

Project/Attribute Variables

Patient demographics

* Gender

- Male dm_g_sex
 Female

* Ethnicity

- Hispanic or Latino dm_g_ethnic
 Not Hispanic or Latino
 Not reported

* Race (select all that apply)

- American Indian or Alaskan Native dm_g_native
 Asian dm_g_asian
 Black or African American dm_g_afamer
 Native Hawaiian or other Pacific Islander dm_g_island
 White dm_g_white
 Not reported dm_g_norace

Demographics complete dm_g_complete **Internal Use**

Death date

Death Date:

_____ deathdt

Study participation

LOTUS Fruit study_lotusfruit **Internal Use**

Enrollment date
study_lotusfruitenrolldt **Internal Use**

Discontinuation date
study_lotusfruitdiscondt **Internal Use**

Date of intubation

* Date of intubation:

dtintub

Outcome data

Project/Attribute Variables

* Was the patient still alive *and* in the study hospital on day 28?

- Yes st_pthospd28
 No

* Was the patient still on mechanical ventilation through an ET tube or tracheostomy for at least part of day 28?

- Yes st_mechventd28 *If YES to "Was the patient alive and in the study hospital on day 28?"*
 No

* Did the patient die prior to (or on) day 28?

- Yes st_ptdead *If NO to "Was the patient alive and in the study hospital on day 28?"*
 No

* Date of death:

st_deathdt *If YES to "Did the patient die prior to (or on) day 28?"*

* Date of study hospital discharge:

st_dischargedt *If NO to "Did the patient die prior to (or on) day 28?"*

* Was the patient discharged on mechanical ventilation through an ET tube or tracheostomy?

- Yes st_ptdischmechvent *If NO to "Did the patient die prior to (or on) day 28?"*
 No

* Date the patient was last on mechanical ventilation through an ET tube or tracheostomy:

st_mechventdt *If NO to "Was the patient discharged on mechanical ventilation..."

* ST discontinuation date

st_discontdt *Internal Use*

ST complete

st_fcomplete *Internal Use*

ICU history

Please record all ICU discharges and re-admissions during study hospitalization up to hospital discharge or to day 28, whichever comes first. This should include any days where the patient spent any time in an ICU.

st_dischargeyn_r1 ** ** Suffix r1-r5 correspond to each subsequent day.

	Admission date	Discharged?	Discharge date	Re-admitted?	
Initial	<i>(On ICU form)</i>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r1</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r1
Second	* <u>st_admitdt_r2</u>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r2</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r2
Third	* <u>st_admitdt_r3</u>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r3</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r3
Fourth	* <u>st_admitdt_r4</u>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r4</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r4

Project/Attribute Variables

	Admission date	Discharged?	Discharge date	Re-admitted?	
Fifth	* <u>st_admitdt_r5</u>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r5</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r5

STICU
complete

sticu_fcomplete

Internal Use

Baseline

Eligibility verification

* Did the patient meet the following inclusion criteria and not meet the following exclusion criteria?

Inclusion:

1. The patient age is > 18 years
2. The patient has respiratory failure requiring invasive mechanical ventilation via an endotracheal tube or tracheostomy in the hospital
3. The patient will receive care in the intensive care unit after intubation (i.e., the patient was either intubated in the intensive care unit, or will be admitted or transferred to an intensive care unit on mechanical ventilation if intubation did not occur in the intensive care unit)

Exclusion:

1. The patient is undergoing chronic mechanical ventilation
2. The patient was extubated prior to transfer to the intensive care unit
3. The patient was intubated outside of the study hospital and presented to the study hospital with more than 24 hours of invasive mechanical ventilation prior to presentation
4. The patient is being care for in an intensive care unit that could not participant in a low tidal volume protocol under the prospective PETAL Network LOTUS study
5. The patient was admitted to the intensive care unit after elective surgery

- Yes `elig_yn`
 No

If the patient does not meet the eligibility requirements, they should not be enrolled. Please click "cancel" in the toolbar above and contact the CCC for instructions on how to un-enroll the patient.

ELIG form complete

`elig_fcomplete` **Internal Use**

Hospital admission

* Age at time of study hospital admission:

_____ years `ha_age`

Date and time of study hospital admission:

* `ha_admdt` * `ha_admtm`

* Is patient height charted in the medical record?

- Yes `ha_heightyn`
 No

* Height: `ha_height` * cm `ha_heightunits` *If YES to "Is patient height charted?"*
 in

* Date and time height recorded or charted in medical record:

- Not charted*
 Date charted `ha_heightavail`
 Date and time charted

* `ha_heightdt` * `ha_heighttm` *If date and time charted*

*If Date charted OR
Date and time charted*

Baseline

* Type of ICU:

- Medical ha_icu
- Surgical
- Medical/Surgical
- Cardiothoracic surgical
- Trauma
- Mixed
- Other

* please specify

ha_icuspec

HOSPADM form complete

- ha_fcomplete *Internal Use*

Intubation

* Location of current intubation:

- EMS (pre-hospital) int_loc
- ED
- Ward
- ICU
- OR
- Referring hospital

Date and time of intubation:

* int_dt * int_tm

* Select the best primary reason for intubation:

- Acute hypoxemic respiratory failure int_reason
- Acute hypercapnic respiratory failure
- Acute hypoxemic and hypercapnic respiratory failure
- Other

* Select reason:

- Altered mental status int_reason2
- Metabolic abnormalities
- Elective intubation for surgery or procedure
- Unclear
- Other

*If OTHER for
"Select the best primary reason for
intubation"*

* please specify:

int_reasonspec

If OTHER

* Select all ARDS risk factors that were present at the time of intubation:

- No ARDS risk factor present int_risknone
- Sepsis int_risksepsis
- Pneumonia int_riskpneumo

Baseline

- Aspiration int_riskaspr
- Smoke inhalation injury int_risksmoke
- Trauma int_risktrauma
- Near drowning int_riskdrown
- Pancreatitis int_riskpanc
- Burn int_riskburn
- Shock int_riskshock
- Drug overdose int_riskdrugod
- Transfusions of blood products (red blood cells, FFP, plasma, platelets) int_riskblood

* Did the patient receive azithromycin in the 48 hours before intubation?

- Yes int_azithro
- No

* Was CPAP or Bilevel Positive Airway Pressure (BiPAP) used in the 12 hours prior to intubation (do not answer yes if used solely for sleep apnea)?

- Yes
- No int_noninvvent

* Was a high flow nasal cannula used in the 12 hours prior to intubation?

- Yes
- No int_hfnascann

INT form complete

- int_fcomplete *Internal Use*

Baseline ventilator data

Date and time of first documented ventilator parameters after intubation:

* blvtdt_dt * blvtdt_tm*

BLVENTDT form complete

- *Internal Use* blvtdt_fcomplete

Ventilator parameters

Enter the first documented parameters **after intubation**.

Enter the first documented parameters **in the ICU**.

Enter ventilator parameters **closest to 0800**.

Baseline

* Ventilator mode:

- Volume assist/control
- Pressure assist/control vent_mode
- Pressure support ventilation
- Volume SIMV
- Pressure SIMV
- Pressure controlled inverse ratio ventilation (PC-IRV)
- High frequency oscillation ventilation (HFOV)
- Pressure regulated volume control (PRVC) / ACV with autoflow
- Other (including dual and alternative modes)
- Not intubated on mechanical ventilation*

* Specify other ventilator mode:

vent_modespec

* Set tidal volume:

_____ mL vent_tidal

Conditions in the CRF instructions

* Total minute ventilation:

_____ L/min vent_minvent

* Total respiratory rate:

_____ breaths/min vent_ratetotal

* Plateau pressure:

_____ cm H2O vent_pplat

VENT form complete

vent_fcomplete **Internal Use**

Baseline ventilator change

* Was the set tidal volume changed at any time within the first 24 hours after intubation?

- Yes vtcg_yn **If Volume assist/control, Volume SIMV or Pressure regulated volume control**
- No

* What was the set tidal volume changed to (if it was changed more than once, please use the first value only):

_____ ml vtcg_tidal **If YES to "Was the tidal volume changed..."**

Corresponding date and time set tidal volume changed: *if YES to "Was the tidal volume changed..."**

* vtcg_dt * vtcg_tm

VENTCHG form complete

vtcg_fcomplete **Internal Use**

ARDS determination

Please answer these questions for the **day of intubation**.

Please answer these questions for the **calendar day**.

* Are there any intubated ABGs available for this time period?

- Yes ards_abgyn
- No

Baseline

* PaO2 value from the worst P/F for the time period:

ards_pao2 *If YES to "Are there any intubated ABGs available..."*

* Were any available intubated SpO2 values between 80% and 96% for this time period?

- Yes ards_spo2yn *If NO to "Are there any intubated ABGs available..."*
- No

* Worst imputed P/F ratio for the time period:

ards_imputedpf *If YES to "Were any available intubated SpO2 values..."*

* Corresponding SpO2: *If YES to "Were any available intubated SpO2 values..."*

ards_spo2

* Corresponding FiO2 *If YES to "Were any available intubated SpO2 values..."* or YES to "Are there any intubated ABGs available..."*

ards_fio2

P/F ards_calcratio *Internal Use*

* If P/F (or imputed P/F) < 300, is there a CXR within 24 hours (before or after) that meets ARDS criteria?

- Yes
- No ards_ardsyn
- P/F does not meet high-altitude ARDS cut-off *If P/F ratio or imputed P/F ratio < 300*
- Patient met ARDS criteria on a previous study day

ARDS form complete

Internal Use

ards_fcomplete

Day 1-3

Ventilator parameters

Enter the first documented parameters **after intubation**.

Enter the first documented parameters **in the ICU**.

Enter ventilator parameters **closest to 0800**.

* Ventilator mode:

- Volume assist/control
- Pressure assist/control
- Pressure support ventilation vent_mode
- Volume SIMV
- Pressure SIMV
- Pressure controlled inverse ratio ventilation (PC-IRV)
- High frequency oscillation ventilation (HFOV)
- Pressure regulated volume control (PRVC) / ACV with autoflow
- Other (including dual and alternative modes)
- Not intubated on mechanical ventilation*

* Specify other ventilator mode:

vent_modespec

* Set tidal volume:

_____ mL vent_tidal *Conditions in the CRF

* Total minute ventilation:

_____ L/min vent_minvent instructions*

* Total respiratory rate:

_____ breaths/min vent_ratetotal

* Plateau pressure:

_____ cm H2O vent_pplat

VENT form complete

vent_fcomplete *Internal Use*

ARDS determination

Please answer these questions for the **day of intubation**.

Please answer these questions for the **calendar day**.

* Are there any intubated ABGs available for this time period?

- Yes ards_abgyn
- No

* PaO2 value from the worst P/F for the time period:

_____ ards_pao2 *If YES to "Are there any intubated ABGs available..."*

* Were any available intubated SpO2 values between 80% and 96% for this time period?

- Yes ards_spo2yn *If NO to "Are there any intubated ABGs available..."*
- No

* Worst imputed P/F ratio for the time period:

ards_imputedpf *If YES to "Were any available intubated SpO2 values..."*

* Corresponding SpO2:

ards_spo2 *If YES to "Were any available intubated SpO2 values..."*

Day 1-3

* Corresponding FiO2 *If YES to "Were any available intubated SpO2 values..."* or YES to "Are there any intubated ABGs available..."*
ards_fio2

P/F ards_calcratio *Internal Use*

* If P/F (or imputed P/F) < 300, is there a CXR within 24 hours (before or after) that meets ARDS criteria?

- Yes
- No ards_ardsyn *If P/F ratio or imputed P/F ratio < 300*
- P/F does not meet high-altitude ARDS cut-off
- Patient met ARDS criteria on a previous study day

ARDS form complete ards_fcomplete *Internal Use*

Agitation

Please answer these questions for the **first 24 hours after intubation before ICU admission.**

Please answer these questions for the **first assessment of agitation after ICU admission and intubation.**

Please answer these questions for the **calendar day (closest to 0800).**

* Was a standardized assessment of agitation/sedation documented for this time period?

- Yes agit_yn
- No

* Scale:

- RASS agit_scale *If YES*
- RIKER
- RAMSAY

* Score:

agit_score *If YES*

AGIT form complete

agit_fcomplete *Internal Use*

Sedation

Please answer these questions for the **first 24 hours after intubation before ICU admission.**

Please answer these questions for the **calendar day starting after ICU admission and intubation.**

Please answer these questions for the **calendar day.**

* During this time, did the patient receive any sedative or analgesic medications?

- Yes sed_yn
- No

* Indicate all sedative or analgesic medications given (do not count meds given for intubation itself):

Benzodiazepine drip (infusion) sed_benzodrip *If YES*

Day 1-3

- Benzodiazepine bolus sed_benzobolus
- Opioid drip (infusion) sed_opioiddrip
- Opioid bolus sed_opioidbolus
- Propofol sed_propo
- Dexmedetomidine sed_dexmed
- Ketamine sed_keta

SED form complete

- sed_fcomplete **Internal Use**

ICU Admission

ICU admission date

Date and time of ICU admission:

* icuadm_dt * icuadm_tm

ICUADM form complete

icuadm_fcomplete *Internal Use*

Intubated in ICU

* Was the patient intubated in the ICU?

Yes inticu_yn
 No

INTICU form complete

inticu_fcomplete *Internal Use*

Ventilator parameters *Only answered if NO for "Was the patient intubated in the ICU"*

Enter the first documented parameters **after intubation**.

Enter the first documented parameters **in the ICU**.

Enter ventilator parameters **closest to 0800**.

* Ventilator mode:

- Volume assist/control
 Pressure assist/control vent_mode
 Pressure support ventilation
 Volume SIMV
 Pressure SIMV
 Pressure controlled inverse ratio ventilation (PC-IRV)
 High frequency oscillation ventilation (HFOV)
 Pressure regulated volume control (PRVC) / ACV with autoflow
 Other (including dual and alternative modes)
 Not intubated on mechanical ventilation

* Specify other ventilator mode:

vent_modespec

* Set tidal volume:

_____ mL vent_tidal

* Total minute ventilation:

_____ L/min vent_minvent

Conditions in the CRF instructions

* Total respiratory rate:

_____ breaths/min vent_ratetotal

* Plateau pressure:

_____ cm H2O vent_pplat

VENT form complete

vent_fcomplete *Internal Use*

Agitation

ICU Admission

Please answer these questions for the **first 24 hours after intubation before ICU admission.**

Please answer these questions for the **first assessment of agitation after ICU admission and intubation.**

Please answer these questions for the **calendar day (closest to 0800).**

* Was a standardized assessment of agitation/sedation documented for this time period?

Yes **agit_yn**

No

* Scale:

RASS **agit_scale** *If YES*

RIKER

RAMSAY

* Score:

agit_score *If YES*

AGIT form complete

agit_fcomplete *Internal Use*

Sedation

Please answer these questions for the **first 24 hours after intubation before ICU admission.**

Please answer these questions for the **calendar day starting after ICU admission and intubation.**

Please answer these questions for the **calendar day.**

* During this time, did the patient receive any sedative or analgesic medications?

Yes **sed_yn**

No

* Indicate all sedative or analgesic medications given (do not count meds given for intubation itself):

Benzodiazepine drip (infusion) **sed_benzodrip**

Benzodiazepine bolus **sed_benzobolus**

Opioid drip (infusion) **sed_opioiddrip** *If YES*

Opioid bolus **sed_opioidbolus**

Propofol **sed_propo**

Dexmedetomidine **sed_dexmed**

Ketamine **sed_keta**

SED form complete

sed_fcomplete *Internal Use*

24 Hours Post Intubation

SOFA

Enter the SOFA values for the first 24 hours after intubation. If no value is available, use the most recent value from the 48 hours prior to intubation.

- * Lowest platelets: sofa_platl $\times 10^3/\mu\text{L}$ ($\times 1000/\text{mm}^3$)
- * Highest bilirubin: sofa_bilih mg/dL
- * Highest creatinine: sofa_creath mg/dL
- * Lowest MAP: sofa_mapl mmHg
- * Did the patient have any vasopressors lasting more than one hour in the 24 hours after intubation (not counting vasopressin)?
- Yes sofa_anyvasoyn
- No
- * Dopamine $\leq 5 \mu\text{g/kg/min}$ or dobutamine (any dose)? *If YES to "Did the patient have any vasopressors..."*
- Yes sofa_dopdobutyn
- No
- * Dopamine $> 5 \mu\text{g/kg/min}$ or Epinephrine/Norepinephrine $\leq 0.1 \mu\text{g/kg/min}$? *If YES to "Did the patient have any vasopressors..."*
- Yes sofa_dopnorepilowyn
- No
- * Dopamine $> 15 \mu\text{g/kg/min}$ or Epinephrine/Norepinephrine $> 0.1 \mu\text{g/kg/min}$? *If YES to "Did the patient have any vasopressors..."*
- Yes sofa_dopnorepihighyn
- No
- Phenylephrine $> 0.22 \mu\text{g/kg/min}$?** *If YES to "Did the patient have any vasopressors..."*
- Yes sofa_phenylephrineyn
- No
- SOFA form complete sofa_fcomplete *Internal Use*

Intubated in ICU

- * Was the patient intubated in the ICU?
- Yes inticu_yn
- No
- INTICU form complete inticu_fcomplete *Internal Use*

Agitation *Only answered if NO for "Was the patient intubated in the ICU"*

Please answer these questions for the **first 24 hours after intubation before ICU admission**.

Please answer these questions for the **first assessment of agitation after ICU admission and intubation**.

Please answer these questions for the **calendar day (closest to 0800)**.

- * Was a standardized assessment of agitation/sedation documented for this time period?
- Yes agit_yn
- No

24 Hours Post Intubation

* Scale:

- RASS **agit_scale** *If YES*
- RIKER
- RAMSAY

* Score:

agit_score *If YES*

AGIT form complete *Internal Use*

Sedation *Only answered if NO for "Was the patient intubated in the ICU"*

Please answer these questions for the **first 24 hours after intubation before ICU admission.**

Please answer these questions for the **calendar day starting after ICU admission and intubation.**

Please answer these questions for the **calendar day.**

* During this time, did the patient receive any sedative or analgesic medications?

- Yes
- No **sed_yn**

* Indicate all sedative or analgesic medications given (do not count meds given for intubation itself):

- Benzodiazepine drip (infusion) **sed_benzodrip**
- Benzodiazepine bolus **sed_benzobolus** *If YES*
- Opioid drip (infusion) **sed_opioiddrip**
- Opioid bolus **sed_opioidbolus**
- Propofol **sed_propo**
- Dexmedetomidine **sed_dexmed**
- Ketamine **sed_keta**

SED form complete *Internal Use*

sed_fcomplete