Frequently Asked Questions (FAQs)

Kingston Health Sciences Centre – HDH COPC & KGH ED

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, and by the Pediatric fluid equipment and at the Unit Clerk stations.

Q: Where do I find randomization envelopes?
A: If you are at KGH ED, randomization envelopes are located at Unit Clerk Station.
If you are at HDH COPC, randomization envelopes are located at the Nursing desk filing cabinet, second drawer.

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) ED Team Instructions Sheet – to assist ED staff through study process
3) 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) IV Hang Tags
2) 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. There will be pre-mixed Lactate Ringers with 5% dextrose and Lactate Ringers with 20 mmol/L of KCl available. Pre-mixed Saline with 5% dextrose, Saline with 20 mmol/L of KCl, and Saline with both 5% dextrose and 20 mmol/L of KCl will be available. If mixing is needed please refer to CHEO outreach for adding ingredients: https://outreach.cheo.on.ca/manual/1433. Fluid additives should be prepared according to KHSC compatibility protocols and procedures.

Q: What about mixing medication infusions?
A: If mixing is needed please refer to CHEO outreach for adding ingredients: https://outreach.cheo.on.ca/manual/1433. Fluid additives should be prepared according to KHSC compatibility protocols and procedures.

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 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.

What about other interventions like antibiotics, vasoactive medications etc.?
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 on the PRoMPT BOLUS website. See QR code for link.

Q: Where do I put the completed Eligibility Form?
A: If you are at KGH ED, please place the completed Eligibility Form in the folder at the Unit Clerk Station. If you are at HDH COPC, please place the completed Eligibility Form in the folder at the Nursing station filing cabinet, second drawer.

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. Anupam Sehgal** at **(416) 333 – 8098** **Anupam.Sehgal@kingstonhsc.ca**
   - **Dr. Anne Moffatt** at **(613) 532 - 4254** **Anne.Moffatt@kingstonhsc.ca**