Using mHealth and Patient-Reported Outcomes to Deliver Evidence-Based Asthma Care

Final Report

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Abstract

Purpose Our purpose was to 1) Design and develop an mHealth application and practice model that implements asthma-related patient centered outcomes research (PCOR) by enabling serial monitoring of patients' symptoms, and 2) Conduct a feasibility test.

Scope mHealth has potential to improve symptom monitoring. There is a need to understand how to incorporate mHealth apps into care.

Methods To design the app and practice model, we applied user-centered design principles through individual design sessions. We then conducted a 6-month feasibility test in two subspecialty care clinics, and evaluated results through analysis of app usage logs and semi-structured interview data.

Results Our practice model involved 4 components: 1) Patients are invited by their physicians. 2) Patients receive weekly 5-item questionnaires and may request a call from a nurse. 3) Patients can view their data graphically. 4) Physicians have access to the data in the EHR. The feasibility test of 26 patients found 24 (92%) were still completing weekly PRO questionnaires with 84% mean completion rate at 6 months. Higher odds of completion were found in female (88% vs 73%, P=0.03) and more educated (94% vs 74%, P=0.04) participants. Interviews with 21 patients suggested that key reasons for continued engagement was that the app was simple and easy to use, increased their awareness of asthma, made them feel more connected to their provider, and avoided emergency care. Providers found minimal burden. Some enhancements are needed for scaling to primary care.

Key words: mHealth, practice model, health information technology, informatics

A. Purpose

We developed an mHealth app and practice model by identifying the core components for implementing a clinically integrated asthma symptom monitoring intervention, and we conducted a feasibility test of the intervention.

We identified the core intervention components using user-centered design methods. We defined the following criteria as design goals:

- Patients would use it. Specifically, a substantial portion of asthma patients would complete a questionnaire about their symptoms on a weekly basis.
- Clinicians would find it clinically beneficial and low burden. Specifically, the intervention would require only minimal changes to workflows.

We selected these proximate objectives for purposes of design because they are necessary conditions for ultimately achieving improvements in health outcomes and utilization, and for scaling. We attempted to reach saturation in intervention components defined as those that users considered as the minimum requirements to achieve the above criteria and would be feasible to develop with modest resources.

After developing the app and practice model, we conducted a feasibility test. Our specific objectives were to:

- Assess the extent to which patients use the app, and better understand the factors that influence their usage;
- Understand the benefits and barriers to integrating the practice model into clinical care from the clinician's perspective;
- Identify opportunities for enhancements to the app and practice model.

B. Scope

Asthma affects more than 25 million individuals in the United States, and causes substantial suffering, disruption in lives, hospitalizations, and early deaths. Recent updates to existing guidelines, which are based on patient centered outcomes research (PCOR), call for clinicians to adjust treatment based on serial monitoring of patients' symptoms, but such monitoring does not occur routinely.

mHealth, and in particular smartphone technology, offers an opportunity to address this challenge. Smartphones allow patients to report symptoms more frequently and conveniently outside of an office visit and to make those data available to clinicians. More than three-quarters of Americans currently own smartphones and rates of smartphone ownership are rising among older adults and people with low household incomes. However, mHealth solutions are not widely used to

facilitate serial collection of asthma-related patient reported outcomes (PROs) for routine use in clinical care.

We recruited physicians and licensed practical nurses (LPNs) from clinical practices at two different sites within Brigham and Women's Hospital, an academic medical center in Boston, MA, from May 2015 through December 2016. We recruited patients for design sessions which took the form of individual semi-structured interviews. We selected patients who were diagnosed with asthma and owned smartphones. We attempted to include ethnically diverse patients and a range of ages and income levels. We implemented the intervention in two subspecialty clinics within the same academic medical center, and recruited 5 clinicians, 1 nurse care manager, and 26 patients from May 2017 through April 2018 (rolling recruitment for a six-month study period). While primary care is the setting in which most asthma patients are treated, for our intervention development and feasibility testing, we chose clinics that specialized in pulmonary or allergic diseases to facilitate recruitment of physicians and diverse patients with difficulty controlling their asthma.

C. Methods

To develop the app and practice model, we applied principles of user-centered design and qualitative research through individual design sessions with a diverse sample of end-users. Because the major benefits of technology arise when work processes are altered to take advantage of the technology's potential, we developed technology and workflows concurrently. We included a patient representative on the research team with whom we consulted about overall design before each development stage and on an ad hoc basis when design questions arose (e.g., when we received conflicting feedback from users). We also alternated our design sessions with patients and with clinicians so that we would be able to develop an intervention that incorporated both perspectives.

The development process proceeded in four broad phases. Although the steps largely occurred in sequence, at times we needed to return to a previous phase (e.g. return to low-fidelity mockups to clarify and improve navigation after app software development had begun). Within each phase we attempted to reach saturation in desired intervention components before advancing to the next phase. In keeping with the intention of identifying core components, components that were viewed as essential to achieve our objectives were included; components that were desired but not essential were deferred to subsequent versions; components that were strongly thought to support objectives but not clearly essential were included if they were feasible to develop and users believed they had minimal chance of detracting from other essential components.

In phase 1, we developed our first workflows and refined them through semi-structured interviews with the goal of understanding users' needs and motivations. We used an interview guide and asked patient-users questions about: general experiences with asthma, motivation for engaging in symptom monitoring, motivation and barriers to answering weekly questions related to asthma symptoms, desired methods and timing for facilitating contact with clinicians as a result of symptom scores, impact of symptom monitoring on relationship with clinician, and the potential role of symptom scores during in-person visits. Physician questions included: invitation processes, types of patients most likely to benefit from symptom monitoring, utility of weekly patient reported symptom scores, score thresholds needed for generating notifications, methods for establishing contact between patient and clinician, and workflow changes that would maximize utility of symptom data.

In phase 2's design sessions, we used updated interview guides, described our proposed intervention, and developed workflow diagrams and low-fidelity mockups (sketches to illustrate rough ideas) of the user interfaces. We asked users to use the "think aloud" protocol when reviewing the mockups. We asked more detailed questions about the topics discussed in phase 1. For example, we asked patients about how they would like to see their own self-reported data, from whom they would like to receive a call if symptoms are worsening, and their reaction to a smiley face as a reward for completing the weekly questionnaire (concept borrowed from gamification). For physicians, we asked about the process for handling notifications and making the symptom data available during in-person visits. For care managers, we asked licensed practical nurses (LPN) about additional time requirements to handle patient-generated notifications and aspects of the notification logic.

As we began to define our functionality, we assessed the technical feasibility of implementing this intervention using our clinical sites' existing EHR. We found that the EHR supported some but not all of our required features, so we contracted with a third-party app development company (ADK Group, Boston, MA) to help develop high-fidelity prototypes and to write the software.

In phase 3's design sessions, we user-tested high-fidelity prototypes (close to a final product) with patients and clinicians, with a focus on clarity of wording, look-and-feel, and navigation. To ensure our design followed best practices for smartphone apps, we reviewed the design with two experts in smartphone user interfaces from Apple, Inc. We also continued to enhance the workflows by providing more detail of the steps and options. In phase 4, we finalized the workflows and worked with our contractor as they wrote the software, and conducted a summative heuristic evaluation.

We implemented the intervention in two subspecialty clinics within the same academic medical center, and recruited 5 clinicians, 1 nurse care manager, and 26 patients in a six-month study period. At the conclusion of each patients' study period, we conducted individual semi-structured interviews via telephone with 21 patients. We also conducted interviews with five providers (three physicians, one physician assistant, and the LPN who served as our nurse care manager) who were involved in the intervention. Each interview was approximately 30 minutes for patients and one hour for providers. We developed separate interview guides for patients, the nurse care manager, and for the physicians and physician assistant. Interview topics included overall perspective of the intervention and app, benefits to patients, technical and workflow barriers, features of the app and practice model, and potential enhancement to include in subsequent intervention development. Each interview was audio recorded and transcribed.

We conducted a sequential-explanatory mixed methods analysis of the data. We first analyzed the patients' usage logs using descriptive statistics and associations with demographic variables, followed by engaging with the qualitative data to explain the quantitative findings and produce a richer understanding of patient and provider experiences with the app and practice model.

For the quantitative analysis, we used patient age, gender, education (less than a bachelor's degree, bachelor's degree or higher), and ethnicity (white, non-white) which were collected upon study enrollment. Patients' clinical characteristics were captured with several metrics, including baseline and average questionnaire scores and the percent of questionnaires with high severity qualifying for the potential to receive a call from a nurse (3 points worse than baseline, 3 points worse than previous week, or most severe an any of the 5 questions of the ACM). In addition, we computed a transition score whereby questionnaire scores were categorized into three levels of severity (well = 0–2, not well = 3–7, very poorly = 8-19) and changes in severity categories were measured for consecutive weeks (same category = 0, change to an adjacent category = 1, and change to a nonadjacent category = 2). The average transition score was computed for each patient as a measure of the volatility of their condition, where higher average transition scores indicate greater volatility. We measured study characteristics, including the percent of study weeks for which patients completed a questionnaire and the percent of the time they received the option to request a call from a nurse due to high symptom severity and declined the call.

Continuous variables were described as mean and standard deviation, and categorical variables were described as frequencies and percentages. Bivariate analyses were conducted to assess the associations between patients' demographic and clinical characteristics and the percent of study weeks for which they completed a questionnaire. Two-sample t-tests were applied to assess differences in percent questionnaire completion between patients by the binary categorical variables

gender, education, and ethnicity. An analysis of variance was conducted to compare completion rate across the providers who recruited patients for the study. Pearson's correlation tests were conducted to assess the association between percent questionnaire completion and the continuous demographic and clinical variables. All analyses were conducted using SAS software (SAS Institute Inc., Cary, NC, USA).

We analyzed responses to the semi-structured interview questions after performing the quantitative analysis. This sequence allowed us to explain the findings, such as questionnaire completion rates, and volumes of requests for phone calls when asthma symptoms exacerbated. To facilitate coding qualitative data, we used Dedoose (SocioCultural Research Consultants, LLC version v8.0.35), a secure online data analysis application. We used both deductive (i.e., based on the interview guide and quantitative findings) and inductive (i.e., emerged from the data) to develop codes, and used the constant comparative methods to refine our codes and interpretations. Based on the interview questions and a review of all transcripts, we created and entered into Dedoose a hierarchically organized codebook. Two ensure consistency, two coders coded two transcripts independently and obtained a kappa=0.82. The coders then coded all subsequent transcripts using top-level codes and added new codes or refined existing ones during the course of the analysis to improve the quality of the coding. The two coders reviewed all transcripts a second time using the final code book and resolved differences by consensus.

D. Results

Component 1: Invitation

A patient's own physician invites her to participate, ideally during an in-person visit, and then hands her off to another staff member who helps the patient set up and become acquainted with the functionality on their phone. Our design sessions with patients and prior experience with PROs support this decision: patients are much more likely to adhere to recommendations made by their physician.

Component 2: Weekly symptom checks and notifications

Each week, patients receive an automatically generated prompt on their smartphone at a designated time, with follow-up reminders if they do not respond. Prompts ask the patient to complete a 5-item asthma questionnaire within a 48-hour window after which the questionnaire expires. As none of our interviewed patients expressed preferences for timing of the prompt, they are generated when convenient for the care manager (e.g. an LPN or medical assistant) to be available to call them

during working hours. (No notifications are issued on Thursday or Friday to try to catch patient's issues during workdays.) After the patient completes the questionnaire, simple logic rules determine if the patient's symptoms are worse than the previous week, worse than baseline or severe on any given question. If the criteria are met, the patient is given the option of requesting a call from a care manager, who works with the patient's physician. We purposefully designed this workflow to be similar to how a care manager might handle a patient phone call about their symptoms so that workflow changes would be minimal. If symptoms meet more severe criteria, the care manager is auto-notified (i.e. patient is not given the option). The care manager will have access to a view of the patient's complete self-reported symptom history.

We encountered two challenges in designing this component. First, some of the patients in our design sessions had difficulty understanding the concept of a baseline and said there was no typical week in terms of their symptoms. Furthermore, their baselines may change by the seasons. We therefore ask patients to choose as their baseline responses symptoms on an average week in which they are not experiencing an asthma "flare" and would probably not call their physician, and we acknowledge that these may not be exact. We did not attempt to design a way to create a new baseline based on season because patients found it challenging to think about this feature without having used the app. Second, some patients asked for a definition of an asthma attack. So as to avoid interrupting the flow of the questions, we included a definition at the beginning of the survey and gave the patients the option to stop showing it in the future.

Component 3: Patient review of symptoms

The app allows patients to review their symptom history at any time. In our design sessions, patients generally agreed to the need to easily review their most recent 1-2 months of scores but have more of their previous data available on demand. However, there was a range in patients' views of the importance of this feature with some finding it more valuable than others. We therefore developed an interactive widget allowing them to review their recent 2- and 6-month symptom scores, as well as the ability to view each question response in graphic form. The data points are color coded per severity according to our notification logic.

Component 4: In-person visit

All patient-reported data are available to the physician through their EHR as a recent note. Most patients emphasized that it would be important to them that their physicians were aware of their reported data during the in-person visit, and if the physicians were not aware, they might lose motivation to continue responding to the weekly questionnaires. Physicians also wanted the recent

scores available. However, physician workflows vary and we found no clear place in this EHR that physicians consistently reviewed before a visit. All physicians we spoke with said that in the existing EHR one place where they would likely notice the data before a visit would be a recent note, but they could not guarantee they would always notice it.

Feasibility test

At the end of six months, 24 of the 26 patients (92%) were still completing weekly PRO questionnaires with 84% mean completion rate. Higher odds of completion were found in female (88% vs 73%, P=0.03) and more educated (94% vs 74%, P=0.04) participants. Of all questionnaire responses, 24% qualified for a possible call from a nurse, and 21 patients (81%) received at least one call. Interviews with 21 patients suggested that key reasons for continued engagement was that the app was simple and easy to use, increased their awareness of asthma, made them feel more connected to their provider, and avoided emergency care. Providers found minimal workflow burden. Patients and providers suggested many enhancements, including recording peak flows and details on recent symptoms and treatment.

We conclude that a simple mHealth app for asthma symptom monitoring can achieve high patient engagement when integrated into clinical care. Some enhancements to the intervention are likely needed for scaling to primary care. This work may serve as a model for developing mHealth tools and practice models for other chronic conditions.

E. Publications

We currently have one journal article published and one under review; we have presented results at two conferences and one webinar; and we have one conference presentation accepted for podium presentation, and another conference presentation submitted for review.

- Rudin RS, Fanta CH, Predmore Z, Kron K, Edelen MO, Landman AB, Zimlichman E, Bates DW. Core Components for a Clinically Integrated mHealth App for Asthma Symptom Monitoring. *Appl Clin Inform.* 2017 Oct;8(4):1031-1043. doi: 10.4338/ACI-2017-06-RA-0096. Epub 2017 Dec 14. PubMed PMID: 29241243; PubMed Central PMCID: PMC5802299.
- Rudin RS, Fanta CH, Qureshi N, Duffy E, Edelen MO, Bates DW. Implementing a clinically integrated mHealth app and practice model by collecting patient-reported

outcomes between visits: a feasibility study in asthma. *J Am Med Inform Assoc.* (Under review)

- Rudin RS, Fanta CH, Predmore Z, Kron K, Edelen MO, Landman AB, Zimlichman E, Bates DW. Critical Components for Asthma Symptom Monitoring through mHealth. 5th *Annual Medical Informatics World Conference*, 2017, Boston, MA. http://www.medicalinformaticsworld.com/telehealth/
- Rudin RS. Mobile Health for Symptom Monitoring: Early Lessons from Asthma. *The International Society for Quality in Health Care.* Webinar presentation. September 2017 https://isqua.org/docs/default-source/education-/isqua-webinar_robert-rudin_september-2017.pdf?sfvrsn=0
- Rudin RS. Using mHealth to Monitor Asthma Symptoms Between Visits. *American Medical Information Association, Annual Symposium 2017*, Washington, DC. https://amia2017.zerista.com/event/member/389393
- Rudin R, Fanta CH, Bates DW. Using mHealth to Monitor Asthma Symptoms Between Visits: Mixed-methods Evaluation of a Pilot Intervention. *American Medical Information Association, Annual Symposium 2018,* San Francisco, CA. (Accepted)
- Rudin RS, Fanta CH, Qureshi N, Duffy E, Edelen MO, Bates DW. Implementing a clinically integrated mHealth app and practice model by collecting patient-reported outcomes between visits: a feasibility study in asthma. *11th Annual Conference on the Science of Dissemination and Implementation in Health,* December 2018. (Under Review)