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Feasibility of Medication Monitoring Sensors in High Risk Asthmatic Children

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Introduction

Daily controller therapy is a mainstay of asthma treatment(1), however adherence to asthma medications is problematic(2). Traditional methods of measuring adherence do not provide day-to-day objective data. Adherence monitoring sensors that are placed directly on inhaled asthma medications attempt to address this problem(3); however it is unknown how feasible it is to integrate such devices among high-risk, asthmatic children and more evidence is needed on how to integrate these types of devices into real-life clinical practice(4).

Our primary objective was to evaluate the feasibility of using a commercially available adherence device in children in a real-life clinical setting. We hypothesized that patients, parents and providers would find the devices easy to use and would continue using them if given the opportunity.

Methods

This study was approved by the Colorado Multiple Institutional Review Board (15–0211) prior to patient recruitment, and is listed on www.clinicaltrials.gov (NCT02617420).

Study Population

Twenty-five children aged 6–17 years old with asthma and at least one hospitalization or 2 emergency room visits for asthma in the last year were recruited. Written consent was obtained. Adherence was monitored for 3 months for each patient. Providers were asked to participate if they had a patient that chose to enroll.

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Clinical Trials.gov registration: <https://clinicaltrials.gov/ct2/show/NCT02617420>

Conflict of Interest:

Drs. Hoch, Kempe and Brinton have no conflicts to disclose. Dr. Szefer is a consultant for Propeller Health.

The Digital Health Platform

The digital health platform consists of medication monitoring devices, an online platform, and a mobile application. The sensors are placed on top of the child's inhalers using a silicone cap. Those with compatible smartphones downloaded the mobile application to access real-time information about the child's medication usage, educational modules, and push notifications if medications were not taken within 15 minutes of the designated time. Data on medication use was sent to family smartphones via Bluetooth. Those without a compatible smartphone were provided a Bluetooth-enabled hub with access to a web dashboard and emails. Patients were instructed on use of the application, but were not told how often to interact with the application. Patients' pulmonary providers were enrolled in the system to receive email notifications and could login to view patient information. Two notification types were sent to both parents and providers: 1) decreased adherence to medications (missing medications for 7 days or more) or 2) worsening in asthma control status (increased rescue medication use). To maintain a realistic clinical setting, the study did not dictate provider action.

Surveys regarding feasibility

Surveys were administered to patients and families at enrollment, at halfway point, and after 3 months (study conclusion). Parents completed surveys for children younger than 12 years old. Providers completed surveys when their first patient entered the study and when the last patient finished.

Results

Twenty five patients (48% male, 6–17 years of age, mean age 10 years, 60% Hispanic, 20% Black, 72% Medicaid) and 8 providers enrolled and completed the surveys. Six (24%) participants were prescribed fluticasone/salmeterol, 7 (28%) mometasone/formoterol and 12 (48%) fluticasone. Entrance survey responses were compared between participants with/without exit survey responses using Wilcoxon rank sum tests for median difference and Fisher's Exact tests for frequency differences. There was no indication of entry survey differences, so survey summaries are reported for the entry survey (N=25) and the exit survey (N=20). Ninety-six percent of patients/families (24/25) owned a smartphone. Ninety-six percent of patients/families reported feeling very comfortable using smartphone applications.

At study end, 90% (18/20) of families reported that the device was either very easy or extremely easy to use. All patients/families (20/20) surveyed reported that the data they received from the application was either very easy or somewhat easy to understand, and 85% (17/20) reported that they found it helped them learn about their child's asthma. During the 3-month observation period, 25% (5/20) discussed the information they gathered from their devices with their healthcare provider. More than half (62.5%, 5/8) of providers indicated that the digital health platform changed some aspect of care. Providers most frequently reported that patient-provider communication changed. They also cited changes in the frequency of follow-up visits and allergy assessments, increased adherence, and increased awareness of asthma trends, triggers and symptoms. Most providers felt that the device

changed some aspect of their care for patients, however they felt that EMR integration would help their workflow.

Most patients (90%, 18/20) would recommend the devices to a friend or family member and would continue using the devices (95%, 19/20), especially if their provider recommended it. Adherence averaged 56%, but declined over the study period (Figure).

Discussion

We found that the digital health platform was well received among providers and families for this 3-month intervention. A modest portion of the study population used a Bluetooth hub compared to a smart phone and any future analysis of the adherence monitoring device should account for the different experience stemming from modality used to collect data. Most providers recommended adoption of the technology in some capacity in the clinical setting. Adherence in this group of patients started high, but decreased over the 3-month monitoring period, consistent with prior studies(4).

There are several limitations to the study. As a pilot feasibility study, there was a limited sample size and no control group with which to compare outcomes. Additionally, these types of devices do not assess technique, so this is a potential downside of devices that strictly monitor temporal adherence. Finally, the short monitoring period may have limited interactions between healthcare providers and patients, as many may not have had another clinic appointment scheduled during the 3-month monitoring period.

The results of this study suggest that it is feasible to use this technology as a tool for evaluating the effectiveness of interventions to improve adherence to asthma medications. Future studies should assess the effectiveness of interventions aimed at behavior change to improve adherence, non-adherence phenotypes, the role of patient-provider communication about adherence and shared decision-making, as well as determining which patients stand to benefit the most from adherence monitoring platforms(5). Digital health platforms should eventually allow for improved personalization of asthma medication therapy, giving providers and patients the tools needed to improve the lives of children with asthma.

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Figure 1.
Adherence rates over the study period.