Transitioning Emergency Asthma Management to Primary Care (TEAM-PC) IRB Proposal
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A. Study Purpose and Rationale

The purpose of this study is to assess the effects of a multifunctional asthma-related smartphone on asthma patients' symptom control, controller medication adherence and follow-up with their primary care providers.

B. Study Design and Statistical Analysis

The study will be a randomized controlled trial comparing the effectiveness of a smartphone app plus asthma education versus education alone in improving patients' symptom control, adherence to asthma controller medications and follow-up rates with their primary care providers (PCPs).

Recruitment and Screening

Patients will be recruited from the pediatric emergency department at NYPH, according to the following criteria.

Inclusion Criteria: Subjects (or their caregivers as appropriate) must

1) be aged 4 years or older
2) have a history of asthma, or a history of 3 or more wheezing episodes that respond to inhaled β-agonists
3) be able to speak and read either English or Spanish
4) own a phone capable of receiving text messages

Exclusion Criteria: Subjects must not

1) have major co-morbid conditions such as cystic fibrosis or chronic obstructive pulmonary disease (COPD)
2) be too ill for participation, as per the treating physician
3) be cognitively impaired
4) be in foster care or a ward of the state

We will aim to enroll 1600 subjects for each group, which will power our study to detect a 5% change in the rate of "poorly controlled" asthma as determined by a chi-squared analysis.

Randomization

Following consent, a research assistant will alert the Data Coordinating Center (DCC) via phone, and will input the age of the patient. The patient will then be randomized to a study arm. Randomization will occur using a computerized block of 10 as set by the DCC. The order of the selection will be chosen randomly by the computer.

Intervention arm

Patients randomized to the intervention arm will provide baseline asthma information by interacting with a computer kiosk. They will be assessed for asthma severity and control (by using the validated Asthma Control Test (ACT) or childhood Asthma Control Test (cACT) as appropriate), asthma-related healthcare utilization (number of asthma-related ED visits in past 12 months), asthma-related quality of life (by using the validated Integrated Therapeutics Group Asthma Short Form (ITG-ASF) or the Integrated Therapeutics Group Child Asthma Short Form (ITG-CASF) as appropriate), and controller medication(s) currently being used. See Section F (Study Questionnaires) for more information on all surveys being used in this study. After completion of the initial surveys, the kiosk will generate an Asthma Action Plan (AAP) with National Asthma Education and Prevention Program (NAEPP) asthma guideline-based recommendations for controller medication(s). The study team will ensure that the treating physician is aware of these recommendations. Next, the study team will have participants review an asthma educational module on a tablet computer, which will provide information on the importance of controller medications, potential side effects, and common misconceptions. After completion of the module, the research assistant will help participants register with PingMD in order to receive the text message reminders and demonstrate how to use the app. Participants will choose the preferred frequency for them to receive text message reminders.

After discharge home, participants will receive text message reminders to take their controller medications at the previously determined times. They will also receive reminders to schedule visits with their PCPs. Once every 2 months over a 12 month period, the PingMD app will prompt them to complete surveys to assess their level of asthma control, health care utilization, and number of school/work days missed. At 6 and 12 months after enrollment, outcome assessors (who are not aware of the study assignment of the participants) will contact the family to determine their level of symptom control, health care utilization,

whether the patient had a follow-up appointment with their PCP, and number of school/work days missed, and asthma quality of life.

Control arm

Patients randomized to the control arm will provide baseline asthma information in the same manner as patients in the intervention arm. They will receive an AAP and be prescribed appropriate controller medications as per the NAEPP asthma guidelines. They will also complete the tablet computer-based asthma education module. The research team will register them with PingMD prior to discharge home from the ED. Once every 2 months over a 12 month period, the PingMD app will prompt them to complete surveys to assess their level of asthma control. At 6 and 12 months after enrollment, outcome assessors will contact the family to determine their level of symptom control, health care utilization, whether the patient had a follow-up appointment with their PCP, and number of school/work days missed, and asthma quality of life.

Data Collection

The intake data we will collect includes:

Patient Demographics	**Patient Asthma Information**
- Age - Gender - Ethnicity and race - Highest educational level of patient and caretaker - Household income	- ACT/cACT - ED visits in past 12 months - Hospital admissions in past 12 months - Controller medications - Asthma quality of life - Number of days missed from school/work in past 12 months

Outcome Measures

The primary outcome will be the patient's asthma control level as measured by the validated ACT or cACT as appropriate. See Section F (Study Questionnaires) for more information on the ACT/cACT. Secondary outcomes will be (1) number of scheduled visits with PCP during the study period, (2) number of unscheduled PCP visits during study period, (3) asthma quality of life, (4) proportion of patients on appropriate therapy for severity level as 6 and 12 months after enrollment, (5) change in asthma-related ED visits before and after intervention, and (6) change in asthma-related hospital admissions before and after intervention.

Study Retention and Duration

We plan to follow patients for 12 months after enrollment to account for seasonal variation in asthma exacerbations. We anticipate that the total duration of the study will be 2 years.

Statistical Analysis

Power analysis was performed using a chi-squared test, presuming a 50% rate of poorly controlled asthma and a 5% minimum effect of clinical interest. Statistical significance for changes in ACT scores and other continuous outcome variables will be calculated using a two-tailed paired t-test, while statistical significance for change in proportion of patients with "poorly controlled" asthma (ACT score < 19) will be calculated using a chi-squared analysis.

C. Study Procedure

Two bilingual (English/Spanish) research assistants will be dedicated to conducting study procedures on a full time basis. They will assist in the recruitment of participants visiting the ED for acute asthma care.

D. Study Drugs

No experimental drugs will be used in this study.

E. Medical Device.

No experimental medical devices will be used in this study.

F. Study Questionnaires

The Asthma Control Test (ACT) is a five item questionnaire for patients aged 12 years and older with a score ranged from 5 to 25; the childhood Asthma Control Test (cACT) is a seven item questionnaire with score ranged from 0 to 27 for patients aged from 4 to 11 years old. Both the ACT and cACT are patient-administered surveys for assessing asthma control.

G. Study Subjects

Patients will be recruited from the pediatric emergency department at NYPH, according to the inclusion and exclusion criteria detailed in Section B.

Vulnerable Populations

We will include children 4 to 17 years old in this study. We will not include children who are currently enrolled in foster care or are wards of the state. It is important to include children in this study as they have a disproportionately high prevalence of asthma as compared with adults. Research assistants will explain the study to both them and their legal guardians. Either written or verbal assent will be obtained from children aged 7 years or older, depending on their literacy level. Parental consent will be obtained from at least one parent prior to enrollment of children into the study.

H. Recruitment of Subjects

Caretakers and their children will be recruited one-on-one in the pediatric ED when coming for asthma-related visits. An MD or research coordinator will approach caregivers and their asthmatic children, explain the study, and obtain consent and assent for the study as appropriate.

I. Confidentiality of Study Data

Intake data will be collected via the Asthma Care and Educational Device (ACED). For a summary of the confidentiality of data collected with the ACED, please refer to IRB-AAI1893. Follow-up data will be collected via the PingMD app, which uses secure log in, server processes, and data encryption to ensure full HIPAA compliance. Prior to statistical analysis, all data will be de-identified. The study PI will work closely with Columbia IT security to ensure that all data is kept securely.

J. Potential Conflict of Interest

The authors of this study have no potential conflicts of interest to disclose.

K. Location of the Study

Recruitment for the study will take place entirely within the Pediatric Emergency Department at NYPH.

L. Potential Risks

There is a potential risk of loss of confidentiality, which will be minimized by restricting access of any personal information to the study team and keeping any personal information in a secure location.

M. Potential Benefits

Participating caretakers of children with persistent asthma will be better equipped to manage their children's asthma and participants can immediately implement the knowledge, resources and tools gained from the study to better care for asthma. Furthermore, they will receive direct help in acquiring proper care for their child's asthma. The children will also benefit in that they will be able to better manage their asthma on their own.

N. Alternative Therapies

Patients and their families who visit the ED may choose not to participate in the study and continue with their asthma management. Patients and their families may also drop out of the study at any time.

O. Compensation to Subjects

To compensate for the time the participants offer for the study, each participant will have a $10 gift certificate mailed to them each time they complete the bimonthly survey. All participants will receive an additional $25 gift certificate for each time they complete the 6-month and 12-month follow-up telephone surveys. We do not believe this will change their intended behaviors

as compensation is given based on completion of questionnaires, not on behavioral changes. We feel that compensation is needed especially for the control group in order to minimize loss to follow-up.

P. Costs to Subjects

We do not anticipate subjects incurring any additional costs as a result of their participation in this study.