

Feasibility and Acceptability of the Propeller Electronic Monitoring Device in Children with Persistent Asthma
Version 13; June 23rd 2022 Propeller Health Study

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DOES THIS PROJECT INVOLVE ANY NICU RESOURCES? ☒ NO ☐ YES
(patients/families, clinical/non-clinical staff, medical records)

IF YES, HAS IT BEEN REVIEWED BY DR. MOORE OR A DESIGNEE? ☐ NO ☐ YES

IF YES, SPECIFY REVIEWER: _____

IS THIS A STUDENT OR TRAINEE PROJECT? ☒ NO ☐ YES

IF YES, INDICATE LEVEL: ☐ Medical/Dental Student
☐ Resident
☐ Fellow
☐ Undergraduate
☐ Other (specify _____)

IF YES, HAS FACULTY ADVISOR REVIEWED THE PROTOCOL? ☐ NO ☒ YES

Note: Student/trainee researchers are required to attend the Scientific Review Committee meeting when their protocol is discussed.

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Version 12; May 10th 2022 Propeller Health Study

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Background/Introduction

Asthma is a respiratory condition marked by bronchoconstriction and difficulty breathing. It is a chronic disease that affects 1 in 13 people and 8.4% of children. Asthma is a leading cause of school absences in children < 18 years old, accounting for more than 13.8 million missed days of school in 2013. Asthma causes a huge financial burden, with medical and loss of work days totaling an average of \$81.9 billion dollars annually.¹

Asthma cannot be cured, but it can be treated with preventive inhalers (inhaled corticosteroids) and rescue inhalers (albuterol). Inhaled corticosteroids and albuterol rescue inhalers are therapeutic mainstays in asthma treatment. Patients with asthma, however, often have low medication adherence, with non-adherence rates ranging between 30-70%.² Asthma patients frequently are non-adherent to their control inhaler for a variety of reasons, including cost, forgetfulness, awkward social situations, and lack of symptom presentation.

According to a recent study³, older children have worse adherence rates than their younger peers, despite having a better understanding of the condition and limitations it might cause. Preliminary evidence suggests that electronic monitoring devices (EMDs) can improve adherence, when implemented and used properly.

Preliminary studies indicate that the Propeller electronic monitoring device (Propeller) can improve adherence rates in children and adults by 34-38%.⁴ It has also been shown to improve symptom-free days and reduce rescue inhaler use.⁵ Propeller is a sensor that attaches to inhalers and uses Bluetooth connection to smartphones to remind patients to take their medication. It also records use of the controller and rescue inhalers, allowing for parents, physicians, and patients to get a fuller and more accurate picture of their adherence to treatment and severity of disease. Thus, EMDs have the potential to successfully help patients to overcome barriers to non-adherence. With improved adherence, asthma control should improve, resulting in a decreased costs and use of services. Not enough is not known, however, about patients' and families' perspectives on the feasibility and acceptability of EMDs. This is critical information, as children and adolescents are more likely to use a device that is acceptable and does not draw peer attention. In addition, device feasibility and acceptability determine how likely a patient is to use the device.⁶

¹ "AAFA." *Asthma Facts* | AAFA.org, www.aafa.org/page/asthma-facts.aspx.

² Lindsay, John T, and Liam G Heaney. "Nonadherence in Difficult Asthma – Facts, Myths, and a Time to Act." *Patient preference and adherence* 7 (2013): 329–336. PMC. Web. 12 June 2018.

³ Elizabeth L. McQuaid, Sheryl J. Kopel, Robert B. Klein, Gregory K. Fritz; Medication Adherence in Pediatric Asthma: Reasoning, Responsibility, and Behavior, *Journal of Pediatric Psychology*, Volume 28, Issue 5, 1 July 2003, Pages 323–333, <https://doi.org/10.1093/jpepsy/jsg022>

⁴ Hoch, H., Kaye, L., Gondalia, R., Theye, B., Barrett, M., Van Sickle, D., Szeffler, S. Stempel, D. (2018). Benefit of Smartphone Alerts to Improve Adherence to Inhaled Asthma Controllers. *Annals of Allergy, Asthma & Immunology*, 121(5), S40.

⁵ Barrett, M., Combs, V., Su, J. G., Henderson, K., Tuffli, M., & AIR Louisville Collaborative. (2018). AIR Louisville: addressing asthma with technology, crowdsourcing, cross-sector collaboration, and policy. *Health Affairs*, 37(4), 525-534.

⁶ Foster, Juliet M., et al. "Patient-Perceived Acceptability and Behaviour Change Benefits of Inhaler Reminders and Adherence Feedback: A Qualitative Study." *Respiratory Medicine*, vol. 129, 2017, pp. 39–45., doi:10.1016/j.rmed.2017.05.013.

Research Question

Is the Propeller system feasible and acceptable for children, adolescents and young adults with persistent asthma following an acute, severe exacerbation?

Primary and Secondary Aims

Assess the feasibility and acceptability of Propeller by evaluating adherence and acceptability survey data one month and three months after an emergency department (ED) visit or hospitalization due to an asthma exacerbation

Outcomes will include:

- Adherence
- Asthma control
- Number of emergency department visits and revisits
- Number of hospitalizations and readmissions
- Number of missed school days and parental work days
- Quality of life
- Symptom-free days

Hypothesis 1: Children, adolescents, and young adults with poorly controlled asthma will find Propeller feasible and acceptable, and Propeller will result in improved medication adherence and asthma control.

Outcome Definitions/Data Points Collected

The primary outcome is regular Propeller use. This will be assessed by recording the number and percentage of the children, adolescents, and young adults still using Propeller one month and three months after initiation. This information will be collected from the Propeller Portal, which provides information on daily use, number of control-inhaler doses, and number of rescue-inhaler doses. Acceptability will be determined by phone interview and survey response to the modified Adolescent Medical Devices Assessment Toolkit (AMDAT)⁷ at one and three months follow-up. Kids under the age of 8 will not be completing the quality of life questionnaires. This includes the PedsQL, TAI and AMDAT questionnaire. Participants will also complete the Asthma Control Test (ACT) at enrollment and one and three months post-enrollment. The purpose of these surveys is not only to determine Propeller feasibility and acceptability, but also to examine the impact on asthma outcomes, including the number of hospitalizations, physician visits, ED visits, activity-level changes, and number of symptom-free days.

At enrollment, and at one and three months post-enrollment, both participants and parents will complete the asthma PedsQL, which is designed to assess quality of life in pediatric patients with asthma. The number of missed days of school and work within the last month, visits to the

⁷ Howard, Sam, et al. "See I Told You I Was Taking It! – Attitudes of Adolescents with Asthma towards a Device Monitoring Their Inhaler Use: Implications for Future Design." *Applied Ergonomics*, vol. 58, 2017, pp. 224–237., doi:10.1016/j.apergo.2016.06.018.

pediatrician, and ED department visits and hospitalizations in the last month will be collected via self-report. **Study Design**

This study is a prospective cohort study using a pre-/post-design.

Target Population

The target population consists of children, adolescents, and young adults ages 4-18 years old making an ED visit, pulmonary clinics, primary care clinics, or admitted to the hospital at Connecticut Children's Medical Center for an asthma exacerbation.

Inclusion/Exclusion Criteria

Inclusion Criteria:

1. Children, adolescents and young adults between 4-18 years old at the:
 - a. ED or inpatient setting presenting with an asthma exacerbation
 - b. Pulmonary Clinics presenting with a diagnosis of asthma. Pediatrics at CHC with Persistent asthma
 - d. Primary care clinics East and West.
2. History of asthma (defined as prescribed a controller medication)
3. Both the child and primary caregiver/parent or adult (18 y/o) participant have access to a smartphone with an activated number
4. Ability of adult (18 y/o) participant or child's parent/legal guardian to understand and the willingness to sign a written informed consent document.

Exclusion Criteria:

1. Participant or parent has no access to a personal smartphone.
2. The participant has another chronic pulmonary condition (for example, cystic fibrosis)
3. Having any chronic condition that could affect the participant's ability to participate in the study (examples: cancer, autism, or cerebral palsy)
4. The subject has an inhaler medication besides the following, given these are the current medications compatible with Propeller.
 - i. Advair HFA
 - ii. Flovent HFA
 - iii. QVAR HFA
 - iv. Ventolin HFA
 - v. ProAir HFA
 - vi. Symbicort
 - vii. Dulera

5. Family/participant does not consent to sharing study information with their primary care provider.

Sampling Method/Recruitment Process

Potential participants will be identified from the inpatient, Pulmonary, primary care and ED logs at Connecticut Children's Medical Center by monitoring for hospitalizations, ED visits for asthma exacerbations and a diagnosis of asthma. We will also be identifying participants at Connecticut Pediatrics at CHC Hartford for patients with asthma. Study personnel scans the EPIC logs everyday for kids with asthma scheduled to come in for a clinic visit (outpatient) or for those newly admitted to the ED or hospital. The RA then calls patients to introduce the study and determine interest.

Consenting process will be completed in person in the ED and inpatient following the correct COVID-19 screening procedures or via phone call or zoom meeting by consenting electronically. Recruitment will be capped at 100 participants, as the sponsor, Propeller Health, will provide only enough EMDs for 100 patients. Potential participants' age, gender at birth, gender identification, race/ethnicity, and whether they have their own mobile phone will be recorded. Participation is voluntary, and potential participants and families are free to refuse participation in the study. Informed consent and assent of both the parent and the child, or young adult participant, will be required before completing a baseline survey, Asthma Control Test, and PedsQL.

Study Retention/Withdrawal

Participants will be tracked through follow-up phone calls at one month and three months post-enrollment, during which they will answer a brief survey, the adapted AMDAT, PedsQL, and ACT. Additionally, participants will be monitored through the Propeller Web Portal, which generates weekly reports on control and rescue inhaler use.

Participation is voluntary, and participants can withdraw from the study at any time. Those withdrawing will be asked to provide a brief exit interview about their opinions regarding Propeller and their reasons for withdrawal. Losses to follow-up and withdrawals will be tracked.

Study Procedures

All patients will receive two Propeller devices (for controller and rescue inhalers), access to the Propeller app for their smartphone, and a free Propeller subscription, which provides access support and services, and hardware and software updates. Both the patient and parent/caregiver will have the app on their smartphone. Families will be required to share study information with their primary care provider, allowing provider to track the participant's adherence via Propeller web portal. The provider will not have Propeller app on his or her smartphone. Families who do not consent to sharing study information with their provider, will be excluded from study.

Data collection will begin as soon as the participant enrolls, and will continue through the three-month follow-up. Propeller Health also provides the option of continuous monitoring

and data collection beyond study cessation.

Data uploads to the portal occur automatically for patients and caregivers who have installed the Propeller App on their smartphone. Additionally, patients' primary-care providers will receive a password allowing them to track and access participants' dashboard. Patients will bring a letter to their primary-care provider explaining that they are part of a study of Propeller Health's EMD, and receive instructions on how to view the dashboard and adherence data.

At enrollment, participants and their parents will complete the ACT and PedsQL, along with providing baseline medical history/asthma history data and sociodemographic information. The ACT and PedsQL surveys will again be completed one and three months post enrollment information. Additionally, participants will answer an adapted AMDAT survey that will be used to provide input on the Propeller device.

Data collected by surveys and interviews will be entered into an excel spreadsheet. Data accuracy and quality will be ensured by double entry. All personnel will be taught how to accurately collect data and follow the same script for the phone-call interviews and surveys, to ensure consistency.

Sample Size Justification

This is a mixed-methods study of feasibility and acceptability, so no sample-size calculation is needed.

Feasibility, Accrual, and Expected Duration of Accrual

On average, five patients are admitted weekly to the CT Children's inpatient ward for an asthma exacerbation. An average of 100 patients are seen in the ED each week for asthma exacerbations. The Pulmonary Clinic at CCMC sees 15-30 patients/day at the Hartford location with 75% of the children having a diagnosis of asthma (~10-20/day), half of whom will be in the desired age range (~5-10) and will be screened. We anticipate enrolling 4-5 subjects/week through the pulmonary clinic, primary care, ED and inpatient and CHC. Patients will be enrolled for three months.

Study Limitations

Not every 4-18 year-old approached will have a smartphone, which could limit generalizability. Additionally, device use cannot be enforced, which could affect the study findings. Other potential limitations include selection bias, as those who agree to take part in this study might be more interested in EMDs; the lack of randomization; and the lack of a control group.

Data Analysis

Statistical tests will be performed to compare baseline, one-month and three-month outcomes, including adherence, asthma control, number of ED visits and revisits, number of hospitalizations and readmissions, number of missed school days and potential work days, quality of life, and symptom-free days. We will use the Chi-square-test or Fisher's exact test to analyze categorical outcomes, such as adherence. For continuous outcomes, such as symptom-

free days, ANOVA or the Wilcoxon non-parametric test will be performed. Pairwise post-hoc tests, such as Fisher's exact test or the t-test, will be conducted, when appropriate. A two-tailed p-value < 0.05 will be considered statistically significant. Mixed logistic regression or mixed linear regression will be used to model repeated-measures outcomes, adjusting for relevant covariates such as age, gender, and race.

Administrative Organization/Roles and Responsibilities

Dr. Jessica Hollenbach, , is responsible for overseeing the proposed project, along with co-investigators, Dr. Alexander Hogan, Dr. Kristin Welch, Dr. Melanie Sue Collins.. Dr. Hogan will supervise IMT recruitment and ED recruitment.. Dr. Melanie Sue Collins will supervise pulmonary recruitment. Dr. Catherine Wiley will supervise Primary care recruitment. Dr. Hollenbach will monitor data collection and advise on study procedures. They will receive logistical support from Sigrid Almeida (Study Coordinator), who will perform recruitment and data collection and qualitative data analysis. Megan Civitello and Abigail Tulchinsky are undergraduate students at UCONN, They will both assist with patient recruitment, data collection, and qualitative data analysis.

Use of Study Results

The study results will be used to determine whether Propeller is feasible and acceptable for children and adolescents with asthma. The study findings will result in a presentation at a national professional conference and a publication in a peer-reviewed journal. These results also will serve as preliminary data for a larger randomized controlled trial and potentially inform future clinical practice.

Study Budget

This device sponsor is Propeller Health. They will provide EMDs, technical support, and training for all participants, but they will not be providing any medications. Connecticut Children's will provide honoraria for all participants and in-kind support for statistical and RA services.

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