Title of Project: iTRACC (Improving Technology-Assisted Recording of Asthma Control in Children)

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Background

Asthma Epidemiology

An estimated 8-10% of children under 18 years of age in the United States (6.3 million) have asthma, although the actual number of children affected is probably higher, as pediatric asthma is often under diagnosed and/or underreported.[1,2] It has been shown that the prevalence of asthma is higher among children living in urban inner-city environments, children with low socioeconomic status, and children with poor access to primary care.[3] In Chicago, prevalence of asthma is substantially higher, with 13.9% of children living with asthma.[4,5] Furthermore, the distribution of asthma in Chicago is highly variable by neighborhood ranging from 2% in some neighborhoods to 44% in others.[4] Asthma rates also vary by race in Chicago, with rates among Africa Americans (21.2%) roughly double those of Whites (9.7%) and Hispanics (11.8%).[6] Children affected by asthma may have impaired health-related quality of life, frequent emergency hospitalizations and school absences, and even death if the disease is not managed appropriately.[7] In addition to emergency department visits, children with asthma are at increased risk of inpatient hospitalization. Asthma is the third-ranking cause of hospitalizations, with more than 200,000 per year,[8] for children under 15 years of age[9] and is the cause of almost 5 million doctor visits.[8] The estimated total annual cost for treating asthma is $56 billion.[10] This huge cost affects not only hospitals but insurers and families as well, as the average cost per child is $1,042.[11] Furthermore, there are other costs to families, such as the indirect costs of decreased productivity and reduced quality of life among both asthmatic children and their parents.[12] Reducing unnecessary costs associated with poorly-controlled asthma is therefore essential to having a significant financial impact on both the healthcare system and affected families.

Asthma Management

For most children with asthma a cornerstone of asthma management is daily use of inhaled corticosteroids (ICS) to prevent exacerbations. Regular use of these "controller" medications, as prescribed, have been demonstrated to reduce airway inflammation and improve asthma outcomes.[13] However, adherence to these preventive therapies has been repeatedly demonstrated to be suboptimal which has led to reduced asthma control in pediatric populations.[14-16] A landmark study in the New England Journal of Medicine found that regular use of controller meds by asthma patients ages 5-44 may reduce asthma-related hospitalization risk by up to 80% and that a patient's risk of death is reduced 21% for each ICS canister used in the prior year.[16] Evidence suggests that Short-acting Beta Antagonist (SABA) "rescue" medications typically prescribed as-needed to patients for treatment of exacerbations, are also occasionally not used as prescribed, leading to suboptimal outcomes.[18]

Most children between 4 and 17 years of age rely on their parents or caregivers for the management of their asthma. Besides ensuring their child's asthma therapies are administered as prescribed, successful asthma management entails knowledge and avoidance of asthma triggers, establishment of an asthma action plan, and the ability to reference it effectively in the event of an exacerbation.[20] This management is often multidimensional, involving the interaction of family, healthcare, and school systems,[21] with the family system having the largest influence on daily asthma management decisions. It may be significantly difficult for families to acquire management skills and adhere to treatment plans, depending on the severity of their child's asthma.[22, 23] One study found that

caregivers who report their child's asthma as more burdensome may find it more difficult to effectively manage, which may in turn increase the risk of unnecessary asthma-related emergency department (ED) visits.[24]

Technology

In recent years, advances in health technology have facilitated the development of various electronic monitoring devices, which aim to improve asthma control by providing objective, detailed, and accurate information about day-to-day patient adherence.[25] Propeller Health utilizes telehealth concepts, including an FDA-approved sensor, mobile apps, predictive analytics, and feedback to help patients and providers better manage asthma.[26,27] The sensor monitors the use of inhaled medications (both rescue inhaler and controller inhaled corticosteroid), capturing the date, time, and number of uses. The sensor transmits this information via Bluetooth to a paired smartphone or hub and securely uploads all data to the cloud. Location data is captured if the sensor is connected and within range to the smartphone at the time the sensor is used. Data is transmitted back to the caregiver's smartphone app or to a web portal and to the their physician and care team to help facilitate improved asthma management by both the caregiver and health care team.[28]

Preliminary Work

Our team has a long-standing history of asthma work, including assessing asthma prevalence and factors associated with described disparities in Chicago. After surveying over 40,000 Chicago schoolchildren, we found asthma prevalence to be 9.7% for white children and 21.2% for Black children.[6] We also found that asthma varies by the child's neighborhood, spanning from 2% to 44%, even in adjacent neighborhoods.[4] We have also published on asthma management and barriers to adherence of guidelines by physicians. Our team members also lead the Asthma Clinical Care Guideline Committee at Lurie Children's Hospital. The interventions put into place by this team have led to hospital-wide decreases in length of stay without increases in readmissions. Furthermore, we developed an inpatient pediatric asthma scoring system that demonstrated good predictive ability, inter-rater agreement, and severity correlation. This scoring system allows for objective evaluation of patients both during initial presentation and for continued assessments as patients receive treatment in the urgent care, emergency department, and inpatient settings.

Our team has worked on many technology-integrated projects in the past focusing on childhood chronic diseases. A successful patient-focused intervention called SMART (Student Media-based Asthma Research Team) was implemented in three separate schools throughout Chicago.[29-31] In these interventions, we partnered with adolescents with documented asthma to learn more about their communities and the factors that negatively or positively affect their asthma. Technology, including photo cameras and video cameras, were used with the goal to empower the student participants to ultimately improve their asthma knowledge and self-efficacy while also promoting asthma awareness in the surrounding community.

We have also developed and tested a low-health literacy Visual Asthma Action Plan to improve physician care, and to bridge the gap between the management counselling received in the primary care setting improve control and management at home.[32] Our team members also utilized a multidisciplinary team of providers to create an electronic asthma action plan available in Epic that can be used in both inpatient and outpatient centers, improving communication between these two arenas. Also within the inpatient arena, our team members have developed best practice alerts to ensure patients are being appropriately weaned on their medications based on reported exam findings.

Finally, we have also worked in Epic to create a clinical decision support tool for primary care physicians to effectively diagnose and treat food allergy. The tool incorporated NIAID guidelines to direct physicians to improve documentation and management of food allergies.[33]

The goal of this study is to determine whether a sensor-enabled, clinically integrated, mobile health asthma program can improve asthma outcomes among 4-17 year old children with moderate-to-severe asthma.

Objective: To improve overall asthma control and asthma management among children 4-17 years old with moderate-to-severe asthma.

Study Aims: For children 4-17 years old with moderate to severe asthma we will:

1) **Determine factors influencing clinical and psychosocial outcomes.**
   We will use clinical chart review data, as well as parent report of the following clinical asthma-related outcome measures:
   1) Asthma-related oral corticosteroid use; 2) Asthma-related ED visits 3) Asthma-related hospitalizations; 4) Asthma symptom control, as measured by the Asthma Control Test (ACT) for adults and childhood Asthma Control Test for children. In addition, patient demographics, co-morbidities, and parent and physician management factors (measured in in aim 2 and 3) will be assessed.

   We will use parent-report surveys of the following psychosocial outcome measures:
   1) Days missed from school due to asthma; 2) Pediatric Asthma-Related Quality of Life (PACQLQ); and 3) Parental Asthma Management Self-Efficacy (PAMSE).

2) **Enhance parental management through improved inhaler use.**
   We will use the Propeller Sensor Platform (referenced as Remote Health Management Platform) to allow parents to track their child's ICS and SABA inhaler use daily (please see the appendices for a list of inhalers that are compatible). The Platform also will have specific educational messaging to help parents and their children achieve adherence to their prescribed plan. This constant feedback and reinforcement may lead to improved asthma control therefore reducing frequency and severity of asthma exacerbations. We will also be assessing the factors associated with the feasibility and sustainability of the Propeller Sensor Platform by observing trends in utilization. Utilization and drop-off will be measured by monitoring use of the inhalers and periodic surveys of families.

3) **Improve management by the healthcare team.**
   We will use the Remote Health Management Platform to integrate inhaler use data into a web portal that the physician's office can access. Through the development of this interface, the Propeller Sensor Platform will be able to provide inhaler use feedback to healthcare teams. Types of feedback:
   - Emergency Management: data on ICS and SABA use
   - Long-term Management: data on ICS and SABA use

   This interface will include data on both ICS and SABA inhaler use. The interface will also have flags to notify the office of under or overuse of inhalers, with a protocol in place to reach out to patients. We will also be assessing the factors associated with the feasibility and sustainability of the Remote Health Management Platform by the healthcare team. This will be done by weekly contact with the healthcare team, rapid cycle improvement of the web portal, and written assessments. Follow-up assessments through interview will be conducted at the end of the trial with health providers.
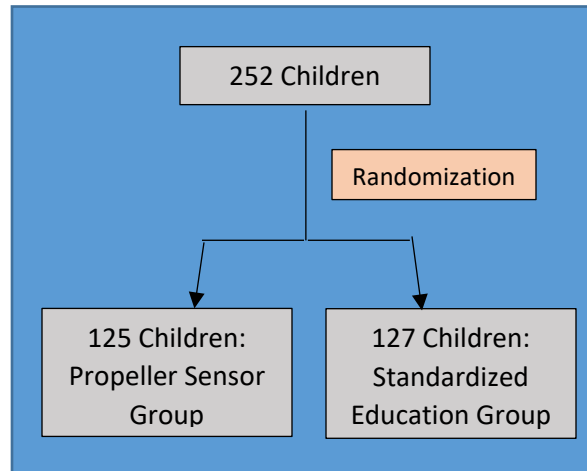
Figure 1. Study Arms

Participant Sites

The participant sites will be pediatric clinics in the Chicagoland Area. Each site in this proposed study has a strong history of research collaborations with Dr. Gupta, which includes the ability to recruit and retain patients in research studies.

We will be recruiting from at least four of the following sites:

- Children's Healthcare Associates
- Chicago Family Asthma and Allergy
- Clark/Deming Resident Clinic (Lurie Children's)
- Pulmonary Clinic (Lurie Children's)
- Lurie Children's Uptown Clinic

Study Design and Procedures

1. **Design:** We will conduct a randomized controlled trial comparing asthma inhaler use and asthma-related outcomes between children who either receive the Remote Health Management Platform (intervention) or Standardized Education (control) for asthma management. We will use a prospective cohort design to determine the effect of the intervention on the aforementioned outcomes.

   We will enroll patients from Chicago pediatric clinics, as well as inpatient units at Lurie Children's Hospital. At enrollment, we will randomize children to either the Remote Health Management Platform (intervention) group or the Standardized Education group (control).

   Children in the Standardized Education group will receive education about NAEPP guideline-based asthma management, including asthma action plans and appropriate and effective inhaler use. During the initial visit, the child participants will get ImmunoCAP allergen testing to ascertain their environmental allergens. This is a simple blood draw that can help further guide the knowledge and overall management of the child's asthma. Allergen testing is not mandatory to participate in this study. They will also receive education on the benefits of an active lifestyle on asthma control and other health outcomes, appropriate physical activity types for asthma control (e.g., aerobic, moderate-intensity physical activities), setting goals for physical activity (e.g., daily step counts, one-hour of moderate-intensity physical activity per day), and recommendations for self-monitoring physical activity levels.

At the enrollment visit, children in the intervention group and their families will receive all devices and software needed to track inhaler use and physical activity, as well as the education that the Standardized Education group receives. The Remote Health Management sensor will be enabled so that both caregivers and healthcare team will be able to track the child participants' inhaler use. The software platform will provide participant families with tailored educational material via a mobile device-based app. A research assistant will provide the education on how to use the sensor device and the app, as well as the standardized education as described above. The child participants will also obtain allergen testing via ImmunoCAP.

All participants will be assigned a study ID number prior to the collection of baseline measurements. Data will be de-identified and linked only by their study ID number. Data from the sensor will be uploaded to a cloud-based storage facility for analysis.

2. **Inclusion Criteria:**
   a. English-speaking parents of:
      i. Children 4-17 years of age. Using both NHLBI (National Heart, Lung, and Blood Institute) guidelines and based off of a physician expert panel, the research team has limited the ages to 4-17 years old. It has been shown to be difficult to properly diagnose individuals less than 4 years of age with asthma. Usually, they are diagnosed with reactive airway disease or bronchial virus.
      ii. Moderate-to-severe persistent asthma, defined by the National Heart, Lung, and Blood Institute. This will be done by a physician-trained RA who will be able to identify potential participants prior to recruitment.
      iii. At least one asthma exacerbation that required a course of oral corticosteroids in the past year
      iv. Prescription and utilization of an ICS inhaler for at least the past year.
      v. Who are seen at: Clark and Deming Resident Clinic, Lurie Children's Pulmonary Clinic, Lurie's Uptown Clinic or Chicago Healthcare Associates
   b. Exclusion criteria:
      i. Non-English speaking parents/families
      ii. Patients seen in the hospital who receive primary care outside of the study's clinics
      iii. Children with any comorbid conditions, which interfere with appropriate assessment of asthma symptoms: Chronic Lung Disease, Broncho-Pulmonary Dysplasia, Cystic Fibrosis, Pulmonary Hypertension, Interstitial Lung Disease, Immunodeficiency, Bronchiectasis, Primary Ciliary Dyskinesia, Chronic Respiratory Insufficiency, Neuromuscular Weakness, Sickle Cell Lung Disease, Restrictive Lung Disease, and Tracheostomy or Ventilator-dependence
      iv. Child-patients who are participating in any other research studies that would interfere with our ability to use and track the inhaler sensor

3. **Pilot Phase**
   a. 10 children and their families will be recruited by their healthcare provider to join this study for 30 days. After enrollment, participants in the pilot phase will receive the Remote Health Management device, as well as the same training and education that the Intervention group will receive, including the allergen testing.

Enrollment: Informed consent will be obtained at the time of enrollment. Families in the Intervention arm will receive Remote Health Management sensors. Data collected at the time of enrollment will include the following for each participant:

    a. Basic demographic and clinical history data (obtained by a review of medical records)
   - a. Include: name, date of birth, date of asthma diagnosis, zip code, history of a course of oral corticosteroid, current medications, phone call/email history to the clinic, asthma exacerbation history, and history of asthma-related ED visits and hospitalizations.
   - b. Parent questionnaires, including the Asthma Control Test (ACT), Parental Asthma Management Self Efficacy (PAMSE) scale, intervention survey, and the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ).

    b. A member of the research team will go in person to each clinic once per week to ensure that the pilot phase is running smoothly and optimally.

    c. A member of the research team will conduct telephone interviews with these families one week after enrollment. These phone calls will determine how the device is working, if participants foresee any obstacles to the use of the device, and to answer any other questions participants might have.

    d. A member of the research team will reach out to enrolled parents via phone, text, or email once a week (4 times in total) to inquire about how well the device is working, and if this is a feasible Platform to use.

    e. After 30 days, a member of the research team will again conduct interviews to get feedback. This pilot group will continue to use the device for one full year and will assist us with trouble shooting throughout the intervention.

4. **Enrollment/Visit 1/Baseline Measurements**

   Informed online consent will be obtained at the time of enrollment. The consent form will be stored utilizing REDCap, which is a secure, online software. Families in the Intervention arm will receive Remote Health Management sensors. Data collected at the time of enrollment will include the following for each participant:

       c. Basic demographic and clinical history data (obtained by a review of medical records)
      - a. Include: name, date of birth, date of asthma diagnosis, zip code, history of a course of oral corticosteroid, current medications, phone call/email history to the clinic, asthma exacerbation history, and history of asthma-related ED visits and hospitalizations.
       d. Parent questionnaires, including the Asthma Control Test (ACT), Parental Asthma Management Self Efficacy (PAMSE) scale, and the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ).

   All enrolled children, regardless of study arm, will have allergen testing via ImmunoCAP. This is a simple blood draw that can help further guide the knowledge and overall managements of child's asthma. This will be incorporated into the Remote Health Management software for the intervention group and be disclosed to the control group as well. The volume of the blood to be drawn for the assessment is 1.3 mL of serum or plasma is required to process the allergen panel we intend to use in the study.

5. **Daily Inhaler Use Management**

The Remote Health Management team (Propeller Health) utilizes telehealth concepts, including an FDA-approved sensor, mobile apps, predictive analytics, and feedback to help patients and providers better manage asthma.[11,12] The sensor monitors the use of inhaled medications (ICS and SABA), capturing the date, time, and number of uses. The sensor transmits this information via Bluetooth to a paired smartphone or hub. The location of the event is also securely uploaded to the cloud if the sensor is connected to the Smartphone at the time the sensor is used. Data can be uploaded to the caregiver's smartphone and to the patient's web portal, which their healthcare team will have access to help overall management.[13]

The sensors will be distributed to participants by the study team. We will aim for participants to engage with the study team before going to the clinic or hospital so the device is ready to use at the time of their appointment. This will require the participants to call the research team and the consent being described over the phone to the participants. At their appointment and when the device is given, the participants will sign the consent.

6. Randomization

After recruitment, participants will be stratified by age, sex, and insurance status. They will then be randomly assigned to one of the two study arms.

After recruitment, participants will be stratified by age (4-7 vs 8-17), sex (M vs F), and insurance type (private vs. public), resulting a total of eight strata (stratum1: 4-7, M, Private, stratum2: 4-7, M, Public, stratum3: 4-7, F, Private, etc.). Since this is not a double-blind study and no centralized randomization system will be implemented, one randomization schedule will be generated for each site. Each randomization schedule will contain all eight strata. To ensure balanced treatment allocations within each stratum, 20 randomization blocks will be generated within each stratum. Each block has a block size of 4 with a random permutation of treatments A and B (eg, block 1=AABB, block2=ABBA, etc). Each site's randomization schedule will begin with a distinct randomization sequence number which is different from the subject ID number. For example, site 1's randomization schedule will begin with randomization sequence number 100001, site 2's randomization schedule will begin with randomization sequence number 2000001, etc.

The site investigator will assign the randomized treatment to a patient in the sequential order, based on the stratum the patient belongs to.

7. Intervention
   a. After enrollment, participants in the Remote Health Management Sensor group will have the full Remote Health Management Sensor Platform (i.e. mobile application, physician access to inhaler use data, etc.). Research staff will review uploaded sensor data on a daily basis. If participants are enrolled into the control group, they will only receive Standard Asthma Education. The Standard Asthma Education follow the NAEPP (National Asthma Education and Prevention Program) guidelines for asthma management. This will include the following list of topics: 1. What is Asthma (Explanation of symptoms); 2. Asthma triggers (what those are and how to avoid them); 3. Using medications (how to use prescribed asthma medications, the difference between controller medications and rescue inhalers, how to appropriately use a spacer, how to appropriately use a mask); and 4. Managing asthma control (purpose of asthma control test and how to complete it, purpose of an asthma action plan and how to read and complete it, how to appropriately use a peak flow meter).

b. All participants will receive allergen testing, done by their physicians to ascertain their environmental triggers. This will be incorporated into the Remote Health Management software for the intervention group.
c. If uploaded data reveals elevated SABA use, healthcare team staff will be expected to contact caregivers if needed to ascertain the context of the elevated use and schedule appointments as needed. Information regarding this contact will be documented in the patient's EMR and available to researchers.
d. The Remote Health Management Platform will send education, based on management plan and identified asthma triggers, to participant in the intervention group.

8. **1 month from start of enrollment**
   a. Control Arm- Caregivers will take the ACT, PAMSE, iTRACC survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.
   b. Intervention Arm- Caregivers will take the ACT, PAMSE, intervention survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.

9. **3 months from start of enrollment**
   a. Control Arm- Caregivers will take the ACT, PAMSE, iTRACC survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.
   b. Intervention Arm- Caregivers will take the ACT, PAMSE, intervention survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.

10. **6 months from start of enrollment**
    a. Control Arm- Caregivers will take the ACT, PAMSE, iTRACC survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.
    b. Intervention Arm- Caregivers will take the ACT, PAMSE, intervention survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.

11. **9 months from start of enrollment**

a. Control Arm- Caregivers will take the ACT, PAMSE, iTRACC survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.

b. Intervention Arm- Caregivers will take the ACT, PAMSE, intervention survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.

12. **Final Visit at 12 Months**
    a. A second clinic visit will occur one year after enrollment. This visit will aim to coincide with participants' annual asthma clinic visits.
    b. **Control Arm- Caregivers will take the ACT, PAMSE, iTRACC survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.**
    c. **Intervention Arm- Caregivers will take the ACT, PAMSE, intervention survey, and PACQLQ. Caregivers will also be asked about acute exacerbations, ED visits, and hospitalizations as visits to out-of-network healthcare facilities may not be visible in the EMR. This information will be collected via email or phone for both groups utilizing a REDCap survey link for each participant.**
    d. During this final study visit, a member of the research team will make sure that that the caregivers have completed the all the study surveys via Propeller or via text, email, or telephone.

13. **Semi-structured interviews (After Participant Completion of Trial)**
    a. From the intervention arm alone, caregivers who responded that they were interested in further contact from the study team on the exit survey will be contacted.
    b. Caregivers will be interviewed about their experience with the intervention (sensor/app) and about how caregiving for their child's asthma is affected by their experiences of family, community, school, and the health care system.
    c. Caregivers will be informed that the in-person, or telephone, interview will be audio-recorded. In-person interviews will be conducted at Northwestern Medical Campus in private, research rooms.
    d. Interviews will last approximately 60 minutes and conducted by research staff.

14. **Semi-structured interviews (Health providers at the end of the trial)**
    a. Health providers (e.g., nurses and physicians), who were involved in the trial, will be invited to participate in exit interviews
    b. Health providers will be interviewed abou their experience using the web portal (Study Aim 3), using the data generated by the sensors, and managing pediatric asthma patients and their interaction with parents
    e. Health providers will be informed that the in-person, or telephone, interview will be audio-recorded. In-person interviews will be conducted at their clinic location in a private office.
    f. Interviews will last approximately 60 minutes and conducted by research staff.

Study Extension

Data analysis will begin 12 months after a participant is enrolled (beginning January 2018.). During the analysis period, we will also determine the feasibility of implementing the intervention more broadly throughout the healthcare system.

Study Subjects:

Eligible participants will be children 4-17 years old with moderate or severe persistent asthma, as diagnosed by their pediatrician, who are primarily seen for their asthma care at one of the participating clinical sites, and who have parents/caregivers willing to participate in this study. Participants will also be required to have received oral corticosteroids in the past year.

Study Enrollment:

Recruitment will occur by a research assistant at all sites. Scheduling of recruitment and participant screening will require the healthcare team to identify potential participants and then the RA either calling or mailing an informational pamphlet to the parents prior to their next appointment. Participants may also be recruited in the clinic by the RA, but will require the RA to follow-up with them via the telephone to properly install and utilize the Remote Health Management Platform. Participants may also be recruited through Lurie Children's Hospital Inpatient service after an asthma exacerbation. Only children who receive their primary care from one of the 5 study clinics will be permitted to be in the study. A member of the research team will work with hospitalists to recruit these individuals.

For the post-trial semi-structured interviews, only those participants who had previously responded that they were interested in further contact by the research team will be recruited. Study staff will contact potential participants for interviews by telephone and only schedule a time if participants remain interested after the interview study has been explained to them.

For post-trial interviews of health providers, all health providers who were in the trial will be invited to participate. Study staff will email health providers for interviews and only schedule time if health providers are interested after the study has been explained to them.

Participant Engagement

Members of the study team will communicate with participants about issues and/or questions throughout the study period via text, email, or phone. Participants will also receive calls from their healthcare provider's office if necessary.

Figure 2. Participant Burden

The healthcare team will comprise of physicians, nurses, nurse practitioners, and respiratory therapists at participating sites. They will have regular contact with the research team. A member of the research team will make frequent in-person appearances in each clinic to make sure that the intervention is running smoothly from a clinical perspective.

Figure 3. Web Portal for Healthcare Team

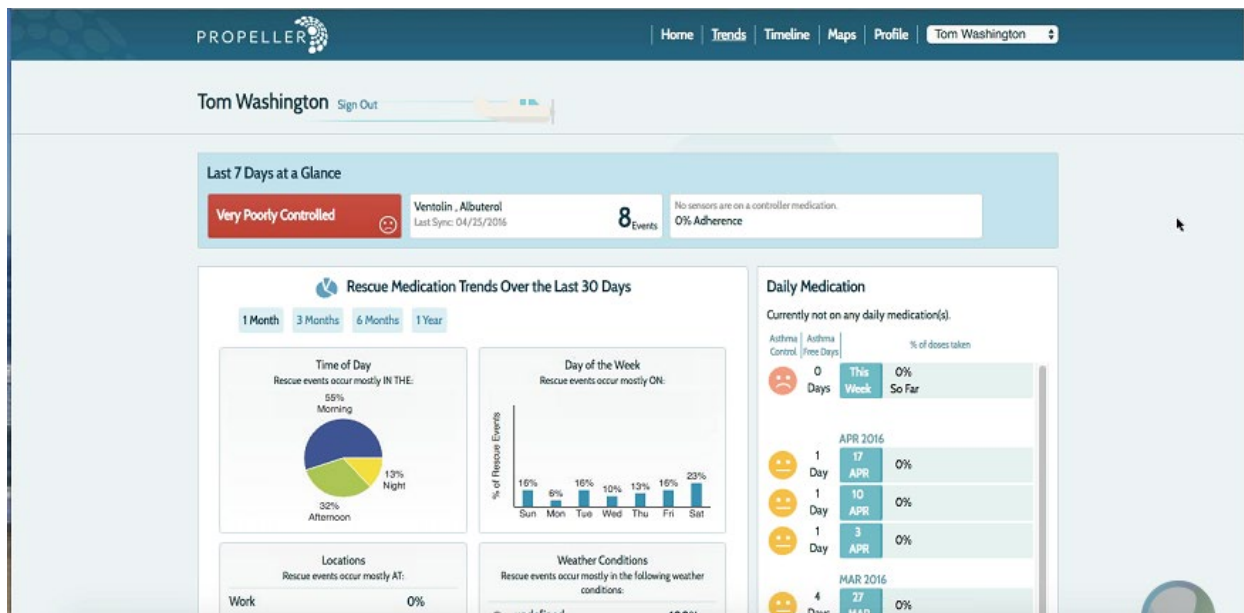Figure 4. Web Portal-At a Glance

Figure 5. Web Portal-at a glance

ImmunoCAP® Allergy Profiles
Region VIII: IA, IL, MO

RESPIRATORY ALLERGY PROFILE

TEST CODE: 10649

SPECIMEN REQUIREMENTS: 2 mL serum, room temperature

CPT CODES*: 86003 x 25 Specific IgE; 82785 Total IgE

- *Alternaria alternata*, m6
- *Aspergillus fumigatus*, m3
- Bermuda grass (*Cynodon dactylon*), g2
- Cat dander, e1
- *Cladosporium herbarum*, m2
- Cockroach, i6
- Common ragweed (Short; *Ambrosia elatior*), w1
- Cottonwood (*Populous deltoides*), t14
- *D. farinae*, d2
- *D. pteronyssinus*, d1
- Dog dander, e5
- Elm (*Ulmus americana*), t8
- Maple (Box elder; *Acer negindo*), t1
- Maple leaf sycamore (London plane), t11
- Mountain cedar (*Juniperus sabinoides*), t6
- Mulberry, t70
- Oak (*Quercus alba*), t7
- Pecan/Hickory (Pecan; *Carya soecue*), t22
- *Penicillium notatum*, m1
- Rough marsh elder (*Iva*), w16
- Rough pigweed (*Amaranthus retroflexus*), w14
- Russian thistle (Saltwort, *Salsola kali*), w11
- Timothy grass (*Phleum pratense*), g6
- Walnut (*Juglans californica*), t10
- White ash (*Fraxinus americana*), t15
- Total IgE

FOOD ALLERGY PROFILE

TEST CODE: 10715

SPECIMEN REQUIREMENTS: 2 mL serum, room temperature

CPT CODES*: 86003 x 12 Specific IgE

- Clam, f207
- Cod fish, f3
- Corn (Maize), f8
- Egg white, f1
- Milk, f2
- Peanut, f13
- Scallop, f338
- Sesame, f10
- Shrimp, f24
- Soybean, f14
- Walnut, f256
- Wheat, f4

ALLERGENS INDICATED BY CAP CODES
d=dust mites (house), e=epidermal, f=food, g=grass, i=insect, m=mold, t=tree, w=weed

*Any profile component listed can be ordered individually. The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

Quest Diagnostics

Figure 6. ImmunoCAP Allergy Profiles for IL

Version: 04/06/2020

ImmunoCAP®' Allergy Profile
## Region VIII: IA, IL, MO

CHILDHOOD ALLERGY (FOOD/ENVIRONMENTAL) PROFILE

TEST CODE: 10659

SPECIMEN REQUIREMENTS: 2 mL serum, room temperature

CPT CODES*: 86003 x 15 Specific IgE; 82785 Total IgE

- *Alternaria alternata, m6*
- Cat dander, e1
- *Cladosporium herbarum*, m2
- Cockroach, i6
- Cod fish, f3
- *D. farinae*, d2
- *D. pteronyssinus*, d1
- Dog dander, e5
- Egg white, f1
- Milk, f2
- Peanut, f13
- Shrimp, f24
- Soybean, f14
- Walnut, f256
- Wheat, f4
- Total IgE
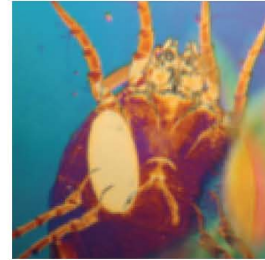
ALLERGENS INDICATED BY CAP CODES
d=dust mites (house), e=epidermal, f=food, g=grass, i=insect, m=mold, t=tree, w=weed

For additional information

- Contact client services for access to medical experts at 1 (800) 323-5917
- Contact your local sales representative for printed patient literature or visit our online patient health library at www.QuestDiagnostics.com/patienthealthlibrary

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Diagnostics

Figure 7. ImmunoCAP Allergy Profiles, **Study Timeline (Intervention):**

Version: 04/06/2020

Tasks	Year 1												
	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Preparation Phase													
Web Portal	X	X											
Pilot Phase			X	X	X	X	X	X	X	X	X	X	x
Adapt Protocol			X	X									
Study Phase													
Recruitment						X	X	X	X	X	X	X	X
Baseline Surveys						X	X	X	X	X	X	X	X
Remote Health Management Device Distribution						X	X	X	X	X	X	X	X
Weekly Calls/Emails to Clinic	x	X	X	X	X	X	X	X	X	X	X	X	X
Retention Phase													
1 month surveys							X	X	X	x	X	X	X
3 month surveys									x	x	X	X	X
Half-Yearly Surveys												X	X
9 month surveys													
Phone/email Follow-up					X	X	X	X	X				
Epic Data Pull		X	X	X	X	X	X	X	X	X	X	X	X

Tasks	Year 2											
	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Retention Phase												
9 month surveys	x	x	x	X	X	X	X	X	X	X	X	X

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Tasks												
End of the Study Surveys	x	X	X	X	X	X	X	X	X	X	X	X
Remote Health Management Data Pull	X	X	X	X	X	X	X	X	X	X	X	X
Web Portal Data Pull	X	X	X	X	X	X	X	X	X	X	X	X
Feasibility Assessment		X	X	X	X	X	X					
Analysis Phase												
Data Analysis		X	X	X	X	X	X	X	X	x		
Publications and Presentations				X	X	X	X	X	X	X	X	X

Study Timeline (Control):

Tasks	Year 1												
	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Preparation Phase													
Web Portal	X	X											
Pilot Phase			X	X	X	X	X	X	X	X	X	X	x
Adapt Protocol			X	X									
Study Phase													
Recruitment						X	X	X	X	X	X	X	X
Baseline Surveys						X	X	X	X	X	X	X	X
Remote Health Management Device Distribution						X	X	X	X	X	X	X	X
Weekly Calls/Emails to Clinic	x	X	X	X	X	X	X	X	X	X	X	X	X
Retention Phase													
1 month surveys							X	X	X	x	X	X	X
3 month surveys									x	x	X	X	X

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Tasks												
Half-Yearly Surveys											X	X
9 month surveys												
Phone/email Follow-up				X	X	X	X	X				
Epic Data Pull		X	X	X	X	X	X	X	X	X	X	X

Tasks	Year 2											
	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Retention Phase												
9 month surveys	x	x	x	X	X	X	X	X	X	X	X	X
End of the Study Surveys	x	X	X	X	X	X	X	X	X	X	X	X
Remote Health Management Data Pull	X	X	X	X	X	X	X	X	X	X	X	X
Web Portal Data Pull	X	X	X	X	X	X	X	X	X	X	X	X
Feasibility Assessment		X	X	X	X	X	X					
Analysis Phase												
Data Analysis		X	X	X	X	X	X	X	X	x		
Publications and Presentations				X	X	X	X	X	X	X	X	X

Clinical Outcomes

Source	Outcome	Time Point
Remote Health Management Application	ICS and SABA use	Monthly download
Web Portal/Epic	Asthma-related ED visits, hospitalizations, and oral corticosteroid prescriptions/courses	Monthly Epic data pull
Web Portal/Epic	Patient demographics pulled	Baseline
Parent report (Survey)	Patient age, family income, race, family makeup (single parent, two-parent household, etc)	Baseline

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Asthma Control Test (ACT) (ages 12 and older Or Childhood Asthma Control Test (ages 4-11)	Parent report of their child's asthma control	5 times in total (baseline, 3 months, 6 months, 9 months, study completion)
Parent-reported Values (un-validated)	Asthma-related oral corticosteroid prescription/use/courses; number of asthma-related hospitalizations; number of asthma-related ED visits	5 times in total (baseline, 3 months, 6 months, 9 months, study completion)
ImmunoCAP Allergen Testing	Environmental Allergens	Baseline

Psychosocial Outcomes

Source	Outcome	Time Point
Parental Asthma Management Self-Efficacy (PAMSE)	Parental self-efficacy survey to assess parent's ability to manage and/or prevent acute exacerbations	5 times in total (baseline, 3 months, 6 months, 9 months, study completion)
Parent-reported values (un-validated)	School days missed due to asthma	5 times in total (baseline, 3 months, 6 months, 9 months, study completion)
Pediatric Caregiver Asthma-related Quality of Life Questionnaire (PACQLQ)	Parent form of how their child's asthma is affecting both their lives and the life of their child	5 times in total (baseline, 3 months, 6 months, 9 months, study completion)

Parental Management Outcomes

Source	Outcome	Time Point
Parent report (Survey)	Feasibility and acceptability of Platform	5 times in total (baseline, 3 months, 6 months, 9 months, study completion)
Remote Health Management Platform	Frequency of use of the application (synching)	Monthly data pull

Physician and Clinical Team Outcomes

Source	Outcome	Time Point
Remote Health Management Platform	ICS and SABA use	Monthly download
Web Portal/Epic	Asthma-related ED visits, hospitalizations, and oral corticosteroid prescriptions/courses	Monthly Epic data pull
Clinician Survey	Feasibility and acceptability of the Platform	1 month into the study, 6 months and study completion
Physician Survey	Feasibility and acceptability of the Platform	1 month and study completion
Remote Health Management Platform	Frequency of use of the web portal	Monthly data pull

Data Analysis:
Primary Outcomes

- *ACT:* Parent-reported test on their child's asthma control
- *Asthma-related hospitalizations:* Data will be obtained from the EMR and parent report.
- *Asthma-related ED visits:* Data will be obtained from the EMR and parent report.
- *Asthma-related oral corticosteroid use:* Prescription/course data will be obtained from the EMR and parent report.

Secondary Outcomes
- *Inhaler Use:* Use data, including frequency of both SABA and ICS inhalers, will be obtained via the sensor throughout the study period.
- *PAMSE:* Parental Asthma Management Self-Efficacy; self-report survey that measures parental self-efficacy for the management and prevention of acute exacerbations of asthma.
- *PACQLQ:* Paediatric Asthma Caregiver's Quality of Life Questionnaire; will assess the impact of their child's asthma on their lives, the lives of their children with asthma, and the family as a whole.
- *Clinical management:* To compare clinical management, data on physician-patient communication and rates of follow up will be obtained from the web portal for all patients for a year for each intervention participant. This will be measured via the number of tasks have been completed. Additionally, in the Intervention group, we will work with physicians to conduct rapid-cycle improvements to the web portal interfaces, through conversations the RA and the PI have with clinicians. We will also follow up with healthcare team to ensure follow-up calls are occurring. Finally, a four-question survey of members of the healthcare team about the acceptability and feasibility of the sensor will be conducted periodically.

Statistical Analysis:
Demographic and baseline characteristics:
Demographic and baseline characteristics including gender, age, race, ethnicity, and co-morbidities will be summarized for each treatment group and overall. The demographic and baseline characteristics summary will be based on all randomized subjects.
Baseline values for efficacy parameters (ACT, quality of life score, PAMSE) will also be presented for each treatment group and overall based on all randomized subjects.

For continuous variables, non-missing will be used to calculate the mean, median, SD, IQR, minimum and maximum by treatment group and overall. For categorical variables, the count and percentages of each possible value will be tabulated by treatment group and overall.

All comparisons of baseline characteristics between treatment groups will be adjusted for potential household clustering using robust standard errors. For continuous variables, comparability of treatment groups will be assessed using general linear models. For discrete variables, comparability will be assessed using the Cochran-Mantel-Haenszel general association test. P-values will be displayed as descriptive statistics of comparability in order to identify potential baseline imbalances with an alpha level of 0.05.

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AIM 1. Determine factors influencing clinical and psychosocial outcomes.
Clinical and psychological outcomes of interest include the 12-month rate of asthma-related oral corticosteroid use, ED visits, and hospitalizations, as well as change in mean ACT scores (range of 0 to 27) from baseline to end line (12 months). Psychological outcomes of interest include quality of life score (range of 1 to 7), parental self-efficacy score, and the number of school days missed due to asthma. Potential predictors of outcomes include age (4 to 7 years vs. 8 to 17 years), gender (M vs. F), race/ethnicity (non-Hispanic white, non-Hispanic Black, Hispanic, vs. others), insurance status (private/public), and co-morbidities.

Each count variable (asthma-related oral corticosteroid use, ED visits, and hospitalizations) will be analyzed by mixed negative binomial regression analysis adjusting for treatment, all potential predictors, and including maximal random effect structures (i.e., slope and intercept as allowed by the model) of family and clinic. VIFs (variance inflation factors) will be computed for each predictor. Highly correlated predictors (i.e. predictors that can be well-explained by other predictors) will be dropped from the model to avoid multicollinearity issues. Model fit criteria, parameter estimates, and precision of parameter estimates will all be evaluated to select the most parsimonious model.

For each continuous primary outcome variable (i.e., ACT score), change-from-baseline score at each visit will be analyzed using mixed linear regression models, adjusting for treatment , time point, baseline score, all potential predictors, and including random effects (i.e., both slope and intercept) of family and clinic. A treatment by time interaction will be included to evaluate whether the effect of the treatment on the primary outcome varies by time point. VIFs will be investigated for each predictor, and those with high VIFs (VIF>=10) will be dropped from the model to avoid multicollinearity issues. An unstructured covariance (UN) matrix will be assumed. Model fit criteria, parameter estimates, and precision of parameter estimates will also be used to select the most parsimonious model.

Model diagnostics will be performed to check model assumptions. All analyses will be performed using statistical analytic software Stata Version 15.1.

AIM 2. Enhance parental management through improved inhaler use.
After the patient's enrollment visit, parents will be contacted via email or phone at 1, 3, 6, 9, and 12 months to complete a REDCap survey. Each quantitative survey item will be summarized using descriptive statistics such as frequencies and percentages along with any corresponding measures of spread. Qualitative data will be coded and analyzed by theme analysis.
The following questions will be asked:
Quantitative Questions:
1. How often do you check the sensor system?
   - More than once a daily
   - Daily
   - Once a week
   - More than once a week
   - Every other week
   - I don't check the Propeller Sensor *(If selected, participants will only answer question 1 and 5)*
2. How often in the past week did you receive useful asthma information through the sensor system?

- Once
- Twice
- Three or more times
- I did not receive useful asthma information through the sensor system

3. How helpful is the sensor system in managing your child's asthma?
   - Extremely helpful
   - Very helpful
   - Helpful
   - A little helpful
   - Not helpful
   - I have not checked the sensor system

4. What do you enjoy most about the sensor system?
   - ☐ Easy to use
   - ☐ Ability to track inhaler use
   - ☐ Asthma Education cards
   - ☐ Other: *fill in the blank*
   - ☐ Nothing

5. Do you have any issues regarding the sensor system?
   - *Comment Box*

AIM 3. Improve management by physician and clinical team.

On a biweekly basis, we will collect quantitative data from clinics on the number of time physicians' follow-up with patients and the follow-up outcome. The research team will know exactly how many alerts physicians are receiving, and how physicians are following-up with patients from the Propeller dashboard. The data from the Propeller dashboard will be summarized with descriptive statistics. Clinicians will also be contacted at 1, 3, 6, 9, and 12 months through REDCap surveys to determine if the data is helping them with management and aspects of the platform they like and dislike. Qualitative data will be coded and analyzed by theme analysis.

The following questions will be asked:

Quantitative Questions:

1. In the past week, how many times did you check the propeller dashboard?
   - ☐ Once time
   - ☐ Twice
   - ☐ 3 or more times
   - ☐ Zero

2. Are the Propeller Dashboard flags useful to you?
   - ☐ Yes
   - ☐ No

3. In the past week, how many times did you have to follow-up with patients due to alerts you received regarding the over use of Albuterol?
   - ☐ Once
   - ☐ Twice
   - ☐ 3 or more times
   - ☐ Zero

4. In the past week, how many alerts did you receive due to patients overusing albuterol?
   - ☐ One
   - ☐ Two

☐   3 or more
5. In the past week, how many times did you have to follow-up with patients regarding their underuse of their controller medication?
    ☐   Once
    ☐   Twice
    ☐   3 or more times
6. In the past week, how many alerts did receive due to patients underusing their controller medication?
    ☐   One
    ☐   Two
    ☐   3 or more
    ☐   Zero
7. On a scale of 1-5 (1 being the least helpful, and 5 being the most helpful), how helpful do you feel calls to patients improve asthma management?
    ☐   1
    ☐   2
    ☐   3
    ☐   4
    ☐   5
8. On a scale of 1-5 (1 being the least useful, and 5 being the most useful) how much do you think the parents found your call useful?
    ☐   1
    ☐   2
    ☐   3
    ☐   4
    ☐   5

Qualitative Questions:
1. What do you find useful about the Propeller dashboard?
2. What changes do you think are needed to improve the Propeller dashboard?
3. How are you currently using the Propeller dashboard? Please describe.
4. Would you utilize the Propeller health management platform for your current practice in the future?

Sample Size Determination:
Assuming asthma exacerbation rate of 0.545 for the intervention arm, and asthma exacerbation rate of 0.75 for the standard treatment arm, resulting odds ratio (OR) equal to 0.3992674, and log(OR)=-0.9181239. Assuming 20% patient drop-out rate, two-sided significance level alpha=0.05, a total of 250 patients (125 per arm) is needed in order to achieve a statistical power of 85%. The sample size calculation was computed using SAS procedure PROC SEQDESIGN.

Qualitative Analyses of Semi-Structured Interviews:
Data will be analyzed systematically using a constant comparative approach; and four analysts (i.e., coders), including Dr. Shaunfield (qualitative methods expert), Dr. Kan, and 2 research team members, will meet to discuss initial thoughts, insights, and observations for the development of initial coding categories (e.g., themes). Through a systematic analysis process, themes will be continually refined by collapsing redundant themes and removing irrelevant themes. Once no new categories have emerged, a

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codebook will be developed for the remaining analysis. We will construct a saturation grid, to track themes as they emerge and determine when no new information is obtained

Study Staff:
Dr. Ruchi Gupta will oversee study operation at participating sites and will be responsible for the acquisition and handling of study data according to the procedures outlined in this protocol. The research team will be comprised of a research managerr, research assistants, research coordinators, a data analyst, and a biostatistician. A member of the research team, along with Propeller Health will be responsible for the web portal integration of sensor data in the web portal. A Lurie Children's Epic personnel will be responsible for extracting EMR data. United Health Care Group will be involved or consulted in every aspect of the study.

Data Privacy and Human Subject Consideration:
Direct benefit:
Remote Health Management Group (Intervention): Children will have use of an inhaler sensor that may improve asthma management by tracking ICS and SABA use. The sensor software also sends tailored education materials to caregivers and alerts primary care physicians of increased SABA use. This enhanced care may lead to fewer asthma exacerbations, resulting in fewer school and/or work days missed, fewer ED visits, and fewer hospitalizations.

Standardized Education Group: Children in this group will have standardized education (proper inhaler technique and a visual action plan), which may lead to better asthma outcomes as well.

Indirect benefit: Eventual development of an insurance-wide program for children to better manage their asthma.

Risks: The primary risk to participants in this study is discomfort related to getting blood drawn for the ImmunoCAP allergen testing. We will teach participating families to properly use all applications before the intervention begins. There is also a risk of confidentiality.

To protect personal health information (PHI), each child will be given a study ID number, which will be kept separate from sensor and questionnaire data on a secure, password-protected database at Northwestern University. All sensor data will be securely downloaded from the cloud by the Remote Health Management provider, and sent securely to Northwestern to store on secure servers. All EMR data will be de-identified and saved in the same manner.

Patient Safety Monitoring Plan:
The patient safety monitoring plan for this study will include:
- Standard clinical management of the enrolled children, which includes in each practice that the families are provided with contact information for the practice. As part of enrollment in this study, each family will be reminded that their child's practice continues to be their resource for any questions or concerns about their child's condition. Each family will be informed that the study does NOT substitute for their child's physician.
- The investigators do not anticipate any safety issues related to the monitoring device itself. However, if a parent or guardian raises any questions about the safety of the monitoring device, the study team will respond promptly to the parent's/guardian's concern. All parent's/guardian's will have contact information of the study coordinator.

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Appendices:
1. Parent questionnaires
    a. ACT
    b. Quality of Life
    c. PAMSE
    d. Intervention Feasibility questionnaire (Intervention Arm)
    e. iTRACC Survey (Control Arm)
2. Physician questionnaires
    a. Technology questionnaire/script
    b. Post-intervention survey
3. Email contact script
4. Randomization Schedule
5. Thermofisher ImmunoCAP Allergy Profiles

Compatible Inhalers (retrieved from: https://www.propellerhealth.com/support/compatible-medications/)
Supported Rescue/Relief Medications:
- Albuterol HFA
- ProAir HFA
- Proventil HFA
- Ventolin HFA
- Xopenex

Supported Controller/Daily Medications:
- Advair HFA
- Advair Diskus
- Asmenex
- Combivent Respimat
- Dulera
- Flovent Diskus
- Flovent HFA
- QVAR
- Serevent Diskus
- Spiriva Respimat
- Striverdi Respimat

Timeline
Pilot: November 2016
- Pilot group of 8-10 families

Phase 1: Enrollment
- December 2016-December 2017
- Collect EMR data from the previous year
- Randomization

Phase 2: Intervention
- December 2016-December 2018
- Intervention Group will have the Remote Health Management device for 1 year
- Standardized Group will receive enhanced, standardized asthma education
- Each group will fill out the following surveys 5x during the study period:
    - ACT
    - PAMSE
    - PACQLQ
    - iTRACC Survey (Control Arm) or Intervention Survey (Intervention Arm)
    - Number of hospitalizations, ED visits, exacerbations
- We will pull information from the EMR to determine oral corticosteroid use

Phase 3: Analysis
- January 2018- December 31, 2018
- All data analyzed
- Preparation and submission of academic abstracts and papers

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- *Help to prepare for full scale rollout, if applicable
- *Semi-structured interviews of subsample of participants
- *Semi-structured interviews of health providers in the trial