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CASE STUDY

The I-READI Quality and Safety Framework: A Health System's Response to Airway Complications in Mechanically Ventilated Patients with Covid-19

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Health care institutions responding to quality and safety challenges during times of crisis, such as emerging infectious diseases or natural disasters, can follow the I-READI conceptual framework: Integration, Root Cause Analysis, Evidence Review, Adaptation, Dissemination, and Implementation. The University of Pennsylvania Health System developed this approach by drawing on lessons learned from rapidly coordinating changes to their ventilator management practices. They modified their practices to improve patient safety after recognizing high rates of airway complications among mechanically ventilated patients with Covid-19. Vertical and horizontal integration of their quality and safety teams helped streamline problem solving, enrich collaboration, and coordinate implementation. Root cause analysis and evidence review framed their practice adaptation, ensuring that they prioritized patient and health care worker safety. Daily safety huddles engaged frontline providers and promoted dissemination of the revised interventions. Telemedicine oversight and real-time ICU dashboards enabled system-wide implementation, goal setting, and continuous performance feedback. Under their revised guidelines, the rate of endotracheal tube obstruction among mechanically ventilated patients with Covid-19 decreased from 9.2% to less than 1%, and reintubation rates decreased from 36% to 9%.

KEY TAKEAWAYS

- » Health systems can follow the I-READI conceptual framework to prepare for and respond to quality and patient safety challenges during times of crisis, such as emerging infectious diseases, natural disasters, or capacity strain.
- » Integrating quality and safety teams, both vertically and horizontally, can help organizations streamline communication of clinical concerns, enrich collaboration on solutions, and coordinate rapid change.
- » Brief daily safety huddles promote a culture of safety and engage frontline providers in rapidly identifying problems and developing clinically informed strategies for risk mitigation.
- » Root cause analysis and evidence review are key for framing practice change that prioritizes patient and health care worker safety.
- » Technology such as ICU telemedicine and real-time ICU dashboards enables standardized implementation, goal setting, and real-time performance feedback to support practice improvements.

The Challenge

To effectively address the Covid-19 crisis, health systems must adapt operations in response to rapidly changing and unpredictable conditions. System leaders and frontline providers must work together to address quality and safety challenges with unprecedented speed and coordination.

In the 2 weeks after the first extubation (breathing tube removal) of a patient with Covid-19 in the University of Pennsylvania Health System (UPHS), which we call in this article "day 0," we noted multiple reports of two airway complications in patients on mechanical ventilators: endotracheal tube (ETT) obstructions and reintubations. ETT obstruction, when a breathing tube becomes completely clogged with mucus and debris, is usually rare but can be life threatening. Reintubation, placing a new breathing tube to put a patient back on a ventilator after initial extubation, is ultimately necessary in about 10% of all mechanically ventilated patients, with associated increased mortality.[1] An important cause of reintubation is upper airway edema (swelling) from damage to the airway during intubation or prolonged irritation from an ETT.[2] Both complications are more likely in patients who have been mechanically ventilated for a long time.

Three sentinel events at two hospitals within a 4-day period led to a comprehensive assessment of these problems: one patient with postextubation stridor (PES) — a sign of airway narrowing caused by edema — died after a failed attempt at reintubation. Two patients experienced ETT obstructions, one causing cardiac arrest and the other resulting in a pneumothorax (collapsed lung) that required chest tube placement. On review, 9.2% of intubated patients during this period required ETT exchange (immediate replacement with a new tube) for tube obstructions, and 36% required reintubation within 48 hours of extubation. Airway management in patients with Covid-19 was recognized as an urgent patient safety issue.

The Goal

Our goal was to quickly adapt our management of ventilated patients with Covid-19 to reduce the high rate of airway complications. To accomplish this, we aimed to: (1) integrate existing quality and safety teams across institutions and disciplines to ensure that safety challenges would be rapidly identified and mitigated; (2) standardize operations and procedures across multiple hospitals, units, and staffing models; and (3) prioritize and ensure the safety of both patients and health care workers, including physicians, advanced practice providers, nurses, respiratory therapists, and certified nursing assistants. We developed the I-READI (for Integration, Root Cause Analysis, Evidence Review, Adaptation, Dissemination, and Implementation) framework on the basis of our experience and retrospective analysis of data from before and after the airway practice improvements.

The Team

As an integrated health system, we leveraged our tiered critical care quality and safety infrastructure. First, we established the UPHS Covid-19 Task Force to coordinate many aspects of coronavirus management. We did so by repurposing our health system's multidisciplinary Critical Care Committee (CCC), which includes clinical leaders from each of our six health system hospitals: UPHS Chief Medical Officer, Chief Operating Officer, Chief Medical Information Officer, and Vice Chair for Quality and Safety; Medical, Surgical, Cardiovascular, Anesthesia, and Neuro Critical Care division chiefs and ICU directors; directors of Medical Critical Care Operations and Respiratory Care Services; nurse managers; clinical pharmacy specialists; and the directors of the Medical Critical Care Bioresponse Team and of our ICU telemedicine program (Penn E-lert eICU). Second, we expanded the representation of respiratory care and airway safety leadership from the health system and hospitals. Third, we included members of hospital-level CCCs and unit-based clinical leadership teams and increased communication among groups on the Covid-19 Task Force. All groups contributed to the development, dissemination, implementation, and monitoring of new airway guidelines.

The Execution

Drawing on lessons learned from our health system's rapidly coordinated changes to ventilator management practices, we developed a conceptual framework for responding to patient safety challenges: the I-READI framework. This approach highlights the strengths of our health system's response: integration of quality and safety teams, root cause analysis, targeted evidence review, adaptation of clinical practice, efficient dissemination, and systematic implementation using technology.

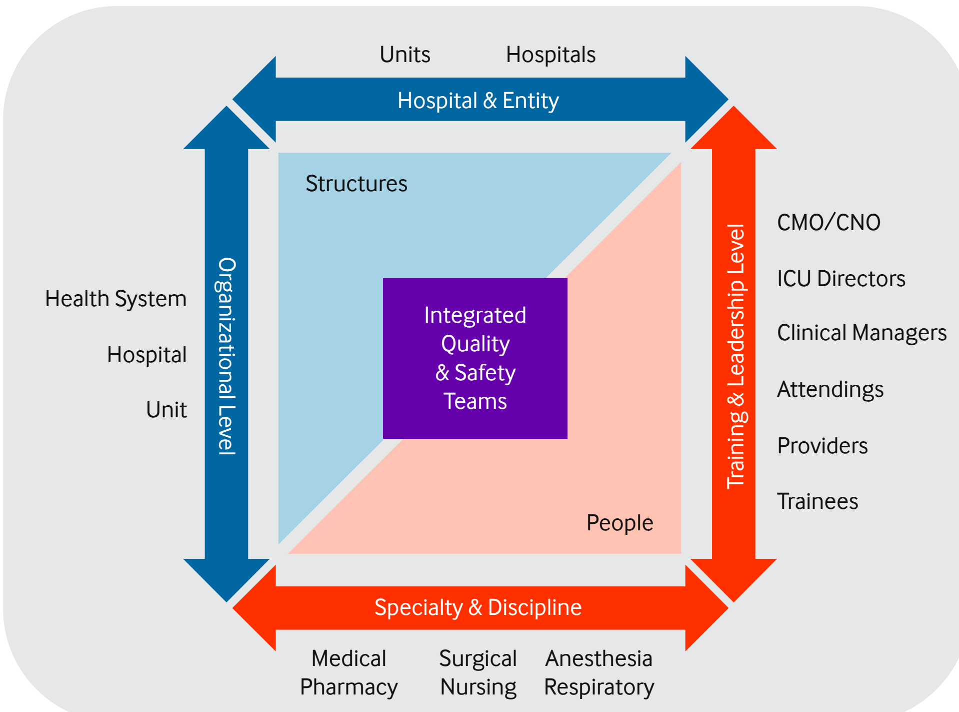
Integration

To facilitate communication and collaboration, we integrated quality and safety teams vertically and horizontally to strengthen our highly matrixed organization (Figure 1).

FIGURE 1

Vertically and Horizontally Integrated Quality and Safety Teams

Integrating the UPHS's quality and safety teams permitted rapid identification of patient safety problems, multidisciplinary collaboration on solutions, and coordinated, efficient, and effective implementation across our health care system. CMO = Chief Medical Officer, CNO = Chief Nursing Officer.



Source: The authors

Vertical integration linked safety efforts at the unit, hospital, and system levels and brought together trainees, advanced practice providers, attendings, ICU and division leaders, and hospital administrators. Horizontal integration engaged participants from across UPHS hospitals and disciplines, such as nursing, respiratory therapy, pharmacy, medicine, surgery, and anesthesiology. We also integrated safety meetings into clinical practice, instituting 15-minute virtual daily safety huddles, led by hospital CCCs and including on-service clinicians, to identify problems, inform decision-making, and disseminate guidelines. We also used system-wide emergency safety huddles as needed to alert clinicians to safety problems.

Root Cause Analysis

We held emergency safety huddles within hours of the sentinel events, which led to an aggregate root cause analysis[3] and a systematic review of both airway complications. Root causes were identified in three domains: (1) inadequate airway humidification; (2) high rates of upper airway edema; and (3) underdetection of high-risk patients.

> *"Institutions can follow the I-READI conceptual framework — Integration, Root Cause Analysis, Evidence Review, Adaptation, Dissemination, and Implementation — to prepare for and respond to quality and safety challenges during crises."*

We initially used heat and moisture exchangers (HMEs) in all ventilator circuits to reduce health care worker exposure risk, given recommendations during the first severe acute respiratory syndrome outbreak.[4,5] However, we suspect that HMEs did not provide adequate humidification for patients with Covid-19,[6,7] who often required high rates of ventilation (minute ventilation more than 10 L). This led to thick secretions, poor airway clearance, and ETT obstruction. Furthermore, a lack of standardized monitoring of airway resistance may have allowed progressive obstruction to go unrecognized. Several reintubated patients had passed cuff leak testing (CLT), but a subsequent review revealed that the test was not performed according to recommendations.[8,9] In addition, none of the reintubated patients were identified as high risk for PES and therefore did not receive preventive steroids.

Evidence Review

During this time, clinicians at other institutions, in informal and published communications, noted a high incidence of reintubation and ETT obstructions in patients with Covid-19, substantiating a safety problem requiring a paradigm shift in how we categorized "high-risk" patients.[10-12] Prior studies support the use of pre-extubation steroids to decrease PES rates and the need to reintubate high-risk patients.[9] Our extubation protocol did not specify a threshold for mechanical ventilation that defines a high-risk extubation, whereas published guidelines recommend a threshold of 6 days.[13] Because many patients with Covid-19 appeared to be at risk for poor airway clearance leading to ETT obstruction, we compared heated humidification (HH) systems, which actively increase the water vapor content of ventilated air, with HME devices, which passively store and release humidity from patients' exhaled breath. We found evidence suggesting that HH may be more effective than HMEs in reducing the risk of obstruction[14,15] and a paucity of evidence that HMEs lower exposure risk for health care workers.

Adaptation

The rising number of airway complications demanded that we rapidly adapt and simultaneously implement multiple interventions. Coordination across hospital CCCs and multidisciplinary collaboration enabled us to achieve efficient widespread adoption. On day 8 after our first routine

Table 1. Ventilator Liberation and Extubation Bundle Components and Rationale

Bundle Component	Intervention	Rationale
Universal HH	HH for all new and existing ventilator circuits	HMEs less effective with high minute ventilation (>10 L)[6,7]
		Less frequent obstruction with HH[14,15]
Active monitoring for ETT obstruction	Airway resistance monitoring every 12 hours	Reductions in ETT diameter detected as an increase in ETT resistance[16]
	Just-in-time education for providers and respiratory therapists	
SBT	Minimal settings for SBT: pressure support 0–5 cm H_2O, PEEP 5 cm H_2O	Identify patients at increased risk of failed extubation[17]
Pre-extubation CLT	CLT 24 hours prior to and immediately before planned extubation	Predict upper-airway obstruction, laryngeal edema, and PES[13]
Pre-extubation steroids	Methylprednisolone 40 mg IV every 12 hours started 12 hours before anticipated extubation regardless of CLT results	Reduce laryngeal edema and risk for PES and reintubation[18,19]
Multidisciplinary airway assessment	If failed pre-extubation CLT, critical care, ENT, and anesthesia team members review case	Coordinated, informed discussion of difficult airway management, consideration of tracheostomy
All Covid-19 extubations high risk	Anesthesia present for all Covid-19 extubations	Immediate availability of the most experienced provider[20]

HH = heated humidification, HME = heat and moisture exchanger, ETT = endotracheal tube, SBT = spontaneous breathing trial, PEEP = positive end-expiratory pressure, CLT = cuff leak testing, PES = postextubation stridor, IV = intravenously, ENT = ear, nose, and throat. This table includes our initial recommendations in response to Covid-19 airway safety concerns. We have continued to update our guidelines; the information presented here does not necessarily reflect current Penn Medicine practice or recommendations. Source: The authors.

Covid-19 extubation, we mandated HH circuits for all new intubations, and on day 11, we transitioned 78 mechanically ventilated patients in seven ICUs from HME to HH within 24 hours. Also on day 11, we convened an emergency safety huddle to revise our ventilator liberation and extubation guidelines. On day 12, we updated our ventilation and extubation protocols with a bundle of new recommendations that considered all patients with Covid-19 high risk for airway complications[6,7,13-20] (Table 1).

Our revised program also standardized an interdisciplinary approach to airway management through the following recommendations: formal designation of intubated patients with Covid-19 as a high-risk extubation in the electronic health record; anesthesia presence at all Covid-19 extubations; surgical or anesthesia consultation for patients who failed pre-extubation CLT; and activation of our airway rapid response system[21] for suspected ETT obstructions.

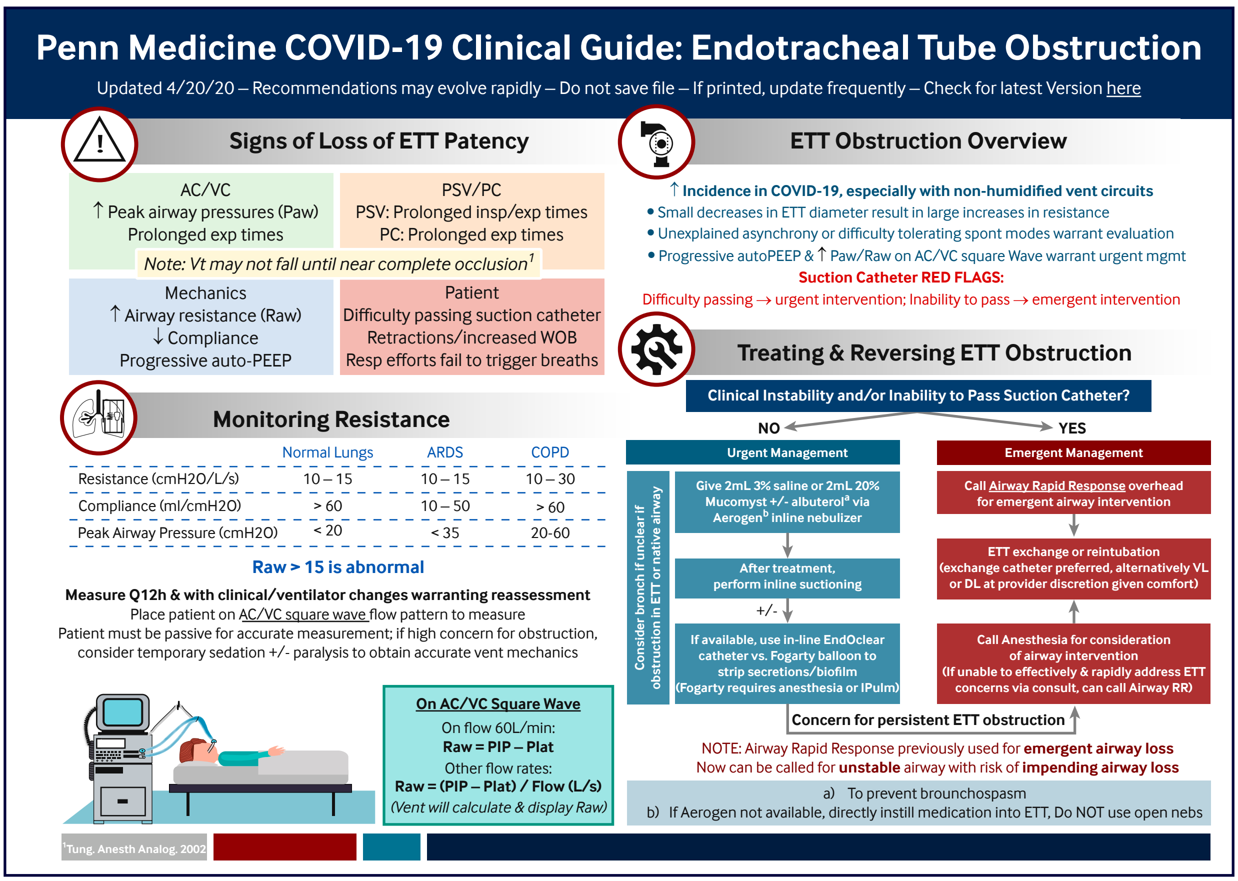
Dissemination

By including on-service clinicians in daily safety huddles, we were able to immediately implement guideline changes. We broadcast the recommendations through many channels, including a publicly accessible Covid-19 Learning website,[22] Pulmonary and Critical Care division faculty meetings, fellow-led educational conferences, and weekly operations and clinical update meetings for health system faculty, fellows, advanced practice providers, and pharmacists providing care in Covid-19 ICUs. Standing conferences, held virtually during the pandemic, enabled clinicians across our hospitals to access the latest recommendations, and we widely distributed one-page clinical guides summarizing the new procedures to facilitate bedside implementation (Figure 2A, Figure 2B).

FIGURE 2A

Penn Medicine Covid-19 Clinical Guide: Endotracheal Tube Obstruction

The UPHS developed two Covid-19 clinical guides summarizing the new recommendations on ETT obstruction and extubation for broad dissemination and bedside implementation. Both included visual aids, algorithms, and embedded links to the most updated version. This figure includes our initial recommendations in response to Covid-19 airway safety concerns. We have continued to update our guidelines; the information presented here does not necessarily reflect current Penn Medicine practice or recommendations. +/− = with or without, AC = assist control, ARDS = acute respiratory distress syndrome, bronch = bronchoscopy, COPD = chronic obstructive pulmonary disease, DL = direct laryngoscopy, exp = expiration, insp = inspiration, IPulm = interventional pulmonology, nebs = nebulizers, PC = pressure control, PEEP = positive end-expiratory pressure, PIP = peak inspiratory pressure, Plat = plateau pressure, PSV = pressure support ventilation, Resp = respiratory, RR = respiratory rate, Q12h = every 12 hours, VC = volume control, Vent = ventilator, VL = video laryngoscopy, Vt = tidal volume, WOB = work of breathing.

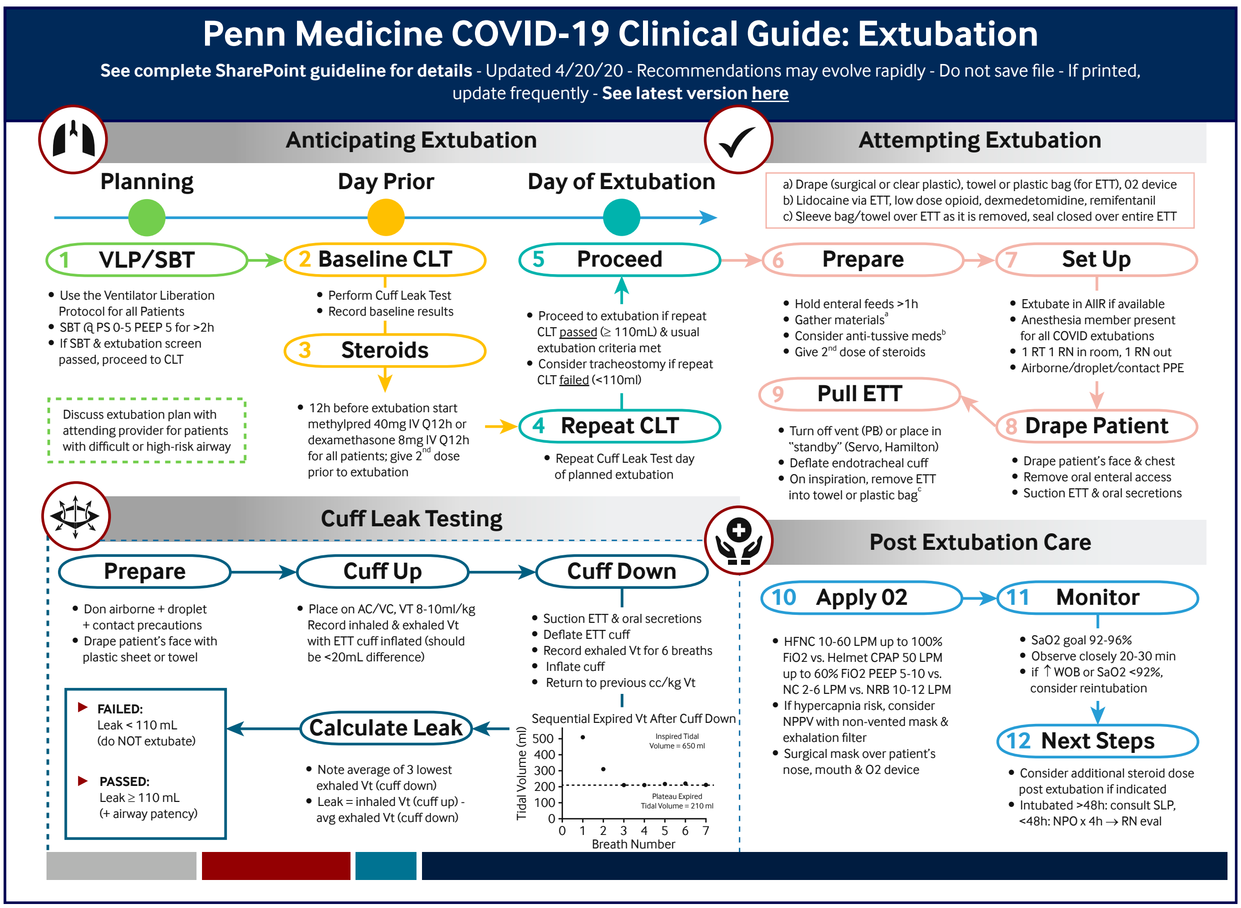


Source: The authors

FIGURE 2B

Penn Medicine Covid-19 Clinical Guide: Extubation

The UPHS developed two Covid-19 clinical guides summarizing the new recommendations on ETT obstruction and extubation for broad dissemination and bedside implementation. Both included visual aids, algorithms, and embedded links to the most updated version. This figure includes our initial recommendations in response to Covid-19 airway safety concerns. We have continued to update our guidelines; the information presented here does not necessarily reflect current Penn Medicine practice or recommendations. AIIR = airborne infection isolation room, CLT = cuff leak test, CPAP = continuous positive airway pressure, h = hour, HFNC = high-flow nasal cannula, IV = intravenous, LPM = liters per minute, min = minutes, NC = nasal cannula, NPO = nothing by mouth, NPPV = noninvasive positive-pressure ventilation, PB = Puritan Bennett, PPE = personal protective equipment, PS = pressure support, Q12h = every 12 hours, RN = registered nurse, RT = respiratory therapist, SBT = spontaneous breathing trial, SLP = speech-language pathologist, VLP = ventilator liberation protocol, Vt = tidal volume, WOB = work of breathing.



Source: The authors

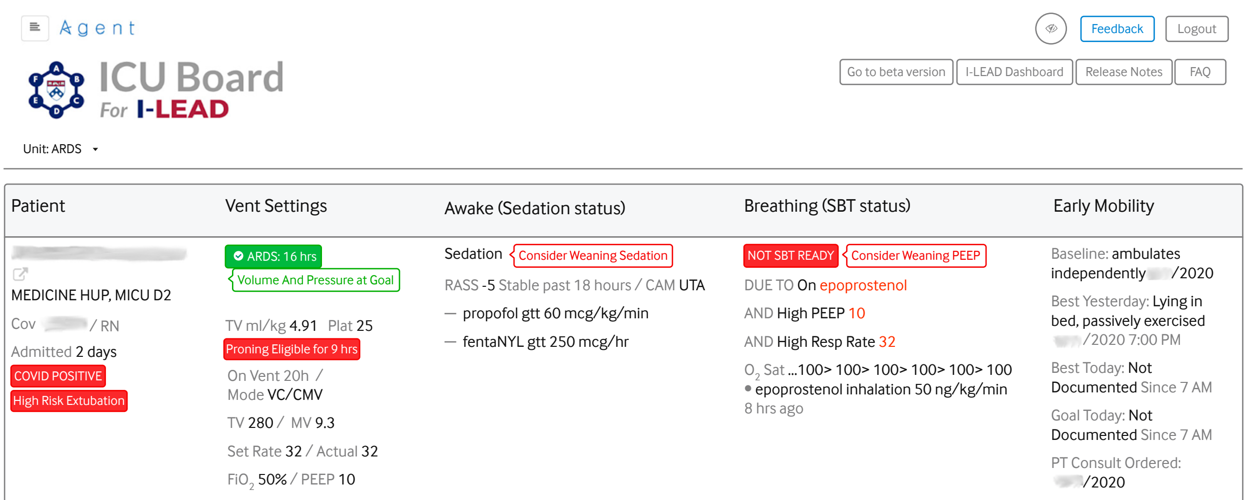
Implementation

Our Web-based ICU Liberation Dashboard (I-LEAD) and Penn E-lert eICU proved vital for systematically scaling up the new recommendations with high reliability. Launched in 2016, the I-LEAD Dashboard displays real-time data and intervention suggestions for ARDS (acute respiratory distress syndrome) metrics, ventilator and sedation liberation (removal), airway management, and early mobilization[23] (Figure 3). We also incorporated the new guidelines into our patient safety checklists, which are reviewed on daily board rounds using the I-LEAD Dashboard as a framework.

FIGURE 3

I-LEAD ICU Dashboard

The UPHS's I-LEAD Dashboard displays real-time clinical metrics, alerts, and suggested interventions for ICU patients. The new Covid-19 airway management safety recommendations for systematic implementation and monitoring were incorporated. Other institutions could use similar dashboard tools to implement and monitor a variety of quality and safety programs. ARDS = acute respiratory distress syndrome, CAM = confusion assessment method, CMV = continuous mandatory ventilation, D2 = day 2, HUP = Hospital of the University of Pennsylvania, MICU = medical ICU, PEEP = positive end-expiratory pressure, PT = physical therapist, RASS = Richmond Agitation Sedation Scale, Resp = respiratory, RN = registered nurse, SBT = spontaneous breathing trial, UTA = unable to assess, VC = volume control, Vent = ventilator.



Source: The authors

We engaged our ICU telemedicine program to provide virtual assistance with ventilator management and extubation protocols through real-time, in-room video chat. Virtual respiratory therapy (eRT) support — delivered by therapists working remotely — provided an additional layer of safety to ensure proper procedures around airway resistance, ventilator settings and alarms, CLT, humidification delivery, and the documentation of extubation risk.

Hurdles

Rapid Consensus

The need to reach rapid consensus on clinical recommendations for Covid-19–related airway management was challenging to coordinate across varied practice patterns and, at times, resulted in dissenting expert opinions. A shared goal of patient and clinician safety promoted open discussion about potential medication side effects, exposure risks, and the availability of resources. We updated the recommendations with ongoing feedback from a variety of stakeholders; for instance, after clinicians raised concerns about steroid-induced delirium, we decreased the recommended dose and duration of pre-extubation steroids.

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Standardization and Quality Assurance

During our crisis response, many respiratory therapists and frontline providers were redeployed outside their usual unit assignments. Educating new staff to critical procedures presented a significant hurdle to quality assurance. For example, even after our switch to universal HH, some respiratory therapists continued to place HMEs for new intubations. Unit-based respiratory and nursing leaders were instrumental in providing just-in-time teaching, reinforced by bedside education and oversight from the eRT program.

Health Care Worker Safety

Some of the new airway management procedures had the potential to increase providers' real and perceived risk of infectious exposure. For example, the risks of using an aerosol-generating procedure like bronchoscopy to check on a possible complication like ETT obstruction had to be weighed against the risks of not checking and then needing an emergent (urgent) intervention, such as ETT exchange or reintubation, both of which also produce aerosols that could infect patients and providers. Expert guidance to minimize exposure was included in all procedural recommendations.

A Moving Target

Keeping our providers and posted protocols up to date was challenging in light of rapidly evolving practice. For example, our ETT obstruction management algorithm initially included trying an ETT clearance device, but this recommendation quickly became obsolete when supplies ran out. To help viewers stay current, we embedded hyperlinks to the latest versions of the guidelines in our online airway management materials.

Metrics

We performed a retrospective review of 170 mechanically ventilated patients with Covid-19 cared for over a 6-week period at our two urban teaching hospitals: Penn Presbyterian Medical Center and the Hospital of the University of Pennsylvania. This project was categorized as Quality Improvement by the University of Pennsylvania's Institutional Review Board.

Reintubation rates were calculated as a percentage of routine (nonpalliative) extubations followed by reintubation within 48 hours. ETT obstruction rates were calculated as a percentage of mechanically ventilated patients requiring ETT exchange for confirmed tube obstruction during a given time period.

In the first 14 days of our Covid-19 extubation experience — before the airway management protocol revisions — nine of 25 routinely extubated patients (36%) required reintubation within 48 hours. Six patients had PES and/or confirmed laryngeal edema, with median time to reintubation of 3.2 hours (interquartile range [IQR] 0.73–4.08). Median duration of mechanical ventilation before extubation among patients who were reintubated was 8.2 days (IQR 4.4–12) and 7.4 days (IQR 4.0–11.7) among all extubations during the same time period. Between day 6 and day 11, 11 patients (9.2%) had ETT obstruction requiring urgent ETT exchange. Median duration of mechanical ventilation before tube exchange was 11.8 days (IQR 5.5–16.2).

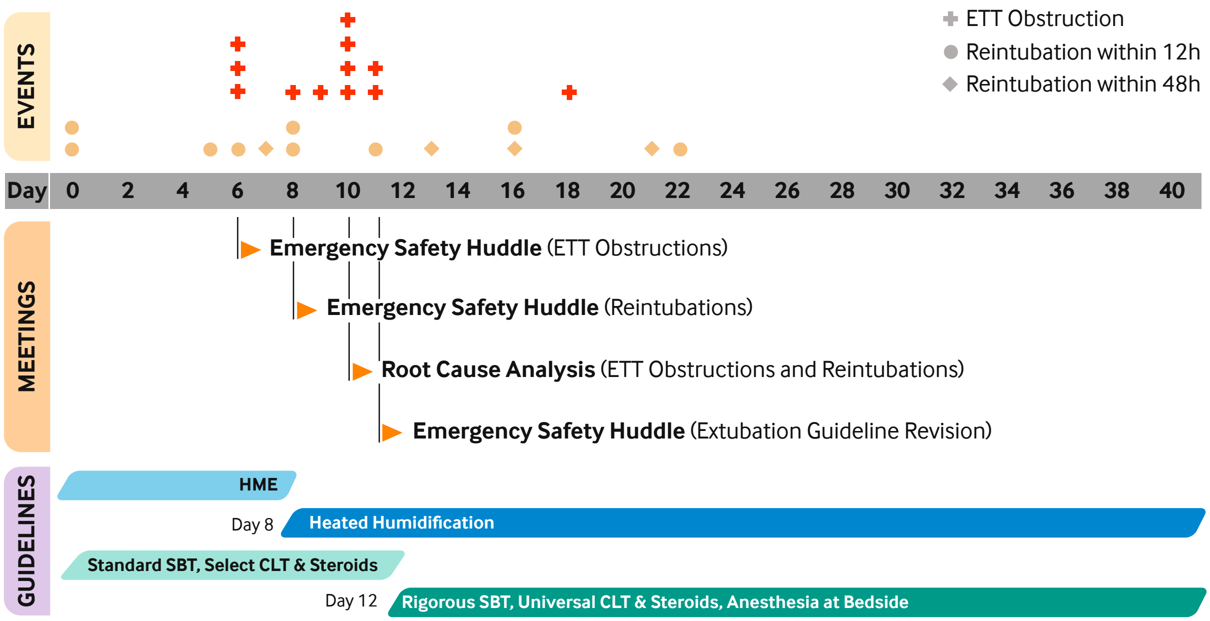
"*Since implementation of our clinical recommendations, both ETT obstruction and reintubations among patients with Covid-19 have declined.*"

Since implementation of our clinical recommendations, both ETT obstruction and reintubations among patients with Covid-19 have declined (Figure 4, Figure 5). The share of patients with an obstructed ETT requiring exchange declined from 9.2% to 0.71% (11 to one) after the guideline changes. Reintubations fell from 36% to 9% (four of 44 patients), despite continued prolonged duration of mechanical ventilation among routinely extubated patients with Covid-19 (median 8.7 days before and 13.0 days after guideline changes). This postintervention reintubation rate resembles our pre–Covid-19 reintubation rate of 10%, which is consistent with the incidence noted in the literature.[1] In the final 19 days of the 6-week study period, we saw no reintubations within 48 hours of extubation.

FIGURE 4

Airway Complications Among Patients with Covid-19 in Relation to Mechanical Ventilation Guideline Changes over Time

Days are numbered from date of first routine extubation in a patient with Covid-19, which the UPHS calls day 0. Endotracheal tube (ETT) obstruction cases were defined by confirmed tube obstruction requiring ETT exchange. CLT = cuff leak testing, HME = heat and moisture exchangers, SBT = spontaneous breathing trial.

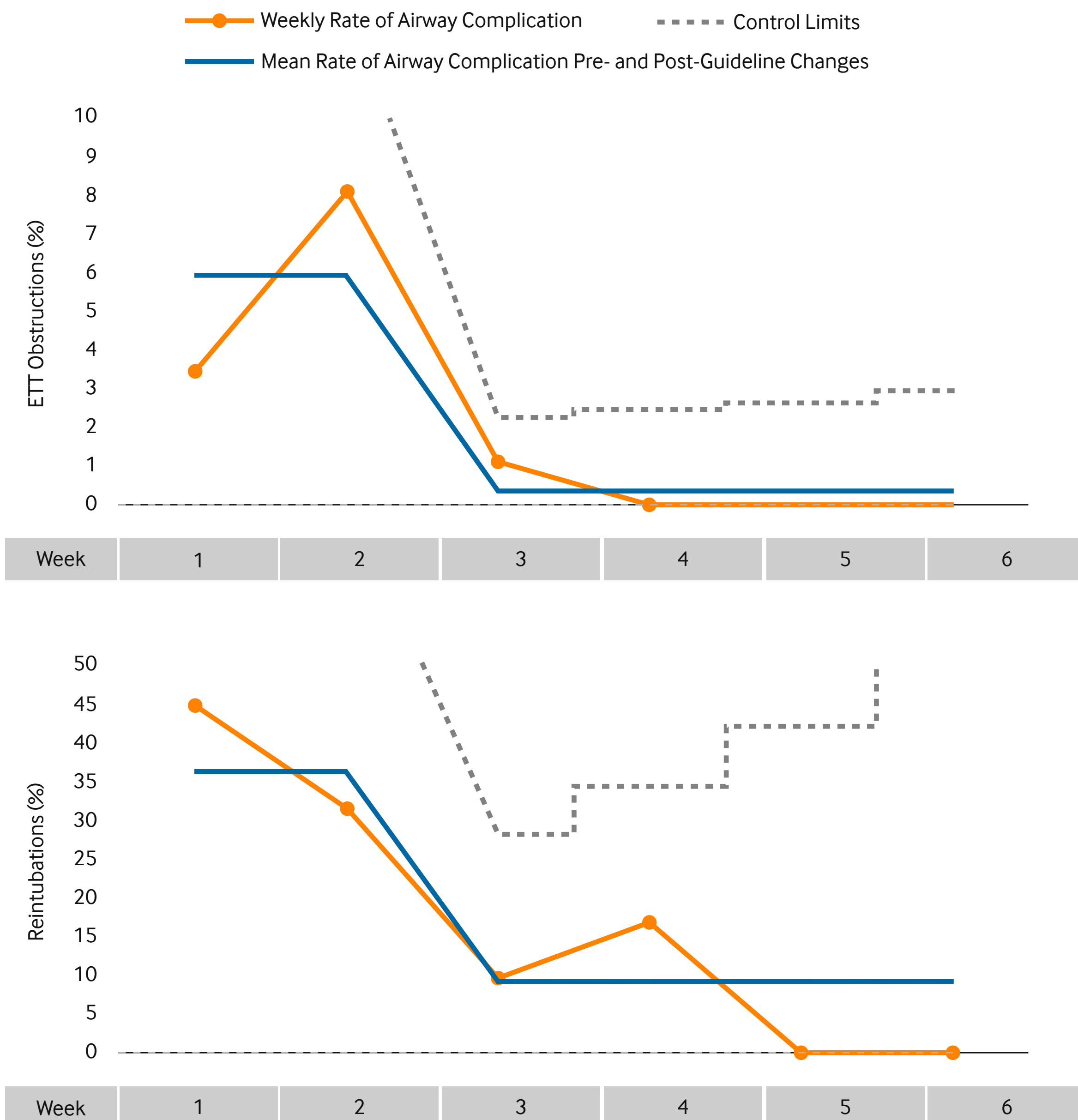


Source: The authors

FIGURE 5

Weekly ETT Obstruction and Reintubation Rates Among Patients with Covid-19

These P-charts depict weekly rates of airway obstruction among patients with Covid-19, along with the mean weekly rates before and after guideline changes at the UPHS. Weeks were defined by 7-day periods from the day of first routine extubation in a patient with Covid-19. Endotracheal tube (ETT) obstruction rates were calculated as a percentage of mechanically ventilated patients requiring ETT exchange for confirmed luminal obstruction.



Source: The authors

Where To Start

Institutions can follow the I-READI conceptual framework (Figure 6) — Integration, Root Cause Analysis, Evidence Review, Adaptation, Dissemination, and Implementation — to prepare for and respond to quality and safety challenges during crises, including periods of capacity strain, limited resources, emerging infectious diseases, natural disasters, or mass casualty events:

- Integrate quality and safety teams vertically and horizontally and institute brief daily safety huddles and ad hoc emergency safety huddles.
- Use aggregate root cause analysis to systematically and simultaneously review multiple cases with a common adverse event.[3]
- Perform an evidence review that considers intervention efficacy and safety for both patients and health care workers.
- Adapt current practice by reframing the application and delivery of known evidence-based interventions.
- Disseminate practice changes directly to on-service providers through standing meetings and visual aids.
- Implement systematic, standardized, and scalable change using innovative tools like virtual dashboards and ICU telemedicine support.

FIGURE 6

I-READI Framework for Quality and Safety Crisis Preparedness

The I-READI Framework for Quality and Safety Crisis Preparedness from the UPHS.

Integration	• Vertical and horizontally integrated safety teams • Daily and ad hoc Emergency Safety Huddles
Root Cause Analysis	• Aggregate review of cases with common events
Evidence Review	• Intervention effectiveness • Patient and health care worker safety
Adaptation	• Reframe application and delivery of evidence-based interventions
Dissemination	• Standing meetings and visual aids
Implementation	• Systematic, standardized, scalable change • Virtual ICU telemedicine suppport, ICU dashboards

Source: The authors

Future Directions

Since this initial safety response, our guidelines have continued to evolve in response to our growing experience. As the Covid-19 pandemic progresses, we will continue to improve our safety strategy and processes, adjusting the frequency of safety meetings to reflect clinical needs. Harnessing resources like our Center for Evidence-based Practice will help streamline additional rapid literature reviews. More work is needed to better incorporate real-time data into ICU dashboards to monitor processes and track goals. To inform care moving forward, institutions should assess the clinical impact and potential unintended consequences of empirically applied clinical practice changes. We plan to examine the influence of our new airway management guidelines on the duration of mechanical ventilation, ICU length of stay, and frequency of tracheostomy placement.

Editors' Note: Barry David Fuchs and Arshad A. Wani are co-last authors of this article.

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