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Project Title: Pathways for Improving Pediatric Asthma Care (PIPA)- Columbia University/NYP Site
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Study Purpose and Rationale:

Asthma is one of the leading causes of pediatric hospital admissions and emergency room visits,[1] which results in frequent missed school days, significant morbidity and $3.8 billion of costs to the healthcare system.[2] However, treatment of asthma with up to date evidenced based medicine is not universally implemented across hospitals and there have been several studies with conflicting results for reducing length of stay (LOS) via an asthma inpatient pathway, likely due to small study sizes and single center outcomes.[3-7] Therefore, Morgan Stanley Children's Hospital of New York (CHONY) is participating in the Pathways for Improving Pediatric Asthma Care (PIPA) quality improvement project to develop clinical pathways that will make it easier to adopt evidence-based guidelines at the bedside and standardize care nationwide for the treatment of asthma.

Specific Aims:

1. Decrease length of inpatient hospital stay by 10%
2. Increase the percent of patients who receive a respiratory score by 10%
3. Increase early transition to administering bronchodilator medications by metered dose inhalers by 40%
4. Decrease prescription of antibiotics at hospital discharge to 10%
5. Increase second hand tobacco smoke screening to 90%
6. Achieve 50% increase in documentation of referral to smoking cessation resources for eligible patients

Study Design and Statistical Analysis:

CHONY is one of 75 hospitals involved in the PIPA quality improvement study to improve the value of hospital care for children with asthma. The study is a part of the Value in Inpatient Pediatrics (VIP) Network that focuses on quality improvement of inpatient pediatric healthcare of both community and academic hospitals. VIP is part of the Quality Improvement Innovation Networks (QuIIN) at the American Academy of Pediatrics (AAP).

The main aim of this study is to reduce the LOS for pediatric patients (2-17yo) admitted from the ED to the hospital wards for an asthma exacerbation. For the purpose of this study, LOS is measured as time of first set of vital signs taken on the floor to time of discharge order entered into the electronic medical record. The main intervention being studied to reduce LOS is the implementation of a respiratory score developed by the CHONY hospitalists and utilized by newly hired asthma respiratory therapists (asthma-RT). The asthma-RTs were recently hired solely to assist in the management of pediatric patients admitted for asthma in order to improve work flow. The respiratory score was designed by CHONY hospitalists about 1.5 years ago to assist in the decision of weaning albuterol. The score consists of respiratory rate, severity of retractions, dyspnea, and auscultation findings. For each category, a numerical value is assigned and based on the sum, the decision to wean albuterol is made. Patients can only be discharged once they have a stable respiratory exam with albuterol use spaced to every four hours. In order to monitor whether shortening LOS increases the risk of adverse outcomes for patients, data will be collected for the balancing measures of transfers to higher levels of care (ie. Pediatric Intensive Care Unit (PICU)) and readmission to the Emergency Department/hospital within 7 and 30 days of discharge. In order to control for outside factors that could influence LOS, such as new hospital policies, data will be collected for average LOS for all other admission diagnoses during the same time periods and to monitor if the scores are being performed while assessing LOS, data will be collected for the percent of patients who have recorded respiratory scores.

Secondary aims focus on improving overall asthma care by initiating asthma education earlier on during the admission. Initiation of asthma education at time of admission will be standardized as the asthma-RTs role will now include educating the patients and their families about: 1. What is asthma?, 2. Asthma triggers, 3. Asthma medications and administration, 4. Asthma equipment use and maintenance, and 5. Asthma action plan. In order to monitor the education of the patients/families and to assess for overall asthma care, data will be collected on antibiotics prescribed at time of discharge, secondhand tobacco screening, smoking cessation referrals and early transition to metered dose inhalers (MDI).

The study will be conducted in three phases: baseline, intervention, and follow up. The baseline phase consists of retrospective data collection from the year prior to implementing the respiratory score. The intervention phase consists of implementing the respiratory score and training the asthma-RTs, nurses, and residents. The follow up phase consists of collecting data for the year following implementation of the respiratory score.

Statistical Analysis

The data from the baseline period will be compared to the follow up period via an unpaired T test for length of stay. Chi-squared analysis will be used for the secondary aims of antibiotic prescriptions, early transition to MDI use, number of patients with recorded respiratory scores, screening for secondary smoke exposure, referrals for smoking cessation, PICU transfers and ED/hospital readmission.

Sample Size Determination and Power Analysis

Based on preliminary data, the average LOS is 40 hours. To show a difference of 10% in LOS after the intervention with a type I error of 5% and a power of 80%, 26 patients are required for the baseline period and follow up period. According to last year's data, about 300 patients were admitted for an asthma exacerbation that fit the study criteria. Therefore, there should be sufficient sample size to determine statistical significance of the intervention and since this is a quality improvement study, the goal is to obtain data from as many patients as possible.

Study Procedure: The only procedure required for the study is introduction of the respiratory score to the hospitalists, residents, and nurses and development of work flow with the new asthma-RTs. The respiratory score will be introduced to the hospitalists, residents, and nurses at their respective weekly conferences/meetings. All asthma-RTs will be trained in the score prior to starting at their position.

The development of the workflow of implementing the respiratory score by all of the care providers is still under development. Currently, the plan is for the asthma-RTs to place the respiratory scores in each patient room and at time of albuterol administration, the nurse, resident/hospitalist, and asthma-RT will each complete their own respiratory score. During the trial period, an MD must still place an order to wean the albuterol.

Study Drugs: No drugs will be used specifically for the purpose of this study. The medications used for asthma management for each patient will be determined by the clinical team.

Medical Device: No medical device will be specifically used for the purpose of this study. Any medical device used (ex. Spacer, nebulizer, peak flow monitor) will be determined by the clinical team.

Study Questionnaires: No questionnaire will be utilized in this study.

Study Subjects: Pediatric patients age 2-17 admitted with the primary diagnosis of asthma exacerbation, excluding patients with comorbid conditions, including chronic lung disease, congenital/acquired heart disease, airway issues, immune disorders, sickle cell anemia, and neuromuscular disorders

Recruitment: Patients, hospitalists, residents, and nurses will not be actively recruited into the study. The respiratory score will be placed in each subject's room to encourage its use and made electronically available.

Confidentiality: Data will be stored in a secure database and access will be limited to the necessary, trained study personnel. The data will de-identified prior to sharing with any other sites involved in PIPA project.

Potential Conflict of Interest: There are no conflicts of interest for any of the investigators.

Location of Study: CHONY Inpatient Pediatric Floor Units

Potential Risks: There is minimal risk to the asthma patients from which the data is collected as it will be a retrospective chart review. However, there is a risk of loss of confidentiality, which will be minimized by storing data on secure sites, limiting access to only qualified study personnel, and deidentifying all information. There are no significant risks anticipated for the residents, hospitalists, nurses, or asthma-RTs.

Potential Benefits: The patients may benefit from decreased LOS by reducing missed school days and faster return to regular activities for improved quality of life and will hopefully have improved education on the pathophysiology and management of asthma to prevent future exacerbations and admissions. Aside from potential improved work flow and increased understanding of asthma management, there are no direct benefits to the residents, nurses, or hospitalists. The hospital may benefit from decreased LOS by reduced costs and increased bed availability for other patients.

Alternative Therapies: N/A

Compensation to Subjects: No compensation will be provided to anyone involved in the study.

Costs to Subjects: The balancing measures will be followed closely to assess for additional costs placed on the patients if reducing LOS results in representation to the ED or admission to the hospital.

Minors as Research Subjects: Data will be collected on pediatric patients (2-17yo) but given the nature of the retrospective chart review, where it will be difficult to contact the patients after discharge and the study is to standardize care at minimal risk to patients, a waiver of consent will be applied for and precautions to protect the identity of the patients will be taken as described above.

Radiation or Radioactive Substances: No additional radiologic studies are being performed for the purpose of the study outside what is determined medically necessary by the clinical team.

References

[1]Agency for Healthcare Research and Quality. Overview of Hospital Stays for Children in the United States, 2012 2014. Available from: ttps://hcup-us.ahrq.gov/reports/statbriefs/sb187-Hospital-Stays-Children-2012.pdf

[2]Centers for Disease Control. Asthma Surveillance Data 2016 [August 2, 2018]. Available from: https://www.cdc.gov/asthma/pdfs/Asthma_Facts_Program_Grantees.pdf

[3]Silber JH, Rosenbaum PR, Wang W, et al. Auditing Practice Style Variation in Pediatric Inpatient Asthma Care. *JAMA Pediatrics.* 2016; 170(9):878–886. doi:10.1001/jamapediatrics.2016.0911

[4]Morse RB, Hall M, Fieldston ES, et al. Hospital-Level Compliance With Asthma Care Quality Measures at Children's Hospitals and Subsequent Asthma-Related Outcomes. *JAMA.* 2011; 306(13):1454–1460. doi:10.1001/jama.2011.1385

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[6]Wisnivesky JP, Lorenzo J, Lyn-Cook R, *et al.* Barriers to adherence to asthma management guidelines among inner-city primary care providers. *Ann Allergy Asthma Immunol*. 2008; 101(3):264-70. doi: 10.1016/S1081-1206(10)60491-7.

[7]Johnson DP, Arnold DH, Gay JC, *et al.* Implementation and Improvement of Pediatric Asthma Guideline Improves Hospital-Based Care. *Pediatrics*. 2018; 141(2). pii: e20171630. doi: 10.1542/peds.2017-1630.