Research Protocol – PEDIATRIC PREHOSPITAL AIRWAY RESUSCITATION TRIAL (PEDI PART)

1. **Purpose:** This is a multi-center study designed to determine the best airway management strategy for children under age 18 requiring life-saving care by EMS personnel.

   - **Phase 1 – Proposed start date: May 2024**
     Patients will be randomized to Bag Valve Mask (BVM) only vs. BVM followed by a supraglottic airway.
   - **Phase 2 – (Start date TBD)**
     Patient will be randomized to superior method from Phase 1 or BVM followed by endotracheal intubation.

RECOGNIZE

2. **Indications:**
   - **Inclusion criteria. Follow procedures below for randomization and reporting if <u>all</u> of the following criteria apply:**
     - At least 1-day-old and less than 18-years-old
     - Cardiopulmonary arrest, major trauma, or respiratory failure
     - Life-saving care initiated or continued by Pedi-PART EMS personnel
     - Requiring active airway management (BVM or higher level of respiratory support)

3. **Contraindications:**
   - **Exclusion criteria. Follow relevant *Maryland Medical Protocols for EMS* if <u>any</u> of the following criteria apply:**
     - Patient is a prisoner or under arrest
     - Patient is known to be pregnant
     - Patient has a tracheostomy in place
     - Patient has a DNR/DNI (MOLST) order in place
     - Another agency initiates care
     - **Parent/Guardian verbalizes objection to research or this study**
       - Paramedic does not need to discuss the study with the patient/parent/guardian as this would interfere with the timeliness of life-saving patient care
       - Research study staff will contact family after patient is stabilized

RANDOMIZE

4. **Procedure: (Phase 1: BVM alone vs BVM + iGel)**
   - Apply Defibrillation pads and attach end tidal CO_2 sensor
   - Follow *Maryland Medical Protocols for EMS* for all other interventions
   - Apply randomized airway strategy: (BVM only vs. BVM followed by iGel)
     - **Even day of the week 7 a.m.–7 a.m.:** Initiate BVM and continue to hospital arrival
     - **Odd day of the week 7 a.m.–7 a.m.:** Initiate BVM while preparing for supraglottic airway (iGel placement). Place iGel to provide oxygenation/ventilation.
   - **Patient safety and the patient's medical needs should always be prioritized**
     - Paramedic can override randomized intervention if deemed medically necessary
     - If unable to achieve adequate oxygenation and ventilation for your patient, despite attempts at correcting issues, paramedic should abort research protocol and follow *Maryland Medical Protocols for EMS* airway management procedures

REPORT

5. **Reporting**
   - Complete eMEDS® report
     - Document airway management details and any adverse events or safety events and time; or clarify if occurred before, during or after the airway intervention Examples of adverse/safety events include: hypoxia, bradycardia, hypotension, regurgitation, trauma to the airway.
   - **Save your cardiac monitor file**
   - **Complete electronic paramedic self-report** (Scan QR code-posted in ambulance) and answer questions

CONTACT

If you have urgent questions or concerns about the study procedures or a patient enrolled in the study, please call the Children's National Emergency Medicine study team at:

- **Day:** 202-476-8877
- **Night:** 202-924-0557