

Low Literacy Asthma Action Plan

Use of a Low Literacy Written Action Plan to Improve Parent Understanding of Pediatric

Asthma Management: A Randomized Controlled Study

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ABSTRACT

Objectives: To determine whether parents who use a low literacy, pictogram- and photograph-based written asthma action plan have a better understanding of child asthma management compared to parents using a standard plan.

Methods: Randomized controlled study in 2 urban pediatric outpatient clinics. Inclusion criteria: English/Spanish-speaking parents of 2-12 year old asthmatic children. Parents were randomized to receive a low literacy or standard asthma action plan (American Academy of Allergy, Asthma and Immunology) for a hypothetical patient on controller and rescue medications. A structured questionnaire was used to assess whether there was an error in knowledge of 1) medications to give everyday and when sick, 2) need for spacer use, and 3) appropriate emergency response to

give albuterol and seek medical help. Multiple logistic regression analyses performed adjusting for parent age, health literacy (Newest Vital Sign); child asthma severity, medications; site.

Results: 217 parents were randomized (109 intervention;108 control). Parents who received the low literacy plan were 1)less likely to make an error in knowledge of medications to take everyday and when sick compared to parents who received the standard plan (63.0 vs. 77.3%, $p = 0.03$; adjusted odds ratio [AOR] = 0.5[95% CI: 0.2-0.9]) and 2)less likely make an error regarding spacer use (14.0 vs. 51.1%, $p < 0.001$; AOR = 0.1[0.06-0.3]). No difference in error in appropriate emergency response was seen (43.1 vs. 48.1%, $p = 0.5$).

Conclusions: Use of a low literacy written asthma action plan was associated with better parent understanding of asthma management. Further study is needed to assess whether use of this action plan improves child asthma outcomes.

ClinicalTrials.gov Identifier: NCT01405625

KEYWORDS

health literacy, asthma action plan, patient education, pictogram.

INTRODUCTION

Asthma is one of the most common chronic childhood illnesses, with nearly 10% of children in the United States (US) diagnosed with this condition.¹ Disparities in asthma prevalence and asthma-related morbidity exist, with low socioeconomic status families, and certain racial/ethnic minorities groups, at particular risk for poor outcomes.^{2,3} While the reasons for such disparities are not well understood, low health literacy is one factor which may contribute to these inequities.^{4,5}

Health literacy refers to an individual's ability to acquire, understand, and make informed decisions using health information, and includes the ability to navigate the healthcare system; the construct of health literacy extends beyond that of literacy, which is typically defined as the ability to read and write.⁶⁻⁹ Over one third of US adults has low health literacy; those from low socioeconomic status backgrounds, and racial/ethnic minorities are disproportionately represented.⁷ Studies examining the relationship between parent health literacy and child asthma-related outcomes have found that children of parents with low health literacy have more severe asthma symptoms, as well as increased asthma-related school absences, emergency department visits and hospitalizations.^{4,10}

One aspect of asthma management requiring the use of health literacy skills involves the ability to understand and act on written asthma action plans (WAAP). WAAPs are written instructions which help parents/patients manage chronic asthma symptoms, including exacerbations.¹¹ While use of WAAPs has been associated with improved asthma management, reduction of ED visits and hospitalizations, and is considered standard of care, physicians often do not give WAAPs to families.¹²⁻¹⁸ One potential explanation for this under-utilization is the

poor readability and format of these forms. Studies examining WAAPs have found that many plans are written at greater than a 6th grade reading level, too high for the average patient to understand.¹⁹

To our knowledge, no studies have examined whether a low literacy, pictogram- and photograph-based action plan, developed using health literacy principles to inform content and design, can improve parent ability to manage their child's asthma care. In this study, we therefore sought to assess whether a low literacy pre-printed WAAP, incorporating health literacy principles, would lead to greater parent understanding of asthma care instructions. We hypothesized that parents who use the low literacy plan compared to a standard plan, would have better understanding of child asthma management and would perceive the plan to be easy to use.

METHODS

Study Design

This study was a randomized controlled experiment to test the efficacy of a low literacy, plain language, photograph- and pictogram-based asthma action plan in enhancing parent understanding of child asthma management (NCT01405625). Institutional Review Board approval was obtained from each site.

Participants

Subjects were enrolled through pediatric outpatient clinics at two sites (8/1/11-8/13/12). Inclusion criteria were: English or Spanish-speaking parent or primary caregiver of a child diagnosed with asthma aged 2-12 years old, who receives asthma care at one of the sites. Exclusion criteria: no legal guardian present.

Procedure

At Site 1's asthma clinic, research assistants (RAs) consecutively enrolled parents of children on the day of a pre-scheduled clinic visit, and at Site 1's general pediatric clinic, a convenience sample was enrolled; assessments were performed on the day of enrollment. At Site 2's general pediatric clinic, eligible parents were contacted directly via phone for study recruitment and in-person assessments were scheduled. Patients were enrolled from two locations of Site 1 to increase the rate of recruitment, due to lower patient volume at this site; we hoped to recruit at about the same rate at the two sites. All parents provided written, informed consent. Interviews were conducted in English and Spanish based on parent preference.

Enrolled parents were randomly assigned to receive either the low literacy or standard action plan (American Academy of Allergy, Asthma, and Immunology (AAAAI)). Randomization was implemented using sealed envelopes arranged in blocks of 50 for each site (random order, with 25 intervention and 25 control assignments included within each block); the lead project coordinator (DS) was responsible for randomization procedures. RAs were blinded to randomization status throughout assessments. Baseline assessments of socio-demographics and asthma-related characteristics were performed prior to assessments involving WAAPs. Study participants were blinded to randomization assignment until assessments involving the WAAPs were conducted. Action plans were presented to parents concealed within portfolios, and parents were instructed not to reveal the concealed action plan to their interviewer. Upon completion of the interview, parents were compensated for their time with a \$25 gift card.

Intervention: Low Literacy Asthma Action Plan

The study intervention was a low literacy, plain language, pictogram- and photograph-based asthma action plan (**Figure 1A**). The plan was created as an extension of a pictogram-based medication instruction sheet intervention, HELPix, which was developed as part of the HELP (Health Education and Literacy for Parents) program.²⁰ For the purposes of the study, we created an action plan for a hypothetical child, Jason, involving a commonly prescribed medication regimen (everyday medicines: fluticasone (i.e. Flovent) and montelukast sodium (i.e. Singulair); rescue medicine: albuterol (i.e. Ventolin)).

The low literacy action plan was carefully developed in collaboration with parents and health care providers, with input from individuals with expertise in asthma management, health literacy, and cognitive science. The tool focuses on three areas of chronic asthma management recognized as being confusing for parents/patients, specifically, knowledge of: 1) medications to give, in particular, understanding the need for everyday preventative medications even when the child is sick;^{12,21} 2) need for spacer use to maximize medication delivery to the lungs;^{22,23} and 3) appropriate emergency response (i.e. giving rescue medication right away and seeking medical help).²⁴ The intervention emphasized these key messages by incorporating specific low literacy techniques including use of plain language, pictorial illustrations, photographs and optimization of design elements (e.g. layout, text design, color) (**Table 1**). An iterative process was involved in creating the low literacy plan, with extensive parent and provider feedback obtained and pilot testing of individual elements as well as the tool as a whole.

Control: Standard of Care Plan

Parents in the control group received a standard WAAP, developed by the AAAAI.²⁵ The medication regimen for the same hypothetical child, Jason, was typed in. This plan was selected as it is a national plan and not state-specific. We also considered the plan to be one of the best available plans with respect to health literacy principles related to content and layout. Like the low literacy action plan, the AAAAI action plan uses green/yellow/red color zones. In each zone, medication information is filled in by the provider within a table format. This is common among most action plans used in the US.²⁶ The “fill in” format of the WAAP gives no guidance to providers on how to format medication directions. The standard plan does not specifically mention spacer use. The standard plan mentions the use of preventative medication in the text of the green zone, and repeats this message in the yellow zone. However, compared to the low literacy plan, the language used is more complex (e.g. control: “CONTINUE your Green Zone medicines PLUS take these quick relief medicines” vs. intervention: “Give everyday medicine and add sick medicine”) and the message is not reinforced with other low literacy techniques such as visual representation via pictorial and/or photographic information.

Assessments*Primary Outcome Variables*

The main outcome measures were evaluated after parents were presented with their assigned action plan, and relate to asthma action plan knowledge, including: 1)Green/Yellow Zone knowledge, specifically error in knowledge of which medications to give everyday and when sick, and error in knowledge of the need for spacer use, and 2)Red Zone knowledge, specifically error in knowledge of appropriate emergency response. We also assessed parent

perceptions regarding the ease of use for each action plan. Parents were asked to refer to the action plan they were given to answer questions, and were allowed as much time as they needed to respond to each question.

Green/Yellow Zone Knowledge

Error in knowledge of which medications to give. To evaluate parent understanding of which medications to give everyday and when sick, parents were given a box containing fluticasone, montelukast sodium and albuterol, and told to look at the WAAP to find the answers to questions. To assess knowledge of which medications to give when the child was well, parents were asked: “*Show me all the medicines you should give Jason on a day when he is feeling well.*” Those who did not chose fluticasone and montelukast sodium as everyday medications were considered to have made an error. To assess knowledge of which medications to give when sick, parents were asked “*Show me all the medicines you should give Jason on a day when he is sick.*” Parents who did not chose albuterol, fluticasone and montelukast sodium as the medications were considered to be incorrect. A composite variable was created for any error in knowledge, to allow for comparison of parents who made at least one medication knowledge error to those who made no errors; analyses were also conducted to look at errors by individual medication.

Error in knowledge of need for spacer use

To evaluate parent knowledge of the need for spacer use for inhaled medications, parents were asked, “*Would you use anything else to help you give the [fluticasone/albuterol]?*” Parents who did not mention spacer use for either fluticasone or albuterol were considered to have made an error in knowledge of the need for spacer use.

*Red Zone Knowledge**Error in knowledge of appropriate emergency response*

To assess parent knowledge of correct emergency response, parents were provided with a hypothetical scenario. Parents were told: *“Let’s say Jason wakes up on Sunday at 10AM and feels sick. He is coughing and wheezing just a bit... After giving Jason medicine on Sunday, Jason feels better. Now, let’s pretend that Jason wakes up the next day at 10 AM on Monday morning and he has a lot of trouble breathing and is coughing a lot. What does the sheet tell you to do?”* These responses were recorded verbatim and later coded dichotomously for 1) knowing to give albuterol right away and 2) seeking emergency medical help (e.g. “Call doctor”, “Go to hospital”, “Call 911”). A composite variable was created such that parents were considered to have made an error in knowledge of appropriate emergency response if they did not mention both responses.

Perceived ease of use of WAAP

To assess perceived ease of use, parents were asked: *“Did you have any trouble reading the sheet?”*, with answer choices of Yes and No. At the end of the assessment, parents were given the opportunity to look at the action plan they were not randomized to and asked to select which sheet they preferred: *“Please take a look at a different version of these sheets. Both sheets tell you what to do if your child has asthma. Which of these sheets is easier to understand?”*

Asthma-related characteristics

Baseline asthma-related characteristics were assessed prior to parents being shown the action plan they were randomized to. Child asthma classification was determined using NHLBI diagnostic guidelines.²⁷ A chart review was conducted to determine if the child was currently

prescribed fluticasone or montelukast sodium; children were categorized as being on fluticasone only, montelukast sodium only, both, or neither. Child asthma severity was determined using the Pediatric Asthma Symptom Scale.²⁸ Asthma knowledge was assessed using the Asthma Knowledge Questionnaire.²⁹ Parents were also asked whether they had ever received a WAAP: “Have you ever been given a sheet of paper that helps you know how to take care of asthma, called an asthma action plan?”, with answer choices of Yes and No.

Sociodemographic characteristics and health literacy.

A structured questionnaire was used to obtain sociodemographic data related to the child (e.g. age and sex) and parent (e.g. age, relationship to child, marital status, country of origin, race/ethnicity, language preference). Parent SES was determined using the Family Hollingshead Four-Factor SES based on education and occupation.³⁰ Parent health literacy was assessed with the Newest Vital Sign (NVS),³¹ with parents categorized as having limited (score <4) or adequate (score ≥4) health literacy.³¹⁻³³

Statistical Analysis

Data were analyzed using SPSS 20.0 (Armonk, NY, 2011). For all analyses, a 2-tailed p-value of ≤0.05 was considered to be statistically significant. Baseline characteristics of parents who received the intervention and standard plan were compared using t-tests, and chi-square or Fisher exact tests, as appropriate. Analyses comparing outcomes related to the low literacy vs. standard WAAP were conducted using chi-square or Fisher exact tests. Multiple logistic regression analyses were also conducted controlling for variables that were different across randomization groups (i.e. parent age, asthma classification) as well as variables identified *a priori* which were thought to be potentially related to outcome variables of interest, including

history of fluticasone/montelukast sodium use (fluticasone only, montelukast sodium only, both, neither; only fluticasone use included for outcome of error in knowledge of spacer use, as albuterol is prescribed to all children with asthma), site (3 sites included: site 1 asthma clinic, site 1 general clinic, site 2), and health literacy.

Sample size estimation

We conservatively estimated that ~40% of parents who received the low literacy action plan would make errors in understanding asthma management compared to ~60% of parents in the control group. To detect this level of difference with 80% power (alpha of 0.05), we calculated a sample size of 200 subjects (100/group).

RESULTS

Sample characteristics

Eligibility criteria was assessed for 934 parents. Based on 1 or more study criteria, 675 (72.3%) were determined to be ineligible (**Figure 2**). 259 parents were found to be eligible; of this group, 217 (83.8%) were enrolled and randomized (24 refused to participate and 18 had logistical difficulties), with 109 (50.2%) allocated to receive the low literacy and 108 (49.7%) the standard plan.

Approximately half of parents were recruited from each site (Site 1 = 119 (54.8%), Site 2 = 98 (45.2%)). At Site 1, the majority (68.1%) were recruited from the asthma clinic.

Randomization groups were comparable across all characteristics except for mean(SD) parent age (intervention vs. control: 36.6(8.8) vs. 34.3(7.7) years, $p = 0.04$), and child asthma classification (mild intermittent vs. mild persistent vs. moderate/intermittent persistent; intervention: 34.9 vs. 25.7 vs. 39.4%; control: 27.8 vs. 44.4 vs. 27.8%, $p = 0.01$) (**Table 2**).

Green / Yellow Zone Knowledge

Error in knowledge of which medications to give. Parents who received the low literacy plan were less likely to make an error in knowledge of all everyday and sick medications compared to the group who received the standard plan (63.0 vs. 77.3%, $p = 0.03$; number needed to treat [NNT] = 7[4-59]) (**Tables 3 and 4**). In multiple logistic regression analyses, parents randomized to the low literacy plan had half the odds of making an error in knowledge of everyday and sick medications, compared to parents randomized to the standard plan (adjusted odds ratio [AOR], 0.5 [95% CI: 0.2-0.9], $p = 0.03$). There was no statistically significant relationship between age or asthma classification and errors in knowledge of all everyday and sick medicines. There was a decreased odds of error among those parents whose children were prescribed the regimen shown on the WAAP (fluticasone and montelukast sodium) (AOR = 0.3[0.1-0.8], $p = 0.02$) compared to those on neither, and a trend for decreased odds of error for those with adequate (vs. limited) health literacy (AOR = 0.5[0.2-1.1], $p = 0.07$); there was no difference in errors for those on fluticasone- or montelukast sodium-only compared to those on neither medication.

Few parents in the intervention and control groups made errors in knowledge regarding giving albuterol when the child was sick (7.0 vs. 10.3%, $p = 0.5$) (**Table 3**). For preventive medicines, nearly a third of parents in both groups made errors in knowledge of giving preventative medications on days when the child was sick (fluticasone: 32.0 vs. 32.0%, $p = 1.0$, montelukast sodium: 41.0 vs. 44.3%, $p = 0.7$).

Error in knowledge of need for spacer use

Parents in the intervention group were less likely to forget spacer use (14.0 vs. 51.1%, $p < 0.001$; NNT = 3[2-4]) (**Table 4**). In logistic regression analyses, parents who received the low literacy

plan had a significantly lower odds of making an error in knowledge of spacer use compared to those who received the standard plan (AOR = 0.1[0.06-0.3], $p < 0.001$). There was no statistically significant relationship between parent age or asthma classification and errors in knowledge of spacer use. There was no association between child current fluticasone use and errors in knowledge of spacer use, although there was a decreased odds of error among those with adequate (vs. low) health literacy (AOR = 0.3[0.1-0.6], $p = 0.003$).

Red Zone Knowledge

Error in knowledge of appropriate emergency response

There were no differences in knowledge of appropriate emergency response across groups (**Table 3**). Few parents made errors in knowing to seek emergency help in the intervention and control groups (10.1 vs. 11.1%, $p = 1.0$); over a third of parents made errors in knowing to give albuterol right away (34.9 vs. 38.0%, $p = 0.7$). Across groups, nearly half of parents were incorrect in knowing to both call for emergency help and give albuterol (intervention vs. control: 43.1 vs. 48.1%; $p = 0.5$).

Perceived Ease of Use of WAAP

No differences were found across groups in action plan ease of use, with 85.3% of parents in the intervention group and 87.7% of parents in the control group reporting no difficulty reading their assigned plan ($p = 0.7$). When given the opportunity to compare both action plans, a majority of parents in both the intervention (70.6%) and control (82.1%) group found the low literacy pictogram and photograph-based action plan to be easier to understand ($p = 0.07$).

DISCUSSION

Although the use of WAAPs is considered to be standard of care, they are often too complex to comprehend, and there has been limited research on the development and efficacy of low literacy asthma action plans.^{17-19, 27} In a randomized controlled experiment, we found that compared to parents who received the standard plan, parents who received the low literacy WAAP had better knowledge of asthma management, including fewer errors in knowledge of which medications to give everyday and when sick, and fewer errors regarding the need for spacer use. These findings, along with the limited resource requirements for this low intensity intervention, support the potential utility of implementing the low literacy plan as part of routine clinical practice.

Parents who received the low literacy intervention made fewer errors in knowledge of which medications to give their child when sick and when well. While error rates related to each individual medication when analyzed separately was not found to be significant, parents in the intervention group made slightly fewer errors related to each medicine, resulting in a cumulative positive effect. As parents may be confused with which inhaler to use for preventative vs. rescue purposes, with a lack of standardization of inhaler colors serving as a potential contributor³⁴, our decision to include photographs of inhalers as part of our low literacy plan may have improved parent comprehension.³⁵

Overall, however, comprehension of the need to give everyday preventive medications when sick was poor, even with the low literacy action plan, consistent with prior research that has demonstrated high rates of underutilization of controller medication among low SES,

minority groups.^{23,36} Our study findings suggest that additional strategies are likely to be needed to reinforce the importance of controller medications, including through supplemental verbal counseling. In addition, the pictograms we included in the yellow zone of our low literacy plan (**Figure 1A**) may not have sufficiently conveyed the need to keep taking green zone “everyday” medications even when the child is sick. To address this potential deficiency, after this study was completed, we designed a new “snapshot” of the green zone to be placed within the yellow zone; this “snapshot” explicitly mentions each everyday medicine in text and includes photographs (**Figure 1B**; to be tested in a separate study).

The low literacy action plan was associated with a ~40% reduction in risk of an error in spacer knowledge for parents who received the low literacy plan compared to parents receiving the standard plan. The low literacy intervention was likely effective as it reinforced the importance of spacer use through repetition in the text as well as through the use of pictograms; prior studies have shown that pictograms, in particular, may be useful in reinforcing written medical directions, especially for low literacy individuals.³⁷⁻⁴⁰

There were no significant differences between groups in knowledge of appropriate emergency response, although only about half of parents correctly stated that they would seek emergency care and give albuterol. It is possible that parents did not know to escalate treatment due to our hypothetical scenario, as this decision is usually based on real-life symptom recognition. Other enhancements may be needed to improve parent skills in symptom recognition, such as links to videos or other visual resources.

Notably, health literacy was associated with knowledge of spacer use, and there was a trend for a relationship with knowledge of everyday medications. This is consistent with prior studies showing an association between low parent health literacy and poorer medication-related knowledge and outcomes.⁴

We found that parents in both groups preferred the low literacy plan. Prior research has found that patients prefer educational materials which use plain language and pictographic information.^{38,40,41} Interestingly, ~30% of parents who received the low literacy plan felt the standard plan was easier to understand, indicating that the experience of navigating the low literacy plan may have been challenging to some parents.

There are limitations to this study. Parent skills were assessed using hypothetical scenarios and may not reflect their knowledge and behaviors in caring for their asthmatic child at home. Parents may have been confused since the hypothetical medication regimen they were presented with may not have been the same as their child's medication regimen. As this was a randomized controlled experiment, we did not evaluate the effectiveness of the intervention in improving real-world asthma outcomes, including impact on asthma symptom severity, or frequency of ED visits and hospitalizations; a study examining these outcomes is in progress. While we sought to recruit intervention and control groups that were comparable across characteristics, our intervention group was slightly older and with more mild intermittent as well as more moderate/severe persistent asthmatics; we do not know why, despite our use of accepted randomization practices, these characteristics differed when other characteristics were comparable across groups. In multiple logistic regression analyses adjusting for these

differences, however, the low literacy intervention remained associated with better parent knowledge of asthma management. We note that we also recruited patients using different strategies at each site, but parents were randomly assigned to receive either the low literacy or standard plan, and notably, our intervention findings were unchanged even when site was controlled for (with no difference in findings when location was included in the model as 2 or 3 sites); site was also not associated with outcomes. In addition, we assessed education level as a proxy for literacy; as education level and health literacy were highly correlated, we did not include both education and health literacy in our regression models, although there was no significant impact on study findings with or without education in the models. Finally, our sample consisted of urban, primarily low SES, immigrant Hispanic parents with limited health literacy, and our results may therefore not be generalizable to other populations. As our study population had an increased risk of poor comprehension of asthma management, it is possible that risk reductions would be smaller in lower-risk populations.

CONCLUSION

We found that use of a plain language, pictogram and photograph-based low literacy written asthma action plan intervention resulted in better parent knowledge of when to give everyday and sick medications, and better parent knowledge of the need for spacer use with inhaled medications. Parents across both randomization groups also found the low literacy plan to be easier to understand compared to the standard asthma action plan. The low literacy asthma action plan intervention may be a promising addition to current asthma counseling tools, as a strategy to improve parent self-management skills and decrease pediatric asthma morbidity,

particularly for families with low health literacy who are at risk for poor asthma-related outcomes.

Declaration of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper. All authors were involved in conceptualizing the study design, drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. All authors have full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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REFERENCES

1. Bloom B, Cohen RA, Freeman G. Summary health statistics for U.S. children: National Health Interview Survey, 2007. *Vital Health Stat 10*. Jan 2009(239):1-80.
2. Akinbami L, Centers for Disease Control, Prevention National Center for Health Statistics. The state of childhood asthma, United States, 1980-2005. *Adv Data*. Dec 12 2006(381):1-24.
3. Akinbami LJ, Moorman JE, Liu X. Asthma prevalence, health care use, and mortality: United States, 2005-2009. *Natl Health Stat Report*. Jan 12 2011(32):1-14.
4. DeWalt DA, Dilling MH, Rosenthal MS, Pignone MP. Low parental literacy is associated with worse asthma care measures in children. *Ambul Pediatr*. Jan-Feb 2007;7(1):25-31.
5. Canino G, McQuaid EL, Rand CS. Addressing asthma health disparities: a multilevel challenge. *J Allergy Clin Immunol*. Jun 2009;123(6):1209-1217; quiz 1218-1209.
6. US Department of Health and Human Services, Office of Disease Prevention, Health Promotion. National action plan to improve health literacy. *Washington, DC*. 2010.
7. Kutner M, Greenburg E, Jin Y, Paulsen C. The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy. NCES 2006-483. *National Center for Education Statistics*. 2006.
8. Nielsen-Bohlman L, Panzer AM, Kindig DA. Health literacy: a prescription to end confusion. National Academies Press; 2004.
9. "Literacy". Merriam-Webster.com. 2016;
<http://www.learnersdictionary.com/definition/literacy>. Accessed November 25, 2016.

10. Wittich AR, Mangan J, Grad R, Wang W, Gerald LB. Pediatric asthma: caregiver health literacy and the clinician's perception. *J Asthma*. Jan-Feb 2007;44(1):51-55.
11. Bhogal S, Zemek R, Ducharme FM. Written action plans for asthma in children. *Cochrane Database Syst Rev*. 2006(3):CD005306.
12. Ducharme FM, Zemek RL, Chalut D, et al. Written action plan in pediatric emergency room improves asthma prescribing, adherence, and control. *Am J Respir Crit Care Med*. Jan 15 2011;183(2):195-203.
13. Ducharme FM, Bhogal SK. The role of written action plans in childhood asthma. *Curr Opin Allergy Clin Immunol*. Apr 2008;8(2):177-188.
14. Ring N, Pinnock H, Wilson C, et al. Understanding what asthma plans mean: a linguistic analysis of terminology used in published texts. *Prim Care Respir J*. Jun 2011;20(2):170-177.
15. Sulaiman N, Aroni R, Thien F, et al. Written Asthma Action Plans (WAAPs) in Melbourne general practices: a sequential mixed methods study. *Prim Care Respir J*. Jun 2011;20(2):161-169.
16. Pollart SM, Compton RM, Elward KS. Management of acute asthma exacerbations. *American family physician*. Jul 1 2011;84(1):40-47.
17. *Asthma Handbook 2006: Asthma Management Handbook*. National Asthma Council Australia;2006.
18. *British Thoracic Society: British Guideline on the Management of Asthma* British Thoracic Society: A National Clinical Guidance (2014). Available at <https://www.brit->

thoracic.org.uk/document-library/clinical-information/asthma/btssign-asthma-guideline-2014/. Accessed September 8, 2016.

19. Forbis SG, Aligne CA. Poor readability of written asthma management plans found in national guidelines. *Pediatrics*. Apr 2002;109(4):e52.
20. Yin HS, Dreyer BP, van Schaick L, Foltin GL, Dinglas C, Mendelsohn AL. Randomized controlled trial of a pictogram-based intervention to reduce liquid medication dosing errors and improve adherence among caregivers of young children. *Arch Pediatr Adolesc Med*. Sep 2008;162(9):814-822.
21. Federman AD, Wisnivesky JP, Wolf MS, Leventhal H, Halm EA. Inadequate health literacy is associated with suboptimal health beliefs in older asthmatics. *J Asthma*. Aug 2010;47(6):620-626.
22. Barnes PJ. Inhaled glucocorticoids for asthma. *The New England journal of medicine*. Mar 30 1995;332(13):868-875.
23. Diaz T, Sturm T, Matte T, et al. Medication use among children with asthma in East Harlem. *Pediatrics*. Jun 2000;105(6):1188-1193.
24. Yoos HL, McMullen A. Symptom perception and evaluation in childhood asthma. *Nurs Res*. Jan-Feb 1999;48(1):2-8.
25. American Academy of Allergy Asthma and Immunology. Asthma Action Plan. http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Libraries/NEW-WEBSITE-LOGO-asthma-action-plan_HI.pdf. Accessed September 8, 2016.

26. Yin HS, Gupta RS, Tomopoulos S, et al. Readability, suitability, and characteristics of asthma action plans: examination of factors that may impair understanding. *Pediatrics*. Jan 2013;131(1):e116-126.
27. National Heart, Lung and Blood Institute. NIH Publication: Guidelines for the Diagnosis and Management of Asthma. 2007;
<http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf>. Accessed September, 8, , 2016.
28. Lara M, Sherbourne C, Duan N, Morales L, Gergen P, Brook RH. An English and Spanish Pediatric Asthma Symptom Scale. *Med Care*. Mar 2000;38(3):342-350.
29. Ho J, Bender BG, Gavin LA, O'Connor SL, Wamboldt MZ, Wamboldt FS. Relations among asthma knowledge, treatment adherence, and outcome. *Journal of Allergy and Clinical Immunology*. 2003;111(3):498-502.
30. Hollingshead AB. Four factor index of social status. *Yale Journal of Sociology*. 2011;8:21-51.
31. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. *Ann Fam Med*. Nov-Dec 2005;3(6):514-522.
32. Dunn-Navarra AM, Stockwell MS, Meyer D, Larson E. Parental health literacy, knowledge and beliefs regarding upper respiratory infections (URI) in an urban Latino immigrant population. *J Urban Health*. Oct 2012;89(5):848-860.
33. Marrie RA, Salter A, Tyry T, Fox RJ, Cutter GR. Health literacy association with health behaviors and health care utilization in multiple sclerosis: a cross-sectional study. *Interact J Med Res*. 2014;3(1):e3.

34. Greene JA, Kesselheim AS. Why do the same drugs look different? Pills, trade dress, and public health. *The New England journal of medicine*. Jul 7 2011;365(1):83-89.
35. Coleman EA, Coon S, Mohrmann C, et al. Developing and testing lay literature about breast cancer screening for African American women. *Clin J Oncol Nurs*. Jan-Feb 2003;7(1):66-71.
36. Smith LA, Bokhour B, Hohman KH, et al. Modifiable risk factors for suboptimal control and controller medication underuse among children with asthma. *Pediatrics*. Oct 2008;122(4):760-769.
37. Houts PS, Doak CC, Doak LG, Loscalzo MJ. The role of pictures in improving health communication: a review of research on attention, comprehension, recall, and adherence. *Patient education and counseling*. May 2006;61(2):173-190.
38. Katz MG, Kripalani S, Weiss BD. Use of pictorial aids in medication instructions: a review of the literature. *Am J Health Syst Pharm*. Dec 1 2006;63(23):2391-2397.
39. Mansoor LE, Dowse R. Effect of Pictograms on Readability of Patient Information Materials. *The Annals of Pharmacotherapy*. 2003;37(7):1003-1009.
40. Michielutte R, Bahnson J, Dignan MB, Schroeder EM. The use of illustrations and narrative text style to improve readability of a health education brochure. *J Cancer Educ*. 1992;7(3):251-260.
41. Butow P, Brindle E, McConnell D, Boakes R, Tattersall M. Information booklets about cancer: factors influencing patient satisfaction and utilization. *Patient education and counseling*. Feb 1998;33(2):129-141.

42. Doak CC, Doak LG, Root JH. *Teaching Patients with Low Literacy Skills*. 2 ed: J.B. Lippincott; 1996.
43. Weiss B. *Health literacy and patient safety help patients understand American*. Chicago: American Medical Association; 2007.
44. Estey A, Musseau A, Keehn L. Patient's understanding of health information: a multihospital comparison. *Patient education and counseling*. Aug 1994;24(1):73-78.
45. Williams MV, Baker DW, Honig EG, Lee TM, Nowlan A. Inadequate literacy is a barrier to asthma knowledge and self-care. *Chest*. Oct 1998;114(4):1008-1015.
46. Brand PL. Key issues in inhalation therapy in children. *Curr Med Res Opin*. 2005;21 Suppl 4:S27-32.
47. Sudore RL, Schillinger D. Interventions to Improve Care for Patients with Limited Health Literacy. *Journal of clinical outcomes management : JCOM*. Jan 1 2009;16(1):20-29.
48. Guss D, Barash IA, Castillo EM. Characteristics of spacer device use by patients with asthma and COPD. *The Journal of emergency medicine*. Nov 2008;35(4):357-361.
49. Garbutt J, Highstein G, Nelson KA, Rivera-Spoljaric K, Strunk R. Detection and home management of worsening asthma symptoms. *Ann Allergy Asthma Immunol*. Dec 2009;103(6):469-473.
50. Zemek RL, Bhogal SK, Ducharme FM. Systematic review of randomized controlled trials examining written action plans in children: what is the plan? *Arch Pediatr Adolesc Med*. Feb 2008;162(2):157-163.
51. Dowse R, Ehlers M. Medicine labels incorporating pictograms: do they influence understanding and adherence? *Patient education and counseling*. Jul 2005;58(1):63-70.

52. The Joint Commission. *"What did the doctor say?:" Improving health literacy to protect patient safety.* Oakbrook Terrace, IL 2007.

TABLE 1. Design of intervention asthma action plan: applying evidence-based low literacy design techniques to address common clinical problems in pediatric asthma management

	Issue Addressed	Intervention Features	Supporting Evidence
Overall Structure		Traffic Light Motif: Information is presented using three distinct and separate color zones.	Prominent use of color used to help support understanding of key concepts. ⁴²
		Plain Language Wording: Section headers use plain language (e.g. “Everyday,” “Sick” and “Very sick”).	Current recommendations call for patient information to be written at the 5 th -6 th grade level for the general population, and 3 rd -5 th grade for those with low literacy. ⁴³ Parents prefer and better

			comprehend information in simplified handouts. ^{41,44}
<i>Knowledge of which medications to give everyday and when sick</i>	Use of daily preventative medications has been found to be the most effective method to prevent asthma exacerbations. These anti-inflammatory medications work best when taken every day, regardless of whether the child is sick or well. ¹³	Repetition of Concepts within Plain Language Banners: To emphasize the need for everyday medications even when sick, plain language banners were included in the green zone (“Give everyday medicine when healthy or sick”) and repeated in the yellow zone (“Give everyday medicine <u>and</u> add sick medicine”).	Repetition of concepts improves understanding of concepts. ⁴⁶
	Suboptimal use of inhaled steroids is more likely among low health literacy patients. ⁴⁵ They are	Pictogram Snapshot: To visually represent and reinforce this concept, a pictogram is included within the yellow zone to represent green zone information. This pictogram snapshot “chunks” green zone information into one unit of knowledge for parents interpreting	Chunking of information helps cluster similar information, making it easier for the brain to process. ^{42,43}

	also more likely to believe that medications are more effective if not used all the time. ²¹	action plan instructions.	
	Patients have been found to confuse preventive and rescue medications, due to lack of standardization in MDI colors. ³⁴	Medication Photographs: All medication instructions are paired with photographs of the actual administration container (e.g. picture of Flovent inhaler).	Photographs visually reinforce real-life concepts, improving patient comprehension and adherence. ^{35,37,47}
<i>Knowledge of need for spacer use</i>	Spacer use in conjunction with inhaled asthma medications is important for maximal delivery of medication to the lungs, which improves medication efficacy. ²² Unfortunately, 1 in 3	Pictogram Reinforcement: Each time inhaler information is provided, spacer use is both shown in pictograms (i.e. child with spacer) and specified in text.	Repetition of key concepts helps reinforce presented information and supports parent understanding. ⁴⁶
			Pictograms have been found to improve

	parents report not having a spacer at home. ^{23,48}		medication self-management. ³⁹
<i>Knowledge of appropriate emergency response</i>	Parents often wait too long before intervening during episodes of asthma exacerbation. ²⁴	Plain Language Banners, Reinforced with Pictograms and Photographs: The red zone banner lists in short, simple sentences the two appropriate emergency actions needed (i.e. Give sick medicine. Get help now!). The information is repeated in text and visually with photographic and pictographic information.	Effective use of layout, including allocation of adequate space to particularly important concepts, can help highlight key concepts. ^{26,42}
	One contributor to lack of appropriate escalation of treatment is difficulty recognizing symptoms of serious asthma exacerbations. ^{24,49}	Explicit Symptom Descriptions: To help parents identify when to appropriately intensify treatment, each zone includes concrete, easy to understand symptoms (e.g. “breathing hard and fast” and “can’t stop coughing”) rather than more general/subjective symptoms (e.g. “difficulty breathing” and	Studies have found that symptom-based action plans are superior to peak flow-based plans, particularly for the prevention of acute care visits. 11,50

		“coughing”).	Describing symptoms in an explicit manner makes instructions more actionable. ⁴²
		Pictogram Reinforcement: Child symptom severity was reinforced with a pictogram showing child status (i.e. red zone pictogram showing child in clear distress).	Pictograms are effective for visually reinforcing concepts, in this case, recognition of a child’s asthma symptoms. ^{20,37-39,51,52}

TABLE 2. Study population characteristics by randomization group^a

	Total Population n = 217	Low Literacy WAAP n = 109	Standard WAAP n = 108	p-value
Child Characteristics				
Age, mean (SD), y	7.5 (3.0)	7.8 (3.3)	7.1 (2.8)	0.1
Gender: Female, n (%)	79 (36.4)	39 (35.8)	40 (37.0)	0.9
Parent Characteristics				
Age, mean (SD), y	35.5 (8.3)	36.6 (8.8)	34.3 (7.7)	0.04
Gender: Female, n (%)	207 (95.4)	102 (93.6)	105 (97.2)	0.3
Relationship to Child: Mother, n (%)	201 (92.6)	97 (89.0)	104 (96.3)	0.1
Marital Status: Single, n (%)	99 (45.6)	53 (48.6)	46 (42.6)	0.4
Hollingshead SES: Level 4 or 5, n (%) ^b	172 (79.3)	84 (77.1)	88 (81.5)	0.5
Country of Birth: Non-US, n (%)	119 (54.8)	59 (54.1)	60 (55.6)	0.9
Race/Ethnicity, n (%)				0.2
Hispanic	127 (58.5)	69 (63.3)	58 (53.7)	
Non-Hispanic				
White, non-Hispanic	5 (2.3)	1 (0.9)	4 (3.7)	

Black, non-Hispanic	68 (31.3)	29 (26.6)	39 (36.1)	
Other, non-Hispanic	17 (7.8)	10 (9.2)	7 (6.5)	
Language: Spanish, n (%) ^c	93 (42.9)	48 (44.0)	45 (41.7)	0.8
Education, n (%)				0.9
Less than HS Graduate	52 (24.0)	26 (23.9)	26 (24.1)	
HS Graduate / Equivalent	37 (17.1)	20 (18.3)	17 (15.7)	
Some College or Greater	128 (59.0)	63 (57.8)	65 (60.2)	
Health Literacy, n (%) ^d				0.2
Limited	151 (69.9)	81 (74.3)	70 (65.4)	
Adequate	65 (30.1)	28 (25.7)	37 (34.6)	
Recruitment Site, n (%)				1.0
Site 1	119 (54.8)	60 (55.0) ^e	59 (54.6) ^f	
Site 2	98 (45.2)	49 (45.0)	49 (45.4)	
Asthma-related Characteristics				
Child Asthma Classification, n (%)				0.01
Mild intermittent	68 (31.3)	38 (34.9)	30 (27.8)	
Mild persistent	76 (35.0)	28 (25.7)	48 (44.4)	
Moderate/severe persistent	73 (33.6)	43 (39.4)	30 (27.8)	

Child Current Everyday Medications				1.0
None	65 (32.5)	34 (33.7)	31 (31.3)	
Fluticasone only	82 (41.0)	41 (40.6)	41 (41.4)	
Montelukast sodium only	20 (10.0)	10 (9.9)	10 (10.1)	
Both fluticasone and montelukast sodium	33 (16.5)	10 (10.1)	17 (17.2)	
Asthma Severity Score, mean (SD) ^g	15.0 (8.8)	16.0 (11.2)	14.0 (5.2)	0.1
Asthma Knowledge Score, mean % (SD) ^h	71.7 (9.5)	70.8 (10.2)	72.6 (8.7)	0.2
Ever given a written asthma action plan: Yes, n (%)	148 (68.2)	77 (70.6)	71 (65.7)	0.5

^aData are mean (SD) or n (%).

^bLower level represents higher SES and greater family resources.

^cLanguage of survey administration.

^dHealth literacy measured using the NVS. Data missing for 1 subject.

^eLow literacy WAAP group includes 42 from the asthma clinic and 18 from the general clinic at Site 1.

^fStandard WAAP group includes 39 from the asthma clinic and 20 from the general clinic at Site 1.

^gParent asthma severity score measured using the Pediatric Asthma Symptom Scale (scored 0-40). Data missing for 1 subject.

^hParent asthma knowledge measured using the Asthma Knowledge Questionnaire (scored 0-25).

TABLE 3. Error in knowledge of asthma medication management and perceptions of ease of use, by randomization group

	Low Literacy WAAP n = 109	Standard WAAP n = 108	p-value
GREEN AND YELLOW ZONE KNOWLEDGE^a			
Error in Knowledge of Which Medications to Give			
Error in knowledge of all every day and sick medications, n (%)	63 (63.0)	75 (77.3)	0.03
Albuterol (Ventolin)	7 (7.0)	10 (10.3)	0.5
When sick: Incorrect, n (%)			
Fluticasone (Flovent)			
Every day: Incorrect, n (%)	20 (20.0)	26 (26.8)	0.3
When sick: Incorrect, n (%)	32 (32.0)	31 (32.0)	1.0
Montelukast Sodium (Singulair)			
Every day: Incorrect, n (%)	30 (30.0)	31 (32.0)	0.9
When sick: Incorrect, n (%)	41 (41.0)	43 (44.3)	0.7
Error in Knowledge of Need for Spacer Use			
Error knowledge of need for spacer ^b	14 (14.0)	48 (51.1)	<0.001

Albuterol (Ventolin): Incorrect, n (%) ^c	26 (25.2)	58 (58.0)	<0.001
Fluticasone (Flovent): Incorrect, n (%) ^d	24 (25.5)	60 (66.7)	<0.001
RED ZONE KNOWLEDGE			
Error in Knowledge of Appropriate Emergency Response			
Give Albuterol: No, n (%)	38 (34.9)	41 (38.0)	0.7
Seek emergency help: No, n (%)	11 (10.1)	12 (11.1)	1.0
Either incorrect, n (%)	47 (43.1)	52 (48.1)	0.5
PERCEIVED EASE OF USE OF WAAP			
Trouble reading sheet: No, n (%)	93 (85.3)	93 (87.7)	0.7
Which sheet easier to understand, n (%)			0.1
Standard WAAP	32 (29.4)	19 (17.9)	
Low Literacy WAAP	77 (70.6)	87 (82.1)	

^a n = 197; 97 standard WAAP, 100 low literacy WAAP; at the beginning of the study, patients were given box of only inhaler medications to select from

^b No mention of spacer use for either albuterol or fluticasone; n = 194; 94 standard WAAP, 100 low literacy WAAP

^c n = 203; 100 standard WAAP, 103 low literacy WAAP; at the beginning of the study, patients were only asked about spacer use if they stated that they would give albuterol

^d n = 184; 94 standard WAAP, 90 low literacy WAAP; at the beginning of the study, patients were only asked about spacer use if they stated that they would give fluticasone

TABLE 4. Error in knowledge of which medications to take every day and when sick, and error in spacer knowledge

	Low Literacy WAAP	Standard WAAP	RR (95% CI)	RRR (95% CI), %	ARR (95% CI), %
	n = 100	n = 97			
Error in knowledge of medications to take every day and when sick	63 (63.0)	75 (77.3)	0.81 (0.68-0.98)	38.7 (4.1-60.8)	14.3 (1.7-26.9)
	n = 100	n = 94			
Error in knowledge of need to use spacer	14 (14.0)	48 (51.1)	0.27 (0.16-0.46)	43.2 (28.4-55.1)	37.1 (24.9-49.2)
	n = 109	n = 108			
Error in knowledge of appropriate emergency response	47 (43.1)	52 (48.1)	0.90 (0.67-1.20)	8.8 (-16.4-28.6)	5.0 (-8.2-18.3)

^aNNT not calculated for nonsignificant results

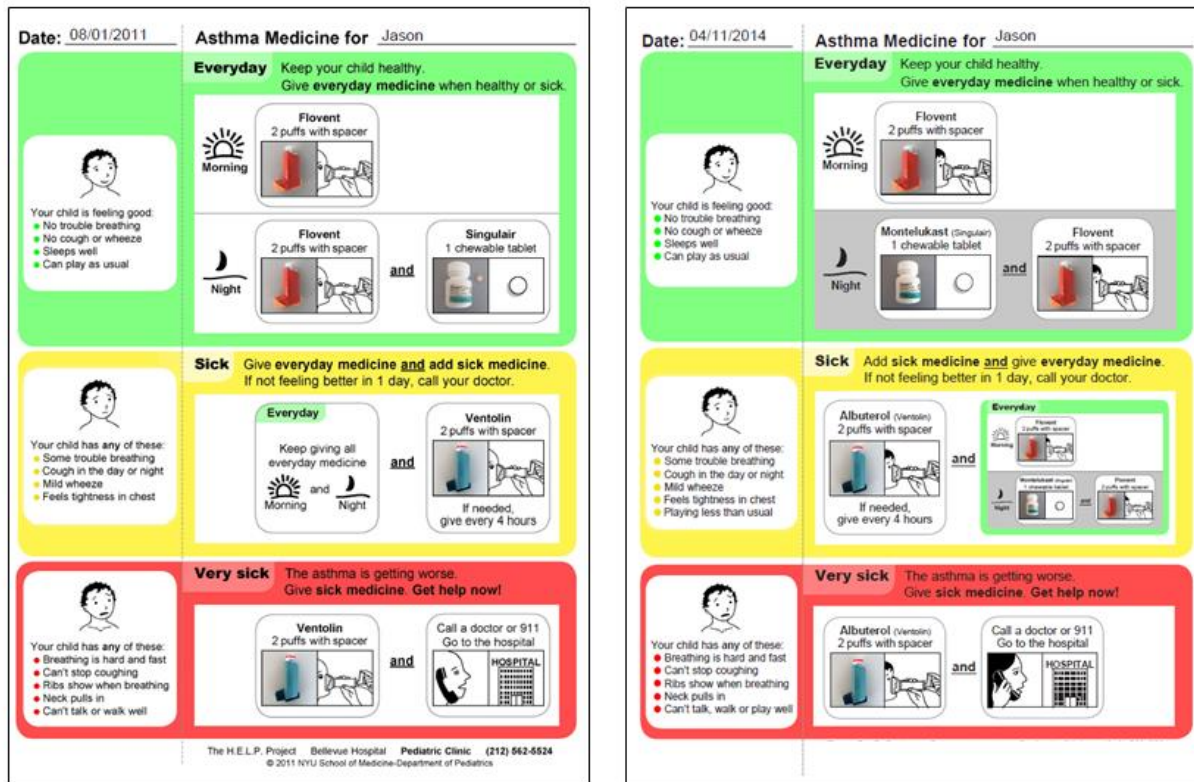
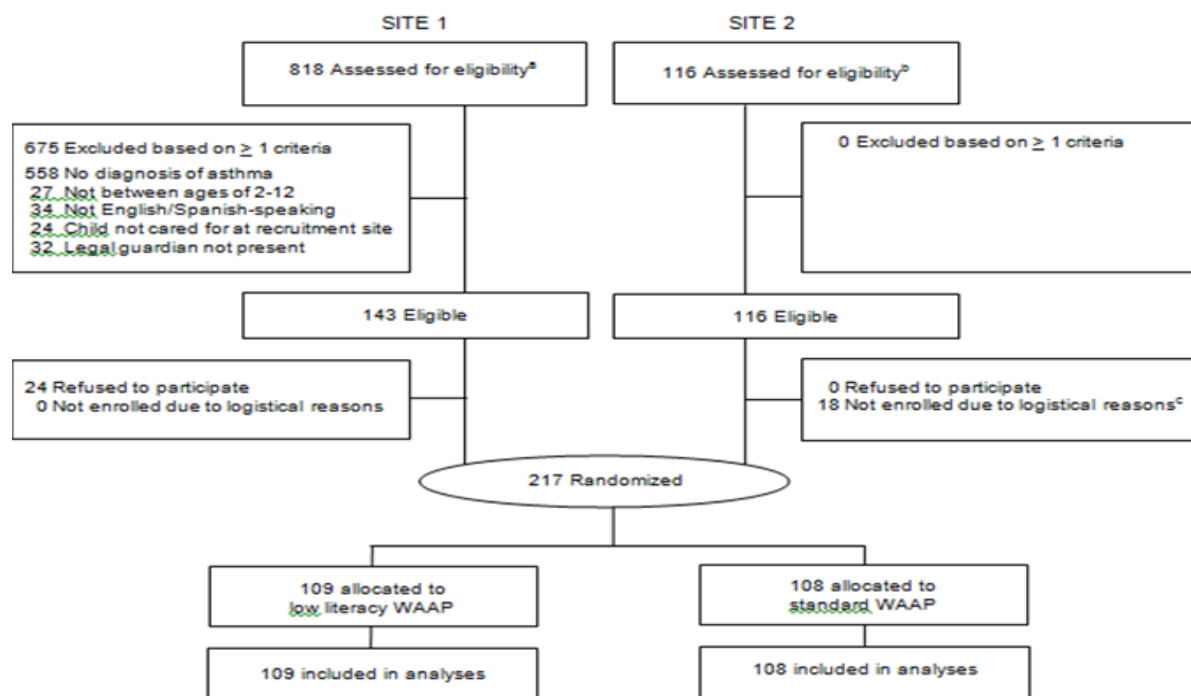


FIGURE 1. Pictogram- and photograph-based low literacy written asthma action plan (WAAP)



^a At Site 1, subjects were recruited from the asthma clinic, as well as the general pediatric clinic.

^b At Site 2, 321 potentially eligible study subjects had been identified by chart review, of which 116 were assessed for full eligibility criteria by phone, 196 were not reached, and 9 declined eligibility screening

^c At Site 2, 18 study subjects were determined to be eligible but were not ultimately enrolled and randomized due to logistical issues (eg. difficulty scheduling a time for the parent to come in, disconnected phone)

FIGURE 2. Study recruitment and randomization