

**Yale University**

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**To:** Marc Auerbach, M.D.  
**From:** **Yale Institutional Review Board**  
**Date:** 12/21/2016  
**Committee Action:** **Exemption Granted**  
**IRB Action Date:** 12/21/2016  
**IRB Protocol #:** 1612018709  
**Study Title:** Fluid Administration with LifeFlow vs Push/Pull.

Educational Research Conducted in Educational Settings. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: i) research on regular and special education instructional strategies, or ii) research on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods

Exempt studies do not require annual IRB review. Modifications to exempt research do not need a formal IRB review unless the proposed revision affects the exempt status of the protocol. Such changes may include, but are not limited to, addition of collection of identifiers when the original protocol included anonymous data only, addition of children or prisoners as study subjects, or addition of procedures that could potentially increase risk to subjects. See the Exemption Guidance (100 GD9) for more information and examples.

Whenever an exempt protocol is modified (regardless of the type of change), updated versions of all research documents affected by the change must be sent to the IRB Office for the file. Revisions to the documents must be tracked. Changes that do not require IRB review will not be acknowledged formally.

Investigators are also required to promptly report any unanticipated problems or complaints to the IRB.

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**Review Comments:**

- EXEMPTION 45 CFR 46.101(b)(1) This research is exempt from IRB review under federal regulation 45 CFR 46.101(b)(1). This part of the regulations covers research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on special education instructional strategies, or (ii) research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

## LifeFlow Protocol:

### Training:

- Participants are randomized to the device.
- A 5-minute training video is viewed on how to use the device that participants are randomized to.
- Participants are given the device, a 1L NS bag, tubing and a 22g IV. They will demonstrate ability to set up the device and fill an empty container with fluid.
- For Lifeflow:
  - Box opened, 2 pieces of tubing removed from box.
  - Blue caps taken off and 2 pieces of tubing connected
  - 1L bag spiked and connected to tubing
  - Device unlocked, opened, and tubing inserted with plunger properly placed
  - Device pointed upward so air rises while device is pumped until primed and air removed from line.
  - Distal tubing connected to IV and participant pumps water through.
  - Participants reminded to change 1L bag when about 2cm fluid remain.
  - Line is changed from first 1L bag to second and device continues to be used.
- For Push/Pull:
  - Tubing, 3-way stopcock, 20cc syringe and 22g IV provided in an equipment box
  - Participants spike bag, connect tubing, and use syringe/stopcock to prime line.
  - Practice changing position of stopcock for fluid to flow through IV
  - Line is changed from first 1L bag to second and device continues to be used
- For Pressure Bag:
  - Tubing, sleeve, and 20 cc syringe provided in an equipment box
  - 1L bag placed in sleeve, spiked and tubing connected to IV.
  - Sleeve pressurized to 300mmHg

### Set up:

- 10 kg child with a 22-gauge IV catheter x 2, device and appropriate tubing
- The distal end of the catheter was secured in an unobstructed manner within conduit tubing leading to a graduated cylinder.
- The graduated cylinder, used to collect and measure fluid kept hidden from the view of participants.
- The proximal end of the intravenous catheter was connected via a catheter extension set to the appropriate technique-dependent setup.
- Cameras set up on graduated cylinder and overall resuscitation.

### Trial:

- Vitals given to participants indicating septic shock
- Algorithm available indicating 20cc/kg boluses x 3: *Clinical practice parameters for hemodynamic support of pediatric and neonatal septic shock: 2007 update from the American College of Critical Care Medicine. Crit Care Med 2009; 37:666.*
- Heart rate and blood pressure slightly improve after each subsequent bolus
- Participants prompted if necessary to continue giving fluids
- Simulation ends after 15 min, expect to also give antipyretics (Tylenol), can obtain labs and should give antibiotics
  - CHARGE NURSE BRINGS IN ANTIBIOTIC AT TIME= 8 MINUTES
- Participants timed on setup, infusion of each bolus, total time for 3 boluses
  - Clock during simulation, verify with video
  - Compare rate of fluid administration between first, second and third boluses
- Participants will be given a follow up questionnaire regarding secondary outcomes.
  - Participants' ability to accurately administer the requested volume (60 ml/kg or 1200ml) to the simulated patient
  - Level of self-reported fatigue

ADDITIONAL SET UP—monitor, fluid pumps, simulated Tylenol and other meds, zofran  
Ceftriaxone and Tylenol/Zofran will arrive from pharmacy, printed copy of labs

PRESSORS and other meds will be “being prepared” and brought into the room

Introduction script:

- Begin the session with an introduction to the project and you/the parent.
- Have participant introduce themselves.
- State your basic assumption: we believe that as a participant you are intelligent, well trained, want to do your best and want to improve.
- Cardinal rule of simulation: What happens in sim stays in sim. Please do not discuss the performance of your peers or these cases outside of this session.
- Use the saying, “What happens in Vegas, stays in Vegas.” In other words, what happens in Sim stays in sim. Remind participants that this is a learning environment and that they will not be judged. Rather is a test of different devices/equipment.
- Reiterate that the participants can use all the tools including computer programs, apps, and code books.
- Review the format of the day. Simulation begins with a “patch” from charge nurse who is bringing patient back. The participants will have 60 seconds to formulate their team before the actual simulation begins. The simulation will begin. It ends when the moderator says, “curtain down.”
- A debriefing of the session will occur and be recorded in the room lasting about 10 minutes.
- Orient them to the mannequin. Walk them from head to toe on what the Megacode kid can and cannot do and what is expected of them. Mention the importance of “suspending disbelief.” The simulator has limitations but the more the participants put into the scenario and caring for the fake child, the more that will be gained. We mention a “Disney World” story where an older sibling points out all the fake things in the amusement park to the younger sibling. But if you believe and use your imagination, the more enjoyment and the more realism will occur.
- Introduce the participants to the medication tray. Review what is expected of the participants(to order, calculate, draw-up, and administer medications as they would with a real patient).
- Discuss that they are expected to DO, not just SAY what they want. For example, if they want 20cc/kg bolus, a team member needs to place and IV or IO, get the fluid, spike the bag, hook it up to the patient, an administer the fluid. All interventions happen in real-time.  
Introduce them to parent actor/character- inform them that this person will give information and at times ask questions (plus can respond to questions at any time)
- You will be videotaped during this session. These videos will be used for research purposes and not for work related evaluations. They will be secured in a safe location and will not be shared outside of this research project.

ORIENTATION TO EQUIPMENT:

- Please hook monitors to the patient when you want to obtain vital signs (SHOW ATTACHMENT OF MONITORS and have data come up on monitor).
- You can press the screen to obtain a blood pressure (SHOW THIS)
- All supplies for case are in this room.
- IVs are in place x 2 (placed at triage)
- Fluid and medication should
- be infused and medications pushed when access is obtained.
- Draw up actual volumes of medications as you would in a real patient. (SHOW HOW IV ACCESS WILL WORK and PUSH
- MEDS)
- The medications are provided in these containers. Please note that they are in alphabetical order. We encourage you to verbalize your orders and use closed loop communication during the cases. If you are looking for a medication not in the container please announce that you are ordering from pharmacy and we will provide.

**Case- Hypovolemia/Sepsis**

Facilitator states case lead in: *EMS brought in a 1-year-old female patient with vomiting, fevers, tachycardia, and ill appearance. She has not had any urine output in 20 hours. Patient is at triage and will be brought back to the resuscitation bay in one minute*

*(Start with patient covered with a sheet and STATE patient has arrived at 1 minute and then remove the sheet)*

Give 60 seconds to organize themselves, remove sheet from baby and announce: “the patient has arrived”.

Start the simulator scenario running, state: patient arrived/begin simulation at sixty seconds

When they are performing initial exam state these findings as team assesses the patient:

Patient is sleepy with minimal movements-

**ILL APPEARING, MOTTLED COLOR, GRUNTING, HOT TO TOUCH CENTRALLY**

HEENT: Dry lips and mouth, PERRL, tm's normal, sunken eyes

RESP: right sided crackles consistent with pneumonia

CV: tachycardic, cap refill 4 seconds

ABD: soft, non-distended, no HSM

Skin: tenting turgor, no petechiae or purpura

EXT: warm, no signs of trauma, no rashes

Vital signs should be activated on simulator software AFTER the monitor is attached (do not show up if not attached)

VITALS: T: 103 RR: 35 HR: 160 BP:80/35 O<sub>2</sub>:96% -- minimal crying but coughing and vomiting

WILL TREND OVER 5 MINUTES to

RR: 45, HR: 185, BP: 70/30

TREND OVER LAST 10 MINUTES—patient starts with more crying and coughing sounds

RR: 30, HR: 140, BP: 85/45

**CASE ENDS WITH SIGN OUT TO PICU @ 15 minutes from start**

**Information provided by parent:**

IMMEDIATELY STATE: RACHEL is a healthy girl, she was sick for a few days and has been seen by her doctor two times, her brother has a cough and runny nose

- She had a fever and was seen yesterday by PMD who diagnosed with an otitis media and started amoxicillin and Zofran
- Hard to wake up today, tried to let her sleep it off but she napped for over 8 hours and cannot get her up to take her medicine.
- Drinking less today. Vomited two times. Soaked through her sheets in sweat

THROUGHOUT CASE ASK FOR UPDATES EVERY FEW MINUTE IF NOT PROVIDED BY TEAM, expect people to inform you of what is going on, you can ask for updates. You will be confused and frustrated.

AT THREE MINUTES STATE: “why is she so sleepy, what is going on, are you helping her”

AT FIVE MINUTES STATE: *Is she going to be OK? Her color looks awful*

AT EIGHT MINUTES STATE: *I need to call her dad- what do I tell him?*

AT ELEVEN MINUTE: *MAKE HERE VOMIT SOUND, parent asks to give her something to stop vomiting*

AT FOURTEEN MINUTES STATE: *Ask what does those numbers on the monitor mean- is she getting better.*

Parent responds to questions when asked by the medical team:

**(S)**How long has she been ill? **Mom:** *She has had a fever for two days, as high as 103. She has vomited 10 times today and once yesterday.*

**(A)**Does she have any allergies? **Mom:** *None that I know of.*

**(M)** Does she take any medicines? **Mom:** *Not regularly- she had Tylenol for her fever, and yesterday at the pediatrician's office, he gave her Amoxicillin/Zofran.*

**(P)** When she was born, were there any difficulties? **Mom:** *She was near term, 39 weeks, and it was a normal delivery.*  
Does she have any past medical history? **Mom:** *She has been perfectly healthy and is up to date with her shots*

**(L)** When was the last time she ate? **Mom:** *She is having trouble drinking today and not keeping anything down.*

**(E)** What was she doing right before you brought her to the ED? **Mom:** *She was really hard to wake up from her nap and she is breathing really heavy. I got really scared and we live close, so I rushed her right over here.*

Has she been using bathroom? **Mom:** *no*

## RESPONSES TO QUESTIONS IF ASKED BY FACILITATOR

### **PHASE 1 Anytime after first fluid bolus:**

What is her work of breathing? **Facilitator:** *She is still grunting and flaring*

What is her capillary refill? **Facilitator:** *still prolonged at 4 sec*

What is her mental status? **Facilitator:** *She is sleepy*

What is her general appearance, color, temperature? **Facilitator:** *She is less grey but she is still very cool in her extremities*

### **PHASE 2 After second fluid bolus:**

What is her work of breathing? **Not terrible**

What is her cap refill? **Facilitator:** *Her capillary refill is better. now 3 seconds*

What is her mental status (if not intubated)? **Facilitator:** *She is starting to respond some more*

What is her general appearance, color, temperature? **Facilitator:** *She has more color now and she is less mottled.*

### **PHASE 3 After third fluid bolus or vasoactive medications are initiated:**

What is her work of breathing? **improved**

What is her capi refill? **Facilitator:** *Her capillary refill is much better at 2 seconds*

What is her mental status (if not intubated)? **improved**

What is her general appearance, color, temperature? **Facilitator:** *She has much better color now and her peripheral pulses are much stronger. Her extremities are warmer*

## **Labs:**

ISTAT 8

Na (135-145) MEQ/L: 140

K (3.6-5.1) MEQ/L: 4.7

Cl (98-110) MEQ/L: 100

CO<sub>2</sub> (20-30) MEQ/L: 10

BUN (6-24) MG/DL: 32

Creat (0.4-1.3) MG/DL: 0.3

iCa (1.1-1.3) Mmol/L: 1.10

Glu (67-109) MG/DL: 195

LACTATE 8.0

## DEBRIEFING SCRIPT QUESTIONS;

REACTIONS: to the general performance, this can include feelings or emotions and medical facts

How did you feel about taking care of this child?

How do you think the team did getting fluids into the patient?

How do you think the team did in managing priorities in the care of this patient?

ANALYSIS: we will discuss the diagnosis management of the case based on the team's performance; this will include identifying gaps in performance and positives.

STEPS: observation + judgment+ inquiry

Ex: I noticed struggle in getting fluid in fast enough, tell me more about what you were thinking

What are some barriers to getting fluid in rapidly

During this time the group can ask questions of the facilitators.

SUMMARY: we review our discussion and findings. Each individual will summarize one thing that they learned from the

case and will apply in future care o

“Drill

-

Down” questions

for use to follow

-

up possible areas of interest

What hindered/prevented you from \_\_\_\_?

How did that (factor/distraction) affect your ability to \_\_\_\_?

What were you concerned about when \_\_\_\_?

Where did you learn how to \_\_\_\_?

What would have improved your ability to (make a decision/do a procedure/work with a

teammate/handle a stressful or difficult situation)?

How did you know that \_\_\_\_?

When did you realize/recognize that \_\_\_\_?

I saw that you (did this). What made you decide to (error of commission)?

What made you decide not to (error of omission)?

What else was going on at the time that made you (error of omission or commission)?

What we

re your priorities at the point in time when \_\_\_\_?

What were you thinking about when this happened?

What were you planning to do when you saw that \_\_\_\_?

What prevented you from carrying out your plan?

How much time did you think you had before you had to respond to \_\_\_\_?

Data collection tools/measurements: