Patient CRF Instructions

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# Baseline

By baseline we are referring to data that is entered into REDCap on Day 1 only.

Day 1 is ICU admission day. (We recognize this may be an incomplete day.)

Data for each study day should be collected following the calendar clock (midnight to midnight).

## Patient Information

|  |  |  |
| --- | --- | --- |
| **Sex** | Place a 🗸 in the appropriate box (male or female). | |
| **Age** | Record patient’s age at the time of screening. | |
| **Hospital Admission Date/Time** | Enter the date and time the patient was admitted to the hospital. This is the formal time when the patient is admitted to the hospital as noted in the medical record. For patients transferred from another institution directly to the ICU, the ICU admission date/time is to be used for the hospital admission date/time. | |
| **ICU Admission Date/Time** | Enter the date and time the patient was admitted to the ICU in your hospital. If the patient has been admitted to your ICU multiple times, use the **most recent** admission. If a patient is transferred from another ICU, enter the date of admission to **your** ICU***.*** If the patient is admitted directly to your ICU, the ICU and hospital admission dates and times will be the same. | |
| **Type of Admission** | Place a 🗸 in only **one** of the following categories:   * **Medical:** defined as a patient admitted to the ICU for treatment of a medical problem (without any surgical intervention). This includes patients admitted from a cardiology/radiology intervention suite and burn patients. Proceed to Taxonomy A for Primary ICU Diagnosis Medical (Non-Operative Condition System). * **Surgical Elective:** defined as a patient admitted to the ICU from the operating room directly or a recovery unit following a planned surgical procedure. Proceed to Taxonomy B for Primary ICU Diagnosis (Operative Condition System). * **Surgical Emergency:** defined as a patient admitted to the ICU from the operating room directly or a recovery unit following an unplanned surgical procedure. Proceed to Taxonomy B for Primary ICU Diagnosis (Operative Condition System).   *Note:* If a surgical patient develops a medical complication and is transferred to the ICU from the surgical ward, this would be a “medical” admission type. | |
| **Primary ICU Diagnosis** | Choose the most pertinent diagnosis from the taxonomy provided that **resulted in the patient’s admission to ICU**. Only **one** diagnosis can be chosen. Remember, symptoms are not an admission diagnosis (e.g. respiratory distress, hypotension, etc).  Example: A patient was admitted to hospital for an elective cholecysectomy. Post-operatively the patient experienced a cardiac arrest on the ward and was subsequently admitted to the ICU. This patient would be classified as *medical* admission type, and *cardiac arrest* as primary ICU diagnosis.  If the admission diagnosis is not present in the taxonomy, under the correct admission type (Medical, Surgical Elective or Surgical Emergency) select “other” under the appropriate body system (Respiratory, Neurologic, etc) and specify the admission diagnosis.  *Note:* We are specifically interested in reporting on patients with **sepsis, pancreatitis, bariatric surgery, ARDS, and burns.** If a suitable diagnosis for a patient includes one of these conditions, select this condition in preference to other diagnoses.  Example: If a patient is admitted with sepsis and pneumonia, select sepsis. | |
| **If ICU Diagnosis = Medical, Burns complete the following section.** | | |
| **Date of burn injury:** | | Record the date of burn injury. |
| **Total body surface area (%TBSA) burn:** | | Record the total burn size as percent Total Body Surface Area (%TBSA). This assessment is made by the attending surgeon/physician based on her/his clinical judgment. Record TBSA in the nearest whole number rounding up from 0.5 and down from 0.4; i.e. 26.5% is recorded as 27% and 26.4% is recorded as 26%. |
| **Type of burn:** | | Place a 🗸 in the box that corresponds to the type of burn the patient has and if the type of burn is not listed, place a 🗸 in the “Other” box and specify the type of burn.   |  |  | | --- | --- | | * Scald | * Radiation | | * Fire | * Unknown | | * Chemical | * Other (specify): | |  |  | |
| **Is there presence of full thickness burn (3rd degree)?** | | Full thickness burns destroy both layers of skin (epidermis and dermis) and may penetrate more deeply into underlying structures. These burns have a dense white, waxy or even charred appearance and the area is stiff. Often there is no pain, as sensory nerves in the dermis are destroyed. |
| **Is Inhalation Injury Present? If yes, specify Severity Score:** | | * 0 – No injury – Absence of carbonaceous deposits, erythema, edema, bronchorrhea, or obstruction * 1 – Mild injury – Minor or patchy areas of erythema, carbonaceous deposits, bronchorrhea, or bronchial obstruction * 2 – Moderate injury – Moderate degree of erythema, carbonaceous deposits, bronchorrhea, or bronchial obstruction * 3 – Severe injury – Severe inflammation with friability, copious carbonaceous deposits, bronchorrhea, or obstruction * 4 – Massive injury – Evidence of mucosal sloughing, necrosis, endoluminal obstruction |
| **If ICU Diagnosis = Surgical, Vascular/Cardiovascular complete the following section** | | |
| Date of cardiac surgery: | | Record the date of the cardiovascular/vascular surgery that resulted in the patient’s admission to ICU. |
| **The Canadian Cardiovascular Society (CCS) grading of angina pectoris** | | The CCS is a clinical tool used to assess the degree of severity of a patient’s angina.   * ***Class 1 (I)*** – Angina only with strenuous exertion. (Presence of angina only during strenuous, rapid, or prolonged ordinary activity (walking or climbing) the stairs. * ***Class 2 (II)–*** Angina with moderate exertion. Slight limitation of ordinary activities when they are performed rapidly, after meals, in cold, in wind, under emotional stress, during the first few hours after waking up, but also walking uphill, climbing more than one flight of ordinary stairs at a normal pace and in normal conditions. * ***Class 3 (III)*** – Angina with mild exertion. Having difficulties walking one or two stores or climbing one flight of stairs at normal pace and conditions. * ***Class 4 (IV)*** – Angina at rest. No exertion needed to trigger angina. |
| **New York Heart Association (NYHA) Functional Classification** | | The NYHA Functional Classification provides a simple way of classifying the extent of heart failure.   * ***Class 1 (I)*** – Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc. * ***Class 2 (II***) – Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity. * ***Clas***s ***3 (III)*** – Marked limitation in activity due to symptoms, even during less‐than‐ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest. * ***Class 4 (IV)*** – Severe limitations. Experiences symptoms even while *at rest*. Mostly bedbound patients. |
| **Left Ventricular Ejection Fraction (LVEF):** | | LVEF is an important measurement in determining how well a patient’s heart is pumping out blood and in diagnosing and tracking heart failure.  Record the most recent LVEF value measured, as a percentage, within 3 months of surgery.  If the echo report includes descriptive results but no percent, document it as the following:   * + Normal = 51%   + Moderate = 35%   + Poor = 25%   + Severe = 20% |
| **Did the patient receive any of the following cardiac medications (select all):** | | * ***ACE inhibitor*** – a class of drugs used primarily for the treatment of hypertension and congestive heart failure. Examples include benazepril, zofenopril, perinodopril, trandolapril, captopril, enalapril, lisinopril and ramipril. * ***Acetylsalicyclic acid (ASA)*** – Aspirin is used long-term to help prevent heart attacks, ischemic stroke and blood clots in people at high risk. * ***Beta*** ***Blockers*** – is a class of drug that are used to manage cardiac arrhythmias and to protect the heart from a second heart attack, after a first heart attack. Examples include propranolol, labetalol, nadolol and oxprenolol. * ***Statins*** – a class of lipid-lowering drugs. Examples include atorvastatin (Lipitor), cerivastatin, lovastatin, and simvastatin. |
| **Urgency of cardiac surgery:** | | * ***Elective*** – routine admission for operation. * ***Urgent*** – patients who have not been electively admitted for operation but who require intervention or surgery on the current admission for medical reasons. These patients cannot be sent home without a definitive procedure. * ***Emergency*** – Operation before the beginning of the next working day after decision to operate. * ***Salvage*** – Patients requiring cardiopulmonary resuscitation (external cardiac massage) en route to the operating theatre or prior to induction of anaesthesia. This does not include cardiopulmonary resuscitation following induction of anaesthesia. |
| **Was the patient considered to be in a critical pre-operative state?** | | Ventricular tachycardia or ventricular fibrillation or aborted sudden death, preoperative cardiac massage, preoperative ventilation before anaesthetic room, preoperative inotropes or IABP, preoperative acute renal failure (anuria or oliguria <10mL/h). |
| **Weight of the intervention** | | This measures the extent or size of the surgical intervention. All major interventions on the heart such as: CABG, valve repair or replacement, replacement of part of the aorta, repair of a structural defect, maze procedure, and/or resection of a cardiac tumour.  Considering the extent of the patient’s surgical procedure, please select the option that most appropriately describes the weight of the intervention:   * Isolated CABG procedure * Isolated (single) non-CABG procedure (e.g. single valve procedure, replacement of ascending aorta, correction of septal defect, etc.); * Two (2) procedures (e.g. CABG + aortic valve replacement), or CABG + mitral valve repair, or aortic valve replacement + replacement of ascending aorta, or CABG + maze procedure, or aortic valve replacement + mitral valve repair, etc.); * Three (3) major procedures or more (e.g. aortic valve replacement + mitral valve repair + CABG, or mitral valve repair + CABG + tricuspid annuloplasty, etc.), or aortic root replacement when it includes aortic valve replacement or repair + coronary reimplantation + root and ascending replacement).   REMEMBER: Only major cardiac procedures should be noted. Examples of procedures which are not to be included are: sternotomy, closure of sternum, myocardial biopsy, insertion of intra-aortic balloon, pacing wires, closure of aortotomy, closure of atriotomy; removal of atrial appendage, coronary endarterectomy as part of CABG, etc. |
| **Did the surgery involve the thoracic aorta?** | | Indicate whether the patient’s surgery involved the thoracic aorta. |
| **Was Cardiopulmonary Bypass (CPB) used?** | | Indicate whether CPB was used during the patient’s cardiac surgical procedure. |
| **Comorbidities** | | |
| Place a 🗸 beside all co-morbidities present using the taxonomy provided. Comorbidities are listed according to body-system. Only those co-morbidities found on the taxonomy listing should be recorded since these are the ones used to calculate the Charlson Comorbidity Index and the Functional Comorbidity Index.  Example: A patient’s primary ICU diagnosis is cardiac arrest, and the patient is asthmatic, has type II diabetes, is obese, and is hearing impaired. Under co-morbidities, select:   * Pulmonary: Asthma * Endocrine: Diabetes Type I or II * Endocrine: Obesity and/or BMI >30 * Miscellaneous: Hearing Impairment | | |
| **Myocardial** | | **Angina:** chest pain caused by reduced blood flow to the heart muscle.  **Arrythmia:** heartbeat is irregular, too fast, or too slow.  **Congestive heart failure:** chronic condition that affects the chambers of your heart where the heart does not function as it should.  **Recent MI:** MI within past 90 days.  **Previous MI:** MI more than 90 days ago.  **Moderate pulmonary hypertension:** RVSP = 31-55 mmHg.  **Severe pulmonary hypertension:** RVSP > 55 mmHg.  **Valvular:** Indicate if the patient currently has any uncorrected valvular heart disease and if YES, indicate the type. Types include: > 2+ AI, > 2+ AS, > 2+ MR and > 3+ TR.  **Active endocarditis:** Patient still on antibiotic treatment for endocarditis at time of surgery.  **Previous Cardiac Surgery:** Prior cardiothoracic surgery causes scar tissue to form and may increase difficulty and or risk in subsequent procedures. Capture (yes/no) both open and minimally invasive procedures. |
| **Vascular** | | **Hypertension:** Physician diagnosis of hypertension.  **Extracardiac arteriopathy:** One or more of the following: claudication, carotid occlusion or >50% stenosis, amputation for arterial disease or previous or planned intervention on the abdominal aorta, limb arteries or carotid.  **Cardiovascular Disease (Stroke or TIA):** Any history of documented neurological symptoms consistent with stroke including, where possible, imaging evidence of ischemic or hemorrhagic damage. |
| **Pulmonary** | | **Chronic Lung Disease (Other than COPD and Asthma):** Interstitial lung disease, or ILD, is a common term that includes more than 200 chronic lung disorders interstitial lung diseases are named after the tissue between the air sacs of the lungs called the interstitium. This tissue can be affected by fibrosis (scarring) and lead to respiratory insufficiency.  **COPD:** Diagnosis is confirmed and severity is graded using pulmonary function testing (PFT). Bronchitis and emphysema are considered COPD, asthma is not. Severe obstructive or restrictive lung disease requiring supplemental O2 at rest (e.g. emphysema, chronic bronchitis). |
| **Neurologic** | | **Dementia:** Indicate if there is a diagnosis of dementia.  **Hemiplegia:** Paralysis of one side of the body.  **Neurologic illness:** Indicate if there is a diagnosis, such as MS or Parkinsons. |
| **Endocrine** | | **Diabetes type 1 or 2 on insulin:** Regardless of the duration of disease, select this option if the patient is prescribed insulin at baseline  **Diabetes type II, not on insulin:** select if the patient is on oral hypoglycemic agents or no diabetes medication  **Diabetes with end organ damage**: In addition to selecting one of the two options above, indicate if end organ damage is present due to the disease  **Obesity:** Select if the patient’s BMI is >30 |
| **Renal** | | **Moderate renal disease:** Creatinine clearance 51-85 mL/min.  **Severe renal disease:** Creatinine clearance <50 mL/min and NOT on dialysis  **Dialysis (regardless of serum creatinine level):** This measure is related to hemodialysis, peritoneal dialysis or CRRT. Does not include ultrafiltration. ***Note: this would exclude the patient from the study if they were on dialysis when randomized.*** |
| **Gastrointestinal** | | **Gastrointestinal disease:** This includes hernias or reflux  **GI Bleeding:** Any history of hemorrhage anywhere in the gastrointestinal tract that was investigated and/or required blood transfusion within the past 6 months.  **Inflammatory bowel:** Indicate if the patient has received this diagnosis  **Mild liver disease:** Raised serum aminotransferase or alkaline phosphatase levels or both, but total serum bilirubin <2.5 mg/dL and no coagulopathy (INR <1.5)  **Moderate or severe liver disease:** liver disease beyond the above definition for mild liver disease  **Peptic ulcer disease:** Any history of ulcers (defined as mucosal erosions equal to or greater than 0.5 cm) on any area of the gastrointestinal tract. |
| **Cancer/Immune** | | Indicate if the patient has a diagnosis of any of the listed comorbidities (AIDS, tumor, leukemia, lymphoma, metastatic solid tumor). |
| **Psychological** | | Indicate if the patient has a diagnosis of any of the listed comorbidities (anxiety, panic disorder, depression) |
| **Musculoskeletal** | | **Arthritis:** Select if the patient has either rheumatoid or osteoarthritis  **Connective Tissue Disease:** Indicate if the patient has received this diagnosis  **Degenerative Disc Disease:** This includes back disease, spinal stenosis or severe chronic back pain  **Osteoporosis:** Indicate if the patient has received this diagnosis |
| **Substance Use** | | **Heavy alcohol use:** if the patient has a documented history of alcohol abuse in the medical chart, it should be recorded here. Heavy alcohol use or binge drinking is defined as >7 drinks/week or >3 drinks/occasion for women and >14 drinks/week or >4 drinks/occasion for men.  **Current Smoker:** “Current smoker” should be selected if the patient stopped smoking < than 6 weeks prior to surgical procedure.  **Drug abuse history:** if the patient has a documented history of drug abuse in the medical chart, it should be recorded here. |
| **Miscellaneous** | | **Hearing impairment:** indicate if the patient is very hard of hearing, even with hearing aids.  **Visual Impairment:** Indicate if the patient has a diagnosis of cataracts, glaucoma or macular degeneration.  **Severe mobility impairment:** Severe impairment of mobility secondary to musculoskeletal or neurological dysfunction. |
| **APACHE II Score** | | |
| **APACHE II Score** | | If routinely calculated, directly enter the score recorded in the patient’s chart. To calculate the score, you may use any tool you wish. We recommend using the following website: [http://www.sfar.org/scores2/apache22. php](http://www.sfar.org/scores2/apache22.%20php). Record the calculated score.  *Remember:*   * For each APACHE variable, use **the single worst value** out of all values from the **first 24 hours** of this ICU admission. If variables are not available from the first 24 hours, use data closest to ICU admission except for GCS score, in which the highest score should be used (ie. the score for when the patient is most oriented – see our website worksheet). * Ensure the units that you are using for serum sodium, potassium and white blood count correspond with the units designated in the tool you are using. * For temperature, rectal is the same as oral, temporal, tympanic and bladder temperatures. If the patient is on a hypothermia protocol (cooling), please use the patient’s temperature before cooling was initiated.   If the calculated APACHE II score is ≤ 10 please indicate if the score was calculated using complete data or if partial data was used (i.e. CBC was never done).  If the APACHE II Score is not available, please provide the reason why the APACHE II Score cannot be calculated   * No bloodwork taken * Data cannot be found |

## Enrollment

**The following data relate to conditions present at the time of enrollment into the study.**

|  |  |
| --- | --- |
| **Definition of Acute Kidney Injury (AKI)** | Acute kidney injury (AKI), or as previously called Acute Renal Failure (ARF), is commonly defined as an abrupt decline in renal function. We are using the uniformly accepted definition of AKI (i.e. RIFLE Criteria) to determine presence of AKI in study patients at baseline. As such the patient’s urine output is captured here. Creatinine values will also be captured during the patient’s participation in the study and will be recorded on a separate CRF.  (NOTE: RIFLE is an acronym or ‘Risk, Injury, and Failure; and Loss; and End-stage kidney disease.’) |
| **Upon enrollment, is the patient suffering from Acute Kidney Injury (AKI)?** | **Does the patient meet any of the criteria, related to urine output, listed below at the time of enrollment.**  If ‘yes’, indicate **urine output (UO) at the time of enrollment**:   * UO < 0.5 mL/kg/h for 6h * UO < 0.5 mL/kg/h for 12h * UO < 0.3 mL/kg/h for 24h (oliguria) * Anuria for 12h   Indicate the **baseline (normal) creatinine prior to illness**. |
| **Wound Definitions** | **Pressure ulcer** – also called ‘bedsores’ or ‘decubitus ulcers’ are injuries to the skin and underlying tissue resulting from prolonged pressure on the skin. They most often develop on skin that covers bony areas, such as heels, ankles, hips and tailbone.  **Enterocutaneous fistula** – is an abnormal connection that develops between the intestinal tract or stomach and the skin. As a result, contents of the stomach or intestines leak through to the skin. Most enterocutaneous fistulas occur after bowel surgery.  **Open abdomen** – An abdominal wall defect created by intentionally leaving on abdominal incision open at the completion of intraabdominal surgery or by opening (or re-opening) the abdomen because of a concern for abdominal compartment syndrome.  **Wound dehiscence** – Is a surgical complication in which a wound ruptures along a surgical incision. |
| **Was a wound present at enrollment?** | If ‘yes’, please indicate all that apply:   * Is it a pressure ulcer? * Is it an enterocutaneous fistula? * Is it an open abdomen? * Is it a wound dehiscence? |

## **Baseline SOFA Score**

SOFA (sequential organ failure assessment) score is used to determine organ dysfunction/failure in the ICU. To calculate, there are variables that **must** be collected at baseline. **These variables must be from the** **first 24hrs after patient’s ICU admission and not according to study day**. If the particular variable is missing for the day, choose the range that includes ‘N/A’.

|  |  |
| --- | --- |
| **Computed SOFA Score already available?** | If yes, you may enter the total computed. |
| If no, each component of the score should be entered into REDCap. |
| **Lowest PaO2/FiO2 Ratio**  (also known as P/F ratio) | This is an indication of the patient’s respiratory status; a lower ratio indicates a worse status. The PaO2 and FiO2 values are from arterial blood gases and can be obtained from nursing/respiratory flowsheets. You will need to determine the **lowest P/F** ratio in the study day regardless of whether the patient is ventilated or not. Some patients may have many PaO2 and FiO2 values available daily and we have provided a table and instructions (see Appendix F) to help you find the lowest ratio. If this data is not available in the first 24 hours of ICU stay, you may extend data collection for the variable to a maximum of 48 hours. |
| **Lowest Platelets** | This is an indication of the coagulation status of the patient and the lower the value, the worse the status. Find the lowest platelets in units x103/mm3 and pick the corresponding range for this value. |
| **Highest Total Bilirubin** | This is an indication of liver function and the higher the value, the worse the status. Find the highest total bilirubin in the day and pick the range that corresponds to this value. Ensure that you are choosing the ranges with the correct units (i.e. mg/dL or micromoles/L). |
| **Vasopressors** | These are drugs for hypotension and the higher the dose needed to maintain a normal blood pressure, the worse the hypotension. Some patients may not be on vasopressors and instead a mean arterial pressure (MAP) is needed.  a) If the patient received vasopressors today (defined as Dobutamine, Dopamine, Epinephrine/Adrenaline or Norepinephrine/Adrenaline) find the **highest** hourly dose received today and pick the corresponding range. We are not interested here in other vasopressors except those listed above, other vasopressors will be recorded on the vasopressors and inotropes form.  b) If the patient did not receive vasopressors today, find the lowest MAP. If this is not on the RN flowsheet, you can calculate this using the formula:  **MAP = 1/3 lowest systolic BP + 2/3 corresponding diastolic BP**  Or use the tool on the website: <http://www.mdcalc.com/mean-arterial-pressure-map/> |
| **Conscious State** | Choose the option from each of the 3 categories (eye opening, verbal response, best motor response that gives the **highest score** **for the first 24 hr period after patient’s ICU admission** If the patient is sedated, go back to the period when the patient was not sedated or approximate what the score would be if sedation was removed. Enter the scores under the 3 separate categories. |
| **Highest Creatinine** | This is an indication of renal status. The higher the creatinine the worse the renal function. Find the **highest** creatinine in the study day and pick the corresponding ranges. Ensure you use the correct units. |
| **Total Urine Output** | This is an indication of renal status. The lower the urine output, the worse the renal function. Find the **total** urine output for the patient’s first 24 hours in ICU and pick the corresponding ranges.  Ex. If patient is admitted at 18:00 on September 20th, calculate the total urine output from 18:00 on September 20th until 18:00 on September 21st.  *Note:* If there is missing urine output data in the first 24-hour period, you may extrapolate the data you have to give an estimate of total urine output for the first 24 hours. Ex. If patient is admitted at 18:00 and has total urine output of 400 ml for the 6 hour period from 18:00-23:59, total urine output can be calculated as 400 ml x 4 = 1600 ml to estimate the 24 hour period. |

## Nutrition Assessment

|  |  |
| --- | --- |
| **Was a formal nutrition assessment done?** | We mean a nutritional assessment completed by a nutrition specialist (e.g. dietitian) where specific requirements of the patient are taken into consideration (e.g. weight loss, malnutrition, clinical condition) and nutrition requirements (ex. calorie requirements, protein requirements, etc). If a physician or other clinician simply uses a weight based goal, such as 25 kcal/kg/day to determine energy requirements, we do not consider this as a formal nutritional assessment.  **If ‘yes’, specify the date of nutrition assessment was completed** |
| Malnutrition (Inclusion Criteria 2b) | |
| **Moderate to Severe Malnutrition** | Indicate if the patient was assessed for and met criteria for moderate to severe malnutrition. Note this question is regarding a diagnosis of malnutrition based on traditional criteria from nutrition societies and validated tools. It is **not** asking about nutrition risk.  If yes, indicate the criteria the patient met from the following five categories (check all that apply):   * Unintentional weight loss * Reduced food intake * BMI * Physical findings – note if your site uses CT or ultrasound to assess muscle and/or fat wasting, please provide the qualitative or quantitative findings from the procedure that you used to determine wasting.   If they met a criteria not listed, enter it under ‘other’ and specify the criteria. |
| Clinical Frailty Scale (Inclusion criteria 2c) | |
| **Clinical Frailty Scale (CFS)** | This questionnaire will help us further understand the patient’s level of fitness or frailty and will be an important subgroup analysis in this trial. The study team member screening the patient will complete this questionnaire with the closest family member or, if possible, by collecting the data directly from the patient later on after they recover.  **We stress that we need this scale recorded on all patients, not just those meeting this inclusion criteria.** So it can be done prior to randomization (if part of the inclusion criteria) or after randomization if they are eligible using some other inclusion criteria.  ***The scale should be completed by considering the participant’s overall condition from prior to getting sick and coming to hospital (within 2 weeks prior to the current hospitalization).***  The interviewer should:   1. Show the family member the pictures on the questionnaire. Read them the accompanying text for each category. 2. The family member should then choose the one that most closely represents the patient’s overall condition within two weeks prior to their current hospital admission.    1. If the family member is not sure if that is the best category for the participant, read them the text for the categories above and below it.   If they are cannot decide between 2 categories, select the category the represents the higher level of function. |
| SARC-F Score (Inclusion criteria 2d) | |
| **SARC-F** | The SARC-F has been developed as a possible rapid diagnostic test for sarcopenia. This questionnaire will help us further understand the patient’s skeletal muscle mass and strength. The study team member screening the patient will complete this questionnaire with the closest family member or, if possible, by collecting the data directly from the patient later on after they recover.  **We stress that we need this scale recorded on all patients, not just those meeting this inclusion criteria.** So it can be done prior to randomization (if part of the inclusion criteria) or after randomization if they are eligible using some other inclusion criteria.  ***The scale should be completed by considering the participant’s overall condition from prior to getting sick and coming to hospital (within 2 weeks prior to the current hospitalization).***  The interviewer should:   1. Ask the family member each of the 5 questions, first reading the question, then listing the response options. 2. The family member should then choose the one that most closely represents the patient’s overall condition within two weeks prior to their current hospital admission. |

## Nutrition Goals

|  |  |  |
| --- | --- | --- |
| **Height** | Record height in **meters**.  If unable to obtain “actual” value, use estimated height or height obtained from family member and check the box indicating the data was estimated. | |
| **Dry Body Weight** | Record patient’s weight based on pre-ICU actual weight in **kilograms.**  If unable to obtain “actual” value, use estimated weight or weight obtained from family member and check the box indicating the data was estimated. | |
| **BMI** | When entering data into REDCap, this BMI value (kg/m2)will be calculated for you once height and dry weight are entered. | |
| Determining the Nutritional Goals | | |
| **Weight used to determine goal calorie requirement (kg)** | **Record the weight that was used to determine the energy goal calculations for the study (i.e. following the patient’s randomization to a study arm).**  **NOTE: This weight may or may not be different from the dry body weight entered above. This weight will be used to determine energy adequacy (see Daily Nutritional Adequacy form).** | |
| **Weight used to determine goal protein requirement (kg)** | **Record the weight that was used to determine the protein goal calculations for the study (i.e. following the patient’s randomization to a study arm).**  **NOTE: This weight may or may not be different from the dry body weight entered above. This weight will be used to determine protein adequacy (see Daily Nutritional Adequacy form).** | |
| **Goal Calorie Requirement**  **(kcal/day)** | Enter the goal kilocalories according to the nutrition assessment. If the requirement is a range, indicate one point in the range or take the **midpoint** of the range. If nutrition goals are initially reduced (eg. due to refeeding syndrome risk, post-op status, concern with feeding intolerance, etc) do **not** enter the reduced calorie requirements. Instead, enter the calories that the patient would ideally receive if these issues were not of concern.  Eg. Mr.X is a 70 kg man and the RD used an equation of 25 kcal/kg/d to calculate calorie  requirements and 1.2 g/kg/d to calculate protein requirements. This equates to 1750 kcal/d  and 84 g protein/d. Enter 1750 for the goal calorie requirements. | |
| **Precise Goal Protein Requirement (within randomized protein group)**  **(g/day)** | Enter the goal for protein, in grams, according to the nutrition assessment. The goal protein requirements must fall within the range the patient was randomized to (≤1.2 g/kg/d or ≥2.2 g/kg/d). If the requirement is a range, indicate a precise requirement or the midpoint of the range. If nutrition goals are initially reduced (eg. due to refeeding syndrome risk, post-op status, concern with feeding intolerance, etc) , do **not** enter the reduced protein requirements. Instead, enter the grams of protein the patient would ideally receive if these issues were not of concern.  Eg. In the example above for Mr.X, the goal protein requirements would be entered as 84 g. | |
| Initiation of Nutrition Therapy **For both enteral nutrition (EN) and parenteral nutrition (PN) enter the start and stop dates.** | | |
| ***When was [EN or PN] first initiated?*** | | Indicate when EN and PN was first initiated, either before this ICU admission, during the first 28 days of ICU admission (include date and time) or not initiated during the first 28 days of this ICU admission. |
| ***When was [EN or PN] discontinued?*** | | If EN or PN were started either prior to ICU admission or in ICU, indicate whether they stopped in ICU during first 28 days (include date and time), or indicate that the patient was still receiving EN or PN in ICU after study day 28. |
| **What was the nutrition delivery technique recommended by physician or dietitian at initial assessment for enteral nutrition?** | | Choose one option from the list which best describes the delivery technique recommended by the physician or dietitian at the initial order of nutrition. This means if an assessment was completed before randomization that is the one that should be used.  Select one of the following:   * **Initiate EN: start at low rate and progress to hourly goal rate**   Eg. Start at 25 ml/hr and increase to 50 ml/hr then 75 ml/hr (hourly goal rate)   * **Initiate EN: start at OR progress to 24 hr Volume Goal Based hourly rate**   Hourly rate is determined by 24hr volume goal. This includes the following scenarios:   * Starting at lower rate on Day 1 and progressing to 24 hr volume based hourly rate. Eg. 24 hr volume goal = 1800 mls (75 ml/hr) and feeds start at 25 ml/hr Day 1 and then progress to full goal volume OR * Starting at full rate on Day 1 as determined by the 24 hr volume. Eg. 24 hr volume goal = 1800 ml (75ml/hr) and feeds start at 75 ml/hr * **Initiate EN: start at hourly goal rate**   Eg. Pt requires 75 ml/hr and feeding starts at 75 ml/hr   * **Initiate EN: keep at low rate (trophic feed: no progression)**   Eg. Start at 10 ml/hr and leave as is   * **Initiate EN: bolus feeds**   Eg. Pt requires 75 ml/hr and starts with boluses of 450 ml q 6 hours.   * **Keep Nil Per Os or Nil By Mouth** * **Oral nutrition** * **Parenteral Nutrition** |

# Daily Data

Collect data daily until ICU discharge, ICU death, or until study day 12, whichever comes first. If the patient remains in ICU past day 12, complete the Daily Protein Data form (days 13-28). Once daily data is complete, proceed to the outcomes forms.

You must collect data on consecutive days following ICU admission, **even if the patient does not receive nutrition**, and even when study days fall on weekends. If you do not work weekends, collect this data retrospectively when you return to work.

REMEMBER: Study day 1 is from ICU admission until midnight on that calendar day. This might be less than 24 hours. Day 2 and subsequent days are labeled by **calendar day** (i.e. midnight to midnight), **not** according to your flowsheet unless your flowsheet runs from midnight to midnight.

Example: A patient is admitted May 2nd at 14:28. Day 1 begins at 14:28 and ends May 2nd at 23:59 (Day 1 is only 9 hrs, 31 min. long). Day 2 begins at 00:00 (midnight) May 3rd, and ends at 23:59 on May 3rd.

## Daily Nutrition Data

|  |  |
| --- | --- |
| **NPO because patient palliating or receiving comfort measures only today?** | Indicate, ‘yes’ if the patient is NPO **because of palliation or comfort measures** for the entire day (i.e. 24h). These are patients who may be undergoing a process of withdrawal of life-sustaining treatments, may be actively dying, or in whom nutrition therapy is not indicated and we don’t need to capture the nutrition processes of care.  If ‘yes,’ no further data is required to be entered on this form for this day*.* |
| **Did the protein goal change to a target outside the range specified by the randomization group?** | **We are not asking about protein intake that does not meet the goal. We are asking about a change to the protein prescription since the patient was randomized to a protein group. For example, was there a clinical reason for why the patient could not remain on their randomized protein goal?**  **If ‘yes,’ there is a change to the protein from the randomization group, specify the reason for this change from the list provided:**   * **No longer critically ill** * **New onset of ARDS** * **Worsening renal function** * **Improved renal function** * **Starting dialysis** * **New wound (non-surgical)** * **New surgical wound** * **Negative nitrogen balance** * **Increased protein losses (e.g. increased ostomy output, pleural fluid drainage, etc)** * **Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Was any nutrition received orally/by mouth?** | Each study day, indicate whether or not the patient received any nutrition orally/by mouth.  NOTE: Data on calories and protein from oral nutrition are **not** collected. |
| **Was morning blood glucose measured?** | If ‘yes’, record the blood sugar reading closest to 08:00 hrs. This can be either serum or capillary. If serum and capillary levels are completed at the same time or if 2 measurements are equidistant to 08:00 hrs, record the highest blood glucose reading.  If no blood sugars were recorded that day, indicate ‘no’. |
| **Did the patient have a hypoglycemic event today?** | A hypoglycemic event is defined as a glucose level of <3.5mmol/L (<63mg/dL).  If ‘yes’, record the blood sugar value, including units. You may record up to 3 episodes per day. If there were more than 3 hypoglycemic events in one day, record the lowest 3 blood glucose values. |
| **Propofol (continuous infusion ≥ 6 hours)** | If the patient receives **a continuous infusion of propofol ≥ 6 hours,** record the total volume administered in millileters (mL).  Select ‘no’ if propofol was NOT given, or if provided intermittently, or if continuous < 6 hours. |
| **Highest Creatinine** | Record the highest creatinine measured this day.  On day 1 only, indicate the units creatinine is measured in. The units you indicate on day 1 will represent the units creatinine is measured in for the duration of data collection.  If not done on a particular day, use the ‘Not Available’ checkbox. |
| **Highest Urea/BUN** | Record the highest urea/BUN measured this day.  On day 1 only, indicate the units urea/BUN is measured in. The units you indicate on day 1 will represent the units urea is measured in for the duration of data collection.  If not done on a particular day, use the ‘Not Available’ checkbox. |
| **Lowest Phosphate** | Record the lowest serum phosphate (PO4) measured this day.  On day 1 only, indicate the units PO4 is measured in. The units you indicate on day 1 will represent the units PO4 is measured in for the duration of data collection.  If not done on a particular day, use the ‘Not Available’ checkbox. |
| **Location of Feeding Tube** | Choose from the list (gastric, small bowel or none in place) to indicate the location of the feeding tube. This refers to any oro/nasogastric tube inserted for the purpose of enterally feeding the patient. If the position is not confirmed by xray or a few days have passed since location was confirmed, give us your guestimate of where the tube is located (best guess given the information you have).  If the feeding tube is in 2 locations on a single day, indicate the location it was in for the most amount of time. |
| **Did the patient receive any motility agents?** | Select all motility agents that apply from the list provided.   |  |  | | --- | --- | | Alizapride | Lesuride | | Cinitapride (Cintapro/Pemix) | Methylnaltrexon | | Domperidone | Metoclopramide | | Erythromycin | Naloxone | | Itopride (Ganaton) | Other, specify: |   You do not need to record the route or dose.  If the patient has been prescribed combination therapy, select all motility agents the patient received on that day. |
| **Definition of Motility Agent** | A drug which enhances gastric emptying and/or gastrointestinal motility by increasing the frequency and/or strength of contractions in the gastrointestinal tract.  This does not include stool softeners or laxatives such as lactulose or herbal remedies. |

## Daily Enteral Nutrition (EN) Data

***REMEMBER: If the patient is receiving a combination of EN and PN, only the calories/protein from EN are recorded on this form. The Daily IV Nutrition Data form will be used to record the data for PN.***

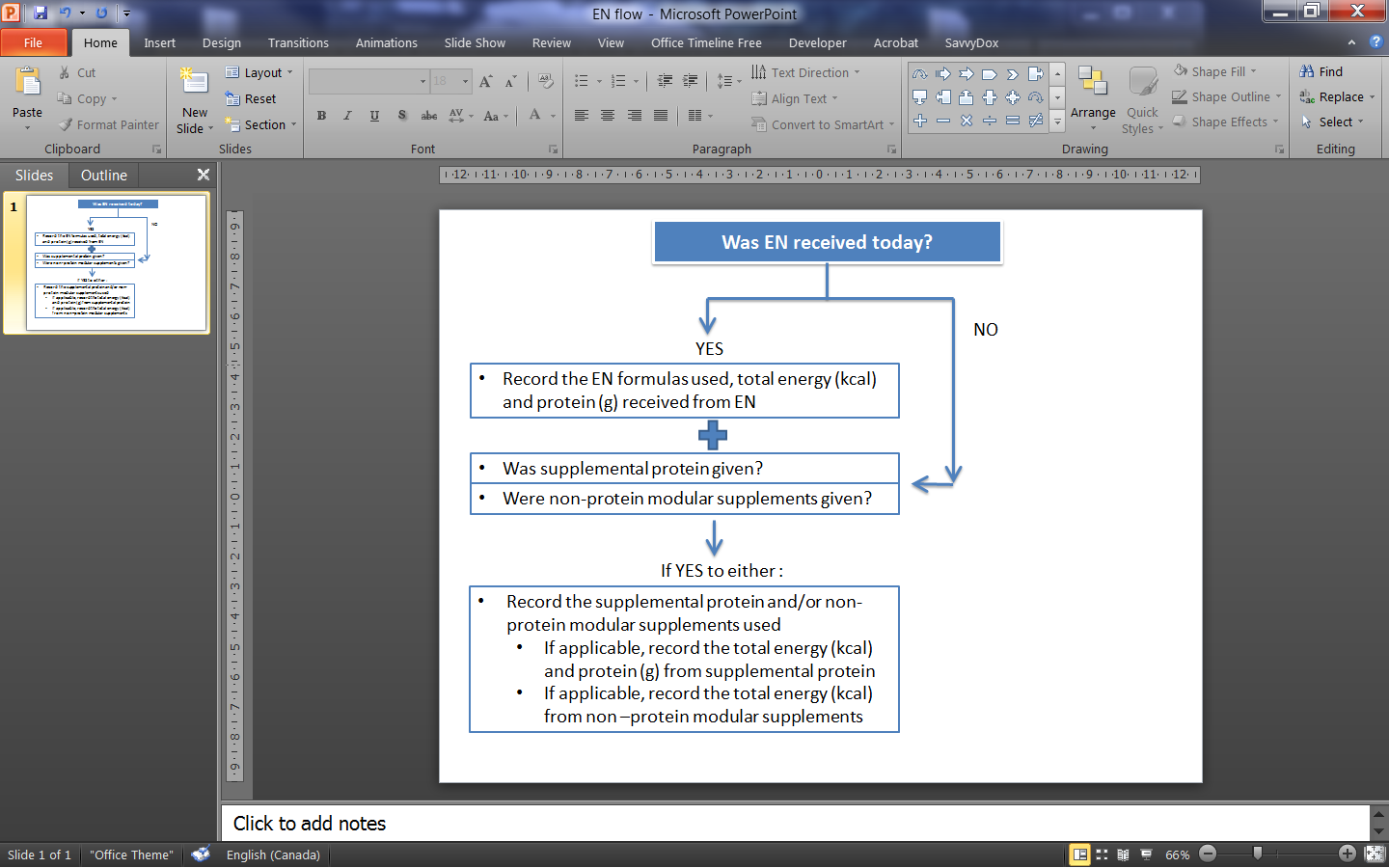
EXCEPTION: Protein received is the only daily data collection that extends past ICU day 12.

Continue to collect this data until ICU day 28, ICU discharge or death, whichever comes first.

Data to be collected on CRF *Daily Protein Data: Days 13-28* for data entry after day 12*.*

Note: record calories/protein from formulas, protein supplements, and other supplements **separately.**

The following diagram illustrates the data required depending on the whether the patient received EN or not on a given day. The instructions regarding each type of data field follow.



|  |  |
| --- | --- |
| **Was enteral nutrition received?** | Each study day, indicate whether or not the patient received EN.  If ‘yes’, record the EN formula(s) used, total energy and protein received from EN. |
| **EN Formula(s)** | Refer to the taxonomy in REDCap to record enteral formula(s) received. You may specify up to 3 formulas per day. If the patient received more than 3 formulas in a day, select the 3 that provided the largest volumes but account for all calories and protein the patient received from EN. If, on any of the first 12 days in ICU, you indicate a formula which is not found in the EN formula taxonomy be sure to specify:   * company and product name * If the product is polymeric * If the product contains supplemental glutamine (>10 g/L) in addition to the glutamine found naturally in the product * If the product contains supplemental arginine (>4.5 g/L) in addition to the arginine found naturally in the product * If the product contains fish oils   *Note:* If you cannot calculate the kcal and protein provided by a formula (e.g. congee, rather than a formula manufactured by a company) this would **not** be considered EN. |
| **Kilocalories received from EN** | The total calories (kcal) from EN formula(s) will need to be calculated by the dietitian daily as follows:   * Include calories from protein * Do **NOT** include calories from other supplements * Do **NOT** include calories from propofol or other IV solutions   + Calories from propofol are to be recorded on the Daily Nutrition Data form.   Include calories from **all** EN formulas, even if the patient received nutrition from >3 formulas/day |
| **Protein received from EN** | Total protein (g) will need to be calculated by the dietitian daily as follows:   * Do **NOT** include protein from additional non-protein supplements * Do **NOT** include protein from glutamine supplements * Include protein from **all** EN formulas, even if the patient received nutrition from >3 formulas/day |
| ****Protein Supplements**** | |
| **Definition of Modular Protein Supplement** | A concentrated protein source. This does not include high-protein enteral formulas. High-protein formulas (that also have lipid, carbohydrate and micronutrient components) should be specified under the EN Formula section. |
| **Was supplemental protein given?** | Indicate yes or no for whether or not a modular protein supplement was given.  If yes, refer to the taxonomy in REDCap to record what supplement was given. If more than one supplement was given, select the one that provided the largest amount of protein.   * Do **not** record glutamine supplements here. |
| **Kilocalories received from Supplemental Protein** | If the patient received a modular protein supplement, indicate total calories received (kcal) from the modular protein supplement (i.e. include calories from protein).   * Include calories from **all** modular protein supplements |
| **Protein received from Supplemental Protein** | If the patient received a modular protein supplement, indicate the protein received (g) from the modular protein supplement.   * Include protein from **all** modular protein supplements * Do **NOT** include protein from glutamine supplements |
| ****Non-Protein Modular Supplements**** | |
| **Definition of Non-Protein Modular Supplement** | Single macronutrients used in addition to enteral formulas. This includes glucose polymers, and fat emulsions. Typically modular supplements do not provide a source of micronutrients. |
| **Were non-protein modular supplements given?** | Indicate yes or no for whether or not non-protein modular supplements were given.  If yes, refer to the taxonomy in REDCap to record supplement(s) provided. If more than two supplements were given, select the two that provided the largest volumes. |
| **Kilocalories from Other Non-protein Supplements** | If the patient received a non-protein modular supplement, indicate calories received (kcal) from the non-protein modular supplement. |
| ****EN Interruption**** | |
| **Definition of EN interruption** | EN being stopped at any point after it was initiated, with the intent that EN be restarted again. This does not include:   * Brief or transient (i.e. less than one hour) interruptions for short bedside procedures * For cyclic or bolus feeding, time the patient was never intended to be fed according to the prescribed feeding schedule * Reduction in rate of feeds * Stopping the feeds permanently and transitioning to oral feeds |
| **Was EN Interrupted today?** | **This question is to be answered if the patient received EN at some point during the day but it was stopped for a reason as seen in the definition below. If the patient did NOT receive any feed for the entire day (i.e. 24h), then this question does not need to be answered.**  Choose “yes” or “no” for whether or not EN was interrupted today.  If yes, indicate the total duration of time the EN was interruption. Record in total number of hours and minutes.  Example 1: EN was initiated at 08:30 on study day 1. EN was stopped at 14:30 for a bedside procedure. EN was started again at 18:30. *The time from 00:00 until 08:30 does not constitute an interruption. EN was interrupted from 14:30 until 18:30, which equals 4 hours (240 minutes).*  Example 2: EN was initiated at 08:30 on study day 1. EN was stopped at 14:30. EN was not started again until study day 3 at 04:30, and then there were no further interruptions. *EN was interrupted from 14:30 until the end of day 1 (midnight), which equals 9 hours and 30 minutes. On day 2, daily EN data is not completed because the patient did not receive EN. On day 3, midnight until 04:30 does not constitute an interruption, so no interruptions are recorded for day 3.*  If EN was interrupted, specify all reason(s) that EN was interrupted, by selecting all that apply from the list provided. |

## 

## Daily IV Nutrition Data

***REMEMBER: If the patient is receiving a combination of EN and PN, only the calories/protein from PN are recorded on this form. The Daily EN Data form will be used to record the data for EN.***

EXCEPTION: Protein received is the only daily data collection that extends past ICU day 12.

Continue to collect this data until ICU day 28, ICU discharge or death, whichever comes first.

Data to be collected on CRF *Daily Protein Data: Days 13-28* for data entry after day 12*.*

The following diagram illustrates the data required depending on the whether the patient received PN or not on a given day. The instructions regarding each type of data field follow.



|  |  |
| --- | --- |
| **Definition of PN** | Provision of carbohydrates plus protein and/or lipid, with or without micronutrients, electrolytes or other additives, delivered directly into a vein.  Infusion of dextrose alone does **not** constitute parenteral nutrition (ie. If a patient only received dextrose in the absence of amino acids, you should answer “no” for whether or not the patient received parenteral nutrition). |
| **Was parenteral nutrition (PN) received?** | Each study day, indicate whether or not the patient received PN. |
| **Kilocalories received from PN** | Total calories received (kcal) will need to be calculated by the dietitian daily as follows:   * Include calories from parenteral protein * Include calories from other parenteral supplements * Do **NOT** include calories from enteral formula or modular supplements * Do **NOT** include calories from propofol as this is to be recorded separately on the Daily Nutrition Data form. * Do **NOT** include calories from other IV solutions |
| **Protein received from PN** | Total protein will need to be calculated by the dietitian daily as follows:   * Include protein from parenteral supplements, if applicable * Do **NOT** include calories from enteral formula or modular supplements * Do **NOT** include protein from glutamine supplements |
| **Did the patient receive IV amino acids (independent of PN)?** | If the patient received IV amino acids in addition to their PN formula, indicate the solution provided, and protein and kcal received from this solution. |
| **Did the patient receive IV amino acids only?** | If the patient received IV amino acids in the absence of dextrose, indicate the solution provided, and protein and kcal received from this solution. |
| **Did the patient receive IV lipids only?** | If the patient received IV lipids in the absence of dextrose, indicate the emulsion provided, and kcal received from this product. |

## Daily Nutritional Adequacy

Once you enter nutrition data in the following forms: Baseline Nutrition Assessment, Daily Nutrition, Daily EN Data and Daily PN Data, this form will automatically calculate daily nutritional adequacy. For information purposes the formulas to calculate each of these calculations is found below.

The table below outlines where each data element found within the formula is found within REDCap.

### ****Energy****

**Table of Data Elements to Calculate Total Energy (kcal)**

|  |  |  |
| --- | --- | --- |
| **Energy Source (Data)** | **REDCap Name** | **REDCap Form Where Located** |
| **Weight for goal energy** | **Weight used to determine goal calorie requirement** | **Nutrition Goals** |
| **Goal energy** | **Goal Calorie Requirement** | **Nutrition Goals** |
| **Propofol** | **Propofol (continuous infusion ≥ 6h)** | **Daily Nutrition Form** |
| **EN** | **Total kilocalories received from all EN** | **Daily EN Data** |
| **Protein Supplements (PS)** | **Kilocalories received from supplemental protein** | **Daily EN Data** |
| **Non-Protein Modular Supplements (NPMS)** | **Kilocalories received from other non-protein modular supplements** | **Daily EN Data** |
| **PN** | **Total kilocalories received from PN** | **Daily IV Nutrition Data** |
| **Amino acids (independent)** | **Kilocalories received from amino acids** | **Daily IV Nutrition Data** |
| **Amino acids (AA) – no PN** | **Kilocalories received from amino acids** | **Daily IV Nutrition Data** |
| **Lipids – no PN** | **Kilocalories received from lipids** | **Daily IV Nutrition Data** |

#### ****REDCap Energy Adequacy Formulas****

|  |  |
| --- | --- |
|  |  |

### Protein

**Table of Data Elements to Calculate Total Protein (g)**

|  |  |  |
| --- | --- | --- |
| **Protein Source (Data)** | **REDCap Name** | **REDCap Form Where Located** |
| **Weight for goal protein** | **Weight used to determine goal protein requirement** | **Nutrition Goals** |
| **Goal protein** | **Precise Goal Protein Requirement (within randomized protein group, enter the precise protein goal)** | **Nutrition Goals** |
| **EN** | **Total protein received from all EN** | **Daily EN Data** |
| **Protein Supplements (PS)** | **Protein (g) received from supplemental protein** | **Daily EN Data** |
| **PN** | **Total protein received from PN** | **Daily IV Nutrition Data** |
| **Amino acids (independent)** | **Protein received from amino acids** | **Daily IV Nutrition Data** |
| **Amino acids (AA) – no PN** | **Protein received from amino acids** | **Daily IV Nutrition Data** |

#### REDCap Protein Adequacy Formulas

|  |  |
| --- | --- |
|  |  |

## Daily Vasopressors/Inotropes

**Did the patient receive a continuous infusion of vasopressors or inotropes today?**

If ‘yes,’ check all that apply from the list. Record the highest hourly infusion rate for each one selected.

|  |  |  |  |
| --- | --- | --- | --- |
| Dopamine (>5ug/kg/min) | Norepinephrine | Phenylephrine (>50ug/min) | Milrinone |
| Dobutamine | Epinephrine | Vasopressin | Levosimendan |

## Daily Renal Replacement Therapy (RRT)

**Did the patient receive RRT today?**

**If ‘yes’, specify all modes received during the day (i.e. 24h period):**

* Intermittent (IHD)
* Continuous (CRRT)
* Sustained low efficiency (SLED)
* Peritoneal (PD)
* Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Outcomes Data

By ‘outcomes data’ we are referring to data that is entered into REDCap at the time of the patient’s discharge, death of Day 28, whichever comes first.

## Vasopressors and Inotropes (Start and Stop Dates)

In addition to capturing daily administration of vasopressors/inotropes (as noted above) we will also capture the use of these medications over the entire duration of the patient’s hospitalization, until the first of day 60, ICU discharge or death by capturing absolute start and stops dates for each medication the patient receives. The purpose of the data elements described below is to capture data to calculate Persistent Organ Dysfunction Syndrome (PODS).

|  |  |
| --- | --- |
| **Did the patient receive vasopressors?** | Only include continuous infusions of vasopressors, do not include single bolus injections.  If ‘yes’, proceed to complete the remainder of the form.  If ‘no’, no further data entry on this form required. |
| **Vasopressor/inotrope Type** | Select all vasopressors and/or inotropes given. For each one selected, the corresponding start and stop dates will be entered (see below). |
| **Date/Time**  Record the date and time the vasopressor or inotrope was initiated and stopped.  If the patient dies while receiving the vasopressor or inotrope, check the appropriate box. REDCap will automatically connect this to the date of death you enter.  If the patient was still receiving the vasopressor or inotrope at Day 60, check the appropriate box.  The patient is considered free of the vasopressor or inotrope if they remain off the vasopressor or inotrope for **≥ 24 hours**. If the vasopressor or inotrope is re‐instituted after 24 hours, this is considered a separate episode, corresponding start and stop dates should be recorded. |

## Mechanical Ventilation (Start and Stop Dates)

|  |  |
| --- | --- |
| **Definition of Invasive mechanical ventilation** | We define invasive mechanical ventilation as any mode of intermittent positive pressure delivered via an oral/nasal tracheal tube or tracheostomy with or without positive end expiratory pressure and high frequency jet ventilation or oscillation. |
| **Ventilation Start Date/Time** | Record the date and time invasive mechanical ventilation was initiated. If the time is not found in the medical record use the ‘Not Available’ checkbox in REDCap. |
| **Ventilation Stop Date/Time** | Indicate when invasive mechanical ventilation was stopped or if still ongoing at day 60, check the ‘still vented at day 60 option.  Patients will be considered breathing without invasive mechanical ventilation if they are:   * extubated and on face mask (nasal prong) OR * intubated or breathing through a t‐tube OR * tracheostomy mask breathing OR * continuous positive airway pressure (CPAP) ≤ 5cm H2O without pressure support or intermittent mandatory ventilation assistance. |
| **Mechanical Ventilation Restarted?** | If the patient is extubated and re-intubated within ***<24 hours***, we consider this the same ventilation event.  If the patient is extubated and re-intubated ***≥ 24 hours***, this is considered a new ventilation event and the new start date/time and stop date/time should be recorded. If applicable, up to 5 ventilation events may be entered for each patient. |

## Renal Replacement Therapy (Start and Stop Dates)

Similar to vasopressors/inotropes, we will be capturing not only daily RRT use but also absolute start and stop dates so we may calculate PODS. Complete this form if the patient received renal replacement therapy during their hospitalization, until the first of day 60, ICU discharge or death.

|  |  |
| --- | --- |
| **RRT Start Date/Time** | If the patient was receiving RRT prior to admission indicate ‘yes.’  If the patient did not start RRT until they were hospitalized, record the start date and time. |
| **RRT Stop Date/Time** | Record the date and time RRT stopped.  If the patient was still receiving RRT following hospital discharge or at Day 60, check the appropriate box. |

## Hospital Outcomes

Complete this form after 60 days from the patient’s initial ICU admission or after their death, whichever comes first.

|  |  |
| --- | --- |
| ****ICU Stay**** | |
| **Was consent withdrawn during this ICU stay?** | **In the event that consent is withdrawn for the patient during their participation in the study, select ‘yes.’** |
| **Date/time consent withdrawn:** | Record the date and time the subject withdrew their consent to participate in the trial. |
| **Type of withdrawal:** | Specify whether the withdrawal of consent refers to the study intervention, data collection or both using the 3 options listed:   * stop intervention, continue data collection * stop intervention, stop data collection (discard previous data) * stop intervention, stop data collection (keep previous data) |
| **ICU Stay** | Indicate if the patient died in the ICU on their initial admission.   * If yes, indicate the date and time of death. * If no, they were discharged, indicate the date and time of discharge.   If the patient was readmitted to the ICU.   * We define readmission as ≥24 hours from ICU discharge. If less than this, consider it the same ICU admission. * If readmitted within 60 days from initial admission, complete the same information for each ICU readmission   Alternatively, if no and they were still in ICU at day 60, check the appropriate box. |
| ****Hospital Discharge**** | |
| **Hospital Discharge** | If the patient was alive and discharged from ICU within 60 days, indicate if they died in hospital.   * If yes, indicate the date and time of death. * If no, they were discharged, indicate the date and time of discharge and where they were discharged to. * Alternatively, if no and they were still in hospital at day 60, check the appropriate box. |
| **Hospital Re-Admission** | If the patient was ever readmitted to hospital within 60 days of their initial ICU admission:   * We define a hospital readmission as ≥24 hours from hospital discharge and being admitted under an inpatient service. This does not include visits to the emergency room that do not result in the patient being under an inpatient service and in a ward bed. * If readmitted within 60 days from initial admission, complete the same information for each hospital readmission |
| ****60-Day Outcome**** | |
| **60-day Outcomes**  **\*\*PRIMARY STUDY OUTCOME** | ***This is our primary outcome and it is important that we record this accurately.***   * If the patient is still alive in hospital on day 60, please record:   + Record the date the patient was last known to be alive; and   + What source of information was used to determine the patient’s survival status, select from the taxonomy provided. (e.g. family physician, medical record, obituaries, etc). * If the patient died in hospital, please record the date and time of death. * If the patient discharged alive from hospital before 60 days, please make an attempt to confirm that they were still alive at day 60 (See below). * If the patient was alive and discharged from hospital within 60 days and they died in the time between when they were discharged from the hospital and 60 days following ICU admission, pleaseindicate the date and time of death. If they did not die, indicate the last date they were known to be alive. This must be at or after day 60.   For either response, indicate the resources used to collect this information. Be sure to exhaust all resources in order to accurately capture this data.   * Family Physician – contact the family physician’s office to determine if the patient remains alive * Medical Records – search electronic medical records for evidence of death or evidence is alive (eg. readmission, seen in clinic, procedure done, etc) * Facility patient was discharged to – if the patient was discharged to another health care facility or long term care, contact them to determine if the patient is alive * Home care – if the patient had home care arranged at discharge, contact them to determine if the patient is alive * Obituaries – search online obituaries for newspapers in the patient’s local area for evidence of death * Internet – Google search the patient for documented evidence of death * Other – specify any other resources used |