SQUEEZE TRIAL

DATA DICTIONARY
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Missing Variable Codes

The following codes are to be used for missing variables. Instructions are provided throughout the Data Dictionary when it is appropriate to use the codes.

7777 = Normal (Value is not reported but local PI deems status normal. This is applicable only to PELOD 2 where values are required for scoring).
9999 = Missing (use for free text fields if value not available)

SCREENING WORKSHEET

Data Field	Options	Definitions
INCLUSION CRITERIA		Screened patients will be those who have received 2 fluid boluses of Normal Saline (NS), Ringer's Lactate (RL) or 5% Albumin and/or have the diagnosis or are based on clinical suspicion for sepsis*(go to definitions page for definition of sepsis and septic shock).
1. Age (Must select 'YES' for the patient to be eligible)	Yes No	29 days to < 18 years of age
2a. Patient has persistent signs of shock defined as one or more of i, ii, iii (please select all that apply).		
i) Vasoactive Medication Dependence (need for vasoactive drug for Hemodynamic support)	Yes No	Vasoactive infusion has already been started during resuscitation of shock (Dopamine, Epinephrine, Norepinephrine, Vasopressin, Phenylephrine, Milrinone)
ii) Hypotension	Yes No	Presence of hypotension (Systolic Blood Pressure and/or mean blood pressure < 5th percentile for age based on AHA PALS guidelines. (See definitions page)
iii) Abnormal Perfusion defined as the presence of 2 or more of the following: (Check all that apply)	Abnormal Capillary Refill Tachycardia Decreased Level of Consciousness Decreased Urine Output None of the above	Check all that apply. Abnormal capillary refill (CR < 1 second (flash) or CR ≥ 3 seconds (delayed), tachycardia (HR > 95th percentile for age), decreased urine output (<0.5 mL/kg/hr),

		based on clinical judgment of the treating physician. See definitions page for tachycardia values.
2b. Suspected or Confirmed Septic Shock.	Yes No	Verify with the clinical care team they suspect septic shock e.g. shock potentially due to infection.
2c. Patient has received one of the following:	**Patients <50 kg:** Minimum 40 mL/kg of isotonic crystalloid (NS or RL) and/or colloid (5% albumin) as fluid boluses within preceding 6 hours **Patients ≥50 kg:** Minimum 2 L of isotonic crystalloid (NS or RL) and/or colloid (5% albumin) as fluid boluses within preceding 6 hours. None of the above.	**MUST HAVE at least** one of the following two options for the patient to be eligible. See bolus definition in the definitions page.
EXCLUSION CRITERIA		All exclusion criteria must be answered "NO" to be eligible
Patient admitted to the Neonatal Intensive Care Unit (NICU)	Yes No	Patient physically located in the NICU (or postpartum care area)
Full active resuscitative treatment is not within the goals of care?	Yes No	Verify with the clinical care team if there is any reason to believe that full resuscitative treatment should not be offered.
Shock secondary to causes other than sepsis (i.e. obvious signs of cardiogenic shock, anaphylactic shock, hemorrhagic shock, spinal shock)	Yes No	The clinical care team indicates there are no obvious signs of cardiogenic, anaphylactic, hemorrhagic or spinal shock.
Patients requiring resuscitation in the Operating Room or Post Anesthetic Care Unit.	Yes No	Patients that require shock resuscitation while in the OR or PACU (Post Anaesthetic Care Unit) are excluded. **Patients receiving resuscitation before or after the OR/PACU are eligible for inclusion.*
Previous enrolment in this trial, where known by the research team?	Yes No	Check encrypted Screening log for evidence of prior enrolment.

ELIGIBILITY: **Based on above Inclusion and Exclusion criteria:** **If the value in the box is 1 this patient IS eligible for the study.** **If the value in the box is 0 this patient is NOT eligible for the study.**	0 1	Redcap will determine eligibility based on your input. 0= Not eligible 1= Eligible
Date patient determined to have met eligibility criteria by Screening Research Staff **Time patient met eligibility criteria**	Day/Month/Year 24 hour time (HH:MM)	
Upload any source documents by clicking on this link		CTCC will request specific documents to be uploaded for data monitoring

RANDOMIZATION

Data Field	Options	Comments
Enter Study ID: First 2 digits: Site ID; followed by a dash; Last 3 digits: Participant ID.	01-003	The first two digits are for site identifier, the last three digits are for participant number.
Date patient randomized **Time patient randomized**	Day/month/year 24 hour time (HH:MM)	Enter your local date and time when screening and randomizing a patient.
Site	Alberta Children's Hospital Children's Hospital of Western Ontario (CHWO) CHU de Québec CHU Sainte-Justine McMaster Children's Hospital Sickkids Stollery Children's Hospital Winnipeg Children's Hospital	Choose your study site.
Patient Randomized:	Usual Care Fluid Sparing	Autopopulated.
Date the research staff communicated the treatment arm with a medical team member. **Time the research staff communicated the treatment arm with a medical team member.**	Day/month/year 24 hour time (HH:MM)	Enter date/time when the treatment arm was communicated to clinical care team.

CONSENT PROCESS

Data Field	Options	Comments
Were Parents/Guardians informed of their child's enrollment into the study (given the one page study information sheet)?	Yes No	Yes=parents given the one page study information sheet. This information should be documented at the time of delivery on the study envelope (see label). If not documented then confirm with parents at the time RS seeks consent.
Date Parents/Guardians informed of enrollment of their child into the study. **Time parents/guardians were informed of enrollment of their child into the study**	Day/month/year 24 hour time (HH:MM)	Enter date/time when parents/guardians were notified.
Date of final consent determination	Day/month/year	Date of final consent determination (final decision made as to consent given or declined)
Time of final consent determination	24 hour time (HH:MM)	Time consent was obtained.
Did participant/parent/SDM agree to be contacted for future research?	Yes No	Say Yes if participant/parent/SDM agreed to be contacted for future research?
Check all that apply:	-The subject meets all eligibility requirements -The subject understands the research and the risks and benefits involved in the study -The subject agrees to participate in the study and current valid REB approved signed consent was obtained from the participant. -The subject agrees to participate in the study and current valid REB approved signed consent was obtained from parent or substitute decision maker. -Signed assent was obtained.	Check all that apply

	-All of the subjects questions were answered/concerns addressed -Subject was given time to review the consent form and to discuss participation in this study with family members/others -A copy of the signed and dated consent form was given to the subject -The original signed and dated consent form was placed in the research record - Consent declined

DEMOGRAPHIC/DESCRIPTIVE DATA

Data Field	Options	Comments
Age	Age of patient in months	Calculate the age in months at time of randomization. Do not round the age. Enter the months and days (i.e. 10.1 months old)
Gender	Male/Female	Gender (NOT biological sex)
Weight	Kilograms	Record weight in kg, rounded to 1 decimal place. If the weight was not measured at the time of randomization use the most recently recorded weight from the same hospital admission.
Location patient deemed eligible	Study Site Emergency Room Study Site Hospital Ward Study Site PICU	Enter the physical location where the patient met eligibility criteria.
Did patient arrive at your site in past 48 hrs	Yes No	
If Yes, specify location:	Transferred in from other medical facility Presented from home	Other medical facility includes: hospital, nursing station, chronic care facility.
Does patient have previous medical co-morbidities?	Yes No	Other medical conditions as listed in the past medical history on the admission note.
Previous medical co-morbidities (check all that apply)	Neurological Cardiac Pulmonary Hematological Malignancy Gastrointestinal Endocrine	e.g. Global developmental delay GDD. See options menu below e.g. GERD

	Metabolic Autoimmune disorder Immunodeficiency Mitochondrial disorder Genetic/Hereditary disorder Renal Other	
Specify other	Free text	Choose 'Other comorbidities' if not specified on the list of co-morbidities and specify
Cardiac Co-morbidities	Congenital Heart Disease Single Ventricle Physiology Cardiac Surgery Depressed Cardiac Function Other	Select patient's cardiac comorbidities.
Other Cardiac Co-morbidities	Free text	If cardiac comorbidities not listed above then select other and specify the cardiac comorbidity.
Renal disease for > 3 months?	Yes, No	Yes=patient has renal comorbidity for more than 3 months.
Renal Disease	Free text	Specify the renal disease.
Is this a surgical associated sepsis?	Yes No	Yes=Surgical or interventional radiology procedure in the 7 days prior or 48 hrs following sepsis onset (removal of tissue or insertion of device or hardware). Exclusions: endotracheal tube insertion; re-insertion of NJ tube.
Admission diagnosis to Hospital	Free text	Admission diagnosis as found in the admission note.

BASELINE CLINICAL DATA

Take the value that falls closest to randomization. Reported value can be collected up to 6 hours prior to randomization.

Data Field	Options	Comments
Heart Rate Available?	Yes, No	
Heart Rate	Beats per minute	
Systolic Blood Pressure available?	Yes No	Record from cuff or arterial line reading. If both modes done at same time record from arterial.
Systolic blood pressure	mmHg	
Diastolic Blood Pressure available?	Yes No	Record from cuff or arterial line reading. If both modes done at same time record from arterial.
Diastolic blood pressure	mmHg	

Mean Blood Pressure available? **Mean blood pressure**	Yes No mmHg	Record from cuff or arterial line reading. If both modes done at same time record from arterial.
Capillary refill time available? **Capillary refill time**	Yes, No Seconds	Use "central" only. If recorded as >5 enter 5.
Does the Patient have altered or changed mental status?	Yes No	Altered mental status as described in the medical notes. If it is not recorded anywhere e.g. consultation note, then it is deemed to be normal. If "Decreased Level of Consciousness" is selected in Screening Worksheet, then Yes is selected for Altered Mental Status.
Respiratory Rate available? **Respiratory rate**	Yes, No Rate Per minute	
Sp02 available? **Sp02**	Yes, No Numerical Value	
Temperature available? **Temperature** **Temperature Route**	Yes, No Celcius Rectal Oral Tymp Esoph Bladder Axillary	 If Core temperature recorded and route not specified select Rectal.
pH value available? **pH**	Yes, No blood gas value	
Lactate available? **Lactate**	Yes, No mmol/L	
HCO3 value available? **HCO3**	Yes No mmol/L	If HC03 or BICARB not available use Total CO2 (TCO2) value.
Glucose available? **Glucose**	Yes No mmol/L	
Potassium value available? **Potassium**	Yes No mmol/L	Values cannot be taken from hemolyzed samples.
Patient positive for Malaria	Yes No Not tested	Known at presentation or found during hospital admission.
Baseline Sodium **Baseline Chloride**		Recorded value from any sample that is felt to be valid.

ANTI-INFECTIVE AGENTS ADMINISTERED IN THE 24 HOUR PERIOD PRIOR TO RANDOMIZATION

Data Field	Options	Comments
Positive organisms on cultures obtained in the 24 hour period PRIOR to randomization?	Yes No	If sample was taken pre randomization but result not until post randomization, it should still be entered on this form.
Site(s) Culture was obtained from (check all that apply).	Blood - Arterial Line Blood - Central Venous Line Blood - Peripheral Chest Tube Cerebral Spinal Fluid Feces Nasopharyngeal Swab Peritoneal Drain Tissue e.g. brain. Urine - Catheter Urine - MSU Other	Record all sites of positive organisms.
Anti-Infective Agents administered in the 24 hour period prior to randomization?	Yes No	Yes =anti-infective agents were administered.
If Yes, Check all that apply	Ampicillin Azithromycin Cefotaxime Ceftriaxone Clindamycin Metronidazol Gentamicin Meropenem Tazocin Vancomycin	Record all antibiotics administered.
Specify other(s) Antibiotics	Other	
Antivirals	Acyclovir Tamiflu/Oseltamivir	Record all antivirals administered.
Other antivirals	Other	

Antifungals	Amphotericin B Fluconazole Voriconazole	Record all antifungals administered.
Other antifungals	Other	

FLUIDS AND BLOOD PRODUCTS RECEIVED IN THE 24 HOUR PERIOD PRIOR TO RANDOMIZATION

Data Field	Options	Comments
Did Patient receive any Intravenous Fluids as Boluses in the 24 hour period PRIOR to Randomization	Yes No	This is a discrete volume of fluid given via the Intravenous (IV) or intraosseous (IO) route over a defined period of time. A bolus is ***typically*** administered in a timeframe ranging from STAT (rapid IV push) to ***typically*** not more than 1 hour. A bolus ***typically*** ranges in volume from not less than 5 mL/kg to not more than 20 mL/kg but a physician may 'round-up or down' the volume e.g. a 19 kg patient, 20 mL/kg would be 380 mL but a physician may order 400 mL to simplify for the nursing staff.
Date of first bolus received **Time of first bolus received**	Day/month/year 24 hour time (HH:MM)	Date/Time of first bolus received
Did patient receive normal saline boluses? **Total Number of normal saline boluses** **Total volume of normal saline boluses**	Yes No Enter total number Enter quantity in mL	Count number and quantity of normal saline boluses received in the 24 hour period prior to randomization. Add up volume of each fluid bolus and record total.
Did patient receive Ringer's Lactate (RL) boluses? **Total Number of RL boluses** **Total volume of RL boluses**	Yes No Enter total number Enter quantity in mL	Count number and quantity of Ringer's Lactate boluses received in the 24 hour period prior to randomization. Add up volume of each fluid bolus and record total.
Did patient receive 5% Albumin boluses? **Total Number of 5% Albumin boluses** **Total volume of 5% Albumin boluses**	Yes No Enter total number Enter quantity in mL	Count number and quantity of 5% Albumin boluses received in the 24 hour period prior to randomization. Add up volume of each fluid bolus and record total.
Did patient receive Plasma-Lyte boluses?	Yes No Enter total number	Count number and quantity of Plasma-Lyte boluses received in the 24 hour period prior to

Total Number of Plasma-Lyte boluses **Total volume of Plasma-Lyte boluses**	Enter quantity in mL	randomization. Add up volume of each fluid bolus and record total.

Please record ALL BLOOD PRODUCTS including doses received in the 24 hour period PRIOR to randomization.

Patient received Red Blood Cells?	Yes No	
Total Volume of Red Blood Cells received	mL	Add up total volume of Red Blood Cells.
Patient received Platelets?	Yes No	
Total Volume of platelets received	mL	Add up total volume of Platelets
Patient received 5% Albumin?	Yes No	
Total Volume of 5% Albumin received	ml	Add up total volume of Albumin.
Patient received 25% Albumin?	Yes No	
Total Volume of 25% Albumin received	mL	Add up total volume of 25% Albumin
Patient received fresh frozen plasma?	Yes No	
Total Volume of fresh frozen plasma received	mL	Add up total volume of fresh frozen plasma
Patient received Cryoprecipitate?	Yes No	
Total Volume of Cryoprecipitate received	mL	Add up total volume of Cryoprecipitate

PRISM IV

Please record most abnormal value 2 hrs prior to and 4 hours post <u>the earliest indication that the child is being admitted to the PICU.</u>

*****Adapt timeframe where needed: If not admitted to PICU then use time of PICU consult, or if no PICU consult then time of randomization. Note: "earliest indication that the child is being admitted to the PICU" *does not include* date/time PICU consult while participant at community hospital or on route. Participant must be at study site.**

Data Field	Options	Comments
Lowest Systolic BP (blood Pressure)	mmHg	Record from cuff or arterial line reading. If both modes done at same time record from arterial.
Highest Heart Rate	Bpm	

Lowest Temperature	Celcius	If only one temperature recorded during applicable timeframe, enter into both Lowest and Highest fields Values may be taken from other facility documents if within 2 hour pre randomization time frame
Temperature Route	Rectal Oral Tymp Esoph Bladder Axillary	If Core temperature recorded and route not specified select Rectal. If temperature route is not recorded for example, in an ambulance report, then leave route blank.
Highest Temperature	Celcius	Follow same instructions for Lowest Temperature and route.
Temperature Route	Rectal Oral Tymp Esoph Bladder Axillary	
Pupillary Reflexes	1 Fixed (non-reactive) Both Fixed (non-reactive) Both reactive (normal)	Sluggish=reactive(normal) Blown pupil=non-reactive If not mentioned record normal.
Glasgow Coma Scale score available? **Lowest GCS**	Yes No 3 – 15	This information can be retrieved from the admission note, neurological evaluation or nursing records. Note if the patient is sedated or paralyzed during the first 4hours of admission, then use the most recent GCS assessment prior to sedation or paralysis.
pH available?	Yes No	
Lowest pH **Highest pH**	Blood gas value from arterial, capillary or venous sample Blood gas value from arterial, capillary or venous sample	If only one pH value recorded during applicable timeframe, enter into both Lowest and Highest fields
Total C02? **Highest Total CO2**	Yes No	If Total C02 not available, use the calculated **bicarbonate (HCO3)** value from blood gas

	Laboratory value from arterial, capillary or venous sample.	results (arterial, venous or capillary)
Pa02 available?	Yes No	This value must come from the lowest arterial blood gas sample available only.
Lowest Pa02	Arterial blood gas ONLY	
pC02 available?	Yes No	Collect the highest pC02 value available from arterial, capillary or venous sample.
Highest pC02	mmHg	
Glucose available?	Yes No	
Highest Glucose	mmol/L	Enter the highest value.
Potassium available?	Yes No	Enter the highest value. Values cannot be taken from hemolyzed samples.
Highest Potassium	mmol/L	
Creatinine available?	Yes No	
Highest Creatinine	Umol/L	Enter the highest value.
Blood Urea Nitrogen Available?	Yes No	
Highest Blood Urea Nitrogen (BUN)	mmol/L	Enter the highest value.
Is a White blood cell count value available?	Yes No	
Lowest White Blood Cell (WBC)	Laboratory value	Enter the lowest value.
PTT (aPTT) available?	Yes, No	
Highest PTT (partial thromboplastin time)	Seconds	Enter the highest value.
PT (INR) available?	Yes No	
Highest PT (prothrombin time)	Seconds	Enter the highest value.
Platelet count available?	Yes No	
Lowest Platelet Count	X 10 9/L	Enter the lowest value.

ACUTE KIDNEY INJURY

Data Field	Options	Comments
Baseline Creatinine Lowest available creatinine (Cr) available for the 365 days prior to randomization	Free Text	Collect baseline creatinine Enter the lowest value available. Not applicable if on dialysis for period in question.
Age and gender specific Creatinine value based on laboratory reference range norms for your site.	Free Text	Average the laboratory reference range used by your hospital laboratory that corresponds to the specific age and gender ***at time of***

		randomization. Round to whole number. ***(amended June 20, 2018 and uploaded into REDCap)***
Hospitalized Creatinine	Free text	Only record if patient hospitalized for 72 hrs or more prior to randomization e.g. was hospitalized for reasons other than septic shock Provide the lowest hospitalized creatinine value since the most recent major medical or surgical event: Major Medical Event: Initiation of Chemotherapy, Bone Marrow Transplant, ICU admission, cardiopulmonary arrest, other known renal insult Major Surgical Event: Cardiac Surgery, Organ Transplant, Other Thoracic or Abdominal Surgery
Peak Creatinine Highest serum Creatinine in the 7 days following randomization	Free text	Enter the highest value available 7 days following randomization. Do not include values obtained following initiation of dialysis.

FLUID ADMINISTRATION/BALANCE DURING THE INTERVENTION PERIOD

Please collect information from randomization to shock reversal.

Data Field	Options	Comments
Shift Start Date **Shift Start Time** **Shift End Date** **Shift End Time**	Day/month/year 24 hour time (HH:MM) Day/month/year 24 hour time (HH:MM)	Complete one form for every 12 hour shift. Shift times will vary depending on institution. e.g. McMaster shift times are 7:01 -19:00; 19:01-7:00, if patient was randomized on May 1st at 12:00 then the 1st form would be completed for May 1, 12:00 – May 1, 19:00. The 2nd form would be completed for May 1, 19:01- May 2 7:00 and so on.
Total fluid intake as IV maintenance fluids	ml	IV Fluids that are used to maintain patency of any intra-vascular access, they are usually given in small volume rates and

		do not contain any medication. e.g. Sodium Chloride; D5W (5% dextrose in water); NACL.
Total fluid intake as IV total parenteral nutrition	ml	IV fluids that include amminoacids and/or lipids to meet nutritional needs. e.g. dextrose/protein/lipids.
Total fluid intake as Fluid Bolus Therapy	ml	This is a discrete volume of fluid given via the Intravenous (IV) or intraosseous (IO) route over a defined period of time. A bolus is ***typically*** administered in a timeframe ranging from STAT (rapid IV push) to ***typically*** not more than 1 hour. A bolus ***typically*** ranges in volume from not less than 5 mL/kg to not more than 20 mL/kg but a physician may 'round-up or down' the volume e.g. a 19 kg patient, 20 mL/kg would be 380 mL but a physician may order 400 mL to simplify for the nursing staff.
Total fluid intake as Enteral Fluid and Nutrition	ml	Any required liquid administration to the gastro-intestinal tract (formula, peptamen, enteral feeds, oral intake). Include such foods as a popsicle if a liquid volume is charted. Refer to definitions page for Enteral Fluid and nutrition options*.
Total fluid intake as Red Blood Cells	mL	Amount of blood products received.
Total fluid intake as Platelets	mL	
Total fluid intake as 5% Albumin.	mL	
Total fluid intake as 25% Albumin	mL	
Total fluid intake as Fresh Frozen Plasma	mL	

Total fluid intake as Cryoprecipitate		
Total fluid as replacement fluid	ml	Amount of IV fluids given to replace fluid loses: eg, chest tube/ JP drain output
Total fluid intake as IV Medication administration	Ml	IV fluid given with a medication (e.g antibiotics) and/or fluid used to dilute a medication to be given continuously (e.g inotropes or insulin). Includes medication flushes. If given medications during dialysis record as IV medication administration. Also includes dialysis fluids: citrate, calcium, heparin
Did patient go to Operating Room	Yes, No	Did the patient go to the Operating room during the intervention period. Answer "No" if OR procedure was done in the ICU and not in the OR suite.
Length of Time in Operating Room	24 hour time (HH:MM)	Amount of time and IV fluids administered while the patient was in the OR.
Total Fluids in Operating Room	ml	
Was a Fluid Bolus #___ administered?	Yes No	Fluid bolus administration that has been given to a patient after randomization. The database has a capacity to record data for up to 15 fluid boluses per 12 hr shift.
Date fluid bolus #_ administered	Day/month/year	Enter date/time when the bolus was administered.
Time fluid bolus #_ administered	24 hour time (HH:MM)	
Fluid bolus type	Normal Saline (NS) Ringer's Lactate (RL) 5% Albumin Plasma-Lyte	
Fluid bolus volume	ml	

For the yellow section below, collect values from timeframe: up to 1 hour prior to time bolus administered. Do not collect values after bolus has been started.
If multiple boluses are given in a short period of time record the value closest in time for each respective bolus given. If there are no new vitals between boluses, collect the most recent values.

Highest Heart Rate	bpm	
Lowest Systolic Blood Pressure **Lowest Mean Blood Pressure**	mmHg	Record from cuff or arterial line reading. If both modes done at same time record from arterial.
Capillary refill time available? **Capillary Refill Time**	Yes, No Seconds	Use Central only. If recorded as >5, enter 5.
Central Line in situ? **Central Venous Pressure**	Yes, No mmHg	Includes central lines (including dialysis catheter) that were in place prior to enrollment in the study and central lines put in place during the intervention period.
Invasive Mechanical Ventilation?	Yes No	Record if participant invasively mechanically ventilated (via endotracheal or tracheostomy tube).
Mean Airway Pressure	cmH20	If the patient is mechanically ventilated, enter this value.
Was a justification for the Fluid Bolus #_ available? **Justification for fluid bolus #_ (for fluid sparing)**	Yes No Description	For Fluid Sparing Arm justification for every fluid bolus is required. This information should be recorded in the 'Fluid Administration Bolus Record'.
FLUID LOSSES OR REMOVAL		*Do not include VAC dressings, weighed dressings, bedsheets or weighed diapers.
Urine output? **Total urine output**	Yes, No ml/12hr	Record total for each 12 hr shift. If EMR combines Urine/Stool amount record this under Urine.
Fluid output from any drains? **Total Fluid Output from Drains**	Yes, No ml/12hr	Any drains e.g. nasogastric tube, Chest/Intrathoracic tube or peritoneal drain etc.
Losses as Vomit/stool **Total Losses as Vomit/Stool**	Yes, No ml/12hr	Enter the total amount for each 12 hour shift.
Was Dialysis performed? **Dialysis**	Yes, No Net fluid removal/12hr	If Dialysis (CRRT, HD or PD) was performed please record total amount of fluid removed per 12 hr shift. CRRT includes CVVH, CVVHD or CVVHDF. See definitions below for detailed explanation of dialysis.

LABORATORY

Collect every 24 hours from randomization until 24 hours post shock reversal.

Collect from Manual Differentials. If no Manual Differential, collect from Automatic. If done more than once per day, pick the 1st values of the day for Neutrophils, Lymphocytes and Band Count and they must be recorded from the same differential.

Data field	Options	Comments
Lowest Hemoglobin	Free text	Enter lowest daily value. If not reported enter 9999.
Neutrophils	Free text	If not reported enter 9999.
Lymphocytes	Free text	If not reported enter 9999.
Band Count	Free text	If not reported, enter 0.
Fibrinogen available?	Yes, No	
Lowest Fibrinogen	Free text	Enter lowest daily value. If not reported enter 9999.

HEMODYNAMICS

Collect during each 12 hour shift until 24 hours post shock reversal.

Data Field	Options	Comments
Highest Heart Rate	bpm	Enter highest value.
Lowest Systolic Blood Pressure	mmHg	Enter lowest value.
Lowest Mean Blood Pressure	mmHg	Enter lowest value. Record from cuff or arterial line reading. If both modes done at same time record from arterial.
Central Venous Pressure	Yes No	
Central Venous Catheter location	Femoral Internal Jugular Subclavian PICC	Patients can have more than one central line. Select the location of the line that was used to obtain the CVP. If location is not charted, leave blank. This field is for central lines (including dialysis catheter that were in place prior to enrollment and put in place during the intervention.
Lowest Central Venous Pressure	MmHg	Enter lowest value.
Highest Central Venous Pressure	mmHg	Enter highest value.
Invasive Ventilation?	Yes, No	
Highest Mean Airway Pressure	cmH20	Enter highest value.

DAILY POSITIVE CULTURE RESULTS DURING INTERVENTION PERIOD

Collect every 24 hours from randomization until 24 hours post shock reversal.

Data Field	Options	Comments
Positive organisms on cultures obtained today?	Yes No	
Site(s) Culture was obtained from.	Blood - Arterial Line Blood - Central Venous Line Blood - Peripheral Chest Tube Cerebral Spinal Fluid Feces Nasopharyngeal Swab Peritoneal Drain Tissue Urine - Catheter Urine - MSU	Select all that apply.
Specify other(s)	Other	
Organism(s) grown	Free text	
Patient on Anti-Infective Agents?	Yes No	
If Yes, check all that apply	Ampicillin Azithromycin Cefotaxime Ceftriaxone Clindamycin Metronidazol Gentamicin Meropenem Tazocin Vancomycin	Select all that apply.
Specify other anti-infective agents	Other	
Antivirals	Acyclovir Tamiflu/Oseltamivir	Collect all antiviral agents administered daily.
Other antivirals	Other	
Antifungals	Amphotericin B Fluconazole Voriconazole	Collect all antifungal agents administered daily.
Other antifungals	other	

VASOACTIVE SCORE

Collect during each 12 hour shift as per Institution <u>until 24 hours post shock reversal</u>.

Record the infusion dose for each vasoactive medication for the point at which the dosage is most intense during each 12 hour shift. Exclude: Bolus doses of vasoactive medications and 'spritzers'; Infusions dosed per hour rather than per minute. If not on vasoactive medication enter 0.

Data Field	Options	Comments
Dopamine	mcg/kg/min	If more than 1 vasoactive medication is administered, choose the highest time point. Refer to vasoactive score formula in definitions page. Only include vasopressin if at shock dose = mU/kg/min, not mU/kg/hr.
Dobutamine	mcg/kg/min	
Epinephrine	mcg/kg/min	
Norepinephrine	mcg/kg/min	
Phenylephrine	mcg/kg/min	
Milrinone	mcg/kg/min	
Vasopressin	mU/kg/min	

PELOD 2

Complete for Days 1, 2, 5, 8, 12, 16 and 18 after randomization or until hospital discharge if earlier than day 18. Do not collect values during the preterminal period (last 4 hours of life).
*****Select the most abnormal value during the 24 hour period. If the variable was not measured assume: 1) the variable was identical to the previous measurement; or 2) the physician considers the value is normal. <u>See data definitions for more detailed instructions to follow if variable not measured</u>**

Data Field	Options	Comments
Study Day	Study day Number Day/month/year	Enter the study day
Pa02 available?	Yes, No	Pa02 and Fi02 are used to calculate the P/F ratio (PaO2 divided by FiO2). This ratio will not need to be calculated by site staff for database entry but staff need to collect the values at which the P/F ratio would be the worst. If Pa02 is not available, record as normal "7777" and record most abnormal Fi02 if available.
Pa02 available	Arterial 02 blood sample **<u>ONLY</u>**	
Fi02 available?	Yes, No	Use the corresponding FiO2 for that PaO2 (e.g. the required FiO2 is to be either before, at the same time or as close to that of the arterial blood gas, (cannot be after). The FiO2 is typically recorded on the blood gas result, or in the respiratory portion of the flowsheet). If
Fi02 available	From arterial Enter FiO2 as a decimal e.g., 0.6 instead of 60%; 1.0 instead of 100% or 0.21 for room air	

		report notes “room air” enter .21. If Fi02not recorded for nasal cannula enter .30. See definitions below for detailed example on how to “eye” the worst PF ratio to know which values to input.
pC02 available? **Highest pC02**	Yes, No From arterial, capillary or venous	Enter highest daily value.
Invasive Ventilation	Yes No	The use of mask ventilation or high-flow nasal prong O2 is not considered mechanical ventilation.
Highest Heart Rate	Bpm	Enter highest daily value.
Lowest systolic BP (blood pressure)	mmHg	Enter lowest daily value. Record from cuff or arterial line reading. If both modes done at same time record from arterial.
Lowest Mean Arterial Pressure	mmHg	Enter lowest daily value.
Lactate available? **Highest Lactate**	Yes, No mmol/L	Enter highest daily value.
GCS available? **Worst GCS (Glasgow Coma Score)**	Yes, No 3-15	GCS=Glasgow Coma Score. Enter lowest daily value. If patient sedated, use most recent GCS. If no assessment, record as normal (15).
Pupillary reaction	Both Reactive Both fixed Other or N/A	Both fixed=non-reactive Sluggish=reactive(normal) Blown pupil=non-reactive If not mentioned record normal.
ALT available? **Highest ALT**	Yes, No UI/L	Enter highest daily value.
PTT (aPTT) available? **Highest aPTT** **PT (INR) available?** **Highest PT (INR)**	Yes, No Seconds Yes, No Seconds	Enter highest daily value.
Creatinine available? **Highest Creatinine**	Yes, No Umol/L	Enter highest daily value.
WBC available? **Lowest White Blood Cell (WBC)**	Yes, No Laboratory value	Enter lowest daily value.
Platelet count available? **Lowest Platelet Count**	Yes, No Laboratory value	Enter highest daily value.

CALCULATION OF VENTILATOR FREE DAYS

Collect daily from randomization **until Day 28**

Data Field	Options	Comments
Is this patient on invasive ventilation (ET tube or Tracheostomy tube) or non-invasive ventilation for any duration for each 24 hr period? **Exclude all of the following:** **-High Flow Nasal Cannula** **-Non-Invasive Ventilation w/ PEEP less than or equal to 5 with or without pressure support of less than or equal to 5. (NIV includes CPAP, BiPAP).** **-Any ventilation at chronic/home settings.**	Yes No	For patients who require invasive or non-invasive mechanical ventilator support from randomization until 28 days after. Examples of non-invasive ventilation include ventilation via face mask or nasal mask device e.g. BiPap. If patient received ventilation in Operating Room, enter "Yes".
Patient with mechanical ventilation (NIV or Invasive Ventilation)	-Invasively Ventilated -Non-Invasively Ventilated -Discharged Home Not Ventilated -Discharged Home Ventilated -Transferred to other hospital ventilated -Transferred to other hospital - not Ventilated -Not ventilated (≥ 24 hrs.) -Dead	Collect daily from randomization: Day 1 to Day 28. Start time/end time of day shift as per institution (i.e. McMaster 07:01 to 07:00; If pt randomized May 1 @ 14:00 then Day 1 = May 1 14:00 to May 2 07:00; Day 2=May 2 07:01 to May 3 07:00) High Flow Nasal Cannula is not considered non-invasive ventilation. Exclude if the patient is mechanically ventilated at home and is admitted to hospital and connected to a ventilator with the same home settings. Check with PI if it is not clear that the ventilation settings are different than at home. If patient in hospital for any duration on the day of discharge, do not record "discharged home".

CLINICAL OUTCOME DATA FOR THE INTERVENTION PERIOD

Collect from randomization until 24 hours post shock reversal.

Data Field	Options	Comments
Highest Sodium **Highest Chloride**		Enter highest value during intervention period from any sample felt to be valid.
Pleural effusion requiring drainage	Yes No	Collect this information from the Radiology reports.
1st Bladder Pressure available **1st Highest Bladder Pressure**	Yes No mmHg	Record highest value.
2nd Bladder Pressure available **2nd Highest Bladder Pressure**	Yes No mmHg	If available, record the 2nd highest value.
Abdominal Compartment Syndrome	Yes No	Criteria: ≥2 bladder pressure readings of ≥ 20 OR surgical intervention AND 1 bladder pressure reading ≥20. Refer to progress notes.
Soft Tissue Edema	None Mild Moderate Severe	Record from nursing documentation. Use best judgment if no comments are charted, i.e. general edema=moderate; pitting edema=severe.
Pulmonary Edema (CXR evidence per Radiology Report)	Yes No	Look for statement within the official (staff not resident read) Radiology Chest Xray (CXR) Report that indicates presence of pulmonary edema (language using terms edema or fluid regarding the lung tissue).
Clinical signs of digital soft tissue ischemia from randomization to 24 hrs. after shock reversal?	Yes No	Language that indicates concern about tissue viability in an anatomically specific location. (skin looks blue, black, white)
Did patient receive Lasix (furosemide) from the time of enrollment to the earliest of PCCU discharge or 7 days after shock reversal?	Yes No	Patient received furosemide during this timeframe.
Day 1 after randomization From randomization until end time of night shift	Yes No	Yes=Lasix (furosemide) was administered on Day 1
Day 2 – 21 after randomization	Yes	

From day shift start time to night shift end time (24 hr period)	No	Complete all eCRFs for Days 2-21.
Enter patient furosemide (Lasix) total dose in milligrams for this study day	Milligrams	Enter total furosemide dose for that day.
Other diuretics. From the time of randomization to the earliest of PCCU discharge or 7 days after shock reversal?	Yes No	Yes=Other diuretics were administered.
List other diuretics administered	Spironolactone Hydrochlorotiazide Metalizone	Select all that apply.

CLINICAL COURSE AND PROCEDURES

Data Field	Options	Comments
Did the participant receive ANY Vasoactive Medications for the treatment of septic shock?	Yes No	
Date of FIRST vasoactive medication given for the treatment of septic shock	Day/month/year	
Time of FIRST vasoactive medication given for the treatment of septic shock	24 hour time (HH:MM)	If started at community hospital and cannot find time in medical records, discuss time to record with PI.
What is the name of the FIRST vasoactive medication administered for the treatment of septic shock?	Dopamine Dobutamine Epinephrine Nor-epinephrine Phenylephrine Milrinone Vasopressin	
Date LAST vasoactive medication infusion for the treatment of septic shock was stopped	Day/month/year	Exact date last vasoactive medication infusion was given until shock reversal.
Time LAST vasoactive medication infusion for the treatment of septic shock was stopped	24 hour time (HH:MM)	Exact time last vasoactive medication infusion was given until shock reversal. Leave Date/Time blank if patient is on vasoactive medication but is put on ECMO or dies.

Was septic shock reversed during the SQUEEZE intervention period of 14 days?	Yes No	Refer to Definitions below or shock reversal.
Date Septic Shock Reversed **Time Septic Shock Reversed**	Day/month/year 24 hour time (HH:MM)	
Was Septic Shock reversed AFTER the SQUEEZE intervention period (after 14 days)?	Yes No	
Date Septic Shock Reversed AFTER the intervention period **Time Septic Shock Reversed AFTER the intervention period**	Day/month/year 24 hour time (HH:MM)	If shock was reversed after 14 day period, refer to Operations Manual for instructions on data collection.
Arterial Line placed during intervention period	Yes No	Enter if an arterial line was placed during the intervention period.
Central Line placed during intervention period	Yes No	Only answer "Yes" if a new central line (including dialysis catheter) was placed during the intervention period. If the patient already had a central line, the answer to this field would be No.
Dialysis?	Yes No	Enter if dialysis was performed during the intervention period
Chest Tube placed during the intervention period	Yes No	Enter if a chest tube was placed during the intervention period
Peritoneal drain placed during the intervention period	Yes No	Enter if a peritoneal drain was placed during the intervention period
Did the patient receive any IV steroids related to the treatment of this episode of septic shock?	Yes No Study Drug	YES: steroids were administered for the treatment of septic shock. e.g. Hydrocortisone, Prednisone NO: No steroids administered **related** to treatment of septic shock. STUDY DRUG: Select if included in an interventional trial involving **<u>blinded</u>** treatment with steroid or placebo for septic shock.
Specify study drug	Other/steroid RCT	
Has the child received ECMO or any other form of mechanical circulatory support during the	Yes No	ECMO and other types of mechanical circulatory support such as Cardio Pulmonary

intervention period to treat refractory shock?		Bypass, Left Ventricle Assist Device or other. **Note** Verify with clinical care team that the use of ECMO, CPB, LVAD or other is for cardiopulmonary resuscitation for refractory septic shock and not for other reasons (see definitions page for instructions of what eCRFs to collect when patient put on mechanical circulatory support)
Date mechanical circulatory support started	Day/month/year	.
Time mechanical circulatory support started	24 hour time (HH:MM)	
Please specify	Free text	Record type of mechanical circulatory support.

CLINICAL OUTCOMES TO 90 DAYS

Data Field	Options	Comments
Patient admitted to the PICU?	Yes No	Admission orders written to PICU service.
Date of PICU admission **Time of PICU admission**	Day/month/year 24 hour time (HH:MM)	Date/time when service changes from ED to PICU.
Date of discharge from PICU **Time of discharge from PICU**	Day/month/year 24 hour time (HH:MM)	
Date of hospital admission	Day/month/year	Enter date when patient was admitted to hospital (not ER visit date).
Date of discharge from hospital **Time of discharge from hospital**	Day/month/year 24 hour time (HH:MM)	
Did the patient die during this hospitalization?	Yes No	Only record date of death if patient died during hospitalization for septic shock at your site. Does not include if patient transferred to another hospital and then died.
Date of Death **Time of Death**	Day/month/year 24 hour time (HH:MM)	
Mode of Death	Brain Death Withdrawal of life support	Includes limitation of resuscitation (can occur from hours to days after presentation); Taken off ECMO support expecting death

	Do Not Resuscitate Order	
	Failure of CPR	Includes failure of resuscitation (acute process)
Mechanism of Death	Predominant Cardiovascular Dysfunction Predominant Respiratory Dysfunction Predominant Neurological Dysfunction Predominant Renal Dysfunction Predominant Hepatic Dysfunction Other (specify):	
Specify Other Mechanism of Death	Text Field	
Cause of Death		
Was death due to refractory septic shock:	Y/N	If NO selected then free text response required
If No, specify		
If patient discharged, please record location patient was discharged to	-Home -Transferred to rehabilitation/long term care facility -Transferred to another hospital	
Did the patient die after this hospital discharge to 90 days?	Yes No	Collect up to 90 days from date of randomization (from EMR or obituary). Includes date of death for those patients transferred to another hospital from your site.
Date of death	D-M-Y	
Mode, Mechanism, Cause of Death may not be available if patient died at another hospital after being transferred from your site. If not available, leave blank.		
Mode of Death	Brain Death	
	Withdrawal of life support	Includes limitation of resuscitation (can occur from hours to days after presentation); Taken off ECMO support expecting death
	Do Not Resuscitate Order	Includes failure of resuscitation (acute process)
	Failure of CPR	
Mechanism of Death	Predominant Cardiovascular Dysfunction	

	Predominant Respiratory Dysfunction Predominant Neurological Dysfunction Predominant Renal Dysfunction Predominant Hepatic Dysfunction	
Specify Other Mechanism of Death	Other (specify): Text Field	If NO selected then free text response required
Cause of Death **Was death due to refractory septic shock:**	Y/N	
If No, specify		
Clinical signs of compromised bowel perfusion as determined by the pediatric surgical consultation censored at 7 days after shock reversal	Yes No	Look for pediatric surgical notes (i.e. necrosis, ischemia, bowel death). Signs of this condition may not present immediately. They may appear for instance when the child is fed. Review notes from randomization up to 7 days after shock reversed. If patient is put on ECMO then this will be censored at 7 days post initiation of ECMO.
Digital (or soft tissue) ischemia requiring revision amputation during the follow up period?	Yes No	Yes=there were signs of digital ischemia (may or may not involve also limb ischemia) or soft tissue ischemia directly related to this episode of septic shock that required revision amputation (removal or soft tissue +/- bony tissue). If tissue ischemia occurred > 24 hours post septic shock reversal, then revision amputation is not related to this episode of septic shock. Collect up to 90 days from date of randomization. Collect this information from the Medical Record.
Please specify anatomical site affected.	Free text	Collect up to 90 days from date of randomization.
Date of amputation	D-M-Y	

SITE OF INFECTION

Choose the site of infection for the most probable cause of septic shock

Data field	Options	Comments
Bacterial Meningitis	Documented by Cerebral Spinal Fluid (CSF) culture, or Blood culture with abnormal CSF (WBC > 6)	Based on laboratory results
	Suspected (but not confirmed as above)	Based on Medical progress notes
Bacteremia (Blood Culture Positive)	Central line as a source	Central line suspected source
	Primary (no known source)	Occult source of infection
	Secondary (from another source)	Obvious/suspected initial site of infection as source of bacteremia e.g. pneumonia
	Endocarditis	Documented in medical record and on Echocardiography report or at Operation (if required)
Specify secondary source site	Free text	
Pneumonia (clinical diagnosis)	Community Acquired Pneumonia	Pneumonia developing in the outpatient setting in non-ventilated patient
	Hospital Acquired Pneumonia (VAP/HAP)	Pneumonia developing in patient ventilated and/or hospitalized for at least 3 days.
	with Empyema	Type of Pleural Effusion.
Urinary Tract Infection	Documented with urine culture	Positive culture growth and clinical impression of UTI in progress notes
	Suspected based on urinalysis (but unable to confirm with urine culture).	Positive leukocytes and/or nitrates on urinalysis and clinical impression in progress notes
Peritonitis	Bowel perforation	Documentation in surgical consultation/notes
	Complication post-operative abdominal surgery	Documentation in surgical consultation/notes
	Appendicitis	Documentation in surgical consultation/notes

	Peritoneal dialysis	Patient will have Peritoneal Dialysis Catheter and dialysis will be documented in nursing record.
	Other cause of peritonitis	Documentation in surgical consultation/notes
Specify other cause of peritonitis	Free text	As applicable
Mediastinitis	Post-operative cardiac surgery Esophageal leak	Documentation in surgical consultation/notes
Other infection site?	Yes, No	Medical progress notes
Specify other infection site	Free text	
Unknown site of infection	Febrile neutropenia Other	Medical progress notes
Specify other unknown site	Free text	As applicable

BIOLOGICAL SAMPLES

Data Field	Options	Comments
SQUEEZE-D		Collect both samples during routine blood work.
Sample A collected?	Yes No	Select Yes if Sample A collected within 6 hours after randomization.
Sample B collected?	Yes No	Select Yes if Sample B collected 24–48 hours post randomization (earliest time during this period that a sample can be obtained).
PERSEVERE		
Sample A collected?	Yes No	Yes: Sample A was collected within 24 hours of study enrollment. Samples are taken from gold top tubes.
Sample B collected?	Yes No	Yes: Sample B collected on Study Day 3 (which represents approximately 48 hours after the timing of the first sample).

ADVERSE EVENT FORM

Data Field	Options	Comments
Description of Event	Free text	Describe the event
Start Date of AE	D-M-Y	Date the AE started
Stop Date of AE	D-M-Y	Date the AE stopped

Grade of the event (according to CTCAE)	**Grade 1** - Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. **Grade 2** - Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental Activities of Daily Living. **Grade 3-5** – prepare Local REB SAE form.	Choose the grade of the event according to the available information.
Is the adverse event related to the study?	Probably related Possibly related Not related	
Action Taken?	Free text	
Did the participant recover from the event?	Completion Resolution Ongoing	

WITHDRAWAL

Data Field	Options	Comments
Patient withdrawal from ongoing participation in the study	Yes No	Yes: withdrawal request is made by patient, parents/SDMs, or the treating physician to withdraw the patient from the study.
Date of Withdrawal	Date	Date withdrawal request was made.
Reason for withdrawal?	Patient request Reason: free text Physician request Reason: free text	Patient request: Select if patient or parents/SDMs requested withdrawal from the study. Record reason provided. Physician request: Select if the treating physician decides to withdraw patient from the study. Record reason provided.

LOCAL PRINCIPAL INVESTIGATOR STATEMENT

Complete after eCRF has been verified by CTCC.

Data Field	Options	Comments
Name of Local Principal Investigator	Free text	Name of LPI
Date	Free text	Enter date when the LPI reviews the eCRF

Time	Free text	Enter time when the LPI reviews the eCRF
I have reviewed the eCRFs and confirm that, to the best of my knowledge, they accurately reflect the study information obtained for this participant. All entries were made either by me or by a person under my supervision who has signed the Delegation and Signature Log.	Add signature	Add electronic signature of LPI

DATA DEFINITIONS

Abdominal Compartment Syndrome

Abdominal Compartment Syndrome, which can be caused by sepsis, occurs when the abdomen becomes subject to increased pressure. Increasing pressure reduces blood flow to abdominal organs and impairs pulmonary, cardiovascular, renal, and gastro-intestinal (GI) function, causing multiple organ dysfunction **syndrome** and death.

Bolus

A (fluid) bolus is a discrete volume of fluid prescribed to be administered intravascularly (IV or IO) over a defined period of time (ranging from STAT i.e. as fast as possible to typically no greater than 60 minutes). A fluid bolus typically ranges in size from usually not less than 5 mL/kg (250 mL for participants ≥ 50 kg) to 20 mL/kg (1 litre for participants ≥ 50 kg, although some clinicians may use per kilogram dosing in larger patients). A documented medical order is required for a fluid bolus. Routine fluid replacement is not considered to be bolus(es).

Inclusion criteria for SQUEEZE: **Patients <50 kg:** Minimum 40 mL/kg of isotonic crystalloid (NS or RL) and/or colloid (5% albumin) as fluid boluses within preceding 6 hours. **Patients ≥50 kg:** Minimum 2 L of isotonic crystalloid (NS or RL) and/or colloid (5% albumin) as fluid boluses within preceding 6 hours.

Dialysis

Dialysis is a process for removing waste and excess water from the blood and is used primarily as an artificial replacement for lost kidney function in people with kidney impairment.

Types of Dialysis:

Hemodialysis: Usually a 3 hour treatment done a few times per week. Processes fluid quickly. This type of dialysis is not typically given to septic shock patients because they cannot handle having a lot of fluid removed over a short period of time.

Peritoneal Dialysis: Home dialysis therapy for patients with end stage renal disease.

Continuous Renal Replacement Therapy – 24 hour per day dialysis treatment used to treat critically ill hospitalized patients.

Any of the above three types will be a "Yes" to dialysis.

Enteral fluids and Nutrition

Any required liquid administered through the gastro intestinal tract (formula, peptamen, enteral feeds through NG tube etc.)

Hypotension: Inclusion Criteria

Systolic/mean blood pressure < 5th percentile for age based on AHA PALS guidelines

Age Group	Systolic Blood Pressure (5th Percentile)[2]	Mean Blood Pressure (5th Percentile)[3]
Less than 1 year	70	40
1 year	72	42
2	74	43
3	76	45
4	78	46
5	80	48
6	82	49
7	84	51
8	86	52
9	88	54
10	90	55
11	90	57
12	90	58
13	90	60
14	90	61
15	90	63
16	90	64
17	90	65

Mechanical Circulatory Support (MCS)

Extracorporeal membrane oxygenation (ECMO)

A technique of providing respiratory support; the blood is circulated through an artificial lung consisting of two compartments separated by a gas-permeable membrane, with the blood on one side and the ventilating gas on the other.

Ventricular assist device (VAD)

VAD takes over the function of one of the ventricles in your heart. It takes blood from chambers of the heart and helps pump it to the body, supporting the heart.

Total artificial Heart (TAH)

This device replaces the function of both ventricles in people with end-stage heart failure.

Cardiopulmonary Byass

CPB temporarily takes over the function of the heart and lungs during surgery maintaining the circulation of blood and the oxygen content of the patient's body.

What to collect when patient on mechanical circulatory support:

Collect all data up until the date/time patient is documented as being 'on ECMO circuit' or other MCS.
Once on ECMO circuit or other MCS only collect:

a) PELOD to study Day 18
b) From Clinical Outcomes to 90 Days eCRF:
   - Survival data
   - Revision Amputation data
   - Signs of compromised bowel perfusion to 7 days post ECMO.

PELOD 2

Collect every 24 hours on days 1, 2, 5, 8, 12, 16 and 18 or until hospital discharge if earlier than day 18. Select the most abnormal value during the 24 hour period. Follow the institution shift time for the 24 hour period (i.e. McMaster- 07:01-07:00) as opposed to the 24 hour clock (00:00 – 23:59).

The only data field on this form that you should select "No" as a response is Invasive Ventilation. For all other responses select "Yes" and follow instructions for values not recorded. Do not collect values during the preterminal period (last 4 hours of life).

Day 1: If Day 1 is a short time frame (i.e. randomized at 03:00 and shift ends at 07:00) and values are not measured during the short time frame, use pre-randomization values.

Day 2: If the value was not measured, check clinical notes to determine if patient normalized. If patient normalized enter 7777. If patient did not normalize enter the values populated in the Day 1 eCRF.

Day 5: If the value was not measured, check clinical notes to determine if patient normalized. If patient normalized enter 7777. If patient did not normalize check values on Days 3 and 4 and enter the most recent value. If no values are entered on Days 3 or 4, enter the values populated in the Day 2 eCRF.

Days 8, 12, 16 and 18: If the value was not measured, check clinical notes to determine if patient normalized. If patient normalized enter 7777. If patient did not normalize check values on the days between the last PELOD2 eCRF and enter the most recent value. If no values are entered on those days, enter the values populated in the last eCRF.

Pa02/Fi02 = P/F Ratio

The PaO2/FIO2 ratio is a commonly used indicator of lung function in critically ill patients. The lower the ratio indicates a worsening disease. The ratio is calculated by dividing Pa02 by Fi02. Research staff do not need to enter the PF ratio into the database, however, they do need to understand how to determine the lowest PF ratio in order to enter the appropriate Pa02 and corresponding Fi02.

The PaO2 must be from the blood gas and the FiO2 at the time the blood gas was drawn or immediately before, but not after it was drawn. If FiO2 not charted consistently, can assume that Fi02 is same as last

recorded value. Some electronic medical records will show Fi02 as a %, but for division purposes it needs to be changed to a decimal (i.e. Fi02 21% = .21).

Normal PaO2:FiO2 = 100 mmHg/0.21 ≈ 500. The lower the Pa02 the worse the value. The higher the Fi02 the worse the value.

Online PF ratio calculator: https://www.merckmanuals.com/medical-calculators/PaO2_FIO2Ratio.htm

Examples of PF ratios.

May 1 @ 13:00	May 1 @ 18:00	May 1 @ 22:00
Pa02 = 39 Fi02 = .85 **PF ratio = 46** **Lowest PF Ratio**	Pa02=59 Fi02=.95 PF ratio = 62	Pa02=60 Fi02=.40 PF = 150
In this example both the Pa02 and Fi02 values are bad which gives the lowest PF ratio. These are the values that would be entered in the database.	In this example you see that the Pa02 value is getting higher, but the Fi02 has worsened.	In this example you see that the Pa02 has almost stayed the same but the Fi02 has gotten better.

Septic Shock

Septic shock can occur as a complication from sepsis. Blood pressure drops which impairs the delivery of blood and oxygen to organs stopping them working properly. Sepsis is an abnormal body-wide inflammatory response to an infection. The inflammation causes dilation of blood vessels which results in decreased blood pressure.

From a pragmatic perspective, the physician contacting the research team simply has to believe, based on their assessment and clinical knowledge, that the child has sepsis.

Shock Reversal

When a patient has achieved all of the following in the absence of mechanical circulatory support. Shock is not considered to be reversed if patient dies or is on ECMO or any other form of mechanical circulatory support.

1. Patient is off vasoactive medication infusions for 24 hours

Within 48 hours from discontinuance of vasoactive medications:

2. Normalization of heart rate (HR) (≤ 95th percentile for age)
3. Normalization of blood pressure (SBP) (≥ 5th percentile for age)
4. Normalization of capillary refill time (CR) (can be peripheral or central)

or return to baseline values if these are clearly documented as being outside expected values for age.

If patient off vasoactive medications for 24 hours but does not meet the other 3 criteria follow these guidelines:

a) If systolic blood pressure and heart rate are normal but CR is not recorded then assume central CR is normal and shock is reversed.
b) If systolic blood pressure and heart rate are normal and central CR is not recorded but peripheral CR is recorded as abnormal assume central CR is normal and shock is reversed.
c) If heart rate, systolic blood pressure and capillary refill do not all normalize within a 48 hour period then RS to review case with PI to determine if shock is reversed.

Normalization of Heart Rate is ≤ the 95th percentile for age

Age Group	Heart Rate – 95th Percentile
0 days to 1 week	180
1 week to 1 month	180
1 month to 1 year	180
2-5 years	140
6-12 years	130
13 to < 18 years	110

Normalization of Capillary Refill Time

Normal: 1-2 seconds

Abnormal
Abnormally fast: <1 second ('flash' capillary refill)
Abnormally delayed: ≥ 3 seconds

Normalization of systolic and Mean Blood Pressure **≥ 5th** percentile values)

Age Group	Systolic Blood Pressure (5th Percentile)[2]	Mean Blood Pressure (5th Percentile)[3]
Less than 1 year	70	40
1 year	72	42
2	74	43
3	76	45
4	78	46
5	80	48
6	82	49
7	84	51
8	86	52
9	88	54
10	90	55
11	90	57
12	90	58
13	90	60
14	90	61
15	90	63
16	90	64
17	90	65

Examples of shock reversal:

<u>Shock Reversal Example for patient on vasoactive medication</u>

May 1st @ 09:00 – vasoactive medication discontinued
May 1st @ 09:01 – May 2nd 8:59 am – review EMR for normalization of systolic blood pressure, heart rate and capillary refill
May 1st @ 11:00 – Heart rate and systolic blood pressure normalize
May 1st @ 13:00 – Capillary refill normalize
Date/Time of Shock Reversal = May 1st @ 13:00

<u>Shock Reversal Example for patient not on vasoactive medication</u>
May 1st, 2017 @ 09:00 – Heart rate normalized

May 1st, 2017 @ 11:00 – Systolic blood pressure normalized
May 1st, 2017 @ 13:00 – Capillary refill normalized
Date/Time of Shock Reversal = May 1st @ 13:00

Site Codes for Study ID

01 - Alberta Children's Hospital
02 – Children's Hospital of Western Ontario
03 - CHU de Quebec
04 - CHU ST Justine
05 - McMaster Children's Hospital
06 - Sickkids
07 – Stollery Children's Hospital
08 – Winnipeg Children's Hospital

Tachycardia: Inclusion Criteria

Heart Rate is >95th percentile for age

Age Group	Heart Rate – 95th Percentile
0 days to 1 week	180
1 week to 1 month	180
1 month to 1 year	180
2-5 years	140
6-12 years	130
13 to < 18 years	110

Vasoactive Score

The Vasoactive Score can be used as a predictor of clinical outcomes. The VAS reflects intensity of hemodynamic support.

Research staff do not need to calculate the vasoactive score for purposes of data entry, but do need to understand the different potencies of vasoactive medications to determine at which point in the 12 hour shift the vasoactive score would be the highest. Once that is determined for all drugs for that time point, the medication doses are entered into the database.

For each time point, the vasoactive score is calculated by adding the potency adjusted amount of each medication to determine the point at which the vasoactive score is the highest.

Example of vasoactive meds over a 6 hour period. The yellow highlight represents the time at which the vasoactive score is the highest over the 6 hour period. The blue highlight represents the values to be entered into the database.

Medication	19:00	20:00	21:00	22:00	23:00	00:00
Vasopressin Potency Adjustment Factor =Dose x 10,000 Potency Adjusted Amount				.0005 5		.0005 5

Dopamine Potency Adjustment Factor =Dose x 1 Potency Adjusted Amount	10 10	10 10	10 10	10 10	10 10	5 5
Epinephrine Potency Adjustment Factor = Dose x 100 Potency Adjusted Amount	.2 20	.2 20				
Norepinephrine Potency Adjustment Factor = Dose x 100 Potency Adjusted Amount		.2 20				.2 20
Milrinon Potency Adjustment Factor = Dose x 10						
Phenylephrine Potency Adjustment Factor = Dose x 10						
Vasoactive Score	30	40	10	15	10	30

Ventilation

Invasive Ventilation

For invasive ventilation, an endotracheal tube is inserted through the patient's mouth or nose, or a tracheostomy tube is inserted through an opening made by incision in the neck.

Non-invasive Ventilation

In non-invasive ventilation, the patient circuit connects to a mask covering the mouth and/or nose or nasal prongs.