1. Title Page

Title of Project
PA-20-070 Integrating Patient-Reported Outcomes into Routine Primary Care: Monitoring Asthma Between Visits

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2. Structured Abstract

Purpose: The goal of this study was to enhance our existing remote symptom monitoring intervention for asthma to meet patient, provider, and health system needs during the pandemic.

Scope: In other work, we developed an mHealth app and clinically integrated remote symptom monitoring intervention for asthma. We evaluated the intervention through a 12-month randomized controlled trial (RCT) conducted between January 2019 and April 2022 at seven primary care clinics affiliated with a large academic health center in Boston, MA. In the context of COVID-19, we integrated a COVID-19 symptom screener into the app.

Methods: We analyzed screener use using descriptive statistics and by conducting exit interviews with patients. To evaluate recruitment practices, we used Fisher's Exact test to compare patient-recorded recruitment method for those enrolled against patient demographics, and multivariable logistic regression to control for each covariate and adjust effect size estimates.

Results: Of 6366 eligible patients who were approached for the RCT, 627 were screened, 445 consented, and 413 enrolled. Over half of those consented (n = 241; 52 percent) reported they were recruited via patient portal message. Among users of the app (n = 190), 154 (81 percent) used the COVID-19 symptom screener at least once. Key recruitment barriers included technology issues (e.g., lack of email access) and facilitators included bilingual study staff, Spanish-language recruitment materials, targeted phone calls, and clinician-initiated "1-click" referrals.

Key Words: remote symptom monitoring, mHealth, asthma, COVID-19

3. Report[1]

Purpose

The goal of this study was to enhance our existing remote symptom monitoring intervention for asthma to meet patient, provider, and health system needs during the pandemic. Our objectives were to: 1) enhance the intervention to add specific COVID-19-related functionality; 2) identify best practices for recruiting patients into preventative remote monitoring interventions during a pandemic; and 3) build a predictive model to identify patients who could most benefit from the intervention. For the third aim, we changed our approach to better utilize our available data: instead of developing a predictive model, we aim to develop a conceptual framework to characterize recruitment approaches and conduct bivariable and multivariable analyses to identify predictors of successful recruitment, based on the 6366 approached patients (results forthcoming).

Scope

Background, Incidence, and Prevalence

COVID-19 has presented an unprecedented risk for patients with chronic lung disease such as asthma, an added strain on health systems, and a burden on healthcare professionals who monitor these patients to ensure compliance with chronic disease management guidelines.[1] The more than 25+ million individuals in the US with asthma are at greater risk of poor health outcomes if they become ill with COVID-19. Furthermore, respiratory viral illnesses, including coronaviruses, are well-established triggers of asthma exacerbations. Up to 34 percent of hospitalized COVID-19 patients have chronic lung disease.[2, 3] The response of the health system to COVID-19 initially placed patients with asthma at greater risk. As a consequence of social and physical distancing guidelines, routine care of patients with chronic disease was challenged and maintenance medications are not filled.[4] Due to fear of contracting COVID-19, many patients were reluctant to seek care until late or acute complications of disease manifest. It is widely established that asthma control can be improved and exacerbations can be prevented by serial symptom monitoring.[1]

Context

Through our other ongoing AHRQ-funded work, we designed, implemented, and evaluated a novel mHealth app and health IT-enabled practice model for between-visit remote patient symptom monitoring of asthma patient-reported outcomes (PROs) in primary care, the setting in which most asthma patients are treated. Through that work, we employed user-centered design practices to develop and evaluate the app and practice model for use with a diverse population of Spanish- and English-speaking patients, including those with low health literacy. We implemented and evaluated the intervention through a randomized controlled trial (RCT) study at seven community-based primary care clinics affiliated with our accountable care organization.

The COVID-19 pandemic began to unfold in the U.S. just as the study was preparing to launch recruitment for the RCT. We applied for supplemental funding from AHRQ in 2021 in order to complement our existing study aims with three separate aims related to better support patients, health care providers, and health systems in responding to the COVID-19 pandemic. By monitoring patients with a chronic medical condition safely at home and treating exacerbations before they put further strain on the healthcare system, we sought to use this supplemental

[1] Much the text in this report is copied verbatim from our published studies that are cited. Some results are preliminary and will be submitted for publication in future.

funding from AHRQ to leverage our ongoing work in support of patients, providers, and participating primary care clinics.

Setting

The study was conducted during a 20-month recruitment period between July 2020 and March 2022 at seven primary care clinics affiliated with Mass General Brigham (MGB), an academic medical center in Boston, MA. All clinics used a commercial EHR system (Epic Systems, Inc.) and were a part of Brigham Health's Primary Care Practice-Based Research Network. All patients can enroll in MGB's patient portal, Patient Gateway, which is powered by MyChart (Epic Systems, Inc.) and is available in Spanish as well as other languages. The Institutional Review Boards of MGB and the RAND Corporation approved all study procedures.

Participants

Potentially eligible adult patients (18 years or older) from these clinics were identified by querying MGB's electronic data warehouse at any time during the 24 months prior to study initiation (July 2020), and from subsequent data refreshes during the recruitment period (July 2020 to March 2022) if they were assigned to a primary care provider (PCP) affiliated with one of the seven primary care clinics and had either one of the following criteria: 1) a prior diagnosis of asthma (ICD-10 code defined as J45.xx) either on their EHR problem list or specified during a subspecialty, inpatient, or emergency department encounter; or 2) a diagnosis of asthma and a referral to an Allergy or Pulmonary subspecialist. Potentially eligible patients who were not considered appropriate (e.g., complex mental health or social issues) for the study per their PCP or clinic medical director were excluded. Of note, patient portal enrollment, defined by an "activated" status in the EHR, was not used to identify this initial cohort.

Methods

Study Design

In the AHRQ-funded study that is the primary award for this supplement, we developed an mHealth app and clinically integrated remote symptom monitoring intervention for asthma. We implemented and evaluated the intervention through a randomized controlled trial (RCT) conducted at seven primary care clinics affiliated with a large academic health center in Boston, MA. All clinics used a commercial EHR system (Epic Systems, Inc.) and were a part of Brigham Health's Primary Care Practice-Based Research Network. All patients could enroll in MGB's patient portal, Patient Gateway, which is powered by MyChart (Epic Systems, Inc.) and is available in Spanish as well as other languages. In the present study, we developed a COVID-19 screener (see 'Intervention' section below), identified best practices for recruitment, and sought to identified predictors of successful recruitment.

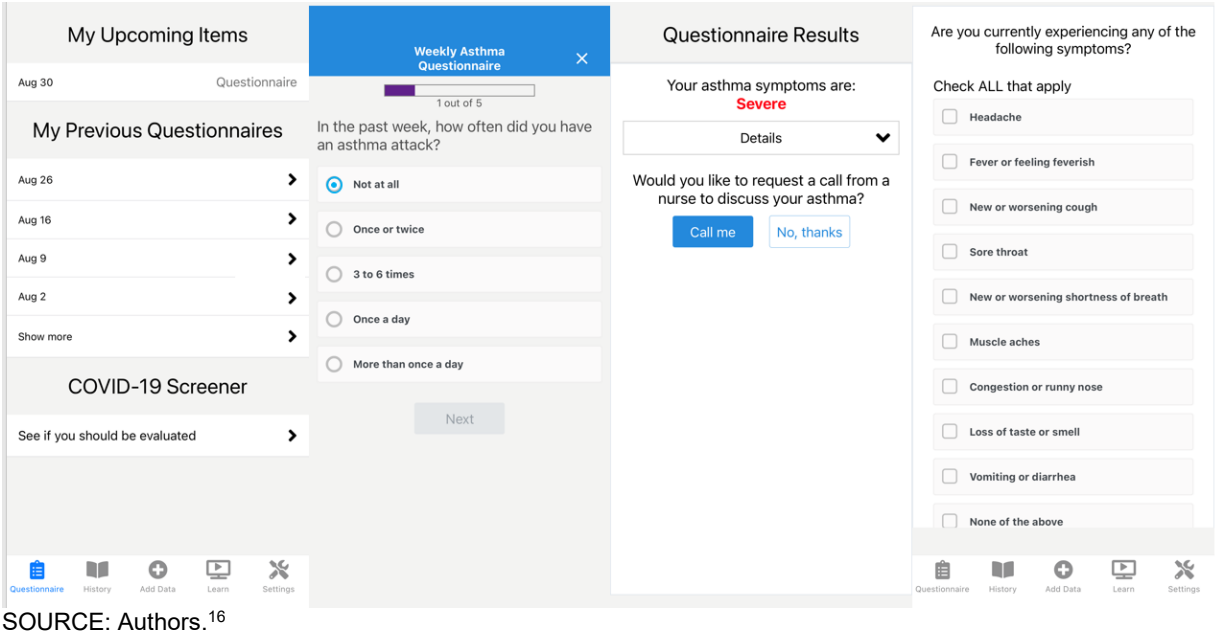
Intervention

The intervention developed in prior work (as part of the primary award associated with this supplement) consisted of remote symptom monitoring via a patient-facing mHealth app, clinician-facing dashboard, and a practice model (i.e., clinic workflows needed to support the symptom monitoring).[12] Patients using the mHealth app completed an initial 5-item baseline questionnaire and then a similar weekly PRO questionnaires for the one-year study period.[13] If the PROs showed "problematic symptoms, defined as worse compared to baseline or previous week, the app gave the patient the option to request a call from a nurse. Patients received

reminders prior to a visit to bring their phone and discuss their asthma with their PCP. The app also allowed patients to enter notes, triggers and peak flow values; view their data as a graph; and watch educational videos such as how to use their inhaler. PCPs had access to the dashboard in the EHR and received EHR inbox messages prior to a visit with a participating patient reminding them to view the data in the dashboard. We implemented the intervention at seven primary care clinics, working closely with clinical leadership, clinicians, and staff in the design, planning, initial testing, and implementation.

In the present study, at the start of the COVID-19 pandemic, we incorporated a publicly available COVID-19 symptom screener that was developed by MGB (Figure 1).[14, 15] The screener was implemented in three distinct use domains. For acute use, patients with new or worsening asthma symptoms as reported in weekly PRO questionnaires received a specific nudge to complete the COVID-19 symptom screener. Second, for routine use, patients received a reminder about the screener each week after completing their weekly PRO questionnaire. Third, the screener was displayed in the app landing page alongside educational material about COVID-19 and asthma. Regardless of the use case, patients who completed the screener and screened positive for possible COVID-19 were instructed to call the MGB COVID-19 hotline for further evaluation.

Figure 1: Screenshots of asthma app and embedded COVID-19 screener



SOURCE: Authors.[16]

With respect to RCT recruitment, potentially eligible patients were approached (detailed below) and further screened using a web-based eligibility questionnaire to confirm that the patient had an asthma diagnosis, were English- or Spanish-speaking, had a PCP from one of the 7 study clinics, and owned and used a smartphone.[5] The web-based eligibility questionnaire was accessed by patients either electronically through a hyperlink from a patient portal message, a link provided in the mailed letter, a QR code provided on a flyer or letter, or by phone with a research assistant during the initial recruitment phone call. The Institutional Review Boards of MGB and the RAND Corporation approved all study procedures.

We defined tiers of varying levels of disease activity based on a targeted review of the literature and consultation with two asthma clinicians (DF, WC – see acknowledgements).[5-7] Disease activity tiers were constructed based on encounter data retrieved from the EDW using the following criteria (1 or more unless otherwise specified) in order of decreasing disease activity: (1) hospital visit, (2) emergency department visit, (3) prednisone prescription, (4) urgent care or walk-in visit, (5) specialist visit, (6) 2 or more visits to any provider, and (7) visit related to asthma in past 2 years and asthma on the problem list. Patients who met the criteria for more than one recruitment tier were placed in the higher activity tier. After initiation of recruitment, we refreshed the cohort at regular 2-month intervals using the above criteria to identify additional patients. Of note, the seventh tier (lowest disease activity) was added after initiating recruitment of patients from the first six tiers (higher disease activity).

Eligible patients were approached using one or more of eight recruitment strategies (Table 1) until they consented or declined to participate in the study. Initially, patients were sent a mailed letter and a patient portal message. For patients who did not respond to the letter or patient portal message, research assistants (Ras) conducted follow-up phone calls and targeted phone calls prior to an upcoming appointment at their primary care clinic. Clinician-centered strategies included "1-click" referrals, a simple digital workflow initiated by referring clinicians from within the EHR, and entries in electronic "huddle" notes in the EHR to remind clinicians to recruit specific eligible patients scheduled for a clinic appointment that day. Targeted, in-person recruitment was conducted by a bilingual RA on days where 4 or more patients had an appointment at a given clinic or if a patient opted to be recruited in person when approached using one of the other strategies. At the outset of our study, we obtained IRB approval for our consent form and protocol, which included a list of initial recruitment strategies. Subsequently, we submitted amendments to our IRB protocol to add new recruitment strategies to the original list, all of which were approved before being implemented.

Table 1. RCT Recruitment Strategies

Recruitment Strategy	Description
Mailed letters	• RA mailed letters to patients through U.S. postal service • Initially, all patients were mailed a hard copy of the study recruitment letter.
Patient portal message	• RA sent a minimum of 2 patient portal messages to patients with an activated patient portal status.
Clinic-centered strategies	• Participating clinics were provided flyers with information for participating in the study and instructed to give them to potentially eligible patients • Study investigators presented an overview of study to primary care providers at participating clinics during clinic staff meetings
Follow-up phone call	• RA made follow-up phone calls to patients who were sent a mailed letter and or patient portal message.
Text messages	• RA sent patients a text message inviting them to participate in the study.

Recruitment Strategy	Description

Clinician-centered strategies	• EHR-based "1-click" referrals [a] (2022 Epic Systems Corporation)
	  ○ Study team designed a "1-click" referral button made available from within the EHR for clinicians to refer a patient to the study.
	  ○ The "1-click" referral generates a message containing the patient medical record number (MRN) that is automatically sent to the study team via email.
	  ○ The Ras followed up with referred patients via follow-up phone call and patient portal messaging if available.
	• "Huddle notes" [b]
	  ○ RA added a recruitment note to patients' charts before their upcoming appointments to remind provider to mention the study.
	• Emails to specific clinicians with scheduled appointments with eligible patients
	• RA emailed clinicians with multiple upcoming appointments in a week, reminding them to mention the study to eligible patients

Targeted phone calls	• Ras called patients before and or after appointments scheduled with a provider in an ambulatory setting to discuss the study
Targeted, in-person	• A bilingual RA recruited patients before or after clinic visit • Ras recruited in-person if there was a cluster of upcoming appointments, or if a patient (English- or Spanish-speaking) opted to be consented in person.

SOURCE: Authors' analysis.[5]
NOTES: RA = research assistant; EHR = electronic health record. [a] *"1-click" referrals* are automatically generated emails initiated by the clinician to the study team using a button available in the patient's chart in the EHR. The email contains patient identifying information for the study team to recruit the patient, [b] *"Huddle notes"* are electronic notes within the eligible patient's chart in the EHR that are reviewed by medical staff during scheduled clinic encounters.

During each month of the recruitment period, we conducted a 20-minute session with research team members using a structured recruitment debrief guide and recorded all input and feedback.[5] The recruitment debrief guide was constructed based on review of the literature and consultation with an expert on health equity (JR), and included monthly recruitment goals, barriers and facilitators to equitable recruitment, and recommended improvements to the recruitment process.[8, 9] Research assistants collected and tracked all recruitment activities in Microsoft Excel. Collected data included dates and strategies by which potentially eligible patients were approached, the recruitment strategy reported to be successful by eligible patients during the consent phone call, and free text field notes of any barriers or facilitators to recruitment reported by patients. We retrieved demographic data, patient portal enrollment status (defined above), and disease activity (defined above) from the EHR for eligible patients. For all consented patient participants, Ras asked patients how they were recruited to the study and recorded the specific strategy by which the patient was recruited.

To better understand successful recruitment approaches, we are developing a conceptual framework that characterizes key elements of recruitment and conducting bivariate and multivariable analysis to identify predictors of successful recruitment. The conceptual model will be informed by a review of the literature and involve key domains such as the recruitment algorithm, factors that inform the recruitment algorithm (equity, value to patients/willingness to participate, and value to other stakeholders), and recruitment strategies used.

Data Sources/Collection and Measures

We analyzed patient use during the 12-month trial period using descriptive statistics. We extracted COVID-19 laboratory testing data from the EHR for exploratory analyses related to screener-related healthcare utilization. Exit interviews were conducted as part of the RCT protocol; therefore we also analyzed patient reported experiences.

For our analysis of recruitment strategies, we defined four groups of patients: 1) potentially eligible patients who *met inclusion criteria* (identified in the EHR using disease activity tier criteria); 2) *approached patients* recruited using one or more strategies; 3) *screened patients* who completed the web-based eligibility questionnaire *and* provided contact information including a phone number and/or email; and 4) *consented patients* who provided written informed consent.[5] For consented patients, we defined two main outcomes: *patient portal recruit*, or participants who reported completing the web-based eligibility questionnaire *on their own* after receiving a patient portal message; and *non-patient portal recruit, or* participants who reported being contacted using any non-patient portal recruitment strategy prior to completing the web-based eligibility questionnaire. We defined dichotomous equity variables for age (greater than 65 years of age vs. less than or equal to 65 years of age), self-identified sex (female vs. male), race (non-White vs. White), ethnicity (Hispanic vs. non-Hispanic), primary language (Spanish vs. English), median income by zip code (≤$63,000 vs. >$63,000), education (no college vs. some college or graduate education), and clinic location (urban vs. suburban). We defined two process outcomes, the mean number of approaches per patient and mean number of unique recruitment strategies used per patient.

We linked data queried from the EHR to corresponding data from our patient recruitment tracker by medical record number. We used descriptive statistics to report demographics of patients who were screened (i.e., met EHR inclusion criteria), approached via the multi-pronged recruitment strategy, completed the web-based eligibility questionnaire, and consented; and to report the number and percentages of *patient portal recruits* and *non-patient portal recruits.* A two-sample t-test was used to compare the mean number of approaches per patient for *consented patients* and *approached patients who were not consented* to examine any recruitment effort disparities between patients who consented and those who did not consent to participate in the study. We used Fisher's Exact test to compare our main outcomes, *patient portal* and *non-patient portal recruits*, by each dichotomized equity variable (above). Multivariable logistic regression was used to adjust effect size estimates and control for all covariates. All quantitative analyses were performed using R Studio (Version 2022.02.0+443 for Windows).[10]

For our qualitative analysis, two members of the research team trained in grounded theory (SP, JSF) independently reviewed and coded all feedback, notes, and responses from monthly recruitment debrief sessions, extracted representative quotes, and identified codes and preliminary themes for key recruitment facilitators and barriers from the research team perspective.[11] Using a similar process, we compiled and analyzed free text entries and notes recorded by RAs in our patient recruitment tracker to identify key facilitators and barriers from the patient perspective. Preliminary themes were reviewed and reconciled during a final group consensus meeting. All qualitative analyses were conducted using Microsoft Excel.

Limitations

At the time we adapted the COVID-19 symptom screener into our existing remote patient monitoring intervention, the screener was new and unvalidated, and it had not been designed with input from patients. It is possible that the screener may have yielded false positives such that some of the referrals to the COVID-19 screener line were unnecessary. There were low rates of asthma exacerbation during the study throughout the pandemic, and therefore it is possible that patients with COVID-19 symptoms but not severe asthma symptoms did not receive a direct prompt to complete the COVID-19 screener (only patients who had problematic asthma symptoms received the direct prompt to complete the screener).

With respect to our multimodal recruitment strategy, our RCT study of the remote asthma symptom monitoring intervention utilized a web-based screening and enrollment process, which may have introduced barriers that produced disparities. We relied heavily on patient portal messages to recruit RCT participants, and patient portal use requires digital literacy. Second, we relied on patient-reported recruitment method in our analyses. Third, given the context of the first few years of the COVID-19 pandemic, patients were facing numerous other challenges which may have influenced their ability to participate in the study.

Results

Principal Findings

Of the 190 patients who used the mHealth app during the study period, 154 (81 percent) used the COVID-19 symptom screener at least once. A total of 1003 screeners were completed. Median screener use was 3.5 times per patient, IQR =4 (6-2). Among completed screeners, 97 (63 percent) reported ≥1 COVID-19 symptom. Demographic and clinical characteristics of app users and COVID-19 screener users are described in Table 2.

Table 2. Characteristics of App Users and Cohort of COVID-19 Screener Users

Characteristic	Enrolled App Users (*n* = 190)[a]	Screener Users Reporting COVID-19 Symptoms (*n* = 154)	Screener Users who did not report COVID-19 symptoms (*n* = 36)
Primary Language Spanish - no.(%)	6 (3.2)	3 (1.9)	3 (1.9)
Age in years - mean (SD)	51.0 (15.6)	51.8 (15.4)	47.7 (16)
Female sex - no.(%)	138 (72.6)	113 (73.4)	25 (69.4)
Race - no.(%)			
American Indian or Alaska Native	1 (0.5)	1 (0.6)	0 (0.0)
Asian	8 (4.2)	7 (4.5)	1 (2.8)
Black	36 (18.9)	29 (18.8)	7 (19.4)
More than one race	18 (9.5)	12 (7.8)	6 (16.7)
Native Hawaiian or Other Pacific Islander	1 (0.5)	1 (0.6)	0 (0.0)
White	117 (61.6)	96 (62.3)	21 (58.3)
Unknown/not reported/Missing	9 (4.7)	8 (5.2)	1 (2.8)
Ethnicity - no. (%)			
Non-Hispanic	136 (71.6)	115 (74.7)	21 (58.3)
Hispanic	39 (20.5)	27 (17.5)	12 (33.3)
Unknown/not reported/Missing	15 (7.9)	12 (7.8)	3 (8.3)

Characteristic	Enrolled App Users (*n* = 190)[a]	Screener Users Reporting COVID-19 Symptoms (*n* = 154)	Screener Users who did not report COVID-19 symptoms (*n* = 36)
Smartphone Type - no. (%)			
iPhone	140 (73.7)	115 (74.7)	25 (69.4)
Android	46 (24.2)	37 (24)	9 (25)
Unknown/not reported/Missing	4 (2.1)	2 (1.3)	2 (5.6)
Education - no. (%)			
No High-School Degree	8 (4.2)	6 (3.9)	2 (5.6)
High-School Degree or GED	15 (7.9)	11 (7.1)	4 (11.1)
Some College	23 (12.1)	19 (12.3)	4 (11.1)
2-Year College	15 (7.9)	10 (6.5)	5 (13.9)
4-Year College	52 (27.4)	42 (27.3)	10 (27.8)
More Than 4 Year College	77 (40.5)	66 (42.9)	11 (30.6)

SOURCE: Authors' analysis.
NOTES: [a]Includes the 190 patients in the intervention arm who completed the baseline ACM questionnaire in the app and who did not withdraw from the study.

Among patients with asthma who reported at least one symptom during the study period, runny nose was the most common symptom reported on the screener (*n* = 144; 59 percent), and diarrhea (*n* = 20; 8 percent), fever (*n* = 19; 8 percent), muscle aches (*n* = 35; 14 percent), and lost smell (*n* = 19; 8 percent) were least common (Table 3). New or worsening shortness of breath was reported in 72 (30 percent) and cough in 74 (31 percent) of screenings, respectively.

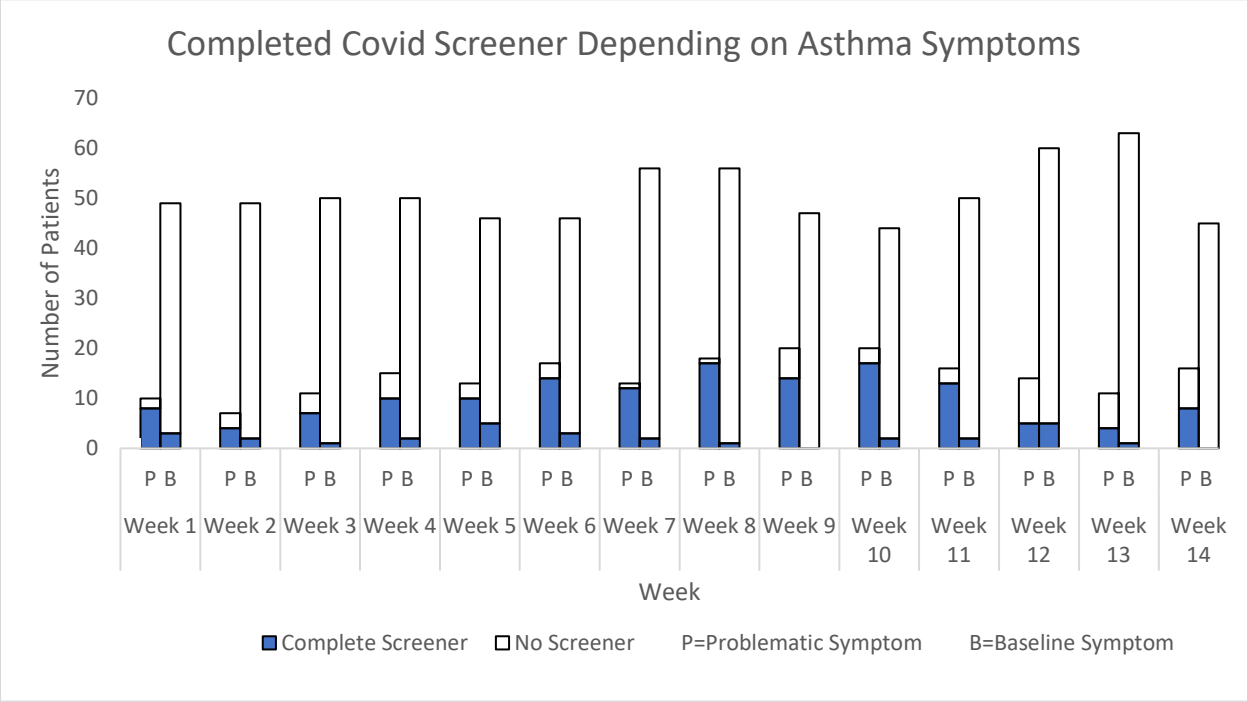
Table 3. COVID-19 symptoms by asthma app users with at least one symptom reported

	Number of times symptom reported	Percentage of at least one symptom reported (*N* = 243)
Runny Nose	144	59.3%
Headache	77	31.7%
Cough	74	30.5%
Breath	72	29.6%
Sore Throat	56	23.0%
Contact	44	18.1%
Muscle Aches	35	14.4%
Diarrhea	20	8.2%
Fever	19	7.8%
Smell	19	7.8%

NOTES: [a]4 patients tested positive for COVID-19 and screener was filled out within 7 days.

COVID-19 screener use was consistently high among patients reporting an ACM score indicating problematic asthma symptoms during the study period (Figure 2). In contrast, patients within their baseline range of ACM score, screener use was minimal.

Figure 2. Completed COVID-19 Screeners after Weekly Questionnaires Depending on Asthma Symptoms, by Study Week



SOURCE: Analysis by authors.

With respect to recruitment, we identified a total of 6853 patients from the EDW who met study inclusion criteria; notably, 5783 (84 percent) were patient portal enrollees. Of these 6853 potentially eligible patients, 6366 (93 percent) were approached, 627 patients (9 percent) were screened using the web-based eligibility questionnaire, and 445 patients (7 percent) consented using our multi-pronged strategy.[5] The demographics of the 627 patients who were approached and completed the web-based eligibility questionnaire were mostly similar to the 5739 patients who were approached but did not complete the eligibility questionnaire (Table 4)

Table 4. Patient Demographics by Recruitment Outcome

Characteristics	Met Inclusion Criteria (*n* = 6853)	Approached (*n* = 6,366)	Did Not Complete Web-Based Eligibility Screener (*n* = 5739)	Completed Web-Based Eligibility Screener (*n* = 627)	Consented (*n* = 445)	p-value[a]
Age in years–mean (SD)	53.8 (17.1)	53.9 (17.1)	55.1 (17.3)	52.5 (15.5)	52.0 (15.5)	0.452
Sex-Female–no. (%)	5158 (75.3)	4793 (75.3)	4293 (74.8)	499 (79.6)	346 (77.8)	0.065
Race/Ethnicity –no. (%)						
American Indian or Alaska Native	9 (0.1)	10 (0.2)	8 (0.1)	2 (0.3)	2 (0.4)	
Asian	188 (2.7)	183 (2.9)	166 (2.9)	18 (2.9)	12 (2.7)	
White Non-Hispanic	3394 (49.5)	3245 (51.0)	2915 (50.8)	331 (52.7)	236 (53.0)	
Black Non-Hispanic	1164 (17.0)	1049 (16.5)	916 (16.0)	130 (20.7)	92 (20.7)	
Hispanic	1837 (26.8)	1642 (25.8)	1519 (26.5)	124 (19.8)	89 (20.0)	
Native Hawaiian/Other Pacific Islander	2 (0.03)	3 (0.05)	2 (0.03)	1 (0.2)	1 (0.2)	
Other	123 (1.8)	110 (1.7)	98 (1.7)	13 (2.1)	6 (1.3)	
Declined/Unavailable/ Missing	136 (2.0)	124 (1.9)	115 (2.0)	8 (1.3)	7 (1.6)	0.005
Marital status – no. (%)						
Partnered	2996 (43.7)	2822 (44.3)	2563 (44.7)	261 (41.6)	189 (42.5)	0.693

Characteristics	Met Inclusion Criteria (*n* = 6853)	Approached (*n* = 6,366)	Did Not Complete Web-Based Eligibility Screener (*n* = 5739)	Completed Web-Based Eligibility Screener (*n* = 627)	Consented (*n* = 445)	p-value[a]
Non-Partnered/Single	3775 (55.1)	3465 (54.4)	3102 (54.1)	361 (57.6)	252 (56.6)	
Unknown/Missing	82 (1.2)	79 (1.2)	74 (1.3)	5 (0.8)	4 (0.9)	
Primary language-Spanish–no. (%)	829 (12.1)	705 (11.1)	670 (11.7)	34 (5.4)	20 (4.5)	<0.001
Education – no. (%)						
Less than high school	659 (9.6)	554 (8.7)	505 (8.8)	47 (7.5)	30 (6.7)	
Graduated high school	2086 (30.4)	1858 (29.2)	1669 (29.1)	188 (30.0)	132 (29.7)	
Graduated college	2512 (36.7)	2425 (38.1)	2185 (38.1)	241 (38.4)	169 (38.0)	
Graduated higher education	741 (10.8)	727 (11.4)	648 (11.3)	80 (12.8)	61 (13.7)	
Unknown/Missing	855 (12.5)	802 (12.6)	732 (12.8)	71 (11.3)	53 (11.9)	0.142
Socioeconomic status[b] – no. (%)						
Less than or equal to $47,000	648 (9.5)	568 (8.9)	510 (8.9)	57 (9.1)	44 (9.9)	
$47,001 to $63,000	776 (11.3)	708 (11.1)	650 (11.3)	58 (9.3)	37 (8.3)	
Greater than $63,000	5399 (78.8)	5060 (79.5)	4554 (79.4)	507 (80.9)	362 (81.3)	
Missing	30 (0.4)	30 (0.5)	25 (0.4)	5 (0.8)	2 (0.4)	0.449
Insurance status – no. (%)						
Commercial	3835 (56.0)	3656 (57.4)	3298 (57.5)	365 (58.2)	257 (57.8)	
Medicaid	1299 (19.0)	1129 (17.7)	1012 (17.6)	116 (18.5)	82 (18.4)	
Medicare	1635 (23.9)	1496 (23.5)	1349 (23.5)	141 (22.5)	104 (23.4)	
Self-Pay	79 (1.2)	80 (1.3)	75 (1.3)	5 (0.8)	2 (0.4)	
Other Government	5 (0.1)	5 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)	0.719
Patient portal enrollees[c] – no. (%)	5783 (84.4)	5575 (87.6)	4992 (87.0)	592 (94.4)	423 (95.1)	<0.001
Charlson Comorbidity Index – mean (SD)	1.8 (1.6)	1.7 (1.6)	1.7 (1.6)	1.7 (1.4)	1.7 (1.5)	0.217

SOURCE: Authors' analysis.[5]
NOTES: [a]Compared met inclusion criteria, approached, completed web-based eligibility questionnaire "yes", and consented. [b]Median income by zip code. [c]Patient portal enrollees = defined as having an "activated" status in the EHR.

We observed no significant difference in the mean (SD) number of approaches per patient between *consented patients* (3.2 (2.1)) and *approached patients who were not consented* (3.1 (1.7)), t = -0.1, 95% CI [-0.20, 0.18], $p = 0.92$. Of the 445 patient enrollees (of whom, 423 (95.1%) were patient portal enrollees), 241 (54.2%) reported being recruited via the patient portal (i.e., completed the eligibility questionnaire after receiving a patient portal message). In unadjusted analyses, patient portal recruits were significantly more likely to be White, non-Hispanic, higher income, and have some college education compared to non-patient portal recruits (Table 5). There were no significant discrepancies for age, sex, or language among patient portal recruits compared to non-patient portal recruits. Patients affiliated with urban clinics were significantly less likely to be recruited via the patient portal. In adjusted analyses, non-White participants (OR 0.46, 95% CI [0.28, 0.77], $p = 0.003$) and participants with no college education (OR 0.60, 95% CI [0.39, 0.91], $p = 0.016$) were significantly less likely to be recruited via the patient portal.

Table 5. Patient Portal Recruits versus Non-Patient Portal Recruits by Equity Variable

	Patient Portal Recruits, n=241	Non-Patient Portal Recruits, n=204	Un adjusted OR	95% CI	p-value	Adjusted OR	95% CI	p-value
Age – no. (%)								
Greater than 65	56 (23.3)	41 (20.3)	1.20	(0.75, 1.95)	0.490	0.80	(0.48, 1.32)	0.385
Less than or equal to 65	185 (76.7)	163 (79.7)						
Sex – no. (%)								
Female	182 (75.8)	164 (80.2)	0.74	(0.46, 1.19)	0.211	0.84	(0.52, 1.36)	0.484
Male	60 (24.2)	40 (19.8)						
Race – no. (%)								
Non-White	84 (34.6)	125 (60.9)	0.34	(0.23, 0.51)	<0.001	0.46	(0.28, 0.77)	0.003[b]
White	157 (65.4)	79 (39.1)						
Ethnicity – no. (%)								
Hispanic	33 (13.3)	56 (26.7)	0.42	(0.25, 0.69)	<0.001	0.82	(0.44, 1.52)	0.535
Non-Hispanic	208 (86.7)	148 (73.3)						
Primary language – no. (%)								
Non-English	7 (2.9)	14 (6.9)	0.41	(0.14, 1.10)	0.071	0.91	(0.31, 2.51)	0.856
English	234 (97.1)	190 (93.1)						
Median income by zip code – no. (%)								
Low Income (≤$63,000)	33 (13.8)	50 (24.3)	0.50	(0.29, 0.82)	0.005	0.91	(0.52, 1.59)	0.736
High Income (>63,000)	208 (86.3)	154 (75.7)						
Education – no. (%)								
No College	95 (39.2)	120 (58.4)	0.46	(0.31, 0.68)	<0.001	0.60	(0.39, 0.91)	0.016[b]
Some College and above	146 (60.8)	84 (41.6)						
Clinic Location[a] – no. (%)								
Urban	133 (55.0)	173 (84.7)	0.22	(0.13, 0.36)	<0.001	0.68	(0.43, 1.04)	0.079
Suburban	108 (45.0)	31 (15.3)						

SOURCE: Authors' analysis.[5]
NOTES: [a]Urban clinics are those located within Boston city limits. [b]Hommel corrected values for Race and Education were p=0.026 and 0.115, respectively.

Eight major themes (3 barriers, 5 facilitators) emerged from the 13 recruitment debrief sessions. Key barriers included: technological issues related to smartphone or email access, caregiver availability for patients who expressed needing support with recruitment procedures, and a small pool of Spanish-speaking patients to recruit (Table 6). Key recruitment facilitators included: availability of bilingual study staff, recruitment from a large pool of eligible patients, use of Spanish-language recruitment materials, conducting targeted recruitment prior to upcoming patient appointments, and clinician-initiated referrals.[5]

Table 6. Monthly Recruitment Debrief Findings: Key Themes and Examples

Theme	Descriptions & Examples
Barriers	
Technological issues	• Lack of access to email and smartphones • Lack of confidence using a smartphone • Limited data plan availability

Theme	Descriptions & Examples
Caregiver availability	• Caregivers unavailable to help patient with recruitment documentation and history.
Small pool of Spanish-speaking patients	• Diminishing number of Spanish-speaking patients to approach for recruitment toward the end of the recruitment period.
Facilitators	
Large pool of eligible patients	• Data refreshes were necessary to ensure a large pool of eligible patients and corresponded to an increase in patients who were successfully recruited. • Addition of two clinics later in the recruitment period increased eligible patient pool.
Bilingual study staff	• Bilingual RA facilitated the recruitment of English- and Spanish-speaking patients. • RA was able to offer in-person recruitment to all patients who requested to be recruited in person. All patients who were ultimately recruited in-person were Spanish-speakers. • Recruitment of Spanish-speaking patients via phone calls around scheduled clinic appointments was a successful strategy for enrollment.
English and Spanish recruitment materials	• Sending patient portal messages, letters, and text messages with improved readability for health literacy in both English and Spanish. • Few patients listed as 'Spanish-speaking' and 'does not need an interpreter' in the EHR preferred Spanish materials or speaking in Spanish."
Targeted recruitment at upcoming patient appointments	• Focusing recruitment efforts (patient portal messages, phone calls, huddle notes) around scheduled patient appointments improved patient engagement. • Higher success rate of patients answering the phone when calling patients within a few days of a scheduled appointments.
Clinician-initiated referrals	• Clinicians sent study referrals using the "1-click" referral button available in the EHR. • Patients reported receiving recommendations from their PCP regarding study enrollment.

SOURCE: Authors' analysis.[5]

Of the 6,366 patients approached, 934 (15 percent) patients reported one or more barriers to participation in the study: mild or well-controlled asthma (331, 35 percent); not interested in participating (161, 17 percent); technology barriers such as not having a smartphone or email access (148, 16 percent); unable to make time commitment (141, 15 percent); health issues (54, 6 percent); spoke a language other than English or Spanish and required an interpreter (35, 4 percent); out of network or had a change in PCP (23, 2 percent); skepticism about participating (22, 2 percent); had cognitive issues or dementia (12, 1 percent); not enough study compensation (7, 1 percent); ineligible due to age (5, 1 percent); or had asthma complications (4, 0 percent).[5]

Discussion and Conclusions

Our findings suggest that integrating COVID-19 assessment tools as part of a remote patient symptom monitoring intervention was successful. Use of the screener facilitated symptom monitoring and acute care management during the COVID-19 pandemic. Our evaluation of recruitment suggests that a primarily digital strategy to recruit patients into a digital health trial is unlikely to achieve equitable participation, even in a population overrepresented by patient portal enrollees. Non-digital recruitment methods that address racial and educational disparities and less active portal enrollees are necessary to ensure equity in clinical trial enrollment. To identify patients most likely to benefit from the intervention we are identifying predictors of successful recruitment through bivariate and multivariate analyses and conducting additional subgroup analyses on our main trail (results forthcoming).

Our study highlights the importance of intentional and targeted efforts to achieve diversity in clinical trial recruitment. To improve recruitment equity, researchers should plan and budget for such efforts in their study design. A practical approach that researchers can adopt is a multi-pronged recruitment strategy, including regular debrief sessions to identify barriers to equitable recruitment. Future studies could maximize recruitment equity by staffing projects with multiple bilingual RAs, principal investigators and study team members. With the trend towards digitization of recruitment into clinical trials, strategies that utilize both digital and non-digital methods will continue to be necessary to ensure clinical trial equity.[5]

List of Publications and Products

Rudin RS, Perez S, Rodriguez JA, Sousa J, Plombon S, Arcia A, Foer D, Bates DW, Dalal AK. User-centered design of a scalable, electronic health record-integrated remote symptom monitoring intervention for patients with asthma and providers in primary care. *J Am Med Inform Assoc*. 2021 Oct 12;28(11):2433-44.

Rudin RS, Qureshi N, Foer D, Dalal AK, Edelen MO. Toward an asthma patient-reported outcome measure for use in digital remote monitoring. *J Asthma*. 2022 Aug;59(8):1697-702.

Rudin RS, Sulca Flores J, Sousa J, Foer D, Dalal AK. Making COVID-19 Screening Part Of Routine Symptom Monitoring. *Health Affairs Forefront*. [Internet]. 2021 Oct 20. Available from: https://doi.org/10.1377/forefront.20211018.47378

Plombon S, Rudin RS, Sulca Flores J, Goolkasian G, Sousa J, Rodriguez J, Lipsitz S, Foer D, Dalal AK. Assessing Equitable Recruitment in a Digital Health Trial for Asthma. *Appl Clin Inform*. [Internet]. 2023. Epub 2023 May 10. Available from: https://doi.org/10.1055/a-2090-5745

References

1. Braido F. Failure in asthma control: reasons and consequences. Scientifica. 2013;2013.
2. Rudin RS, Fanta CH, Predmore Z, Kron K, Edelen MO, Landman AB, et al. Core components for a clinically integrated mHealth app for asthma symptom monitoring. Applied clinical informatics. 2017;8(04):1031-43.
3. Wang T, Srebotnjak T, Brownell J, Hsia RY. Emergency department charges for asthma-related outpatient visits by insurance status. Journal of health care for the poor and underserved. 2014;25(1):396.
4. Mehrotra A, Chernew M, Linetsky D, Hatch H, Cutler D. The Impact of the COVID-19 Pandemic on Outpatient Visits: A Rebound Emerges [Internet]. New York, NY: Commonwealth Fund; May 19 [cited January 26, 2021]. Available from: https://www.commonwealthfund.org/publications/2020/apr/impact-covid-19-outpatient-visits.
5. Plombon S, Rudin RS, Sulca Flores J, Goolkasian G, Sousa J, Rodriguez J, et al. Assessing Equitable Recruitment in a Digital Health Trial for Asthma. Appl Clin Inform. 2023 May 10.
6. Taylor DR, Bateman ED, Boulet LP, Boushey HA, Busse WW, Casale TB, et al. A new perspective on concepts of asthma severity and control. Eur Respir J. 2008 Sep;32(3):545-54.
7. Fuhlbrigge A, Peden D, Apter AJ, Boushey HA, Camargo CA, Jr., Gern J, et al. Asthma outcomes: exacerbations. J Allergy Clin Immunol. 2012 Mar;129(3 Suppl):S34-48.
8. Alcaraz KI, Vereen RN, Burnham D. Use of Telephone and Digital Channels to Engage Socioeconomically Disadvantaged Adults in Health Disparities Research Within a Social Service Setting: Cross-Sectional Study. J Med Internet Res. 2020;22(4):e16680.
9. Consolidated Framework for Implementation Research [Internet]. 2022 [cited 2022. Available from: https://cfirguide.org/constructs/.
10. Allaire J. RStudio: integrated development environment for R. Boston, MA. 2012;770(394):165-71.
11. Strauss A, Corbin J. Basics of qualitative research: Techniques and procedures for developing grounded theory, 2nd ed. Thousand Oaks, CA, US: Sage Publications, Inc; 1998.
12. Rudin RS, Perez S, Rodriguez JA, Sousa J, Plombon S, Arcia A, et al. User-centered design of a scalable, electronic health record-integrated remote symptom monitoring intervention for patients with asthma and providers in primary care. J Am Med Inform Assoc. 2021 Oct 12;28(11):2433-44.
13. Rudin RS, Qureshi N, Foer D, Dalal AK, Edelen MO. Toward an asthma patient-reported outcome measure for use in digital remote monitoring. J Asthma. 2022 Aug;59(8):1697-702.
14. Zhang H, Dimitrov D, Simpson L, Plaks N, Singh B, Penney S, et al. A Web-Based, Mobile-Responsive Application to Screen Health Care Workers for COVID-19 Symptoms: Rapid Design, Deployment, and Usage. JMIR Form Res. 2020 2020/10/8;4(10):e19533.
15. Lai L, Wittbold KA, Dadabhoy FZ, Sato R, Landman AB, Schwamm LH, et al. Digital triage: Novel strategies for population health management in response to the COVID-19 pandemic. Healthcare. 2020 2020/12/01/;8(4):100493.
16. Rudin RS, Flores JS, Sousa J, Foer D, Dalal AK. Making COVID-19 Screening Part Of Routine Symptom Monitoring. Health Affairs Forefront. 2021.