PRoMPT BOLUS

PRagMatic Pediatric Trial of Balanced vs nOrmaL Saline FlUid in Sepsis

A research study information for the ACH ED MDs

Protocol: PRoMPT BOLUS-01

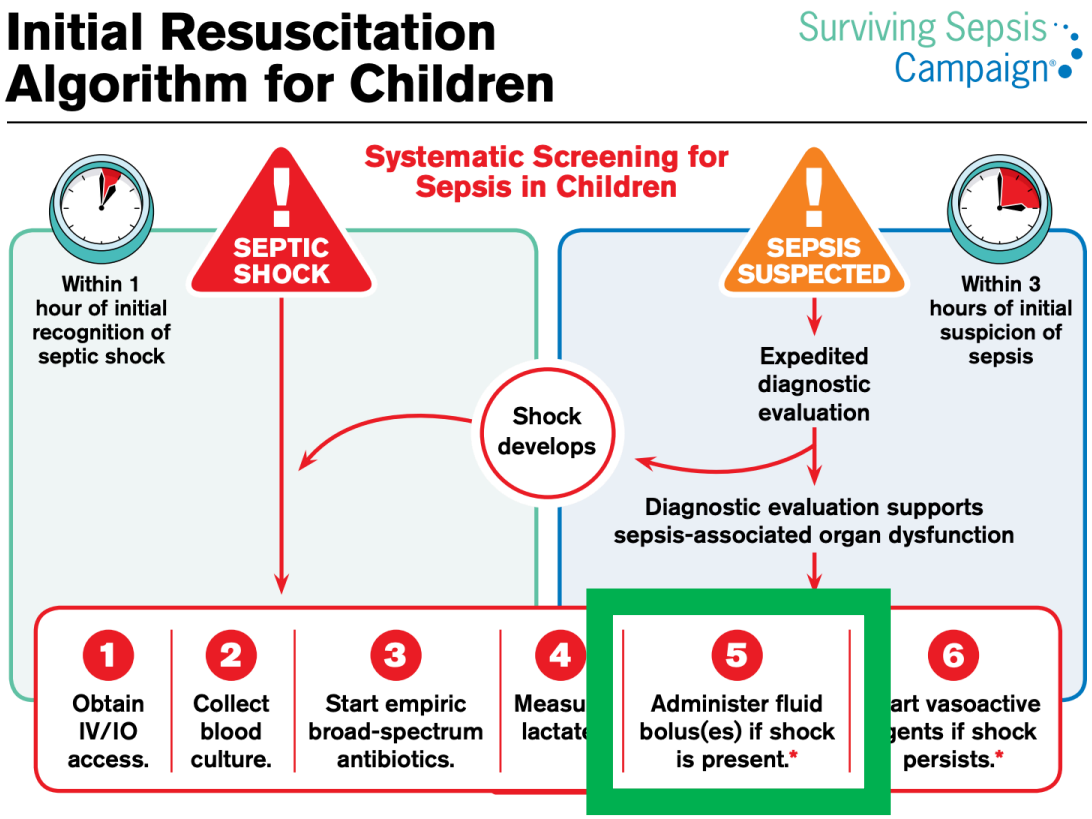
Protocol Version: 4.0, 17-May-2023

Objectives

- Provide an overview of fluid management in children with sepsis
- Introduce the PRoMPT BOLUS study
- Provide details about ED team responsibilities

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

Fluid boluses are a cornerstone of resuscitation in children presenting with suspected sepsis.



PCCM 2020 21(2):e52

Traditionally we use Normal Saline.

But really… which crystalloid is the best option?

0.9% NaCl PlasmaLyte Lactated Ringers

Balanced Fluids

Crystalloid Fluid Composition

	Blood	Normal Saline	Lactated Ringers	Plasma-Lyte
Na (mEq/L)	140	154	130	140
Cl (mEq/L)	100	154	109	98
K (mEq/L)	4	0	4	5
Ca (mEq/L)	5	0	2-3	0
Buffer	multiple	None	Lactate	Acet/Gluc
pH	7.4	5	6.5	7.4
SID	24	0	28	49
Osmolality	290	308	273	295

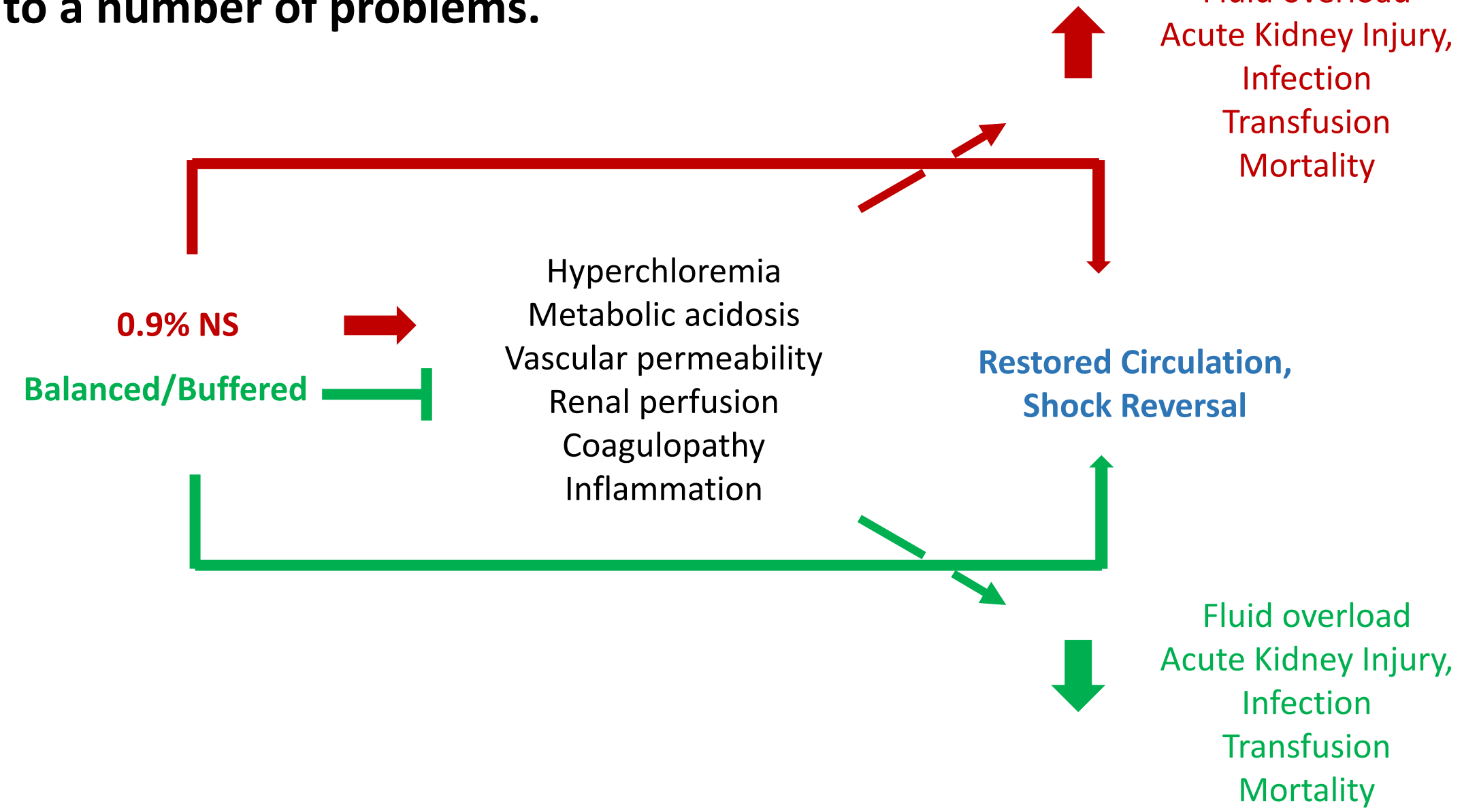
SID = Strong Ion Difference

If we compare Crystalloid Fluids to Blood we see some significant differences.

Particularly in the amount of Chloride, the pH and the Strong Ion Difference

Crit Care 2013; *JAMA* 2012

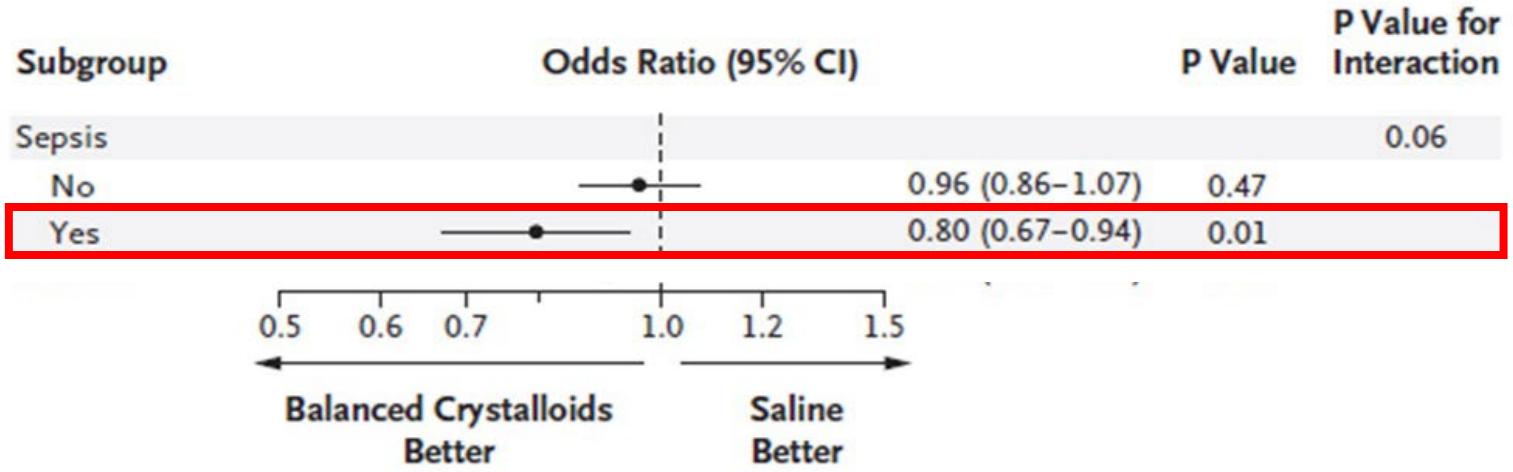
Excessive use of NaCl has the potential to lead to a number of problems.



ORIGINAL ARTICLE

Balanced Crystalloids versus Saline in Critically Ill Adults

Some studies in Adults have shown lower mortality rates in those treated with Balanced Fluids



NEJM 2018

Hyperchloremia is associated with acute kidney injury in pediatric patients with septic shock

Erin K. Stenson[1*], Natalie Z. Cvijanovich[2], Geoffrey L. Allen[3], Neal J. Thomas[4], Michael T. Bigham[5], Scott L. Weiss[6], Julie C. Fitzgerald[6], Parag N. Jain[7], Keith Meyer[8], Michael Quasney[9], Mark Hall[10], Rainer Gedeit[11], Robert J. Freishtat[12], Jeffrey Nowak[13], Riad Lutfi[14], Shira Gertz[15], Jocelyn R. Grunwell[16], Hector R. Wong[17] and Nick Anas[18]

Exposure	Outcome	aOR (95% CI)
Minimum Chloride **≥ 110 mmol/L**	Stage 2/3 AKI	2.4 (1.2-4.9)
Minimum Chloride **≥ 110 mmol/L**	Mortality	4.1 (2.1-8.1)

aOR – adjusted Odds Ratio

Septic children with higher chloride levels were more likely to have acute kidney injury (AKI) and more likely to die.

Ped Crit Care Med 2018

Crystalloid Fluid Choice and Clinical Outcomes in Pediatric Sepsis: A Matched Retrospective Cohort Study

Scott L. Weiss, MD, MSCE[1], Luke Keele, PhD[2], Fran Balamuth, MD, PhD, MSCE[3,4], Neika Vendetti, MPH[3], Rachael Ross, MPH[3], Julie C. Fitzgerald, MD, PhD[1], and Jeffrey S. Gerber, MD, PhD[3,5]

Resuscitation With Balanced Fluids Is Associated With Improved Survival in Pediatric Severe Sepsis*

Elizabeth T. Emrath, MD[1]; James D. Fortenberry, MD, MCCM[1,2]; Curtis Travers, MPH[3]; Courtney E. McCracken, PhD[3]; Kiran B. Hebbar, MD, FCCM[1,2]

BUT.....

2 large health record studies comparing children with sepsis who received
Normal Saline vs Balanced Fluids had conflicting results.

J Peds 2017

Crit Care Med 2017

Surviving Sepsis Campaign International Guidelines for the Management of Septic Shock and Sepsis-Associated Organ Dysfunction in Children

Current Surviving Sepsis Campaign Guidelines State:

"We suggest balanced crystalloids, rather than 0.9% saline, for resuscitation of children with septic shock"

(weak recommendation, very low quality of evidence)

Balanced crystalloid vs 0.9% saline is a

knowledge gap and research opportunity

PCCM 2020

ICM 2020

PRoMPT BOLUS

PRagMatic Pediatric Trial of Balanced vs nOrmaL Saline FlUid in Sepsis

Our Research Question

In children aged 2 months to < 18 years

presenting to the Emergency Department in septic shock,

does resuscitation with Balanced Fluids

improve clinical outcomes

compared to resuscitation with Normal Saline?

PRoMPT BOLUS

PRagMatic Pediatric Trial of Balanced vs nOrmaL Saline FlUid in Sepsis

Study Summary

- **Design:** International pragmatic open-label RCT
- **Population:** Suspected septic shock, 2 mo to <18 yr
- **Setting:** Emergency Department (extension to wards, PICU)
- **Intervention:** Balanced Fluids (LR or PlasmaLyte) vs Normal Saline
- **1° outcome:** Major adverse kidney events (MAKE30)
- **Duration:** 4.5 years enrolment

PRoMPT BOLUS

PRagMatic Pediatric Trial of Balanced vs nOrmaL Saline FlUid in Sepsis

perc
Pediatric Emergency Research Canada

PECARN

PREDICT
Paediatric Research in Emergency Departments International Collaborative

3 PEM Networks

4 Countries

8800 Participants

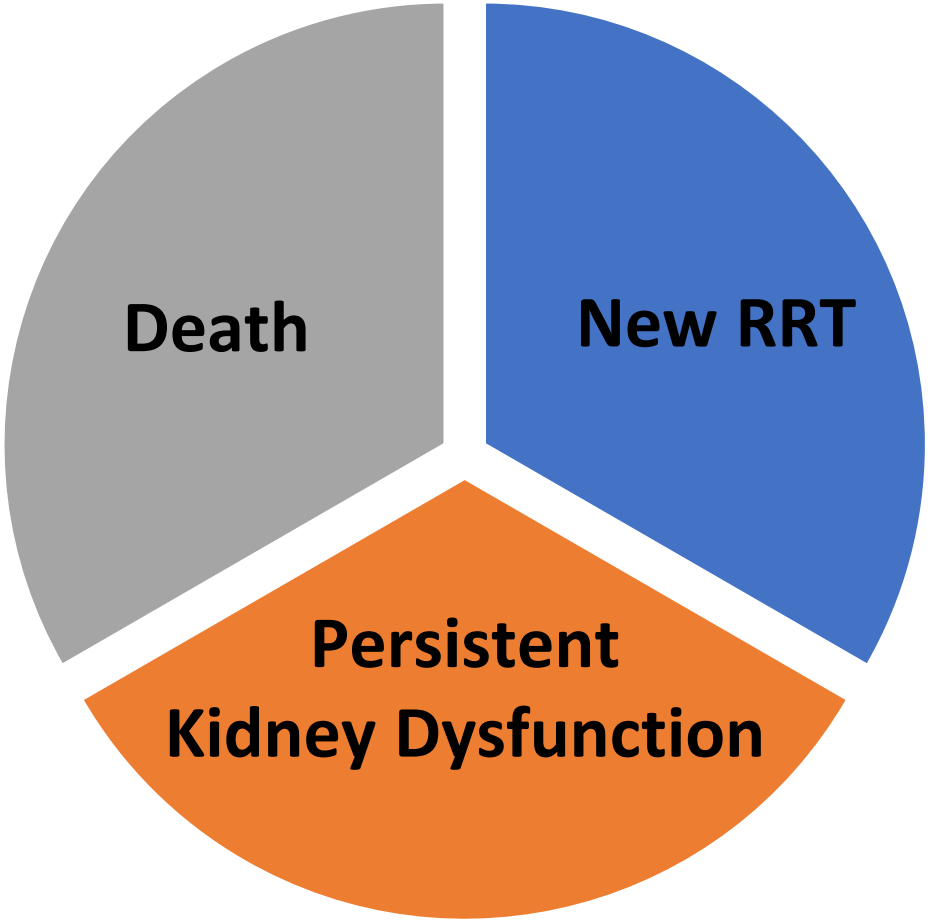
perc

Pediatric Emergency Research Canada

n= 2718

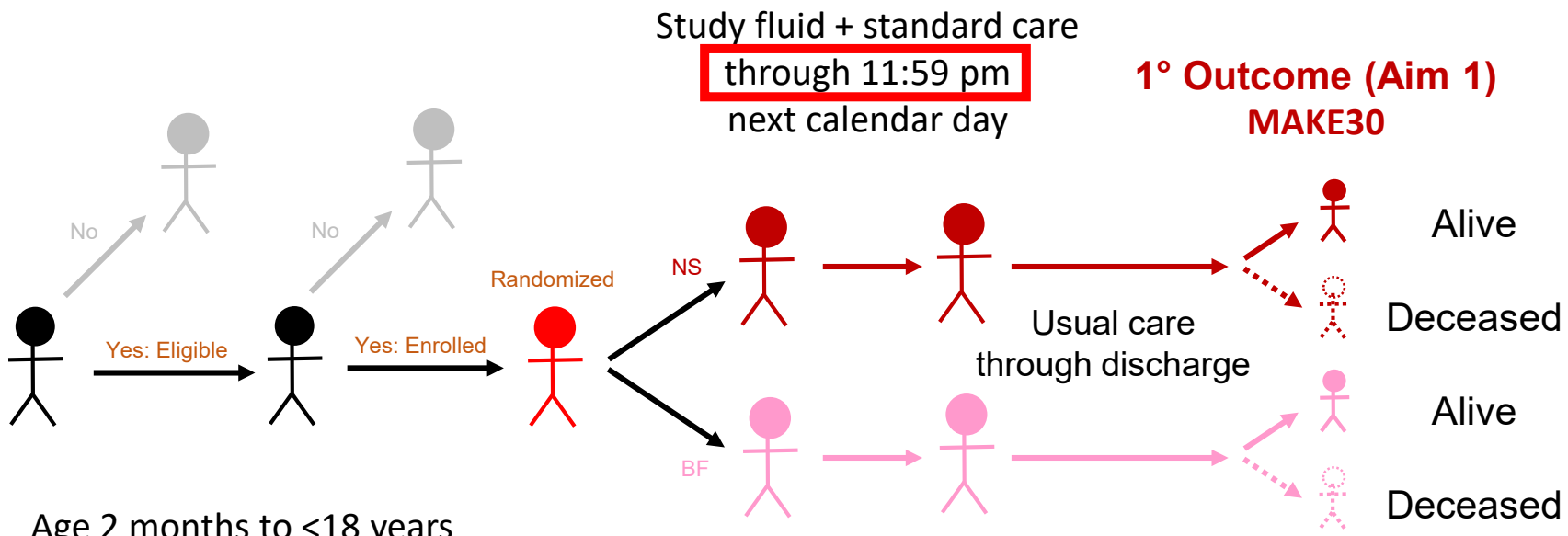
Primary Endpoint

Major Adverse Kidney Events within 30 days (MAKE30)



MAKE30 has been recommended by NIH as a patient-centred outcome for phase 3 clinical trials.

Study Design Overview



- Age 2 months to <18 years
- Suspected septic shock
  - Parenteral antibiotics
  - Blood culture
  - 20 mL/kg for abnormal perfusion or hypotension

  OR
  - Initiate sepsis pathway
  - Expect >1 fluid bolus

Observe for safety and efficacy outcomes (Aim 2)

Ongoing Care

The timing and amount of fluids, use of antibiotics, vasoactive meds and all other care is at the discretion of the managing clinical team

Tri-Council Policy Statement

Ethical Conduct for Research Involving Humans

TCPS2 2018

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council

Article 3.8 Consent for Research in Individual Medical Emergencies

(Deferred Consent)

Deferred Consent

- Participant requires immediate intervention;
- No standard efficacious care exists OR research offers a realistic possibility of direct benefit
- Risk is not greater than standard efficacious care OR is clearly justified by the prospect for direct benefits
- Participant is unconscious or lacks capacity
- Third party authorization cannot be secured in sufficient time
- No relevant prior directive by the participant is known to exist.

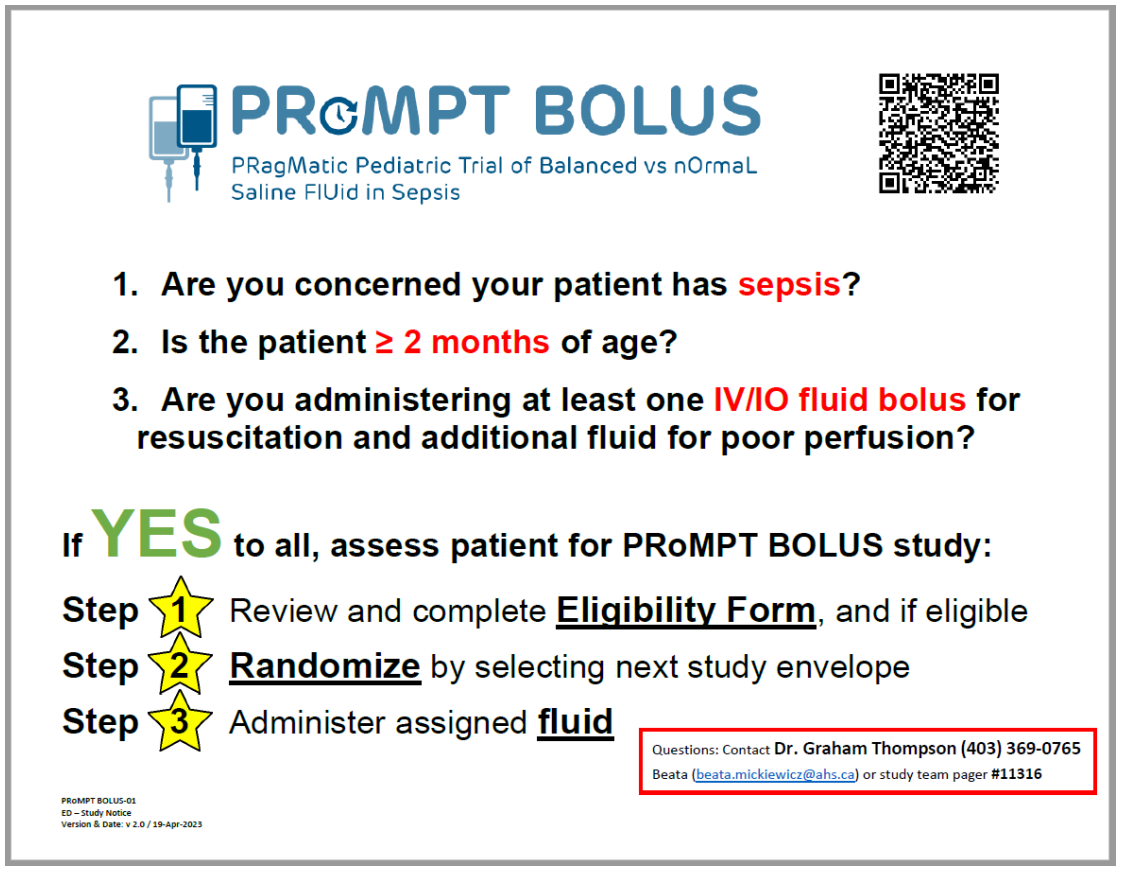
PRoMPT BOLUS has been approved by our local Research Ethics Board to operate using Deferred Consent.

So what does all this mean for me?
(i.e. ED Responsibilities)

1. Recognize potential participants
2. Check for eligibility (MDs)
3. Randomize (MDs)
4. Stickers and Tags and Stuff
5. Communicate / Handover

And of course manage your patient!!!

Step 1: Recognize a potential participant



Screen your patients
to see if they might be eligible…
If YES, notify MD

We really, really need your help with this!!!!

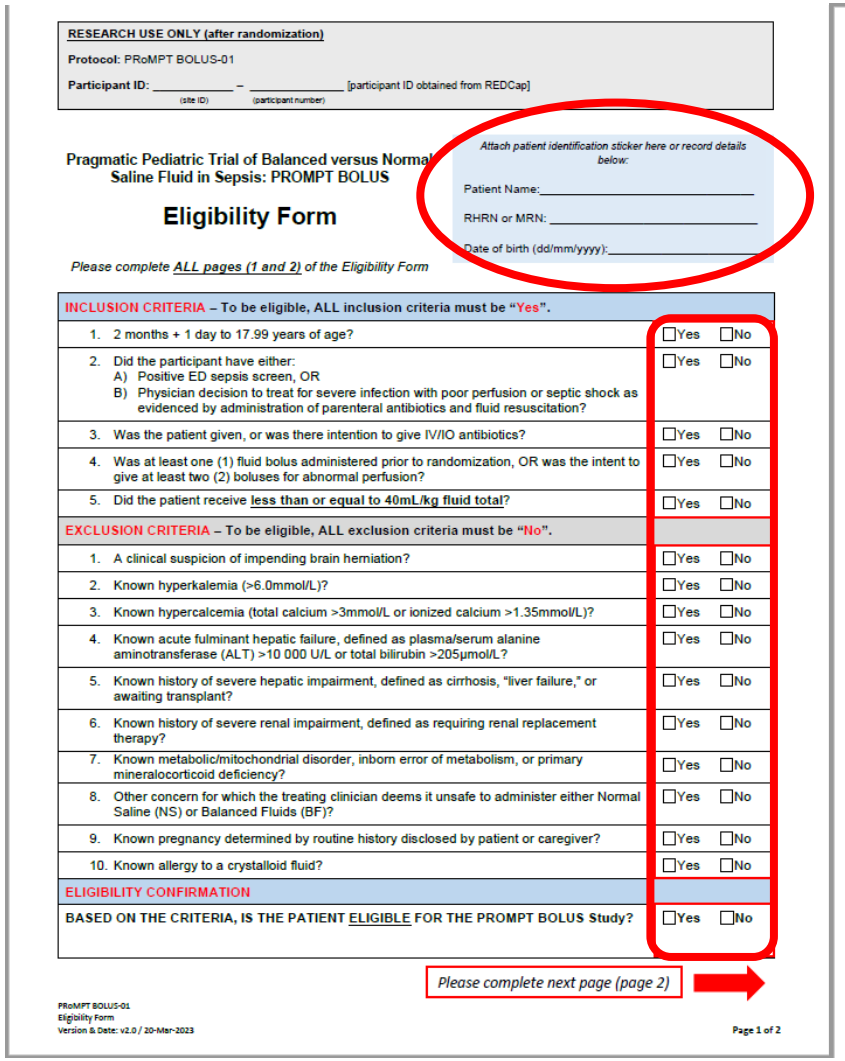
Screening Posters are located

- on the wall in both Resuscitation Rooms
  - in each pod
- on the Sepsis Cart

Step 2: Check for Eligibility

- **Eligibility Forms** located on side wall of each Resusc Bay & in Sepsis Cart
- Attach **patient sticker**
- Complete **Eligibility Criteria**
  - If not Eligible, Sign/Date
  - If Eligible, Sign/Date/Time and take a Randomization Envelope

Get MD to complete Eligibility Record
(It's really quick!!)



RESEARCH USE ONLY (after randomization)

Protocol: PRoMPT BOLUS-01

Participant ID: _____ (site ID) – _____ (participant number) [participant ID obtained from REDCap]

Pragmatic Pediatric Trial of Balanced versus Normal Saline Fluid in Sepsis: PROMPT BOLUS

Eligibility Form

Attach patient identification sticker here or record details below:

Patient Name: _____

RHRN or MRN: _____

Date of birth (dd/mm/yyyy): _____

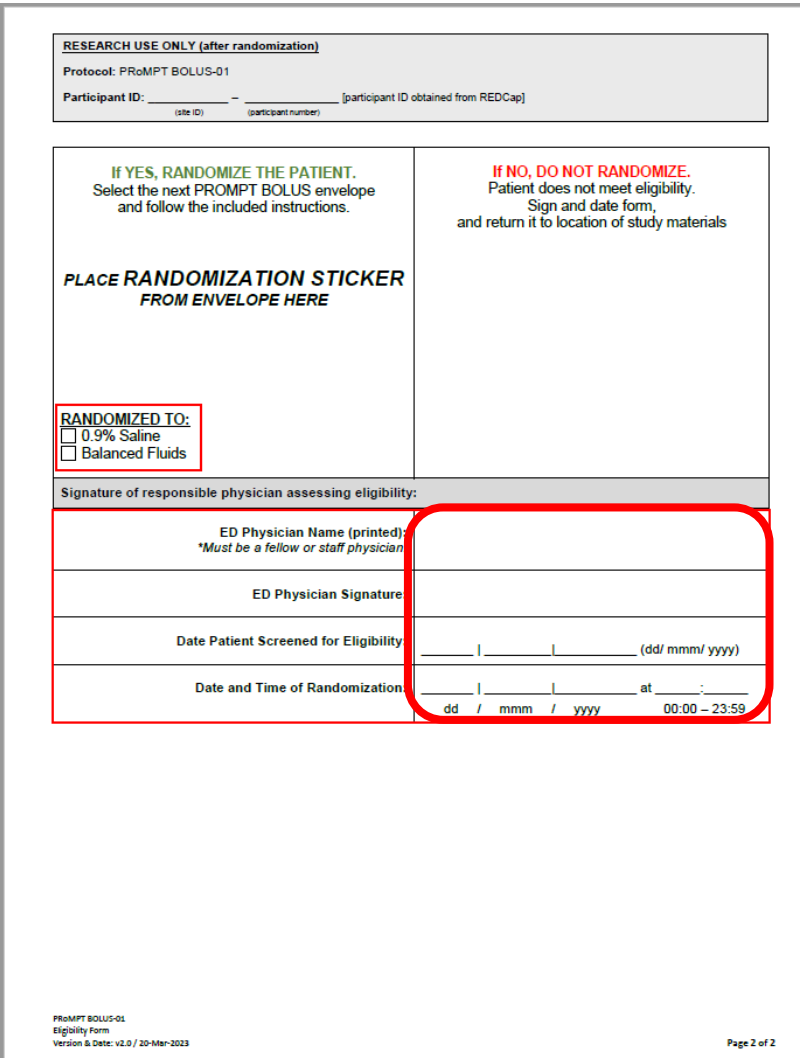
Please complete ALL pages (1 and 2) of the Eligibility Form

INCLUSION CRITERIA – To be eligible, ALL inclusion criteria must be "Yes".	
1. 2 months + 1 day to 17.99 years of age?	☐Yes ☐No
2. Did the participant have either: A) Positive ED sepsis screen, OR B) Physician decision to treat for severe infection with poor perfusion or septic shock as evidenced by administration of parenteral antibiotics and fluid resuscitation?	☐Yes ☐No
3. Was the patient given, or was there intention to give IV/IO antibiotics?	☐Yes ☐No
4. Was at least one (1) fluid bolus administered prior to randomization, OR was the intent to give at least two (2) boluses for abnormal perfusion?	☐Yes ☐No
5. Did the patient receive less than or equal to 40mL/kg fluid total?	☐Yes ☐No
EXCLUSION CRITERIA – To be eligible, ALL exclusion criteria must be "No".	
1. A clinical suspicion of impending brain herniation?	☐Yes ☐No
2. Known hyperkalemia (>6.0mmol/L)?	☐Yes ☐No
3. Known hypercalcemia (total calcium >3mmol/L or ionized calcium >1.35mmol/L)?	☐Yes ☐No
4. Known acute fulminant hepatic failure, defined as plasma/serum alanine aminotransferase (ALT) >10 000 U/L or total bilirubin >205µmol/L?	☐Yes ☐No
5. Known history of severe hepatic impairment, defined as cirrhosis, "liver failure," or awaiting transplant?	☐Yes ☐No
6. Known history of severe renal impairment, defined as requiring renal replacement therapy?	☐Yes ☐No
7. Known metabolic/mitochondrial disorder, inborn error of metabolism, or primary mineralocorticoid deficiency?	☐Yes ☐No
8. Other concern for which the treating clinician deems it unsafe to administer either Normal Saline (NS) or Balanced Fluids (BF)?	☐Yes ☐No
9. Known pregnancy determined by routine history disclosed by patient or caregiver?	☐Yes ☐No
10. Known allergy to a crystalloid fluid?	☐Yes ☐No
ELIGIBILITY CONFIRMATION	
BASED ON THE CRITERIA, IS THE PATIENT ELIGIBLE FOR THE PROMPT BOLUS Study?	**☐Yes ☐No**

Please complete next page (page 2)

PRoMPT BOLUS-01
Eligibility Form
Version & Date: v2.0 / 20-Mar-2023

Page 1 of 2



RESEARCH USE ONLY (after randomization)

Protocol: PRoMPT BOLUS-01

Participant ID: _____ (site ID) – _____ (participant number) [participant ID obtained from REDCap]

If YES, RANDOMIZE THE PATIENT. Select the next PROMPT BOLUS envelope and follow the included instructions.	If NO, DO NOT RANDOMIZE. Patient does not meet eligibility. Sign and date form, and return it to location of study materials
PLACE RANDOMIZATION STICKER FROM ENVELOPE HERE	
RANDOMIZED TO: ☐ 0.9% Saline ☐ Balanced Fluids	
Signature of responsible physician assessing eligibility:	
ED Physician Name (printed): **Must be a fellow or staff physician*	
ED Physician Signature	
Date Patient Screened for Eligibility	_____ / _____ / _____ (dd/ mmm/ yyyy)
Date and Time of Randomization	_____ / _____ / _____ at _____:_____ dd / mmm / yyyy 00:00 – 23:59

PRoMPT BOLUS-01
Eligibility Form
Version & Date: v2.0 / 20-Mar-2023

Page 2 of 2

Step 3: Randomize Participant

- **Randomization Envelopes**: box under hanging cupboard in Trauma D or Sepsis Cart outside the A pod
- Fluid allocation is **colour coded**
- Place one **randomization sticker** on the **Eligibility Form**
- **Sign** and indicate **date and time of randomization** on the **Eligibility Form**

PRoMPT BOLUS Study
This patient has been randomized to:

0.9 % Normal Saline

for bolus and maintenance fluids

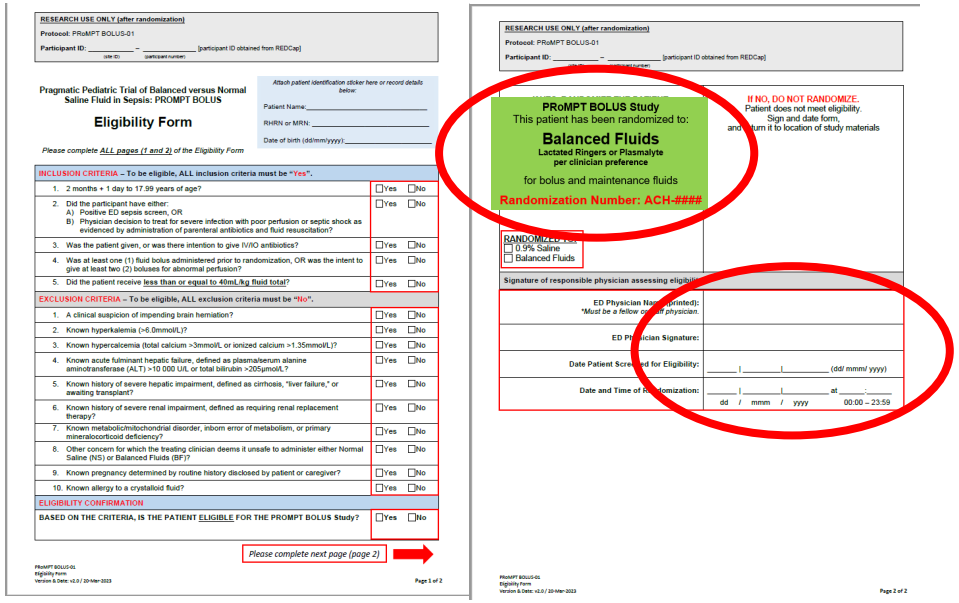
Randomization Number: ACH-####

PRoMPT BOLUS Study
This patient has been randomized to:

Balanced Fluids
Lactated Ringers or Plasmalyte per clinician preference

for bolus and maintenance fluids

Randomization Number: ACH-####



RESEARCH USE ONLY (after randomization)
Protocol: PRoMPT BOLUS-01
Participant ID: _____ – _____ [participant ID obtained from REDCap]

Pragmatic Pediatric Trial of Balanced versus Normal Saline Fluid in Sepsis: PROMPT BOLUS

Eligibility Form

Please complete ALL pages (1 and 2) of the Eligibility Form

Attach patient identification sticker here or record details below:
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RHRN or MRN:
Date of birth (dd/mm/yyyy):

INCLUSION CRITERIA – To be eligible, ALL inclusion criteria must be "Yes".		
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2. Did the participant have either: A) Positive ED sepsis screen, OR B) Physician decision to treat for severe infection with poor perfusion or septic shock as evidenced by administration of parenteral antibiotics and fluid resuscitation?	☐Yes	☐No
3. Was the patient given, or was there intention to give IV/IO antibiotics?	☐Yes	☐No
4. Was at least one (1) fluid bolus administered prior to randomization, OR was the intent to give at least two (2) boluses for abnormal perfusion?	☐Yes	☐No
5. Did the patient receive less than or equal to 40mL/kg fluid total?	☐Yes	☐No
EXCLUSION CRITERIA – To be eligible, ALL exclusion criteria must be "No".		
1. A clinical suspicion of impending brain herniation?	☐Yes	☐No
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3. Known hypercalcemia (total calcium >3mmol/L or ionized calcium >1.35mmol/L)?	☐Yes	☐No
4. Known acute fulminant hepatic failure, defined as plasma/serum alanine aminotransferase (ALT) >10 000 U/L or total bilirubin >205µmol/L?	☐Yes	☐No
5. Known history of severe hepatic impairment, defined as cirrhosis, "liver failure," or awaiting transplant?	☐Yes	☐No
6. Known history of severe renal impairment, defined as requiring renal replacement therapy?	☐Yes	☐No
7. Known metabolic/mitochondrial disorder, inborn error of metabolism, or primary mineralocorticoid deficiency?	☐Yes	☐No
8. Other concern for which the treating clinician deems it unsafe to administer either Normal Saline (NS) or Balanced Fluids (BF)?	☐Yes	☐No
9. Known pregnancy determined by routine history disclosed by patient or caregiver?	☐Yes	☐No
10. Known allergy to a crystalloid fluid?	☐Yes	☐No
ELIGIBILITY CONFIRMATION		
BASED ON THE CRITERIA, IS THE PATIENT ELIGIBLE FOR THE PROMPT BOLUS Study?	☐Yes	☐No

Please complete next page (page 2)

PRoMPT BOLUS-01
Eligibility Form
Version & Date: v2.0 / 10-Mar-2023
Page 1 of 2

RESEARCH USE ONLY (after randomization)
Protocol: PRoMPT BOLUS-01
Participant ID: _____ – _____ [participant ID obtained from REDCap]

PRoMPT BOLUS Study
This patient has been randomized to:
Balanced Fluids
Lactated Ringers or Plasmalyte per clinician preference
for bolus and maintenance fluids
Randomization Number: ACH-####

RANDOMIZED TO:
☐ 0.9% Saline
☐ Balanced Fluids

IF NO, DO NOT RANDOMIZE.
Patient does not meet eligibility.
Sign and date form, and return it to location of study materials

Signature of responsible physician assessing eligibility

ED Physician Name (printed): *Must be a fellow or staff physician.	
ED Physician Signature:	
Date Patient Screened for Eligibility:	_____ / _____ / _____ (dd/ mmm/ yyyy)
Date and Time of Randomization:	_____ / _____ / _____ at _____ : _____ dd / mmm / yyyy 00:00 – 23:59

PRoMPT BOLUS-01
Eligibility Form
Version & Date: v2.0 / 10-Mar-2023
Page 2 of 2

Randomization

PRoMPT BOLUS Study
This patient has been randomized to:

0.9 % Normal Saline

for bolus and maintenance fluids

Randomization Number: ACH-####

PRoMPT BOLUS Study
This patient has been randomized to:

Balanced Fluids
Lactated Ringers or Plasmalyte per clinician preference

for bolus and maintenance fluids

Randomization Number: ACH-####

Randomization Labels
(to be placed on Eligibility Record)

PRoMPT BOLUS – Research
Administer 0.9% Normal Saline per order

PRoMPT BOLUS – Research
Administer Balanced Fluids per order

Participant Wrist Bands
(to be placed on Patient)

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

RESEARCH

Administer:

Normal Saline (0.9% NaCl)

for all fluid administration (bolus and maintenance) until 11:59pm the day following ED randomization

Fluid Start Date and Time:
_____ at ____:____

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

RESEARCH

Administer:

Balanced Fluids
(Lactated Ringers or PlasmaLyte)

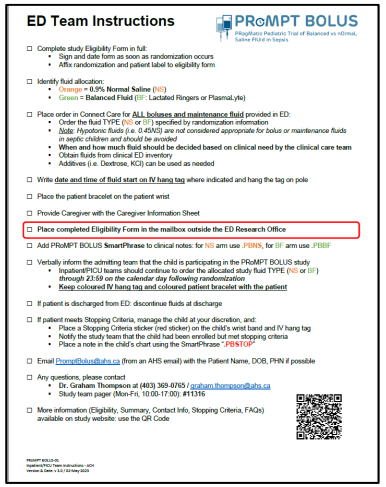
for all fluid administration (bolus and maintenance) until 11:59pm the day following ED randomization

Fluid Start Date and Time:
_____ at ____:____

IV hang tags
(to write in Time of Randomization & place on IV Pole)

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

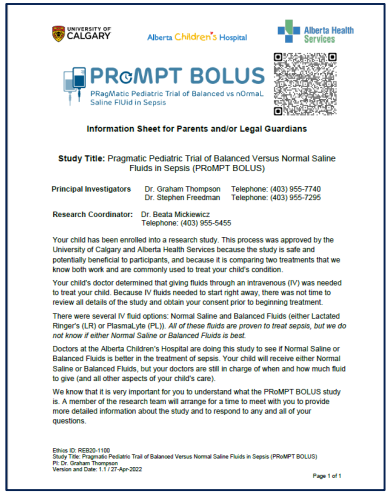
Randomization Envelope


ED Team Instructions

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

- ☐ Complete study Eligibility Form in full:
  - Sign and date form as soon as randomization occurs
  - Affix randomization and patient label to eligibility form
- ☐ Identify fluid allocation:
  - Orange = 0.9% Normal Saline (NS)
  - Green = Balanced Fluid (BF: Lactated Ringers or PlasmaLyte)
- ☐ Place order in Connect Care for ALL boluses and maintenance fluid provided in ED:
  - Order the fluid TYPE (NS or BF) specified by randomization information
  - *Note: Hypotonic fluids (i.e. 0.45NS) are not considered appropriate for bolus or maintenance fluids in septic children and should be avoided*
  - When and how much fluid should be decided based on clinical need by the clinical care team
  - Obtain fluids from clinical ED inventory
  - Additives (i.e. Dextrose, KCl) can be used as needed
- ☐ Write date and time of fluid start on IV hang tag where indicated and hang the tag on pole
- ☐ Place the patient bracelet on the patient wrist
- ☐ Provide Caregiver with the Caregiver Information Sheet
- ☐ Place completed Eligibility Form in the mailbox outside the ED Research Office
- ☐ Add PRoMPT BOLUS SmartPhrase to clinical notes: for NS arm use .PBNS, for BF arm use .PBBF
- ☐ Verbally inform the admitting team that the child is participating in the PRoMPT BOLUS study
  - Inpatient/PICU teams should continue to order the allocated study fluid TYPE (NS or BF) *through 23:59 on the calendar day following randomization*
  - Keep coloured IV hang tag and coloured patient bracelet with the patient
- ☐ If patient is discharged from ED: discontinue fluids at discharge
- ☐ If patient meets Stopping Criteria, manage the child at your discretion, and:
  - Place a Stopping Criteria sticker (red sticker) on the child's wrist band and IV hang tag
  - Notify the study team that the child had been enrolled but met stopping criteria
  - Place a note in the child's chart using the SmartPhrase ".PBSTOP"
- ☐ Email PromptBolus@ahs.ca (from an AHS email) with the Patient Name, DOB, PHN if possible
- ☐ Any questions, please contact
  - Dr. Graham Thompson at (403) 369-0765 / graham.thompson@ahs.ca
  - Study team pager (Mon-Fri, 10:00-17:00): #11316
- ☐ More information (Eligibility, Summary, Contact Info, Stopping Criteria, FAQs) available on study website: use the QR Code

ED Study Instructions


UNIVERSITY OF CALGARY · Alberta Children's Hospital · Alberta Health Services

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

Information Sheet for Parents and/or Legal Guardians

Study Title: Pragmatic Pediatric Trial of Balanced Versus Normal Saline Fluids in Sepsis (PRoMPT BOLUS)

Principal Investigators Dr. Graham Thompson Telephone: (403) 955-7740
Dr. Stephen Freedman Telephone: (403) 955-7295

Research Coordinator: Dr. Beata Mickiewicz Telephone: (403) 955-5455

Your child has been enrolled into a research study. This process was approved by the University of Calgary and Alberta Health Services because the study is safe and potentially beneficial to participants, and because it is comparing two treatments that we know both work and are commonly used to treat your child's condition.

Your child's doctor determined that giving fluids through an intravenous (IV) was needed to treat your child. Because IV fluids needed to start right away, there was not time to review all details of the study and obtain your consent prior to beginning treatment.

There were several IV fluid options: Normal Saline and Balanced Fluids (either Lactated Ringer's (LR) or PlasmaLyte (PL)). *All of these fluids are proven to treat sepsis, but we do not know if either Normal Saline or Balanced Fluids is best.*

Doctors at the Alberta Children's Hospital are doing this study to see if Normal Saline or Balanced Fluids is better in the treatment of sepsis. Your child will receive either Normal Saline or Balanced Fluids, but your doctors are still in charge of when and how much fluid to give (and all other aspects of your child's care).

We know that it is very important for you to understand what the PRoMPT BOLUS study is. A member of the research team will arrange for a time to meet with you to provide more detailed information about the study and to respond to any and all of your questions.

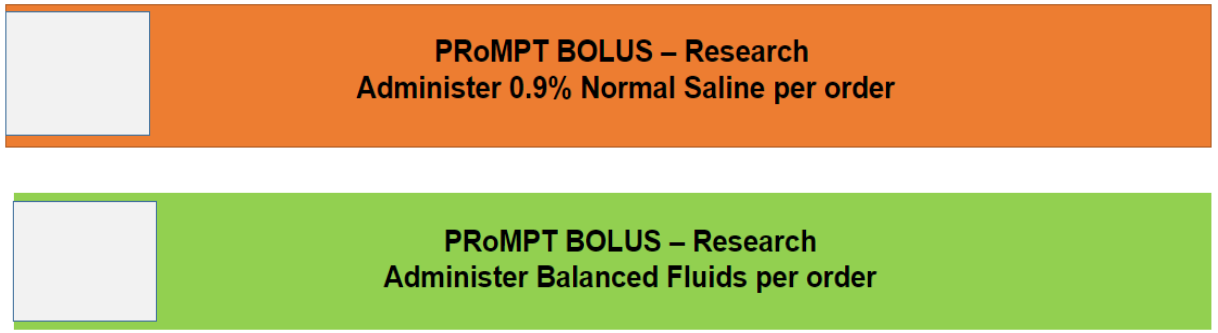
Ethics ID: REB20-1100
Study Title: Pragmatic Pediatric Trial of Balanced Versus Normal Saline Fluids in Sepsis (PRoMPT BOLUS)
PI: Dr. Graham Thompson
Version and Date: 1.1 / 27-Apr-2022

Page 1 of 1

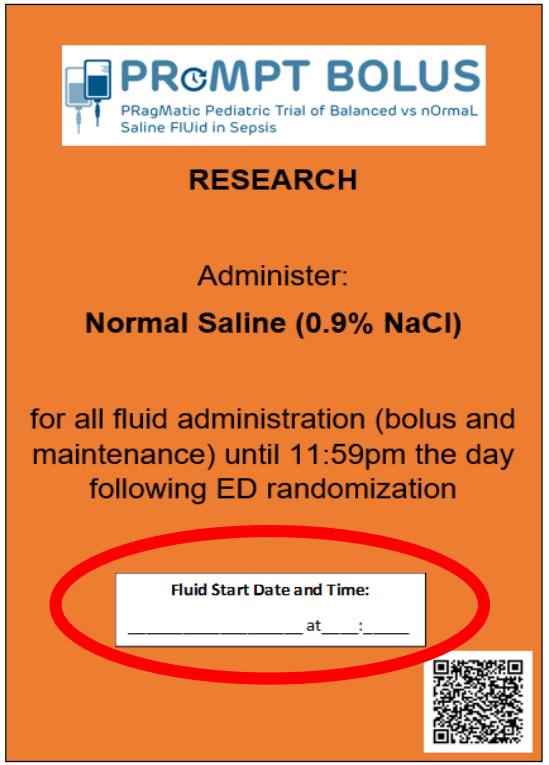
Caregiver Information
(to give to Caregiver ***before*** leaving the ED)

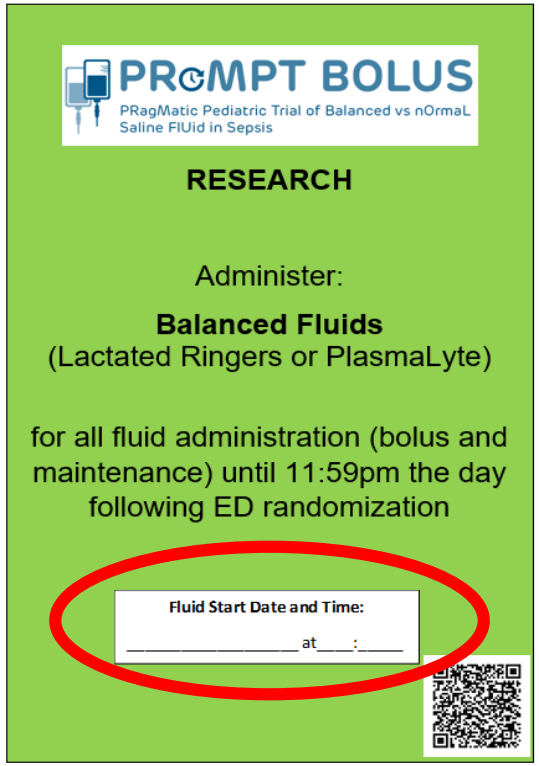
Step 4: Stickers, Tags and Stuff

- Place **wrist band** on participant
- Write **date/time** of randomization on IV hang tags
- Place **hang tag** on IV pole



Place on Patient

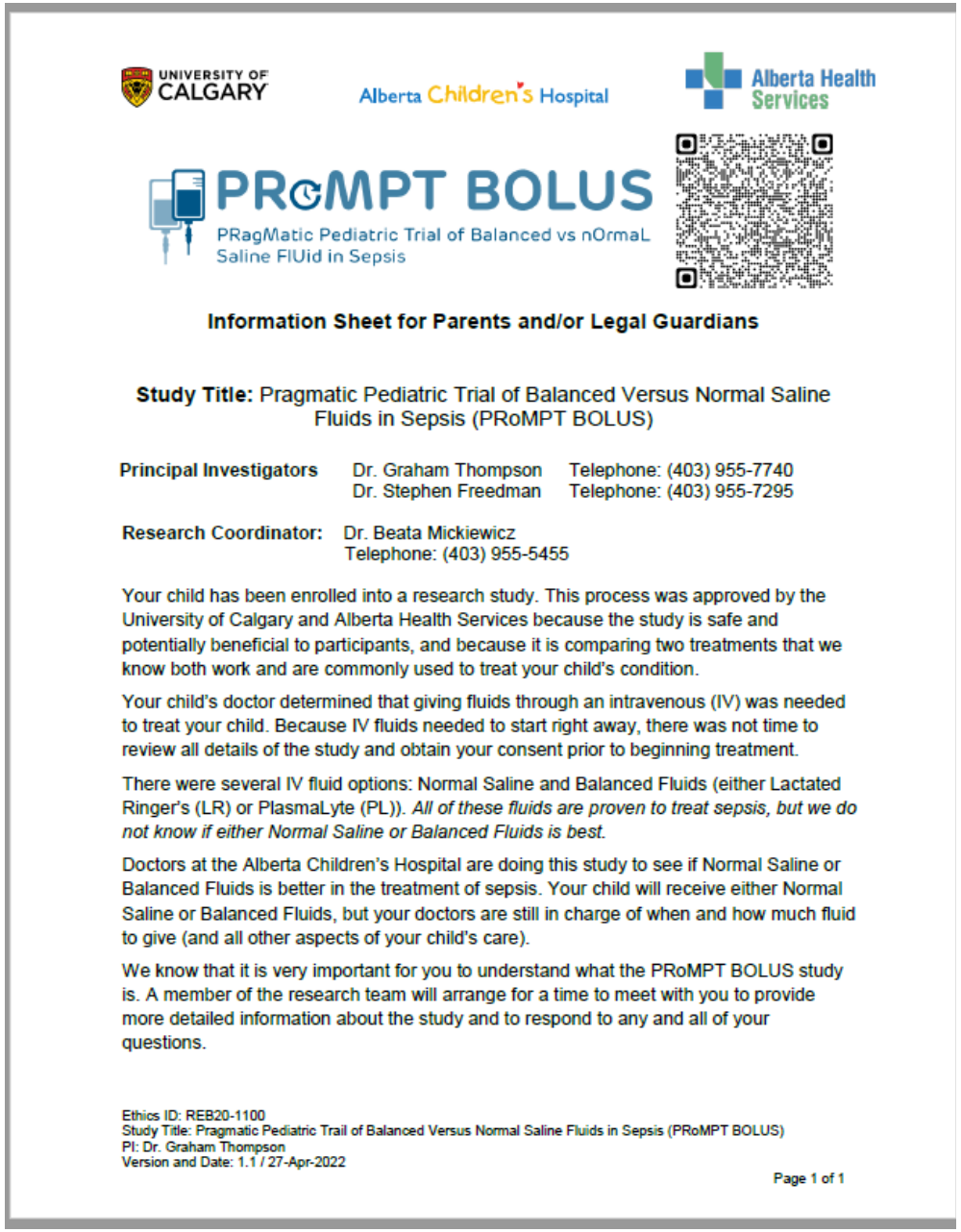




Write in Time of Randomization & Place on IV Pole

Step 5: Communicate!

- Provide **Caregiver Information Sheet** to notify family of enrolment
- Add PRoMPT BOLUS **Connect Care SmartPhrase** to clinical notes:
  - for NS arm use **.PBNS**
  - for BF arm use **.PBBF**
- Inform admitting team of enrolment!
- Inform research team of enrolment
  - email at PromptBolus@ahs.ca
- Place all completed Eligibility Form in the mailbox outside the ED Research Office



UNIVERSITY OF CALGARY · Alberta Children's Hospital · Alberta Health Services

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

Information Sheet for Parents and/or Legal Guardians

Study Title: Pragmatic Pediatric Trial of Balanced Versus Normal Saline Fluids in Sepsis (PRoMPT BOLUS)

Principal Investigators Dr. Graham Thompson Telephone: (403) 955-7740
Dr. Stephen Freedman Telephone: (403) 955-7295

Research Coordinator: Dr. Beata Mickiewicz
Telephone: (403) 955-5455

Your child has been enrolled into a research study. This process was approved by the University of Calgary and Alberta Health Services because the study is safe and potentially beneficial to participants, and because it is comparing two treatments that we know both work and are commonly used to treat your child's condition.

Your child's doctor determined that giving fluids through an intravenous (IV) was needed to treat your child. Because IV fluids needed to start right away, there was not time to review all details of the study and obtain your consent prior to beginning treatment.

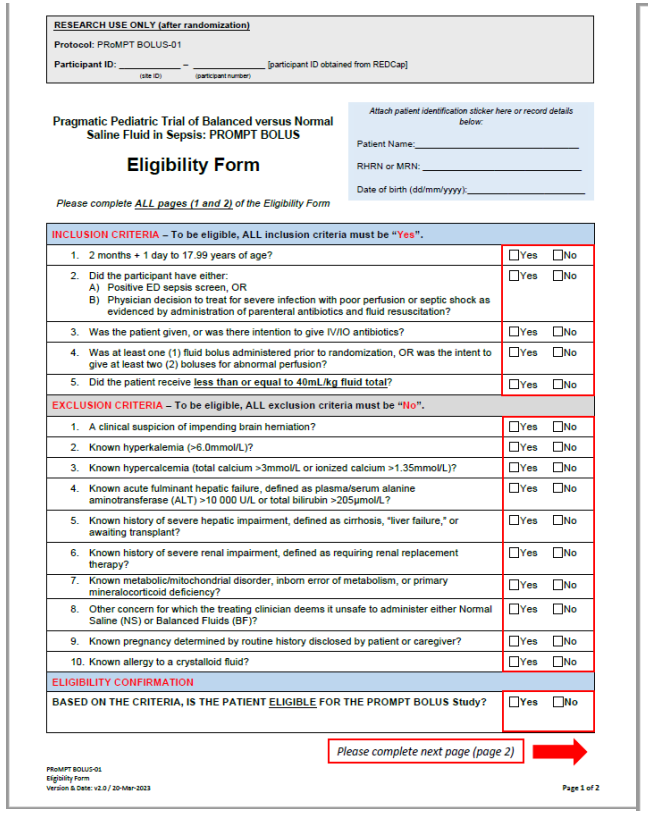
There were several IV fluid options: Normal Saline and Balanced Fluids (either Lactated Ringer's (LR) or PlasmaLyte (PL)). *All of these fluids are proven to treat sepsis, but we do not know if either Normal Saline or Balanced Fluids is best.*

Doctors at the Alberta Children's Hospital are doing this study to see if Normal Saline or Balanced Fluids is better in the treatment of sepsis. Your child will receive either Normal Saline or Balanced Fluids, but your doctors are still in charge of when and how much fluid to give (and all other aspects of your child's care).

We know that it is very important for you to understand what the PRoMPT BOLUS study is. A member of the research team will arrange for a time to meet with you to provide more detailed information about the study and to respond to any and all of your questions.

Communication is Key!!

- Place completed Eligibility Form in mailbox outside ED research office
- Inform Admitting Team of study participation.
- Write a communication note in Connect Care!!



RESEARCH USE ONLY (after randomization)

Protocol: PRoMPT BOLUS-01

Participant ID: _____ – _____ [participant ID obtained from REDCap]
(site ID) (participant number)

Pragmatic Pediatric Trial of Balanced versus Normal Saline Fluid in Sepsis: PROMPT BOLUS

Eligibility Form

Please complete ALL pages (1 and 2) of the Eligibility Form

Attach patient identification sticker here or record details below:

Patient Name:_____

RHRN or MRN: _____

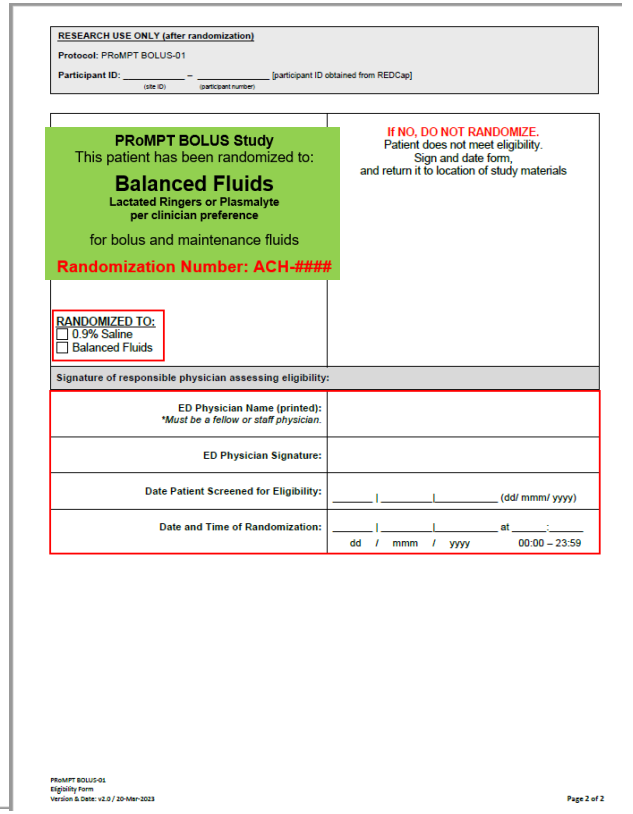
Date of birth (dd/mm/yyyy):_____

INCLUSION CRITERIA – To be eligible, ALL inclusion criteria must be "Yes".	
1. 2 months + 1 day to 17.99 years of age?	☐Yes ☐No
2. Did the participant have either: A) Positive ED sepsis screen, OR B) Physician decision to treat for severe infection with poor perfusion or septic shock as evidenced by administration of parenteral antibiotics and fluid resuscitation?	☐Yes ☐No
3. Was the patient given, or was there intention to give IV/IO antibiotics?	☐Yes ☐No
4. Was at least one (1) fluid bolus administered prior to randomization, OR was the intent to give at least two (2) boluses for abnormal perfusion?	☐Yes ☐No
5. Did the patient receive less than or equal to 40mL/kg fluid total?	☐Yes ☐No
EXCLUSION CRITERIA – To be eligible, ALL exclusion criteria must be "No".	
1. A clinical suspicion of impending brain herniation?	☐Yes ☐No
2. Known hyperkalemia (>6.0mmol/L)?	☐Yes ☐No
3. Known hypercalcemia (total calcium >3mmol/L or ionized calcium >1.35mmol/L)?	☐Yes ☐No
4. Known acute fulminant hepatic failure, defined as plasma/serum alanine aminotransferase (ALT) >10 000 U/L or total bilirubin >205µmol/L?	☐Yes ☐No
5. Known history of severe hepatic impairment, defined as cirrhosis, "liver failure," or awaiting transplant?	☐Yes ☐No
6. Known history of severe renal impairment, defined as requiring renal replacement therapy?	☐Yes ☐No
7. Known metabolic/mitochondrial disorder, inborn error of metabolism, or primary mineralocorticoid deficiency?	☐Yes ☐No
8. Other concern for which the treating clinician deems it unsafe to administer either Normal Saline (NS) or Balanced Fluids (BF)?	☐Yes ☐No
9. Known pregnancy determined by routine history disclosed by patient or caregiver?	☐Yes ☐No
10. Known allergy to a crystalloid fluid?	☐Yes ☐No
ELIGIBILITY CONFIRMATION	
BASED ON THE CRITERIA, IS THE PATIENT ELIGIBLE FOR THE PROMPT BOLUS Study?	☐Yes ☐No

Please complete next page (page 2)

PRoMPT BOLUS-01
Eligibility Form
Version & Date: v2.0 / 20-Mar-2023

Page 1 of 2



RESEARCH USE ONLY (after randomization)

Protocol: PRoMPT BOLUS-01

Participant ID: _____ – _____ [participant ID obtained from REDCap]
(site ID) (participant number)

PRoMPT BOLUS Study
This patient has been randomized to:

Balanced Fluids
Lactated Ringers or Plasmalyte per clinician preference

for bolus and maintenance fluids

Randomization Number: ACH-####

RANDOMIZED TO:
☐ 0.9% Saline
☐ Balanced Fluids

If NO, DO NOT RANDOMIZE.
Patient does not meet eligibility.
Sign and date form,
and return it to location of study materials

Signature of responsible physician assessing eligibility:

ED Physician Name (printed): **Must be a fellow or staff physician.*	
ED Physician Signature:	
Date Patient Screened for Eligibility:	_____ | _____ | _____ (dd/ mmm/ yyyy)
Date and Time of Randomization:	_____ | _____ | _____ at _____:_____ dd / mmm / yyyy 00:00 – 23:59

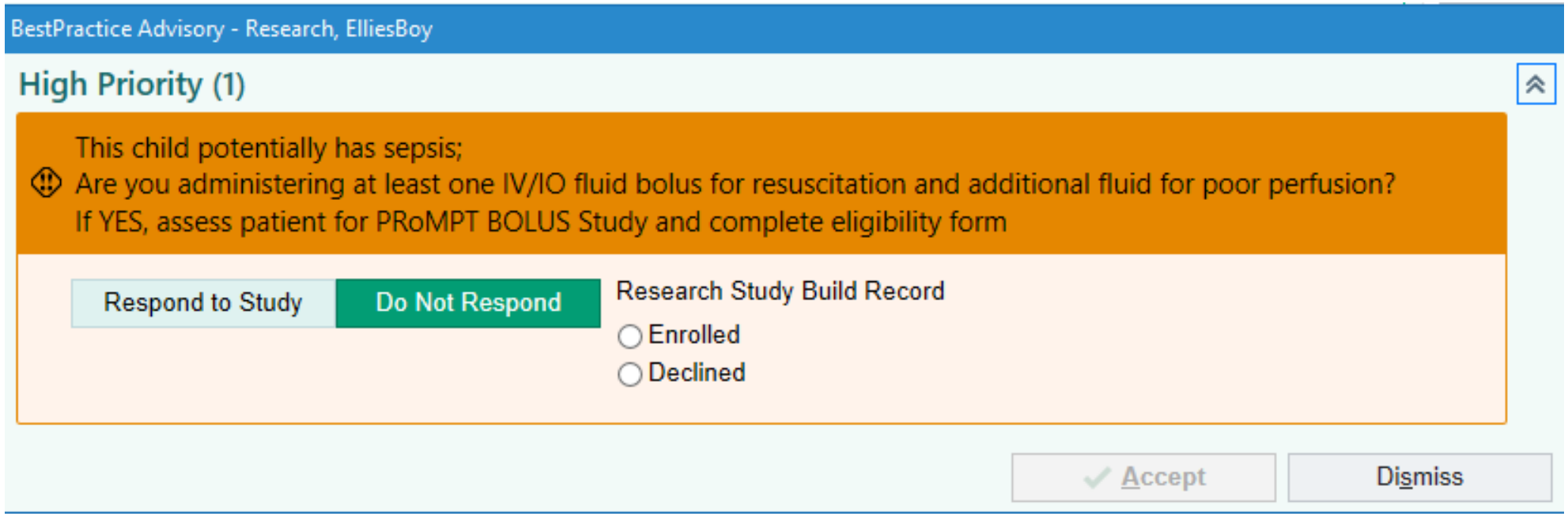
PRoMPT BOLUS-01
Eligibility Form
Version & Date: v2.0 / 20-Mar-2023

Page 2 of 2

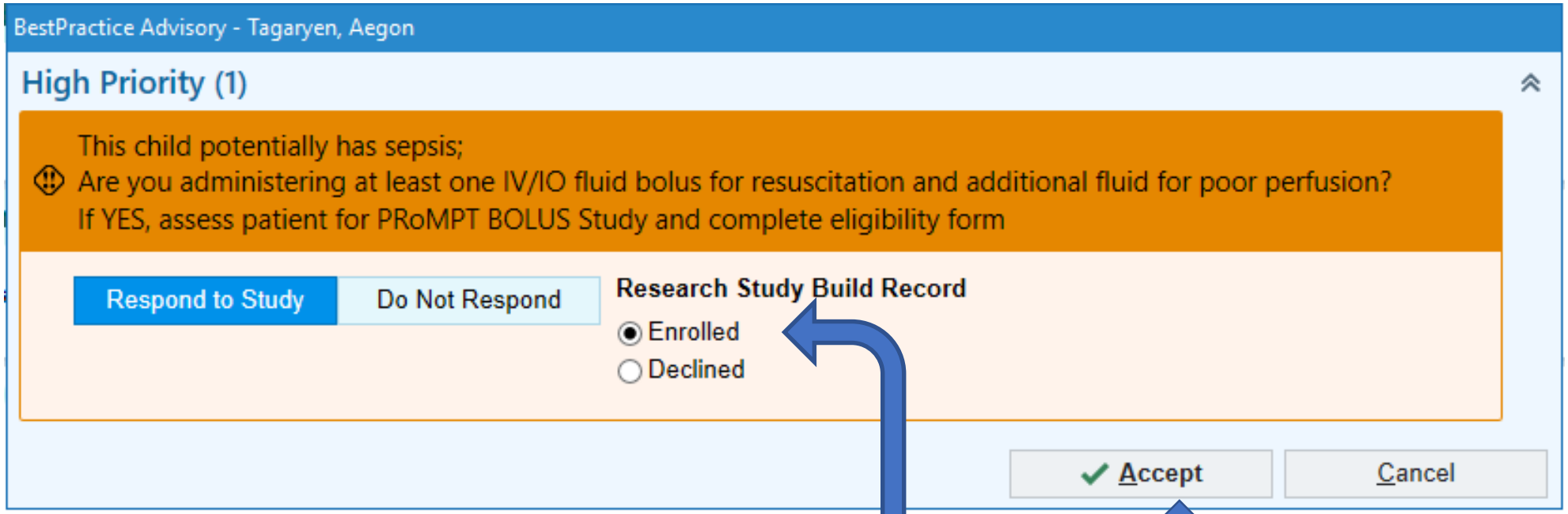
Connect Care: Study BPA

The purposes of the PRoMPT BOLUS BPA are:

- Help ED clinicians to identify potential study participants
  (it will notify ED clinician when the Orders activity is opened)
- Support communication with ED and Inpatient teams related to study participant enrolment

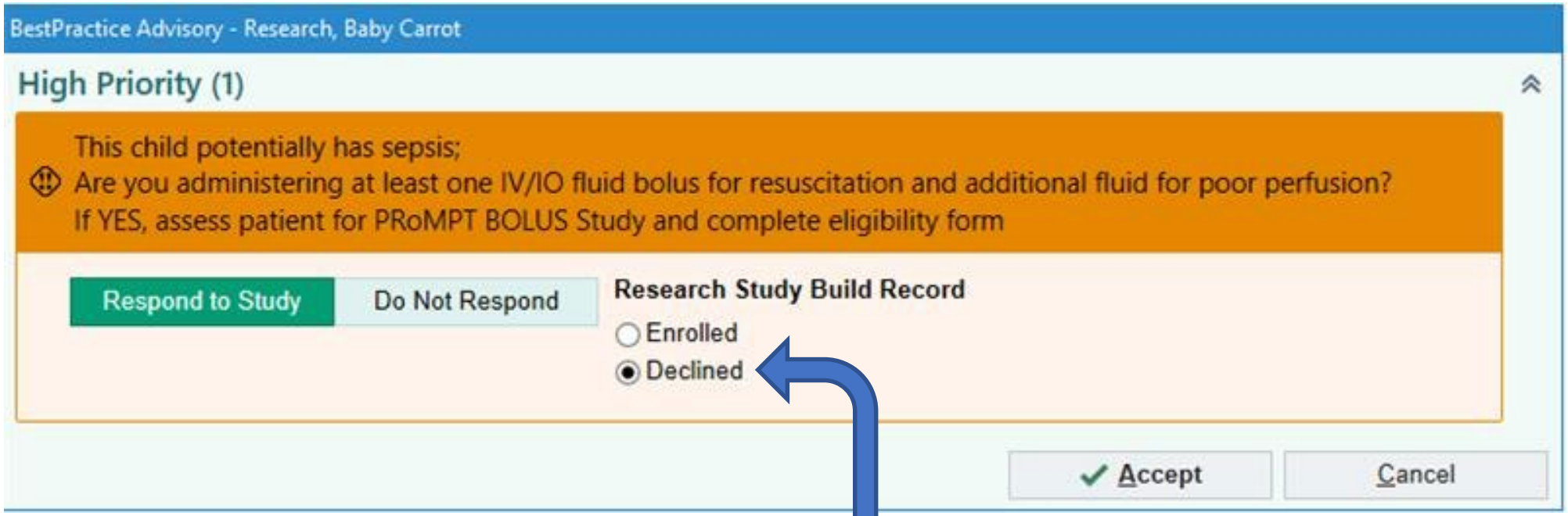


To ENROLL a patient (PRoMPT BOLUS eligibility criteria met)



To ENROLL a participant (i.e. eligibility criteria met and you are opening a randomization envelope) click on: Enrolled & Accept

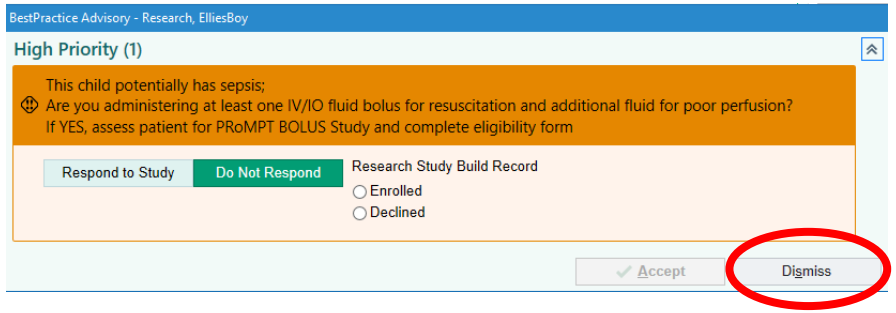
To DECLINE enrolment (PRoMPT BOLUS eligibility criteria NOT met)

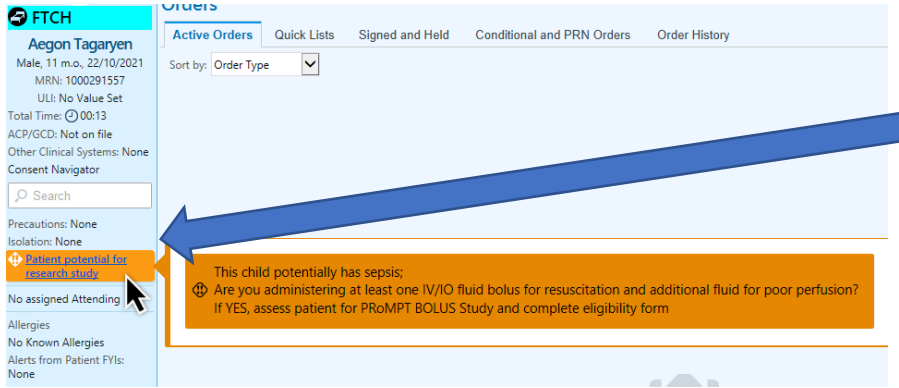


To DECLINE a participant (does NOT meet eligibility criteria), click on: Declined & Accept

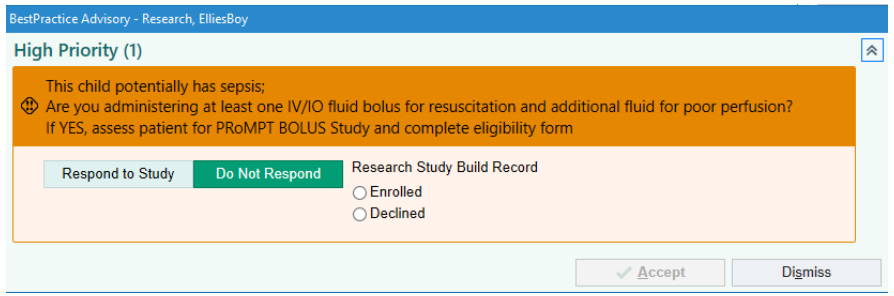
NOTE: If you decline, ALL notifications will disappear.

If unsure & need to check Eligibility Criteria





1) Click on Dismiss.
   A small orange BPA notification will appear on the Story Board (hover to discover)



2) Complete the study Eligibility Form, Sign/Date
3) Go back into CC and click on orders tab
4) BPA will appear back: choose Enrolled or Declined, then Accept

RESUS ROOM

RESEARCH USE ONLY (after randomization)

Protocol: PRoMPT BOLUS-01

Participant ID: _____ – _____ [participant ID obtained from REDCap]

(site ID) (participant number)

Pragmatic Pediatric Trial of Balanced versus Normal Saline Fluid in Sepsis: PROMPT BOLUS

Eligibility Form

Please complete ALL pages (1 and 2) of the Eligibility Form

Attach patient identification sticker here or record details below:

Patient Name:_____

RHRN or MRN: _____

Date of birth (dd/mm/yyyy): _____

INCLUSION CRITERIA – To be eligible, ALL inclusion criteria must be "Yes".		
1. 2 months + 1 day to 17.99 years of age?	☐Yes	☐No
2. Did the participant have either: A) Positive ED sepsis screen, OR B) Physician decision to treat for severe infection with poor perfusion or septic shock as evidenced by administration of parenteral antibiotics and fluid resuscitation?	☐Yes	☐No
3. Was the patient given, or was there intention to give IV/IO antibiotics?	☐Yes	☐No
4. Was at least one (1) fluid bolus administered prior to randomization, OR was the intent to give at least two (2) boluses for abnormal perfusion?	☐Yes	☐No
5. Did the patient receive less than or equal to 40mL/kg fluid total?	☐Yes	☐No
EXCLUSION CRITERIA – To be eligible, ALL exclusion criteria must be "No".		
1. A clinical suspicion of impending brain herniation?	☐Yes	☐No
2. Known hyperkalemia (>6.0mmol/L)?	☐Yes	☐No
3. Known hypercalcemia (total calcium >3mmol/L or ionized calcium >1.35mmol/L)?	☐Yes	☐No
4. Known acute fulminant hepatic failure, defined as plasma/serum alanine aminotransferase (ALT) >10 000 U/L or total bilirubin >205µmol/L?	☐Yes	☐No
5. Known history of severe hepatic impairment, defined as cirrhosis, "liver failure," or awaiting transplant?	☐Yes	☐No
6. Known history of severe renal impairment, defined as requiring renal replacement therapy?	☐Yes	☐No
7. Known metabolic/mitochondrial disorder, inborn error of metabolism, or primary mineralocorticoid deficiency?	☐Yes	☐No
8. Other concern for which the treating clinician deems it unsafe to administer either Normal Saline (NS) or Balanced Fluids (BF)?	☐Yes	☐No
9. Known pregnancy determined by routine history disclosed by patient or caregiver?	☐Yes	☐No
10. Known allergy to a crystalloid fluid?	☐Yes	☐No
ELIGIBILITY CONFIRMATION		
BASED ON THE CRITERIA, IS THE PATIENT ELIGIBLE FOR THE PROMPT BOLUS Study?	☐Yes	☐No

Please complete next page (page 2) ➡

PRoMPT BOLUS-01
Eligibility Form
Version 5; Date: v1.0 / 30-Mar-2023

Page 1 of 2

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

1. **Are you concerned your patient has sepsis?**
2. **Is the patient ≥ 2 months of age?**
3. **Are you administering at least one IV/IO fluid bolus for resuscitation and additional fluid for poor perfusion?**

If **YES** to all, assess patient for PRoMPT BOLUS study:

Step 1 Review and complete **Eligibility Form**, and if eligible

Step 2 **Randomize** by selecting next study envelope

Step 3 Administer assigned **fluid**

Questions: Contact **Dr. Graham Thompson (403) 369-0765**
Beata (beata.mikkelsen@ahs.ca) or study team pager **#11310**

PROMPT BOLUS-01
ED – Adult Notice
Version 5; Date: v 1.0 / 30-Apr-2023

Frequently Asked Questions (FAQs)

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

ED – Alberta Children's Hospital (ACH)

Q: Who should I think about enrolling?
A: Children aged 6mo 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 rooms 12-15.

Q: Where do I find randomization envelopes?
A: Randomization envelopes are located in the following 2 locations:
1) The desk in the resuscitation room
2) A drawer in the Sepsis Cart located in the hallway by rooms 12-15

Q: What is in the randomization envelopes, and what do I do with it?
A: Randomization envelopes include the following:
1) Randomization Stickers – place one on the completed eligibility form and one on the patient's health record
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) Patient Door Signs – keep on the health record for the admitting team to post on the patient's room door
5) ED Information Sheet – to assist you through ED study processes
6) Inpatient Information Sheet – to assist admitting staff through inpatient study processes. Please keep on the health record for the admitting team
7) 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 Fluids, Orange = Normal Saline) including:
1) Patient Wrist Bands
2) IV hang tags
3) Patient Door Signs
4) 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?

PROMPT BOLUS-01
FAQ Sheet – ED – ACH
Version 5; Date: v1.0 / 30-Sep-2021

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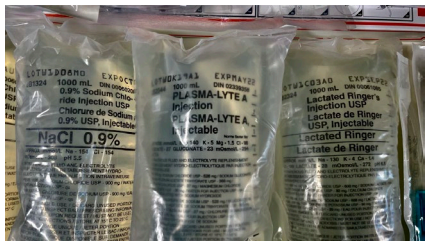
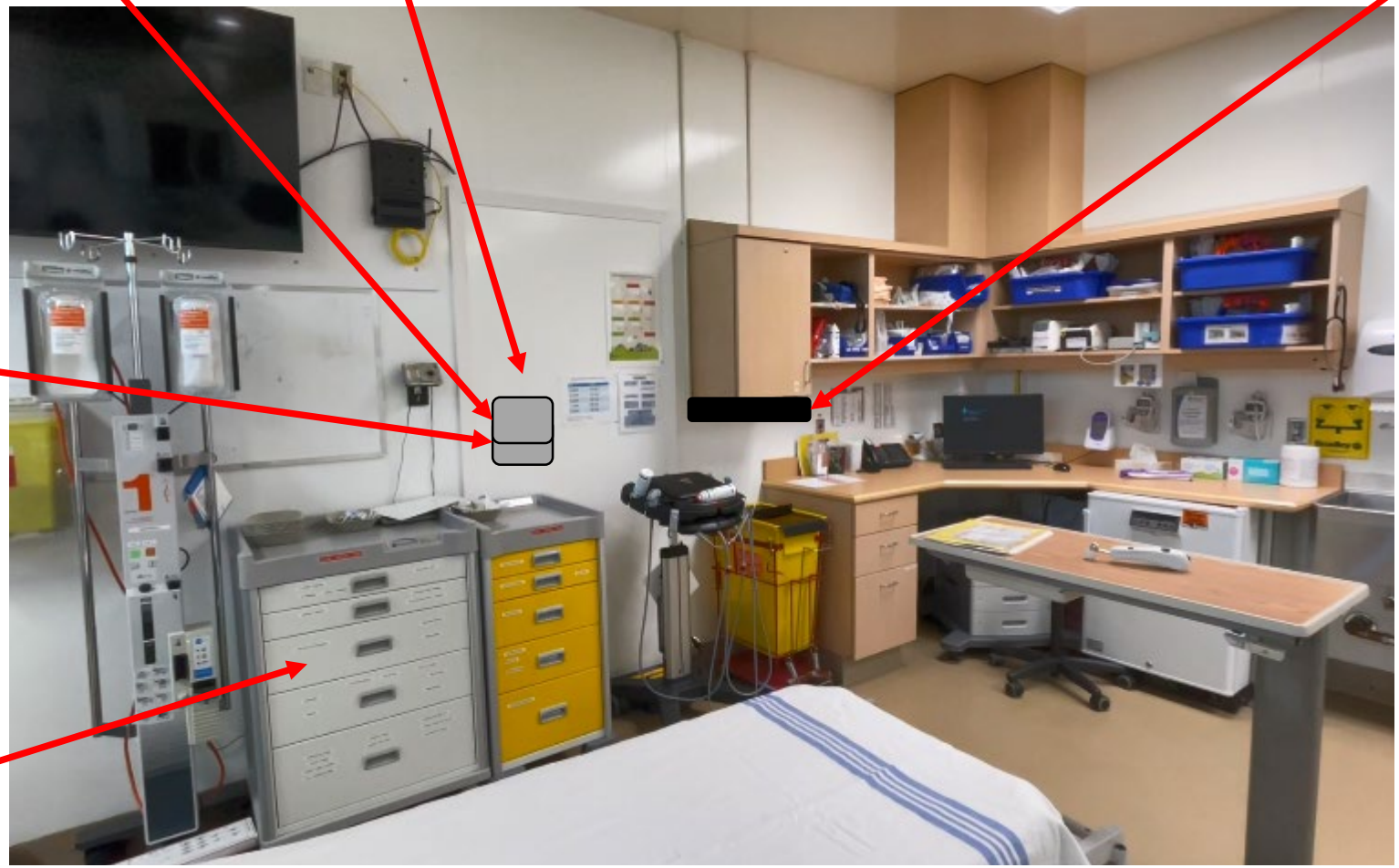


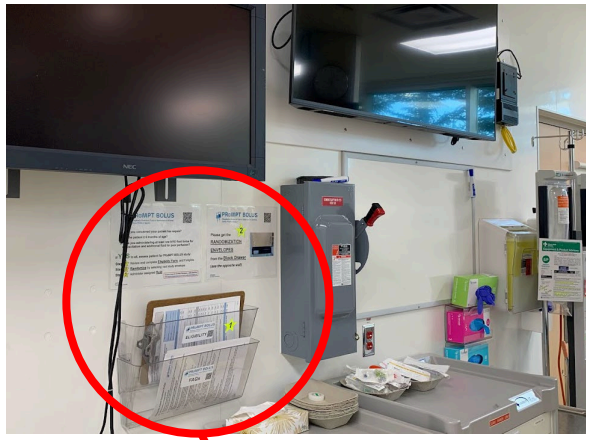


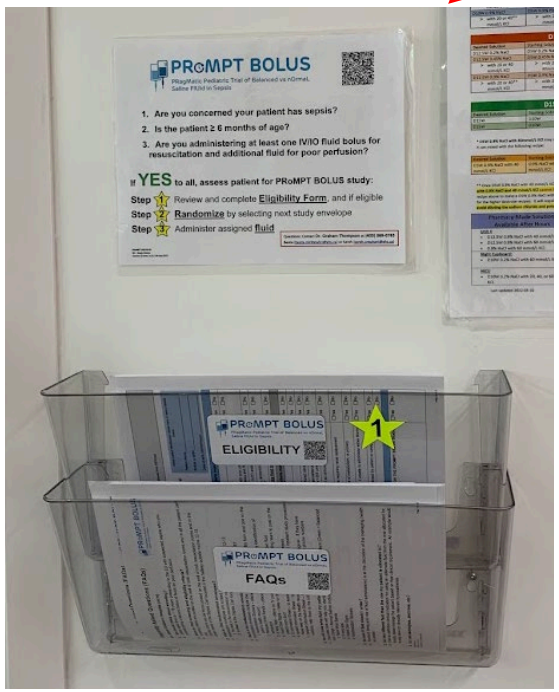
PRoMPT BOLUS
PRagMatic Pediatric Trial of Balanced vs nOrmaL Saline FlUid in Sepsis

Randomization Envelope

RESUS ROOM

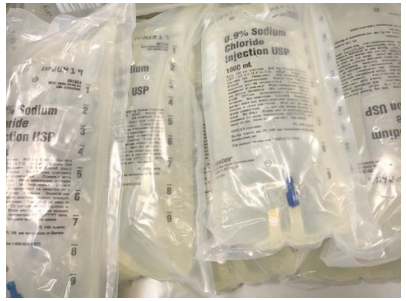
(study materials are on both walls of the room)



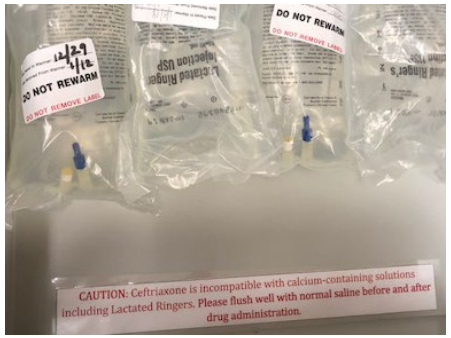


SEPSIS CART

(located in hallway outside the A pod)



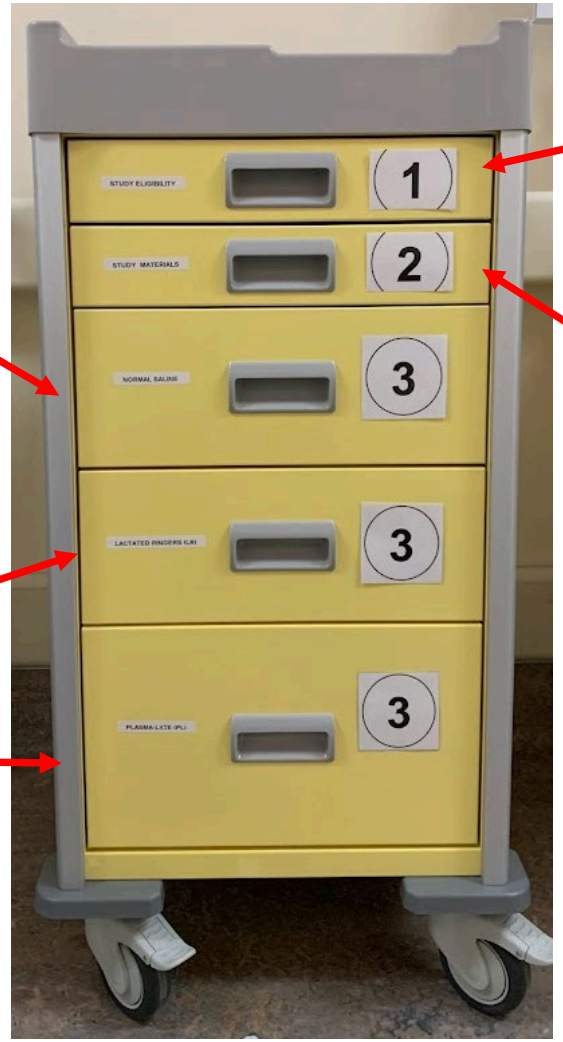
Normal Saline



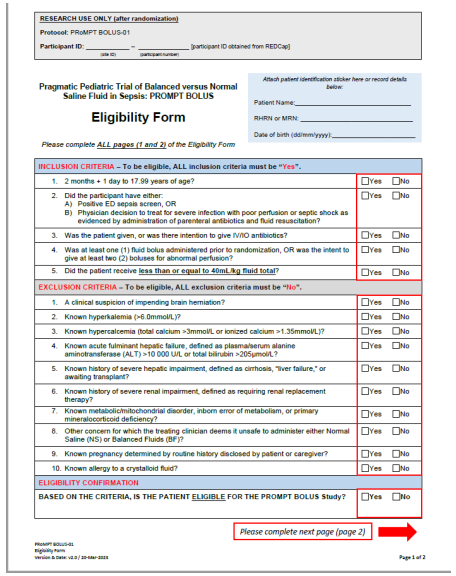
Balanced Fluids

Lactated Ringers

PlasmaLyte



Eligibility Forms, FAQs



RESEARCH USE ONLY (after randomization)

Protocol: PRoMPT BOLUS-01

Participant ID: _____ – _____ [participant ID obtained from REDCap]

(site ID) (participant number)

Pragmatic Pediatric Trial of Balanced versus Normal Saline Fluid in Sepsis: PROMPT BOLUS

Eligibility Form

Attach patient identification sticker here or record details below:

Patient Name: _____

RHRN or MRN: _____

Date of birth (dd/mm/yyyy): _____

Please complete ALL pages (1 and 2) of the Eligibility Form

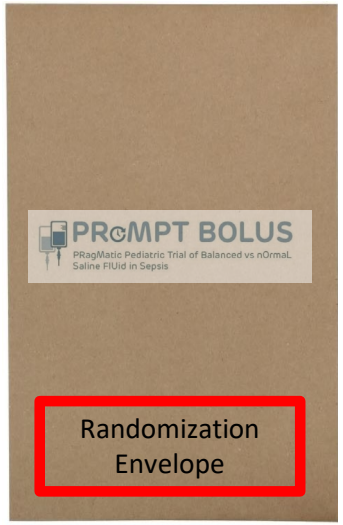
INCLUSION CRITERIA – To be eligible, ALL inclusion criteria must be "Yes".	
1. 2 months + 1 day to 17.99 years of age?	☐Yes ☐No
2. Did the participant have either: A) Positive ED sepsis screen, OR B) Physician decision to treat for severe infection with poor perfusion or septic shock as evidenced by administration of parenteral antibiotics and fluid resuscitation?	☐Yes ☐No
3. Was the patient given, or was there intention to give IV/IO antibiotics?	☐Yes ☐No
4. Was at least one (1) fluid bolus administered prior to randomization, OR was the intent to give at least two (2) boluses for abnormal perfusion?	☐Yes ☐No
5. Did the patient receive less than or equal to 40mL/kg fluid total?	☐Yes ☐No
EXCLUSION CRITERIA – To be eligible, ALL exclusion criteria must be "No".	
1. A clinical suspicion of impending brain herniation?	☐Yes ☐No
2. Known hyperkalemia (>6.0mmol/L)?	☐Yes ☐No
3. Known hypercalcemia (total calcium >3mmol/L or ionized calcium >1.35mmol/L)?	☐Yes ☐No
4. Known acute fulminant hepatic failure, defined as plasma/serum alanine aminotransferase (ALT) >10 000 U/L or total bilirubin >205µmol/L?	☐Yes ☐No
5. Known history of severe hepatic impairment, defined as cirrhosis, "liver failure," or awaiting transplant?	☐Yes ☐No
6. Known history of severe renal impairment, defined as requiring renal replacement therapy?	☐Yes ☐No
7. Known metabolic/mitochondrial disorder, inborn error of metabolism, or primary mineralocorticoid deficiency?	☐Yes ☐No
8. Other concern for which the treating clinician deems it unsafe to administer either Normal Saline (NS) or Balanced Fluids (BF)?	☐Yes ☐No
9. Known pregnancy determined by routine history disclosed by patient or caregiver?	☐Yes ☐No
10. Known allergy to a crystalloid fluid?	☐Yes ☐No
ELIGIBILITY CONFIRMATION	
BASED ON THE CRITERIA, IS THE PATIENT ELIGIBLE FOR THE PROMPT BOLUS Study?	☐Yes ☐No

Please complete next page (page 2)

PROMPT BOLUS-01
Eligibility Form
Version & Date: v2.0 / 22-Mar-2023

Page 1 of 2

Randomization Envelopes



SEPSIS CART
(Located in hallway outside A pod)

Eligibility Forms
FAQs

Randomization envelopes

Fluids!!

Fluids Available for Use

Bolus Fluids

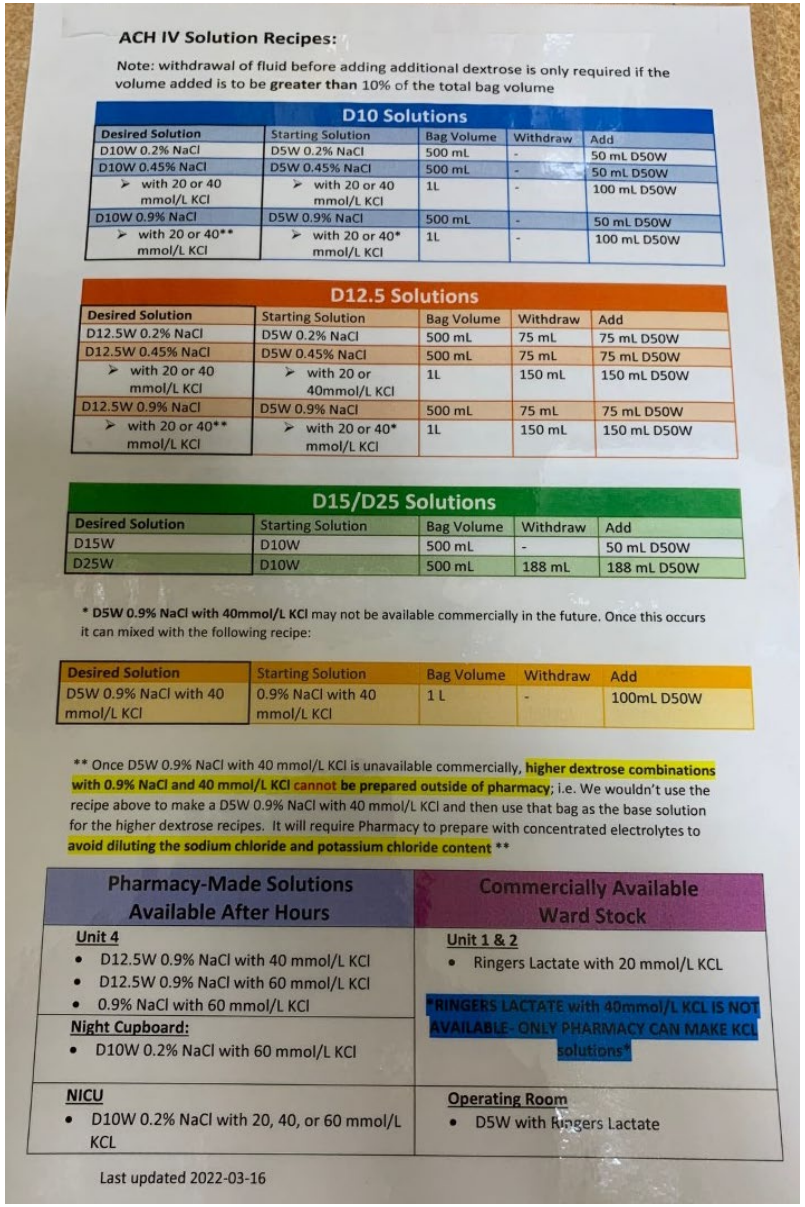
- NS
- LR
- PL

Maintenance Fluids

- NS, NS + 20K, D5NS, D5NS + 20K
- LR, LR + 20K, D5LR
- PL

Other Solutions to mix in ED

- (LR+20K) + D5
- Order as LR+20K and include “please add dextrose to make D5 equivalent”



ACH IV Solution Recipes:

Note: withdrawal of fluid before adding additional dextrose is only required if the volume added is to be **greater than** 10% of the total bag volume

D10 Solutions

Desired Solution	Starting Solution	Bag Volume	Withdraw	Add
D10W 0.2% NaCl	D5W 0.2% NaCl	500 mL	-	50 mL D50W
D10W 0.45% NaCl	D5W 0.45% NaCl	500 mL	-	50 mL D50W
➢ with 20 or 40 mmol/L KCl	➢ with 20 or 40 mmol/L KCl	1L	-	100 mL D50W
D10W 0.9% NaCl	D5W 0.9% NaCl	500 mL	-	50 mL D50W
➢ with 20 or 40** mmol/L KCl	➢ with 20 or 40* mmol/L KCl	1L	-	100 mL D50W

D12.5 Solutions

Desired Solution	Starting Solution	Bag Volume	Withdraw	Add
D12.5W 0.2% NaCl	D5W 0.2% NaCl	500 mL	75 mL	75 mL D50W
D12.5W 0.45% NaCl	D5W 0.45% NaCl	500 mL	75 mL	75 mL D50W
➢ with 20 or 40 mmol/L KCl	➢ with 20 or 40mmol/L KCl	1L	150 mL	150 mL D50W
D12.5W 0.9% NaCl	D5W 0.9% NaCl	500 mL	75 mL	75 mL D50W
➢ with 20 or 40** mmol/L KCl	➢ with 20 or 40* mmol/L KCl	1L	150 mL	150 mL D50W

D15/D25 Solutions

Desired Solution	Starting Solution	Bag Volume	Withdraw	Add
D15W	D10W	500 mL	-	50 mL D50W
D25W	D10W	500 mL	188 mL	188 mL D50W

* **D5W 0.9% NaCl with 40mmol/L KCl** may not be available commercially in the future. Once this occurs it can mixed with the following recipe:

Desired Solution	Starting Solution	Bag Volume	Withdraw	Add
D5W 0.9% NaCl with 40 mmol/L KCl	0.9% NaCl with 40 mmol/L KCl	1 L	-	100mL D50W

** Once D5W 0.9% NaCl with 40 mmol/L KCl is unavailable commercially, **higher dextrose combinations with 0.9% NaCl and 40 mmol/L KCl cannot be prepared outside of pharmacy**; i.e. We wouldn't use the recipe above to make a D5W 0.9% NaCl with 40 mmol/L KCl and then use that bag as the base solution for the higher dextrose recipes. It will require Pharmacy to prepare with concentrated electrolytes to **avoid diluting the sodium chloride and potassium chloride content** **

Pharmacy-Made Solutions Available After Hours	Commercially Available Ward Stock
Unit 4 • D12.5W 0.9% NaCl with 40 mmol/L KCl • D12.5W 0.9% NaCl with 60 mmol/L KCl • 0.9% NaCl with 60 mmol/L KCl	**Unit 1 & 2** • Ringers Lactate with 20 mmol/L KCL *RINGERS LACTATE with 40mmol/L KCL IS NOT AVAILABLE - ONLY PHARMACY CAN MAKE KCL solutions*
Night Cupboard: • D10W 0.2% NaCl with 60 mmol/L KCl	
NICU • D10W 0.2% NaCl with 20, 40, or 60 mmol/L KCL	**Operating Room** • D5W with Ringers Lactate

Last updated 2022-03-16

Fluids Available for Use

Base	Solution	Location
0.9% NaCl (NS)	NS	ED/PICU/wards
	NS + 20KCl	ED/PICU/wards
	NS + 40KCl	ED/PICU/wards
	NS + 60KCl	Unit 4
	D5NS	ED/PICU/wards
	D5NS + 20KCl	ED/PICU/wards
	D12.5NS + 40KCl	Unit 4
	D12.5NS + 60KCl	Unit 4
	Other dextrose mixtures	Mix in ED^
Lactated Ringers (LR)	LR	ED/PICU/wards
	LR + 20KCl	PICU/Unit1/Unit2
	D5LR	PICU/OR
	(LR + 20KCl) + D5	Mix in ED^
PlasmaLyte (PL)	PL*	ED/PICU/wards

* AHS Pharmacy does not endorse additives to PL

^ IV Solution mixtures as per ED/PICU/Pharmacy policy.

What about Fluid Additives?

- Dextrose, K^+ etc can be added as clinically indicated
- Unable to add directly to PL or LR bags
  - AHS Provincial Pharmacy

WARNING: Compatibilities

- Lactated Ringers is NOT compatible with the following items:
  - Ceftriaxone
  - Some Blood Products

- Please use a 2nd line if available. If not, exceptional IV flushing standards are vital.

- Please comply with all AHS compatibility protocols and procedures.

Stopping Criteria (for NS and BF)

Item	Definition
Hyperkalemia*	K^+ >6 mEq/L
Hypercalcemia*	Ca^{+2} >3 mmol/L *OR* iCa^{+2} >1.35 mmol/L
Severe hepatic impairment	ALT > 10 000 U/L *OR* total bilirubin >205 umol/L
Severe renal impairment	Urine output <0.5 ml/kg for 16 hrs (continuous) *OR* Initiation of new Renal Replacement Therapy
Hypersensitivity to allocated fluids	Based on managing clinical team

***confirmed by immediate retesting**

Stopping Criteria (for NS and BF)

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**

Stopping Criteria stickers are located next to the Eligibility Forms (on side wall of each Resusc Bay & in Sepsis Cart)

FLUIDS?

SEPSIS?

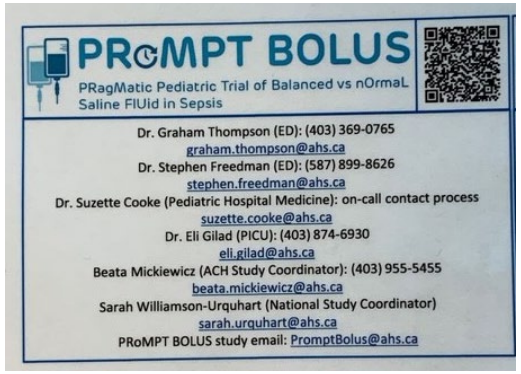
THINK

PRoMPT BOLUS

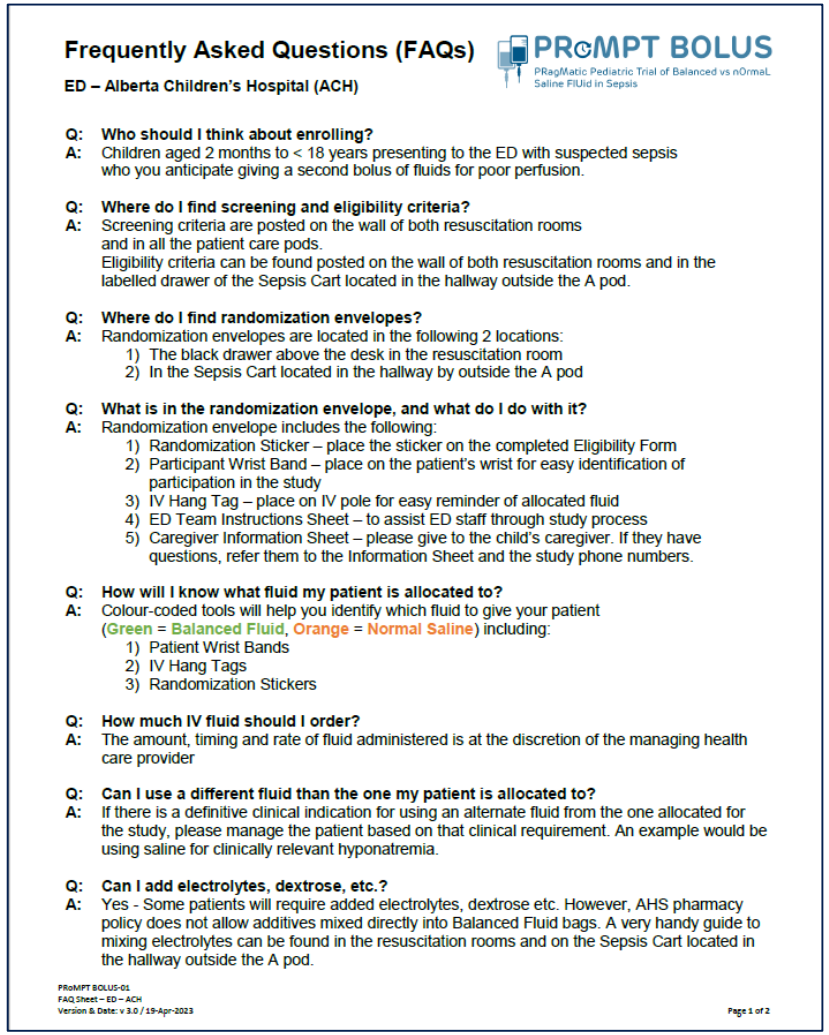
PRagMatic Pediatric Trial of Balanced vs nOrmaL Saline FlUid in Sepsis

Found on all study documents

Study Summary
Eligibility Criteria
ED Study Information
Inpatient/PICU Study Information
Fluid Additives
Stopping Criteria
FAQ



PromptBolus@ahs.ca



Frequently Asked Questions (FAQs)

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

ED – Alberta Children's Hospital (ACH)

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.

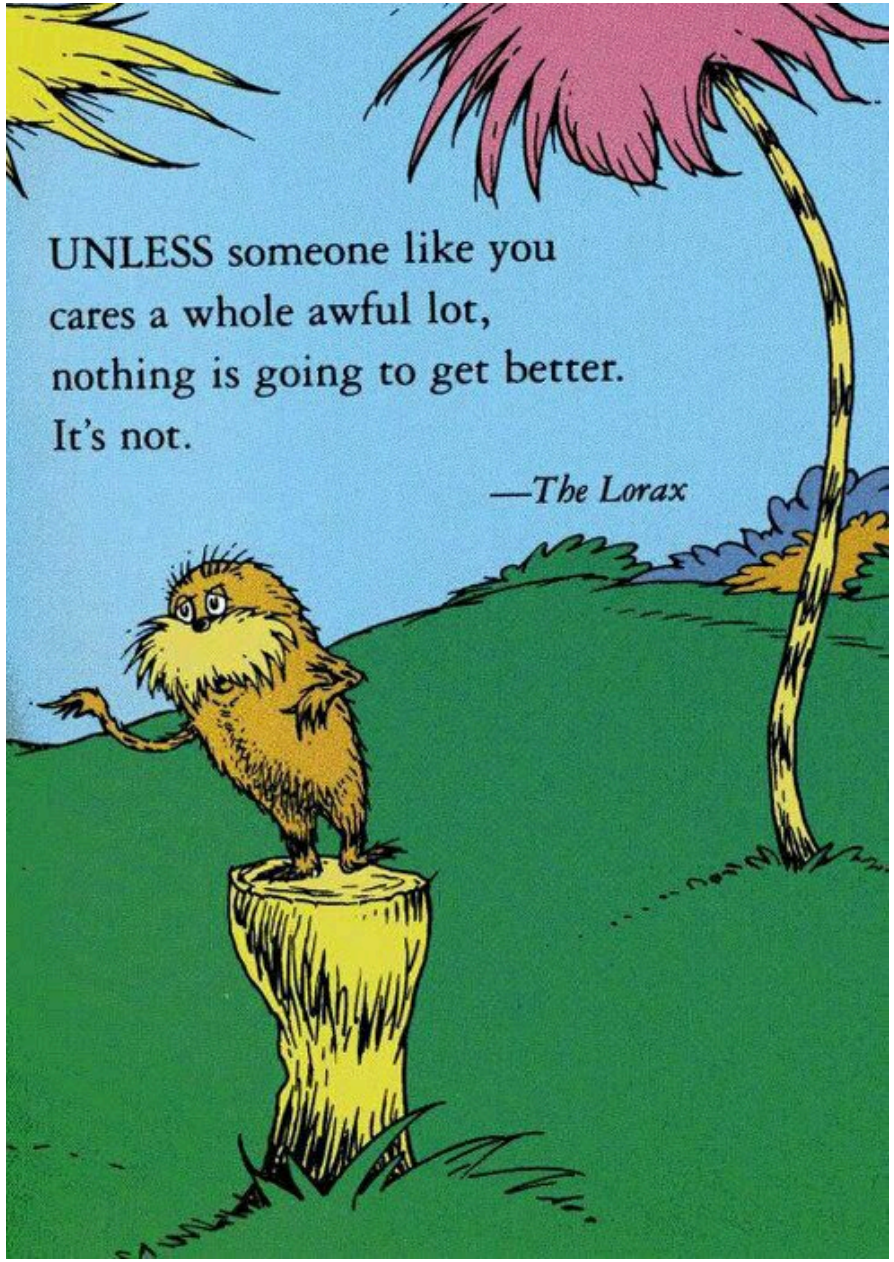
PRoMPT BOLUS-01
FAQ Sheet – ED – ACH
Version & Date: v 3.0 / 19-Apr-2023
Page 1 of 2

☐ Any questions, please contact
- **Dr. Graham Thompson** at **(403) 369-0765** / graham.thompson@ahs.ca
- Study team pager (Mon-Fri, 10:00-17:00): **#11316**

Contact Information

ED

- Dr. Graham Thompson: graham.thompson@ahs.ca
  (403) 369-0765
- Study team pager (Mon-Fri, 10:00-17:00): **#11316**
- PERT Research Office (52309)
- Study email: PromptBolus@ahs.ca



The Lorax, Dr. Seuss

Anticipated Impact

1,275 fewer cases of MAKE30

242 fewer cases of CKD

50 fewer deaths

$35 million less in health care costs

US estimates

Weiss, Balamuth et al *CJASN* 2019

Acknowledgements

perc
Pediatric Emergency Research Canada

PECARN

PREDICT

PALISI
Pediatric Acute Lung Injury & Sepsis Investigators

ANZICS

CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

NIH
NICHD

NHMRC

BUILDING A HEALTHY AUSTRALIA

Alberta Children's Hospital Research Institute

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CAN'T DO IT
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