OPTIMIZING DISCHARGE AFTER EMERGENCY DEPARTMENT VISITS FOR CHILDREN WITH UNCONTROLLED ASHTMA

Version 9-28-18

PROJECT SUMMARY: The objective of this project is to develop a systematized method to prescribe inhaled corticosteroids (ICS) to children with uncontrolled asthma after an emergency department (ED) visit. ICS are indicated for children with uncontrolled asthma according to national guidelines, but it is unclear if prescription of ICS in the emergency department setting results in improved outcomes. Currently, ICS prescriptions are provided infrequently (<5% of visits for children with asthma). We will systematize ICS prescription using the Pediatric Asthma Control and Communication Instrument (PACCI), which we have demonstrated is a useful tool for ED clinicians to rapidly assess asthma control. The PACCI is easy to use, can be completed by families, and contains an algorithm that helps clinicians decide when ICS are indicated. We will use a randomized controlled trial (RCT) to compare asthma morbidity in children receiving ICS prescription to children receiving routine asthma care.

PROJECT BACKGROUND: Asthma is a common pediatric illness and results in significant morbidity and health care costs.(1) Use of ICS for children with persistent level asthma has been demonstrated to reduce symptom frequency and improve quality of life.(2, 3) Frequently children that meet criteria for ICS use are not using these medications; this is particularly true of children who visit EDs for acute asthma exacerbations.(4) ED visits are ideal for interventions in children, as during these visits, parents are receptive to interventions because of heightened concern based on the acute, visible manifestations of the child's asthma.

Interventions for families of children with asthma have been attempted in the ED but have not consistently demonstrated improvement in long-term asthma-related outcomes.(5-11) Despite these equivocal results, many experts continue to emphasize the role of ED clinicians in preventative care,(12, 13) with a focus on improving chronic asthma management.(14, 15) Several recent publications have identified ICS prescriptions by ED clinicians for uncontrolled asthma as a feasible intervention that is likely to benefit children.(16-18) This is potentially effective given that ED visits for children with asthma often indicate high-risk asthma.(19, 20) Also, children that visit EDs are less likely to have a regular source of care for asthma,(4, 21) more likely to have poorly controlled asthma,(17, 22) are less likely to be using appropriate controller medications,(4) and often belong to underserved populations that are at risk for asthma-related morbidity.(21, 23-27) ED visits for children with asthma also represent a teachable moment.(13, 28) Manifestations of asthma are most salient at these visits, and parents may be more receptive to interventions to improve disease management. Because parents often view asthma as episodic rather than chronic in nature, they may be less likely to follow through with interventions when disease manifestations are not as readily apparent.(29) All

of these factors contribute to the ED being an important setting for interventions to improve disease management. The goal of this research plan is to optimize the delivery of ICS prescriptions using a standardized tool (PACCI) to identify children with uncontrolled asthma. Our second goal is to develop an educational component to be delivered at the time of ICS prescription to enhance subsequent medication adherence.

In a recent study using the National Hospital Ambulatory Medical Care Survey (NHAMCS), we demonstrated that ICS are prescribed during only 4% of pediatric asthma visits at U.S. EDs, despite approximately 800,000 visits for pediatric asthma annually.(18) We also calculated that ICS prescriptions are indicated in 20%-23% of ED visits for children with asthma exacerbations. These figures indicate that nationally, a systematized approach to prescribing ICS for children with uncontrolled asthma in the ED could result in 150,000 children per year having an appropriate first-line controller medication prescribed after an ED visit.

After identifying prescription of ICS as a potential intervention, we investigated a mechanism to facilitate use of this strategy in the ED setting. We validated use of the PACCI in the ED in collaboration with colleagues at Johns Hopkins. The PACCI allows clinicians to rapidly assess chronic asthma control based on responses to questions about asthma over sub-acute (1-2 weeks) and longer (12 month) time periods.(30) Our preliminary validation of the PACCI in 56 children with asthma in our ED has shown that it is: 1) Effective (accuracy of ED clinicians at identifying poorly controlled asthma was 95% with PACCI versus 56% without, P=0.03), and 2) Raises awareness of the need to assess chronic asthma control during ED visits, based on feedback from ED clinicians in the study.

KEY PERSONNEL:

Principal Investigator: Aris Garro, MD, MPH

Co-Investigator: Elizabeth Goldberg, MD

Research Coordinator: Dominic Wu

Research Assistant: TBD

Research Nurses: TBD

PROTOCOL:

Participants: This study will include a convenience sample of children who present to the ED with an asthma exacerbation when research staff is present. Potential participants will be identified by research nurses who encounter children with complaints of “asthma exacerbation”, “wheezing”, “cough”, “dyspnea” or “shortness of breath”. We plan to enroll 143 children 3-12 years old who: 1) have physician-diagnosed asthma based on parental report, and 2) are not already using an ICS. Exclusion criteria will include: 1) Previous participation in the study, 2) Co-morbid

cardiorespiratory disease (e.g.: cystic fibrosis), 3) If the parents do not speak English, or 4) If the children are hospitalized.

If the child is eligible, a member of the research team will approach the family to obtain informed consent for study participation. Informed consent will include permission to review the child's medical records and pharmacy records using the standard release of information forms used in the Hasbro ED. After consent, the participant and their family will complete the PACCI. If the responses indicate that they have "controlled" asthma then they will be excluded from further study procedures, otherwise they will be eligible for the study procedure and will be randomized (see Randomization below). For each participant, the following demographic/clinical data will be collected: date of birth, date of ED visit, gender, race/ethnicity (using NIH reporting guidelines),(31) family socioeconomic status (using the National Opinion Research Council system(32)), income-to-needs ratio,(33) insurance, ETS exposure, name of the child's primary doctor, name/location/phone number of child's primary pharmacy, and family contact information. A baseline quality of life score will also be obtained using the Integrated Therapeutics Group Child Asthma Short Form (ITG-CASF). Treatment by the ED staff during the visit will not be affected by study participation. After data collection, researchers will inform parents of the follow up schedule, and pro-rated compensation ($10 for the one week doser CT delivery visit, $10 for the one month Doser CT retrieval visit, and $20 for completion of the 6 month follow-up phone calls).

Randomization: Participants will be randomized to the ICS prescription arm or the routine asthma care arm. We will use block randomization to balance the number of participants in each arm, and varied block sizes (4 – 8) because of incomplete blinding of assignments. The allocation ratio between intervention and control arms will be 1:1. Random treatment assignments in each block will be generated in advance using a computer algorithm. Assignments will be placed in sealed, opaque, consecutively numbered envelopes by a person not involved in the study. When a participant is enrolled, the RA will take the next envelope, record the envelope study ID for that participant, and open the envelope to determine the assignment.

ICS Prescription Arm Protocol: Participants in the ICS prescription arm will follow the treatment plan, discharge instructions, and follow up recommendations provided by the treating clinicians while they are in the ED. During discharge, the study nurse will provide the asthma discharge instructions (see attached instructions) to the family and inform them that the child has met criteria for prescription of an ICS to help control the asthma. The families preferred pharmacy will be determined and a prescription for the first-line ICS covered by the participant's insurance will be called in within 24 hours by the study PI or co-Investigator (both licensed clinicians). Dosing will follow the recommendations outlined in the NHLBI asthma guidelines for low dose ICS in this age group for the respective medication.(19) In addition to the standard instructions, the nurse will give specific instructions for ICS use including how to administer medication, use of

spacer devices to be used with the MDI, recommendations for daily use, possible side effects of medication use, and distinction between controller and quick-relief rescue medications. Parents will be informed that they should follow up with their primary care provider to discuss the length of ICS use.

One week after study enrollment, the pharmacy to which the prescription was called will be contacted to determine any prescriptions for asthma medications that were filled. Delivery of a doser CT device, which is used to assess medication adherence, will occur approximately one week after study enrollment. This device will be coupled with the ICS MDI (if one was obtained from the pharmacy) or with an albuterol MDI (if no ICS was filled), Families will be called two weeks after the ED visit to determine if there are any issues with device use. To ensure proper communication, a checking-in mailer will be sent out two weeks post-enrollment. This mailer will serve as a reminder to contact staff if participants encounter any issues with the doser CT device or if their contact information has changed. A home visit will be scheduled at one month to arrange for retrieval of the doser CT device. An "Unable to Contact Mailer" will be sent out to participants if staff are unable to contact them after several attempts.

Routine Asthma Care Arm Protocol: Participants in the routine asthma care arm will follow the treatment plan developed by the treating clinicians as part of routine care. The study nurses will provide the same asthma discharge instructions (see attached instructions), except for those instructions specific to ICS use.

One week after study enrollment, the child's pharmacy will be contacted to determine any prescriptions for asthma medications that were filled. Delivery of a doser CT device, which is used to assess medication adherence, will occur approximately one week after study enrollment. Unlike in the ICS Prescription Arm, the doser CT device for children in the control arm will be used with their albuterol MDI. Although this data will not be used for analysis, it makes the control arm intevention similar to the intervention arm from the perspective of the study participants. Families will be called after two weeks to determine if there are any issues with device use. To ensure proper communication, a checking-in mailer will be sent out two weeks post-enrollment. This mailer will serve as a reminder to contact staff if participants encounter any issues with the doser CT device or if their contact information has changed. A home visit will be scheduled at one month to arrange for retrieval of the doser CT device. An "Unable to Contact Mailer" will be sent out to participants if staff are unable to contact them after several attempts.

Summary of Intervention and Control Protocol

Timing after enrollment	**Study Procedure**	**Purpose**	**Intervention Arm**	**Control Arm**

Just prior to ED discharge	Study nurse performs discharge instructions; ICS prescription arm provides preferred pharmacy info	To provide education to both arms (ICS specific for ICS Prescription Arm)	X	X
Within 24 hours	Study clinician (PI) calls preferred pharmacy	To arrange ICS prescription	X	
Within 7 days	Researcher contacts pharmacy	To determine which participants filled an ICS prescription	X	X
One week	Research coordinator or RA arranges for home visit to deliver doser CT device*	To monitor medication adherence	X	X**
Two weeks	RA calls families who received Doser CT devices. A two week checking-in mailer is sent out.	To discuss any problems with the Doser CT device and changes in contact information.	X	X
One month	RA arranges home visit to retrieve Doser CT devices*	Retrieve CT Doser device	X	X
One, Two and four months	RA calls family	To reduce attrition and keep family excited about study	X	X
Six months***	Blinded researcher follow-up phone call	Outcome data collection	X	X

***** Participants will be mailed $20 compensation for their effort upon completing the 6 month follow-up.

** In Control Arm, Doser CT device will be used with albuterol MDI as sham intervention.

*** If follow-up phone call is unsuccessful, researcher will attempt home visits to collect outcome data.

6 Month Follow-up Phone Call and Outcome Variables: Six months after study enrollment, all participants will be contacted by telephone to collect outcome data. The researcher making the follow up phone calls will be blinded to the study arm of the participants. Telephone calls to participants will continue until follow up is complete, or further participation is refused. Informed consent at the time of enrollment will include permission to perform home-visits if telephone contact is unsuccessful. Participants will be mailed $20 compensation for their effort upon completing the 6 month follow-up.

Outcome data collected will include unscheduled doctor's office visits, ED visits, hospitalizations, or oral steroid courses for asthma in the 6 months following enrollment. Unscheduled doctor's visits will be corroborated by contacting the child's primary doctor and obtaining a visit history (using the Release of Information form signed during consent). Visits in the week following enrollment will not be included as they will be considered part of the initial exacerbation. To corroborate oral steroid courses, we will contact the participant's pharmacy, using the Release of Information signed during consent.

Another outcome variable collected using a script during the telephone call will be the quality of life, using the ITG-CASF. The ITG-CASF has been validated in the ED setting for children 2 to 17 years old (34), is reliable (Cronbach's α =0.70), can be administered by telephone (34), requires only 10 questions, and has been used in studies with similar follow up timeframes.(10) Each item is rated on a 5-point scale. Each response is scaled as a percentage of the maximum response, and the total score is the maximum percentage based on the number of questions answered. The scores range from 0 – 100, with higher scores reflecting better quality of life. The change in ITG-CASF scores for children with improved overall clinical status are 10 points higher than when children have not improved.(34)

Data Analysis Plan: Participants will be analyzed in the group to which they were randomized using an intention-to-treat approach. We hypothesize that children in the intervention arm will have less unscheduled health care use at 6 month follow up, and increased quality of life compared to children receiving routine asthma care. We will use chi-square testing for the health care use variable, and Student's t-test for the continuous quality of life variable.

Power Analysis: Sample size was calculated to power hypothesis testing for dichotomous health care use outcomes as they require the largest sample size. Using preliminary data to estimate baseline health care use in our study population,(35) we calculated the sample size needed to detect a difference in the proportion of children with unscheduled health care use in the intervention arm

(p_1=0.35) compared to the routine asthma care arm (p_0=0.6), with 80% power to detect a statistically significant difference at an alpha of 0.05. Assuming 20% of participants will not be reached for follow up, and who will not have outcome data available when electronic medical records are audited, we will recruit 143 participants to achieve our sample size of 114.

Data Safety and Monitoring Plan (DSMP): The goals of the DSMP are three-fold. First, it is to ensure that there is no statistical difference in adverse events between the two study arms. Second, all serious adverse events will be reviewed by the members to provide direction on study continuation. Serious adverse events are considered very unlikely with this study protocol, since the two treatment conditions are both commonly utilized treatments in clinical practice. The third goal is to ensure that the intervention arm is not performing significantly better than the routine asthma care arm, as if this was identified early in the study, it would be unethical to withhold the intervention from the control arm.

Prior to beginning enrollment, we will have a conference call at which time the DSMP will be reviewed by the study PI and 2 Emergency Medicine attendings not affiliated with the study. The first DSMP data review will occur 6 months after the first participant has their 6 month data collection. Therefore this meeting will likely occur 12 months after study enrollment begins. Reviews will occur every 6 months thereafter.

The following outcome data will be provided to the DSMB along with the randomization assignments:

- Unscheduled medical visits to primary doctor's office for asthma
- ED visits for asthma
- Hospitalization for asthma
- Oral steroid courses for asthma
- Quality-of-life scores from the ITG-CASF
- Adverse events reported by parents at 6 month follow-up phone call
- Adverse events reported by study personnel
- Serious adverse events reported by study personnel*

* Any serious adverse events will be reported within 24 hours of occurrence to the IRB and DSMB. Study enrollment will be suspended until the DSMB and IRB have reviewed the event and made recommendations to the study PI.

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Appendix A. Interviews at Home Visits

Overview: In addition to the RCT, we are adding a series of interviews of participants to help design the educational component that ED clinicians will provide to families at the time of ICS prescription to promote adherence. These interviews will occur during the second home visit of the original protocol during which the Doser CT devices, used to measure medication adherence will be queried.

Recruitment: Parents of children that were part of the ICS prescription arm in the RCT will be eligible for these interviews. Interviews will involve a convenience sample of these participants, occurring only when researchers trained in interviewing techniques are performing the home visit. Interviews will be recorded using two electronic recording devices (extra device to protect against primary device failure). Verbal consent will be used as the transcripts of the interviews will not include identifying information, and therefore a written consent would be the only link identifying the participant in this portion of the protocol.

Participants will be classified in one of three groups:

> Group 1 (Did not fill ICS prescription) – Based on pharmacy calls outlined in the original protocol, we will determine which participants did not fill the ICS prescription by one week after enrollment.
>
> Group 2 (Filled prescription, but non-adherent with appropriate ICS administration) – At the home visit, the Doser CT devices will be queried. Adherence will be defined as ≥ 4 days in the most recent 4 weeks of data with 4 doses of medication administered. If participants do not meet these criteria, they will be classified as non-adherent and included in Interview Group 2.
>
> Group 3 (Filled prescription, and adherent with appropriate ICS administration) – Unlike group 2, participants will be in this group if they meet the adherence criteria outlined above.

Interview Protocol: Using convergent interviewing techniques, we will perform a series of interviews with these three participant groups. Convergent interviewing uses a single open ended question, and allows the research participant to respond in an open-ended fashion for as long as possible. Probes are developed in response to these open-ended responses. After interim analysis of interviews, subsequent interviews may involve more focused probes. Because of this open-ended interviewing style, an interview guide is not used. The open-ended question that will be posed to early participants will be tailored to the 3 groups as follows:

> Group 1 – “One of the ways to treat your child’s asthma is with inhaled steroids. At your recent emergency department visit, this was one of the recommendations made by the person that discharged you from the emergency department. What did you think of this recommendation?”

Groups 2 and 3 – "After your child's recent visit to the emergency department, you filled a prescription for an inhaled steroid. Tell me what you think about using that medicine."

Participants will be aware they are being recorded, and will be informed that all identifying information will be removed from transcripts that will be made from the recordings. Interviews will last approximately 30-45 minutes. Participants will be compensated $20 for their time in completing the interview. These will be mailed as a check to the participant.

Interviews will be continued until the point where data saturation is reached which is defined by Attwater et al. as when two consecutive interviews occur in which no new themes are generated.[1]

Data analysis: Based on the techniques outlined for convergent interviewing by Attwater, et al.[1] the following steps will be employed:

1. The interviewer will analyze the data by coding the transcript passages into content codes using NVivo (version 8) a software program used to facilitate qualitative data analysis. The coding style will involve content analysis with codes in a tree node format.

2. A second researcher will code the same transcript independently.

    a. Content codes will be developed *during the course* of the analysis as follows. As the first two transcripts are being analyzed content codes will be proposed by the two coders (one of whom is the PI). These content codes will be discussed and modified by consensus agreement of the two coders. If a given content code is agreed upon, it will be added to the coding scheme.

    b. The coding scheme derived after the first two transcripts are analyzed will then be used for the next two transcripts.

        i. If new content codes are identified by individual coders during coding of the second transcript, these will again be discussed and modified by consensus agreement and added to the coding scheme if agreed upon.

    c. This process will continue with analysis occurring after every two interviews.

3. After every two interviews within a participant group, the interviewers will again meet to compare codes assigned to each transcript. At these meeting, themes developed from the content will also be discussed and agreed upon themes recorded.

4. For each theme generated, previous content will be reviewed to look for disagreement and agreement.[2]

    a. When agreement with previous content is identified, probes will be developed for use in subsequent interviews to test the validity of this apparent agreement by looking for disconfirming views, and identify how widely this phenomenon occurs.

b. When disagreement with previous content is identified, probes will be developed for use in subsequent interviews to provide an explanation for this disagreement and identify how widely this phenomenon occurs.

5. This process of recycling will continue until two successive interview within a given interview group provide no new information.

Protecting Confidentiality: The content of the focus group discussions will be transcribed and de-identified by removing names and any other identifying information. When transcription is complete, digital recording files will be erased.

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