# A PROSPECTIVE COMPARISON OF THE DISPOSABLE I-VIEW VERSUS THE DURABLE VIDEO LARYNGOSCOPES IN THE EMERGENCY DEPARTMENT

March 8, 2021
NCT: TBD

**PROTOCOL TITLE: A prospective comparison of the disposable i-view versus the durable video laryngoscopes in the emergency department**

## SECTION A: RESEARCH TEAM AND LOCATIONS

### A1. RESEARCH TEAM

| Study Role | Institution/Company and Contact Information |
|---|---|
| **Sponsor** | *Organization/Institution/Company:* N/A<br>*Address:* N/A<br>*Point of Contact:* N/A<br>*Name and Degree:* N/A<br>*Title:* N/A<br>*Phone Number:* N/A<br>*Email:* N/A |
| **Principal Investigator** | *Name, Rank, and Degree:* Steven Schauer, MAJ, DO MSCR<br>*Title:* Physician<br>*Institution:* US Army Institute of Surgical Research<br>*Address:* 3698 Chambers Pass, JBSA Fort Sam Houston, TX 78234<br>*Phone Number:* 210-771-0706<br>*Email:* steven.g.schauer.mil@mail.mil |
| **Associate Investigator(s)** | *Name, Rank, and Degree:*<br>*Title:*<br>*Institution/Company:*<br>*Address:*<br>*Phone Number:*<br>*Email:* |
| **Ombudsperson** | *Name, Rank, and Degree:* N/A<br>*Title:* N/A<br>*Institution/Company:* N/A<br>*Address:* N/A<br>*Phone Number:* N/A<br>*Email:* N/A |

### A2. ROLES AND RESPONSIBILITIES

#### A2.1 Principal Investigator

*Name:* Steven Schauer
*Study Responsibilities:* Responsible for the conduct of the study in accordance with the protocol. Responsible for the conduct of the study in accordance with the protocol. Maintenance of a list of appropriately qualified persons to whom significant study-related responsibilities have been delegated.

#### A2.2 Associate Investigator(s)

*Name(s):* N/A
*Study Responsibilities:* N/A

### A2.3 Ombudsperson

*Name(s):* N/A
*Study Responsibilities:* N/A

## A3. RESEARCH LOCATIONS

US Army Institute of Surgical Research
Brooke Army Medical Center

## A4. MULTISITE RESEARCH

***Lead Site**:*
*Lead Site Investigator:*
*IRB that will review for the lead site:*
*Function/Role of Lead Site*:

***Performance Site**:*
*Performance Site Investigator*:
*IRB that will review for the Performance Site*:
*Function/Role of Performance Site*:

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## SECTION B: RESEARCH METHODOLOGY

## B1. ABSTRACT

The US Military is rapidly transitioning into preparing for multi-domain operations. Previous data demonstrates that the most common airway replaced in the prehospital combat setting is endotracheal intubation. Previous studies have suggested that video laryngoscopy (VL) is superior to direct laryngoscopy (DL), which is most prominently noted in novice users. However, the current durable equipment video laryngoscopes are very expensive and cost prohibitive for dispersion around the battlefield. The i-view is a novel video laryngoscope that is marketed for VL and is inexpensive and disposable. Both the durable VL and the i-view are already in use in our emergency department (ED). We are also already collecting data using these devices as part of an approved protocol for an airway registry. We are seeking to utilizing a clinical rotating protocol to compare these two devices in the emergency department.

## B2. BACKGROUND AND SIGNIFICANCE

The emergency department (ED) at the Brooke Army Medical Center (BAMC) has collecting data under protocol C.2015.140 for an airway registry and is part of our routine business operations.[1, 2] The registry is primarily targeted at collecting data on every intubation that happens in the ED. Our department has been capturing data under this protocol for several years and all our staff are voluntarily providing case report form data. We will leverage the experience with this previous study to support this current protocol. We are seeking to conduct this study over-the-top of that protocol in the form of a clinical rotating protocol.

Effective prehospital interventions for combat injuries are critical for combat casualty survival. Airway compromise is the second leading cause of potentially preventable death in the prehospital, combat setting – second only to hemorrhage.[3, 4] Airway skills can be difficult to obtain and maintain for those in the prehospital combat setting.[5] The prehospital, combat environment is chaotic with significant challenges not present in the fixed-facility setting. Video laryngoscopy (VL) came about in the early 2000s. VL is a device that allows the operator to get a view of the intubating airway anatomy indirectly through a camera that projects

onto a monitor.[6, 7] While definitive evidence is lacking, observational evidence suggests that VL is superior to DL.[8, 9]

The US military forward stages the GlideScope® VL to many of the Role 2s and Role 3s, however, the Glidescope is not part of the sets, kits and outfits (SKO) for the Role 1 or Role 2 (without surgical team augmentation). However, the cost of acquiring this device has been cost prohibitive to push far-forward to all locations of care early in the chain-of-survival. A VL device is on the market – the i-view® (https://us.intersurgical.com/info/i-view) - which is fully disposable and single-use. The device costs approximately $100 (USD) which is fraction of the cost of a GlideScope which the Army pays $12,292.67 per device. (NSN 6515-01-572-7262, ZLIN Z05814) Moreover, it is one-time use and disposable. If an i-view device malfunctions or gets used in a far-forward area it is simply disposed of, whereas a Glidescope requires specialized skills to repair them if it malfunctions as well as proper cleaning equipment. Due to its inexpensive design, the i-view would be an ideal device to push to far-forward areas where maintenance, battery charging, repairs and stocking of accessories would become much less challenging.

In our department we routinely use VL devices for intubation including the reusable GlideScope and Storz systems. The i-view is disposable VL device and is already in use in our ED as part of routine clinical care.[10] This FDA-approved device is technically equivalent and we are using it in the FDA-cleared manner. However, it remains unclear whether it performs similarly in a pragmatic, clinical environment. We seek to determine if this device has similar performance characteristics in an emergency airway management setting.

## B3. MILITARY RELEVANCE

Airway obstruction is cited as the second leading cause of potentially preventable death on the battlefield.[4] Relative to hemorrhage, there has been relatively little scientific development for airway management on the battlefield. Direct laryngoscopy is a challenging skill to develop and maintain which is a primary reason why it is not in the combat medic armamentarium. However, the advent of video laryngoscopy has significantly improved intubation success, likely side-stepping some of the skills required for direct laryngoscopy. Until now, dispersion of video laryngoscopes across the battlefield into the combat medic aid bags has been cost prohibitive. A new video laryngoscope, the i-view, is single-use and inexpensive – a potentially feasible technology for the far forward medical provider.

## B4. OBJECTIVES/SPECIFIC AIMS/RESEARCH QUESTIONS

We are seeking to implement a clinical rotating protocol in which we will use alternating months for which VL device is to be used comparing the i-view to the reusable devices within our department.

We are seeking to answer the following questions:

(1) Does the i-view have similar first pass success rates compared to the reusable VL devices (e.g. GlideScope, C-Mac)?
(2) Does the i-view have similar attempts required for placement compared to the reusable VL devices?

## B5. RESEARCH PLAN

### B5.1 Research Design

We are seeking to conduct a prospective study comparing outcomes between the disposable i-view and our other reuseable VL devices.

### B5.2 Research Subjects/Population(s)

#### B5.2.1 Subject Population(s)

We are seeking all patients undergoing intubation for which the clinician *chooses* to use VL.

#### B5.2.2 Number of Subjects, Records, and/or Specimens

We are seeking all encounters for which a VL intubation happens over the course of 2 years. Our limit will be based on the number of times the procedure occurs. Based on previously published data, we are estimating ~200 intubations with 55% using VL per year based on our previous experience.[2]

#### B5.2.3 Inclusion Criteria

We are seeking any encounter for which the patient undergoes VL intubation as part of routine clinical care.

#### B5.2.4 Exclusion Criteria

No intubation will be excluded so long as VL is used.

### B5.3 Research Procedures

| | |
|---|---|
| Intubation Procedure | All intubations will be performed at the direction of the attending clinician. The decision to intubate is based purely on clinical factors by the primary team. The decision to use VL device will be at the direction of the clinical team. No patient will be recruited specific for this procedure. |
| Clinical Rotating Protocol | Currently in our emergency department, there are multiple VL devices that are already in use. These devices include the i-view as well as multiple reusable VL devices such as the GlideScope and the Storz C-Mac system. To ensure that we get high quality data, we are seeking to implement a clinical rotating protocol in which we will alternate months. For the clinical rotating protocol, one month will be the i-view and the next month will be the durable VL devices (e.g. January will be i-view, February will be the durable VL devices). As part of the clinical rotating protocol, we will place clinician-facing signage to the clinician work areas, on the airway boxes, and on the equipment in the department indicating which device is for that month if choosing to participate in the study. During the i-view month we may use a colored bag over the durable VL devices. Of note, our devices are routinely covered in a protective bag to keep it clean when not in use (e.g. aerosolized COVID, etc.) During the durable VL month we will place signs on the i-view device indicating that it is not an i-view month. We will use educational reminders to the staff about the protocol schedule and the purpose of the study throughout. We must note, however, the devices will remain in the department should the attending clinician need to break the protocol and obtain any of the devices. We will ensure that clinicians are able to access any of the equipment that they may want to utilize easily during emergent situations. |
| Data Collection | Data will be collected using the standardized data collection form that gathers routine healthcare data in a standardized form and ensures that the study team can identify intubations that occur. That information will then be linked to patient outcome data extracted by study team members. |

### B5.4 Data Collection

| Data Element/Variable | Source | Operational Specific |
|---|---|---|
| Demographics, procedural data, complications, procedural operator data | Case report form | The data will be extracted into a Microsoft Excel database |
| Outcome data – Please see data variable collection appendix listed below | Case report form/T-system/trauma flow sheets/AHLTA/Impax/Essentris/MHS | The data will be extracted into a Microsoft Excel database |

| | | |
|---|---|---|
| | Genesis | |

### B5.5 Managing Data and/or Human Biological Specimens for this Research

Data will be documented using the enclosed case report form which is the same form already in use for BAMC protocol C.2015.140. This will ensure that our department personnel are already familiar with the documentation, the flow of documentation, and minimizing duplication of efforts. Upon completion of case report form, it will be combined with the data collection from the EMR and collated into a study database using Microsoft Excel using the same sequential numbering scheme. This dataset will be stored on government-issued computers and/or IMD-approved network shared drives available to the study team members. If data needs to be transmitted electronically, we will use official email communications or and approved file transfer system.

### B5.6 Managing Data and/or Human Biological Specimens for Future Research

N/A – This section is not applicable

### B5.7 Devices, Drugs, Dietary Supplements, Nutritional Supplements, And Biologics

#### B5.7.1 Devices

##### 5.7.1.1 FDA-approved device being used in this research according to the approved labeling

1. GlideScope (https://accessgudid.nlm.nih.gov/devices/00879123006400)
2. Storz C-Mac (https://accessgudid.nlm.nih.gov/devices/04048551409381)
3. i-view (https://www.intersurgical.com/content/files/108253/-1977057700)

##### 5.7.1.2 FDA-approved device being used in this research in a manner other than its approved labeling

N/A – This section is not applicable.

##### 5.7.1.3 Any device not approved by the FDA

N/A – This section is not applicable.

#### B5.7.2 Drugs

##### B5.7.2.1 FDA-approved and used in accordance with the approved labeling

N/A – This section is not applicable.

##### B5.7.2.2 FDA-approved and used in a manner not in accordance with its approved labeling

N/A – This section is not applicable.

##### B5.7.2.3 Any drug not approved by the FDA

N/A – This section is not applicable.

## B8 Statistical Analysis

### B5.8.1 Sample Size Estimation

A power analysis in SAS version 9.4 (SAS Institute, Cary, NC) indicated that a total sample of 122 would be needed to find that the i-view is non-inferior to the reusable VL if the expected outcome rate (proportion of patients experiencing first-pass success) for the i-view is 87%, the expected outcome rate for the reusable VL is 92%, the noninferiority margin is 5%, power is 80%, and alpha is 5%.

### B5.8.2 Data analysis

We will use the Farrington-Manning score test for non-inferiority to test the first two hypotheses (that the i-view has a non-inferior proportion of patients experiencing hypoxic events, and that the i-view has a non-inferior first-pass success rate compared to the reusable VL devices). The Farrington-Manning score test computes the proportion (risk) difference and 90% confidence interval (for a one-sided test) with regards to a predetermined non-inferiority limit. We will use pairwise deletion to handle missing data points (i.e., will only exclude observations if missing data relevant to the specific analysis). Moreover, we may perform regression modeling to adjust for confounders. We performed all statistical analysis using Microsoft Excel (version 10, Redmond, Washington) and JMP Statistical Discovery from SAS (version 13, Cary, NC) or another available commercial software package. We will present continuous variables as means and 95% confidence intervals, non-parametric continuous variables and ordinal variables as medians and interquartile ranges, and nominal variables as percentages and numbers. Significance will be set at p=0.05. We will compare binomial variables using the Chi-square test, normally distributed continuous variables using the Student's t-test, and non-parametric and ordinal variables using the Wilcoxon Rank sum test.

## SECTION C: HUMAN RESEARCH PROTECTIONS

## C1. RECRUITMENT AND CONSENT

### C1.1 Identification and Selection of Subjects

Patients will not be specifically recruited for this study. The decision to perform an intubation using VL will be purely at the direction of the attending clinician.

### C1.2 Recruitment Process

N/A – This section is not applicable.

### C1.3 Eligibility

N/A – This section is not applicable.

### C1.4 Consent Process

We are seeking a wavier of consent for this clinical rotating protocol as we have done with BAMC protocol C.2015.140. All the devices of interest in this study are already in use in the ED and, while we are seeking to establish a clinical rotating protocol, clinicians can always break the protocol if indicated per their discretion. The procedure itself – emergency intubation – does not normally require consent in the emergency setting.

#### C1.4.1 Research involving subjects with cognitive impairment or who lack capacity to provide informed consent

N/A – This section is not applicable.

#### C1.4.2 Research involving non-English speaking subjects

N/A – This section is not applicable.

#### C1.4.3 Research involving a waiver of the requirement to obtain informed consent OR alteration of the elements of informed consent

*The research involves no more than minimal risk to the subjects; and*
*The waiver or alteration will not adversely affect the rights and welfare of the subjects;*

We are seeking to capture data that is part of routine healthcare operations. The data that we are capturing represents data that is routine in the clinical setting and thus does not elevate the risk above that of routine patient care. The clinical rotating protocol is using devices that are already in use in the department, are being use for their FDA cleared indications, and are all considered technically equivalent devices. The intubation procedure itself is purely at the direction of the attending clinician.

*The research could not practicably be carried out without the waiver or alteration;*

We are specifically seeking out encounters in which an intubation occurs under this clinical rotating protocol. Intubations are only performed in patients that are critically ill and unable to participate in the consent process. We routinely perform these procedures without consent due to their underlying illness, and thus it would be impractical to attempt to consent them for the purpose of a clinical rotating protocol using devices that are already in use in the department. Moreover, attempting to consent them would result in delays in their care.

*Whenever appropriate, the subjects will be provided with additional pertinent information after participation.*

Many of the patients that we are intubating are critically ill and not expected to survive. As such, it would be impractical to attempt to provide them with information on a procedure that occurred as part of their routine clinical care.

#### C1.4.4 Research involving a waiver of the requirement for investigator to obtain a signed consent form

N/A – This section is not applicable.

#### C1.4.5 Waivers of assent or parental permission when the research involves children

N/A – This section is not applicable.

#### C1.4.6 Research involving data collection for the USAMRDC Volunteer Registry Database

N/A – This section is not applicable.

## C2. COMPENSATION FOR PARTICIPATION

Patients will not be compensated for participation as we are only collecting data in conjunction with routine clinical care.

## C3. WITHDRAWAL FROM RESEARCH PARTICIPATION

For the clinician centered data we do not anticiapet any withdrawal form the study. We have been collecting data on airway interventions since 2015 as part of BAMC protocol C.2015.140 without any enconters for which a clinician asked that we cease data collection, declined participation, or asked that their data be withdrawn. However, in the event that a clinician asks to be withdrawn we will will only use their CRFs that were collected up to that point. If a reason is provided, we will document such.

For the patient EMR-based data we do not anticipate any patient withdrawal as we are seeking a waiver of informed consent and HIPAA waiver and thus they will likely not be aware of the study. However, in the event that a patient does request withdrawal in writing to the PI or a study team member we will cease data collection from that point forward. Data that was already collected will still be retained for use. Since the overwhelming majority of our data comes from medical records review, we cannot make any changes, removal, or revisions to the data in the EMR system even if the patient were to request such.

## C4. PRIVACY FOR SUBJECTS

We are not intending any direct interaction between study team members and subjects for the study with the exception of the clinical personnel. They may interact with the subjects only for routine healthcare and will not be for the purposes of this study. As we are requesting a HIPAA waiver and consent waiver, additional privacy for recruitment and such will not be required and standard measures for privacy will be maintained per usual methods for healthcare delivery. The data will be maintained and stored as outlined.

## C5. CONFIDENTIALITY PROCEDURES FOR RESEARCH RECORDS, DATA, HUMAN BIOLOGICAL SPECIMENS

The hard-copy forms will be immediately deposited into a secured lock-box in the ED and destroyed by shredder once entered in the database(s). The data collection tool is password protected, encrypted Regarding the component of the study using data to include the case report form, these will include minimal PHI in the form of a patient sticker that we routinely use for patient care labeling. The CRF data will be converted into an electronic database and linked with outcome data. Please see data variable collection appendix listed below. Data will be stored on a password-protected Excel database maintained on a government computer for the period of the study protocol. All of these forms will also be destroyed immediately after entry into the Excel database.

## C6. RISKS OF HARM, MEASURES TO REDUCE THE RISKS OF HARM, AND BENEFITS OF PARTICIPATION

### C6.1 Risks of Harm

No procedures or interventions are being performed because of this study. We are only seeking to answer a specific research question as part of a clinical rotating protocol using devices that are already in use and indicated for the same situations. While the critical nature of their illness and the mere need puts them at high risk as part of their routine medical care. We do not believe the use of a rotating protocol places them at additional risk. Moreover, clinicians can break the protocol if there is a specific clinical indication without any penalty.

### C6.2 Incidental or Unexpected Findings

N/A – This section is not applicable. Unexpected or incidental findings are not expected as part of this study. If, in the unlikely event something is discovered, we will refer the information back to the primary attending clinician.

### C6.3 Potential Benefits

The study subjects will experience no direct benefits as a result of participating in this study given that it is purely observational . That said, their participation will facilitate the informing of best intubation practice which could conceivably benefit them in the future should they again require emergency airway management.

## C7. DATA AND SAFETY MONITORING

N/A – This section is not applicable.

## C8. REPORTABLE EVENTS

### C8.1 Expected adverse events

There are a multitude of expected events related to the intubation procedure that are all considered part of routine clinical care. Examples of such events include hypoxia, aspiration, dental or other oral injury, multiple intubation attempts, false intubation into the esophagus, injury from the device, infection, and other anatomical injuries. More severely, hypoxic events resulting in anoxic brain injury or peri-intubation cardiac arrest are also well-described events associated with intubation and are not expected to be a result of the research study.[11]

### C8.2 Unexpected adverse events and unanticipated problems

We do not anticipate unexpected adverse events as the decision to intubate is purely at the direction of the attending clinician. The devices are already in use in the department and are being used in their FDA cleared manner. If an adverse event occurs specific to the research, the adverse event will be reported to the PI or a member of the study team. If the event is determined to be related to the research the PI will follow standard reporting procedures for reporting the even to the regulatory office. If in the event there is an unexpected adverse event and unanticipated problem, PI or research staff will report to ISR Research Regulatory Compliance Division (RRCD) by e-mail to usarmy.jbsa.medcom-aisr.mbx.rcd-human@mail.mil. A complete written report will follow the initial notification.

### C8.3 Adverse device effects

We do not anticipate adverse events that are specific to this clinical rotating protocol. As the devices in the protocol are already in use in the department, any device related malfunction or risks are similar to that associated with the procedure itself.

### C8.4 FDA-regulated research under IND and IDE

N/A – This section is not applicable.

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## SECTION D: REFERENCES

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3. Eastridge, B.J., et al., *Died of wounds on the battlefield: causation and implications for improving combat casualty care.* J Trauma, 2011. **71**(1 Suppl): p. S4-8.
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10. Schauer, S.G., et al., *A Prospective Assessment of a Novel, Disposable Video Laryngoscope With Physician Assistant Trainees Using a Synthetic Cadaver Model.* Mil Med, 2020.

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## SECTION E: ABBREVIATIONS AND ACRONYMS

BAMC = Brooke Army Medical Center
CAC = Common access card
CRF = Case report form
DL = Direct laryngoscopy
HIPAA = Health Insurance portability and accountability act
ICTL = Individual critical task list
ICU = Intensive care unit
IMD = Information Management Division
MAMC = Madigan Army Medical Center
PHI = Protected health information
USAISR = US Army Institute of Surgical Research
VL = Video laryngoscopy

## SECTION F: DoD PRIVACY RULE AND PROTECTED HEALTH INFORMATION (HIPAA).

NA – institution is not a covered entity

NA – will not use or disclose protected health information

HIPAA authorization will be obtained

X An application for waiver/alteration of HIPAA authorization will be submitted

## APPENDIX – Data Collection Variables

| | |
|---|---|
| Was the patient ALREADY receiving intravenous fluid bolus? | Yes/no |
| Estimated volume of fluid bolus infused before meds (mL) | Volume |
| Induction/sedation and total doses | Etomidate<br>Ketamine<br>Ativan<br>Versed<br>Morphine<br>Fentanyl<br>Propofol<br>Other (free text)<br>None |
| Post-intubation sedation | Etomidate<br>Ketamine<br>Ativan<br>Versed<br>Morphine<br>Fentanyl<br>Propofol<br>Other (free text)<br>None |
| Gender | Male/female |
| Body Mass Index (BMI) | Numeric |
| Self-identified race (from medical record) | White<br>Black/African American<br>Asian<br>American Indian or Alaska Native<br>Native Hawaiian or Other Pacific Islander |
| Chronic respiratory comorbidities | Asthma<br>COPD<br>Cystic fibrosis<br>Interstitial lung disease<br>Malignancy<br>Neuromuscular weakness<br>Obstructive sleep apnea<br>Pulmonary hypertension<br>Recurrent aspiration<br>Other (free text) |
| Chronic non-respiratory comorbidities | Atrial fibrillation<br>Cerebrovascular accident<br>Chronic kidney disease<br>Cirrhosis<br>Congestive heart failure<br>Coronary artery disease<br>Diabetes mellitus<br>End-stage renal disease<br>Hypertension<br>Malignancy, leukemia or lymphoma active<br>Solid organ transplant<br>stem cell transplant<br>Bone marrow transplant |

| | |
|---|---|
| | Spinal CORD injury<br>Traumatic brain injury<br>Other (free text) |
| Primary admit diagnosis | Trauma/non-trauma |
| Active neurologic conditions at the time of intubation | Altered mental status<br>Intracranial hemorrhage<br>Cord compression or epidural abscess<br>Meningitis or encephalitis<br>Myasthenic crisis<br>Seizure or status of left against<br>Stroke<br>traumatic brain injury |
| Active cardiac conditions at the time of intubation | Cardiac arrest<br>Cardiogenic permanent edema<br>Congestive heart failure<br>Echogenic shock<br>Hypertensive urgency or emergency<br>Myocardial infarction |
| Active pulmonary conditions at the time of intubation | Acute respiratory distress syndrome<br>Asthma<br>Aspiration<br>COPD<br>Hypercarbic respiratory failure<br>Hypoxemic respiratory failure<br>Pneumonia<br>Upper airway obstruction |
| Active gastrointestinal conditions at the time of intubation | Acute liver failure<br>Bowel obstruction<br>Bowel perforation<br>Gastrointestinal bleeding<br>Hepatorenal syndrome<br>Pancreatitis |
| Prior to intubation, had the patient received ketamine or etomidate during this hospitalization (during a previous procedure or intubation | Ketamine<br>Etomidate |
| Was the patient on corticosteroids at the time of enrollment? | Yes/no |
| Vasopressors or inotropes in the hour prior to enrollment? | Yes/no |
| Which vasopressor or inotrope? | Epinephrine<br>Norepinephrine<br>Phenylephrine<br>Dopamine<br>Dobutamine<br>Milrinone<br>Angiotensin II |
| Was the patient on BIPAP or HFNC for respiratory failure in the 1 hour prior to enrollment (excluding pre-oxygenation)? | Yes/no |
| Was the patient on BIPAP or HFNC for respiratory failure in the 1 hour prior to enrollment (excluding pre-oxygenation)? | Optiflow, Vapotherm |

| | |
|---|---|
| Highest FIO2 delivered in the 1 hour prior to enrollment (excluding preoxygenation for the procedure). | For patients on nasal cannula, use estimation that FIO2 = 0.21 + 0.03*(LPM of NC O2) |
| Neuromuscular Blockers | Rocuronium<br>Vecuronium<br>Succinylcholine<br>Cisatracurium<br>Other<br>None<br>Unknown |
| Total dose of each agent given peri-intubation | Numeric |
| Initial laryngoscope device type | Free text |
| Difficult airway characteristics (active at the time of intubation) | Vomiting<br>Witnessed aspiration<br>Upper GI bleeding<br>Epistaxis or oral bleeding<br>Upper airway mass, infection, trauma<br>Head and neck radiation<br>Obesity, BMI greater than 30<br>Limited neck mobility<br>Limited mouth opening<br>History of OSA<br>Other, free text |
| Vital signs at 24 hours | Systolic blood pressure<br>Diastolic blood pressure<br>SPO2<br>FiO2<br>PEEP |
| Vasopressors or ionotropes used at 24 hours after intubation? | Epinephrine<br>Norepinephrine<br>Phenylephrine<br>Dopamine<br>WB<br>Milrinone<br>Angiotensin II |
| Is a chest x-ray available between intubation and 48 hours after intubation? | Was a NEW pneumothorax present on the first chest x-ray obtained in the first 48 hours after intubation? Is there evidence of new pneumonia? Yes/no |
| Cardiac arrest within 1 hour of intubation? | Yes/no |
| Death within 1 hour of intubation? | Yes/no |
| Did the patient die before discharge from the hospital? | Yes/no |
| Duration of mechanical ventilation (days)? | Number of days from study intubation until achieved achieved final unassisted breathing during this hospitalization or death. Note: After extubation, a reintubation for less than 24 hours and for the purpose of a procedure will not count as a ventilator day. Information censored at hospital discharge. IGNORE data from outpatient records or readmissions. |
| Did the patient die in the ICU? | Yes/no |
| Duration of mechanical ventilation (days)? | Numeric |
| Duration of vasopressor support (days) | Numeric |

| | |
|---|---|
| ICU length of stay (days) | Numeric |