Frequently Asked Questions (FAQs)

ED – Alberta Children's Hospital (ACH)

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

Q: Who should I think about enrolling?
A: Children aged 2 months 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 are posted on the wall of both resuscitation rooms and in all the patient care pods. Eligibility criteria can be found posted on the wall of both resuscitation rooms and in the labelled drawer of the Sepsis Cart located in the hallway outside the A pod.

Q: Where do I find randomization envelopes?
A: Randomization envelopes are located in the following 2 locations:
1) The black drawer above the desk in the resuscitation room
2) In the Sepsis Cart located in the hallway by outside the A pod

Q: What is in the randomization envelope, and what do I do with it?
A: Randomization envelope includes the following:
1) Randomization Sticker – place the sticker on the completed Eligibility Form
2) Participant Wrist Band – place on the patient's wrist for easy identification of participation in the study
3) IV Hang Tag – place on IV pole for easy reminder of allocated fluid
4) ED Team Instructions Sheet – to assist ED staff through study process
5) 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 (**Green** = **Balanced Fluid**, **Orange** = **Normal Saline**) including:
1) Patient Wrist Bands
2) IV Hang Tags
3) 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, AHS pharmacy policy does not allow additives mixed directly into Balanced Fluid bags. A very handy guide to mixing electrolytes can be found in the resuscitation rooms and on the Sepsis Cart located in the hallway outside the A pod.

Q: What about mixing medication infusions?
A: Please follow routine 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 cannot be provided through the same IV line at the same time as ceftriaxone or 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 AHS 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 intervention. These include:

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

Definitions of Stopping Criteria can be found on the PRoMPT BOLUS website. See QR code for link.

Q: What should I do if a child meets Stopping Criteria?

A: If a child meets one of the Stopping Criteria, they are no longer required to receive the allocated study fluid. Manage the child at your discretion. However, the child is still a study participant and we need to collect safety data outcomes. Please follow the following steps:

1) Place a Stopping Criteria sticker (red sticker) on the child's wrist band and IV hang tag
2) Notify the study team that the child had been enrolled but met stopping criteria
3) Place a note in Connect Care in the child's chart using the SmartPhrase "**.PBSTOP**"

Q: Where do I put the completed Eligibility Form?

A: Please place the completed Eligibility Form in the mailbox outside the ED Research Office.

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) PRoMPT BOLUS website (see QR code for link)
3) Contact a study team member
   - **Dr. Graham Thompson** at **(403) 369-0765** graham.thompson@ahs.ca
   - Study team pager (Mon-Fri, 10:00-17:00): **#11316**