Frequently Asked Questions (FAQs)

Inpatient – IWK Children's Health Centre

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

Q: **What is this study all about?**
A: The PRoMPT BOLUS study will determine if resuscitation with balanced fluids results in improved outcomes in children aged 6 mos to <18 yrs presenting to the Emergency Department with sepsis.

Q: **Will children who become septic on the ward/in the PICU be eligible for enrollment?**
A: No. This study is enrolling exclusively in the Emergency Department. This is to avoid any confounding from fluids previously administered on the ward, in the PICU or during transport.

Q: **How will I know if my patient is enrolled in the study?**
A: The ED clinical staff will inform the admitting team about enrollment during handover.
We are using multiple colour-coded visual cues (Purple – Balanced Fluids such as Ringer's Lactate or PlasmaLyte); Orange – Normal Saline) to let you know about the study:

1) Randomization Labels (on the paper Health Record)
2) Patient Wrist Bands
3) IV Hang Tags
4) Patient Door Signs

Participants will also arrive for admission with Inpatient Study Instructions in the Health Record.

Q: **Will I know which fluids my patient is allocated to?**
A: Yes. This is an open-label study (i.e., not blinded).
Multiple colour-coded visual cues (Purple – Balanced Fluids; Orange – Normal Saline) will remind you what fluid the participant has been allocated to.

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: **Are there special study-specific fluid bags?**
A: No. You will use the fluids that are available as part of the routine hospital stock.

Q: **Can I use a different fluid than the one my patient is allocated to?**
A: Adherence to the allocated fluid is very important to maintain the quality of the evidence derived from the study. However, 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 (**note**: these cases should be rare/exceptional). 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: When does the study intervention end?

A: The study intervention period continues until midnight (23:59) the day following randomization. The allocated fluid should be provided until that point. Following the intervention period, you can continue the allocated fluid should you choose, or switch to any fluid of your choice.
Note: the date/time of randomization will be written on the IV Hang Tags and the Patient Door Signs.

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: Are there any reasons I should withdraw a child from the study?

A: There are several rare but 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: What about consent?

A: Due to the emergent nature of sepsis, and the need for immediate administration of fluid management, it is not feasible to obtain true informed consent at the time of fluid initiation in the ED. This study has been approved by our local REB for deferred consent. A Caregiver Information Sheet was provided to the family in the ED. A member of the research team will approach the family at the most optimal time to further discuss the study and obtain deferred consent.

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