TITLE PAGE

Title of Project: Adapting, Scaling, and Spreading an Algorithmic Asthma Mobile Intervention to Promote Patient-Reported Outcomes (PROs) Within Primary Care Settings

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Organization: Albert Einstein College of Medicine, Bronx, New York

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Federal Project Officer: Christine Dymek, Ed.D.

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STRUCTURED ABSTRACT

Purpose: Through this project, we developed, implemented, and evaluated the ASTHMAXcel PRO mobile application, which facilitated the collection and response to PRO measures, for adult asthma patients within our urban healthcare system's outpatient primary care setting.

Scope: The New York City borough of the Bronx has the highest asthma burden in New York State. Factors contributing to high asthma rates in the Bronx include poverty, environmental triggers, and poor self-management skills. There are challenges to delivering patient education and using patient-reported outcome (PRO) measures in the primary care setting. The lack of evidence-based, tailored, and user-centered mobile applications that collect and address PRO measures in primary care marks a gap in the realm of patient-centered health technologies.

Methods: To adapt ASTHMAXcel PRO for primary care, we conducted participatory design (PD) sessions with asthma patients and primary care clinicians. For four weeks, we field-tested the adapted tool with asthma patients and conducted formative and summative evaluations; we subsequently conducted the RCT. Due to the Covid-19 pandemic, field-testing and RCT visits were remotely conducted through a virtual cohort study.

Results: PD sessions included nine patients and seven clinicians and contributed to several features (e.g. user leaderboard) within the mobile platform. Field-testing included twenty-eight patients and demonstrated app acceptance and user satisfaction with the app. The RCT enrolled 110 participants and the ASTHMAXcel mobile intervention was linked to significant improvements in asthma quality of life, asthma control, and asthma knowledge and decreased healthcare utilization. Higher baseline eHealth literacy was significantly associated with worse asthma quality of life and more app logins. These findings suggest that ASTHMAXcel PRO is a user-centered, acceptable, and clinically impactful mobile intervention.

Key Words: Mobile health, asthma, user-centered

PURPOSE

This study's objectives are:

Objective 1. To adapt, test, and iteratively refine the ASTHMAXcel application for the primary care setting

Objective 2. To conduct an RCT to compare the adapted and refined ASTHMAXcel mobile intervention to usual care

Objective 3. To evaluate the process of ASTHMAXcel implementation within the primary care setting

SCOPE

Background and Prevalence: Asthma mortality rates in the Bronx are the highest in NY State, and almost every Bronx community has asthma hospitalization and emergency department (ED) visit rates triple the state average regardless of age group. Within the Bronx, Blacks and Hispanics are more likely than non-Hispanic whites to be hospitalized for asthma (rate per 10,000 = Blacks: 52.7 hospitalizations; Hispanics: 48.7 hospitalizations; non-Hispanic Whites: 16.1 hospitalizations).

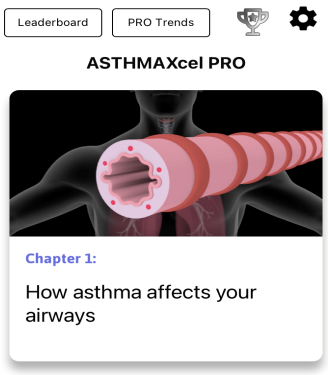
Context: Many factors combine to raise Bronx asthma rates and worsen outcomes among underserved minority patients. The Bronx is one of the poorest urban counties in the United States and multiple factors contribute to asthma disparities. Outpatient healthcare provider (HCP) practice behaviors, suboptimal access to healthcare, lack of patient knowledge regarding proper medication use, and patients' difficulty adhering to medical regimens contribute to poor asthma outcomes. With appropriate medical care including education and the implementation of patient-reported outcomes (PROs) to facilitate self-management and shared decision-making, patients can achieve optimal asthma control. However, there are critical barriers to providing effective patient education and implementing PROs in the outpatient primary care setting, such as time constraints and prioritizing other issues (recent asthma exacerbations, co-morbidities). HCP behaviors, including adherence to

guidelines and asthma education, are important to achieving asthma control. Though changes in HCP behavior may be needed to collect PROs while improving patient education and asthma outcomes, successful efforts require multidimensional and patient-centered interventions with HCP buy-in. For these reasons, our team adapted ASTHMAXcel PRO for the outpatient primary care setting through this study to leverage the scalable, easily accessible, and convenient nature of mobile apps. Collecting PRO measures is at the core of ASTHMAXcel PRO, and is crucial to the app's adaptive and personalized nature. This study has directly addressed the following considerations in the realms of available mobile health technologies for adult asthma patients: 1) HCPs and patients must both be closely involved from the start of mobile intervention development and throughout the implementation and refinement processes; 2) mobile interventions must be tailored to the needs and abilities of patients and HCPs; 3) tools must be optimized for the outpatient clinical workflow, especially with HCP input; and 4) while many of the available apps adequately collect PRO measures, there are very few adaptive, comprehensive, and personalized mobile health tools that embed PRO measures while promoting sustained PRO collection and long-term use. While occurring during the Covid-19 pandemic, this project has represented a remotely conducted clinical study with the corresponding aspects (e.g. electronic consent, telehealth-based study visits).

Settings and Participants: Through this study, we have been collaborating with the Montefiore Medical Group (MMG) to implement our mobile intervention at 3 outpatient primary care sites within the Bronx. Since these target sites span nearly 70 miles, this project has been a regional collaborative initiative. We implemented a scale and spread approach by collaborating with one MMG primary care site through Objective 1 in order to adapt, test, and iteratively refine the study intervention. Our lessons learned though Objective 1 informed the adapted and refined ASTHMAXcel PRO mobile platform, which we evaluated through an RCT (Objective 2) in collaboration with three MMG outpatient primary care sites. Study participants' inclusion and exclusion criteria were common to Objectives 1 and 2 with the inclusion criteria: English-speaking individuals ≥18 years with: (a) persistent asthma (diagnosis made by a HCP) on a daily controller medication; (b) able to give informed consent; and (c) Smartphone (iOS or Android) access. Exclusion criteria: (a) use of oral corticosteroids in the 2 weeks prior to the baseline visit; (b) pregnancy; and (c) severe psychiatric or cognitive problems that would prohibit an individual from completing the protocol.

METHODS

Study Design: Year 1 (Objective 1) included the following activities: conducting participatory design sessions with patients and HCPs; adapting ASTHMAXcel PRO based on user feedback; performing field-testing of the adapted app with patients and HCPs; and conducting formative and summative evaluations to iteratively refine the mobile platform. Years 2 and 3 (Objective 2) involved an RCT at outpatient primary care sites to compare the redeveloped (i.e. adapted and refined) app to usual care with regards to process outcomes, asthma knowledge, PROs, and clinical outcomes. To assess the process of ASTHMAXcel implementation within the primary care setting, we used the RE-AIM evaluation framework[1] to assess the intervention's Reach (e.g. recruitment rate as defined by the percentage of individuals who gave informed consent among everyone approached, representativeness of study sample), Effectiveness (intervention's impact on process, asthma knowledge, PRO, and clinical outcomes), Adoption (user acceptance of the intervention), Implementation (e.g. user engagement with key features of the ASTHMAXcel tool during the study period), and Maintenance (user satisfaction with the intervention) (Objective 3).



ASTHMAXcel PRO Main Screen.

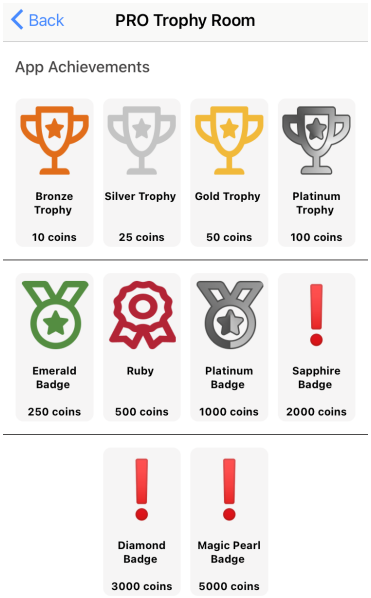
Data Sources/Collection: We have been using our project's secure REDCap database to collect data regarding demographics, process outcomes, asthma knowledge, PROs, and clinical outcomes. The ASTHMAXcel PRO mobile intervention has been collecting patient-level and aggregated data regarding app usage (e.g. number of app log-ins per week, app chapters visited and how many times), numbers of push notifications delivered to each participant, self-assessment quiz responses (e.g. percentage of correct responses), and PROs (e.g. numbers of PROs collected). We collected and qualitatively analyzed participatory design session responses from HCPs and patients, summative evaluation feedback through Objective 1, and post-RCT evaluative feedback. All

Animated Video.

patient data have been de-identified and securely stored in our REDCap database and on the project's secure cloud-based server.

Interventions: The ASTHMAXcel PRO mobile intervention is publicly available on the iOS and Android app stores and includes 9 chapters corresponding with a different guideline-based asthma education topic. Each chapter has a 1-2 minute animated video (see Figures) with educational content and an end-of-chapter assessment tool to: 1) evaluate patient knowledge through questions (easy, medium, difficult) that we created based on educational content delivered in the chapter; and 2) collect PRO measures. The app includes push notification functionality, which occurs in 4 forms: 1) daily medication reminders and medication self-report; 2) weekly messages provide encouragement and behavioral support; 3) weekly check-in messages collect information regarding PRO measures (NIH PROMIS items); and 4) monthly check-in messages capture information regarding recent asthma emergency department visits, hospitalizations, and steroid courses for asthma exacerbations. The mobile platform includes a secure web-based administrative panel, which enables the study team to: 1) schedule and automate each user's notifications; and 2) visualize aggregated and user-level analytics data (e.g. app usage, self-assessment quiz responses). Based on patient feedback obtained through Objective 1, ASTHMAXcel PRO includes a PRO self-tracker, PRO leaderboard, and virtual incentives (e.g. coins for logging on to the app and submitting PROs, virtual trophies for achieving coin 'milestones' as per the Figure). The mobile platform includes aggregated and user-level data analytics (e.g. user engagement patterns).

Measures: This study's primary outcome is asthma quality of life, as measured by the mini-Asthma Quality of Life Questionnaire (mini-AQLQ).[2] We also measured the following process outcomes: 1) Patient satisfaction through the validated Client Satisfaction Questionnaire (CSQ-8);[3] 2) User interaction satisfaction (Questionnaire for User Interface Satisfaction (QUIS))[4] and acceptance (Unified Theory of Acceptance and Use of Technology (UTAUT))[5] in the intervention group; and 3) Patient (log-ins, time spent, content use) app usage. We collected data regarding asthma knowledge (asthma illness representation scale),[6] PROs (Patient Health Questionnaire (PHQ-9) for depression),[7] and clinical outcomes (Asthma Control Test (ACT),[8] asthma hospitalizations in the past 2 months, prednisone courses in the past 2 months). We collected baseline data regarding participant sociodemographics, health literacy (Newest Vital Sign),[9] and digital health literacy.[10]



Virtual Trophies.

Limitations: This study's main limitations have been regarding the research-related challenges due to the Covid-19 pandemic. From March 2020 through the Fall 2020, our institution implemented a 'research pause' for on-site research activities. During this time, we were unable to conduct on-site recruitment for the RCT from MMG primary care sites and 'virtualized' the study design to enable all study activities (recruitment, electronic consent, data collection) to be remotely conducted. Due to the reduced outpatient primary care volume through 2020, our final recruitment numbers were below the initially proposed target and we experienced delays regarding the study implementation and data analyses (currently being conducted). However, we learned important lessons in how to conduct a decentralized clinical trial and established the foundation for our mobile platform-based pragmatic studies.

In-app PRO Tracker.

RESULTS

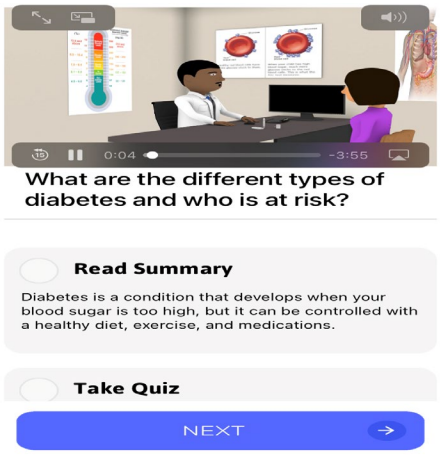
Principal Findings and Outcomes: For this project's PD component, 9 patients (67% female with mean

age of 48 years) and 7 clinicians (71% female with a mean age of 54.6 years) participated in the study. Qualitative analyses of both patient and clinician sessions suggested the improvement of four primary themes/features within the app: asthma education; PRO self-tracking (see Figure); social network and peer support; and motivational content. Patients and clinicians acknowledged that patients often continue to miss signs of asthma exacerbations and may lack the knowledge for appropriate self-management. Both groups recommended the addition of specific educational content including medication side effects and sought the ability to track symptoms and medications through the mobile platform.

For the field-testing component, 28 patients (75% female with mean age of 45.5 years) completed baseline assessments. Twenty-three patients preferred to complete the first session over the phone (electronic consent: 15, verbal consent: 8) while the remaining five patients completed the first session through secure video conferencing (electronic consent: 4, verbal consent: 1). All study participants had access to a smartphone or tablet and to the internet. Most participants utilized a smartphone to access the application (75%) and a minority of participants utilized a tablet (25%). Moreover, more than half of participants utilized the Android platform (57.1%) and less than half utilized the iOS platform (42.9%). Of the twenty-eight participants, 13 (46.4%) had a total score of 4-6 that represented adequate literacy, 12 (42.9%) had a score of 2-3 that represented possibly limited literacy, and 3 (10.7%) had a score of 0-1 that represented highly limited literacy. There were no significant relationships between age or gender and health literacy. An education level of college or above was associated with adequate health literacy (Pearson's correlation r=0.52, p=0.0045). UTAUT and QUIS scores were good at baseline with the mean UTAUT total score of 64.2±10.1 (out of 80) and the mean QUIS of 6.78±2.17 (out of 9). UTAUT total score as well as the instrument's four domain scores showed statistically significant increases from baseline to 4-weeks (p<0.02). QUIS total score and three QUIS domain scores (screen, system capabilities, usability) increased from baseline to 4-weeks (p=0.03, 0.01, 0.03, 0.01, respectively). Semi-structured summative interview feedback on the app included that the app was helpful, informative, and easy to understand and use. Regarding video features, patients cited the end-of-video quizzes as helpful for capturing attention. Key suggestions from interview participants for improvement of the app included adding a search function to find specific information quickly, ability to take notes, and re-tests for retaining information.

Regarding our study results, in an analysis of 69 participants (79.7% female with mean age of 47.1 years), increased depressive symptoms were associated with worse asthma control (β = -.55, p < .001) and asthma quality of life (QOL) (β = -.50, p < .001), but not eHealth literacy. Higher eHealth literacy was associated with worse asthma QOL (β = -.53, p = .016) and more app logins (β = .66, p= .038). Regarding the mobile intervention's impact on clinical outcomes from baseline to 6 months, we observed significant improvements in mini-AQLQ and ACT scores and significant decreases in asthma hospitalizations and prednisone use. We observed significant increases in asthma knowledge from baseline to 6 months.

The ASTHMAXcel intervention was assessed through the RE-AIM framework. Regarding the Reach domain, 1,550 potential study participants were initially approached via telephone and 207 agreed to participate while 103 did not agree to participate. Of these individuals, 138 completed the baseline visit. Thirty-six percent of the study participants were Hispanic and 49.3 percent were non-Hispanic Black, and were therefore representative of the Bronx population. Regarding the Effectiveness domain, ASTHMAXcel was linked to significant improvements in asthma quality of life (baseline: 55.5, 6 months: 64.2, p = .02), asthma control (baseline: 15.1, 6 months: 17.9, p = .003), and asthma knowledge (baseline: 11.7, 6 months: 13.1, p = .005) and decreased asthma hospitalizations (baseline: 0.3, 6 months: 0, p = .002) and prednisone use (baseline: 1.2, 6 months: 0.3, p = .0003). For the Adoption domain, UTAUT total scores significantly increased from baseline to follow-up (64.2 to 69.8, p = .002). Regarding the Implementation domain, study participants completed 7,179 educational chapters within ASTHMAXcel, received a total of 175,581 push notifications throughout the study period, and submitted 6,744 PRO measures. Regarding the subjects in each range of PRO numbers submitted, 26% of participants submitted 0 to 5 PROs, 27% submitted 6 to 10 PROs, 21% submitted 11 to 20



Diabetes Animated Video.

PROs, 10% submitted 21 to 30 PROs, 5% submitted 30 to 50 PROs, 3% submitted 51 to 100 PROs, 3% submitted 100 to 200 PROs, and 5% submitted 200 or more PROs. For the Maintenance domain, study participants reported a high level of satisfaction with the study intervention and the user interaction. Satisfaction scores, as measured by the QUIS, significantly increased from baseline to follow-up (6.78 to 7.81, $p = .03$).

Discussion and Conclusions: Our study objectives and design resulted in a user-centered mobile intervention that is acceptable to adult asthma patients and outpatient HCPs in the primary care setting. Through the participatory design sessions, patients and HCPs recommended engaging intervention features such as PRO self-tracking, tailored medication reminders, and a user leaderboard to encourage the collection of PROs. Field-testing, formative, and summative evaluation findings demonstrated that the corresponding iterative refinements were linked to increasing user satisfaction and app acceptance. The field-testing sample's baseline sociodemographics indicate the accessibility of ASTHMAXcel PRO by underserved patient populations. Acceptance of digital health tools by our study participants is further demonstrated by our observation that the majority of participants who completed the baseline sessions preferred to electronically consent rather than verbally consent. Our study findings demonstrated that eHealth literacy was associated with increased patient engagement with ASTHMAXcel PRO and worse asthma QOL, which may reflect patients with worse QOL seeking out health information on the internet. The ASTHMAXcel intervention was linked to significant improvements in asthma quality of life, asthma control, and asthma knowledge and decreased healthcare utilization. These findings suggest that ASTHMAXcel can favorably impact asthma self-management and reduce asthma morbidity among patients receiving care in the outpatient primary care setting. As the outpatient setting is characterized by critical time constraints and the lack of time for comprehensive asthma education, ASTHMAXcel can effectively fill this important gap. This digital tool can be rapidly scaled to ambulatory settings that lack a health educator. The RE-AIM findings demonstrate that: 1) Virtual recruitment for mobile intervention studies can be effective and contribute to a representative study sample; 2) ASTHMAXcel is a clinically useful mobile intervention that promotes the collection of PRO measures for the outpatient setting; 3) ASTHMAXcel has been linked to a high degree of user acceptance and satisfaction with the intervention, thereby suggesting that the tool has the potential for sustained use; and 4) ASTHMAXcel has key features (e.g. educational chapters, push notifications) that continually engage mobile platform users at scale. This type of patient engagement would otherwise be difficult to achieve through traditional approaches (e.g. human-delivered education).

Significance and Implications: This study has met our initial objective to establish a user-centered, acceptable, and clinically impactful patient-facing mobile platform to collect and address PROs within the outpatient primary care setting. In light of the clinical utility of the ASTHMAXcel PRO intervention, this study offers important lessons learned regarding the implementation of virtual cohort studies with innovative capabilities (e.g. electronic consent).

Regarding informational resources, ASTHMAXcel was the first mobile app launched by our institution and has since been extended to 9 additional patient-facing mobile applications (see Figure) for other medical conditions (type 2 diabetes, Covid-19). By launching these apps, we learned how to build a multi-disciplinary team to develop, implement, validate, and disseminate mobile health technologies. We also learned about the required data security and legal (e.g. Terms of Use, Privacy Policy) best practices surrounding mobile apps. We secured foundation-based grant funding for adaptations (e.g. a gamified version for youth) of ASTHMAXcel. Our team has been raising scientific awareness regarding mobile intervention development and validation through invited presentations at national meetings, poster presentations, and the publication of manuscripts. We have specifically been raising awareness about this study and the ASTHMAXcel PRO mobile intervention through our mobile platform's website, several recent podcast segments (see List of Publications and Products below), and via social media platforms such as Twitter and Instagram. Dr. Jariwala also serves as a leader for several regional and national health technology-related organizations (the NYC RING practice-based research network; AAAAI health informatics, technology, and education committee) through which this study's findings have been disseminated.

Regarding institutional resources, this project has had the following impact: 1) Our team's mobile application development and validation efforts contributed to our institution's decision to create a division (within the Department of Medicine) of Clinical & Research Innovation (Dr. Jariwala is the founding Director of Clinical &

Research Innovation); 2) To encourage the mentored training of our institution's faculty, allied health (nurses, social workers, pharmacists) personnel and trainees (medical students, fellows) in the mobile health intervention development and validation arena, Dr. Jariwala created and launched the Montefiore Einstein Innovation Biodesign Training Program.

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LIST OF PUBLICATIONS AND PRODUCTS

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Electronic Resources Related to this Study

Websites

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- https://apps.apple.com/us/app/asthmaxcel-pro/id1500992014
- https://play.google.com/store/apps/details?id=com.asthma.ahrq&hl=en_US&gl=US
- https://www.einsteinmed.edu/departments/medicine/innovation/

Podcasts

- https://education.aaaai.org/podcasts/podcast_mhealth

- https://anchor.fm/montebiodesign/episodes/Digital-Health-Innovation-and-Biodesign-em6i83

Social Media

- https://twitter.com/asthmaxcel1
- https://www.instagram.com/asthmaxcel/
- https://www.facebook.com/asthmaxcel.app.98
- https://www.youtube.com/channel/UCXqQGwaFewUzr56EPKy_zIQ

Our Team's National and Regional Presentations Related to this Study (all presentations given by Dr. Jariwala)

National Presentations

Innovative Methods to Improve the Collection of Patient-Reported Outcomes. American Academy of Allergy, Asthma & Immunology Annual Meeting, February 2019. San Francisco, CA.

Innovative Methods to Improve the Collection of Patient-Reported Outcomes. American Academy of Allergy, Asthma & Immunology Annual Meeting, March 2020. Philadelphia, PA.

How to Develop and Evaluate Patient-Facing Mobile Health (mHealth) Applications for Asthma and Allergic Diseases. American Academy of Allergy, Asthma & Immunology Annual Meeting, March 2020. Philadelphia, PA.

Healthcare Apps for you and your patients. American Academy of Allergy, Asthma & Immunology Annual Meeting, March 2020. Philadelphia, PA.

Healthfirst Best Practices Webinar Series. Access to Care: Technology Solutions. September 2020. New York, NY.

Innovative Methods to Improve the Collection of Patient-Reported Outcomes. American Academy of Allergy, Asthma & Immunology Annual Meeting. March 2021. Virtual Meeting.

Developing, Implementing, and Evaluating Digital Technologies to Improve Clinical Care. National Onboarding Summit for Medical Trainees. March 2021. Virtual Meeting.

Digital Assessment Tools and Remote Monitoring Devices for Allergy Practice. American Academy of Allergy, Asthma & Immunology Practice Management Workshop. June 2021. Virtual Meeting.

Hospital Innovation Centers. U.S. Department of Health and Human Services Office of the National Coordinator for Health IT Innovation Roundtable Series. September 2021. Washington, D.C.

Health Technology Innovation Biodesign. American Academy of Allergy, Asthma & Immunology Practice Management Webinar. January 2022. Virtual Meeting.

Asthma Care and Digital Health Technologies. Atlantic Medical Imaging and Sidney Kimmel Medical College of Thomas Jefferson University Webinar. January 2022. Virtual Meeting.

The Role of Patient-Facing Mobile Health Technologies in Asthma Management. American Academy of Allergy, Asthma & Immunology Annual Meeting, February 2022. Phoenix, AZ.

Problem-Based Learning (PBL): The Importance of Digital Medicine in the Treatment of Severe Asthma/Asthma and Chronic Obstructive Pulmonary Disease (COPD). American Academy of Allergy, Asthma & Immunology Annual Meeting, February 2022. Phoenix, AZ.

Regional Presentations

Telehealth strategies for asthma. The City University of New York School of Medicine Grand Rounds, New York, NY. February 28, 2019.

The Patient Voice. The Health Care Club, New York, NY. July 17, 2019.

Westchester County Biosciences Accelerator – Provider Reverse Pitch Panel. March 2021. Virtual Meeting.

Developing and Evaluating Digital Health Technologies through Needs-Based Innovation. Division of General Internal Medicine and Clinical Innovation Research Seminar. NYU Langone Hospital, New York, NY. October 29, 2021.

How Allergists Can Develop, Implement, and Evaluate Mobile Health Technologies to Improve Clinical Care. New York Allergy & Asthma Society, New York, NY. May 2022.