

Validating a Patient-Reported Outcome Measure to Improve Emergency Department Asthma Care: An Observational Study Protocol

Michelle Lin, Lauren Gordon, Lynne D Richardson

Submitted to: JMIR Research Protocols
on: October 04, 2024

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 26

 Figures 27

 Figure 1..... 28

 Figure 2..... 29

 Multimedia Appendixes 30

 Multimedia Appendix 1..... 31

 Multimedia Appendix 2..... 31

Validating a Patient-Reported Outcome Measure to Improve Emergency Department Asthma Care: An Observational Study Protocol

Michelle Lin¹ MD, MPH, MS; Lauren Gordon² MPH, CHES; Lynne D Richardson² MD

¹ Stanford University PALO ALTO US

² Icahn School of Medicine at Mount Sinai New York US

Corresponding Author:

Michelle Lin MD, MPH, MS

Stanford University
900 Welch Road
Suite 350
PALO ALTO
US

Abstract

Background: Asthma affects 1 in every 12 persons in the U.S., resulting in 1.9 million emergency department (ED) visits annually. However, the lack of patient-reported outcomes measures (PROMs) validated for use in the ED limits the evaluation of interventions to improve ED asthma care.

Objective: To address this knowledge gap, this study protocol will (1) develop and test the validity and reliability of the Patient Reported Outcomes for Acute Asthma Care and Treatment instrument; 2) test whether receiving more guideline-concordant emergency Department (ED) care is associated with improved PROAECT responses; and 3) evaluate the association between PROAECT score and subsequent ED revisits and hospitalizations.

Methods: This is a prospective cohort study of adult patients visiting the ED for acute asthma exacerbation across 3 EDs at an urban, tertiary care health system. Eligible patients are age 18 or older, have a prior diagnosis of asthma (self-reported or documented in the electronic health record), English-speaking, and experiencing an ED visit for asthma exacerbation as determined by treating clinician. Enrolled participants complete an initial PROM survey during their ED visit assessing their symptoms in the preceding seven days, then complete a follow-up survey 7 days after ED discharge assessing changes in the symptoms in the subsequent seven days. To test whether guideline-concordant care is associated with improved PROAECT scores, we will conduct retrospective chart review of medications ordered during the ED visit, then compare guideline adherence to changes in PROAECT scores. To test whether improved PROAECT scores are associated with fewer return ED visits and hospitalizations, we will extract all-cause ED visits and hospitalizations within 30 days from a regional health information exchange, then compared utilization to changes in PROAECT scores. We will use item response theory to develop scale responses based on summed item responses, which will allow us to test associations with clinical outcomes, including adherence to guideline-recommended care and return ED visits and hospitalizations.

Results: Recruitment is ongoing and has experienced numerous challenges related to the COVID pandemic. To date, we have enrolled over 250 participants and have completed over 200 follow-ups. Recruitment is expected to conclude in spring 2025.

Conclusions: Our study is intended to validate the use of PROMs during ED visits for acute asthma exacerbation among adult patients. Completion of the proposed aims will result in one of the first PROMs intended for use among adult ED patients and support the feasibility of collecting PROMs in the ED setting. Clinical Trial: ClinicalTrials.gov, NCT04349020

(JMIR Preprints 04/10/2024:67195)

DOI: <https://doi.org/10.2196/preprints.67195>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <https://www.jmir.org/preprint/67195>

No. Please do not make my accepted manuscript PDF available to anyone. I understand that if I later pay to participate in <https://www.jmir.org/preprint/67195>

Original Manuscript

Original Paper

Title: Validating a Patient-Reported Outcome Measure to Improve Emergency Department Asthma Care: An Observational Study Protocol

Authors:

Lauren Gordon, MPH, CHES- 1

Lynne Dr. Richardson, MD- 1,2

Michelle P. Lin, MD, MPH, MS- 3

Affiliations:

1 – Department of Emergency Medicine, Mount Sinai Health System, New York, NY

2— Institute for Health Equity Research, Mount Sinai Health System, New York, NY

3 – Department of Emergency Medicine, Stanford University, Palo Alto, CA

Corresponding Author:

Michelle P. Lin, MD, MPH, MS

Stanford University Department of Emergency Medicine

3145 Porter Drive B213

Palo Alto, CA, 94304

Word Count: 4991 words

Tables and Figures: 1 table and 2 figures

Funding: LG, MPL, LR are supported by grant funding from the National Heart, Lung, Blood Institute (K23 HL143042).

Abstract

Introduction: Asthma affects 1 in every 12 persons in the U.S., resulting in 1.9 million emergency department (ED) visits annually. However, the lack of patient-reported outcomes measures (PROMs) validated for use in the ED limits the evaluation of interventions to improve ED asthma care.

To address this knowledge gap, this study protocol will (a) develop and test the validity and reliability of the Patient Reported Outcomes for Acute Asthma Care and Treatment instrument; b)

test whether receiving more guideline-concordant emergency Department (ED) care is associated with improved PROAECT responses; and c) evaluate the association between PROAECT score and subsequent ED revisits and hospitalizations.

Methods: This is a prospective cohort study of adult patients visiting the ED for acute asthma exacerbation across 3 EDs at an urban, tertiary care health system. Eligible patients are age 18 or older, have a prior diagnosis of asthma (self-reported or documented in the electronic health record), English-speaking, and experiencing an ED visit for asthma exacerbation as determined by treating clinician. Enrolled participants complete an initial PROM survey during their ED visit assessing their symptoms in the preceding seven days, then complete a follow-up survey 7 days after ED discharge assessing changes in the symptoms in the subsequent seven days. To test whether guideline-concordant care is associated with improved PROAECT scores, we will conduct retrospective chart review of medications ordered during the ED visit, then compare guideline adherence to changes in PROAECT scores. To test whether improved PROAECT scores are associated with fewer return ED visits and hospitalizations, we will extract all-cause ED visits and hospitalizations within 30 days from a regional health information exchange, then compared utilization to changes in PROAECT scores. We will use item response theory to develop scale responses based on summed item responses, which will allow us to test associations with clinical outcomes, including adherence to guideline-recommended care and return ED visits and hospitalizations.

Results: Recruitment is ongoing and has experienced numerous challenges related to the COVID pandemic. To date, we have enrolled over 250 participants and have completed over 200 follow-ups. Recruitment is expected to conclude in spring 2025.

Discussion: Our study is intended to validate the use of PROMs during ED visits for acute asthma

exacerbation among adult patients. Completion of the proposed aims will result in one of the first PROMs intended for use among adult ED patients and support the feasibility of collecting PROMs in the ED setting.

Trial Registration: Clinical Trials.gov, NC04349020

Keywords: Asthma; Patient-reported outcome measures (PROMs)



Introduction

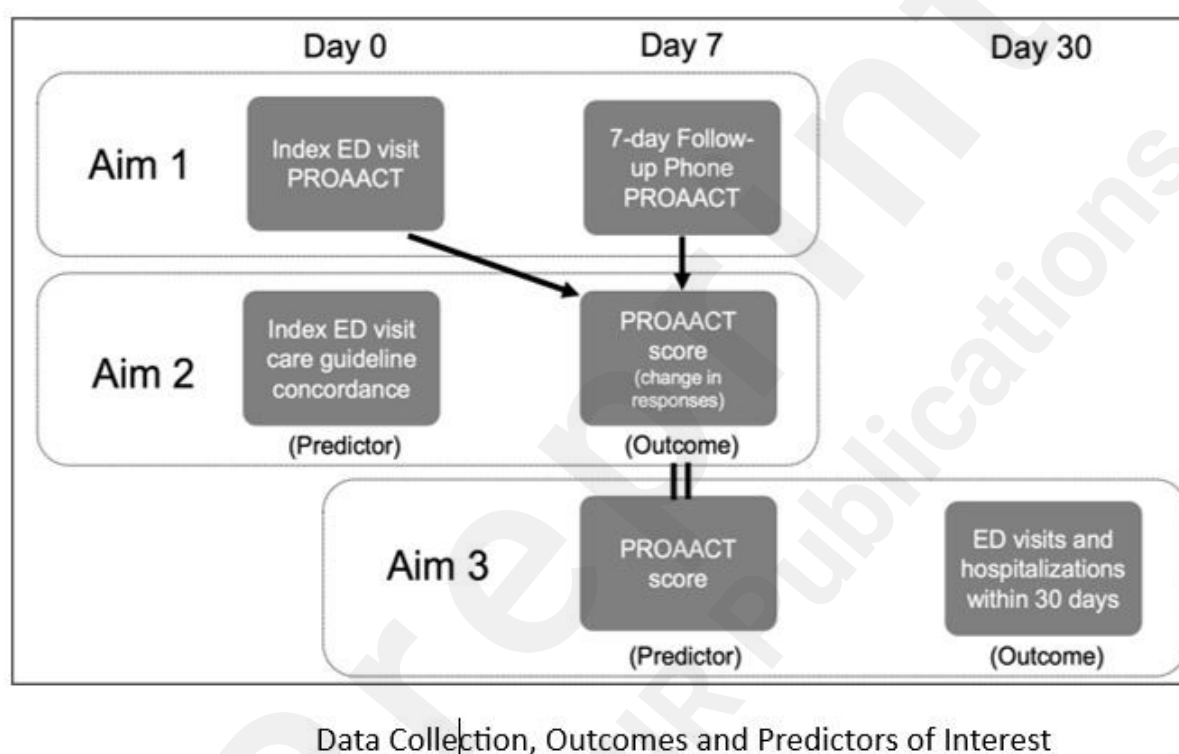
Asthma affects 1 in every 12 persons in the U.S. [1], resulting in 1.9 million emergency department (ED) [2] visits annually; however, the impact of ED care on patient-reported outcomes after acute exacerbations is unknown. Racial and ethnic minorities and individuals with low socio-economic status are more likely to have asthma and experience worse health outcomes, including asthma-related ED visits and hospitalizations. [3] According to the CDC, female, Black and Hispanic patients with asthma are more likely to seek care in the ED, be hospitalized, and die of asthma-related complications. [4, 5] Thus, patients who seek asthma care in the ED represent a population in critical need of interventions to improve clinical and patient-reported outcomes.

Patient-reported outcomes measures (PROMs) are surveys that have been developed to ensure valid and reliable measurement of these patient-reported outcomes.[6] The National Institutes of Health and National Quality Forum have endorsed the use of PROMs to assess health outcomes and quality of care.[6-8] However, the adoption of PROMs in clinical settings remains limited, in part due to the lack of PROMs validated for use in ED settings. [9] Existing PROMs assess disease control and outpatient disease management; [10-15] however, they have not yet been validated or used among patient seeking ED care for acute asthma exacerbations. Existing PROMs such as the Asthma Control Test (ACT) [12] and Asthma Quality of Life Questionnaire (AQLQ) [10] primarily assess disease control, or specific constructs such as quality of life, and were intended for—and thus developed exclusively in—clinical trials and outpatient disease management.

To assess this knowledge gap, we developed the Patient Reported Outcomes for Acute Asthma Care and Treatment (PROAACT) survey to evaluate PROMs among patients seeking care for acute asthma exacerbations in the ED. This study builds on our preliminary work of assessing the feasibility of administering a PROM in the ED and the ability to engage ED patients in PROM development. [9]

Our study has three aims: we will first assess the psychometric validity and reliability of the

PROA ACT survey to assess outcomes prioritized by adult ED asthma patients; then, we will test whether receiving more guideline-concordant ED care is associated with improved PROA ACT responses 7 days after ED discharge; and finally, we will evaluate the predictive validity by testing the association between PROA ACT responses and 30-day ED revisits and hospitalizations (see **Figure 1**).

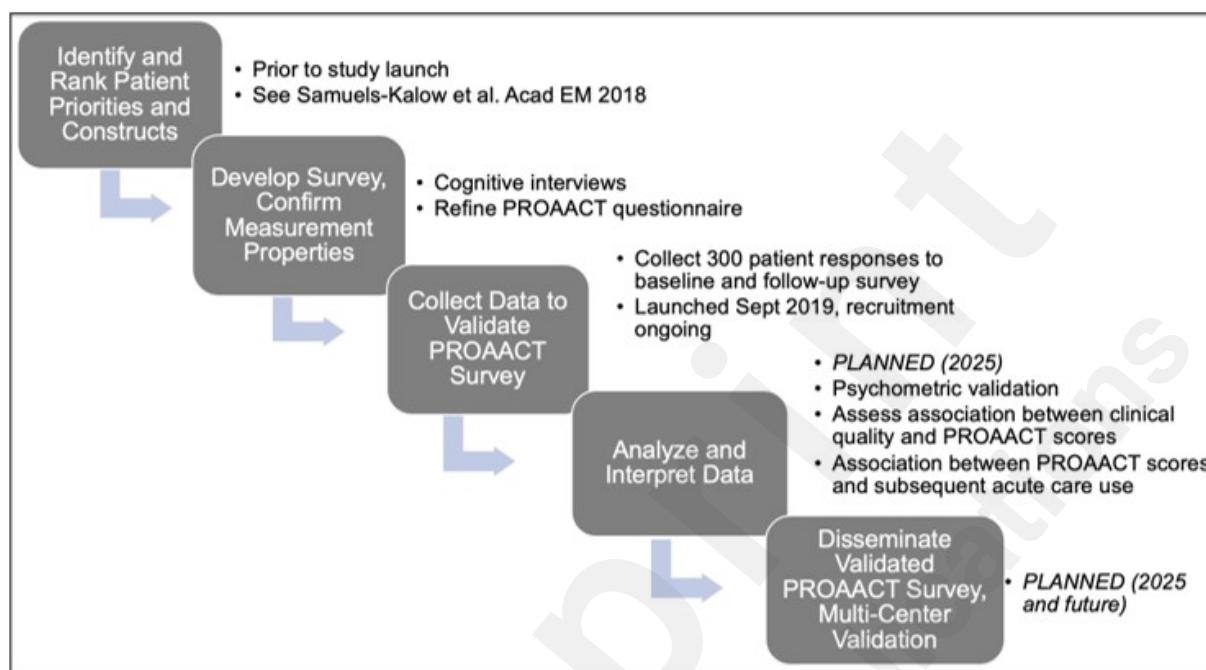


Methods

Study Design

This is a prospective cohort study enrolling a convenience sample of adult patients experiencing an ED visit for acute asthma exacerbation. The hospital Institutional Review Board approved the study. We registered the trial at ClinicalTrials.gov (NCT 04349020). We developed questions to be used in the PROA ACT questionnaire based on prior published work [16] identifying outcomes of key importance to ED patients experiencing asthma exacerbation (see **Figure 2**). After reviewing PROMs assessed in asthma studies and related constructs, we updated the item set by mapping ranked constructs to previously validated Patient Reported Outcome Measurement

Information System (PROMIS) [17] item banks and Consumer Assessment of Healthcare Providers and Systems (CAHPS)[18] Survey (see **Table 1**). The complete baseline and follow-up PROACT surveys are included in the supplementary Appendix.



PROACT Survey Development Process

Table 1: Key PROM Constructs, Patient Priority Ranking and Validated Question Source

Domain	Ranking	Construct	PROMIS Short Form
Access to Care	1	Able to Get Medication Supplies	Consumer Assessment Of Health Care Provider and Systems (CAHPS) ^a
	6	Follow-Up with Primary Care Doctor	
Dyspnea/Symptoms	2	Breathing Better/Less Wheezing/Coughing	Dyspnea Severity
Self-Efficacy	3 (tie)	Taking Medications Right	Self-Efficacy for Managing Medications

	5	Knowing Enough About Asthma and Your Plan	Self- Efficacy for Managing Symptoms
Ability to Participate in Activities	3 (tie)	Return to Normal Activities/Sleeping Well	Ability to Participate in Social Roles and Activities
	7	Return to Work/Return to School	Satisfaction with Participation in Social Roles
Anxiety/Stress	8	Not Needing to Go Back to the ER	CAHPS ^a
		Feeling Less Worried/Feeling Less Stressed	Dyspnea Emotional Response

^aNot PROMIS Short Forms

Study Population and Setting

Participants are eligible to be approached for the study if there are 18 years of age or older, English Speaking, with respiratory complaint (ex. “shortness of breath” or “wheezing”), and a self-reported or documented past medical history of asthma, and experiencing an ED visit for asthma as per the treating ED clinician. Because this project is intended to focus specifically on outcomes after ED care, eligible patients include those intended to be discharged to home after the current ED visit for asthma. Patients who are admitted to the hospitalization after ED evaluation and treatment receive further treatment from inpatient providers and specialists; thus, PROMs in these conditions reflect the entire acute care episode, not solely care provided in the ED.

Exclusion criteria: Participants who speak a language other than English are not be included in the study due to lack of validation of the study survey in other languages. Participants admitted to the hospital were also excluded for the study. Other exclusions are: inability to consent (e.g.: due to dementia, psychosis, altered mental status, intoxication, hemodynamic instability), serious diagnosis identified in the ED (e.g. clinically significant dysrhythmia, structural heart disease, gastrointestinal hemorrhage, myocardial infarction, pulmonary embolism, aortic dissection, ectopic pregnancy, subarachnoid hemorrhage, or stroke), pregnancy, acute COVID infection (probable or confirmed), either symptomatic within 10 days of onset, or asymptomatic within 5 days of positive test and prior

diagnosis of COPD, inability to read in English (if a friend or family member can read follow-up survey questions, they may still be eligible, however if they cannot complete the follow-up survey, they are ineligible for the study. Additional exclusions included lack of phone number or mailing address including zip code, email addresses, visually or hearing impaired, and persons in law enforcement custody due to inability to collect 7-day post-discharge surveys.

Setting: Participants are identified and enrolled at three urban academic EDs. Site 1 is a 1,171-bed tertiary- and quaternary-care teaching facility with approximately 110,000 annual ED visits. Site 2 is an 856-bed teaching hospital with approximately 100,000 annual ED visits. Site 3 is a 495-bed hospital serving 130,000 annual ED visits. The racial and ethnic distribution of the patient population served by these EDs is 35% Hispanic, 29% African-American, 19% White, 1% Asian, 16% other. With respect to insurance, 13% of adult patients had no insurance, 42% had Medicaid, 24% private insurance, and 21% had Medicare.

Aim 1: Prospective Recruitment

Study data is collected and managed using REDCap [19, 20] electronic data capture tools. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing a) an intuitive interface for validated data capture; b) audit trails for tracking data manipulation and export procedures; c) automated export procedures for seamless data downloads to common statistical packages; and d) procedures for data integration and interoperability with external sources.

A trained research coordinator screens participants for eligibility using the electronic health record. Participants are recruited in the ED from 8 am to 8 pm, Monday through Friday, during their ED visit for asthma and prior to discharge from the ED. After screening for eligibility criteria (age, presenting problem), the research coordinator approaches an ED clinician (physician, mid-level, or nurse) to confirm the subjects is proficient in English, being treated for asthma and is appropriate to participate in a survey study.

After confirming eligibility with the clinician, the research staff approach patients in person

to explain the study purpose and what study enrollment entails, including benefits and risks of participation. Written informed consent is then obtained by the research coordinator to participate in the survey. We use the electronic study database REDCap to capture electronic consent. The e-consent function in REDCap allows us to create a template of the IRB approved consent forms, which participants can review and sign electronically, as well as receive a completed copy of the signed copy via email. E-consent [21] may improve recruitment and retention in clinical research studies by addressing cultural and literacy barriers by including optional explanatory material (e.g., defining terms by hovering over them with the cursor). After documenting informed consent, a paper document outlining the purpose of the study, the requirements, risks, and benefits is given to all potentially interested participants to review. Patients are reminded that their clinical care is in no way be affected by their acceptance or refusal to participate in the study.

Data Collection: Data is collected and stored in REDCap. After obtaining consent, participants are encouraged to complete the initial PROAAct survey questions by entering responses into the REDCap questionnaire via iPad. Research coordinators are available to assist those with limited literacy and are available to clarify survey items or read survey questions verbatim as needed by participants. Research coordinators then enter name, phone number, email, medical record number, demographic information as per participant self-report (gender, race, ethnicity, educational attainment, employment status). Research coordinators also document the extent to which they assisted participants with completion of the survey.

Follow-Up Procedures: Seven days after enrollment and completion of the PROAAct survey at the index ED encounter, participants are asked to self-administer a post-ED discharge follow-up survey using an individualized REDCap survey linked to each participant. Research coordinators contact participants via email, phone, and text message using the contact information they provided at the time of enrollment. Emails and text messages are sent once daily up to 3 consecutive days starting on day 6 to remind participants of their 7-day follow-up survey. Text

messages are sent through Twilio (Twilio Inc., San Francisco, CA) [22] for automated SMS survey distribution and response collection, a third-party web service that integrated with REDCap, allowing users to send survey invitations and alerts to participants as SMS text messages. Research staff also attempt to call subjects a maximum of 3 times using on-site telephones in the ED research office. Upon establishing contact, subjects are reminded of the study and asked if they are able to complete the telephone survey.

Upon completion of the telephone survey, subjects receive a \$20 electronic or mailed gift card as an incentive. Subject names and mailing addresses are written directly onto envelopes to be mailed and are not stored. Participants may decline or withdraw from the study by written or verbal request; however, they do not receive the incentive if they elect to withdraw.

Aims 2 and 3: Assessing Concordance

To assess the association between PROAACT responses and adherence to guideline-recommended ED care, we will perform structured extraction of EHR data at the conclusion of enrollment using the institutional data warehouse. We will collect patient-level factors, including age, sex, past medical history, medication history (to assess asthma severity), insurance status, smoking history, vital signs at triage, medications administered in the ED, and medications prescribed upon ED discharge.

We will obtain data on repeat ED visits and hospitalizations from a regional health information exchange. Prior studies have demonstrated that over 1 in 3 patients who have a repeat ED visit after discharge visit a different facility.[23] Among patients who frequently visit the ED (≥ 4 ED visits in 30 days), HIE (health information exchange) data from the Healthix regional health information organization (RHIO) data identified 16% more ED visits than single-site data.[24] Healthix data will be linked to PROAACT responses and patient-level variables collected from the HER using patient name and date of birth.

Analysis

We plan to administer the baseline and follow-up PROAACT survey to 300 adult ED asthma

patients. Based on historical data on annual ED visits by adult patients for asthma across all sites, we estimate a total population size of approximately 4,500 over 3.5 years. Thus, a sample of 300 subjects will allow us to approximate a 5% margin of error within a 95% confidence interval. In order to obtain 300 completed follow-up surveys, we anticipate needing to enroll 350 patients in the initial survey phase. Although a baseline sample of 300 is too small for evaluating measurement equivalence, it is adequate for selected latent variable models used in factor analyses. [25]

Aim 1 Analysis: Preliminary analyses with item response theory are conducted to examine information functions and derive item parameters for comparison with other socio-demographic groups from data collected in future studies. We evaluate candidate items for item reduction to generate the item set that provides maximum test information at the mean responses, which serve as the final, short-form survey for subsequent external validation, dissemination, and implementation. As part of the psychometric analysis, we develop scale responses based on summed item responses. This enables us to examine construct, convergent, criterion, and predictive validity by examining associations with clinical outcome variables, including adherence to guideline-recommended care and return ED visits and hospitalizations.

Aim 2 Analysis: Next, we will test the hypothesis that improved PROAECT responses are associated with guideline-adherent ED care. We will assess concordance with Level A GINA recommendations: [26] (1) treatment with inhaled β -agonists in the ED; 2) treatment with systemic corticosteroids in the ED for patients who do not respond completely to initial short-acting β -agonist therapy; 3) treatment with inhaled corticosteroids in the ED for those not receiving systemic corticosteroids, and 4) **not** treating with intravenous beta-agonists in the ED. Given prior research suggesting high adherence for some guidelines (ex. inhaled β -agonists), we will examine concordance as a composite binary predictor (adherence to all 4 guidelines vs. not) and separately, evaluate each recommendation as an independent predictor. We exclude the level A recommendation to administer magnesium for severe asthma exacerbations because patients with severe asthma are

likely to be admitted, and likely unstable to participate in a survey.

We will assess the PROAACT responses (primary outcome) using a distribution-based approach such as paired *t*-statistic to evaluate the change in responses in relation to the probability that the change occurred at random. We will calculate baseline descriptive statistics for patient characteristics (sex, age, race, insurance, burden of comorbid illness). We will analyze guideline concordance of ED care both for all patients and stratified by patient characteristic (sex, age category, race, insurance, burden of comorbid illness), ED provider, and institution (MSH, MSBI, MSM) in order to identify potential baseline disparities by patient characteristic and/ or differences in provider or institutional adherence to guidelines. We will analyze the relationship between guideline concordance of ED care and PROAACT responses in a multivariable regression applying generalized hierarchical mixed effects models to account for repeated measures of the same patient, as well as within-provider and within-hospital correlation of observed outcomes. We anticipate a sample size of 300 with an alpha level of 0.05 and 80% power will detect a 12% difference in PROAACT responses between groups receiving guideline-concordant care vs. not.

Aim 3 Analysis: To test our hypothesis that patients report greater improvement in patient-reported outcomes after ED discharge will have fewer ED visits and hospitalizations during the ensuing 30 days. The primary outcome is the rate of acute care encounters (all-cause ED revisit and/or hospitalization) within 30 days after the index ED discharge. We anticipate an overall event rate of 30-40% based on the observed statewide rate of 26% in our preliminary data and higher prevalence of risk factors for increased asthma utilization in our patient population (Black and Hispanic race, exposure to urban pollution including indoor pests and allergens, limited health care access, lower income). ED revisits resulting in admission will count as one event. Secondary outcomes include all-cause ED revisits and hospitalizations within 180 days. We use all-cause ED revisits and/or hospitalizations given our preliminary data showing a substantial majority of repeat ED revisits and admissions were asthma-related in New York State in 2013 and because the

reliability of Healthix diagnosis codes vary by institution. While a sample size of 300 and 35% event rate may not be sufficient to quantify the magnitude of the relationship between PROA ACT responses and subsequent health care utilization, our test for association and directionality will support the predictive and longitudinal validity of PROA ACT as a standalone measure of asthma quality.

We will calculate 30-day event rates (for ED revisits and hospitalizations) using each patient's index ED visit as the unit of analysis. We will first perform univariate analyses using chi-squared tests to compare groups with and without improved PROA ACT responses. To test the adjusted association between PROA ACT responses and acute care use, we will conduct multivariable regression, using rate-based outcome distribution such as negative binomial or Poisson with zero inflation in a hierarchical model to account for patient and hospital-level confounders, such as age, sex, race, ethnicity, burden of chronic conditions, and site of index ED visit.

Ethical Considerations

This study was approved by the Mount Sinai Institutional Review Board (IRB): "The IRB has determined that this research involves no greater than MINIMAL RISK. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45CFR.46.102; 21CFR50.3k).The IRB approved this research under expedited review procedure category(ies) 5 and 7."

Informed Consent: Study participants provided written informed consent.

Privacy and Confidentiality: Participant data is secure and confidential in encrypted and password protected REDCap database. Data include identifiers to link PROA ACT survey responses to utilization data regarding subsequent ED revisits.

Compensation Details: Participants were paid \$20 via gift card upon completion of the follow up survey.

Results:

Recruitment was launched in September 2019. As of 2024, we have enrolled over 200 participants towards our goal of 300. Recruitment is expected to conclude in 2025, and we anticipate peer-reviewed publication of our findings in 2026.

Discussion:

Although patient-reported outcome measures (PROMs) are necessary to evaluate the impact of ED Asthma care, no PROMs have been developed or validated in adult ED asthma patients to date. To our knowledge, this study will be among the first PROMs validated specifically with ED patients for use in ED settings. The diverse population of patients presenting to the Emergency Department for asthma at our study sites has the potential to increase the generalizability of our findings.

We anticipate the successful completion of the PROAACT scale's psychometric and predictive validity will enable its use to assess and improve the quality of ED care. The multidimensional nature of the PROAACT scale, which assesses not just physical symptoms such as dyspnea, but also perceptions of access to care, will enable targeted improvements to ED asthma care. Further, if we find patients who do not report improvement on the PROAACT scale have received care that is not concordant with GINA guidelines, we could develop interventions to improve provider adherence to guidelines, e.g. clinical decision support, audit-and-feedback, etc. Similarly, if patients without improvement in PROAACT responses are shown to have a higher risk of subsequent ED visits, care management programs may target these individuals for more closely coordinated follow-up care after ED discharge.

Despite their importance and patient-centeredness, PROMs are difficult to collect in the ED. The ED is a fast-paced clinical environment that imposes time and workflow constraints. Many

patients are acutely ill and suffer from impaired cognition, which limits their ability to provide reliable responses. Health conditions are often multifactorial and undifferentiated in the ED, which is less problematic for patients with a history of asthma who present with clinical symptoms of acute asthma exacerbation, but may result in the exclusion of patients with new onset asthma who present with dyspnea and other respiratory symptoms. Many EDs are safety-net institutions with limited technology, poor integration of PROMs with technology systems such as electronic health records (EHRs), and lack of resources to act on PROM data. Our study is intended as a validation study; however, overcoming these logistic barriers is important to enable routine PROM collection in acute care settings.

This study specifically focuses on ED patients who are discharged so that PROMs reflect the care that was provided in the ED setting. Over 80% of adult asthma patients are discharged nationally,[24] thus, these patients represent the majority of patients presenting to the ED with asthma. While the inclusion of admitted patients may allow for higher clinical severity, patients who are admitted to the hospital receive interventions such as specialist consultation, respiratory therapy treatments, and other types of care that do not reflect the quality of care provided in the ED.

We also considered alternative time periods for the follow-up survey in 7 days; however, we sought to adapt the PROAECT items from previously validated sources whenever possible. Thus, because seven days [27] as previously been used as a time period for assessing post-ED discharge outcomes and the Patient-Reported Outcomes Measurement Information System (PROMIS) scales assessing key domains prioritized by patients (dyspnea, ability to participate in daily activities, etc.) had previously been validated for use on a 7-day time scale, we proceeded with a 7-day interval to assess changes in responses.

Limitations

Our study has several limitations. First, this study will be conducted in three urban, academic EDs in the Northeast, and the study results may not be generalizable to other EDs. However, we are

enrolling a racially, ethnically, and socioeconomically diverse population that will provide useful insights for many clinical ED settings. Second, the PROAECT survey is not yet translated or validated in non-English-speaking populations; due to this, we have excluded non-English speakers. We anticipate including non-English speakers in a future study, which will require additional qualitative interviews and validation. Finally, recruitment was launched in late 2019, and impacted by the COVID-19 pandemic shortly thereafter, which has resulted in the following key modifications:

First, the recruitment period, initially intended to be 3.5 years in duration, has been extended to five years due to the COVID emergency pandemic occurring in March 2020. Recruitment for the study was paused from April through June 2020 coinciding with the initial surge of the COVID-19 pandemic in New York City. Active recruitment resumed in July 2020 and have been actively screening and enrolling patients since then; however, total ED visit volumes continued to be lower than pre-COVID levels, consistent with national trends showing reductions of up to 42% compared to 2019. [28] While ED visit volumes have since increased in each subsequent year, they have not yet returned [29, 30] to pre-COVID levels. Thus, recruitment is still ongoing. We also experienced substantial turnover in staff which delayed our ability to recruit eligible patients. These workforce changes are consistent with national trends showing double the historical rate of job resignations in 2021. [29, 31] To fill this gap, we utilized medical students and undergraduate students to supplement recruitment needs.

Conclusion

Our study is among the first PROMs developed specifically with ED patients for use in ED settings have the potential to be used in future interventions to improve ED asthma care. We anticipate study results will inform a future study in which there will be a multi-center validation and implementation study of PROAECT. The validation of a PROM for ED asthma will enable the

evaluation of interventions to improve ED asthma care and accelerate improvements in asthma care quality.

Acknowledgements:

We would like to acknowledge Steven Abreu, Mustafa Ali, Ofree Chen, Fresa Estevez, Chyla Everett, Alexandra Gootman, Isabella Hanesworth, Sophie Karwoska-Kligler, Ted Kuke, Angie Lopez, Natalie Massenburg, Claire Shubeck, Samuel Vargas, and Albert Williams for their contributions.

Conflicts of Interest:

None of the authors have financial or non-financial conflicts of interest to disclose.

During the conduct of this study, MPL received funding from the Agency for Healthcare Research and Quality (AHRQ) and National Institute on Aging (NIA) unrelated to this work; LG received funding from the National Institute of Minority Health and Health Disparities (NIMHD), National Institute of Drug Abuse (NIDA), Department of Defense, and University of California at Davis unrelated to this work; and LDR received funding from the National Heart, Lung, and Blood Institute, National Cancer Institute, NIMHD, NIDA, and Leidos Biomedical Research, Inc unrelated to this work.

Multimedia Appendix 1: NIH Summary Statement of Peer Review. Summary Statement Lin 1K23HL143042-01

References

1. Masoli M, Fabian D, Holt S, Beasley R. The global burden of asthma: executive summary of the GINA Dissemination Committee report. *Allergy*. 2004 May;59(5):469-78. PMID: 15080825. doi: 10.1111/j.1398-9995.2004.00526.x.
2. Akinbami LJ, Moorman JE, Bailey C, Zahran HS, King M, Johnson CA, et al. Trends in asthma prevalence, health care use, and mortality in the United States, 2001-2010. *NCHS Data Brief*. 2012 May(94):1-8. PMID: 22617340.
3. Sullivan K, Thakur N. Structural and Social Determinants of Health in Asthma in Developed Economies: a Scoping Review of Literature Published Between 2014 and 2019. *Curr Allergy Asthma Rep*. 2020 Feb 6;20(2):5. PMID: 32030507. doi: 10.1007/s11882-020-0899-6.
4. Moorman JE, Akinbami LJ, Bailey CM, Zahran HS, King ME, Johnson CA, et al. National surveillance of asthma: United States, 2001-2010. *Vital Health Stat* 3. 2012 Nov(35):1-58. PMID: 24252609.
5. Collaboration TC. *Cochrane Handbook for Systematic Reviews of Interventions*. In: Higgins JPT GS, editor. 2011.
6. Wang PS, Beck A, Berglund P, Leutzinger JA, Pronk N, Richling D, et al. Chronic medical conditions and work performance in the health and work performance questionnaire calibration surveys. *Journal of occupational and environmental medicine*. 2003 2003/12//;45(12):1303-11. PMID: 14665817. doi: 10.1097/01.jom.0000100200.90573.df.
7. Loerbroks A, Herr RM, Subramanian S, Bosch JA. The association of asthma and wheezing with major depressive episodes: an analysis of 245 727 women and men from 57 countries. *Int J Epidemiol*. 2012 Oct;41(5):1436-44. PMID: 22879363. doi: 10.1093/ije/dys123.
8. Oraka E, Iqbal S, Flanders WD, Brinker K, Garbe P. Racial and ethnic disparities in current asthma and emergency department visits: findings from the National Health Interview Survey, 2001-2010. *J Asthma*. 2013 Jun;50(5):488-96. PMID: 23544662. doi: 10.3109/02770903.2013.790417.
9. Lin MP, Kligler SK, Friedman BW, Kim H, Rising K, Samuels-Kalow M, et al. Barriers and Best Practices for the Use of Patient-Reported Outcome Measures in Emergency Medicine. *Annals of emergency medicine*. 2023 Jul;82(1):11-21. PMID: 36682996. doi: 10.1016/j.annemergmed.2022.12.017.
10. Juniper EF, Guyatt GH, Epstein RS, Ferrie PJ, Jaeschke R, Hiller TK. Evaluation of impairment of health related quality of life in asthma: development of a questionnaire for use in clinical trials. *Thorax*. 1992 Feb;47(2):76-83. PMID: 1549827. doi: 10.1136/thx.47.2.76.
11. Apfelbacher CJ, Jones C, Hankins M, Smith H. Validity of two common asthma-specific quality of life questionnaires: Juniper mini asthma quality of life questionnaire and Sydney asthma quality of life questionnaire. *Health Qual Life Outcomes*. 2012 Aug 20;10:97. PMID: 22906054. doi: 10.1186/1477-7525-10-97.
12. Schatz M, Sorkness CA, Li JT, Marcus P, Murray JJ, Nathan RA, et al. Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. *J Allergy Clin Immunol*. 2006 Mar;117(3):549-56. PMID: 16522452. doi: 10.1016/j.jaci.2006.01.011.
13. Yeatts KB, Stucky B, Thissen D, Irwin D, Varni JW, DeWitt EM, et al. Construction of the Pediatric Asthma Impact Scale (PAIS) for the Patient-Reported Outcomes Measurement Information System (PROMIS). *J Asthma*. 2010 Apr;47(3):295-302. PMID: 20394514. doi: 10.3109/02770900903426997.
14. Hyland ME, Lanario JW, Pooler J, Masoli M, Jones RC. How patient participation was used to develop a questionnaire that is fit for purpose for assessing quality of life in severe asthma. *Health Qual Life Outcomes*. 2018 Jan 27;16(1):24. PMID: 29374455. doi: 10.1186/s12955-018-0851-9.
15. Juniper EF, Svensson K, Mörk AC, Ståhl E. Measuring health-related quality of life in adults

during an acute asthma exacerbation. *Chest*. 2004 Jan;125(1):93-7. PMID: 14718426. doi: 10.1378/chest.125.1.93.

16. Samuels-Kalow ME, Rhodes KV, Henien M, Hardy E, Moore T, Wong F, et al. Development of a Patient-centered Outcome Measure for Emergency Department Asthma Patients. *Academic emergency medicine : official journal of the Society for Academic Emergency Medicine*. 2017 May;24(5):511-22. PMID: 28146297. doi: 10.1111/acem.13165.

17. Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *Journal of clinical epidemiology*. 2010 Nov;63(11):1179-94. PMID: 20685078. doi: 10.1016/j.jclinepi.2010.04.011.

18. Agency for Healthcare Research and Quality. CAHPS Surveys and Guidance. Rockville, MD; Available from: <http://www.ahrq.gov/cahps/surveys-guidance/index.htm>.

19. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009 Apr;42(2):377-81. PMID: 18929686. doi: 10.1016/j.jbi.2008.08.010.

20. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform*. 2019 Jul;95:103208. PMID: 31078660. doi: 10.1016/j.jbi.2019.103208.

21. Mazzochi AT, Dennis M, Chun HY. Electronic informed consent: effects on enrolment, practical and economic benefits, challenges, and drawbacks-a systematic review of studies within randomized controlled trials. *Trials*. 2023 Feb 21;24(1):127. PMID: 36810093. doi: 10.1186/s13063-022-06959-6.

22. Twilio. How to Use Our REST APIs. 2023; Available from: <https://www.twilio.com/docs/usage/api>.

23. Duseja R, Bardach NS, Lin GA, Yazdany J, Dean ML, Clay TH, et al. Revisit rates and associated costs after an emergency department encounter: a multistate analysis. *Ann Intern Med*. 2015 Jun 2;162(11):750-6. PMID: 26030633. doi: 10.7326/m14-1616.

24. Shy BD, Kim EY, Genes NG, Lowry T, Loo GT, Hwang U, et al. Increased Identification of Emergency Department 72-hour Returns Using Multihospital Health Information Exchange. *Academic emergency medicine : official journal of the Society for Academic Emergency Medicine*. 2016 May;23(5):645-9. PMID: 26932394. doi: 10.1111/acem.12954.

25. Fries JF, Bruce B, Cella D. The promise of PROMIS: using item response theory to improve assessment of patient-reported outcomes. *Clin Exp Rheumatol*. 2005 Sep-Oct;23(5 Suppl 39):S53-7. PMID: 16273785.

26. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention,. 2018 Update, ; Available from: <https://ginasthma.org/2018-gina-report-global-strategy-for-asthma-management-and-prevention>.

27. Lin MP, Burke RC, Orav EJ, Friend TH, Burke LG. Ambulatory Follow-up and Outcomes Among Medicare Beneficiaries After Emergency Department Discharge. *JAMA Netw Open*. 2020 Oct 1;3(10):e2019878. PMID: 33034640. doi: 10.1001/jamanetworkopen.2020.19878.

28. Hartnett KP, Kite-Powell A, DeVies J, Coletta MA, Boehmer TK, Adjemian J, et al. Impact of the COVID-19 Pandemic on Emergency Department Visits - United States, January 1, 2019-May 30, 2020. *MMWR Morb Mortal Wkly Rep*. 2020 Jun 12;69(23):699-704. PMID: 32525856. doi: 10.15585/mmwr.mm6923e1.

29. James. A. A Sobering Year for Emergency Departments and Their Patients,. 2023; Available from: <https://www.acepnow.com/article/a-sobering-year-for-emergency-departments-and-their>

patients/.

30. KFF. Hospital Emergency Room Visits per 1,000 Population by Ownership Type,. [9/24/2024]; Available from: <https://www.kff.org/other/state-indicator/emergency-room-visits-by-ownership/?>

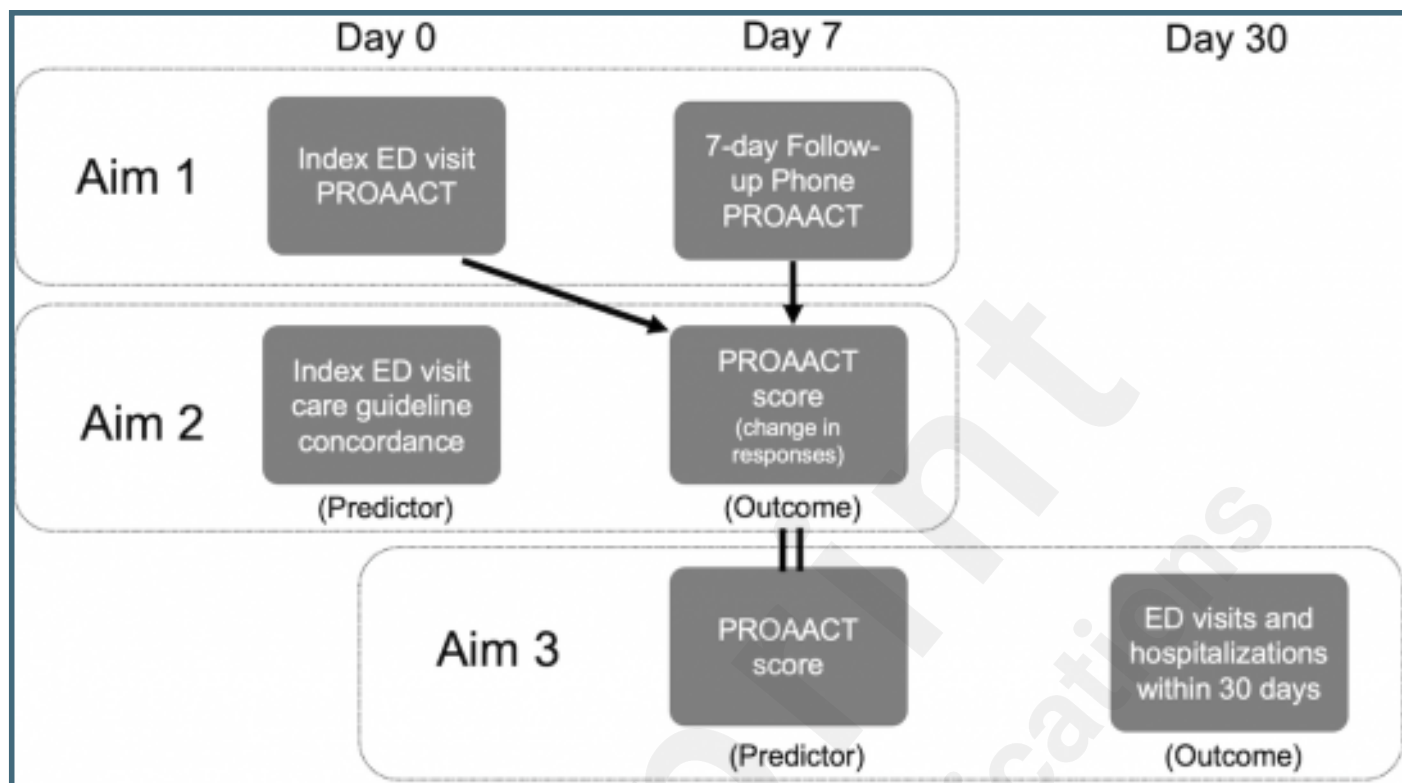
activeTab=graph¤tTimeframe=0&startTimeframe=23&selectedDistributions=total&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22L.

31. Bureau of Labor Statistics US Department of Labor. The “Great Resignation” in perspective. 2022 [6/10/2024]; Available from: <https://www.bls.gov/opub/mlr/2022/article/the-great-resignation-in-perspective.htm>.

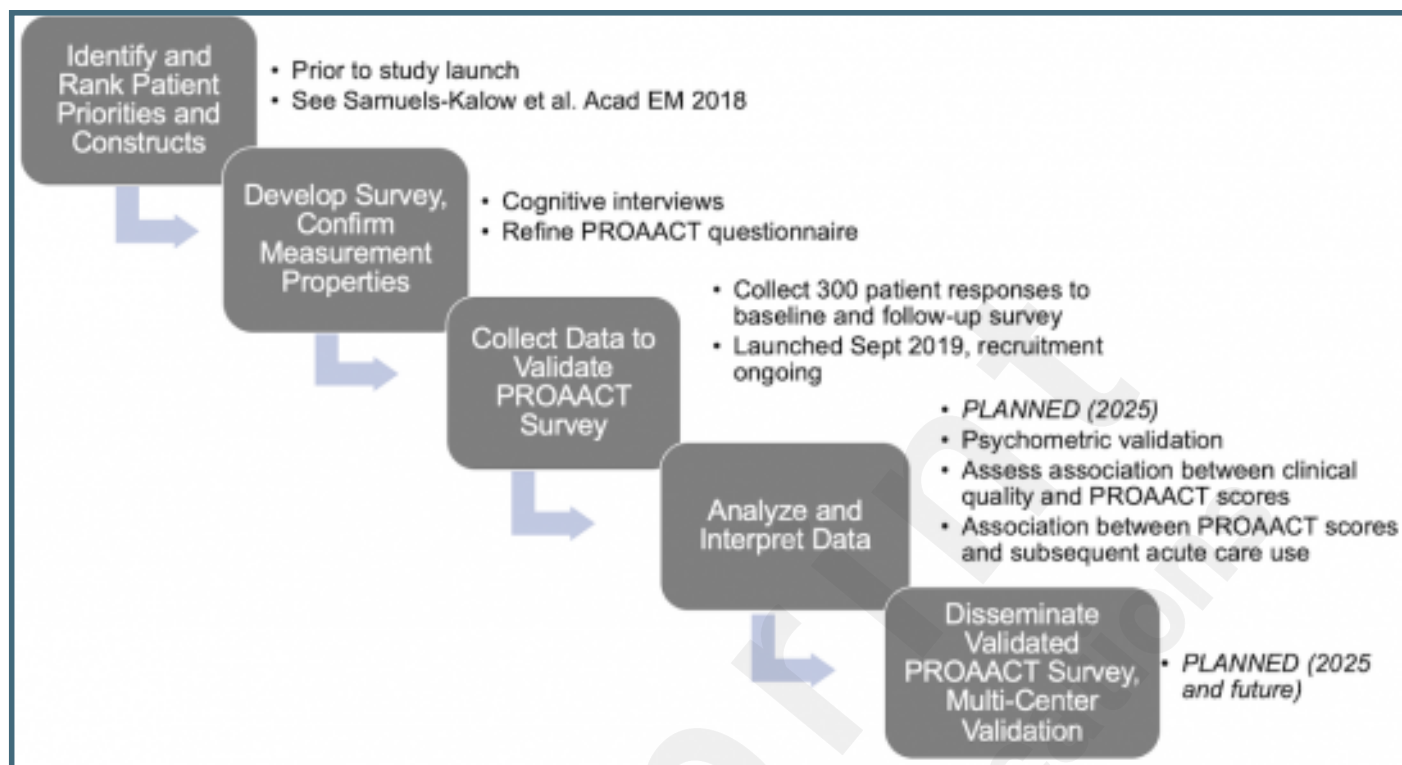
Supplementary Files

Figures

Data Collection, Outcomes and Predictors of Interest.



Study Workflow and Timeline.



Multimedia Appendixes

NIH Summary Statement of Peer Review.

URL: <http://asset.jmir.pub/assets/03c3e62d09189248c7128728457e524d.pdf>

PROAACT Survey.

URL: <http://asset.jmir.pub/assets/4962cc09890ffef28ed866e5ac68ec72.pdf>

