

Frequently Asked Questions (FAQs)



PRoMPT BOLUS

PRagMatic Pediatric Trial of Balanced vs nOrmal Saline FIUId in Sepsis

ED – Hospital for Sick Children (HSC)

Q: Who should I think about enrolling?

A: Children aged ≥ 2 mo 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 sepsis carts as well as in the trauma room. Eligibility criteria forms can be found in the labelled drawer of the Sepsis Carts located on WEST: between rooms 6 and 8, and EAST: by the RN station near the lac and burn carts, as well as on the wall of the trauma room.

Q: Where do I find randomization envelopes?

A: Randomization envelopes are located in the following 2 locations:

- 1) In the Sepsis Carts located on WEST (between Rms 6 and 8), and on EAST (near lac and burn carts).
- 2) The trauma room

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.
- 6) Ward/ICU Team Instructions Sheet – please send to ward/ICU with patient

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 = Lactated Ringer's**, **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. These additives can be mixed directly into Lactated Ringer's bags just as you would Normal Saline. To create a

customized LR fluid order in EPIC, type custom IV fluid into EPIC orders, choose Lactated Ringers, and follow steps to add additional electrolytes if needed. Bags <1000ml can be tubed via the tube system.

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 with Lactated Ringer's?

A: Lactated Ringer's (LR) cannot be provided through the same IV line at the same time as ceftriaxone or blood products. Options include a second IV line, or a very careful IV flush prior to- and after- the use of these medications. Please review and follow all SickKids 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 stop the study fluids?

A: There are several clinical situations in which you should stop study fluids. 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: Place the completed Eligibility Form in the lockboxes (one found on each sepsis cart and in the trauma room)

Q: HELP!!! I have questions about the patient in front of me...what do I do?

A: Refer to:

- 1) ED Study Information Sheet
- 2) PRoMPT BOLUS website (see QR code for link)
- 3) Contact a study team member
 - **Dr. Adrienne Davis** at (647)-712-4648
adrienne.davis@sickkids.ca
 - Bethany Lerman
bethany.lerman@sickkids.ca / (647) 461-5159
 - Ask the SEARCH team (available 7 days per week, 10am-10pm, in the east alcove)

