The Utility of LifeFlow rapid infuser in critical and non-critical pediatric patients: a mixed-method pilot study protocol (CHLA) – Non-Critical Patients receiving Pelvic Ultrasounds

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A Objectives/Purpose

To describe fluid infusion experiences in the clinical setting for rapid fluid delivery among non-critical pediatric patients.

B Hypotheses

The null hypothesis is that both groups of fluid delivery will have no difference in duration in ultrasound completion.

C Background

The LifeFlow® is a hand-operated rapid infuser designed to administer fluids to patients by a single user, for clinical situations in which a large volume or rapid infusion of fluid or colloid is required. The device delivers fluid in 10mL increments with each complete handle compression, which refills during release, automating a push-pull mechanism. The syringe then automatically refills with handle release.

In simulation studies, the LifeFlow® device compared to the push-pull techniques was able to deliver 1L of fluid in an average of 5.3 minute compared to 12.1 minutes, respectively, which fulfills the Davis et al. recommendation of 20mL/kg fluid bolus within 5 minutes (for a 50kg child).[3]

D Significance of the research

To describe fluid infusion experiences in the clinical setting for rapid fluid delivery among critical pediatric patients.

E Study Design

This is an unblinded, randomized control study examining two fluid delivery modalities for non-critical female patients with a planned transabdominal pelvic ultrasound requiring intravenous fluid boluses.

F Research Plan

1 Subjects

a Number of Subjects

This is a preliminary pilot study to establish outcome values and no formal sample size is calculated. We will enroll a minimum of 30 subjects, 15 in each arm.

b Inclusion criteria

Inclusion criteria apply to patients older than 1 month and <18 years requiring IV crystalloid bolus fluids before a pelvic ultrasound in the ED at CHLA.

c Exclusion criteria

Exclusion criteria apply to subjects with known cardiac insufficiency or significant cardiac surgery, hepatic insufficiency, or renal insufficiency, or any known fluid overload states (e.g. ascites, pulmonary edema). Additional exclusion criteria include subjects on diuretic or antihypertensive therapy, and subjects with a positive pregnancy test.

d Recruitment Methods

Subjects will be verbally solicited in the Emergency Department

e Informed Consent Process

Informed consent will be conducted in a private room by a member of the research team. Assent will be obtained if necessary.

f Vulnerable Subjects

This research will be conducted on children and non-English speaking populations.

g Compensation to Subjects

No financial compensation

h Treatment for Research-Related Injuries

This research study is funded by Atlanta Pediatric Device Consortium. Participants and their families are not responsible for any costs involved with recording data from the medical records for this study.

2 Research Methods and Procedures

a General description of methods and procedures

- Surveillance of board for pelvic ultrasound orders on female patients
- Approach care team (attending and nurse) and explain study, confirm that they are okay with patient participating. Explain that if the participant is assigned to the LifeFlow group, the nurse must be present to administer fluids with LifeFlow device.
- Approach family and verify inclusion/exclusion criteria. If family is eligible, begin informed consent process.
- Use randomization scheme to assign to group, tell care team and family which group the patient is assigned to
- Record the participant's age, weight, BMI, clinical dehydration score, suspected diagnosis.

3 Summary of Visits and Procedures

a Procedures Just for Research Purposes

Randomization into LifeFlow or Alaris pump group

b How Participation Differs from Standard-of-Care

This study includes procedures that are also a part of the standard treatment the patient's condition. The transabdominal pelvic ultrasound is being done as part of standard of care and it is also standard of care to fill the patient's bladder with IV fluids before the ultrasound

c Study Duration

The study will last the duration of time it takes to fill the patient's bladder

4 Data Analysis Plan, Statistical Tests, and Sample Size Rationale

This is a preliminary pilot study to establish outcome values and no formal sample size is calculated. We will enroll a minimum of 30 subjects, 15 in each arm. Univariate statistics will examine associations between the predictor variables and the outcome variable; an ANCOVA will be used to determine differences between the two fluid delivery modalities and the primary outcome.

G Risks and Benefits

1 Potential Risks due to Study participation

There is the potential of accidental release of confidential information. Participants may experience a cold sensation with fluid administration by any device, including the LifeFlow® or an IV pump such as the Alaris ® pump. Participants may also experience some discomfort around the IV site.

2 Minimizing Risks

All clinical staff will monitor for signs of IV discomfort.

3 Potential Benefits

A possible benefit from this study is that patients' ultrasound may be completed more quickly in the LifeFlow group because fluid is delivered faster. In addition, information from this study will help doctors understand fluid infusion experiences in the Emergency Department and Pediatric Intensive Care Unit.

H Procedures to Maintain Privacy and Confidentiality

The data collected as part of this study will be de-identified and coded before being entered into the REDCap Database. All identifiable data will be kept in locked cabinets or in password protected electronic files only accessible by the research team.