Published in final edited form as:

Acad Pediatr. 2013 ; 13(5): 408–420. doi:10.1016/j.acap.2013.04.015.

The Role of Lay Health Workers in Pediatric Chronic Disease: A Systematic Review

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Abstract

Background—Children with chronic diseases represent a high-cost and resource-intensive population of children. With continued gaps in chronic disease management and persistent fragmentation in the health care system, stakeholders are seeking new strategies to address the needs of these children.

Objective—To systematically assess the effectiveness of lay health worker interventions in improving health care utilization, symptom management, and family psychosocial outcomes for children with chronic conditions.

Data Source—PubMed, PsycINFO, and Web of Science (January 1961- February 2013).

Study Eligibility Criteria, Participants, and Interventions—We developed a strategy to search citations to identify relevant articles. Search terms included randomized controlled trial (RCT), lay worker, parent mentor, peer mentor, peer educator, community health workers, community health aids, patient advocate, patient facilitator, patient liaison, promotoras (es), care ambassadors, patient navigator, and non-professional. Additional studies were identified by searching the reference lists of retrieved articles and contacting clinical experts. RCTs of lay health worker interventions for children with chronic conditions were included. Studies were restricted to those concentrated on children 0–18 years of age with chronic illnesses.

Study Appraisal and Synthesis Methods—Abstracts were independently screened by 2 reviewers. Articles with relevant abstracts underwent full text review and were evaluated for inclusion criteria. A structured tool was used to abstract data from selected articles. Due to heterogeneous interventions and outcomes, we did not conduct a meta-analysis.

Results—The search yielded 736 unique articles, of which 17 met inclusion criteria. All interventions focused on specific conditions: asthma, type I diabetes, obesity, and failure to thrive.

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The authors have no conflicts of interest.

Interventions were heterogeneous in frequency, mode, and duration of interactions between lay health workers and subjects. Several interventions were multi-faceted, including both one-on-one and group interactions. Improved outcomes most commonly reported were reduced urgent care use, decreases in symptoms, fewer missed work and school days, and increased parental quality of life. One study demonstrated that lay health worker interventions were cost-effective.

Conclusions—Lay health workers interventions in children with chronic conditions may lead to modest improvements in urgent care use, symptoms, and parental psychosocial outcomes. Such interventions may also be cost-effective. Future research should focus on interventions targeted toward other chronic conditions such as sickle cell disease or cystic fibrosis and medically complex children whose conditions are non-categorical.

MeSH Keywords

COMMUNITY HEALTH WORKERS; CHRONIC DISEASE; ASTHMA; OBESITY; DIABETES MELLITUS TYPE 1; FAILURE TO THRIVE; INFANT; NEWBORN; INFANT; CHILD; PRESCHOOL; CHILD; ADOLESCENT

INTRODUCTION

Children with chronic diseases represent a high-cost and resource-intensive group of children. The prevalence of chronic conditions in children has quadrupled in the past four decades, now comprising 12–16% of the pediatric population.^{1–4} The impact of pediatric chronic diseases on child health-related cost is enormous with respect to health care utilization, school and work absenteeism, and family functioning.^{3,5–8} Minority and low-income children with chronic diseases are particularly vulnerable as they experience inequities in access to care, utilization, unmet medical needs, and patient satisfaction.^{9,10} There is mounting concern that the current model of pediatric primary care is not equipped to support the provision of high quality care for chronically ill children.^{11–13}

With continued gaps in chronic disease management and persistent fragmentation in the health care system, policy makers, clinicians, and other stakeholders are seeking new strategies to promote partnership models of care in which patients take a more active role in their own management.^{14–16} Increasing evidence suggests that patients with chronic diseases may potentially benefit from individualized assistance to navigate the health care system.^{15,17–19} Lay health worker interventions (e.g., community health workers, patient navigators) for chronic disease have emerged as innovative models of individualized care. Lay health workers are individuals who perform functions related to health care delivery.²⁰ Since they have no formal or paraprofessional training, they are typically provided with informal job-related training. They may work in paid positions or as volunteers. The term lay health workers is broad in scope and could include community health workers, village health workers, and cancer supporters.

Although heterogeneous in specific content and delivery, lay health workers programs provide flexible and tailored one-on-one guidance to individuals. Previous studies among adults indicate that such interventions improve diabetes knowledge, hypertension management, timeliness of cancer care, health care utilization, and patient satisfaction.^{21–25}

While numerous individual studies have assessed lay health worker interventions in pediatrics, there is little consensus about the effectiveness of such programs for children with chronic conditions.¹⁸ Previous reviews of lay health worker interventions have been adult-focused, disease specific, or limited to outcomes in preventive care.^{15,18,20,26} For example, a prior review of lay health worker interventions among children narrowly focused on asthma with heavy emphasis on environmental controls. Evidence for the effectiveness of

these interventions among a broad spectrum of children with chronic conditions is needed, particularly with respect to health care use, symptom management, and family psychosocial outcomes. The objectives of this study were to summarize the available studies on lay health worker interventions, determine the efficacy of such programs for children with chronic conditions, and identify gaps in current knowledge regarding efficacy.

METHODS

Eligibility Criteria

We searched for randomized controlled trials (RCT) of interventions that were delivered by lay health workers to families of children 18 years of age or less with chronic health conditions. Lay health workers were identified as individuals who were specifically trained to deliver a health-related intervention but had no formal professional or paraprofessional training in health care. A lay health worker could not be a family member trained to provide care or support exclusively for members of their family. Since by definition, lay health workers deliver one-on-one guidance, interventions had to have one-on-one interactions between the lay health worker and family. All RCTs were included, regardless of type. We excluded studies that focused on adults, studies evaluating pediatric to adult transition, non-empirical work such as case studies or commentaries, and unpublished literature. From included studies, we extracted data on characteristics, theoretical frameworks, training, intervention types, outcomes, and cost-effectiveness.

Information Sources

We conducted a systematic search of 3 major electronic databases comprising medical and social science studies (PubMed, PsycINFO, and Web of Knowledge) for titles and abstracts relevant to our research question (January 1961-February 2013). We additionally hand searched bibliographies from retrieved articles and from published reviews. Local experts in behavioral interventions were consulted for additional studies. We did not contact study authors for further details with respect to methodology or reporting of results.

Search Terms

Based on our inclusion/exclusion criteria, we started with Medical Subject Headings (MESH) and keyword search terms: *lay worker*, *parent mentor*, *peer mentor*, *community health worker*, and *promotoras(es)*. We added more terms by identifying keywords associated with these searches or within articles found with these searches. The final compiled list of search terms consisted of the following keywords or keyword combinations: *lay worker*, *parent mentor*, *peer mentor*, *peer educator*, *community health workers*, *community health aids*, *patient advocate*, *patient facilitator*, *patient liaison*, *promotoras(es)*, *care ambassadors*, *patient navigator*, and *non-professional*.

Study Selection

Publications were screened and selected in a two-step process in order to minimize bias. In the first phase, publications were screened for inclusion independently by 2 investigators (J.R. and A.R.) using titles of articles and, if available, the abstracts derived from the search. The inclusion criteria were RCTs of lay health worker interventions among children with chronic conditions. In the second phase, full text articles that met inclusion criteria were retrieved and independently reviewed by J.R. and A.R. The investigators met regularly to discuss the design and validity of the studies to determine if they met inclusion criteria. Any disagreements were resolved by consensus between investigators.

Data Collection Process

We developed a data extraction document based on the Cochrane Consumers and Communication Review Group's data extraction template²⁷, pilot tested it on ten included studies, and refined it accordingly. J.R. and A.R. independently collected the following data elements from the included studies: design, trial inclusion and exclusion criteria, condition type, population characteristics, setting, theoretical framework, lay health worker training, and intervention type (including duration and frequency).

Assessment of Risk of Bias of Included Studies

The methodological risk of bias of included studies was assessed in accordance with the Cochrane Handbook and the guidelines of the Cochrane Consumers and Communication Review Group²⁸, which recommends the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; and other sources of bias. J.R. and A.R. independently assessed the risk of bias of all included studies, with any disagreements resolved by discussion and consensus.

Summary Measures

Given that there are no standard outcome measures for lay health worker interventions, we did not pre-specify or place limitations on the outcomes examined. We used all outcomes for each study. To minimize bias, we only report results from pre-specified analyses and do not include findings of post hoc analyses.

RESULTS

Results of the Search

The literature review yielded 736 unique articles, of which 27 articles met criteria for initial review (Figure 1). After abstract review, 10 of the 27 studies were excluded because they did not meet inclusion criteria: 8 articles were eliminated due to non-randomized design and 2 were eliminated because the study design did not include one-on-one interaction with the lay health workers. The final group of 17 studies comprised four specific pediatric chronic conditions: asthma, type I diabetes, obesity, and failure to thrive (FTT). The heterogeneity of interventions and outcomes precluded us from conducting any meta-analysis.

Quality of Studies

None of the studies scored low risk of bias in all of the seven items assessed (Table 1). Six studies were rated high risk in at least one category of risk of bias. These articles were rated low risk or unclear risk in all other categories and were therefore deemed appropriate to include in the review. However, the results of included studies are stratified according to whether they rate as high risk in any categories or not. Certain quality limitations were common in most articles. Three-quarters of the articles did not adequately describe the allocation concealment process. Due to the design of the interventions, which required the lay health workers to have face-to-face contact with the subjects, it was impossible to blind the study participants and personnel. Of all the articles, 8 stated that the outcome assessment was blinded; 2 stated that the outcome assessment was not blinded; and the rest of the articles made no statement regarding blinding of the outcome assessment.

Study Characteristics

Theoretical frameworks for lay health worker interventions documented in 10 of 17 studies^{29–38} included social cognitive theory, self-efficacy theory, and social support theory.

All studies were two- or three- arm RCTs conducted in urban areas (Table 2), and 3 of the 17 studies were multi-center trials.^{34,36,37} The included studies involved 3,806 children 0–18 years old, with the majority of the study populations having a mean age of 5–8 years, and the total study size ranging from 46 to 937 children. The subjects were followed between 3 and 24 months post intervention. Most studies targeted minority populations of low socioeconomic status. Subjects were recruited from schools, outpatient clinics, and emergency departments (ED).

Lay Health Worker Training Characteristics

In most studies, lay health workers were chosen based on social congruence with the study population, based on race/ethnicity, socioeconomic status, or having a child with the same chronic condition. All of the lay health workers received training prior to beginning the study intervention, although 7 studies^{29,31–34,39,40} did not describe training details (Table 3). Six studies^{30,35,41–44} reported oversight by trained professionals or use of protocols to maintain the quality, accuracy, and consistency of the lay health worker interventions.

Interventions

Interventions consisted of lay health worker-family interactions through home visits, phone calls, or emails (Table 3). The services provided by lay health workers varied across studies. The lay health workers in the 11 studies of asthma primarily focused on education about environmental trigger reduction, provision of engineering controls (e.g., air filters, mattress encasements), asthma action plans, medication management, and increasing parental recognition of symptoms. Two asthma interventions involved monthly group meetings in the community.^{35, 42} Of the four studies addressing type I diabetes care, two focused on peer parental support and education,^{36,37} and two studies involved clinic-based care ambassadors who made efforts to improve clinic attendance and follow-up visits to clinic by phone or letters.^{40,45} The one study on children with failure to thrive (FTT) focused on providing emotional support and modeling healthy parent-child behavior.³⁸ The single study on children with high risk body mass index (BMI) centered primarily on nutritional education.⁴⁴ The frequency of interactions between the lay health workers and the subjects varied among studies and was inconsistently reported. Most of the studies did not report the duration of individual encounters.

Study Findings

Results were stratified according to the following categories: studies that rated low risk or unclear risk in all risk of bias elements and studies that had any element rated as high risk. Given the heterogeneity of outcomes assessed and analyses performed, standardized measures of intervention effect could not be reported across the different studies. We present the most informative measures of effect and statistical confidence available from the published studies (Table 4).

Asthma (low or unclear risk in all categories)—Of the 7 studies that rated low or unclear risk in all categories,^{29,31,33,35,39,41,42} 4 reported decreased asthma symptoms in the intervention group versus control,^{29,31,35,42} and 3 reported no significant differences between the groups (Table 4).^{33,39,41} The study by Flores et al. showed a decrease in rapid breathing episodes per month (57.3 to 41.5) in the intervention but not control group.⁴² This study also demonstrated significant reductions in asthma exacerbations per year (2.9 to 1.8) in the intervention but not control group. The study by Krieger et al. (2009) reported an increase in symptom-free days by 24.4 days/year in the intervention group.²⁹ Two studies reported decreased activity limitation in the intervention group compared to control group.^{33,35} Two of the studies reported decreased use of urgent health services (i.e., ED or

clinic visits),^{33,42} and of the remaining five, 3 studies reported no significant differences in urgent health services use after the intervention,^{29,39,41} and 2 did not include urgent care use as an outcome.^{31,35}

Three studies assessed the impact of lay health worker interventions on school and work attendance.^{29,33,42} In the study by Flores et al., the mean number of school days missed by the child in the past month decreased by 2.9 days.⁴² The mean number of work days missed by the parent decreased by 2.6 days. The remaining two studies assessing school and work days did not show significant differences between intervention and control groups.^{29,33}

Five of the seven studies assessed psychosocial or behavior outcomes among caregivers.^{29, 33,35,41,42} Four studies reported improvement in at least one measurable or observable outcome.^{29,33,35,42} Improved outcomes included caregiver quality of life and caregiver depressive symptoms. The study by Bonner et al. reported a 41% increase in participant self-efficacy for managing asthma versus only a 9% increase in the control group.³⁵

Asthma (high risk of bias in at least 1 category)—Of the 4 studies that rated high risk in at least one risk of bias element,^{30,32,34,43} 3 reported decreased asthma symptoms in the intervention group versus control group,^{30,32,34} and 1 study did not assess asthma symptoms.⁴³ Parker et al. demonstrated that, over 12 months, the proportion of the intervention group that needed unscheduled clinic visits decreased by 6%, whereas the control group's unscheduled visits increased by 15%.³⁰ In the study by Morgan et al., there were significant reductions in the disruption of caretakers' plans and school days missed by the children in the intervention group.³⁴ One of 2 studies assessing psychosocial or behavior outcomes among caregivers showed significant findings.^{30,43} Parker et al. demonstrated a decrease in depressive symptoms in the intervention group relative to the control group.³⁰

Type I Diabetes—Of the two studies assessing parental psychosocial outcomes,^{36,37} the study with low or unclear risk of bias in all categories showed no differences in parental concern, worry, confidence, or diabetes impact on family.³⁷ The study which rated high risk of bias in one category showed that fathers increased their confidence related to managing their child's diabetes.³⁶

The two studies assessing clinic outcomes rated low or unclear risk in all risk of bias elements.^{40,45} The studies by Laffel et al. and Svoren et al. measured severe hypoglycemic events, glycemic control, outpatient clinic visits, and emergency care visits and hospitalizations.^{40,45} Both of these studies reported improved glycemic control in the intervention groups. In addition, both reported increased outpatient clinic attendance and a decrease in hospitalization and ED visits for the intervention group. In the study by Laffel et al., appointment attendance in the diabetes clinic improved with a mean of 7.1 visits/ 24 months for the intervention group compared to 5.2 visits/24 months for the control group.

Obesity—The study by Resnick et al. (high risk in one category) reported a modest reduction of children's BMI percentile. The mean BMI percentile decreased from 94.1 to 90.6 at the end of the 12 month intervention for all children (intervention and control).⁴⁴ There were no differences in BMI reductions between groups.

Failure to Thrive—The lay health worker intervention in the study by Black et al. (low or unclear risk in all categories) resulted in improved growth parameters for children with FTT regardless of intervention status.³⁸

Long-Term Intervention Effects

Two studies related to asthma assessed the sustainability of intervention outcomes. In the study by Krieger et al. (low or unclear risk of bias in all categories), the sustainability of the intervention outcome was assessed 6 months after exit from the intervention group.³³ Improvements in caregiver quality of life, urgent care use, and days with activity limitation were all sustained. The control group was not followed since members of this group crossed over and received the intervention. In the study by Morgan et al. (high risk of bias in 1 category) sustained intervention effects (relative to control) were observed 12 months after exit for caretaker nighttime waking, missed school days, and number of days with symptoms.³⁴

Cost-Effectiveness and Cost Savings

Two studies (both low or unclear risk of bias in all categories) examined cost-effectiveness or cost savings of lay health worker interventions. In the study by Flores et al.,⁴² the average monthly cost of the intervention per patient was \$60.42. The intervention group experienced savings of \$361.48 for hospitalizations and \$50.33 for ED encounters. The mean reduction in asthma exacerbation days was 1.26 days for the intervention group and 0.78 for the control group. The incremental cost-effectiveness ratio for the intervention group was -\$597.10 per asthma exacerbation-free day gained, indicating a total cost savings for the intervention group. In the study by Krieger et al. (2005), the estimated marginal cost of the high-intensity intervention relative to the low-intensity intervention was \$1124 per child.³³ The savings in urgent care costs (ED visits, hospitalization, and unscheduled clinic visits) during a 2-month period was calculated to range from \$57 to \$80 per child.

DISCUSSION

The evidence for lay health worker interventions improving the care of children with chronic conditions is generally positive according to this review. Benefits of interventions included reduced urgent health care use, decreased symptoms, improved child health status, fewer missed parental work days, fewer missed child school days, improved parental quality of life, and increased self-efficacy. However, these findings were not consistent across all studies. Two studies demonstrated that intervention effects may be sustained long after the intervention ends. Additional studies indicated that lay health worker interventions may offer cost savings. Current data is limited to outcomes among a small number of specific diseases. In our review, the majority of interventions were conducted in asthma with far fewer in diabetes, obesity, and failure to thrive. Overall, the current evidence suggests that lay health worker interventions may provide an important strategy for improving care and therefore warrant further study.

This work adds to the findings of previous reviews of lay health worker interventions.^{15, 18, 46} A review by Foster et al. assessed the effectiveness of lay-led self management programs for adults with chronic conditions.¹⁵ This review included 17 trials involving 7442 participants. It concluded that lay health worker interventions led to modest, short-term improvements in patients' confidence to manage their condition and perceptions of their own health without altering health care utilization or quality of life. A review by Postma et al. specifically assessed the effectiveness of community health worker interventions for children with asthma.¹⁸ Seven studies with 2,316 participants were examined. The review found positive outcomes associated with lay health worker interventions, including decreased asthma symptoms, day-time activity limitations, and urgent care use. Six of the studies in Postma et al.'s review were among the 11 included in our review. A most recent review conducted by the Agency for Healthcare Research and

Quality on adults and children concluded that evidence of the effectiveness of lay health worker interventions is mixed.²⁶

The development of innovative and effective care delivery mechanisms for children with chronic conditions has evolved as a central priority in redefining pediatric practice. Various models of care (e.g., medical homes, comprehensive hospital-based care programs) have been implemented with limited evidence and variable results.^{47–50} In adult care, newer lay health worker interventions have provided insights on how to facilitate timely, high quality care for those with chronic conditions. Most recently, patient navigation has emerged as an innovative care model with the principal function of eliminating barriers to timely delivery of services for individual patients across the health care continuum.^{24,51} While patient navigation includes components grounded in self-efficacy and social support theories similar to lay health worker interventions, it also incorporates practical assistance to achieve desired outcomes. It has its conceptual and theoretical roots in cancer care where it was developed in order to support and guide adults with abnormal cancer screening or a new cancer diagnosis.²⁵ Patient navigators are non-health workers who target at-risk populations such as racial/ethnic minorities and those from low-income populations for delays in care.^{17,52,53} Positive outcomes associated with patient navigation have included timeliness of diagnosis, time to initiation of primary therapy, patient satisfaction, quality of life, and cost-effectiveness.^{25,54–56} Patient navigation may represent a new model for lay health worker intervention for children in the future.

There were several strengths to this review. These included a focus on children with chronic conditions, inclusion of conditions other than asthma, and incorporation of more current studies. The inclusive search strategy and rigorous evaluation of risk of bias have resulted in a comprehensive and critical assessment of the current state of the science for lay health worker interventions. However, limitations to this review also merit discussion. While the individual studies assessed a diverse set of outcomes, they did little in providing a theoretical basis for improvements. Only 10 of the 17 studies cited specific conceptual models that informed the interventions. Of the studies that did use conceptual models, few operationalized theoretical concepts in such a way that the mediators of behavioral change could be identified. For example, if an intervention resulted in improved quality of life, it could not be determined which element of the intervention led to the change. Therefore it was not possible to summarize the individual elements of the causal pathways that led to improvements. As more lay health worker or patient navigation interventions are developed, more attention must be directed towards the operationalization of the theoretical models underpinning these interventions and analysis of which elements lead to improvements. Only two studies in this review examined costs. Though both studies documented cost-savings, they did not rigorously assess cost-effectiveness as recommended for such studies.^{57,58} Most studies were limited to a small set of chronic conditions in urban populations. Future studies should focus on other chronic conditions and different settings (e.g., rural).

There were also limitations inherent to the review methodology. The gray literature (evaluation of theses, dissertations, or unpublished work) was not included in the search due to limitations in resources. The studies that met the inclusion criteria were heterogeneous with varied medical conditions, designs, interventions, and outcome measures. The reporting of results by individual studies also varied widely with authors reporting intervention effects, percentage changes, or simply p values to demonstrate outcomes. These differences limited comparisons among studies. Given the heterogeneity of outcomes, we could not construct a funnel plot to assess publication bias or perform a meta-analysis. Future studies should report intervention effects with confidence intervals and all elements of study design that could lead to systematic bias.

Policy Implications

While statistically significant positive outcomes of lay health worker interventions have been demonstrated, the clinical benefits are relatively small in scale. Though any improvement is noteworthy, a critical question for policy makers will be whether this scale of improvement will make any appreciable impact on costs associated with management of pediatric chronic disease, particularly when there is increasing emphasis on identifying interventions to produce cost savings. Even if lay health worker interventions do result in cost savings, the returns might not go to those who fund the programs but might be realized by other parties. Therefore, cost savings must be considered from the perspective of all stakeholders, both within and outside the health care system. This determination may better elucidate which entities should be most invested in funding these programs (e.g., hospitals, insurers, or employers). Aside from cost, another challenge to implementation of lay health worker interventions will be the current dynamic context of health care. Increasing focus on health literacy and technology-based interventions may change the role of lay health workers, as well as how they communicate with patients.

Conclusions

Lay health worker interventions are emerging as innovative models of care for individuals with chronic conditions, especially those from minority and low socioeconomic backgrounds. Many of the pediatric studies of lay health worker interventions report modest positive results including reduced health care use, decreased symptoms, and improved parental quality of life. Gaps in knowledge remain regarding the long-term sustainability of these benefits or cost-effectiveness of such programs. Core metrics must be identified to elucidate the impact of lay health worker interventions on children with chronic conditions. Lay health worker interventions should be further assessed in other specific conditions such as sickle cell disease and cystic fibrosis as well as among medically complex children who have multiple diagnoses and medical needs. Since most lay health worker studies have been conducted in urban areas, more trials in rural areas are warranted.

Acknowledgments

This study was funded by a grant to Dr. Raphael, NIH Grant Number 1K23 HL105568-01A1.

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Figure 1.
Flow of titles, abstracts, and articles included in review.

Table 1

Risk of Bias for Included Studies

Trials	Random Sequence Generation	Allocation Sequence Concealment	Blinding (participants, personnel)	Blinding (outcome assessment)	Completeness of Outcome Data	Selective Outcome Reporting	Other Bias
Asthma							
Bryant-Stephens (2009)	Unclear	Unclear	N/A	Unclear	Low risk	Low risk	Low risk
Flores (2009)	Low risk	Unclear	N/A	Low risk	Low risk	Low risk	Low risk
Krieger (2005)	Low risk	Low risk	N/A	Unclear	Low risk	Low risk	Low risk
Bryant-Stephens (2008)	Unclear	Unclear	N/A	Unclear	Low risk	Low risk	Low risk
Parker (2008)*	Low risk	Unclear	N/A	Unclear	Low risk	Low risk	High risk Physician aware of intervention status
Williams (2006)	Unclear	Unclear	N/A	Unclear	Low risk	Unclear	Low risk
Eggleston (2005)*	Low risk	Unclear	N/A	Low risk	Low risk	Unclear	High risk Groups told purpose of study
Krieger (2009)	Low risk	Low risk	N/A	Low risk	Low risk	Low risk	Low risk
McConnell (2005)*	Unclear	Low risk	N/A	High risk Not blinded	Low risk	Low risk	Low risk
Morgan (2004)*	Low risk	Unclear	N/A	High risk Interviewers could see study materials in home	Low risk	Low risk	Low risk
Bonner (2002)	Unclear	Unclear	N/A	Low risk	Low risk	Low risk	Low risk
Diabetes							
Sullivan- Bolyai (2011)*	High risk Fathers assigned to intervention to which wife randomized	Unclear	N/A	Unclear	Unclear	Low risk	Low risk
Sullivan- Bolyai (2010)	Low risk	Unclear	N/A	Unclear	Low risk	Low risk	Low risk
Svoren (2003)	Unclear	Unclear	N/A	Low risk	Low risk	Low risk	Unclear
Laffel (1998)	Low risk	Low risk	N/A	Low risk	Low risk	Low risk	Low risk
Obesity							
Resnick (2009)*	Unclear	Unclear	N/A	Low risk	Low risk	Low risk	High risk Lengthy enrollment process likely attracted

Trials	Random Sequence Generation	Allocation Sequence Concealment	Blinding (participants, personnel)	Blinding (outcome assessment)	Completeness of Outcome Data	Selective Outcome Reporting	Other Bias
Failure to Thrive							
Black (1995)	Low risk	Unclear	N/A	Low risk	Low risk	Low risk	Low risk

motivated participants

N/A – non applicable

* High risk of bias in 1 or more quality category

Table 2

Study Characteristics

Primary Author (year), Study Design	Study n	Target Population	Eligibility Requirements	Recruitment
Asthma				
Bryant-Stephens (2009) 2 arm RCT	264	Urban minority, Low SES	2–16 years of age Physician diagnosed On controller medication 1 hospitalization or 2 ED visits within 12 months	Self-referral or from physician
Flores (2009) 2 arm RCT	220	Urban minority	2–18 years of age AA/LA Asthma as primary ED or hospital diagnosis	ED or inpatient service at 4 local hospitals
Krieger (2009) 2 arm RCT	271	Low SES	3–13 years of age Persistent or poorly con-trolled asthma Income<200% FPL or on Medicaid	Community and public health clinics
Bryant-Stephens (2008) 3 arm RCT	281	Urban minority	2–16 years of age 2–16 years of age Receive primary care at Children's Hospital of Philadelphia 1 hospitalization or 2 ED visits within 12 months	Self-referral or from physician
Parker (2008) * 2 arm RCT	298	Low SES, minority, near industrial facilities	7–11 years of age Persistent asthma	Schools
Williams (2006) 2 arm RCT	161	Low SES federally designated census tract	5–12 years of age 1 ED visit	ED of local children's hospital
Eggleston (2005) * 2 arm RCT	97	Inner city children	6–12 years of age Physician diagnosed Current symptoms	Graduates of school-based asthma education program
Krieger (2005) 2 arm RCT	274	Ethnically diverse urban children	4–12 years of age Persistent asthma Income<200% FPL or on Medicaid	Community and public health clinics
McConnell (2005) * 2 arm RCT	150	Urban Hispanic children	6–14 years of age 3 outpatient visits Persistent asthma Positive skin test for allergens	School-based mobile asthma clinic Allergy clinic
Morgan (2004) * 2 arm RCT	937	Census tracts with high proportion of low SES	5–11 years of age	Research centers

Primary Author (year), Study Design	Study n	Target Population	Eligibility Requirements	Recruitment
		households	Physician diagnosed 20% of households in census tract had incomes below FPL	
Bonner (2002) 2 arm RCT	119	Urban African-American and Hispanic children	Age criteria NR Asthma Established care for previous 12 months	General pediatric practice or pulmonary clinic of university hospital
Type 1 Diabetes				
Sullivan-Bolyai (2011) * 2 arm RCT	28	No specification	Age < 13 years Newly diagnosed	Diabetes center
Sullivan-Bolyai (2010) 2 arm RCT	60	No specification	Age < 13 years Newly diagnosed	Diabetes center
Svoren (2003) 3 arm RCT	299	No specification	7–16 years of age Diabetes >6 months 1 outpatient visit to Diabetes center in last 12 months	Diabetes center
Laffel (1998) 2 arm RCT	171	No specification	10–15 years of age Diabetes >12 months 1 outpatient visit to Diabetes center in last 12 Months	Diabetes center
Obesity				
Resnick (2009) * 2 arm RCT	46	No specification	Age criteria NR BMI 85%ile Enrolled at 1 of 2 study schools K through 5th grade	School
Failure to Thrive				
Black (1995) 2 arm RCT	130	Low-income children	<25 months of age Weight for age<5%ile Gestational age 36 weeks Weight appropriate for gestational age	Pediatric clinics Community health maintenance organizations

BMI = body mass index; ED = emergency department; FPL = federal poverty limit; NR = not reported SES = socioeconomic status

* High risk of bias in 1 or more quality category

Table 3

Intervention Characteristics

Primary author (year)	Lay Health Worker Training	Content	Mode	Dose/frequency	Intervention Length	Assessment frequency	Control group study protocol
Asthma							
Bryant-Stephens (2009)	Didactic training with practice assessments	Home education and environmental intervention	HV	Active phase: Biweekly visits for 24 weeks Inactive phase: Monthly visits for 6 months	12 months	Monthly for 12 months	Observation (crossover)
Flores (2009)	Training for 2.5 days Training manual	Asthma education Peer support	HV, phone calls, group meetings	2 HV/ year Monthly phone calls	12 months	Monthly for 12 months	Observation only
Krieger (2009)	NR	Action plan development Review of educational topics Social support	HV, phone calls	Initial visit plus 0-5 follow up visits (mean 3.1)	12 months	At 12 months	Clinic visits with asthma nurses
Bryant-Stephens (2008)	NR	Asthma education Review of medications and asthma action plan Pest control	HV	Assessment HV + 5 weekly f/u visits, then 1 HV/month to collect symptom diaries, review medications and action plans	12 months	At 12 months	Given information about asthma self-management classes
Parker (2008) *	4 week training program	Action plan development Asthma & trigger education	HV	Mean 9.24 (range 1-17) HV in one year	12 months	At 12 months	Observation only
Williams (2006)	NR	Education and assistance on asthma management Environmental intervention	HV, phone calls	HV and phone calls at 0, 4, 8 and 12 months	12 months	4,8,12 months	Delayed intervention
Eggleston (2005) *	NR	Education on avoiding allergens Modeling on how to reduce exposures	HV, phone calls	Three HV at 0, 6 and 12 months, and quarterly phone calls during 12 month period	12 months	3,6,9,12 months	Observation only
Krieger (2005)	NR	Support, education, resources to reduce exposures	HV	Mean of 7 visits/yr	12 months	12, 18 months	Single visit

Primary author (year)	Lay Health Worker Training	Content	Mode	Dose/frequency	Intervention Length	Assessment frequency	Control group study protocol
McConnell (2005) *	Urban health education for immigrants Allergy and Asthma Foundation of America	Education modules on remediation of exposure to indoor allergens	HV	2 HV in 4 months	4 months	At 4 months	Observation only
Morgan (2004) *	NR	Education modules on remediation of exposure to indoor allergens	HV, phone calls	Median of 5 HV (range, 0–7)	12 months	6,12,18, 24 months	Observation only
Bonner (2002)	One month training by pulmonary division and project coordinator	Social support Asthma diary monitoring Family coaching Reduction of triggers	HV, phone calls, accompanied family to clinic visits, group workshops	Phone calls Workshops 1x/month 3 HV 1–2 doctor visit accompaniments	3 months	At 3 months	Observation only
Type 1 Diabetes							
Sullivan-Bolyai (2011) *	Parent mentor curriculum	Education Affirmation and emotional support	HV, phone calls, email	Average of 5 parent contacts in one year	12 months	3,6,12, months	Contact information for experienced parent
Sullivan- Bolyai (2010)	Parent mentor curriculum	Education Affirmation and emotional support	HV, phone calls, email	Average of 5 (range 1–25) contacts in one year	12 months	3,6,12 months	Contact information for experienced parent
Svoren (2003)	Training by research and medical staff	CA group received information on scheduling clinic visits with monitoring of clinic attendance CA +group received 8 written teaching modules over 2 years about Type 1 DM care	Sessions in the clinic by CA	CA group, mean of 7.3 visits in 24 months CA+ group, mean of 7.5 visits in 24 months	24 months	4,8,12, 24 months	Delayed intervention
Laffel (1998)	NR	CA assisted with appt. scheduling, monitored clinic attendance and contacted families who missed their appointments	In clinic visits, phone calls, letters	Followed patients for 24 months	24 months	Every visit for 24 months	Observation only
Obesity							

Primary author (year)	Lay Health Worker Training	Content	Mode	Dose/frequency	Intervention Length	Assessment frequency	Control group study protocol
Resnick (2009) *	36 hour training	Evidence-based counseling on dietary changes, reducing TV viewing, increasing physical activity	HV, phone calls, email	Average personal encounters 3.4/12 months	12 months	At 12 months	Educational materials via mail
Failure to Thrive							
Black (1995)	8 session training	Hawaii Early Learning Program	HV	Range from 0-49 visits in one year, mean of 19.2/yr (SD11.5)	12 months	At 12 months	Clinic-based multidisciplinary services

CA = care ambassador; ED = emergency department; HV = home visit; NR = not reported

* High risk of bias in 1 or more quality category

Table 4

Findings

Primary author (year)	Psychosocial/Behavior Outcomes	Health Related Outcomes Symptoms/Medication use	Urgent Care Use
Asthma			
Bryant- Stephens (2009)	No difference in knowledge [‡]	No difference in nighttime cough, wheeze, or albuterol use	No difference in ED visits or hospitalizations
Flores (2009)	know when serious breathing problem controllable at home 0.7 unit increase, p=0.02 No differences in QOL, asthma satisfaction	rapid breathing episodes/mo 57.3 to 41.5, p=.04 asthma exacerbations/mo 2.9 to 1.8, p=.01 wheezing episodes/mo 92 to 60, p=.01 missed parental work days/mo 2.9 to 0.3, p=.01 missed school days/mo 3.7 to 0.8, p=.03	ED visits/yr 0.5 to 0.1, p=.03 No differences for hospitalizations, urgent care visits
Krieger (2009)	in Mean Caregiver QOL score 5.6 to 6.2, p<.001 No differences in behavior change	# of symptom free days/2wk IE 0.94 (.02, 1.86) or 24.4 more days/yr No differences in missed work or school days	No differences in urgent services use
Bryant-Stephens (2008)	Not assessed	No differences in symptoms or medication use	No differences in ED visits or hospitalizations
Parker (2008) [*]	caregiver depressive symptoms 1.62 to 1.5, p value not reported	nadir PF IE 8.2 (1.1, 15.2) nadir FEV1 IE 10.0 (0.9,19.1) persistent cough 3.81 to 3.36 cough with exercise 4.27 to 3.69 any symptoms for more than 2 day/ week and not on controller medication IE 0.39 (0.20, 0.73)	unscheduled urgent care IE for last 12 mo 0.40 (0.22, 0.74) IE for last 3 mo 0.43 (0.23, 0.80)
Williams (2006)	Not assessed	asthma functional severity score 33% to 20%, p<0.01	Not assessed
Eggleston (2005) [*]	Not assessed	daytime symptoms/9mo Treatment group OR 0.55 (0.31–0.97) compared to control	No differences
Krieger (2005)	Caregiver QOL score IE 0.58 (0.18, 0.99)	# days activity limitations/2 wk IE -1.5 (-2.84, -0.15) No differences in symptoms No differences in missed work or school days	urgent health services use/2 wk IE -0.97 (-1.8, -0-12)
McConnell (2005) [*]	No differences	Not assessed	Not assessed
Morgan (2004) [*]	Not assessed	# days with symptoms/2wk -0.82, p<.0001 @ 12 mo -0.60, p<.0001 @ 24 mo caretaker nights wakening/2wk -0.61, p<.0001 @ 12 mo -0.37, p=.006 @ 24 mo Days caretaker plans changed/2wk -0.31, p<.0001 @ 12 mo missed school days/2wk -0.17, p=.003 @ 12 mo -0.17, p=.009 @ 24 mo	# visits/ year to ED or clinic -0.35, p=.04 @ 12 mo
Bonner (2002)	asthma knowledge, p<0.001	symptom persistence, p<0.01 activity restrictions, p<0.01	Not assessed

Primary author (year)	Psychosocial/Behavior Outcomes	Health Related Outcomes Symptoms/Medication use	Urgent Care Use
	self-efficacy for managing asthma, $p<0.001$	family adherence, $p<0.001$ prophylactic use of bronchodilator, $p<0.05$ physician pharmacotherapy, $p<0.001$	
Type 1 Diabetes			
Sullivan-Bolyai (2011) *	father confidence related to managing DM, $p=.02$ No differences in paternal concern, worry, DM impact, perceived amount and helpfulness of daily management	Not assessed	Not assessed
Sullivan-Bolyai (2010)	No differences in parental concern, worry, confidence, DM impact on family	Not assessed	Not assessed
Svoren (2003)	Not assessed	rate of severe hypoglycemic events 45.4/100 patient-yrs in CA+ vs. 60.6/100 patient-yrs in SC plus CA, $p=.02$ severe hypoglycemic events requiring parenteral therapy 4.2/100 patient-yrs in CA+ vs. 10.5/100 patient-yrs in SC plus CA, $p=.01$ risk of worsening glycemic control SC plus CA 3.4 times higher compared to CA+, $p=.002$	mean #clinic follow up visits at 24 mo in both intervention groups CA 7.3, CA+7.5, SC 5.4, $p=.0001$ hospitalization 8.9/100 patient-yrs in CA+ vs. 15.3/100 patient-yrs in SC plus CA, $p=.04$ ED visits 21/100 patient-yrs in CA+ vs. 34.9/100 patient-yrs in SC plus CA, $p=.004$
Laffel (1998)	Not assessed	rate of severe hypoglycemic events 10.1/100 patient-yrs vs. 22.5/100 patient-yrs, $p=.009$	ED visits or hospitalizations 10.6/100 patient-yrs vs. 20.5/100 patient-yrs, $p=.034$ mean #clinic visits/24mo 7.1 visits for intervention vs. 5.2 for control, $p=.0001$
Obesity			
Resnick (2009) *	No differences in parent confidence No differences in behavior	No differences in BMI	Not assessed
Failure to Thrive			
Black (2005)	Not assessed	No differences in weight	Not assessed

CA = care ambassador; ED = emergency department; FEV1 = forced expiratory volume at one second ; IE = intervention effect; Confidence intervals are denoted in (); PF = peak expiratory flow;

QOL = quality of life; SC = standard care

* High risk of bias in 1 or more quality category

‡ The term difference refer to statistically significant differences for intervention group relative to control