TITLE:
Utility of Continuous Pulse Oximetry for Pediatric Patients with Stable Respiratory Illness

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Protocol

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Study Overview:

Background: Respiratory illnesses are among the most common causes for inpatient pediatric hospitalizations every year [1]. The most common respiratory illnesses that make up these hospitalizations include pneumonia, acute bronchiolitis, and asthma [1].

Pneumonia is one of the top three illnesses requiring pediatric hospitalization and is a significant cause or morbidity and mortality [4,5]. The incidence of pediatric pneumonia varies depending on the country and age group, but worldwide the annual incidence in children younger than five years of age is 150 million and approximately 2 million pediatric deaths, per year, are attributed to pneumonia [5]. Therefore, it is important to understand this disease and how it impacts pediatric hospital admissions.

Pneumonia is defined as an acute infection of the lung parenchyma secondary to an infectious etiology such as viruses or bacteria [2,3]. When an infectious organism is present, the defense mechanisms of the body, including the lungs, are disturbed and the resultant inflammation gives rise to parenchymal damage [3]. Symptoms can include fever, cough, and shortness of breath [5]. Findings on imaging can demonstrate infiltrates in the lungs [5]. Vital sign testing can show elevations in a child's heart rate and decreases in the amount of oxygen present in the blood (pulse oximetry) secondary to the infiltrative processes in the lungs.

Pneumonia is the most common serious infection in the pediatric population and accounts for up to 1-4% of all pediatric Emergency Department (ED) visits in the United States (US) [4]. Furthermore, of the pediatric patients that present to the ED with pneumonia, 20-25% are admitted to the inpatient pediatric unit for further management [4]. This decision to admit a child to the hospital depends on various underlying factors including age, medical conditions, and severity of illness [2]. One of the factors that is considered when deciding whether to admit a child to the hospital for pneumonia is oxygen saturation, or the amount of oxygen in the blood.

Bronchiolitis is another common respiratory illness in the pediatric population and is estimated to account for up to 100,000 US hospital admissions annually [6]. There is a seasonality with most infections occurring in the fall and winter months [6]. It is the leading cause of hospitalization in infants and young children with most cases involving children less than two years of age [6].

Acute bronchiolitis refers to lower airway inflammation and obstruction secondary to a viral infection [6]. When a virus infects the terminal bronchiolar epithelial cells of the lower airways in the lungs, damage to these cells results and subsequently causes cellular sloughing and inflammation [6]. This inflammation, coupled with mucous build-up, accounts for the obstruction that is seen in acute bronchiolitis [6]. Symptoms include rhinitis, congestion, cough, tachypnea, wheezing, and accessory muscle use [6]. Like pneumonia, hypoxemia (decreased oxygen content in the blood) can occur with acute bronchiolitis with the most severe complication being acute respiratory failure requiring mechanical ventilation [6].

The third most common respiratory illness that accounts for pediatric hospital admissions is asthma. Asthma affects 1 in 12 children in the US and is a leading cause of ED visits [8]. It is the most common chronic disease in childhood in developed countries and an estimated 8.3% of children in the US had been diagnosed with asthma in 2016 [9].

Asthma is a complex, multifactorial, immune-mediated disease and is defined by episodic and reversible airway constriction and inflammation [8]. Triggers for asthma exacerbations can include infections,

environmental allergens, and other irritants [8]. Smooth muscle constriction in the airways and inflammation/edema result in intermittent and reversible lower airway obstructions [8]. Symptoms of asthma include cough, wheezing, shortness of breath, and chest tightness. Like the other respiratory illnesses mentioned, asthma can also result in hypoxemia.

Respiratory illnesses, including pneumonia, acute bronchiolitis, and pneumonia pose a significant threat to the pediatric population and are major causes of morbidity and mortality throughout the world. In the US, most pediatric hospital admissions are secondary to these illnesses and determining how to best monitor and manage these patients while in the hospital is important. Specifically, the most ideal technique to monitor for hypoxemia is one of current debate.

Currently, there are two main ways to monitor for hypoxemia in a hospital setting. The first is to have a pediatric patient on continuous monitoring, which involves the child being continuously connected to a monitor that displays various vital signs, one of which being oxygen saturation (SpO2). This technique has been studied over the last several years and many concerns have been raised regarding alarm fatigue, or the phenomenon that occurs when a patient is continuously connected to a monitor and the monitor alarms an overwhelming amount [10]. One study found that this form of monitoring was used in up to 50% of children in non-ICU settings and that up to 99% of the alarms did not require clinical action [10]. In fact, this study found that more than 10,000 alarms can occur in a pediatric unit in 1 week and that greater than 150 alarms can occur on any one patient each day [10]. Furthermore, while these continuous monitors are meant to identify patients who are deteriorating, it has been suggested that the efficacy is limited by alarm fatigue and that evidence has not shown them to improve patient outcomes [10]. Finally, a recent study also demonstrated that the second form of monitoring, scheduled vital checks, may be superior to electronic measurements when assessing patients for deterioration [10]. Currently, there are no guidelines to recommend what form of monitoring, continuous monitoring or scheduled vital checks, is superior and studies evaluating the rationale behind widespread continuous monitoring techniques are lacking [10].

Primary Objective:

- To determine if there is a difference in hospital length of stay between patients receiving continuous hardwire cardiorespiratory monitoring and those receiving intermittent vital sign measurements, among pediatric patients admitted for uncomplicated respiratory illness.

Secondary Objective:

- To assess the comfort level of parents in taking their children home prior to complete resolution of illness after having continuous hardwire cardiorespiratory monitoring vs intermittent measurement of vital signs during their hospital stay.

Methodology:

- Randomized, prospective study
- Number of participants: 80

Inclusion Criteria:

- Admission for respiratory illness
- Corrected gestational age greater than 3 months
- Age <14 years
- Admission to Beaumont Children's Hospital Pediatrics Unit, Royal Oak.

Exclusion Criteria:

- Primary admission for non-respiratory illness
- Corrected gestational age less than 3 months
- Age greater =>14 years
- History of Chronic Lung Disease and age less than 1 year
- Home oxygen use
- Tracheostomy dependent
- Neuromuscular disease or hypotonia secondary to a chronic/congenital disease
- Cardiac malformation treated with medication
- Transfers from the Beaumont Children's Hospital Pediatric Intensive Care Unit

Methodology Continued: Participants will be screened and enrolled on the pediatric floor at William Beaumont Hospital. The explanation to participants and the families of the participants (given that participants are minors) will include brief descriptions, in simple terms, of common respiratory illnesses that children are admitted to the hospital for. Participants will be told about the two main ways that we monitor patients admitted for respiratory illnesses (continuous monitoring and vital checks) and that both are considered to be standard of care. Participants will be told that through a randomized process one of these monitoring systems (continuous monitoring or vital checks) will be used through the hospital stay. They will also be informed that if at any point a child required increased monitoring, they will received that increased monitoring and be removed from the study. Participants will be told that they will be given a survey to complete at the time of discharge. They will be informed that no names or identifying information will be presented but that only the chief investigators will have access to that information through the data collecting process. Participants will have the option to opt out of the study at any time and this information will be included in the initial consent explanation. Participants will be given the opportunity to ask questions about their involvement in the study.

Information sheets will be handed out either by nursing staff or the resident working who will be obtaining consent from the family/participants, which will only be Paige Bicoll, DO. The questionnaires will be handed out by nursing staff once the participant has given consent to participate in the study and will be collected by nursing staff prior to discharge. If nursing staff is unable to hand out or collect questionnaires because they are involved in other patient care, residents will be handing out and collecting completed questionnaires.

Proposed Intervention: Randomized assignment to either continuous vital monitoring or vital sign checks (intermittent monitoring every 4 hours). Additionally, a survey will be handed out to parents to gauge their comfort in discharge.

- When a child who meets inclusion criteria is admitted to the pediatric floor, the primary resident conducting the research (Paige Bicoll, DO) will hand out an information sheet to the legal guardian(s) of the child to be enrolled in the study. The resident will then obtain consent from the family and either place the child on continuous monitoring or vital sign checks in the computer. This will be randomized. At the end of the hospital stay, the parents/legal guardians will receive a survey which they will be asked to fill out and return prior to discharge. The length of stay will then be tracked for all patients and a comparison will be made between the two groups (continuous monitoring and vital sign checks). There will be a container of envelopes in the resident work room on the pediatric floor. When there is a child that can be enrolled in the study, the next up envelop will be chosen and it will tell the primary resident which group (continuous

monitoring or vital sign checks) to place the patient in. The patient's MRN will then be placed on the envelop for data collection later on. When the survey is completed, this will also have the patients MRN on it and will be placed with the envelop for data collection.

- If a patient decompensates and requires closer monitoring, the patient will be removed from the study.

Risks: none

Benefits: none

Eligibility Criteria: minors will be included in the study. Pregnant women will be excluded. Neonates and fetuses are excluded. Economically or educationally disadvantaged individuals will not be purposely included or excluded. No information will be gathered regarding economic or educational background on research subjects. Any concern regarding a subject's participation due to economic or educational disadvantages will be addressed on an individual basis. To address educationally disadvantaged individuals, the study participation consent will be explained and written in simple terms.

Data Analysis: Data will be collected on length of stay for all participants and survey answers. The data will be analyzed to determine if there is a difference in length of stay between the two groups and if there is a difference between legal guardian comfort in discharge between the two groups. This information can be used to help guide monitoring guidelines for inpatient pediatric patients with stable respiratory illnesses in the future.

Existing Data: No similar study was done and is available for review in the literature.

References:

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