Understanding Participant Perspectives in the iCARE Asthma Study: Themes from Qualitative Interviews

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Objectives

- Evaluate perspectives of patients enrolled in the **Feasibility Phase** of the iCARE Asthma study using patient interviews to extract feedback to implement **into** the larger cohort study
- Determine the effectiveness of study protocol on asthma treatment and outcomes and improve ease of patient understanding of study protocol and medication use

Background

- Asthma patients, particularly those with moderate to severe disease, continue to face frequent exacerbations, despite standard maintenance and rescue therapies, that can lead to emergency care, missed work or school, and decreased quality of life {1,2]
- The iCARE study (Improving the Quality of Care for Asthma Patients at Risk of Exacerbations) evaluates two evidence-based approaches to asthma symptom management: Maintenance and Reliever Therapy (MART) and Patient Activated Reliever Triggered Inhaled Corticosteroids (PARTICS) [3]
  - MART regimen: combination therapy of inhaled corticosteroids (ICS) with a long-acting beta-agonist (LABA) inhaled medication for both rescue and maintenance use
  - PARTICS regimen: Two puffs of ICS metered-dose inhaler (ICS) are taken with each rescue inhaler use, and 5 puffs of ICS are taken after each nebulizer use
- Both regimens have shown promise in reducing asthma exacerbations, but their comparative effectiveness and feasibility in real-world settings remains unclear [4,5]
- This qualitative sub-study focuses on patient experiences, medication adherence, and implementation barriers observed during the feasibility phase of the iCARE study
- Understanding these factors will help optimize asthma management strategies and inform the design of large-scale asthma studies

Methods

- 14 of the 50 patients enrolled in the study were sent requests for an optional series of two virtual interviews (1-month and 3 months post-enrollment), with $50 compensation for completion of each interview. These 14 were sampled purposively to reflect diversity of enrollment site, MART vs PARTICS study arm, and frequency of nebulizer use.
- Interviews done 1-month post-enrollment were standardized to a series of reflective questions concerning asthma history and severity before and during the study involvement, the enrollment process including feedback on educational materials and consent forms, as well as study compensation and cost of medications. Interviews done 3-months post-enrollment were standardized to a series of questions concerning ongoing experience with study medications, feedback on monthly surveys, and medication refills. **As this study is ongoing, not all 3-month-post interviews have been completed to date.**
- Interviews were recorded and transcribed for analysis. Data from the all 11 1-month-post interview transcripts were summarized and charted according to domains of interest in the interview (see Table 1). A similar table will be configured for 3-month-post interviews upon completion.
- Additional demographic data was collected from patient surveys completed at the time of enrollment.

Results

- 11 of the 14 recruited patients opted into the interview series. Of these 11 participants:
  - 3 participants were recruited from the study site at Duke University, 1 from the University of Pennsylvania, 3 from University of Wisconsin Madison, 2 from Yale University, and 2 from Washington University
  - Participant ages ranged from 25 to 65 years old, with an average age of 52.4 years.
  - 6 participants were AFAB (assigned female at-birth), while 5 were AMAB.
  - 7 participants self-identified as White, 3 self-identified as Black, and 1 self-identified as Hispanic

Table 1: Patient Interviews 1 Month Post Enrollment

Participant	Study Arm Assigned	Diagnosed with Asthma	Baseline Asthma Control Test (ACT) Score	Reason for Interest in Study	Impact on Asthma on Life	Care Oversight	Compensation for Cost of Medications Feedback
A	MART	<12	18	Treatment helpful, children	Severe	Study Team	Fair Compensation
B	MART	>20	21	Children	Severe	Clinician	Fair Compensation
C	MART	<12	18	Treatment helpful, meaningful work	Severe	Clinician	Challenges receiving medication and preferred more tools over cash compensation
F	MART	<12	17	Low commitment, meaningful work	Severe	Clinician	More compensation as had out of pocket cost of-$40-60
I	MART	<12	23	Treatment helpful, meaningful work	Mild	Study Team and Clinician	Fair Compensation
J*	MART	<12	21	Not Clear	Mild	Study Team	Fair Compensation
K	MART	>60	11	Treatment helpful, education	Severe	Study Team	Fair Compensation
D	PARTICS	>30	18	Treatment helpful	Severe	Study Team and Clinician	Fair Compensation
E*	PARTICS	>20	21	Financial incentive, meaningful work	Moderate	Study Team	Out of pocket cost of study medication - $5-10
G*	PARTICS	>40	17	Treatment helpful	Severe	Study Team	Challenges receiving medication
H*	PARTICS	<12	10	Treatment helpful, meaningful work	Severe	Study Team and Clinican	Fair Compensation

*Participants who frequently reported nebulizer use

Conclusions Post 1-Month Enrollment Interviews

- **Enrollment and Consent Process (Time, Clarity, Technology)**
  - Virtual check-in visits and remote enrollment were preferred
  - Technology did not appear to pose a significant challenge for participants, with study staff readily available to address any issues or questions
- **Educational Materials**
  - Arm-specific instructional packets were generally viewed as clear and accessible.
    - Some uncertainty during consent process about differences between two arms
  - <50% of patients interviewed watched the instructional videos, but those who watched found them educational.
    - Patients cited pre-existing familiarity with asthma medication as well as written materials being sufficient for comprehension as reasons for not watching videos
- **Cost of Medication**
  - Considered reasonable by most patients; cost of drug depended on what pharmacy was used – since patients were recruited at different sites and often was done virtually, multiple pharmacies with variable pricing were used to obtain study drugs
- **Medication Experience**
  - Symptom improvement and reduced albuterol reliance were frequently reported with both study arms
  - Increased medication adherence reported in both arms
    - *Patient H (PARTICS) experienced increased dryness and hoarseness from medication use - yet noted overall improvement in condition due to increased mucus clearance.*
  - Directions on when to take rescue medication pre/post exercise
- **Compensation**
  - Compensation of $100 dollars to join study (plus additional $50 and $20 payouts for continued engagement) reported as fair to cover medication costs
    - Some participants frustrated if compensation was delivered to them AFTER obtaining medication and paying for copay out of pocket.

Patient Perspectives

Table 2: Patient Comment at 1 Month Post Enrollment Interview

Participant	Context	Comment
G	Participant reported some confusion in taking the study medication	"When I say that, but it's like a little confusing because I didn't know how to take it at first. And it was, it was scary."
A	Participant explaining why this asthma study was so important to them	"[As] I've gotten older, the asthma issues that I deal with are...upper respiratory infection[s]. And my interest in managing that so that they don't take such deep root and you know basically compromise me to the nth degree"
H	Participant expressed how some of the side effects of the study treatment affected them.	"And I noticed that like in the morning after I wake up, I'm especially... a little hoarse and dry from [inhaler], especially when I use it five times at night.

Next Steps and Future Directions to Address Common Concerns

Immediate Next Steps -

- Educational Materials
  - Include a summary sheet, highlighting key protocols of the study, including treatment arm, dosing, and emergency instructions BOTH in the consent form and in the patient packet materials
    - Add a simple, step-by-step instruction sheet and/or visual flowchart to consent forms and enrollment packets, including example contexts of when to use medication
    - Can schedule (email/text) follow-ups if requested around Day 7 and Day 21 to reinforce study steps.
- Medications
  - With pre-loaded cards, mail prior to pharmacy visits and add activation reminders, allowing patients to use card rather than having to pay out of pocket.
- Clinical Side Effects
  - can be mitigated by increased encouragement of the use and/or provision of spacers with study arm drugs, particularly with older patients who may struggle to coordinate breath with inhaler actuation.

Future Directions

- Conduct more guided patient interviews – this is a small sample size and the guidelines here as 11 participants were interviewed
  - If possible, create more focused questions regarding study treatment and experience
    - Further analyze if differences emerge with nebulizer use
  - Gather feedback closer to event date as many participants reported limited recall of the consent process, so feedback lacked the details
- Finish 3-month interviews and check to see if feedback remains consistent or if there are additional areas of improvement
- Continue to gather further feedback from focus groups (including study pharmacists, site investigators, and study coordinators)

References

1. Mazurek, J. M., & Syamlal, G. (2018). Prevalence of asthma, asthma attacks, and emergency department visits for asthma among working adults — National Health Interview Survey, 2011–2016. *Morbidity and Mortality Weekly Report, 67*(13), 377–386. https://doi.org/10.15585/mmwr.mm6713a1
2. American Lung Association. (2024). *Asthma Trends and Burden*. Retrieved August 7, 2025, from https://www.lung.org/research/trends-in-lung-disease/asthma-trends-brief/trends-and-burden
3. Israel, E. (2024, September 19). Improving the Quality of Care for Asthma Patients at Risk of Exacerbations (iCARE). (*ClinicalTrials.gov*. Identifier NCT06596512. https://clinicaltrials.gov/study/NCT06596512
4. Sobieraj, D. M., Weeda, E. R., Nguyen, E., Coleman, C. I., White, C. M., Lazarus, S. C., Blake, K. V., Lang, J. E., & Baker, W. L. (2018). Association of Inhaled Corticosteroids and Long-Acting β-Agonists as Controller and Quick Relief Therapy With Exacerbations and Symptom Control in Persistent Asthma: A Systematic Review and Meta-analysis. *JAMA*, *319*(14), 1485–1496. https://doi.org/10.1001/jama.2018.2769
5. Cardet, J. C., Bailey, J. M., Hurley, L. P., Maher, N. E., Staton, E. W., Yawn, B. P., Zaeh, S. E., Israel, E., other PREPARE investigators;, Apter, A. J., Bradford, P., Calderon-Candelario, R. A., Carroll, J. K., Chupp, G. L., Cohen, R., Ericson, B., Fuhlbrigge, A. L., Kaplan, B. M., Kruse, J. M., Nazario, S., … Wechsler, M. E. (2025). Maintenance of an Asthma Intervention Post-Trial: Use of a Patient-Activated Reliever-Triggered Inhaled Corticosteroid (PARTICS) Strategy in Black and Latinx Patients. *Journal of the American Board of Family Medicine : JABFM*, *38*(2), 378–382. https://doi.org/10.3122/jabfm.2024.240014R2

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