Frequently Asked Questions (FAQs)

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

ED – Children's Hospital of Eastern Ontario

Q: Who should I think about enrolling?
A: Children aged 2 months + 1 day 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 in the resuscitation rooms and eligibility criteria can be found posted on the PRoMPT Sepsis Cart and on the bedside tables in Resus.

Q: Where do I find the cart with study materials?
A: Study materials including randomization envelopes are located in the Sepsis Cart located in the resuscitation room near AR-04.

Q: What is in the randomization envelopes, and what do I do with it?
A: Randomization envelopes include the inclusion/exclusion form to be completed, signed and dated by the Treating MD. The randomization category will also be found along with the study ID barcode to scan once PRoMPT fluids have been ordered.

Q: What is in the large envelopes, and what do I do with it?
A: The large envelopes include the following:

1) Participant Wrist Bands – place on the patient's wrist for easy identification of participation
2) IV Hang Tags – write the start date/time of fluids and place on IV pole for easy reminder of allocated fluid
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** = Normal Saline, Pink = Balanced Fluids) including:

1) Patient Wrist Bands
2) IV hang tags

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. Once this clinical indication has resolved, please return to the randomized fluid.

Q: Can I add electrolytes, dextrose, etc?
A: Yes - Some patients will require added electrolytes, dextrose etc.

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 CHEO 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, **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)

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 notify the study team that the child has been enrolled, but met stopping criteria.

Q: Where do I put the completed Eligibility Form?

A: Please ensure the completed eligibility form is placed back in the PRoMPT Sepsis cart in the drawer labelled "Completed Forms".

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) Contact a study team member:
    - Dr. Waleed Alqurashi (walqurashi@cheo.on.ca)
    - Dr. Fuad Alnaji (falnaji@cheo.on.ca)
    - Cheryl Kreviazuk (ckreviazuk@cheo.on.ca)