Frequently Asked Questions (FAQs)

ED – IWK Children's Health Centre

PRoMPT BOLUS
PRagMatic Pediatric Trial of Balanced vs nOrmaL Saline FlUid in Sepsis

Q: Who should I think about enrolling?
A: Children aged 6mo to < 18 years presenting to the ED with suspected sepsis who you anticipate giving a second bolus of fluids for poor perfusion.

Q: Where do I find screening and eligibility criteria?
A: Screening criteria and eligibility criteria are posted in the triage area, on the wall of the trauma (resuscitation) room, Room C, and in the main ED write up area.
Eligibility criteria is also found within the dedicated PRoMPT BOLUS study boxes.

Q: Where do I find randomization envelopes?
A: Randomization envelopes are located in the following 3 locations:
1) The PRoMPT BOLUS study box in the **trauma room**
2) The PRoMPT BOLUS study box in **room C**
3) The PRoMPT BOLUS study box in the **clean utility room**

Q: What is in the randomization envelopes, and what do I do with it?
A: Randomization envelopes include the following:
1) *Randomization Stickers* – place one on the completed eligibility form and one on the patient's health record
2) *Participant Wrist Bands* – place on the patient's wrist for easy identification of participation
3) *IV Hang Tags* – place on IV pole for easy reminder of allocated fluid
4) *Patient Door Signs* – keep on the health record for the admitting team to post on the patient's room door
5) *ED Information Sheet* – to assist you through ED study processes
6) *Inpatient Information Sheet* – to assist admitting staff through inpatient study processes. Please keep on the health record for the admitting team
7) *Caregiver Information Sheet* – Please give to the child's caregiver. If they have questions, refer them to the Information Sheet and the study phone numbers

Q: How will I know what fluid my patient is allocated to?
A: Colour-coded tools will help you identify which fluid to give your patient (Purple = Balanced Fluids such as Ringer's Lactate or PlasmaLyte; Orange = Normal Saline) including:
1) Patient Wrist Bands
2) IV hang tags
3) Patient Door Signs
4) Randomization Stickers

Q: How much IV fluid should I order?
A: The amount, timing and rate of fluid administered is at the discretion of the managing health care provider

Q: Can I use a different fluid than the one my patient is allocated to?
A: If there is a definitive clinical indication for using an alternate fluid from the one allocated for the study, please manage the patient based on that clinical requirement. An example would be using saline for clinically relevant hyponatremia.

Q: Can I add electrolytes, dextrose, etc?
A: Yes - Some patients will require added electrolytes, dextrose etc. However, as per usual IWK protocols, please consult the IWK Parenteral drug and fluid guides on the IWK Pulse website

Q: What about mixing medication infusions?
A: Please follow routine IWK pharmacy directives for mixing medications, regardless of what study fluid your patient has been allocated to.

Q: Are there any compatibility issues?
A: There are several well-known compatibility issues for Lactated Ringers (LR). LR can not be provided through the same IV line at the same time as ceftriaxone or some blood products. Options include the use of a second IV line, or a very careful IV flush prior to- and after- the use of these medications. Please review and follow all IWK pharmacy administration guidelines for all medication administration and compatibility concerns.

Q: Is informed consent needed before starting fluids for study purposes?
A: No – Because sepsis is a life-threatening condition requiring timely intervention, PRoMPT BOLUS has been approved by the Research Ethics Board as a deferred consent study where research teams will collect consent when clinically appropriate. Please provide the "Study Information Sheet" to the caregiver. This info sheet outlines the deferred consent process.

Q: What about other interventions like antibiotics, vasoactive medications etc?
A: This study only controls the type of fluid administered to the child. ALL other interventions are to be done according to best practice at the discretion of the managing health care provider.

Q: Do I have to do any special lab tests, imaging etc.?
A: No – there are no study-specific lab tests or imaging. All labs/imaging are at the discretion of the managing health care provider for clinical purposes.

Q: Are there any reasons I should withdraw a child from the study?
A: There are several concerning clinical situations in which a child should be stopped from the study. These include:

1) Significant electrolyte abnormalities such as hyperkalemia and hypercalcemia,
2) Significant end organ damage such as severe hepatic or renal impairment,
3) Hypersensitivity to the allocated fluid

Formal definitions can be found below and on PULSE – see **PRoMPT BOLUS**.

Q: Where do I put all the study documents?
A: Please keep all documents on the health record including the completed Eligibility Form, Patient Door Sign and Inpatient Study Instructions.

Q: HELP!!! I have questions about the patient in front of me…what do I do?
A: Please refer to the following resources for more help:

1) ED Study Information Sheet
2) PULSE – see **PRoMPT BOLUS**
3) Call a study team member at (902) 293-1582 (Dr. Jason Emsley, Site PI) or (902) 877-6683 (Nick McCaughey, Research Coordinator)
4) Email Dr. Jason Emsley at jason.emsley@nshealth.ca or Nick McCaughey at emergencyresearch@iwk.nshealth.ca

Stopping Criteria:

Recognizing that hepatic and renal injury are a) common in septic shock, b) often improved by fluid resuscitation, and c) vary along a spectrum of mild dysfunction (common) to severe failure (uncommon), stopping criteria are defined when either an **immediate unsafe condition is noted or when persistent or worsening organ injury indicates that continued LR administration may be cumulatively unsafe** (e.g., potassium administration despite worsening oliguria or lactate administration despite worsening hepatic function).

Early Termination Rules (Stopping Criteria)

Item	Definition
Hyperkalemia*	K^{+} >6 mEq/L
Hypercalcemia*	Ca^{+2} >3 mmol/L OR iCa^{+2} >1.35
Severe hepatic impairment	ALT > 10000U/L OR total bilirubin >205 umol/L
Severe renal impairment	Urine output <0.5 ml/kg for 16 hrs (continuous) OR Initiation of new Renal Replacement Therapy
Hypersensitivity to allocated fluids	Based on managing clinical team

*confirmed by immediate retesting