Frequently Asked Questions (FAQs)

ED – BC Children's Hospital (BCCH)

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

Q: Who should I think about enrolling?
A: Children aged 2mo 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: Eligibility criteria forms can be found beside the Omnicells/Trauma Ordersets in the Trauma Bays and in the PRoMPT BOLUS File Organizer in Orca 1 (in the corner opposite of the Unit Clerk)

Q: Where do I find randomization envelopes?
A: Randomization envelopes are located in the following 2 locations:
1) beside the Omnicells/Trauma Ordersets in the Trauma Bays
2) in the PRoMPT BOLUS File Organizer in Orca 1 (in the corner opposite of the Unit Clerk)

Q: What is in the randomization envelopes, and what do I do with it?
A: Randomization envelopes include the following:
1) Randomization Sticker – place one on the completed eligibility form
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) ED Information Sheet – to assist you through ED study processes
5) Inpatient Information Sheet – to assist admitting staff through inpatient study processes. Please put with the physical chartlet for the admitting team
6) Caregiver Information Sheet – Please give to the child's caregiver. If they have questions, refer them to the Information Sheet.

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 Fluids, Yellow = 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. Please discuss with BCCH pharmacy.

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 can not 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 BCCH 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 on the PRoMPT BOLUS website. See QR code for link.

Q: Where do I put all the study documents?
A: Please place the completed Eligibility Form in the PRoMPT BOLUS File Organizer in Orca 1 (in the corner opposite of the Unit Clerk). Please ensure the Inpatient Study Instructions are placed in the patient's physical chartlet.

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
3) Contact a study team member: Dr. Pavan Judge at pavan.judge@cw.bc.ca

For More Information, visit the PRoMPT BOLUS Resource Website or contact Dr. Pavan Judge at Pavan.Judge@cw.bc.ca