Requestor: PETAL Network
Funding Source: National Heart, Lung, and Blood Institute

RFP for EHR Data Collection Center

Overview:

The PETAL network is preparing to conduct a pragmatic trial investigating different oxygenation targets for patients on mechanical ventilation. This study will access data from the Electronic Health Records (EHR) of 24 of the 50 hospitals that are affiliated with the PETAL network. The project will require extraction of EHR data for mechanically ventilated adults in intensive care units (ICUs) and emergency departments (EDs) during an observational period of several months prior to the trial and then during the 12-month trial. The PETAL Network seeks to fund a sub-contract for an EHR Data Collection Center to lead efforts for extracting data from the EHR of participating hospitals. Please be advised that the approval of this study is pending and an award will only be made if the study is approved.

Scope of Work:

The responsibilities of the subcontractor will be to:

1. Collect the study data (appendix 1) from the EHR of the participating hospitals,
2. Develop a module that will sample approximately 1 out of 10 patients who will be approached for the long term follow up study. This should happen within approximately 5 days of the patient entering the hospital.
3. Organize the data in a format specified by the PETAL Network Clinical Coordinating Center (CCC),
4. Perform data transformations per specifications developed by the CCC (appendix 2),
5. Transmit the data to the CCC either continuously or periodically (approximately monthly)

The CCC will query the subcontractor after receiving the data, with any issues regarding it. The CCC realizes that the content of the EHR cannot be changed and the purpose of queries will be to insure that the data from each hospital's EHR has been correctly mapped to the data that the CCC has requested. The content of the queries will be worked out between the CCC and the contractor; the purpose of queries is to insure that statistical reporting on the data is possible.

The Massachusetts General Hospital serves as the CCC for the project and will be facilitating the selection process and issuing the subcontract. The CCC is located in the Biostatistics Center in the Department of Medicine and would work closely with the subcontractor.

Format: The data should be made available to the CCC as a set of CSV files. If it is significantly easier for the subcontractor, we can discuss supporting FHIR/XML or FHIR/JSON data.

RFP Requirements:

- Limit response to no more than 5 pages (Arial 11, with standard 0.5 margins). θ
- Description of prior experience with the collection of collecting EHR data including examples of prior performance metrics when available.
- Listing of key personnel.

- Description of the proposed structure and staffing model for the center.
- Detailed scope of work describing the proposed methods for collecting EHR data, curating it and transmitting it to the CCC
- Detailed budget utilizing the standard PHS 398 NIH forms showing first year and subsequent year.
- Estimation of the staffing and equipment requirements for each site that will contribute data

Review Criteria

Selected members of the PETAL Network steering committee will review all submissions and make recommendations. Members from applicant institutions will recuse themselves. Review criteria are the applicants experience, robustness of proposal for collecting data, the budget, the staffing and equipment requirements for each site.

Proposals should be sent to Nancy Ringwood at the PETAL CCC:
nringwood@mgh.harvard.edu

Appendices

1. A list of data to be collected
2. A tentative list of data transformations

Attachment

Results of a survey regarding EHRs at PETAL sites are included as a separate attachment.

Appendices

1. Data Elements for Enrolled Patients

Data Element	Group	Subgroup	Type	Responses
Study ID	Baseline	Administrative	Integer	--
Date and time of presentation to the study hospital	Baseline	Administrative	Date & time	mm/dd/yy hh:mm
Time Zero – Date and time of study enrollment (Date and time of first receipt of invasive mechanical ventilation in a participating study location)	Baseline	Administrative	Date & time	mm/dd/yy hh:mm
Location at study enrollment (time zero)	Baseline	Administrative	Categorical	Emergency Department, Intensive Care Unit
Was the patient admitted to a participating ICU? (no = COROLLA-ED population)	Baseline	Administrative	Categorical	Yes, No
Date and time of admission to the participating ICU	Baseline	Administrative	Date and time	mm/dd/yy hh:mm
Type of participating ICU in which the patient was located	Baseline	Administrative	Categorical	Medical, Surgical, Neurological, Cardiovascular, Trauma, Burn, Mixed, Other
Source of admission to the participating ICU	Baseline	Administrative	Categorical	ED, OR, PACU, hospital ward, outside hospital, other
Age at enrollment (years)	Baseline	Demographic	Number	Range 18 – 120
Sex	Baseline	Demographic	Categorical	Male / Female
Race	Baseline	Demographic	Categorical	Alaskan/Indian, Asian, Black, Pacific Island, White, Declined, Unknown
Ethnicity	Baseline	Demographic	Categorical	Non-Hispanic, Hispanic, Declined, Unknown
Height (centimeters)	Baseline	Demographic	Number	Range 50 – 250
Weight (kg)	Baseline	Demographic	Number	Range 20 – 700
Elixhauser comorbidity index	Baseline	Comorbidity	Number	Range −19 to 89
Heart rate	BL / OS*	Physiologic	Integer	Range 20 – 300
Systolic blood pressure	BL / OS*	Physiologic/SOFA	Integer	Range 20 – 300
Diastolic blood pressure	BL / OS*	Physiologic/SOFA	Integer	Range 20 – 300
Exhaled tidal volume (mL)	BL / OS*	Physiologic/Vent	Integer	Range 20 - 3000
Observed respiratory rate (breaths per min)	BL / OS*	Physiologic/Vent	Integer	Range 2 – 100
Fraction of inspired oxygen (FiO2)	BL / OS*	Physiologic/Vent	Percentage	Range 21% - 100% (or 0.21 – 1.0)
Positive end-expiratory pressure (cmH20)	BL / OS*	Physiologic/Vent	Integer	0 – 100
Non-invasive oxygen saturation by pulse oximetry (SpO2)	BL / OS*	Physiologic	Percentage	Range 20% - 100%
Glasgow Coma Scale	BL / OS*	Physiologic/SOFA	Integer	Range 3 – 15
pH [ABG]	BL / OS*	Labs	Number	5.0 – 8.0
Partial pressure of oxygen (PaO2) (mmHg) [ABG]	BL / OS*	Labs/SOFA	Integer	Range 20 – 700
PaCO2 [ABG]	BL / OS*	Labs	Number	10 – 200
SaO2 [ABG]	BL / OS*	Labs	Number	0 – 700
White blood cell count ($x10^3$/microliter) [CBC]	BL / OS*	Labs	Number	0 -- 300
Hemoglobin (g/dL) [CBC]	BL / OS*	Labs	Number	0 – 60
Hematocrit (%) [CBC]	BL / OS*	Labs	Number	0 – 100
Platelet count ($x10^3$/microliter) [CBC]	BL / OS*	Labs/SOFA	Integer	Range 0 – 3,000

Sodium (mmol/L) [BMP]	BL / OS*	Labs	Number	90 – 200
Potassium (mmol/L) [BMP]	BL / OS*	Labs	Number	0.5 - 20
Chloride (mmol/L) [BMP]				
Bicarbonate (mmol/L) [BMP]	BL / OS*	Labs	Number	0 – 70
Creatinine (mg/dL) [BMP]	BL / OS*	Labs/SOFA	Number	0.01 – 100
Blood urea nitrogen (mg/dL) [BMP]	BL / OS*	Labs	Number	0 – 400
Glucose (mmol/L) [BMP]	BL / OS*	Labs	Number	20 – 3000
Serum albumin (g/dL)	BL / OS*	Labs	Number	0 -- 10
Total bilirubin (mg/dL)	BL / OS*	Labs/SOFA	Number	Range 0.1 – 100
Lactic acid (mmol/L)	BL / OS*	Labs	Number	0.1 – 100
Troponin	BL / OS*	Labs	Number	0 – 300
Did the patient die prior to hospital discharge?	Outcomes	Outcomes	Categorical	Yes / No
If the patient died prior to hospital discharge, what was the date and time of death?	Outcomes	Outcomes	Date & time	mm/dd/yy hh:mm
Date and time of first liberation from invasive mechanical ventilation during the index hospitalization.	Outcomes	Outcomes	Date & time	mm/dd/yy hh:mm
Date and time of final liberation from invasive mechanical ventilation during the index hospitalization.	Outcomes	Outcomes	Date & time	mm/dd/yy hh:mm
Did the patient receive vasopressors between enrollment and hospital discharge prior to day 28?	Outcomes	Outcomes	Categorical	Yes, No
Date and time of first vasopressor receipt after enrollment	Outcomes	Outcomes	Date & time	mm/dd/yy hh:mm
Date and time of final vasopressor receipt between enrollment and hospital discharge	Outcomes	Outcomes	Date & time	mm/dd/yy hh:mm
Did the patient receive renal replacement therapy between enrollment and hospital discharge before day 28?	Outcomes	Outcomes	Categorical	Yes / No
Date and time of final transfer out of the participating intensive care unit during the index hospitalization.	Outcomes	Outcomes	Date & time	mm/dd/yy hh:mm
Date and time of final transfer out of any intensive care unit during the index hospitalization.	Outcomes	Outcomes	Date & time	mm/dd/yy hh:mm
Date and time of discharge from the hospital for the index hospitalization.	Outcomes	Outcomes	Date & time	mm/dd/yy hh:mm
ICD-10 discharge diagnoses (list up to 20 ICD-10 codes) for index hospitalization	Discharge	Administrative	ICD-10 code	letter-number combination
Was patient selected for cognitive outcome assessment?	Discharge	Discharge	Categorical	Yes / No

2. Preliminary specification of the required data transformations

- **Included in COROLLA primary analysis** – Using the data-point "Was the patient admitted to a participating ICU" to separate out patients in the main trial from patients in the COROLLA-ED report.
- **SOFA score at baseline and on each study day** – Calculated from each of the elements marked as "SOFA"
- **Elixhauser comorbidity index** – calculated using the Elixhauser formula from the ICU-10 discharge diagnoses
- **Ventilator-free days** – calculated from death (Y/N) and the date of first and final mechanical ventilation
- **Vasopressor-free days** – calculated from death (Y/N) and the date of first and final vasopressor receipt
- **ICU-free days** – calculated from death (Y/N) and the date of final ICU transfer