PREVENT HAIs Healthcare-Associated Infections

AHRQ Safety Program for Mechanically Ventilated Patients

Photo courtesy of Parkland Health & Hospital System

Agency for Healthcare Research and Quality

AHRQ Safety Program for

Mechanically Ventilated Patients

Final Report

Prepared for:

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Contract No. HHSA290201000027I

Prepared by:

Johns Hopkins Medicine | Armstrong Institute for Patient Safety and Quality
Baltimore, MD

AHRQ Publication No. 16(17)-0018-1-EF
January 2017

This project was funded under contract number HHSA290201000027I from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.

The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or the U.S. Department of Health and Human Services. None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this document.

Contents

1.0. Executive Summary 8
1.1. Background 8
1.2. Results and Impact 9
1.3. Lessons Learned 10
1.4. Conclusion 11

2.0. Background 12

3.0. National Project Team 14

4.0. Program Implementation 17
4.1. Technical Interventions 18
4.1.1. Daily Care Processes 18
4.1.2. Early Mobility 18
4.1.3. Low Tidal Volume Ventilation 19
4.1.4. Structural or Policy-Based Interventions 19
4.2. Adaptive Components 21
4.3. Educational Program 23
4.3.1. Onboarding and Kickoff Webinars 23
4.3.2. Content/Project Webinars 23
4.3.3. Coaching Calls 24
4.3.4. Coordinating Entity Calls 24
4.3.5. Infection Prevention/Affinity Group Webinars 24
4.3.6. Data Facilitator Webinars 24
4.3.7. Miscellaneous/Supplemental Events 25
4.3.8. Digests 25
4.4. Web Portal 25
4.5. Recruitment 25
4.5.1. Recruitment Strategy 26
4.5.2. Randomization 30
4.5.3. Project Retention 30

5.0. Program Impact 32
5.1. Timeline and Data Collection 32
5.2. Measures 34
5.2.1. VAE Outcome Measures 34
5.2.2. Objective Outcome Measures 34
5.2.3. Daily Care Process Measures 34
5.2.4. Early Mobility Measures 35
5.2.5. Low Tidal Volume Ventilation Measures 35
5.3. Results 36
5.3.1 Characteristics 36
5.3.2. VAE Outcome Measures 37
5.3.3. Complete VAE data 42
5.3.4. Objective Outcome Measures 47
5.3.5. Daily Care Process Measures 50

5.3.6. VAE/VAP Prevention Bundle Compliance *51*
5.3.7. Daily Early Mobility Measures *59*
5.3.8. Low Tidal Volume Ventilation Measures *72*

6.0. Adaptive Components: HSOPS **80**
6.1. Methods 80
6.2. Outreach and Approach 80
6.2.1 Project helpdesk *81*
6.2.2 Email reminders *81*
6.2.3. Phone contact *81*
6.2.4. Survey period extensions *82*
6.2.5. Analyses *82*
6.3. Results 82
6.3.1. HSOPS Data Submission *82*
6.3.2. HSOPS: Survey Response Rates and Descriptive Analyses *84*
6.3.3. HSOPS: Independent Groups Pre-Post Analyses *85*
6.3.4. HSOPS: Paired Pre-Post Analyses *87*
6.3.5. HSOPS: Comparison of High Versus Low Engagement Units *88*

7.0. Discussion **95**
7.1. Comparisons to Published Research 95
7.2. Intangible Benefits 95
7.3. Future Collaborative Efforts 96

8.0. Lessons Learned **97**
8.1. VAE Data and Surveillance Definitions 97
8.2. Data Collection, Entry Burden, and Use of Electronic Health Records (EHR) 97
8.3. Site Selection and Organizational Capacity 98
8.4. Effect of Coordinating Entities on Site Participation 99
8.5. Changes Implemented Between Cohorts 99

9.0. Conclusion **101**

References **102**

Appendixes **104**
Appendix A. Data Measure Definitions 105
Appendix B. Data Submission Summaries 109
Appendix C. HSOPS Paired Group Comparison 119
Appendix D. PT or OT Participation Rates 121

Figures

Figure 1. Overview of Interventions for the AHRQ Safety Program for Mechanically Ventilated Patients 17
Figure 2. VAE Incidence Rate per 1,000 Ventilator-Days (All Cohorts) 39
Figure 3. IVAC Incidence Rate per 1,000 Ventilator-Days (All Cohorts) 40
Figure 4. PVAP Incidence Rate per 1,000 Ventilator-Days (All Cohorts) 41
Figure 5. VAE Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data) 43
Figure 6. IVAC Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data) 44
Figure 7. PVAP Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data) 45
Figure 8. Objective Outcome Measures (All Cohorts Aggregate) 49
Figure 9. VAE/VAP Prevention Bundle Compliance Rates (All Cohorts) 52
Figure 10. Daily Care Processes Sedation Scale (All Cohorts) 55
Figure 11. Daily Care Processes Delirium Assessment (All Cohorts) 57
Figure 12. Daily Early Mobility Sedation Scale (All Cohorts) 60
Figure 13. Daily Early Mobility Delirium Assessment (All Cohorts) 62
Figure 14. Distribution of the Highest Level of Mobility (All Cohorts) 65
Figure 15. Adverse Event Rate (All Cohorts) 69
Figure 16. Tidal Volume Value Distribution for Patients With ARDS (All Cohorts) 73
Figure 17. Tidal Volume Value Distribution for Patients Without ARDS (All Cohorts) 76
Figure 18. PEEP Compliance Rate (≥5 cm H_2O) (All Cohorts) 78
Figure 19. Independent Groups Comparison of Unit-Level Baseline (n=65) and Followup (n=33) HSOPS Dimension Scores 85
Figure C-1. Paired Groups Sample Comparison of Unit (n=28) Baseline and Followup HSOPS Dimension Scores 119
Figure D-1. PT or OT Participation Rate (All Cohorts) 121

Tables

Table 1. National Project Team of AHRQ Safety Program for Mechanically Ventilated Patients 14
Table 2. Stakeholders of AHRQ Safety Program for Mechanically Ventilated Patients 15
Table 3. Technical Expert Panel Members 16
Table 4. State and Hospital Recruitment Timeline by Cohort 26
Table 5. Hospital Recruitment by State, Cohort 1 27
Table 6. Hospital Recruitment by State, Cohort 2 28
Table 7. Hospital Recruitment by State, Cohort 3 29
Table 8. Data Collection Timeline for Process and Outcome Measures (by May 29, 2016) 33
Table 9. Characteristics of Participating Hospitals and ICUs 37
Table 10. VAE Incidence Rate per 1,000 Ventilator-Days (All Cohorts) 39
Table 11. IVAC Incidence Rate per 1,000 Ventilator-Days (All Cohorts) 40
Table 12. PVAP Incidence Rate per 1,000 Ventilator-Days (All Cohorts) 41
Table 13. VAE Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data) 43
Table 14. IVAC Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data) 44
Table 15. PVAP Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data) 45
Table 16. VAE Outcomes Incidence Rate Ratios Based on Mixed Effects Poisson Regression Models 46
Table 17. Objective Outcome Measures (All Cohorts Aggregate) 50
Table 18. VAE/VAP Prevention Bundle Compliance Rates (All Cohorts) 53
Table 19. Daily Care Processes Sedation Scale (All Cohorts) 56
Table 20. Daily Care Processes Delirium Assessment (All Cohorts) 58
Table 21. Daily Early Mobility Sedation Scale (All Cohorts) 61
Table 22. Daily Early Mobility Delirium Assessment (All Cohorts) 63
Table 23. Distribution of the Highest Level of Mobility (All Cohorts) 66
Table 24. Distribution of Perceived Barriers (All Cohorts) 68
Table 25. Adverse Event Rate (All Cohorts) 70
Table 26. Distribution of Adverse Events for Ventilated Patients (All Cohorts) 71
Table 27. Tidal Volume Value Distribution for Patients With ARDS (All Cohorts) 74
Table 28. Tidal Volume Value Distribution for Patients Without ARDS (All Cohorts) 77
Table 29. PEEP Compliance Rate (≥5 cm H_2O) (All Cohorts) 79
Table 30. HSOPS Survey Submission Rates by Cohort at Baseline and Followup 83
Table 31. Hospital Characteristics by Cohort at Baseline (B) and Followup (F) 84
Table 32. Independent Groups Comparison of Unit Baseline (n=65) and Followup (n=33) HSOPS Dimension Scores 86

Table 33. Baseline Comparison of High (n=21) and Low (n=13) Engagement Units 90
Table 34. Followup Comparison of High (n=14) and Low (n=6) Engagement Units 91
Table A-1. VAE Outcome Measures 105
Table A-2. Objective Outcome Measures 105
Table A-3. Daily Care Process Measures 106
Table A-4. Daily Early Mobility Measures 107
Table A-5. Low Tidal Volume Ventilation Measures 108
Table B-1. VAE Outcomes Data Submissions Summary: Cohort 1 109
Table B-2. VAE Outcomes Data Submission Summary: Cohort 2 110
Table B-3. VAE Outcomes Data Submission Summary: Cohort 3 111
Table B-4. VAE Outcomes Data Submission Summary: Cohort 1, Units With Complete VAE Data 112
Table B-5. VAE Outcomes Data Submission Summary: Cohort 2, Units With Complete VAE Data 113
Table B-6. VAE Outcomes Data Submission Summary: Cohort 3, Units With Complete VAE Data 114
Table B-7. Objective Outcomes Data Submission Summary: Cohort 1 115
Table B-8. Objective Outcomes Data Submission Summary: Cohort 2 115
Table B-9. Objective Outcomes Data Submission Summary: Cohort 3 115
Table B-10. Daily Care Processes Data Submission Summary: Cohort 1 115
Table B-11. Daily Care Processes Data Submission Summary: Cohort 2 116
Table B-12. Daily Care Processes Data Submission Summary: Cohort 3 116
Table B-13. Daily Early Mobility Data Submission Summary: Cohort 1 116
Table B-14. Daily Early Mobility Data Submission Summary: Cohort 2 117
Table B-15. Daily Early Mobility Data Submission Summary: Cohort 3 117
Table B-16. Low Tidal Volume Ventilation Data Submission Summary: Cohort 1 117
Table B-17. Low Tidal Volume Ventilation Data Submission Summary: Cohort 2 118
Table B-18. Low Tidal Volume Ventilation Data Submission Summary: Cohort 3 118
Table C-1. Paired Groups Sample Comparison of Unit (n=28) Baseline and Followup HSOPS Dimension Scores 120
Table D-1. PT or OT Participation Rate (All Cohorts) 121

1.0. Executive Summary

1.1. Background

Ventilator-associated pneumonia (VAP) is among the most common healthcare-associated infections (HAIs) in the intensive care unit (ICU) and is associated with significant morbidity and mortality. Historically, 10 to 20 percent of patients ventilated for longer than 48 hours develop VAP,[1] and subsequent attributable mortality is approximately 10 percent.[2–4] In addition, ventilator-associated events (VAEs)—which include acute respiratory distress syndrome (ARDS), acute lung injury, pneumothorax, pulmonary embolism, atelectasis, and pulmonary edema, in addition to VAP—are associated with increases in duration of mechanical ventilation, ICU and hospital length of stay (LOS), use of antimicrobial medications, and direct medical costs.[5–8] Each year these preventable infections kill as many as 36,000 patients and result in billions of dollars of unnecessary attributable health care costs in the United States.[9] VAEs are health care challenges in need of a generalizable solution.

The Comprehensive Unit-based Safety Program (CUSP), developed at the Johns Hopkins University and Johns Hopkins Hospital, is an innovative safety and quality intervention that helps teams identify and learn from defects, improve safety culture, and improve teamwork and communication. CUSP has been linked with improvements in clinical outcomes, such as the reduction of HAIs, and human resource outcomes, such as nurse staffing and turnover.

In 2004, the seminal Michigan Keystone ICU project implemented the CUSP framework to increase adherence to evidence-based recommendations for both central line-associated blood stream infections and VAP. Implementation of the CUSP model led to a substantial and sustained 71-percent reduction in VAP rates. Additionally, compliance with evidence-based therapies for VAP increased from 32 percent at baseline to 75 percent at 16–18 months and to 84 percent at 28–30 months post-implementation.[10] In light of these results, widespread implementation of CUSP to increase adoption of a technical bundle of evidence-based recommendations may significantly reduce VAE/VAP. This program builds on the subsequent implementation of CUSP in a pilot project in two States, which was a forerunner of the current project's nationwide implementation of CUSP for VAP.[11]

In conjunction with CUSP, this program advocated three main interventions to improve care for mechanically ventilated patients:

- Daily Care Processes (DCP)
- Early Mobility (EM)
- Low Tidal Volume Ventilation (LTVV)

The program comprised three cohorts. In Cohorts 1 and 2, data for each technical intervention was collected on a rotating data collection schedule. A staggered implementation strategy provided hospital teams a chance to focus on each intervention in daily patient care workflow.

Cohort 3 hospitals were limited to 12 months for interventions. Hospital teams elected either DCP or EM interventions. Hospital teams had the option of selecting both categories, and in

fact, most teams did choose both interventions. Hospital teams also had the optional opportunity to submit LTVV data.

1.2. Results and Impact

The Agency for Healthcare Research and Quality (AHRQ) Safety Program for Mechanically Ventilated Patients has served to advance science and improve care for mechanically ventilated patients in diverse hospital settings across the United States. Implementation of CUSP was associated with significant improvement in compliance with important evidence-based care processes, with the most success seen in compliance with head-of-bed elevation, coordinated spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs), SBTs while sedatives are off, and routine delirium screening. While improvement of VAE rates was variable across cohorts, Cohort 1 and 2 teams achieved reductions in VAE rates (17–25%). Cohort 1 had a reduction in infection-related ventilator-associated complications (48%). Cohorts 1 and 2 had reductions in possible ventilator-associated pneumonia rates (44–55%). Rates for Cohort 3 remained stable.

Based on the analysis of a limited amount of self-reported aggregate data, CUSP implementation was also associated with significant reductions in average duration of mechanical ventilation per episode (6%) and per patient (6%) and average hospital LOS (3%).

Finally, implementation of CUSP was associated with improvements in Hospital Survey on Patient Safety Culture (HSOPS) scores, which varied across cohorts. In the independent group comparison analysis, Cohort 1 and 2 HSOPS scores significantly improved for several areas, including hospital management support, feedback and communication, and communication openness, and improvements in several of these areas surpassed the AHRQ benchmarks. Through the Implementation Assessments, unit staff repeatedly emphasized that participation in the program led to multiple sustained successes in improving patient care and hospital culture. Among these many successes, units reported the following:

- increased use of Staff Safety Assessments
- improved leadership support, often leading to procurement of better equipment (e.g., mobilization supplies, new subglottic secretion drainage endotracheal tubes)
- standardization of SAT/SBT and EM protocols
- structured integration of multidisciplinary rounds and shadowing
- highly involved and invested CUSP teams

At the conclusion of this program in September 2016, the materials developed for hospital teams have been assembled into a complete guide of evidence-based, practical resources and teaching tools for providers in acute care settings. Providers interested in improving care for mechanically ventilated patients will have access to a variety of customizable data collection tools designed to assist in the tracking and analysis of VAE rates, performance and compliance rates for EM efforts, DCP, and LTVV strategies. To support the use of these data collection tools,

multiple comprehensive guides have been developed to help providers apply each technical and adaptive intervention to their unique quality improvement initiatives. Literature reviews, factsheets, and a suite of educational presentations that can be used to introduce, train, and refresh the principles of this program will also be provided to any group seeking to contribute to improving the care of mechanically ventilated patients. In 2017, the guides and materials will be broadly available for download from the AHRQ Web site at www.ahrq.gov/haimvp.

1.3. Lessons Learned

The execution of this program offered extensive opportunities to gain valuable insight on the design, conduct, and management of a large-scale, complex collaborative such as this. The National Project Team (NPT) found that many of the challenges faced during the execution of this program are likely universal and that solutions to mitigate them have the potential to be broadly applied:

- VAE data and surveillance definitions—Because the current surveillance definitions and algorithms for VAE were released less than a year before the program began, many teams had not yet begun to implement the new surveillance methods. As a result, there was a noticeable delay in data collection and submission. Future collaboratives involving new or less specific surveillance definitions may benefit from providing targeted training during onboarding designed to acclimate units to less familiar surveillance strategies.
- Data collection entry burden—The volume of data collection posed problems for units struggling with a lack of dedicated resources. In order to establish higher data submission rates, careful consideration should be paid to developing processes that minimize the data collection burden.
- Site selection and organizational capacity—Units were asked to implement the CUSP model and assemble a multidisciplinary team. However, many units found they lacked the infrastructure and organizational capacity to do so. Large-scale programs involving a significant number of units should consider conducting feasibility assessments prior to enrollment. This will ensure teams not only receive support from their own organization but will help project teams better anticipate ways to assist units and hospitals if they encounter difficulties with program implementation.
- Coordinating entity (CE) effect on participation—Teams affiliated with active CEs had a higher level of involvement compared to those with less proactive CEs. Additionally, teams affiliated with CEs with previous CUSP experience were also more involved. The NPT found the contributions of the CEs to be instrumental in the successful conduct of a large-scale collaborative and noted that future efforts to promote enthusiasm and knowledge sharing among the CEs may have a profound effect on their teams.
- Changes made between cohorts—While the program progressed through each cohort, the NPT made a concerted effort to identify challenges and address them appropriately for benefit of the subsequent cohort(s). In doing so, it became apparent that, within a

complex program, there is a need to allow flexibility into the design in order to best respond effectively to the needs of participants. However, the significant changes between cohort implementations made comparison between cohorts and aggregate analysis of the project's impact challenging.

1.4. Conclusion

The AHRQ Safety Program for Mechanically Ventilated Patients successfully demonstrated that, through hospital engagement, improved teamwork and communication through CUSP and the use of educational materials and data collection tools specifically designed to target the reduction of VAE/VAP increased compliance with multiple, evidence-based technical intervention bundles are not only possible but have the potential to reduce the medical and public health toll from VAE/VAP.

As the largest national collaborative to involve the collection of process measure data, this program shed considerable light on the many challenges involved in developing a framework to support the implementation of quality improvement projects that require multiple intervention measures and for which success may be dependent on non-clinical factors, such as hospital infrastructure and physician and executive support.

As VAE/VAP remains a morbid complication, the AHRQ Safety Program for Mechanically Ventilated Patients provides important insights and a strong foundation to successfully address the culture changes and clinical attention needed to proactively reduce VAE rates in acute care settings.

2.0. Background

It is estimated that over 300,000 patients receive mechanical ventilation in the United States each year. While mechanical ventilation is an indispensable therapy for critically ill patients, its use is not without significant risk. Patients requiring mechanical ventilation are subject to increased risk of developing life-threatening complications and are more likely to experience poor outcomes. One such complication is ventilator-associated pneumonia (VAP), a type of nosocomial pneumonia that develops when bacteria are introduced into the lungs during the course of mechanical ventilation. VAP is one of the four most common healthcare-associated infections, and despite significant local, regional, and national efforts to reduce VAP, including isolated examples of sustained success, each year, these preventable infections kill as many as 36,000 patients and result in billions of dollars of unnecessary attributable health care costs in the United States.[7]

Until recently, surveillance definitions for VAP were extremely subjective, leading to inaccurate reporting of events.[12–14] The use of clinical signs and symptoms in addition to technical elements such as chest radiographs resulted in disagreement and poor interrater reliability among physicians. These inconsistencies led to unreliable approaches to VAP surveillance and subsequent prevention strategies. In January of 2013, to respond to these discrepancies, the National Healthcare Safety Network at the Centers for Disease Control and Prevention (CDC) introduced a new surveillance definition for VAP with an aim to reduce ambiguity and improve accuracy of diagnosis.[5,15] With this updated surveillance definition, the focus has shifted away from the generalized surveillance of VAP to include a broader scope of complications associated with mechanical ventilation, called ventilator-associated events (VAEs).[15]

VAE surveillance is triggered by a specified increase in oxygen demands. Specifically, a patient must be ventilated and in stable condition for more than 2 calendar days before the onset of worsening oxygenation, defined by an increase in the daily minimum fraction of inspired oxygen or positive end-expiratory pressure (PEEP) values from the baseline period of stability and lasting for at least 2 consecutive days. This worsening oxygenation scenario is used to define the presence of a ventilator-associated condition (VAC).

Following the determination of a VAC, a tiered approach is used to determine whether the event may be further classified as an infection-related ventilator-associated complication (IVAC) or possible ventilator-associated pneumonia (PVAP) based on additional criteria. The presence of an IVAC is determined by the presence of—

- A temperature higher than 38 degrees Celsius or lower than 36 degrees Celsius **OR** a white blood cell count of at least 12,000 cells/mm^3 or equal to or less than 4,000 cells/mm^3.
  AND
- A new antimicrobial agent as defined by the CDC that has been started and continued for at least 4 calendar days.

Following determination of an IVAC, the event may again be further classified as a PVAP if any one of three defined microbiological criteria is met.

A retrospective cohort study examining over 20,000 episodes of mechanical ventilation was conducted by Klompas et al. and published in Infection Control & Hospital Epidemiology in 2014.[5] Through multivariate analysis of over 20,000 episodes of mechanical ventilation, the authors concluded that mechanically ventilated patients who suffered a VAE experienced more days to extubation, more days to hospital discharge, and higher hospital mortality rates when compared to mechanically ventilated patients without a VAE diagnosis. Ultimately, this research confirmed that VAEs are both common and morbid, thus necessitating prevention strategies that specifically target VAEs. There are a number of recommended interventions and infection control practices to prevent VAE/VAP. However, implementation of these recommendations in practice is suboptimal. Approaches to improve adherence to guideline recommendations are needed to reduce the medical and public health toll from VAE/VAP.

Units that care for mechanically ventilated patients have exceedingly complex social structures and political hierarchies, comprised of multidisciplinary sub-teams with critical care physicians and nurses, pharmacists, and respiratory, physical, and occupational therapists. While some programs to reduce VAP have been successful,[16] they have not addressed the many other harms associated with mechanical ventilation. Improving care for mechanically ventilated patients is an emerging focus for quality improvement and patient safety.

To address this problem, this safety program aims to improve care for mechanically ventilated patients. The program helps acute care clinicians apply the proven principles of the Comprehensive Unit-based Safety Program to reduce complications of mechanical ventilation.

3.0. National Project Team

The Agency for Healthcare Research and Quality (AHRQ) Safety Program for Mechanically Ventilated Patients was developed, implemented, and evaluated by the National Project Team (NPT), a partnership between Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality, Harvard Pilgrim Health Care, and the Michigan Health & Hospital Association: A Keystone Center (MHA) (Table 1).

Table 1. National Project Team of AHRQ Safety Program for Mechanically Ventilated Patients

PARTNER	ROLE
Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality	The Armstrong Institute was responsible for program management, budget oversight, recruitment of coordinating entities (CEs), and development of resources. As content experts, Armstrong Institute faculty provided educational content and resources for AHRQ Safety Program for Surgery implementation at the hospital level.
Michigan Health & Hospital Association Keystone Center (MHA)	MHA provided program management, recruitment of CEs, and provided extensive coaching resources and content expertise gained from successful implementation of other patient safety and quality improvement projects.
Harvard Pilgrim Health Care Institute Department of Population Medicine	Harvard Pilgrim provided clinical expertise, assistance with study design and development, and guidance for program evaluation.
Technical Expert Panel (TEP)	The TEP was composed of clinicians, researchers, quality improvement experts, and State hospital association staff. The TEP provided guidance on program messaging, implementation, and evaluation. Table 3 details the members and qualifications of the TEP members.

Conducive to large-scale implementation research, the NPT was structured with decentralized leadership to leverage collaborative decision making, promote operational flexibility, and maximize engagement amongst diverse stakeholder groups. The leadership core was headed by Principal Investigator Sean Berenholtz, M.D., M.H.S., FCCM, core faculty at the Armstrong Institute, and Professor in the departments of Anesthesiology, Critical Care Medicine, and Surgery at the Johns Hopkins University School of Medicine and in Health Policy and Management in the Johns Hopkins Bloomberg School of Public Health. Numerous faculty and specialists of varying disciplines provided support as co-investigators for this program, and additional Armstrong Institute staff served as program leaders for each cohort of hospital units.

Harvard Pilgrim Health Care provided additional leadership as well as considerable expertise in the areas of healthcare-associated infections and ventilator-associated events (VAEs) prevention programs as well as program evaluation. MHA made significant contributions based on its expertise in patient safety and quality improvement programs, as well as with project management of large-scale national programs.

The NPT tapped the collective wisdom of frontline clinicians, quality improvement experts, and diverse stakeholder groups (Table 2) to create an innovative national program to improve care for mechanically ventilated patients and reduce harms associated with ventilator-associated event/ventilator-associated pneumonia (VAE/VAP). A technical expert panel (TEP) was also formed so that content experts and representatives of relevant professional organizations could provide robust conversation, problem solving, and guidance throughout the design and implementation of the program. Members and professional affiliations of the TEP members are summarized in Table 3.

Table 2. Stakeholders of AHRQ Safety Program for Mechanically Ventilated Patients

PARTNER	ROLE
Department of Health and Human Services (HHS)	HHS is the United States Federal Government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.
Agency for Healthcare Research and Quality (AHRQ)	One of the 11 agencies within HHS, AHRQ works to improve the health care delivered to Americans. The AHRQ mission is to produce evidence to make health care safer, higher quality, more accessible, equitable and affordable, and to work with HHS and other partners to make sure that the evidence is understood and used. AHRQ funded this Safety Program for Mechanical Ventilation.
Coordinating entities (CEs)	CEs recruited hospital ICU teams, led monthly coaching calls, and coordinated the program at the State or regional level. CEs were State hospital associations (SHAs) or Hospital Engagement Networks (HENs). The Center for Medicare and Medicaid Innovation HENs coordinate a range of collaborative improvement activities with hospitals, including efforts to reduce VAE/VAP among other harms.
Patients and families or caregivers	Because this quality improvement collaborative was centered on improving patient care, patients and families were considered the driving stakeholders for this program. Additionally, patients, families, and caregivers provided important guidance during program development and participated regularly during content and coaching calls.

Table 3. Technical Expert Panel Members

MEMBER	POSITION
Richard Branson, MS, RTT	Professor of Surgery Emeritus—University of Cincinnati
Sara Cosgrove, MD, MS	Associate Professor of Medicine and Epidemiology—Johns Hopkins Hospital
Chris Goeschel, ScD, MPA, MPS, RN	Assistant Vice President for Quality—MedStar Health Research Institute
Rachel Hardegree, MPH, RRT	Senior Director, Quality Programs/Initiatives—Texas Hospital Association
Yael Harris, PhD, MHS	Director, Division of Healthcare Quality—Department of Health and Human Services
Robert Hyzy, MD	Director, Critical Care Medicine Unit—University of Michigan
Michael Klompas, MD, MPH, FRCPC	Associate Professor—Harvard Medical School and Harvard Pilgrim Health Care Institute
Cathy Krsek, MSN, MBA, RN-FAAN	Senior Director, Quality Operations—University HealthSystem Consortium
Shelley Magill, MD, PhD	Infectious Disease Specialist—Centers for Disease Control and Prevention
M. Susan Ridgely, JD	Senior Policy Analyst—RAND Corporation
Thomas Talbot, MD, MPH	Assistant Professor, Chief Hospital Epidemiologist—Vanderbilt University
Rhonda Urbanovsky, RN, BSN	CTICU Nurse Manager—Scott and White Memorial Hospital

4.0. Program Implementation

The Agency for Healthcare Research and Quality (AHRQ) Safety Program for Mechanically Ventilated Patients bundles evidence-based technical interventions designed to improve the care of mechanically ventilated patients with the adaptive, culture-focused components of the Comprehensive Unit-based Safety Program (CUSP). The technical interventions in this program are similar to those found in the 2004 Michigan Keystone ICU project, which implemented the CUSP framework to increase adherence to evidence-based recommendations ("bundles") for central line-associated blood stream infections and ventilator-associated pneumonias (VAPs). Implementation of CUSP was associated with a 71 percent reduction in VAP rates and an increase in VAP bundle compliance from 32 percent to 84 percent at 28–30 months post-implementation.[7] This project built on those successes by including further strategies that were not previously addressed, such as delirium assessment, Early Mobility (EM) efforts, and the use of low tidal volume ventilation (LTVV). The implementation of and compliance with these technical interventions were used to evaluate their impact on the duration of mechanical ventilation, intensive care unit (ICU) mortality, and unit and hospital lengths of stay.

The three technical interventions implemented in this program were Daily Care Processes (DCP), EM, and LTVV. Each intervention also included individual care recommendations. Figure 1 below presents a visual overview of the combined interventions used in the implementation of this safety program. The first two cohorts began implementing each intervention in a staggered pattern to allow hospital teams the chance to embed the interventions into their workflow. The third cohort elected either DCP or EM, though some hospitals selected both intervention bundles. The implementation of LTVV was optional for Cohort 3 because of time constraints.

Figure 1. Overview of Interventions for the AHRQ Safety Program for Mechanically Ventilated Patients

4.1. Technical Interventions

4.1.1. Daily Care Processes

The DCP bundle targets daily care practices at the bedside and consists of six evidence-based measures:[17]

1. **Use subglottic secretion drainage endotracheal tubes for patients expected to be intubated for more than 72 hours.** Continuous subglottic suctioning and frequent intermittent subglottic suctioning drainage of subglottic secretions, via a cuffed endotracheal tube.
2. **Elevate the head of the bed to at least 30 degrees.** Elevation of the head of bed to a semirecumbent position (30°–45°) rather than a supine (flat) position.
3. **Minimize sedation level.** Titration of sedative medications to maintain a light rather than a deep level of sedation. When a patient is under light sedation, the patient is arousable and able to purposefully follow simple commands. The patient's actual Richmond Agitation-Sedation Scale (RASS) score should be {−1 or 0 or 1}, or the patient's actual Riker Sedation-Agitation Scale (SAS) score should be {4 or 5}.
4. **Assess then address delirium.** Evaluate patients daily using a validated delirium screening tool, such as the Confusion Assessment Method for the ICU (CAM-ICU). If completing the CAM-ICU is not possible, perform the Attention Screening Exam (ASE), a subset of the CAM-ICU. The 10–20 second test of attention is the cardinal feature of a delirium diagnosis. Delirium should first be addressed using nonpharmacological, and then pharmacological, methods.
5. **Perform spontaneous awakening trials (SATs).** Perform SATs daily if patients pass a safety screen. All patients on continuous sedative infusions or standing orders for sedating medications every 6 hours or more are eligible for an SAT safety screen. If the patient passes the SAT screen, they are eligible for the SAT. An SAT should last until one of the following conditions occurs: 1. Patient becomes agitated, 2. Patient is awake (able to pass the CAM-ICU or ASE), or 3. Sedatives have been stopped for ≥4 hours.
6. **Perform spontaneous breathing trials (SBTs).** If the patient passes the SAT, perform SBT screen. If the patient passes the SBT screen, they are eligible for the SBT. An SBT should last until one of the following conditions occurs: 1. Patient becomes agitated, 2. Respiratory rate falls outside the range of 8–33 breaths per minute, 3. Blood oxygen levels fall below 88 percent, or 4. Patient experiences acute cardiac dysrhythmia. SAT and SBT protocols should be coordinated.

4.1.2. Early Mobility

The EM bundle is designed to achieve the maximum level of patient mobility as soon as is clinically safe to do so and consists of three recommendations:[17]

1. **Minimize sedation level.** Titration of sedative medications to maintain a light rather than a deep level of sedation. When a patient is under light sedation, the patient is arousable and able to purposefully follow simple commands. The patient's actual RASS score should be {−1 or 0 or 1}, or the patient's actual SAS score should be {4 or 5}. Heavily sedated patients cannot participate in an early rehabilitation program.
2. **Assess then address delirium.** Evaluate patients daily using the CAM-ICU. If completing the CAM-ICU is not possible, patients can undergo the ASE, which is feature 2 of the CAM-ICU. The 10–20 second test of attention is the cardinal feature of a delirium diagnosis. Delirium should first be addressed using nonpharmacological, and then pharmacological, methods.
3. **Tailor goals to maximize mobility.** 1. Facilitate multidisciplinary teamwork—the joint participation of nurses, physicians, respiratory therapists, rehabilitation therapists, and local hospital administrators, 2. Use a standard screening algorithm to determine which patients may safely participate in mobilization, and 3. Employ a nurse-driven protocol to achieve the highest level of mobility daily.

4.1.3. Low Tidal Volume Ventilation

The LTVV bundle should be used to treat patients with acute respiratory distress syndrome (ARDS) and for the prevention of acute lung injury—one of the conditions detected as a ventilator-associated condition by ventilator-associated event (VAE) surveillance. Interventions consist of the following four items:[10,18]

1. **Use appropriate tidal volume.** Promote compliance with maintaining a low set tidal volume of 6–8 mL/kg water (H_2O) for patients without ARDS and 4–6 mL/kg H_2O for patients with ARDS.
2. **Maintain plateau pressure.** Plateau pressure should be maintained at ≤30 cm H_2O.
3. **Use positive end-expiratory pressure (PEEP).** Maintain PEEP ≥5 cm H_2O unless contraindicated, and avoid the use of zero end-expiratory pressure.
4. **Prevent ARDS.** Promote compliance with lung-protective mechanical ventilation strategies.

4.1.4. Structural or Policy-Based Interventions

Structural and policy-based interventions target hospital and unit-based policies and procedures focused on VAE/VAP prevention. Teams worked to align their policies and procedures with the following current evidence-based practices to care for mechanically ventilated patients:[17,19-20]

1. **Use a closed endotracheal tube suctioning system.** Use a cuffed endotracheal tube with inline or subglottic suctioning.

2. **Change closed suctioning catheters only as needed.** Ventilator circuits should not be changed routinely for infection control purposes.
3. **Change ventilator circuits only if circuits become damaged or soiled.** New circuits should be used for each new patient but only changed if the circuits become soiled or damaged.
4. **Change heat-moisture exchanger (HME) every 5–7 days and as clinically indicated.** Change HME when it malfunctions mechanically or becomes visibly soiled, but not more frequently than every 48 hours.
5. **Use non-invasive ventilation whenever possible.** Provide easy access to non-invasive ventilator equipment, and institute protocols to promote use.
6. **Remove condensate from circuits periodically; keep the circuit closed during the removal; take precautions to avoid condensate draining toward the patient.** Contaminated condensate should be carefully emptied from ventilator circuits and condensate should be prevented from entering either the endotracheal tube or inline medication nebulizers.
7. **Use an EM protocol.** Incorporate EM into the daily care of patients.
8. **Perform hand hygiene.** Decontamination of hands by washing them with either antimicrobial soap and water or with nonantimicrobial soap and water or by using an alcohol-based waterless antiseptic agent.
9. **Avoid supine position.** Patients should be kept in the semirecumbent position 30–45 degrees rather than supine unless contraindicated.
10. **Use standard precautions while suctioning respiratory tract secretions.** Appropriate infection prevention and control practices are used at all times, including aseptic techniques when suctioning secretions and handling respiratory therapy equipment.
11. **Use orotracheal intubation instead of nasotracheal intubation.** Based on an observed trend toward reduction in VAP rates and avoidance of sinusitis, the use of the orotracheal route for intubation is recommended.
12. **Avoid the use of prophylactic systemic antimicrobials.** Prophylactic aerosolized or systemic antimicrobials should not be used for routine VAE/VAP prevention.
13. **Avoid nonessential tracheal suctioning.** Tracheal tube suctioning should not be carried out on a routine basis, but rather out of clinical need to maintain the patency of the tracheobronchial tree.
14. **Avoid gastric overdistention.** Evaluate mechanically ventilated patients for gastric overdistention in order to avoid aspiration.

4.2. Adaptive Components

Health care organizations around the world are increasingly focused on patient safety and health care quality. While health care providers are committed to improvement efforts, many struggle to create and sustain positive change. CUSP is among the best validated approaches to improve teamwork and safety climate.

In the AHRQ Safety Program for Mechanically Ventilated Patients, we worked with ICU teams to achieve their goals of successful implementation and sustainment with the use of CUSP. CUSP, together with the implementation of the Science of Safety and Translating Evidence into Practice (TRIP), are innovative tools used to build a culture of safety within a patient care unit.

CUSP focuses on building local capacity by engaging frontline staff in quality improvement. CUSP includes five iterative steps:

1. **Educate your staff on the Science of Safety.** Assure all staff on your unit view the Science of Safety Video (can be found on the AHRQ Web site: http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/modules/understand/index.html). The video discusses the difference between a punitive culture and one in which problem solving is handled on a systems level and how implementation of a systems-level approach can improve the attitudes of staff on the unit.
2. **Identify defects.** A defect is anything that happens on the unit that you don't want to happen again. By using the Staff Safety Assessment, you can find out what potential safety situations are occurring on the unit.
3. **Partner with a senior executive.** Recruit a senior executive to attend CUSP meetings and give input to the issues and potential solutions from the administrative point of view. The executive can also help facilitate the solutions the team develops.
4. **Learn from defects.** Problem-solve solutions for the identified defects. Use a step-by-step process to identify system level factors, and then implement and beta-test the solution. Use this process to iteratively develop a solution that works.
5. **Improve teamwork and communication**. Implement various tools to improve interdisciplinary teamwork and communication. For this project, teams were encouraged to implement daily multidisciplinary rounds and a Daily Goals checklist to help ensure patients received the recommended evidence-based interventions for the prevention of VAE/VAP.

Translating Research Into Practice (TRIP) focuses on the implementation of the recommended evidence-based interventions for the prevention of VAE/VAP. There are four steps in the TRIP implementation model:

1. **Summarize the evidence in a checklist.** Develop strategies, including checklists of the interventions that need to be completed every day to ensure your patients receive the care they deserve.
2. **Identify local barriers to implementation.** Barriers to implementation often include awareness (providers do not know the recommendation exists), agreement (providers do not agree with the recommendation), and ability (providers encounter system level barriers to implement the recommendations). Teams used structured tools to identify local barriers and develop strategies to address unique barriers.
3. **Measure performance.** Collect both process and outcome data as you implement the interventions. You can track your progress as you work on integrating the interventions into your daily patient care practices. Share data by reporting your findings with staff on the unit. It will help them see that they are making a difference.
4. **Ensure all patients receive the benefits from using the evidence:**
    a. **Engage the staff.** Make sure everyone is on board with the program. Use the current literature and flyers to show staff the interventions are based on best practices.
    b. **Educate the staff.** Along with ensuring staff understand the ideas of the intervention, educate them on the implementation. Look at who, when, and how as well as the why, and share that information with staff.
    c. **Execute the interventions.** Start the intervention, taking care to pause to re-engage and re-educate as needed. Use a kickoff event to gain everyone's interest.
    d. **Evaluate change.** Gather and use data to track your progress, both in implementation and in outcomes. Share your reports with unit staff to maintain engagement.

Team progress on the adaptive portion of the project was evaluated using the AHRQ Hospital Survey on Patient Safety Culture (HSOPS), the Implementation Assessment, and the Exposure Receipt Assessment.

HSOPS is a reliable and valid survey [21] designed to assess clinician and staff perceptions of the culture of safety within their unit, work setting, and overall hospital. The instrument is designed to measure work setting-referenced safety culture dimensions, hospital-referenced dimensions, and outcome variables. For each cohort, this instrument was administered to all staff in the unit two to three times during the project to help teams determine whether safety culture had changed during the implementation process. Teams were debriefed on the results and were provided a Culture Check-Up Tool in order to help debrief their frontline staff. Reports were also posted on the project portal and were readily available to all teams.

An Implementation Assessment was developed and used to help teams monitor their progress over time for both the technical and adaptive aspects of the program. Project leads were

interviewed at least twice in each cohort. Both quantitative and qualitative data were collected. Reports were posted in the project portal.

An Exposure Receipt Assessment was developed and used to help teams determine if their educational efforts were reaching the frontline staff. This assessment looked at both the technical and adaptive aspects of the project and was designed to help project leads to determine whether they needed to adapt their education processes to reach more staff. Results were reviewed with teams via conference calls, and reports were posted in the project portal.

4.3. Educational Program

The "clinical communities" conceptual model heavily influenced the design of the program implementation. Clinical communities are groups of people who share a commitment to achieve specific goals, often related to improving quality in health care. Teams that are part of clinical communities agree to work collaboratively to achieve these goals and take responsibility for delivering on their commitments. A key benefit of such a network of organizations may lie in their role in the efficient and effective sharing of knowledge and their support for improvement and innovation. Networks are not simply pipelines for knowledge—they also have important influences on norms and behaviors.[22]

The National Project Team (NPT) used a collaborative model, based on the successful Michigan Keystone ICU Project, to establish and foster a clinical community through immersion training and by facilitating peer-to-peer learning between hospital units. The collaborative model included onboarding and kickoff calls, monthly content/project calls, and monthly coaching calls. The calls were supported by recordings and archived as Webinars, posted on the project Web site, and available for any project participant to download and watch at their convenience. Coordinating entity (CE) leads were encouraged to organize in-person kickoff and annual meetings for their participating teams.

4.3.1. Onboarding and Kickoff Webinars

Onboarding conference calls were used as introductory sessions for teams to become acclimated with the project components and ask project-related questions in preparation for project implementation. A kickoff call was used to mark the beginning of the project implementation phase.

4.3.2. Content/Project Webinars

Content calls offered all project participants the opportunity to implement CUSP and learn about VAE/VAP prevention strategies. The conference calls were supported through online meeting spaces that easily allowed for interactive content sharing and presentation. Content calls for Cohorts 1 and 2 ranged from 60 to 90 minutes, while Cohort 3 calls lasted between

90 minutes and 2 hours, depending on which interventions each team selected. Faculty clinicians, implementation science researchers, subject matter experts, and multidisciplinary frontline staff led didactic sessions followed by an open dialogue with the teams. Patients and patients' families also shared their experiences as it pertained to mechanical ventilation. Project-related performance data were also reviewed during the calls.

In addition, annual "year in review" sessions as well as program-end sustainability sessions were conducted. These calls covered topics on strategies for teams to sustain the successful implementation of both adaptive and technical interventions as well as project highlights and accomplishments. Communication about events was shared via electronic digests, coaching calls, Web banners, and published schedules.

4.3.3. Coaching Calls

Coaching calls were facilitated by the NPT, but organized and led by the various CEs. The coaching calls provided clinical teams with an opportunity to ask questions, share challenges and triumphs, and review data reports aggregated at the CE level. The NPT assigned a coach and coordinator to conduct monthly calls with each CE. During calls, the coach reinforced key concepts related to technical and adaptive work and the research staff coordinator highlighted project milestones and facilitated action planning. This feedback structure enabled the NPT to make informed adjustments to instructional strategies and standard operating procedures.

4.3.4. Coordinating Entity Calls

The NPT led CE calls that were designed to provide the CEs with meaningful feedback on their teams' progress and for reviewing project milestones. Teams' challenges and triumphs were also discussed, and the calls served as opportunities to glean wisdom from the CEs. The CEs were encouraged to share their project-related challenges and feedback with the NPT and their peers. Like with the coaching calls, this feedback structure enabled the NPT to make informed adjustments to instructional strategies and standard operating procedures.

4.3.5. Infection Prevention/Affinity Group Webinars

Additional Webinars were held to discuss specialized topics on VAE prevention and LTVV strategies. The VAE Affinity, or Infection Preventionist (IP), Webinars were open to all participants, but were recommended for IPs and others interested in VAE prevention techniques and the theory behind VAE.

4.3.6. Data Facilitator Webinars

Data facilitator Webinars were held to provide training on collecting project data and interpreting data reports. Recordings were archived on the project portal Web site for future reference.

4.3.7. Miscellaneous/Supplemental Events

As the project proceeded, the NPT also held supplemental informational calls. These calls covered project-related content, such as debriefing data and train-the-trainer opportunities for hospital team leads and CEs. For example, an Executive Engagement special topic was presented by Dr. Peter Pronovost, the Director of the Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality. Hospital teams were encouraged to invite their executives to join the call as a means to further engage them in the AHRQ Safety Program for Mechanically Ventilated Patients. Dr. Pronovost spoke on the importance and role of engaged executives, strategies for successful patient safety efforts, creation of a business case for quality improvement projects, and development of an infrastructure to engage frontline staff and improve organizational quality.

4.3.8. Digests

Electronic digests were sent semimonthly to communicate project-related activities, milestones, and special events. Significant efforts were made to continuously highlight teams' successful efforts throughout the project and to facilitate peer-to-peer learning. Digests went to all cohort participants and provided frequent opportunities to assist teams with implementation. They also served as platforms to highlight project-related scholarly articles on reducing VAEs/VAPs.

4.4. Web Portal

The NPT developed a password-protected project portal in conjunction with CECity, the health care industry's leading "software as a service" provider. It served as a central repository for all project content and data. This site housed the data entry portal and access to real-time reports, as well as the educational materials developed for each cohort of the program. Educational materials included literature reviews, informational factsheets, implementation guides for both technical and adaptive components, content presentations, and Webinar recordings.

4.5. Recruitment

The AHRQ Safety Program for Mechanically Ventilated Patients succeeded in recruiting 214 hospitals across 38 States, Puerto Rico, and Saudi Arabia (Table 4).

Table 4. State and Hospital Recruitment Timeline by Cohort

	STATES	HOSPITALS	START OF RECRUITMENT	START OF ONBOARDING	START OF IMPLEMENTATION
Cohort 1 (complete)	11	63	Nov 2013	None	Feb 2014
Cohort 2 (goal)	18	180	Sept 2014	Nov 2014	Jan 2015
Cohort 2 (actual)	17	54	Sept 2014	Nov 2014	Jan 2015
Cohort 3 (goal)	15	150	Mar 2015	July 2015	Aug 2015
Cohort 3 (actual)	29	97	Mar 2015	Sept 2015	Sept 2015

4.5.1. Recruitment Strategy

4.5.1.1. Cohort 1

Planning for recruitment began in September 2013 with a working group composed of members of the Armstrong Institute for Patient Safety and Quality (AI), Michigan Health & Hospital Association (MHA), and AHRQ. The working group identified our target audience, developed collateral materials, and identified a recruitment approach.

Acute care and long-term facilities that care for adult mechanically ventilated patients across the United States and Puerto Rico were eligible to participate in the program. Cohort 1 recruitment began in November 2013. Although some CEs elected to conduct their own recruitment efforts, the majority requested outreach from the NPT. This streamlined process for recruitment was facilitated mainly by the Hospital Engagement Networks (HENs) and State hospital associations (SHAs) through the following activities:

1. MHA Keystone Center created a recruitment Web site, featuring information about the project, enrollment instructions, and documents.
2. MHA Keystone Center created both PDF and Web-based registration forms.
3. Both the MHA Keystone Center and the AI Marketing and Communication teams created an e-blast for all recruitment milestones:
    a. an invitation to recruitment Webinars,
    b. reminder emails before recruitment Webinars, and
    c. deadline emails for enrollment document submissions.
4. E-blast email was sent to the MHA Keystone Center's HEN, SHA, and Quality Improvement Organizations email lists.
5. MHA Keystone Center recruited and marketed the project in person at the biannual State Hospital Association conference.

6. Several professional organizations were contacted for possible referrals:
    a. Association for Professionals in Infection Control and Epidemiology,
    b. Society for Healthcare Epidemiology of America,
    c. Centers for Disease Control and Prevention, and
    d. U.S. Department of Veterans Affairs.

These recruitment efforts along with the use of Johns Hopkins University social networking services resulted in the recruitment of 63 hospitals across 11 States (Table 5).

Table 5. Hospital Recruitment by State, Cohort 1

STATE	HOSPITALS IN COHORT 1
Michigan	20
New Jersey	15
South Carolina	9
Tennessee	9
Texas	4
Virginia	1
West Virginia	1
North Carolina	1
New Mexico	1
Missouri	1
Florida	1
Total	63

4.5.1.2. Cohort 2

Recruitment efforts for Cohort 2 started in September 2014 with the goal of securing participation in 18 States with 10 hospitals in each State. Because the Centers for Medicare & Medicaid Services had not yet announced the HENs' funding status for 2015, the recruitment strategy was refined to emphasize hospital-level recruitment. To supplement the steps implemented for Cohort 1, the NPT contacted both the AI network of hospitals and professional organizations, as well as the MHA hospital contacts, recruiting hospitals with or without a SHA or HEN-based CE. We again reached out to the national professional organizations above and additional partners, including the American Physical Therapy Association, American Association of Critical-Care Nurses, and American Association for Respiratory Care. As a result of these additional efforts, the NPT was able to nearly reach the State enrollment goal of 18 by securing

participation in 17 States. However, only 54 hospitals were enrolled to participate (Table 6). The predominant barriers to recruitment included lack of funding for participation and potential teams being overburdened by other quality improvement initiatives.

Table 6. Hospital Recruitment by State, Cohort 2

STATE	HOSPITALS IN COHORT 2
Michigan	16
New York	13
Nevada	7
California	2
Delaware	2
New Jersey	2
Oklahoma	2
Pennsylvania	2
Florida	1
Illinois	1
Maryland	1
Ohio	1
Utah	1
Virginia	1
West Virginia	1
Wisconsin	1
Total	54

4.5.1.3. Cohort 3

As the recruitment for Cohort 2 reached an end in January 2015, the NPT again reassessed recruitment strategies in preparation for Cohort 3. Having learned from the recruitment challenges in Cohorts 1 and 2, the NPT opted for a 6-month lead time to the kickoff for Cohort 3. In addition, recruitment efforts were expanded to include several national meetings including the Society of Critical Care Medicine Annual Congress, the National Patient Safety Foundation, and the annual American Association of Critical-Care Nurses meeting. Email lists were expanded to connect with a broader audience and included the utilization of the AHRQ patient safety email list of hospitals and organizations. Cohort 3 recruitment reached 65 percent of the enrollment goal, which increased from 30 percent of the goal in Cohort 2. The NPT was also able to recruit 11 hospitals from Puerto Rico and 13 from Saudi Arabia (Table 7). The predominant barriers to recruitment included lack of funding for participation and competing quality improvement initiatives.

Table 7. Hospital Recruitment by State, Cohort 3

STATE *	HOSPITALS IN COHORT 3
Illinois	19
Saudi Arabia	13
Puerto Rico	11
Pennsylvania	6
Alabama	5
Indiana	4
Oregon	4
Tennessee	4
Texas	3
California	2
Hawaii	2
New York	2
Ohio	2
Utah	2
Virginia	2
Wyoming	2
Arizona	1
Arkansas	1
Connecticut	1
Florida	1
Georgia	1
Louisiana	1
Maine	1
Maryland	1
Minnesota	1
Mississippi	1
Missouri	1
Nebraska	1
New Jersey	1
North Carolina	1
Oklahoma	1
Total	98

* Puerto Rico and Saudi Arabia are counted as States for purposes of this table.

4.5.2. Randomization

The project was originally envisioned as a stepped wedge trial in which the implementation of interventions by the participating teams would occur at different time periods over the course of the project. This approach was considered ideal because all teams (hospital or cluster of hospitals) would receive the interventions but the precise amount of pre- and post-intervention data for each team or cluster would vary based on their randomization placement. The rationale for including groups with a relatively long pre-intervention period was to give us the ability to assess whether any differences detected in outcomes were because of secular changes, as well as allow for control and intervention group comparison. Participating CEs would be randomly assigned to the "early" adoption of CUSP or "late" adoption of CUSP, thus leading to each group receiving the three interventions at slightly staggered times. The exceptions were the University Hospital Consortium and MHA CEs that were randomized within the CE on the hospital level and stratified based on whether a hospital had a neuro ICU and/or a surgical ICU.

This randomization strategy proved problematic as hospitals did not, or were unable to, adhere to the randomization assignments. This strategy relied on the units' readiness to implement the intervention components at the time they were assigned to enter the study. However, many hospitals agreed to their randomization assignment only to later realize they were not prepared to begin the interventions by the time data collection was scheduled to begin. In addition, many hospitals randomized to late adoption were unwilling to delay implementation.

4.5.3. Project Retention

Hospital units wishing to participate in the program were required to complete three steps in order to become "participants." First, a signed Letter of Commitment (LOC) must be submitted to the NPT. Next, a signed Data Use Agreement (DUA) must also be submitted. Finally, the hospital unit must register as a participant on the data portal Web site. Hospitals were considered "recruited" when their LOC was received, "enrolled" after their DUA was received, and having "participated" when they registered on the data portal Web site.

4.5.3.1. Retention Strategies

As hospitals were not compensated directly for participation, hospital retention in the project was done through team engagement, including data feedback and peer-peer learning. By developing a structured syllabus of educational Webinars, in the form of project and content calls, CE-led calls, and coaching calls tailored for each cohort, the NPT coordinators were able to facilitate close working relationships with the participating entities. These relationships incentivized participation by reinforcing our appreciation of the teams and the value of their work. Involving the CEs as early as possible proved valuable as they had relationships with the individual hospitals and had the capabilities to rally their groups to continue with their forward momentum. As the project progressed and data collection increased, the NPT was able to further hospital engagement by actively disseminating quarterly standardized performance

reports; as team members saw their aggregated data points trending over time, it created a deeper sense of accomplishment and added value to their work.

4.5.3.2. Retention Challenges

The NPT encountered barriers to retaining hospitals between the time of enrollment and participation. Many hospitals reported being overburdened by competing quality improvement initiatives. These hospitals left their respective cohort because of an overextended workload. Another retention barrier was the significant turnover some hospitals faced, leading to lack of real ownership of the ongoing project. Extended workloads and high turnovers also led hospitals to encounter difficulty in acclimating new staff to the project requirements.

5.0. Program Impact

5.1. Timeline and Data Collection

Participating facilities were asked to submit monthly data for ventilator-associated event (VAE) outcomes and objective outcomes (OO) for a 6-month baseline period and the entire intervention period. VAE data were reported to the Centers for Disease Control and Prevention National Healthcare Safety Network (NHSN) by infection preventionists. Coordinating entity leads, participating teams, and the National Project Team (NPT) extracted VAE data from NHSN and uploaded the data into the project data portal every calendar quarter.

For Cohorts 1 and 2, the three categories of technical interventions—Daily Care Processes (DCP), Early Mobility (EM), and Low Tidal Volume Ventilation (LTVV)—were rolled out in a staggered fashion following a specified timeline (Table 4). Using an established intermittent sampling strategy,[23] process measure data for these interventions were collected on a daily basis for an entire quarter at the beginning, and then for 7 consecutive days out of a month in each quarter plus additional days as necessary for each unit to obtain at least 30 ventilator-days for that month, whenever possible.

For Cohort 3, participating facilities chose to implement either DCP or EM, or both if feasible given the shorter timeframe. LTVV was optional. For the first 2 months, data were collected every day; then for all subsequent months, data were collected for 7 consecutive days out of a month plus additional days as necessary for each unit to obtain at least 30 ventilator-days for that month, whenever possible.

Previous implementation experience suggests that 3–6 months is required for teams to familiarize themselves with the data collection tools and the intervention elements. Thus, when summarizing the process measure data, we defined the first 3–6 months of implementation as the early intervention period, and the time after as the late intervention period. The choice of 3 or 6 months was based on the length of the data collection period in each cohort for each intervention tool and was fully specified in Table 8.

The data were extracted for analysis on May 29, 2016. A full data set will be available after the program concludes in September 2016.

Table 8. Data Collection Timeline for Process and Outcome Measures (by May 29, 2016)

Cohort 1	Year	2013	2013	2013	2013	2013	2014	2014	2014	2014	2014	2014	2014	2014	2014	2014	2014	2014	2015	2015	2015	2015	2015	2015	2015	2015	2015	2015	2015	2015	2016
	Month	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1
	Quarter							1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8
	DCP							E	E	E	E				7		7		7					7			7			7	
	EM										E	E	E	E		7		7					7			7			7		
	LTVV																			E	E	E			7			7			7
	VAE	O	O	O	O	O	O	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	OO	O	O	O	O	O	O	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Cohort 2	Year	2014	2014	2014	2014	2014	2014	2015	2015	2015	2015	2015	2015	2015	2015	2015	2015	2015	2015	2016	2016	2016	2016	2016
	Month	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5
	Quarter							1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6
	DCP							E	E	E	7	7	7			7			7			7		
	EM											E	E	E	E		7	7			7			7
	LTVV																E	E	E	E			7	
	VAE	O	O	O	O	O	O	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
	OO	O	O	O	O	O	O	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

Cohort 3	Year	2015	2015	2015	2015	2015	2015	2015	2015	2015	2015	2016	2016	2016	2016	2016
	Month	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5
	Quarter							1	1	1	2	2	2	3	3	3
	DCP							E	E	7	7	7	7	7	7	7
	EM							E	E	7	7	7	7	7	7	7
	LTVV															
	VAE	O	O	O	O	O	O	X	X	X	X	X	X	X	X	
	OO	O	O	O	O	O	O	X	X	X	X	X	X	X	X	

DCP: Daily Care Processes.

EM: Daily Early Mobility.

LTVV: Low Tidal Volume Ventilation.

VAE: Ventilator-Associated Event.

OO: Objective Outcomes.

E: collect and enter data daily for the entire month.

7: collect and enter data daily for at least 7 consecutive days out of the month plus additional consecutive days as necessary to obtain at least 30 ventilator-days for that month whenever possible.

O: enter monthly data for baseline time period.

X: enter monthly data for intervention time period.

Light gray: early intervention.

Dark gray: late intervention.

5.2. Measures

The following measures were reported. Detailed definitions for each measure can be found in Appendix A.

5.2.1. VAE Outcome Measures

- *VAE* (ventilator-associated condition + Infection-Related Ventilator-Associated Complication (IVAC) + possible ventilator-associated pneumonia (PVAP)) *incidence rate per 1,000 ventilator-days*
- *IVAC* (IVAC + PVAP) *incidence rate per 1,000 ventilator-days*
- *PVAP incidence rate per 1,000 ventilator-days*

Data for a second denominator, episodes of mechanical ventilation, were also extracted from NHSN and uploaded to the data portal. However, most participating units did not submit any valid data for this denominator; therefore, we did not report incidence rates using this denominator.

5.2.2. Objective Outcome Measures

- *mortality rate*
- *average duration of mechanical ventilation per episode*
- *average duration of mechanical ventilation per patient*
- *average hospital length of stay per patient*

5.2.3. Daily Care Process Measures

Three categories of measures together form the DCP measures. They include the ventilator-associated event/ventilator-associated pneumonia (VAE/VAP) prevention bundle, sedation assessment, and delirium assessment.

5.2.3.1. VAE/VAP Prevention Bundle

- *subglottic secretion drainage endotracheal tube (SSD-ETT) compliance rate*
- *head of bed (HOB) compliance rate*
- *spontaneous awakening trial (SAT) compliance rate*
- *spontaneous breathing trial (SBT) compliance rate*
- *percentage of ventilated patient-days without sedation*
- *SBT with sedatives off compliance rate*

5.2.3.2. Sedation Assessment

- *Percentage of achieving Richmond Agitation-Sedation Scale/Sedation-Agitation Scale (RASS/SAS) target*
- *Percentage of RASS/SAS actual being {−1, 0, 1} or {4, 5}*

5.2.3.3. Delirium Assessment

- *Delirium assessment utilization rate*
- *Percentage of Confusion Assessment Method for the ICU (CAM-ICU)/Attention Screening Exam (ASE) UTA (Unable to Assess)*
- *Percentage of correctly reporting CAM-ICU/ASE UTA*
- *Percentage of CAM-ICU negative or ASE ≤2 (no delirium)*

5.2.4. Early Mobility Measures

Three categories of measures together form the EM measures. They include sedation assessment, delirium assessment, and mobility.

5.2.4.1. Sedation Assessment

- *percentage of achieving RASS/SAS target*
- *percentage of RASS/SAS actual being {−1, 0, 1} or {4, 5}*

5.2.4.2. Delirium Assessment

- *delirium assessment utilization rate*
- *percentage of CAM-ICU/ASE UTA*
- *percentage of correctly reporting CAM-ICU/ASE UTA*
- *percentage of CAM-ICU negative or ASE ≤2 (no delirium)*

5.2.4.3. Mobility

- *distribution of the highest level of mobility*
- *distribution of perceived barrier to achieving higher level of mobility*
- *EM adverse event rate*
- *distribution of adverse events*
- *physical therapy (PT) or occupational therapy (OT) participation rate*

5.2.5. Low Tidal Volume Ventilation Measures

Two categories of measures together form the LTVV measures. They include tidal volume and positive end-expiratory pressure (PEEP).

5.2.5.1. Tidal Volume

- *Patients with acute respiratory distress syndrome (ARDS): Percentage of tidal volume values, measured in mL/kg predicted body weight (PBW), falling in the following five categories: <4, 4–6, 6–8, 8–10, ≥10*
- *Patients without ARDS: Percentage of tidal volume values, measured in mL/kg PBW, falling in the following five categories: <4, 4–6, 6–8, 8–10, ≥10*

5.2.5.2. PEEP

- *PEEP compliance rate, for patients with ARDS*
- *PEEP compliance rate, for patients without ARDS*

5.3. Results

5.3.1. Characteristics

Through an online registration process on the data portal, we collected participating sites' characteristics, including hospital type, academic status, hospital size, location, and unit type. Descriptive characteristics of participating facilities were summarized and are reported in Table 9. A total number of 254 units from 178 hospitals in 38 States submitted registration data to the project data portal, with 48, 74, and 132 units registered to Cohorts 1, 2, and 3, respectively.

Table 9. Characteristics of Participating Hospitals and ICUs

CHARACTERISTICS	COHORT 1 N (%)	COHORT 2 N (%)	COHORT 3 N (%)	ALL COHORTS N (%)
HOSPITALS (N)	**35**	**52**	**93**	**178***
Hospital Type				
Adult acute care	35 (100%)	52 (100%)	89 (96%)	174 (98%)
Long-term care	0 (0%)	0 (0%)	4 (4%)	4 (2%)
Academic Facility				
Yes	17 (49%)	30 (58%)	44 (47%)	90 (51%)
No	18 (51%)	22 (42%)	49 (53%)	88 (49%)
Hospital size (beds)				
Small (≤99)	7 (20%)	6 (12%)	11 (12%)	23 (13%)
Medium (100–499)	20 (57%)	32 (62%)	64 (69%)	115 (65%)
Large (≥500)	8 (23%)	14 (27%)	18 (19%)	40 (22%)
Urban/Rural Status				
Urban	9 (26%)	30 (58%)	42 (45%)	80 (45%)
Rural	9 (26%)	9 (17%)	27 (29%)	44 (25%)
Suburban	17 (49%)	13 (25%)	24 (26%)	54 (30%)
UNITS (N)	**48**	**74**	**132**	**254**
Unit Type				
Cardiac	14 (29%)	13 (18%)	32 (24%)	59 (23%)
Medical	11 (23%)	24 (32%)	36 (27%)	71 (28%)
Mixed	8 (17%)	17 (23%)	23 (17%)	48 (19%)
Surgical/Trauma	13 (27%)	17 (23%)	26 (20%)	56 (22%)
Other	2 (4%)	3 (4%)	15 (11%)	20 (8%)

* The total number of hospitals in the project (178) is smaller than the sum of the individual numbers of hospitals from the three cohorts (35+52+93=180) because two hospitals participated in two different cohorts.

5.3.2. VAE Outcome Measures

For each cohort, we reported a data submission summary including information on study quarter, calendar quarter, number of units, number of expected unit-months, number of actual unit-months, and number of ventilator-days. For each event type, we calculated and reported quarterly numbers of events, incidence rates, and percentage of unit-months with zero incidences.

We then conducted a sensitivity analysis in which only units with complete VAE data submission (data submitted for every month of the respective cohort timeline) were included. Based on this complete VAE dataset, we assessed the impact of the intervention bundle by comparing VAE outcome rates per 1,000 ventilator-days in the baseline and intervention periods using multilevel regression models. To explore the relationship between VAE, IVAC, and

PVAP rates and the implementation of intervention, we used generalized linear mixed effects models with a log-link and Poisson distribution variance for the monthly numbers of events, including the log of ventilator-days as an offset term. Unit was included as a random intercept to account for the data's longitudinal nature. We included 6-month period indicators in the regression model, estimating the intervention effect at each 6-month intervention period compared with the 6-month baseline.

Overall, VAE data submission rate was fair, with 71 percent to 83 percent of the participating units ever submitting VAE data in the three cohorts. The specifics of VAE data submission are summarized in Appendix B, Tables B-1–6.

The impact of program implementation on VAE rates was variable across cohorts.

Evaluating all available VAE data, Cohort 2 had the lowest baseline VAE and IVAC rates. (Figures 2–4, Tables 10–12). Of note, Cohort 2 is limited to 5 post-implementation quarters, and Cohort 3 is limited to baseline and 3 post-implementation quarters.

For Cohort 1:

- VAE rate decreased from 11.4 to 8.6 per 1,000 ventilator-days (24.6% relative reduction)
- IVAC rate decreased from 4.8 to 2.5 per 1,000 ventilator-days (47.9% relative reduction)
- PVAP rate decreased from 2.0 to 0.9 per 1,000 ventilator-days (55.0% relative reduction)

For Cohort 2:

- VAE rate decreased from 7.1 to 5.9 per 1,000 ventilator-days (16.9% relative reduction)
- IVAC rate stayed relatively stable, from 2.4 to 2.6 per 1,000 ventilator-days
- PVAP rate decreased from 0.9 to 0.5 per 1,000 ventilator-days (44.4% relative reduction)

For Cohort 3:

- VAE rate stayed relatively stable, from 7.6 to 7.8 per 1,000 ventilator-days
- IVAC rate stayed relatively stable, from 2.8 to 2.8 per 1,000 ventilator-days
- PVAP rate stayed relatively stable, from 0.7 to 0.8 per 1,000 ventilator-days

Figure 2. VAE Incidence Rate per 1,000 Ventilator-Days (All Cohorts)

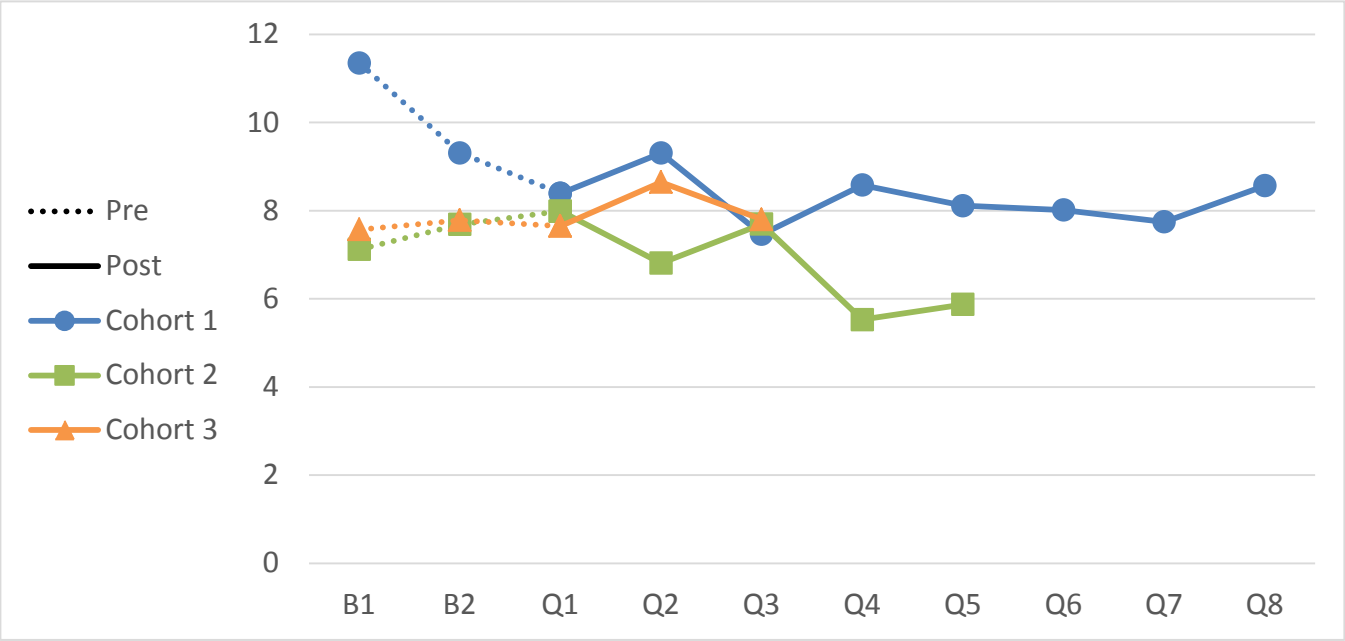


Table 10. VAE Incidence Rate per 1,000 Ventilator-Days (All Cohorts)

	B1	B2	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Cohort 1	11.4 (144/ 12,687)	9.3 (159/ 17,080)	8.4 (152/ 18,115)	9.3 (144/ 15,475)	7.5 (95/ 12,731)	8.6 (129/ 15,037)	8.1 (94/ 11,585)	8.0 (89/ 11,103)	7.7 (85/ 10,973)	8.6 (75/ 8,755)
Cohort 2	7.1 (137/ 19,243)	7.7 (189/ 24,588)	8.0 (209/ 26,164)	6.8 (175/ 25,704)	7.7 (188/ 24,430)	5.5 (127/ 22,972)	5.9 (111/ 18,902)			
Cohort 3	7.6 (125/ 16,512)	7.8 (134/ 17,216)	7.7 (209/ 27,315)	8.6 (333/ 38,520)	7.8 (184/ 23,593)					

Figure 3. IVAC Incidence Rate per 1,000 Ventilator-Days (All Cohorts)

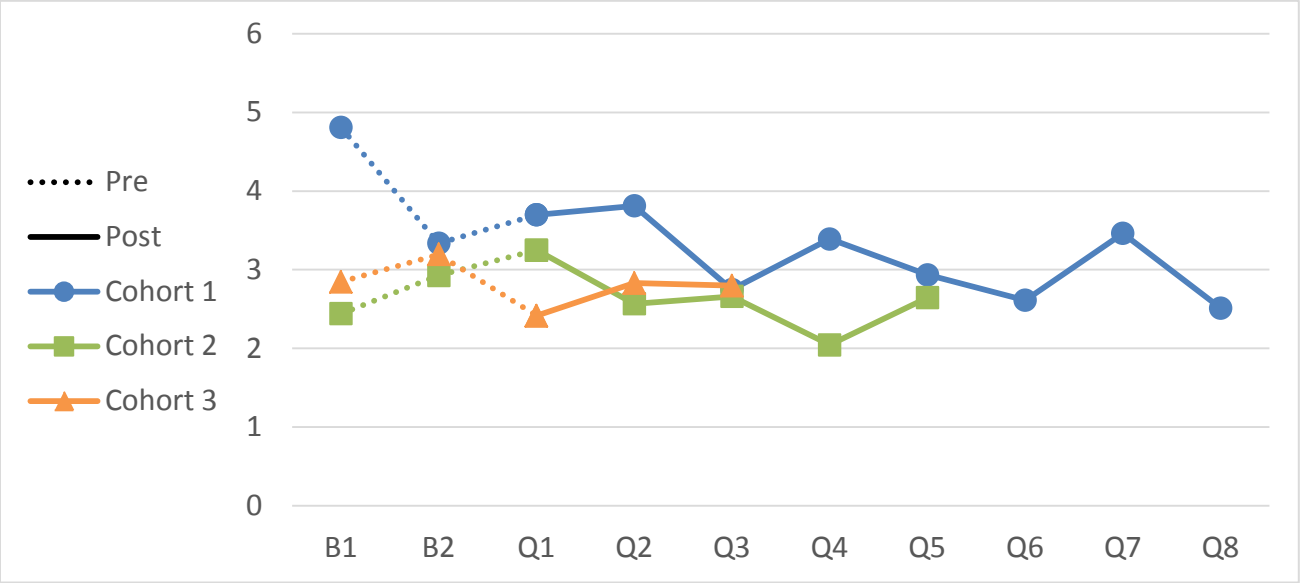


Table 11. IVAC Incidence Rate per 1,000 Ventilator-Days (All Cohorts)

	B1	B2	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Cohort 1	4.8 (61/ 12,687)	3.3 (57/ 17,080)	3.7 (67/ 18,115)	3.8 (59/ 15,475)	2.7 (35/ 12,731)	3.4 (51/ 15,037)	2.9 (34/ 11,585)	2.6 (29/ 11,103)	3.5 (38/ 10,973)	2.5 (22/ 8,755)
Cohort 2	2.4 (47/ 19,243)	2.9 (72/ 24,588)	3.2 (85/ 26,164)	2.6 (66/ 25,704)	2.7 (65/ 24,430)	2.0 (47/ 22,972)	2.6 (50/ 18,902)			
Cohort 3	2.8 (47/ 16,512)	3.2 (55/ 17,216)	2.4 (66/ 27,315)	2.8 (109/ 38,520)	2.8 (66/ 23,593)					

B1 and B2 are baseline quarters.

Figure 4. PVAP Incidence Rate per 1,000 Ventilator-Days (All Cohorts)

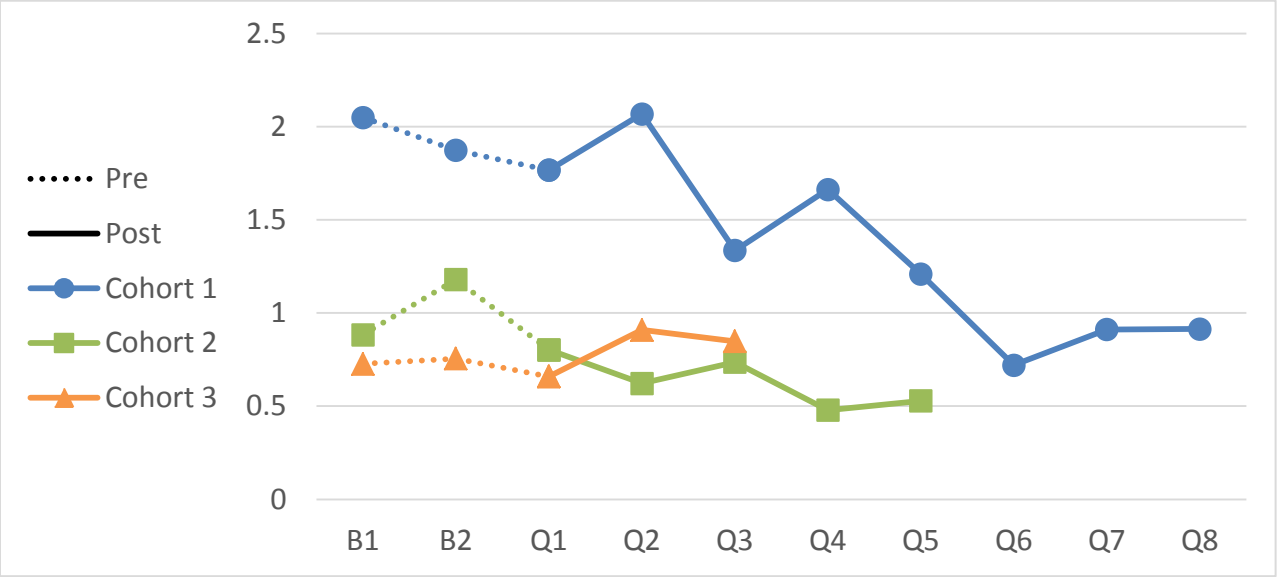


Table 12. PVAP Incidence Rate per 1,000 Ventilator-Days (All Cohorts)

	B1	B2	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Cohort 1	2.0 (26/ 12,687	1.9 (32/ 17,080)	1.8 (32/ 18,115)	2.1 (32/ 15,475)	1.3 (17/ 12,731)	1.7 (25/ 15,037)	1.2 (14/ 11,585)	0.7 (8/1 1,103)	0.9 (10/ 10,973)	0.9 (8/ 8,755)
Cohort 2	0.9 (17/ 19,243)	1.2 (29/ 24,588)	0.8 (21/ 26,164)	0.6 (16/ 25,704)	0.7 (18/ 24,430)	0.5 (11/ 22,972)	0.5 (10/ 18,902)			
Cohort 3	0.7 (12/ 16,512)	0.8 (13/ 17,216)	0.7 (18/ 27,315)	0.9 (35/ 38,520)	0.8 (20/ 23,593)					

B1 and B2 are baseline quarters.

One factor impacting the observed level of reduction is that baseline VAE rates were lower than expected, though still within the average range indicated by current literature. Results were especially affected by the already low baseline VAE rates in Cohort 2. Entering the program with low rates did not provide a comparable opportunity for improvement. Similarly, all cohorts already had high process measure rates. We did, however, still observe decreases in VAE.

5.3.2.1. Percentage of Unit-Months With Zero Incidences

In Cohort 1, comparing baseline quarter 1 with intervention quarter 8, the percentage of unit-months with zero incidences remained approximately the same for VAEs (45 percent to

42 percent), increased from 66 percent to 71 percent for IVACs, and increased from 79 percent to 87 percent for PVAP.

In Cohort 2, comparing baseline quarter 1 with intervention quarter 5, the percentage of unit-months with zero incidences decreased from 60 percent to 52 percent for VAEs, decreased from 76 percent to 69 percent for IVACs, and remained approximately the same for PVAP (88 percent to 91 percent).

In Cohort 3, the percentage of unit-months with zero incidences remained approximately the same for all three event types. A slight increase was observed; however, the short post-implementation period limited our ability to see improvements. Despite this, many units did self-report improvements in VAE reduction, which lends support to the NPT's opinion that, while not statistically significant, this slight increase may still be indicative of a continued trend toward unit-months with zero incidences.

5.3.3. Complete VAE Data

There were 10 (21%), 34 (46%), and 19 (14%) units that submitted complete VAE data in the three cohorts, respectively. (Figures 5–7 and Tables 13–15)

Among units with complete VAE data, Cohort 1 units have the highest baseline VAE, IVAC, and PVAP rates, and Cohort 2 units have the lowest baseline VAE and IVAC rates.

For Cohort 1:

- VAE rate decreased from 11.1 to 7.7 per 1,000 ventilator-days (30.6% relative reduction; p=0.109).
- IVAC decreased from 5.2 to 2.4 per 1,000 ventilator-days (53.8% relative reduction; p=0.036).
- PVAP decreased from 2.3 to 1.0 per 1,000 ventilator-days (56.5% relative reduction; p=0.129).

For Cohort 2:

- VAE rate stayed relatively stable, within the range of 4.3 to 6.5 per 1,000 ventilator-days.
- IVAC rate stayed relatively stable, within the range of 1.5 to 2.8 per 1,000 ventilator-days.
- PVAP rate stayed relatively stable, within the range of 0.4 to 0.8 per 1,000 ventilator-days.

For Cohort 3:

- VAE rate decreased from 9.2 to 7.7 per 1,000 ventilator-days (16.3% relative reduction; p=0.411).

- IVAC decreased from 3.4 to 1.7 per 1,000 ventilator-days (50.0% relative reduction; p=0.120).
- PVAP decreased from 0.7 to 0.2 per 1,000 ventilator-days (71.4% relative reduction; p=0.411).

Figure 5. VAE Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data)

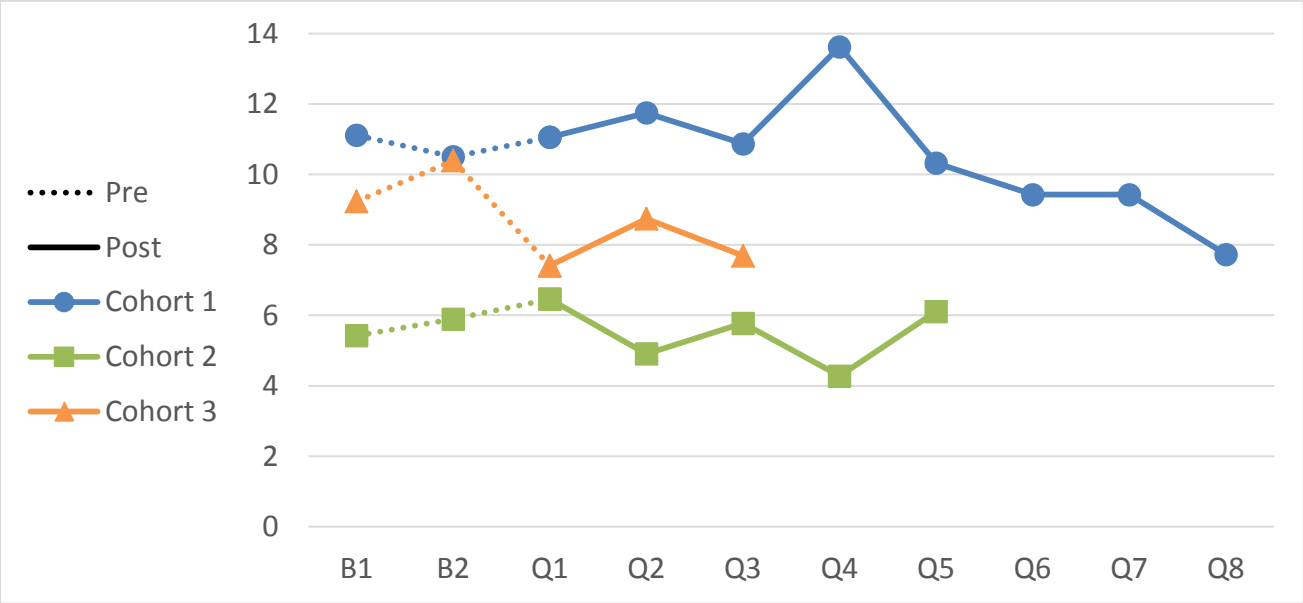


Table 13. VAE Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data)

	B1	B2	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Cohort 1	11.1 (49/ 4,410)	10.5 (56/ 5,331)	11.1 (57/ 5,156)	11.7 (54/ 4,597)	10.9 (45/ 4,139)	13.6 (68/ 4,992)	10.3 (50/ 4,844)	9.4 (44/ 4,667)	9.4 (46/ 4,880)	7.7 (39/ 5,047)
Cohort 2	5.4 (79/ 14,562)	5.9 (91/ 15,447)	6.5 (97/ 15,016)	4.9 (73/ 14,870)	5.8 (79/ 13,685)	4.3 (67/ 15,674)	6.1 (99/ 16,204)			
Cohort 3	9.2 (66/ 7,145)	10.4 (60/ 5,774)	7.4 (46/ 6,208)	8.7 (60/ 6,863)	7.7 (40/ 5,202)					

B1 and B2 are baseline quarters.

Figure 6. IVAC Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data)

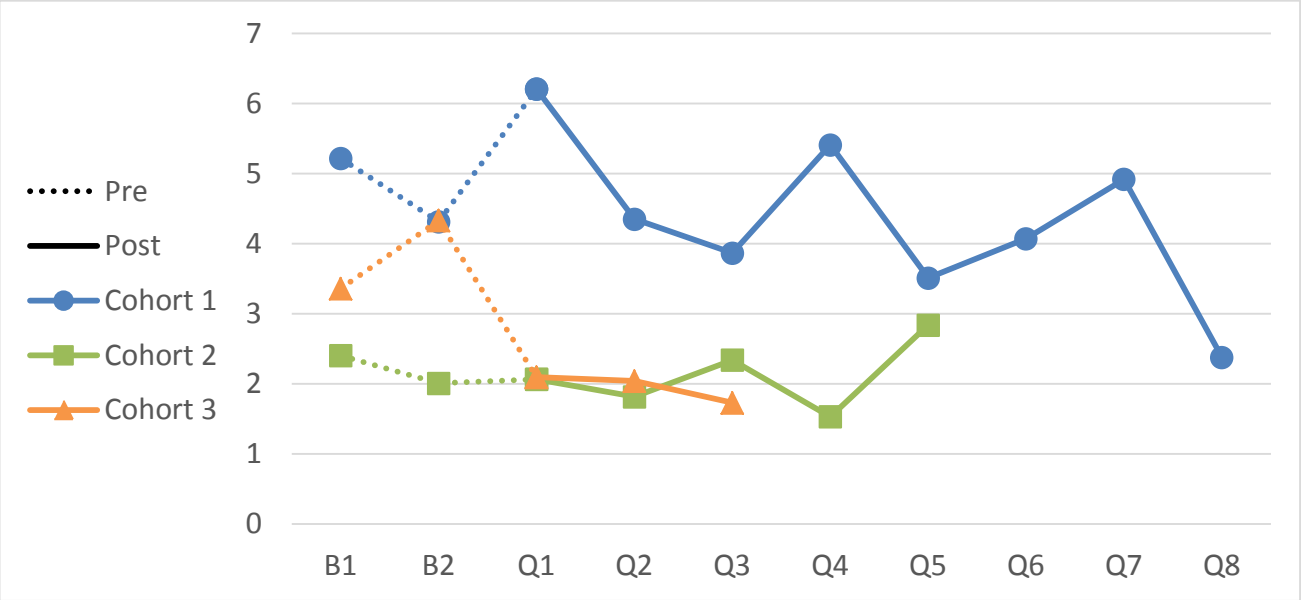


Table 14. IVAC Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data)

	B1	B2	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Cohort 1	5.2 (23/ 4,410)	4.3 (23/ 5,331)	6.2 (32/ 5,156)	4.4 (20/ 4,597)	3.9 (16/ 4,139)	5.4 (27/ 4,992)	3.5 (17/ 4,844)	4.1 (19/ 4,667)	4.9 (24/ 4,880)	2.4 (12/ 5,047)
Cohort 2	2.4 (35/ 14,562)	2.0 (31/ 15,447)	2.1 (31/ 15,016)	1.8 (27/ 14,870)	2.3 (32/ 13,685)	1.5 (24/ 15,674)	2.8 (46/ 16,204)			
Cohort 3	3.4 (24/ 7,145)	4.3 (25/ 5,774)	2.1 (13/ 6,208)	2.0 (14/ 6,863)	1.7 (9/ 5,202)					

B1 and B2 are baseline quarters.

Figure 7. PVAP Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data)

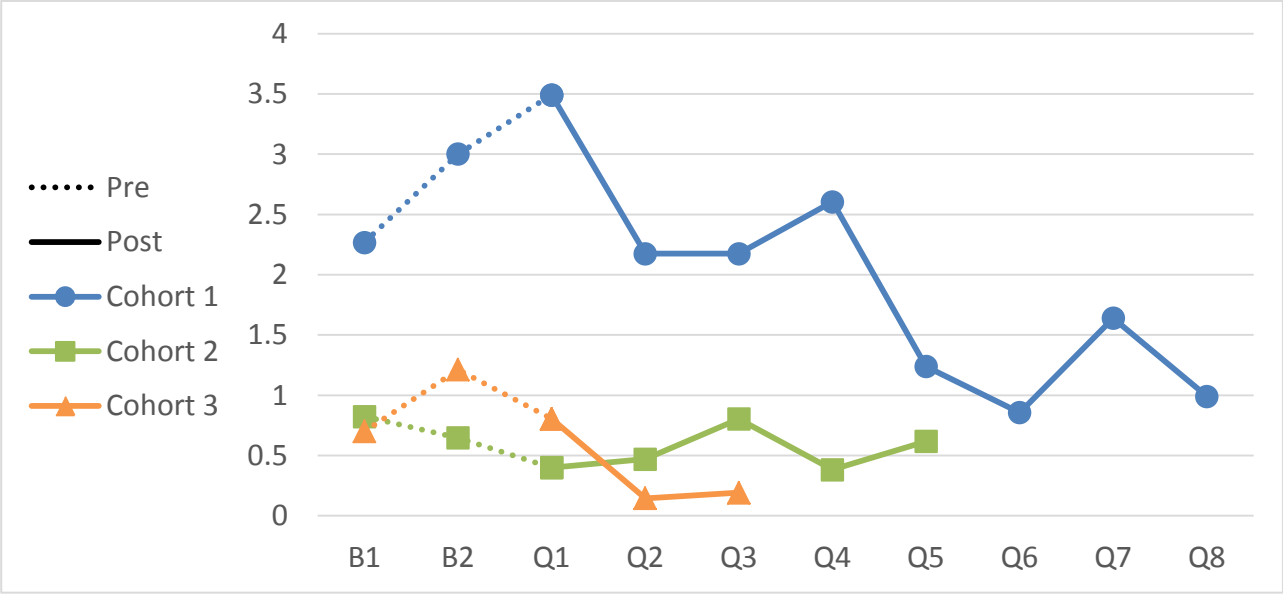


Table 15. PVAP Incidence Rate per 1,000 Ventilator-Days (All Cohorts, Units With Complete VAE Data)

	B1	B2	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Cohort 1	2.3 (10/ 4,410)	3.0 (16/ 5,331)	3.5 (18/ 5,156)	2.2 (10/ 4,597)	2.2 (9/ 4,139)	2.6 (13/ 4,992)	1.2 (6/ 4,844)	0.9 (4/ 4,667)	1.6 (8/ 4,880)	1.0 (5/ 5,047)
Cohort 2	0.8 (12/ 14,562)	0.6 (10/ 15,447)	0.4 (6/ 15,016)	0.5 (7/ 14,870)	0.8 (11/ 13,685)	0.4 (6/ 15,674)	0.6 (10/ 16,204)			
Cohort 3	0.7 (5/ 7,145)	1.2 (7/ 5,774)	0.8 (5/ 6,208)	0.1 (1/ 6,863)	0.2 (1/ 5,202)					

B1 and B2 are baseline quarters.

5.3.3.1. Percentage of Unit-Months With Zero Incidences

In Cohort 1, comparing the percentage of unit-months with zero incidence from baseline quarter 1 with intervention quarter 8:

- VAE: rate of zero increased from 30 percent to 43 percent (p=0.422)
- IVAC: rate of zero increased from 53 percent to 63 percent (p=0.601)
- PVAP: rate of zero increased from 70 percent to 83 percent for PVAP (p=0.354)

In Cohort 2, comparing the percentage of unit-months with zero incidence from baseline quarter 1 with intervention quarter 5:

- VAE: rate of zero decreased from 58 percent to 50 percent for VAEs (p=0.326)
- IVAC: rate of zero decreased from 75 percent to 68 percent for IVACs (p=0.354)

PVAP zero rate incidence remained approximately the same (89% to 90%).

In Cohort 3, comparing the percentage of unit-months with zero incidence from baseline quarter 1 with intervention quarter 3:

- VAE: rate of zero increased from 39 percent to 53 percent (p=0.255)
- IVAC: rate of zero increased from 68 percent to 79 percent (p=0.372)
- PVAP: rate of zero increased from 93 percent to 97 percent (p=0.645)

Additional details can be found in Appendix B, Tables B-4–6.

The regression model suggests Cohort 1 and 3 teams achieved reductions in VAE rates (18–21%), IVAC (23–49%), and PVAP rates (49–60%) (Table 16). Statistical significance should be interpreted with caution. Given that only 14–46% of units submitted complete VAE data, the vast majority of confidence intervals (CIs) are wide, and non-significant results cannot exclude clinically important reductions.

Table 16. VAE Outcomes Incidence Rate Ratios Based on Mixed Effects Poisson Regression Models

		VAE	IVAC	PVAP
Cohort 1	Baseline	Reference	Reference	Reference
	Intervention Half Year 1	1.06 [0.81, 1.38]	1.15 [0.77, 1.70]	1.11 [0.65, 1.88]
	Intervention Half Year 2	1.14 [0.87, 1.49]	0.99 [0.66, 1.51]	0.93 [0.53, 1.63]
	Intervention Half Year 3	0.93 [0.70, 1.23]	0.82 [0.53, 1.26]	0.41 [0.20, 0.86]
	Intervention Half Year 4	0.79 [0.60, 1.06]	0.77 [0.50, 1.19]	0.51 [0.26, 0.98]
Cohort 2	Baseline	Reference	Reference	Reference
	Intervention Half Year 1	1.02 [0.83, 1.26]	0.89 [0.63, 1.26]	0.61 [0.31, 1.22]
	Intervention Half Year 2	0.90 [0.73, 1.13]	0.88 [0.62, 1.25]	0.83 [0.44, 1.56]
	Intervention Half Year 3	1.15 [0.90, 1.47]	1.36 [0.94, 1.97]	0.94 [0.44, 1.99]
Cohort 3	Baseline	Reference	Reference	Reference
	Intervention (8 months)	0.82 [0.65, 1.04]	0.51 [0.34, 0.78]	0.40 [0.16, 1.03]

In the final 6-month period compared with the baseline 6 months, Cohort 1 achieved a 21% reduction in VAE rate (Incidence Rate Ratio [IRR] 0.79), 23% reduction in IVAC rate (IRR 0.77), and a 49% reduction in PVAP rate (IRR 0.51). Only the PVAP reduction was statistically significant (95% CI 0.26-0.98).

Cohort 3 achieved an 18% reduction in VAE rate (IRR 0.82), 49% reduction in IVAC rate (IRR 0.51), and a 60% reduction in PVAP rate (IRR 0.40). Only the IVAC reduction was statistically significant (95% CI 0.34-0.78).

Cohort 2 VAE and IVAC rates increased and PVAP rates decreased slightly; however, none of the Cohort 3 results were statistically significant.

5.3.4. Objective Outcome Measures

Overall data submission for OO is poor, and the collection of objective outcome data was challenging. Because these data are not always readily available to all unit staff, the initial intention was for a hospital billing analyst to download these data on a monthly basis from their administrative database and enter the information into the project data portal. However, many units found this process to be impracticable.

None of the Cohort 1 units submitted more than 1 month (January 2014) of baseline data for OO. Thus, we considered the 6-month period including January 2014 and the first 5-month intervention period (February to June 2014) as the pseudo baseline for units in Cohort 1.

The data submission summary reported information on study time period, calendar time period, number of units, number of expected unit-months, and number of unit-months in each time period for each cohort.

Given high missing data rates, data for units with both baseline (pseudo baseline for Cohort 1, actual baseline for Cohorts 2 and 3) and intervention period data from all three cohorts were extracted and combined. The objective outcome measures data were aggregated for the baseline and intervention periods, and then Chi-squared tests or two-sample Poisson tests were performed to compare the time periods. A comparison of the intervention data distributions of the units that submitted both baseline and intervention period data with the units that submitted intervention data only for each measure using Mann-Whitney tests was also performed.

Following teams' implementation of interventions, we observed a small impact on OO. It is important to interpret these data with a degree of caution because of the amount of missing data. Continuing to examine why there was a higher than expected amount of missing data, it can be noted that, while hospitals themselves do collect data on these measures, they are typically not easily accessible to unit staff. The NPT did provide resources with which to collect objective outcome measures; however, many units lacked the infrastructure to obtain and report these data.

There are 20 (42%), 38 (51%), and 41 (31%) units that ever submitted objective outcome data in the three cohorts, respectively. From the data submission summary, we observed that the

numbers of units submitting baseline data are significantly smaller than those of the ones submitting intervention data (9 vs. 20 in Cohort 1, 18 vs. 38 in Cohort 2, and 7 vs. 37 in Cohort 3; Appendix B, Tables B-7–9).

Combining data from all three cohorts, there are a total of 30 units that submitted data for both baseline and intervention periods. Four units had only baseline data, and 65 had only intervention data. Comparing the 30 units that submitted data for both baseline and intervention periods with the 65 units, we found no significant difference in the distribution of the two groups for any of the OO measures (data not normally distributed, Mann-Whitney tests $p>0.357$).

From baseline to intervention, mortality rate decreased from 20 percent to 19 percent ($p=0.450$), average duration of mechanical ventilation per episode decreased from 4.62 to 4.33 days ($p<0.001$), average duration of mechanical ventilation per patient decreased from 4.97 to 4.65 days ($p<0.001$), and average hospital LOS per patient decreased from 11.55 to 11.23 days ($p<0.001$). The detailed results are reported in Figure 8, Table 17.

Figure 8. Objective Outcome Measures (All Cohorts Aggregate)

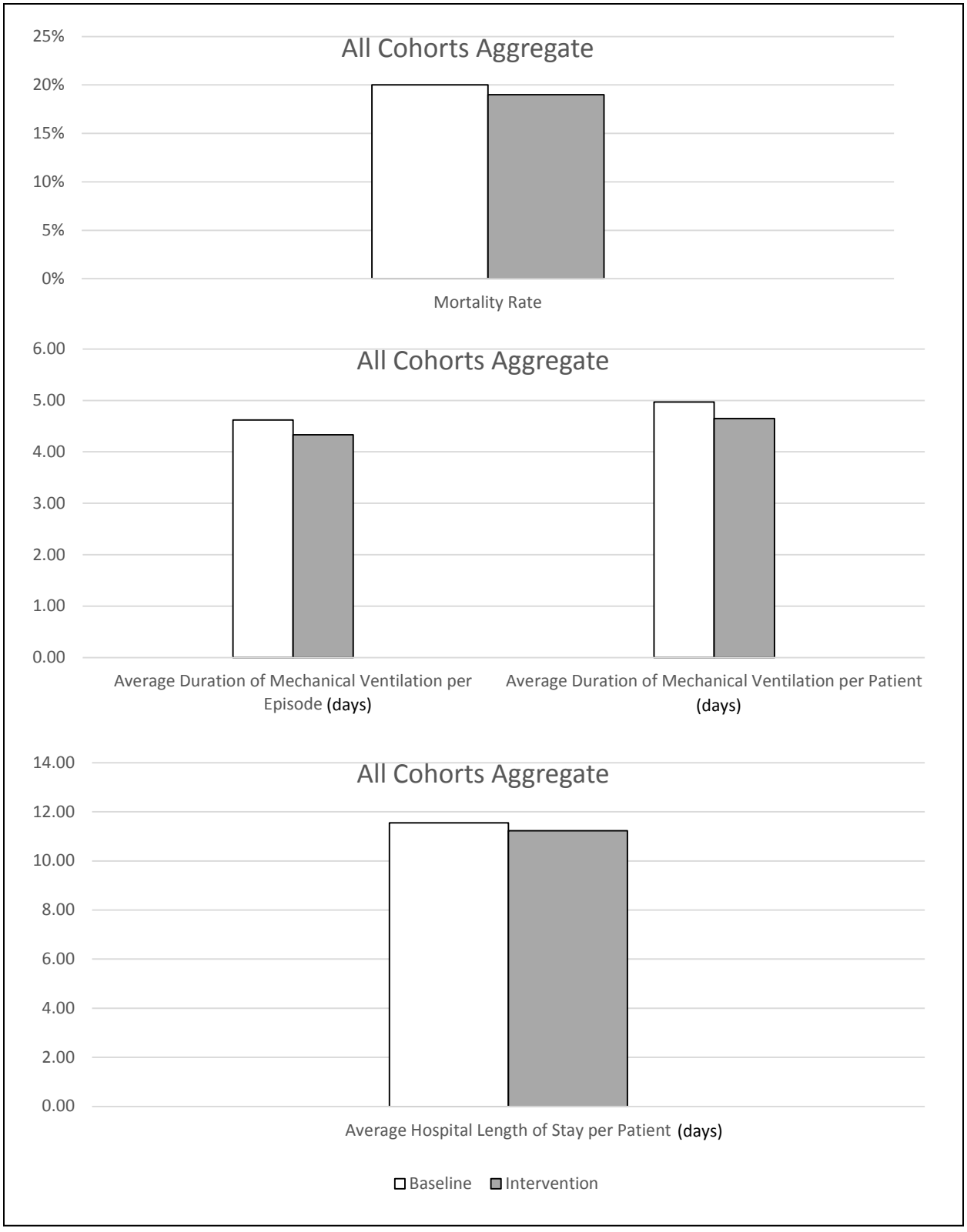


Table 17. Objective Outcome Measures (All Cohorts Aggregate)

COHORT	MEASURE	BASELINE	INTERVENTION	PERCENT CHANGE	P-VALUE
All Cohorts Aggregate	Mortality Rate	20% (1,032/5,241)	19% (2,752/14,330)	−2%	0.450
All Cohorts Aggregate	Average Duration of Mechanical Ventilation per Episode (days)	4.62 (23,703/5,135)	4.33 (65,890/15,229)	−6%	<0.001
All Cohorts Aggregate	Average Duration of Mechanical Ventilation per Patient (days)	4.97 (24,338/4,897)	4.65 (67,416/14,501)	−6%	<0.001
All Cohorts Aggregate	Average Hospital Length of Stay per Patient (days)	11.55 (60,527/5,241)	11.23 (159,398/14,196)	−3%	<0.001

5.3.5. Daily Care Process Measures

Improvement in DCP was seen across all cohorts. Most notably, progress was made in improving the assessment of delirium, but an increase in incorrectly reported UTA rates show that teams need more training on how to accurately use the assessment tools provided. Errors were identified when UTA was indicated despite the patient's not reaching an appropriate sedation score to justify UTA per reporting.

Bundle compliance also increased, with HOB elevation and SAT/SBT trials showing the most improvement.

For all process measures, individual measures for the early and late intervention periods were reported, and then Chi-squared tests were performed to compare the time periods for these measures. For all DCP process measure figures and tables below, early intervention for Cohort 1 and Cohort 2 is the first two quarters of DCP data collection and for Cohort 3 is the first quarter of DCP data collection. All remaining study quarters are defined as late intervention. Percentages were rounded to zero decimal places. All analyses were done using STATA 14 or R 3.3.0. A 95-percent CI that does not include 1 or a p-value less than 0.05 was considered to be significant.

In Cohort 1, 35 (73%) units ever submitted DCP data, providing 343 unit-months and 21,288 ventilator-days of data. Of these 35 units, 29 and 33 units contributed data to the early intervention period (6 months) and the late intervention period (18 months), respectively, and 27 contributed data to both time periods.

In Cohort 2, 59 (80%) units ever submitted DCP data, providing 565 unit-months and 42,031 ventilator-days of data. Of these 59 units, 59 and 51 units contributed data to the early intervention period (6 months) and the late intervention period (11 months), respectively, and 51 contributed data to both time periods.

In Cohort 3, 82 (62%) units ever submitted DCP data, providing 562 unit-months and 34,572 ventilator-days of data. Of these 82 units, 77 and 80 units contributed data to the early intervention period (3 months) and the late intervention period (6 months), respectively, and 75 contributed data to both time periods.

Further specifics of DCP data submission can be found in Appendix B, Tables B-10–12.

5.3.6. VAE/VAP Prevention Bundle Compliance

In Cohort 1, compliance with four out of the six recommended process measures (HOB, SAT, SBT, and SBT without sedation) increased significantly ($p<0.001$ for all) from the early to late intervention periods. Compliance with SAT and SBT process measures increased the most by 23 percent and 34 percent, respectively, from the early to late intervention periods.

In Cohort 2, compliance with five out of the six recommended process measures (SSD-ETT, HOB, SAT, SBT, and SBT without sedation) increased significantly ($p<0.001$ for all) from the early to late intervention periods. Compliance with SSD-ETT and SBT process measures increased the most by 34 percent and 17 percent, respectively, from the early to late intervention periods.

In Cohort 3, compliance with five out of the six recommended process measures (HOB, SAT, SBT, no sedative use, SBT without sedation) increased significantly ($p<0.001$ for all) from the early to late intervention periods. Compliance with SAT and no-sedative-use process measures increased the most by 15 percent and 33 percent, respectively, from the early to late intervention periods.

The significant increases in bundle compliance are highly encouraging. For instance, elevating the HOB is a non-invasive, evidence-based, and cost-effective intervention, yet early compliance data showed it was not frequently utilized. The increase in compliance with this particular intervention across all three cohorts is indicative of the positive effect of simply providing educational and structural guidance. Further, the increase in compliance with performing paired SAT and SBT trials conveys that promoting the use of a multidisciplinary team may help with the ability of the critical care staff to coordinate complex care protocols.

The detailed results are reported in Figure 9 and Table 18.

Figure 9. VAE/VAP Prevention Bundle Compliance Rates (All Cohorts)

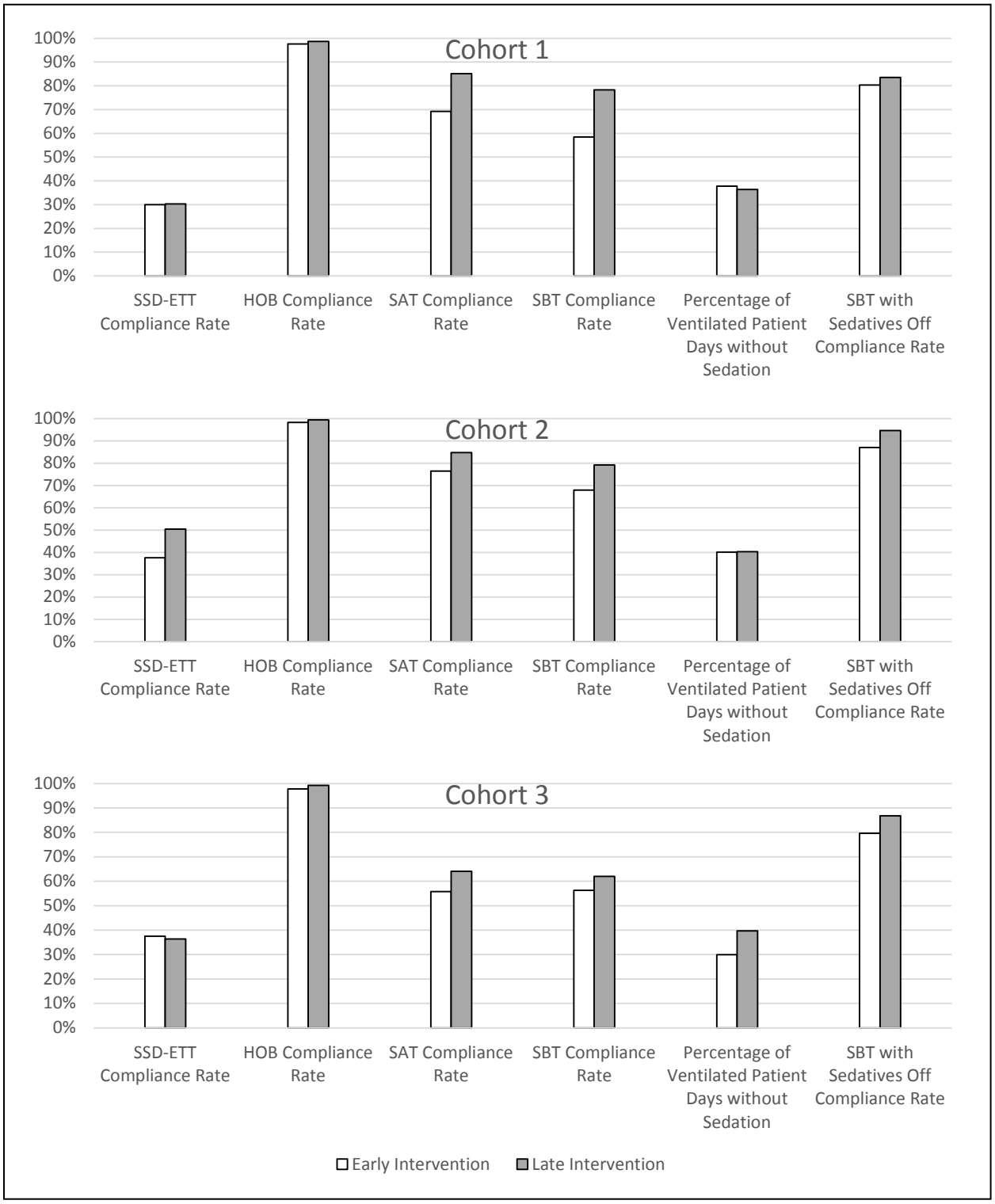


Table 18. VAE/VAP Prevention Bundle Compliance Rates (All Cohorts)

COHORT	COMPLIANCE RATE	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	SSD-ETT Compliance Rate	30% (349/1,164)	30% (735/2,423)	1%	0.830
1	HOB Compliance Rate	98% (6,706/6,866)	99% (13,800/13,983)	1%	<0.001
1	SAT Compliance Rate	69% (2,575/3,718)	85% (6,411/7,530)	23%	<0.001
1	SBT Compliance Rate	58% (2,726/4,663)	78% (6,127/7,820)	34%	<0.001
1	Percentage of Ventilated Patient-Days Without Sedation	38% (2,258/5,976)	36% (4,301/11,831)	−4%	0.062
1	SBT with Sedatives Off Compliance Rate	80% (2,189/2,726)	84% (5,121/6,127)	4%	<0.001
Cohort 2	SSD-ETT Compliance Rate	38% (1,249/3,324)	50% (1,494/2,965)	34%	<0.001
2	HOB Compliance Rate	98% (21,031/21,408)	99% (19,982/20,093)	1%	<0.001
2	SAT Compliance Rate	77% (8,165/10,673)	85% (8,451/9,977)	11%	<0.001
2	SBT Compliance Rate	68% (9,354/13,773)	79% (10,191/12,879)	17%	<0.001
2	Percentage of Ventilated Patient-Days Without Sedation	40% (7,154/17,827)	40% (6,752/16,729)	1%	0.662
2	SBT with Sedatives Off Compliance Rate	87% (8,140/9,354)	95% (9,638/10,191)	9%	<0.001
Cohort 3	SSD-ETT Compliance Rate	38% (602/1,604)	36% (1,344/3,691)	−3%	0.438
3	HOB Compliance Rate	98% (11,381/11,640)	99% (22,372/22,537)	2%	<0.001
3	SAT Compliance Rate	56% (3,921/7,031)	64% (7,184/11,219)	15%	<0.001
3	SBT Compliance Rate	56% (4,331/7,701)	62% (8,684/14,019)	10%	<0.001
3	Percentage of Ventilated Patient-Days Without Sedation	30% (3,002/10,033)	40% (7,381/18,600)	33%	<0.001
3	SBT with Sedatives Off Compliance Rate	80% (3,448/4,331)	87% (7,541/8,684)	9%	<0.001

5.3.6.1. Sedation Assessment

In all three cohorts, the percentage of ventilator-days during which the sedation target score set by providers was actually achieved significantly increased from the early to late intervention

periods. There was no significant change in the percentage of ventilator-days during which a mildly sedated or an awake and calm state was achieved from the early to late intervention periods in any of the cohorts (Figure 10, Table 19). It is unclear, however, whether this was a result of a true improvement in reaching the sedation target or whether clinicians reevaluated their target scores and changed them in order to create a more realistic goal they felt they would be able to reach.

Figure 10. Daily Care Processes Sedation Scale (All Cohorts)

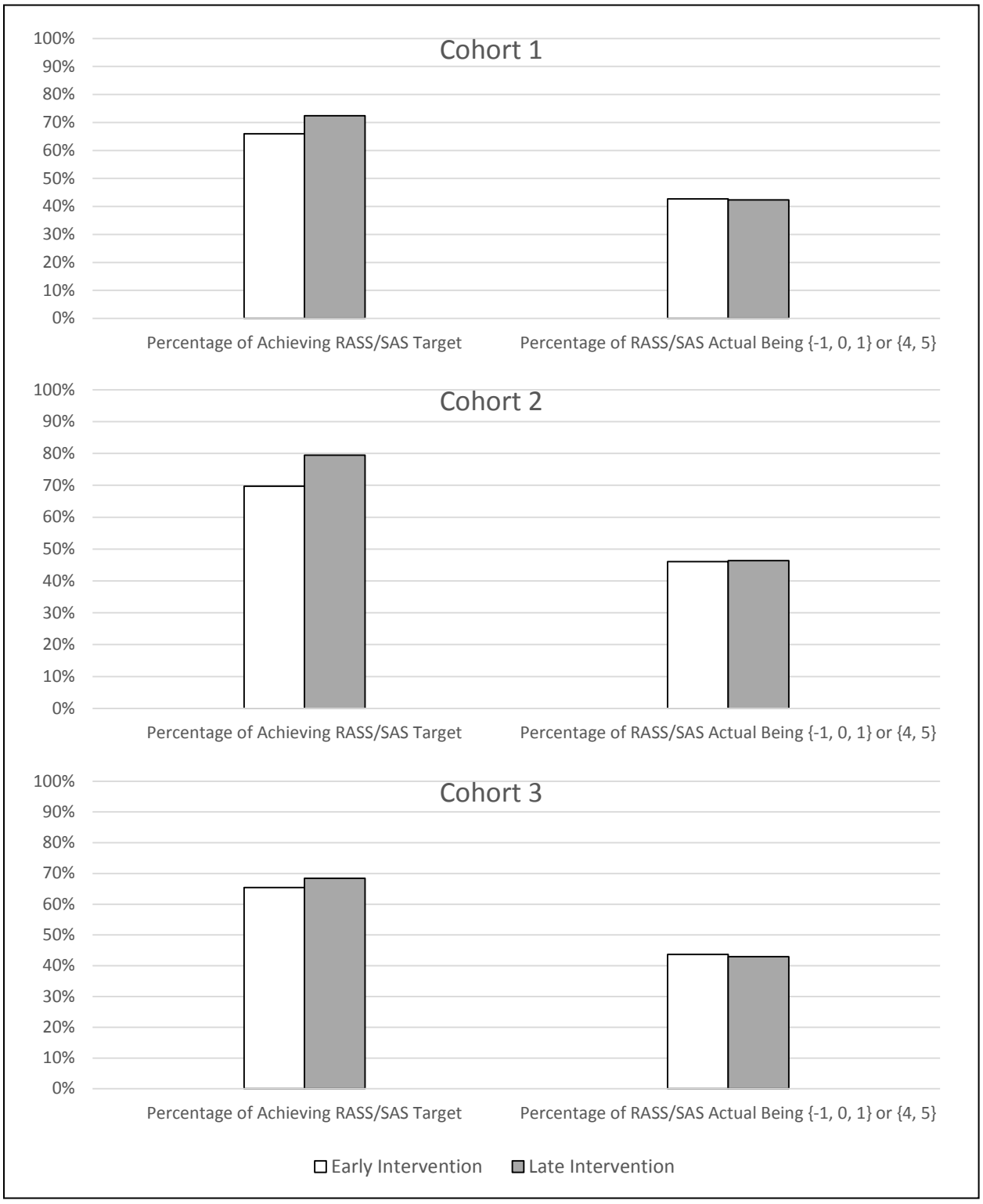


Table 19. Daily Care Processes Sedation Scale (All Cohorts)

COHORT	SEDATION SCALE	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	Percentage of Achieving RASS/SAS Target	66% (3,352/5,083)	72% (7,814/10,785)	10%	<0.001
1	Percentage of RASS/SAS Actual Being {−1, 0, 1} or {4, 5}	43% (2,468/5,780)	42% (4,934/11,661)	−1%	0.626
Cohort 2	Percentage of Achieving RASS/SAS Target	70% (9,075/13,025)	79% (8,763/11,025)	14%	<0.001
2	Percentage of RASS/SAS Actual Being {−1, 0, 1} or {4, 5}	46% (7,473/16,229)	46% (6,847/14,778)	1%	0.615
Cohort 3	Percentage of Achieving RASS/SAS Target	65% (4,527/6,920)	68% (9,372/13,692)	5%	<0.001
3	Percentage of RASS/SAS Actual Being {−1, 0, 1} or {4, 5}	44% (4,051/9,274)	43% (7,535/17,532)	−2%	0.269

5.3.6.2. Delirium Assessment

In Cohorts 1 and 2, delirium assessments and the percentage of delirium-free ventilator-days significantly increased from the early to late intervention periods. The percentage of ventilator-days during which providers were UTA delirium significantly increased, while the percentage of correct UTA determinations significantly decreased from the early to late intervention periods. In Cohort 3, delirium assessment increased significantly, and there was a slight but significant decrease in the percentage of delirium-free ventilator-days from the early to late intervention periods. The percentage of ventilator-days during which providers were UTA delirium slightly though significantly increased, while the percentage of correct UTA determinations remained unchanged from the early to late intervention periods. Most notably, progress was made in improving the assessment of delirium, but an increase in UTA rates shows that teams need more training on how to accurately use the assessment tools provided.

The detailed results are reported in Figure 11 and Table 20.

Figure 11. Daily Care Processes Delirium Assessment (All Cohorts)

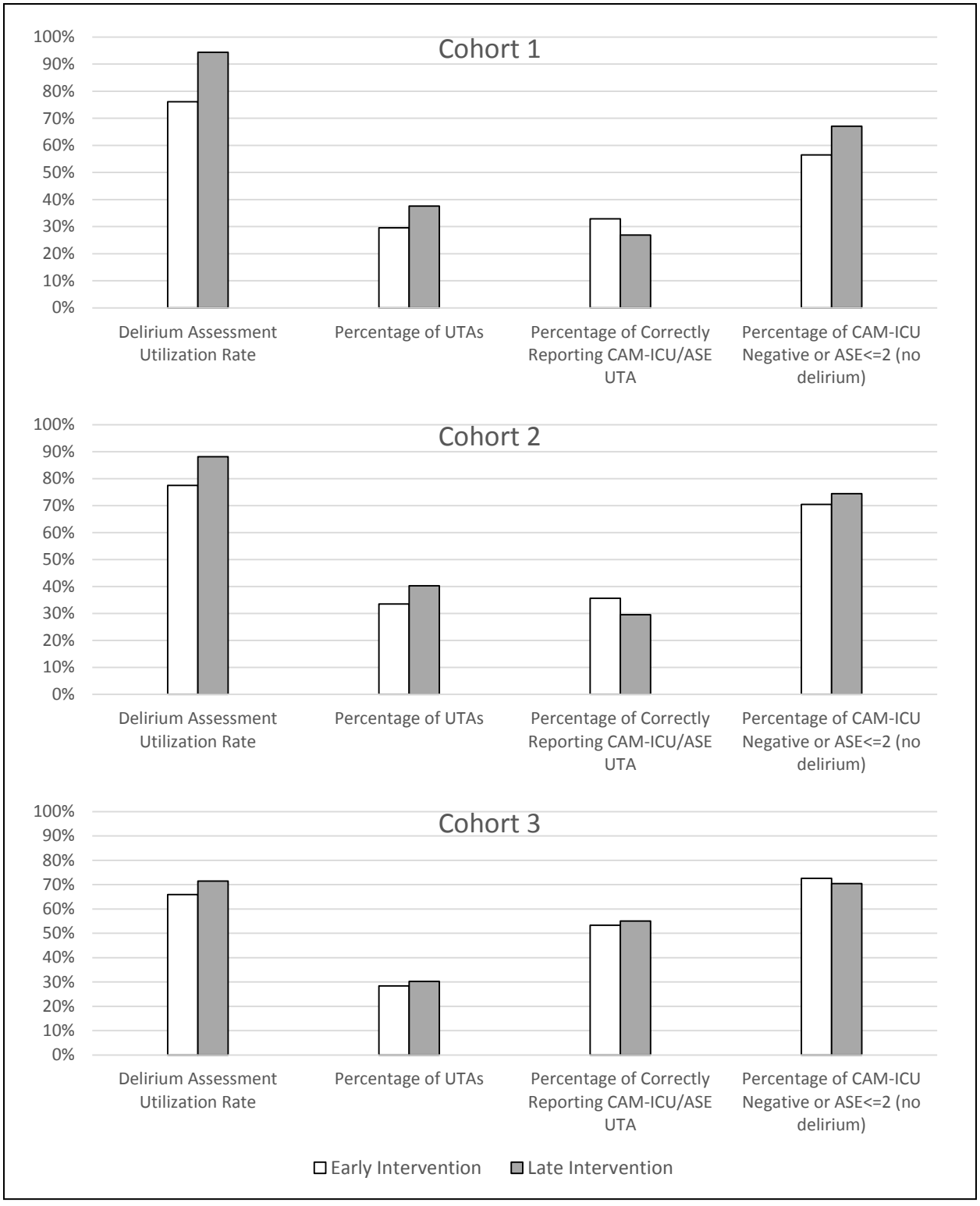


Table 20. Daily Care Processes Delirium Assessment (All Cohorts)

COHORT	DELIRIUM ASSESSMENT	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	Delirium Assessment Utilization Rate	76% (2,293/3,015)	94% (7,153/7,581)	24%	<0.001
1	Percentage of UTAs	30% (1,264/4,279)	38% (4,559/12,140)	27%	<0.001
1	Percentage of Correctly Reporting CAM-ICU/ASE UTA	33% (415/1,264)	27% (1,226/4,559)	−18%	<0.001
1	Percentage of CAM-ICU Negative or ASE ≤2 (no delirium)	56% (1,295/2,293)	67% (4,800/7,153)	19%	<0.001
Cohort 2	Delirium Assessment Utilization Rate	77% (6,747/8,712)	88% (6,574/7,460)	14%	<0.001
2	Percentage of UTAs	34% (4,392/13,104)	40% (5,028/12,488)	20%	<0.001
2	Percentage of Correctly Reporting CAM-ICU/ASE UTA	36% (1,565/4,392)	30% (1,488/5,028)	−17%	<0.001
2	Percentage of CAM-ICU Negative or ASE ≤2 (no delirium)	70% (4,754/6,747)	74% (4,892/6,574)	6%	<0.001
Cohort 3	Delirium Assessment Utilization Rate	66% (3,341/5,066)	71% (7,143/9,998)	8%	<0.001
3	Percentage of UTAs	28% (2,009/7,075)	30% (4,339/14,337)	7%	0.005
3	Percentage of Correctly Reporting CAM-ICU/ASE UTA	53% (1,071/2,009)	55% (2,388/4,339)	3%	0.199
3	Percentage of CAM-ICU Negative or ASE ≤2 (no delirium)	73% (2,425/3,341)	70% (5,033/7,143)	−3%	0.025

5.3.7. Daily Early Mobility Measures

In Cohort 1, 27 (56%) units ever submitted EM data, providing 249 unit-months and 13,556 ventilator-days of data. Of these 27 units, 26 and 23 units contributed data to the early intervention period (6 months) and the late intervention period (15 months), respectively, and 22 contributed compliance data to both time periods.

In Cohort 2, 42 (57%) units ever submitted EM data, providing 294 unit-months and 24,581 ventilator-days of data. Of these 42 units, 40 and 35 units contributed data to the early intervention period (5 months) and the late intervention period (8 months), respectively, and 33 contributed data to both time periods.

In Cohort 3, 69 (52%) units ever submitted EM data, providing 387 unit-months and 20,547 ventilator-days of data. Of these 69 units, 61 and 62 units contributed data to the early intervention period (3 months) and the late intervention period (6 months), respectively, and 54 contributed data to both time periods.

EM also showed improvement; across all cohorts there was an increase from no EM (indicated by a selection of "nothing" on the data collection tool) to a higher level of mobilization. The activity scale for EM is ordinal and thus the focus should be the overall migration to a higher level of activity as opposed to the ventilator-days within the individual categories. EM efforts were impacted because safely executing them requires an infrastructure that not all hospitals were able to support, thus creating a challenge to implementation.

For all EM measure figures and tables below, early intervention for Cohort 1 and Cohort 2 is the first two quarters of EM data collection and for Cohort 3 is the first quarter of EM data collection. All remaining study quarters are defined as late intervention.

Further specifics of EM data submission can be found in Appendix B, Tables B-13–15.

5.3.7.1. Sedation Assessment

In all three cohorts, the percentage of ventilator-days during which the sedation target score set by providers was actually achieved significantly increased from the early to late intervention periods. In Cohort 1, there was a significant decrease in the percentage of ventilator-days during which a mildly sedated or an awake and calm state was achieved, while in Cohorts 2 and 3, there was a significant increase from the early to late intervention periods (Figure 12, Table 21).

Figure 12. Daily Early Mobility Sedation Scale (All Cohorts)

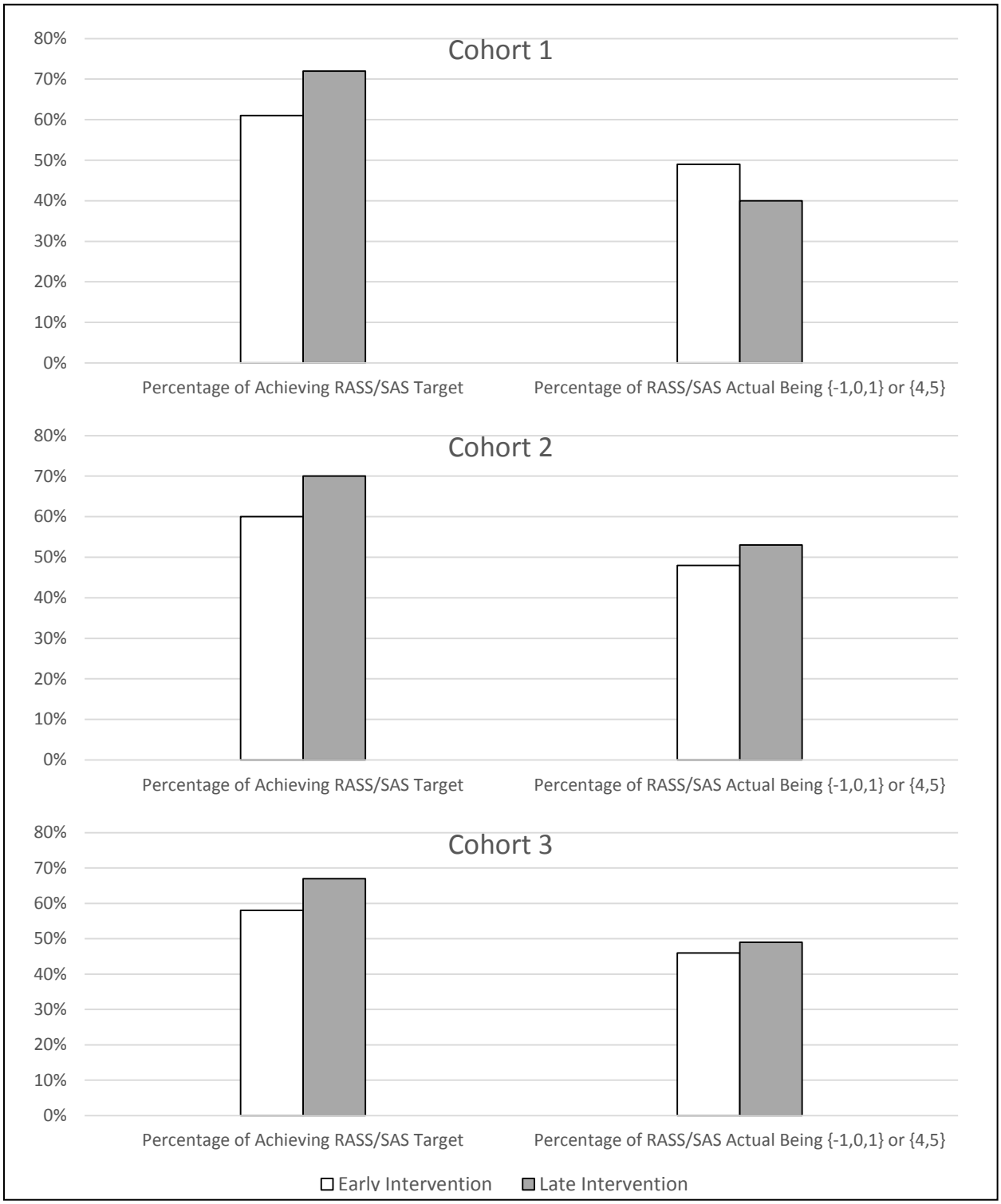


Table 21. Daily Early Mobility Sedation Scale (All Cohorts)

COHORT	SEDATION SCALE	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	Percentage of Achieving RASS/SAS Target	61% (1,888/3,082)	72% (5,544/7,717)	17%	<0.001
1	Percentage of RASS/SAS Actual Being {−1, 0, 1} or {4, 5}	49% (1,803/3,675)	40% (3,249/8,077)	−18%	<0.001
Cohort 2	Percentage of Achieving RASS/SAS Target	60% (4,536/7,525)	70% (5,518/7,904)	16%	<0.001
2	Percentage of RASS/SAS Actual Being {−1, 0, 1} or {4, 5}	48% (5,026/10,451)	53% (5,494/10,320)	11%	<0.001
Cohort 3	Percentage of Achieving RASS/SAS Target	58% (3,092/5,294)	67% (5,932/8,849)	15%	<0.001
3	Percentage of RASS/SAS Actual Being {−1, 0, 1} or {4, 5}	46% (2,976/6,439)	49% (4,990/10,107)	7%	<0.001

5.3.7.2. Delirium Assessment

In Cohort 1, delirium assessment and the percentage of delirium-free ventilator-days significantly increased from the early to late intervention periods. The percentage of ventilator-days during which providers were UTA delirium significantly increased, while the percentage of correct UTA determinations significantly decreased from the early to late intervention periods. These results are encouraging.

In Cohort 2, delirium assessment and the percentage of delirium-free ventilator-days remained unchanged from the early to late intervention periods. The percentage of ventilator-days during which providers were UTA delirium significantly decreased, while the percentage of correct UTA determinations significantly decreased from the early to late intervention periods.

In Cohort 3, delirium assessment and the percentage of delirium-free ventilator-days significantly increased from the early to late intervention periods. The percentage of ventilator-days during which providers were UTA delirium remained unchanged, while the percentage of correct UTA determinations significantly decreased from the early to late intervention periods. These results are also encouraging.

The detailed results are reported in Figure 13 and Table 22.

Figure 13. Daily Early Mobility Delirium Assessment (All Cohorts)

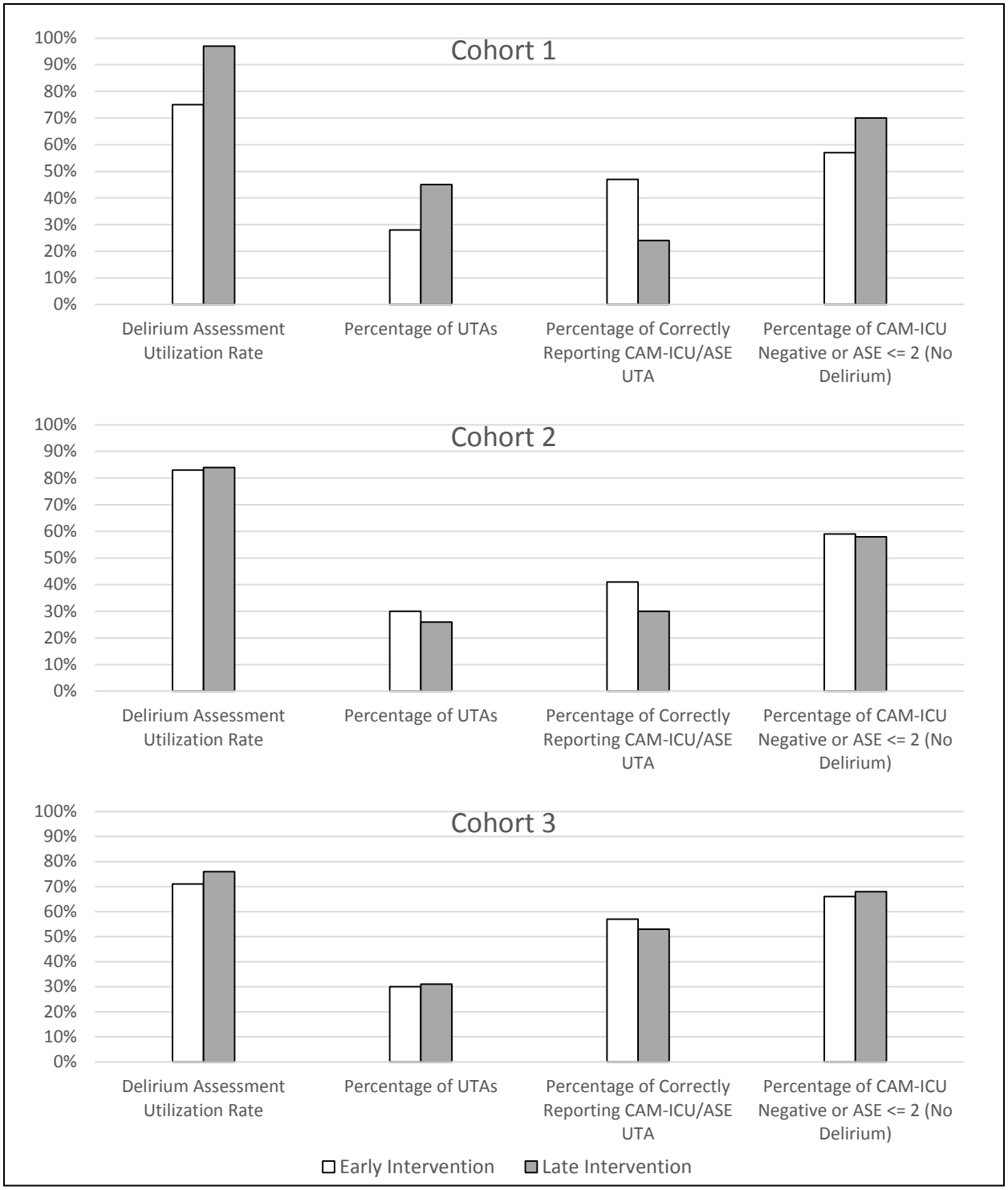


Table 22. Daily Early Mobility Delirium Assessment (All Cohorts)

COHORT	DELIRIUM ASSESSMENT	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	Delirium Assessment Utilization Rate	75% (1,891/2,538)	97% (4,508/4,665)	30%	<0.001
1	Percentage of UTAs	28% (970/3,508)	45% (3,827/8,492)	63%	<0.001
1	Percentage of Correctly Reporting CAM-ICU/ASE UTA	47% (452/970)	24% (917/3,827)	−49%	<0.001
1	Percentage of CAM-ICU Negative or ASE ≤2 (No Delirium)	57% (1,070/1,891)	70% (3,141/4,508)	23%	<0.001
Cohort 2	Delirium Assessment Utilization Rate	83% (5,980/7,195)	84% (6,864/8,174)	1%	0.157
2	Percentage of UTAs	30% (3,102/10,297)	26% (2,914/11,088)	−13%	<0.001
2	Percentage of Correctly Reporting CAM-ICU/ASE UTA	41% (1,258/3,102)	30% (864/2,914)	−27%	<0.001
2	Percentage of CAM-ICU Negative or ASE ≤2 (No Delirium)	59% (3,540/5,980)	58% (3,975/6,864)	−2%	0.145
Cohort 3	Delirium Assessment Utilization Rate	71% (2,608/3,654)	76% (4,908/6,474)	6%	<0.001
3	Percentage of UTAs	30% (1,569/5,223)	31% (2,958/9,432)	4%	0.101
3	Percentage of Correctly Reporting CAM-ICU/ASE UTA	57% (900/1,569)	53% (1,570/2,958)	−7%	0.006
3	Percentage of CAM-ICU Negative or ASE ≤2 (No Delirium)	66% (1,721/2,608)	68% (3,359/4,908)	4%	0.033

5.3.7.3. Highest Level of Activity

In Cohort 1, between early and late intervention periods, we saw a significant increase in the percentage of ventilator-days during which:

- Patients were transferred from bed to chair.
- Patients performed exercises in bed.
- Patients walked.

During the same time period, there was a significant decrease in the percentage of ventilator-days during which:

- Patients did not move.
- The mobility level was recorded as “unknown.”

However, there was also a decrease in the number of days in which patients were transferred from bed to chair with standing.

In Cohort 2, between early and late intervention periods, we saw a significant increase in the percentage of ventilator-days during which:

- Patients performed exercises in bed.

However, there was also a significant increase in the number of days in which the mobility level was recorded as "unknown" and a significant decrease in the percentage of ventilator-days during which:

- Patients stood.
- Patients were transferred from bed to chair with standing.
- Patients were transferred from bed to chair without standing.

In Cohort 3, between early and late intervention periods, we saw a significant increase in the percentage of ventilator-days during which mobility level was recorded as "unknown" and a significant decrease in the percentage of ventilator-days during which patients were transferred from bed to chair without standing.

These results show variable success with improving EM. Overall, the vast majority of patients did not receive EM. For example, patients received "no mobility" on 71–80% of patient-days. While Cohort 1 and 2 teams achieved significant reductions in the number of "no mobility" ventilator-days, the percent change was small (1–3%), and Cohort 3 compliance did not improve. Perceived barriers to EM were exceedingly common (73–90% of ventilator-days) and underscore the complexity of successful implementation. While it is difficult to determine whether there was a true migration to higher mobility levels, it remains promising to note even a small reduction of no-mobility days given the already high percentage of patient-days with no mobility.

The detailed results are reported in Figure 14 and Table 23.

Of note, early intervention for Cohort 1 and Cohort 2 is the first two quarters of EM data collection, and for Cohort 3, is the first quarter of EM data collection. All remaining study quarters are defined as late intervention.

Figure 14. Distribution of the Highest Level of Mobility (All Cohorts)

Table 23. Distribution of the Highest Level of Mobility (All Cohorts)

COHORT	MOBILITY LEVEL	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	Nothing	78% (3,351/4,275)	75% (6,957/9,281)	−4%	<0.001
1	Transfer from bed to chair without standing	6% (241/4,275)	8% (712/9,281)	36%	<0.001
1	Sitting in bed/exercises in bed	6% (245/4,275)	12% (1,073/9,281)	>100%	<0.001
1	Sitting at edge of bed	3% (115/4,275)	2% (184/9,281)	−26%	0.011
1	Standing	<1% (17/4,275)	<1% (35/9,281)	−5%	0.976
1	Transfer from bed to chair with standing	2% (91/4,275)	1% (135/9,281)	−32%	0.006
1	Marching in place	<1% (10/4,275)	<1% (20/9,281)	−8%	0.988
1	Walking	<1% (20/4,275)	1% (109/9,281)	>100%	<0.001
1	Unknown	4% (185/4,275)	1% (56/9,281)	−86%	<0.001
Cohort 2	Nothing	80% (9,964/12,456)	79% (9,576/12,125)	−1%	0.05
2	Transfer from bed to chair without standing	4% (553/12,456)	3% (377/12,125)	−30%	<0.001
2	Sitting in bed/exercises in bed	8% (1,056/12,456)	9% (1,147/12,125)	12%	0.008
2	Sitting at edge of bed	2% (298/12,456)	2% (277/12,125)	−5%	0.605
2	Standing	1% (89/12,456)	<1% (42/12,125)	−52%	<0.001
2	Transfer from bed to chair with standing	1% (162/12,456)	1% (102/12,125)	−35%	0.001
2	Marching in place	<1% (34/12,456)	<1% (19/12,125)	−43%	0.068
2	Walking	1% (94/12,456)	1% (81/12,125)	−11%	0.464
2	Unknown	2% (206/12,456)	4% (504/12,125)	>100%	<0.001
Cohort 3	Nothing	71% (5,465/7,687)	72% (9,208/12,860)	1%	0.445
3	Transfer from bed to chair without standing	6% (475/7,687)	4% (549/12,860)	−31%	<0.001
3	Sitting in bed/exercises in bed	11% (867/7,687)	10% (1,340/12,860)	−8%	0.057
3	Sitting at edge of bed	3% (268/7,687)	4% (519/12,860)	16%	0.051
3	Standing	1% (92/7,687)	1% (139/12,860)	−10%	0.487
3	Transfer from bed to chair with standing	2% (156/7,687)	2% (272/12,860)	4%	0.715
3	Marching in place	<1% (24/7,687)	<1% (52/12,860)	30%	0.350
3	Walking	2% (132/7,687)	2% (230/12,860)	4%	0.748
3	Unknown	3% (208/7,687)	4% (551/12,860)	58%	<0.001

5.3.7.4. Perceived Barriers

In Cohort 1, the most commonly cited barrier as to why a patient could not advance to a higher level mobility was “medically inappropriate due to circulatory or respiratory reason.” The second most commonly cited barrier was “patient at the highest possible level of mobility.” The third most commonly cited barrier was “patient is too weak to progress to a higher level of mobility.”

In Cohort 2, the most commonly cited barrier as to why a patient could not advance to a higher level mobility was “patient at the highest possible level of mobility.” The second most commonly cited barrier was “medically inappropriate due to circulatory or respiratory reason.” The third most commonly cited barrier was “patient is too weak to progress to a higher level of mobility.”

In Cohort 3, the most commonly cited barrier as to why a patient could not advance to a higher level mobility was “medically inappropriate due to circulatory or respiratory reason.” The second most commonly cited barrier was “patient is too weak to progress to a higher level of mobility.” The third most commonly cited barrier was that the “patient is sedated and on a sedative infusion.”

As noted, barriers to performing EM occurred between 73 and 90 percent of patient-days. This not only supports the understanding that promoting EM can be a highly complex process but also provides compelling data that may lead to a better understanding of how to develop both technical and adaptive infrastructures designed to mitigate some of the most prohibitive barriers.

The detailed results are reported in Table 24.

Table 24. Distribution of Perceived Barriers (All Cohorts)

CATEGORY	COHORT 1	COHORT 2	COHORT 3
Percentage of Ventilated Patient-Days With a Barrier Reported *	87%	73%	90%
BARRIER †			
0) Not Applicable—Patient at highest possible level of mobility	1,767 (13%)	6,757 (27%)	1,990 (10%)
1) Bed rest orders	1,052 (8%)	1,981 (8%)	1,802 (9%)
2) Patient on comfort/palliative care measures	206 (2%)	231 (1%)	808 (4%)
3) Patient sedated (RASS −4 or −5; or SAS 1 or 2) and on infusion of benzodiazepine, narcotic, or propofol	1,007 (7%)	1,393 (6%)	2,273 (11%)
4) Patient sedated (RASS −4 or −5; or SAS 1 or 2), but NOT on infusion of benzodiazepine, narcotic, or propofol	470 (3%)	357 (1%)	922 (4%)
5) Medically inappropriate (orthopedic reason; e.g., fracture of long bone, spine, or pelvis)	200 (1%)	277 (1%)	303 (1%)
6) Medically inappropriate (circulatory or respiratory reason) as delineated in the medical screening algorithm	4,485 (33%)	6,020 (24%)	3,543 (17%)
7) Medically inappropriate (new deep vein thrombosis) as delineated in the medical screening algorithm	9 (<1%)	42 (<1%)	40 (<1%)
8) Medically inappropriate (femoral sheath) as delineated in the medical screening algorithm	91 (1%)	166 (1%)	177 (1%)
9) Medically inappropriate (for any other reason; e.g., unstable, active gastrointestinal bleeding)	795 (6%)	2,064 (8%)	1,238 (6%)
10) Patient unavailable throughout the day	87 (1%)	113 (<1%)	182 (1%)
11) Staffing (registered nurse, PT, and OT) unavailable throughout the day	406 (3%)	164 (1%)	372 (2%)
12) Patient declined mobilization throughout the day	65 (<1%)	109 (<1%)	268 (1%)
13) Patient is too weak to progress to higher level of mobility	1,438 (11%)	2,830 (12%)	3,319 (16%)
14) Other barrier not listed above	455 (3%)	1,140 (5%)	1,553 (8%)
15) Unknown barrier	1,023 (8%)	937 (4%)	1,757 (9%)

* This percentage is calculated by subtracting the percentage of "0) Not Applicable" from 100% (e.g., 1−0.13 = 0.87).

† This ordinal scale was used in the data collection tool (except for "15 Unknown barrier"). The order was determined by how modifiable the reasons were, listed from the most modifiable to the least modifiable from 0–14.

5.3.7.5. Adverse Events

In Cohort 1, the adverse event rate remained unchanged at 1 percent from the early to late intervention periods. The most commonly reported adverse events were hypotension, desaturation, and endotracheal tube dislodgement, in descending frequency of occurrence.

In Cohort 2, the adverse event rate increased from 2 to 3 percent from the early to late intervention periods. The most commonly reported adverse events were "other," desaturation, and hypotension, in descending frequency of occurrence.

In Cohort 3, the adverse event rate increased from 2 to 4 percent from the early to late intervention periods. The most commonly reported adverse events were hypotension, "other," and desaturation, in descending frequency of occurrence.

Changes in the adverse event rates, either increasing or decreasing, were not statistically significant. While unable to show a statistically significant conclusion that this program will reduce adverse events during EM efforts, the findings do strongly support the current consensus that beginning EM exercises with mechanically ventilated patients when medically appropriate is a safe and low-cost intervention.

The detailed results are reported in Figure 15, Tables 25-26.

Figure 15. Adverse Event Rate (All Cohorts)

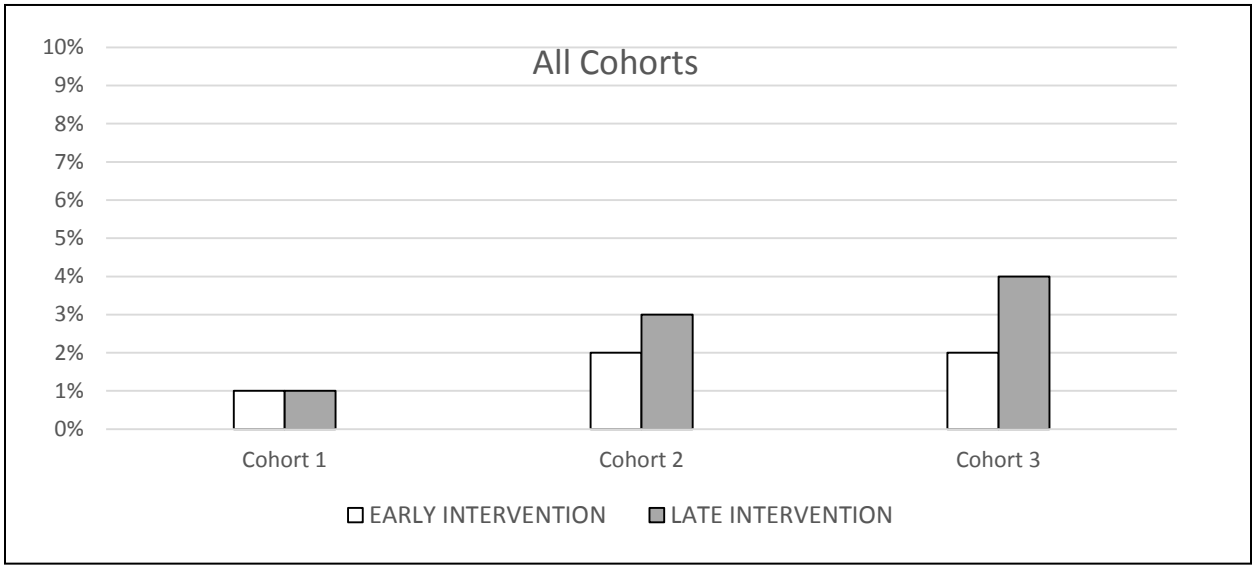


Table 25. Adverse Event Rate (All Cohorts)

COHORT	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	1% (62/4,275)	1% (127/9,281)	−6%	0.765
Cohort 2	2% (201/12,456)	3% (334/12,125)	71%	<0.001
Cohort 3	2% (126/7,687)	4% (488/12,860)	>100%	<0.001

Note that it was specified in the standard EM data collection instructions that an "event" should be reported to this project only if it occurred to patients while being mobilized. Up to three adverse events can be reported for each ventilated patient-day. Among all the participating units that responded to the inquiry, only one unit had a death event actually occurring during a mobilization session, and all other death events occurred during patients' hospital stay, and were unrelated to mobilization. The data were corrected to reflect stated definitions on the data measures collection tool. Because of the size of the program, it was not feasible to follow up on the other reported events.

Table 26. Distribution of Adverse Events for Ventilated Patients (All Cohorts)

	COHORT 1	COHORT 2	COHORT 3
Total Number of Adverse Events (Denominator)	219	656	673
Percentage of Ventilated Patient-Days With at Least One Adverse Event	1%	2%	3%
ADVERSE EVENT			
1) Endotracheal tube dislodgement	30 (14%)	17 (3%)	35 (5%)
2) Tracheostomy dislodgement	4 (2%)	7 (1%)	5 (1%)
3) Nasal feeding tube dislodgement	2 (1%)	2 (<1%)	21 (3%)
4) Oral feeding tube dislodgement	0 (0%)	1 (<1%)	5 (1%)
5) Percutaneous feeding tube dislodgement	4 (2%)	1 (<1%)	6 (1%)
6) Central venous catheter dislodgement (not femoral site), including peripherally inserted central catheter line	7 (3%)	1 (<1%)	6 (1%)
7) Central venous catheter dislodgement (femoral site)	0 (0%)	0 (0%)	0 (0%)
8) Arterial catheter dislodgement (not femoral site)	1 (<1%)	1 (<1%)	3 (<1%)
9) Arterial catheter dislodgement (femoral site)	2 (1%)	0 (0%)	4 (1%)
10) Dialysis catheter dislodgement (not femoral site), including tunneled or nontunneled	0 (0%)	0 (0%)	1 (<1%)
11) Dialysis catheter dislodgement (femoral site)	0 (0%)	0 (0%)	0 (0%)
12) Pulmonary artery catheter dislodgement (not femoral)	0 (0%)	0 (0%)	0 (0%)
13) Pulmonary artery catheter dislodgement (femoral site)	3 (1%)	0 (0%)	1 (<1%)
14) Chest tube dislodgement	2 (1%)	1 (<1%)	3 (<1%)
15) Wound or dressing disrupted or new bleeding at site	3 (1%)	2 (<1%)	20 (3%)
16) Cardiac device dislodgement (i.e., temporary pacemaker wire, intra-aortic balloon pump)	2 (1%)	1 (<1%)	1 (<1%)
17) Hypotension (change in mean arterial pressure to <55 mmHg, or if intervention required [i.e., fluid bolus or new/increased vasopressor dose])	84 (38%)	166 (25%)	180 (27%)
18) Hypertension (change in mean arterial pressure to >140 mmHg, or if intervention required)	5 (2%)	17 (3%)	16 (2%)
19) Desaturation (oxygen saturation <85% or if intervention required [i.e., increase in fraction of inspired oxygen])	38 (17%)	169 (26%)	138 (21%)
20) Cardiac arrest requiring cardiopulmonary resuscitation	12 (5%)	26 (4%)	9 (1%)
21) New arrhythmia (excludes sinus tachycardia, premature ventricular contractions, or preexisting arrhythmia that did not worsen during mobilization)	9 (4%)	41 (6%)	25 (4%)
22) Fall WITH staff assisting in lowering patient	0 (0%)	0 (0%)	0 (0%)
23) Fall WITHOUT staff assisting in lowering patient	3 (1%)	1 (<1%)	3 (<1%)
24) Death	3 (1%)*	0 (0%)	13 (2%)*
25) Other	5 (2%)	202 (31%)	178 (26%)

* Death was only to be reported if it occurred during the mobilization process; however, some units reported deaths that occurred any time during hospitalization. Followup with units in all cohorts confirmed that only one death occurred during mobilization. That death event occurred in Cohort 1.

5.3.8. Low Tidal Volume Ventilation Measures

Of the 254 participating intensive care units (ICUs) in the project, 91 submitted LTVV data. Within the LTVV data collection periods, 28 (58%), 35 (47%), and 28 (21%) teams submitted LTVV data for Cohorts 1, 2, and 3, respectively. There was a relatively high data submission rate among those who collected data. Further specifics of LTVV data submission can be found in Appendix B, Tables B-16–18. For all LTVV measure tables and figures below, early intervention for Cohort 1 is the first two quarters of LTVV data collection and is the first quarter of LTVV data collection for Cohorts 2 and 3. All remaining study quarters are defined as late intervention.

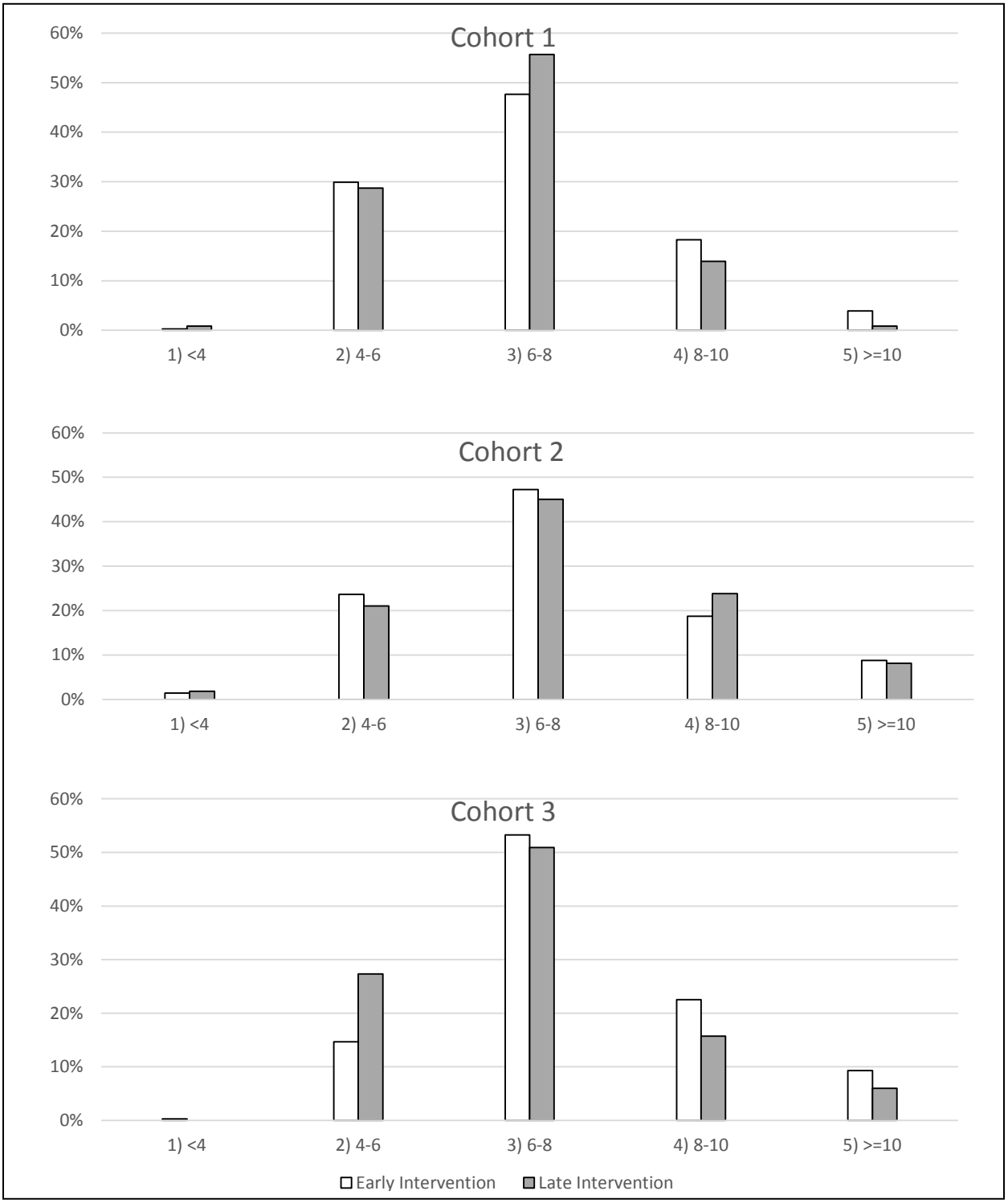
5.3.8.1. Patients With ARDS Diagnosis

For patients with ARDS, comparing the early and late intervention periods, Cohort 1 data showed no significant change in compliance with the recommended tidal volume range of greater than or equal to 4 and less than or equal to 6 mL/kg PBW. However, there was a significant increase in the percentage of ventilated patient-days with tidal volume value falling in the range of greater than 6 and less than 8 mL/kg PBW (48% vs. 56%, p=0.031), and a significant decrease in the use of higher tidal volume values of greater than or equal to 10 mL/kg PBW (4% vs. 1%, p=0.020).

Cohort 2 data showed a significant increase in the greater than 8 and less than 10 mL/kg PBW category (19% vs. 24%, p=0.011) and no significant changes in other categories of tidal volume values.

Cohort 3 data displayed a similar trend to Cohort 1 of increased migration to lower tidal volumes, with a significant increase in compliance with the recommended tidal volume range of greater than or equal to 4 and less than or equal to 6 mL/kg PBW for patients (15% vs. 27%, p<0.001), and a significant decrease in the use of the higher tidal volume range of greater than or equal to 8 and less than 10mL/kg PBW in the late intervention period compared with early intervention period (23% vs. 16%, p=0.012). Further details can be found in Figure 16 and Table 27.

Figure 16. Tidal Volume Value Distribution for Patients With ARDS (All Cohorts)*



* Early intervention for Cohort 1 is the first two quarters of LTVV data collection and is the first quarter of LTVV data collection for Cohorts 2 and 3. All remaining study quarters are defined as late intervention.

Table 27. Tidal Volume Value Distribution for Patients With ARDS (All Cohorts)

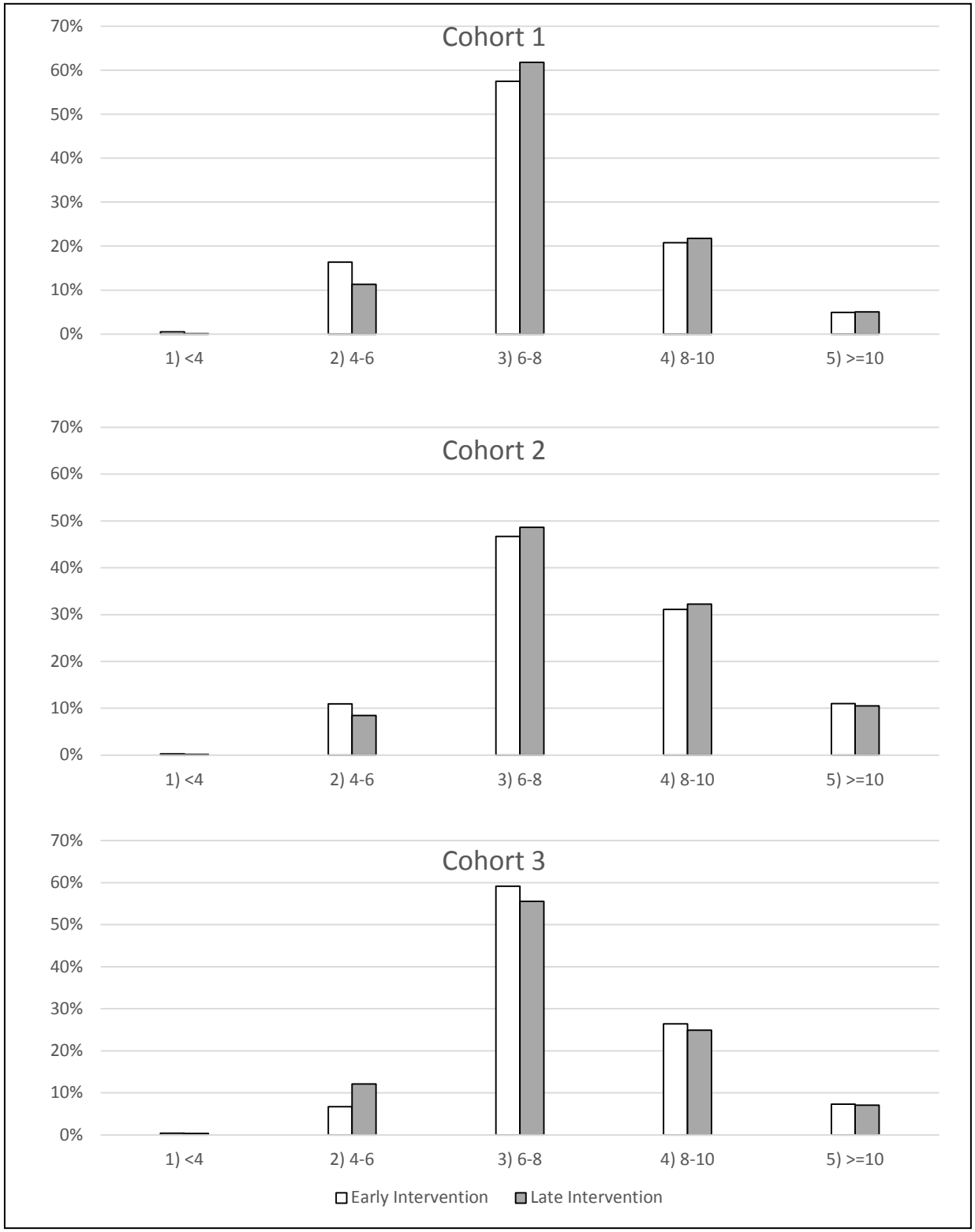
COHORT	TIDAL VOLUME VALUE RANGE (FOR PATIENTS WITH ARDS)	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	<4 mL/kg PBW	<1% (2/722)	1% (2/237)	>100%	0.257
Cohort 1	≥4 and ≤6 mL/kg PBW	30% (216/722)	29% (68/237)	−4%	0.720
Cohort 1	>6 and <8 mL/kg PBW	48% (344/722)	56% (132/237)	17%	0.031
Cohort 1	≥8 and <10 mL/kg PBW	18% (132/722)	14% (33/237)	−24%	0.122
Cohort 1	≥10 mL/kg PBW	4% (28/722)	1% (2/237)	−78%	0.020
Cohort 2	<4 mL/kg PBW	1% (16/1,077)	2% (12/650)	24%	0.570
Cohort 2	≥4 and ≤6 mL/kg PBW	24% (255/1,077)	21% (137/650)	−11%	0.212
Cohort 2	>6 and <8 mL/kg PBW	47% (509/1,077)	45% (293/650)	−5%	0.377
Cohort 2	≥8 and <10 mL/kg PBW	19% (202/1,077)	24% (155/650)	27%	0.011
Cohort 2	≥10 mL/kg PBW	9% (95/1,077)	8% (53/650)	−8%	0.631
Cohort 3	<4 mL/kg PBW	<1% (1/355)	0% (0/483)	−100%	0.424
Cohort 3	≥4 and ≤6 mL/kg PBW	15% (52/355)	27% (132/483)	87%	<0.001
Cohort 3	>6 and <8 mL/kg PBW	53% (189/355)	51% (246/483)	−4%	0.509
Cohort 3	≥8 and <10 mL/kg PBW	23% (80/355)	16% (76/483)	−30%	0.012
Cohort 3	≥10 mL/kg PBW	9% (33/355)	6% (29/483)	−35%	0.072

5.3.8.2. Patients Without ARDS Diagnosis

For patients without ARDS, Cohorts 1 and 2 data showed a significant increase in compliance with the recommended tidal volume range of greater than or equal to 6 and less than or equal to 8 mL/kg PBW (Cohort 1: 57% vs. 62%, p<0.001; Cohort 2: 47% vs. 49%, p=0.017), as well as a decrease in the use of the lower tidal volume range greater than or equal to 4 and less than 6 mL/kg PBW (Cohort 1: 16% vs. 11%, p<0.001; Cohort 2: 11% vs. 8%, p<0.001).

Cohort 3 data showed a significant decrease in compliance with the recommended tidal volume range of greater than or equal to 6 and less than or equal to 8 mL/kg PBW (59% vs. 56%, $p<0.002$), and a significant increase in the use of the lower tidal volume range greater than or equal to 4 and less than 6 mL/kg PBW (7% vs. 12%, $p<0.001$). Further details can be found in Figure 17 and Table 28.

Figure 17. Tidal Volume Value Distribution for Patients Without ARDS (All Cohorts)*



* Early intervention for Cohort 1 is the first two quarters of LTVV data collection and is the first quarter of LTVV data collection for Cohorts 2 and 3. All remaining study quarters are defined as late intervention.

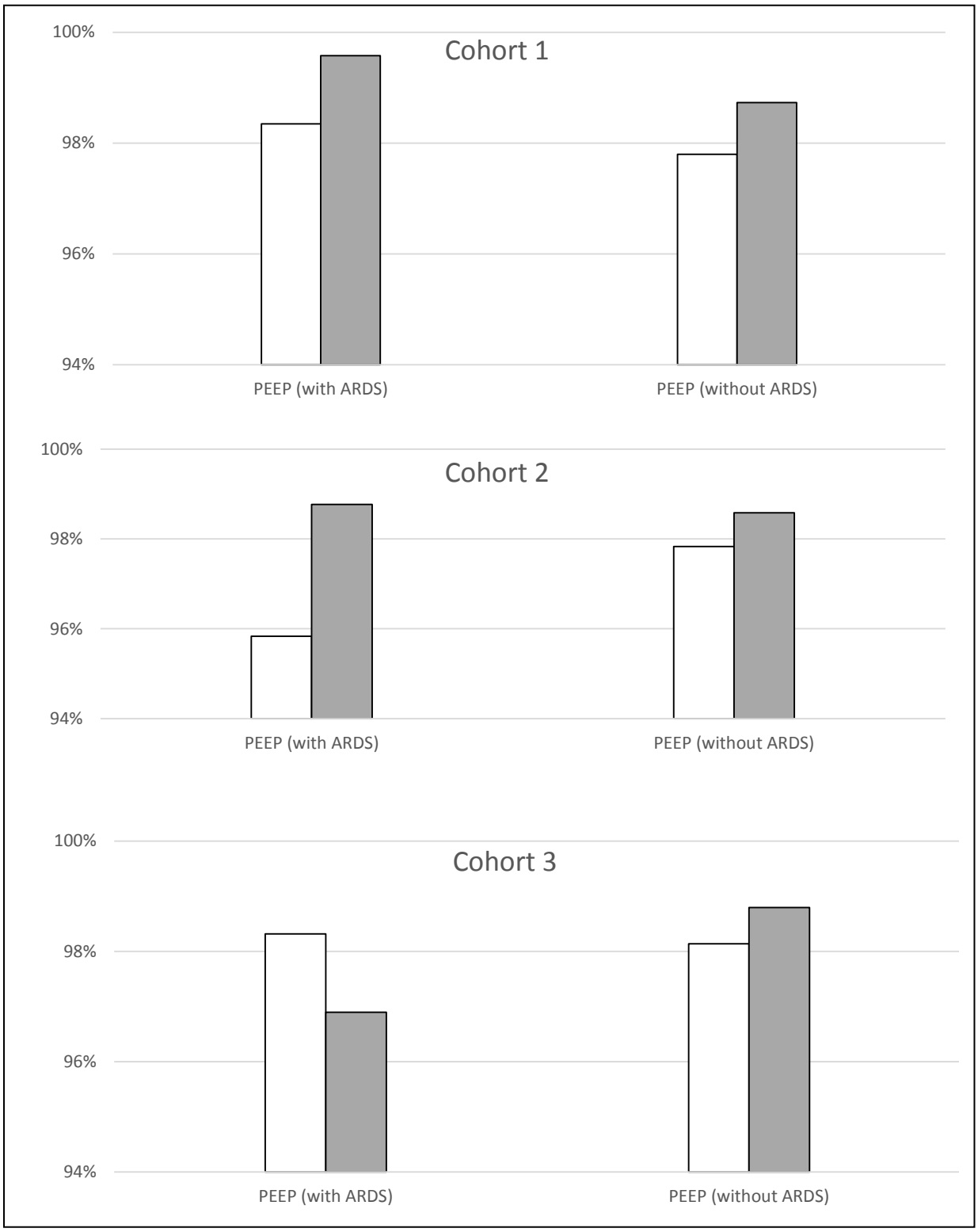
Table 28. Tidal Volume Value Distribution for Patients Without ARDS (All Cohorts)

COHORT	TIDAL VOLUME VALUE RANGE (FOR PATIENTS WITHOUT ARDS)	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	<4 mL/kg PBW	<1% (41/8,484)	<1% (3/3,543)	−82%	<0.001
Cohort 1	≥4 and <6 mL/kg PBW	16% (1,388/8,484)	11% (401/3,543)	−31%	<0.001
Cohort 1	≥6 and ≤8 mL/kg PBW	57% (4,878/8,484)	62% (2,190/3,543)	8%	<0.001
Cohort 1	>8 and <10 mL/kg PBW	21% (1,760/8,484)	22% (770/3,543)	5%	0.226
Cohort 1	≥10 mL/kg PBW	5% (417/8,484)	5% (179/3,543)	3%	0.752
Cohort 2	<4 mL/kg PBW	<1% (19/7,090)	<1% (14/8,231)	−37%	0.192
Cohort 2	≥4 and <6 mL/kg PBW	11% (777/7,090)	8% (696/8,231)	−23%	<0.001
Cohort 2	≥6 and ≤8 mL/kg PBW	47% (3,312/7,090)	49% (4,004/8,231)	4%	0.017
Cohort 2	>8 and <10 mL/kg PBW	31% (2,204/7,090)	32% (2,654/8,231)	4%	0.125
Cohort 2	≥10 mL/kg PBW	11% (778/7,090)	10% (863/8,231)	−4%	0.330
Cohort 3	<4 mL/kg PBW	<1% (10/2,564)	<1% (21/5,471)	−2%	0.970
Cohort 3	≥4 and <6 mL/kg PBW	7% (173/2,564)	12% (663/5,471)	80%	<0.001
Cohort 3	≥6 and ≤8 mL/kg PBW	59% (1,516/2,564)	56% (3,038/5,471)	−6%	0.002
Cohort 3	>8 and <10 mL/kg PBW	26% (677/2,564)	25% (1,363/5,471)	−6%	0.152
Cohort 3	≥10 mL/kg PBW	7% (188/2,564)	7% (386/5,471)	−4%	0.653

5.3.8.3. Positive End-Expiratory Pressure

PEEP compliance rates data remained high (≥96%) for patients with and without ARDS for all cohorts. Also, statistically significant increases in PEEP compliance with small magnitudes were observed for Cohort 1 patients without ARDS, Cohort 2 patients with and without ARDS, and Cohort 3 patients without ARDS. Further details can be found in Figure 18 and Table 29.

Figure 18. PEEP Compliance Rate (≥5 cm H_2O) (All Cohorts)*



* Early intervention for Cohort 1 is the first two quarters of LTVV data collection and is the first quarter of LTVV data collection for Cohorts 2 and 3. All remaining study quarters are defined as late intervention.

Table 29. PEEP Compliance Rate (≥5 cm H_2O) (All Cohorts)

COHORT	PEEP COMPLIANCE RATE (≥5 CM H_2O)	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	PEEP compliance (with ARDS)	98% (714/726)	>99% (236/237)	1%	0.205
1	PEEP compliance (without ARDS)	98% (8,357/8,545)	99% (3,508/3,553)	1%	<0.001
Cohort 2	PEEP compliance (with ARDS)	96% (1,035/1,080)	99% (643/651)	3%	<0.001
2	PEEP compliance (without ARDS)	98% (6,949/7,103)	99% (8,131/8,248)	1%	<0.001
Cohort 3	PEEP compliance (with ARDS)	98% (350/356)	97% (468/483)	−1%	0.193
3	PEEP compliance (without ARDS)	98% (2,527/2,575)	99% (5,414/5,480)	1%	0.010

6.0. Adaptive Components: HSOPS

An important early step in the Comprehensive Unit-based Safety Program (CUSP) process includes systematically measuring frontline care provider perceptions of the culture of safety in which improvement efforts are unfolding. Hospital Survey on Patient Safety (HSOPS) is a validated survey [21] designed by the Agency for Healthcare Research and Quality (AHRQ) to assess clinician and staff perceptions of the culture of safety within their unit, work setting, and overall hospital. The instrument is designed to measure seven work setting-referenced safety culture dimensions, three hospital-referenced dimensions, and four outcome variables. Scores on each of the dimensions represent the percent of respondents who responded positively to the items demonstrative of each dimension. Composite scores for the overall scale, hospital-referenced dimensions, and unit-referenced dimensions were also calculated to summarize general improvement trends within the data.

6.1. Methods

All participating hospitals within each cohort were invited to submit patient safety climate survey data collected with the HSOPS survey at two time periods throughout the project: baseline data were collected starting during the kickoff period for their cohort, and followup data were collected months later. Cohort 1 collected baseline data over 4 months from 2/1/14 to 5/31/14 and followup data over 4 months from 2/1/15 to 5/31/15. Cohort 2 collected baseline data over 3 months from 12/1/14 to 2/28/15 and followup data over 3½ months from 1/1/16 to 4/18/16. Cohort 3 collected baseline data over 3 months from 9/1/15 to 11/30/15, and followup data collection is planned for a 2-month period from 7/1/16 to 8/31/16.

Because of the overall project timeline, Cohorts 1 and 2 collected followup data 12 and 13 months after baseline, respectively, while Cohort 3 collected followup data 7 months after baseline.

Data submission period extensions for each cohort were afforded as needed based on data submission rates. Units could request individual team extensions as well.

Participating teams had two possible data submission methods: either collect new HSOPS data using the online HSOPS survey tool available in the project portal, or upload HSOPS survey data previously collected during annual safety culture assessments conducted by their organizations. For both baseline and followup data sets, teams were asked to upload only data collected in the 12 months prior to the start of the data submission period.

6.2. Outreach and Approach

In line with the original project management strategy, information concerning the baseline HSOPS data submission periods for Cohorts 1 through 3 was mediated through the participating

coordinating entities (CEs). The CEs served as the liaison between the National Project Team (NPT) and the participating hospitals; the CEs were therefore responsible for communicating project information, including HSOPS data submission periods and reminders, directly with survey coordinators at each participating hospital. This model limited direct contact between the NPT and survey coordinators on each team with the exceptions of content and technical training Webinars or hospital team-initiated email or phone communication with the NPT helpdesk. The NPT elected to provide additional support to the hospital teams in order to increase the response rates. With permission from CEs, the NPT did some direct outreach to hospitals by both email and phone.

For valid inferences from the HSOPS data, the NPT sought a minimum response rate of 60 percent for hospital safety culture assessments. The NPT utilized several pathways to increase data submission rates: email helpdesk, email reminders, phone contact, and survey period extensions.

6.2.1. Project Helpdesk

Hospitals, teams, and survey coordinators could directly contact the NPT via the helpdesk. Helpdesk inquiries included requests for information about the data upload procedure, the process for entering participant email addresses to the Web site, and the HSOPS survey open and close dates.

6.2.2. Email Reminders

Reminder emails were typically sent within the first 4 weeks of the HSOPS survey administration period to hospitals that had yet to begin survey upload. These hospitals were asked whether they were facing any problems conducting or uploading the surveys. Although few replies were received, those who responded indicated that they were collecting participant emails to upload into the program Web portal. The NPT sent reminder emails near the end of the baseline and followup data collection periods with the approaching survey closure dates.

6.2.3. Phone Contact

In the fourth week of each cohort's data collection period, hospitals were contacted by phone and informed of their current HSOPS response rate(s). This call was intended to check-in with the hospitals and serve as a reminder to those that had not yet started to begin survey administration or data upload. We prompted several hospitals to begin data collection; some hospitals teams forgot about the survey deadline, while others elected not to participate in the HSOPS data collection process. Through this direct contact, we were able to identify barriers to data collection, such as a lack of understanding of how to upload the data to the online Web portal or an inability to find the raw data to upload. Some hospitals used these calls as an opportunity to report difficulties with participants receiving the survey notification emails, resulting in low participation rates. Help was offered to find and upload the raw data and

resend survey notification emails. Though time intensive, direct contact helped us understand the issues the hospitals were facing, and we were able to increase hospital participation and individual response rates.

6.2.4. Survey Period Extensions

Extensions were granted to hospitals that needed extra time to complete their HSOPS surveys. Extensions were granted to all participants in Cohort 1's baseline data collection, with the close date extended to 5/31/2014 from the planned 3/31/2014, as well as Cohort 2's followup data collection, which was extended to close on 4/18/16 from 3/31/16 as planned. Twenty-five of the Cohort 2 units requested additional extensions and remain open as of 6/6/16.

6.2.5. Analyses

Mean comparison analyses were carried out to test change in perceptions of safety culture from baseline to followup. To be included in initial analyses, units were required to have submitted baseline or followup from five or more respondents (unit response rate was allowed to range between 0 and 100 percent). Analyses of baseline-to-followup changes in HSOPS dimensions scores were assessed using a two-tailed, independent groups t-test. To capture the shift in safety culture over time from baseline to followup, secondary mean comparison analyses were conducted on units that submitted both baseline and followup data for four or more respondents (unit response rate was allowed to range between 0 and 100 percent). Additional t-tests were conducted to compare cohort means within both the independent groups and paired group samples at baseline and followup. These analyses were completed to assess the suitability of combining data across cohorts. Bivariate correlations were conducted on the paired groups sample to examine the relationships between unit response rate, sample size, safety culture outcomes (i.e., frequency of events reported, patient safety grade, and perceptions of safety), HSOPS summary scores, and the 10 HSOPS dimensions.

6.3. Results

6.3.1. HSOPS Data Submission

Table 30 summarizes HSOPS data submission within and across all project cohorts. Over 2,800 individual intensive care unit (ICU) clinicians and staff ($n_{respondents}$=2,844) representing over half (55%) of the ICUs that registered for the project voluntarily submitted HSOPS data at baseline (n_{units}=67). Over 1,100 contributed HSOPS data (n=1,178) representing 28% of enrolled ICUs submitted HSOPS during the +12-month followup assessment period (n_{units}=34).

Table 30. HSOPS Survey Submission Rates by Cohort at Baseline and Followup

COHORT	DATA COLLECTION PERIOD	TOTAL ICU'S SUBMITTING ANY HSOPS DATA	TOTAL ICU'S ENROLLED IN COHORT	% OF REGISTERED ICU'S THAT SUBMITTED HSOPS DATA	TOTAL # INDIVIDUAL RESPONDENTS
1	Baseline Feb 1, 2014, to May 31, 2014	30	48	63%	1,171
1	Followup +12m Feb 1, 2015, to May 31, 2015	17	48	35%	762
2	Baseline Dec 1, 2014, to Feb 28, 2015	37	74	50%	1,673
2	Followup +12m Jan 12, 2016, to April 18, 2016	17	74	23%	416
Total	Baseline	67	122	55%	2,844
Total	Followup	34	122	28%	1,178

The characteristics of the ICUs that submitted HSOPS data are summarized in Table 31. The majority of data were submitted by ICUs in academic hospitals (n=42 ICUs at baseline and n=24 ICUS at followup). ICUs that contributed HSOPS data represented hospitals of medium size (100–499 beds) and submission of HSOPS data to the project database did not differ by ICU type.

Table 31. Hospital Characteristics by Cohort at Baseline (B) and Followup (F)

	Cohort 1				Cohort 2				Total			
	Baseline		+12month Followup		Baseline		+12month Followup		Baseline		+12month Followup	
	(n = 30)		(n = 17)		(n = 37)		(n = 17)		(n = 67)		(n = 34)	
Hospital Location												
Urban	13	43%	7	41%	21	57%	13	76%	34	51%	20	59%
Suburban	12	40%	6	35%	10	27%	1	6%	22	33%	7	21%
Rural	5	17%	4	24%	6	16%	3	18%	11	16%	7	21%
Hospital Type												
Adult acute care	30	100%	17	100%	37	100%	17	100%	67	100%	34	100%
Long-term care	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Teaching												
Academic	18	60%	11	65%	24	65%	13	76%	42	63%	24	71%
Nonacademic	12	40%	6	35%	13	35%	4	24%	25	37%	10	29%
Bed size												
Large (500+ beds)	13	43%	6	35%	12	32%	6	35%	25	37%	12	35%
Medium (100–499 beds)	15	50%	10	59%	22	59%	9	53%	37	55%	19	56%
Small (<99 beds)	2	7%	1	6%	3	8%	2	12%	5	7%	3	9%
ICU Type												
Surgical/Trauma	11	37%	5	29%	9	24%	5	29%	20	30%	10	29%
Cardiac	8	27%	5	29%	5	14%	2	12%	13	19%	7	21%
Medical	8	27%	5	29%	15	41%	5	29%	23	34%	10	29%
Mixed	3	10%	2	12%	8	22%	5	29%	11	16%	7	21%

NOTE: Percentages may not add to 100% because of rounding.

6.3.2. HSOPS: Survey Response Rates and Descriptive Analyses

Unit response rate was not correlated with any of the HSOPS dimension scores at either baseline or followup. However, as expected, many of the HSOPS dimensions were correlated with each other at both baseline and followup.

6.3.3. HSOPS: Independent Groups Pre-Post Analyses

Units that submitted HSOPS data from five or more respondents at either baseline (n=65) or followup (n=33) were included in the independent group analyses. Unit response rates ranged from 4 percent to 100 percent (mean [M]=64.2, standard deviation [SD]=29.0) at baseline and 16 percent to 100 percent (M=55.3, SD=27.7) at followup. Results for the independent group analyses can be found in Figure 19 and Table 32.

Figure 19. Independent Groups Comparison of Unit-Level Baseline (n=65) and Followup (n=33) HSOPS Dimension Scores

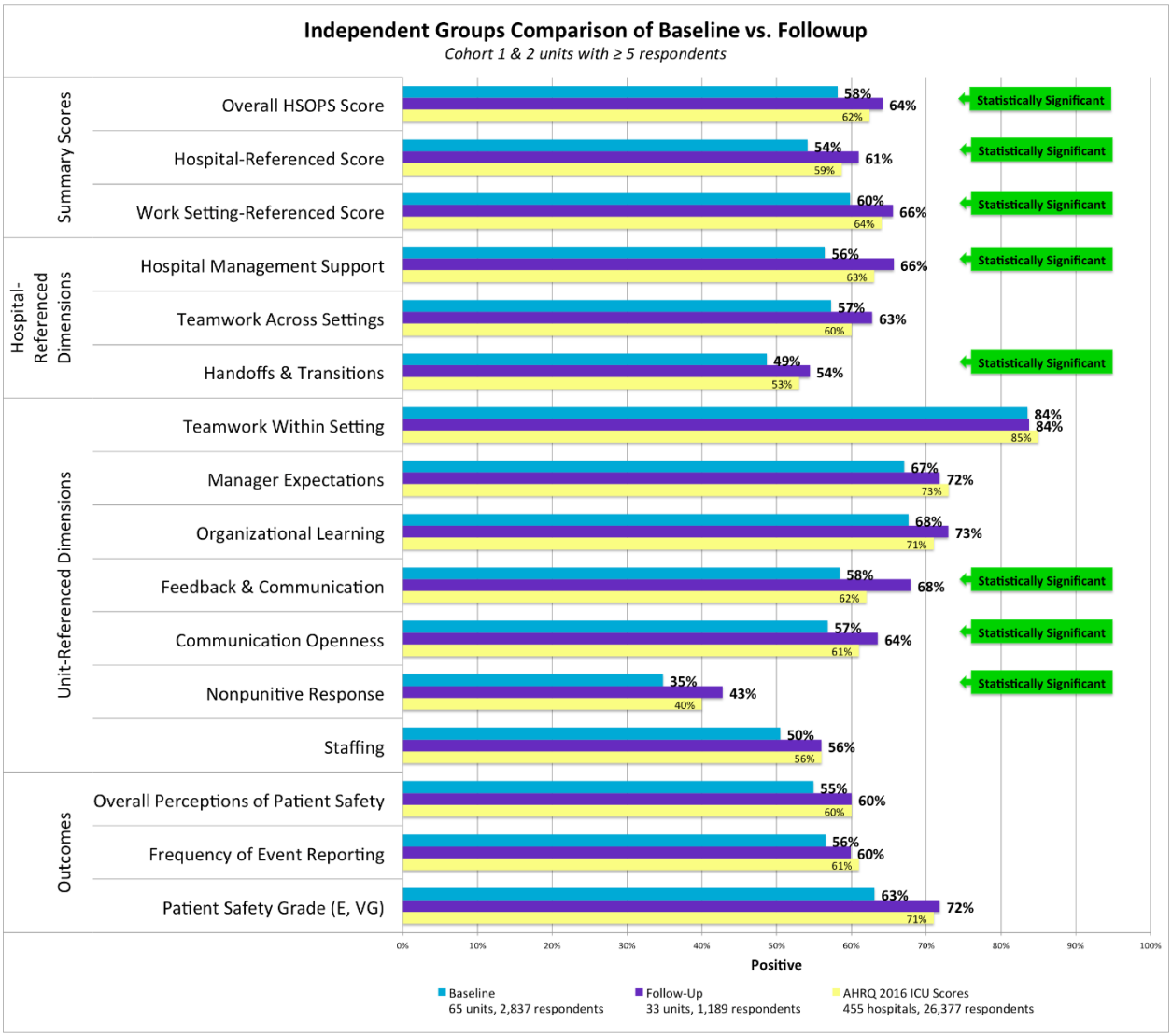


Table 32. Independent Groups Comparison of Unit Baseline (n=65) and Followup (n=33) HSOPS Dimension Scores

DIMENSIONS	% MEAN BASELINE (N=65)	% MEAN FOLLOWUP (N=33)	% MEAN DIFFERENCE	STANDARD ERROR DIFFERENCE	P-VALUE
OUTCOMES					
Overall perceptions of safety	54.92	60.03	5.11	3.31	0.13
Frequency of event reporting	56.49	59.86	3.37	3.03	0.27
Grade (excellent–very good)	63.08	71.82	8.74	4.69	0.07
HSOPS SUMMARY SCORES					
Overall composite average score	58.11	64.15	6.04	2.48	0.02*
Hospital-referenced composite average score	54.12	60.94	6.82	2.76	0.02*
Unit-referenced composite average score	59.82	65.52	5.70	2.99	0.03*
HOSPITAL-REFERENCED DIMENSIONS					
Hospital management support	56.45	65.64	9.19	3.75	0.02*
Teamwork across units	57.25	62.79	5.54	2.87	0.07
Handoffs and transitions	48.66	54.40	5.74	2.72	0.04*
UNIT-REFERENCED DIMENSIONS					
Teamwork within units	83.55	83.73	0.18	2.80	0.95
Supervisor expectations	67.06	71.81	4.75	3.27	0.15
Organizational learning	67.62	72.93	5.31	2.84	0.07
Communication openness	56.81	63.52	6.71	2.92	0.02*
Feedback and communication	58.41	67.92	9.51	3.30	0.01*
Non-punitive response	34.81	42.78	7.97	2.59	0.03*
Staffing	50.47	55.97	5.50	3.45	0.12

* $p<0.05$

Figure 19 presents baseline and followup percent positive scores for three HSOPS summary indices (i.e., overall, unit-referenced, and hospital-referenced dimensions), seven unit-referenced domains, three hospital-referenced domains, and three outcome dimensions. Each of these scores are compared to aggregate ICU data from AHRQ's Hospital Survey on Patient Safety Culture Comparative Database,[24] a central repository for survey data from hospitals that have administered HSOPS. The database serves as a resource for comparing patient safety culture survey results to those of other hospitals in support of patient safety culture improvement. The 2016 user comparative database report presents data from 447,584 hospital staff respondents surveyed across 680 hospitals (mean response rate=55%). To present a relevant comparator for the ICU data collected in the current study, the AHRQ benchmark data presented in this report are from a subsample of 26,377 hospital staff respondents in 455 hospitals who indicated the ICU as their primary work setting.

Results of the independent groups t-test analysis to compare baseline and followup mean differences are presented in Table 32. Dimensions showing the largest improvements were feedback and communication (+9.5%), hospital management support for safety (+9.2%), non-punitive response to error (+7.8%), communication openness (+6.7%), and handoffs and transitions (+5.7%). In addition to these dimensions, statistically significant improvements ($p<.05$) were observed for the three HSOPS summary scores, overall composite (+6.0%), hospital-referenced composite (+6.8%), and unit-referenced composite (+5.7%).

6.3.3.1. Comparisons Between Cohorts

Some variability was observed in Cohort 1 and Cohort 2's baseline scores. In general, Cohort 1 reported scores slightly higher than Cohort 2. However, there was only a statistically significance difference ($p \leq 0.05$) between cohorts for the hospital-referenced composite score (57.4% and 51.3% for Cohorts 1 and 2, respectively) and teamwork across settings (62.4% and 52.9% for Cohorts 1 and 2, respectively). Cohort 1 and Cohort 2's followup scores were much more similar and no statistically significant differences were detected across any of the HSOPS dimensions, summary indices, or outcomes.

6.3.4. HSOPS: Paired Pre-Post Analyses

Average HSOPS percent positive scores from the 28 units that submitted HSOPS data from five or more respondents at both baseline and followup are presented in Appendix C, Figure C-1. Unit response rates ranged from 12 percent to 100 percent (M=66.8, SD=25.6) at baseline and 16 percent to 100 percent (M=56.0, SD=27.8) at followup. Scores are presented for the three HSOPS summary indices, seven unit-referenced dimensions, three hospital-referenced dimensions, and three outcome domains. ICU scores from AHRQ's 2016 HSOPS database are also presented as benchmark comparators.

Paired groups t-test analyses were conducted on those 28 units to provide a more refined picture of observed mean changes in the 12 months between baseline and followup. Results of

these analyses are presented in Appendix C, Table C-1. Dimensions showing the largest improvements are listed below:

- Non-punitive response to error (+6.07%)
- Feedback and communication (+5.8%)
- Hospital management support for safety (+5.3%)
- Staffing (+5.2%)
- Organizational learning (+5.1%)

However, no statistically significant improvements were observed among any of the dimensions tested in the paired groups sample.

6.3.4.1. Comparisons Between Cohorts

Paired groups t-test analyses indicate some differences between Cohort 1's and Cohort 2's baseline and followup scores. However, differences were only statistically significant ($p \leq 0.05$) for overall perceptions of patient safety (65.0% and 54.1% for Cohort 1 and Cohort 2, respectively) at baseline and supervisor/manager expectations (72.7% and 73.8% for Cohort 1 and Cohort 2, respectively) at followup.

6.3.4.2. Sensitivity Analysis

Additional paired groups t-test analyses were conducted on 14 units that submitted data at both baseline and followup with five or more respondents and response rates greater than 50 percent. Similar to the paired analysis, results showed no statistically significant changes from baseline to followup across any of the HSOPS dimensions, composite summaries, or outcomes.

6.3.5. HSOPS: Comparison of High Versus Low Engagement Units

Additional analyses were conducted to compare units identified as highly engaged (n=36) in the CUSP process to units identified as demonstrating low engagement (n=19).

The quantitative portion of the Implementation Assessment contains a variety of questions addressing multiple aspects of unit- and hospital-level participation in the AHRQ Safety Program for Mechanically Ventilated Patients. Five questions out of this assessment were identified as proxies for identifying and differentiating between high performing teams and low performing teams. These questions focus on the implementation of several CUSP components and the level of support and engagement seen from leadership at various levels.

The possible responses to each of the five questions were dichotomized in order to categorize respondents as either high or low performers. The units that responded were then sorted into the two categories five separate times. The tendencies per unit were analyzed across these five questions to produce a comprehensive list of 40 high performers and 26 low performers.

Results of independent groups t-test analyses conducted on baseline and followup data are presented in Tables 33 and 34, respectively. Baseline means were compared across 21 high engagement units versus 13 low engagement units. Followup means were compared across 14 high engagement units versus 6 low engagement units. Findings do not show statistically significant ($p \leq 0.05$) differences on most HSOPS dimensions between the two engagement groups with four exceptions. Statistically significant differences were found at baseline for feedback and communication about error (+10.8%), frequency of events reported (+12.7%), and overall perceptions of patient safety (+10.4%). At followup a statistically significant difference was observed for staffing.

With the enrollment of 122 units, this project represents a national large-scale, multicenter effort to evaluate the impact of a comprehensive intervention package designed to reduce preventable harm and improve patient safety in intensive care areas. A total of 71 units voluntarily submitted patient safety culture data collected with the HSOPS instrument for their work areas. Of these, 67 units submitted data at baseline and 34 submitted followup data. Analyses were conducted on an independent groups sample of units with data from five or more respondents to compare the mean change in percent positive scores from baseline (n=65) to followup (n=33). Across these units, a statistically significant ($p \leq 0.05$) average improvement of 6.0 percent was observed for all 10 of the HSOPS dimensions. Respective improvements of 6.8 percent and 5.7 percent for the hospital-referenced and unit-referenced composite scores were also statistically significant. Moderate but non-significant improvements were observed for the outcomes measured by HSOPS. The domains with the largest improvements included feedback and communication (58.4% at baseline and 67.9% at followup), hospital management support (56.5% at baseline and 65.6% at followup), non-punitive response to error (34.8% at baseline and 42.8% at followup), communication openness (56.7% at baseline and 63.5% at followup), and handoffs and transitions (48.7% at baseline and 54.4% at followup). These increases were statistically significant at conventional cutoff values ($p \leq 0.05$).

Table 33. Baseline Comparison of High (n=21) and Low (n=13) Engagement Units

DIMENSIONS	% MEAN HIGH (N=21)	% MEAN LOW (N=13)	% MEAN DIFFERENCE	STANDARD ERROR DIFFERENCE	P-VALUE
OUTCOMES					
Overall perceptions of safety	61.58	51.18	10.40	4.99	0.05*
Frequency of event reporting	63.38	50.70	12.68	3.96	0.00*
Grade (excellent-very good)	69.74	56.40	13.34	7.05	0.07
HSOPS SUMMARY SCORES					
Overall composite average score	61.35	54.81	6.54	3.98	0.11
Hospital-referenced composite average score	58.33	50.95	7.38	4.60	0.12
Unit-referenced composite average score	62.64	56.46	6.18	3.83	0.12
HOSPITAL-REFERENCED DIMENSIONS					
Hospital management support	63.12	52.02	11.10	6.29	0.09
Teamwork across units	59.97	56.16	3.82	4.74	0.43
Handoffs and transitions	51.89	44.67	7.22	3.90	0.07
UNIT-REFERENCED DIMENSIONS					
Teamwork within units	83.03	82.91	0.12	3.34	0.97
Supervisor expectations	68.31	66.07	2.24	5.66	0.70
Organizational learning	71.15	63.78	7.37	4.32	0.10
Communication openness	60.87	53.52	7.35	4.33	0.10
Feedback and communication	64.08	53.18	10.91	5.02	0.04*
Non-punitive response	37.38	30.30	7.08	5.71	0.22
Staffing	53.65	45.48	8.16	5.64	0.16

* $p \leq 0.05$

Table 34. Followup Comparison of High (n=14) and Low (n=6) Engagement Units

DIMENSIONS	% MEAN HIGH (N=14)	% MEAN LOW (N=6)	% MEAN DIFFERENCE	STANDARD ERROR DIFFERENCE	P-VALUE
OUTCOMES					
Overall perceptions of safety	58.40	54.80	3.60	5.97	0.55
Frequency of event reporting	60.21	49.55	10.66	8.13	0.21
Grade (excellent-very good)	70.96	64.66	6.30	9.38	0.51
HSOPS SUMMARY SCORES					
Overall composite average score	62.33	59.27	3.05	4.75	0.53
Hospital-referenced composite average score	57.55	58.38	−0.82	5.35	0.88
Unit-referenced composite average score	64.37	59.66	4.72	3.52	0.36
HOSPITAL-REFERENCED DIMENSIONS					
Hospital management support	61.72	63.35	−1.63	7.50	0.83
Teamwork across units	59.04	61.96	−2.92	5.83	0.62
Handoffs and transitions	51.90	49.82	2.08	5.22	0.70
UNIT-REFERENCED DIMENSIONS					
Teamwork within units	80.53	83.17	−2.63	6.50	0.69
Supervisor expectations	67.70	70.01	−2.30	6.99	0.75
Organizational learning	69.45	74.26	−4.82	5.21	0.37
Communication openness	65.77	53.86	11.91	5.86	0.06
Feedback and communication	66.43	63.37	3.06	7.45	0.69
Non-punitive response	40.45	33.31	7.14	6.74	0.30
Staffing	60.29	39.63	20.66	6.47	0.01*

* $p \leq 0.05$

The unequal sample sizes in the independent groups comparison limit our ability to meaningfully assess the changes in patient safety culture scores observed from baseline to

followup. To provide a purer appraisal of actual changes in safety culture and strengthen the inferences drawn from our findings regarding the extent of improvement attributable to the intervention package, we conducted additional analyses of the 28 units that provided HSOPS data from a minimum of five respondents at both baseline and followup. The domains demonstrating largest improvements were similar to those from the independent group analyses and included non-punitive response to error (36.3% and 42.4% at baseline and followup, respectively), feedback and communication (62.2% and 68.1% at baseline and followup, respectively), and hospital management support for safety (60.9% and 66.2% at baseline and followup, respectively). Staffing (51.1% and 56.2% at baseline and followup, respectively) and organizational learning (70.5% and 75.5% at baseline and followup, respectively) surpassed communication openness and handoffs and transitions in the paired sample. However, though the domains demonstrating the greatest improvements were similar across the independent groups and paired sample analyses, the trends were slightly compressed within the paired sample analyses, and none of the dimensions, outcomes, or summary composites reached conventional levels of statistical significance. In general, the attenuated changes observed in the paired sample can be attributed to slightly inflated percent positive scores at baseline. These results indicate that the units that submitted data at both time points tended to have slightly better initial safety culture scores than the units that submitted data at baseline but not followup. Attrition may be caused by an inability of units with weaker safety cultures to manage all the project requirements.

6.3.5.1. Comparison of High and Low Engaged Units

In an effort to more precisely determine whether the positive changes in patient safety culture can be attributed to the CUSP intervention package, we conducted additional independent groups t-test analyses to compare patient safety culture of units identified as highly engaged in implementing core components of the CUSP toolkit with those units that implemented fewer elements and were thus considered to be less engaged in the project and CUSP, in particular. We expected that units in each engagement group would demonstrate similar culture scores at baseline but that at followup the highly engaged group would demonstrate stronger patient safety culture scores than the low engagement group. Surprisingly, our results contradicted our expectations. There were few statistically significant differences between the two groups at either baseline or followup. Indeed, though non-significant, larger mean differences were observed at baseline.

6.3.5.2. Comparison to AHRQ Benchmarks and Other National Implementation Projects

Within both the paired and independent groups samples, units that submitted HSOPS data to the project tended to have lower scores at baseline than the ICU benchmarks reported in the 2016 AHRQ HSOPS User Comparative Database. However, by followup, unit scores were either comparable or exceeded the benchmark scores. These observed trends are encouraging,

indicating that the CUSP intervention package is a useful tool for enhancing local ICU patient safety cultures to a level similar to or better than those of their peers.

In addition to comparing culture scores to national benchmarks offered by AHRQ, we can look to results from other national safety improvement projects. Evaluations of national efforts to reduce blood stream infections in the ICU found significant improvements in two unit-referenced HSOPS dimensions among adult ICUs (feedback and communication about error and teamwork within unit).[25,26] In contrast to these earlier evaluations, we did not find a statistically significant improvement across the HSOPS domains when considering only those 28 units that submitted both baseline and followup data. In fact, teamwork within units demonstrated only small improvements in our study. This small incremental change may be related to the higher levels of within-unit teamwork at baseline. Teamwork within units was already quite strong with 83 percent of respondents rating it positively. Given that we often recommend prioritizing strengthening culture domains that score under an 80-percent threshold, it is understandable that high-scoring domains like teamwork within units would not be explicitly targeted by intervention efforts and thus would not demonstrate large improvements. However, consistent with previous national projects, feedback and communication about error demonstrated one of the largest mean changes, increasing 5.8 percent from baseline to followup.

One of the more exciting findings from this study that has not been as prevalent from previous safety improvement work was the comparatively large increase in non-punitive response to error scores. This domain is typically the weakest of all the safety culture domains. This fact is supported by data from previous national projects as well as the 2016 AHRQ Comparative Database. While statistically non-significant in the sample of paired units, non-punitive response to error demonstrated the largest improvement (6.1%) over the 12 months between baseline and followup. It is important to note that statistical significance does not always align with practically meaningful improvements. Given that safety culture change is difficult and takes time, a 6-percent increase in non-punitive response to error over the course of 12 months is encouraging and suggests that, with continued efforts, these scores might continue to improve.

6.3.5.3. Limitations

There are several limitations from this work that are worth noting. These include the voluntary nature of the safety culture data submission process and attrition of units over time. A 60-percent data submission rate was desired at minimum, yet 55 percent of units enrolled in the study submitted HSOPS survey culture data at baseline, and the submission rate fell to 28 percent at followup. Data submission rates were impacted by a variety of factors. For instance, some organizations enrolled in the study regularly use other survey tools (e.g., the Safety Attitudes Questionnaire)[27] to collect safety culture data during their hospital-wide assessments and therefore did not participate in collecting additional data using the HSOPS tool. Multiple outreach efforts, including emails and phone calls, were made during both baseline and followup periods in an attempt to increase data submission. Reasons cited for failing to submit data included failure to remember their participation in the project, lack of

access to raw data, difficulties uploading data to the submission portal, and competing priorities. The NPT made all reasonable efforts to assist with data uploads.

Attrition was a second limitation of the current study. The unequal sample sizes limited our ability to draw conclusions based on analysis of all the units that submitted data at baseline and followup. Therefore, we conducted additional analyses on a subset of the 28 units that submitted baseline and followup data. However, none of the analyses conducted on this subset of units reached statistical significance. Although power was reduced, conducting analyses on only those units that submitted pre- and post-data strengthens our inferences regarding the improvements observed.

Finally, we categorized units as being high or low engagement based on self-report data about the extent that CUSP tools were adopted by the units. These data were collected via a self-report implementation survey completed by a single representative from each unit. Given the possibility of a social desirability response bias, it is possible that these data are an unreliable means for determining unit engagement in the CUSP process. Therefore, the findings presented here should be interpreted given these limitations.

In a national multisite evaluation of intensive care work settings, perceptions of patient safety grade, non-punitive response to error, hospital management support, feedback and communication, staffing, and organizational learning all demonstrated moderate, though not statistically significant, improvements of greater than 5 percent following a 12-month implementation of CUSP. We are encouraged by the results suggested by these analyses. Future work will continue to explore the contextual factors that likely moderate safety culture improvements.

7.0. Discussion

7.1. Comparisons to Published Research

The sheer scale of this program—including the number of participating teams, the wide scope of interventions and process measures, and the volume of data—makes a comparison to previously published ventilator-associated event (VAE) research challenging. Likewise, a comparison to other national collaboratives such as those for catheter-associated urinary tract infection (CAUTI) and central line-associated blood stream infection (CLABSI) is difficult because the complexity of this safety program's interventions is far greater. Adding to this complexity is the lack of widely accepted VAE definitions. Whereas definitions for CAUTI and CLABSI are more mature, clinical opinions still differ on such matters as whether 1,000 ventilator-days or episodes of mechanical ventilation is the most appropriate denominator for calculating the incidence of VAEs. With regard to direct analyses, although ventilator-days are traditionally used in infection control programs,[28] having used a denominator of 1,000 ventilator-days in this program provides further challenges to comparison. For example, because episodic data were not collected, it would be inaccurate to compare this program to the CDC Prevention Epicenters' Wake Up & Breathe Collaborative in which episodes were used in order to avoid a misleading impression of static or increasing VAE rates. Notably, when Klompas et al. published the results of Wake Up & Breathe, a secondary analysis of VAE risk per ventilator-days showed no change in VAE/ventilator-associated condition or Infection-Related Ventilator-Associated Complication risk, though there was a statistically significant reduction in VAE per episode of mechanical ventilation.[28]

7.2. Intangible Benefits

While challenging to quantify, through the Implementation and Exposure Receipt Assessments many teams provided feedback reinforcing the belief that simply participating in this effort raised awareness of VAE and accelerated existing efforts to not only improve care of mechanically ventilated patients, but in quality improvement efforts in general. We also know that, through participation in this program, hospitals were driven to create provider teams dedicated to quality improvement and that, through our engagement efforts, peer learning communities came together to share tools and engagement strategies, mitigating the need to spend resources redeveloping existing strategies. As well, the community engagement gave hospitals and providers the opportunity to form connections and remove themselves from their silos in an environment such as health care where this opportunity is often lacking, despite the similar challenges faced by nearly all hospitals and providers.

7.3. Future Collaborative Efforts

Having reached the conclusion of this program and looking toward the future, the following needs were identified to support the success of large-scale, national collaboratives such as this:

1. An enabling infrastructure for use in diverse settings
2. Assurance of clinician agreement and comfort with standard outcome definitions
3. Standard measurement methodology and data collection tools
4. Web-based portal with real-time access to performance reports
5. Engaged clinicians and executives
6. Centralizing technical work with Translating Research Into Practice framework
7. Empowering and tapping the wisdom of frontline staff through the implementation of Comprehensive Unit-based Safety Program
8. Facilitating the procurement of resources through executive engagement
9. Encouraging accountability and inciting change through transparent reporting

8.0. Lessons Learned

8.1. VAE Data and Surveillance Definitions

Frontline clinicians, the target of the behavior change interventions, must believe the reported data are valid in order to garner support for prevention efforts and for assessing the effectiveness of prevention strategies. In January of 2013, the new National Healthcare Safety Network (NHSN) surveillance definitions and surveillance algorithm for ventilator-associated events (VAEs) were released by the Centers for Disease Control and Prevention, less than a year before this program began. At that time, many physicians and their staff felt, and still feel, these definitions don't reflect clinical reality, that possible ventilator-associated pneumonias are detected when there is no ventilator-associated pneumonia and vice versa, and that while ventilator-associated conditions are ventilator associated, they aren't preventable.

As NHSN VAE surveillance is voluntary and clinicians struggled with accepting the validity of the new definitions, many teams had not implemented this surveillance in their infection prevention department upon joining the project. As each cohort started, the National Project Team (NPT) held educational sessions specifically addressing this topic to help teams begin their surveillance. Still, some teams labored for a quarter or more before they were able to effectively begin the surveillance. This differed from previous experiences with central line-associated blood stream infections (CLABSIs) in the On the CUSP: Stop BSI and in the Agency for Healthcare Research and Quality (AHRQ) Safety Program for Surgery (both Comprehensive Unit-based Safety Program (CUSP) initiatives), in which surveillance definitions were firmly in place and widely accepted. To mitigate these issues, future strategies to include training on VAE surveillance definitions during the onboarding process as opposed to after may alleviate some of the problems surrounding the slow start for VAE data submission.

8.2. Data Collection, Entry Burden, and Use of Electronic Health Records (EHRs)

This is the first national collaborative to collect process measures data that adds further complexities and challenges to the level of progress monitoring. Teams were asked to collect data for each of the interventions on a schedule. In Cohorts 1 and 2, the interventions were staggered—teams started with Daily Care Processes (DCP), followed by Early Mobility (EM), and followed by Low Tidal Volume Ventilation (LTVV). Interventions were started over 3 months and, after the introductory period, we asked them to collect process measure data for one intervention each month for 7 days. While the measures, collection tools, and sample schedule were carefully designed to minimize the burden of data collection and most interventions were widely accepted after an initial period of education, data collection remained a struggle. The volume of data requested was burdensome to many units, and teams subsequently felt overwhelmed by the requirements, especially for the vast majority of teams

that lacked resources dedicated to data collection and entry. However, some teams used manual data collection as an educational opportunity when lapses in care were discovered.

The data collection burden also added an unforeseen problem to implementation. By the time the project began to focus attention on LTVV, teams were already overwhelmed by the data collection for the first two technical interventions, DCP and EM. As a result, many teams simply did not attempt this third intervention as they felt there were already sufficient interventions on which to focus. As a result, implementation of LTVV suffered, which subsequently led to a lack of data. In fact, of the 254 units participating in the program, only 91 (36%) submitted LTVV data. For the purposes of future collaboratives involving a large volume of data collection, there remains a considerable need to streamline data collection methods so that duplicate efforts, such as reporting data for clinical purposes and reporting it elsewhere for research purposes, do not continue to pose such challenges.

Many teams felt that a mechanism by which to glean these data from the patient's EHR would have been extremely helpful in reducing the data collection burden as much of the information requested was already collected in the course of providing usual care to patients. Given the lack of interoperability of EHR systems, working with individual EHR vendors to develop algorithms and interfaces to automate data extraction was not feasible or successful for the majority of hospitals. This will likely remain a complicating factor in data collection over the next several years as EHR systems become more complex and specifically designed to fill the unique needs of the health care systems they serve. The highly technical nature of EHR systems requires an unprecedented level of coordination between vendors, frontline staff, research and quality improvement teams, patient safety organizations, and hospital leadership in order to develop a methodology through which data is able to be easily and effectively gathered, disseminated, and utilized. The ability to seamlessly integrate data extraction methods for the purposes of safety and quality improvement into the technical design of multiple EHR systems will not only provide programs such as this the opportunity to collect more robust and detailed data, but improve the ways such data are made available and actionable for frontline staff.

8.3. Site Selection and Organizational Capacity

Acute care and long-term care facilities that care for adult mechanically ventilated patients across the United States and Puerto Rico were eligible to participate in the program and were targeted for outreach during the recruitment process. All hospital units and coordinating entities (CEs) signed letters of commitment (LOC) indicating they would implement the CUSP model as well as assemble a multidisciplinary team within their intensive care units. Additionally, the LOC also required signatures from three "key players": a hospital executive champion, a physician champion, and a project team leader. However, there were no formal measures taken to assess the organizational capacity and unit infrastructure to ensure participating sites were reasonably capable of handling the roll out of multiple complex interventions—both technical and adaptive—including the ability to provide the dedicated time staff would need to perform data entry. The technical interventions of this collaborative, in particular, were much more complicated than those implemented to reduce CLABSI or

catheter-associated urinary tract infections. For example, it is more challenging to establish an infrastructure to routinely awaken and mobilize mechanically ventilated patients than to ensure physicians wear a gown to place a central line. For future programs, evaluating the organizational capacity and infrastructure of participating hospital units prior to registration through feasibility assessments may provide important insights into potential implementation challenges and allow the NPT to preemptively identify areas in which program delivery and support may require modification to ensure success. Attention should also be paid to the observations from the program's technical expert panel (TEP), which noted the AHRQ Safety Program for Mechanically Ventilated Patients was "beyond the magnitude" of other healthcare-associated infection initiatives because of the number of teams and the complexity of the interventions. With this in mind, focusing on fewer interventions at a time may allow the NPT to increase the investment in participating units by providing more intense support and attention.

8.4. Effect of Coordinating Entities on Site Participation

With few exceptions, teams affiliated with an active CE and those that had previous experience with CUSP had higher levels of involvement than those who entered the project unfamiliar with the CUSP principles. CEs with strong leadership abilities and who guided their groups with an eye toward the participation of all teams were more effective in facilitating the communication and support necessary to fully engage their units. These CEs encouraged teams to present at each coaching call and were enthusiastic about having their teams present at the cohort level. To address these exceptions in the future, issues such as lack of engagement may be alleviated by investing more time working with the CEs prior to kickoff. The importance of adopting and implementing the CUSP framework before becoming immersed in the technical interventions should be stressed. It may be helpful to provide targeted additional training to those CEs who do not have previous CUSP experience. CEs were entrusted with an extremely critical role in this program. To address their challenges, providing additional infrastructure and in-person training when possible can help CEs develop strong leadership leading to higher engagement.

8.5. Changes Implemented Between Cohorts

While two pre-kickoff Webinars were held in order to introduce the basic program components, a more immersive orientation session for Cohort 1 participants was not held until such time as data collection was scheduled to begin. Without the orientation, most teams did not have the infrastructure to set up their CUSP teams, begin staff education, collect DCP measures, or initiate VAE surveillance.

Teams struggled from the beginning, many trying to understand the idea of CUSP and how it could fit into improving the care of mechanically ventilated patients, and this contributed to a slow start. As a result, the initial focus on DCP lagged behind and the scheduled implementation of the EM program 3 months later coincided with the teams' late implementation of DCP.

Therefore, the teams' focus on EM was delayed several months later than expected as they acclimated to the interventions.

In subsequent cohorts, this issue was addressed by holding six onboarding sessions prior to the program kickoff. By the time teams started the program, they had a better grounding in both CUSP and the technical components. For Cohort 2, the timing of the EM and LTVV portions of the project were adjusted so that EM started 6 months after the kickoff instead of 3, and LTVV started 6 months later, at 1 year after kickoff.

Because of the compressed timeline of Cohort 3, the teams determined themselves whether they would focus on DCP, EM, or both. LTVV data collection was also voluntary. This gave teams the ability to select an intervention most suited to their abilities and to omit those that may cause excessive burden. Even with this choice, most Cohort 3 teams elected to pursue implementation of both DCP and EM, which indicated success in improving our site engagement and enthusiasm for the program.

While these were complicating factors, these challenges provided valuable insight into the design and conduct of a large collaborative project such as this one. Most importantly, there is a need to build a degree of flexibility into the design and implementation strategies as well as anticipate and respond accordingly to the needs of the participants. The TEP advice that we allow more flexibility and "meet hospitals where they are" in terms of readiness and ability reinforced these lessons.

9.0. Conclusion

The Agency for Healthcare Research and Quality (AHRQ) Safety Program for Mechanically Ventilated Patients was a highly involved, complex, and far-reaching national improvement collaborative. It demonstrated the potential to reduce ventilator-associated events (VAEs) and ventilator-associated pneumonias (VAPs) and improve the care of mechanically ventilated patients by applying the Comprehensive Unit-based Safety Program (CUSP) to increase the adoption of and compliance with technical bundles of evidence-based recommendations. As the largest national collaborative to involve the collection of process measure data, this program shed considerable light on the many challenges involved in developing a framework to support the implementation of quality improvement projects that require multiple intervention measures and for which success may be dependent on non-clinical factors, such as hospital infrastructure and physician and executive support.

In observing the trend toward reduction in VAE, infection-related ventilator-associated complications, and possible ventilator-associated pneumonia rates, as well as observing and celebrating the numerous individual successes of participating teams, the National Project Team is greatly encouraged by the results of this program. The AHRQ Safety Program for Mechanically Ventilated Patients successfully demonstrated that, through hospital engagement, improved teamwork and communication through CUSP, and the use of educational materials and data collection tools specifically designed to target the reduction of VAE/VAP, increased compliance with multiple evidence-based technical intervention bundles is not only possible but has the potential to reduce the medical and public health toll from VAE/VAP.

As VAE/VAP remains a morbid complication, the AHRQ Safety Program for Mechanically Ventilated Patients provides important insights and a strong foundation to successfully address the culture changes and clinical attention needed to proactively reduce VAE rates in acute care settings.

References

1. Dudeck MA, Horan TC, Peterson KD, et al. National Healthcare Safety Network (NHSN) report, data summary for 2010, device-associated module. Am J Infect Control. 2011 Dec;39(10):798-816. PMID: 22133532.
2. Nguile-Makao M, Zahar JR, Francais A, et al. Attributable mortality of ventilator-associated pneumonia: Respective impact of main characteristics at ICU admission and VAP onset using conditional logistic regression and multi-state models. Intensive Care Med. 2010 May;36(5):781-9. PMID: 20232046.
3. Bekaert M, Timsit JF, Vansteelandt S, et al. Attributable mortality of ventilator-associated pneumonia: A reappraisal using causal analysis. Am J Respir Crit Care Med. 2011 Nov 15;184(10):1133-9. PMID: 21852541.
4. Melsen WG, Rovers MM, Koeman M, et al. Estimating the attributable mortality of ventilator-associated pneumonia from randomized prevention studies. Crit Care Med. 2011 Dec;39(12):2736-42. PMID: 21765351.
5. Klompas M, Kleinman K and Murphy MV. Descriptive epidemiology and attributable morbidity of ventilator-associated events. Infect Control Hosp Epidemiol. 2014 May;35(5):502-10. PMID: 24709718.
6. Klompas M, Magill S, Robicsek A, et al. Objective surveillance definitions for ventilator-associated pneumonia. Crit Care Med. 2012 Dec;40(12):3154-61. PMID: 22990454.
7. Hayashi Y, Morisawa K, Klompas M, et al. Toward improved surveillance: The impact of ventilator-associated complications on length of stay and antibiotic use in patients in intensive care units. Clin Infect Dis. 2013 Feb;56(4):471-7. PMID: 23118272.
8. Safdar N, Dezfulian C, Collard HR, et al. Clinical and economic consequences of ventilator-associated pneumonia: A systematic review. Crit Care Med. 2005 Oct;33(10):2184-93. PMID: 16215368.
9. Klevens RM, Edwards JR, Richards CL, Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep. 2007 Mar-Apr;122(2):160-6. PMID: 17357358.
10. Berenholtz SM, Pham JC, Thompson DA, et al. Collaborative cohort study of an intervention to reduce ventilator-associated pneumonia in the intensive care unit. Infect Control Hosp Epidemiol. 2011 Apr;32(4):305-14. PMID: 21460481.
11. Rawat N. Two-state collaborative cohort study of a multi-faceted intervention to decrease ventilator-associated events. unpublished manuscript.
12. Stevens JP, Silva G, Gillis J, et al. Automated surveillance for ventilator-associated events. Chest. 2014 Dec;146(6):1612-8. PMID: 25451350.
13. Melsen WG, Rovers MM, Groenwold RH, et al. Attributable mortality of ventilator-associated pneumonia: A meta-analysis of individual patient data from randomised prevention studies. Lancet Infect Dis. 2013 Aug;13(8):665-71. PMID: 23622939.
14. Melsen WG, Rovers MM and Bonten MJ. Attributable mortality of ventilator-associated pneumonia—authors' reply. Lancet Infect Dis. 2013 Dec;13(12):1015,3099(13)70326-8. PMID: 24262298.
15. Magill SS, Klompas M, Balk R, et al. Developing a new, national approach to surveillance for ventilator-associated events. Crit Care Med. 2013 Nov;41(11):2467-75. PMID: 24162674.
16. Pronovost PJ, Berenholtz SM, Goeschel CA, et al. Creating high reliability in health care organizations. Health Serv Res. 2006 Aug;41(4 Pt 2):1599-617. PMID: 16898981.
17. Coffin SE, Klompas M, Classen D, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals. Infect Control Hosp Epidemiol. 2008 Oct;29 Suppl 1S31-40. PMID: 18840087.
18. Determann RM, Royakkers A, Wolthuis EK, et al. Ventilation with lower tidal volumes as compared with conventional tidal volumes

for patients without acute lung injury: A preventive randomized controlled trial. Crit Care. 2010;14(1):R1. PMID: 20055989.

19. Hess D. Infection control in the intensive care unit. the role of the ventilator circuit. Minerva Anestesiol. 2002 May;68(5):356-9. PMID: 12029245.
20. Hess DR, Kallstrom TJ, Mottram CD, et al. Care of the ventilator circuit and its relation to ventilator-associated pneumonia. Respir Care. 2003 Sep;48(9):869-79. PMID: 14513820.
21. Agency for Healthcare Research and Quality. HSOPS Safety Culture Dimensions and Reliabilities.
22. Dixon-Woods M, Bosk CL, Aveling EL, et al. Explaining Michigan: Developing an ex post theory of a quality improvement program. Milbank Q. 2011 Jun;89(2):167-205. PMID: 21676020.
23. Diehl A, Yang T, Speck K, et al. Evaluating the accuracy of sampling strategies for estimation of compliance rate for ventilator-associated pneumonia process measures. Infect Control Hosp Epidemiol. 2016 Jun 201-7. PMID: 27322932.
24. Agency for Healthcare Research and Quality. 2016 user comparative database report.
25. Agency for Healthcare Research and Quality. Eliminating CLABSI, a national patient safety imperative: final report on the Nation On the CUSP: Stop BSI Project.
26. Agency for Healthcare Research and Quality. Eliminating CLABSI, a national patient safety imperative: final report companion guide.
27. Sexton JB, Helmreich RL, Neilands TB, et al. The safety attitudes questionnaire: Psychometric properties, benchmarking data, and emerging research. BMC Health Serv Res. 2006 Apr 3;644. PMID: 16584553.
28. Klompas M, Anderson D, Trick W, et al. The preventability of ventilator-associated events. The CDC Prevention Epicenters Wake Up and Breathe Collaborative. Am J Respir Crit Care Med. 2015 Feb 1;191(3):292-301. PMID: 25369558.

Appendixes

A. Data Measure Definitions
B. Data Submission Summaries
C. HSOPS Paired Group Comparison
D. PT or OT Participation Rates

Appendix A. Data Measure Definitions

Table A-1. VAE Outcome Measures

INCIDENCE RATE	DEFINITION
VAE incidence rate per 1,000 ventilator-days	Numerator: total number of VAC, IVAC, and PVAP events multiplied by 1,000 Denominator: total number of ventilation days
IVAC incidence rate per 1,000 ventilator-days	Numerator: total number of IVAC and PVAP events multiplied by 1,000 Denominator: total number of ventilation days
PVAP incidence rate per 1,000 ventilator-days	Numerator: total number of PVAP events multiplied by 1,000 Denominator: total number of ventilation days

Table A-2. Objective Outcome Measures

MEASURE	DEFINITION
Mortality Rate	Numerator: Total number of deaths of patients that received mechanical ventilation Denominator: Total number of patients that received mechanical ventilation
Average Duration of Mechanical Ventilation per Episode	Numerator: Total number of ventilator-days Denominator: Total number of episodes of mechanical ventilation
Average Duration of Mechanical Ventilation per Patient	Numerator: Total number of ventilator-days Denominator: Total number of patients that received mechanical ventilation
Average Hospital Length of Stay per Patient	Numerator: Total number of hospital days for patients that received mechanical ventilation Denominator: Total number of patients that received mechanical ventilation

Table A-3. Daily Care Process Measures

MEASURE	DEFINITION
SSD-ETT Compliance Rate	Out of the total number of patients intubated for more than 72 hours with a first SSD-ETT value being "Y" (Yes) or "N" (No), the percentage of patients with first SSD-ETT value being "Y" (Yes)
HOB Compliance Rate	Out of the total number of ventilated patient-days with HOB at ≥30° being "Y" (Yes) or "N" (No), the percentage of days with HOB at ≥30° being "Y" (Yes)
SAT Compliance Rate	Out of the total number of ventilated patient-days with SAT being "Y" (Yes) or "N" (No), the percentage of days with SAT being "Y" (Yes)
SBT Compliance Rate	Out of the total number of ventilated patient-days with SBT being "Y" (Yes) or "N" (No), the percentage of days with SBT being "Y" (Yes)
Percentage of Ventilated Patient-Days Without Sedation	Out of the total number of ventilated patient-days with SAT being "Y" (Yes), "N" (No), or "NS" (Not Sedated), the percentage of days with SAT being "NS" (Not Sedated)
SBT With Sedatives Off Compliance Rate	Out of the total number of ventilated patient-days with SBT being "Y" (Yes), the percentage of days with SBT with sedatives off being "Y" (Yes)
Percentage of Achieving RASS/SAS Target	(1) For units collecting RASS scores: out of the total number of ventilated patient-days for which a patient has RASS target and actual scores, the percentage of days that a patient has a RASS actual score equal to RASS target score or RASS actual score is less than or equal to +1 and is greater than the RASS target score (2) For units collecting SAS scores: out of the total number of ventilated patient-days for which a patient has SAS target and actual scores, the percentage of days that a patient has a SAS actual score equal to SAS target score or SAS actual score is less than or equal to 5 and is greater than the SAS target score
Percentage of RASS/SAS Actual Being {−1,0,1} or {4,5}	Out of the total number of ventilated patient-days for which a patient has a RASS or SAS actual score, the percentage of days that a patient has either a RASS actual score of {−1, 0, or 1} or a SAS actual score of {4 or 5}
Delirium Assessment Utilization Rate	Out of the total number of ventilated patient-days for which a patient has either CAM-ICU or ASE data, the percentage of days that CAM-ICU is marked "P" (Positive) or "N" (Negative), or ASE is numeric
Percentage of CAM-ICU or ASE UTAs	Out of the total number of ventilated patient-days for which a patient has either CAM-ICU or ASE data, the percentage of days that CAM-ICU or ASE is marked "UTA" (Unable to Assess)
Percentage of Correctly Reporting CAM-ICA/ASE UTA	Out of the total number of ventilated patient-days for which a patient has either CAM-ICU or ASE marked "UTA," the percentage of days that their RASS actual score is {−4 or −5} or their SAS actual score is {1 or 2}
Percentage of CAM-ICU Negative or ASE ≤2 (No delirium)	Out of the total number of ventilated patient-days for which a patient has either (1) CAM-ICU is marked "P" (Positive) or "N" (Negative), or (2) ASE has a numeric value, the percentage of days that CAM-ICU is marked "N" (Negative), or ASE is ≤2 (number of errors is ≤2), respectively

Table A-4. Daily Early Mobility Measures

MEASURE	DEFINITION
Percentage of Achieving RASS/SAS Target	(1) For units collecting RASS scores: out of the total number of ventilated patient-days for which a patient has RASS target and actual scores, the percentage of days that a patient has a RASS actual score equal to RASS target score or RASS actual score is less than or equal to +1 and is greater than the RASS target score (2) For units collecting SAS scores: out of the total number of ventilated patient-days for which a patient has SAS target and actual scores, the percentage of days that a patient has a SAS actual score equal to SAS target score or SAS actual score is less than or equal to 5 and is greater than the SAS target score
Percentage of RASS/SAS Actual Being {−1,0,1} or {4,5}	Out of the total number of ventilated patient-days for which a patient has a RASS or SAS actual score, the percentage of days that a patient has either a RASS actual score of {−1, 0, or 1} or a SAS actual score of {4 or 5}
Delirium Assessment Utilization Rate	Out of the total number of ventilated patient-days for which a patient has either CAM-ICU or ASE data, the percentage of days that CAM-ICU is marked "P" (Positive) or "N" (Negative), or ASE is numeric
Percentage of UTAs	Out of the total number of ventilated patient-days for which a patient has either CAM-ICU or ASE data, the percentage of days that CAM-ICU or ASE is marked "UTA" (Unable to Assess)
Percentage of Correctly Reporting CAM-ICA/ASE UTA	Out of the total number of ventilated patient-days for which a patient has either CAM-ICU or ASE marked "UTA," the percentage of days that their RASS actual score is {−4 or −5} or their SAS actual score is {1 or 2}
Percentage of CAM-ICU Negative or ASE ≤2 (No delirium)	Out of the total number of ventilated patient-days for which a patient has either (1) CAM-ICU is marked "P" (Positive) or "N" (Negative), or (2) ASE has a numeric value, the percentage of days that CAM-ICU is marked "N" (Negative), or ASE is ≤2 (number of errors is ≤2), respectively
Distribution of the Highest Level of Mobility	Out of the total number of ventilated patient-days, the percentage of days each level of mobility (0 to 8) is marked as the highest level of mobility
PT or OT Participation Rate	Out of the total number of ventilated patient-days, the total number of days that either PT or OT is marked as being used
Distribution of Perceived Barriers to Achieving a Higher Level of Mobility	Out of the total number of ventilated patient-days, the total number and percentage of days each barrier (0 to 15) is marked as the perceived barrier to achieving a higher level of mobility
Adverse Event Rate	Out of the total number of ventilated patient-days, the percentage of days on which any adverse event(s) occurred (excluding category 0: None)
Distribution of Adverse Events	Out of the total number of adverse events occurring on ventilated patient-days (up to three adverse events can be reported for each ventilated patient-day), the total number and percentage of adverse events in each of the 25 categories (excluding 0: None)

Table A-5. Low Tidal Volume Ventilation Measures

MEASURE	DEFINITION
Tidal Volume Value Distribution for Patients With ARDS	Out of the total number of ventilated patient-days on which ventilator mode * is "1" or "2" and patient has ARDS, the percentage of tidal volume values, measured in mL/kg predicted body weight (PBW), falling in each the following five categories: <4, 4–6, 6–8, 8–10, ≥10
Tidal Volume Value Distribution for Patients Without ARDS	Out of the total number of ventilated patient-days that ventilator mode is "1" or "2" and patient does not have ARDS, the percentage of tidal volume values, measured in mL/kg PBW, falling in each the following five categories: <4, 4–6, 6–8, 8–10, ≥10
PEEP Compliance Rate (≥5 cm H_2O) for Patients With ARDS	Out of the total number of ventilated patient-days that ventilator mode is "1" or "2" and patient has ARDS, the percentage of ventilated patient-days that PEEP ≥5 cm H_2O
PEEP Compliance Rate (≥5 cm H_2O) for Patients Without ARDS	Out of the total number of ventilated patient-days that ventilator mode is "1" or "2" and patient does not have ARDS, the percentage of ventilated patient-days that PEEP ≥5 cm H_2O

* Ventilator mode: 1, Volume Cycled Modes include Continuous Mandatory Ventilation (CMV), Assist Control (AC), Synchronized Intermittent Mandatory Ventilation (SIMV), Volume Support (VS), and Pressure Regulated Volume Control (PRVC); 2, Pressure Cycle Modes include Pressure Support (PS), Continuous Positive Airway Pressure (CPAP), Pressure Control (PC), Airway Pressure Release Ventilation (APRV), and BiLevel Ventilation; 3, Other Modes include Proportional Assist Ventilation (PAV), Adaptive Support Ventilation (ASV), Inverse Ratio Ventilation, High Frequency Oscillatory Ventilation (HFOV), Extracorporeal Membrane Oxygenation (ECMO), and Other.

Appendix B. Data Submission Summaries

Table B-1. VAE Outcomes Data Submissions Summary: Cohort 1

STUDY QUARTER	CALENDAR TIME	UNITS (N=40*)	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS	PERCENTAGE OF UNIT-MONTHS WITH ZERO VAE	PERCENTAGE OF UNIT-MONTHS WITH ZERO IVAC	PERCENTAGE OF UNIT-MONTHS WITH ZERO PVAP
B1	Aug 13–Oct 13	34 (85%)	120	91 (76%)	12,687	45%	66%	79%
B2	Nov 13–Jan 14	37 (93%)	120	101 (84%)	17,080	42%	65%	74%
Q1	Feb 14–Apr 14	39 (98%)	120	117 (98%)	18,115	50%	68%	80%
Q2	May 14–Jul 14	40 (100%)	120	112 (93%)	15,475	46%	70%	78%
Q3	Aug 14–Oct 14	37 (93%)	120	105 (88%)	12,731	55%	73%	85%
Q4	Nov 14–Jan 15	35 (88%)	120	103 (86%)	15,037	49%	68%	82%
Q5	Feb 15–Apr 15	31 (78%)	120	91 (76%)	11,585	51%	71%	86%
Q6	May 15–Jul 15	29 (73%)	120	85 (71%)	11,103	47%	73%	91%
Q7	Aug 15–Oct 15	28 (70%)	120	83 (69%)	10,973	55%	70%	92%
Q8	Nov 15–Jan 16	28 (70%)	120	62 (52%)	8,755	42%	71%	87%

*Total number of units that ever submitted VAE data is 40, which is 83% of the 48 cohort 1 units.

B1 and B2 are baseline quarters.

Table B-2. VAE Outcomes Data Submission Summary: Cohort 2

STUDY QUARTER	CALENDAR TIME	UNITS (N=60*)	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS	PERCENTAGE OF UNIT-MONTHS WITH ZERO VAE	PERCENTAGE OF UNIT-MONTHS WITH ZERO IVAC	PERCENTAGE OF UNIT-MONTHS WITH ZERO PVAP
B1	Jul 14–Sep 14	47 (78%)	180	139 (77%)	19,243	60%	76%	88%
B2	Oct 14–Dec 14	52 (87%)	180	151 (84%)	24,588	50%	72%	85%
Q1	Jan 15–Mar 15	59 (98%)	180	171 (95%)	26,164	49%	71%	91%
Q2	Apr 15–Jun 15	56 (93%)	180	167 (93%)	25,704	58%	78%	93%
Q3	Jul 15–Sep 15	58 (97%)	180	166 (92%)	24,430	53%	75%	89%
Q4	Oct 15–Dec 15	50 (83%)	180	146 (81%)	22,972	55%	75%	93%
Q5	Jan 16–Mar 16	41 (68%)	180	117 (65%)	18,902	52%	69%	91%

*Total number of units that ever submitted VAE data is 60, which is 81% of the 74 cohort 2 units.

B1 and B2 are baseline quarters.

Table B-3. VAE Outcomes Data Submission Summary: Cohort 3

STUDY QUARTER	CALENDAR TIME	UNITS (N=94*)	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS	PERCENTAGE OF UNIT-MONTHS WITH ZERO VAE	PERCENTAGE OF UNIT-MONTHS WITH ZERO IVAC	PERCENTAGE OF UNIT-MONTHS WITH ZERO PVAP
B1	Mar 15–May 15	50 (53%)	282	144 (51%)	16,512	51%	76%	93%
B2	Jun 15–Aug 15	58 (62%)	282	165 (59%)	17,216	54%	74%	93%
Q1	Sep 15–Nov 15	88 (94%)	282	228 (81%)	27,315	51%	79%	93%
Q2	Dec 15–Feb 16	89 (95%)	282	246 (87%)	38,520	47%	73%	89%
Q3	Mar 16–Apr 16	72 (77%)	188	117 (62%)	23,593	50%	75%	92%

*Total number of units that ever submitted VAE data is 94, which is 71% of the 132 cohort 3 units.

B1 and B2 are baseline quarters.

Table B-4. VAE Outcomes Data Submission Summary: Cohort 1, Units With Complete VAE Data

STUDY QUARTER	CALENDAR TIME	UNITS (N=40*)	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS	PERCENTAGE OF UNIT-MONTHS WITH ZERO VAE	PERCENTAGE OF UNIT-MONTHS WITH ZERO IVAC	PERCENTAGE OF UNIT-MONTHS WITH ZERO PVAP
B1	Aug 13–Oct 13	10 (25%)	120	30 (25%)	4,410	30%	53%	70%
B2	Nov 13–Jan 14	10 (25%)	120	30 (25%)	5,331	27%	53%	57%
Q1	Feb 14–Apr 14	10 (25%)	120	30 (25%)	5,156	23%	37%	57%
Q2	May 14–Jul 14	10 (25%)	120	30 (25%)	4,597	37%	53%	67%
Q3	Aug 14–Oct 14	10 (25%)	120	30 (25%)	4,139	37%	60%	73%
Q4	Nov 14–Jan 15	10 (25%)	120	30 (25%)	4,992	27%	53%	67%
Q5	Feb 15–Apr 15	10 (25%)	120	30 (25%)	4,844	43%	63%	83%
Q6	May 15–Jul 15	10 (25%)	120	30 (25%)	4,667	33%	53%	87%
Q7	Aug 15–Oct 15	10 (25%)	120	30 (25%)	4,880	47%	57%	83%
Q8	Nov 15–Jan 16	10 (25%)	120	30 (25%)	5,047	43%	63%	83%

*Total number of units that ever submitted VAE data is 40, which is 83% of the 48 cohort 1 units.

B1 and B2 are baseline quarters

Table B-5. VAE Outcomes Data Submission Summary: Cohort 2, Units With Complete VAE Data

STUDY QUARTER	CALENDAR TIME	UNITS (N=60*)	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS	PERCENTAGE OF UNIT-MONTHS WITH ZERO VAE	PERCENTAGE OF UNIT-MONTHS WITH ZERO IVAC	PERCENTAGE OF UNIT-MONTHS WITH ZERO PVAP
B1	Jul 14–Sep 14	34 (57%)	180	102 (57%)	14,562	58%	75%	89%
B2	Oct 14–Dec 14	34 (57%)	180	102 (57%)	15,447	50%	77%	91%
Q1	Jan 15–Mar 15	34 (57%)	180	102 (57%)	15,016	46%	75%	95%
Q2	Apr 15–Jun 15	34 (57%)	180	102 (57%)	14,870	62%	79%	95%
Q3	Jul 15–Sep 15	34 (57%)	180	102 (57%)	13,685	54%	75%	89%
Q4	Oct 15–Dec 15	34 (57%)	180	102 (57%)	15,674	52%	76%	94%
Q5	Jan 16–Mar 16	34 (57%)	180	102 (57%)	16,204	50%	68%	90%

*Total number of units that ever submitted VAE data is 60, which is 81% of the 74 cohort 2 units.

B1 and B2 are baseline quarters.

Table B-6. VAE Outcomes Data Submission Summary: Cohort 3, Units With Complete VAE Data

STUDY QUARTER	CALENDAR TIME	UNITS (N=94*)	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS	PERCENTAGE OF UNIT-MONTHS WITH ZERO VAE	PERCENTAGE OF UNIT-MONTHS WITH ZERO IVAC	PERCENTAGE OF UNIT-MONTHS WITH ZERO PVAP
B1	Mar 15–May 15	19 (20%)	282	57 (20%)	7,145	39%	68%	93%
B2	Jun 15–Aug 15	19 (20%)	282	57 (20%)	5,774	49%	70%	88%
Q1	Sep 15–Nov 15	19 (20%)	282	57 (20%)	6,208	42%	79%	91%
Q2	Dec 15–Feb 16	19 (20%)	282	57 (20%)	6,863	46%	81%	98%
Q3	Mar 16–Apr 16	19 (20%)	188	38 (20%)	5,202	53%	79%	97%

*Total number of units that ever submitted VAE data is 94, which is 71% of the 132 cohort 3 units.

B1 and B2 are baseline quarters.

Table B-7. Objective Outcomes Data Submission Summary: Cohort 1

STUDY PERIOD	CALENDAR TIME	UNITS (N=20)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS
Baseline	Jan 14–Jun 14	9 (45%)	120	41 (34%)
Intervention	Jul 14–Jan 16	20 (100%)	380	266 (70%)

* Total number of units that ever submitted OO data is 20, which is 42% of the 48 Cohort 1 units.

Table B-8. Objective Outcomes Data Submission Summary: Cohort 2

STUDY PERIOD	CALENDAR TIME	UNITS (N=38)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS
Baseline	Jul 14–Dec 14	18 (47%)	228	94 (41%)
Intervention	Jan 15–Apr 16	38 (100%)	608	455 (75%)

* Total number of units that ever submitted OO data is 38, which is 51% of the 74 Cohort 2 units.

Table B-9. Objective Outcomes Data Submission Summary: Cohort 3

STUDY PERIOD	CALENDAR TIME	UNITS (N=41)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS
Baseline	Jan 15–Aug 15	7 (17%)	246	25 (10%)
Intervention	Sep 15–Apr 16	37 (90%)	328	183 (56%)

* Total number of units that ever submitted OO data is 41, which is 31% of the 132 Cohort 3 units.

Table B-10. Daily Care Processes Data Submission Summary: Cohort 1

STUDY PERIOD	CALENDAR TIME	UNITS (N=35)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS †	VENTILATOR-DAYS
Early Intervention	Feb 14–Jul 14	29 (83%)	140	95	7,068
Late Intervention	Aug 14–Jan 16	33 (94%)	210	248	14,220

* Total number of units that ever submitted DCP data is 35, which is 73% of the 48 Cohort 1 units.

† The number of unit-months per intervention period may exceed the number of expected unit-months because some units participated in optional data submission.

Table B-11. Daily Care Processes Data Submission Summary: Cohort 2

STUDY PERIOD	CALENDAR TIME	UNITS (N=59)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS †	VENTILATOR-DAYS
Early Intervention	Jan 15–Jun 15	59 (100%)	354	269	21,735
Late Intervention	Jul 15–May 16	51 (86%)	177	296	20,296

* Total number of units that ever submitted DCP data is 59, which is 80% of the 74 Cohort 2 units.

† The number of unit-months per intervention period may exceed the number of expected unit-months because some units participated in optional data submission.

Table B-12. Daily Care Processes Data Submission Summary: Cohort 3

STUDY PERIOD	CALENDAR TIME	UNITS (N=82)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS
Early Intervention	Sep 15–Nov 15	77 (94%)	246	170	11,817
Late Intervention	Dec 15–May 16	80 (98%)	492	392	22,755

* Total number of units that ever submitted DCP data is 82, which is 62% of the 132 Cohort 3 units.

Table B-13. Daily Early Mobility Data Submission Summary: Cohort 1

STUDY PERIOD	CALENDAR TIME	UNITS (N=27)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS †	VENTILATOR-DAYS
Early Intervention	May 14–Oct 14	26 (96%)	135	91	4,275
Late Intervention	Nov 14–Jan 16	23 (85%)	108	158	9,281

* Total number of units that ever submitted Daily EM data is 27, which is 56% of the 48 Cohort 1 units.

† The number of unit-months per intervention period may exceed the number of expected unit-months because some units participated in optional data submission.

Table B-14. Daily Early Mobility Data Submission Summary: Cohort 2

STUDY PERIOD	CALENDAR TIME	UNITS (N=42)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS †	VENTILATOR-DAYS
Early Intervention	May 15–Sep 15	40 (95%)	168	128	12,456
Late Intervention	Oct 15–May 16	35 (83%)	168	166	12,125

* Total number of units that ever submitted Daily EM data is 42, which is 57% of the 74 Cohort 2 units.

† The number of unit-months per intervention period may exceed the number of expected unit-months because some units participated in optional data submission.

Table B-15. Daily Early Mobility Data Submission Summary: Cohort 3

STUDY PERIOD	CALENDAR TIME	UNITS (N=69)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS
Early Intervention	Sep 15–Nov 15	61 (88%)	207	126	7,687
Late Intervention	Dec 15–May 16	62 (90%)	414	261	12,860

* Total number of units that ever submitted Daily EM data is 69, which is 52% of the 132 Cohort 3 units.

Table B-16. Low Tidal Volume Ventilation Data Submission Summary: Cohort 1

STUDY PERIOD	CALENDAR TIME	UNITS (N=28)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS
Early Intervention	Feb 15–July 15	27 (96%)	112	101	9,336
Late Intervention	Aug 15–Jan 16	20 (71%)	56	51	3,797

* Total number of units that ever submitted LTVV data is 28, which is 58% of the 48 Cohort 1 units.

Table B-17. Low Tidal Volume Ventilation Data Submission Summary: Cohort 2

STUDY PERIOD	CALENDAR TIME	UNITS (N=35)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS‡	VENTILATOR-DAYS
Early Intervention	Oct 15–Dec 15	31 (89%)	105	68	8,275
Late Intervention	Jan 16–May 16	33 (94%)	70	100	8,931

* Total number of units that ever submitted LTVV data is 35, which is 47% of the 74 Cohort 2 units.

‡ The number of unit-months per intervention period may exceed the number of expected unit-months because some units participated in optional data submission.

Table B-18. Low Tidal Volume Ventilation Data Submission Summary: Cohort 3

STUDY PERIOD	CALENDAR TIME	UNITS (N=28)*	EXPECTED UNIT-MONTHS	UNIT-MONTHS	VENTILATOR-DAYS
Early Intervention	Sep 15–Nov 15	24 (86%)	N/A ‡	48	2,943
Late Intervention	Dec 15–May 16	24 (86%)	N/A	115	6,002

* Total number of units that ever submitted LTVV data is 28, which is 21% of the 132 Cohort 3 units.

‡ Cohort 3 was not required to submit LTVV data during any quarter.

Appendix C. HSOPS Paired Group Comparison

Figure C-1. Paired Groups Sample Comparison of Unit (n=28) Baseline and Followup HSOPS Dimension Scores

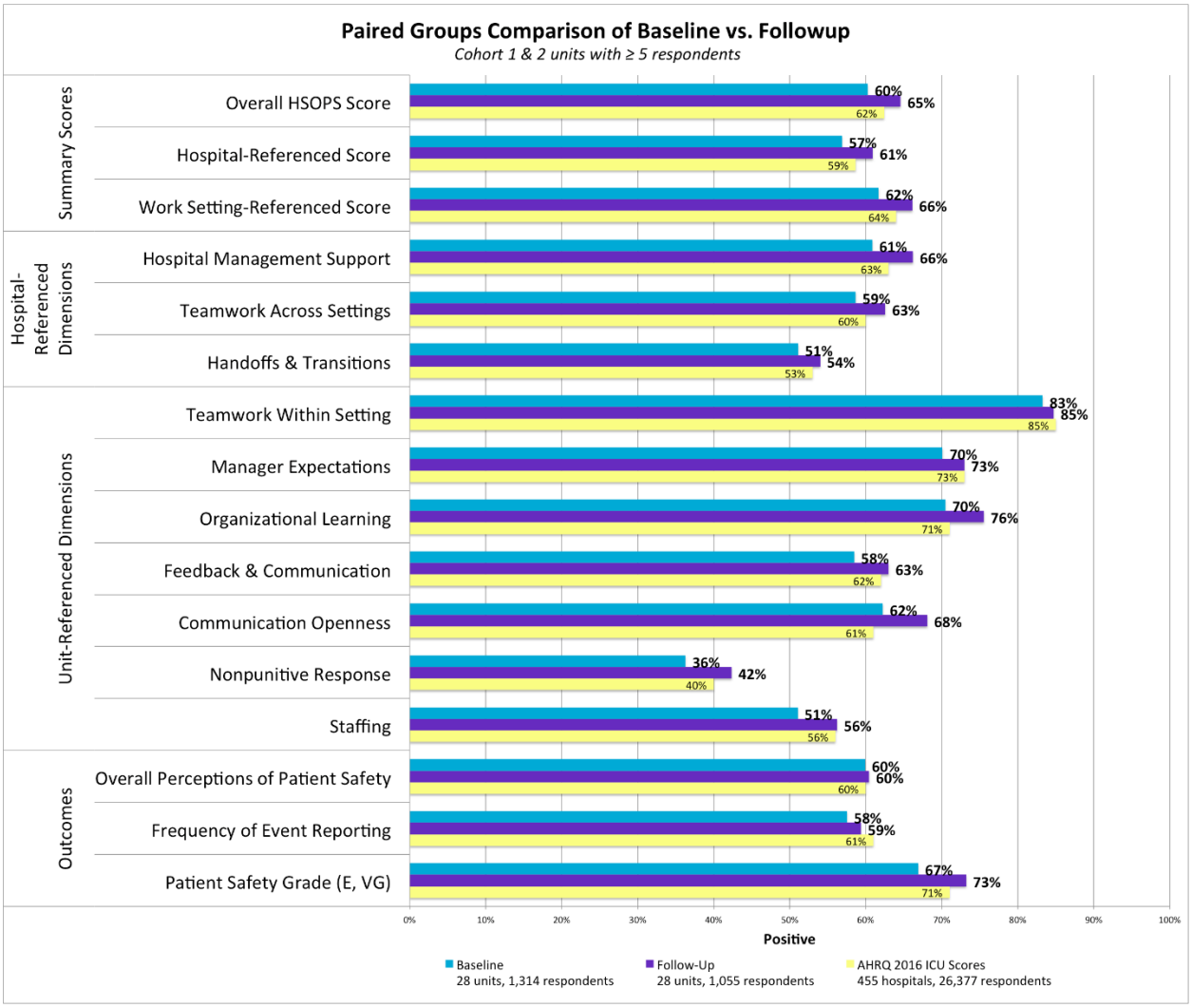


Table C-1. Paired Groups Sample Comparison of Unit (n=28) Baseline and Followup HSOPS Dimension Scores

DIMENSIONS	% MEAN BASELINE (N=28)	% MEAN FOLLOWUP (N=28)	% MEAN DIFFERENCE	STANDARD ERROR DIFFERENCE	P-VALUE
OUTCOMES					
Overall perceptions of safety	59.90	60.43	0.54	2.80	0.85
Frequency of event reporting	57.53	59.35	1.82	3.71	0.63
Grade (excellent–very good)	66.90	73.20	6.30	4.16	0.14
HSOPS SUMMARY SCORES					
Overall composite average score	60.26	64.56	4.31	2.40	0.08
Hospital-referenced composite average score	56.88	60.92	4.04	2.58	0.13
Unit-referenced composite average score	61.70	66.12	4.42	2.48	0.09
HOSPITAL-REFERENCED DIMENSIONS					
Hospital management support	60.87	66.21	5.34	2.98	0.08
Teamwork across units	58.68	62.55	3.88	2.83	0.18
Handoffs and transitions	51.10	54.00	2.90	2.68	0.29
UNIT-REFERENCED DIMENSIONS					
Teamwork within units	83.28	84.72	1.44	2.52	0.57
Supervisor expectations	70.11	72.95	2.84	3.49	0.42
Organizational learning	70.46	75.53	5.08	3.16	0.12
Communication openness	58.49	63.01	4.52	2.58	0.09
Feedback and communication	62.24	68.08	5.84	3.35	0.09
Non-punitive response	36.28	42.35	6.07	3.47	0.09
Staffing	51.05	56.22	5.17	3.01	0.10

Appendix D. PT or OT Participation Rates

Figure D-1.PT or OT Participation Rate (All Cohorts)

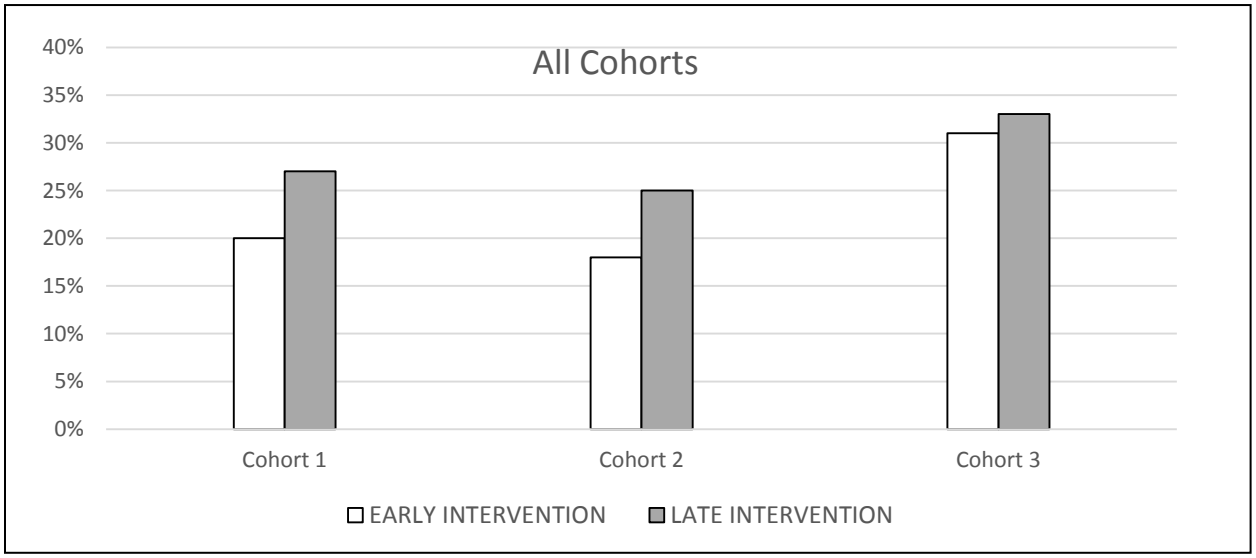


Table D-1. PT or OT Participation Rate (All Cohorts)

COHORT	EARLY INTERVENTION	LATE INTERVENTION	PERCENT CHANGE	P-VALUE
Cohort 1	20% (875/4,275)	27% (2,470/9,281)	3%	<0.001
Cohort 2	18% (2,293/12,456)	25% (3,010/12,125)	35%	<0.001
Cohort 3	31% (2,371/7,687)	33% (4,244/12,860)	7%	0.001