Public Use Dataset
Annotated eCRF

# Translating an Adult Ventilator Computer Protocol

# To Pediatric Critical Care

# (Vent CDS R21)

# CPCCRN Protocol Number 011

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Collaborative Pediatric Critical Care Research Network

*Eunice Kennedy Shriver* National Institute for Child

Health and Human Development (NICHD)

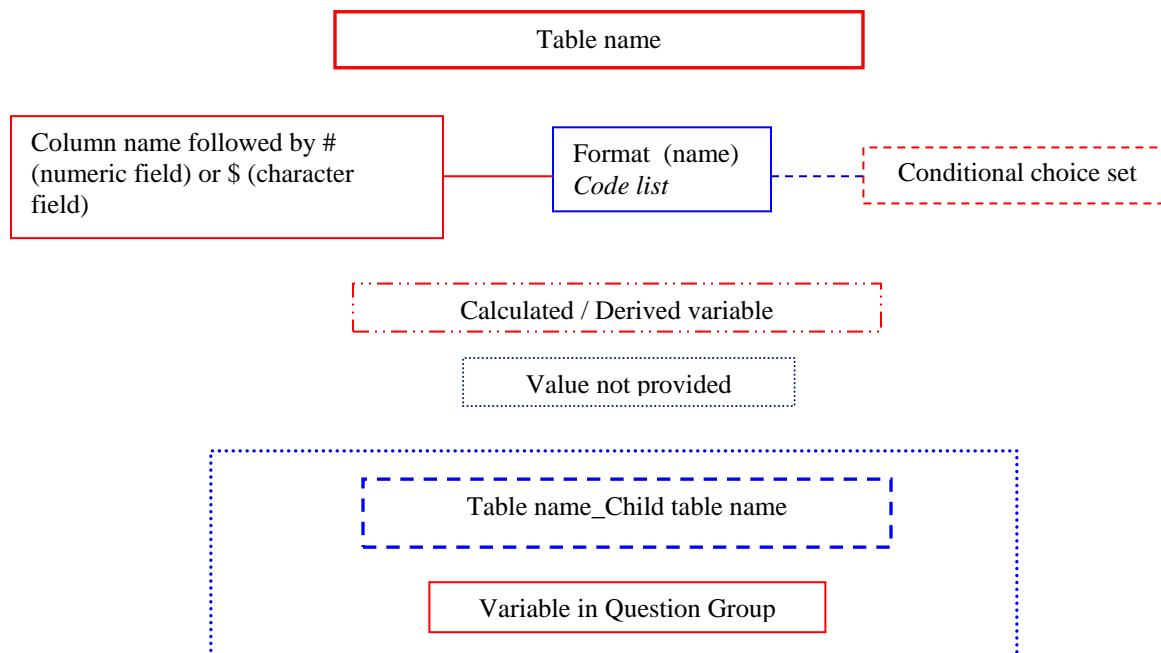Protocol Version 1.00

Version Date: April 29, 2011

Annotated eCRF Version 2.0

Version Date: April 19, 2017

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## Notes

StudySubjectID was replaced by SubjectID, sequential integers, that uniquely identifies a patient across datasets, it does not contain information about original site or medical record number. ItemGroupRepeatKey is also a unique subject identifier.

Sensitive and/or identifying information entered in free text fields have been removed from the public use datasets.

'Date' variables are replaced with 'day' variables. Day variables are populated with the number of days since the reference date, the date of the first ventilator reading. The date of the first ventilator reading is coded as 0 (Day 0) and all other dates will be recoded as number of days after Day 0 (if any dates occur before the first ventilator reading day, these dates will have a negative value).

**R21 Eligibility v1.0:**

SubjectID #    ScreenDay #

◄ Inclusi...(0/4)   Exclusi...(0/5)   **Demog (0/12)** ► -- Select to Jump --

**Title: Patient Demographics**

Age: Value not provided    Age unit: (select one) Value not provided

Gender
1 = Male
2 = Female

Sex: (select one)   Sex, #

Ethnicity: ○ Hispanic or Latino
○ Not Hispanic or Latino
○ Unknown or Not Reported

Ethnic
1 = Hispanic or Latino
2= Not Hispanic or Latino
92 = Unknown or Not Reported

Ethnicity, #

Race: (select all that apply)
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Unknown or Not Reported

*Race, #

Primary Diagnosis: PrimaryDiagnosis, $

Is this patient chronically ventilated? ○ Yes ○ No   ChronicVent, #

YesNo
1=Yes
0=No

Height: Height, # (cm)    Weight: Weight, # (kg)

Ulna length: (if available) UlnaLength, # (cm) NOTE: If your site does not collect these data, please leave blank.

Make & Model of ventilator: VentilatorMake, $    Make & Model of oximeter: OximeterMake, $

Race
3=Black or African American
5=White
92 =Other/Unknown

*Recoded values 1 (American Indian or Alaska Native), 2 (Asian), and 4 (Native Hawaiian or Other Pacific Islander) as 95 (Other/Unknown).

# R21 Blood Gases and Ventilator Information v1.0:

SubjectID #    ItemGroupRepeatKey #

◄ | SPO2End...(0/4) | BloodGas (0/8) | Ventila...(0/24) | ► | -- Select to Jump -- ▼

**Title: SPO2 and End Tidal CO2 Log**

Instructions: Please record *ALL* available SPO2 and End Tidal CO2 values during this patient's ventilation data collection time period (up to 168 hours, or extubation or death, whichever comes first).

| Date (DD-MMM-YYYY) | Time (HHMM) | SPO2 (pulse oximeter) (%) | End Tidal CO2 (mmHg) | |
|---|---|---|---|---|
| SPO2Day, # | SPO2Time, $ | SPO2, # | EndTidalCO2, # | X |
| ADD   ABGVent_SPO2 | | | | |

◄ | SPO2End...(0/4) | **BloodGas (0/8)** | Ventila...(0/24) | ► | -- Select to Jump -- ▼

**Title: Blood Gases Log**

Instructions: Please record *ALL* available arterial and capillary blood gases during this patient's ventilation data collection time period (up to 168 hours, or extubation or death, whichever comes first).
You have an option to upload a file with these data, instead of entering data in OpenClinica, if your site is capable of pulling blood gas data from the medical record and has received approval from the DCC to do this.

| Date (DD-MMM-YYYY) | Time (HHMM) | Source of Blood | pH (#.##) | PCO2 (mmHg) | PO2 (mmHg) | HCO3 (mEq/L) | |
|---|---|---|---|---|---|---|---|
| | | (select one) ▼ | | | | | X |
| ADD | | | | | | | |

BloodGasLabDay, #    BloodGasLabTime, $    pH, #    PaCO2, #    PaO2, #    HCO3, #

Upload ABG file (optional):

| | bad file | BloodGasSource, # | | X |

ADD   ABGVent_BloodGas

Blood
1 = Arterial
2 = Capillary
92 = Unknown

# R21 Blood Gases and Ventilator Information v1.0:

SubjectID #    ItemGroupRepeatKey #

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| SPO2End...(0/4) | BloodGas (0/8) | **Ventila...(0/24)** | -- Select to Jump -- |
|---|---|---|---|

**Title: Ventilator Settings Log**

Instructions: Please record *ALL* ventilator settings during this patient's data collection time period (up to 168 hours, or extubation or death, whichever comes first). At a minimum, ventilator settings should be recorded 4 times/day.

Record date and time patient was started on the ventilator

Date: _____ (DD-MMM-YYYY)    VentStartDay, #

Time: _____ (HHMM)    VentStartTime, $

Record the date and time patient was removed from the ventilator

Date: _____ (DD-MMM-YYYY)    Value not provided

Time: _____ (HHMM)    Value not provided

**Ventilator Settings**

| Date (DD-MMM-YYYY) | Time (HHMM) | Ventilator Mode | Ventilator Rate (bpm) | Spontaneous respirations? | Tidal Volume Exhaled (mL/kg) | PIP (cmH20) |
|---|---|---|---|---|---|---|
| VentDay, # | VentTime, $ | VentMode, # (select one) | VentilatorRate, # | SpontaneousResp, # | VTExhaled, # | PIP, # |

ADD    ABGVent_Vent

**VentMode**
1 = Pressure Control
2 = PRVC
3 = HFOV
4 = Volume Control

**YesNoS**
1=Yes
0=No

| Pressure Support (cmH20) | Mean Airway Pressure (cmH20) | PEEP (cmH20) | ETT Leak (%) | HFOV Frequency | HFOV Amplitude |
|---|---|---|---|---|---|
| PS, # | MAP, # | PEEP, # | ETTLeak, # | HFOVFrequency, # | HFOVAmplitude, # |

ABGVent_Vent

| FiO2 (#.##) *MUST be a decimal* | Primary reason for FiO2 change | Other FiO2 change (specify) | Primary reason for ventilator change | Other ventilator change (specify) | Extubation readiness test performed? | Notes |
|---|---|---|---|---|---|---|
| FiO2, # | FiO2Reasonfor Change, # | FiO2OthReasonFor Change, $ | VentReasonFor Change, # | VentOthReason ForChange, $ | Extubation, # (select one) | VentNote, $ |

ABGVent_Vent

**FiO2Chng**
1 = PO2 or SPO2 too high
2 = PO2 or SPO2 too low
90 = Other
3 = No change made
4 = Not Reported

**VentChng**
1 = PCO2 too high
2 = PCO2 too low
3 = pH too high
4 = pH too low
5 = End Tidal CO2 too high
6 = End Tidal CO2 too low
7 = VT too high
8 = VT too low
90 = Other
9 = No change made
10 = Not Reported

**YesNoS**
1=Yes
0=No

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# R21 Lab and Radiology Information v1.0:

SubjectID #          ItemGroupRepeatKey #

**Lab (0/3)**   Radiolo...(0/11)   ► -- Select to Jump --

**Title: Hemoglobin Lab Results**

Instructions: Please record a daily hemoglobin value if obtained as standard of care. If more than one hemoglobin value per day is available, record the value that is closest to one of the ventilator data capture points.

| Date (DD-MMM-YYYY) | Time (HHMM) | Hgb (g/dL) | |
|---|---|---|---|
| HemLabDay, # | HemLabTime, $ | Hemoglobin, # | X |

ADD     LabRad_HemLabs

Lab (0/3)   **Radiolo...(0/11)**   ► -- Select to Jump --

**Title: Radiology Information**

Instructions: Please record a daily chest x-ray if obtained as standard of care.

**Record if the following were reported/seen for each chest x-ray (CXR)**

| Date (DD-MMM-YYYY) | Lung volume (inflation) | Atelectasis? | Pneumothorax? | Pneumomediastinum? | Subcutaneous emphysema? |
|---|---|---|---|---|---|
| CXRDay, # | CXRLungVolume, # | CxrAtelectasis, # | CxrPneumothorax, # | CxrPneumomedia, # | CxrSubqEmphysema, # |

ADD     LabRad_CXR

LungVol
1 = Normal
2 = Hyperinflation
3 = Low (under) inflation
99= Not reported

YesNoNR
1=Yes
0=No
99 = Not Reported

| Pneumoperitoneum? | Cardiomegaly? | Infiltrates? | Pulmonary Edema? | Number of quadrants? | |
|---|---|---|---|---|---|
| CxrPneumoperit, # | CxrCardiomegaly, # | CxrInfiltrates, # | CxrPulmonaryEdema, # | CxrQuadrants, # | X |

LabRad_CXR

Infilt
91 = None
1 = Unilateral
2 = Bilateral
99= Not reported

Quad
0 = 0
1 = 1
2 = 2
3 = 3
4 = 4
99= Not reported

## R21 Additional Data Elements v1.0:

SubjectID #

**Data (0/6)**

**Title: Additional Data Elements**

Demographics

Date of birth: | AgeYears, # | (DD-MMM-YYYY)

Date and time patient was removed from the ventilator

ActualVentStopDay, #

Date: | (DD-MMM-YYYY)   Time: | ActualVentStopTime, $ | (HHMM)   ☐ Discharged from hospital on mechanical ventilation

DischargeOnVent, #

Vital Status

Vital Status at ICU Discharge: (select one) ▼   ICUVitalStatus, #

VitStat
1 = Alive
0 = Dead

YesNo
1 = Yes

Vital Status at Hospital Discharge: (select one) ▼   HospVitalStatus, #

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## Ventilator Settings Log Joined with SPO2 and Blood Gases Log

This dataset is based on the ABGVent_Vent dataset with some observations excluded:

- If the time of the ventilator setting is missing, then the observation is excluded.
- If multiple observations with identical date and time exist for the same subject, the observation with the largest ItemGroupRepeatKey is kept.

Variables that come from the ABGVent_SPO2 and ABGVent_BloodGas datasets are joined to the observations from the ABGVent_Vent dataset in the following manner. The value for each of these variables comes from the last observation (most recent) in the relevant dataset that has a date and time equal to or less than the date and time of the ventilator setting. For cases when the most recent observation is more than 4 hours before the date and time of the ventilator setting, the value of the variable is set to missing. Additionally, for variables that come from the ABGVent_BloodGas dataset, only observations where BloodGasSource is Arterial or Capillary are considered.

| Variable | Format | Type | Label | Algorithm / Notes |
|---|---|---|---|---|
| SubjectID | | # | Subject ID | Randomly generated ID number that uniquely identifies an eligible subject across datasets |
| itemgrouprepeatkey | | # | ItemGroupRepeatKey | = ItemGroupRepeatKey from ABGVent_Vent dataset. SubjectID + ItemGroupRepeatKey uniquely identifies records in this dataset |
| VentDay | | # | Day of ventilator reading (relative to the date of the first ventilator reading) | = VentDay from ABGVent_Vent dataset |
| VentTime | | # | Time of ventilator reading | = VentTime from ABGVent_Vent dataset |
| TotalTimeMin | | # | Minutes since first ventilator reading | = Time, in minutes, since the time of the first ventilator reading |
| VentMode | VentMode<br>1 = Pressure Control<br>2 = PRVC<br>3 = HFOV<br>4 = Volume Control | # | Ventilator Mode | = VentMode from ABGVent_Vent dataset |

| Variable | Format | Type | Label | Algorithm / Notes |
|---|---|---|---|---|
| VentilatorRate | | # | Ventilator Rate (bpm) | = VentilatorRate from ABGVent_Vent dataset |
| SpontaneousResp | YesNoS 1=Yes 0=No | # | Spontaneous Respiration | = SpontaneousResp from ABGVent_Vent dataset |
| VTExhaled | | # | VT exhaled (mL/kg) | = VTExhaled from ABGVent_Vent dataset |
| PIP | | # | PIP (cmH20) | = PIP from ABGVent_Vent dataset |
| PS | | # | pressure support (cmH20) | = PS from ABGVent_Vent dataset |
| MAP | | # | mean airway pressure (cmH20) | = MAP from ABGVent_Vent dataset |
| PEEP | | # | PEEP (cmH20) | = PEEP from ABGVent_Vent dataset |
| ETTleak | | # | ET tube leak (%) | = ETTleak from ABGVent_Vent dataset |
| HFOVFrequency | | # | HFOV frequency | = HFOVFrequency from ABGVent_Vent dataset |
| HFOVAmplitude | | # | HFOV amplitude | = HFOVAmplitude from ABGVent_Vent dataset |
| FiO2 | | # | FiO2 | = FiO2 from ABGVent_Vent dataset |
| SPO2Day | | # | SPO2/End Tidal Day (relative to the date of the first ventilator reading) | = SPO2Day from ABGVent_SPO2 dataset |
| SPO2Time | | # | SPO2/End Tidal Time | = SPO2Time from ABGVent_SPO2 dataset |
| SPO2 | | # | SPO2 pulse oximetry O2sat (%) | = SPO2from ABGVent_SPO2 dataset |
| EndTidalCO2 | | # | End tidal CO2 (mmHg) | = EndTidalCO2from ABGVent_SPO2 dataset |
| BloodGasLabDay | | # | Day of Blood Gas Lab (relative to the date of the first ventilator reading) | = BloodGasLabDay from ABGVent_BloodGas dataset |
| BloodGasLabTime | | # | Time of Blood Gas Lab | = SPO2Time from ABGVent_ BloodGas dataset |

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| Variable | Format | Type | Label | Algorithm / Notes |
|---|---|---|---|---|
| BloodGasSource | Blood<br>1 = Arterial<br>2 = Capillary<br>92 = Unknown | # | Source of Drawn Blood | = SPO2Time from ABGVent_ BloodGas dataset |
| pH | | # | pH (#.##) | = pH from ABGVent_ BloodGas dataset |
| PaCO2 | | # | PaCO2 (mmHg) | = PaCO2from ABGVent_ BloodGas dataset |
| PaO2 | | # | PaO2 (mmHg) | = PaO2from ABGVent_ BloodGas dataset |
| HCO3 | | # | HCO3 bicarb (mEq/L) | = HCO3from ABGVent_ BloodGas dataset |
| OXYGEN_INDEX | | # | Oxygenation Index | = NULL if PaO2 = NULL<br>= 0 else if PaO2 = 0<br>= (FiO2 x 100 x MAP)/PaO2 otherwise |
| oxygen_sat_index | | # | Oxygen Saturation Index | = NULL if SPO2 = NULL<br>= NULL else if SPO2 > 97<br>= 0 else if SPO2 = 0<br>= (FiO2 x 100 x MAP)/SPO2 otherwise |
| SF_RATIO | | # | S/F Ratio | = NULL if FiO2 = NULL<br>= 0 if FiO2 = 0<br>= NULL else if SPO2 > 97<br>= SPO2/FiO2 otherwise |
| PF_RATIO | | # | P/F Ratio | = NULL if FiO2 = NULL<br>= 0 if FiO2 = 0<br>= PaO2/FiO2 otherwise |

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## Subject-level Derived Variables

| Variable | Format | Type | Label | Algorithm / Notes |
|---|---|---|---|---|
| SubjectID | | # | Subject ID | Randomly generated ID number that uniquely identifies an eligible subject across datasets |
| VentFreeDays | | # | 28 Day ventilator-free days | = NULL if Hospital Vital Status is Dead AND time from ventilator start to ventilator stop is < 28 days<br>= 0 else if subject was discharged from hospital on mechanical ventilation<br>= 0 else if time from ventilator start to ventilator stop is >= 28 days<br>= 28 – (time from ventilator start to ventilator stop) otherwise |
| PredictedWeight | | # | Predicted Weight (kg) | For subjects with available height, weight, and gender recorded, predicted body weight calculated using a calculator (Relcore, Inc., Los Angeles, CA) |
| FirstPFRatio | | # | First available PF Ratio | Patient's first non-missing value for PF Ratio as defined in the VentChanges dataset. |
| FirstPFRatioHours | | # | Time of first available PF Ratio (hours after time of first recorded ventilator settings) | Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the first available PF Ratio. |
| FirstSFRatio | | # | First available SF Ratio | Patient's first non-missing value for SF Ratio as defined in the VentChanges dataset. |
| FirstSFRatioHours | | # | Time of first available SF Ratio (hours after time of first recorded ventilator settings) | Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the first available SF Ratio. |

| Variable | Format | Type | Label | Algorithm / Notes |
|---|---|---|---|---|
| FirstOI | | # | First available Oxygenation Index | Patient's first non-missing value for Oxygenation Index as defined in the VentChanges dataset. |
| FirstOIHours | | # | Time of first available Oxygenation Index (hours after time of first recorded ventilator settings) | Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the first available Oxygenation Index. |
| FirstOSI | | # | First available Oxygen Saturation Index | Patient's first non-missing value for Oxygen Saturation Index as defined in the VentChanges dataset. |
| FirstOSIHours | | # | Time of first Oxygen Saturation Index (hours after time of first recorded ventilator settings) | Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the first available Oxygen Saturation Index. |
| PFRatio24 | | # | PF Ratio closest to 24 (+/- 9) hours after time of first recorded ventilator settings | Patient's PF Ratio, as defined in the VentChanges dataset, that is closest to 24 hours after the time of the first recorded ventilator setting. Only values that were between 15 and 33 hours after the time of the first recorded ventilator setting are considered. |
| PFRatio24Hours | | # | Time (hours) of PF ratio closest to 24 (+/- 9) hours | Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the PF Ratio closest to 24 hours. |
| SFRatio24 | | # | SF Ratio closest to 24 (+/- 9) hours after time of first recorded ventilator settings | Patient's PS Ratio, as defined in the VentChanges dataset, that is closest to 24 hours after the time of the first recorded ventilator setting. Only values that were between 15 and 33 hours after the time of the first recorded ventilator setting are considered. |
| SFRatio24Hours | | # | Time (hours) of SF ratio closest to 24 (+/- 9) hours | Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the SF Ratio closest to 24 hours. |

| Variable | Format | Type | Label | Algorithm / Notes |
|---|---|---|---|---|
| OI24 | | # | Oxygenation Index closest to 24 (+/- 9) hours after time of first recorded ventilator settings | Patient's Oxygenation Index, as defined in the VentChanges dataset, that is closest to 24 hours after the time of the first recorded ventilator setting. Only values that were between 15 and 33 hours after the time of the first recorded ventilator setting are considered. |
| OI24Hours | | # | Time (hours) of Oxygenation Index closest to 24 (+/- 9) hours | Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the Oxygenation Index closest to 24 hours. |
| OSI24 | | # | Oxygen Saturation Index closest to 24 (+/- 9) hours after time of first recorded ventilator settings | Patient's Oxygen Saturation Index, as defined in the VentChanges dataset, that is closest to 24 hours after the time of the first recorded ventilator setting. Only values that were between 15 and 33 hours after the time of the first recorded ventilator setting are considered. |
| OSI24Hours | | # | Time (hours) of Oxygen Saturation Index closest to 24 (+/- 9) hours | Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the Oxygen Saturation Index closest to 24 hours. |
| BilateralInfiltrates | YESNO<br>1 = Yes<br>0 = No | # | Bilateral Infiltrates | = Yes if CXRInfiltrates (from LabRad_CXR dataset) is Bilateral for at least one record<br>= No otherwise |
| QuadrantInfiltrates | YESNO | # | Quadrant Infiltrates | = Yes if CXRQuadrants (from LabRad_CXR dataset) is 1 or 2 or 3 or 4 for at least one record<br>= No otherwise |