Overcoming Barriers to Care for Vulnerable Children with Asthma
R40 MC 08044 Seid, PI
The Maternal and Child Health Research Program

Final Comprehensive Report

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I. Introduction
    A. Nature of the research problem

Asthma continues to take a toll on the health of America's children, disproportionately so for children made vulnerable due to race/ethnicity, parental language, poverty, and/or insurance status. While the U.S. health care system has made great technological achievements, barriers to care, especially for vulnerable families of children with asthma, still exist. Research is needed to identify and test potentially efficacious interventions to help families overcome these barriers to care and, thus, improve the health of these children. This research tested the efficacy of two such interventions for families of children with persistent asthma. We used a randomized controlled clinical trial to compare the efficacy of home-visiting interventions, home-visiting *plus* problem-solving skills training, and a waitlist control in improving health-related quality of life (HRQOL) for children with persistent asthma. We pursued additional analyses of the data to further understand the role of barriers to care in affecting care processes and outcomes for these children.

    B. Purpose, scope, and methods of the investigation

The **long term goal** of this research was to improve quality of care and health outcomes for vulnerable children with asthma. The **main objective** of the research project was to develop and test culturally and linguistically appropriate brief interventions to reduce barriers to health care for vulnerable children with persistent asthma. We sought to determine whether a culturally and linguistically appropriate problem-solving skills training intervention combined with asthma home visiting improves outcomes for vulnerable children with persistent asthma. We compared a waitlist control (WL), a home-visitor asthma education/care coordination intervention (CC), and a combined intervention (home-visitor asthma education/care coordination *plus* in-home problem-solving skills training; PST). We tested the a priori hypothesis that, compared to WL or CC, PST would improve parent proxy–report of children's health-related quality of life (HRQOL). Secondary outcomes included child self-reported HRQOL, asthma symptoms, and asthma-related utilization. In addition to testing the efficacy of these interventions, we also examined, for the whole sample, the relationships among barriers to care, health care processes, and clinical and HRQOL outcomes.

    C. Nature of the findings

With regard to efficacy, we found, for our primary outcome, a significant (p = 0.05) intervention effect; the PST intervention yielded higher HRQOL scores than WL (83.8 vs 79.8), adjusted mean difference of 4.0 points (95% CI 0.63 to 7.4). No significant difference was observed between CC and WL. For secondary outcomes, nighttime symptoms had a significant time by condition interaction (p = 0.011): PST participants at T2 had 1/3 the odds (OR = 0.32; 95% CI: 0.13 – 0.82) of having > 1 nighttime symptom/week compared to WL. In separate analyses, we also found that that barriers to care were associated with primary care quality even after controlling for access to care, demographics, and asthma severity and that barriers to care were associated with underclassification of asthma severity, which in turn, was related to poorer primary care, a lower likelihood of having a preventive medication, and worse symptoms and HRQOL.

II. Review of the Literature

Asthma, the most common childhood chronic health condition, is associated with significant morbidity and mortality.[1, 2] One reason for asthma's continuing toll is that the health care system itself is not well-suited to deliver high-quality care for chronic health conditions.[3, 4] Despite the best efforts of clinicians, administrators, and others within health care, timely receipt of appropriate, high quality health services is by no means assured.[3, 5-7] Children with asthma, especially those vulnerable to poor health outcomes[8] because of poverty, race/ethnicity, lack of health insurance, parental education or language, are more likely

to be underdiagnosed,[9] to have problems accessing and using care,[10, 11] to receive poorer quality care,[12-14] to have lower satisfaction,[15, 16] and to be hospitalized.[17, 18] These disparities exist despite clear guidelines for optimal asthma care.[19, 20]

A common approach for addressing these barriers in vulnerable communities is paraprofessional home visitors delivering in-home asthma education and care coordination. Despite its intuitive appeal, the evidence for this approach is equivocal. Non-randomized program evaluations – single group pre-post evaluations[21, 22] and even more sophisticated quasi-experimental designs[23] – suggest that such interventions improve outcomes. Randomized trials are less likely to show positive effects.[24]

Seid and colleagues[25, 26] have proposed a conceptual model for understanding how vulnerable children access and navigate the health care system, their health care experiences within the system, and their resultant outcomes. This model can be used to identify *modifiable* factors that can be targeted to improve outcomes for vulnerable children. Given barriers to access, use, and receipt of quality care, interventions that better equip families to interact productively with the health system may improve health outcomes for vulnerable children with asthma.[25, 27, 28] Problem-solving skills training (PST) is a psychoeducational intervention for teaching specific strategies to resolve daily problems. PST can reduce emotional distress in individuals with chronic conditions such as cancer,[29-31] psychiatric disorders such as depression and anxiety disorder,[32, 33] and in families of children with chronic conditions such as cancer[34, 35] or traumatic brain injury.[36] It can also improve adherence to medical regimens in children with chronic health conditions[37] and reduce relapses in outpatients with bipolar disorder.[38] Problem-solving may be useful in helping families identify problem areas, develop new ways of approaching the problem, and implement effective strategies. In the case of vulnerable families of children with asthma, who may have to overcome logistical, educational, attitudinal, and cultural barriers to accessing, using, and receiving quality care,[27] PST could provide families the practical daily skills and strategies to overcome these barriers.

III. Study Design and Methods

A.   Study design

This was a single-site randomized controlled clinical trial with repeated outcome measures (clinicaltrials.gov Identifier: NCT00250588). It was approved by the Institutional Review Boards at Rady Children's Hospital, the RAND Corporation, and Cincinnati Children's Hospital Medical Center.

Interventions

The five-session (45-60 minutes, weekly) CC was based on NHLBI guidelines[39] and the Robert Wood Johnson Foundation's Allies Against Asthma community health worker model[40] and was delivered by two bachelor's level bilingual, bicultural asthma home visitors. The home visitors implemented a structured set of educational interventions, with written materials in English or Spanish, on the following topics: what is asthma, asthma medications and devices, asthma action plan, how to recognize and respond to symptom onset, and how to reduce irritants and allergens in the home. Home visitors referred families, when necessary, to existing health insurance enrollment assistance, smoking cessation, and other community support services. Home visitors communicated with the primary care provider via FAX, giving summaries of interventions, updates on progress, and noting family difficulties and needs (for example, needing equipment, prescriptions, or an (updated) asthma treatment plan).

The PST consisted of CC plus a six-session (45-60 minutes, weekly) problem-solving skills training intervention carried out by a bilingual, bicultural master's level health educator. PST is a generic psychoeducational approach in which problems are normalized and participants are taught to approach problems proactively, define the problem, generate alternative solutions, choose the best solution, implement the solution, and evaluate how well that solution worked. PST, based on D'Zurilla's[41,42] conceptualization and adapted from a manual used in a previous trial of PST in mothers of children with cancer,[43] was aimed at the primary caregiver, although children were encouraged to participate.
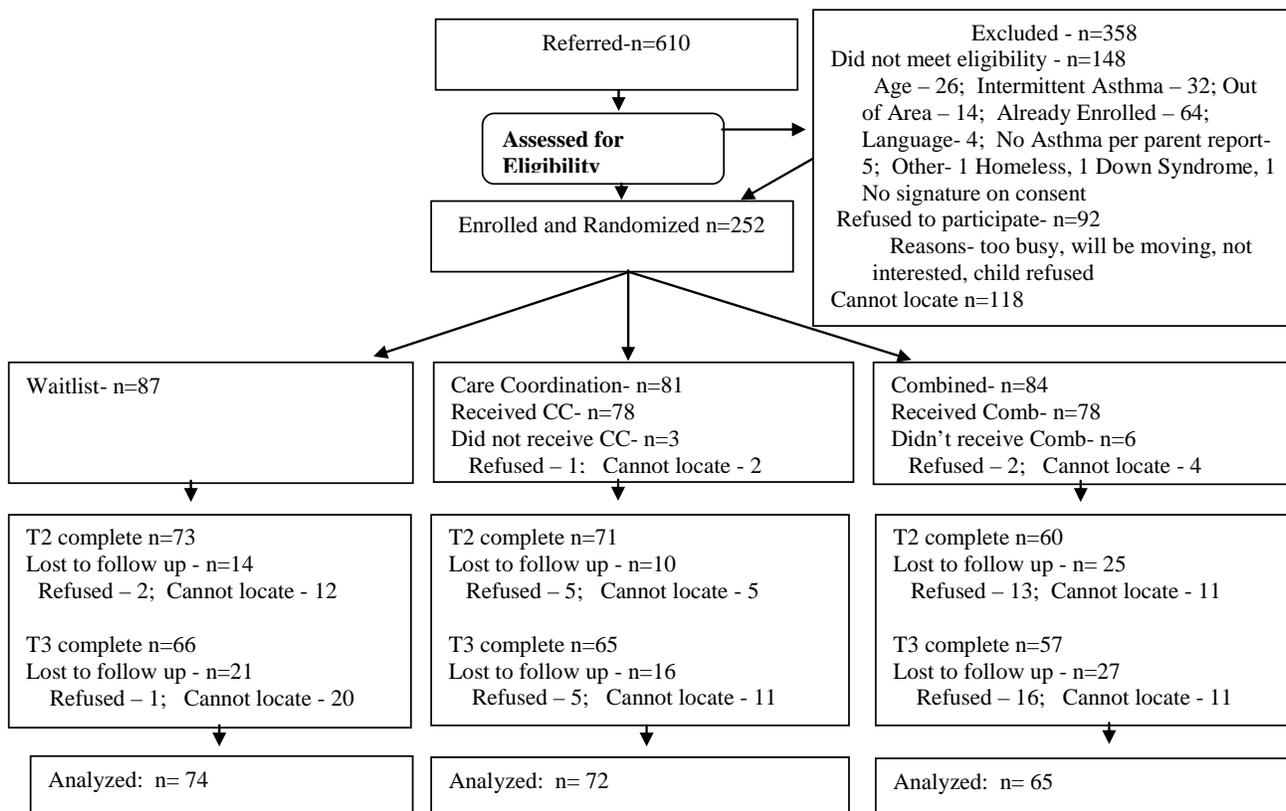
Intervention fidelity

Interventionists received two weeks of training, including didactic instruction, role-playing, and shadowing an experienced interventionist. All interventions were audio-taped. Weekly supervision, using audio-taped sessions, prevented interventionist drift. Interventions were responsive to family needs, but essential intervention behaviors were standardized via training manuals, standard materials, and behavioral checklists denoting specific prescribed intervention behaviors. These checklists were used by the interventionist to structure the intervention. A random 10% of audio-tapes were coded by two project

personnel against the checklists (discrepancies resolved through consensus) to determine the rate at which prescribed behaviors were performed. Materials and checklists are available from the Principal Investigator.

B.   Population studied and sample selection

Families were recruited in San Diego County, California from Federally Qualified Health Centers (FQHCs; n = 212), a commercial HMO (n = 15), school/daycare (n = 11), local asthma initiatives (n = 3), or were self-referred (n = 11). Sampling was based on a convenience sample of patients being cared for at these sites and who were referred by their treating physician. Eligible patients were 2 - 14 years old with a physician diagnosis of persistent asthma (mild, moderate, or severe) and parents who spoke English or Spanish. Patients with a comorbid condition that could affect care or outcomes (e.g., Down Syndrome, other pulmonary disease) were ineligible.

Figure 1: Participant flow

Referred-n=610

Assessed for Eligibility

Enrolled and Randomized n=252

Excluded - n=358
Did not meet eligibility - n=148
    Age – 26; Intermittent Asthma – 32; Out of Area – 14; Already Enrolled – 64; Language- 4; No Asthma per parent report- 5; Other- 1 Homeless, 1 Down Syndrome, 1 No signature on consent
Refused to participate- n=92
    Reasons- too busy, will be moving, not interested, child refused
Cannot locate n=118

Waitlist- n=87

Care Coordination- n=81
Received CC- n=78
Did not receive CC- n=3
    Refused – 1: Cannot locate - 2

Combined- n=84
Received Comb- n=78
Didn't receive Comb- n=6
    Refused – 2; Cannot locate - 4

T2 complete n=73
Lost to follow up - n=14
    Refused – 2; Cannot locate - 12

T3 complete n=66
Lost to follow up - n=21
    Refused – 1; Cannot locate - 20

T2 complete n=71
Lost to follow up - n=10
    Refused – 5; Cannot locate - 5

T3 complete n=65
Lost to follow up - n=16
    Refused – 5; Cannot locate - 11

T2 complete n=60
Lost to follow up - n= 25
    Refused – 13; Cannot locate - 11

T3 complete n=57
Lost to follow up - n=27
    Refused – 16; Cannot locate - 11

Analyzed: n= 74

Analyzed: n= 72

Analyzed: n= 65

Instruments used

Measurement occurred at baseline (T1), post intervention (approximately 3 months after baseline; T2), and at six-month follow-up (approximately 9 months after baseline; T3). Bilingual, bicultural research staff, blinded to intervention group, administered surveys in English or Spanish in participants' homes. When in-person measurement was not possible, the surveys were completed by telephone or by mail. Blinding success was demonstrated by the fact that measurement staff guessed the subject's group correctly at T2 and T3 only 43% of the time – somewhat better than chance.

Primary Outcome: Parent-reported child generic HRQOL was measured by the PedsQL™ 4.0 Generic Core Scales Total Scale Score (PedsQL™), which has been shown to be reliable, valid, and responsive to indicators of clinical change for children with asthma.[44, 45] The PedsQL™ yields a score of 0 to 100 (higher scores are better) and includes parallel child self-report (ages 5-18 years) and parent proxy-report (ages 2-18 years) forms. We measured both self- and proxy-report, although our a priori primary outcome was parent proxy-report.

Secondary Outcome: Asthma symptoms were assessed using the PedsQL™ 3.0 Asthma Module Asthma Symptoms Scale.[46] Higher scores indicate fewer symptoms. Example items include "It is hard to

take a deep breath."; "I feel wheezy."; "My chest hurts or feels tight."; "I cough."; "I get out of breath." Asthma symptom frequency was measured via the number of days and nights with asthma symptoms.[47-49]

Secondary Outcome: Utilization was measured by parent recall of emergency room, inpatient, or urgent doctor's appointments for asthma over the last 6 months (at T1), 3 months (at T2), and 6 months (at T3).

Additional measures:

Financial, Potential, and Realized Access. Financial access was measured by parents report of whether or not their child had health insurance. Potential access was assessed by parent report of whether their child had a regular source of care.[50] Realized access was measured through parents' reports of foregone care[51] ("In the past 12 months, has there been any time when you thought your child should get medical care, but did not?" Response options: Yes/No).

Barriers to Care: The Barriers to Care Questionnaire (BCQ). The BCQ measures parents' reports of experiences or circumstances that may interfere with access to or use of care, with making the most of the clinical encounter, or with adhering to medical instructions. It is feasible, reliable, and valid for use with CSHCN.[28] The BCQ yields a 0-100 score (higher scores are better –fewer barriers) for the Total scale (an overall index) and for the subscales. BCQ subscales include: *Pragmatics* refers to logistical and cost issues that might prevent or delay appropriate utilization. *Skills* are a set of acquired or learned strategies to navigate through, manipulate, or function competently within the health care system. *Expectations* refer to parent expectations of receiving poor quality care. *Marginalization* refers to the internalization and personalization of negative experiences within the health care system. *Knowledge and beliefs* include lay or popular ideas about the nature and treatment of illness, which may differ from those of mainstream allopathic medicine.

Primary Care Experiences: The Parent's Perceptions of Primary Care (P3C). Parents' perceptions of primary care experiences were measured via the P3C, a brief parent report of their experiences with their children's primary care. The P3C is feasible, reliable and valid for describing primary care.[52] The P3C is based on the Institute of Medicine definition of primary care,[53] which is similar to the American Academy of Pediatrics' concept of medical home.[54] Using this definition as a criterion, the P3C was designed to measure six components of care which, when present, constitute high quality primary care experiences. High scores reflect care conforming to this a priori definition. The six components of primary care measured by the P3C are defined as follows. *Longitudinal continuity* is the parent's report of the length of time they have been bringing their children to a regular place or physician. *Access* is the parent's report of timely and convenient access to care for their children. *Communication* is the parent's report of how well the physician listens and explains during their interactions. *Contextual knowledge* is the parent's report that the physician knows his or her values and preferences about medical care issues, clearly understands his or her child's health needs, and knows the child's medical history. *Comprehensiveness* is the parent's report of the extent to which a regular place and/or doctor provides care for acute and chronic problems and preventive services. *Coordination of care* is the parent's report of their physician's knowledge of other visits and visits to specialists, as well as the follow-up of problems through subsequent visits or phone calls.

C.   Statistical techniques employed

Sample size was based on the PedsQL™, which was assumed to be continuous and approximately normally distributed. The repeated measures at T2 and T3 were regarded as a vector of responses with pairwise correlations assumed to be 0.50. Sample size was based on two a priori comparisons of interest: PST vs. CC, and PST vs. WL. A PedsQL™ difference of 4.5 points has been determined to be a minimal clinically important difference.[55] Based on previous literature, we assumed a standard deviation of 12. With 80% power, (alpha=0.05, two-sided), assuming 20% attrition, 107 subjects per group (321 total) were required.[56]

Randomization was blocked randomization, stratified by site of care (FQHC versus other) and disease severity (mild vs. moderate or severe). Prepared randomization lists were created by the statistician and concealed until intervention assignment. A pediatrician with asthma expertise verified eligibility prior to assignment and the project manager carried out the assignment.

Analysis. All analyses were intent-to-treat and carried out according to a pre-established plan using SAS 9.1.3. PedsQL™ scores were analyzed as continuous normal outcomes with mixed effects regression models, which accounts for repeated measures over time for T2 and T3. Since mixed effects models do not require complete data across all time periods, all subjects with data at T2 or T3 were included in the

analyses. The missing data mechanism for mixed effects models is missing at random.[57] For all models, independent variables included baseline measure, time, asthma severity, condition, and condition by time interaction. Analyses were repeated adjusting for child's age, race/ethnicity, language, and mother's education.

Symptom frequency and utilization were analyzed using generalized linear mixed models (GLMM), with appropriate distribution and link functions. All analyses accounted for repeated measures and included the same terms in the model described previously. For daytime symptoms, GLMM was set up as an ordinal regression. Nighttime symptoms is a dichotomous outcome and a logistic model was constructed. Although number of emergency room visits and unscheduled doctor visits were counting outcomes, poor fit precluded attempts to fit a Poisson model. Both variables were dichotomized. Again, a logistic model was utilized. Attempts to analyze hospital visits failed even after dichotomizing due to minimal outcome variability.

IV. Detailed Findings

Participant flow

Of 610 referrals received, 144 (23.6%) could not be located, 122 (20%) were ineligible, and 344 (56.4%) were eligible. Of the eligibles, 252 (73.3%) enrolled and 92 (26.7%) refused. There were no differences between participants and eligible refused in child age or gender, referral source, or severity. Participants (77%) were more likely than eligible refused (50%) to prefer Spanish as the interview language . Participant flow is shown in Figure 1. Dropout rates were 16%, 12%, and 29% at T2 and 24%, 20% and 32% at T3 for WL, CC, and PST respectively. T2 PST dropout rate was greater than CC (X^2(2) = 7.8, p = 0.02). Dropout rates did not differ significantly across condition at T3.

Implementation of intervention

Intervention fidelity (Table 2), as measured by percent of sessions delivered, was 91.6% for CC and 71.8% for PST. The relatively low rate for PST is reflected in the fact that, while most families received at least some care coordination sessions, 23.8% received no problem-solving sessions and 52.4% received all PST sessions. Treatment fidelity, in terms of the percent of prescribed intervention behaviors performed, was 98.4% for CC and 97.5% for PST.

Table 1: Intervention Fidelity

Variable	Care Coordination	Problem-Solving
Behavioral fidelity	744/756=98.4%	1121/1150=97.5%
completed all sessions	71/81=87.7%	44/84=52.4%
average % sessions completed	371/81*5=91.6%	663/84*11=71.8%
zero problem-solving sessions	-	20/84=23.8%
zero care coordination sessions	3/81=3.7%	7/84=8.3%

Recruitment

Participants were recruited between June 11, 2004 and January 15, 2007. The final T3 follow up was completed on October 16, 2007.

Baseline data

Most participants were Hispanic (83.3%), 56.3% spoke only Spanish, and 72.6% of mothers (73.4% of fathers) had not completed high school. There were no demographic differences across conditions (Table 2).

Numbers analyzed

Subjects with at least one follow-up measure were included in the analyses. Consequently, for most analyses, sample sizes were: 74 (WL), 72 (CC) and 65 (PST). For the PedsQL™, sample sizes were: 59 (WL), 54 (CC) and 52 (PST) for both child and parent.

Outcomes and estimation

Tables 3 and 4 provide descriptive statistics and results from the mixed effects and GLMM models. The condition main effect for the primary outcome, parent proxy-report PedsQL™, was statistically significant (p=.05) (Table 3). A priori hypotheses indicated two comparisons: PST vs WL, and CC vs WL. Applying a Bonferroni adjustment, PST was significantly higher than WL (83.8 vs 79.8), with an adjusted mean difference of 4.0 (95% CI 0.63 to 7.4). CC and WL did not differ.

For secondary outcomes, we observed a significant time by condition interaction for night time symptoms (p=.011) (Table 7). Stratifying by time, we found a significant condition effect at T2. PST participants had 1/3 the odds (OR=.33; 95% CI: .13 - .82) at T2 of having more than one nighttime symptom per week compared to WL. No T3 differences existed (p=.20).

Table 2: Demographics of Participants

Variable % (n)	Overall (n=252)	Waitlist (n=87)	Care Coordination (n=81)	Problem-Solving (n=84)	P value
Age mean (SD) ttest	7.37 (3.07)	7.26 (3.02)	7.47 (3.13)	7.37 (3.10)	0.911
Gender					0.122
Male	61.1 (154)	60.9 (53)	69.1 (56)	53.6 (45)	
Ethnicity					0..668
Hispanic	83.3 (210)	80.5 (70)	86.4 (70)	83.3 (70)	
non-Hispanic White	4.4 (11)	5.7 (5)	2.5 (2)	4.8 (4)	
non-Hispanic Black	8.3 (21)	10.3 (9)	4.9 (4)	9.5 (8)	
Other	4.0 (10)	3.4 (3)	6.1 (5)	2.4 (2)	
Language Preference					0.260
Pref Eng Bilingual	7.9 (20)	5.7 (5)	13.6 (11)	4.8 (4)	
Pref Spa Bilingual	20.6 (52)	20.7 (18)	23.5 (19)	17.9 (15)	
Pref Eng Not Bilingual	15.1 (38)	18.4 (16)	12.3 (10)	14.3 (12)	
Pref Span Not Bilingual	56.3 (142)	55.2 (48)	50.6 (41)	63.1 (53)	
Mother's education					0.411
\< 6th grade	25.8 (65)	23.3 (20)	26.6 (21)	28.6 (24)	
7th – 9th grade	23.0 (58)	18.6 (16)	26.3 (21)	25.0 (21)	
10th – 12th grade	23.8 (60)	25.6 (22)	17.5 (14)	28.6 (24)	
High School graduate	8.3 (21)	9.3 (8)	10.0 (8)	6.0 (5)	
Some college	13.1 (33)	17.4 (15)	11.3 (9)	10.7 (9)	
College graduate	4.8 (12)	5.8 (5)	7.5 (6)	1.2 (1)	
Grad/Prof Degree	0.4 (1)	0.0 (0)	1.3 (1)	0.0 (0)	
Father's Education					0.578
\< 6th grade	27.5 (57)	22.7 (15)	27.5 (19)	31.9 (23)	
7th – 9th grade	25.1 (52)	25.8 (17)	24.6 (17)	25.0 (18)	
10th – 12th grade	20.8 (43)	19.7 (13)	20.3 (14)	22.2 (16)	
High School graduate	8.2 (17)	12.1 (8)	8.7 (6)	4.2 (3)	
Some college	11.1 (23)	7.6 (5)	11.6 (8)	13.9 (10)	
College graduate	6.8 (14)	10.6 (7)	7.2 (5)	2.8 (2)	
Grad/Prof Degree	0.5 (1)	1.5 (1)	0.0 (0)	0.0 (0)	
Severity On intake					0.566
Mild	27.0 (68)	25.3 (22)	28.4 (23)	27.4 (23)	
Moderate	40.5 (102)	43.7 (38)	33.3 (27)	44.0 (38)	
Severe	32.5 (82)	31.0 (27)	38.3 (31)	28.6 (23)	

No differences were found for emergency room or unscheduled office visits. The odds ratios consistently showed PST had about half the odds of one or more visits versus WL, but sample sizes were too small to detect a significant difference. All results were nearly identical after adjusting for child's age, race/ethnicity, Spanish language, and mother's education.

Additional data analysis suggests that barriers to care explain variance in primary care quality over and above that explained by sociodemographics or traditional indicators of financial, potential, and realized access.[58]

V. Discussion and Interpretation of Findings
   A. Conclusions to be drawn from findings (with reference to data supporting each).

This randomized controlled clinical trial showed that problem-solving skills training combined with home visiting education/care coordination can improve child HRQOL in a highly vulnerable sample of children with persistent asthma. The PST vs. WL difference in PedsQL™ scores (the a priori primary outcome) was statistically significant and approached the clinically important difference of 4.5 points.[55] No effect were found for child self-reported HRQOL, the PedsQL™ Asthma Symptoms, daytime symptoms, or utilization, though there was an effect at the 3-month follow-up for nighttime symptoms.

Table 3: PedsQL Parent Proxy-Report and Child Self-Report Total and Asthma Scales: Comparisons Among the Three Conditions Using Mixed Effects Models Adjusting for the Baseline Level of Outcome and Baseline Severity				
	Differences in Adjusted Means (95% CI)		P-value of Effects	
	CC - WL	PST - WL	Time by Condition	Condition
PedsQL Scale				
Total Scale				
Proxy-Report	3.1 (-.21, 6.4)	4.0 (.63, 7.4)	.85 (.86)[A]	.05 (.047)
Self-Report	1.9 (-2.8, 6.6)	1.6 (-3.1, 6.4)	.54 (.57)	.69 (.75)
Asthma Scale				
Proxy-Report	2.9 (-3.1, 7.6)	1.4 (-4.8, 7.5)	.82 (.85)	.64 (.84)
Self-Report	3.7 (-1.9, 9.2)	-2.6 (-8.2, 3.0)	.77 (.80)	.10 (.23)
[A] P-value based on additional adjustment for age, race/ethnicity, Spanish language and mother's education. CC: Care Coordination WL: Wait List PST: Problem Solving Skills Training				

This contribution is important for two reasons. First, as a psychoeducational intervention, PST has often been targeted at areas traditionally considered within the realm of health psychology, such as adherence behaviors, emotional distress, and emotional or behavioral disorders. This study suggests a broader sphere of potential targets for such an intervention. A growing literature on managing chronic illness stresses the importance of an informed, activated patient[59] and the need for joint problem solving.[60] Our findings support the use of PST as a key component of self-management of chronic illness in children.

Second, testing the efficacy of interventions to improve families' abilities to access and navigate the health care system represents a shift in research on health care disparities from description to intervention. The existence of disparities is well known.[61-64] There is less research, however, on interventions to ameliorate these disparities.[65] In part, this may be due to the way disparities have been conceptualized in terms of vulnerability factors (race/ethnicity, SES, language, poverty, insurance). While knowledge of *which* groups are at greater risk for poor care is important, understanding *why* and *how* this may occur[27] is necessary for developing and implementing practice and policy interventions to reduce such disparities. Seid[25, 28] and Sobo[27] posit that 'barriers to care' are key to understanding the *why* and *how* – the sociobehavioral processes behind these indicators. A recent review by Cabana and colleagues[65] cited multiple factors associated with disparities in asthma care, including "structural barriers (*eg*, ability to access the health-care system), process-of-care barriers (*eg*, ability to navigate the health-care system), and process-of-care barriers at the interpersonal level (*eg*, ability to work effectively with a health-care provider)" as well as "a dearth of evidence regarding the most effective and efficient methods to address these factors, due to the lack of controlled evaluations of interventions" (p. 815S). The current trial responds to these needs and suggests that an intervention combining education, care coordination, and problem-solving skills may be a promising way to reduce asthma disparities.

Our study failed to find an effect for CC. Our enrollment, and therefore power, was lower than anticipated, so it is possible that failing to reject the null hypothesis (equivalence between CC and WL) is a type II error. However, the 3-point difference in PedsQL™ scores between these two conditions is not at the level of clinical significance: Enrolling more subjects could have resulted in a statistically, but not clinically significant result. As suggested by a recent review of extant asthma programs,[24] evaluations of increasing methodological rigor tend to be equivocal in support of the efficacy of these types of programs. Our findings echo this, and are explained, in part, by improvement in the WL condition. Our data suggest that home

visiting education and care coordination programs, without a problem-solving component, are no more efficacious than regular care. The data also suggest, however, that adding (or enhancing) problem-solving skills training to existing programs is likely to boost efficacy.

   B. Explanation of study limitations

   This study has limitations. First, the exact mechanisms by which PST affected HRQOL are not clear. That is, we do not know exactly *how* the intervention had its effect on child HRQOL. We did not find differences across the intervention conditions for primary care quality, nor the rate of prescriptions for inhaled corticosteroids. Other aspects of care might have changed or problem-solving may have affected other areas such as adherence. Further research will be needed to understand the exact mechanism of effect. Second, there was substantial dropout, particularly from the PST condition. Subjects who dropped out suggested to research staff that there were too many intervention sessions. Effectiveness of this intervention – how well it works in practice - might be lower than its efficacy – how well it works in controlled conditions. Research is needed to develop and test a brief intervention. The problem-solving component of PST took place after the care-coordination component, so there may have been intervention burn-out even prior to the problem-solving component. Third, generalizability is an issue. Participants were referred by their health care providers and may therefore be systematically different from families with similar sociodemographics who have been unable to access health care. The greater percentage of Hispanics in the study reflects county demographics, as well as the fact that subjects were recruited predominantly from FQHCs. We do not have information on subjects referred but not located and cannot determine whether these were systematically different from eligibles.

Table 4: Comparisons Among the Three Conditions Using Generalized Linear Mixed Models Adjusting for the Baseline Level of Outcome and Baseline Severity					
		Odds Ratios (95% CI)		P-value of Effects	
	WL	CC	PST	Time by Condition	Condition
Outcomes					
Day Time Symptoms[A]	1.0	.73 (.39, 1.37)	.90 (.48, 1.71)	.32 (.32) [B]	.55 (.75)
Night Time Symptoms					
Post-Int	1.0	.83 (.38, 1.81)	.33 (.13, .82)	.011 (.0067)	---
6-months	1.0	.99 (.38, 2.54)	1.95 (.78, 4.83)		---
Visits to Emergency Room	1.0	1.22 (.53, 2.83)	.49 (.18, 1.38)	.85 (.82)	.21 (.17)
Unscheduled Office Visits	1.0	1.03 (.56, 1.91)	.59 (.30, 1.14)	.94 (.92)	.19 (.17)
[A] Odds ratios for day time symptoms are interpreted as an increasing frequency of symptoms. [B] P-value based on additional adjustment for age, race/ethnicity, Spanish language and mother's education. CC: Care Coordination WL: Wait List PST: Problem Solving Skills Training					

   C. Comparison with findings of other studies

   Other studies have shown effects of PST on parental distress in families of children with cancer[34, 35] and traumatic brain injury[36] and on improving adherence in children with cystic fibrosis.[37] This study, however, is the first we are aware of to show the efficacy of PST on issues regarding accessing and navigating the health care system.

   D. Possible application of findings to actual MCH health care delivery situations and policy
      (including recommendations when appropriate)

   This study has several possible applications to actual MCH health care delivery and policy. First, the findings suggests that, in order to have a real effect on child HRQOL, community asthma programs should include a problem-solving skills component to their intervention. Those programs that already include problem-solving skills, should enhancing this aspect of their program. Second, the study suggests that pediatricians treating patients with asthma should consider ways to help their patients improve their problem-solving skills. Third, the study suggests that researchers studying disparities could turn their

attention from documenting disparities to developing and implementing interventions to help patients and families overcome these disparities.

      E. Suggestions for further research

   Further research is required. Because we were not able to determine the mechanism of action, research is needed to establish how the intervention achieved its gains in child HRQOL. If we could pinpoint this mechanism, it would enable a clearer focus on those elements of the intervention that most directly affected that mechanism. Given the high dropout rate, research is needed to develop and test brief versions of the intervention. Finally, it is necessary to determine the extent to which this intervention or those like it are applicable to other MCH populations beyond that studied here.

     VI. List of products (peer reviewed articles, books, chapters in books, master and doctoral dissertations, conference presentations, etc.).

Published and In Press
Seid, M (2008). Barriers to care and primary care for vulnerable children with asthma. Pediatrics, 122(5), 994-1002.
Seid, M., Limbers, CA, Driscoll, K, Opipari-Arrigan, L.A., Reyes Gelhard, L, & Varni, J.W., (in press). Reliability, validity, and responsiveness of the Pediatric Quality of Life Inventory™ (PedsQL™) Generic Core Scales and Asthma Symptoms Scale in vulnerable children with asthma Journal of Asthma.
Under Review
Seid, M., Opipari-Arrigan, L., Reyes Gelhard, L, Varni, J.W., & Driscoll, K (revision under review). Beyond access: Parents' reports of barriers to care are responsive to change in realized access to care and predict primary care, quality of life. Ambulatory Pediatrics.
Seid, M., Varni, J.W., Gidwani, P., Reyes Gelhard, L., & Slymen, D. (under review). Problem-solving skills training plus asthma home visits improved child health-related quality of life in vulnerable families of children with asthma: Report of a randomized trial. Archives of Pediatrics & Adolescent Medicine.
Seid, M., & Opipari-Arrigan, L (under review). Underclassification of asthma severity in vulnerable children: Relationship to barriers to care, primary care quality, asthma symptoms, and health related quality of life. Journal of Pediatrics.
In preparation
Opipari-Arrigan, L, Varni, J.W., & Seid, M (in preparation). Barriers to care predict health-related quality of life for vulnerable children with asthma.

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