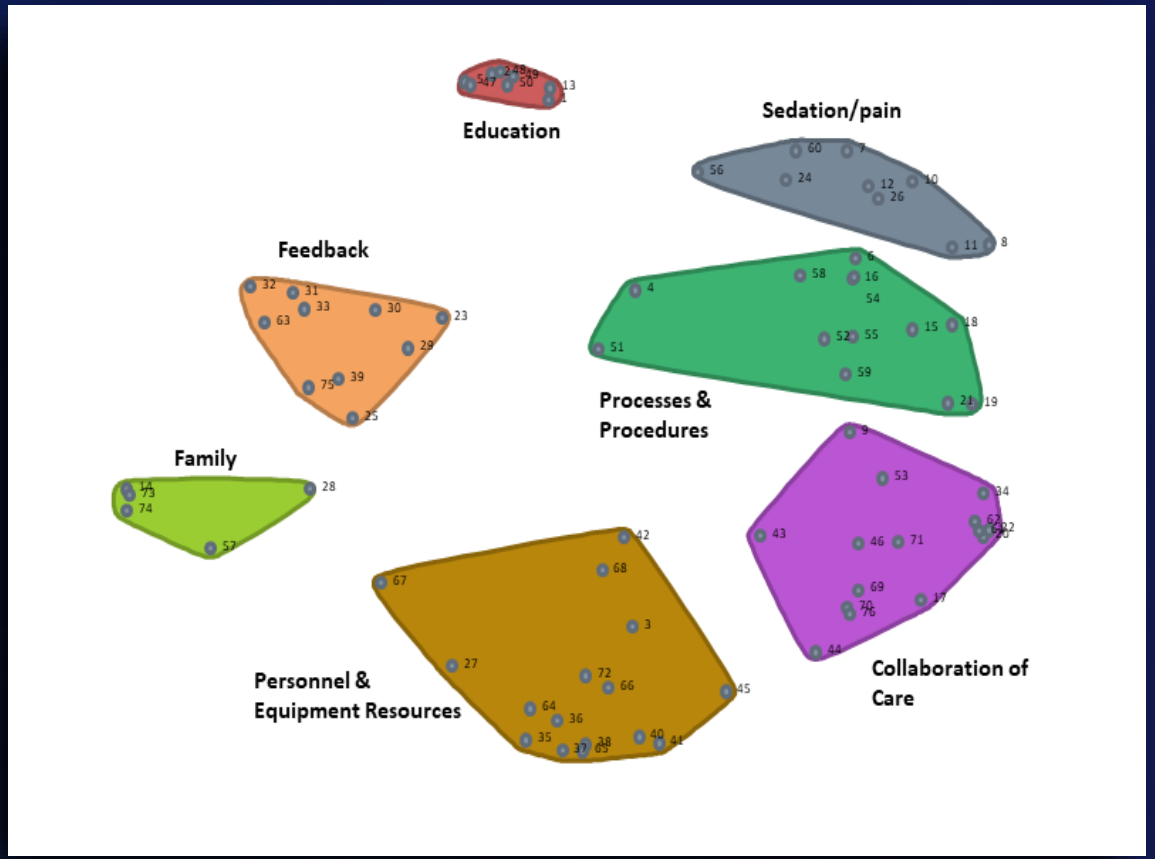
Brainstorming:

- "To successfully deliver the ABCDEF bundle on a daily basis in the ICU, a specific thing that should be in place or included is ….."
- Rated by necessity & current use

Prior review by Costa et al. found >100 barriers to ABCDEF bundle implementation

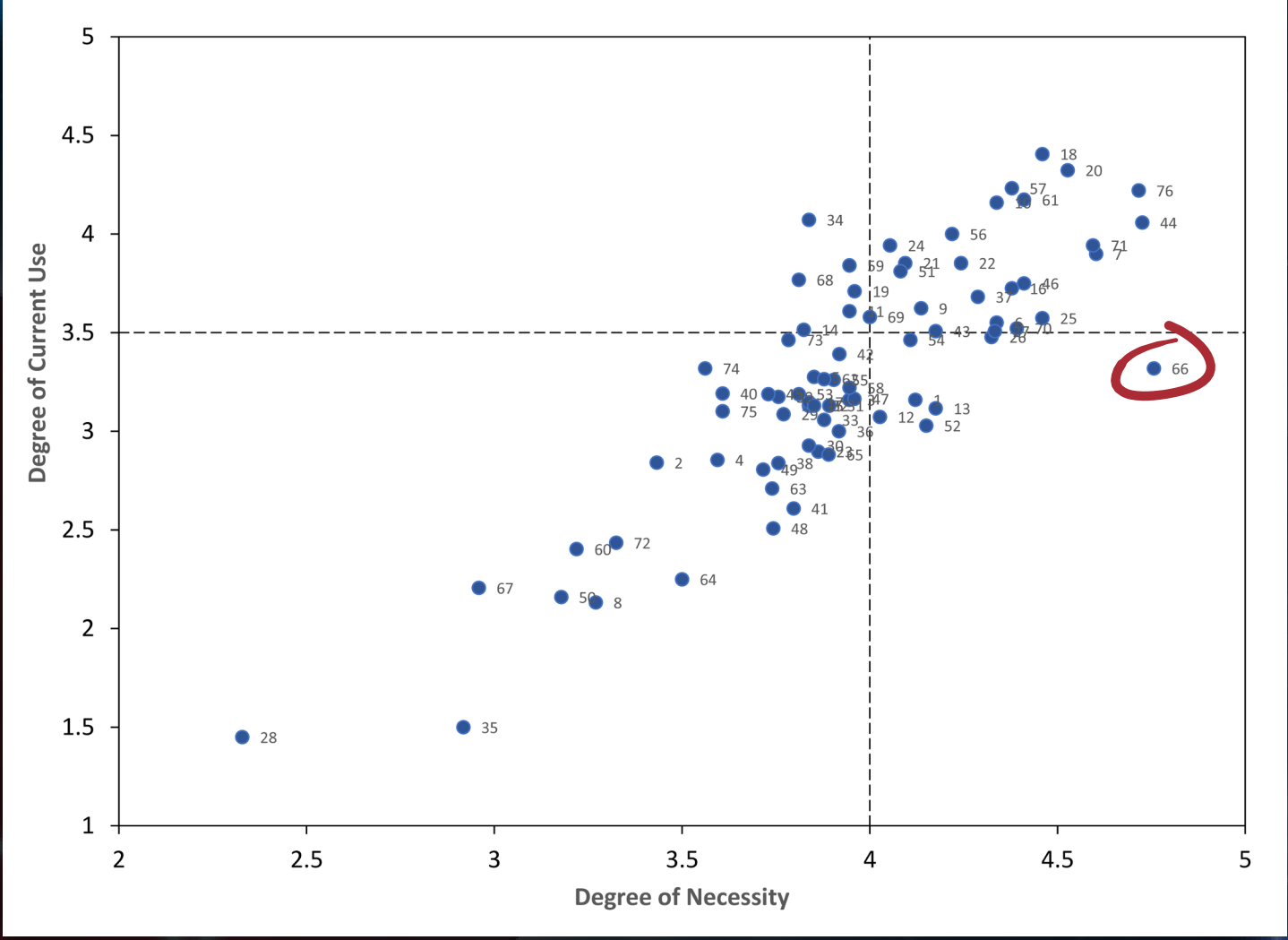
Group Concept Mapping (GCM)

Recruited interdisciplinary staff from the ICU Liberation Collaborative



Mion, L, et al., Critical Care Explorations 5(3):p e0872, March 2023.

Implementation Challenges: Numerous & Complex



Go Zone (Bottom Right Quadrant): One of the highest necessity & least implemented items:

Item 66

(adequate staffing)

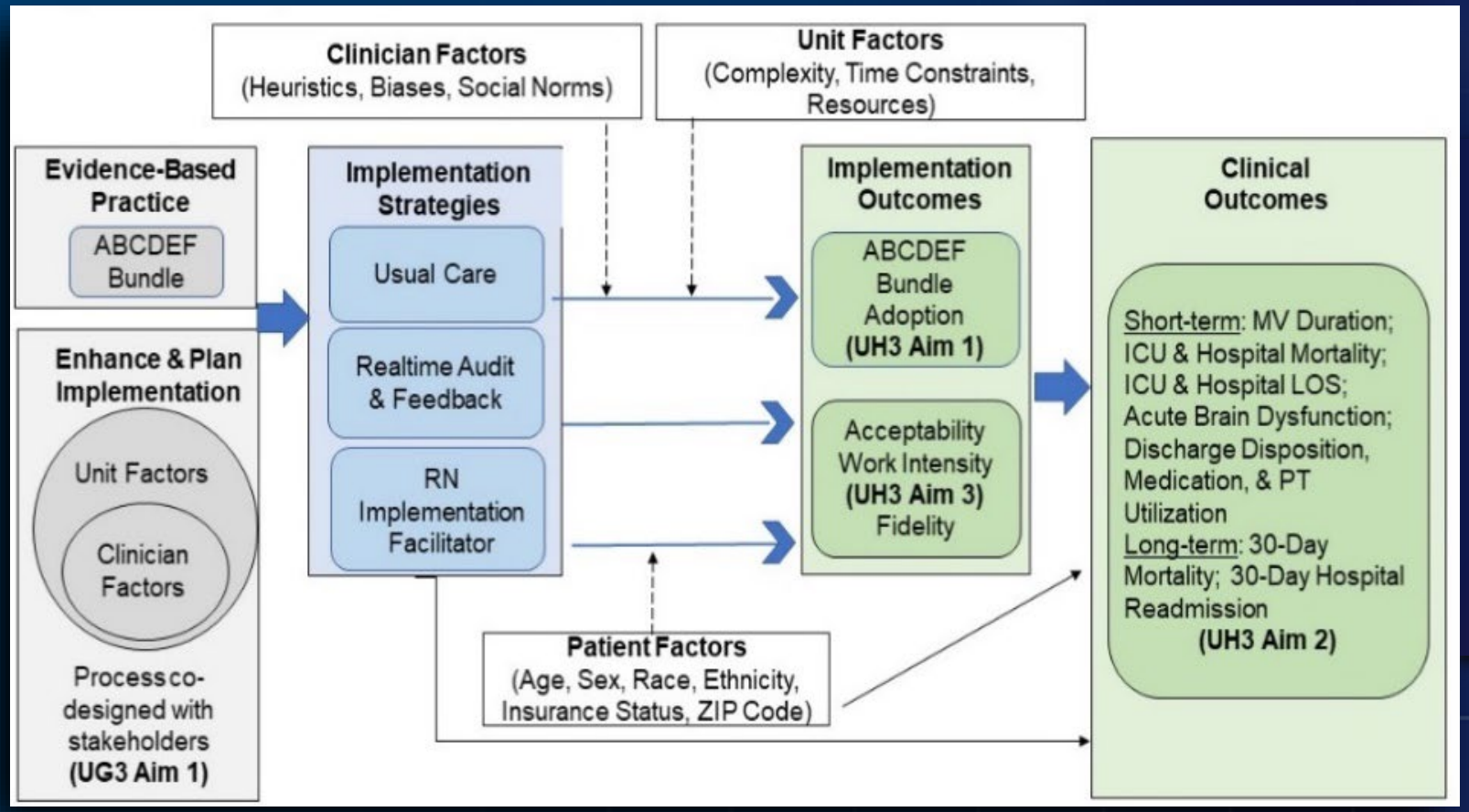
Mion, L, et al., Critical Care Explorations 5(3):p e0872, March 2023.

Behavioral Economic & Staffing Strategies To Increase Adoption of the ABCDEF Bundle in the ICU (BEST-ICU)

2

BEST ICU

Objective: Evaluate two discrete strategies grounded in behavioral economic & implementation science theory to increase adoption of the ABCDEF bundle



Strategies being evaluated target a variety of ICU team members & known behavioral determinants of ABCDEF bundle performance

BEST ICU Study Aims

Aim 1: Primary Implementation Objective

Compare the effectiveness of real-time audit & feedback & RN implementation facilitation on proportional ABCDEF bundle performance (primary study outcome)

Aim 1: Secondary Implementation Objective

Compare the effectiveness of real-time audit & feedback & RN implementation facilitation on complete ABCDEF bundle performance

BEST ICU Study Aims

Aim 2: Primary Clinical Objective

Compare the effectiveness of real-time audit & feedback & RN implementation facilitation on duration of mechanical ventilation

Aim 2: Secondary Clinical Objective

Compare the effectiveness of real-time audit & feedback & RN implementation facilitation on other patient-centered outcomes

(e.g., ICU, hospital, & 30-day mortality; ICU & hospital LOS; ICU days with acute brain dysfunction; ICU physical restraint use; daily & total opioid, benzodiazepine, sedative/hypnotic, & antipsychotic medication use in ICU stay & at hospital discharge; ICU days with a family visit; discharge disposition; ICU readmission)

BEST ICU Study Aims

Aim 3: Identify & describe key stakeholders' experiences with, and perspectives of, real-time audit & feedback & RN implementation facilitation

- **Aim 3.1**: Compare the effects of real-time audit & feedback & RN implementation facilitation on work intensity
- **Aim 3.2**: Compare the acceptability of real-time audit & feedback & RN implementation facilitation
- **Aim3.3:** Assess the association of work intensity with acceptability & proportional bundle performance
- **Aim 3.4:** Assess provider perspectives of barriers & facilitators to adoption of real-time audit &feedback & RN implementation facilitation

Participants

Hospitals

- 3 geographically & organizationally separate safety net hospitals

ICUs

- 12 ICUs that each admit at least 300 patients requiring MV annually

UNMC Nebraska Medicine

1. Medical ICU
2. Surgical ICU
3. Surgical (Cancer)
4. Neuro ICU

The Ohio State University Wexner Medical Center

1. Medical ICU
2. Surgical ICU
3. Neuro ICU
4. Medical (Cancer) ICU
5. Cardiovascular ICU

IOWA HEALTH CARE

1. Medical ICU
2. Surgical ICU
3. Cardiovascular ICU

Participants

Clinicians

- Physicians,
- advanced practice providers,
- RNs, LPNs, CNAs,
- RTs,
- PTs, OTs, &
- Pharmacists who practice in participating ICUs

Patients

Preexisting EHR data on 8,100 patients

Included: ≥19 years old, received invasive MV in the ICU, & ICU LOS of at least 24 hours

Excluded: Admitted to the hospital already on chronic long term MV from the home, assisted living facilities, or long-term care settings & prisoners

Design

Pragmatic, stepped-wedge, cluster-randomized, hybrid type III effectiveness-implementation trial

Randomization

Covariate-constrained randomization

ICUs randomized to 2 implementation strategies. Either:

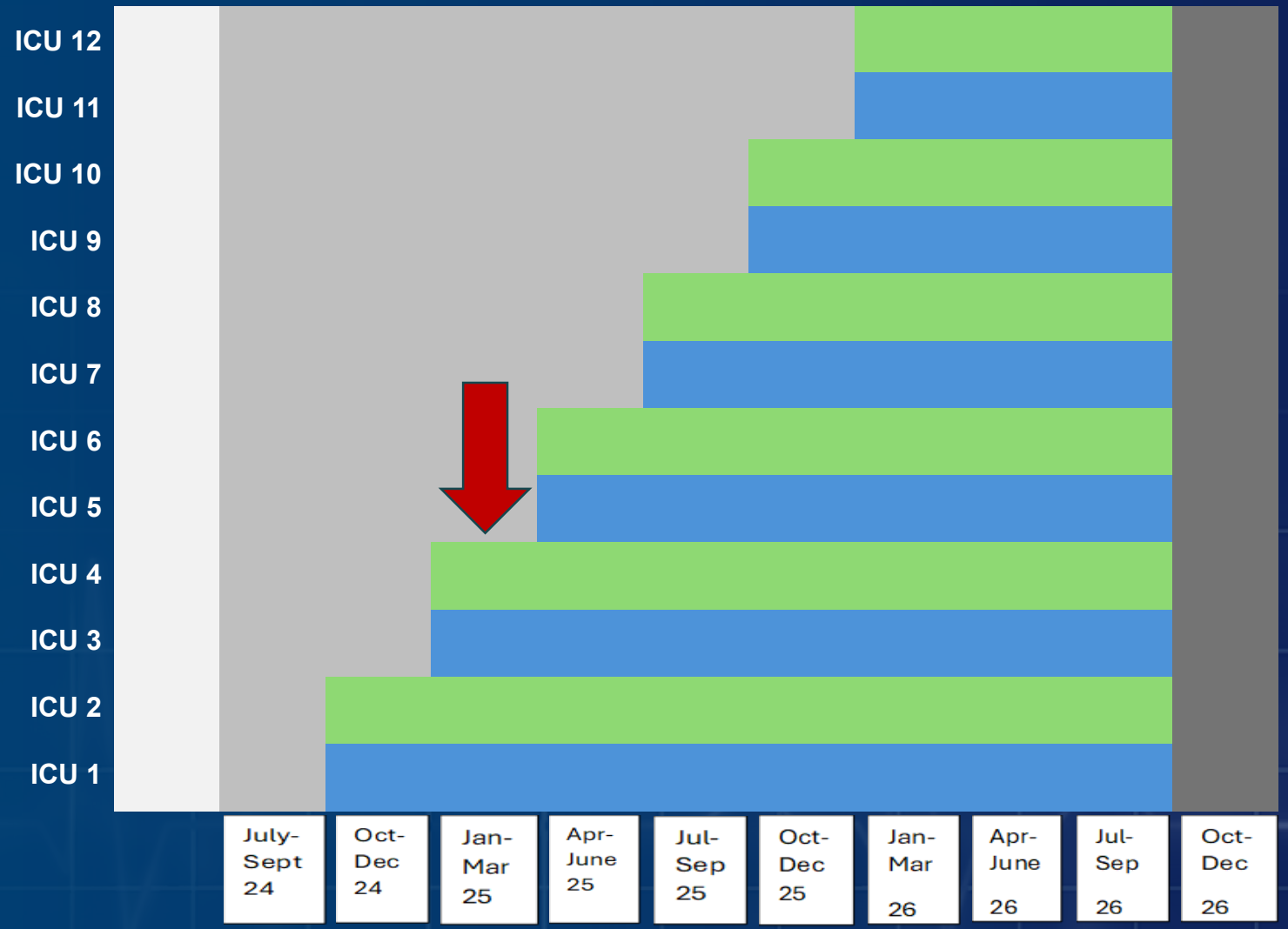
- Real-time audit & feedback – OR-
- RN implementation facilitator

Duration

Each ICU will take 33 months to complete all study-related tasks

All patient-level data will be extracted from the EHR for the primary hospital encounter up to 31 days post discharge

Study Design, Randomization, & Duration

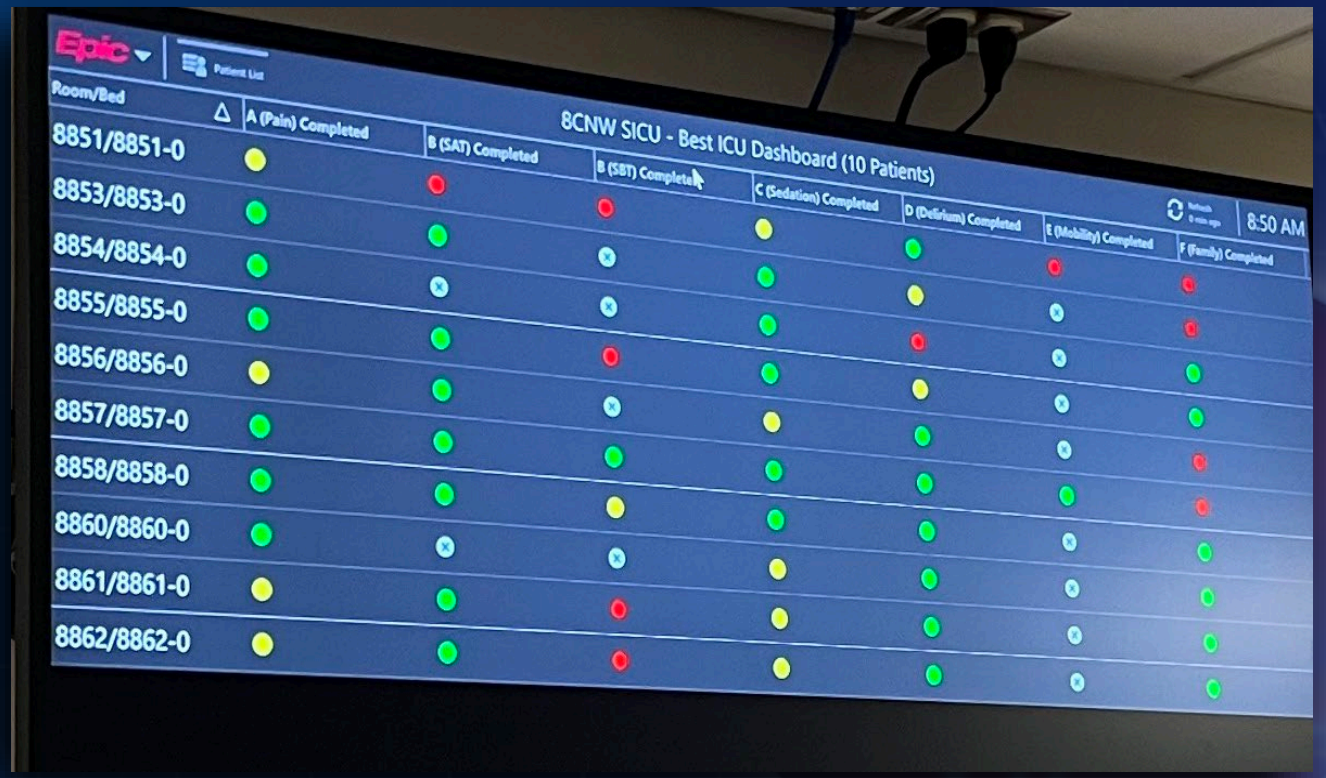


EHR Integration & Training
Control
Unit Dashboard
Nurse Facilitator
Washout

Each ICU will be notified of its assignment 6 months prior to the start date

Implementation Strategies: Intervention Arm 1
Real-Time Audit & Feedback

- Real-time A&F displayed on centrally placed dashboard
- All ICU providers have dashboard access
- Dashboard created using established flowsheets, procedures, application reports, activity & navigator records, BPAs, & tasks within Epic
- Includes daily bundle element completion status by ICU room



Implementation Strategies: Intervention Arm 2 - RN Implementation Facilitator

Practical clinical facilitator

- Acts as extra support to carry out functions of ABCDEF bundle

Coordinator

- Coordinate ABCDEF practices across specialties

Champion

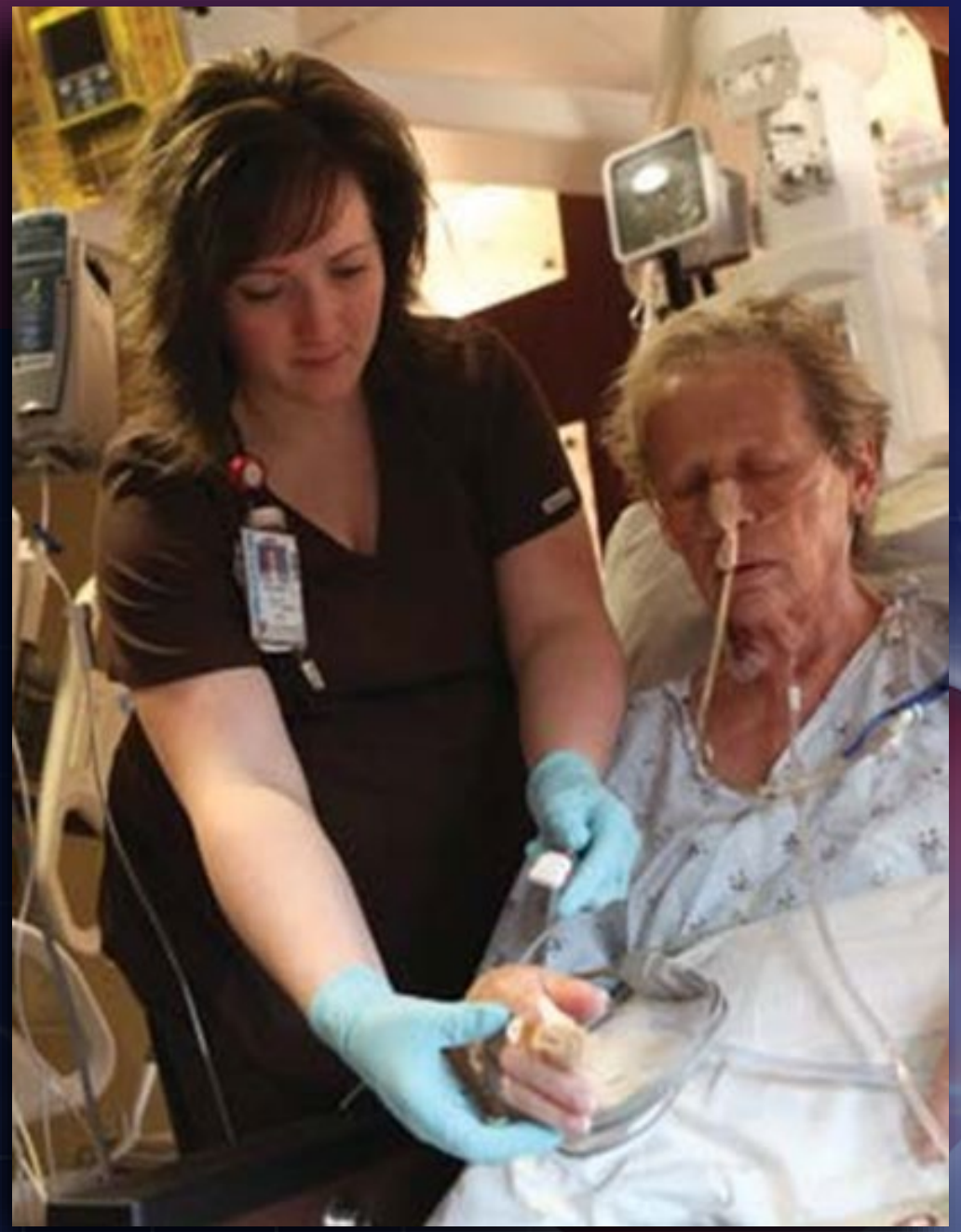
- Promote clinician behavior change

Coach

- Facilitate team members bundle elements training

Implementation Strategies: Intervention Arm 2 - RN Implementation Facilitator

- Internal facilitator (RN already working on participating ICU)
- Works day shift (when most bundle elements performed)
- Always free from a patient assignment
- ICUs continue normal staffing practices
- RN implementation facilitator paid from grant

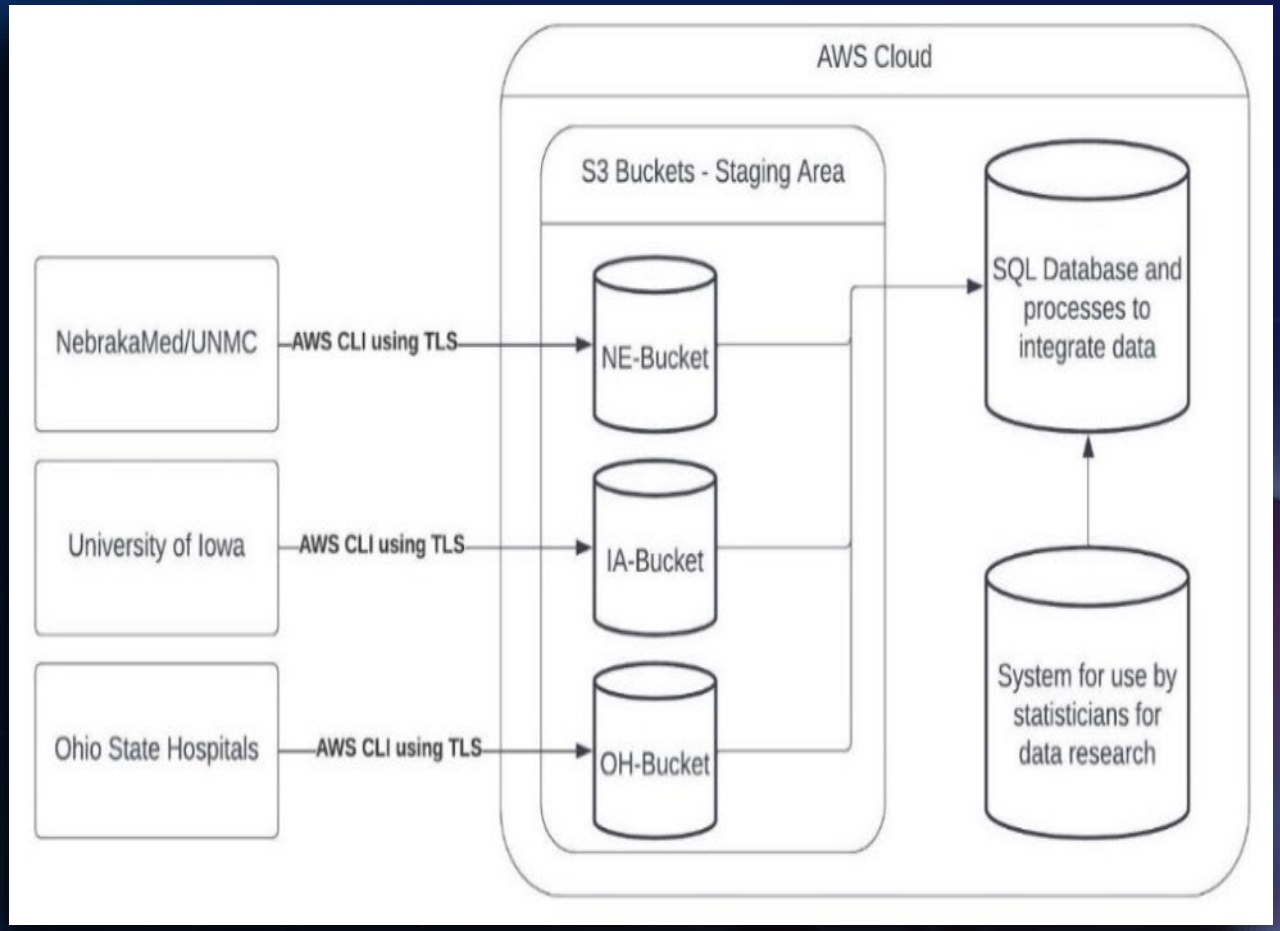


BEST-ICU: Data Sources, Data Collection, & Fidelity Monitoring

3

Electronic Health Record Data

- Epic® EHR at all sites
- All Sites have a certified PCORnet datamart that extract clinical data from Epic CLARITY® repository
- Quarterly data extraction per site protocols
- Data extracted with computable phenotypes
  - Eligibility data
  - Enrollment data
  - Clinical risk factor data
  - Primary & secondary implementation outcomes
  - Primary &secondary clinical outcome



BEST ICU Amazon Web Services (AWS) Data Management Environment

Data Collection

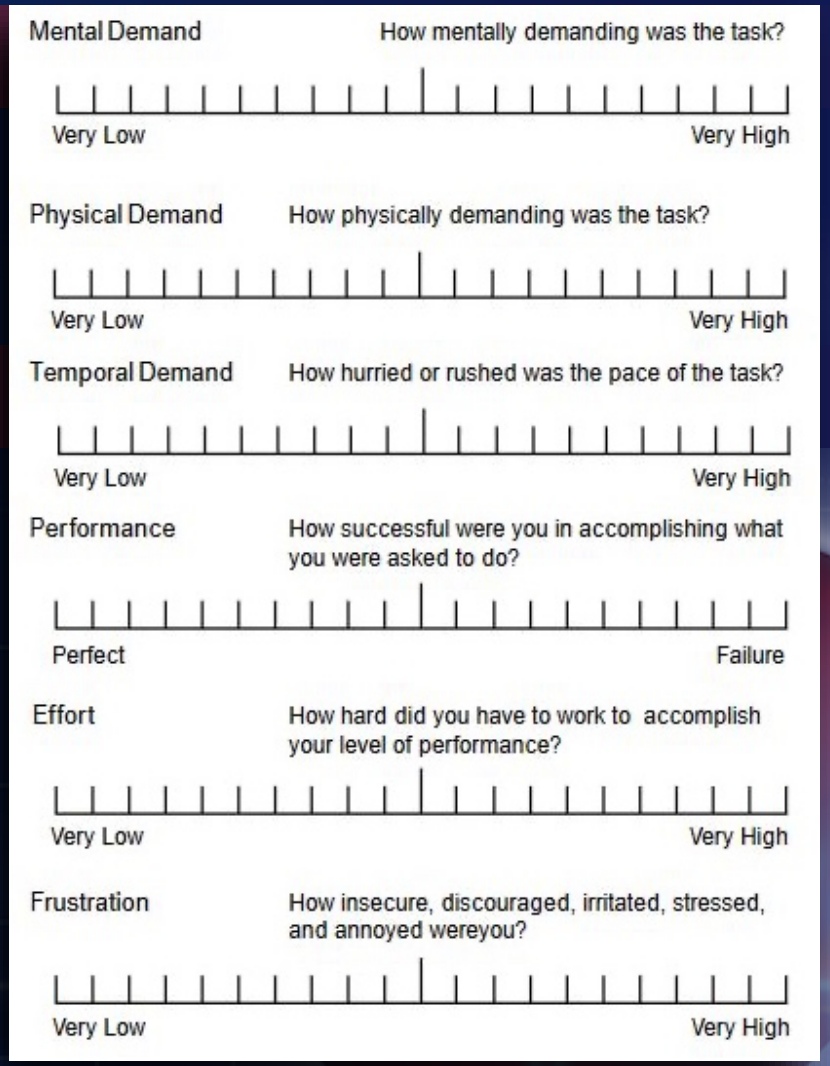
Bundle performance & patient outcomes

Electronic Health Record Capture, PCORnet datamart, study database

Provider - Throughout trial

Work Intensity:

- Measured via the 6-item NASA-TLX
  - Includes physical, mental, temporal demands, performance, effort, & frustration dimensions
- < 1 minute to complete, paper form
- Administered to all ICU team members who work day shift 4X month (random times) during clinical trial



NASA TLX

Data Collection

Provider - One time; End of trial; Administered to all ICU team members; < 1 minute to complete

- **Acceptability**:
  - Measured via the 4-item Acceptability of Intervention Measure Specifically designed to measure intervention acceptability
    1. XXX meets my approval
    2. XXX is appealing to me
    3. I like XXX
    4. I welcome XXX

Responses range from 1=completely disagree to 5=completely agree

Data Collection

Focus groups

- Purposeful sample of 60 ICU providers based on trial arm & AIM survey results (low, middle, high)
- Participants will be asked about overall perceptions & experiences on implementation strategy as well as barriers & facilitators specific to CFIR domains & constructs

Rigorous Fidelity Monitoring Plan

Real-time Audit & Feedback

- Monthly monitoring of audit & feedback intervention
  - Centrally placed monitor?
  - Patients on dashboard match patients in unit?
  - Correct display of each ABCDEF bundle element across patients?

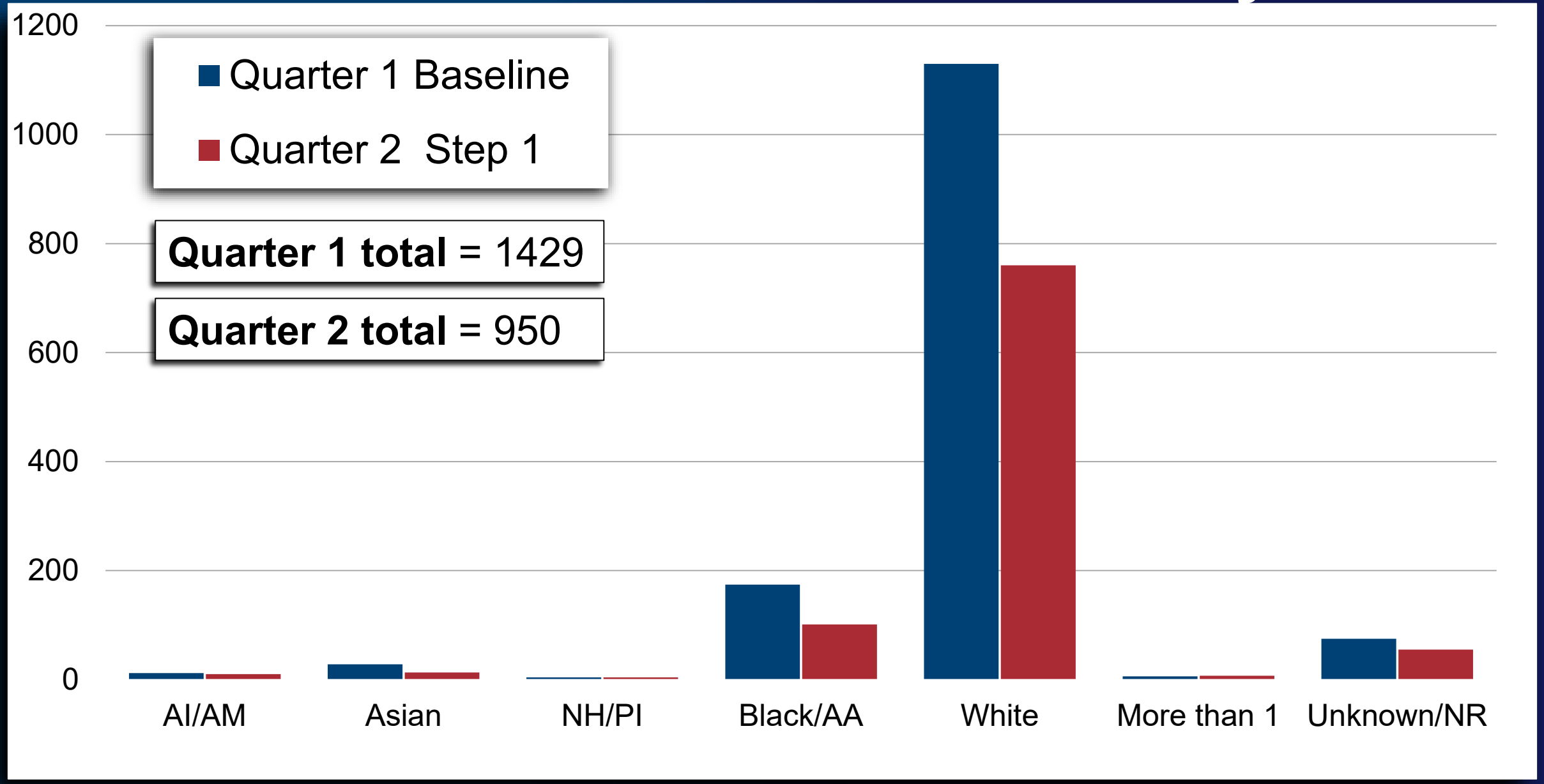
RN Implementation Facilitator

- Unit staffing monitoring
- RN Implementation Facilitator daily fidelity tool & 3, 6-month form
- Direct observation by independent monitor (monthly)

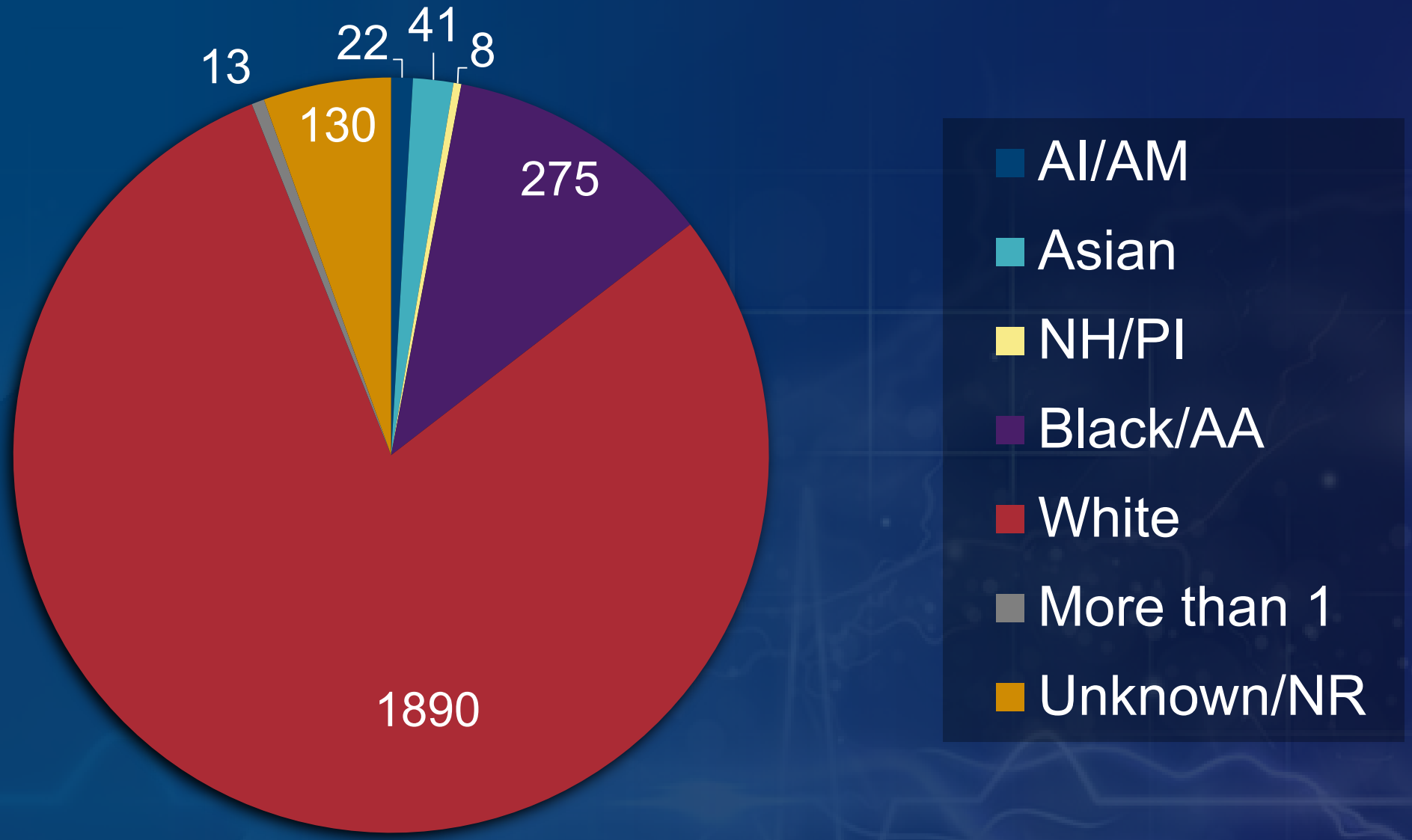
BEST-ICU: Progress to Date & Lessons Learned

4

BEST-ICU Patient Enrollment by Race

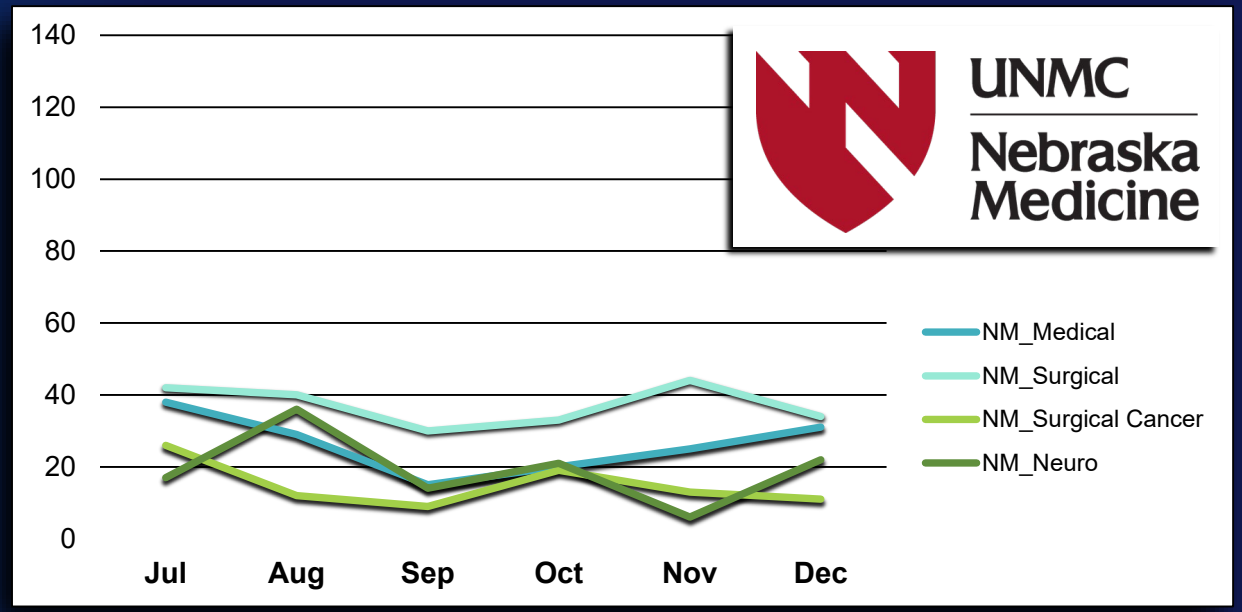


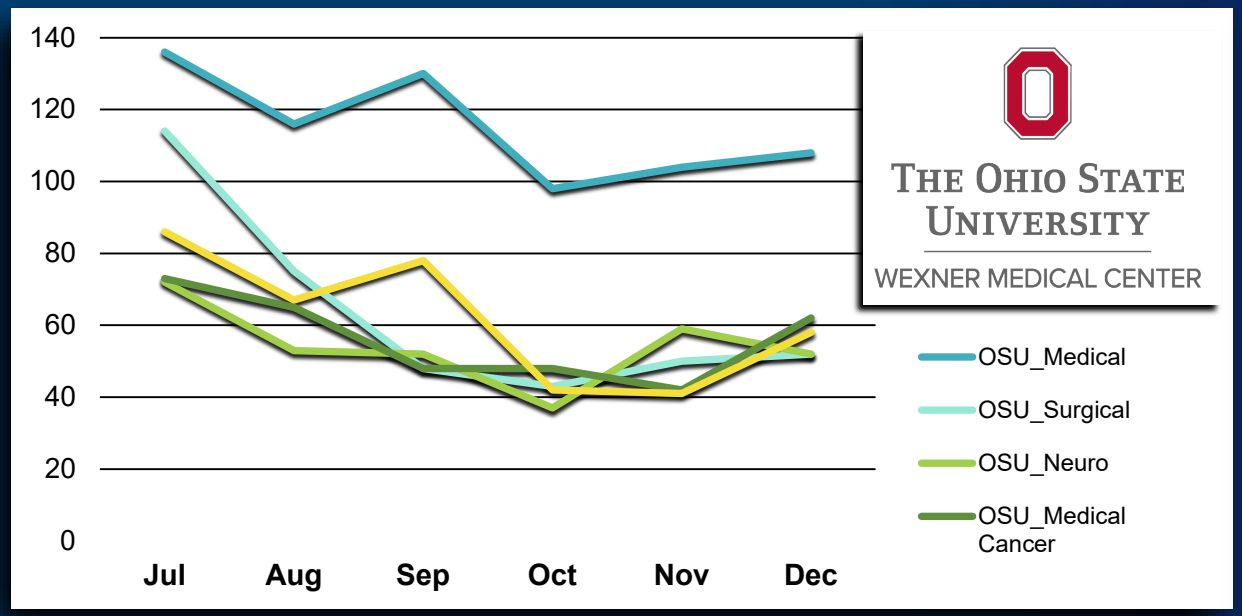
Total Enrolled N = 2,379

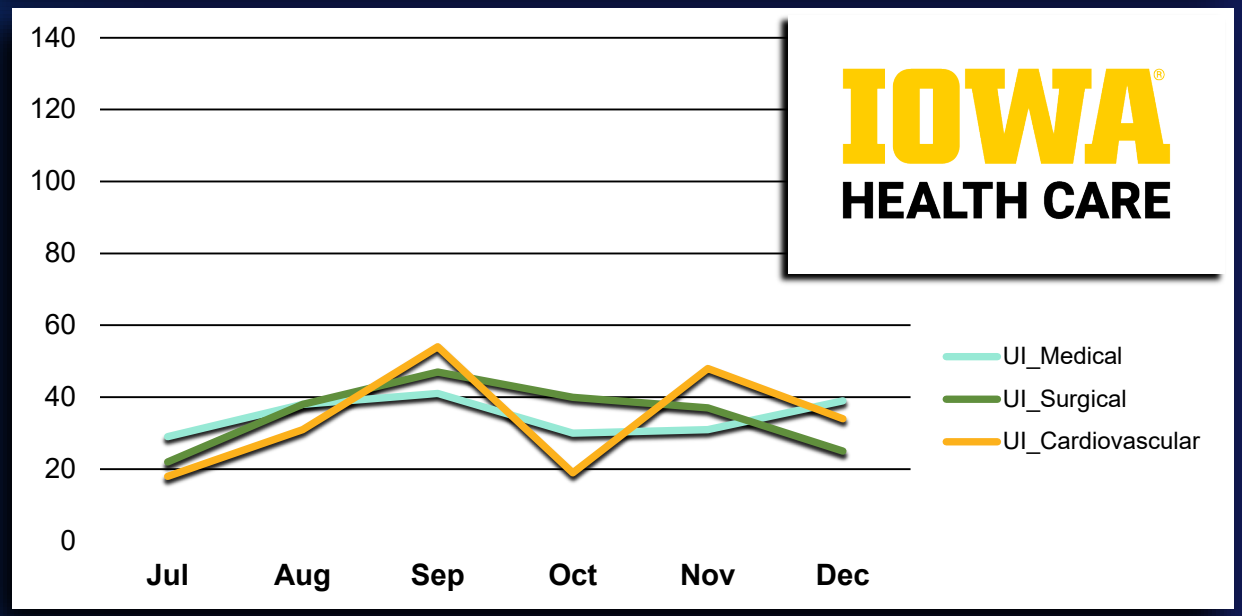


Work Intensity Survey Data

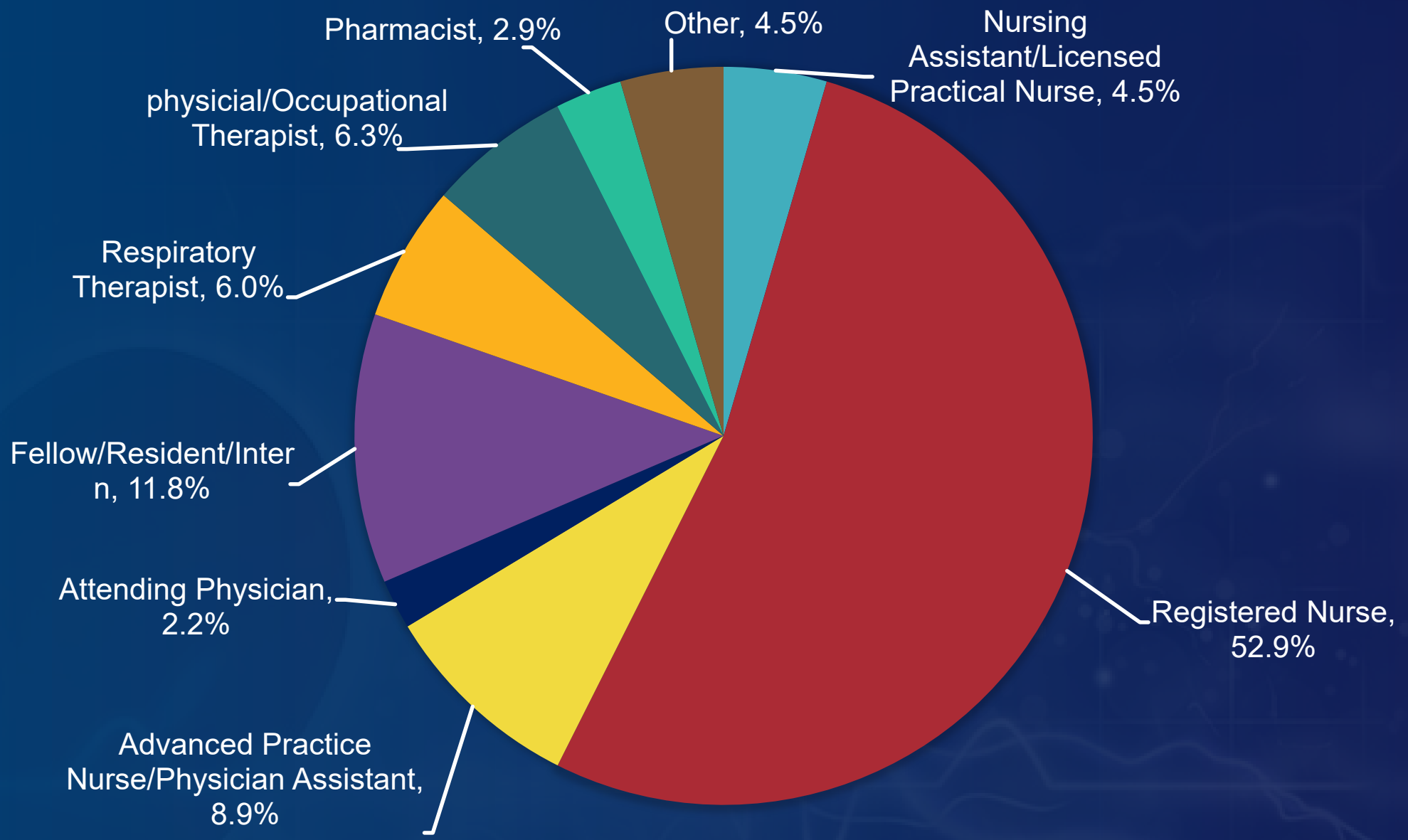
Total Work Intensity Surveys Completed to Date
N = 3,317



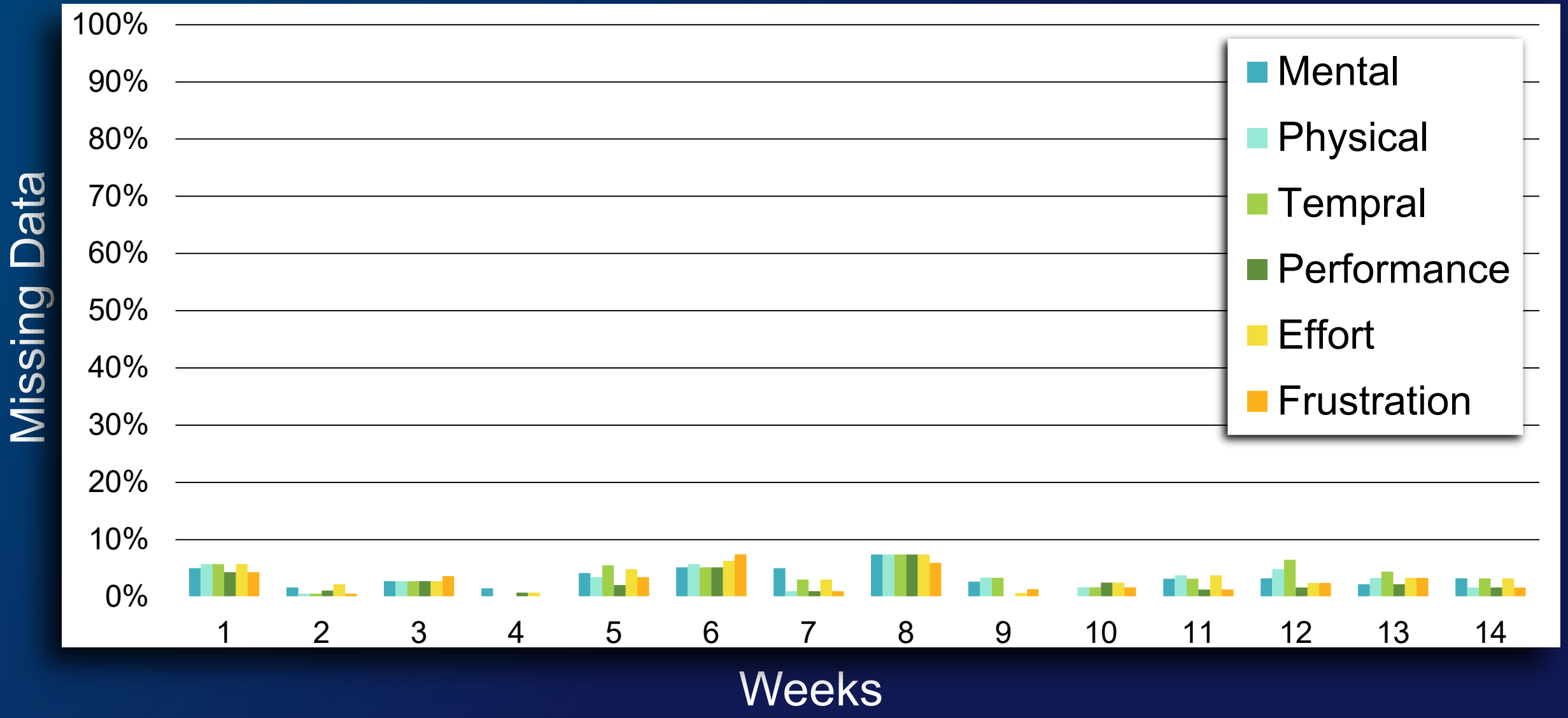




Work Intensity Survey Data: Provider Type



Baseline Proportions of Missing Data on Work Intensity Measures (All Sites)



BEST-ICU: Lessons Learned

5

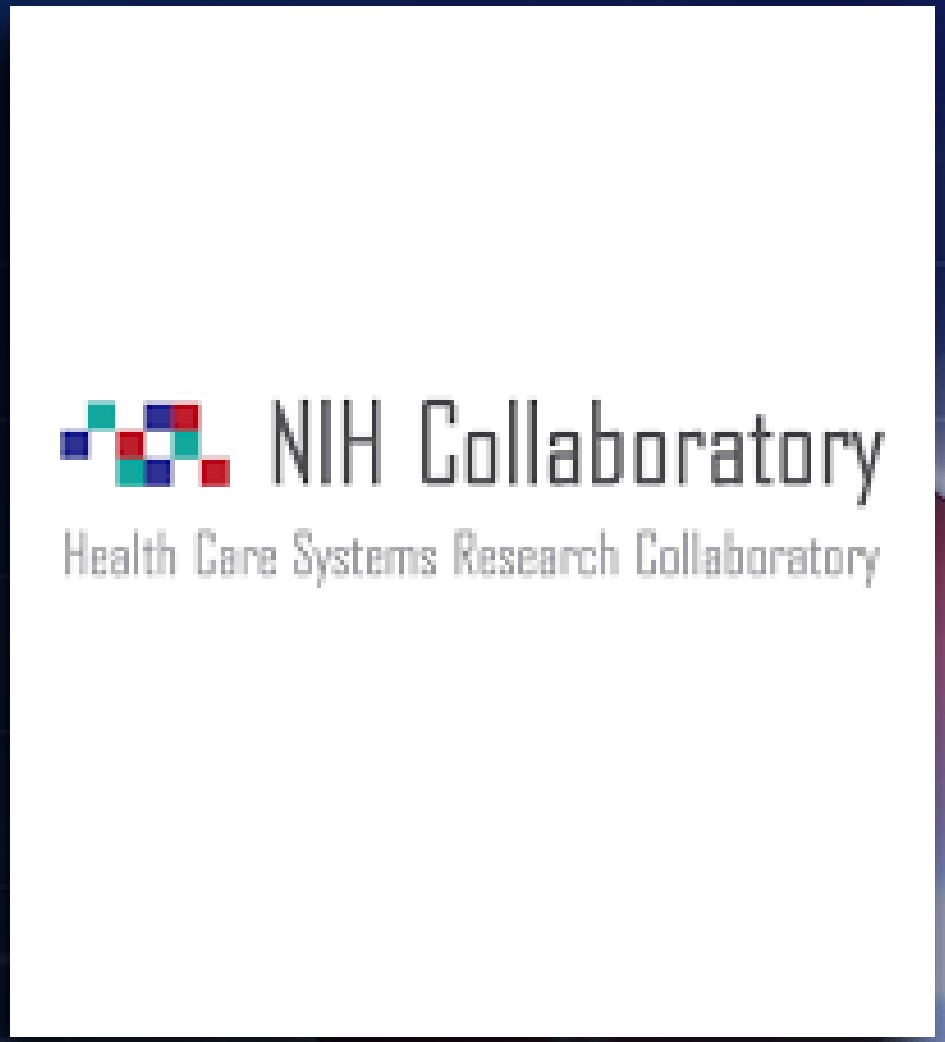
Administrative, Ethics, & Regulatory

Staged award & NIH Collaboratory

- Strengthened scientific approach
  - Consent process
  - Randomization
  - Planned outcome analyses
- Unique logistical considerations

DSMB & DSMP

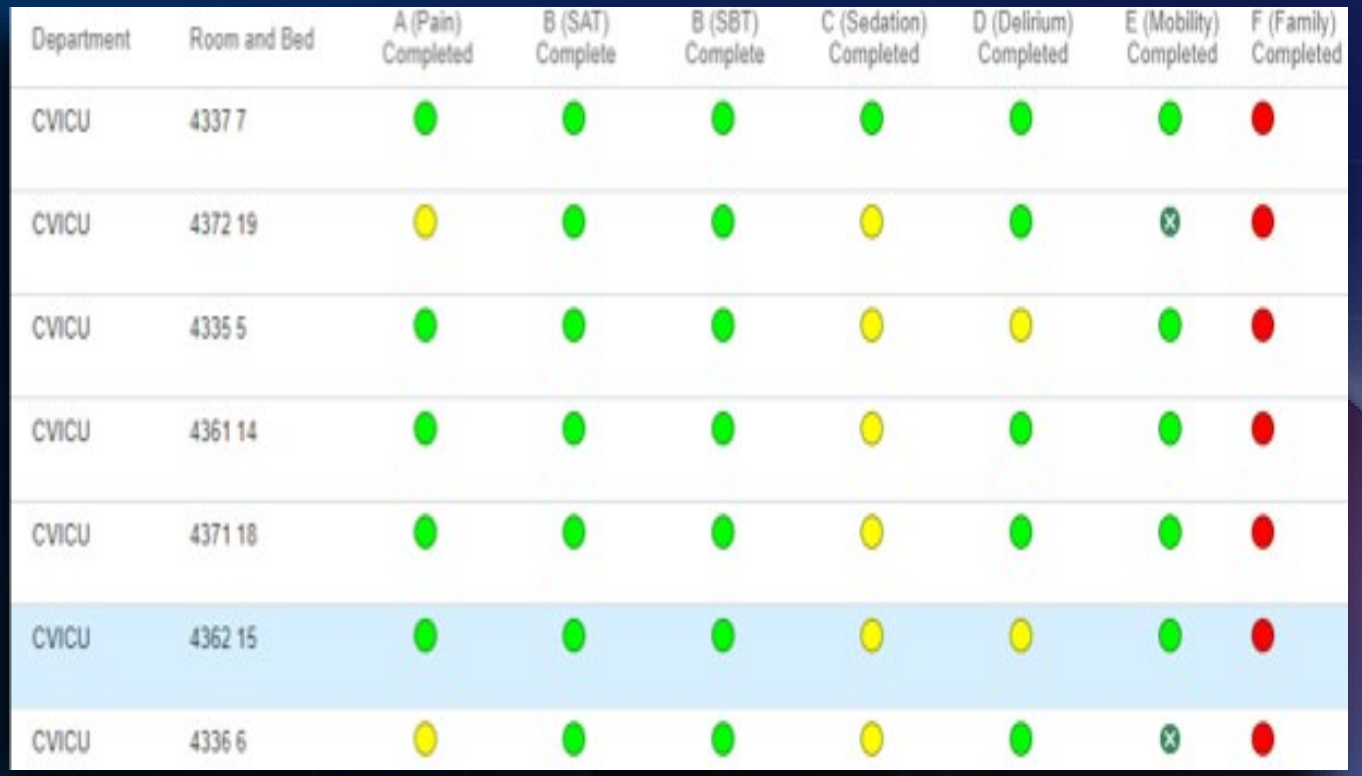
- Adverse events versus clinical outcomes
- Timing of electronic health data



Dashboard Development

Challenges

- Different starting lines
- ABCDEF policy variability
  - e.g. independence vs. dependence of spontaneous awakening trial from spontaneous breathing trial
- EPIC® build variability
  - “Foundation” vs not
- Workflows
  - Entry of Data
  - Data consumption & visualization



Department	Room and Bed	A (Pain) Completed	B (SAT) Complete	B (SBT) Complete	C (Sedation) Completed	D (Delirium) Completed	E (Mobility) Completed	F (Family) Completed
CVICU	4337 7	●	●	●	●	●	●	●
CVICU	4372 19	●	●	●	●	●	⊗	●
CVICU	4335 5	●	●	●	●	●	●	●
CVICU	4361 14	●	●	●	●	●	●	●
CVICU	4371 18	●	●	●	●	●	●	●
CVICU	4362 15	●	●	●	●	●	●	●
CVICU	4336 6	●	●	●	●	●	⊗	●

Real-Time Audit & Feedback Dashboard

Solutions

- Address bundle process & policy gaps
- Standardized definitions for bundle process elements:
  - Safety screen criteria
  - Pass/failure criteria
  - Independence of each process element
- EPIC developers & clinician engagement
- Weekly collaborative workgroup to share definitions, code, & ideas
- Use of test environment

Data Acquisition & Sharing

Goal: Collaborating sites utilize existing certified PCORnet datamart to track all clinical processes & outcomes for Study Aims 1 & 2

Challenges

- Develop data repository for all 3 sites & gain necessary approvals
- University vs. Health-System
- Standardize data definitions/data dictionary
- Identify existing data-element gaps in site-specific PCORnet datamarts
  - -Many ICU elements not part of existing PCORnet
- Variability in set-specific resources & requirements for development work
- Variability site-specific PCORnet timelines for approvals, data-reporting

Computable Phenotypes: Enrollment

Requires invasive mechanical ventilation

- Patient may have multiple ICU stays in one hospitalization
- Endotracheal tubes are placed
  - En route to the hospital
  - Emergency departments and hospital floors
  - In operating rooms
  - In ICUs

Mechanical ventilation initiation & termination

- Flow sheets rows differ across sites
- Different respiratory flow sheet rows may best indicate start & stop

Data Acquisition & Sharing

Solutions

- Engagement of clinical, operational, & legal leadership from University & Health System
- PCORnet expertise / data analyst / bioinformatics
- Regular (weekly to biweekly) meetings to address approvals, data definitions, timing
- Stage data development
  - Phase 1 (Eligibility, Enrollment, DSMB, Primary outcomes)
  - Phase 2 (Will need to accomplish all secondary data analyses)

BEST-ICU

UNMC Nebraska Medicine

The Ohio State University Wexner Medical Center

IOWA Health Care

Wisconsin University of Wisconsin–Madison

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Thank You!