Asthma in Families Facing Out-of-pocket Requirements Due to COVID-19

Protocol

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RESEARCH PROTOCOL

In addition to its devastating impact on health, particularly among racial/ethnic minority populations and those with chronic conditions,[1-3] the COVID-19 pandemic has led to major disruptions to the economy. An unprecedented 31 million new unemployment claims were filed in the first two months of the pandemic, disproportionately among African-Americans and Hispanics (RQ-3).[4,5] Nearly 27 million people could lose employer-sponsored insurance coverage as a result of job loss,[6] placing them at risk for cost-related unmet health care needs and financial burden (RQ-3).[7,8] Even under normal circumstances, obtaining coverage can be challenging for consumers who are not used to searching among numerous plans without an employer to vet and narrow down options and facilitate enrollment.[9,10] Eligibility for public programs and subsidies can be limited, and those who do not qualify can face plans with steep premiums, high-deductibles, and potential for substantial out-of-pocket costs for health care.[11-14] Applying for coverage will be even more difficult as COVID-related social distancing and closures reduce the availability of in-person assistance.[15,16]

Patients with asthma are at risk for adverse health outcomes during the COVID-19 pandemic. Although it is unclear if asthma is associated with worse COVID-19 outcomes,[17,18] disruptions to employment and insurance coverage during the pandemic threaten to negatively affect asthma care and outcomes, especially for racial/ethnic minority populations who are at greater risk at baseline.[19-23]

Our current PCORI-funded project, known as AFFORD (Asthma in Families Facing Out-of-pocket Requirements with Deductibles), suggests that patients with asthma may be particularly vulnerable to insurance-related cost barriers. We found that patients with asthma often find it challenging to navigate health insurance and their responses to the high costs of asthma care may have negative consequences for medication adherence, symptom control, and family well-being. As part of AFFORD's unique partnership with the Asthma and Allergy Foundation of America (AAFA), we developed an asthma chat bot to help patients with asthma navigate insurance benefits and optimize health care decisions. The chat bot is an artificial intelligence-enabled interactive online tool that can answer clinical and insurance-related questions and provide information on coverage options and how to find lower-cost alternatives for asthma care. Chatbots are increasingly being used to transmit personalized health care information, including for COVID-19-related information,[24,25] but there is little rigorous evidence about their impact on health insurance navigation and health care access.(RQ-1)

In this supplement, we propose to extend and capitalize on the formative work of AFFORD to understand and address the insurance and health care cost challenges faced by patients with asthma who lose employer-sponsored coverage due to COVID-19. Specifically, our Aims are (RQ-2):

1. To conduct a pilot randomized controlled trial to evaluate the effectiveness and implementation outcomes (e.g. feasibility, acceptability) of an existing insurance navigation intervention, including the chat bot, to help patients with asthma regain coverage after the loss of job-related insurance during the COVID-19 pandemic
2. To qualitatively explore the experiences of Aim 1 participants to understand barriers and facilitators to accessing coverage and asthma care more broadly during the COVID-19 pandemic

Findings will provide evidence about the effectiveness of patient-centered technological strategies to obtain coverage and maintain access to affordable asthma care and can inform ongoing and future decision making in response to the COVID-19 pandemic and other public health and economic threats (RQ-3). If this pilot suggests feasibility and effectiveness, the intervention can be readily scaled for studies in larger populations of patients with asthma or other chronic conditions and can be

adopted by health plans and clinical settings to help patients find affordable coverage that meets their asthma and other health care needs.

Research Design and Methods

Study Setting

Study participants will be recruited through the Asthma and Allergy Foundation of American (AAFA) and Harvard Pilgrim Health Care (HPHC). AAFA is a national non-profit organization founded in 1979 to control and prevent asthma and allergic conditions through patient education, public awareness, and support for research. AAFA's websites host an average of 700,000 unique visitors each month (www.aafa.org and www.kidswithfoodallergies.org). As in AFFORD, the proposed study will take advantage of AAFA's wide national reach and role as a trusted information source to recruit a national sample of patients with asthma or parents of children with asthma who lost employer-sponsored insurance coverage after February 2020 when coronavirus (COVID-19) began to spread in the US. We will also recruit through HPHC, a regional non-profit health plan that offers insurance plans in Massachusetts, Maine, New Hampshire, and Connecticut.

Aim 1:

Overview

In this aim, we will conduct a pilot randomized controlled trial of patients with asthma or parents of children with asthma who lost employer-sponsored coverage during the COVID-19 pandemic. Potential study subjects will be recruited through AAFA and HPHC. Eligible participants will be randomized into one of two study groups: 1) an intervention group that receives access to an asthma chat bot and personalized insurance navigation (n=145), or 2) a wait-list control group (n=285). At study entry, participants will receive an online baseline survey to assess outcomes related to insurance coverage, asthma severity and control, medication use and adherence, asthma care access and affordability, and COVID-19 related illness. The intervention group will be offered the chat bot and AAFA navigation services. Navigation will be provided through AAFA's existing online patient community platform that provides assistance with clinical, educational and financial questions and includes secure, personal messaging capabilities that will be supplemented with telephonic outreach. One month later, we will field a follow-up survey to measure short-term changes in outcomes; for the intervention group, this survey will also measure implementation outcomes including uptake, feasibility, acceptability, and usability. Four months later, we will field a second follow-up survey to measure longer-term changes in outcomes. Control subjects will be offered the chat bot after completion of the follow-up surveys. If findings suggest that the intervention is feasible and effective, we will use effect sizes from this pilot to power a larger comparative effectiveness trial in the future.

Participants

Eligible subjects will include adults aged 18-64 years who have asthma or have a child with asthma aged 4-17 years, and lost employer-sponsored health insurance after February 2020. Only one person per household will be eligible. Potential subjects will be recruited through AAFA, who will send out a description of the study to potential subjects through its online community, email listserv, website, Facebook page, and newsletter, and through its partner hospital programs and Medical Scientific Council (PC-2). Potential subjects will also be recruited through HPHC. Members who

disenrolled from employer-sponsored plans after February 2020 will be identified, and those aged 4-64 with an ICD-10 diagnosis code for asthma in claims data after January 1, 2019 will be contacted by email and invited to participate. Recruitment materials will include a description of the study and a RedCap survey link which will ask screening questions to determine eligibility. Any participant suspected of being duplicative or fraudulent will be ineligible for the study and removed. We will collect information on race/ethnicity and select a sample representative of the racial/ethnic distribution of patients with asthma, with no more than 60% non-Hispanic White selected for the sample (PC-2). The estimated racial/ethnic and gender of the study population is described in Table 1.

Table 1. Estimated Racial/Ethnic and Gender Enrollment

Race	Male (N)	Female (N)	Total (N)
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Black/African American	19	96	115
Hawaiian/Pacific Islander	0	0	0
White	76	201	277
Multirace	19	19	38
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina)	10	19	29
Non-Hispanic	104	297	401

Design

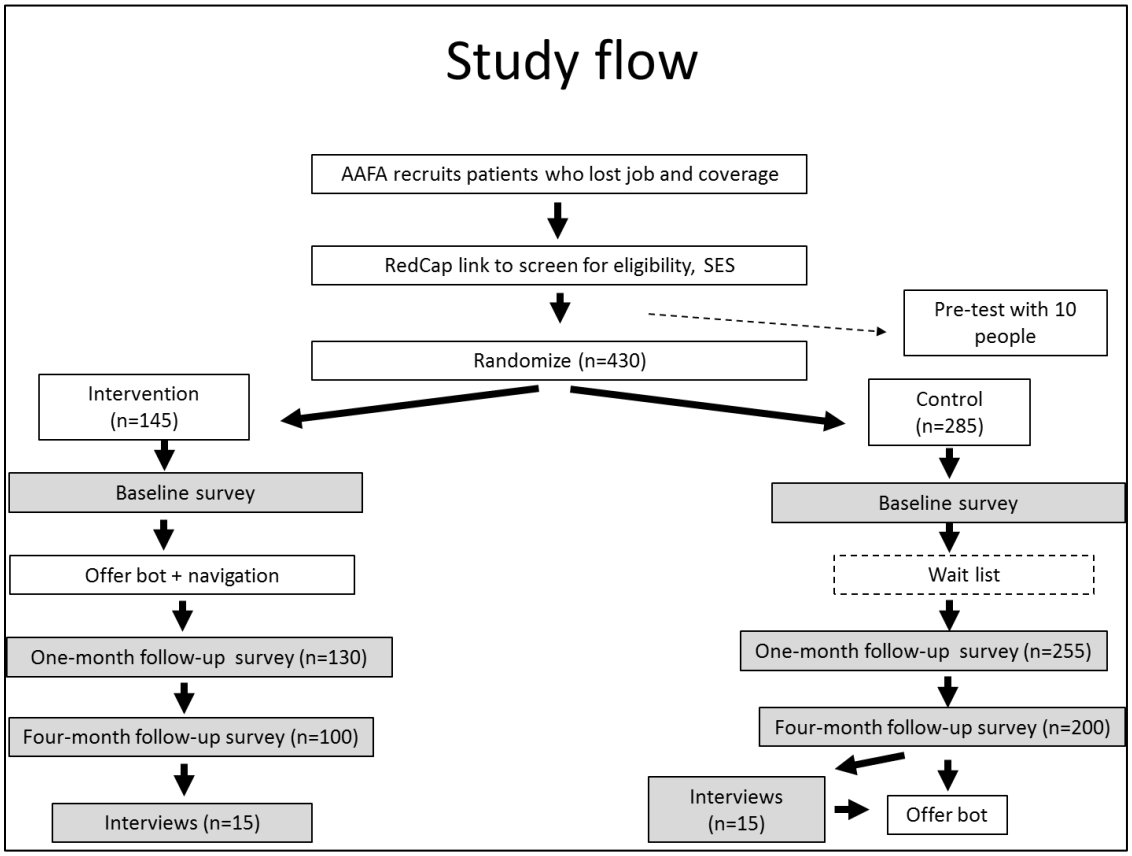
We will conduct a pilot randomized controlled trial where we will randomize participants who lost coverage to: 1) be offered a combination of automated chat bot and personalized outreach provided by AAFA-affiliated navigators (n=145), or 2) be a wait-list control (n=285). We will use a wait-list, usual care control group as the comparator given that there is no other standard treatment or practice for people with asthma who lose insurance coverage to which to compare our navigation intervention (RQ-5). A diagram of the study flow can be found in Figure 1. After randomization, participants will be given a RedCap link for a baseline survey. REDCap is a HIPAA secure web-application that the Harvard Pilgrim IRB has approved for securely collecting survey data via email which allows study subjects to enter data directly into a form that is then transmitted securely to the Harvard Pilgrim server. The survey instrument will contain structured, closed-ended questions designed to be completed in an average of 20 minutes. The survey will assess past and current insurance coverage, asthma severity and control, medication use and adherence, other asthma care use, current access and cost challenges, and COVID-19 related illness. We will offer a $20 gift card for completion of the survey.

<u>Intervention</u>

After completion of the baseline survey, intervention subjects will be sent an email with information about AAFA's asthma chat bot and a link to access it and information about AAFA's insurance navigation program, how it can help with finding coverage and managing asthma costs, and how to access it via group and private messaging within AAFA's asthma community platform with the availability of telephonic follow-up from AAFA navigators. Subjects can access AAFA's community

platform through a password-protected account, through which they can join the private group where they can ask questions and share resources, with moderation by AAFA staff. They will be able to send a "group private message" that includes the subject, the AAFA staff providing navigation support, and the AAFA administrator. Subjects will then communicate with AAFA staff about insurance issues, access to asthma care, and assistance with asthma costs. Messages are referred

Figure 1: Study flow



to trained AAFA staff who respond by the next business day—and usually within the same day— with answers, referrals, or other follow-up. AAFA's online community is staffed with trained community engagement managers during "normal" business hours as well as nights and weekends in order to be available for patients when they need support. For subjects in this study, AAFA staff will offer telephonic follow-up as needed to help identify available insurance options and eligibility criteria and suggest important insurance plan attributes and cost management strategies to consider.

Data collection

One month after receiving the intervention, subjects will be emailed a RedCap link to a follow-up survey to measure changes in insurance coverage and other outcomes. The follow-up survey will be structured similarly to the baseline survey, with closed-ended questions about insurance coverage, asthma care and control, health care access and affordability. For intervention subjects, the follow-up survey will also ask closed and open-ended questions about implementation outcomes such as uptake, acceptability, feasibility, usability, and fidelity. The survey will be designed to be completed in an average of 20 minutes and we will offer a $20 gift card for completion.

Four months later, intervention and control subjects will be emailed a RedCap link to a similar follow-up survey to measure changes in insurance coverage, asthma care and control, health care access,

and affordability. The survey will be designed to be completed in an average of 20 minutes and we will offer a $20 gift card for completion. We will attempt to contact non-responders by telephone to encourage them to complete the surveys (MD-1). Survey subjects will be asked for permission to be contacted again for participation in a telephone interview for Aim 2.

Outcomes

Outcomes include patient-centered, patient-reported outcomes that people with asthma have raised as concerns in our prior qualitative work in the parent project and that have been identified as meaningful in the parent AFFORD project by our stakeholder partners from AAFA, the Patient Family Advisory Council, and the AFFORD Advisory Board (RQ-6, PC-1, PC-3). The primary outcome will be whether the participant with asthma (or their child with asthma) has insurance coverage. Secondary outcomes will include whether the person with asthma used less asthma medication than prescribed because of cost, and whether they experienced health care-related financial burden (problems paying medical bills and/or paying off medical bills over time, having to set up a payment plan with a doctor or hospital, having trouble paying for other basic bills like food, heat, or rent because of medical costs). Other outcomes will assess asthma care use, asthma control using the Asthma Control Test (ACT), health status, mental health/worry, and material hardships such as food or housing insecurity. These include validated measures and measures used in prior surveys by the study team and others (IR-4).[26-33]

Analysis Plan (IR-3)

We hypothesize that participants receiving the intervention will be more likely to have coverage at four-month follow up (primary outcome) and will be less likely to report non-adherence to asthma medications, delayed/forgone asthma care, and financial burden than those receiving usual care (secondary outcomes).

We will compare unadjusted outcomes between the intervention and control groups using chi square and t tests; because of the randomized study design this difference measures the causal impact of the intervention. We will conduct post hoc exploratory analysis to assess differences in intervention effectiveness by race/ethnicity to assess whether the intervention reduces racial/ethnic coverage disparities (RQ-4; HT-1). Given the small pilot nature of this study, these analyses will be hypothesis-generating rather than hypothesis-testing (HT-2-4). The survey will measure important co-variates such as age, gender, income, race/ethnicity, education, state of residence, asthma severity, and family composition, and analyses will adjust for any co-variates that are not balanced between study groups (IR-1). In this pilot study, efficacy testing will be limited but we expect to have 100 intervention and 200 control subjects with follow-up data to be able to detect absolute differences of 10% or more between study groups in changes in uninsurance rates with 80% power with a two-tailed alpha of 0.05. We assume 30% loss to follow-up from baseline to four-month follow-up. Given the small pilot nature of this study, we will track dropout carefully in order to inform feasibility assessment and planning for a larger trial. We will closely monitor timing of dropout, impact of strategies such as telephone outreach, and characteristics of those dropping out compared to those retained, and will use multiple imputation methods to conduct a sensitivity analysis to test the sensitivity of findings analyzed with and without imputed data (MD-2-5). Findings will be reported using CONSORT reporting guidelines (IR-6).

Patient stakeholders from the AFFORD Patient Family Advisory Council will provide input on interpretation of study findings in the context of their lived experience, and will provide input on strategies for dissemination to key stakeholders (PC-1, PC-4).

Aim 2:

Overview

In this aim, we will conduct in-depth qualitative interviews to better understand barriers and facilitators to accessing coverage and asthma care more broadly during the COVID-19 pandemic. Study subjects will be selected from among those who completed the follow-up survey and gave permission to be re-contacted for a telephone interview. We will approach 100 eligible survey participants by email to invite them to participate in an interview. We expect to complete 30 phone interviews, half from the intervention group and half from the control group. Interviews will use open-ended questions to explore patients' experiences related to obtaining coverage after job loss and associated asthma care access and affordability challenges and facilitators. Interviews will be conducted by the study investigators and will be audio recorded and the recordings will be transcribed.

Participants

Eligible participants will be intervention and control participants who complete the four-month follow-up survey, give permission to be re-contacted for an interview, and provide an email and/or phone number to use to contact them. We will seek to maximize variation in our sample by using survey data to identify potential subjects with a range of races/ethnicities, incomes, geographic residences, ages (child vs adult), and asthma severity.

Data Collection

We will collect data from 30 study participants through in-depth qualitative interviews. We will approach 100 eligible survey participants by email to invite them to participate in an interview. We will then follow up by phone to schedule an interview. After scheduling a telephone interview and describing the study, we will obtain verbal informed consent. Interviews will last for approximately 45 minutes and will be audio recorded with permission and transcribed verbatim. Participants will receive a $50 gift card as an incentive for participation. We estimate completing 30 phone interviews, half with participants from the intervention group and half from the control group.

Analysis Plan

We will transcribe recordings of the interviews and analyze these data via thematic content analysis. Using a codebook, 2 trained coders will independently code transcripts using NVivo, resolving disagreements via discussion. We will describe data thematically to probe quantitative findings and describe strengths, weaknesses, and perceived intervention impact.

Patient stakeholders from the AFFORD Patient Family Advisory Council will provide input on interpretation of study findings in the context of their lived experience, and will provide input on strategies for dissemination to key stakeholders (PC-1, PC-4).

Limitations

Our study subjects will be recruited from the AAFA community, so generalizability may be limited. Those who participate in the AAFA community may not be representative of the national population of patients with asthma. Among those eligible, we will oversample racial/ethnic minority participants to ensure a more diverse sample. As this is a pilot study, efficacy testing will be limited but we expect to have a large enough sample size to detect moderate to large differences in coverage. Given the pilot nature of the study, we will not be able to measure longer-term health and well-being outcomes. Survey outcome measures may be subject to recall bias, but the use of a one-month survey will allow a shorter timeframe for participants to recall.

Timeline

TIMELINE	Year 1						Year 2		
Activity	**Jul-20**	**Sep-20**	**Nov-20**	**Jan-21**	**Mar-21**	**May-21**	**Jul-21**	**Sep-21**	**Nov-21**
Aim 1									
IRB approval									
Train navigators on study protocol, pretest intervention									
Recruit study sample through AAFA									
Field baseline survey									
Provide intervention									
Field follow-up surveys			1-month		4-month				
Analyze follow-up survey data					1-month	4-month			
Presentations, manuscripts					1-month		4-month		
Aim 2									
Conduct interviews									
Analyze interview data									
Presentations, manuscripts									

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