Behavioral Economic & Staffing Strategies To Increase Adoption of the ABCDEF Bundle in the ICU

NIH

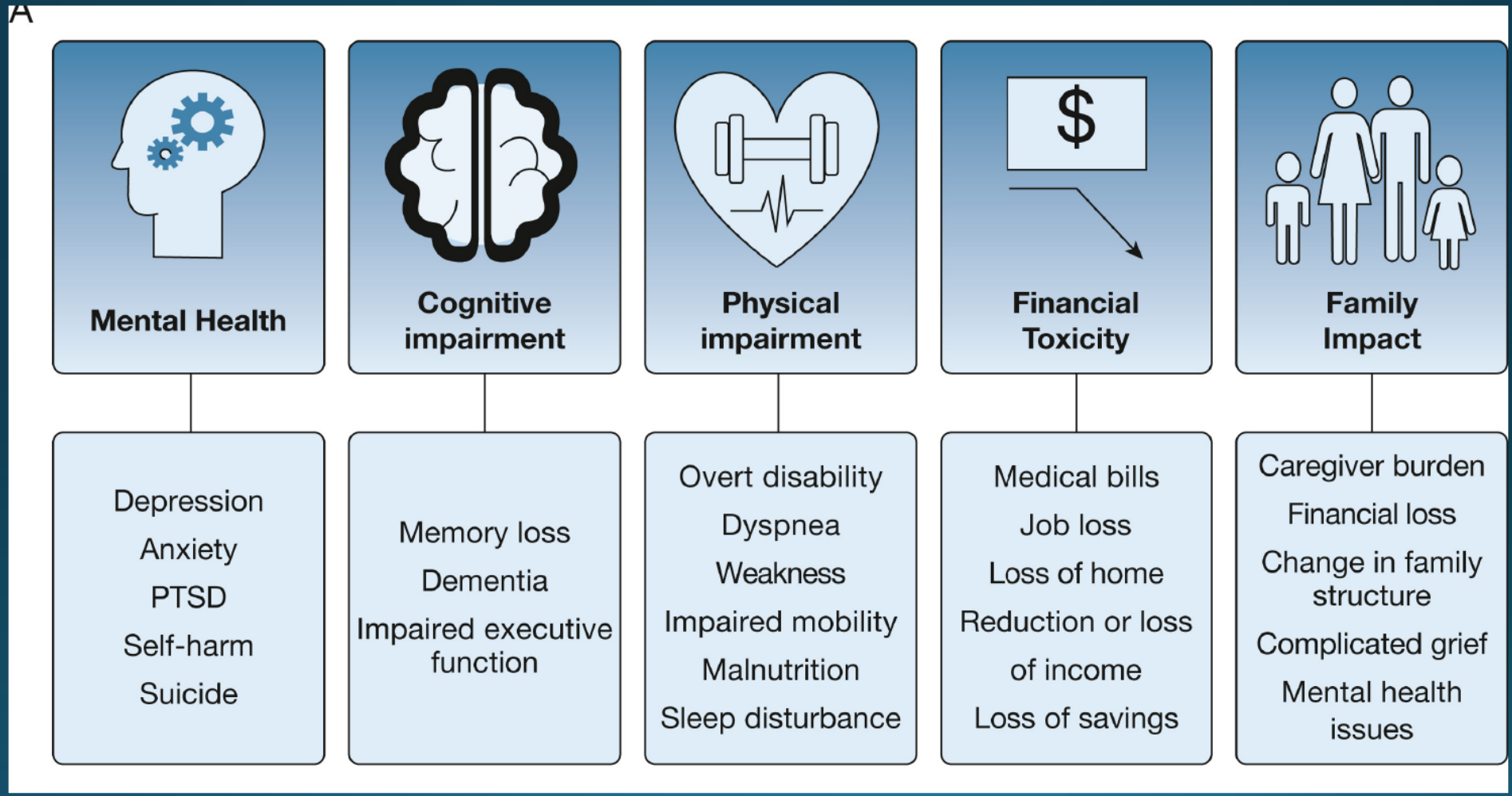
BEST-ICU

National Heart, Lung, and Blood Institute

National Institute of Nursing Research

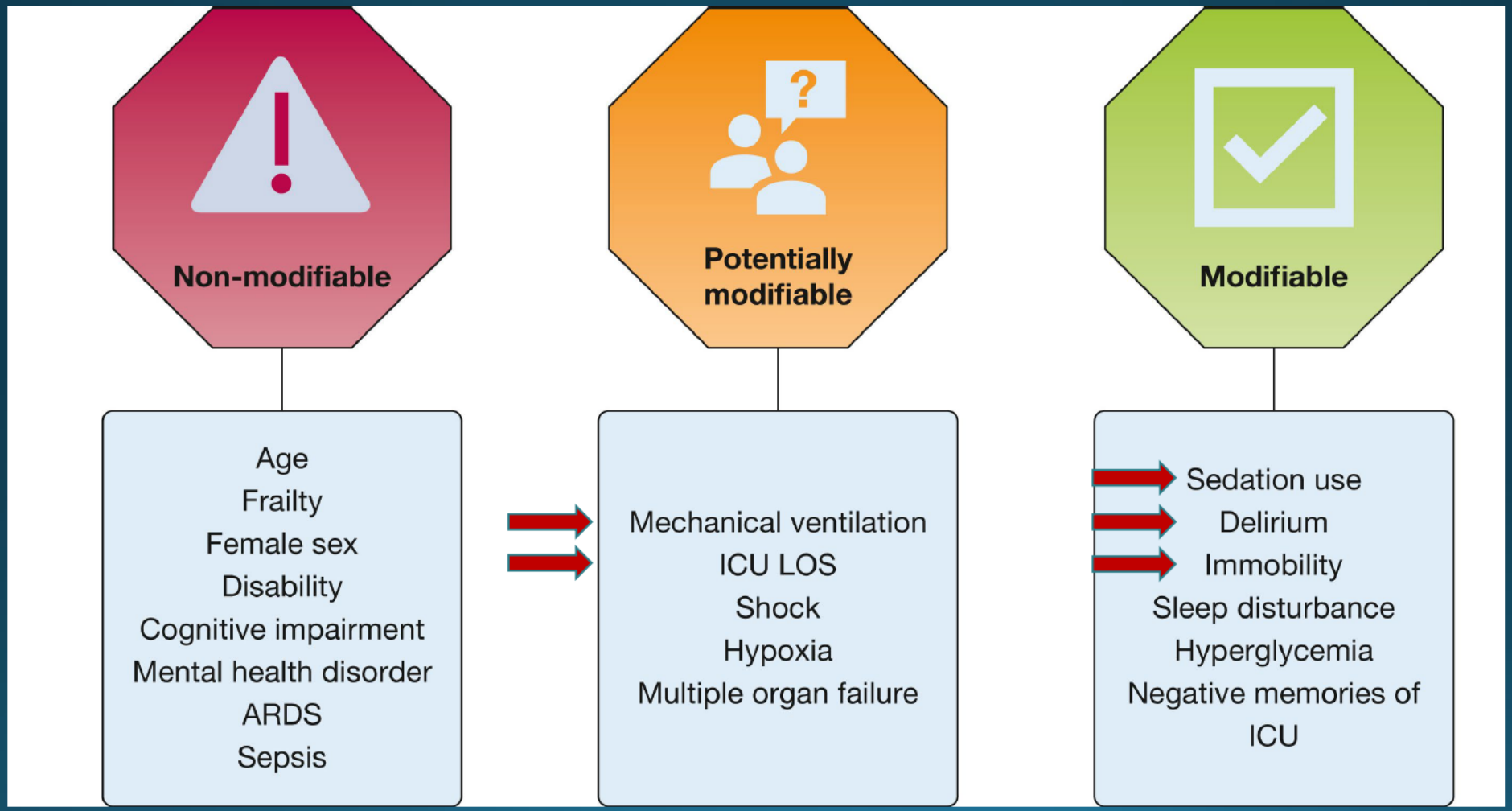
Significance: Post Intensive Care Syndrome (PICS)

Human & Financial Costs of Increasing ICU Survivorship



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

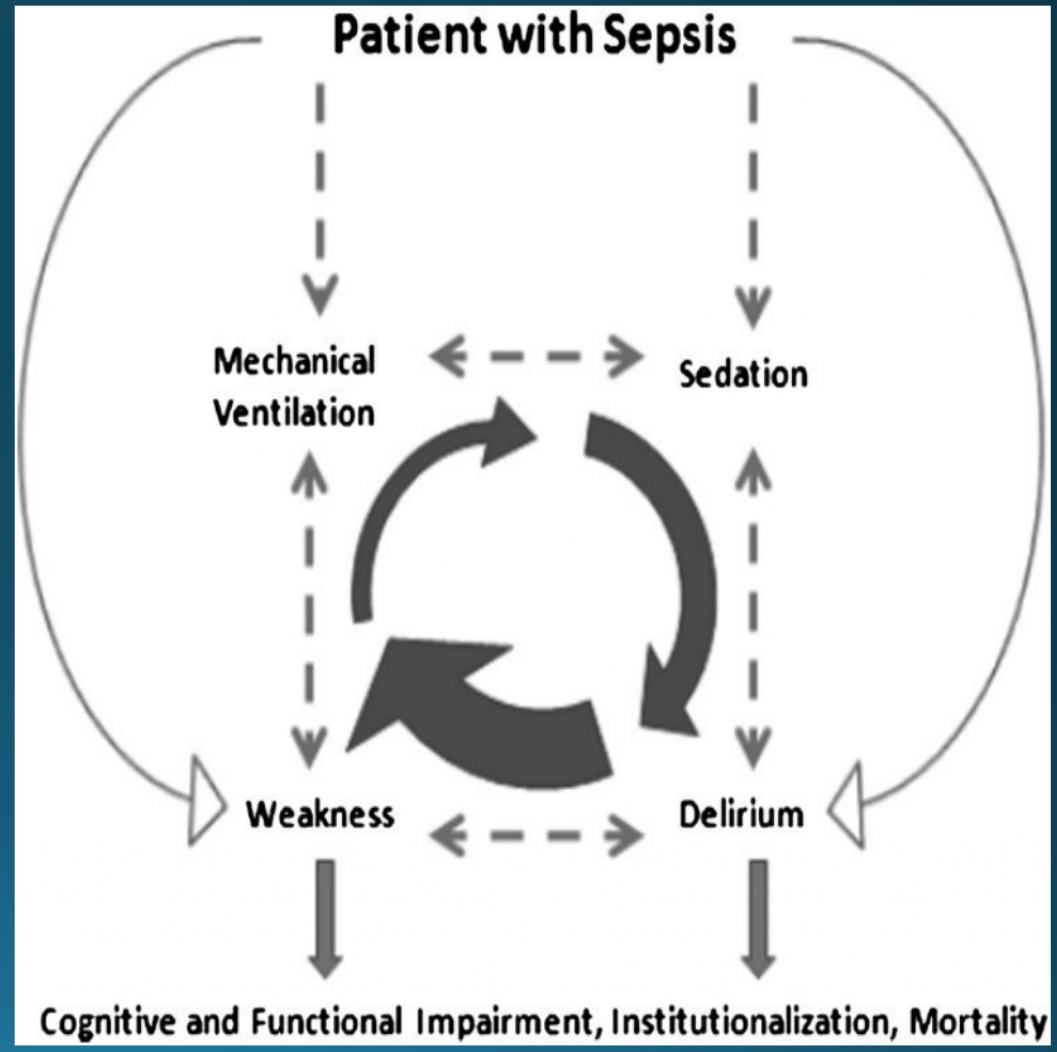
Conditions Associated with PICS



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

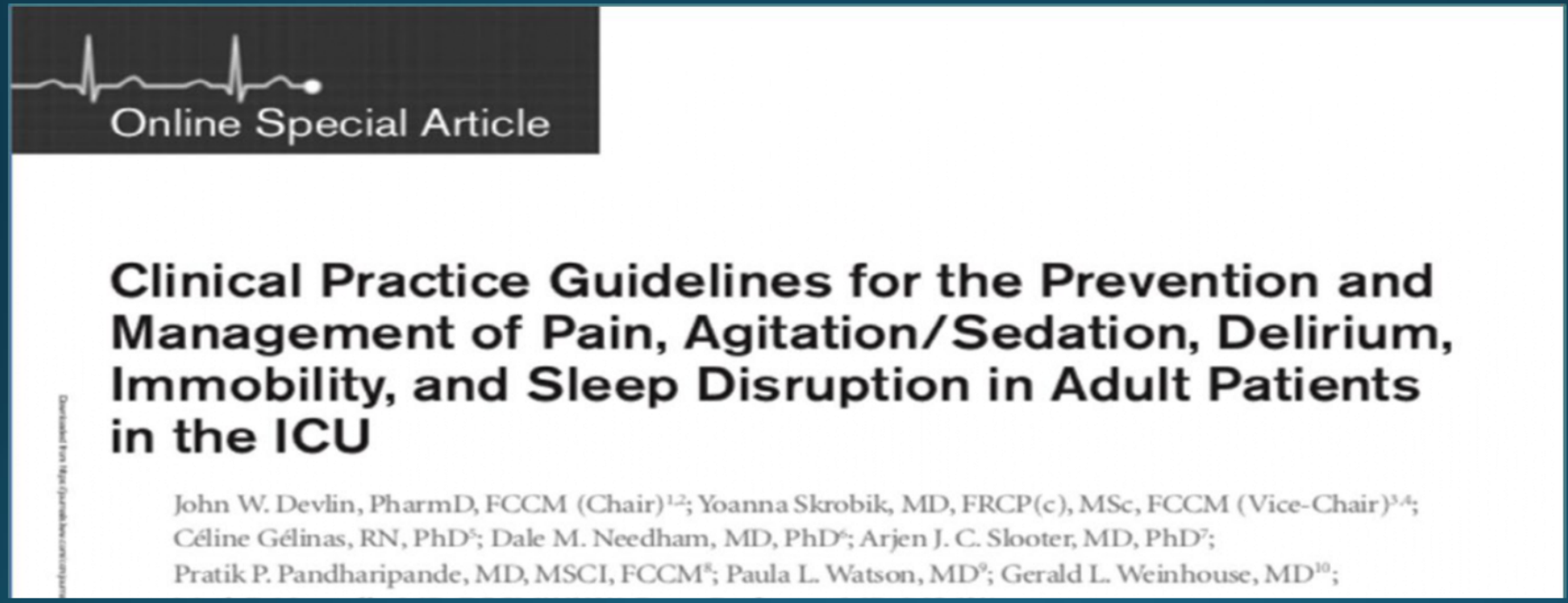
Modifiable Conditions Associated with PICS

- Mechanical ventilation
- Pain
  - Up to 70% of all ICU patients
  - Distressing, undertreated
- Delirium
  - Up to 80% of patients on mechanical ventilation (MV)
  - Increased mortality, complications, MV days, ICU & hospital LOS, new institutionalization, cognitive impairment
- Weakness
  - Up to 50% of all ICU patients
  - Increased muscle wasting, functional decline, delirium



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

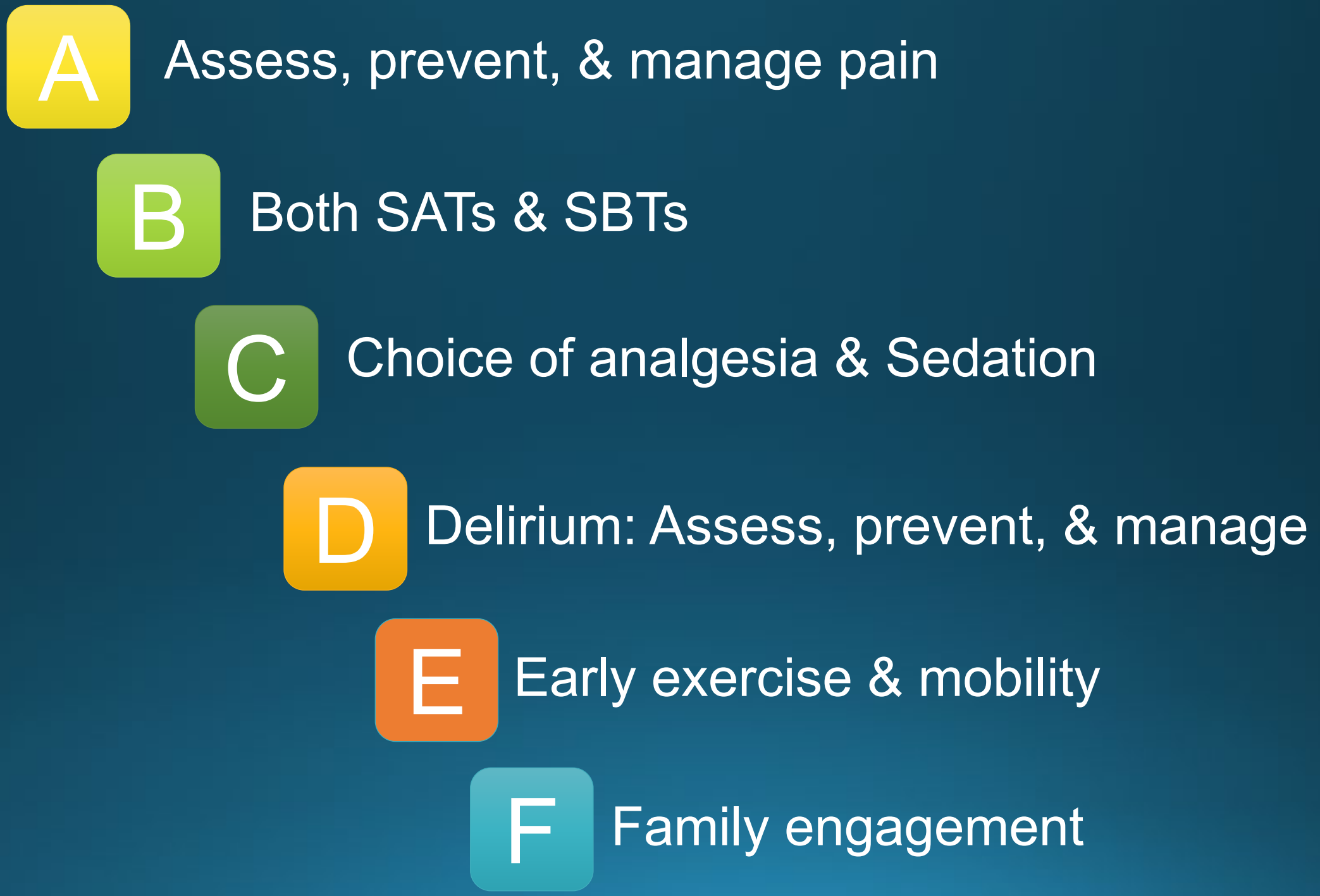
Highly Efficacious & Safe MV Liberation, Symptom Management, & Mobility Interventions Exist



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

Interventions include:

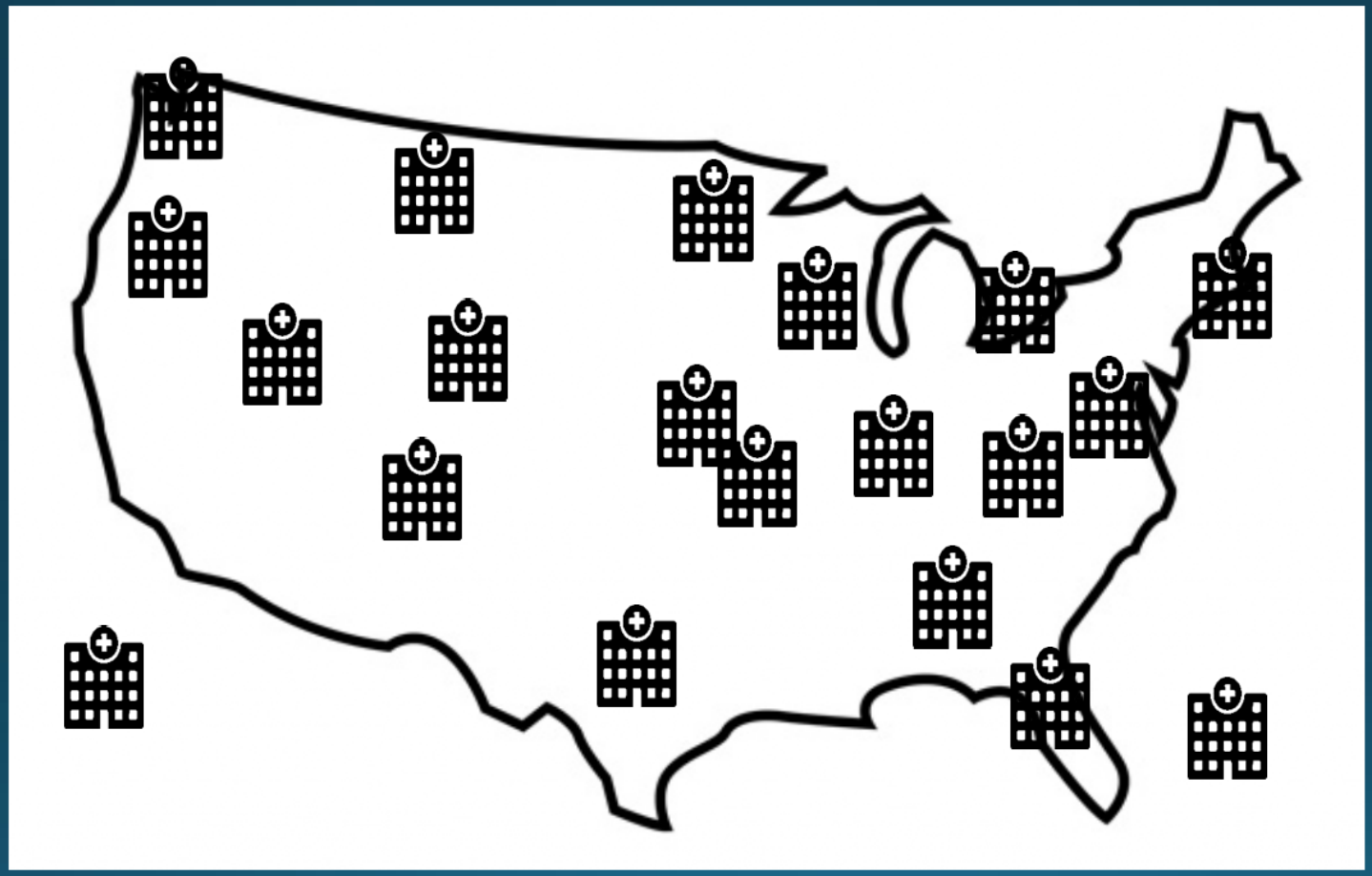
- Routine monitoring of pain, level of arousal, & delirium using valid & reliable tools
- Maintaining patients at a “light” level of sedation by using daily spontaneous awakening trials (SATs), target-based sedation protocols, or an analgesia-based sedation approach
- Avoiding benzodiazepines
- Performing early & frequent mobilization
- Combining MV discontinuation protocols that include daily SATs & spontaneous breathing trials (SBTs)
    - Paired SATs/SBTs reduce the number of days patients are on MV (3-day reduction), hospital LOS (4-day difference), and mortality (for every 7 patients treated with coordinated SATs/SBTs 1 life is saved) when compared with SBTs alone


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

Process Outcome Measures

- Effect of giving all ABCDEF bundle vs effect of giving some of the ABCDEF bundle
  - Is there a dose response effect?
- Complete bundle performance
  - Received every eligible bundle element on any given day
- Proportional bundle performance
  - Percentage of eligible bundle elements performed on any given day

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

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

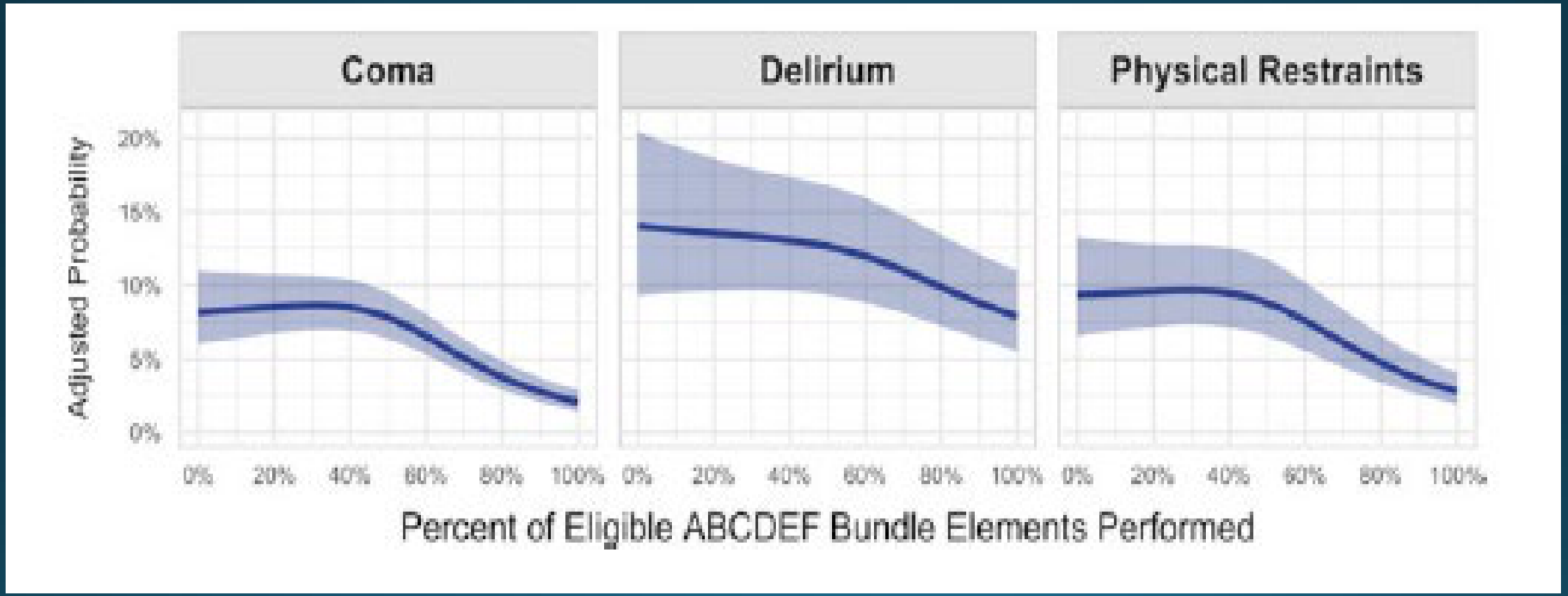
Clinical Outcomes

Outcomes	Complete Bundle Performance*	P Value
ICU readmission	0.54 (037–0.79)	< 0.001
Discharge destination	0.64 (0.51–0.80)	< 0.001

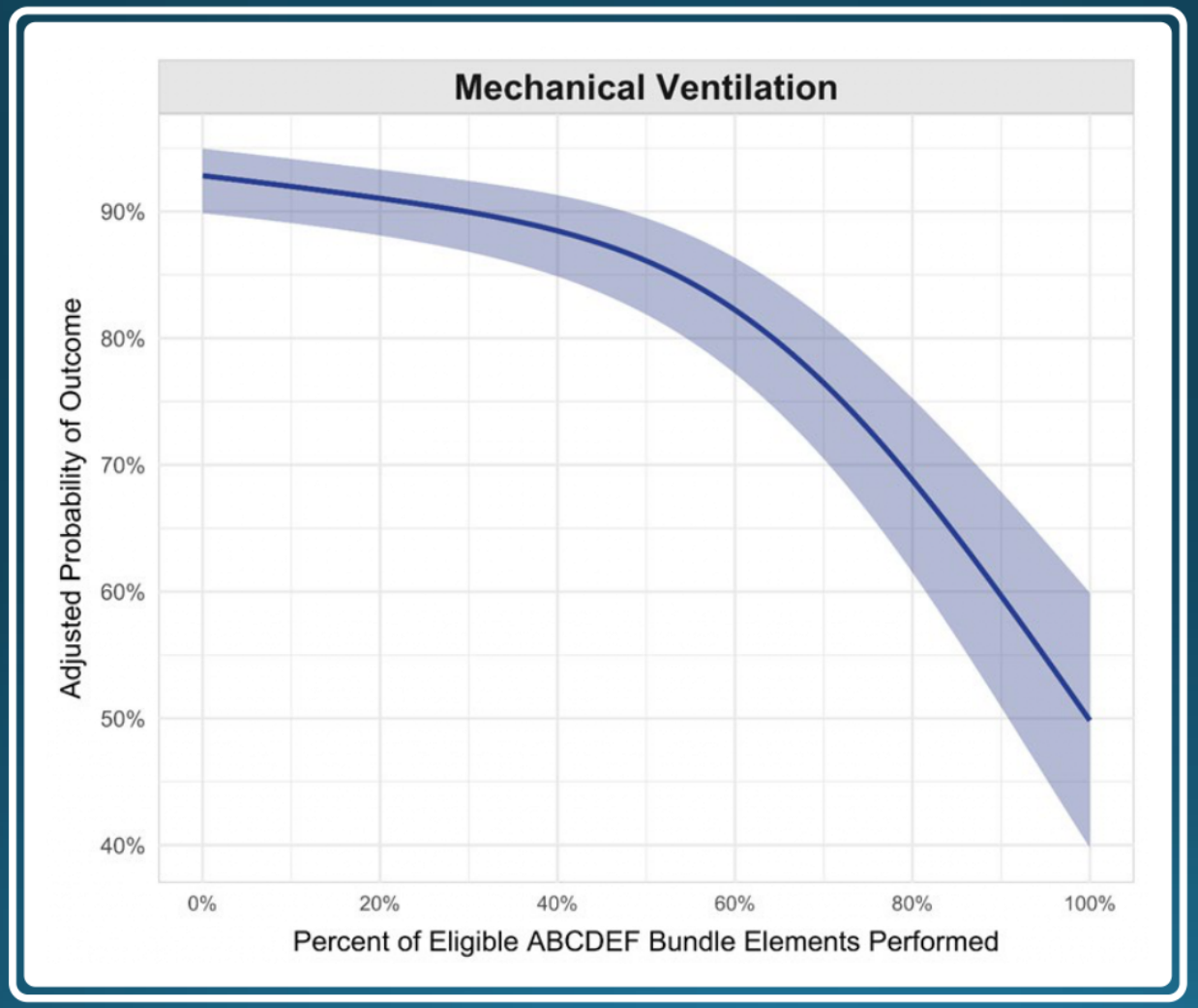
Partial bundle performance

Improved outcomes

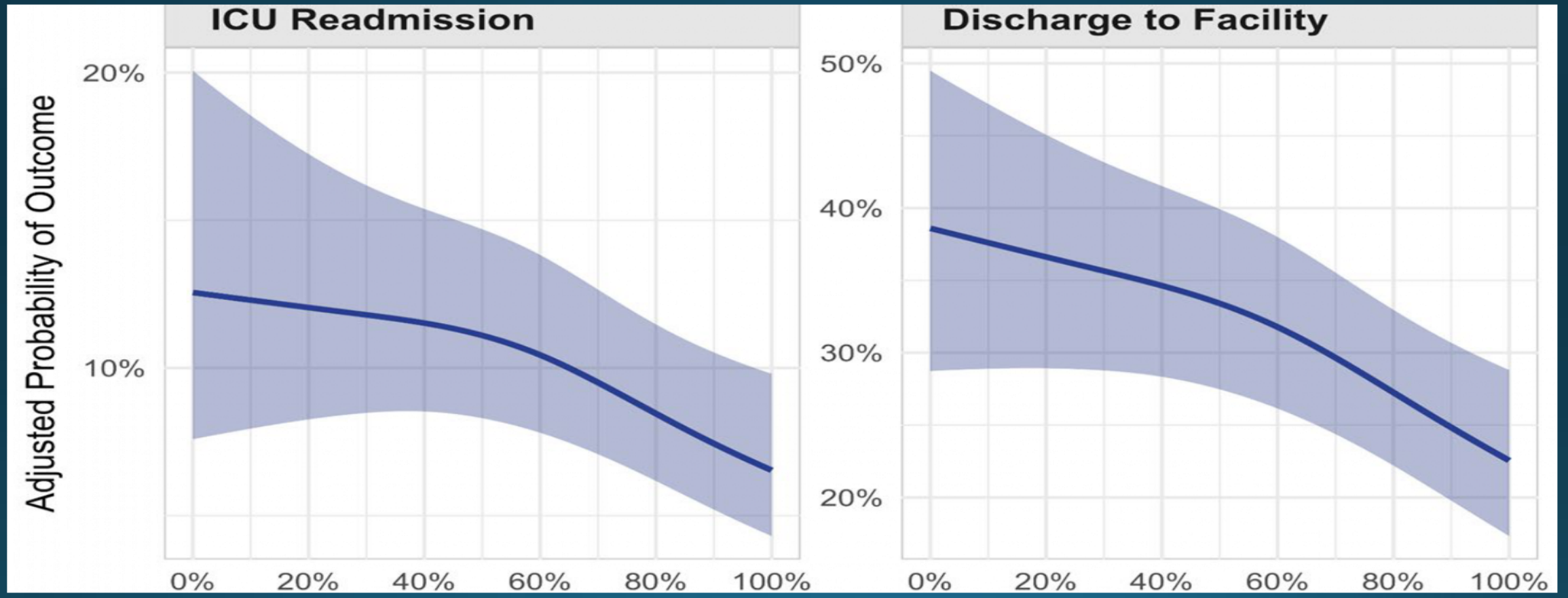
Clinical Outcomes



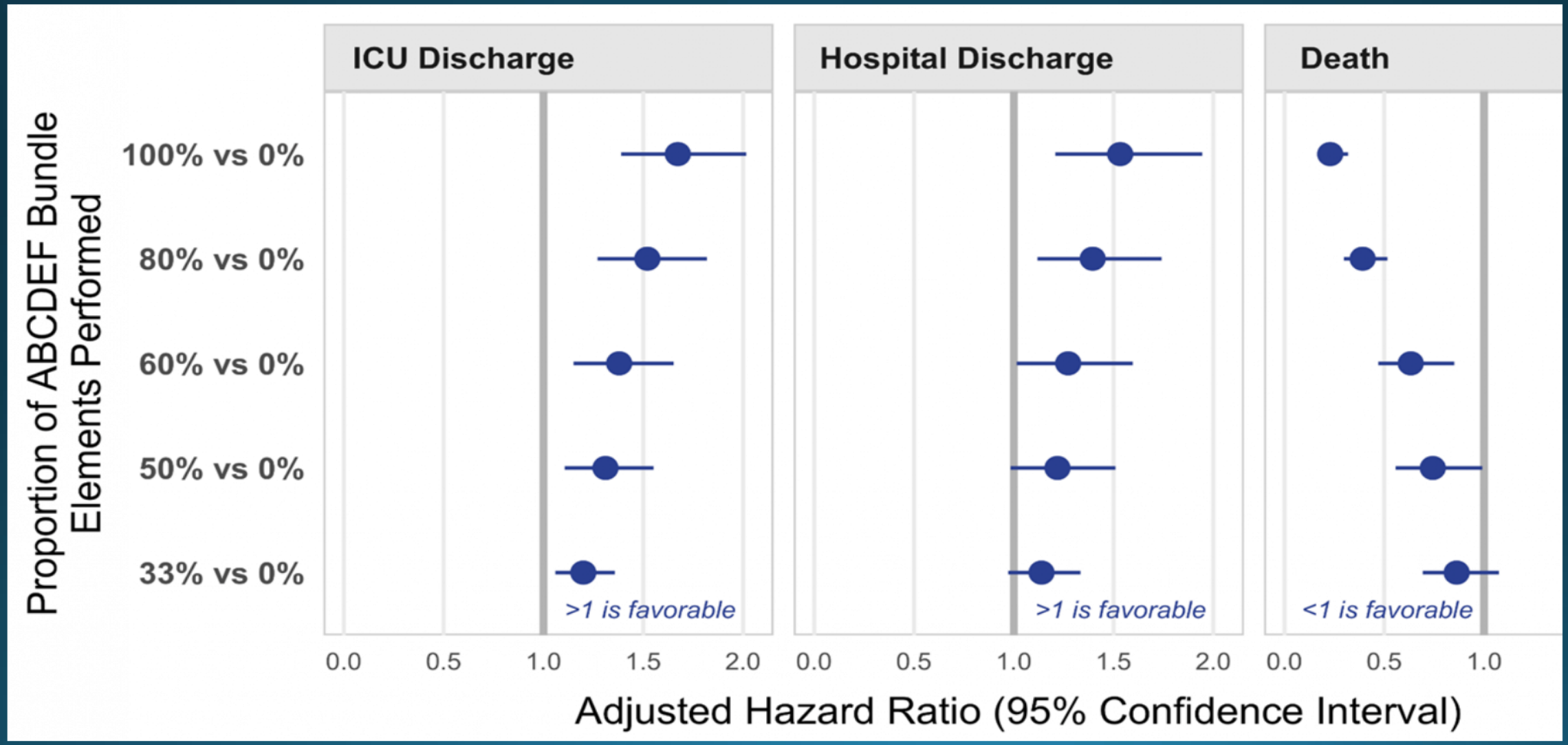
Clinical Outcomes



Clinical Outcomes



Clinical Outcomes



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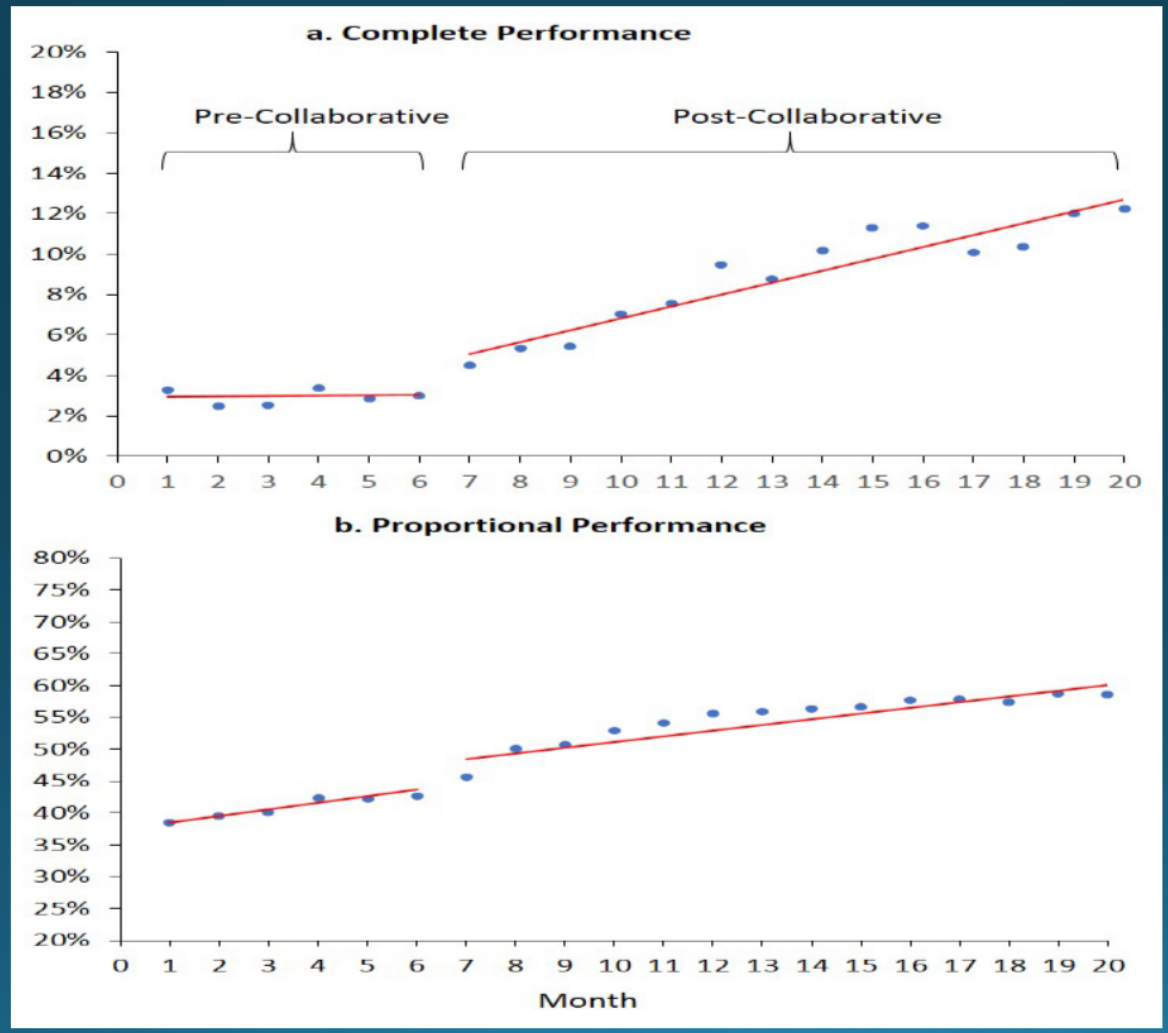
Implementation Gaps: Continual Low Bundle Adoption



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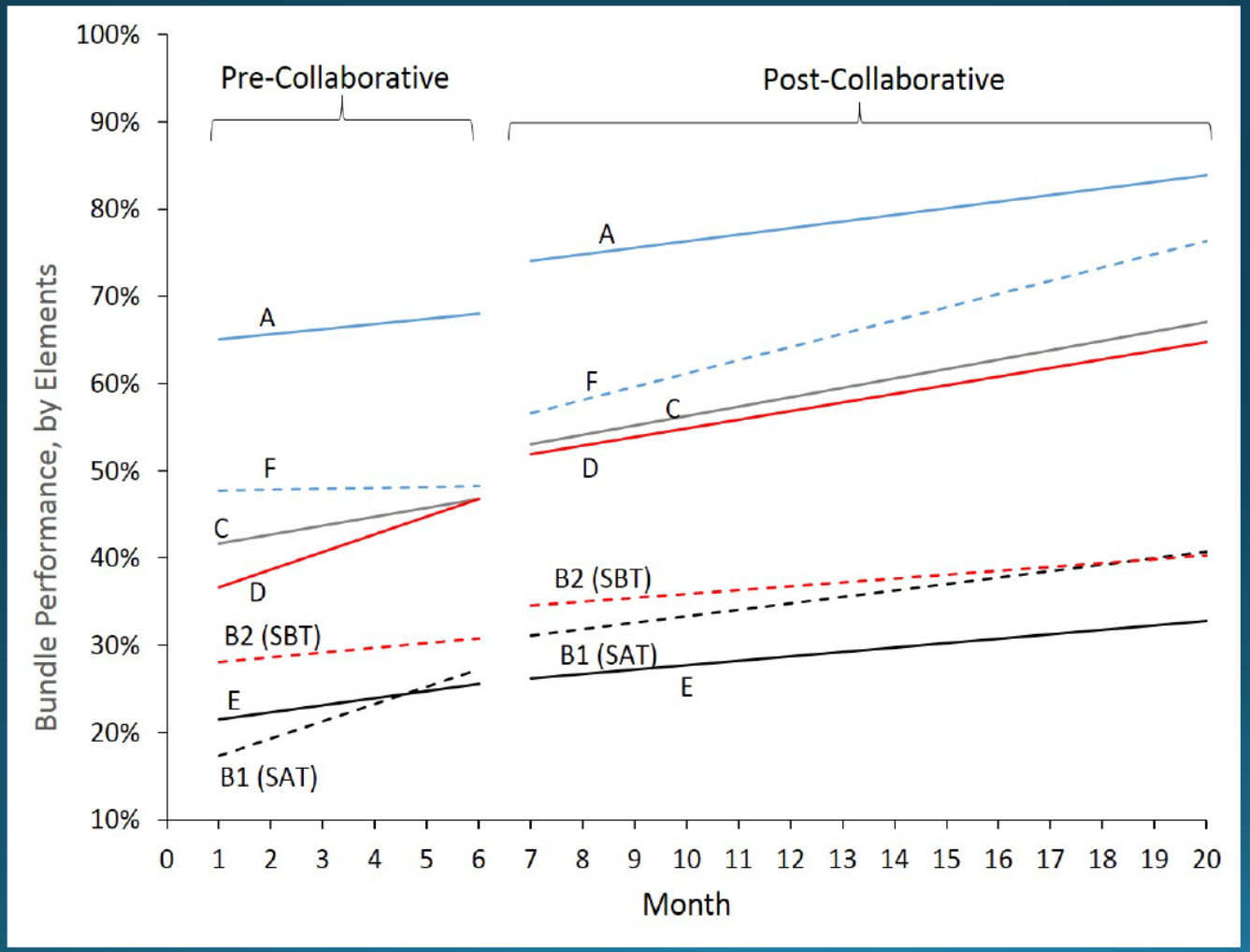

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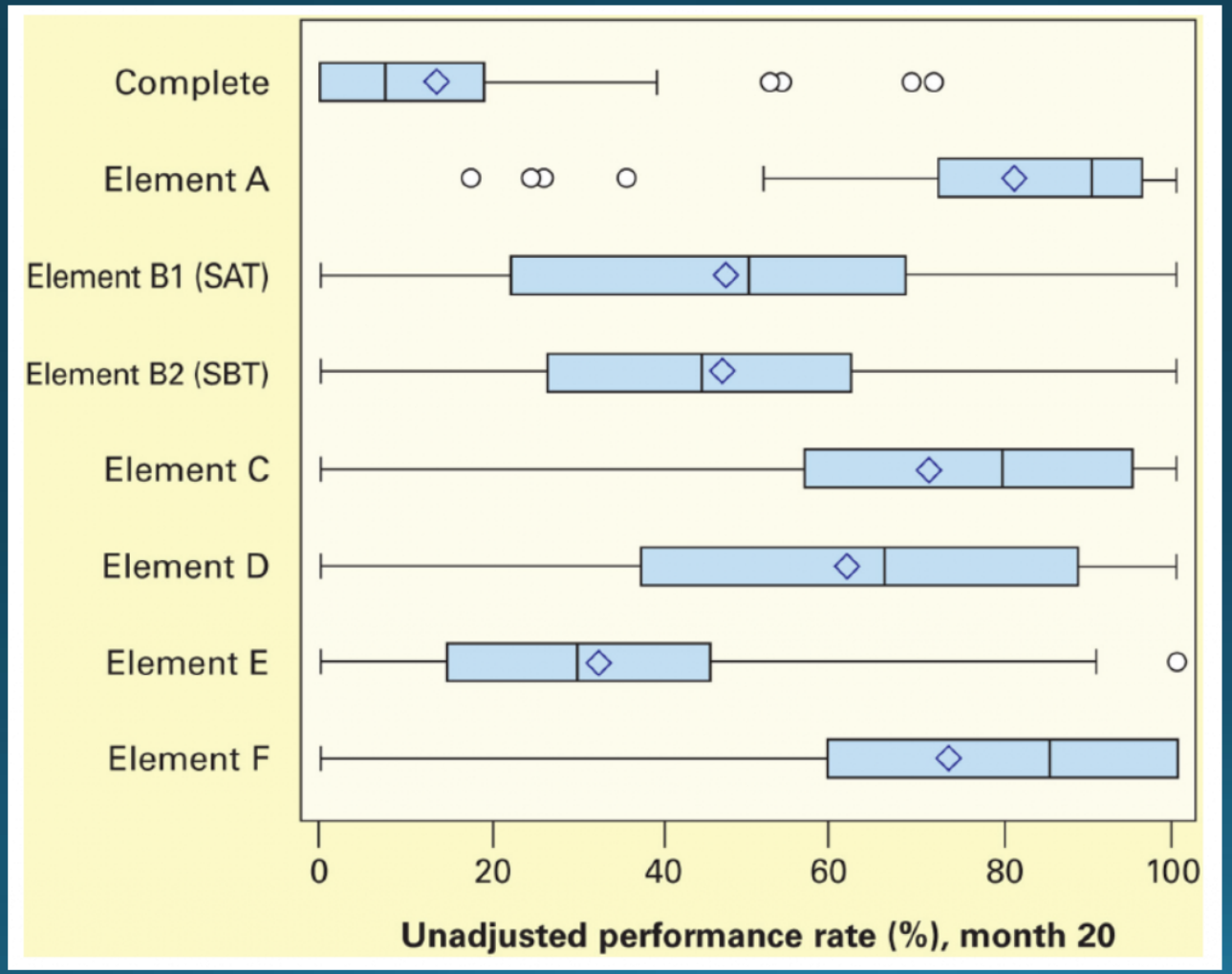
Implementation Gaps: High Variability



National Heart, Lung, and Blood Institute

CRITICAL CARE

What Factors Are Associated With Spontaneous Awakening Trial (SAT) and Spontaneous Breathing Trial (SBT) Performance?

CHEST

STUDY DESIGN

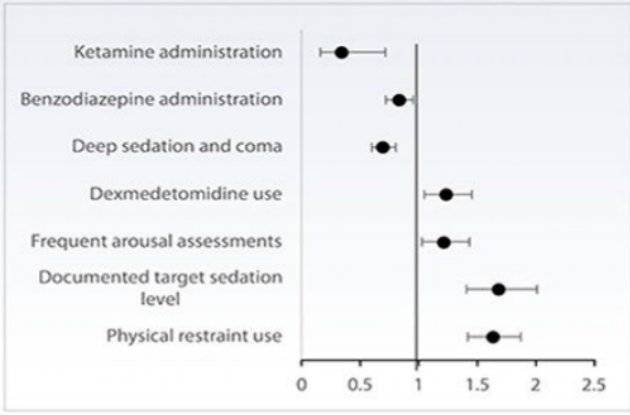
- Secondary analysis of a national quality improvement collaborative comprised of 68 diverse ICUs
- Included critically ill adult patients on mechanical ventilation and continuously infused sedatives

4,847
included in SAT analysis

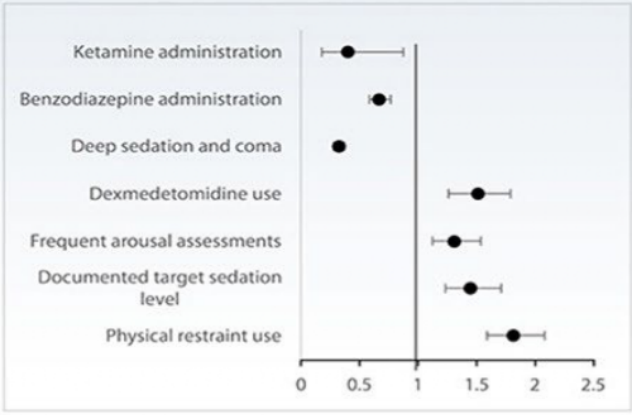
4,936
included in SBT analysis

RESULTS

Odds of a Next-Day SAT



Odds of a Next-Day SBT



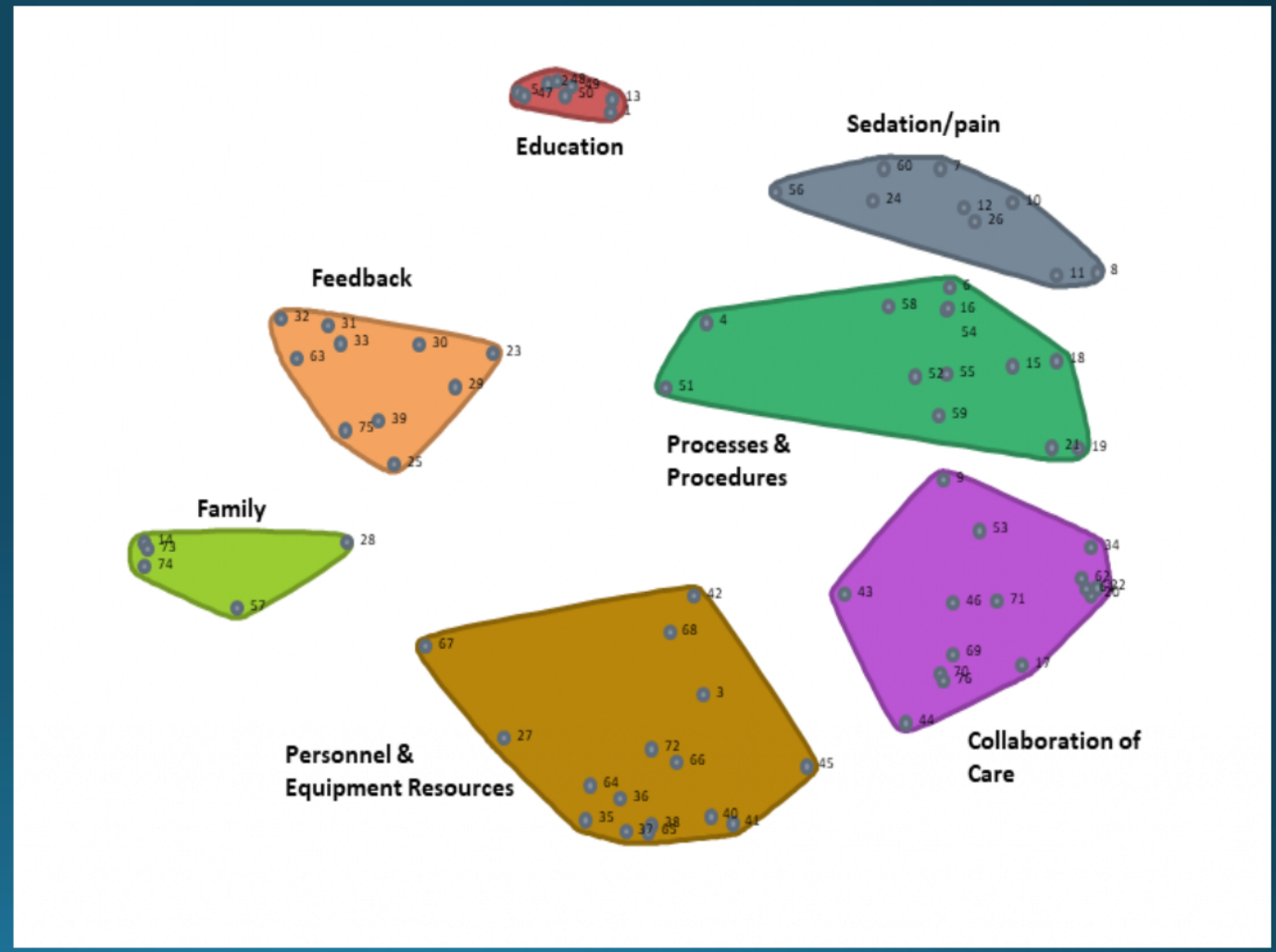
There are several modifiable factors associated with SAT and SBT performance that are amenable to the development and testing of implementation interventions.

Balas M, et al. *CHEST* September 2022 | @journal_CHEST | https://doi.org/10.1016/j.chest.2022.01.018

National Heart, Lung, and Blood Institute

Implementation Challenges: Numerous & Complex

- 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
- 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



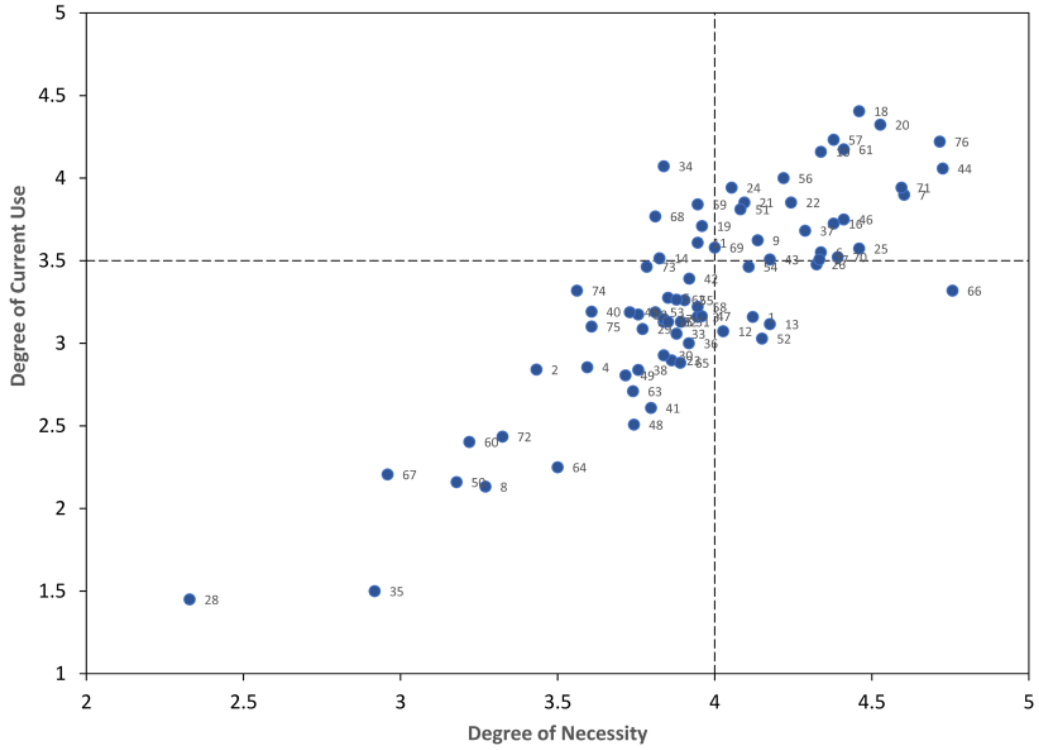
Mion, L, et al., Critical Care Explorations 5(3):p e0872, March 2023.

National Heart, Lung, and Blood Institute

Implementation Challenges: Numerous & Complex

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

Item 66 (adequate staffing)



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National Heart, Lung, and Blood Institute

National Institute of Nursing Research

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

Balas, M.C. (Co-PI), Vasilevskis, E (Co-PI). Campbell, J., Hetland, B., Wichman, K., Horner, R., Kim, J., Ultican, T. Krupp, A., Blum, J., Exline, M., Gerlach, T.

BEST ICU

- Overarching goal: Support the “real-world” assessment of strategies used to foster adoption of several evidence-based clinical practices in healthcare systems that provide care to critically ill adults with known health disparities

- 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

- Proposed project includes two phases & four specific aims

Phase 1: UG3

	Approved Milestone Title
1	Collaborate with NIH's Healthcare Systems Research Collaboratory Coordinating Centers to refine implementation practices
2.	Finalize study protocol & study related documents
3.	Establish Data Safety and Monitoring Board (DSMB)
4.	DSMB review & approval
5.	IRB approval
6.	Enrollment of the first participant in focus groups
7.	Clinical trials.gov
8.	Realtime audit & feedback display finalization
9.	Finalize EHR data collection capture & sharing plans
10.	Site selection & detailed plans for site implementation

- **UG3 Aim 1**: Enhance & finalize the implementation strategies & research methods used to facilitate & evaluate the effectiveness of ABCDEF bundle adoption

Phase 2: UH3

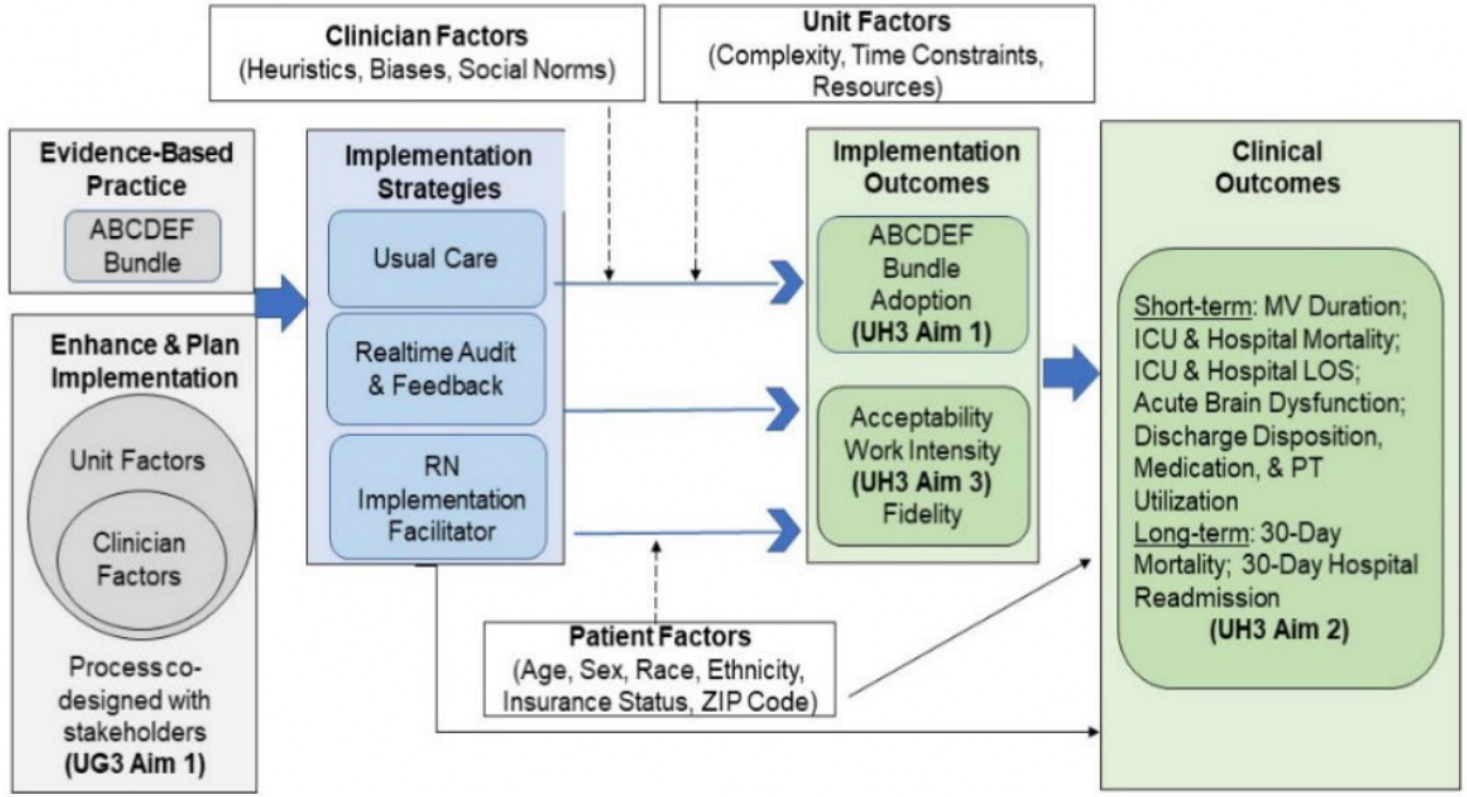
- **UH3 Aim 1:** Compare the effectiveness of real-time audit & feedback & RN implementation facilitator on ABCDEF bundle adoption (**primary study outcome**)

- **UH3 Aim 2:** Compare the effectiveness of real-time audit & feedback & RN implementation facilitator on clinical outcomes (duration of MV; ICU, hospital, & 30-day mortality; ICU & hospital length of stay; days with acute brain dysfunction; discharge disposition, psychoactive medication, discharge physical therapy utilization; & 30-day hospital readmission)

- **UH3 Aim 3:** Identify & describe key stakeholders' experiences with, & perspectives on, the acceptability & impact on work intensity of real-time audit & feedback & RN implementation facilitator

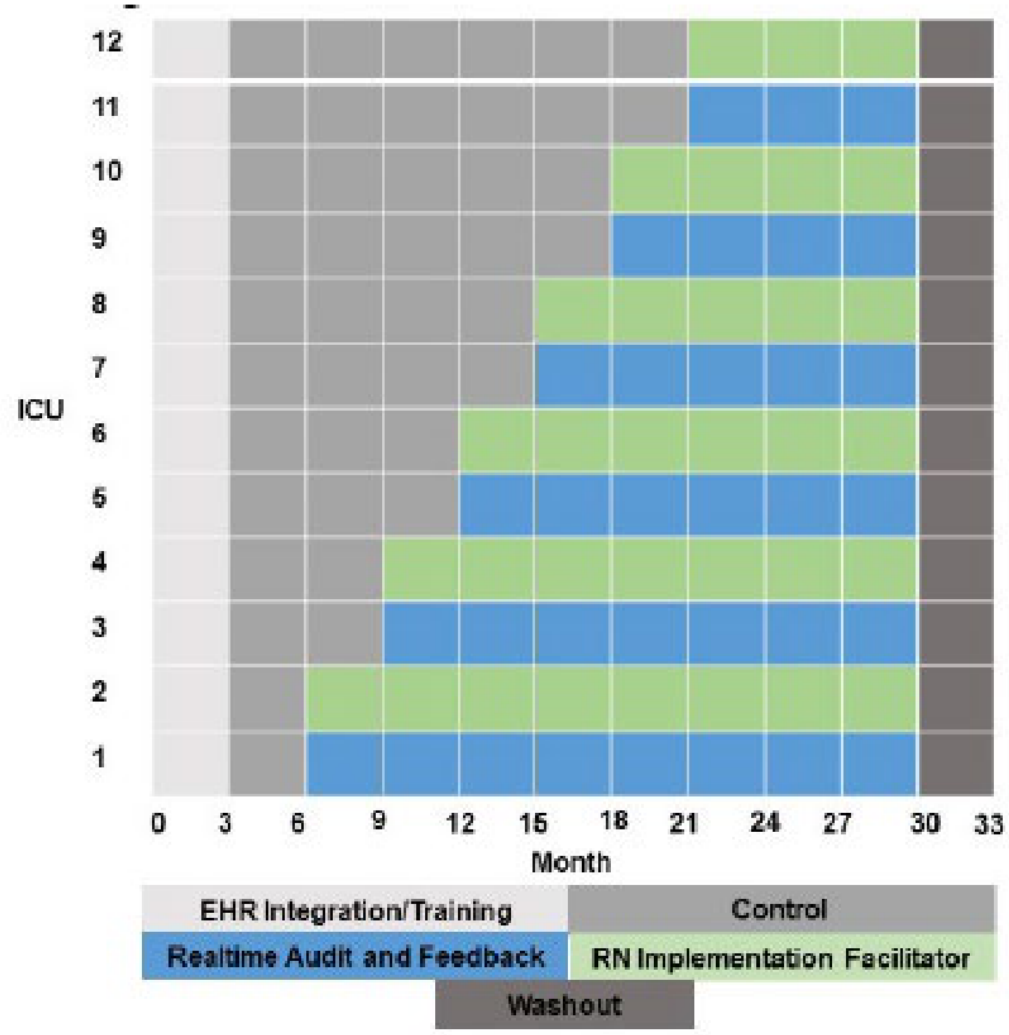
Research Framework

Figure 3. Conceptual Model



Study Design & Randomization

- **3-arm, pragmatic, stepped-wedge, cluster randomized hybrid type III effectiveness- implementation trial**
- Unit of Randomization: ICU
- Block randomization: Hospital as block
- To improve group balance, will create matched pairs based on:
  - ICU type (medical, surgical)
  - Baseline bundle proportional performance (above & below median)
- Within matched pairs, each ICU will be assigned to strategy A or B, & matched pairs will be randomly assigned to one of six wedges which will determine the strategy initiation dates.
- All hospitals will contribute a minimum of 3 mos. of data prior to adopting an implementation strategy. By the completion of the 27-month trial, all ICUs will contribute a minimum of 9 mos. of data with an assigned strategy in place. At trial end, both strategies will be removed but we will continue to follow implementation & clinical outcomes to assess the effect of de-implementation of the strategies. During this time, we will also assess key stakeholders' perceptions of their assigned implementation strategies & how each strategy affected their clinical workload.



Participants

Hospitals: 3 geographically & organizationally separate safety net hospitals

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

Clinicians: Physicians, advanced practice providers, RNs, RTs, pharmacists, PT/OTs, ICU/hospital administrators, & IT specialists, participate Aim 3

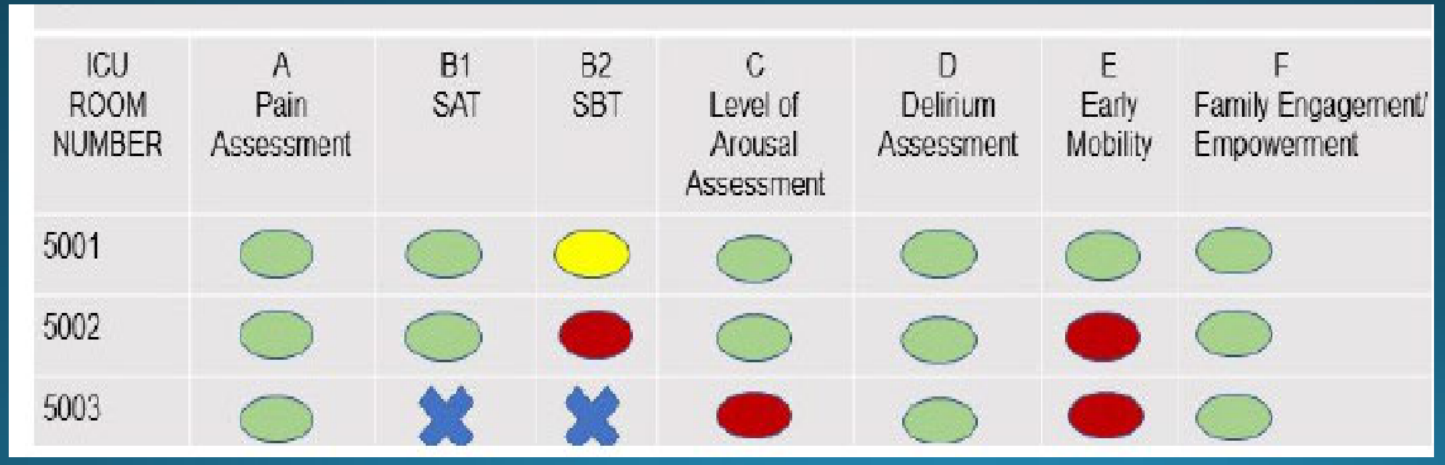
Patients: All adults treated with MV admitted to a participating ICU

Table 2. Site Characteristics

Site, Number Hospital Admits Jan. 2021-Jan. 2022	NMC (N= 66,484)	UIC (N=22,555)	OSU-WMC (N=31,028)
Age > 60	32,828 (49.3%)	10,999 (48.8%)	10,882 (37.6%)
Race			
Black	6,826 (10.3%)	1,394 (6.2%)	3,940 (12.7%)
Asian	863 (1.3%)	301 (1.3%)	583 (1.9%)
American Indian or Alaska Native	579 (0.9%)	61 (0.3%)	Not reported
Native Hawaiian or Other Pacific Islander	201 (0.3%)	24 (0.1%)	11 (0.1%)
Other Race	5,280 (7.9%)	1,453 (6.4%)	4,560 (14.7%)
White	52,735 (79.3%)	19,322 (85.7%)	21,934 (70.7%)
Rurality			
Urban	52,602 (79.1%)	12,197 (54.0%)	Not reported
Rural	7,934 (11.9%)	9,936 (44.1%)	Not reported
Unable to map	5,948 (8.9%)	422 (1.9%)	Not reported
Primary Insurance			
Medicare	9,384 (14.1%)	9,404 (41.7%)	9,989 (32.2%)
Medicaid	3,336 (5.0%)	4,104 (18.2%)	7,732 (24.9%)
Private	7,821 (11.8%)	7,181 (31.8%	11,914 (38.4%)
Other Insurance/ Unknown	45,943 (69.1%)	1,866 (8.3%)	1,482 (4.8%)

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

- Real-time A&F via a centrally placed visual display (dashboard)
- All providers practicing in the ICU will have access to the dashboard which will be updated in real-time (i.e., past 24 hours)
- Dashboard will be created using already established flowsheets, procedures, application reports, activity & navigator records, BestPractice Advisories (BPAs), & tasks within Epic along with the additions already created at the NMC.
- Will include the completion status of each of the daily bundle elements by ICU room number (see Figure)



ICU ROOM NUMBER	A Pain Assessment	B1 SAT	B2 SBT	C Level of Arousal Assessment	D Delirium Assessment	E Early Mobility	F Family Engagement/ Empowerment
5001							
5002							
5003							

Implementation Strategies: Intervention Arm 2
RN Implementation Facilitator

- **Practical clinical facilitator**: Acts as extra support to carry out the functions of the ABCDEF bundle
- **Coordinator**: Coordinate ABCDEF practices across specialties
- **Champion**: Promote clinician behavior change
- **Coach**: Facilitate training of bundle elements to team members
- Internal facilitator (RN already working on ICU)
- ?? Day shift (when most bundle elements performed); ?? Amount of time

Evaluation Framework

- Primary Study Outcome: ABCDEF Bundle adoption
- Adoption defined as: Proportional bundle performance (i.e., % of eligible elements a patient receives on a given ICU day "bundle dose")
- Secondary implementation outcomes
  - Complete bundle performance
  - Individual bundle element performance
  - Bundle maintenance
  - Acceptability
  - Work Intensity
  - Reach

Table 3. Trial Outcomes Categorized by REAIM Framework

Element	Endpoints	Data Collection
Reach	ICUs and providers (N) participating in trial	Site participation logs
	Eligible patients (N) receiving care in participating ICUs	EHR
Effectiveness	**Primary clinical endpoint:** Duration of MV	EHR
	Secondary clinical endpoints: ICU, hospital, and 30-day mortality; ICU and hospital length of stay; ICU days with acute brain dysfunction; Discharge disposition, medication, and physical therapy utilization; 30-day hospital readmission	EHR; Social Security Death Index
Adoption	Fidelity of the implementation strategies	Direct observation; Staffing data
Implementation	**Primary study outcome (Primary implementation endpoint):** Proportional ABCDEF bundle performance	EHR
	Secondary implementation endpoints: Acceptability; Work intensity	Surveys; Interviews
	Safety: Reintubation; ICU fall rates	EHR
Maintenance	Continued ABCDEF bundle performance among patients after clinical trial	EHR

Evaluation Framework

- Primary Clinical Effectiveness Outcome: Duration of MV
- Secondary clinical effectiveness outcomes
  - ICU, hospital, & 30-day mortality
  - ICU & hospital LOS
  - ICU days with acute brain dysfunction
  - Discharge
    - Disposition
    - Medication use
    - PT utilization
  - 30-day hospital readmission
  - Safety

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Maintenance	Continued ABCDEF bundle performance among patients after clinical trial	EHR

Data Collection

- Clinical Outcomes
  - Electronic Health Record Capture
  - PCORnet datamart
- Social Determinants of Health
  - Age, sex, race, ethnicity, insurance status, rurality, Area Deprivation Index
- Secondary
  - Work Intensity: **6-item NASA-TLX**
    - Includes physical, mental, temporal demands, performance, effort, & frustration dimensions
    - < 1 minute to complete
    - All ICU team members, day shift, online survey, **4X month during clinical trial**
  - Acceptability: **4-item Acceptability of Intervention Measure**
    - Specifically designed to measure intervention acceptability
    - All ICU team members, ICU & hospital administrators, IT specialists
  - Focus group
    - Purposeful sample of 60 ICU providers based on trial arm & AIM result (low, middle, high)

Sample Size & Power

- **Estimated 6,400-8,100 MV patients over 27 months of study**
- 12 clusters are sufficient to detect a difference in proportion between any of the strategy combinations & control with **>80% power if the observed effect is ≥12%**
- Sample size analysis was repeated for being able to detect a minimum mean difference of 1.5 days on MV between any strategy & control, or between the two strategies using a standard deviation for the random cluster effect of 1.0, an ICC of 0.15, and a residual error of 3.4.
  - At a conservative significance level of 0.01 for alpha, the current design achieves **87.7% power to detect a 1.5-day difference**.

Analysis by Aim

- Aim 1
  - **Analysis plan will be conducted on two levels: modified (mITT) & true intention to treat (ITT)**
    - Patients that were placed on MV prior to admission to the ICU or whose MV straddles transition points in the study will be excluded from the primary analysis (mITT)
    - ITT secondary analysis will include those patients that were on MV prior to ICU admission and those that straddle transition points
  - **Individual-level generalized linear mixed models with random effects for hospital & ICU within hospital & fixed effects for both calendar time & exposure time will be utilized to quantify group differences in the primary outcome of proportional bundle performance**
  - 3 primary comparisons of interest: strategy A vs control; strategy B vs control; and strategy A vs strategy B
  - Type I error rate will be controlled at 0.05 by utilizing the Holm-Bonferroni adjustment for multiple comparisons
  - Analyses will be adjusted for patient level covariates that were present prior to ICU admission:
    - Sex, age, race, insurance status, rurality, comorbidity score, LOS in hospital prior to ICU admission, LOS in ICU prior to MV, & duration of MV prior to ICU admission
    - Specifically interested in whether SDOH modifies the effect of the intervention on bundle performance. As such, we will specifically examine SDOH-intervention interaction terms to understand the extent to which a given SDOH may change the effect of specific interventions on proportional performance of the ABCDE bundle.

Analysis by Aim

- Aim 2
  - Individual level clinical outcomes will be analyzed utilizing the **same model outlined for Aim 1**, with the exception that the link function will change based on the nature of the outcome being modelled (e.g., continuous outcomes will utilize the identity link and count data may use the logit or log link dependent on the assumed distribution)
  - Covariates identified in the Aim 1 analysis plan will be considered in all Aim 2 analyses
  - Biologically reasonable interactions will be considered, but only retained in models if the p-value is ≤ 0.10.

Analysis by Aim

- Aim 3
  - Acceptability
    - Summary statistics will be used to describe acceptability scores for each implementation strategy. Bivariate analysis (t-test, ANOVA) will be used to compare acceptability score among different types of implementation strategies.
  - Work Intensity
    - Individual work intensity (NASA-TLX scores, 0-100) will be aggregated by each ICU & averaged weekly to assess trends over time. We will then correlate work intensity score by acceptability score & adoption rate using Pearson or Spearman correlation analysis. Since the provider responses are correlated within a ICU, we will use **linear mixed models to examine the association between work intensity & implementation outcomes (acceptability, adoption), controlling for provider characteristics & work-system factors**.
  - Focus groups
    - **Quantitative & qualitative analysis** results will be synthesized to gain deep understanding of stakeholder's perspectives on acceptability & staff work intensity

BEST-ICU: Where are We Now?

UG3 Milestones

Milestone	
Collaborate with NIH Health System Research Collaboratory	In Progress
Finalize study protocol and procedures	In Progress
Establish DSMB	Finalizing
DSMB review and approval	To Do
Enrollment of first participant in focus groups	Completed
Clinical Trials.Gov Registration	To Do
Real-time Audit and Feedback Display	In Progress
Finalize Electronic Data Collection Capture and Sharing Plans	In Progress
Site Selection and Implementation Plans	In Progress

Efforts To Date

- Weekly team meetings
  - 3 Sites; EHR data team, Dashboard development team, Implementation team, Regulatory team, Collaboratory team
- ABCDEF bundle policy collection & review completed
  - Draft policy created for further dissemination (manuscript 1)
- Focus group TNMC complete (N=20)
  - 2 more focus groups at Ohio & Iowa (manuscript 2)
- Data & Safety Monitoring
  - Finalizing DSMB membership, creating DSMB Charter, draft DSMP complete with preliminary NIH review
- Data sharing plan (revised)
- EHR data collection capture, data dictionary

BEST-ICU: Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects		X			
Engagement of clinicians and health systems		X			
Data collection and merging datasets					X
Regulatory issues (IRBs and consent)		X			
Stability of control intervention	X				
Implementing/delivering intervention across healthcare organizations					X

*Your best guess!
1 = little difficulty
5 = extreme difficulty

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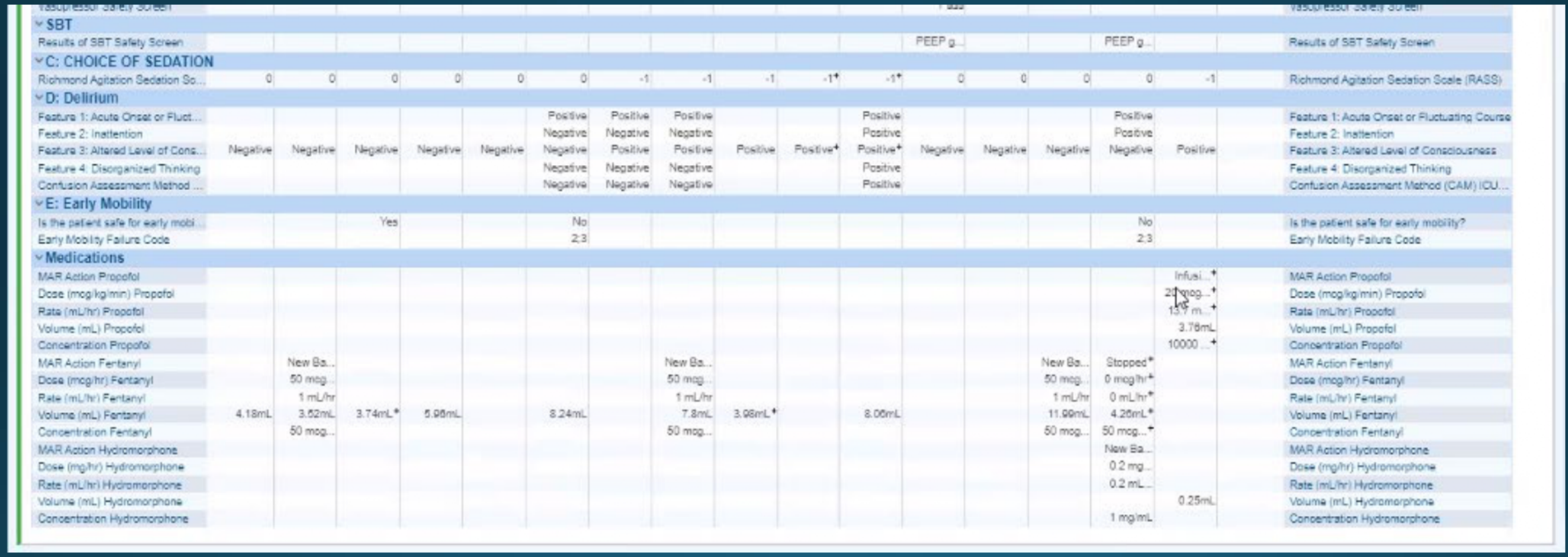
Date Sharing UG3

- What is your current data sharing plan & do you foresee any obstacles?
- What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent, if applicable?
- What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?

Development of Data Management Process

Step	Process
1	**Define research data needs**: Identify reports and data elements needed for a)data quality/validation queries, b)safety monitoring queries and c)query for final report of data for statistical analysis and testing of research hypothesis. (any reporting needs I have missed?)
2	Analyze reporting needs for inventory of Epic data items required from site build
3	Standardize datamart extracts across 3 sites to assure interoperable deployment into PCORnet CDMV6.1. (Work with sites to resolve any limitations in their data inventory)
4	Build queries for process and safety monitoring, data quality testing and validation, and final outcomes reporting.
5	Run data quality/validation query at all sites and reconcile any outliers. Repeat process step per exec committee.
6	Run safety monitoring query every ___ (weeks/months) with report to safety committee
7	Test and validate query for final (statistical) report with statician
8	Run final query and prepare database for statistician approval.
9	Prepare for web publication of final study data per NIH guidelines.

Dashboard Development



SBT																
Results of SBT Safety Screen											PEEP g...			PEEP g...		Results of SBT Safety Screen
C: CHOICE OF SEDATION																
Richmond Agitation Sedation So...	0	0	0	0	0	0	-1	-1	-1	-1	-1	0	0	0	0	-1	Richmond Agitation Sedation Scale (RASS)
D: Delirium																
Feature 1: Acute Onset or Fluct...						Positive	Positive	Positive			Positive				Positive		Feature 1: Acute Onset or Fluctuating Course
Feature 2: Inattention						Negative	Negative	Negative			Positive				Positive		Feature 2: Inattention
Feature 3: Altered Level of Cons...	Negative	Negative	Negative	Negative	Negative	Negative	Positive	Positive	Positive	Positive	Positive	Negative	Negative	Negative	Negative	Positive	Feature 3: Altered Level of Consciousness
Feature 4: Disorganized Thinking						Negative	Negative	Negative			Positive						Feature 4: Disorganized Thinking
Confusion Assessment Method ...						Negative	Negative	Negative			Positive						Confusion Assessment Method (CAM) ICU...
E: Early Mobility																
Is the patient safe for early mobi...			Yes			No								No			Is the patient safe for early mobility?
Early Mobility Failure Code						2:3								2:3			Early Mobility Failure Code
Medications																
MAR Action Propofol															Infusi...		MAR Action Propofol
Dose (mcg/kg/min) Propofol															20 mcg...		Dose (mcg/kg/min) Propofol
Rate (mL/hr) Propofol															13.7 m...		Rate (mL/hr) Propofol
Volume (mL) Propofol															3.76mL		Volume (mL) Propofol
Concentration Propofol															10000 ...		Concentration Propofol
MAR Action Fentanyl		New Ba...					New Ba...					New Ba...		Stopped			MAR Action Fentanyl
Dose (mcg/hr) Fentanyl		50 mcg...					50 mcg...					50 mcg...		0 mcg/hr			Dose (mcg/hr) Fentanyl
Rate (mL/hr) Fentanyl		1 mL/hr					1 mL/hr					1 mL/hr		0 mL/hr			Rate (mL/hr) Fentanyl
Volume (mL) Fentanyl	4.18mL	3.52mL	3.74mL	5.98mL		8.24mL	7.8mL	3.96mL		8.06mL		11.99mL		4.26mL			Volume (mL) Fentanyl
Concentration Fentanyl		50 mcg...					50 mcg...					50 mcg...		50 mcg...			Concentration Fentanyl
MAR Action Hydromorphone														New Ba...			MAR Action Hydromorphone
Dose (mg/hr) Hydromorphone														0.2 mg...			Dose (mg/hr) Hydromorphone
Rate (mL/hr) Hydromorphone														0.2 mL...			Rate (mL/hr) Hydromorphone
Volume (mL) Hydromorphone															0.25mL		Volume (mL) Hydromorphone
Concentration Hydromorphone														1 mg/mL			Concentration Hydromorphone

Re-run Report | Select All

COST CENTER OF HOSPITAL UNIT	Department	Room and Bed	A (Pain) Completed	B (SAT) Completed	B (SBT) Completed	C (Sedation) Completed	D (Delirium) Completed	E (Mobility) Completed	Spe
CARDIAC CATH LAB [7089]	NM 1UCATHPERIOP	1690 PERIOP	●	●	●	●	●	●	Car