AdheRence to Inhaled Corticosteroids in Asthma

Research Summary

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Purpose of the Study

This study aims to develop a clinical intervention to improve the health outcomes of adult African Americans (AAs) with asthma. Toward that end, we intend to refine a novel patient-centered inhaled corticosteroid (ICS) adherence intervention called ARICA (AdheRence to Inhaled Corticosteroids in Asthma), using qualitative methods and usability testing.

Background & Significance

Asthma in adult AAs is a significant health problem.(Jimenez-Gonzalez, Santini et al. 2008) Many national organizations, including the National Heart, Lung, and Blood Institute's (NHLBI) Center for Translational Research and Implementation Science (CTRIS) are working to identify gaps and research opportunities to address inequities in a variety of health conditions, including asthma. ICS adherence in adult AAs is one potentially important target for interventions. ICS adherence rates are 22%-64% in the general population and worse in adult AAs (adjusted OR 0.35, 95% CI, 0.13-0.95). ICS adherence is associated with reduced asthma exacerbations, reduced asthma-related acute care utilization, and reduced health care cost.(Bender, Milgrom et al. 2003, Haynes, Ackloo et al. 2008, National Asthma and Prevention Program . Third Expert Panel on the Management of 2010, Williams, Peterson et al. 2011, Ivanova, Bergman et al. 2012, Moullec, Gour-Provencal et al. 2012, Viswanathan, Golin et al. 2012, Denford, Taylor et al. 2014) Though we do not have specific ICS adherence rates in North Carolina or the Duke Health System, there is no evidence to suggest that rates are different than nationally reported estimates.

Adherence interventions in adult AAs have not been effective. I conducted a systematic review that found ICS adherence interventions in adult AAs(Martin, Catrambone et al. 2009, Apter, Wang et al. 2011, Apter, Wan et al. 2013, Kolmodin MacDonell, Naar et al. 2016) to be ineffective in improving ICS adherence, health care utilization, FEV1, asthma control, or asthma quality of life (manuscript under review). Interventions did not target multiple barriers to adherence and were not consistently informed by behavior change theory or stakeholder engagement—recommended strategies for developing behavior change interventions in minorities.(Martin, Catrambone et al. 2009, Apter, Wang et al. 2011, Press, Pappalardo et al. 2012, Apter, Wan et al. 2013, Kolmodin MacDonell, Naar et al. 2016)

Theory-informed, multi-component approaches may be critical for successful behavior change.(Michie, van Stralen et al. 2011, French, Green et al. 2012) I conducted a scoping literature review and engaged local community stakeholders to identify the most common patient-reported barriers to asthma medication adherence in adult AAs (drafting). I then mapped the barriers to the Theoretical Domains Framework (TDF), a behavior change theory with 14 domains covering a wide range of potential barriers that is thought to be able to identify a higher number of potential intervention strategies than a single behavior theory. (Michie, van Stralen et al. 2011, Cane, O'Connor et al. 2012) The most common types of patient barriers, when classified by TDF domains, were: knowledge (e.g., do not know when to use ICS), belief about consequences (e.g., belief ICS is not needed for asthma control), environmental context and resources (e.g., costs), skills (e.g., cannot technically use inhaler), emotion (e.g., fear of side effects or dependence), and memory, attention, and decision processes (e.g., too busy). Using the Behavior Change Wheel, a systematic and evidence-based approach to developing an intervention, I identified intervention strategies and created a preliminary logic model for a novel intervention package, called ARICA (Figure 1). (Michie, van Stralen et al. 2011, Cane, O'Connor et al. 2012) Using online questionnaires, patients will identify the extent of their nonadherence and their barriers to

adherence. Then I will select an evidence-based intervention strategy to remediate each identified barrier.(Michie, van Stralen et al. 2011, Cane, O'Connor et al. 2012) Each category of barriers (TDF domains) is connected to an intervention activity (Figure 1 legend). For example, patients who cannot afford medications will be enrolled in a copayment assistance program and those who do not believe adherence is needed for control will receive objective feedback on asthma control using spirometry. In addition to the interchangeable activities, everyone will receive texts/emails dispelling asthma myths to help reinforce adherence after the core intervention activities. Their providers will receive alerts about nonadherent patients identifying their barriers to adherence as well as recommended provider intervention strategies (e.g., referrals) and discussion points to be used at the next encounter. All adherence information and recommendations will be added to the chart so it will be readily available during encounters.

ARICA is a personalized, patient-centered adherence intervention designed to remediate barriers to adherence by focusing on 3 areas of interest for REACH Equity: (a) improving the quality of the clinical encounter by facilitating patient-provider communication about the extent of adherence and barriers to adherence; (b) promoting interpersonal relationship building by providers helping patients understand their barriers and acknowledge the difficulty of adherence; and, (c) targeting the whole person by customizing intervention components according to each patient's unique barriers.

The proposed research is novel in at least 4 ways. (1) Unlike most adherence studies,(Martin, Catrambone et al. 2009, Apter, Wang et al. 2011, Apter, Wan et al. 2013, Kolmodin MacDonell, Naar et al. 2016) we are targeting African Americans. This is important because AAs have disproportionately high asthma morbidity and mortality.(Adams, Kirzinger et al. , Agency for Healthcare Research Quality , Centers for Disease Control , Goeman, Aroni et al. 2004) (2) Our intervention's theory-based approach may yield a more potent intervention than those identified and studied in the past. There is increasing evidence that theory-informed, multi-component approaches are critical for successful behavior change.(Michie, van Stralen et al. 2011, French, Green et al. 2012) A meta-analysis of 147 medication adherence studies that used behavior theory to inform intervention development reported a statistically significant improvement in medication adherence outcomes.(Conn, Enriquez et al. 2016) To our knowledge, the proposed research is the first to use the TDF, behavior theory, and the Behavior Change Wheel (intervention development framework) to design an ICS adherence intervention in adult AAs with asthma. (3) We will engage key stakeholders to ensure our interventions are relevant and can be easily translated into routine clinical practice. Stakeholder engagement is critical to the success of asthma interventions in minorities.(Press, Pappalardo et al. 2012) (4) We will target multiple barriers for ICS adherence and poor asthma outcomes among adult AAs. Prior ICS adherence interventions in adult AAs have targeted one barrier to ICS adherence. The proposed research targets multiple barriers to ICS adherence that have been identified at the national level in my scoping review and confirmed locally by community stakeholders.

Design & Procedures

Study the feasibility and acceptability of ARICA in Duke Health.

Study Design: I will (1) implement ARICA in Duke Health and (2) evaluate the feasibility and acceptability of the implementation of ARICA in a randomized controlled study employing mixed methods (i.e., quantitative and qualitative assessments).

Procedures: Consented subjects will receive a modified (adapted for patients with asthma who have been shown to face similar barrier to adherence) version of the validated Voils adherence questionnaire, which assesses 7-day self-reported medication adherence and barriers to adherence.(Voils, Maciejewski et al. 2012) If nonadherent, participants will select all their barriers to adherence, which will inform the development of a personalized adherence intervention targeting the patient's unique needs. The specific intervention components for each patient will depend on the barriers identified. Patients will retake the Voils adherence questionnaire every month for up to 3 months. All patients will receive weekly text and email alerts dispelling asthma medication myths to help reinforce adherence for the study period (4 months).

The asthma self-management course (group or individual depending on scheduling) will be held in a clinic conference room. For example, the conference room in the Duke Asthma Allergy and Airway Center, Duke Outpatient Clinic and Croasdaile Primary Care Clinic.

Data Collection: Data will be collected through RedCap surveys. Patients will have the option of completing the surveys online, via phone interview, or in person as part of a guided interview with the CRC (preferred). In the ARICA exit interview, questions were added about COVID-19 and how it affected the participant's asthma and stress.

Outcome Measures: The primary outcome is feasibility and acceptability, which will be assessed using qualitative methods (i.e., semi-structured interviews) at up to 3 months with the goal of characterizing and profiling how intervention components, as well as the unique case context of their use, may have impacted participants' experiences. This will allow us to explore how the intervention may target or miss each patient's needs and explore variability across providers and practices. We will use the barriers identified to facilitate discussion about how the intervention strategy impacted their ability to communicate about and get help with barriers to adhering and asthma management. In addition, we will contact patients and providers to ask them how easy the intervention was to use, whether there were barriers to use, how the intervention could be improved, and the extent to which the intervention hinders or facilitates clinical care. We will also seek to contact participants who drop out of the study to elicit their feedback, which may be distinctly different than that of participants who complete the study.

Secondary Outcomes: We will collect secondary outcomes at baseline and up to 3 months. Baseline medication possession ratio (MPR) and asthma exacerbations will be calculated from the 6 and 12 months prior to consent, respectively. Asthma exacerbation will be defined as any use of systemic steroids or an increase in daily systemic steroids for 3 or more days to treat respiratory symptoms or any asthma-related acute care utilization over the study period. The ACT, AQLQ, and the asthma KASE questionnaire are valid and reliable self-administered measures, validated in AA populations. We will also assess interpersonal communcation between patients and providers using the Interpersonal Process of Care Survey. During the baseline assessment, I will also collect demographics using a standardized questionnaire. Additional outcomes are listed in the Questionnaire Packet.

Analysis: Primary Outcome: I will perform stakeholder (e.g., patient, provider, staff) to inform intervention modification. Interviews will be transcribed, coded independently by two members of the team, and analyzed to identify emergent themes. I will present preliminary findings to stakeholders to review the results and aid in the interpretation/significance of findings. Secondary Outcomes: I will assess the magnitude of change and confidence intervals for all quantitative outcomes. The proposed

study will not be powered to detect an effect size because the primary outcome is feasibility and acceptability.

Selection of Subjects

Patients

Inclusion Criteria for Aim 1:
- At least 18 years of age
- Self-identifying African American
- Self-reported current asthma
- Prescribed an inhaled corticosteroid (alone or combination) for ≥ 1 month
- Presented at ANY Primary Care clinic visit within the past 3 years

Inclusion Criteria for Aim 2:
- At least 18 years of age
- Self-identifying African American
- Self-reported current asthma
- Prescribed an inhaled corticosteroid (alone or combination)
- Presented at a Duke Primary Care clinic visit within the past 3 years

Exclusion for Aims 1 and 2:
- Unable or unwilling to provide informed consent

Patients will be identified through MaestroCare, DEDUCE queries, clinic visits, direct referrals, and community recruitment

Providers

Inclusion Criteria for Aims 1:
- Must be a pulmonary or primary care provider (MD, DO, NP, or PA) having practiced for ≥ 1 year
- Must clinically manage adult African Americans with asthma

Exclusion Criteria for Aims 1
- Unable or unwilling to provide informed consent

Pulmonary providers will be recruited from Duke's three pulmonary practices: Duke Raleigh; Duke Asthma, Allergy, and Airway Center; and the Duke South 2F/2G Pulmonary Clinic. Primary care providers will be recruited from Duke, UNC and private practices in North Carolina

Community Stakeholders

Inclusion:
- Must work with Durham County, NC residents
- Must work with or advocate for African American communities (e.g. leadership/staff of nonprofit organizations, religious leaders, health insurance payers, government agency employees, etc.)

Exclusion:
- Belong to organizations focused exclusively on non-African American communities
- Unable or unwilling to provide informed consent

Potential participants will be recruited from the REACH Equity Community Advisory Board and organizations involved in the asthma stakeholder meeting reported in the background data collection (e.g. Durham Housing Authority, Lincoln Community Health Center, Project Access, Clean Air, AME Zion, etc.).

Subject Recruitment and Compensation
Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.
Patients

Patients will be recruited through direct referral, patient lists, Duke Asthma Allergy Airway research database, direct referral from community stakeholders and events, DEDUCE/EPIC query, MyChart Research Team query, or in the event that an eligible participant calls the recruitment team to express interest. We will use Duke's new cold-call policy.

Using the results from MyChart Research Team's query, we will send a mychart message to all eligible participants from Dr. Riley describing the study and offering these patients an opportunity to participate in the study or to opt-out from participation. If the study team has not heard from a potential participant after 3 days, then a member of the study team will contact that individual using a phone script to confirm eligibility, answer questions, and schedule study activities if the individual expresses interest. The study team will not attempt to contact subjects who have opted out of research in MyChart.

Providers
Potential participants will be contacted by email and personal (verbal) invitation by the PI.

Community Stakeholders
Potential participants will be contacted by email and personal (verbal) invitation by the PI.

Data Analysis & Statistical Considerations

Primary Outcome: I will perform patient interviews to inform intervention refinement. Interviews will be transcribed, coded independently by two members of the team, and analyzed to identify emergent themes. I will present preliminary findings to stakeholders to review the results and aid in the interpretation/significance of findings. Secondary Outcomes: I will assess magnitude of change and confidence interval for quantitative outcomes, and patient's medication adherence rates based on pharmacy refill rate, Asthma Quality of Life AQLQ, and Asthma Control Test, (ACT). The proposed study will not be powered to detect an effect size because the primary outcome is feasibility and acceptability.

An outside vendor, (ETR Services) is being contracted to provide data analysis of the study audio recordings, the recordings will be transmitted for analysis via a secure Duke BOX folder. No data will be sent until a work agreement with ETR Services is in place.

Data & Safety Monitoring

Dr. Riley will supervise this study at all times and will be in close and frequent contact with the Clinical Research Coordinator and Maestro Care Research group. Investigators will adhere to established federal and institutional patient safety and protection guidelines. To assure data accuracy, Dr. Riley and the CRC will review the iterative qualitative results on a biweekly basis. Protocol compliance will be reviewed during weekly meetings between the clinical research coordinator and Dr. Riley (more frequent if required).

We will closely safeguard participant privacy regarding protected health and personal information. Subject descriptive characteristics will be collected and stored in a REDCap database. Study ID numbers, generated at the time of enrollment, are linked to a separate Duke DHTS-maintained database that contains patient names and descriptors (e.g., patient, stakeholder, provider) that will be stored on the secured pulmonary drive on Duke's server.

As described previously, this project will utilize a REDCap database system customized for our data needs. For data validation, a series of project-defined data checks and conditional constraints can be required to ensure the highest quality data collection.