Evaluation of a School Nurse-led Intervention for Children with Severe Obesity in New York City Schools

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Submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy under the Executive Committee of the Graduate School of Arts and Sciences

COLUMBIA UNIVERSITY

ABSTRACT

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Background and Significance: Severe childhood obesity, the fastest growing subcategory of childhood obesity, affects 4-6% of youth. Children from racial/ethnic minority groups and low income households are disproportionately affected. Severe obesity increases risk for metabolic syndrome, cardiovascular disease, non-alcoholic fatty liver disease, musculoskeletal problems, poor health-related quality of life, bullying, low self-worth, absenteeism, and adult obesity. One method of addressing childhood obesity is through school-based interventions. School nurses may be well-suited to lead obesity interventions because of their healthcare expertise, long-term relationships with students and families, and availability to students without financial burden. **Purpose:** The overarching aim of this mixed methods dissertation was to evaluate the implementation and efficacy of the Healthy Options and Physical Activity Program, a school nurse-led intervention for children with severe obesity attending New York City schools. This evaluation focused on the 2012/2013 school year, the first full year of program implementation. **Methods:** Aims 1 and 2 were conducted to prepare for the Healthy Options and Physical Activity Program evaluation. Aim 1 included conduct of a systematic review and meta-analysis of existing literature to examine the role and impact of nurses in school-based obesity interventions. Aim 2 studied application of 3 propensity score methods to the observational Healthy Options and Physical Activity Program data set to determine which best removed significant differences in 11 potential confounders between the 1,054 kindergarten through fifth grade children who participated in the program in 2012/2013 and the 19,464 children who were

eligible but did not participate. Aims 3-6 comprised the Healthy Options and Physical Activity Program evaluation. Aims 3, 4, and 5, utilized a retrospective cohort design to examine program implementation and its one year impact on body mass index percentile, school absences, and walk-in school nurse visits. Analytic methods included descriptive statistics, Wilcoxon signed rank tests, McNemar's test, and logistic regression. Aim 6 qualitatively explored perceived barriers to and facilitators of implementing the Healthy Options and Physical Activity Program from the perspective of school nurses, using individual semi-structured interviews. Interview data were analyzed using content analysis.

Results/findings: Of 11 studies eligible for systematic review, 8 met inclusion for meta-analysis. Pooled findings suggest that school nurse led interventions decreased BMI percentile by -0.41 (95%CI: -0.60, -0.21; I²=0, Cochrane Q=2.0). The comparison of propensity score methods demonstrated that only propensity score matching removed all significant differences between children who received the Healthy Options and Physical Activity Program and children who were eligible for but did not receive the program. The program evaluation demonstrated that the program had limited reach (5% of eligible children) and low intensity (median 1 session/year, parent attendance at 3.2% of sessions). Factors associated with selection for program enrollment included attending a school with low school nurse workload (OR 2.4, 95% CI 2.0-2.8), low school poverty (OR 1.6, 95%CI 1.3-1.9), and lack of chronic illness comorbidity (OR 0.5, 95%CI 0.5-0.6). After propensity score matching, program participants failed to decrease body measures, school absences, or school nurse visits at 1 year. Themes of interviews with 19 school nurses suggest that nurses encountered barriers to program implementation: parental and administrative resistance, heavy workload, and obesogenic environments. Despite barriers, nurses implemented the program to the best of their ability using creativity and teamwork.

Conclusion: As implemented, the Healthy Options and Physical Activity Program was not effective in reducing body mass index percentile, absences or school nurse visits in youth with severe obesity. Barriers such as limited time and lack of parental and administrative support prevented nurses from fully implementing the program. However, school nurses with their clinical knowledge base, cost-free accessibility to children and families, and long-term relationship with students may be able to successfully employ other school-based obesity interventions. Therefore future research should use rigorous methods to develop and test school-based interventions implemented by school nurses, with a focus on intervention feasibility and sustainability.

Implications for the Profession: This dissertation has implications for nursing practice, health policy, and nursing science. Findings of this mixed methods evaluation suggests that nurses may not have the resources necessary to implement intensive school-based obesity interventions.

Nurses who are planning to implement such an intervention may want to carefully consider program intensity and feasibility. In addition, careful attention to increasing parent buy-in and ensuring administrator support are key. In addition, policy that supports adequate school nurse staffing can support appropriate nursing workload and may allow nurses time to implement health promotion programs and obesity interventions. During the qualitative portion of this dissertation, nurses reported the obesogenic environment as a barrier to healthful living that impacted the program's effectiveness; obesogenic environmental factors (e.g., unhealthy school meals) will need to be addressed via legislation. Lastly, nurse scientists can work to increase the literature surrounding school-based obesity interventions, particularly with randomized controlled trials of interventions and qualitative work with nurses, parents, school administrators, and children. In addition, school-based obesity interventions must be developed and tested that

consider the challenges faced by vulnerable children such as children living and attending school in high poverty neighborhoods.

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Acknowledgements

This dissertation was generously supported by the National Institute of Nursing Research through Grant Number T32 NR014205, the National Center for Advancing Translational Sciences through Grant Number UL1 TR000040, and Sigma Theta Tau International through Small Grant Number 10169. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or Sigma Theta Tau International.

The New York City Department of Health and Mental Hygiene Health Research Training Program and Office of School Health, particularly Tracy Agerton, Kathleen Mulholland, Catherine Travers, and Kevin Konty, provided indispensable guidance and resources to support this dissertation work.

The author would also like to thank her dissertation advisor (Arlene Smaldone), interdisciplinary co-advisor (Y. Claire Wang), dissertation committee (Haomiao Jia, Maureen George, Sharron Close), T32 advisor (Patricia Stone), husband, parents, family, and friends for their contributions to and support during the conduct of this work.

Chapter 1

In this chapter, the background and organization of this dissertation are presented. First, information regarding the prevalence of severe obesity during childhood and its impact on health outcomes and resource use are discussed. Second, school-based obesity interventions and the role and impact of nurses in these interventions are examined. Third, the Healthy Options and Physical Activity Program (HOP), which was evaluated in this study, is described. Fourth, the theoretical frameworks that guided this study are presented. Lastly, the four separate manuscripts that address six research aims are summarized. Currently, one manuscript (Chapter 2) is published in the *Journal of School Health*, one manuscript (Chapter 3) is under revision at *Nursing Research*, and one manuscript (Chapter 5) reflects preliminary findings due to ongoing subject enrollment. The chapter concludes with an overall aim of the proposed dissertation as well as its potential contribution to the childhood obesity literature.

Childhood Obesity and Severe Childhood Obesity

Childhood obesity affects the long-term health of American youth and contributes to health disparities. Childhood obesity impacts 16.9% of children in the United States (Ogden, Carroll, Kit, & Flegal, 2014), with 4-6% of American children being severely obese (Kelly et al., 2013). In New York City (NYC) schools, 20.7% of students are obese and 5.7% are severely obese before the age of 14 years (Day, Konty, Leventer-Roberts, Nonas, & Harris, 2014). It has been hypothesized that current severe obesity rates are underestimated by about 1% (Freedman et al., 2016), meaning that true prevalence is even greater. In both NYC and nationwide, groups that suffer from health disparities (Villarruel, 2001), such as racial/ethnic minorities (Cunningham, Kramer, & Narayan, 2014; Freedman, Khan, Serdula, Ogden, & Dietz, 2006;

Ogden et al., 2014) and children from low-income households (Boelsen-Robinson, Gearon, & Peeters, 2014; Cunningham et al., 2014; Shrewsbury & Wardle, 2008), are disproportionately affected.

Childhood obesity has many negative health consequences. Children with obesity (defined as body mass index [BMI] for age and sex ≥95th percentile (Ogden, 2010)) are at risk for hypertension, left ventricular hypertrophy, atherosclerosis, metabolic syndrome, type 2 diabetes, asthma, obstructive sleep apnea, nonalcoholic fatty liver disease, musculoskeletal issues, non-Hodgkin lymphoma, and depression (Daniels, 2006; Kelly et al., 2013). Obese youth are also at high risk for adult obesity (Freedman et al., 2005; Guo & Chumlea, 1999) and its many associated comorbidities (Hageman, Pullen, Hertzog, Boeckner, & Walker, 2012; National Heart Lung and Blood Institute, 1998).

Severe obesity, defined as a BMI at or above the 99th percentile for age and gender or 120% of the 95th percentile (Flegal et al., 2009), poses even greater health risks. Compared to their overweight or obese peers, children with severe obesity are more likely to have metabolic syndrome, higher levels of serum inflammatory markers, and poorer health-related quality of life (Kelly et al., 2013). Case reports of cardiac abnormalities (Obert et al., 2012) and cirrhosis requiring liver transplantation (Jonas, Krawczuk, Kim, Lillehei, & Perez-Atayde, 2005) have been reported in this population. Severity of cardiovascular disease risk factors, non-alcoholic fatty liver disease, decreased insulin sensitivity, and musculoskeletal problems increase with degree of adiposity (Henderson et al., 2016; Kelly et al., 2013; Parker et al., 2016).

Obesity is associated with significant healthcare costs and ineffective resource use. The medical costs of preventable diseases associated with obesity are predicted to increase by \$48 to \$66 billion per year in the United States by 2030 (Wang, McPherson, Marsh, Gortmaker, &

Brown, 2011). Increased medical costs begin in childhood. The direct medical costs of an obese 10 year old child are \$19,000 more than a child who is not obese (Finkelstein, Graham, & Malhotra, 2014). Children with obesity have increasing rates of hospitalization (Trasande, Liu, Fryer, & Weitzman, 2009) and bariatric surgery (O'Brien et al., 2010; Pratt et al., 2009), undergo increased lab testing (Hampl, Carroll, Simon, & Sharma, 2007), and may (Kesztyüs et al., 2013) or may not (Hampl et al., 2007) have increased health care visits. In addition, children with obesity are absent from school more frequently than their non-obese peers (Datar & Sturm, 2006; Geier et al., 2007; Pan, Sherry, Park, & Blanck, 2013; Rappaport, Daskalakis, & Andrel, 2011), which can harm their academic performance (Lamdin, 1996; Öhlund & Ericsson, 1994) and may impair aspirations for adult employment (Gillman & Block, 2015). Because of increased severity of comorbid illness with increasing degree of adiposity (Kelly et al., 2013), the effects of obesity on healthcare costs and resource use are likely to be increased for children with severe obesity.

School-based Obesity Interventions

Interventions that effectively treat childhood obesity are needed. The Institute of Medicine recommends that schools be a focal point for childhood obesity interventions (Institute of Medicine, 2012). Existing meta-analyses provide conflicting evidence regarding success of school-based obesity interventions, with some suggesting effectiveness (Katz, O'Connell, Njike, Yeh, & Nawaz, 2008; Sobol-Goldberg, Rabinowitz, & Gross, 2013; Wang et al., 2013; Waters et al., 2011) and others suggesting lack of effectiveness (Gonzalez-Suarez, Worley, Grimmer-Somers, & Dones, 2009; Harris, Kuramoto, Schulzer, & Retallack, 2009; Hung et al., 2015; Kanekar & Sharma, 2009). Previous studies have suggested that predictors of effectiveness include parent involvement (Katz et al., 2008; Safron, Cislak, Gaspar, & Luszczynska, 2011; Sobol-Goldberg et al., 2013), intervention duration greater than one year, comprehensive

intervention content (e.g., addressing multiple health behaviors and environmental change)
(Bagby & Adams, 2007), family and community-based components (Wang et al., 2013), and focus on reducing sedentary behavior or increasing moderate to vigorous physical activity (Safron et al., 2011). School-based obesity interventions that target younger school children (i.e., 6-12 years) may be more effective that those that target adolescent and teenage children (Waters et al., 2011) because persistence of weight status increases with age (Singh, Mulder, Twisk, Van Mechelen, & Chinapaw, 2008).

It is important to note that school-based interventions to treat severe obesity will require novel approaches, compared to interventions used to treat obesity. Children with severe obesity have poorer health and therefore more comorbidities than their peers who are overweight or obese (Kelly et al., 2013). Lifestyle approaches and standard behavioral interventions have been shown to be less effective in children with severe obesity (Danielsson, Kowalski, Ekblom, & Marcus, 2012; Johnston et al., 2011), with modest beneficial effects that often disappear after the intervention's conclusion. Traditionally, interventions for severe obesity have included intensive family-based treatment (sometimes as an inpatient) (Luca et al., 2015; Taylor, Peterson, Garland, & Hastings, 2016; van der Baan-Slootweg, Benninga, Beelen, & et al., 2014), bariatric surgery (Nobili et al., 2015; Schmitt et al., 2016; Thakkar & Michalsky, 2015), medication (Boland, Harris, & Harris, 2015), and/or long-term treatment using a chronic care model (Rijks et al., 2015). Therefore, school-based obesity programs for children with severe obesity will require novel approaches that focus on comorbidity management and reduction in disease risk; drastic BMI reduction cannot be expected to result from school-based interventions. (In fact, drastic BMI reduction for severely obese children often results only from bariatric surgical intervention, which is a potential treatment modality for adolescents with severe obesity (Kelly et al., 2013)).

In addition, school-based programs for children with severe obesity must be able to coordinate with more intensive medical treatment that occurs outside of school in a clinical setting (e.g., medication management, planning for bariatric surgery).

One potential way to increase the effectiveness and sustainability of school-based obesity interventions is to involve school nurses. School nurses may be well-suited to lead school-based childhood obesity interventions (Morrison-Sandberg, Kubik, & Johnson, 2011; Pbert et al., 2013b) due to their healthcare expertise, continuity of relationships with students and families, accessibility to students, and connection with parents and primary care providers. In addition, school nursing services are cost-beneficial (Wang et al., 2014). Furthermore, school nurses can provide a means of sustainability for an obesity intervention. While many school-based obesity interventions may terminate when a research team completes their study, school nurses remain present in schools and available to work with children. School nurses may be particularly well-suited to work with children with severe obesity, because of their clinical knowledge and the high rates of comorbidities in this population. However, there is a paucity of research on school-based obesity interventions delivered by nurses despite calls for school nurse involvement (Kubik, Story, & Davey, 2007; National Association of School Nurses, 2013).

Healthy Options and Physical Activity Program (HOP)

In NYC schools, 131,500 students are obese and 41,000 are severely obese before the age of 14 years (Day et al., 2014). To address this problem, experts from the Office of School Health at the NYC Department of Health and Mental Hygiene implemented the Healthy Options and Physical Activity Program (HOP). HOP is a school nurse-led intervention for severely obese students attending NYC schools. HOP entails one-on-one meetings with a child and the school nurse in the school nursing office. At each session, school nurses provide health behavior

education and tailored counseling, and assist the child with goal setting around five health behaviors: (5 fruits/vegetables per day, \leq 2 hours of sedentary screen time, \geq 1 hour of physical activity, 0 sugar-sweetened beverages, healthy portion sizes). Parents are encouraged to participate in HOP sessions either in person or via phone.

As demonstrated in Figure 1.1, a child selected for HOP enrollment beings the program by attending an enrollment session. During this session, the nurse assesses presence of comorbidities such as asthma and the child is referred to a physician as needed. Baseline BMI percentile is measured and plotted and current nutrition/physical activity practices are assessed with a health behavior questionnaire. If present, a parent assists with completion of the health behavior questionnaire. The nurse then provides health education and helps the child to set health behavior goals. Obesity education handouts are sent home to parents. Six months later, the child attends a follow up HOP session. At follow up HOP sessions, BMI percentile is again measured and plotted and change is examined. Current nutrition/physical activity practices are assessed using the same health behavior questionnaire. Additional health education is provided and goals are revised. If the school nurses determines a need, the child and family are referred to school and community resources as appropriate. Of note, even though HOP guidelines require a session once every 6 months, nurses are given latitude on session frequency based upon the child's clinical need and nursing workload. In addition, it is important to highlight that while nurses are given resources to support HOP implementation ("HOP binder," described below), nurses independently tailor session focus and determine what session content to deliver. Therefore, there exists no universal HOP program delivery; nurses have the flexibility to tailor program intensity, content, and delivery as they see fit.

Prior to HOP's implementation in the NYC school system, all school nurses attended a full day HOP training, which included training on HOP components and implementation, as well as obesity physiology, clinical assessment of a child with obesity, and the psychological/behavior/cultural influences on obesity. In addition, all school nurses are provided with a "HOP binder" which includes 100 pages of resources, including program algorithm, the process for measuring and documenting BMI percentile, suggestions for creating a healthy school environment, resources for health behavior education and goal setting (e.g., worksheets, colorful handouts), a list of online resources for children, parents, and nurses, and tips for communication with parents about obesity. While HOP has been continuously implemented at various levels since 2010, this dissertation focuses on the first year of full implementation — school year 2012-2013.

The BMI percentile of all students in NYC schools is assessed each October during annual fitness assessments. Trained physical education teachers measure students' height and weight using a digital beam scale and stadiometer with the students' shoes and heavy clothing removed (New York City Department of Education, 2015). Based on a BMI percentile measurement \geq 99th percentile for age and gender, students are identified for HOP eligibility. Parents receive a letter explaining the HOP program. Although parents have the opportunity to opt out, this option is taken by only less than 1% of parents. If a child's parent does not opt out, the school nurse can enroll him/her in HOP. A rigorous and comprehensive HOP evaluation was needed to assess program efficacy, refine HOP if needed, and guide further dissemination with the NYC school system.

Theoretical Framework

This quantitative potion of this study (aims 1-5) was guided by the Ecological Model of Health Behavior, a socio-ecological model (McLeroy, Bibeau, Steckler, & Glanz, 1988). Socio-ecological models are applied in many research fields and stress the impact of contextual and environmental influences on health, the effectiveness of a health program, or health behavior change (Sallis, Owen, & Fisher, 2008). The Ecological Model of Health Behavior posits that health behavior is influenced by factors at five levels: intrapersonal, interpersonal, organizational, community, and public policy (McLeroy et al., 1988). An extensive body of research supports application of socio-ecological models to childhood obesity interventions (National Heart Lung and Blood Institute, 2007), as contextual and environmental factors are known to impact obesity (Booth, Pinkston, & Poston, 2005; Ferreira et al., 2007; Lake & Townshend, 2006; Lobstein, Baur, & Uauy, 2004). In the proposed study, factors at community, institutional, interpersonal, and intrapersonal levels were examined for association with the implementation and efficacy of HOP. Variables at each level of the model are listed in Figure 1.2; additional description about each variable is provided in Chapter 4.

The qualitative study to achieve aim 6 was guided by the RE-AIM Framework. The RE-AIM Framework can guide evaluations of programs (such as HOP), by examining presence of essential program elements and guiding translation of research-based programs into practice (Glasgow, Vogt, & Boles, 1999; RE-AIM.org, 2015). Each level of the RE-AIM framework focuses on a distinct portion of program implementation. The interview guide for aim 6 addressed each component of the RE-AIM Framework; the guide was used during interviews with the New York City school nurses who participated in the qualitative study. Further details about how the Re-AIM framework was applied to the interview guide are provided in Table 1.1.

IRB Approval

This study required approval from three Institutional Review Boards (IRBs): Columbia University Medical Center Institutional Review Board (IRB) (protocol # AAAP6367), NYC Department of Health and Mental Hygiene (protocol #15-056), and the NYC Department of Education (protocol number 1106). All approvals were obtained prior to initiation of the research.

Aims and Organization of Proposed Dissertation

The six aims of this dissertation are addressed in four manuscripts that are presented in the next four chapters of this dissertation. Each aim is described in Table 1.2. Chapter 2 is a systematic review of the role of nurses in school-based obesity interventions and a meta-analysis of the impact of these interventions on participants' change in body measures. This manuscript, "Are school nurses an overlooked resource in reducing childhood obesity? A systematic review and meta-analysis," was accepted for publication on October 29, 2015 by the Journal of School Health (Schroeder, Travers, & Smaldone, 2016). Chapter 3 is a methods paper that examines the application of three propensity score methods to the HOP data to determine which method best reduced bias. Bias was defined as significant differences in characteristics between children who participate in HOP and children who were eligible for but not enrolled in HOP. This manuscript is currently under revision following an initial positive review by Nursing Research. Chapter 4 presents the results of the HOP evaluation. In this chapter, descriptive statistics were used to examine HOP implementation, logistic regression was used to determine factors associated with HOP enrollment, and Wilcoxon signed rank tests were used to evaluate HOP's impact on BMI percentile change, school absences, and walk-in nurse visits. This manuscript, currently in draft form, is targeted for submission to the Western Journal of Nursing Research: Special Issue on

Weight Management and Obesity. Chapter 5 reports the preliminary findings of a qualitative exploration of school nurses' barriers to and facilitators of HOP implementation. Collectively, these papers generate a comprehensive analysis of the implementation and efficacy of a school nurse-led school-based obesity intervention in NYC schools.

Conclusion

The overall aim of the proposed research was to evaluate the implementation and impact of a school nurse-led school-based obesity intervention in NYC schools. The research addresses an important problem because childhood obesity negatively impacts the health of millions of American children, with severe obesity posing even greater health risks. Effective interventions are desperately needed. In addition to dissemination in peer-reviewed journals, results will be shared with leadership at the Office of School Health at the NYC Department of Health and Mental Hygiene (via a summary report and presentations to Office of School Health leadership) and via presentations at conferences. To date, findings have been presented at the Annual Scientific Sessions of the Eastern Nursing Research Society (Chapters 2, 3, and baseline data from Chapter 4). Chapter 3 has also been accepted for a poster presentation at the June 2016 Academy Health Annual Research Meeting. In addition to informing implementation of HOP in NYC schools, this study also contributes to the obesity and child health literature. The proposed project is the first to evaluate the impact of a large-scale school nurse-led childhood obesity intervention and has the potential to contribute to improved child health, not only in NYC, but also across the nation.

Table 1.1. Application of the RE-AIM Framework to the Interview Guide for the qualitative study described in Chapter 5

		Application in Interview
Level of Framework	Description	Guide
R – Reach	Number, proportion, and	Selection of HOP
	representativeness of	participants, appropriateness
	individuals who are willing to	of HOP eligibility criteria
	participate in a given	
E - Effectiveness or efficacy		
	•	1
		1 1
		* *
	economic outcomes	1
		1
A - Adoption by target staff.	Number, proportion, and	<u> </u>
- · ·		
	and intervention agents who	administrators and parents on
	are willing to initiate a	HOP adoption, students'
	program	reactions to nurses during
		HOP sessions
*	•	•
= =	<u> •</u>	•
delivery	(consistency, time, cost)	_
		•
M - Maintenance of	Extent to which a program or	
	•	r
time	<u> =</u>	
	practices and policies	
E - Effectiveness or efficacy A - Adoption by target staff, settings, or institutions I - Implementation consistency, costs and adaptions made during delivery M - Maintenance of intervention effects in individuals and settings over time	initiative Impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes Number, proportion, and representativeness of settings and intervention agents who are willing to initiate a program Intervention agents' fidelity to the various elements of an intervention's protocol (consistency, time, cost) Extent to which a program or policy becomes institutionalized or part of the routine organizational	HOP adoption, students' reactions to nurses during

RE-AIM Framework (Glasgow et al., 1999; RE-AIM.org, 2015)

Table 1.2. Dissertation chapters, manuscript titles and aims addressed

Chapter	Title	Aim(s)
2	Are school nurses an overlooked resource in reducing childhood obesity? A systematic review and meta-analysis	1. Synthesize the peer-reviewed, published research to examine the role of nurses in school-based obesity interventions and the impact of the interventions on change in body measures
3	Reduction of bias in evaluation of a childhood obesity intervention: A comparison of propensity score methods	2. Apply three propensity scoring methods to the HOP data set in order to determine which best reduces bias
4	Implementation and efficacy of a school nurse-led severe obesity intervention for NYC	3. Examine demographic and medical characteristics of children who are eligible for HOP
	students: Impact on BMI, absences, and school nurse visits	4. Examine implementation of HOP, including session frequency, session content, and factors associated with participant enrollment
		5. Examine impact of HOP on BMI percentile change, school absences, and school nurse visits
5	Perceived barriers and facilitators to implementing a school nurse-led childhood obesity intervention in NYC schools	6. Explore school nurses' perceptions of factors that promote or hinder optimal implementation of HOP

Figure 1.1. Process for implementation of HOP

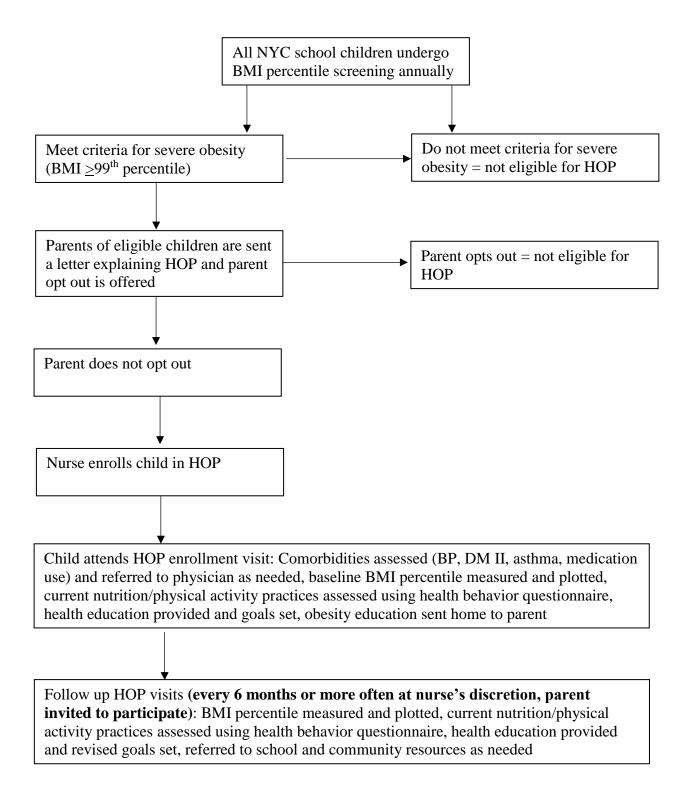
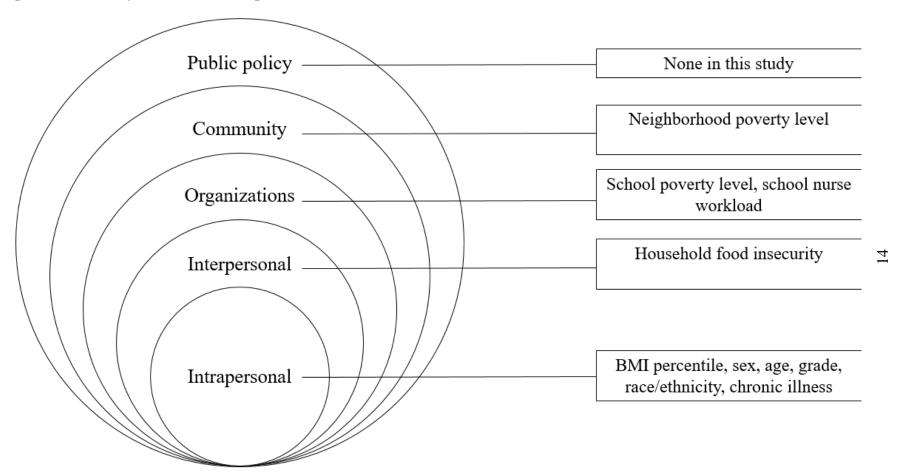


Figure 1.2. Study variables at each level of the Ecological Model of Health Behavior (McLeroy et al., 1988), guiding the quantitative study described in Chapter 5



Chapter 2: Are school nurses an overlooked resource in reducing childhood obesity? A systematic review and meta-analysis

This chapter addresses aim 1 and is a synthesis of the peer-reviewed, published research to assess the role and impact of nurses in school-based childhood obesity interventions. To satisfy this aim, a systematic review and meta-analysis of the literature was conducted between June 2014 and June 2015. The manuscript, included below, was published in the May 2016 issue of the *Journal of School Health* (Schroeder et al., 2016).

Background

Childhood obesity affects 16.9% of children in the United States, with an additional 14.9% being overweight (Ogden et al., 2014) with children from racial minority groups and low-income households disproportionately affected (Ogden et al., 2014; Wang & Lim, 2012). Childhood obesity is associated with morbidity, premature mortality (Reilly & Kelly, 2011), and obesity in adulthood (Freedman et al., 2005; Guo & Chumlea, 1999). As a result, decreasing childhood obesity is a national (United States Department of Health and Human Services, 2014) and global (World Health Organization, 2012) priority.

In their recent report, *Accelerating Progress in Obesity Prevention: Solving the Weight of the Nation*, the Institute of Medicine recommended that schools be a focal point of the fight against obesity (Institute of Medicine, 2012). There is a growing body of research on school-based obesity interventions; however, findings are conflicting, with some demonstrating effectiveness (Katz et al., 2008; Sobol-Goldberg et al., 2013; Wang et al., 2013; Waters et al., 2011) and others finding that school-based interventions are not effective (Gonzalez-Suarez et al., 2009; Harris et al., 2009; Hung et al., 2015; Kanekar & Sharma, 2009).

One potential means of implementing effective school-based interventions is to involve school nurses. School nurses may be well-suited to fight childhood obesity because of their ongoing connection with students and families, continual presence in schools, and cost-free accessibility to students (Morrison-Sandberg et al., 2011; Pbert et al., 2013a; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015). In addition, school nursing services are cost-beneficial (Wang et al., 2014). School nurses may provide a means of sustainability for an obesity intervention. While many school-based obesity interventions may terminate when the research team completes their study, school nurses remain present in schools and available to work with children.

Previous systematic reviews and meta-analyses of school-based obesity interventions have not examined school nurse involvement. Therefore, the purpose of this study was to examine the efficacy of school-based obesity interventions that involve nurses.

Methods

Eligibility criteria.

Studies of interest included school-based interventions to prevent or treat childhood obesity. Studies were included if they 1) were of quasi-experimental or experimental design, 2) reported body weight or body mass index (BMI/BMIz/BMI percentile) as an outcome measure, 3) were conducted in a primary, middle, or high school setting, 4) involved nurses in the conduct of the study in a role beyond anthropometric measurement, 5) were published in a peer-reviewed journal, and 6) in the English language. Year of publication and duration of follow-up was not restricted. We included interventions implemented by registered nurses as their scope of practice is concordant with that of school nurses. However, studies reporting interventions delivered solely by student nurses or advanced practice nurses (nurse practitioners or clinical nurse

specialists) were excluded, as their scope of practice differs significantly from that of registered nurses and school nurses.

Information Sources and Search

The research team developed a comprehensive search strategy in consultation with a research librarian (Figure 2.A1). To ensure broad capture, search terms included BMI, overweight, obesity, adiposity, weight, schools, children, adolescents, teenagers, students, and nursing. Terms were searched in the title, abstract, and text. The search was performed within the Cumulative Index of Nursing and Allied Health Literature (CINAHL), Medline, PsychInfo, Proquest, and Education Resources Information Center (ERIC) databases in June 2014 and updated in March 2015. Search limitations were placed on source (peer-reviewed journals only) and language (English only). Reference lists of resulting studies were searched to ensure identification of any missed articles.

Study Selection

After search completion, title and abstracts were screened for eligibility criteria using Covidence (Covidence, 2013), a software program designed to support the systematic review process. Each study was screened based on inclusion/exclusion criteria with the reason for decision entered into Covidence by one researcher (KS). At each level of screening (title screen, abstract screen, full text screen), references were filtered into groups (included or excluded). Any uncertainty regarding study inclusion was resolved through discussion among the research team.

Data Extraction and Data Items

One researcher (KS) read each full-text article and extracted data into an Excel template that included details of study design, study location, study type (obesity prevention or obesity

treatment), sample size and characteristics, intervention components, dose, and duration, methods of outcome measurement, and anthropometric outcomes and the time point of measurement.

Quantitative Synthesis

Studies that reported body measure change (BMI, BMIz, or BMI percentile) and a measure of variance (standard deviation, standard error) or p-value were eligible for inclusion in the meta-analysis. When sufficient data for effect size calculation was not provided in the manuscript, study authors were contacted for additional information. Effect sizes were calculated and pooled using Comprehensive Meta-analysis version 3 (Comprehensive Meta-analysis, 2015). Effect sizes were combined using the inverse variance weighted method in a random effects model (Borenstein, Hedges, Higgins, & Rothstein, 2009). For effect size calculations, a pre/post correlation of anthropometric measures was assumed to be 0.90, based on published reports (Lin et al., 2010), with sensitivity analyses conducted with a range of 0.80 to 0.99. When outcomes at different time points were reported, results from the longest follow-up were used. Heterogeneity of each model was assessed using Cochran's Q and I-squared tests. Where heterogeneity was present, subgroup and sensitivity analyses were conducted to explore potential sources of heterogeneity and assess robustness of the point estimate. To assess publication bias, we conducted a failsafe N test and visually inspected funnel plots (Borenstein et al., 2009).

Risk of Bias

Risk of bias was assessed using *The Checklist for Measuring Quality*, developed by Downs and Black (1998). This 27 item checklist assesses five aspects of a study: reporting (10 items), external validity (3 items), bias (7 items), confounding (6 items), and power analysis (1 item). Each item is scored as 0 or 1 (with the exception of item 5, which addresses distribution of

confounders between groups of participants and can receive a score between 0 and 2) resulting in a total quality index score ranging between 0 and 28 with a higher score indicating higher study quality. The tool is a reliable and valid measure that can be applied to quasi-experimental and experimental health care intervention studies (Downs & Black, 1998). Two reviewers (KS, JT) independently appraised each study. Following evaluation completion, ratings were compared with discrepancies discussed until consensus was achieved.

Results

Study selection.

Figure 2.1 displays the results of the search and study selection. The search resulted in 2,412 articles, with an additional study arising from a manual screen of reference lists. During screening, 243 studies were excluded due to duplication, 2,020 studies were excluded based on title, and 118 were excluded based on abstract. An additional 20 articles were excluded based on exclusion criteria during full-text review. Eleven studies met all criteria and were included in the systematic review; eight were included in the meta-analysis. Four authors (Hawthorne, Shaibi, Gance-Cleveland, & McFall, 2011; Speroni, Earley, & Atherton, 2007; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015; Wright, Giger, Norris, & Suro, 2013) were contacted for further information and two provided additional data enabling inclusion in the meta-analysis (Speroni et al., 2007; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015).

Risk of bias.

Figure 2.2 provides detail regarding the results of the quality appraisal. Regarding study reporting, all studies reported clear study objectives and outcomes of interest, though only one reported adverse events such as the child feeling stigmatized by participating in the intervention

(Melin & Lenner, 2009). Only two studies reported characteristics of patients lost to follow up (Johnston, Moreno, El-Mubasher, et al., 2013; Pbert et al., 2013a). Three studies reported attrition rates, with rates ranging from no attrition at 6 months (Pbert et al., 2013a) to 21.2% attrition at 24 months (Johnston, Moreno, El-Mubasher, et al., 2013). Concerning external validity, no study addressed whether the baseline sample was representative of the recruited population. Regarding internal validity, most studies did not report blinding of participants (except one which included an attention control (Robbins, Pfeiffer, Maier, Lo, & Wesolek, 2012)) or outcomes assessors. Regarding confounding, although each quasi-experimental study provided a partial list of cofounders to be considered in group comparisons, statistical adjustment for confounders was incomplete (Hawthorne et al., 2011; Melin & Lenner, 2009; Robbins et al., 2012; Speroni et al., 2007; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015; Williams & Warrington, 2011; Wong & Cheng, 2013). No study reported their method of allocation concealment. Only three studies (Robbins et al., 2012; Wong & Cheng, 2013; Wright et al., 2013) reported a priori power analyses. Quality scores ranged between 12 (Johnston, Moreno, El-Mubasher, et al., 2013) and 19 (Hawthorne et al., 2011; Pbert et al., 2013a; Wong & Cheng, 2013) points.

Characteristics of the included studies.

An overview of study characteristics is presented in Table 2.1. Seven studies employed a quasi-experimental design (Hawthorne et al., 2011; Melin & Lenner, 2009; Robbins et al., 2012; Speroni et al., 2007; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015; Williams & Warrington, 2011; Wong & Cheng, 2013) and four were randomized controlled trials (RCT) (Bonsergent, Thilly, et al., 2013; Johnston, Moreno, El-Mubasher, et al., 2013; Pbert et al., 2013a; Wright et al., 2013). All RCTs randomized participants at the school level. One RCT

(Bonsergent, Thilly, et al., 2013) used a 2x2x2 factorial design, with one arm including nurses. The data extracted for this review were limited to the nursing arm. A second manuscript (Bonsergent, Agrinier, et al., 2013) arising from the same study more fully described each arm; this was referenced for additional information as needed. Four studies restricted their sample to overweight or obese students (Bonsergent, Thilly, et al., 2013; Melin & Lenner, 2009; Pbert et al., 2013a; Wong & Cheng, 2013) and were categorized as obesity treatment interventions. Seven studies included all students in the intervention (Hawthorne et al., 2011; Johnston, Moreno, El-Mubasher, et al., 2013; Robbins et al., 2012; Speroni et al., 2007; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015; Williams & Warrington, 2011; Wright et al., 2013) and were categorized as obesity prevention interventions.

Obesity treatment.

Of the four obesity treatment studies, two were RCTs (Bonsergent, Thilly, et al., 2013; Pbert et al., 2013a) and two were quasi-experimental (pretest-posttest) design (Melin & Lenner, 2009; Wong & Cheng, 2013). Study samples included school-age children (Melin & Lenner, 2009; Wong & Cheng, 2013) and teenagers (Bonsergent, Thilly, et al., 2013; Pbert et al., 2013a). Sample sizes varied ranging from 39 (Melin & Lenner, 2009) to 3,191 students (Bonsergent, Thilly, et al., 2013). One study was conducted in the United States (Pbert et al., 2013a), with the remaining studies conducted in Asia (Wong & Cheng, 2013) and Europe (Bonsergent, Thilly, et al., 2013; Melin & Lenner, 2009). In one intervention, approximately half of the children were from low income households and eligible to receive free or reduced school lunches (Pbert et al., 2013a).

Intervention follow-up varied ranging from 3.5 (Wong & Cheng, 2013) to 24 months (Bonsergent, Thilly, et al., 2013). Intervention dosage ranged from near weekly (6 sessions over

8 weeks) (Pbert et al., 2013a), to monthly (Melin & Lenner, 2009), to one time only (with optional follow-up sessions, declined by approximately 75% of eligible participants)
(Bonsergent, Thilly, et al., 2013). In one Wong and Cheng (2013) study, registered nurses, trained in motivational interviewing and weight management, counseled students about health behavior change during 6 sessions over 14 weeks, with decreasing frequency as the intervention progressed.

All interventions included student education and counseling (Bonsergent, Thilly, et al., 2013; Melin & Lenner, 2009; Pbert et al., 2013a; Wong & Cheng, 2013) with two of the interventions (Melin & Lenner, 2009; Wong & Cheng, 2013) involving parents. Parent roles included participating in telephone consultations (Wong & Cheng, 2013) or attending their child's nutritional counseling sessions (Melin & Lenner, 2009). Three interventions were delivered during the school day (Bonsergent, Thilly, et al., 2013; Melin & Lenner, 2009; Pbert et al., 2013a). Effects on body measures, presented in Table 2.2, ranged from -0.06 (Bonsergent, Thilly, et al., 2013) to -1.48 (Wong & Cheng, 2013) for BMI, -0.09 (Bonsergent, Thilly, et al., 2013) to -0.22 (Melin & Lenner, 2009) for BMIz, and -0.02 (Sharon Tucker & Lorraine M. Lanningham-Foster, 2015) and -0.32 (Williams & Warrington, 2011) for BMI percentile.

Obesity prevention.

Of the seven obesity prevention studies, two were RCTs (Johnston, Moreno, El-Mubasher, et al., 2013; Wright et al., 2013) and five were quasi-experimental studies (Hawthorne et al., 2011; Robbins et al., 2012; Speroni et al., 2007; Sharon Tucker & Lorraine M.

Lanningham-Foster, 2015; Williams & Warrington, 2011). All were conducted in the United States and targeted school-age children. Sample sizes ranged from 68 (Sharon Tucker & Lorraine M. Lanningham-Foster, 2015) to 1,074 students (Hawthorne et al., 2011). Five studies included

students from populations that are known to suffer from health disparities such as racial/ethnic minorities (Johnston, Moreno, Gallagher, et al., 2013; Speroni et al., 2007; Williams & Warrington, 2011) or students from low-income households (Hawthorne et al., 2011; Robbins et al., 2012; Williams & Warrington, 2011).

Intervention follow-up ranged from 3 (Sharon Tucker & Lorraine M. Lanningham-Foster, 2015; Williams & Warrington, 2011) to 24 months (Johnston, Moreno, El-Mubasher, et al., 2013). Intervention intensity ranged from daily (via integrated curriculum) (Johnston, Moreno, El-Mubasher, et al., 2013), to three times per week (Hawthorne et al., 2011), to weekly (Robbins et al., 2012; Speroni et al., 2007; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015; Wright et al., 2013). One intervention was initiated via a one-time educational assembly with teachers encouraged to regularly incorporate the intervention into class curriculum (Williams & Warrington, 2011).

Intervention components varied and included parent education and counseling (Wright et al., 2013), staff education (Johnston, Moreno, El-Mubasher, et al., 2013; Wright et al., 2013), physical activity (Hawthorne et al., 2011; Robbins et al., 2012; Speroni et al., 2007; Williams & Warrington, 2011; Wright et al., 2013), and student education and counseling (Robbins et al., 2012; Speroni et al., 2007; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015). Some interventions occurred after school (Hawthorne et al., 2011; Robbins et al., 2012; Speroni et al., 2007; Wright et al., 2013), while others occurred during the school day (Johnston, Moreno, El-Mubasher, et al., 2013; Sharon Tucker & Lorraine M. Lanningham-Foster, 2015). Three studies actively involved parents via participation in either an educational support group (Wright et al., 2013) or attendance at student counseling (Johnston, Moreno, El-Mubasher, et al., 2013) or student nutrition education sessions (Speroni et al., 2007). Control groups received either no

intervention (Speroni et al., 2007; Wright et al., 2013), part of but not all of the same intervention as the intervention group (Williams & Warrington, 2011), or an attention control (Johnston, Moreno, El-Mubasher, et al., 2013; Robbins et al., 2012). Effect on body measures ranged from 0.02 (Johnston, Moreno, El-Mubasher, et al., 2013) to -0.37 (Robbins et al., 2012) for BMI, -0.08 (Johnston, Moreno, El-Mubasher, et al., 2013) to -0.34 (Robbins et al., 2012) for BMIz, and -0.02 (Sharon Tucker & Lorraine M. Lanningham-Foster, 2015) to -0.22 (Robbins et al., 2012) for BMI percentile (Table 2.2).

Quantitative synthesis.

Three studies were excluded from meta-analysis due to outcomes being in an unusable format (i.e., "no significant change") (Hawthorne et al., 2011), no comparison group (Sharon Tucker & Lorraine M. Lanningham-Foster, 2015), and report of only adjusted and genderspecific outcomes. In one study (Wong & Cheng, 2013) two intervention approaches were tested compared to a control group. The results of the pooled analysis for decreases in body mass index (6 studies), BMIz score (5 studies) and BMI percentile (3 studies) are presented in Figure 2.3 (BMI) and Figure 2.A2 (BMIz, BMI percentile); they represent data from 6,050, 5,863 and 416 children respectively. The pooled decrease in BMI was -0.48 (95% CI: -0.84, -0.12; I²=91.2%, Cochran Q=68.1). Heterogeneity was higher than would be expected by chance. To explore heterogeneity, we performed a sensitivity analysis by removing the study with the largest effect size (Wong & Cheng, 2013) and conducting subgroup analyses with and without the outlier. After removing this study, the pooled effect size was attenuated to -0.06 (95% CI: -0.17, -0.01; I²=0, Cochran Q=2.3). The pooled decreases in BMIz and BMI percentile were -0.10 (95% CI: -0.15, -0.05; $I^2=0$, Cochrane Q=2.3) and -0.41 (95%CI: -0.60, -0.21; $I^2=0$, Cochrane Q=2.0) respectively. We conducted sensitivity analyses to broaden the range of correlation assumptions

from 0.80 and 0.99 between baseline and post intervention BMI, BMIz and BMI percentile. The pooled effects ranged between -0.34 (95% CI: -0.67, -0.10) and -1.12 (95% CI: -1.85, -0.38) for BMI and -0.36 (95% CI: -0.60, -0.12) to -0.62 (95% CI: -1.03, -0.21) for BMI percentile; there was no change in BMIz effect across the range of correlation assumptions. Table 2.3 presents the results of subgroup analysis with and without the study demonstrating the largest BMI reduction (Wong & Cheng, 2013). When all studies were included there were significant differences in BMI reduction based on study duration and study design. However, when one study was removed, there were no differences in BMI reduction by subgroup.

Figure 2.A3 presents the funnel plot of all studies included in the meta-analysis. The two dots to the left of the pyramid indicate the study with the largest effect size (Wong & Cheng, 2013). Otherwise, there is relative symmetry of the study distribution within the pyramid demonstrating that publication bias is unlikely. The failsafe N test demonstrated that 114 additional studies would need to be added to the meta-analysis before loss of statistical significance occurred.

Discussion

Our findings demonstrate that school-based interventions that involve nurses lead to small but significant decreases in BMI, BMIz and BMI percentile. Eight prior meta-analyses (Gonzalez-Suarez et al., 2009; Harris et al., 2009; Hung et al., 2015; Kanekar & Sharma, 2009; Katz et al., 2008; Sobol-Goldberg et al., 2013; Wang et al., 2013; Waters et al., 2011) published between 2008 and 2015 have examined the effectiveness of school-based interventions. Four (Katz et al., 2008; Sobol-Goldberg et al., 2013; Wang et al., 2013; Waters et al., 2011) found effectiveness of school-based interventions; interventions that included nutrition and physical activity components, (Katz et al., 2008; Sobol-Goldberg et al., 2013), lasted greater than one

year, involved parents, and entailed a comprehensive approach were found to be most effective (Sobol-Goldberg et al., 2013). Although four reviews (Gonzalez-Suarez et al., 2009; Harris et al., 2009; Hung et al., 2015; Kanekar & Sharma, 2009) concluded that school-based obesity interventions were not effective, subgroup analyses found that interventions of RCT design, interventions that included a nutrition component, and interventions that included only one component (versus multifaceted) (Hung et al., 2015) were effective in reducing BMI.

In our analysis, pooled effect sizes were similar across all anthropometric outcomes and similar to the findings of some prior meta-analyses (Gonzalez-Suarez et al., 2009; Harris et al., 2009; Hung et al., 2015; Kanekar & Sharma, 2009; Katz et al., 2008; Sobol-Goldberg et al., 2013; Wang et al., 2013; Waters et al., 2011). Only one study demonstrated a notably large decrease in BMI across both intervention arms (Wong & Cheng, 2013). This intervention, conducted in Hong Kong, included formal involvement of parents as a pillar of the intervention. In addition, cultural factors may have contributed to the intervention's success, as Asian children may differ in cultural perceptions of obesity compared to Western children (Marsh, Hau, Sung, & Yu, 2007).

Although obesity interventions that involve nurses are effective; barriers exist to involvement of school nurses in implementation of childhood obesity interventions. Previous studies have suggested time to be a barrier to implementation, despite school nurses' interest in and willingness to execute obesity initiatives (Kubik et al., 2007). School nurses report that lack of confidence in counseling methods and poor parental support limit the nurses' willingness to provide obesity interventions (Morrison-Sandberg et al., 2011; Moyers, Bugle, & Jackson, 2005). Across the United States, understaffing of school nurses is a concern due to budget constraints for hiring and shortages of professional school nurses (Gordon & Barry, 2009; Robert

Wood Johnson Foundation, 2013; Wang et al., 2014). Considering the widespread prevalence and negative health effects of childhood obesity, school administrators and policy makers must carefully consider the need for adequate school nurse staffing.

The small effect sizes for change in BMI, BMIz and BMI percentile support the argument that the substantial body weight changes needed to help children shift from obese or overweight to a healthy weight may require more intensive intervention than can be provided solely in a school setting. Many factors outside the school setting impact health, nutrition and body weight (Rutter, 2011). The American environment has been called obesogenic (Booth et al., 2005; Lake & Townshend, 2006; Lobstein et al., 2004) with factors such as advertising of unhealthy foods (Harris et al., 2013), suburban sprawl and decreased walkability (Vandegrift & Yoked, 2004), and large portion sizes (Pourshahidi, Kerr, McCaffrey, & Livingstone, 2014) promoting obesity. Thus, even effective school-based interventions face an uphill battle because addressing obesity, a complex problem, requires multifaceted societal change (Block & Roberto, 2014).

The findings of this review suggest that anthropometric outcomes were similar for obesity treatment and obesity prevention interventions. School-based interventions may be better suited for obesity prevention. All of the interventions in this review entailed healthy habits education or counseling which is appropriate for children of all body weights. School-based obesity prevention interventions also avoid concerns about stigmatizing children with obesity because all children, not only those who are obese, receive the intervention. In addition, it may be difficult for schools to implement intensive treatment regimens; prevention interventions may be more feasible. Intensive intervention may be easier to administer in primary care or an obesity clinic under the medical guidance of a child's primary care provider.

Our systematic review has implications for future work. We suggest that more school

nurse-led interventions be implemented and evaluated, as limited evidence exists. Future research should include studies with strong designs for inferring causality, larger samples and longer follow up times.

Limitations

Our systematic review has several limitations. Only English language and peer-reviewed studies were included. We did not consider grey literature, dissertations, and conference abstracts leading to possible omission of studies. It is plausible that our search strategy omitted studies, despite our efforts at developing a comprehensive strategy.

Conclusion

School-based obesity interventions are one potential solution to the childhood obesity crisis and school nurses are optimally poised to play a role in these interventions. Findings of this systematic review suggest that school nurses may be beneficial in implementation of sustainable interventions for reducing childhood overweight/obesity. Development of evidenced-based school-based obesity interventions that incorporate school nursing expertise can result in effective management of childhood obesity and improved child health.

Implications for School Health

Our review demonstrated that school-based interventions that involve nurses help children to significantly decrease body measures. In developing obesity interventions, schools should consider involving school nurses as key players and include them in a role beyond anthropometric measurement. The results of this review do not demonstrate any particular characteristics that promote or hinder effectiveness of school-based interventions that involve nurses. However, schools can consider designing their nurse-led programs to incorporate factors

that have been found to increase success of other school-based interventions, such as including nutrition (Hung et al., 2015) or nutrition and physical activity components (Katz et al., 2008; Sobol-Goldberg et al., 2013), lasting longer than 1 year (i.e., continuing a child's involvement in the program as (s)he moves into the next grade), taking a comprehensive approach (i.e., attitudinal and behavior change, health education, and environmental modification) (Sobol-Goldberg et al., 2013), and involving parents (Sobol-Goldberg et al., 2013). Of note, because we found that both obesity treatment and obesity prevention programs are effective, schools do not have to single out children with overweight or obesity and can consider implementing prevention programs that are appropriate for all members of the student body.

Because out review demonstrated effectiveness of school-based obesity interventions that involve nurses, schools can feel confident in providing school nurses with the necessary resources (i.e., time, administrative support) to implement obesity programs. In doing so, schools are supporting development of sustainable, effective interventions that can promote child health and healthy body weight for their students.

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Obesity Treatment Bonsergent 2012 I: 2641 C: 271 Attrition NR Melin 2009 I: 20	3 Race: NR	RCT	24	I: Students screened for height, weight, and waist circumference; overweight/obese students counseled regarding screening results; students who screened positive invited to join health education program (25% participated)	Y Assisted physician with individual counseling, body measurement
C: 271 Attrition NR Melin 2009 I: 20	Race: NR	RCT	24	height, weight, and waist circumference; overweight/obese students counseled regarding screening results; students who screened positive invited to join health education program (25%	Assisted physician with individual counseling, body
				1 /	
C: 19 Attritic NR	I: 8.1 years C: 8.0 years on: Race: NR Overweight/obese	Pretest-posttest	12	C: No intervention I: Dietitian interviewed children and families at baseline about dietary habits, PA, and well-being and gave individual health advice; monthly counseling, education, and weight monitoring with school	Y Individual counseling and education, body measurement

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Table 2.1. (Con't.)

Author, Year	Sample Size	Sample Characteristics	Study Design	Follow- up in	Intervention vs Control	School Nurse (Y/N)		
	Attrition	(Mean Age, Race,		Months				
	Rate	Other)				Nursing Role		
Pbert 2012	I: 42	I: 15.9 years	RCT	6	I: Six counseling sessions	Y		
	C: 40	C: 15.7 years			with school nurse over two			
					months	Individual		
	Attrition:	Asian: NR				counseling		
	0%	Black: 14.3%			C: Six informational			
		Hispanic: 14.3% White: 73.8%			pamphlets on weight management given during			
		Willie. 73.070			school nurse visits			
		Overweight/obese			Serioof name visits			
		Free/reduced lunch: 47.6%						
Wong 2013 ^a	I (A): 70	9-10 years	Pretest-	3.5	I (A): Motivational	N		
	I (B): 66		posttest		interviewing with students			
C: 49	C: 49	Race: NR					focused on dieting and exercise	Motivational interviewing
	Attrition:	Obese				C		
	NR				I (B): Intervention A plus parental counseling via telephone			
					C: No intervention			

Table 2.2. (Con't.)

Author, Year	Sample Size	Sample Characteristics	Study Design	Follow- up in	Intervention vs Control	School Nurse (Y/N)	
	Attrition	(Mean Age, Race,		Months			
	Rate	Other)				Nursing Role	
Obesity prevention							_
Hawthorne 2011	I: 1074	K to 6 th Grade	Pretest- posttest	4	I: Walking track during recess; mileage check-off	N	
	Attrition:	Asian: NR			card for incentives and	Designed	
	NR	Black: NR			prizes	intervention,	
		Hispanic: 43%				implemented	
		White: NR			C: No control group	physical activity	
		Low income school				program	
Johnston 2013	I: 392 C: 237	I: 7.8 years C: 7.7 years	RCT	24	I & C: One day training for teachers and school staff,	Y	32
	C. 237	C. 7.7 years			provision of curriculum	Counseling	(4)
	Attrition:	Asian: 27.0%			with health information,	C	
	21.2%	Black: 21.4%			teaching aids, and		
		Hispanic: 24.4% White: 27.3%			health/nutrition educations materials		
					I only: Health professional		
					at school three days per		
					week to assist with daily integration of curriculum,		
					one nutrition counseling by		
					school nurse at either parent request or by teacher		
					referral		

Table 2.1. (Con't.)

Author, Year	Sample Size	Sample	Study	Follow-	Intervention vs Control	School Nurse	
		Characteristics	Design	up in		(Y/N)	
	Attrition	(Mean Age, Race,		Months			
	Rate	Other)				Nursing Role	
Robbins 2012	I: 37	I: 11.5 years	Pretest-	6	I: Daily after school PA	Y	
	C: 32	C: 11.4 years	posttest		club; three motivational		
					interviewing sessions with	Motivational	
	Attrition:	Asian: NR			school nurse (one every two	interviewing	
	NR	Black: 49.7%			months)	_	
		Hispanic 21.6%					
		White: 24.4%			C: Six monthly afterschool workshop, three health		
		Free/reduced lunch:			education sessions with		
		75%			school nurse (one every two months)		
					,		33
Speroni 2007	I: 80	I: 9.4 years	Pretest-	6	I: Weekly after school	N	
1	C: 105	C: 9.2 years	posttest		program with physical		
		y	1		activity, fitness education,	Design and	
	Attrition:	Asian: NR			and nutrition education	coordination,	
	NR	Black: NR				body	
		Hispanic: NR White: 78.3%			C: No intervention	measurement	

Table 2.1. (Con't.)

Author, Year	Sample Size	Sample	Study	Follow-	Intervention vs Control	School Nurse	
		Characteristics	Design	up in		(Y/N)	
	Attrition	(Mean Age, Race,		Months			
	Rate	Other)				Nursing Role	
Tucker 2015	I (A): 48	9-11 years	Pretest-	I (A): 7	I (A) & I (B): Weekly class	Y	
	I (B): 20		posttest	I (B): 3	presentations by school		
		Asian: 8.3%			nurse on Let's Go 5-2-1-0	Classroom	
	Attrition:	Black: 5.6%			program behaviors	education	
	5.6%	Hispanic: 5.6%			(fruit/vegetable intake,	sessions	
		White: 84.7%			screen time, physical		
					activity, and sugary		
					beverages); 14-21		
					reinforcement sessions		
					during school lunch and/or		
					recess with senior nursing		_
					students; group A and B		,
					received same intervention		
					– only duration of		
					intervention differed		
					C: No control group		

34

Table 2.1 (Con't.).

Author, Year	Sample Size	Sample	Study	Follow-	Intervention vs Control	School Nurse
		Characteristics	Design	up in		(Y/N)
	Attrition	(Mean Age, Race,		Months		
	Rate	Other)				Nursing Role
Williams 2011	I: 56 C: 175	8-10 years	Pretest- posttest	3	I: Walking education, walking supplies, and	N
	Attrition:	Asian: NR Black: 99.3% Hispanic: NR White: NR			prizes; teachers received suggestions about how to engage children and bring walking into curriculum	Study management
		Free/reduced lunch: 80%			C: Received all or part of the intervention but did not complete full 12 week program	
Wright 2013	I: 91 C: 99	I: 9.0 years C: 8.3 years	RCT	12	I: 6 week after school program with PA groups for	N
					children and support groups	Assisted with
		Asian: NR			focusing on education and	intervention
		Black: 2.4%			behavior modification for	design, led
		Hispanic: 94% White: NR			parents; creation of School	parent
		wnite: NK			Health Advisory Council, staff professional development seminars	education and support groups
					C: No intervention	

NR = not reported, I = intervention, C = control, RCT = randomized controlled trial, PA=physical activity

Table 2.2. Outcomes and effect sizes of included studies

36	Measure	Outcome Studied	Study Result: Interventions vs Control*	Effect Size	
	Ob	esity treatmer	nt		
Bonsergent 2012	Mean change at 24 months	BMI	0.64 (1.44) vs. 0.72 (1.49)**	-0.06	
_	-	BMIz	-0.09 (0.44) vs -0.05 (0.43)**	-0.09	
Melin 2009	Mean change at 12 months	BMI	1.9 (1.7) vs. 2.1 (1.5)	-0.13	
		BMIz	-0.05 (0.5) vs. 0.04 (0.3)**	-0.22	
Pbert 2012	Mean change at 2 months	BMI	0.01 (1.64) vs. 0.14 (1.14)	-0.09	
		BMIz	0.00 (0.17) vs. 0.01 (0.11)	-0.15	
	Mean change at 6 months	BMI	-0.01 (1.98) vs. 0.26 (1.59)	-0.07	
	-	BMIz	0.00 (0.21) vs. 0.01 (0.17)	-0.05	
	Mean difference in change at 2 months,	BMI	-0.09 (3.40)		36
	adjusted for age, gender, school, baseline weight, baseline differences between groups (free lunch, confidence, soda consumption, barriers to exercise)	BMIz	-0.01 (0.37)		
	Mean difference in change at 6 months, adjusted as per 2 months	BMI BMIz	-0.22 (4.62) -0.02 (0.47)	 	
Wong 2013	Mean change at 3.5 months	BMI	A: -0.67 (1.01) vs 0.81 (0.92)** B: -1.17 (0.99) vs 0.81 (0.92)**	-1.09 -1.48	

Table 2.2. (Con't.)

Author, Year	Measure	Outcome Studied	Study Result: Interventions vs Control*	Effect Size
	Ob	esity preventi	on	
Hawthorne 2011	Mean change at 4 months	BMI percentile	Not reported	
Johnston 2013	Mean change at 12 months	BMI	0.8 (1.3) vs. 0.78 (1.4)	0.02
		BMIz	-0.07 (0.24) vs0.05 (0.25)	-0.08
	Mean change at 24 months	BMI	1.67 (1.67) vs. 1.92 (1.91)	-0.14
	Ç	BMIz	-0.08 (0.27) vs0.02 (0.27)**	-0.22
Robbins 2012	Mean change at 6 months	BMI	0.41 (1.02) vs. 0.74 (0.73)	-0.37
	Ç	BMIz	0.06 (0.18) vs. 0.12 (0.18)	-0.34
M	Mean change at 6 months	BMI percentile	1.94 (4.59) vs. 3.05 (5.68)	-0.22
	Linear regression models, adjusted for	BMI	-0.33 (0.22)	
	baseline measures	BMIz	-0.04 (0.04)	
		BMI percentile	-0.57 (0.97)	
Speroni 2007	Mean change at 6 months	BMI percentile	-2.3 (p 0.01) vs. (p 0.01)**	-0.56
Tucker 2015	Mean change at 3 months	BMI	-0.6	-0.02
	Mean change at 7 months	percentile	-2.3	-0.09

Table 2.2. (Con't.)

Author, Year	Measure	Outcome Studied	Study Result: Interventions vs Control*	Effect Size
Williams 2011	Mean change at 3 months	BMI percentile	-2.57 vs. 1.07	-0.32
Wright 2013	Mean change at 12 months, adjusted for baseline scores, race and parent marital status	BMI	Boys: -2.56 (10.68) vs. 1.35 (31.79) Girls: -3.65 (14.06) vs. 1.23 (26.28)	
		BMIz	Boys: -0.19 (4.85) vs. 0.79 (13.16)	
			Girls: -0.70 (2.09) vs. 0.58 (11.90)**	

^{*}Results are unadjusted unless otherwise indicated. Results from unadjusted analyses used to calculate effect size. Results presented as mean (standard deviation) unless otherwise indicated.

38

^{**}Statistically significant at p<0.05

 $\begin{tabular}{ll} Table 2.3. Subgroup analyses for change in body mass index with and without outlier study removed \end{tabular}$

Subgroup Analysis	Number of studies	Difference in Means	95% CI
Study design*	Staares	Tyledilis	
RCT	3	-0.06	-0.11, -0.01
Quasi-experimental	3	-0.80	-1.38, -0.21
Study purpose:			
Obesity treatment	4	-0.58	-1.19, 0.03
Obesity prevention	2	-0.18	-0.38, 0.02
Parent involvement:			
Yes	3	-0.72	-1.42, -0.01
No	3	-0.06	-0.11, -0.01
Study duration*			
<6 months	1	-1.28	-1.66, -0.90
≥6 months	5	-0.06	-0.12, -0.01
≥50% children from racial/ethnic			
minority group or low income			
household			
Yes	3	-0.18	-0.36, 0.01
No	3	-0.69	-1.47, 0.10

^{*}Significant differences between groups noted. After removal of outlier study, no subgroup differences remained

Figure 2.1. Summary of the literature search

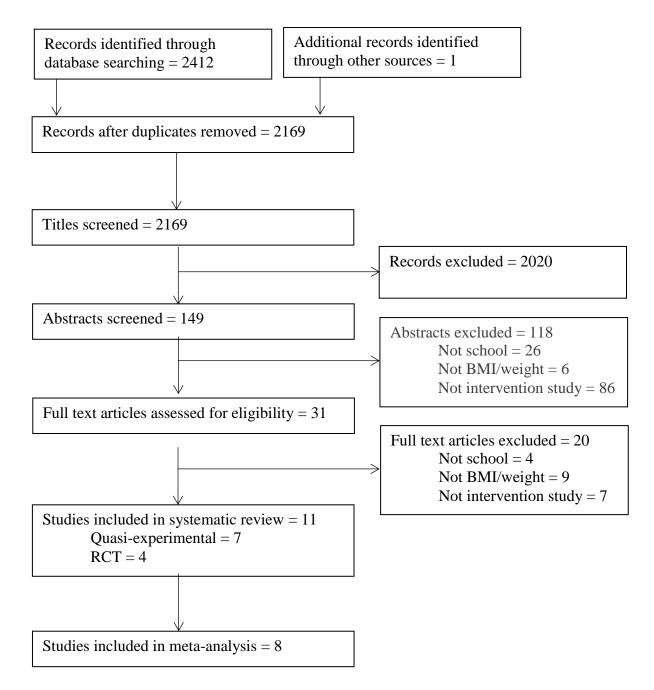
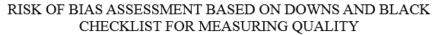
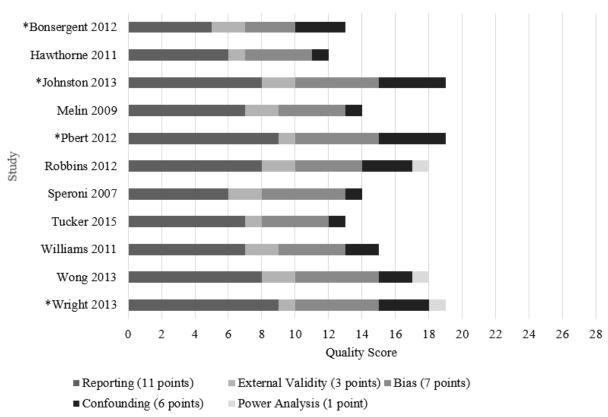


Figure 2.2. Risk of bias of included studies





^{*}Randomized controlled trial

Figure 2.3. Forest plots of studies included in meta-analysis (BMI outcome)

BMI

Study name	Std diff in means		Upper limit	p-value	Forest Plot				
Bonsergent 2012		-0.11	0.00	0.05	· - .				
Johnston 2013	-0.14	-0.36	0.08	0.21					
Melin 2008	-0.12	-0.75	0.50	0.70					
Pbert 2013	-0.15	-0.58	0.28	0.50	· -■¬				
Robbins 2012	-0.37	-0.85	0.12	0.14	· - 				
Wong 2013 (A)	-1.09	-1.49	-0.69	0.00					
Wong 2013 (B)	-1.48	-1.91	-1.05	0.00	•				
	-0.48	-0.84	-0.12	0.01	-2.00 -1.00 0.00 1.00 2.00				
					Favors Intervention Favors Control				

Figure 2.A1. Search strategy

<u>Databases: Cumulative Index for Nursing and Allied Health Literature (CINAHL), Education Resources Information Center (ERIC), PsycINFO <June 20, 2014></u>

Search Strategy:

- 1 schoolchildren
- 2 school children
- 3 teen*
- 4 preschool student*
- 5 child*
- 6 youth*
- 7 adolescen*
- 8 kid*
- 9 Boy*
- 10 Girl*
- 11 paediatr*
- 12 pediatr*
- 13 student*
- 14 Elementary School Student*
- 15 Junior High School Student*
- 16 High School Student*
- 17 Middle School Student*
- 18 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
- body mass index
- 20 BMI
- 21 obes*
- 22 overweight*
- 23 body fat*
- 24 weigh*
- 25 adipos*
- 26 19 or 20 or 21 or 22 or 23 or 24 or 25
- 27 School*
- 28 Nurs*
- 29 18 and 26 and 27 and 28 (1572)

Database: MEDLINE <June 20,2014>

Search strategy:

- 1 (schoolchildren or school children).mp
- 2 teen*.mp
- 3 exp preschool students/
- 4 child*.mp
- 5 youth*.mp
- 6 adolescen*.mp
- 7 kid*.mp

- 8 boy*.mp
- 9 girl*.mp
- 10 paediatr*.mp
- 11 pediatr*.mp
- 12 student*.mp
- 13 Elementary School Students/ or Junior High School Students/ or High School Students/
- 14 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
- 15 Exp body mass index/
- 16 exp obesity/
- 17 exp overweight/
- 18 body fat/
- 19 exp weight loss/
- 20 exp weight gain/
- 21 body fat/
- 22 15 or 16 or 17 or 18 or 19 or 20 or 21
- 23 exp school based intervention/
- 24 exp after school programs OR school*.mp
- exp schools/
- exp Junior High Schools/ or High Schools/ or exp Middle Schools/ or exp Nursery Schools/ or Elementary Schools/
- 27 23 or 24 or 25 or 26
- 28 exp nurses/ or nursing/
- 29 14 and 22 and 27 and 28 (14)

Database: Proquest < June 20, 2014>

Search Strategy:

- 1 schoolchildren
- 2 school children
- 3 teen*
- 4 preschool student*
- 5 child
- 6 youth*
- 7 adolescen*
- 8 kid*
- 9 boy*
- 10 girl*
- 11 paediatr*
- 12 pediatr*
- 13 student*
- 14 Elementary School Student*
- 15 Junior High School Student*
- 16 High School Student*
- 17 Middle School Student*
- 18 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17

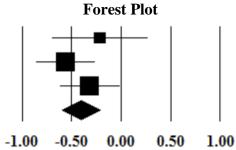
- 19 body mass index
- 20 BMI
- obes* 21
- overweight* body fat* weigh* 22
- 23
- 24
- 25 adipos*
- 19 or 20 or 21 or 22 or 23 or 24 or 25 school* 26
- 27
- 28 nurs*
- 29 18 and 26 and 27 and 28 (826)

Figure 2.A2. Forest plot of studies included in the meta-analysis (BMIz and BMI percentile outcome)

BMI percentile

Study name	Std diff in means			p-value	1
Robbins 2012		-0.70		0.38	-
Speroni 2007	-0.56	-0.86	-0.27	0.00	
Williams 2011	-0.32	-0.62	-0.02	0.04	
	-0.41	-0.60	-0.21	0.00	1.00
					-1.00

Q=2.0, p=0.37; $I^2=0\%$

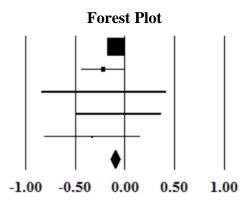


Favors Intervention Favors Control

BMIz

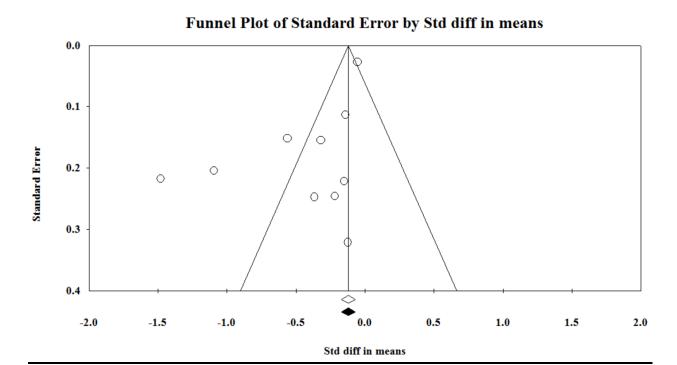
Study name	Std diff in means			r p-value
Bonsergent 2012	-0.09	-0.15	-0.04	0.00
Johnston 2013	-0.22	-0.44	0.00	0.05
Melin 2008	-0.22	-0.85	0.41	0.50
Pbert 2013	-0.07	-0.50	0.36	0.75
Robbins 2012	-0.33	-0.82	0.15	0.18
	-0.10	-0.15	-0.05	0.00

Q=2.3, p=0.68; I²=0%



Favors Intervention Favors Control

Figure 2.A3. Potential for publication bias



The funnel plot represents the mean differences in body measures for overweight/obese youth who received obesity treatment or prevention interventions delivered in school settings with those who did not. The plot shows the standard error of the mean difference in body measure (Y axis) versus the reported mean difference (X axis). The open diamond indicates the pooled effect size and its 95% confidence interval, and the filled diamond indicates the pooled effect size and 95% confidence interval when missing studies suggested by publication bias analysis are included.

Chapter 3: Reduction of bias in evaluation efficacy of a childhood obesity intervention: A comparison of propensity score methods

This chapter addresses aim 2 and examines three propensity score methods to determine which method best reduced bias for the data set that was used to assess implementation and efficacy of the HOP program. The methods used to accomplish this aim included a review of the literature on three common propensity score methods and application of each method to the HOP data set. This manuscript was submitted to *Nursing Research* in February 2016 and is currently under revision following a favorable review. The chapter reflects the manuscript as originally submitted to *Nursing Research*.

Introduction

Childhood obesity is one of the nation's greatest child health threats, with 17% of children meeting criteria for obesity (body mass index (BMI) ≥ 95th percentile for age and sex) (Ogden et al., 2014). Childhood obesity is associated with many health comorbidities during childhood, negative psychosocial and academic outcomes, and adult obesity (Daniels, 2006; Freedman et al., 2005; Rappaport et al., 2011). Schools are an ideal setting in which to implement childhood obesity interventions (Institute of Medicine, 2012; Waters et al., 2011), and school-based obesity interventions can be effective in reducing children's BMI percentile (Katz et al., 2008; Schroeder et al., 2016; Sobol-Goldberg et al., 2013; Waters et al., 2011). However, many school-based obesity interventions are implemented in a voluntary manner, with only students who are interested in the intervention actually receiving the intervention. Students who do not want to participate (or whose parents do not want their child to participate) do not receive the intervention. As a result of lack of randomization, key differences may exist between

intervention participants and non-participants (Shadish, Cook, & Campbell, 2011). Such differences may include factors that are known to influence childhood obesity (e.g., gender, race/ethnicity, socioeconomic status) (Davison & Birch, 2001); these differences can confound the relationship between the intervention and outcome of interest, in this case BMI percentile change. Therefore, statistical methods that reduce bias in observational studies are required.

Various statistical methods can be used by the researcher to control for bias in observational studies, including propensity scoring (Rosenbaum & Rubin, 1983). A propensity score (PS), developed by Rosenbaum and Rubin (1983), is the probability of an individual being in the intervention group given his or her baseline characteristics. The PS is calculated using logistic regression, in which the individual's characteristics (potential confounders) are the predictors and probability of being in the intervention group is the outcome. Propensity scoring can be applied in observational studies to reduce bias in understanding the relationship between an intervention and outcome. Based on the potential outcomes framework, the unconfounded effect of an intervention can be ascertained when the PS balances all confounders between the nonrandomized intervention and control groups (Rubin & Zell, 2016). Various methods of propensity scoring exist (Rosenbaum & Rubin, 1983). Propensity scoring may be superior to other methods of controlling for confounding in nursing research such as sample stratification and matching (which can only account for a limited number of known confounders) or regression analysis (which may result in residual bias if the intervention and control group are heavily imbalanced on baseline characteristics) (D'Agostino & Kwan, 1995; Qin, Titler, Shever, & Kim, 2008; Rosenbaum & Rubin, 1983).

The scholarly discussion about and use of propensity scoring in both the general biomedical and nursing literature has markedly increased during the past 10 years (*Figure 3.1*),

necessitating that nurse scientists who work with observational data have a working knowledge of this analytic technique (Eckardt, 2012; Qin et al., 2008; Shadish & Steiner, 2010). Need for PS use will likely increase with the explosion of observational data available to nurse scientists via electronic medical records (EMRs) (Clarke & Cossette, 2000; Lin, Jiao, Biskupiak, & McAdam-Marx, 2013). Currently, many papers in the nursing literature that discuss propensity scoring do so by applying propensity scores during their study analyses (e.g., (Moser et al., 2014; Stimpfel, Rosen, & McHugh, 2015)). This paper is one of the few within the nursing literature to focus on PS methodology (Eckardt, 2012; Qin et al., 2008; Shadish & Steiner, 2010) and, to our knowledge, the first in the nursing literature to examine effects of different PS methods on bias reduction.

The purpose of our study is to apply 3 propensity scoring methods to an observational data set in order to determine which method best reduced bias. In this paper, we define bias as number of significant differences in confounders between the intervention and control group. We chose this definition because it is easily observable, quantifiable, and applicable across PS methods.

Methods

Propensity scores: Definition and Creation

Rosenbaum and Rubin (Rosenbaum & Rubin, 1983) define a PS as the conditional probability of assignment to an intervention given a vector of observed covariates. Applied to non-randomized studies, a participant's PS is the likelihood that (s)he would receive the treatment or intervention in question given his/her characteristics (e.g., gender, race, neighborhood poverty level). Because a PS is a probability, a PS may range from 0 to 1. Two participants with identical propensity scores can be considered to have the same probability of

receiving the intervention. In this manner, the PS can help create a proxy intervention group or proxy control group within observational cohort data (D'Agostino, 1998; D'Agostino & Kwan, 1995). For example, a student with a PS of 0.72 who received the intervention can be considered as assigned to the intervention group; a student with a PS of 0.72 who did not receive the intervention can be considered as assigned to the control group. These two participants, because of their identical propensity scores, can be considered comparable, as the PS has adjusted for their differences. It is important to note that propensity scores are created using measured covariates only. Therefore, while propensity scoring can be used to approximate a quasi-experimental design, it cannot approximate a randomized controlled trial (D'Agostino, 1998; D'Agostino & Kwan, 1995; Wagner, 2015). However, in large observational data sets, often many variables (i.e. potential confounders) are available and can be used in creation of a PS, reducing the risk of excluding important confounders (Brookhart et al., 2006; D'Agostino, 1998).

A PS is traditionally created through use of logistic regression, with the predicted outcome being the probability of receiving the intervention. When determining which predictors to include in the PS model, Rosenbaum (2002) cautions against using only predictors which significantly differ between groups because 1) this does not consider the relationship between predictor and outcome, 2) just because the difference between groups on a predictor is not statistically significant, it doesn't mean that it can be ignored, and 3) this process considers predictors only one at a time whereas the logistic model will consider the predictors as a group. As such, it is suggested that all available predictors related to the outcome are included in a PS model unless there is a theoretical reason not to do so (Brookhart et al., 2006).

After creation of the PS, data should be further examined before proceeding with analysis. The researcher should inspect the distribution of propensity scores by group via

graphical display using a histogram or boxplot. Presence of a large overlapping area of propensity scores, or "common support," indicates that the use of propensity scores will help to balance the intervention and control groups on key confounders (Wagner, 2015). Though there is no theoretical guidance on what exactly merits common support, it can be considered the range where the range of propensity scores where there are at least five observations in both the intervention and control group (Li, Kleinman, & Gillman, 2014). It is suggested that researchers consider limiting their analysis to only participants whose propensity scores fall under the common support, because characteristics of individuals outside the common support may be too different to compare without introducing significant bias (Li, Morgan, & Zaslavsky, 2014; Wagner, 2015). After the common support is examined, the PS can be applied to the data using multiple methods. We compared 3 methods: PS matching, stratification, and PS weighting to determine what method best reduced bias in this data set. Sample SAS code for all 3 methods are presented in Table 3.A1.

PS Method 1: Matching

Using this method, participants who received the intervention are matched by PS to participants who did not receive the intervention (Rosenbaum & Rubin, 1985b), creating two groups comparable on potential confounders. After creation of the groups, the outcomes for each group can be directly compared to estimate the intervention effect (Peter C. Austin, 2011; D'Agostino, 1998; Hill & Reiter, 2006; Rosenbaum & Rubin, 1985b).

When implementing PS matching the researcher must make several methodological decisions: (1) ratio of control to intervention group, (2) replacement versus nonreplacement, (3) greedy versus optimal, and (4) nearest neighbor versus caliper matching. Ratio, which refers to how many control subjects are matched to an intervention subject, is usually done in a 1:1 ratio,

though many to one matching may be employed (Gu & Rosenbaum, 1993). Matching can be performed either with or without replacement (Peter C. Austin, 2011). If matching with replacement, control participants who are matched to intervention participants are returned to the pool for potential matching with another intervention participant. Of note, matching with replacement requires a special variance estimator to consider the fact that one control participant may be matched to multiple intervention participants (or vice versa) (Hill & Reiter, 2006). Another consideration when using matching methods is greedy versus optimal matching. Using greedy methods, the intervention participant is matched to the closest control participant, regardless of whether the control participant would be a closer match for another intervention participant. Alternatively, optimal matching is based on minimizing the total within-pair difference on propensity scores (Peter C. Austin, 2011) but has been found to be no better than greedy matching in reducing bias (Gu & Rosenbaum, 1993). Lastly, PS matching may be performed using either nearest neighbor or caliper methods (or a combination of both methods). Using nearest neighbor methods, an untreated participant is matched to a treated participant with the closest PS, but there is no defined PS distance that is considered too great for matching. Alternately, in caliper matching, a predetermined distance between propensity scores, defined by the investigator, is considered the maximum allowable distance. Using the caliper matching approach, a participant lacking a match within that caliper will be excluded from analysis. Recommended optimal caliper distances range between 0.05 (Kurth et al., 2006) and 0.2 SD of the logit (PS log(PS/(1-PS)) to be optimal (Peter C. Austin, 2011). The nearest neighbor method is the easiest from a computation standpoint and may be superior to caliper matching methods in minimizing risk of bias (Austin, 2010), though nearest neighbor matching within calipers defined by the PS may be superior in balancing covariates between groups (Rosenbaum & Rubin,

1985a). Of note, PS matching may lead to some participants being excluded from the final matched sample because they do not have a match within the specified caliper (e.g. closet match is within 0.07 but specified caliper is 0.05) or exceed the matching ratio (e.g., data set includes more control than intervention participants but matching ratio is 1:1).

PS Method 2: Stratification

In PS stratification, participants are first ranked by PS and then divided into strata (Peter C. Austin, 2011). Five strata are typically recommended, as 5 can reduce up to 90% of bias (Rosenbaum & Rubin, 1984). Every participant is included in one of the 5 strata. Within each strata, participants' propensity scores are very similar, more similar than they are across the sample as a whole. After participants are divided into strata, an outcome can be estimated for the intervention versus control group for each stratum. A pooled outcome for the entire sample can be calculated by weighting the outcome of each strata by the percentage of participants within that stratum (Peter C. Austin, 2011). For example, if participants are divided into 5 strata, then each stratum's outcome will be weighted by 1/5, or 0.20, when computing the outcome.

PS Method 3: Weighting

In PS weighting, each participant is weighted by the inverse of his/her PS. This weighted sample can be used to determine an unconfounded estimate of the outcome (F. Li et al., 2014). Intervention participants are weighted using the equation 1/PS; participants who did not receive the intervention are weighted by 1/(1-PS). PS weighting uses the exact PS values which avoids the risk of residual confounding with inexact matching and stratification (F. Li et al., 2014). One concern with this method is that standard errors may be larger than with other PS methods due to extreme weighting of participants with propensity scores near 0 or near 1. One potential solution to this issue is trimming weights (Potter, n.d.) and excluding individuals with very small

propensity scores (e.g., <0.05) from the analysis. Doing so may increase accuracy of the predicted outcome (Kurth et al., 2006). Another method to minimize extreme weighting is to use bounded overlap weights. A discussion of bounded overlap weights method is beyond the scope of this paper, but interested readers are referred to Li and colleagues (2014).

Of note, final analytic sample size differs for each PS method: for PS 1:1 matching the sample size is twice the number of intervention participants, for PS stratification the sample size includes all intervention and control participants, for PS weighting the sample size includes all intervention and control participants. Sample SAS code used for implementing each PS method is listed in *Appendix A*.

Data Source

We used an observational data set to examine the effect of a school nurse-led obesity program on BMI percentile of kindergarten to 5th grade students who meet the criteria for severe obesity (Body Mass Index (BMI) for age and sex at the 99th percentile or 120% of the 95th percentile) (Flegal et al., 2009). The program, the Healthy Options and Physical Activity Program (HOP), was implemented in New York City (NYC) schools in 2010. The goal of HOP is to help children improve health behaviors and maintain or decrease BMI percentile. During HOP sessions, school nurses provide education and counseling, and assist students with goal setting around five health behaviors: fruit/vegetable intake, sedentary media use, physical activity, sugar-sweetened beverage intake, and portion size. School nurses document participation in the program in the student's electronic medical record. During the 2012/2013 school year, 1,054 children participated in HOP (intervention group) and 19,464 were eligible for but did not participate in HOP (control group). However, because HOP is voluntary and not randomly assigned, there are likely inherent differences between children with severe obesity

who received HOP and children with severe obesity who were eligible for but did not receive HOP. Data used in the creation of the PS came from three sources: the schools' EMR, the NYC Department of Health and Mental Hygiene Office of School Health Reports, and the NYC Center for Economic Opportunity. Variables were organized by the Socio-ecological Model, which acknowledges that individual, family, institution, and community-level factors influence a child's body weight (Davison & Birch, 2001).

PS Creation

To create the PS, a binary measure of HOP (intervention) participation (1=yes, 0=no) was regressed on 11 potential confounder variables: community poverty level, school poverty level, school nurse workload, household food insecurity, baseline BMI, baseline BMI percentile, age, race/ethnicity, grade, gender, and diagnosis of at least one chronic illness. Following creation of the PS, a histogram was examined to assess common support and each PS method was applied.

Using PS matching, each intervention child was matched to a control child (1:1 matching) with the most similar PS (caliper of 0.05). Greedy matching without replacement was employed. Once a pair was matched, the control child was not returned to the pool for further matching. Using PS stratification, intervention children and control children were divided into five equal strata based on propensity scores. Using PS weighting, each intervention child was assigned a weight of 1/PS, and each control child was assigned a weight of 1/PS. Weights were then normalized by dividing each weight by the mean weight.

Statistical Testing for Reduction of Bias

Distribution of key confounders between the intervention and control groups was compared before and after use of each PS methods. For each of the 11 confounders of interest, the difference between the intervention and groups was tested for significance using Wilcoxon

signed rank tests for continuous variables or chi-square tests for dichotomous or categorical variables. For each PS method, the total number of significant differences between the intervention and control groups was calculated. Of note, for PS stratification, differences between the intervention and control group were tested within each of the five strata; if a significant difference existed in at least one strata then the confounder was counted as a significant difference even if it did not differ within the other four strata. All analyses were performed using SAS 9.4. Institutional Review Board approval was obtained from the New York City Department of Health, NYC Department of Education, and Columbia University Medical Center.

Results

Of 20,518 children with severe obesity, 1,054 received the HOP intervention. Baseline characteristics of the sample prior to application of propensity scores are listed in Table 3.1. Groups differed on 7 of the 11 potential key confounders. On average, intervention children went to a school where fewer students received free/reduced lunch and the nurse workload was lower. Intervention children had higher baseline body measures, were older, and were more likely to have at least one chronic condition.

PS Creation

Data from one or more variables required for PS creation were missing from 75 participants (3.7%) leaving a total sample of 1,049 children in the intervention group and 19,394 children in the control group for PS analysis. Propensity scores ranged between 0.0019 and 0.6205. The mean propensity scores were 0.0849±0.0626 (range 0.0050-0.4913) and 0.0495±0.0403 (range 0.0019-0.6205) for the intervention and control groups respectively.

Visual inspection of a histogram demonstrated that there appeared to be good common support between groups (*Figure 32*).

PS Matching

Two equal groups of 1,049 participants were created. It was possible to match each intervention child with a control child within a 0.05 caliper. Using this method, all significant differences between the intervention and control groups were removed. Results using this method are presented in additional detail in Table 3.A2.

PS Stratification

PS stratification resulted in creation of five strata, with similar propensity scores within each strata. While all strata included the same number of children, the number of intervention children differed among strata because intervention children had higher propensity scores than control children. Stratum 1 had 59 intervention children (1.4% of stratum), stratum 2 had 90 intervention children (2.2% of stratum), stratum 3 had 145 intervention children (3.6% of stratum), stratum 4 had 277 intervention children (6.8% of stratum), and stratum 5 had 478 intervention children (11.7% of stratum). While one significant difference (grade) was removed from all 5 strata, new significant differences were created for 2 confounders (household food insecurity, race/ethnicity), though these differences occurred in only 1 and 2 of the 5 strata, respectively. Differences between the intervention and control groups remained for six variables: school poverty level (2 of 5 strata), school nurse workload (3 of 5 strata), baseline BMI percentile (1 of 5 strata), baseline BMI (3 of 5 strata), age (1 of 5 strata), diagnosis of at least 1 chronic illness (1 of 5 strata). Detailed esults using this method are presented in Table 3.A2. Following use of PS stratification, differences between the intervention and control groups remained for 8 of the 11 confounders.

PS Weighting

PS weighting applied a normalized weight to each child in the sample. Weights differed between groups. For the control group, normalized weights ranged between 0.5005 and 1.3164 (mean 0.5267 and median 0.5200). For the intervention group, normalized weights ranged from 1.0168 to 99.3865 (mean 9.7506 and median 7.2419). Because of these differences, we explored limiting the sample to children with normalized weights between the 5th and 95th percentile (Kurth et al., 2006; Potter, n.d.). This action resulted in exclusion of 98% of children from the intervention group and therefore was not employed. After application of normalized weights to the full sample, 1 difference between groups was removed (grade) and 2 new differences (household food insecurity, race/ethnicity) were created. Additional details may be found in Table 3.A3. To further explore this result, two analyses were performed using the normalized log of the weight and the normalized square root of the weight. Results using the square root of the weight were similar (1 difference removed, 2 differences created), as were the results using the log of the weight (0 difference removed or created). Therefore, following PS weighting, differences between groups remained for 8 of 11 confounders. Table 3.2 summarizes confounder distribution before and after application of each PS method.

Discussion

We compared three PS methods by applying them to one data set of children with severe obesity. Use of propensity scores was effective in reducing significant differences between groups. Prior to propensity scoring, groups differed on 7 of 11 potential confounders. After PS matching, 0 confounders differed between groups. After PS stratification, 8 potential confounders differed between groups, though only 2 confounders differed in more than half of

the 5 strata. After PS weighting, 8 potential confounders differed between groups. For this data set, PS matching was most effective in reducing bias.

Weighting likely increased differences between groups because in this data set receipt of the intervention was a rare event (~5%%; 1,059 of 20,443 students). Rare events result in very small propensity scores (intervention group 0.0849; control group 0.0495). As a result, weights for the intervention group (1/PS) were much larger than the weights for the control group (1/(1-PS)). Further testing using the log of the normalized weights and the square root of the normalized weights did not improve the results. Therefore, despite the reported strengths of the weighting method (Kurth et al., 2006; F. Li et al., 2014), we conclude that PS weighting may not be well suited for data sets where receipt of the intervention of interest is rare.

While propensity scores are useful to the researcher, the method has inherent limitations. First, the PS only can adjust for confounders placed in the PS logistic model. It cannot adjust for unknown confounders (Peter C. Austin, 2011; Rosenbaum & Rubin, 1983). Large data sets with many available confounders are ideal for use with propensity scoring, yet no data set will include all possible confounders. Because randomization theoretically balances groups on both known and unknown confounders, it remains superior in minimizing bias. Second, use of propensity scoring reduces bias in observational data and more closely approximate a randomized design. However, propensity scoring only reduces and does not remove the limitations inherent to observational data - findings are limited to association and causality may not be inferred (Peter C. Austin, 2011; Rosenbaum & Rubin, 1983). Therefore, a randomized controlled trial remains the gold standard for evaluating an intervention and inferring causality (Shadish et al., 2011).

Many researchers implement a PS method without first examining the reduction of bias resulting from implementation of the PS or evaluating different PS methods (Austin & Mamdani,

2006). To our knowledge, our study is the first within the nursing literature to compare multiple PS methods. Examples from other fields have demonstrated conflicting results. In one study researchers demonstrated that both stratification and matching removed confounder differences between groups, though matching did so more effectively (Austin & Mamdani, 2006). The researchers noted one weakness of matching to be the loss of participants due to inability to find a match; this was not a concern in our study because of the large pool of untreated participants. Another study (Kurth et al., 2006) demonstrated that different PS methods yielded widely differing results when extreme PS values (<5th percentile) were included. When the data were clipped to remove such values, the methods become comparable. However, the authors noted that neither method was necessarily superior in reducing bias; the best method depends on the sample of interest, the clinical question, and the data (Kurth et al., 2006).

Our study has several limitations. For example, our results reflect PS application to only one data set. Our data set also may not be typical in that only a small number of subjects (5%) received the intervention, which led to differences in sample size between PS matching (n=2,058) and PS stratification and PS weighting (n=20,443). Therefore, our comparison of the three methods was biased towards finding fewer significant differences between groups in the matching analysis because the sample size was smaller. In addition, we only apply the three most common PS methods; additional methods exist (Peter C. Austin, 2011; Rosenbaum & Rubin, 1983). Also, our measure of bias considered only whether or not a significant confounder differed between the intervention and control groups; it did not consider magnitude of differences between the intervention and control groups nor did it consider significance of differences in bias reduction between PS methods (Gelman & Stern, 2006). Lastly, additional

potential cofounders that would be ideally included in our PS, such as parental attitudes towards HOP, were not available in our data set.

Conclusion

Our analysis of applying propensity scores to a data set of a nurse-led obesity intervention demonstrates that propensity scoring can be effectively applied to reduce bias in observational studies. Of the three methods compared, we found that PS matching removed all significant differences between groups while PS stratification and weighting removed some existing differences and created new differences. These results are likely influenced by the fact that only a small proportion of participants received the intervention. Because of these differences, we recommend that nurse scientists test multiple PS methods before selecting a method for use in their analyses. By adding PS methods to their toolbox, nurse scientists can harness the increasingly available large data sets to conduct studies with reduced bias to create a stronger body of knowledge to improve health.

Table 3.1. Sample demographics organized by Socio-Ecological Model constructs

Variable	Intervention Group	Control Group	Absolute Difference	P-value	
	N=1,054	N=19,464			
	<u>Co</u>	mmunity Level			
Student community poverty level (mean %±SD)	23.4 (±6.3)	23.8 (±6.5)	0.4	0.06	
	<u>Inst</u>	titutional Level			
School poverty level (mean±SD)	71.0 (±20.1)	74.1 (±18.0)	3.1	< 0.01	
School nurse workload* (mean±SD)	13.2 (±6.6)	14.6 (±6.4)	1.4	<0.01	
	<u>Inte</u>	rpersonal Level			
Household Food Insecurity (%) Yes No	82.6 17.4	81.2 18.8	1.4 1.4	0.26	(
	<u>Inc</u>	dividual Level			
BMI (mean±SD)	29.8 (±4.9)	27.1 (±4,4)	2.7	< 0.01	
BMI percentile (mean±SD)	99.5 (±0.3)	99.4 (±0.3)	0.1	<0.01	
Gender (%)					
Male Female	58.8 41.2	61.6 38.4	2.8 2.8	0.07	
Age in months (mean±SD)	99.5 (±19.8)	91.0 (±21.5)	8.5	< 0.01	

Variable	Intervention Group	Control Group	Absolute Difference	P-value	
	N=1,054	N=19,464			
Grade (%)					
Kindergarten	6.9	20.6	13.7		
First	16.3	20.2	3.9		
Second	21.6	18.9	2.7		
Third	18.8	15.6	3.2		
Fourth	19.2	13.1	6.1		
Fifth	17.2	11.5	5.7	< 0.01	
Race/ethnicity (%)					
Non-Hispanic White	10.7	9.9	0.8		
Non-Hispanic Black	21.5	25.3	3.8		
Hispanic	58.8	56.4	2.4		
Asian**	7.9	7.3	0.6		
American Indian**	0.6	0.8	0.2		
Multi-racial	0.5	0.3	0.2	0.10	
At least 1 chronic illness (%)	46.0	30.5	15.5	< 0.01	

^{*}Composite measure of workload intensity based on number of children with diabetes, medication administrations, and walk-in visits at each school. Range from 1.6 to 36.5 (mean 13.3) for this sample.

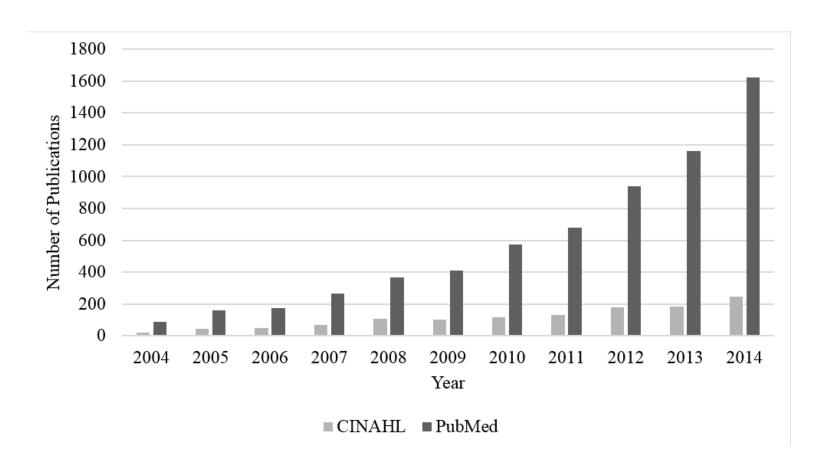
**Asian= Asian/Native Hawaiian/Pacific Islander, American Indian= American Indian/Alaskan Native

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Table 3.2. Confounder distribution between groups before and after application of three PS methods

	No	PS	PS	PS
	Propensity Scoring (n=20,518)	Matching (n=2,098)	Stratification (n=20,443)	Weighting (n=20,443)
Community poverty level	N	N	N	N
School poverty level	Y	N	Y	Y
School nurse workload	Y	N	Y	Y
Household food insecurity	N	N	Y	Y
BMI	Y	N	Y	Y
BMI percentile	Y	N	Y	Y
Gender	N	N	N	N
Age	Y	N	Y	Y
Grade	Y	N	N	N
Race/ethnicity	N	N	Y	Y
At least 1 chronic illness	Y	N	Y	Y
Differences removed		7	1	1
Differences created		0	2	2
Total differences	7 of 11	0 of 11	8 of 11	8 of 11

Figure 3.1. Publications retrieved from PubMed and Cumulative Index to Nursing and Allied Health Literature (CINAHL) using key term "propensity scor*" (2004-2015)



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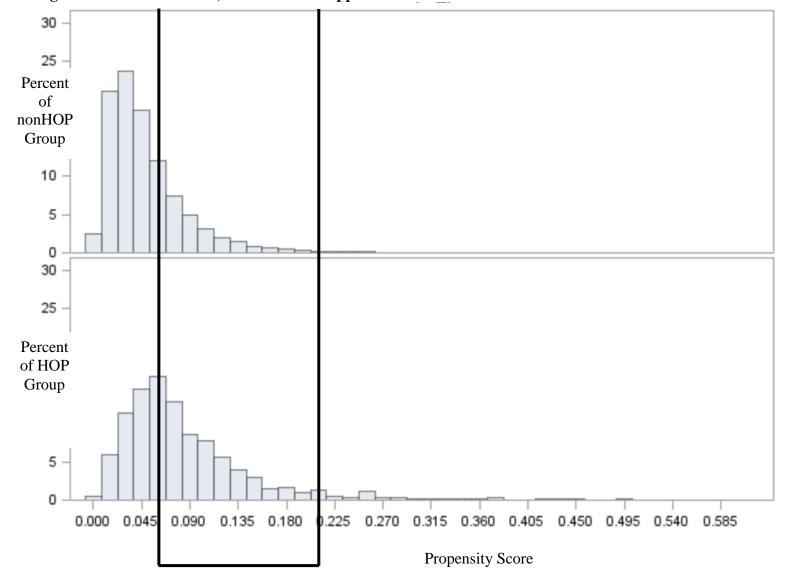


Figure 3.2. PS distribution, with common support identified in brackets

Table. 3.A1. SAS Codes with annotations

Action	SAS Code	Annotation
	Create PS using logistic regression	<pre>proc logistic descending data = ps_est; title 'PS Estimation';</pre>
		model hop = var1-var3/lackfit outroc = ps_r; output out= ps_p XBETA=ps_xb STDXBETA= ps_sdxb PREDICTED = ps_pred; run;
	data one;	This provides an example of 1:1 matching without
	set ps_p;	replacement. Of note, after matching, data are paired,
	ranvar = ranuni(0);	and it is recommended that a paired test (i.e.,
	run;	McNemar's, paired t-test) be used for data analysis.
	proc sort data = one;	
	by hop ranvar;	
	run;	
	<pre>proc transpose data = one out = data1; by hop; var ps_pred hop ranvar StudentID; run;</pre>	Data must be transposed by HOP status to facilitate the matching process.
	data id_t (rename=(COL1-COL1,049 = tid1-tid1,049)); set data1; if hop = 1 and _NAME_ = 'StudentID';	First, a data set is created that includes the identifier and PS for each subject in the intervention group. Note that number of columns is number of observations in
	data ps_t (rename=(COL1-COL1,049 = tps1-tps1,049)); set data1;	intervention group.
	if hop = 1 and _NAME_ = 'ps_pred';	
	data id_c (rename=(COL1-COL19,394 = cid1-	
	cid19,394));	

Table 3.A1. (Con't.)

Action	SAS Code	Annotation
	set data1; if hop = 0 and _NAME_ = 'StudentID'; data ps_c (rename=(COL1-COL19,394 = cps1-cps19,394)); set data1; if hop = 0 and _NAME_ = 'ps_pred';	This procedure is repeated for the control group.
	data all; merge id_t ps_t id_c ps_c; caliper = .05; array treat_id (Potter) \$ tid1-tid1,049; array treat_jd {*} \$ cid1-cid19,394; array treat_p {*} tps1-tps1,049; array ctl_p {*} cps1-cps19,394; array used_i {*} used1 - used19,394; array matched_t {*} \$ m_tid1-m_tid1,049; array matched_c {*} \$ m_cid1-m_cid19,394; match_N = 0; do i = 1 to 1,049; min_diff = 1; best_match = 0; do j = 1 to 19,394; if used_i[j] = . then do; if ABS(treat_p[i] - ctl_p[j]) < caliper then do; if ABS(treat_p[i] - ctl_p[j]) < min_diff then do; min_diff = ABS(treat_p[i] - ctl_p[j]); best_match = j; end; end; end;	Using lengthy code, the data sets are merged, and subjects are matched using a caliper width of 0.05. Note that the caliper for matching (here this is 0.05) is specified in the "caliper" line.

Table 3.A1. (Con't.)

Action	SAS Code	Annotation
	<pre>end; if best_match > 0 then do; match_N = match_N + 1; used_i[best_match] = 1; matched_t[match_N] = treat_id[i]; matched_c[match_N] = ctl_id[best_match]; end; end;</pre>	A data step is used to create a data set that includes only matched participants.
	<pre>set all; array matched_t {*} \$ m_tid1-m_tid1,049; array matched_c {*} \$ m_cid1-m_cid19,394; do match = 1 to match_N; Intervention_IDN = matched_t[match]; Control_IDN = matched_c[match]; output; end; keep match intervention_idn control_idn; run;</pre>	
PS method 2: Stratification	<pre>proc rank data = ps_p out= ps_strataranks groups=5; var ps_pred; ranks ps_pred_rank; run;</pre>	First, subjects are divided into quintiles based on PS.
	data final.strata; set ps_strataranks; run; proc sort data=final.strata; by ps_pred_rank; run;	The data are then sorted by the strata ranks.

Table 3.A1. (Con't.)

Action	SAS Code	Annotation
PS method 3:	data ps_weight;	First the weights are created.
Weighting	set ps_p;	
	if hop = 1 then ps_weight = 1/ps_pred;	
	else ps_weight = 1/(1-ps_pred);	
	run;	
	<pre>proc means noprint data = ps_weight;</pre>	
	var ps_weight;	
	output out = q mean = mn_wt;	
	run;	
	data ps_weight2;	Then the weights are normalized. Wt2 is the new
	if $_n = 1$ then set q;	normalized weight.
	retain mn_wt;	
	set ps_weight;	
	wt2 = ps_weight/mn_wt; run;	
Examining	<pre>proc sort data = ps_p;</pre>	A boxplot and histogram are then used to examine
common support	by ps_pred HOP;	common support. The common support can be considered the areas where the propensity scores overlap.
••	<pre>proc boxplot data=ps_p;</pre>	A limited common support means that PS will have
	symbol width = 2;	limited ability to improve the analysis.
	plot ps_pred*HOP;	
	run;	
	proc univariate data=ps_p noprint;	
	class HOP;	
	var ps_pred;	
	histogram ps_pred; run;	
SAS Code Add	anted from SAS Global Forum (Lanehart et al., 2012a)	

SAS Code Addapted from SAS Global Forum (Lanehart et al., 2012a)

Table 3.A2. Sample characteristics after PS matching. No significant differences existed after matching.

Characteristic	Total Sample (n=20,443)	Intervention	Control Group (n=1,049)	Absolute Difference
	(II=20,443)	Group (n=1,049)	(II=1,049)	Difference
Community poverty level				
(mean±SD)	$23.6 (\pm 6.5)$	23.4 (±6.3)	23.8 (±6.7)	0.4
School poverty level				
(mean±SD)	71.2 (±19.7)	$71.1 (\pm 20.0)$	71.3 (±19.5)	0.2
School nurse workload				
(mean±SD)	$13.3 (\pm 6.2)$	$13.3 (\pm 6.7)$	13.3 (±5.8)	0
Household food Insecurity				
(%)	82.4	82.8	82.1	0.7
Yes	17.6	17.3	17.9	0.6
No				
BMI (mean±SD)	29.7 (±5.0)	29.7 (±4.8)	29.6 (±5.1)	0.1
BMI percentile (mean±SD)	99.5 (±0.3)	99.5 (±0.3)	99.5 (±0.2)	0
Gender				
Male (percent)	59.1	58.6	59.6	1
Female (percent)	40.9	41.4	40.4	1
Age (mean±SD)	99.50 (±20.1)	99.4 (±19.8)	98.5 (±20.7)	0.9
Grade (%)				
Kindergarten	6.8	6.9	6.6	0.3
First	17.2	16.4	17.9	1.5
Second	21.2	21.6	20.7	0.9
Third	18.5	18.9	18.2	0.7
Fourth	19.5	19.3	19.8	0.5
Fifth	16.8	16.9	16.8	0.1
Race/ethnicity (%)				
Non-Hispanic White	10.6	10.6	10.7	0.1
Non-Hispanic Black	21.5	21.6	21.4	0.2
Hispanic	58.4	58.9	58.0	0.9
Asian**	8.3	7.8	8.8	1
American Indian**	0.6	0.6	0.6	0
Multi-racial	0.6	0.5	0.7	0.2

Table 3.A2. (Con't.)

Characteristic	Total Sample (n=20,443)	Intervention Group (n=1,049)	Control Group (n=1,049)	Absolute Difference
Diagnosis of at least 1 chronic illness (%)	46.7	46.1	47.2	1.1

^{**}Asian= Asian/Native Hawaiian/Pacific Islander, American Indian= American Indian/Alaskan Native

Table 3.A3. Sample characteristics after PS stratification

Characteristic	Stratum	Total Sample	Intervention	Control Group	Absolute
		(n=20,443)	Group	(n=19,394)	Difference
			(n=1,049)		
Community	1	24.2 (±6.2)	25.5 (±5.8)	24.2 (±6.2)	1.3
poverty level	2	$24.0 (\pm 6.3)$	$23.6 (\pm 6.3)$	$24.0 (\pm 6.3)$	0.4
(mean±SD)	3	$24.0 (\pm 6.4)$	$23.8 (\pm 6.3)$	$24.1 (\pm 6.4)$	0.3
	4	$23.5 (\pm 6.6)$	$23.6 (\pm 6.3)$	$23.5 (\pm 6.6)$	0.1
	5	22.9 (±6.8)	$22.8 (\pm 6.2)$	$23.0 (\pm 6.8)$	0.2
School poverty	1	77.3 (±15.0)	80.6 (±12.5)	77.3 (±15.0)	3.3
level (mean±SD)	2	$76.4 (\pm 16.1)$	$77.1 (\pm 17.1)$	$76.4 (\pm 16.2)$	0.7
	3	$75.0 (\pm 16.8)$	$77.6 (\pm 17.1)$	$74.9 (\pm 16.8)$	2.7
	4	$72.7 (\pm 18.4)$	$72.8 (\pm 17.1)$	$72.8 (\pm 18.5)$	0
	5	68.2 (±21.8)	66.0 (±22.4)	68.5 (±21.7)	2.5
School nurse	1	17.1 (±7.2)	19.7 (±7.6)	17.0 (±7.2)	2.7
workload	2	$15.7 (\pm 6.4)$	$18.0 (\pm 7.2)$	$15.6 (\pm 6.4)$	2.4
(mean±SD)	3	$14.6 (\pm 6.0)$	$14.4 (\pm 7.0)$	$14.6 (\pm 6.0)$	0.2
	4	13.5 (±5.8)	$13.0 (\pm 6.2)$	$13.5 (\pm 5.8)$	0.5
	5	12.0 (±5.2)	$11.4 (\pm 5.5)$	12.1 (±5.1)	0.7
Household food	1	Yes: 79.9	Yes: 96.6	Yes: 79.7	Yes: 16.9
insecurity (%)		No: 20.1	No: 3.4	No: 20.3	No: 16.9
	2	Yes: 80.0	Yes: 75.6	Yes: 80.1	Yes: 4.5
		No: 20.0	No: 24.4	No: 19.9	No: 4.5
	3	Yes: 80.1	Yes: 80.7	Yes: 80.1	Yes: 0.6
		No: 19.9	No: 19.3	No: 19.9	No: 0.6
	4	Yes: 82.8	Yes: 83.4	Yes: 82.8	Yes: 0.6
		No: 17.2	No: 16.6	No: 17.2	No: 0.6
	5	Yes: 83.9	Yes: 82.6	Yes: 84.1	Yes: 2.5
		No: 16.1	No: 17.4	No: 15.9	No: 2.5
BMI (mean±SD)	1	22.8 (±2.1)	23.4 (±2.0)	22.8 (±2.1)	0.6
	2	$25.6 (\pm 2.8)$	26.7 (±3.0)	$22.6 (\pm 2.8)$	4.1
	3	27.3 (±3.0)	$27.4 (\pm 2.9)$	$27.3 (\pm 3.0)$	0.1
	4	28.8 (±3.3)	$28.8 (\pm 3.5)$	$28.8 (\pm 3.3)$	0
	5	31.7 (±4.6)	32.3 (±4.9)	31.6 (±4.6)	0.7
BMI percentile	1	99.4 (±0.3)	99.5 (±0.3)	99.4 (±0.3)	0.1
(mean±SD)	2	99.4 (±0.3)	99.4 (±0.3)	99.4 (±0.3)	0
	3	99.4 (±0.2)	99.4 (±0.3)	99.4 (±0.2)	0
	4	99.4 (±0.2)	99.4 (±0.2)	99.4 (±0.2)	0
	5	99.5 (±0.2)	99.5 (±0.2)	99.5 (±0.2)	0

Table 3.A3. (Con't.)

Table 3.A3. (Con't.)						
Characteristic	Stratum	Total Sample	Intervention	Control Group	Absolute	
		(n=20,443)	Group	(n=19,394)	Difference	
			(n=1,049)			
Gender (%)	1	M: 65.9	M: 57.6	M: 66.0	M: 8.4	
M=Male		F: 34.1	F: 42.3	F: 34.0	F: 8.3	
F=Female	2	M: 63.8	M: 71.1	M: 63.6	M: 7.5	
		F: 36.2	F: 28.9	F: 36.4	F: 7.5	
	3	M: 62.6	M: 62.1	M: 62.6	M: 0.5	
		F: 37.4	F: 37.9	F: 37.4	F: 0.5	
	4	M: 59.2	M: 56.3	M: 59.4	M: 3.1	
		F: 40.8	F: 43.7	F: 40.6	F: 3.1	
	5	M: 56.0	M: 56.7	M: 55.9	M: 0.8	
		F: 44.0	F: 43.3	F: 44.1	F: 0.8	
Age in months	1	69.9 (±12.6)	68.4 (±8.8)	70.0 (±12.6)	1.6	
(mean±SD)	2	86.8 (±18.9)	91.0 (±20.5)	86.7 (±18.8)	4.3	
	3	95.3 (±18.9)	$94.4 (\pm 17.8)$	95.4 (±18.9)	1	
	4	$100.2 (\pm 18.7)$	$100.3 (\pm 18.2)$	$100.2 (\pm 18.7)$	0.1	
	5	104.9 (±17.8)	105.8 (±17.4)	104.8 (±17.9)	1	
Grade (%)*	1	K: 70.3	K: 69.5	K: 70.4	K: 0.9	
` ,		1st: 18.1	1st: 22.0	1st: 18.0	1st: 4	
		2nd: 5.6	2nd: 8.5	2nd: 5.6	2nd: 2.9	
		3rd: 3.4	3rd: 0	3rd: 3.4	3rd: 3.4	
		4th: 1.4	4th: 0	4th: 1.4	4th: 1.4	
		5th: 1.2	5th: 0	5th: 1.2	5th: 1.2	
	2	K: 19.9	K: 21.1	K: 19.9	K: 1.2	
		1st: 29.8	1st: 23.3	1st: 30.0	1st: 6.7	
		2nd: 19.4	2nd: 14.4	2nd: 19.6	2nd: 5.2	
		3rd: 14.9	3rd: 14.4	3rd: 14.9	3rd: 0.5	
		4th: 18.4	4th: 12.2	4th: 8.3	4th: 3.9	
		5th: 7.5	5th: 14.4	5th: 7.4	5th: 7	
	3	K: 6.2	K: 4.8	K: 6.2	K: 1.4	
		1st: 23.3	1st: 26.2	1st: 23.2	1st: 3.0	
		2nd: 23.5	2nd: 29.0	2nd: 23.3	2nd: 5.7	
		3rd: 19.8	3rd: 16.6	3rd: 19.9	3rd: 3.0	
		4th: 14.5	4th: 11.7	4th: 14.6	4th: 2.9	
		5th: 12.7	5th: 11.7	5th: 12.8	5th: 1.1	
	4	K: 2.4	K: 1.1	K: 2.4	K: 1.3	
		1st: 17.5	1st: 17.7	1st: 17.5	1st: 0.2	
		2nd: 24.0	2nd: 24.2	2nd: 24.0	2nd: 0.2	
		3rd: 20.4	3rd: 21.7	3rd: 20.3	3rd: 1.4	
		4th: 18.7	4th: 19.5	4th: 18.6	4th: 0.9	
		5th: 17.1	5th: 15.9	5th: 17.2	5th: 1.3	

Table 3.A3. (Cor	1't.)				
Characteristic	Stratum	Total Sample	Intervention	Control Group	Absolute
		(n=20,443)	Group	(n=19,394)	Difference
			(n=1,049)		
	5	K: 0.5	K: 0.6	K: 0.5	K: 0.1
		1st: 11.5	1st: 10.7	1st: 11.6	1st: 0.9
		2nd: 22.9	2nd: 20.9	2nd: 23.2	2nd: 2.3
		3rd: 20.6	3rd: 21.1	3rd: 20.5	3rd: 0.6
		4th: 24.4	4th: 25.1	4th: 24.4	4th: 0.7
		5th: 20.1	5th: 21.6	5th: 19.9	5th: 1.7
D / . 41	1	W. 0.7	W. 17	W . 0 0	XX7. F. 1
Race/ethnicity	1	W: 8.7	W: 1.7	W: 8.8	W: 7.1
(%)**		B: 31.2	B: 25.4	B: 31.3	B: 5.9
		H: 52.0	H: 64.4	H: 51.9	H: 12.5
		As: 6.5	As: 3.4	As: 6.6	As: 3.2
		Am: 1.3	Am: 5.1	Am: 1.2	Am: 3.9
	2	M: 0.2	M: 0	M: 0.2	M: 0.2
	2	W: 8.7	W: 8.9	W: 8.7	W: 0.2
		B: 29.5	B: 26.7	B: 29.6	B: 2.9
		H: 53.9	H: 58.9	H: 53.8	H: 5.1
		As: 6.6	As: 4.4	As: 6.6	As: 2.2
		Am: 1.2	Am: 1.1	Am: 1.2	Am: 0.1
	_	M: 0.2	M: 0	M: 0.2	M: 0.2
	3	W: 10.1	W: 7.6	W: 10.2	W: 2.6
		B: 26.1	B: 30.3	B: 25.9	B: 4.5
		H: 55.7	H: 51.0	H: 55.9	H: 4.9
		As: 7.2	As: 9.0	As: 7.2	As: 1.8
		Am: 0.6	Am: 2.1	Am: 0.6	Am: 1.5
		M: 0.2	M: 0	M: 0.2	M: 0.2
	4	W: 11.2	W: 12.6	W: 11.1	W: 1.5
		B: 21.5	B: 22.7	B: 21.5	B: 1.2
		H: 58.5	H: 53.4	H: 58.8	H: 5.4
		As: 7.9	As: 10.8	As: 7.7	As: 3.1
		Am: 0.5	Am: 0.4	Am: 0.5	Am: 0.1
		M: 0.4	M: 0	M: 0.4	M: 0.4
	5	W: 10.8	W: 11.7	W: 10.6	W: 1.1
		B: 17.2	B: 17.0	B: 17.2	B: 0.2
		H: 62.5	H: 63.8	H: 62.2	H: 1.6
		As: 8.5	As: 6.9	As: 8.7	As: 1.8
		Am: 0.4	Am: 0.2	Am: 0.4	Am: 0.2
		M: 0.7	M: 0.4	M: 0.7	M: 0.3

Table 3.A3. (Con't.)

Tuble of the (Con t.)					
Characteristic	Stratum	Total Sample	Intervention	Control Group	Absolute
		(n=20,443)	Group	(n=19,394)	Difference
			(n=1,049)		
At least 1	1	13.4	23.7	13.3	10.4
chronic illness	2	16.9	23.3	16.7	6.6
(%)	3	23.0	24.8	22.9	1.9
	4	38.1	34.7	38.3	3.6
	5	64.5	66.3	64.7	3.6

^{*}K=Kindergarten

^{**}W=Non-Hispanic White, B=Non-Hispanic Black, H=Hispanic, As=Asian/Native Hawaiian/Pacific Islander, Am=American Indian/Alaskan Native, M=Multi-racial Items in bold significantly differed after PS stratification.

Table 3.A4. Sample characteristics after PS weighting

Table 3.A4. Sample chara Characteristic	Total Sample	Intervention	Control Group	Absolute
	(n=20,443)	Group	(n=19,394)	Difference
	-, -,	(n=1,049)	(- , ,	
Community poverty level		, ,		
(mean±SD)	$23.8 (\pm 6.3)$	23.9 (±19.2)	23.8 (±4.7)	0.1
Sahaal navanty laval				
School poverty level (mean±SD)	74.6 (±17.7)	75.2 (±0.5)	73.9 (±13.1)	1.3
(mean±5D)	74.0 (±17.7)	73.2 (±0.3)	73.7 (±13.1)	1.3
School nurse workload				
(mean±SD)	$15.0 \ (\pm 7.0)$	15.5 (±23.4)	$14.6 \ (\pm 4.6)$	0.9
Household food				
insecurity (percent)				
Yes	82.6	83.9	81.3	2.6
No	17.4	16.1	18.7	2.6
BMI at baseline	27.3 (±4.4)	27.4 (±13.4)	27.2 (±3.2)	0.2
(mean±SD)				
BMI percentile	99.4 (±0.3)	99.4 (±0.8)	99.4 (±0.2)	0
(mean±SD)	,		,	
Gender				
Male (percent)	39.2	39.9	38.5	1.4
Female (percent)	60.8	60.1	61.5	1.4
Age (mean±SD)	91.2 (±21.5)	91.0 (±67.1)	91.4 (±15.6)	0.4
Grade (percent)				
Kindergarten	21.0	22.1	19.9	2.2
First	19.8	19.5	20.0	0.5
Second	18.9	18.7	19.1	0.4
Third	15.3	14.7	15.8	1.1
Fourth	13.2	12.9	13.5	0.6
Fifth	11.9	12.0	11.8	0.2

Table 3.A4. (Con't.)

Table 3.A4. (Coll t.)				
Characteristic	Total Sample	Intervention	Control Group	Absolute
	(n=20,443)	Group	(n=19,394)	Difference
	,	(n=1,049)	, ,	
Race/ethnicity (percent)				
Non-Hispanic	9.2	8.5	9.9	1.4
White	24.5	23.9	25.1	1.2
Non-Hispanic	57.5	58.6	56.5	2.1
Black	7.1	6.9	7.3	0.4
Hispanic				
Asian**	1.2	1.6	0.8	0.8
American Indian**				
Multi-racial	0.4	0.5	0.3	0.2
At least 1 chronic illness				
(percent)	32.7	34.2	31.3	2.9

^{**} Asian= Asian/Native Hawaiian/Pacific Islander, American Indian= American Indian/Alaskan Native

Items in bold significantly different after PS weighting.

Chapter 4: Efficacy of a school nurse-led severe obesity intervention for NYC school students: Impact on BMI, absences, and school nurse visits

This chapter addresses aims 3, 4, and 5, to evaluate implementation of the HOP program, determine factors associated with program enrollment, and assess the program's impact on BMI percentile change, school absences, and walk-in school nurse visits. Data were collected as part of routine documentation of NYC school nurses in the Automated Student Health Record (ASHR); no additional subject recruitment or data collection was necessary. When assessing HOP's implementation and enrollment, the entire sample of eligible children during the 2012-2013 school year, the first year of full-scale HOP implementation, was used (n=20,518). When assessing HOP's efficacy, two groups of severely obese children were compared: 1,049 children who received HOP and 1,049 propensity score-matched children who were eligible for but did not receive HOP. This manuscript is targeted for submission to the *Western Journal of Nursing Research: Special Issue on Weight Management and Obesity*.

Introduction

Childhood obesity affects 12.7 million children in the United States (Ogden et al., 2014), with 2.7 million being severely obese (Skelton, Cook, Auinger, Klein, & Barlow, 2009).

Children affected by severe obesity are at increased risk for many chronic health conditions in both childhood and adulthood (Daniels, 2006; Kelly et al., 2013). Because of their healthcare expertise, school nurses are well suited to implement school-based interventions for children with severe obesity, assisting with health behavior improvement, weight control, and chronic illness management. However, to our knowledge no school nurse-led severe obesity intervention has been implemented or evaluated. The first intervention of this type, the Health Options and

Physical Activity Program (HOP), was implemented in New York City (NYC) schools during the 2012-2013 school year.

Background: Prevalence and Health Risks of Severe Childhood Obesity

Childhood obesity affects 16.9% of children in the United States (Ogden et al., 2014);

3.8% of American children are severely obese (Skelton et al., 2009). In NYC schools, 20.7% of students are obese and 5.7% of students are severely obese before the age of 14 years (Day et al., 2014). In both NYC and nationwide, groups that suffer from health disparities (Villarruel, 2001) such as racial/ethnic minorities (Cunningham et al., 2014; Freedman et al., 2006; Ogden et al., 2014) and children from low-income households (Boelsen-Robinson et al., 2014; Cunningham et al., 2014; Shrewsbury & Wardle, 2008) are disproportionately affected. Causes of obesity and severe obesity are complex, including individual, family, and community level factors (Davison & Birch, 2001).

Severe childhood obesity poses serious risks to health during both childhood and in adulthood (Daniels, 2006; Kelly et al., 2013). Children with severe obesity have a greater risk for metabolic syndrome and higher levels of serum inflammatory markers (Kelly et al., 2013). Severity of cardiovascular disease risk factors (e.g., hypertension, elevated serum triglycerides), non-alcoholic fatty liver disease, and musculoskeletal problems such as knee pain increase with degree of adiposity (Kelly et al., 2013; Li et al., 2016; Skinner, Perrin, Moss, & Skelton, 2015). The health-related quality of life for children with severe obesity is similar to that of children with cancer. Compared to healthy children, their health-related quality of life is worse all domains (physical, psychosocial, emotional, social, and school functioning) (Schwimmer, Burwinkle, & Varni, 2003).

School nurse-led intervention for severe childhood obesity

HOP is a program for children with severe obesity who attend New York City (NYC) schools. Children who meet criteria for severe obesity (defined as a BMI for age and sex at 120% of the 95th percentile (Flegal et al., 2009; Kelly et al., 2013)) during annual fitness assessments (New York City Department of Education, 2015) are identified for potential HOP participation. Parents of identified children receive a letter from the school explaining program processes and goals. Although parents have the opportunity to opt out, this option is taken by less than 1% of parents. If parents do not opt out, school nurses enroll children in HOP. HOP session duration, frequency, and focus are at the discretion of the school nurse, though program guidelines require one session at least every six months (1.7 sessions per 10 month school year). HOP sessions may include counseling with a focus on BMI tracking, goal setting, and education around 5 health behaviors (sedentary media use, sugar sweetened beverage consumption, portion size, physical activity, and fruit and vegetable intake). Referrals to school health physicians or primary care providers are made as needed for management of associated health conditions, such as hypertension or type 2 diabetes. Parents are encouraged to participate in HOP sessions either in person or via phone. Prior to program implementation in 2012, all school nurses attended a full day training which included education on HOP components and implementation, as well as biological overview of obesity (e.g., common comorbidities), methods for clinical assessment of a child with obesity (e.g., how to plot BMI percentile), and the psychological/behavior/cultural influences on obesity (e.g., association between obesity and bullying, cultural perceptions of appropriate body size). In addition, all nurses are given a binder of HOP resources that contains the suggested timeline for HOP visits, activity sheets to use during HOP sessions, and criteria for provider referral.

Purpose

The purpose of this study was to evaluate implementation and impact of HOP in order to guide program refinement and further dissemination within the NYC school system. HOP's implementation was evaluated by examining the proportion of eligible children who participated in HOP, HOP session frequency and content, and factors associated with student enrollment in the program. Program impact at 1 year was evaluated by examining change in BMI percentile, school absences, and number of school nurse visits of HOP participants compared to propensity score-matched children who were eligible for but not enrolled in the program.

Methods

Design, sample, and ethical approval

This was a retrospective cohort study of kindergarten through fifth grade students who were identified with severe obesity and thus eligible for HOP. This study focuses on the 2012-2013, the first school year of full scale HOP implementation. Approval for this study was obtained from the Institutional Review Boards for Columbia University Medical Center, the NYC Department of Health and Mental Hygiene, and the New York City Department of Education.

Data set and variables

The study was guided by the Socio-ecological Model (Davison & Birch, 2001; McLeroy et al., 1988); when evaluating HOP, we examined factors at the individual, family, school, and community levels. Data were collected from 3 sources: student electronic health record, NYC Department of Health and Mental Hygiene Office of School Health records, and the New York Center for Economic Opportunity poverty data. The electronic health record used by NYC

school nurses was the primary data source and includes details of student demographics, participation in school programs such as HOP, and school nurse visits. The electronic health record also included BMI percentile calculated from height and weight measurements by school nurses. For school nurse visits we excluded visits for reasons other than acute illness or injury (e.g., receipt of vaccination, routine medication administration). School level variables (school poverty level, school nurse workload) were collected from records of the NYC Department of Health and Mental Hygiene Office of School Health. School nurse workload was represented by a composite metric developed by the DOHMH ranging from 1 to 36 points that incorporated number of children at a school and number of children with diabetes, asthma, or requiring medication administration during school hours. We categorized school nurse workload into tertiles representing low (<10.8 points), moderate (10.8-16.8 points) and high (>16.9-35.6 points) workload. School poverty level, the percent of registered students who receive free/reduced school lunches, was dichotomized into those above the New York State average of 51.7% and those equal to or below the New York State average for kindergarten through sixth graders in schools (New York State Kids' Well-being Indicators Clearinghouse, 2016).

Data analysis

HOP implementation was examined by proportion of eligible children who were enrolled in HOP, HOP session frequency and content, and factors associated with student enrollment. All HOP-eligible children were included in the implementation analyses. We analyzed program implementation using descriptive statistics and multivariate logistic regression. Characteristics of children enrolled in the program were compared to those of eligible children who were not enrolled. Factors that significantly differed between HOP participants and nonparticipants (p<0.05) or theoretically associated with childhood obesity (Davison & Birch, 2001) were

included in the regression model.

To examine the impact of HOP participation on BMI percentile, absences, and school nurse visits, we compared children who participated in HOP with 1:1 propensity score matched children who were eligible for but not enrolled in the program. The propensity score matched group served as a control group to limit the confounding relationship between HOP and outcomes of interest. Consistent with recommendations for analysis using propensity matched groups (Austin, 2008; P. C. Austin, 2011; Lanehart et al., 2012b), data were analyzed using Wilcoxon signed rank test for continuous variables and McNemar's test for dichotomous variables. Because BMI prevalence and growth trajectory (i.e., puberty onset) differ by gender, all analyses of HOP impact were stratified by gender (Kelly et al., 2013; Robbins, 2015; Wisniewski & Chernausek, 2009).

Results

HOP Implementation

During the 2012-2013 school year, 20,518 kindergarten through fifth grade children met criteria for severe obesity and were therefore eligible for HOP. Sample characteristics are listed in Table 4.1. The mean BMI percentile of these students was 99.4±0.3. The majority of the eligible children were male (61.6%) and of Hispanic ethnicity (56.4%). Most received free/reduced lunch (81.2%) and lived in communities where, on average, 1 of 4 (23.8%) participants lived under the federal poverty level. Almost one third of the children (30.5%) had at least one chronic illness; of these, the most common diagnosis was asthma (29.4%). Prior to propensity score matching, HOP participants were more likely to attend a school with a lower poverty level (71.0% versus 74.1%), be in a higher grade (i.e., 6.9% versus 20.6% in kindergarten), and have a chronic illness (46.0% versus 30.5%) compared to those who were

eligible for but not enrolled in HOP (data not shown). Five children who participated in HOP and 70 children who were eligible for but not enrolled in HOP were missing variables required for propensity score matching; they were therefore excluded from further analysis. Of the 20,443 eligible children, 1,049 (5.1%) were enrolled in HOP.

Details of HOP implementation are presented in Table 4.2. Most (61.1%) HOP sessions included 1 of the 3 program components. Almost all (92.2%) HOP sessions included BMI measurement and tracking. In addition, sessions sometimes included health behavior education (44.9%); the focus of these health discussions in order of frequency were "5 fruits and vegetables per day" (31%), "0 sugar sweetened beverages" (19%), "1 hour of physical activity" (19%), "2 hours or less of screen time" (16%), and "portion control" (15%). Goal setting and measurement of goal achievement was documented less frequently (18.2%). Most participants had 1 HOP session (median 1, mean 2.1±1.6, range 1-11) during the 2012-2013 school year. Approximately half (46.4%) participated in 2 or more sessions. Parent participation occurred at 3.2% of HOP sessions.

Factors that significantly predicted a child's enrollment in HOP are presented in Table 4.3. Children who attended schools with lower school poverty levels and lower school nurse workload, who had higher BMI percentiles, or were diagnosed with at least one chronic illness were more likely to be enrolled in HOP.

HOP Impact

Outcomes of program participation are presented in Table 4.4. After propensity score matching, there were no significant differences between the HOP group and the propensity score-matched control group. For girls, there were no significant differences in BMI change in HOP participants when compared to the control group. For boys, HOP participants significantly

decreased BMI percentile by 0.07 less than the control group. There were no differences in school absences. For both girls and boys, HOP participants demonstrated more visits to the nurse's office (5.0 versus 3.7 for boys, 5.9 versus 3.2 for girls, p<0.01) compared to the control group.

Discussion

This study examined the implementation and outcomes of HOP, a school-based program for children with severe obesity. The HOP enrollment rate was 5.1%, despite rare parental opt out. Approximately half (46.4 %) of program participants had the number of HOP sessions recommended by program guidelines. Parental participation occurred at 3.2% of HOP sessions and most HOP sessions included BMI measurement and tracking and/or health behavior education. Factors such as lower school nurse workload and higher grade level were associated with higher odds of enrollment in HOP. Program participation did not significantly decrease body measure in females; in males, HOP participants demonstrated a significantly smaller change in BMI percentile compared to propensity score matched boys who did not participate in the program. Children in the HOP group had the same number of annual absences, but slightly more school nurse visits, than their matched peers who were eligible for but did not participate in the program.

Possible reasons for HOP's lack of impact on BMI percentile may be its 1) low-intensity (one session every 6 months), as higher intensity programs are often needed to change body measures in children with severe obesity (Kelly et al., 2013), 2) focus on children with severe obesity, who may require intensive (e.g., inpatient, weekly, etc.) treatment in order to decrease body measures (Kelly et al., 2013; Levine, Ringham, Kalarchian, Wisniewski, & Marcus, 2001; van der Baan-Slootweg et al., 2014), and 3) implementation in the school setting only (not the

home environment or community). It is important to note that children with severe obesity may have adopted unhealthy dietary and sedentary habits over a long period of time (Kelly et al., 2013); it is therefore challenging to significantly reverse these behavioral patterns with infrequent interventions.

Overall, the HOP program experienced a low rate of implementation and low session intensity. The majority of children received only one session during the school year. During most sessions the focus of the visit interaction was BMI tracking with health education and/or goal setting around a health behavior a less frequent occurrence. This reflects either variation in documentation or implementation. Either way, it speaks to the challenge of implementing an intervention targeted to children with severe obesity in a real-world setting. In the vibrant environment of an urban school, it may be challenging for school nurses to implement HOP with the higher frequency and duration. This is supported by the finding that lower school nurse workload was associated with higher odds of participation in HOP.

We hypothesize that our findings related to nurse visits (more nurse visits for HOP participants) may arise from the association between obesity and bullying (Griffiths, Wolke, Page, & Horwood, 2006; Janssen, Craig, Boyce, & Pickett, 2004) and bullying and somatic complaints (Lien, Green, Welander-Vatn, & Bjertness, 2009; Rigby, 1999; Sansone & Sansone, 2008; Williams, Chambers, Logan, & Robinson, 1996). It is know that school nurse visits for somatic complains may be increased for students who are victims of bullying (Schneider, Friedman, & Fisher, 1995; Vernberg, Nelson, Fonagy, & Twemlow, 2011). Therefore, it is possible that students who participate in HOP may feel more comfortable with the school nurse and therefore more likely to visit the nurse with somatic complaints secondary to bullying (even if they do not report the bullying to the nurse).

When examining whether school-based obesity interventions are efficacious, it is important to consider how these interventions are structured and delivered. While four recent meta-analyses (Katz et al., 2008; Sobol-Goldberg et al., 2013; Wang et al., 2013; Waters et al., 2011) have found that school-based interventions are effective, other meta-analyses have found that school-based obesity interventions are not effective. Structural factors such as inclusion of nutrition and physical activity components, (Katz et al., 2008; Sobol-Goldberg et al., 2013), duration greater than one year, parental involvement, and comprehensive approach (Sobol-Goldberg et al., 2013) support intervention effectiveness. The inclusion of school nurses in the delivery of obesity interventions has not yet been widely studied (Schroeder et al., 2016). However, it is hypothesized that school nurses are well-suited to deliver such interventions because of their clinical expertise, cost-free accessibility to students, and ongoing relationship with children and families (Morrison-Sandberg et al., 2011; Pbert et al., 2013b; Sharon Tucker & Lorraine M Lanningham-Foster, 2015). The involvement of nurses in school-based obesity interventions merits further exploration. The low enrollment rate of eligible children in HOP suggests that nurses' perceived barriers to delivering such programs must also be examined in future work.

HOP is unique among school-based programs in its focus on severe obesity. For this population, who face greater health risks than their obese, overweight, and normal weight peers (Kelly et al., 2013), intensive family based care is often required to manage comorbidities, decrease weight, and promote health (Kelly et al., 2013; Levine et al., 2001; van der Baan-Slootweg et al., 2014). Intensive clinical management, such as inpatient treatment and bariatric surgery (for adolescents), has been found to be successful (Pratt et al., 2009; van der Baan-Slootweg et al., 2014). School-based interventions for children with severe obesity must be

coupled with more intensive treatment to lead to clinically meaningful decreases in body measures. However, the fact that school-based obesity interventions may be less intensive than clinical interventions does not mean that school interventions cannot be useful for promoting health in children with severe obesity. School-based interventions for children with severe obesity may be best suited when used as clinical management programs. These programs can be applied to manage comorbidities, facilitate communication between the medical team and educational team, and support the child's treatment plan in the school environment, where children spend 50% of their waking hours (Foster et al., 2008). School nurses, with their clinical expertise, may be the ideal leaders for such programs.

School-based childhood obesity interventions, no matter how well-designed and efficacious, maximize their potential for impacting the health of children if they involve all levels of the socio-ecological model: interpersonal, institutional, societal (Davison & Birch, 2001). At the interpersonal level, involvement of parents and the family is key to helping a child attain a healthy body weight. This may be particularly true for young children, who have limited control over their home food environment and meal preparation (Hesketh & Campbell, 2010; Knowlden & Sharma, 2012). At the societal level, it is known that neighborhood factors, such as walkability and access to healthy foods, may influence body weight (Casey et al., 2014; Economos & Tovar, 2012; Rahman, Cushing, & Jackson, 2011). Children who live in neighborhoods with high poverty levels or a high proportion of racial/ethnic minorities may face greater barriers to a healthy body weight than children who do not (Bethell, Simpson, Stumbo, Carle, & Gombojav, 2010; Taveras, Gillman, Kleinman, Rich-Edwards, & Rifas-Shiman, 2013; Zilanawala et al., 2015). Without a healthy home and community environment, school-based obesity interventions face an uphill battle.

This study has several limitations. First, it is a retrospective study using secondary data. Data were not collected for the purpose of evaluating HOP. Because data come from an electronic health record, variations in data quality and data collection methods exist. However, the electronic health record was the best available source of health and obesity data for children in the NYC schools. Second, students were not randomized to HOP. Propensity score matching was used to minimize bias resulting from lack of randomization. However, propensity scoring can only reduce differences in known variables between groups and cannot remove all potential sources of bias. Therefore, interpretation is limited to association and causality cannot be inferred. Third, HOP is set in a large, diverse, urban, public school system and the findings of this research may not be generalizable to all school settings. In addition, because the data used in this study were not collected for the purpose of examining HOP, other variables that may be important (e.g., parent weight status, access to safe park/play space in home neighborhood) were not available. Also, health behavior data such as 24 hour dietary recalls to assess food intake were not available. Lastly, rigorously collected BMI measurements only occur yearly in NYC schools, which precludes measurement of BMI change at shorter intervals.

In conclusion, findings from this study can inform development of school-based nursing interventions for children with severe obesity. Potential for refinement, resource allocation, and broader implementation of HOP exists. Areas of focus should include increasing frequency and comprehensiveness of HOP sessions and promoting parental involvement. Because of the serious health risks due to severe obesity and the high rate of comorbidities in this population, school nurses are the ideal school staff members to implement programs for children with severe obesity.

Table 4.1. Demographic characteristics of the sample

Characteristic	Total Sample	By HOP Enrollment		
	All eligible children (N=20,518)	Enrolled (n=1,054)	Not Enrolled (n=19,464)	
Community poverty level ^a (mean±SD)	23.8±6.3	23.4±6.3	23.8±6.7	_
Borough				
Bronx	26.6	20.6	26.9	
Brooklyn	29.7	21.9	30.1	
Manhattan	10.1	7.5	10.2	
Queens	27.1	46.0	26.0	
Staten Island	6.6	3.91	6.8	
School poverty level ^b (mean±SD)	74.6±17.7	71.1±20.0	71.3±19.5	
School nurse workload ^c (mean±SD)	15.0±7.0	13.3±6.7	13.3±5.8	92
Free/reduced lunch (%)				
Yes	82.6	82.6	81.2	
No	17.4	17.4	18.8	
BMI percentile (mean±SD)	99.4±0.3	99.5±0.3	99.4±0.3	
BMI percentile category (%)				
Higher (>99.5)	38.8	53.1	38.4	
Lower (99.0-99.5)	61.2	46.9	61.7	
Gender (%)				
Male	60.8	58.8	61.6	
Female	39.2	41.2	38.4	

Table 4.1. (Con't.)

Characteristic	Total Sample	By HOP Enrollment		_
	All eligible children	Enrolled	Not Enrolled	
	(N=20,518)	(n=1,054)	(n=19,464)	
Grade (%)				
Kindergarten	21.0	6.9	20.6	
First	19.8	16.3	20.2	
Second	18.9	21.6	18.9	
Third	15.3	18.8	15.6	
Fourth	13.2	19.2	13.1	
Fifth	11.9	17.2	11.5	
Race/ethnicity ^c (%)				93
Non-Hispanic White	9.2	10.6	9.9	•
Non-Hispanic Black	24.5	21.6	25.3	
Hispanic	57.5	58.8	56.4	
Asian	7.1	7.8	7.3	
Other	1.6	0.11	0.11	
At least 1 chronic illness (%)	32.7	46.0	30.5	

a: Percent of individuals in student's home community living below federal poverty level (NYC Center for Economic Opportunity, 2015)

b: Percent of children in student's school receiving free/reduced lunch

c: Composite metric developed by the New York City Department of Health and Mental Hygiene that incorporates number of children at a school and number of children with diabetes, asthma, or requiring medication administration during school hours

d: Asian= Asian/Native Hawaiian/Pacific Islander, Other= American Indian/Alaskan Native, Multi-racial

Table 4.2. HOP implementation

Table 4.2. 1101 implementation	
Variable	
Sessions/school year (median (range))	1 (1-11)
Focus of HOP session	
Health behavior education (%)	44.9
Health behavior education focus (%)	
	21
Fruit/vegetable intake	31
Sugar sweetened beverage intake	19
Physical activity	19
Screen time	16
Portion control	15
BMI measurement and tracking (%)	92.2
Goal setting (%)	18.2
Comprehensiveness of HOP session ^a (%)	
Included all components	6.3
Included 2 of 3 components	32.6
Included 1 component	61.1
included i component	01.1
Parent participation (%)	3.2

n=1,049. a: Program components include health behavior education, BMI measurement and tracking, and goal setting

Table 4.3. Factors associated with enrollment of eligible children in HOP

Predictor	Odds Ratio	95% CI
School poverty level		
Lower than New York state average	1.6	1.3, 1.9
At or higher than New York state average	1.0	Reference
School nurse workload		
Low	2.4	2.0, 2.8
Middle	1.2	1.0, 1.4
High	1.0	Reference
Borough		
Bronx	1.8	1.3, 2.6
Brooklyn	1.6	1.1, 2.2
Manhattan	1.3	0.9, 2.0
Queens	4.2	2.9, 5.9
Staten Island	1.0	Reference
BMI percentile		
99.0-99.5%	0.5	0.4, 0.6
>99.5%	1.0	Reference
Gender		
Male	1.2	1.0, 1.3
Female	1.0	Reference
Grade		
Kindergarten	0.2	0.1, 0.2
First	0.4	0.3, 0.5
Second	0.7	0.5, 0.8
Third	0.8	0.6, 1.0
Fourth	1.0	0.8, 1.2
Fifth	1.0	Reference
Race/ethnicity ^a		
Non-Hispanic Black	0.7	0.4, 1.3
Hispanic	0.9	0.6, 1.2
Asian/Native Hawaiian/Pacific Islander	1.0	0.8, 1.3
Other	0.6	0.5, 0.8
Non-Hispanic White	1.0	Reference
Diagnosis of ≥1 chronic illnesses		
No –	0.5	0.5, 0.6
Yes	1.0	Reference

n=20,443. a: Other race = American Indian/Alaskan Native and Multi-racial (1.1% of children)

Table 4.4. Program outcomes at 1 year

Outcome and Gender	HOP Group	Matched Control Group	P value
	(n=1,049)	(n=1,049)	
Change in BMI percentile			
Males	-0.19 ± 0.4	-0.26+0.5	< 0.01
Females	-0.14 ± 0.4	-0.16±0.5	0.52
School absences during year of HOP participation	n		
Males	12.7±11.8	13.4±12.2	0.40
Females	13.4±11.4	14.7±13.2	0.16
School nurse visits during year of HOP participat	ion		
Males	5.0 ± 5.6	3.7 ± 5.1	< 0.01
Females	5.9 ± 6.9	3.2 ± 4.8	< 0.01

Chapter 5: Perceived barriers and facilitators to implementing a school nurse-led childhood obesity intervention in NYC schools

Chapter 5 addresses aim 6, to explore the perceived barriers and facilitators of implementing the HOP program in NYC schools. The methods used to accomplish this aim included individual semi-structured interviews with a purposive sample of school nurses who are employed in the NYC school system. Data collection began in the fall of 2015 and remains ongoing. Audio recordings from interviews were transcribed verbatim and then inductive, descriptive content analysis was used to identify key themes. The preliminary findings reported in this chapter reflect 14 of approximately 20 anticipated interviews

Introduction

School nurses may be well-suited to contribute to school-based obesity programs (Morrison-Sandberg et al., 2011; Pbert et al., 2013b; Sharon Tucker & Lorraine M Lanningham-Foster, 2015) due to their clinical expertise, accessibility to students, and ongoing relationship with children and families (Morrison-Sandberg et al., 2011; Pbert et al., 2013b; Sharon Tucker & Lorraine M Lanningham-Foster, 2015). However nurses are not commonly involved in these programs. A recent systematic literature review and meta-analysis of 11 school-based obesity interventions demonstrated that the children who participated in interventions where nurses had a meaningful role demonstrated small but statistically significant decrease in body measures (Schroeder et al., 2016).

The Healthy Options and Physical Activity Program (HOP) is a school nurse-led obesity program that was implemented in New York City (NYC) schools starting in the 2012-2013 school year. Children identified as having severe obesity (a body mass index (BMI) for age and

gender at 120% of the 95th percentile (Flegal et al., 2009; Kelly et al., 2013)) during an annual fitness assessment (New York City Department of Education, 2015) are identified for potential HOP participation. Parents of these students receive a letter about the program; children may be enrolled into the program unless parents opt out. HOP session duration, frequency and focus are at the discretion of the school nurse, though at least one session every six months is required per program guidelines. Sessions may include BMI measurement, health behavior goal setting, and education around sedentary media use, sugar sweetened beverage consumption, portion size, physical activity, and fruit and vegetable intake. Parents may participate in HOP sessions either in person or via telephone. Prior to program implementation in 2012, all school nurses attended a comprehensive full day training which included education on HOP components and implementation, as well as biological overview of obesity, how to measure BMI percentile, and the psychological/behavioral/cultural influences on obesity. In addition, each nurse was given a binder of HOP resources such as posters and activity sheets to use during HOP sessions.

Program delivery and efficacy during its first year of implementation (2012-2013) was evaluated. Of 20,518 eligible kindergarten to fifth grade students identified with severe obesity, only 1,054 (5%) received the program despite less than 1% formal parental opt out. The purpose of this study was to explore school nurses' barriers to and facilitators of HOP implementation, with the goal of better understanding the reasons for the low HOP implementation rate and informing further HOP dissemination within the NYC school system.

Methods

Participants

A purposive sample of school nurses working in NYC Schools was recruited. All NYC school nurses who worked with kindergarten through fifth grade children were eligible, with the

exception of nurses who worked in schools where the student body were exclusively children with disabilities/special education needs. Nursing Supervisors at the NYC Department of Health and Mental Hygiene Office of School Health provided names and contact information of potential subjects. To ensure a broad understanding of school nurses' experiences, nurses with extensive, limited, and no experience implementing HOP within the past year were recruited. Nurses were considered to have "extensive experience" if they implemented HOP with at least 6 children and to have "intermediate experience" if they implemented HOP with at least one but less than six children during the past school year. No specific number of nurse participants was targeted, as power analysis is not appropriate for qualitative research (Vaughn, Shay Schumm, & Sinagub, 1996).

Recruitment. Eligible nurses were contacted via email or phone to provide information about study purpose, confidentiality procedures, provision of a \$50 Visa gift card incentive, and to confirm eligibility criteria. Confidentiality during the interviews was assured. Nurses were given a choice about location and type of interview (phone or face-to-face). Each subject provided signed informed consent including permission to audio record the interview prior to participation. Two days prior to participation, participants were reminded about the time and place of the interview.

Procedure

Prior to beginning the interview, participants completed a 14 item question demographic questionnaire that included level of nursing education and prior experiences with HOP implementation. Interviews lasted approximately 45 minutes with 15 minutes devoted to introduction of the PI, introduction of study, eligibility screening, completion of demographic data forms, and closing. Interview discussion was guided by a 17 item interview guide structured

by RE-AIM (Glasgow et al., 1999; RE-AIM.org, 2015), a framework that guides evaluation of a program's translation into practice. The framework examines an intervention for more than just efficacy in order to promote adoption of sustainable, impactful interventions (Glasgow et al., 1999; RE-AIM.org, 2015). Interview questions were also informed by a March 2013 email survey completed by 735 school nurses about barriers to and facilitators of HOP implementation. Table 5.1 includes the interview guide questions. Interview recordings were transcribed by a professional transcriptionist. Transcripts of the recordings served as source records. Transcripts were uploaded to NVivo (QSR International, n.d.) for data analysis. Data collection is ongoing and will continue until data saturation has been achieved.

Data analysis

Data were analyzed using content analysis (Holsti, 1969; Krippendorf, 2003; Neuendorf, 2002) and the unit of analysis was the interview transcript. Data analysis was an iterative process and began following completion of the first interview. After multiple readings of each transcript and guided by the RE-AIM framework (Glasgow et al., 1999; RE-AIM.org, 2015), the researchers marked ideas, terms, and phrases of meaning to develop codes. Codes were iteratively grouped, in order to identify categories and link them to themes (Glaser, 1965). The researcher met with one or more members of the research team weekly in order to discuss the analytic process and developing findings, including codes, categories, themes, and illustrative examples from transcript text. Discrepancies were resolved through consensus. These meetings facilitated analyst triangulation, which can contribute to the verification and validation of qualitative research (Patton, 1999). The research team included the authors, the nursing supervisors who assisted with identification of potential participants, and the Director of Nursing at the NYC DOHMH Office of School Health. Credibility was further enhanced through

triangulation of data sources by sampling nurses with a wide range of HOP experience in order to broadly understand barriers to and facilitators of HOP implementation (Graneheim & Lundman, 2004; Patton, 1999). To ensure dependability, an audit trail was maintained with each step of the analysis process documented sequentially in NVivo and Excel. Data saturation will be achieved when interviews become redundant, when comprehensive themes encompass all data, and when further theme development is no longer possible (Fusch & Ness, 2015; Guest, Bunce, & Johnson, 2006). Member checking will be conducted with two participants (one with extensive experience, one with intermediate experience) to ensure that the findings reflect participants' perceptions.

Results

Of 31 nurses recruited, 19 participated (4 with Extensive HOP Experience, 7 with Intermediate HOP Experience, and 7 with No HOP Experience in the current school year) have participated to date. All nurses with No HOP Experience were familiar with the program and all except one had presented lessons based on the HOP curriculum (nutrition, physical activity) at the classroom level. Extensive Experience nurses had each worked with a mean of 11 children in HOP during this school year; Intermediate Experience nurses had worked with a mean of 3 children in HOP during this school year. Both extensive and intermediate experience participants had, on average, 5 years of experience implementing HOP. An overview of sample characteristics is presented in Table 5.1. Eight themes emerged from the data. Each theme, organized by the RE-AIM framework 12.13, is presented below.

Reach

Gatekeepers. Nurses reported that parents and school administrators limited nurses' ability to implement HOP with children who they felt may benefit from the program. Some

parents were insulted or angered after receiving the letter about their child's eligibility for HOP; others who did not formally opt out, expressed anger after the nurse began to work with their child as part of the program.

"I can't even begin to tell you the phone calls that I received...It was basically how dare I intrude...'We're big-boned people.' 'I have a pediatrician that deals with my child's health.' 'I understand that you're there for an emergency or to give out medications, but I do not want you to speak to my child again about nutrition." – Participant 12, Intermediate Experience

School principals sometimes pressured nurses to not implement HOP to avoid the actual or perceived risk of upsetting parents.

"The reason that I am not doing the HOP program here is because the principal, every year she says she wants to opt out of the program...because the parents were feeling offended by the opt-out letter that was mentioning the 'obesity'...They were calling the principal and complaining about the nurse giving them those letters." – Participant 6, No HOP Experience

"The principal doesn't want that one-on-one [HOP sessions] because she doesn't want the parents to get insulted." – Participant 7, No HOP Experience

It takes a team. In schools more receptive to HOP implementation, nurses described the importance of parent and school personnel cooperation when implementing HOP. More often than not, teachers worked with nurses to help eligible children participate in the program.

"And [the teachers] are very receptive.... That helps a lot. I don't have any of the teachers saying 'Oh, you can't take them out of class.' And if I ask them to do anything for me, they would do it." – Participant 16, Extensive Experience

Some principals also helped nurses to overcome obstacles to implementing HOP.

"If I'm getting so behind seeing the kids...I would ask my principal if she can send an email to the teachers, like for the first two periods not to send anybody to the medical room...And right away, she responds. She sends an email." – Participant 4, Extensive Experience

While less common, some parents encouraged the nurses' implementation of HOP.

"...One parent was like, "Yes. Anything you can do. Please, your suggestion. I'm trying to get on him, or whatever you can do." – Participant 8, Intermediate Experience

Effectiveness

An uphill battle. Almost all nurses expressed that helping a child to reach a healthy body weight was an uphill battle and described contextual factors as barriers to HOP's potential effectiveness. One factor commonly cited was the home food environment.

"Every parent that I talk to said 'Oh, this is so great. Maybe you can help me get them thinner.' It kills me, because they're the ones giving them the food. They're young kids, they can't go out and buy it themselves." – Participant 14, Extensive Experience

Nurses also described the school and community environments as promoting unhealthy choices.

"And there are too many fast-food chains in the neighborhood where my school is...So if you can get... fries and soda and chicken nuggets for \$1.99, why would I cook?" – Participant 4, Extensive Experience

Adoption

Stigma. Some nurses were hesitant to adopt the HOP program due to concerns about participants feeling stigmatized due to their weight. Nurses took special measures in schools where HOP was implemented to be sensitive to the child's self-esteem.

"Yeah, it's bad enough being a heavyweight child let alone being embarrassed in front of the class. 'Oh my god, they have to go and get a lesson from the nurse, because she's fat."" – Participant 2, No HOP Experience

"I would always be very sensitive to that because they don't want to be called out of class...I can get [the student] quietly in the hall and say, 'Hey, I just want to talk to you if you get a break today,' and he would say, 'Okay,' and he would come back maybe after lunch or something like that." – Participant 8, Intermediate Experience

While nurses frequently described concern about potential stigmatization, not all perceived that children felt singled out by being selected for program participation. Some mentioned that older children were sensitive about their weight, but others noted that many younger children enjoyed participating in HOP and demonstrated no embarrassment about attending HOP sessions.

"I don't think that there was really any negative effects mentally for them. I don't think they were upset over it." – Participant 1, Intermediate experience

"I mean, they love coming to my office...I don't think they thought of it as, 'Oh, there's something wrong with me." – Participant 11, No HOP Experience (speaking about her experience implementing HOP in prior years)

Fitting HOP into a heavy workload. Many nurses cited their workload as the biggest barrier to implementing HOP. They described being too busy with walk-in visits, medication administration, and documenting care. Nurses who worked in schools with fewer students noted that their lighter workload made it easier for them to implement HOP.

"I'm so busy that I feel guilty. I want to spend more time with this kid, but I just can't. I just don't have the time to spend more time with these children." – Participant 4, Extensive Experience

"Have you ever walked into a public school into the medical room? ...It's very busy...

Yes, nurses can do a lot, but unfortunately they cannot educate a thousand children about nutrition, and that's a fact." – Participant 6, No HOP Experience

Nurses who implemented HOP reported making special efforts to fit HOP into their busy schedule. For example, one nurse met with a student after school before his school bus arrived. Others made efforts to collaborate with other school administrators and staff to gain support for HOP implementation.

"I would say not my time [is a barrier], because once I decide to take a child on, I make the time." – Participant 9, Intermediate Experience

"I even spoke at a PTA meeting at the beginning of each school year and kind of talked a little bit about HOP...I brought this up to the administration, the dean, the [teachers' union] leader...just kind of letting them know about the program and that this is what we are trying to do as school nurses." – Participant 12, Intermediate Experience

Implementation

Creativity and tailoring. While HOP protocol guides program content and session frequency, nurses have autonomy to tailor the program. Many nurses adapted the program to meet the constraints of their school. For example, one nurse with a high nurse to student ratio met with children in groups of three instead of individually to increase the number of children who could participate. Many used creative activities such as making smoothies to teach the children about nutrition. Others shared nutrition and physical activity education with children outside of HOP sessions, such as during walk-in visits.

"Let's say an overweight child walks to our room, so we provide health education without the student realizing, okay, they are talking to me this way because I am obese...We can say in the conversation, what did you eat for breakfast today if they come with a stomachache. And that makes them discuss about the healthy products." — Participant 6, No HOP Experience

Economic and cultural considerations. Nurses recognized that a child's cultural or socioeconomic background impacted his/her nutritional intake, physical activity habits, and HOP efficacy. They attempted to adapt HOP to the unique needs of their student population.

"Since I was in a Hispanic community, I...went ahead and got [nutrition education] that was more useful for them...It's mostly a Hispanic community, so what happens is the

children eat a lot of rice and beans. And I think that it's cheaper for the parents also." – Participant 1, Intermediate Experience

"And I tell [the parents] that any city hospital has a Green Market that has fresh fruits and vegetables, and that they can use food stamps [to pay for it]." – Participant 14, Extensive Experience

Occasionally, though much less often, economic status was mentioned as a facilitator to HOP implementation.

"He was also trying to go to the gym. So that was another good thing that he had the resources that he was able to do that...I always want to say that the economic background on these children was a little bit more affluent, so they also had the ability to at least have these things available to them." – Participant 8, Intermediate Experience

Maintenance

None of the nurses seemed to be in the maintenance phase of HOP implementation.

However, most nurses described ways of tailoring HOP so that it could be implemented in a more sustainable way.

Improving HOP for the future. Recommendations for expanding HOP implementation and to promote program sustainability largely fell into three categories: provide more support to busy nurses, increase parent involvement, and implement HOP at the classroom level instead of the individual level. Nurses noted the need for additional staff, such as public health aids or additional nurses, to decrease their workload so that they could devote more time to HOP implementation. One nurse described working with local nursing students who helped her to

implement HOP at the classroom level; she found that to be successful and feasible. Nurses also had various ideas for increasing parent involvement, though they realized doing so would be a challenge based on some parents' resistance to the program and parents' busy schedules. In addition, nurses noted that parents, teachers, and administrators were more receptive to classroom education versus individual HOP counseling and that the children enjoyed the classroom sessions.

Discussion

In this study, we examined nurses' perceptions of facilitators of and barriers to implementing HOP, a school-based program for children with severe obesity. Findings demonstrated that the reach of HOP is sometimes hindered by parents who are concerned about their child receiving treatment for obesity from the school nurses; some felt insulted by their child's eligibility for the program. Similar to parents, principals also served as gatekeepers, sometimes preventing nurses from implementing HOP. In schools where HOP was more widely implemented, nurses reported that effective teamwork with parents, teachers, and principals was key to expanding HOP's reach. Nurses expressed frustration with helping children to decrease BMI percentile and improve health behaviors; they felt that many aspects of a child's environment promoted unhealthy behaviors. When adopting HOP into their clinical practice, some nurses expressed concern about stigmatizing obese children whereas other nurses felt that children (especially young children) often enjoyed HOP. Nurses' workload was reported as the greatest barrier to adopting HOP into their school health practice; nurses who were successful in doing so often exerted extra effort to make HOP feasible. HOP implementation required creativity and nurses often tailored HOP to meet the cultural and economic background of their students. Lastly, nurses felt that in order to make HOP more sustainable, increased parental

involvement and minimized nursing workload were required; some also reported successes with implementing general obesity prevention education in a classroom setting.

Most of our results are concordant with existing literature that examines school nurses' role in helping children to manage weight and measuring BMI (Kubik et al., 2007; Stalter, 2010; Stalter, 2011). As with previous research, nurses found workload, parental involvement, and concerns about stigma limited their ability to implement such as program (Stalter, Chaudry, & Polivka, 2011; Steele et al., 2011). In addition, they found support of school partners to be helpful in implementing HOP (Kubik et al., 2007). Surprisingly, in contrast to previous work, lack of knowledge about obesity and lack of confidence in knowledge about obesity did not emerge as barriers to program implementation (Steele et al., 2011). This may be because the full-day training received prior to program initiation was adequate preparation. It remains unclear if ongoing educational refreshers would benefit program implementation.

One interesting finding from this study was that nurse did not think that HOP participants felt stigmatized by being in the program, despite concerns about stigmatization from nurses, parents, and principals. Prior research has identified risks of bullying, social isolation, and stigmatization for children with obesity (Griffiths et al., 2006; Janssen et al., 2004). This is particularly true for older and female children (Griffiths et al., 2006). It is possible that parents and administrators resisted HOP implementation due to concerns about the child feeling stigmatized. Nurses described their special efforts to ensure that children did not feel embarrassed by participating in HOP. While some nurses noted that weight was a sensitive issue for the children, none found that children did not want to participate in HOP for this reason. In fact, many nurses described that young children enjoyed participating in HOP. Future work

should examine the perceptions of children participating in obesity programs, particularly those programs that are targeted to individual children who are overweight or obese.

One barrier that nurses may be able to directly address is the barrier arising from principal resistance. Many nurses noted that principal opposition either made HOP implementation more difficult, or in some cases, completely prohibited implementation of the program. The principals' concern arose from the actual or perceived risk of upsetting parents; and as demonstrated, many parents did become upset. Parents felt insulted that their child was considered obese or feared that their child would be stigmatizing by program participation. Nurses can take action to address principals' apprehension about parent concerns. First, nurses can ensure that principals are closely informed about the obesity intervention prior to implementation. Specifically, principals may be interested in efforts to avoid stigmatization (i.e., a positive focus on healthy goal setting, maintenance of privacy during intervention counseling sessions). In addition, principals may also be interested to hear what efforts the nurse has made to ensure parent support of the program. For example, principals may be interested to learn of how parents were informed about the intervention, how parent consent will be obtained, and how parent concerns will be addressed. By meeting with the principal prior to intervention implementation (during the planning process), a stronger nurse and principal partnership for implementing the obesity intervention may be formed.

An unexpected finding of this study was some nurses' preference for general classroom obesity education compared to one-on-one HOP sessions. Some nurses had already incorporated HOP curriculum into classroom education and found it to be enjoyed by the children and acceptable to parents, teachers, and administrators. Other nurses had not yet implemented classroom sessions but suggested that it may be a way to avoid current barriers to HOP. While

general classroom education would avoid the resistance related to a program targeted to children with obesity, it would not alleviate the barriers related to nurses' workload. Classroom sessions may be a good alternative or complement to HOP, particularly because the HOP curriculum focuses on development of healthy nutrition and physical activity habits that would benefit all children.

Implications for school health

Our findings demonstrate the importance of staff input when working to refine and expand obesity program implementation; the experiences of the nurses in this study provided key insights into the HOP program as currently implemented. While nurses may be well-suited to implement obesity programs (Morrison-Sandberg et al., 2011; Pbert et al., 2013b; Sharon Tucker & Lorraine M Lanningham-Foster, 2015), they face multiple barriers in their ability to do so. When planning for the implementation of a school nurse-led obesity program, a key consideration must be the nurses' workload. Does the nurse have the time to implement such a program? Factors that might support a nurse's ability to implement programs such as HOP include support staff such as a public health aide/nursing aide who can receive walk-in visits and screen for emergencies during HOP sessions. Other factors such as a nurse-to-student workload (1:750) that meets suggested recommendations (National Association of School Nurses, 2015) could also support the nurse having time to implement obesity interventions. For more intensive school-based programs, it is likely that nurses cannot implement it alone and would require the efforts of other school partners such as teachers. An interdisciplinary program may be best coordinated in school in which there is an established wellness committee. General classroom education for all students could be one component of such a program in addition to one-on-one counseling for children who meet criteria for obesity. Any program targeted to children with

severe obesity should incorporate partnerships with a child's primary care provider for the more intensive clinical management required for this condition.

Parental support would also be key to implementation of such as program. To foster such support, the program should be explained to parents at parent teacher association meetings prior to implementation. Carefully worded letters about the program to avoid blame or stigmatization could also be sent home to parents. Nurses may want to call parents and discuss the program with parents prior to sending home consent forms. It would be important to stress that the obesity program focuses on promoting health, not blaming a child or parent for obesity. In addition, nurses would need to be prepared for the intervention with adequate resources, such as ongoing training, referral to appropriate websites, and in-service education on obesity etiology and treatment. Level of training should be tailored to the baseline knowledge of the school nurses, which may vary between nurses and school districts. With careful attention to these barriers, nurses may be able to play a unique role in implementing school-based obesity programs and promoting child health.

Table 5.1. Interview guide used in semi-structured interviews with study participants

Question

To get started with our discussion, please tell me about your experience with HOP. How many children have you worked with, and how often do you meet with them?

Reach

How do you select students for HOP implementation?

Do you feel that there are children who could benefit from HOP but do not receive it? If so, can you tell me about those students?

Effectiveness

What aspects of HOP can help students decrease BMI or change health behavior? Do you think there are any aspects that would need to change to allow HOP to work better? Do you think HOP has any negative effects on children? (prompt: Do you think children that are selected for HOP might be subject to additional bullying or teasing because they are in HOP?)

Did you find that HOP had any unexpected effects (positive or negative) on children who participated?

<u>Adoption</u>

What kinds of things make it easier for you to implement HOP?

What kinds of things make it harder for you to implement HOP?

What is your experience with the principal and administrators, when it comes to HOP? What about with parents?

How do students react to HOP? Describe a typical interaction with a student during a HOP session.

Implementation

Do you have a good understanding of how HOP is supposed to be implemented? Is the HOP binder helpful to you?

How helpful (or unhelpful) is ASHR to your implementation of HOP?

Do you feel that you have enough knowledge about childhood obesity to implement HOP? What helps you to implement HOP as you see fit? Or, what changes would need to be made to allow you to implement HOP as you see fit?

Maintenance

What are your suggestions for implementing HOP in the future?

What would make it easier for you to implement HOP with more children?

Table 5.2. Participant Characteristics

Table 5.2. Participant Characteristics Characteristic	N (%)
Female Gender	19 (100)
Age	
25-44	3 (16%)
45-64	5 (26%)
>65	11 (58%)
Race	
White	12 (63%)
Black	2 (11%)
Asian	5 (26%)
Ethnicity	
Hispanic	3 (16%)
Non-Hispanic	16 (84%)
Total Years Worked as a School Nurse	
3-5	2 (11%)
6-10	3 (16%)
11-15	5 (26%)
>15	9 (47%)
Highest Degree Attained in Nursing	
Associates	5 (26%)
Bachelors	13 (68%)
Masters	1 (5%)
School Wellness Committee	
Yes	3 (16%)
No	16 (84%)
Approximate Number of Students Under	
Nurse's Care	
0-250	3 (16%)
251-500	2 (11%)
501-750	4 (21%)
751-1000	9 (47%)
1001-1250	1 (5%)

Chapter 6: Conclusion

The overall aim of the proposed research was to evaluate the implementation and impact of a school nurse-led school-based obesity intervention in NYC schools. This dissertation includes a systematic review of the role and impact of nurses in school-based obesity interventions, a formal evaluation of implementation and efficacy of a school nurse-led obesity intervention designed for children with severe obesity, and a qualitative exploration of school nurses' perceptions of implementing the intervention. The results of this dissertation, by Chapter, are summarized below.

Summary of results

The systematic review and meta-analysis conducted for Chapter 2 provided background, context, and data from which to estimate an effect size to determine efficacy of the HOP intervention evaluated in Chapter 4. Only 11 studies that meaningfully involve nurses met criteria for inclusion in the systematic review; of these, no study examined nurse involvement in an intervention targeted to children with severe obesity. (This is likely because interventions for severe obesity are not often school-based; they often occur in obesity clinics, hospitals or surgical centers for bariatric surgery, or take place in an inpatient treatment setting (Beamish, Johansson, & Olbers, 2015; Danielsson et al., 2012; Nobili et al., 2015; O'Brien et al., 2010; Schmitt et al., 2016; Taylor et al., 2016; Thakkar & Michalsky, 2015; van der Baan-Slootweg et al., 2014)). Examination of the 8 studies that met criteria for the meta-analysis demonstrated that, on average, children who participate in these interventions experienced significant, though small, decreases in body measures. The included studies varied greatly in intervention components, role of nursing, duration, and involvement of parents. Subgroup analyses (after removal of one outlier

study) demonstrated that meta-analytic findings remained largely unchanged when comparing interventions by study design, intervention purpose (treatment versus prevention), parental involvement, study duration, or inclusion of children from racial/ethnic minority groups or low-income households. Overall, quality of included studies was moderate. To improve upon existing weaknesses in the literature, future research should pay careful attention to reporting attrition, documenting external validity, describing presence of blinding and methods of allocation concealment, and conducting a priori power analyses.

The observational nature of the HOP data necessitated controlling for differences between children who received HOP and children who were eligible for but did not receive HOP. Methods of reducing these differences prior to conducting the implementation and efficacy evaluation were detailed in Chapter 3. Chapter 3 reported a comparison of three different propensity score methods to identify the method that best reduced bias for this study data set. Propensity score 1:1 matching was superior to propensity score weighting and propensity score stratification as it removed all significant differences between children with severe obesity who did and did not participate in HOP. Propensity score weighting and propensity score stratification removed one and created two new differences. These results persisted after sensitivity analyses. Manuscripts often omit details of propensity score method selection; the results of Chapter 3 highlight the importance of doing so in order to deduce the effectiveness of propensity score application.

Chapter 4 reported findings of a study that aimed to evaluate HOP program implementation and efficacy among kindergarten through fifth grade students with severe obesity attending NYC schools. Findings demonstrated that many HOP-eligible children were members of racial/ethnic minority groups or lived in communities with high levels of poverty

and were therefore at risk for health disparities. Surprisingly, the HOP program was implemented for only 1 in 20 children at risk. For those who received the intervention, the program was implemented at a lower intensity than recommended by program guidelines. Most HOP sessions focused on BMI measurement and tracking rather than health behavior education and goal setting. Students at highest BMI percentiles, diagnosed with at least one chronic illness, or who attended schools in high poverty communities or with lower school nurse workload were more likely to be enrolled in HOP. Children who participated in HOP did not decrease body measures or school absences at one year. Of interest, HOP participants had more visits to the school nurse; the reasons for this remain unclear.

Chapter 5 provided context to Chapter 4 and reports preliminary findings of an ongoing qualitative study of 14 school nurses about their perceptions of barriers to and facilitators of HOP implementation. With interview questions guided by the RE-AIM Framework, eight themes emerged from the data. Themes demonstrated that nurses face multiple barriers to implementing HOP, including resistance from parents and principals and heavy workload. In addition, some nurses reported concern about stigma that may result from HOP participation, though other nurses noted that children who participated did not seem to feel embarrassed by participating. Unhealthy home and community environments were viewed as impediments to helping a child practice healthy habits and maintain a healthy body weight. To address these barriers, nurses used creative methods to implement HOP to the best of their ability. Nurses had multiple suggestions for improving HOP's sustainability, including increasing parental involvement, alleviating nurses' heavy workload, and considering focusing HOP on general classroom education instead of one-on-one counseling.

Key findings

Considered comprehensively, these individual studies contribute to a better understanding of school-based school nurse-led childhood obesity interventions. The literature review presented in Chapter 2 demonstrated that school-based obesity interventions that involve nurses, such as HOP, can be effective in leading to small but significant decreases in body measures. However, the low HOP implementation rate reported in Chapter 4 rate suggests that in their current environment, school nurses may lack the resources to implement HOP as intended. This was reinforced in the qualitative interviews reported in Chapter 5, in which school nurses detailed their barriers to implementing HOP. Because the collective results of Chapters 4 and 5 suggest that school nurses may lack the resources to implement programs that require greater intensity, nurses may be better suited to implement general obesity prevention interventions rather than intensive severe obesity treatment interventions. However, nurses can contribute to the management of severe childhood obesity in the school setting by implementing comorbidity management program for children with severe obesity as part of an interdisciplinary approach.

For school nurses to be effective, increased resources and support are needed.

Findings of the HOP evaluation and qualitative analysis suggest that nurses may not have the resources necessary to implement intensive school-based obesity interventions. HOP was implemented with only 5% of eligible children; children who participated received only some intervention components with less intensity than program guidelines recommend. During qualitative interviews, school nurses reported that despite their creative efforts, multiple barriers prevented them from being able to enroll children in HOP. Nurses felt that increased support from parents and school administrators, as well as a decrease in nurse workload, would be

required for the nurses to implement HOP per program guidelines. Some nurses also expressed concern about stigma related to HOP's focus on children with severe obesity.

Specific resources may be needed to increase the ability of school nurses to implement obesity interventions. For example, the lack of time available to implement HOP was frequently discussed in the qualitative interviews. Nurses' competing demands included allocating time for children requiring routine medication administration, walk-in visits for student injuries, documenting care, and implementing other health behavior education programs such as asthma classes. One way to increase nurses' time available for HOP would be to decrease nurse-tostudent ratio. The National Association recommends one nurse for every 750 healthy students as a general guideline (National Association of School Nurses, 2015); for nurses in this study, the median was 705 students per nurse with some having as many as 1180 under their care. However, this option may be cost-prohibitive. Another option would be to have trained personnel, other than school nurses, implement HOP. For example, nursing students could implement HOP; they would present no cost to schools, have developing expertise in working with children and parents, and could use school nurses as a resource as needed during program implementation. However, this would require oversight by the school nurses and a partnership between a nursing education program and the school administration.

Some school nurses expressed concern about bias and stigma and how to talk to children in an encouraging and supportive manner about weight management. Training in methods such as motivational interviewing can help nurses to counsel children about sensitive issues such as weight. Motivational interviewing is a focused, goal-directed form of counseling that allows the counselor to recognize that the participant may or may not be ready to accept change; the counselor can use motivational interviewing to help the children make changes in a supportive

and meaningful way (Miller & Rollnick, 2004; Rollnick & Miller, 1995). Nurses and healthcare providers have been successfully trained in motivational interviewing in classes as short as 9 to 16 hours (Madson, Loignon, & Lane, 2009; Söderlund, Madson, Rubak, & Nilsen, 2011).

Increased parent engagement would also help nurses to implement HOP by addressing two key issues that arose during qualitative interviews: 1) parental anger when their child is selected for HOP 2) suboptimal home environments. Providing nurses with resources to engage parents can help address both of these issues. For example, encouraging nurses to speak with parents about HOP at Parent Teacher Association meetings may help parents to be more accepting of HOP. In addition, active school wellness committees can provide free health education for parents at events such as health fairs. Educating parents about nutrition and physical activity can help them be active partners to managing their child's body weight.

For school nurses, obesity prevention interventions may be superior to obesity treatment interventions.

During qualitative interviews, nurses expressed that they enjoy providing health behavior education in the classroom. School nurses reported that they have the knowledge and teacher support to implement this type of education in the classroom setting. Classroom education includes all children regardless of weight status and avoids the potential stigmatization of programs such as HOP that are focused on children with severe obesity. The argument for focus on obesity prevention interventions is supported by findings of our systematic review and meta-analysis (Chapter 2) which demonstrated a similar effect of obesity prevention and obesity treatment interventions on body measures.

School nurses and severe obesity: Interdisciplinary management versus treatment

Severe obesity is associated with many comorbid conditions. In this study, 46% of those who participated in HOP were diagnosed with at least one other health condition such as asthma. The intensive treatment required to treat severe obesity (Danielsson et al., 2012; Johnston et al., 2011; Kelly et al., 2013) may not be possible in a busy school environment. This does not mean that school nurses should not be involved in management of severe obesity. School nurses can play a unique role as a clinical support person during the school day to interface with the clinician who takes primary responsibility for helping the child to lose weight. In this role, school nurses can help manage the child's comorbidities, communicate with the child's primary care provider, and help ensure that the obesity treatment care plan is adhered to during the school day.

Implications for clinical nursing

This dissertation has implications for nurses working in school health; more specifically, it provides guidance for development or implementation of obesity interventions in school settings. The findings regarding HOP implementation can help guide nurses' expectations regarding intervention feasibility. If nurses are aiming to do one-on-one counseling, they should develop a low intensity program or ensure involvement of other partners, such as primary care physicians or physical education teachers. The findings from the qualitative study suggest that when designing programs nurses should consider the barriers they may face and plan proactively to address them. For example, nurses can plan specific ways to engage with parents about the obesity intervention. Alternatively, nurses could plan to implement general health, nutrition, and physical activity education in classroom settings in order to avoid the resistance of parents and administrators. Lastly, nurses can use the results of this study to advocate for more support (e.g.,

public health aid) in doing the important work of obesity prevention and treatment; qualitative and quantitative findings suggested that low resources and high nurse workload may have prevented nurses from implementing HOP in a broader or more intensive manner.

Implications for health policy

This dissertation has important implications for policy. Qualitative findings indicated that nurses lack the resources to implement obesity programs at their optimal intensity. This suggests that increased attention must be paid to school nurse workload and staffing if programs such as HOP are to be successful (Gordon & Barry, 2009; Robert Wood Johnson Foundation, 2013; Wang et al., 2014). Students who attended schools where nurse workload was high were less likely to be enrolled in HOP. Some nursing tasks may be able to be handled by other support personnel such as public health aides, present in the nursing office in some schools. The need for school-based interventions is particularly acute for children who don't have regular primary care; an available school nurse who provides health behavior education can play an important role in child health, but only if (s)he has a workload that allows him/her to do so. Support for the NURSE Act, which will allow schools or state agencies to apply for federal grants to reduce the cost of hiring a nurse, may help improve nurse staffing and make implementation of programs like HOP more feasible (U.S. Senate, 2016).

The findings of the qualitative portion of this study also suggest broader societal level factors must be addressed before school-based programs can seriously impact the obesity epidemic. Nurses noted that they feel barriers outside their control impact child weight. For example, parents who work long hours at low wage jobs cannot afford the time or money to shop for or prepare more expensive healthier foods. Urban children often live in apartment buildings where access to open areas for exercise is limited. In addition, the neighborhoods where students

attend school are often filled with fast food restaurants and corner stores stocking unhealthy foods. Until broader policy changes that impact poverty and food access (particularly in neighborhoods of color or poverty) are implemented, school-based programs can only have a small impact on obesity. A discussion of broad policy changes are outside the scope of this dissertation, but include resisting efforts to change the Supplemental Nutrition Assistance Program ("food stamps") to a block grant program (Food Research and Action Center, 2015), ensuring funding for urban park systems (National Recreation and Parks Association, n.d.), and providing incentives for corner stores to stock healthier foods (The Food Trust, n.d.).

Implications for future research

This dissertation research suggests avenues for future work. First, an evidence base must be developed to guide best practices for school-based interventions for children with obesity and severe obesity. Future research should include randomized controlled trials and qualitative inquiry about nurses' experiences with obesity interventions. Nurses' perception of their role in these interventions and their preparation for these roles could also be examined. In addition, studies must ensure a focus on intervention sustainability. What is feasible for busy school nurses to implement in a particular school? What factors make it easier to implement and sustain such a program? In addition, future research should examine, from the child and parent perspective, whether participating in obesity counseling is associated with stigma. If the evidence regarding children's feelings of stigmatization is clear, those feelings can better be addressed. Lastly, school-based obesity interventions must be developed and tested that consider the challenges faced by vulnerable children such as many of those who were eligible for HOP. For example, eating the recommended number of fruits and vegetables each day may be challenging for children living in poverty unless the parents are educated about available resources such as

local Farmers Markets that accept "food stamps." More creative messaging may be required, such as tailoring education to eating healthy on a limited budget.

Strengths and limitations

Strengths of this dissertation study include its novel focus on nurses' role in obesity interventions, the large sample of New York City school children included in the HOP evaluation, and the use of mixed methods to better understand HOP implementation from the school nurses' perspective. Another key strength is a focus on program implementation in real world settings, which is key to assessing an intervention's failure or success. There are several limitations of this research. Only peer-reviewed English language studies were included in the systematic review. This may have led to exclusion of relevant studies. The dataset used for evaluation and efficacy of the HOP program was retrospective and was not collected for this purpose. Further the dataset did not include other relevant variables such as parental BMI and 24 hour dietary recall. Lack of randomization introduced potential for bias that could not be completely controlled by the application of propensity scores. Lastly, inclusion of only school nurses in the qualitative sample limited the ability to understand the program from the perspective of other stakeholders such as parents or teachers.

Conclusion

School nurses may be able to uniquely contribute to school-based obesity interventions, particularly for children with severe obesity. However, this dissertation demonstrates that current barriers such as limited time and lack of parental and administrative support may prevent nurses from implementing interventions as designed. Future research should use rigorous methods to develop and test school-based interventions implemented by school nurses, with a focus on

intervention feasibility, sustainability, and sensitivity to the unique needs of the participating student population.

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Appendix 1. New York City Department of Health and Mental Hygiene Institutional

Review Board Approval Letter

May 31, 2016

Re: 15-056, Evaluation of a School Nurse-led Case Management Program for Severely Obese

New York City Public School Students

Principal Investigator: Catherine Travers, MS

This Action: Continuation Approval by the Expedited Procedure

Expiration Date: May 30, 2017

Catherine Travers, MS NYC Department of Health and Mental Hygiene 42-09 28th St Queens,

NY 11101

Dear Ms. Travers:

Your application to continue the study, Evaluation of a School Nurse-led Case Management

Program for Severely Obese New York City Public School Students, has been approved by the

Institutional Review Board (IRB) under 45 CFR §46.110(b)(1)(category F5 and F7).

As Principal Investigator (PI), you are responsible for the overall management of this study and

for ensuring that the study is conducted in accordance to the protocol as approved by the IRB.

Requests to modify the protocol must be submitted in writing to the IRB for review and may not

be implemented prior to obtaining written approval from the IRB.

Physical or psychological adverse events (AE) affecting a study participant, violation of the data security protocol, or a breach of confidentiality must be reported in writing to the IRB within 5 days of occurrence. Serious Adverse Events (SAEs) or Unanticipated Problems (UPs) must be reported to the IRB in writing within 24 hours. You are responsible for the accurate documentation, investigation, and follow-up of all study-related events involving additional harm or risks to participants. At the conclusion of an investigation, a detailed report on the resolution of the event must be submitted to the IRB within 10 days, if applicable. Additional actions may be required by the IRB.

This approval expires on May 30, 2017. Requests to continue or close the study must be submitted to the IRB in writing. Requests to continue the study must be submitted at least four weeks prior to the expiration date. All research-related activities, including data analysis, are required to cease during a lapse of IRB approval.

The New York City Department of Health and Mental Hygiene appreciates your commitment towards the ethical conduct of research involving human subjects. If you have any questions, please contact the IRB.

Regards,

Diana Wong, Chair

Institutional Review Board

New York City Department of Health and Mental Hygiene

Appendix 2: Columbia University Medical Center Institutional Review Board Approval

Letter

May 4, 2016

Arlene Smaldone

800100X - NUR Nursing General

Protocol Number: IRB-AAAP6367

Title: Evaluation of a School Nurse-led Intervention for Severely Obese New York City Public

School Students

Approval Date: 04/30/2016 Expiration Date: 04/29/2017

Event Identifier: Renewal (Y02M00)

The above-referenced event was reviewed by Columbia University IRB Exp.

Level of review and outcome: Approved by Expedited review

To view a list of documents that were included in this approval (if applicable) and all other

currently approved documents for this study, please refer to the Print Menu for this Event in

Rascal. It is important to confirm the status of each document, e.g., active, stamped, etc. Only

stamped, active documents can be used with research participants.

Study Status: Open to enrollment or ongoing review of records/specimens

Consent Requirements:

Informed consent with written documentation will be obtained from the research participant or

appropriate representative

Modifications to the protocol included with this renewal:

- Decrease in target enrollment to 20

Important Reminder:

1) At the time of the next submission, please:

a) Update the Rascal Consent Form to list the Anticipated Number of Subjects as 20.

b) Reformat the Rascal Consent Form so that the last paragraph falls on the same page as the

signature lines.

Electronically signed by: Santos, Rafael

Appendix 3. New York City Department Education Institutional Review Board Approval

Letter

Research and Policy Support Group 52 Chambers Street Room 310 New York, NY 10007

October 20, 2015

Ms. Catherine Travers 42-09 28th St (CN#25) Queens, NY 11101-4132

Dear Ms. Travers:

I am happy to inform you that the New York City Department of Education Institutional Review

Board (NYCDOE IRB) has approved your research proposal, "Evaluation of a School Nurse-led

Case Management Program for Severely Obese New York City School Students." The

NYCDOE IRB has assigned your study the file number of 1106. Please make certain that all

correspondence regarding this project references this number. The IRB has determined that the

study poses minimal risk to participants. The approval is for a period of one year:

Approval Date: October 20, 2015

Expiration Date: October 19, 2016

Responsibilities of Principal Investigators: Please find below a list of responsibilities of

Principal Investigators who have DOE IRB approval to conduct research in New York City

public schools.

- -Approval by this office does not guarantee access to any particular school, individual or data. You are responsible for making appropriate contacts and getting the required permissions and consents before initiating the study.
- -When requesting permission to conduct research, submit a letter to the school principal summarizing your research design and methodology along with this IRB Approval letter. Each principal agreeing to participate must sign the enclosed Approval to Conduct Research in Schools/Districts form. A completed and signed form for every school included in your research must be emailed to IRB@schools.nyc.gov . Principals may also ask you to show them the receipt issued by the NYC Department of Education at the time of your fingerprinting.
- -You are responsible for ensuring that all researchers on your team conducting research in NYC public schools are fingerprinted by the NYC Department of Education. Please note: This rule applies to all research in schools conducted with students and/or staff. See the attached fingerprinting materials. For additional information click here. Fingerprinting staff will ask you for your identification and social security number and for your DOE IRB approval letter. You must be fingerprinted during the school year in which the letter is issued. Researchers who join the study team after the inception of the research must also be fingerprinted. Please provide a list of their names and social security numbers to the NYC Department of Education Research and Policy Support Group for tracking their eligibility and security clearance. The cost of fingerprinting is \$130. A copy of the fingerprinting receipt must be emailed to IRB@schools.nyc.gov.

- -You are responsible for ensuring that the research is conducted in accordance with your research proposal as approved by the DOE IRB and for the actions of all coinvestigators and research staff involved with the research.
- -You are responsible for informing all participants (e.g., administrators, teachers, parents, and students) that their participation is strictly voluntary and that there are no consequences for non-participation or withdrawal at any time during the study.
- -Researchers must: use the consent forms approved by the DOE IRB; provide all research subjects with copies of their signed forms; maintain signed forms in a secure place for a period of at least three years after study completion; and destroy the forms in accordance with the data disposal plan approved by the IRB.

Mandatory Reporting to the IRB: The principal investigator must report to the Research and Policy Support Group, within five business days, any serious problem, adverse effect, or outcome that occurs with frequency or degree of severity greater than that anticipated. In addition, the principal investigator must report any event or series of events that prompt the temporary or permanent suspension of a research project involving human subjects or any deviations from the approved protocol.

Amendments/Modifications: All amendments/modification of protocols involving human subjects must have prior IRB approval, except those involving the prevention of immediate harm to a subject, which must be reported within 24 hours to the NYC Department of Education IRB.

Continuation of your research: It is your responsibility to insure that an application for continuing review approval is submitted six weeks before the expiration date noted above. If

you do not receive approval before the expiration date, all study activities must stop until you

receive a new approval letter.

Research findings: We require a copy of the report of findings from the research. Interim

reports may also be requested for multi-year studies. Your report should not include

identification of the superintendent, district, any school, student, or staff member. Please send an

electronic copy of the final report to: irb@schools.nyc.gov.

If you have any questions, please contact Dr. Mary Mattis at 212.374.3913.

Good luck with your research.

Sincerely,

Mary C. Mattis, PhD

Director, Institutional Review Board

cc: Barbara Dworkowitz

Appendix 4: Interview Script for Semi-structured Interviews Conducted for Qualitative

Study Reported in Chapter 5

Script: Thank you for participating in this discussion about your experiences with HOP. My

name is Krista Schroeder and I am a nurse and the researcher conducting this study. The

purpose of this study to learn about your familiarity with and experiences implementing HOP.

Your participation is entirely voluntary.

I am tape recording this session for research purposes. The recording will be destroyed once a

transcript is complete; no one will be identified by name in the transcript; the transcript and

recording will be available only to the research team. Nothing that you say here has the ability

to affect your job.

Before we start, can you please read and sign the informed consent form and complete a

<u>demographic information sheet?</u>

OR

Before we start, I am going to go through some questions with some basic demographic

information.

Do you have any questions?

Introduction

Script: To get started with our discussion, please tell me about your experience with HOP. How many children have you worked with, and how often do you meet with them?

RE-AIM Framework

Reach:

How do you select students for HOP implementation?

Do you feel that there are children who could benefit from HOP but do not receive it? If so, can you tell me about those students?

Effectiveness:

What aspects of HOP can help students decrease BMI or change health behavior? Do you think there are any aspects that would need to change to allow HOP to work better?

Do you think HOP has any negative effects on children? (prompt: Do you think children that are selected for HOP might be subject to additional bullying or teasing because they are in HOP?)

Did you find that HOP had any unexpected effects (positive or negative) on children who participated?

Adoption:

What kinds of things make it easier for you to implement HOP?

What kinds of things make it harder for you to implement HOP?

What is your experience with the principal and administrators, when it comes to HOP? What about with parents?

How do students react to HOP? Describe a typical interaction with a student during a HOP session.

Implementation:

Do you have a good understanding of how HOP is supposed to be implemented? Is the HOP binder helpful to you?

How helpful (or unhelpful) is ASHR to your implementation of HOP?

Do you feel that you have enough knowledge about childhood obesity to implement HOP?

What helps you to implement HOP as you see fit? Or, what changes would need to be made to allow you to implement HOP as you see fit?

Maintenance:

What are your suggestions for implementing HOP in the future?

What would make it easier for you to implement HOP with more children?

What do you think could make HOP more effective?

Closing

Script: Thank you very much for your participation in this interview. Your feedback is very important to the research effort, and I appreciate your time today. I will send you a \$50 gift card via email; you should receive it within 24 hours. If you have any further thoughts about HOP, you may send an email or call me.

Appendix 5: Codes Used in First Level of Coding for Qualitative Study Reported in

Chapter 5

Code	Description
Administration - Barrier	Principle as a barrier to HOP implementation/effectiveness, more principle support is required for HOP implementation/effectiveness
Administration - Facilitator	Specific examples of administration acting as a facilitator to HOP implementation/effectiveness
Children - Facilitator	Children as facilitator to HOP implementation/effectiveness by (for example) enthusiastic participation
Culture	Cultural factors influencing obesity and/or HOP implementation/effectiveness
Economic - Barrier	Child's economic status as a barrier to HOP implementation/effectiveness
Economic - Facilitator	Child's economic status as a facilitator to HOP implementation/effectiveness
Education - Barrier	Education level as a barrier to HOP implementation/effectiveness, more education is required for HOP implementation/effectiveness
Education - Facilitator	Education level as a facilitator to HOP implementation/effectiveness
Education/experience - Barrier	Nurses' education/clinical experience as a barrier to HOP implementation/effectiveness
Education/experience - Facilitator	Nurses' education/clinical experience as a facilitator to HOP implementation/effectiveness
Education/expertise - Barrier	Nurses' education/clinical experience as a barrier to HOP implementation/effectiveness
Frustrations	Frustrations of nurses experienced related to HOP implementation
	1.50

Appendix 5. (Con't.)

Appendix 5. (Con't.)	Description
Code	Description HOP
	Actionable suggestions for improving HOP implementation/effectiveness (NOT for improving
Improvements	obesity prevention efforts overall)
improvements	obesity prevention errorts overally
	Someone (i.e., parent, child) feels insulted as a result
Insult	of HOP eligibility or participation
	Nursing care/workload as a barrier to HOP
Nursing care/workload - Barrier	implementation/effectiveness
	N ' / 11 1 C 'I' / HOD
Numaina aana/yyanklaad Easilitatan	Nursing care/workload as a facilitator to HOP
Nursing care/workload - Facilitator	implementation/effectiveness
	Parent as a barrier to HOP
	implementation/effectiveness, more parent support is
Parents - Barrier	required for HOP implementation/effectiveness
	•
	Specific example of parents acting as a facilitator to
Parents - Facilitator	HOP implementation/effectiveness
	December (in the first HOD (minima) and harming to
	Resources (including HOP training) as a barrier to HOP implementation/effectiveness, more resources
Resources - Barrier	are needed for HOP implementation/effectiveness
Resources - Barrier	are needed for fror implementation/effectiveness
	Specific examples of resources (including HOP
	training) as a facilitator to HOP
Resources - Facilitator	implementation/effectiveness
	Nurses' experiences of feeling rewarded, happy, or
Rewarding	satisfied when implementing HOP, children enjoying
Kewaiunig	НОР
	School environment as a barrier to HOP
	implementation/effectiveness, healthier school
	environment is required for HOP
School environment - Barrier	implementation/effectiveness
	School environment as a facilitator to HOP
	implementation/effectiveness, healthy school
School environment - Facilitator	environment is helping HOP implementation/effectiveness
School chynolinicht - I achitatol	implementation/effectiveness

Appendix 5. (Con't.)

Code	Description
School partners	Need to work together with school colleagues to implement HOP or support HOP's effectiveness
Stigma/bullying	Presence of, lack of, or concern about stigma resulting from HOP or obesity
Teacher - Barrier	Teachers as a barrier to HOP implementation/effectiveness, more teacher support is required for HOP implementation/effectiveness
Teacher - Facilitator	Specific examples of teachers as a facilitator to HOP implementation/effectiveness
Work-arounds	Tailoring HOP to make it easier to implement or more effective, making changes to HOP protocol to meet administrator or parents demands