Pediatric airway management complications during the COVID-19 pandemic. An International, Multicenter, Observational registry: The PAWS-COVID-19 (Pediatric AirWay complicationS COVID-19) Registry.

Protocol ID: **PAWS-COVID-19 Registry**

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Summary

The COVID-19 pandemic caused by the novel SARS-CoV-2 virus has disrupted anesthesia care all over the world. There remains very little data on current practice patterns and patient outcomes in anesthetized children. Children with COVID-19 may have more airway-related complications than other patients because of the pulmonary effects of the disease and barriers being used by clinicians to protect themselves from viral droplets and aerosols.

The PeDI-C [Pediatric Difficult Intubation collaborative] group is an international multicenter group focused on research, quality improvement, and education about difficult pediatric airway management. Members of the PeDI-C collaborated with international researchers to create the **PAWS-COVID-19** registry.

The **PAWS-COVID-19 registry** collects data on pediatric airway management during this pandemic to determine complications in patients with COVID-19 and learn about clinical practice changes, particularly related to the use of personal protective equipment. Institutions participating in the **PAWS-COVID-19** registry will enter de-identified data into the registry for two consecutive weeks of their choice during the study period. Data collected will be analyzed to determine the incidence of complications, variations in practice, concordance of practice with current recommendations, and risk factors for peri-intubation complications.

The collaborative group designed this prospective observational multicenter study [**PAWS-COVID-19 Registry**] with the following aims.

Primary Aim:
To compare the incidence of complications (particularly hypoxemia) in patients with COVID-19 to those who are COVID-19 negative during airway management.

Hypothesis:
We hypothesize that patients with COVID-19 will have more complications like hypoxemia than other groups of patients during this pandemic.

Secondary Aims:

1. To determine the incidence of complications related to airway management in patients with COVID-19 (positive and suspected) and COVID-19 negative
2. To determine the variability in the use of PPE for tracheal intubation globally
3. To determine the variability in practice for induction of anesthesia
4. To compare the first attempt success rate of tracheal intubation in patients with the disease to those without the disease
5. To determine the Incidence of failed intubation
6. To determine risk factors related to complications (PPE type, Location, Age, Baseline Saturation, Induction technique, clinician type)

Our Sample size calculation is based on addressing the primary objective of this trial to compare the incidence of hypoxemia during intubation between the two groups. Based on a prior prospective study (VISI trial), we assumed that the incidence of hypoxemia during intubation for patients without COVID-19 was 3% (SD: 3%). We assumed the incidence of hypoxemia in the COVID-19 patients to be 33% higher than the control group; incidence of 4% (SD 3%). Using a t-test for two independent groups and assuming an equal variance of the incidence of hypoxemia during intubation for both groups, a sample size of 191 participants per group (382 total) will result in a power of 90% to detect at least a 33% increase in the incidence of hypoxemia during intubation between the two groups (assuming an alpha of 0.05).
To achieve this sample size, we are proposing a two-week data collection at participating sites. Assuming there are 5-10 COVID-19 cases in two weeks from each site, we would need 30-40 sites to achieve our required sample size.

Methodology
The **PAWS-COVID-19 Registry** is a prospective observational multicenter/multinational cohort survey of clinical practice aimed at collecting data for two consecutive weeks in all patients undergoing anesthesia for surgical and non-surgical procedures. Data will be retrospectively collected from medical and anesthetic records at the end of each case and entered into a web-based data entry portal using a Research Electronic Data Capture (REDCap) database.
No patient or clinician identifier is collected or can be shared in the database, and the data will be stored in the Children's Hospital of Philadelphia secure and redundant data Warehouse.

After IRB/Ethics approval, every center will identify a convenient two-week period of data collection between April 29th and October 30th, 2020.

The **PAWS-COVID-19 Registry** will involve institutions that are already part of the PEDI collaborative group. European centers are welcome to join the study through the ESA (European Society of Anesthesiology) network. Institutions from any part of the world that care for children are welcome to join the registry.

Study population

The study population will include all children (from birth to 18yrs) receiving sedation or general anesthesia for an elective, emergency, or urgent diagnostic or surgical procedure.

Inclusion criteria

Consecutive patients from birth to 18 years old admitted to participating centers during the two-week recruitment period for:

- An inpatient or outpatient procedure under general anesthesia with or without regional analgesia
- A diagnostic procedure under sedation or general anesthesia
- An urgent or emergent procedure performed during and outside of the regular operating room schedule hours.

Exclusion criteria

- Age > 18 years.
- Children admitted to the operating room already intubated
- Children who require tracheal intubation for life-threatening conditions in the emergency department, intensive care, or hospital ward.

Outcomes

The primary outcome is the occurrence of complications during airway management with or without intubation, at the induction of anesthesia. The secondary outcomes include the occurrence of complications at emergence/extubation, excluding patients transferred to the intensive care unit intubated. For all patients, the study will terminate at the end of anesthesia. Other secondary outcomes include the induction of anesthesia management, the type of device inserted for airway control, and the type of PPE (Personal Protective Equipment) used by anesthetists and assistants during airway management. The registry will collect the SARS-CoV-2 infection status of the patient at the time of anesthesia.

Data collection and definitions

- Demographics. Includes age, weight, and gender.
- ASA physical status. This ranges from I to VI, including the condition of "emergency" for each ASA physical status if the procedure is an emergency.

- History of a difficult airway. This identifies whether the patient has a previous history (including congenital diseases and syndromes) of difficult airway management or any physical examination finding that is associated with a difficult airway.
- Normal pre-anesthetic oxygen saturation. Patients with oxygen saturation above 95% in room air.
- Location. Identifies the place where the patient's airway was managed.
- COVID Status. Reports the patient's COVID-19 infection status at the time of the anesthetic.
    - COVID positive: a recently performed test (within the last 48hrs) which is positive for coronavirus infection
    - COVID negative: a recently performed test (within the last 48hrs) which is negative for coronavirus infection
    - COVID unknown: patients in whom the COVID-19 infectious status is unknown with or without COVID-19 laboratory test pending.
- Recent (2 weeks) COVID-19 Exposure. Reports whether the patient has been exposed to someone with COVID-19 or has been in a high prevalence area within the past two weeks
- Presumed CPVID-19 Status
    - Presumed positive
        - The clinician assumes the patient is positive
    - Presumed negative

      The clinician assumes the patient is negative
- Context of airway management. This identifies the primary reason why the anesthetic team is managing the patient's airway. Options include an anesthetic for a diagnostic procedure or surgery, or a life-threatening condition requiring emergency airway management (acute cardio-respiratory condition).
- Type of room. Identifies the location where airway management is performed and the type of pressurization of the location. Rooms can be positive, negative, neutral pressure, or unknown.
- The number of people assisting in airway management. This refers to the number of people involved in the initial airway management, and not those present in the room during airway management.
- Clinicians attire. The type of PPE worn by the clinicians directly involved in the initial airway management. All items that apply should be checked (gloves, type of mask, gown, eyes protection, etc.).
- Induction technique. This reports the anesthetic drugs used for induction. If combinations of techniques are used, only the first technique should be checked. Choices are intravenous, intramuscular, inhalational, rapid sequence induction, and modified rapid sequence induction.
- Medication used for induction. All drugs given for induction of anesthesia should be reported.
- Airway adjuncts during induction. Any additional oxygen delivered through nasal cannula (low or high flow) or mask assisted ventilation should be reported. In particular,

low flow nasal oxygen is defined as a flow of oxygen ≤0.5 L/kg/min, high flow nasal oxygen is defined as a flow of oxygen > 0.5 L/kg/min.

- Attempts. Indicates the number of attempts performed to successfully insert the airway device. An attempt is defined as "the act of inserting an airway device into the pharynx or nostril with the intent to perform tracheal intubation or place a laryngeal mask." The attempt ends if the device is removed from the pharynx or nostril. The number of attempts until successful airway management should be documented as well as device used for each attempt. This applies only for tracheal intubation and laryngeal mask.
- Barrier used to prevent droplet and aerosol spread during intubation. Any physical barrier used for preventing droplets and aerosol spread during intubation should be reported. They might be a plastic barrier, transparent box, etc.
- Extubation. Information similar to intubation should also be reported for extubation, in terms of location and barriers used to prevent droplet or aerosol spread.
- Complications might occur during intubation, extubation, or both. Below is the list of complications with definitions.
    - Hypoxemia. Drop in oxygen saturation below 90% (for all patients with normal oxygen saturation at baseline) or 10% decline from the baseline saturation for those patients with pre-existing abnormal oxygen saturation (congenital heart disease, chronic lung disease, etc.).
      Desaturation is identified as:
        - Mild: drop in saturation < 90% (10% decline from baseline)
        - Moderate: drop in saturation < 80% (20% decline from baseline)
        - Severe: drop in saturation < 50% (50% decline from baseline)
    - Laryngospasm. Complete airway obstruction associated with rigidity of the abdomen or chest wall leading to difficult facemask ventilation requiring the administration of high levels of continuous positive airway pressure (CPAP) or administration of medication or emergent tracheal intubation.
    - Bronchospasm. An increased respiratory effort, especially during expiration, and wheeze on auscultation. If the patient is ventilated, bronchospasm is associated with a significant increase in peak inspiratory pressure (under volume-controlled ventilation) or a significant decrease in tidal volume (under pressure-controlled ventilation). It may require the administration of bronchodilator medication.
    - Coughing/Bucking. Forced expelled air usually with sharp sound/Sudden jerking body movements with or without forced exhalation of air
    - Esophageal intubation. A Tracheal Tube inserted in the esophagus with immediate (no EtCO2 curve or respiratory sound at auscultation) or late (acute oxygen desaturation) identification.
    - Airway trauma. Any identified injury related to the act of securing the airway (induction of anesthesia) or removing the airway device (emergence from anesthesia). Trauma can be minor (dental or lip trauma) or severe (oropharynx/glottis/sub-glottis).
    - Vomiting: regurgitation of gastric content in the pharynx/larynx.
    - Vomiting with aspiration: is defined as the presence of any secretions (gastric, bilious, or particulate) in the airway evidenced by laryngoscopy or tracheal

suctioning or bronchoscopy (chest x-ray may show signs of pulmonary aspiration if a large volume aspirate).
- Bradycardia. An acute decrease in heart rate requiring administration of medication(s).
- Arrhythmia. Any ECG anomaly requiring administration of medication(s), excluding bradycardia which should be reported separately (see above).
- Cardiac arrest: isoelectric ECG or ventricular fibrillation with the cessation of circulation or severe bradycardia requiring chest compressions or full cardiopulmonary resuscitation.
- Death
- Other. Any other complication occurring at the induction of anesthesia or emergence from anesthesia should be reported.

Study participation

The PAWS-COVID-19 study will recruit as many participating institutions as possible from the PeDI collaborative group, the ESA Council and Europe, and any other part of the world interested in participating. The steering committee will coordinate all aspects of the study.
The recruitment will take place over **two consecutive weeks**, including weekends and after-hours. The 2-week recruitment period will be chosen by each sites local coordinator to occur between April 29th and October 30th, 2020.

Before the inclusion of the first patient, each institution will fill in a **pre-study survey** declaring their interest in joining the registry. Information in the pre-study survey will include the type and size of the hospital, the number of COVID-19 positive cases per 100,000 in the region/city of the healthcare center, the pre-study estimated percentage of anesthetic volume relative to the same period in 2019.

At the end of data collection, the local investigator will be required to fill in a **post-study survey** which will include an estimate of anesthetic volume relative to 2019 at the end of the data collection, the number of COVID-19 positive cases per 100,000 at the end of data collection and an estimate of the percentage of cases entered into the registry.

Each center will have a local coordinator who will be in contact with the steering committee and will be responsible for data collection and data entry. The local PI will have the opportunity to be an author on any publication related to the PAWS-COVID-19 Registry provided they meet all the criteria for authorship as outlined by the International Committee of Medical Journal Editors. Otherwise, the local investigator (and their assistants) will be listed as collaborators.

The ICMJE recommends that authorship be based on the following four criteria:
- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Figure 1. Protocol Flowchart: schematic diagram of data collection