Study protocol
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Patient-Centered Outcomes Research Institute, contract # AS 1307-05420
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I. Executive summary

Chicago is an epicenter for asthma health disparities in the United States, with African American children 5-11 years old bearing a disproportionate share of the burden. Gaps in implementation at provider and patient levels contribute to these asthma disparities, with studies suggesting that minority children are less likely than white children to be prescribed and use guideline-recommended asthma care, respectively. Effective strategies to implement national asthma guideline recommendations in this population are needed. As part of a Patient-Centered Outcomes Research Institute contract (AS 1307-05420; Coordinated Healthcare Interventions for Childhood Asthma Gaps in Outcomes [CHICAGO] Plan), we used methods in user-centered design to inform the development of interventions to implement asthma guidelines in the ED and at home. We then conducted a pragmatic trial to evaluate the effectiveness of ED and home-based interventions on patient- and caregiver-centered endpoints.

II. Overview of the pragmatic trial

The CHICAGO Plan was a randomized 3-arm parallel group, multi-center pragmatic trial in six Emergency Departments (EDs) affiliated with public or private hospitals who served a high proportion of black or Latino children in Chicago to compare: 1) an ED-only intervention 2) an ED-plus-home intervention; and 3) Enhanced usual care. Eligibility criteria were intended to be clinically applicable and recruitment took place in multiple EDs serving underserved communities in Chicago (six Clinical Centers serving different populations of children 5-11 years presenting with asthma). Data collection employed validated approaches, but were also intended to minimize participant burden

III. Primary and secondary aims

Primary aim
Conduct a 3-arm multi-center pragmatic trial comparing the effectiveness of the ED-only, ED-plus-home, and usual care strategies.

Secondary aims

- Examine the potential for heterogeneity of treatment effects.
- Identify barriers and facilitators of successfully implementing the interventions to inform subsequent research to accelerate the uptake of study findings.

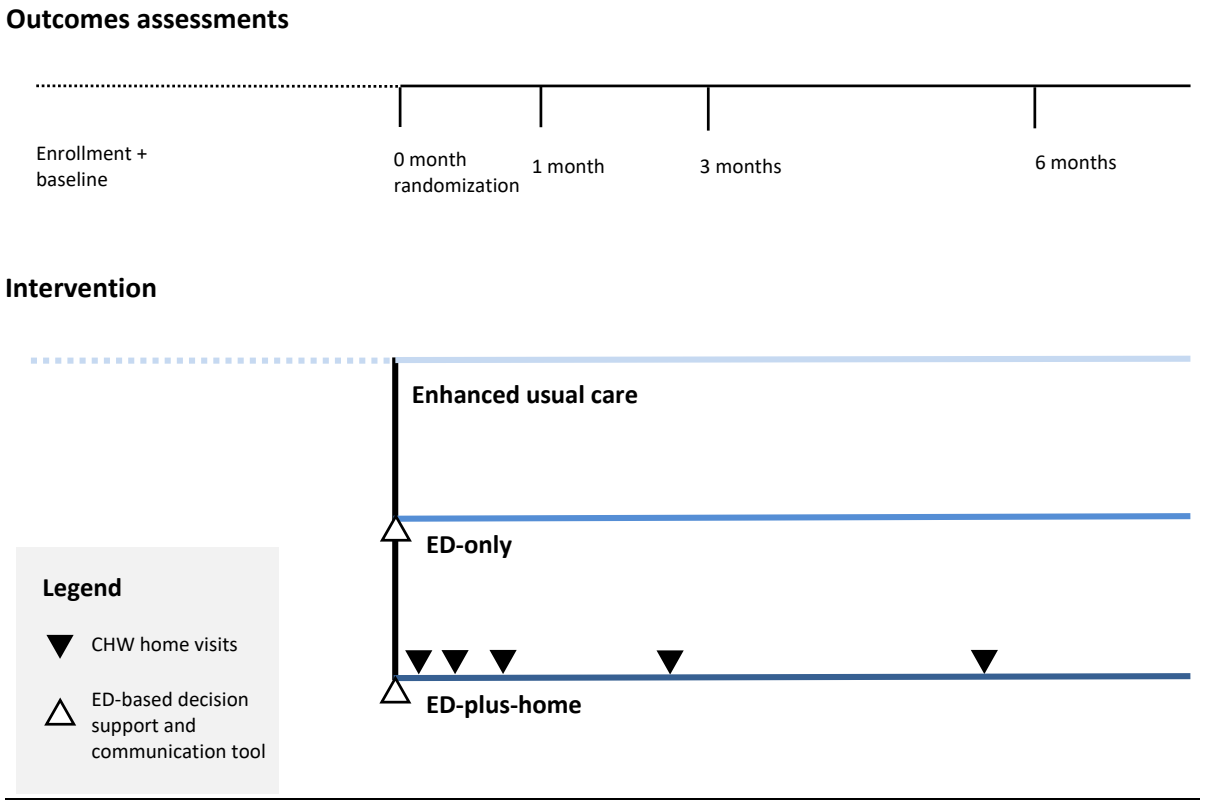

Figure 1: Children ages 5 to 11 years who presented with uncontrolled asthma to the emergency department (ED) were randomly allocated to one of three groups: Enhanced usual care vs. ED-based intervention using the CHICAGO Action Plan after Emergency department discharge (CAPE) decision support and communication tool for children and caregivers (ED-only), vs. the same ED-only intervention plus community health worker-led home visits at 2-3 days, 2 weeks, 1 month, 3 months, and 6 months after ED discharge to help implement the CAPE and reduce environmental triggers (ED-plus-home). Outcomes were assessed at baseline (in-person prior to ED discharge), 1 month (via phone), 3 months (via phone), and 6 months (in-home or via phone; time point for the primary outcome) after ED discharge.

IV. Study population

Eligibility criteria were designed to be clinically relevant and feasible to implement in an ED setting. Due to lower than expected randomizations during the first half of the recruitment period, we modified the study eligibility criteria after review by an independent Data and Safety and Monitoring Board, institutional IRBs (Site-specific IRB approval dates: Lurie – 9/14/2015; Rush – 9/8/2015; Sinai – 9/10/2015; Stroger – 8/18/2015; UC – 9/1/2015; UIC – 7/28/2015), and discussions with the program officer from the Patient-Centered Outcomes Research Institute. Original and revised eligibility criteria are below; to be eligible, patients needed to meet all inclusion criteria and none of the exclusion criteria below.

ORIGINAL ELIGIBILITY CRITERIA:

Original eligibility criteria approved by prime site IRB (UIC #2014-1214) on 12/19/2014.

Inclusion criteria (all of the following):

1. Child is 5-11 years of age (a population in whom a diagnosis of asthma is generally reliable, and in whom exacerbations are common);
2. Child is presenting to the ED, urgent care center, or observation unit at a participating clinical center (Anne and Robert H. Lurie Children's Hospital of Chicago, Sinai Health System's Mount Sinai Hospital, John H. Stroger Jr. Hospital of Cook County Health & Hospitals System, Rush University Medical Center, University of Chicago Medicine Comer Children's Hospital, and the University of Illinois Hospital & Health Sciences System);
3. Child is treated with at least 1 dose of an inhaled or nebulized short-acting bronchodilator (quick-relief medication);
4. Child received systemic corticosteroids in the ED;
5. Child and caregiver approached at least 1 hour after receipt of the first dose of quick-relief medication or systemic corticosteroids, whichever occurred last;
6. Diagnosis of asthma exacerbation by treating clinician;
7. Treating ED clinician indicates the child is likely to be discharged to home;
8. Caregiver reports that English or Spanish is the preferred language at home.

Exclusion criteria (none of the following):

1. Caregiver declines to provide informed consent, or the child declines to provide assent;
2. Child is discharged to a location other than home (e.g., hospital or another healthcare facility);
3. Child or another member of the child's primary household is a current or previous participant in the CHICAGO Plan;
4. Child is enrolled in another study involving a health-related intervention;
5. A CHW is already visiting the home as part of another program;
6. Child is expected to move out of Chicago within the next 6 months.

REVISED ELIGIBILITY CRITERIA:

Revised eligibility criteria approved by prime site IRB (UIC #2014-1214) on 7/28/2015. Revisions occurred over a period of a few months across all of the other clinical centers (after local institutional review).

Inclusion criteria (all of the following):

1. Child is 5-11 years of age (a population in whom a diagnosis of asthma is generally reliable, and in whom exacerbations are common);
2. Child is presenting to the ED, urgent care center, or observation unit at a participating clinical center (Anne and Robert H. Lurie Children's Hospital of Chicago, Sinai Health System's Mount Sinai Hospital, John H. Stroger Jr. Hospital of Cook County Health & Hospitals System, Rush University Medical Center, University of Chicago Medicine Comer Children's Hospital, and the University of Illinois Hospital & Health Sciences System);
3. Child is treated with at least 1 dose of an inhaled or nebulized short-acting bronchodilator (quick-relief medication);
4. Child received systemic corticosteroids in the ED OR the caregiver reported at least 1 additional acute care visit for asthma in the previous 6 months (defined as an asthma-related ED visit or urgent care visit, or course of systemic corticosteroids);
5. Child and caregiver approached at least 1 hour after receipt of the first dose of quick-relief medication or systemic corticosteroids, whichever occurred first;

6. Diagnosis of asthma exacerbation by treating clinician;
7. Treating ED clinician indicates the child is likely to be discharged to home;
8. Caregiver reports that English or Spanish is the preferred language at home.

Exclusion criteria (none of the following):

1. Caregiver declines to provide informed consent, or the child declines to provide assent;
2. Child is admitted to an intensive care unit or transferred to another healthcare facility;
3. Child or another member of the child's primary household is a current or previous participant in the CHICAGO Plan;
4. Child is enrolled in another study involving a health-related intervention;
5. A Community Health Worker (CHW) is already visiting the home as part of another program;
6. Child does not reside in Chicago.

V. Interventions and comparators

All children who participated in the CHICAGO Plan received asthma care per their ED clinicians. In addition, the CHICAGO Plan's ED Coordinator provided all participants two metered dose inhaler (MDI) spacers free-of-charge and used teach-to-goal methodology (repeated rounds of education and evaluation until the child achieves mastery) to educate the child and the caregiver about appropriate MDI inhaler technique. Patient education regarding the MDI device was selected because it is commonly used for quick-relief medications and is also the device for many inhaled controller medications. Children were then randomly assigned to either of two active comparators or enhanced usual care.

1. ED-only. Based on feedback from our stakeholders, we developed the CHICAGO Action Plan after Emergency department discharge tool (CAPE; APPENDIX A1); a culturally tailored and literacy-appropriate communication tool for use on ED discharge. Based on the ED treating clinician's discharge instructions, a CHICAGO Plan ED Coordinator utilized the CAPE to support guideline recommended asthma care on ED discharge (a course of systemic corticosteroids; daily inhaled corticosteroids or other controller; as needed quick-relief inhaled medication; education about the medications and appropriate inhaler technique; education about asthma trigger avoidance; and a post-discharge follow-up appointment) and to support appropriate asthma self-management in the home. The CAPE tool uses simplified language, visual learning, and options for individualization to facilitate communication about discharge instructions between clinicians and the child and caregiver.

2. ED-plus-home. Participants randomly allocated to the ED-plus-home intervention received the same ED-only intervention described above but were also offered up to five home visits over 6 months conducted by a CHW visits to: 1) assist in the implementation of the ED discharge instructions, 2) update the asthma treatment plan with input from the patient's ambulatory clinician utilizing the CAPE tool called the Asthma Home Plan (APPENDIX A2), 3) develop a plan to manage asthma during school hours (e.g., access to quick-relief medications, action plan in case of respiratory difficulty), and 4) develop a specific and feasible plan to reduce environmental triggers at home (e.g., environmental tobacco smoke, roach, mice). Home visits were scheduled for 60 to 90 minutes, and occurred

approximately at 2-3 days, 2 weeks (14 days), 1 month (30 days), 3 month (90 days), and 6 months (180 days) after ED discharge.

3. Enhanced usual care. Based on stakeholder feedback, we modified usual care so that children in the "usual care" group also received teaching about appropriate MDI technique using teach-to-goal methodology and two MDI spacers free-of-charge, as well as doorknob hangers depicting facts about asthma unrelated to the study interventions. We therefore refer to this group as "Enhanced usual care." To describe usual care at each site, the site project manager conducted chart abstractions (masked to treatment assignment). Site project managers were to complete chart abstractions within 3 business days of enrolling the participant in the study.

VI. Randomization

Randomization occurred at the patient level, with permuted block sizes stratified by site and race (black vs. non-black). Based on data from the Clinical Centers, we expected about 70% of enrolled participants to be black, 23% to be white, and that the remainder would be mostly Asian. Of the planned enrollment of 640 children, we expected 15% to be Hispanic/Latino. Stratification by race for the purposes of randomization was "Black" (those who selected Black or African American, includes multi-race if at least one race was Black or African American) vs. "non-Black" (American Indian/Alaskan Native, Asian, Native Hawaiian or other Pacific Islander, white, and multi-race if none are Black or African American).

The CHICAGO Plan Research Electronic Data Capture (REDCap) system for study personnel (available 24 hours x7 days/week) provided the random treatment assignment: ED-only, ED-plus-home, or Enhanced usual care.

VII. Data collection

A. Screening and enrollment (registration) into the study (in person; ~40 minutes). The ED coordinator, a member of the research team, at each Clinical Center screened patients in the ED, Urgent Care, or Observation Unit after treatment initiation for asthma exacerbation and before discharge. The ED coordinator obtained verbal assent from the ED clinician prior to approaching the child/caregiver for informed consent. Following informed consent, the ED coordinator obtained Baseline data, registered the patient in a customized, secure, on-line CHICAGO Plan REDCap portal developed by the DCC, then obtained the treatment assignment (ED-only, ED-plus-home, or Enhanced usual care). The ED Coordinator offered to arrange the date/time of the 1-month follow-up visit (see below).

B. 1-month follow-up contact after discharge (telephone; ~15 minutes). Post-baseline data collection was performed by the DCC Research Assistant, who was masked to treatment assignment. The Research Assistant conducted a telephone interview to assess outcomes approximately 1 month after discharge. The interview was also designed to collect / update contact information and to promote retention in the CHICAGO Plan. The DCC Research Assistant arranged date/time of the 3-month follow-up visit (see below), or inquired about the best time to call again.

C. 3-month follow-up contact after ED discharge (telephone; ~15 minutes). The DCC Research Assistant, masked to treatment assignment, conducted a telephone interview to assess outcomes approximately 3 months after ED discharge. The interview was also designed to collect / update contact information and to promote retention in the CHICAGO Plan. The DCC Research Assistant arranged date/time of the 6-month follow-up visit (see below), or inquired about the best time to call again.

D. 6-month follow-up contact after discharge (in person or by telephone; ~40 minutes). The DCC Research Assistant, masked to treatment assignment, conducted a study visit in person or via telephone (per participant preference) to assess outcomes approximately 6 months after discharge. The in-person visit afforded the ability to conduct an assessment of home trigger avoidance;

review inhaler technique; and assess cACT (child) and PACQLQ, which are more easily collected during in-person visits.

E. 12-month follow-up contact after discharge (in person or by telephone; ~40 minutes). We proposed re-assessing outcomes at 12 months to examine the durability of effects observed at 6 months. Despite significant efforts, retention in the study also proved to be challenging, and therefore the 12-month follow-up visit was discontinued at the request of PCORI in September 2016.

VIII. Outcomes

The selection of primary outcomes was based on several criteria: 1) patient-centeredness, defined as domains identified as important by children and their caregivers; as described in our previous publications; 2) availability of validated measures in English and in Spanish that could be administered in person and by phone; 3) plausibility that such measures could be responsive to an effective intervention in the target population; and 4) limited burden (e.g., time) for study participants. On this basis, we selected two NIH Patient-Reported Outcomes Measurement Information System (PROMIS) measures as primary outcomes (1 for the child and 1 for the caregiver). Several measures were selected for secondary outcomes to address recommendations of national asthma guidelines, expressed preferences of caregivers and other stakeholders, and to compare results of the CHICAGO Plan with previous studies.

A. Primary outcomes

1. The change in asthma impact at 6 months compared to the baseline assessed in the ED served as the primary outcome in children. In children 5 to 7 years, we assessed asthma impact using the PROMIS Parent Proxy Short Form v1.0 – Asthma Impact 8a. In children 8 to 11 years, we used the PROMIS Pediatric Short Form v1.0 – Asthma Impact 8a.

2. The change in Satisfaction with Participation in Social Roles at 6 months compared to the baseline assessed in the ED served as the primary outcome in the caregiver. We used the PROMIS Short Form v1.0 – Satisfaction with Participation in Social Roles 4a.

B. Secondary outcomes

For children:

1) The Childhood Asthma Control Test (cACT) at 6 months compared to the baseline assessed in the ED
2) Acute care visits at 6 months (number of all-cause urgent care visits, ED visits, hospitalizations, using electronic health records)

For caregivers:

1) Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) at 6 months compared to the baseline assessed in the ED
2) NIH PROMIS measures for anxiety, depression, fatigue, sleep disturbance at 6 months compared to the baseline assessed in the ED

Indicators of guideline-consistent asthma care provided on ED discharge:

1) Systemic corticosteroids prescribed for use at home (yes/no)
2) Inhaled corticosteroids or another controller medication prescribed for use at home (yes/no)
3) Quick-relief medications prescribed for use at home (yes/no)
4) Follow-up appointment scheduled (yes/no)

Child's/caregiver's self-management practices after ED discharge:

1) Filled prescriptions for systemic corticosteroids within 7 days of ED discharge (yes/no)
2) Filled prescription for inhaled corticosteroids or other asthma controller within 7 days of ED discharge (yes/no)
3) Attendance at outpatient appointment with patient-identified asthma provider within 4 weeks of ED discharge (yes/no)

IX. Analysis plan

All primary and secondary outcomes were analyzed according to the intention-to-treat principle. All randomized subjects were included in the primary analysis, unless subjects were terminated due to ineligibility. Baseline sociodemographic and clinical characteristics in the intervention and control groups were compared using the frequency and percentages for categorical variables and median with inter-quartile or mean with standard error for continuous variables. For bivariate analyses, the pairwise comparisons between three intervention arms for the change in primary and some secondary outcomes from baseline to 3 or 6 months were tested by Wilcoxon rank sum test. The W statistic, p-value and mean rank were reported together with horizontal mirror bar plots. For primary outcomes, a statistical significance occurred when p-value was less than 0.0167 after Bonferroni correction for three pairwise comparisons (0.05/3). In addition, chi-square tests were also conducted for other secondary outcomes.

To address missing data in the analyses, we checked the missing completely at random (MCAR) assumption and then employed a multiple imputation strategy. Using a logistic regression method described in Hedeker & Gibbons (2006), we found that the current outcome missingness was not statistically associated with previous observed outcomes across time. Additional characteristics comparisons between participants with and without missing primary outcomes across time was also done using Chi-square tests for categorical variables and Mann-Whitney U test for continuous variables. No statistical difference was observed between the two groups (i.e. with and without missing primary outcomes). We therefore used a fully conditional specification (FCS) approach to impute the missing values with variables of interest in the primary analysis models for 30 imputations. The raw and imputed data had similar distributions (mean, standard deviation, minimum and maximum values).

Since the two primary outcomes were not normally distributed and our data satisfied the MCAR assumption, we used generalized estimating equations (GEE) to examine the effect of intervention group on outcomes at 3 and at 6 months compared to that of the enhanced usual care group using ordinal logistic regression models; the continuous dependent variables were categorized into quartiles. The main predictors of the unadjusted GEE models were time (0, 1, 3, and 6 months), intervention group, and their interactions. In an adjusted model, we added pre-specified covariates including, race (Black vs. non-Black), ethnicity (Latino vs. non-Latino), gender (boy vs. girl),

health insurance (Public aid vs. Other), site enrolled (sites 1 to 6), number of all-cause acute care use in the 12 months prior to enrollment (at least one vs. none). To access the intervention effect between groups across time, we reported our results as odds ratios (ORs for higher quartiles) of interactions between study group and time and their 98% confident intervals [CIs; corresponding to a 2-sided alpha=0.0167) to account for Bonferroni adjustments for the three pairwise comparisons.

In secondary analyses, we explored heterogeneity of treatment effects by adding a three-way interaction between intervention, time, and a subgroup factor in the model described previously. Pre-specified subgroup factors included race (Black vs. non-black), ethnicity (Latino vs. non-Latino), gender (boy vs. girl), and number of all-cause acute care use in the 12 months prior to enrollment (at least one vs. none).

Power / sample size calculation. The power analyses did not incorporate adjustment for the presence of two primary outcomes. Such an adjustment is not commonly made in biomedical trials, as multivariate (viz. MANOVA) analyses are not commonly conducted. The power analysis for single outcomes employed the Rochon (1991) method based on Hotelling's T-squared, which was adapted to a 3-group comparison by adjusting the alpha level using a Bonferroni-style technique. This approach tends toward a conservative (larger) sample size. We proposed to enroll and randomize 640 participants over 18 months (~200-215 for each of the 3 treatment groups). Assuming evaluable data in 80% of enrolled participants (n=512) at 6 months (the time-point for the analyses of the primary outcomes), sample size calculations suggest ample power. Our approach was based on the methods of Rochon, with a Bonferroni adjustment for 3 pair-wise comparisons (2-sided $\alpha = 0.05/3 = 0.0167$; enhanced usual care and two active intervention groups), power 80%, 4 measurements per individual (0, 1, 3, and 6 months), within individual correlation 0.80, correction for within ED clustering (design effect of 2), and a coefficient of determination (R2) for control of individual-level demographics = 0.15. Based on these considerations, a sample size of 426 (well within the expected sample size of 512) was estimated to be sufficient for a minimum detectable difference of 0.35 standard deviations (SDs) (midway between Cohen's "small" (0.2 SDs) and "medium" (0.5 SDs) effect sizes) for each of the two primary continuous outcomes compared pairwise across the three treatment groups. The minimum detectable difference of 0.35 SDs corresponds to sufficient power to detect a T-score difference of 3.5, which is approximately mid-way between estimates of the minimum important difference (MID) for PROMIS T-scores (2 to 5).

X. Barriers and facilitators of successfully implementing the intervention (Secondary aim)

Health system interventions are often multi-component, and when they successfully improve care or outcomes, it is helpful to know whether all components of the intervention were necessary for success. Also, when care outcomes are not improved, it is unclear if barriers to implementation (fidelity) or lack of efficacy contributed to a lack of effect. We therefore a mixed -methods approach to 1) assess the fidelity of implementing the ED-only and ED-plus-home interventions; and 2) conduct interviews to debrief with study staff and a convenience sample of caregivers.

(1) Intervention fidelity: We assessed our key performance indicators (see APPENDIX B) as completed or not completed to measure the extent to which each patient received each component of the CHICAGO Plan intervention, based on their allocation to the three treatment groups.

(2) Focus groups: We completed debrief interviews with caregivers to better understand if they were satisfied with the content, comprehension, and relevance of the intervention material. We also asked about the satisfaction with the interventions provided by the ED coordinator and CHWs, and any other comments the patient or caregiver would like to offer about how to improve the CHICAGO Plan. We informed the participants that their responses would be used to help determine how to improve studies in the future (UIC IRB # 2017-0888).

(3) Interviews of ED Coordinators, DCC Research Assistants, and CHWs: We asked study staff provide feedback about barriers and facilitators to completing study procedures (e.g., space or time constraints when providing ED-based instruction; availability of participants at scheduled home visit times). We informed study staff that their responses would be used to help determine how to improve studies in the future (UIC IRB # 2017-0888).

XI. Timeline / milestones

We originally proposed a 15 month recruitment period, which was extended to be 18 months because of slow enrollment after approval by the Patient-Centered Outcomes Research institute. The planned date for end of the follow-up was also modified to allow the last enrolled participant to complete the 6-month follow-up assessment (primary endpoint).

Key dates

	Original date	**Final date (approved by study funder and DSMB)**
Start of enrollment	March 1, 2015	March 1, 2015 (no change)
End of enrollment period	May 31, 2016	August 31, 2016
End of study visits/data collection	November 30, 2016	March 31, 2017

XII. Protection of human subjects

A. Risks to human subjects

Human subjects involvement and characteristics
The trial aimed to include approximately 640 children ages 5-11 years and their caregivers. The eligibility criteria are discussed in an earlier section of this protocol. Children and caregivers were randomly allocated to 1) ED-only; 2) ED-plus-home; or 3) Enhanced usual care. All participants were asked to complete study procedures for at least 6 months, regardless of the group they are assigned to; a study coordinator (masked to the treatment assignment) conducted assessment visits at baseline, 1, 3, and 6 months post index ED visit.

B. Sources of materials

Sources of materials included: Questionnaires administered by the ED coordinator (baseline data), and those administered by the DCC research assistant (follow-up data); Pharmacy dispensation data and electronic health records (EHR); Direct observation (e.g., home inspection / completion of environmental assessment checklist; review of inhaler technique using checklist).

C. Potential risk

Participants and caregivers were subject only to minimal risks through this research; we were testing two different approaches to promoting guideline recommended care (ED-only; ED-plus-home) compared to usual Enhanced usual care. Potential risks included inconvenience or embarrassment involved in completing questionnaires or demonstrating self-management skills, or permitting the CHW (or research assistant) to conduct home visits for interventions (or for assessments), or in allowing the DCC to obtain pharmacy dispensation records (used for measuring adherence). The caregiver was not required to answer any questions (or conduct any part of the study) that he/she was reluctant to discuss/conduct. There was also a risk of loss of confidentiality. The CHW was instructed to avoid providing patients/caregivers with any type of medical advice, but had direct access to health care providers to address any patient/caregiver clinical questions or concerns. If the CHW was contacted about clinical questions, the CHW was instructed to connect the participant/caregiver with a health care provider familiar with the participant's medical condition immediately. On enrollment, caregivers were instructed to call their health care provider or seek emergency services in case of worsening symptoms, as opposed to directing questions to the CHW. All participants were informed in advance that they may withdraw from the study at any time without negatively affecting their medical care or any other benefits they might receive.

D. Adequacy of protection against risks

<u>Recruitment and informed consent/assent</u>
We sought informed assent in all children that were capable of providing assent (age ≥7 years old) and permission of their caregiver in the ED. In children < 7 years old, consent was obtained from the caregiver in the ED. As this study was no greater than minimal risk, the permission of only one parent or guardian was sufficient for research to be conducted under the Additional Protections for Children Involved as Subjects in Research (45 CFR Part 46.404). Assent from the child and

permission or consent from the parent/guardian was be obtained by the ED coordinator at each participating clinical site. All staff were trained in informed consent/assent procedures and were available to read the consent/assent forms to individual with low literacy levels. The consent/assent forms were available in English and Spanish.

All caregiver/family information, including contact information, questionnaires, pharmacy dispensation and clinical information was available only available to designated members of the research team. Case report forms were locked in cabinets and electronic data was stored on password-protected files. Only authorized study staff had access to study data. Study reports presented to external collaborators did not contain any identifiable information and findings were presented in aggregate (or by treatment group).

Incomplete disclosure

As participants in this trial were aware of which treatment group they are assigned to, there was a risk for Hawthorne effect (change in behavior as a result of monitoring alone) and information bias as it relates to answering questions for the patient-reported outcomes (the primary outcomes and several secondary outcomes). Although there may have been changes in behavior (e.g., improved adherence to corticosteroids), our studies and those of others have shown that monitoring does not itself result in sustained adherence. To minimize this risk, however, there was incomplete disclosure of the interventions in the CHICAGO study during informed consent. The study was described as testing different communication strategies combining written and verbal instructions to all participants. Using doorknob hangers, as was successfully performed in a recent study, we aimed to mask the participants. Regardless of the arm the participant is randomized in, children and caregiver/families will receive a doorknob hanger in the form of a plasticized document, depicting one or more facts about asthma unrelated to the study interventions (e.g., recommendations for influenza vaccinations). To minimize the risk of bias, the DCC research assistant who collected outcome data was be masked to the treatment group.

Incomplete disclosure is generally necessary in studies of bias or social desirability (such as monitoring of adherence) and is considered acceptable by medical ethicists, the American Psychological Association, and IRBs when certain strict criteria are met. In designing this study, as with previous studies conducted by Dr. Krishnan, we had been guided by the American Psychological Association (APA) Ethics Code for conducting research. Specifically, we believed that incomplete disclosure was minimal risk to participants and was unavoidable since we were proposing to monitor behavior while minimizing the risk of Hawthorne effect. Moreover, we followed the recommendations of the APA and Bersoff et al. that call for a full debriefing of participants at the conclusion of the study.

E. Potential benefits of the proposed research to the subjects and others

It is difficult to know if the participants benefited from the research. All study participants/caregivers received instruction about appropriate MDI use with the teach-to-back methodology; they also received two MDI spacers for their use. Other than these specific benefits, we did not indicate any benefits from participating.

F. Importance of the knowledge to be gained

African American and Latino children suffer disproportionate asthma outcomes compared to non-Latino whites, as evidenced by emergency department (ED) visits for uncontrolled asthma. This study aimed to evaluate the effectiveness of using multi-level interventions to increase self-management skills and patient-centered outcomes in a minority pediatric ED population with uncontrolled asthma. If this intervention proves successful, it could make a significant impact in adherence to the asthma guidelines and equalize asthma care and health care utilization, among African American and Latino children with asthma. Risks to participants and their caregivers involved in the research were minimal.

G. Data safety monitoring plan

The study was reviewed by the IRB at each participating institution and approval was sought before study activities begin. We also submitted IRB continuing reviews annually and adverse event reports as specified by each IRB. This study used a Data and Safety Monitoring Board (DSMB) which included 5 individuals who were not affiliated with any of the participating institutions (1 chair with extensive expertise multi-center clinical trials, 2 pediatricians, 1 statistician, and 1 caregiver). The DSMB convened once in Year 1 (review/approve final study protocol) and twice per year in Year 2 and Year 3. The DSMB made affirmative decisions at each meeting whether to continue or terminate the study. Early termination was always an option for the DSMB, particularly if there were serious concerns about patient safety or there is evidence of futility or sufficient evidence of efficacy; decisions regarding early termination were made by the DSMB during convened meetings. No interim analyses of outcomes for efficacy or futility were planned before the study or requested by the DSMB throughout the study. In general, the DSMB was provided data grouped by treatment (i.e., masked to treatment assignment). If the DSMB had requested, for the purpose of competent deliberation, to see the treatment assignments (by group or individual), these would have been provided by the DCC biostatistician. Insofar as possible, the investigators remained masked to the treatment assignments of individual patients unless it was judged that it was in the best interests of an individual patient.

H. ClinicalTrials.gov requirements

This trial was registered in ClinicalTrials.gov prior to start of enrollment of participants. The results of the trial will be reported within the required timeframe. The registration will be updated and results be made available according to the requirements.

I. Inclusion of women and minorities

The proportion of girls included in the study intended to mirror the prevalence of this condition in the community and the patient population of the medical centers in which the study took place. The study took place at different medical centers that serve a large number of racial or ethnic minorities. The investigators anticipated that approximately 70% of participants would be African American, 15% Latino, 8% Caucasian and 7% other (Asian, Native American, Pacific Islander) reflecting the racial and ethnic background of our patient populations. Minorities were enrolled as they presented to enrollment sites, and Spanish-speaking participants were included.

XIII. References

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XIV. Appendices

A. CAPE tool

B. Key performance indicators

725 **APPENDIX A1. CAPE -Asthma Discharge Plan (Version June 19, 2015)**
726

Asthma discharge plan

June 19, 2015

_____
Child's name

_____
Today's date

_____ _____
Doctor's signature *Date*

1 Take your asthma medicine

Your oral steroid is: _____


☐ Pills


☐ Liquid

1st dose time/date _____
How much _____
How often _____
For how long _____
☐ *It is very important you complete the dosage*

Things to know about oral steroids:
- is another powerful "rescue" medicine
- if you were given these in the emergency room, it is very important that you finish them!

Your "rescue" medicine is: _____


☐ Inhaler


☐ Spacer


☐ Mask


☐ Nebulizer

1st dose time/date _____
Number of puffs _____
How often _____
For how long _____
☐ *After that, use ONLY when symptoms occur*

Things to know about rescue medicine:
- should be used only if your child is having symptoms during an asthma attack/ with symptoms
- is typically albuterol with a name like: Proventil, Pro-Air, Ventolin, Xopenex

Mark your meds at the pharmacy:
red sticker for **"rescue" medicine**

Your "controller" medicine is: _____


☐ Inhaler


☐ Spacer


☐ Mask


☐ Nebulizer

1st dose time/date _____
Number of puffs _____
How often _____
☐ *Take every day EVEN IF no visible symptoms*

Things to know about controller medicine:
- should be used every day, even if your child has no symptoms
- examples include Pulmicort, Flovent, Azmacort, Advair
- may be an allergy medication, such as Singulair and Accolate

Mark your meds at the pharmacy:
green sticker for **"controller" medicine**

Other: _____

2 See your child's doctor within 3 days of your ER visit

_____ _____ _____
Doctor's name *Clinic telephone number* *Your appointment date and time*

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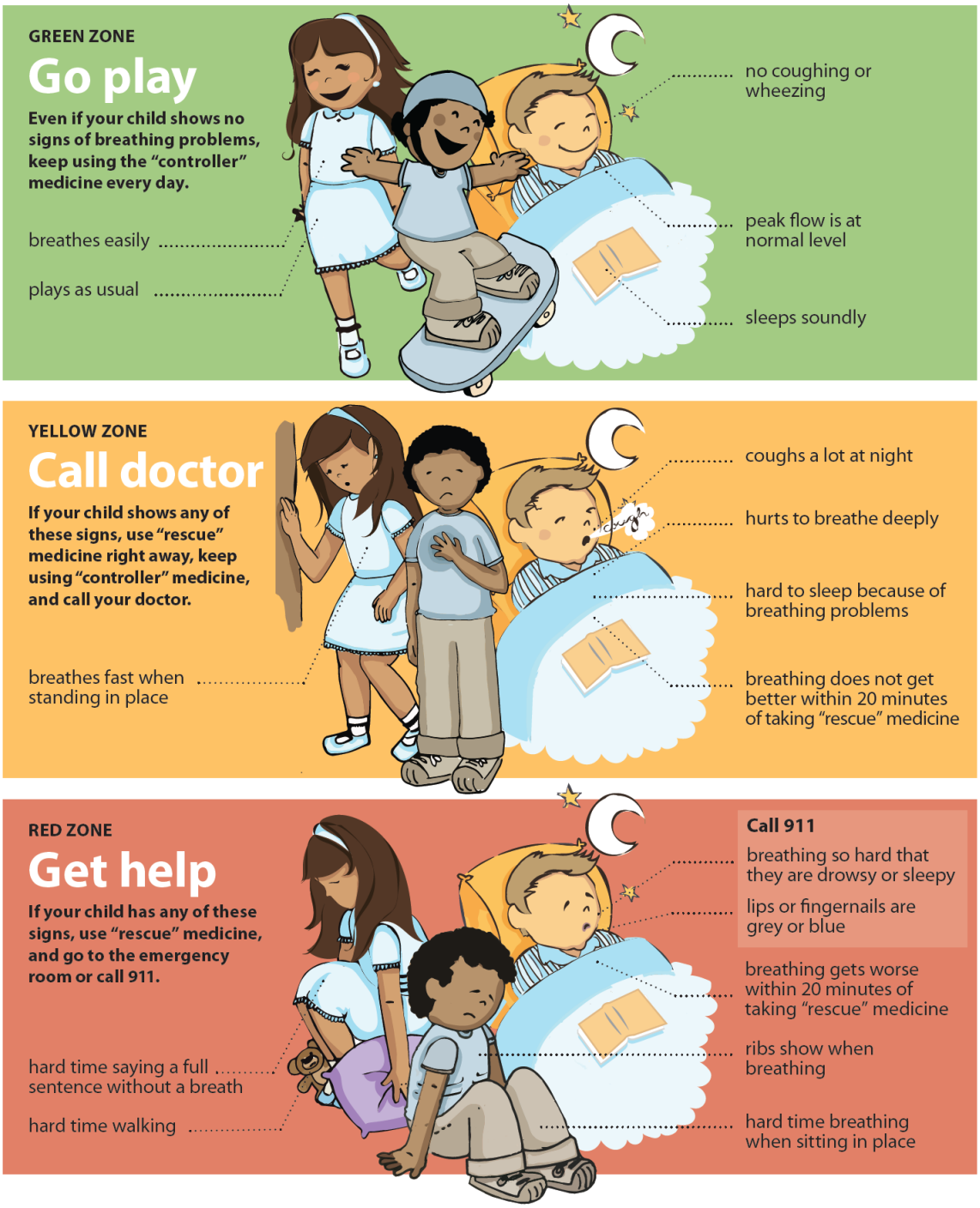
June 19, 2015

3 Read the signs



Illustrations by Paula Falco

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4 Stay on top of asthma

June 19, 2015

Don't wait! Call with questions

Call your child's regular doctor as soon as possible to help you understand your child's asthma and home treatment plan.

Identify your child's asthma triggers

Build a trigger list of what seems to make your child's asthma act up. Add to that list as you notice new triggers. Try to help your child avoid these!

If your child has a cold, use your child's action plan; and help them to blow their nose.

Avoid smoking—a known asthma trigger—and avoid having your child in a house where someone smokes.

Here are some examples of common asthma triggers:

What are your child's triggers?

_____ _____

_____ _____

_____ _____

_____ _____

Give medications as prescribed

Review how to use the inhalers with your child's doctor.

Develop tricks to help remind you to give the medications.

What might be useful tricks?

_____ *set an alert on your smartphone*

_____ *keep medicine by your coffee pot*

_____ _____

_____ _____

Take your child to the doctor regularly

Your child's doctor is there to help— they want to see how well your child is doing and to review your child's symptom control.

Together you and your doctor will discuss a new Asthma Home Plan, with instructions for when your child's asthma is under control and when it is not well-controlled.

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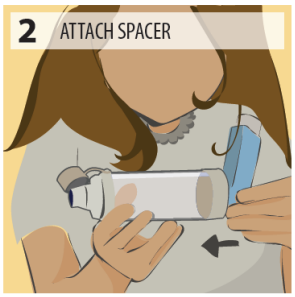
How to use an inhaler with a spacer
Works as well as a nebulizer!

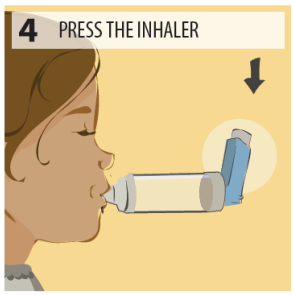
June 19, 2015

Take cap off the inhaler. Check for and remove any dust, lint, or other objects. Shake the inhaler well.



Attach the inhaler to the spacer.

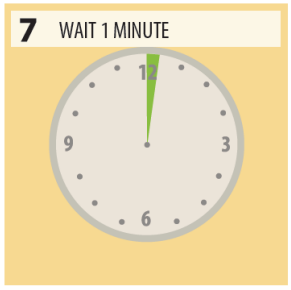
Breathe out all the air, away from the spacer.



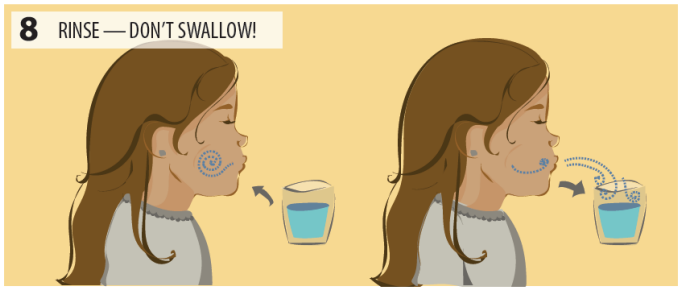
Put lips around device, press inhaler one time. This puts one puff of medicine into the spacer.

Breathe in deeply and slowly, and hold your breath.

Remove the device from the mouth. Then **hold** your breath for 5 secs. Then breathe normally **away** from the spacer.



If your child needs to take another puff of medicine, wait 1 minute. After one minute, repeat steps 3 to 6.



Rinsing is only necessary if the medicine you just took was an inhaled steroid. Have your child rinse his or her mouth out with water after the last puff of medicine. **Make sure your child spits the water out.** Do not allow the child to swallow the water. Recap the inhaler.

From the American College of Chest Physicians
Illustrations by Paula Falco

The CHICAGO Plan is a PCORI-funded study comparing asthma interventions. For questions regarding this document or the CHICAGO Plan, contact: Trevonne Thompson, MD, tthomps@uic.edu

What is this? This is a QR code. To use it, go to the app store on your smartphone, search for 'QR code readers' and download the free app.

To learn more about asthma, scan this code with the app to link to the Respiratory Health Association website. Or go to the link below:

www.tinyurl.com/asthmalib

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738 **APPENDIX A2. CAPE -Asthma Home Plan (Version May 22, 2015)**
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Asthma home plan

Child's name _____

Today's date _____

Doctor's signature _____ *Date* _____

May 22, 2015

1 Take your asthma medicine

Your "controller" medicine is: _____


☐ Inhaler


☐ Spacer


☐ Mask


☐ Nebulizer

Number of puffs _____

How often _____

☐ *Take every day EVEN IF no visible symptoms*

Things to know:

- should be used every day, even if your child has no symptoms
- examples include Pulmicort, Flovent, Azmacort, Advair
- may be an allergy medication, such as Singulair and Accolate

Mark your meds at the pharmacy:

green sticker for **"controller" medicine**

Your "rescue" medicine is: _____


☐ Inhaler


☐ Spacer


☐ Mask


☐ Nebulizer

Number of puffs _____

How often _____

☐ *Use when symptoms occur*

☐ *Use 5 -15 minutes before exercise*

Things to know:

- should be used only if your child is having symptoms during an asthma attack/ with symptoms
- is typically albuterol with a name like: Proventil, Pro-Air, Ventolin, Xopenex

Mark your meds at the pharmacy:

red sticker for **"rescue" medicine**

Other: _____

2 See your child's doctor regularly

Doctor's name and phone number _____

Next appointment date and time _____

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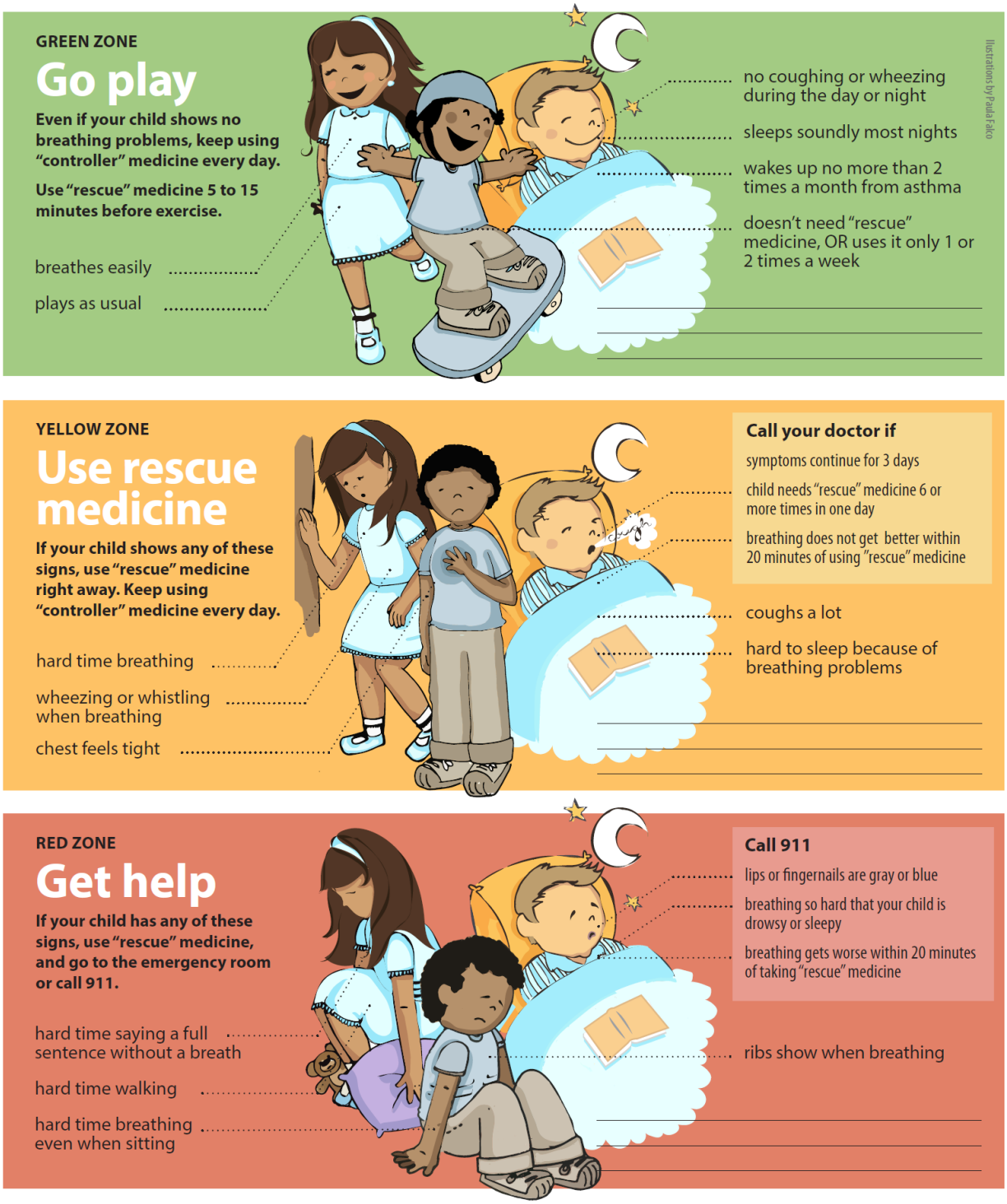
May 22 , 2015

3 Read the signs



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4 Stay on top of asthma

May 22 , 2015

Don't wait! Call with questions

Call your child's regular doctor with any questions about how to use your child's Asthma Home Plan.

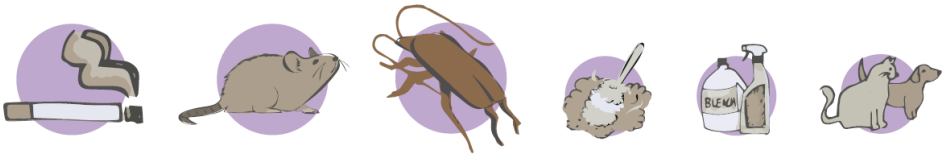
Identify your child's asthma triggers

Build a trigger list of what seems to make your child's asthma act up. Add to the list as you notice new triggers. Try to help your child avoid these!

If your child has a cold, use your child's action plan; and help them to blow their nose.

Avoid smoking—a known asthma trigger—and avoid having your child in a house where someone smokes.

Here are some examples of common asthma triggers:



What are your child's triggers?

_____ _____

_____ _____

_____ _____

_____ _____

Give medications as prescribed

Review how to use the inhalers with your child's doctor.

Develop tricks to help remind you to give the medications.

What might be useful tricks?

_____ *set an alert on your smartphone*

_____ *keep medicine by your coffee pot*

_____ _____

_____ _____

Take your child to the doctor regularly

Your child's doctor is there to help—they want to see how well your child is doing and to review your child's symptom control.

Together you and your doctor will talk about your Asthma Home Plan. Your doctor will make changes to the plan to help you stay on top of your child's asthma.

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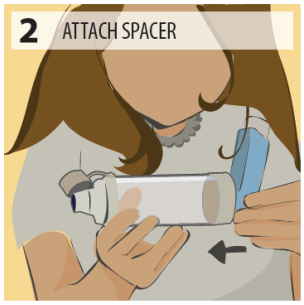
May 22, 2015

How to use an inhaler with a spacer
Works as well as a nebulizer!

Take cap off the inhaler. Check for and remove any dust, lint, or other objects. Shake the inhaler well.



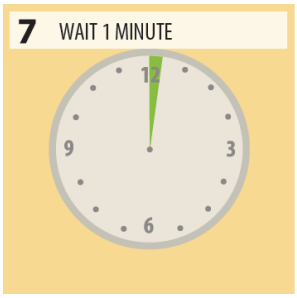
Attach the inhaler to the spacer.

Breathe out all the air, away from the spacer.

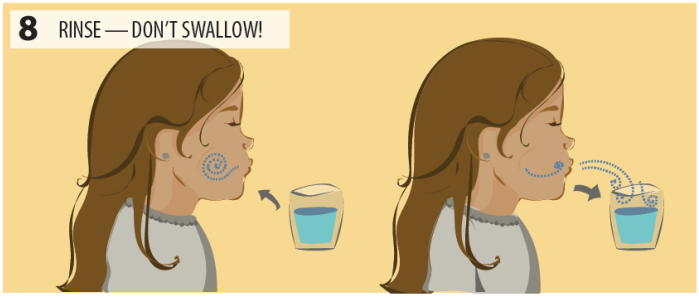
Put lips around device, press inhaler one time. This puts one puff of medicine into the spacer.

Breathe in deeply and slowly, and hold your breath.

Remove the device from the mouth. Then **hold** your breath for 5 secs. Then breathe normally **away** from the spacer.



If your child needs to take another puff of medicine, wait 1 minute. After one minute, repeat steps 3 to 6.



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www.tinyurl.com/asthmalib

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APPENDIX B: Key performance indicators

For each, we will monitor the % completion on a monthly basis at our Steering Committee meetings and provide these key performance metrics to the DSMB prior to the scheduled meetings.

A. Emergency Department (ED)-level intervention performance metrics

(1) Randomize n children/caregivers per month per site X 15 months (hereafter referred to as participants). The per-site n values are based on historical data from each site:

A. John H. Stroger Jr. Hospital of Cook County: 1.7 children/caregivers per month

B. Lurie Children's Hospital of Chicago: 17.5 children/caregivers per month

C. Rush University Medical Center: 3.9 children/caregivers per month

D. Sinai Health System: 4.0 children/caregivers per month

E. University of Chicago: 12.7 children/caregivers per month

F. University of Illinois Hospital & Health Sciences System/University of Illinois at Chicago: 2.6 children/caregivers per month

(2) % of participants who meet study eligibility criteria

(3) % of participants who have appropriate documentation of informed consent (written informed consent and assent) Age that assent is needed varies by site, listed below (site: age for assent):

A. John H. Stroger Jr. Hospital of Cook County: 7 years old

B. Lurie Children's Hospital of Chicago: 12 years old

C. Rush University Medical Center: 8 years old

D. Sinai Health System: 8 years old

E. University of Chicago: 8 years old

F. University of Illinois Hospital & Health Sciences System/University of Illinois at Chicago: 7 years old

(4) % of participants who receive the intervention as per randomized treatment assignment: (a) for the Usual Care group, the ED coordinator provides MDI instruction and Doorknob hanger; (b) for CAPE group, ED coordinator provides MDI instructions, Doorknob hanger, and completes the CAPE with the participants prior to ED discharge; (c) for ED-plus-home group, ED coordinator provides MDI instructions, Doorknob hanger, completes the CAPE with the participants prior to ED discharge, and arranges appointment for the first home visit by the community health worker.

Additional ED-level performance indicators for participants assigned to CAPE groups (ED-only or ED-plus-home):

(5) % of participants who were prescribed a systemic corticosteroid for use after ED discharge (as measured by documentation of a new prescription, an active prescription, or other instructions to use systemic corticosteroids after discharge.)

(6) % of participants who) were prescribed inhaled corticosteroids (or another controller) for use after ED discharge (as measured by documentation of a new prescription, an active prescription, or other instructions to use inhaled corticosteroids or another controller after discharge)

(7) % of participants who received a post-ED follow-up appointment with the child's provider within 28 days of ED discharge (date/time/name),

(8) % of participants who were prescribed a rescue /quick-relief medication for use after ED discharge (as measured by documentation of a new prescription, an active prescription, or other instructions to use a rescue/quick-relief medication after discharge)

(9) % of participants who received instruction using teach-to-goal methodology to (a) increase comprehension about (5) to (8), (b) green/yellow/red zones of the asthma action plan, and (c) need to avoid known environmental triggers;

The site project manager will conduct ED chart reviews within 3-4 business days of discharge for all study participants to assess (5) to (9). These data will be used to assess performance and to also evaluate the extent to which there is contamination across treatment groups. Training or re-training will be performed and documented on a case-by-case basis.

B. Home visit-level intervention performance metrics (for participants randomized to ED-plus-home)

Performance metrics for completion of home visits by community health worker (CHW) . We will consider 3 levels of completion: within window, after window has ended, and not completed for the following metrics:

(10) % of participants who receive Home Visit #1 within 3 business days of discharge (window ends 3 business days after discharge)

(11) % of participants who receive Home Visit #2 within 17 calendar days of discharge (window is 14 days +/- 3 calendar days)

(12) % of participants who receive Home Visit #3 within 37 calendar days of discharge (window is 30 days +/- 7 calendar days)

(13) % of participants who receive Home Visit #4 within 97 calendar days of discharge (window is 90 days +/- 7 calendar days)

(14) % of participants who receive Home Visit #5 within 187 calendar days of discharge (window is 180 days +/- 7 calendar days)

Performance metrics for completion of all elements of each home visit:

(15) % of participants who receive each of the following elements by the CHW during Home Visit #1: introduction and explanation of the CHICAGO Plan; review asthma action plan developed in ED (CAPE); review of asthma basics; review of symptom recognition and understanding of controlled (green zone) vs. uncontrolled asthma (yellow/red zones): teach-to-goal instruction about use of MDIs; assistance to develop a behavior change plan (related to preceding elements)

(16) % of participants who receive each of the following elements by the CHW during Home Visit #2: review asthma action plan updated since ED discharge in collaboration with patient's provider (CAPE); review of asthma basics; review of symptom recognition and understanding of controlled (green zone) vs. uncontrolled asthma (yellow/red zones): teach-to-goal instruction about use of MDIs; identification of and help with strategies to reduce the 3 major triggers; assess progress towards behavior change plan developed during home visit #1 and assistance to develop updated plan (related to preceding elements); educate about 504 plan and how to submit paperwork (school nursing and administrative support)

(17) % of participants who receive each of the following elements by the CHW during Home Visit #3: review asthma action plan updated since ED discharge in collaboration with patient's provider (CAPE); teach-to-goal instruction about use of MDIs; identification of and help with strategies to reduce the 3 major triggers; assess progress towards behavior change plan developed during home visit #2 and assistance to develop updated plan (related to preceding elements); educate about 504 plan and how to submit paperwork (school nursing and administrative support)

(18) % of participants who receive each of the following elements by the CHW during Home Visit #4: review asthma action plan updated since ED discharge in collaboration with patient's provider (CAPE); teach-to-goal instruction about use of MDIs; identification of and help with strategies to reduce the 3 major triggers; assess progress towards behavior change plan developed during home visit #3 and assistance to develop updated plan (related to preceding elements); educate about 504 plan and how to submit paperwork (school nursing and administrative support)

(19) % of participants who receive each of the following elements by the CHW during Home Visit #5: review asthma action plan updated since ED discharge in collaboration with patient's provider (CAPE); teach-to-goal instruction about use of MDIs; identification of and help with strategies to reduce the 3 major triggers; assess progress towards behavior change plan developed during home visit #4 and assistance to develop updated plan (related to preceding elements); educate about 504 plan and how to submit paperwork (school nursing and administrative support).

The Data Coordinating Center collected these data in the REDcap database, which was used by the CHW to document attempted and completed home visits. The Supervising CHWs (from the Sinai CHW Coordinator Center) accompanied CHWs during home visits in a sample of home visits to review in-person site-specific CHW performance. Training or re-training was performed and documented on a case-by-case basis.

C. DCC data collection performance metrics (for all participants)

Performance metrics for data collection. We considered 3 levels of completion: within window, after window has ended, and not completed for the following metrics:

(20) % of participants with in-person BASELINE data collection prior to ED discharge

(21) % of participants with 1-month FOLLOW-UP data within 52 calendar days of discharge (window is 38 days + 14 calendar days)

(22) % of participants with 3-month FOLLOW-UP data within 112 calendar days of discharge (window is 98 days + 14 calendar days)

(23) % of participants with 6-month FOLLOW-UP data within 202 calendar days of discharge (window is 188 days + 14 calendar days)

(24) % of participants with 12-month FOLLOW-UP data within 367 calendar days of discharge (window is 360 days +/- 7 calendar days); this data collection time-point is only for those participants enrolled within first 7.5 months of enrollment period (50% of enrollment period) to ensure there is adequate observation time for data collection at 12 months.

During the conduct of the study, we reviewed missing data and time to complete data collection; these data were used to provide feedback and additional training to study staff as needed.

The Data Coordinating Center collected these data in the REDcap database, which will be used by the DCC research assistants to document attempted and completed outcome assessments. Training or re-training was performed and documented on a case-by-case basis.

The study design employed the "large simple trial" or "pragmatic trial" format, rather than an efficacy design. The target performance varied by metric. For elements linked to human subjects protection (e.g., obtaining written informed consent from the caregiver; assent from the child >7yrs), the definition for major protocol deviation is <100%. For elements linked to implementing the interventions or data collection linked to specific time points, the definition for major protocol deviation is <50%. The goal is 100% performance on all metrics; we will ask site PIs to develop a written corrective action plan if site-level performance for implementing the protocol is <80% (<100% if there are deviations linked to human subjects protection). We reported major protocol deviations to the DSMB within 14 days after the event has been discovered by the contact PI. Depending on the site-specific reporting requirements, we may also report major deviations to the site's Institutional Review Board (IRB); for example, we will report all instances where informed consent was not obtained, but, depending on the institution may not need to report completion rates of study visits prior to the annual continuing review date for that institution's IRB.