

RESEARCH ARTICLE

Improving Access through Implementation of Site Based Well-Child Visits in Head Start

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Children in poverty are at greater risk for developmental and health problems and face significant barriers in accessing routine preventive healthcare. Evidence based guidelines recommend stricter adherence to the schedule of well-child care to promote early identification and treatment. Literature indicates that well-child visits in school settings make a difference among low-income children with unmet preventive healthcare needs. This study describes the implementation of a well-child visit program in a Head Start site with enrollments of children living in poverty. The comparison study design measured the aggregate percentage of children up to date with well-child visits against historical pre-data. There were clinical increases in the proportion of children up to date with the site-based intervention. Implications support the establishment of school-based health centers in Head Start sites that provide well-child visits as well as illness management.

Keywords: school based clinic; school based health center; nurse practitioner; preschool; head start; low-income children; well-child care; preventive pediatric health

When compared to all children, children in poverty face significant barriers in accessing preventive care that includes regular assessment of growth, health, and development alongside early diagnosis and treatment (American Academy of Pediatrics, 2013). At least 11.4 million children in the U.S., or 16% of all children, do not see a health care provider for an annual preventive well child visit due to issues involving health care access (Data Resource Center for Child and Adolescent Health, 2012). Lack of insurance, insurance coverage gaps and transportation are among these barriers.

In 2012, the poverty rate for children under age 6 was 24.4%, or 5.8 million kids (U.S. Census Bureau, 2013). Compared with the health of higher income peers, low-income families experience higher rates of infant mortality, and their children evidence slower childhood growth,

poorer nutrition, and more frequent and severe chronic diseases such as asthma (Child Trends, 2012). They also have lower immunization rates, increased obesity, and obesity-related complications (American Academy of Pediatrics, 2013). Due to the increased health risks associated with poverty, the American Academy of Pediatrics (2000) and the Agency for Healthcare Research and Quality (2011) have developed evidenced based guidelines that recommend stricter adherence to an age specific schedule of preventive visits for youth in low-income families.

Head Start is a federal program that promotes the school readiness of children ages birth to five by enhancing their cognitive, social, and emotional development (U.S. Department of Health and Human Services, 2011). Its enrollments are comprised mainly of children from families living at or below the federal poverty level which is defined as a monthly household income at or less than \$1,962, or an annual household income at or less than \$23,550 for a family of four (U.S. Office of the Federal Register, 2013). In an effort to address health disparities among children in poverty and promote early identification and treatment, all Head Start sites are mandated to ensure at least 90% of enrolled children are up to date on the age specific schedule of preventive well-child care (U.S. Department of Health and Human Services, 2009).

Research has shown that site based well-child visits provided in school settings, such as Head Start, can make a difference in access to care among low income children with unmet preventive healthcare needs. Silberberg and Cantor (2008) conducted an observational case study among four elementary schools with a high level of unmet health needs among low-income children. The study demonstrated that school-based visits significantly improved health service utilization, yet only among the neediest children. A similar comparison study by Wade, Mansour, Line, Huentelman and Keller (2008) concluded that the school based model of health care delivery demonstrated statistically significant improvement of student reported quality of life among elementary and middle school students. More influence was found on children that generally have impeded access to care, specifically those without private health insurance, and those with lower household income levels.

Transferrable models for site based well-child care come from school based or school linked health centers in which services are shaped to meet the needs of the setting. School based health services can encompass a full or limited range of healthcare depending on the unique needs of the population. The essential component is having a designated area that is devoted to service provision. Once the specific services and space have been determined, consideration must be given to required administrative approvals, hours of availability, supplies, equipment, and staffing (Illinois Maternal and Child Health Coalition, 2013).

This quality improvement study introduced a site based well-child program at a Southeastern U.S. Head Start location in order to increase the percentage of enrolled children who were up to date with the American Academy of Pediatrics' age specific preventive visit guidelines. The study site operates a large Head Start program and has encountered challenges in meeting the 90% mandate. At the end of the 2009-2010 school year, 88% of children were up to date with well-child visits. The 2010-2011 end of school year rate was 88%, and the 2011-2012 end of school year rate was 83%. The 2012-2013 school year was the first time in decades that the site achieved a 90% compliance rate. Sustaining that momentum and driving that compliance rate even higher would entail determining and addressing the historical root causes of access disparities in the county. A root cause analysis determined that parents faced a number of barriers in accessing preventive healthcare for their children that mirror the obstacles noted at

the national level. The site specific barriers included lack of health insurance, inability to pay out of pocket, and lack of transportation (S. Yellock, personal communication, February 11, 2013).

Objectives and Aims

This study was designed to assess if provision of site-based well-child care increased compliance with the recommended schedule of preventive visit guidelines in a Head Start program. The aim was to increase the percentage of enrolled children who were up to date with the American Academy of Pediatrics' age specific preventive visit guidelines so that a 95% compliance goal was met.

METHODS

Design

A comparison study design spanned an implementation period of five months, August through December, 2013. Pre-implementation discussion and planning occurred June and July 2013. Implementation began in August and ended in December. The percentage of children who were up to date with age-specific preventive healthcare guidelines was measured after the intervention and compared to historical pre-data.

Setting

The setting was a Head Start program in the Southeastern United States that has been a federal Head Start grantee for more than four decades. The vast majority of children in Head Start come from families that are at or below the federal poverty level as eligibility for Head Start services is based on meeting federal poverty guidelines. Since Head Start is federally funded, enrolled children and their families receive Head Start services at no cost.

The study site has 10 child development centers that meet high standards for program quality, facilities, and ratio of children to caregivers. All have a 5-star rating as issued by the local Division of Child Development, and are accredited by the National Association for the Education of Young Children therein meeting national standards of quality for early childhood education. The Head Start program runs on a nine-month calendar year that begins in August and ends the following May. Center hours of operation are Monday through Friday, 8:00 a.m. to 2:00 p.m.

At the beginning of the 2013-2014 school year, the program reported an enrollment of 1072 students consisting of 796 three to five year olds, and 276 children aged birth to two years (G. Highsmith, personal communication, June 18, 2013). Among children ages three to five, 82% met eligibility criteria for living below the federal poverty line. Ethnic demographics consisted of 20% Hispanic or Latino, and 80% Non-Hispanic or Non-Latino in origin. In regards to racial demographics, 72% were Black or African American, 4% were White, 3% were Biracial/Multi-racial, and 3% were Asian. Parents of the remaining 18% declined to identify

their child's race. Additionally, 72% of children in Head Start lived in a household with only one parent.

Sample

Inclusion criteria for a site based well-child visit were children ages 3-5 years who were not up to date with the age specific schedule of well-child care, and who were experiencing a barrier in access to care. Eligible children were identified by Head Start staff from among the 10 center sites using a web-based software system called Child Plus that tracks and indicates when a child is due, or past due, for a well-child visit. Once identified, staff contacted the parent via face to face contact, phone call, or letter and inquired if the family was experiencing a barrier in access to preventive healthcare for the child. The presence of a barrier to access was substantiated by the parent's report and encompassed the domains of healthcare availability, accessibility, accommodation, affordability, and acceptability (Penchansky & Thomas, 1981). Each eligible child was offered a site-based well-child visit when all three inclusion criteria of age, not being up to date, and access barrier were met. Parents either declined the visit, or agreed to and scheduled a visit. This resultant sample size was 37 participants.

Description of Intervention

Site-based preventive visits were made available at the start of the 2013-2014 school year. The preventive visit was performed by a volunteer nurse practitioner with available appointments two weekday evenings every month in 2 hour blocks of time. Some appointments were offered on one Saturday morning each month to accommodate parent work schedules. Saturday appointments coincided with the weekends that the Central Office was open for community workshops. Each two hour time block allowed a minimum of six 20 minute visits, which translated to a minimum capacity of 12 to 18 preventive health visits each month.

The well-child visits incorporated the age-specific guidelines specified by the American Academy of Pediatrics (2000) and the Agency for Healthcare Research and Quality (2011). A Head Start health unit staff member, all of whom were either certified medical or nursing assistants, performed the pre-visit work up by obtaining biometric measurements, conducting sensory screenings, and administering a developmental and behavioral assessment. The medical or nursing assistant also reviewed the available health information and prepared referral information as appropriate for hemoglobin testing as well as immunizations. Once the visit work up was complete, the nurse practitioner gathered the child's medical history and performed a physical examination. Age appropriate anticipatory guidance was delivered to parents in the form of written and verbal communication using the American Academy of Pediatrics Bright Futures guidelines (2008).

This project did not intend to serve as a medical home for participants, but as a safety net for children without continuous accessible medical care who were due for a single well-child visit. Every parent-child dyad was referred to a family advocate for support and guidance in accessing resources and navigating the health care system in order to address and overcome access barriers. Study approval was obtained from Duke University Institutional Review Board,

and Head Start's governing Board of Directors, Policy Council, and Health Services Advisory Committee.

Evaluation Measures

The primary outcome was compliance with the recommended schedule of pediatric preventive health care visits. The well-child care program was the independent variable, or input, while the compliance rate was the dependent variable, or effect. Secondary outcomes included identified health conditions, treatments provided and referrals made, along with measurement of parent and staff satisfaction.

Compliance with the recommended schedule of well-child care was operationally defined as the proportion of children that were up to date divided by the total number of children in the Head Start program. Ransaville and Hakim (2000) determined levels of compliance with the American Academy of Pediatrics' preventive healthcare visit guidelines based on a lenient ± 2 month window around the due date based on the child's date of birth, or the date of the last documented preventive health visit. For project purposes, the proportion of children that were compliant, or up to date, was defined as having the recommended well visit within ± 2 months of the due date, and noncompliance was defined as not having the recommended well visit within ± 2 months of the due date.

Treatment provided and referrals made for health conditions identified during visits were also tracked and measured to capture effectiveness as the principle of the preventive visit is early screening, diagnosis, and treatment. Treatment and referral was operationally defined as the number of children treated and/or referred divided by the total number of children seen in the well-child program.

The third and fourth outcomes were parent and staff satisfaction. Satisfaction results were captured using Likert survey questionnaires. Surveys inquired re ease of making an appointment, convenience of visits, ease in obtaining referral information, and overall care and experience. In addition to assessing satisfaction, these surveys allowed parents and staff an opportunity to provide suggestions that would afford additional justification for project sustainability and recommendations for changes.

Data Collection Procedure

To protect participant's privacy, all data collected was either aggregated, de-identified or anonymous in nature, and no protected health information was collected. Data forms and surveys were kept at the site in a locked file cabinet in a locked records room that only staff had access to. The final electronic dataset was stored in a limited access folder that only the principal investigator and study personnel had access to. Anonymous and aggregated compliance rates were provided monthly to study personnel. De-identified demographic and health information was captured on data collection forms completed by study personnel at the time of the well-child care visit and included: visit month, child age, access barrier, health insurance carrier (current or within last 3 months), medical home, diagnosis, treatment provided and referral made. Parent surveys were distributed following the well-child visit, and staff surveys were distributed post implementation. All surveys were anonymous and optional.

Analysis

The proportion of students that were compliant with the recommended schedule of pediatric preventive healthcare was reported monthly to study personnel. The post intervention percentage was then compared to the prior year's historical data. Percent complaint Year 1 with no intervention was compared to percent complaint Year 2 with intervention. The remainder of the collected data was input into SPSS software and analyzed using descriptive statistics. Response rates for both the parent and staff survey questionnaires were also calculated and analyzed using descriptive statistics.

RESULTS

A total of 37 children were seen with the majority presenting during the month of September (Table 1). The age group that received the highest number of well-child care visits was the 4 year olds. The single most commonly reported access to care barrier was a lack of insurance followed by not being able to get an appointment within the needed time-frame.

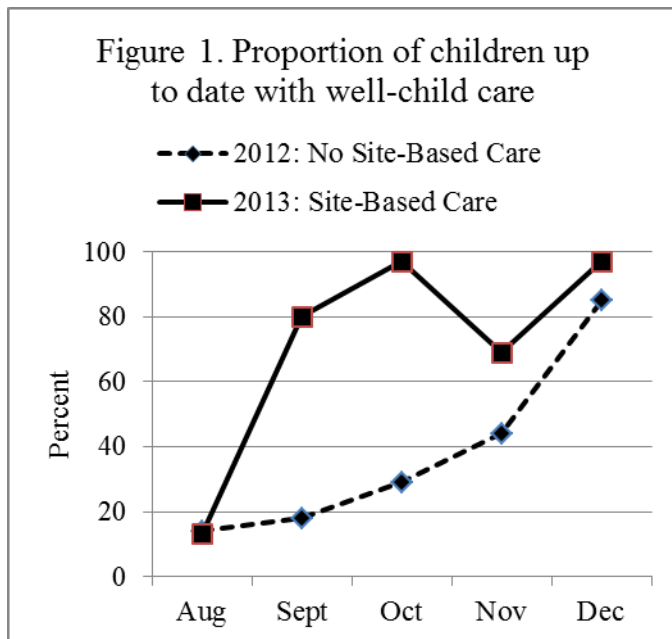
TABLE 1
Visits per Month, Age, Barrier, and Insurance

	n=37	%
Visits per month		
Aug	3	8
Sept	22	59
Oct	6	16
Nov	5	14
Dec	1	3
Age		
3	6	16
4	25	68
5	6	16
Barriers to access of care		
Cannot locate provider	1	3
No available appointment	12	32
Transportation	0	0
Cannot afford to pay	1	3
No insurance	19	51
Prefer another provider	4	11
Insurance		
Medicaid	22	60
Private	3	8
None	12	32

Most parents identified Medicaid as their child’s current or most recent health insurance coverage. There were 7 children whose parents indicated that the child currently had no insurance coverage, yet did have coverage within the prior 3 months. Medical home data indicated that 32% of children identified a local Federally Qualified Health Center as their usual source of ongoing healthcare, and 30% identified no medical home. Over the course of the implementation period, there were a total of 11 children that did not show for their well-child appointment with one no-show in August, four in September, and two each month in October, November, and December.

Well-Child Compliance Rates

The proportion of children that were up to date with well-child care at the beginning of both school years was nearly equal at 14% in 2012 and 13% in 2013 (Figure 1). During August through December 2012, there was a slight and steady percentage increase each month (August, 14%; September, 18%; October, 29%; November, 44%, December, 85%). During the same time period in 2013, there was an 84% increase in August through October with a 28% loss in November followed by recovery of the prior gain in December (August 13%; September 80%; October 97%; November 69%; December 97%).



Health Conditions Identified

A number of health conditions were identified during the well-child visits (Table 2). The most common diagnosis was seasonal allergies found among 30% of children. Twenty-seven percent needed immunizations, and 22% had asthma. The remaining other 22 medical ailments included: insect dermatitis (1), anemia (1), lymphadenopathy (1), umbilical hernia (1), developmental

delay (1), heart murmur (3), upper respiratory infection (5), hives (1), peanut allergy (1), speech delay (2), visible dental decay (1), rash (1), behavioral concerns (1), ear-wax impaction (1), and enlarged tonsils (1). Of note is the observation that of the n=37 children, only 5 (14%) had no health conditions identified. Twelve children (32%) had one detected illness, and 20 (54%) had anywhere from two to four co-occurring health ailments.

TABLE 2
Health Conditions Found During Examinations

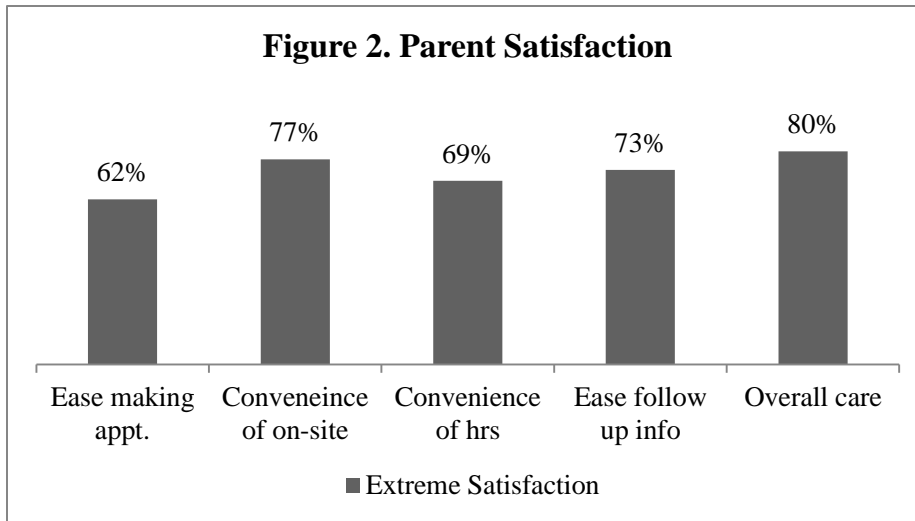
	n=37
Asthma	8
Allergies	11
Eczema	3
Failed Vision	4
Failed Hearing	3
Need Immunizations	10
Underweight	2
Overweight	2
Other	22

Treatments and Referrals

Of the 32 children identified with a medical diagnosis, 13 received treatment only, 3 received referral only, and 16 received both treatment and referral. Treatment only was provided mostly for children with acute illnesses such as viral upper respiratory infections, rash, and ear wax impaction. Referrals only were made to the local health department for past due immunizations, and for dental services due to visible tooth decay. Children that received a combination of treatments and referrals were for diagnoses that required ongoing medical treatment and management such as asthma, anemia, heart murmur, developmental delay, and food allergy. Most of the children with chronic ongoing medical diagnoses were already known to the Head Start staff, thus the healthcare provider's role entailed reinforcing established management plans, and ensuring appropriate documentation so that Head Start staff could follow through and make certain health needs were being fully addressed.

Parent Satisfaction

The response rate for parent satisfaction surveys was 70% (n=26). Extremely satisfied received the highest rating among all 5 survey measures (Figure 2). Overall care was the survey item that received the highest percentage of extreme satisfaction (80%), and was followed by convenience of on-site services (77%). There was more satisfaction with ease in obtaining follow up information (73%) as compared to the convenience of hours offered (69%). Ease of making an appointment had the lowest percentage in regards to parent satisfaction (62%). One respondent indicated extreme dissatisfaction in all aspects of parent satisfaction.



Thirty percent of parents wrote comments in the section of the survey for additional feedback and suggestions. Quality of service was the most common theme and was observed in 8 of the 11 surveys. Parents used terms such as “A+ service”, “helpful”, “informative”, and “great”. Customer service attributes were described in 45% of the returned surveys with words to describe the health care team as “kind”, “gentle”, “nice”, “friendly”, and “professional”. Terms specific to thankfulness and appreciation were written in 5 of the 11 parent surveys. One parent suggested “have(-ing) someone there on a day to day basis”.

Staff Satisfaction

Eighty-three percent (n=20) of the health and family services staff responded to the staff satisfaction survey. Convenience of on-site services received the highest proportion of extreme satisfaction (60%) among all the staff satisfaction measures (Figure 3). Ease of making appointments had a 25% extreme satisfaction rate followed by an equal frequency distribution among very satisfied (35%) and satisfied (35%). Fifteen percent of staff was extremely satisfied with the ease of receiving follow up information, and this was the only measure where staff responded in all five satisfaction categories. Twenty-five percent of staff was very satisfied, and a total of 20% were either very or extremely dissatisfied. In regards to overall experience, no staff member reported being either dissatisfied or extremely dissatisfied. Thirty-five percent were extremely satisfied, 30% were very satisfied, and 35% were satisfied. Nine staff members, or 38%, wrote comments on the staff satisfaction survey. Two described the site based well-child program as an asset by describing it as “a beneficial service” and “great resource”. Two others spoke to their satisfaction indicating they were “pleased” and “extremely satisfied” with the service, while two staff members commented on the convenience of site based preventive visits. Three suggestions were made. The first was that each center “have well-child check-ups...here at school”, the second was that “lead hemoglobin checks” be provided on-site, and the last suggestion was that there be a “more timely response in receiving completed exam forms (i.e. documentation) after well-child visits.”

DISCUSSION

Implications

The study demonstrated a clinical increase with improved well-child compliance rates. The Year 1 December 84% compliance rate with no intervention increased to 97% at December Year 2 with intervention. This 13% increase was of practical importance in sustaining the momentum and meeting the 90% compliance rate goal at the end of the school year in May.

The focus of this study was well-child visits, yet the study reinforced the recommendation that any Head Start program implementing school based services should tailor the services based on individual program needs. The Head Start program had needs beyond those of well-child care for which such services were not offered, three services in particular.

The first was treatment of acute ailments as multiple times during project implementation the nurse practitioner was asked if sick children could be seen although this was not within the scope of the study. Within the first four months of the program year there were 126 children that had at least one or more occurrences of 3 day consecutive absences due to illness (I. Cuthrell, personal communication, March 12, 2014).

The second service need was for immunizations. Twenty-seven percent of the children seen in the site based well-child program needed immunizations. Additionally, according to the Child Plus tracking system, only 30% of all the children enrolled at Head Start were up to date with immunizations at the end of project implementation in December (S. Yellock, personal communication, March 12, 2014).

Lastly, 22% of the children seen in the well-child program had asthma, and program wide there were 66 children had asthma diagnoses with no asthma care plan noted in the Child Plus tracking system (S. Yellock, personal communication, March 12, 2014). This substantiates the need for school based healthcare aimed at the treatment and management of asthma.

The appointment scheduling process is also pivotal with school based healthcare. Setting up an appointment should be efficient for both staff and parents as this directly impacts the perception and ease of making an appointment. With this study, parents communicated with family advocates to schedule an appointment. Family advocates then contacted health staff who then contacted the nurse practitioner who then confirmed the slot or responded back with an alternative time. This cumbersome process reflected in the lower satisfaction scores among parents and staff in regards to ease of making appointments. Much like a medical office, there should be a straight line process where parents speak to one person who can look at the schedule and make an appointment.

Additionally, a "straight line" process must be in place for getting documentation of the well-child visit to the family advocate staff person that is responsible for ensuring all enrolled children have proof of being up to date with well-child visits. During implementation, the documentation was given to health staff at the end of the visit, and health staff forwarded the completed form to the family advocate. Yet, there was often a lag in response time and the family advocate often did not know if the child kept the appointment or not. The family advocate had the charge of ensuring each child had documentation of a well-child visit on file before being enrolled, or within 30 days following enrollment as mandated by the Division of Child Development (North Carolina General Statute Chapter 110, 2014). Not having the documentation in a timely fashion impedes the decision making process about whether a child is permitted to attend, and could've resulted in unwarranted absences. This reflected in staff's

satisfaction with the ease of receiving follow up information which was the only survey item where respondents selected items in all five satisfaction choices.

In this study, a nurse practitioner performed the well-child visit, yet the option exists for registered nurses to perform a Health Check screening visit that meets well-child visit requirements. The North Carolina General Statute Chapter 110-91(1) (2014) states that a required health assessment can be done by a public health nurse meeting the department's standards for the Early, Periodic Screening, Diagnosis and Treatment program. Under this statute, registered nurses may complete the Child Health Training Program that is a standardized curriculum that focuses on the American Academy of Pediatrics age specific and evidenced based guidelines entitled Bright Futures. Once certified, registered nurses are able to perform a comprehensive history and complete physical assessment that includes all the required components of the well-child visit and is billable under Medicaid (University of North Carolina Gillings School of Global Public Health, 2014). In such a scenario, a registered nurse could triage and screen children and refer those with identified or suspected health conditions to be seen and evaluated by a consulting nurse practitioner, physician assistant, or physician.

Initiation of site based healthcare is an accomplishment with two feasible options for sustainability that build upon community partnerships. The first involves a framework wherein a local Federally Qualified Health Center (FQHC) provides outreach to Head Start with the specific goal of facilitating access to healthcare. FQHCs and Head Start serve similar, if not overlapping, populations, and both have complementary purposes. Both understand the role and value of the early screening, diagnosis, and treatment, and both are federally funded grant programs with many of the same grant requirements (Beckerman & Evans, 2011). The second possibility is a community-academic partnership wherein a local school of nursing at a higher institution of learning works to establish a nurse managed health center (NMHC) model. Through either a FQHC or a NMHC, the Affordable Care Act has specific provisions authorizing federal grants for operations and construction of school based health centers. Not only can such collaboration enhance compliance with well-child care, but there is also the opportunity to prevent consecutive absences for acute illness (rash, fever, etc.), promote immunization rates, and ensure care planning and treatment for chronic conditions including asthma. All of the aforementioned are key indicators for the Program Information Report that all Head Start sites submit annually to the Office of Head Start. Also, under health care reform, a larger portion of children may have health insurance which presents the opportunity for third party reimbursement through Medicaid or commercial insurance for site based services (Holmes, 2010).

Direction for future study may include expanding the study to span a full school year and measuring the compliance of other key health indicators such as treatment of chronic conditions, immunization rates, and dental exams. The option also exists to study school based healthcare in the context of illness related absences to assess the impact on absenteeism as poor attendance is linked to overall lower academic achievement and end-of-grade failure (Kerr et al., 2012). Experimentation with site based healthcare in Head Start could occur by having control and intervention sites in programs with multiple locations. The opportunity also exists to explore other variables that impact compliance rates with well-child care particularly the level of staff support provided to parents navigating the health care system. Further analysis could entail recording multiple barriers that parents face versus only recording one primary barrier.

LIMITATIONS

The study aim was to increase the proportion of compliance with the age specific schedule of well-child care to 95%. The compliance rate at December Year 1, with no intervention, was 84% which was along the upper end of the measure. In Year 2, with intervention, the rate of compliance at the end of December was 97%. The Year 1 84% starting point teeters on ceiling effect as the score is near the highest possible value prior to intervention. This constrains the amount of upward change possible and reduces the variability needed to support statistical analyses.

In a program with 1,072 children, a priori sample size estimation using G*Power software suggested a minimum sample size of 192 children to find a significant difference based on an estimated effect size of 0.10, $\alpha = 0.05$ and 80% power (Faul, Erdfelder, Lang & Buchner, 2007). Approximately half of the sample, 96 children, would've been randomly selected from historical surveillance in Year 1 without intervention, and the remaining half from Year 2 with the site based intervention. In this study the sample size ($n=37$) was not large enough to perform tests of statistical significance, thus it is not known to what extent the increase in compliance is attributed to chance given the overall historical trend.

Head Start staff used a variety of methods to engage parents and recruit participants. These methods included face to face contact, phone calls and letters sent home with children. The study did not employ a script or defined recruitment steps and instead relied on historical processes when identifying children who were behind with well child visits. It is likely that such variability impacted participation and ultimately sample size.

Access to the site based well-child visits could have been further promoted by having the nurse practitioner on site during morning and afternoon hours. Expanding the hours offered to include daytime appointments may have allowed for more access that may have also increased the sample size therein permitting statistical analyses. The evening and weekend hours may have served as an access to care barrier for some families. In retrospect, it would have been insightful to capture data about how many children were offered a site based visit yet declined to make an appointment and why, as well as how many children did not keep an appointment due to the hours services were offered.

CONCLUSIONS

School based healthcare plays a central role in increasing access among the medically underserved (Clark & Jones, 1997). It also supports the view that alternative methods must be identified and implemented to ensure the provision of preventive pediatric health care services (Kataoka-Yahiro & Munet-Vilaro, 2002). The Early Head Start National Resource Center and the Head Start Bureau have recommended the utilization of community partnerships with local healthcare providers for preventive health services, and have encouraged Head Start programs to collaborate with a local clinic willing to donate well-child exams to families with no means to pay (Early Head Start National Resource Center, 2004). Results of this study reveal that site based healthcare in a Head Start program through community partnerships is feasible and has the potential to improve access to care by addressing the gap between literature and practice and placing school based health centers at Head Start programs.

DECLARATION OF INTEREST

There were no potential conflicts of interest and no financial support received with respect to the research, authorship, and/or publication.

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